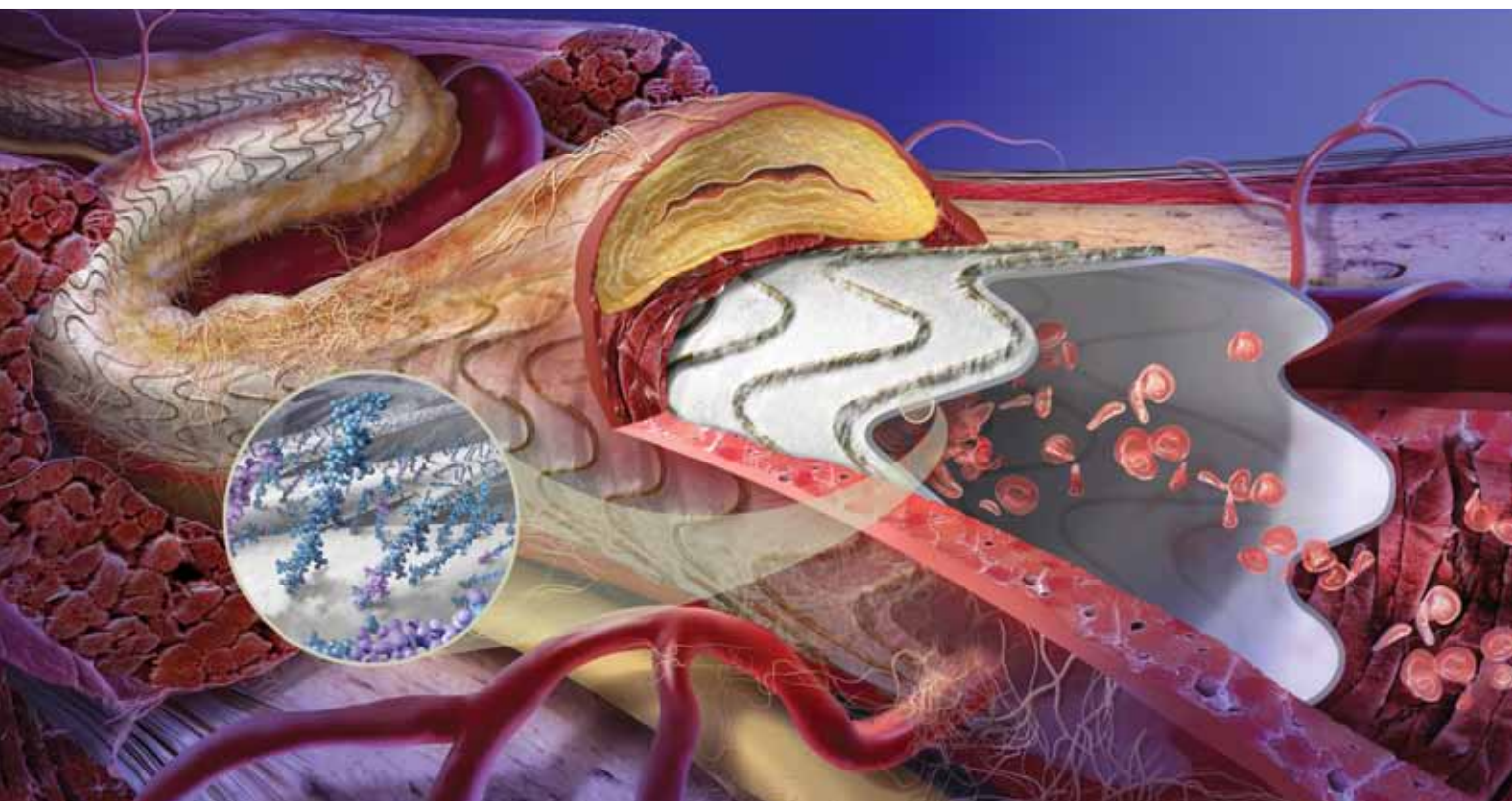


# Endovascular TODAY

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## INNOVATIONS IN THE ART OF STENT GRAFTING



**Utilizing the GORE® VIABAHN® Endoprosthesis  
to treat complex SFA and iliac artery disease.**

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# Technical Considerations for Achieving Success With the GORE® VIABAHN® Endoprosthesis

Thought leaders in the field weigh in on the key aspects of this device at the GORE® VIABAHN® Endoprosthesis Forum.

