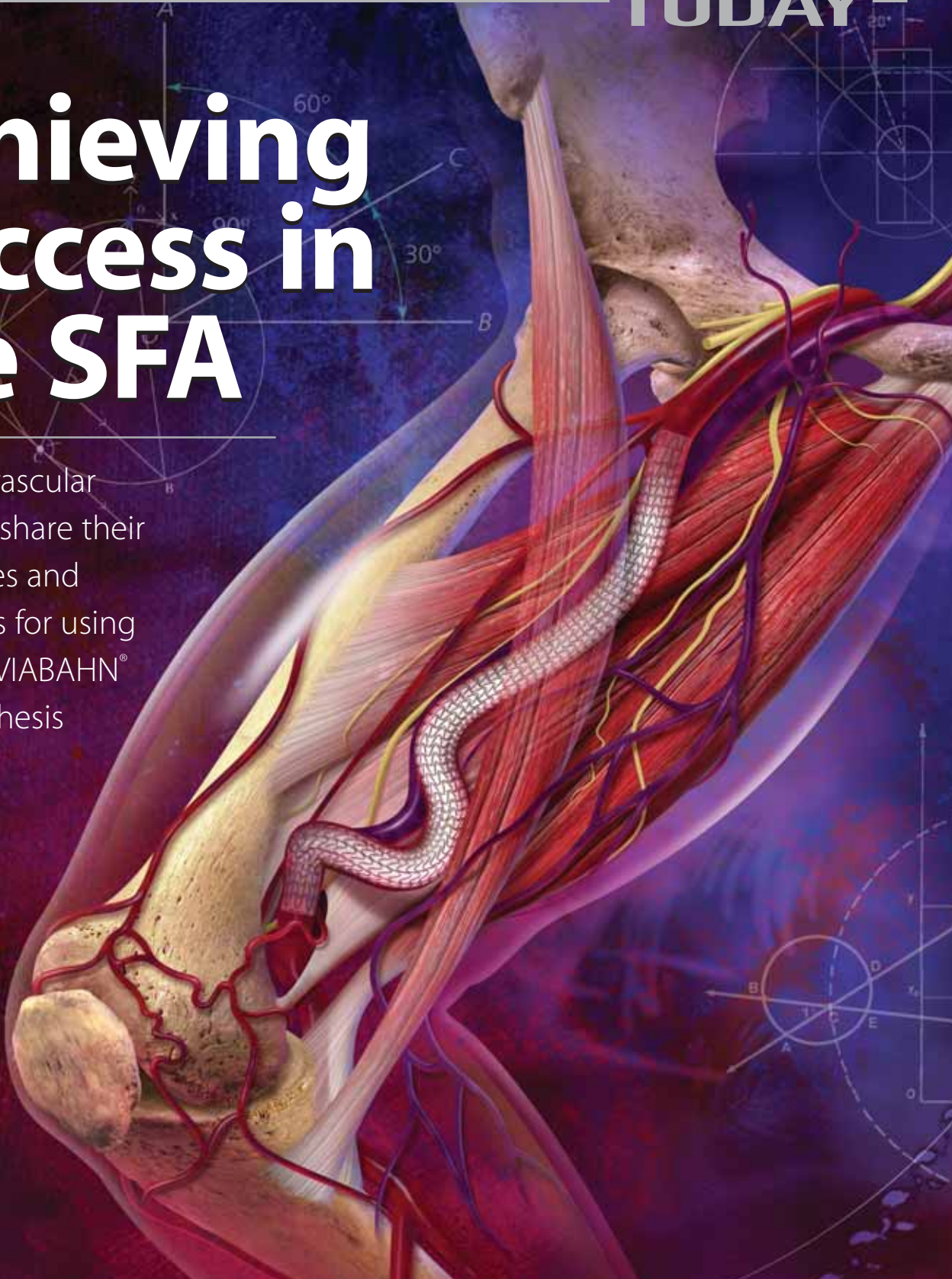


Endovascular TODAY

August 2005

Achieving Success in the SFA

Top endovascular specialists share their experiences and techniques for using the GORE VIABAHN® Endoprosthesis in the SFA



Achieving Success in the

The unique characteristics of the superficial femoral artery (SFA) present challenging clinical scenarios for treating disease in this anatomy. Although acute success is often achieved in many lesions, restenosis is commonly seen upon mid- and long-term follow-up after treatment with many of today's technologies due to the harsh nature of the vessel's natural forces. In addition to the rigorous stress inherent in this anatomy, the disease encountered in or near the SFA varies significantly, from short, focal stenoses to calcified chronic total occlusions.

In order to safely and effectively treat this multivariate disease state in such a difficult location, a versatile treatment option is necessary. The GORE VIABAHN® Endoprosthesis (W. L. Gore & Associates, Flagstaff, AZ) was designed to meet these needs with a single device both strong and flexible enough to withstand the SFA's anatomi-

cal forces without compromising its structural integrity. The VIABAHN device has been tested in numerous SFA applications, including total occlusions and long, complex lesions, with success and durability.

This supplement to *Endovascular Today* features six articles detailing some of the experiences to date using the VIABAHN device. The contributing authors describe the challenges of the anatomy, previously published experiences, procedural planning considerations, proper device selection, and useful techniques. The articles illustrate high rates of procedural success and favorable follow-up results to date across single-center study populations, as well as excellent long-term results in individual case studies.

We hope you find this supplement to be educational and of practical use in your efforts to provide your patients with optimal SFA treatment options.

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Use of the VIABAHN[®] Stent Graft for PVD in the Femoropopliteal Arterial Segment

One center's experience in 60 patients.

BY PARAMJIT "ROMI" CHOPRA, MD

Approximately 10 million people in the US alone have peripheral vascular disease (PVD). Moreover, PVD typically affects people older than 50 years, so the number of cases is increasing rapidly as the US population ages. Finally, PVD is especially prevalent among patients with diabetes, and the World Health Organization has estimated that the number of people with diabetes worldwide will double

by 2030. This will substantially increase the population at risk for PVD in the next 25 years.

The most common site for PVD is the femoropopliteal arterial segment in the lower limb, where more than 50% of atherosclerotic plaque lesions occur. The lesions may be focal and discrete or involve the entire 30 cm of the vessel. Stenoses, occlusions, or both may be present, although occlusions (which are often quite long) are



Figure 1. Right lower-extremity digital subtraction arteriogram showing stenotic disease in the proximal superficial femoral artery (SFA) (A) and occlusion in the distal segment (B). The lesions were crossed with a catheter and wire combination (C). The lesions were treated with angioplasty with a 6-mm X 10-cm balloon and the follow-up arteriography showed extensive dissection (D). Initially, the distal occluded SFA segment was covered with a VIABAHN (W. L. Gore & Associates, Flagstaff, AZ) endograft (E), however, the proximal stenosis persisted. Angiography after complete coverage of the entire SFA shows a widely patent SFA (F). An arteriogram obtained in this patient 18 months later shows an appearance similar to that of the postprocedure angiogram.



TABLE 1. TASC CLASSIFICATIONS AND RECOMMENDATIONS FOR PVD LESIONS

Lesion Grade	Lesion Characteristics	Treatment Recommendations
TASC A	Single stenosis <3 cm	Endovascular
TASC B	Single stenosis 3-10 cm (not involving the popliteal artery); or multiple stenoses, each <3 cm; or single or multiple lesions in the absence of continuous distal run-off	Endovascular treatment is more frequent, but more evidence is needed
TASC C	Single stenosis or occlusion >5 cm	Surgery, but more evidence is needed
TASC D	Complete common or superficial femoral artery occlusion; or popliteal and trifurcation occlusion	Surgery

three times more common than stenoses. In many patients with PVD, more than one vessel is affected.

The symptoms of PVD include intermittent claudication in the legs, ischemic pain at rest in the feet and toes, and tissue loss, which may eventually necessitate amputation. Interestingly, according to the American Heart Association, nearly 75% of patients with PVD have no symptoms. In the past, patients with claudication simply had to live with their pain, even when it prevented them from performing normal activities. Now, however, patients demand treatment because they want to maintain more active, pain-free lifestyles.

The treatment options for PVD include modification of atherosclerotic risk factors (such as smoking cessation and getting more exercise), bypass surgery using autologous saphenous vein or a prosthetic graft, and endovascular revascularization, including balloon percutaneous transluminal angioplasty (PTA), thrombolysis, stenting with bare stents, and stenting with covered stents (also called stent grafts, endoprotheses, or endografts). Autologous vein above-the-knee femoropopliteal bypasses have 4-year primary and secondary patency rates of approximately 70% and 80%, respectively. The 4-year primary and secondary patency rates for prosthetic above-the-knee bypasses, which are commonly performed in patients with no available saphenous vein, are approximately 50% and 60%, respectively. Although autologous vein bypass is considered the gold standard treatment for PVD in the femoropopliteal segment, interest in endovascular therapy has recently increased dramatically among physicians, patients, and medical device manufacturers because of its proven or potential advantages over surgery. These benefits include its less-invasive nature, lower cost, quicker patient recovery, and reduced complications.

PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY

Balloon PTA was the first endovascular technique used to treat PVD in the femoropopliteal segment. The technical success and durability of PTA revascularization depends largely on lesion morphology¹⁻⁵ and, in general, the results obtained in long stenoses and occlusions have not been encouraging. For instance, although a 5-year cumulative patency rate of 75% can be expected for short focal stenoses, the 1-year rate for occlusions longer than 3 cm is significantly lower.² The 6-month cumulative patency rate for stenoses shorter than 7 cm was reported to be approximately 87%, whereas the rate for longer stenoses was 23%.³ In addition, PTA revascularization for lesions shorter than 5 cm is more durable than that for lesions longer than 10 cm.⁴

TRANSATLANTIC INTER-SOCIETY CONSENSUS

The Transatlantic Inter-Society Consensus (TASC) document,⁵ published in 2000, was produced by a consensus development conference involving 16 internationally recognized professional societies and expert physicians. The conference's recommendations for classifying and managing PVD were derived from both clinical experience and a review of the literature. For PVD in the femoropopliteal segment, vascular lesions were assigned a letter grade (A to D) that was based on whether a stenosis or an occlusion was present, along with other variables known to affect the success and patency rates of PTA (Table 1). According to the TASC document, TASC A lesions are most suitable for endovascular procedures, whereas TASC D lesions require surgery. The TASC document also states that more evidence is needed to make firm recommendations about the role of PTA in the treatment of TASC B

and C lesions. Such lesions may resolve after PTA, but technical success and long-term patency rates are relatively low.

The TASC document remains useful for classifying vascular lesions, but its treatment recommendations were based primarily on results obtained with PTA and early bare metallic stents. Since the publication of the document, numerous new endovascular devices, such as nitinol stents and endografts, have become available and have been found to be useful in treating TASC C and TASC D lesions.

BARE STENTS

Stents were initially used mainly in the iliac vessels. In the SFA, excellent technical results were achieved with early metallic stents, particularly when employed to bail out a failed balloon PTA treatment in which extensive dissection, recoil, or acute thrombosis had occurred.^{5,6} However, the long-term data on metallic stents were discouraging: the devices had limited effectiveness in preventing intimal hyperplasia and long-term restenosis in the infrainguinal region. The 2000 TASC document states that femoropopliteal stenting is not indicated as the primary treatment for intermittent claudication or chronic limb ischemia, although it may have a limited salvage role in cases in which PTA fails or complications develop.⁵ This recommendation was based on early experience with the balloon-expandable Palmaz stent (Cordis Corporation, a Johnson and Johnson company, Miami, FL) and the self-expandable Wallstent (Boston Scientific Corporation, Natick, MA).⁶ Subsequently, newer metallic stents, such as the self-expandable nitinol Smart stent (Cordis Corporation), began to be used increasingly in the femoropopliteal segment. Good short-term results were achieved in short, stenotic lesions, but mid-term data in longer lesions were not promising.

ENDOGRAFTS

Covered stents were first used in aortic applications, but a great deal of interest in employing them in smaller vessels soon emerged. Early results with devices such as the Dacron-covered Wallgraft (Boston Scientific Corporation) and the Cragg system (MinTec, Freeport, Bahamas) for treatment of PVD in the SFA were disappointing, with low patency rates and a substantial number of complications such as thrombosis, hematoma, perforation, and migration.⁷ Subsequently, most attention focused on the HEMOBAHN endograft (now called the GORE VIABAHN Endoprosthesis, W. L. Gore & Associates). The VIABAHN device has been used with considerable success in a number of investigational stud-

ies in patients with femoropopliteal disease.⁷⁻¹² In June 2005, the US Food and Drug Administration approved the marketing of the VIABAHN endograft for use in the SFA.

EXPERIENCE WITH THE VIABAHN ENDOGRAFT

We began to use the VIABAHN endograft in patients with femoropopliteal disease early in 2003. In our experience with the device in the first 60 patients (70 limbs) treated, the patients' symptoms included moderate-to-severe lifestyle-limiting claudication and rest pain, with or without tissue loss. The SFA and above-the-knee popliteal artery were treated with the endograft.

Insertion Technique

The series consisted of patients in whom a VIABAHN endograft was used to treat SFA disease at our institute between January 2002 and May 2005. Informed consent was obtained from all patients before the procedure. For insertion of the device, femoral artery access was achieved either in a retrograde fashion to place an 8-F sheath over the aortic bifurcation or in an antegrade fashion to place an 8-F sheath in the ipsilateral common femoral artery. The retrograde approach was preferred if the lesion was close to the origin of the SFA. Conventional catheter and guidewire techniques were used to cross the lesion. Occlusions were crossed with a straight hydrophilic catheter and straight or angled hydrophilic wire combination. Road mapping was used to guide recanalization of the occluded SFA and gain re-entry into the patent true lumen. An Outback Re-Entry Catheter (LuMend, Redwood City, CA) was used in two cases. Stenotic lesions were crossed with an atraumatic, soft-tip, .035-inch wire and a straight hydrophilic catheter. Typically, lesions were dilated with a 5- or 6-mm X 10-cm angioplasty balloon.

The endograft length was selected to cover the lesion (Figure 1), and the VIABAHN device was deployed so that its two ends were in relatively disease-free segments. Extreme care was taken to avoid any overlap at the origin of the profunda femoris artery. When multiple endografts were required to ensure coverage over the entire length of the lesion, the devices were overlapped by at least 1 cm. Most of the endografts used were 6 mm in diameter, but some 5-mm devices were employed in smaller vessels. After deployment of the endograft, it was dilated, usually with a 5- or 6-mm balloon catheter, with care taken to avoid dilatation outside the device. In two cases in which extensive plaque was observed at the origin of the SFA, plaque excision using a SilverHawk device (FoxHollow Technologies, Redwood City, CA) was performed to debulk the lesion.



During the procedure, patients received either heparin (5,000 units) or bivalirudin administered according to a regimen similar to that used in coronary artery interventions. The day after the procedure, patients began to receive oral clopidogrel (75 mg per day). If this treatment was tolerated, they continued to take this agent indefinitely.

Outcome Measures and Follow-Up

Technical success for the endograft insertion procedure was defined as a patent vessel and endograft with <30% residual stenosis after the procedure. Clinical success¹³ was defined as an improvement in ankle-brachial index of at least .10 after the procedure, relief or improvement of the presenting symptom (claudication or rest pain), and improvement of at least one Rutherford-Becker category above the baseline finding. Clinical improvement according to these criteria was observed in 97% of the limbs treated (n = 68).

During follow-up, patients were evaluated using color duplex imaging and measurements of segmental pressure and ankle-brachial indices at 1, 3, 6, 9, and 12 months after the procedure, and at 6-month intervals thereafter. Duplex ultrasonography and Doppler-derived velocity assessments were used. Focal doubling of the peak systolic velocity at the treatment site was considered to represent restenosis and loss of primary patency of the endograft.¹⁴ Any complications of treatment were recorded.

Patency

Kaplan-Meier life-table analysis was used to calculate the hemodynamic primary patency rate for the endografts from the time of device insertion, with patency uninterrupted by hemodynamic endograft failure.

Results

Between January 2003 and May 2005, a VIABAHN endograft was used to treat 70 lower limbs (35 in men and 35 in women) in 60 patients (mean age, 70 years; range, 52-86 years) with femoropopliteal lesions causing chronic limb ischemia. Symptoms included moderate-to-severe lifestyle-limiting claudication, rest pain, or tissue loss. One of the vascular lesions was a TASC A, two were TASC B, 27 were TASC C, and 40 were TASC D. Twenty lesions were stenoses; 50 were occlusions. A total of 158 endografts were used (mean number per limb, 2.6). The mean lesion length was 20 cm (range, 2-38 cm). The technical success rate in the series was 98%. In three cases, the occlusion was too extensive to cross. There were no device failures or procedure-related deaths. All grafts were between 5 and 6 mm in diameter. Excellent angiographic

results were obtained in all patients, with no residual thrombus in the lumen of the graft.

Complications

Among the major procedure-related complications were two requiring emergency repair of the femoral artery: in one patient, there was a vascular injury at the catheter entry site; in the other, the endograft was inadvertently deployed across the origin of the profunda femoris artery, and the device had to be trimmed after open arteriotomy. Other major complications were one distal embolus, which was treated successfully with catheter-directed lytic therapy, and one acute (within 2 days of deployment) endograft occlusion caused by embolization of the internal mechanism of a percutaneous closure device. The only minor procedure-related complications were two hematomas, both of which developed in patients who had undergone antegrade puncture of the common femoral artery. The hematomas resolved without intervention.

Clinical Outcomes

The follow-up period in the series ranged from 30 days to 31 months. All but three patients returned for all follow-up assessments. No patient required an amputation. During follow-up, clinical improvement was observed in 97% of patients.

Within the follow-up period, a stenosis of >50% developed in the SFA in four limbs, but no intragraft stenosis was observed. The mean time to this hemodynamic endograft failure was 195 days (range, 2 days to 18 months). The hemodynamic patency rates at 6, 12, 18, and 24 months were 97%, 93%, 89%, and 87%, respectively. The secondary patency rates were 99%, 96%, 91%, and 89%, respectively.

Discussion

In our series of 60 patients in whom a VIABAHN endograft was used to treat limb ischemia due to stenosis or obstruction of the SFA, the prosthesis provided promising patency results in a patient population with all grades of TASC lesions (A to D). The technical success rate was high and few complications occurred. Of the complications that were observed, only one was device related and—probably more important—operator related.

The VIABAHN endograft was used in several earlier, generally small, series of patients with femoropopliteal disease. In conjunction with a variety of conventional recanalization techniques, Bauermeister⁸ deployed 47 VIABAHN devices in 35 patients with long-segment femoropopliteal occlusions. The technical success rate was 100%. One-year primary and secondary patency rates were 73% and 83%, respectively. Bray et al⁹ used VIABAHN endografts to treat 59 long symp-

tomatic SFA occlusions in 54 patients. Cumulative primary patency rates at 1, 6, and 12 months were 88%, 67%, and 58%, respectively; the corresponding secondary rates were 92%, 82%, and 73%. Patency results did not vary significantly according to presenting symptoms, lesion length, endograft length, or distal run-off. The investigators noted that the patency rates they achieved were similar to those for open synthetic femoropopliteal bypass procedures.

In our series, higher 1-year and 2-year primary patency rates were achieved without using adjunctive therapy. The primary reasons may be that our series was a one-operator series and that the endograft extended from the normal vessel both proximally and distally. Patients also received aggressive follow-up. Moreover, the majority of patients had claudication, with 86% having two- or three-vessel run-off. Most failures occurred at the end of the endograft as a result of edge stenosis and the patient having only one-vessel run-off. Finally, all patients received antiplatelet agents continuously.

Hartung et al⁷ treated 34 TASC A, TASC B, or TASC C SFA lesions (TASC D lesions were excluded) in 32 patients with either claudication or critical acute limb ischemia by using VIABAHN endografts. Their technical success rate was 100%. The 1-year primary patency rate was 81% in patients with claudication and 89% in those with critical ischemia ($P = \text{ns}$); the secondary rate in both groups was 88%. Lammer et al¹¹ inserted VIABAHN endografts in 80 femoral arteries in patients with symptomatic PVD disease and achieved 1-year primary and secondary patency rates of 91% and 93%, respectively. Our results are similar to those of Lammer et al and provide further substantiation that higher patency results can be obtained in this patient population. We believe that attention to technical detail, coverage of all diseased portions of the vessel with the endograft, aggressive follow-up, and antiplatelet therapy are important in this regard.