COMPILED BY RENÉE J. ROBILLARD, MA, ELS

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*The following is a summary of a panel discussion that was held on October 9–11, 2011, at the GORE® VIABAHN® Endoprosthesis Forum in Scottsdale, Arizona.*

The GORE® VIABAHN® Endoprosthesis With Heparin Bioactive Surface (W. L. Gore & Associates, Flagstaff, AZ), which consists of a nitinol frame lined with expanded polytetrafluoroethylene (ePTFE), received US Food and Drug Administration (FDA) approval for use in treating occlusive superficial femoral artery (SFA) disease in 2005. It remains one of the only FDA-approved stent grafts for this endovascular application. The newest generation of the GORE® VIABAHN® Device has a lower-profile delivery system (6 F for 5- and 6-mm devices and 7 F for 7- and 8-mm devices, delivered over a 0.018- or 0.014-inch guidewire), a scalloped (contoured) edge at the proximal end, and a heparin-bonded surface.

In several randomized studies and large, multicenter series, the GORE® VIABAHN® Device has provided good patency and limb salvage results in patients with SFA disease of various degrees of severity, including TransAtlantic Inter-Society Consensus (TASC II) C and D lesions. Moreover, any restenosis that does occur is generally located at the edges of the device ("edge stenosis") rather than within it. In-stent restenosis of a GORE® VIABAHN® Device has rarely been reported, which is probably because the ePTFE lining provides a barrier from tissue ingrowth into the lumen. Other reported advantages of the stent graft include a high degree of flexibility, a very low rate of stent fracture, and efficacy in the treatment of long-segment disease.



**TOP 10 TECHNICAL CONSIDERATIONS IN USING THE GORE® VIABAHN® DEVICE**

- 1. Avoid oversizing.** Do not use an endoprosthesis with a diameter that is more than 20% larger than the diameter of the patient's SFA. Oversizing increases the risk of edge restenosis (due to intimal hyperplasia and/or thrombus formation adjacent to the stent) and a subsequent loss of patency. A diameter difference of  $\leq 10\%$  may be optimal.
- 2. Treat all disease.** Preserve collateral vessels whenever possible, but do not refrain from covering them in cases in which all existing lesions would not otherwise be treated. Never cover the profunda femoris artery with a stent graft.
- 3. Prescribe adequate postprocedure antiplatelet therapy.** After implantation of a GORE® VIABAHN® Device, prescribe aspirin for life and clopidogrel for at least 3 to 12 months for patients who can tolerate it.
- 4. Confirm adequate inflow and outflow.** Before device implantation, use an imaging technique to confirm that the patient has good inflow into the treatment area, at least one adequate run-off vessel, and no flow-limiting distal popliteal disease.
- 5. Place the device flush with the origin of the SFA to cover all disease.** After predilation or debulking in the diseased segment, place the end of the endoprosthesis flush with the SFA origin so that the device covers any disease that extends from healthy segment to healthy segment, thereby decreasing the likelihood of developing edge stenosis. Adequate preparation of the vessel near the SFA origin to create a landing zone (eg, with PTA or atherectomy) may be critical to achieving success. In addition, imaging using oblique angiography views to accurately identify the SFA origin should be routinely employed.
- 6. Provide a 1-cm overlap between devices.** When using multiple stent grafts in a vessel segment, overlap them by at least 1 cm to reduce the risk of separation of the devices during movement.
- 7. Postdilate the stent graft.** Use a high-pressure balloon to seat the stent graft, but do not dilate the edges of the device.
- 8. Do not balloon outside of the stent graft.** Restrict preimplantation and postimplantation balloon dilation to within the endoprosthesis (between the landing zones) to avoid barotrauma to the adjacent vessel, which may induce intimal hyperplasia.
- 9. Use duplex ultrasonography during follow-up.** Monitor patients for stent graft patency and progression of disease every 3 months during the first year after device implantation and then yearly using duplex ultrasound surveillance. Progression of disease at the edge of stent grafts may not be evident by patient symptoms or ankle-brachial index assessment due to the generally focal nature of the disease.
- 10. Treat progressing disease.** Failure of a GORE® VIABAHN® Device generally occurs because of narrowing at the edges due to intimal hyperplasia, disease progression, or both. Thrombolysis or thrombectomy of occluded stent grafts can be employed to restore flow and reveal the culprit lesion prior to treatment. Stenosis at the edges can generally be treated using interventional techniques.

The GORE® VIABAHN® Endoprosthesis Forum was convened to bring together 11 highly experienced practitioners of peripheral artery disease treatment, including use of the GORE® VIABAHN® Device, for 3 days of presentations, discussion, and brief, anonymous surveys pertaining to the physicians' current practices and opinions. The goal of the forum was to identify the specific technical aspects of device implantation that optimize patient outcomes. Of the many issues discussed, three were identified as being the most important: avoiding device oversizing, covering the entire

diseased vessel segment, and prescribing adequate postprocedure antiplatelet therapy. Techniques for achieving thrombolysis in a GORE® VIABAHN® Device were also presented. Please see the *Top 10 Technical Considerations in Using the GORE® VIABAHN® Device* sidebar for a summary of the views of the participants who participated in the forum.