Jahnke et al¹² implanted 63 VIABAHN devices in 52 patients with medium- or long-segment femoropopliteal disease. Their technical success rate was 100%, although their procedure-related complication rate was relatively high (23%). Primary patency rates at 12 and 24 months were 78% and 74%, respectively; secondary rates were 88% and 83%. Interestingly, Jahnke et al found that primary patency rates did not differ significantly according to lesion length.

In contrast to these encouraging results was the experience of Deutschmann et al¹⁰ in a small series of 17 patients. Their initial angiographic results with the VIABAHN endograft were excellent, but primary patency had decreased to 61% by 3 months after the procedure and to 49% by 6 months. Deutschmann et al acknowledged that their expe-

rience with the VIABAHN device was different from that of others and speculated that this may have been due to differences in patient selection or run-off characteristics and technique. Devices were not overlapped but rather only placed at the stenotic lesion locations and allowed native vessel between devices. Unlike Jahnke et al and other researchers, Deutschmann et al found that patency rates for longer endografts were significantly lower than those for shorter devices.

CONCLUSION

Our results indicate that the VIABAHN device is effective in treating occlusive disease of the SFA. Our series predominantly included longer SFA lesions and occlusions. Close follow-up and antiplatelet therapy are essential. Follow-up arteriograms in patients who had other interventions as late as 18 months after VIABAHN device insertion showed minimal intimal hyperplasia in the endograft. Use of the VIABAHN endograft to treat occlusive disease in the femoropopliteal segment appears to be feasible and safe. Investigation of this device in long-term, randomized studies is warranted. ■

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Endoluminal Bypass Utilizing the VIABAHN[®] Endoprosthesis

A case report and review of the literature.

BY JOHN G. ADAMS, JR, MD; PAUL W. HUMPHREY, MD; AND RICHARD D. COATS, MD

CASE PRESENTATION

The patient was a 69-year-old woman who presented with a 2-month history of progressively worsening right lower-extremity rest pain and nonhealing ulceration. The patient had noted claudication symptoms of the right calf 6 to 7 months before her initial presentation. She had no symptoms of claudication or rest pain on the left.

The patient's medical history was significant for diabetes mellitus, hypertension, chronic renal insufficiency, and emphysema, with numerous previous hospitalizations for respiratory failure, chronic atrial fibrillation, known asymptomatic bilateral carotid artery stenosis, and atherosclerotic cardiovascular disease. She had undergone repair of an atrial-septal defect in 1968 and 1970. Percutaneous transluminal coronary angioplasty of multiple vessels was performed on three separate occasions in the 1990s, and the most recent procedure was performed in 1997. Cardiac catheterization in 2004 showed a critical stenosis of the right coronary artery with good left-to-right collateralization, mild-to-moderate disease of the distal circumflex and left main, and moderate impairment of left ventricular systolic function with an ejection fraction of 25%.

The patient continued to use tobacco and smoked one to two packs per day. She had a 100 pack-

year tobacco history. Pertinent physical findings included a right carotid bruit, diffuse expiratory wheeze, irregular/irregular cardiac rhythm without murmur/gallop/rub, no abdominal masses/bruits, 2+ femoral pulses, and absent bilateral popliteal and pedal pulses. An ulceration was noted on the anterior aspect of the right leg measuring 1 cm X 1 cm with adherent pale, yellow exudative tissue without evidence of granulation. No erythema or drainage was noted.

Baseline laboratory testing revealed a creatinine level of 1.7 mg/dL. Noninvasive vascular laboratory examination revealed an ankle-brachial index of .47 on the right, with monophasic signals and .70 on the left, with biphasic signals. Segmental pressure and waveform analysis suggested right femoral, popliteal, and tibial artery disease, and left femoral artery disease.

Abdominal aortography and selective arteriography of the right lower extremity was performed (Figure 1). This



Figure 1. The superficial femoral artery (SFA) was occluded just distal to the origin with reconstitution in the above-knee popliteal artery. The anterior tibial and posterior tibial arteries were occluded with runoff via the peroneal artery.

revealed no significant aortoiliac or renal disease. The SFA was occluded just distal to the origin, with reconstitution in the above-the-knee popliteal artery. The anterior tibial and posterior tibial arteries were occluded, with runoff via the peroneal artery.

TREATMENT OPTIONS

Traditional treatment of infrainguinal arterial disease in patients with threatened limb loss has been revascularization utilizing bypass with autologous conduit, if available. Long-term patency and limb-salvage rates of femoral-distal artery vein grafts are excellent at 60% to 70% and 80% to 90%, respectively.¹⁻³ However, major morbidity and mortality associated with this procedure continues to be as high as 5% to 10% and 1% to 5%, respectively, even in modern series.¹⁻⁴

Percutaneous techniques of revascularization include angioplasty, stenting, atherectomy, and endoluminal bypass. The obvious advantages of percutaneous interventions include decreased morbidity and mortality, shorter hospital stays, and shorter time to recovery. However, long-term patency rates of most percutaneous procedures have not equaled the long-term patency rates of femoral-distal bypass.

Recently, several investigators have described their experience using the VIABAHN endoprosthesis (W. L. Gore & Associates, Flagstaff, AZ) for endoluminal bypass.⁵⁻⁹ Technical success rates and short-term patency rates have been excellent.

SELECTED TREATMENT

The patient was taken to the endovascular suite and underwent selection of the right external iliac artery from a contralateral approach. An 8-F sheath was then positioned in the right external iliac artery. A multipurpose catheter and a Jindo (Cordis Corporation, a Johnson & Johnson company, Miami, FL) wire were used to cross the chronic occlusion of the right SFA. Balloon angioplasty of the SFA was performed with a 6-mm X 8-cm balloon. Endoluminal bypass was accomplished from just distal to the origin of the SFA to the popliteal artery utilizing two 6-mm X 15-cm VIABAHN endoprostheses and a 6-mm X 5-cm VIABAHN endoprosthesis with 1-cm overlap of components. Postdeployment angioplasty of the VIABAHN device

components was performed with a 6-mm X 8-cm balloon. Completion angiography revealed a widely patent SFA without residual stenosis (Figure 2).

OUTCOMES/FOLLOW-UP

The patient was observed overnight in the hospital with complete resolution of rest pain. Clopidogrel 300 mg was administered immediately after the procedure and was continued at 75 mg per day for 30 days. She was discharged home the morning after the procedure and was placed in our vascular surveillance program. Duplex examination and an ankle-brachial index of the right lower extremity performed at 1 and 6 months after the procedure showed a patent VIABAHN endoprosthesis without stenosis and an ankle-brachial index >1.0, with biphasic signals in the pedal vessels. The right lower-extremity ulceration healed approximately 3 months after the procedure.

DISCUSSION

There have been many percutaneous procedures used in the treatment of lower-extremity arterial occlusive disease since the initial description of balloon angioplasty by Dotter and Judkins.¹⁰ Standard balloon angioplasty, cryoplasty, stenting, atherectomy, and endoluminal bypass continue to be used with varying degrees of success. Restenosis secondary to intimal hyperplasia remains the most common etiology of treatment failures after these procedures.

Covered stents have the theoretical advantages of excluding the diseased artery segment, decreasing acute thrombosis secondary to elastic recoil of the vessel, preventing intimal dissection, and inhibiting intimal hyperplasia. Presumably, the material covering the stent reduces tissue ingrowth in the treated arterial segment, thereby preventing the intimal hyperplastic response. Specifically, polytetrafluoroethylene-covered stents placed in the intraluminal location have been shown in numerous studies to reduce intimal hyperplasia in the peripheral arterial system.¹¹⁻¹⁵



Figure 2. Completion angiography revealed a widely patent SFA without residual stenosis.



The 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. Several investigators have now reported their experience with the VIABAHN endoprosthesis placed in the femoropopliteal location.

Lammer reported a prospective, multicenter study in which 127 patients with lower-extremity arterial occlusive disease were treated using the VIABAHN endoprosthesis.⁵ In 74 patients (80 limbs), the endoprosthesis was placed in the femoropopliteal location. Technical success was 100%. There were two major and 12 minor complications—most of the complications occurred at the access site. Primary and secondary patency rates at 1 year were 79% and 93%, respectively.

Bauermeister reported a series of 35 patients with long-segment occlusions in the femoropopliteal location who underwent revascularization using the VIABAHN endoprosthesis.⁹ Technical success was achieved in all patients. Primary and secondary patency rates at 1 year were 73.2% and 82.6%, respectively.

Jahnke published a series of 52 patients who underwent endoluminal stent graft placement of the VIABAHN endoprosthesis in the femoropopliteal arteries.⁶ Again, all procedures were technically successful. Procedure-related complications were observed in 12 (23.1%) patients. These consisted of four episodes of embolization (7.7%), seven groin hematomas (13.5%), and one arteriovenous fistula (1.9%). None of these complications required intervention or prolonged hospital stays. Primary assisted patency rates at 1 year were 82.4% \pm 5.3 and 80.3% \pm 5.6 at 2 years.

To date, our group has treated 52 limbs in 28 patients with lower-extremity occlusive disease with endoluminal bypass using the VIABAHN endoprosthesis. These patients were believed to be at a prohibitively high risk for surgery because of comorbid factors. The mean age was 74 years (range, 49-87 years). Debilitating claudication was the indication for intervention in 67% of patients; rest pain and/or tissue loss was the indication in 33%. Endoprostheses were placed in the SFA in the majority of patients (n=18) followed by the SFA and popliteal artery (n=5), popliteal only (n=1), and other arteries (n=4). Complete occlusion of the artery was encountered in 15 patients (54%). Six (21%) complications occurred—four (14%) minor and two (7%) major. The minor complications consisted of three dissections and one perforation—none of which were felt to be significant. The major complications were two episodes of thrombosis at the time of endoprosthesis insertion—one required thrombolysis and one required open revascularization. Follow-up ranged from 1 to 9 months (mean, 2 months). There were two “silent” endoprosthesis occlusions detected

during surveillance, yielding a primary patency rate of 93%. Limb salvage was 100%.