**AVOID OVERSIZING**

The GORE® VIABAHN® Device is indicated for use in patients in whom the reference SFA diameter ranges

from 4 to 7.5 mm. The device is available in various length, width, and delivery-profile configurations, including diameters of 5, 6, 7, and 8 mm and profiles of 6, 7, and 8 F. The recommended device diameters are 5 mm for vessels with a diameter of 4 to 4.7, 6 mm for 4.8- to 5.5-mm vessels, 7 mm for 5.6- to 6.5-mm vessels, and 8 mm for 6.6- to 7.5-mm vessels.

Both clinical experience and the findings of formal studies, including the recently completed VIPER trial,<sup>1</sup> show that following these sizing recommendations (ie, using a GORE® VIABAHN® Device with a diameter that is sized appropriately for the patient's SFA) can lead to optimal long-term patency of the stent graft. There should never be more than a 20% difference between the luminal diameter of the vessel at the ends of the device and that of the stent graft. A difference of no more than 10% may provide the best results.

The primary mode for failure of stent grafts is focal edge stenosis,<sup>2</sup> although the mechanism of this failure in cases of oversizing is not known. One possibility is that placement of the stent graft and subsequent balloon dilation may cause injury to the arterial wall that induces intimal hyperplasia adjacent to the prosthesis. Another possibility is the mismatched sizing of the stent graft. The mismatched diameters may also result in a turbulent flow pattern at the edge of the graft, which may trigger either thrombus accumulation or intimal hyperplasia. Finally, it is possible that if the stent graft is not able to fully expand and appose the vessel wall, thrombus may collect in the resulting gaps and folds in the ePTFE graft material.

However, oversizing a GORE® VIABAHN® Device is not uncommon, especially among new users of the device. Some clinicians may oversize because they believe that smaller-diameter SFA stent grafts are more likely to occlude, as was indicated by the results of a clinical series reported by Saxon et al in 2007.<sup>3</sup> Others may not use an accurate method for estimating the diameter of the SFA, perhaps because their institution lacks the necessary imaging equipment or expertise. Finally, there may be an overriding perception that most SFAs have a diameter of 5 to 6 mm, which may not be the case in patients with heavily diseased vessels.

Intravascular ultrasound and quantitative angiography are commonly used to determine vessel size. Intravascular ultrasound can be used at the distal and proximal landing zones to visualize and measure the vessel cross-section. With quantitative angiography, the landing zone diameter can be estimated using a calibrated intravascular catheter or guidewire or with an external radiographic ruler as a size reference. In addition, in-vessel inflation of an angioplasty balloon

## Treating the full extent of disease in the SFA is also important in achieving optimal results with the GORE® VIABAHN® Device.

to its nominal diameter represents a size reference that can provide a rough determination of vessel size. It is essential to keep in mind that the smaller the vessel, the greater the importance of accurate sizing and that the GORE® VIABAHN® Device should not be used in an SFA with a luminal diameter of < 4 mm.

Most of the published experience with the GORE® VIABAHN® Device so far has been with previous generations of the device, which did not have a heparin surface, contoured proximal end, or 6-F delivery profile. The recently completed VIPER study, in which the GORE® VIABAHN® Devices used did have a heparin surface, found that 1-year primary patency outcomes were significantly better when appropriate sizing at the landing zones was achieved, even in patients with extensive vessel disease.<sup>1,4</sup> The VIPER study also showed that outcomes with 5-mm GORE® VIABAHN® Devices can be similar to those with 6-mm devices (possibly because of the new heparin surface), thereby permitting successful treatment of 4- to 4.7-mm-diameter vessels.

## TREAT ALL DISEASE

Treating the full extent of disease in the SFA is also important in achieving optimal results with the GORE® VIABAHN® Device. Leaving significant uncovered atherosclerotic plaque adjacent to the device allows disease progression that may limit flow and lead to patient symptoms or device failure. However, there has been some speculation about whether it is harmful to cover collateral vessels with the stent graft.