CONCLUSION

Endoluminal bypass in the femoropopliteal arteries is an attractive treatment approach with excellent rates of technical success and acceptable 1- and 2-year patency rates, especially in patients believed to be at high risk for open revascularization. The VIABAHN endoprosthesis may offer distinct advantages over other covered stent grafts because of the expanded polytetrafluoroethylene and nitinol stent configuration. ■

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Endovascular Femoropopliteal Bypass With Multiple Stent Grafts

Subintimal angioplasty and stenting of long-segment superficial femoral artery occlusive disease remain challenging.

BY THOMAS F. PANETTA, MD

Angioplasty and stenting of long-segment superficial femoral artery (SFA) lesions still remains a challenge to the vascular interventionist. Recent advances, including subintimal angioplasty, microchannel dissectors, re-entry devices, cutting balloons, new atherectomy devices, cryoplasty, partially covered stents, and fully covered expanding polytetrafluoroethylene (ePTFE) endoprotheses have added to the complexity of treating long-segment SFA occlusions. Although these techniques have improved the ability to perform endoluminal therapy of these long SFA occlusions, they raise issues of cost-effectiveness, technical considerations and, most importantly, long-term results.

Historical data for SFA angioplasty clearly demonstrate that patency is inversely proportional to lesion length, severity of symptoms, and length of occlusion.¹⁻⁷ Lesions <3 cm have up to an 82% 1-year patency compared to 22% 1-year patency for lesions longer than 15 cm. Three-year patency is 62% for angioplasty performed for claudication compared to 43% when the limb was ischemic. Four-year patency was 80% for stenotic lesions and only 39% for total occlusions. More recently, reports of subintimal angioplasty of long-segment SFA occlusions have not provided durable results.^{8,9} The use of ePTFE-covered stents in the SFA has been reported, but there is little experience with multiple stents for long-segment occlusions.¹⁰⁻¹⁴

Our experience with subintimal angioplasty and stenting with ePTFE-covered endoprosthesis for long-segment SFA occlusions is presented (Figure 1). Technique, treatment of multilevel adjunctive lesions, and normalization of popliteal pressures to eradicate pressure gradients across the long segments are important factors that may

translate into long-term patency comparable to open femoropopliteal bypass.

METHODS

Endoluminal angioplasty and stenting with multiple 6-mm-diameter VIABAHN® (W. L. Gore & Associates Inc., Flagstaff, AZ) endoprotheses were performed in 41 cases. Anatomical prerequisites included minimal common



Figure 1. Long-segment SFA occlusion with proximal wire (A) and distal wire (B) for combined antegrade and retrograde subintimal angioplasty.

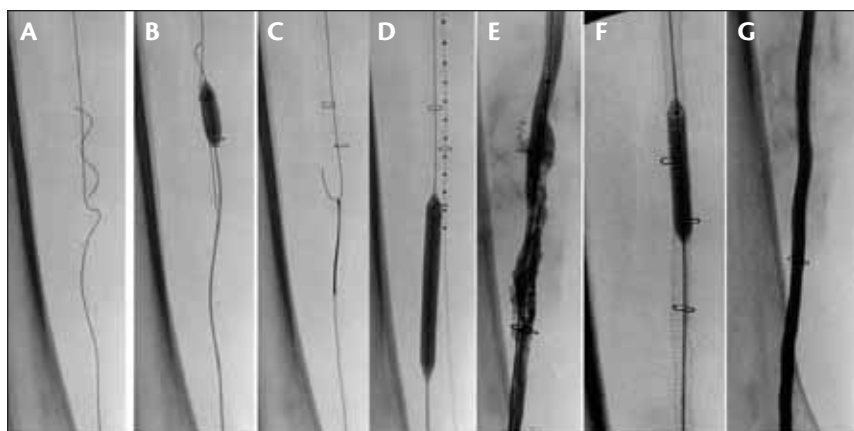


Figure 2. Technique of endoluminal femoral popliteal bypass. Antegrade and retrograde wires (A). Lead balloon for calcified lesions (B). Wire is snared (C). Subintimal angioplasty with 6-mm balloon (D). Completion angiogram of subintimal angioplasty (E). Endoprosthesis ballooned to 6 mm (F). Completion angiogram (G).

femoral artery disease, a patent popliteal artery below the knee and patent for 2 cm above the knee joint, and at least single vessel runoff. Forty-seven percent of patients had concomitant treatment of iliac or profunda femoral arterial lesions. The average length of occlusion was 30.4 ± 14.1 cm, with a range of 8 cm to 45 cm. More than 90% of cases had occlusions >15 cm in length. The average number of VIABAHN grafts used was $2.5 \pm .8$.

TECHNIQUE

The technique was performed from an antegrade approach in 27% of the cases and from a combined antegrade and retrograde approach in 73% of cases. A contralateral femoral arterial sheath (6 F for retrograde and 8 F for antegrade) was placed. For retrograde cases, an 8-F sheath was placed in the popliteal artery.

Antegrade and retrograde subintimal dissection was performed to preserve as much proximal and distal true lumen as possible (Figure 2A). In 36% of cases with severe calcification, a lead balloon was necessary to advance the wire through the occluded SFA (Figure 2B). The wire was snared in the midsegment of the SFA occlusion (Figure 2C). The subintimal dissection plane was ballooned to 6 mm in diameter (Figure 2D). After completion of the balloon angioplasty (Figure 2E), a popliteal pressure measurement was obtained. A pressure gradient was almost always present until the last endoprosthesis was ballooned to a 6-mm diameter following deployment of the device. The VIABAHN endoprostheses were placed and postballooned to 6 mm (Figure 2F). Completion angiograms and completion popliteal pressure measurements were obtained

(Figure 2G). At the completion of all procedures, the popliteal pressure was normalized, with no pressure gradient across the endoluminal graft segments.

Adjunctive stents were placed in common femoral arteries (20%), profunda femoral arteries (17%), and iliac arteries (23%). Figure 3 demonstrates wire protection of the profunda femoral artery and adjunctive stenting using a .014-inch wire system.

RESULTS

Technical success was 97.6%, with only one conversion to open bypass. Intraoperative pressure measurement revealed full normalization of distal pressure gradients, with a mean increase of 76 ± 16 mm Hg at the completion of the procedure. One- and 2-year primary patency was 86% and 76.8%, respectively. Limb salvage was 86.8%. There were no deaths or device failures. All postoperative ankle-brachial indices improved with a mean of $.47 \pm .19$, and clinical improvement was noted in 94% of patients. Postoperative duplex surveillance demonstrated mean velocities >80 cm/sec, with failing grafts decreasing below 40 cm/sec. There were three amputations: one from graft failure and two from progressive gangrene despite graft patency. There was one nonfatal cardiac event, one late endoleak that was repaired with an additional endoprosthesis, and three deep vein thromboses. Figure 4 is an example of a completion angiogram demonstrating a 6-mm-diameter lumen for the entire bypass.

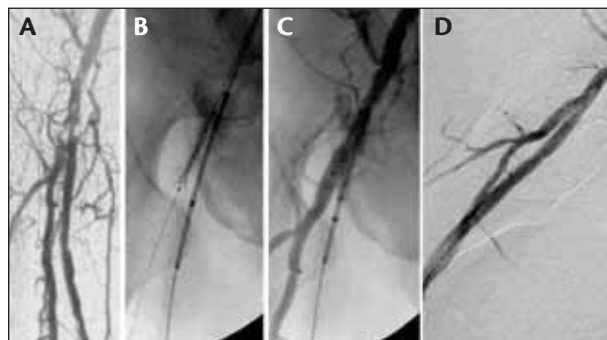


Figure 3. Combined SFA and profunda femoral disease (A). The profunda is stented over a contralateral .014-inch wire (B), which protects the profunda during SFA stenting (C). Completion angiogram (D).



Figure 4. Completion angiogram of proximal bypass (A), midendoprosthesis (B), and distal endoprosthesis with runoff (C).

DISCUSSION

Treatment of long-segment SFA occlusions is the new frontier for the vascular interventionist. Plaque characteristics of the SFA, especially chronic calcification, and the technical aspects of subintimal angioplasty and stenting are unique to the SFA. In cases with limited outflow and/or small vessel calcification, the ability to achieve long-term patency is further compromised.

Improved results with long-segment SFA lesions may be the result of normalization of popliteal artery pressures, flow dynamics of long-segment covered endoprostheses, and combined treatment of adjunctive lesions. Although anatomical prerequisites and patient selection are emphasized, these data suggest other theoretical advantages of stenting the subintimal angioplasty with an ePTFE-coated nitinol stent that may be important. The VIABAHN endoprosthesis is a flexible conduit with a nitinol exoskeleton. The thickness of the endoprosthesis is 100 μ m compared to 400- μ m for a thin-wall ePTFE graft. Although both open and endoluminal femoropopliteal bypass normalize arterial pressure at the distal end of the graft, the turbulent flow at a distal end-to-side anastomosis is avoided. Flow dynamics at the distal end of the endoluminal grafts are shown to be laminar on duplex ultrasonography, and there are no elevated velocities at the distal anastomosis with more uniform peak systolic velocities throughout the endoluminal graft.

Disadvantages of the technique include increased cost, technical difficulties, re-entry problems, operative times (1.5 to 3 hours), and the learning curve. Although this

technique is in its infancy, as with most minimally invasive techniques, it only requires a 1-day hospital stay for most patients, procedures can be performed under local anesthesia, and long-segment SFA occlusions can be recanalized.

For long-segment SFA occlusions, subintimal angioplasty combined with multiple ePTFE-covered endoprostheses demonstrate 2-year outcomes comparable to traditional revascularization and better outcomes than subintimal angioplasty alone. The importance of eliminating all pressure gradients across long-segment endoprostheses is emphasized.

CONCLUSION

Endovascular femoropopliteal bypass with multiple ePTFE endoprostheses is technically feasible, although a challenging procedure for the vascular interventionist. Several issues remain unanswered. These include the best approach for recanalizing the calcified SFA, re-entry techniques, cost-effectiveness, and long-term patency. Clearly, this technique will have a role in the treatment of long-segment femoral artery occlusions. ■

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Treating Total Occlusions and Long Lesions With the VIABAHN[®] Device

Preliminary results from a single-center study have shown technical feasibility and excellent in-stent primary patency at 6 months.

BY SUHAIL ALLAQABAND, MD; SEPIDEH KAZEMI, MD; AND TANVIR BAJWA, MD

In the past 25 years, significant advances in endovascular treatment for peripheral vascular disease (PVD) have given doctors and their patients minimally invasive alternatives to major surgical procedures that carry significant morbidity and mortality. Atherosclerotic occlusive disease is two to five times more frequent in femoropopliteal arteries than in iliac arteries. Patients vary in their clinical presentation from claudication to rest pain and leg ischemia. Whereas choices for managing suprainguinal disease are clear-

cut, choices for managing disease in the femoropopliteal arteries are not supported by strong evidence for or against percutaneous intervention (ie, percutaneous transluminal angioplasty, atherectomy, laser, stenting, or a combination of these) or peripheral bypass surgery. Although opinions vary regarding how to treat patients who have claudication, when pulsatile flow must be restored to prevent limb loss in patients who have rest pain or leg ischemia, some form of intervention is imperative.

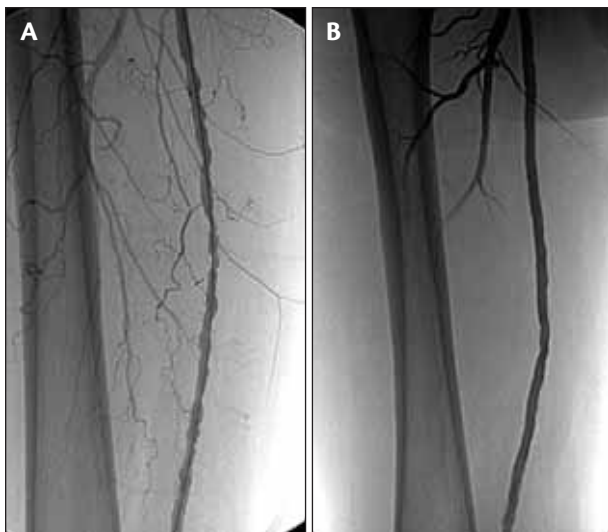


Figure 1. A 74-year-old man with lifestyle-limiting claudication underwent endovascular revascularization with two VIABAHN (W. L. Gore & Associates, Flagstaff, AZ) stent grafts (6 mm X 15 cm, 6 mm X 10 cm) in the right superficial femoral artery (SFA). Preoperative image (A); postoperative image (B).



Figure 2. An 83-year-old man with severe lifestyle-limiting claudication of the left leg underwent endovascular revascularization with two VIABAHN stent grafts (6 mm X 15 cm, 6 mm X 10 cm). Preoperative image (A); postoperative image (B).

Percutaneous angioplasty and stent placement, because of its less-invasive nature, is preferred over surgery in the treatment of patients with SFA occlusive disease needing revascularization. However, the results of percutaneous interventions in the SFA vary widely. A meta-analysis of more than 4,300 procedures by Becker et al¹ shows a 67% 4-year patency for SFA balloon angioplasty. Based on objective follow-up techniques, such as duplex ultrasound and exercise ankle-brachial indices, the primary patency of percutaneous transluminal angioplasty is much worse.² The primary patency rate in lesions longer than 10 cm has been reported to be as low as 20% at 1 year.³ Although primary patency rates in the SFA have improved with the use of stents, restenosis remains a major problem. A higher frequency of restenosis is seen in patients who present with total occlusions, long lesions, small-diameter vessels, and poor distal run-off vessels.⁴⁻⁸

There have been multiple studies evaluating the patency rates of different types of stents in the SFA. The 1-year primary patency rate of stainless-steel self-expanding, as well as balloon-expandable, stents (Wallstent [Boston Scientific Corporation, Natick, MA], Palmaz [Cordis Corporation, a Johnson & Johnson Company, Miami, FL]) has been shown to be approximately 40% to 60%.^{9,10} The self-expanding nitinol stents (Smart, Cordis Corporation) have shown a better 1-year patency rate (approximately 70% to 75%).¹¹ However, most of the studies involved patients with shorter lesions, usually <10 cm long.

Recently, stent grafts have been utilized in the treatment of long SFA lesions in the hope of reducing restenosis rates and improving long-term patency; however, initial reports have been mixed. A 59% primary

TABLE 1. BASELINE DEMOGRAPHICS

Number of patients	28
Age (years)	63.5±15
Gender	12 women, 16 men
Resting pain/Ischemic ulcer	6 (20%)
Fontaine class IIb or IIIa	22 (80%)
Diabetic mellitus	14 (50%)
Smoking	7 (25%)

patency was reported for a polyethylene terephthalate-covered stent graft at 18 months.¹² Results of a more recent study using an unsupported, expanded polytetrafluoroethylene (ePTFE)-covered device, were worse, registering only a 29% primary patency at 1 year.¹³

It appears that patency is at least partially dependent on the type of graft material used and also on device design. Dacron-coated stent grafts have poor results in the SFA and seem to elicit a significant inflammatory reaction, with pain and fevers that have been known as “postimplantation syndrome.” Recent trials with commercially available Dacron-covered devices have shown patency rates as low as 23% at 1 year, with a high early thrombosis rate.¹⁴ On the other hand, Diethrich et al¹⁵ reported a 72% primary patency at 8 months in patients with long stenosis and occlusions that averaged more than 15 cm in length.

In an international feasibility trial, the commercially available HEMOBAHN endoprosthesis (W. L. Gore & Associates) was assessed to have a 100% technical success rate and a primary patency of 90% at 6 months and 79% at 1 year.¹⁶

The VIABAHN endoprosthesis is constructed with a biocompatible ePTFE liner attached to the external nitinol stent structure. We evaluated the potential of the VIABAHN stent

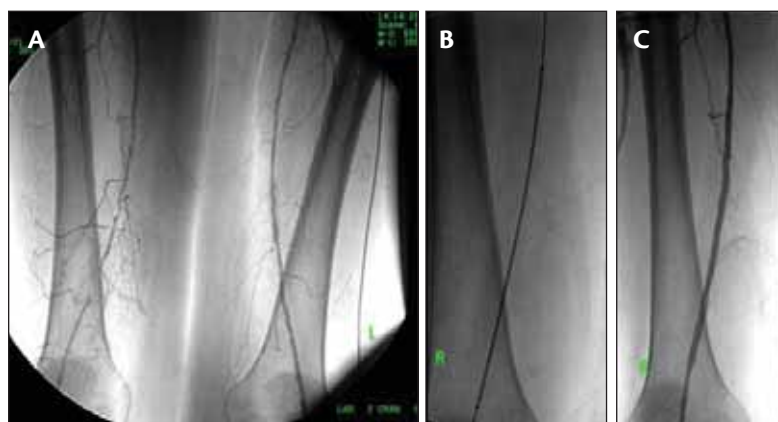


Figure 3. A 77-year-old woman with resting pain of the right leg and history of angioplasty of the left leg in the past. Preoperative image (A); positioning a 6 X 15 cm VIABAHN in the right SFA (B); Postoperative image (C).

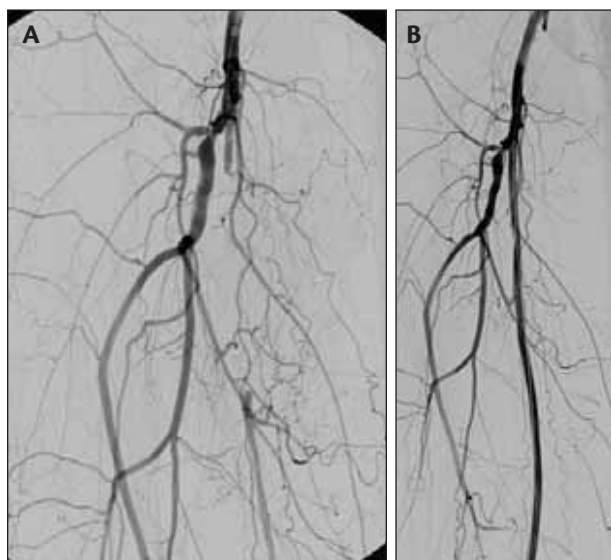


Figure 4. A 57-year-old man with a nonhealing ulcer of the right leg, with total occlusion of the right SFA and a high-grade lesion in the profunda femoris on angiogram, underwent endovascular revascularization with two 6-mm X 15-cm VIABAHN stent grafts. Preoperative image (A); postoperative image (B).

graft to improve the long-term outcome of percutaneous intervention in the SFA.

METHODS

Between August 2004 and April 2005, 28 patients (12 women, 16 men; mean age, 63.5 ± 15 years) presented to our institution with lifestyle-limiting claudication or limb-threatening ischemia. Fourteen patients (50%) had diabetes mellitus and seven (25%) were smokers. Table 1 demonstrates the baseline clinical characteristics of the patients. The procedural data are shown in Table 2. Lower-extremity angiography revealed total SFA occlusions in 13 patients (46%), and the remainder had high-grade stenosis ($>80\%$ stenosis). The mean distal vessel run-off was two vessels.

A total of 57 VIABAHN stent grafts were deployed in 32 legs (average, two stents per patient). The average stent length was 15 cm (range, 5-35 cm) and the average stent diameter was 6 mm (range, 5-7 mm). The initial technical success was 100%. There was no in-hospital mortality or morbidity. All patients were discharged on aspirin and clopidogrel therapy.

STENT GRAFT PLACEMENT

The procedures were performed under sterile conditions in the cardiovascular catheterization lab. All patients were administered 81 mg to 325 mg of aspirin and 300 mg of clopidogrel before the procedure and 75 mg of clopidogrel along with aspirin (81 mg to 325 mg once a day) continuously thereafter. Vascular access was obtained from either the contralateral femoral artery, or in an antegrade manner from the ipsilateral femoral artery using a modified Seldinger technique, and an 8-F sheath was placed in the femoral artery. In patients with contralateral access, an 8-F, 45-cm sheath was advanced over the aortic bifurcation over a .035-inch Magic torque wire (Boston Scientific Corporation). Patients were then anticoagulated with bivalirudin or heparin using a weight-based dose. The lesion was then accessed using a 5-F multipurpose catheter and crossed with a .035-inch Terumo Glidewire (Terumo Medical Corporation, Somerset, NJ). In patients with total occlusions, the lesion was crossed with a Terumo Glidewire using a subintimal dissection technique with crossover into true lumen distally confirmed by hemodynamic and angiographic evaluation. The Glidewire was exchanged with a .035-inch Magic torque wire. Predilatation was performed in 80% of cases using an undersized short balloon (usually 4.0 mm X 40 mm). The VIABAHN endoprosthesis was then deployed, with care taken to cover both the diseased segment and the balloon-injured segment completely. Postdilatation was performed in 100% of cases using a 1:1 sized balloon with high-pressure inflation

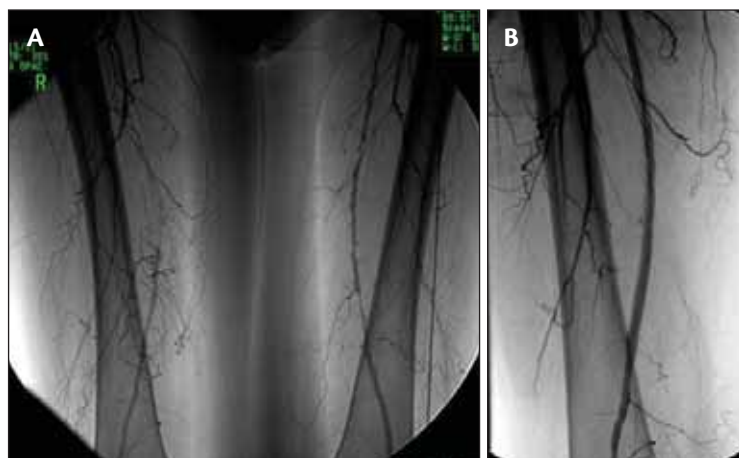


Figure 5. A 74-year-old man with resting pain of the right leg. His symptoms resolved completely after endovascular revascularization with two VIABAHN stent grafts in the right SFA (6 mm X 15 cm, 6 mm X 10 cm). Preoperative image (A); postoperative image (B).

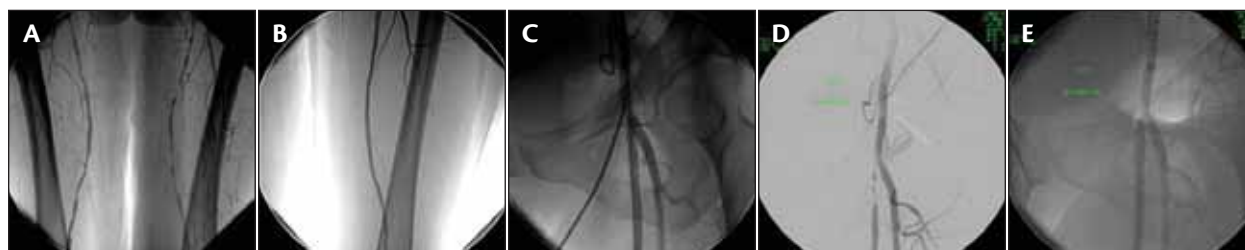


Figure 6. A 61-year-old woman with severe claudication in both legs had two 6-mm X 15-cm VIABAHN stent grafts placed in the left SFA and a 6-mm X 20-mm Smart stent placed at the ostium of the SFA. In-stent restenosis is visible in the Smart stent 5 months later, but the VIABAHN stent is patent. Preoperative image (A); postoperative image (B); Smart stent in the ostium of the SFA (C); restenosis of the Smart stent 5 months later, VIABAHN stent is patent (D); postangioplasty: 6-mm X 20-mm cutting balloon of the Smart stent (E).

(12-16 atm) to properly expand the endoprosthesis. Care was taken to avoid any balloon dilatation outside of the stent graft edges, using magnified fluoroscopic views to visualize the ends of the endoprosthesis. If the lesion involved the ostium of the SFA, a short, self-expanding nitinol stent (Smart, Cordis Corporation) was deployed at the ostium to ensure that the stent graft did not cover the origin of the profunda femoris artery. If the edges of the stent graft were not properly expanded, a Smart stent was deployed at the edge so that balloon dilatation of the edges could be performed properly within the stented segment. Technical success was defined as reduction of stenosis to <20%, with restoration of brisk antegrade flow without any visible thrombus or dissection. Anticoagulation was discontinued at the end of the procedure in the catheterization laboratory.

PATIENT FOLLOW-UP

Duplex ultrasound and ankle-brachial index were performed in all patients at 1 month, 3 months, 6 months, and 1 year after the procedure. Patients were also followed clinically 2 weeks after the procedure and every 3 months thereafter. In-stent restenosis was defined as >50% stenosis by duplex ultrasound. Per protocol, patients with in-stent restenosis were required to undergo lower-extremity angiography for confirmation of restenosis and further therapy if needed.

RESULTS

VIABAHN stent grafts were successfully deployed in 100% of patients (Figures 1 through 5). The edges of the stent graft were overlapped by a Smart stent in 15 patients. All stent grafts were between 5 mm to 7 mm in diameter and between 5 cm to 15 cm in length. The average length was 15 cm. Fifteen patients had 25-cm to

35-cm stent grafts in an overlapping manner. There were no in-hospital deaths, major adverse cardiovascular events, or access site complications. Clinical and hemodynamic improvement was noted in all patients.

TABLE 2. PROCEDURAL DATA

Total occlusion	13 (46%)
Average number of patent distal run-off vessels	2
Contralateral access	27 (96%)
Antegrade access	1 (4%)
Number of stent grafts	57
Average stent graft length	10 cm (5-35 cm)
Average stent graft diameter	6 mm (5-7 mm)
Average stent graft per patient	2
Initial technical success	100%
Mean follow-up	6 months
Primary patency of stent grafts	100%
In-segment patency	84%
Target vessel revascularization	2 (16%)
Stent graft thrombosis	0%



All of the VIABAHN stent grafts were patent at follow-up, with no patient experiencing acute or subacute stent graft thrombosis. In three of the patients who had overlapping Smart stents, there was in-stent restenosis in the Smart stent, but the VIABAHN stent graft was totally patent, resulting in 100% patency of the VIABAHN stent graft and 84% in-segment patency (Figure 6). The two patients with edge restenosis were successfully treated with cutting-balloon angioplasty.

DISCUSSION

Previous studies have shown that long lesions in the SFA yield poor long-term results after percutaneous interventions with angioplasty or stenting. Other novel interventions such as laser revascularization, atherectomy, and even drug-eluting stents have failed to improve long-term patency rates in such patients. Many of these patients have significant cardiovascular comorbidities, which put them at a high surgical risk.

Endovascular intervention using stent grafts for these long SFA stenoses/occlusions is a promising option with its high, initial, clinical, hemodynamic, and angiographic success along with improved long-term patency. Although some early studies with stent grafts had poor results, the initial results with the VIABAHN stent graft look more promising. Also, better implantation techniques and advances in anticoagulation therapies, such as the use of dual antiplatelet therapy combining aspirin and clopidogrel, have improved immediate and long-term patency of stent grafts. Interestingly, during our study, we observed increased intimal proliferation when the Smart stents were used at the edges of the stent graft. We, therefore, abandoned the technique of overlapping the edges of the VIABAHN endoprosthesis with Smart stents. We also determined that covering the diseased segment of the artery in its entirety, along with exerting extreme care to avoid balloon injury on the outside edges of the stent graft, are crucial to reduce the chance of edge restenosis.

CONCLUSION

Based on the preliminary results of our study, in a group of patients who were a high risk for restenosis based on their initial presentation (46% total occlusions, 90% >10-cm lesions), we believe that endovascular intervention in the SFA with the VIABAHN stent graft is technically feasible and provides excellent in-stent primary patency (100%) at 6 months. With careful attention to proper deployment technique and the use of dual antiplatelet therapy, no cases of acute or subacute thrombosis were seen in this group of patients. ■

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Using the VIABAHN[®] Device in the SFA

Optimizing the use of the VIABAHN device in treating SFA occlusive disease.

BY GARY M. ANSEL, MD; CHARLES F. BOTTI, JR, MD; AND MITCHELL J. SILVER, DO

Recently, the FDA approved a covered nitinol stent graft (VIABAHN, W. L. Gore & Associates, Flagstaff, AZ) for use in the superficial femoral artery (SFA). The VIABAHN stent graft consists of a self-expanding helical nitinol stent and a tube of radially reinforced 0.1-mm-thick expanded polytetrafluoroethylene (ePTFE). The pore diameter is approximately 30 μ m. The favorable interaction between ePTFE and tissue is well documented. Complete neointima formation has been recorded previously.¹ It appears that complete endothelialization takes some time. Marin et al studied the development of intima in humans and found that at 3 months, endothelium could be found up to 3 cm into the stent graft, whereas at 5 months, endothelium could be found at 8 cm.^{2,3}

Review of the available literature studying utilization of ePTFE self-expanding covered stents in the SFA suggests that with proper technique, they may be an excellent option for the patient with occlusive disease (Figure 1), but, a dichotomy exists between some of these studies. Most of the published studies show favorable results with 1- and 2-year primary

patency rates of approximately 82% and 77%, respectively.⁴⁻⁹ However, three studies that demonstrated poor results stand out with 1-year patency rates <50%.¹⁰⁻¹² The apparent causation for the poor results seen in these three studies may be traced to known shortcomings that have led to poor results in many stent studies. These shortcomings include not completely covering the predilated area, poor utilization of antiplatelet therapy, severe arterial calcification, and poor distal runoff. VIABAHN stent coverings are the

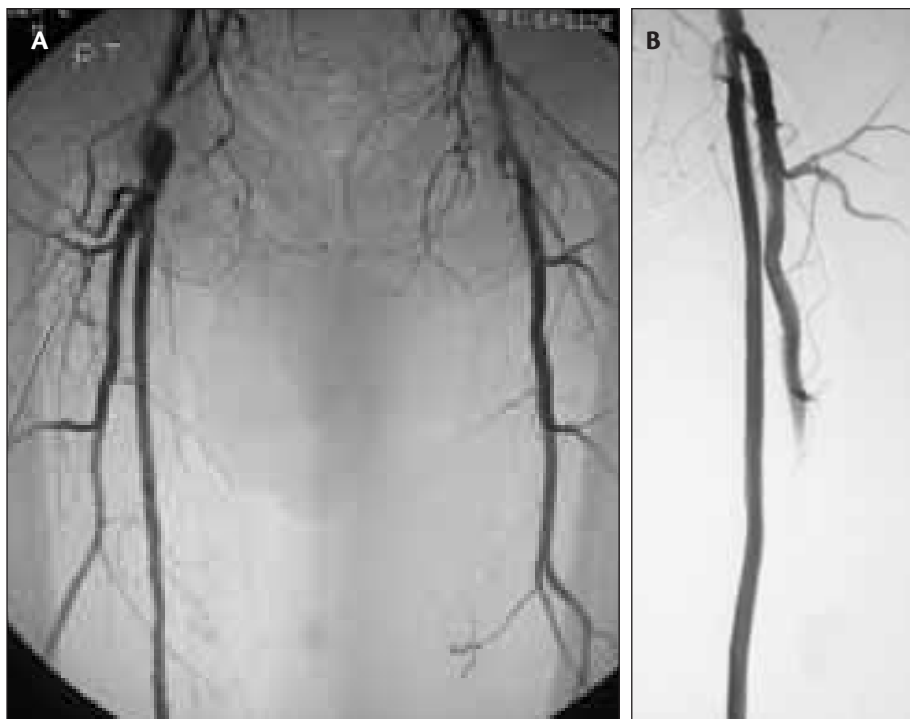


Figure 1. Angiography illustrating a long total occlusion of the left SFA (A). Final angiography after balloon angioplasty and VIABAHN stent graft placement (B).



TABLE 1. VARIABLES TO OPTIMIZE STENT GRAFT USE

- Adequate inflow of iliac and common femoral arteries
- Adequate outflow (optimally two to three tibial vessels)
- Adequate predilation
- Optimum stent graft-to-vessel diameter sizing
- High-pressure postdeployment balloon angioplasty
- Above knee position
- Prolonged antiplatelet therapy
- Minimum 15 mm of overlap for multiple stents
- Assess potential for collateral coverage
- Regular surveillance program

same ePTFE coverings utilized in vascular grafts used for bypass in the infrainguinal area. Although venous bypass has been shown to be more favorable when crossing the knee, prosthetic material has similar patency in above-the-knee bypass.¹³ Further insight into optimizing patency for the VIABAHN device may be obtained by reviewing both the extensive surgical and endovascular literature bases that have studied prosthetic bypass and endovascular stent patency. Table 1 provides a summary of some of the key variables known to effect long-term patency.

GENERAL PROCEDURAL FAILURE

The etiology of surgical or endovascular procedural failure can be defined as early, intermediate, or late. Early failure and thrombosis has been reported in up to 17% of bypass grafts to the popliteal artery.¹⁴ Early thrombosis of infrainguinal covered and uncovered stents has been reported, albeit less frequently.^{4,6} Early thrombosis is usually due to technical failure, hyperco-

agulable state, lack of periprocedural anticoagulation, or a period of hypoperfusion or hypotension. Technical failure of stents or stent grafts would primarily include incomplete arterial stent dilation and excessive stent graft oversizing leading to material redundancy. An intermediate procedural failure, which occurs between 6 and 24 months after the procedure, is most commonly due to intimal hyperplasia, whereas late failure, which occurs longer than 24 months, is often due to progression of proximal or distal disease.

INFLOW

Because atherosclerosis is a diffuse progressive disease process, surgeons well know that adequate inflow to the proximal graft is of utmost importance. Even minor stenoses $\geq 20\%$ proximal to a bypass graft have been correlated with a decrease in long-term graft patency due to progression of atherosclerotic disease.¹⁵ Thus, it appears important to place a VIABAHN stent graft only after ensuring that proximal iliac and common femoral disease has been adequately addressed. One should also place the stent graft with the ends in as near to normal artery as possible.

OUTFLOW

The patency status of the runoff vessels has been shown to affect both surgical bypass and endovascular procedure patency. Although poorly studied in the endovascular literature, plantar arch patency is associated with improved bypass graft patency.¹⁶ Patency of tibial vessel runoff has been shown to also be a strong predictor of long-term success in endovascular procedures, with two- to three-vessel runoff associated with two to three times the patency of patients with zero- to one-vessel runoff.^{17,18} This variable may also be the main reason that both surgical and endovascular procedures appear to be more durable in claudicants than in patients with critical limb ischemia. In their study of ePTFE stent grafts in the SFA, Fischer et al¹² found significantly lower patency in patients with zero- to one-vessel runoff.

DIAMETER

Unless there is significant graft-to-vessel size mismatch, larger diameter prosthetic bypasses appear to be associated with improved patency. Significant calcification has been associated with lower long-term patency after balloon angioplasty. With the use of a stent graft, significant arterial calcification may impede full deployment and result in a much smaller end diameter. It would appear to make scientific sense to

optimize the VIABAHN stent graft deployment diameter and to size the VIABAHN device to the true vessel size by aggressive poststent graft placement balloon dilation. For example, aggressive balloon dilation requires high pressures to achieve the true diameter of the graft within the vessel. After using intravascular ultrasound in many of our procedures, we have found that the angiographic appearance of the VIABAHN endograft should be perfect or the device has often not been optimally deployed. In this instance, we have also found that high-pressure angioplasty with shorter (2- to 4-cm) balloons allows for improved deployment and outcomes over long 10-cm balloons.

ANATOMIC POSITION

Patency of distal popliteal venous bypass appears to be superior to an above-the-knee position by decreasing the chance for distal disease progression. However, this is not true for below-the-knee prosthetic grafts in which 4-year primary patency is reported to be approximately 40%. Although not currently studied in the occlusive disease population, studies evaluating covered stent grafting of popliteal aneurysms have reported that stent graft occlusion occurs in 20% to 22% of procedures (1 year).^{19,20} The current device is not approved for use in the popliteal artery, and the risk/benefit ratio would need to be clear before off-label use could be recommended.

ANTIPLATELET THERAPY

Long-term use of acetylsalicylic acid can be recommended in all peripheral vascular patients whether having undergone a procedure or not based on its ability to reduce thrombotic events in vascular patients. Likewise, clopidogrel has been noted to decrease cardiac and cerebrovascular events in patients with coexistent coronary and peripheral vascular disease.²¹ Acetylsalicylic acid has been shown to reduce thrombotic closure of above-the-knee prosthetic grafting.²² Similar improved patency has been seen with ticlopidine in a randomized multicenter trial.²³ Clopidogrel use has been associated with improved patency in popliteal stent graft use.²⁰ The use of intravenous IIb/IIIa inhibitors has not been reported with bypass, but in a randomized trial during SFA, nitinol stenting has not shown benefit.²⁴

UNIQUE ASPECTS OF COVERED STENTS

Predilation

Although direct stenting, especially of total occlusions, has gained popularity, we do not recommend

the technique for stent graft placement. Aggressive predilation will allow for testing the native vessel's ability to undergo successful dilation, which is important. Adequate predilation will also help to ensure even deployment of the stent graft. It should be noted that with total occlusions, this technique could theoretically increase the likelihood of distal embolization. Anecdotally, we often debulk these lesions in an effort to decrease the likelihood of occurrence.

Overlap

With bare metal stents, excessive overlap may lead to increased rigidity and possibly increase the likelihood for potential stent fracture. The VIABAHN endograft is very flexible and in our own experience, too-short overlap may lead to stent graft separation. Thus, our own technique includes overlapping stent grafts by at least 15 mm in atherosclerotic disease.

Collaterals

Using a stent graft such as the VIABAHN device, although it offers a potential breakthrough in the treatment of SFA disease, is not without potential drawback. The addition of ePTFE to the stent certainly may limit restenosis in the body of the stent graft. However, bare metal stents are often able to preserve collateral vessels, whereas stent graft coverage would not preserve covered collaterals. One would need to depend on the development of new collaterals to prevent the potential development of limb-threatening ischemia in the case of thrombosis. Certainly, this issue becomes more important as one treats more distally in the infringuinal area. Although the development of severe symptoms from closure has been very rare in our own experience, these occurrences are not enough, and more study in larger numbers of patients will be necessary to fully understand this issue. Until more knowledge has been obtained, physician operators must weigh the benefit to the patient with the risk of collateral coverage as they treat their patients.

Inflammation

Thigh discomfort has been reported in approximately 6% to 20% of patients undergoing placement of stent grafts in the SFA.^{5,8} It is believed that this symptom may represent an inflammatory response. However, many centers are very aggressive in postdilation, which may manifest as thigh pain due to procedural trauma. Symptoms may be accompanied by low-grade fever and usually respond to conservative care and anti-inflammatory or analgesic medications.



APPROPRIATE STENT GRAFT SURVEILLANCE

Surveillance programs have shown convincing evidence of benefit for detecting vein graft stenoses predictive of progression to occlusion.²⁵ However, duplex imaging has not consistently been shown to be effective for the detection of failing prosthetic grafts.^{26,27} With prosthetic grafts, most stenoses are in the outflow vessel, inflow vessel, or at an anastomosis. There are no data on surveillance programs for femoral stent grafts such as the VIABAHN device. However, most of the loss of patency appears to occur during the first year after placing the VIABAHN device. Restenosis at the distal ends of the stent grafts has been seen in stent graft occlusions treated with thrombolysis. In our institution, we have not found it difficult to perform color-flow duplex scanning on the VIABAHN endograft, and it appears that intimal hyperplasia and restenosis can be readily visualized. It seems prudent to, at a minimum, have the patient return at regular intervals to obtain a clinical history and perform a vascular examination, resting and (if possible) a postexercise ankle-brachial index, and consider color-flow duplex scanning. There will be reimbursement issues that may need to be addressed.

SUMMARY

The recent approval of the VIABAHN stent graft is a step forward for percutaneous endovascular treatment of SFA obstruction. The lessons and principles that have been previously learned from prosthetic bypass and endovascular intervention are good starting points for proper patient selection and optimizing patency. ■

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Use of the VIABAHN[®] Stent Graft to Treat Long-Segment SFA Disease

A clinical case with more than 5-year follow-up.

BY RICHARD R. SAXON, MD

Despite the investigation of a multitude of different techniques from freezing to atherectomy, from stent placement to subintimal recanalization, few techniques have demonstrated long-term (>1 year) patency improvements in the femoropopliteal artery when compared to plain old balloon angioplasty. However, a number of studies have been completed on the use of the HEMOBAHN or VIABAHN stent grafts (W. L. Gore & Associates, Flagstaff, AZ) that have demonstrated relatively impressive long-term patency rates. Although not all of the results have been published in

peer-reviewed publications, the patency by ultrasound follow-up for average lesion lengths of >13 cm averaged 77% at 1 year and 65% at 3 years, rivaling femoral to popliteal bypass.¹⁻¹²

Unlike other “uncovered” stents, no significant issues with stent fracture have been reported with this stent graft. The VIABAHN device has just been approved by the FDA for use in the superficial femoral artery (SFA) for atherosclerotic occlusive disease based on the data from a multicenter, randomized trial versus angioplasty alone. To my knowledge, this is the second implantable device to be



Figure 1. Images from the preprocedure diagnostic arteriogram obtained in 1999. The severely calcified target lesion was a relatively long stenosis of the distal SFA (A). The more proximal vessel was of a larger caliber and relatively free of significant disease (B). The below-knee outflow was excellent, with three-vessel runoff (C).



Figure 2. Image taken during the pre-stent graft angioplasty. Note the severe calcification of the lesion. Importantly, however, no areas were seen that were resistant to dilation.

approved for use in the SFA. Therefore, it seems appropriate to share a case that illustrates the type of candidate who is suitable for this technique and to demonstrate the long-term durable primary patency that can be achieved when stent grafts are used in the SFA.

CASE REPORT

Presentation

A 77-year-old man with severe cardiac disease presented in March 1999 with debilitating short-distance claudication of his right leg. The claudication was interfering with his cardiac rehabilitation. He underwent aortography and runoff arteriography, which showed a severely calcified, 9-cm-long area of stenosis in his distal right SFA. Focal areas of near occlusion were noted in the lesion (Figure 1A). The in-flow and outflow, however, were widely patent (Figure 1B,C).

The patient was enrolled in the initial US Multicenter HEMOBAHN device approval trial and was randomized to stent graft placement. The lesion was traversed with a 5-F angled catheter and an angled hydrophilic guidewire and was then dilated with an 8-cm-long X 6-mm-wide balloon (Figure 2).

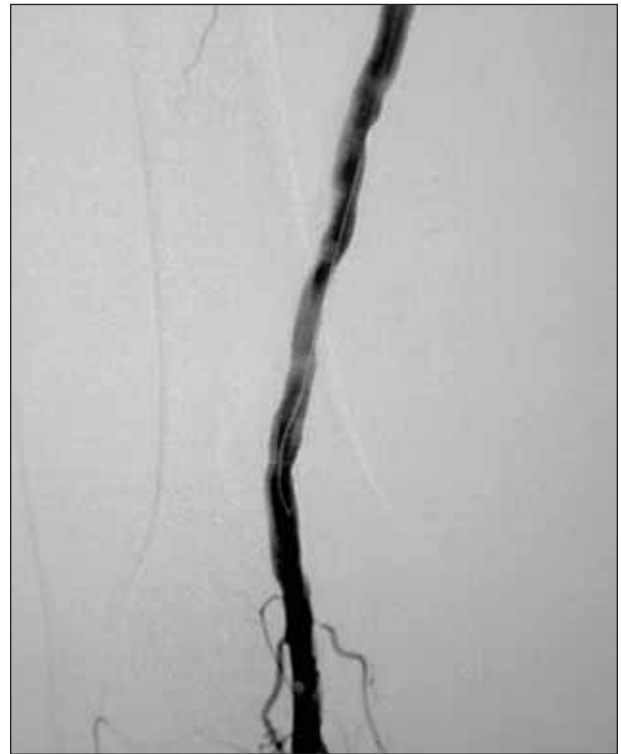


Figure 3. The arteriogram obtained immediately after VIABAHN endograft placement and postdilation demonstrates mild areas of residual narrowing, but an improved lumen with no areas of significant residual recoil.

Procedural Considerations

One of the issues with such a calcified lesion is ensuring that the device can be placed across the lesion prior to deployment. Predilation is mandatory before placing the stent graft. One must be certain that the lesion is not resistant to dilation. Sometimes the use of high-pressure balloons may be required. Even after successful percutaneous transluminal angioplasty, areas of dense calcification or recoil may prevent passage of the VIABAHN device (the device is not covered by its own sheath). Therefore, it is sometimes useful to place a long sheath across the lesion prior to placing the device. This ensures that one can maneuver the device into position without getting it stuck on areas of calcification. In this case, although the balloon inflated well without areas that were resistant to dilation, the percutaneous transluminal angioplasty result was poor, with significant recoil. The device was successfully placed using a long sheath.

The patient's artery above and below the lesion measured 6.3 mm, and therefore a 15-cm-long X 7-mm stent graft was placed. Careful attention to sizing is essential to achieving optimal results. Although a 10-cm device could conceivably



Figure 4. Follow-up arteriogram obtained 2 years after VIABAHN endograft placement. The stent graft is widely patent.

have been used, it is preferable to use longer devices and to overlap devices when necessary to ensure that the stent graft extends into a relatively normal area of the vessel that has not been injured by the balloon. After postdilation, a markedly improved lumen was observed (Figure 3).

Outcome

The impressive element of this case is the patient's clinical outcome. He remains asymptomatic more than 6 years after stent graft placement, with an ankle-brachial index >1.0. Angiography was performed in 2001 during treatment of the contralateral limb, and the stent graft was found to be widely patent (Figure 4). Finally, a follow-up ultrasound in October 2004 also showed a widely patent stent graft, 67 months after placement.

CONCLUSION

VIABAHN stent graft availability in the US for nonvascular indications has changed our approach to treating long-segment TASC B-D lesions. We believe patency is largely independent of lesion length with these devices, unlike any other treatments for femoropopliteal occlu-

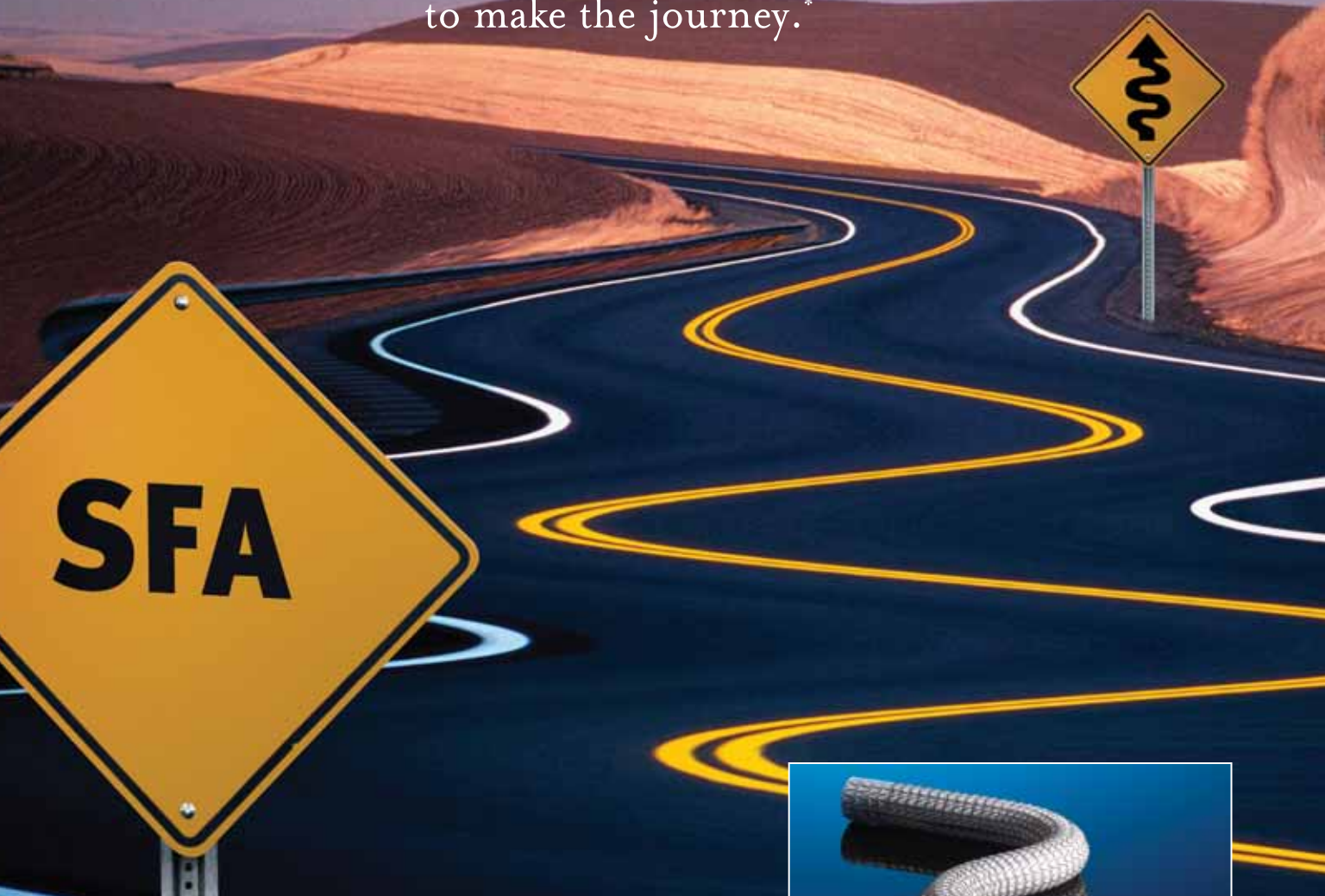
sive disease. Therefore, we have treated lesions up to 38 cm in length, obviating the need for a bypass operation in many cases.

This case demonstrates the potential durability of the VIABAHN stent graft. Despite placement in this "mobile location" (extending across the adductor canal), the device performed extremely well. We now use these devices regularly in patients with long-segment disease in whom the vessels are of adequate diameter (>4.5 mm) and with adequate outflow (at least one nonstenotic runoff vessel). Proper device sizing and patient selection is also critical to a good long-term outcome. The arterial approval of the VIABAHN stent graft should allow for more widespread application of this technique in the future, with continued refinement of which patients will most benefit from this approach. ■

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