When stent grafts were first introduced for use in the SFA, some clinicians assumed that collateral vessels may mitigate the risk of limb-threatening ischemia by providing flow if a stent graft occludes suddenly and that such vessels should therefore always be preserved. However, occlusion of GORE® VIABAHN® Devices has not been associated with a higher rate of acute limb ischemia than occlusion of bare-metal stents, which have fenestrations that, theoretically, would allow flow to continue through collateral vessels during occlusion.<sup>4</sup>

In addition, investigators have noted re-recruitment of collateral vessels during progression of disease at

the edge of a stent graft.<sup>5</sup> Moreover, preservation of a distal collateral often results in not covering all of the disease adjacent to that collateral, thus allowing progression of disease and increasing the risk for loss of patency. Therefore, the best practice is to preserve collateral vessels whenever possible but to not refrain from covering them in cases in which all existing lesions would not otherwise be treated. Completely covering disease in the proximal SFA is especially important, and the GORE® VIABAHN® Device can be accurately placed flush with the origin of the SFA when the vessel has been properly prepared by predilation or debulking. The profunda femoris artery, which is essential to the lower limb circulation, should never be covered by a stent graft.

### **PRESCRIBE ADEQUATE POSTPROCEDURE ANTIPLATELET THERAPY**

Patients who have undergone placement of a GORE® VIABAHN® Device (either heparin-bonded or non-heparin-bonded) should, if they can tolerate it, take aspirin for the rest of their lives. Concomitant administration of clopidogrel (Plavix, Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership, New York, NY) for at least

3 to 12 months is highly recommended, and a number of physicians who have reported excellent results with the GORE® VIABAHN® Device have used this approach. This is consistent with the CASPAR study, in which dual-antiplatelet therapy provided a distinct benefit in patients who underwent synthetic bypass graft implantation.<sup>6</sup> However, for at least 3 to 12 months, adverse effects (particularly bleeding), may limit the use of clopidogrel in some patients. In addition, patients with no or inadequate health insurance may not be able to take clopidogrel because they cannot afford to pay for it. Fortunately, this may change as the US patent for Plavix expired in 2012. ■

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# The Importance of Accurate Femoropopliteal Artery Sizing in Endovascular Therapy

Recognizing the current shortcomings of vessel measurement standards.

BY RICHARD R. SAXON, MD, FSIR

Endovascular therapy is often an appropriate method for treating symptomatic femoropopliteal artery (FPA) occlusive disease, but few comparative data are available to aid in the determination of the best strategy for an individual patient. Various patient and lesion characteristics can adversely impact long-term patency after an FPA intervention.<sup>1-3</sup> For example, with most endovascular techniques, patency clearly decreases with increasing lesion length and complexity. Patency after angioplasty is worse when occlusions, rather than stenoses, are treated or when densely calcified lesions, rather than lesions with no calcification, are addressed.

The recognition of such facts led to the TASC classification system and the current recommendation that endovascular therapy is most appropriate for lesions that are shorter than 15 cm in length.<sup>1</sup> However, because results vary according to treatment modality and change as new and improved devices become available, broad generalizations, such as those in the TASC document, may be inaccurate or outdated and difficult to use as a decision-making tool for a specific patient. For example, stent graft treatment is likely an exception to the “rule” that patency after endovascular therapy diminishes with increasing lesion length. Most studies, including the recently completed VIPER trial, have shown that patency with stent grafts is essentially independent of lesion length.<sup>4-6</sup>

## LACK OF DATA IN CURRENT PRACTICE

Unfortunately, many aspects of the techniques needed to achieve the best long-term results with a given treatment have yet to be thoroughly studied; instead, “con-

sensus” tends to rule the day. For instance, in the early days of angioplasty, balloons were routinely oversized by 10% or more, relative to the vessel being treated. This was done partly to account for the parallax and magnification created by “cut-film” angiography, but it was also thought that the vessels should be overdilated by 5% to 10% to create a larger vessel lumen and overcome negative remodeling that might occur over time. Today, however, most interventionists try to match the balloon size to the vessel size with the aim of promoting better patency. They assume that this approach minimizes barotrauma to the vessel wall, even though there is no proof that this “kinder and gentler” method of angioplasty has clinical benefits.

Another example of a consensus-based practice is the use of longer balloons so that balloon length is matched with lesion length. Prolonged balloon inflations (2–4 minutes) are now commonly performed. These approaches are based on an assumption that better results will be achieved—with greater luminal gain and fewer dissections—if less damage occurs during dilation of the viscoelastic arterial wall. It is often stated that long balloons and prolonged inflations decrease dissections and obviate the need for stents in some cases. But are there any data that substantiate this claim? Although I use these techniques routinely and believe they are helpful, as far as I know, the possible benefits of matching the balloon diameter with the vessel size, employing longer balloons, and using prolonged inflation have not been established by means of quantitative analysis.

Quantitative data on the optimal stent diameter for a specific vessel luminal size are also lacking.

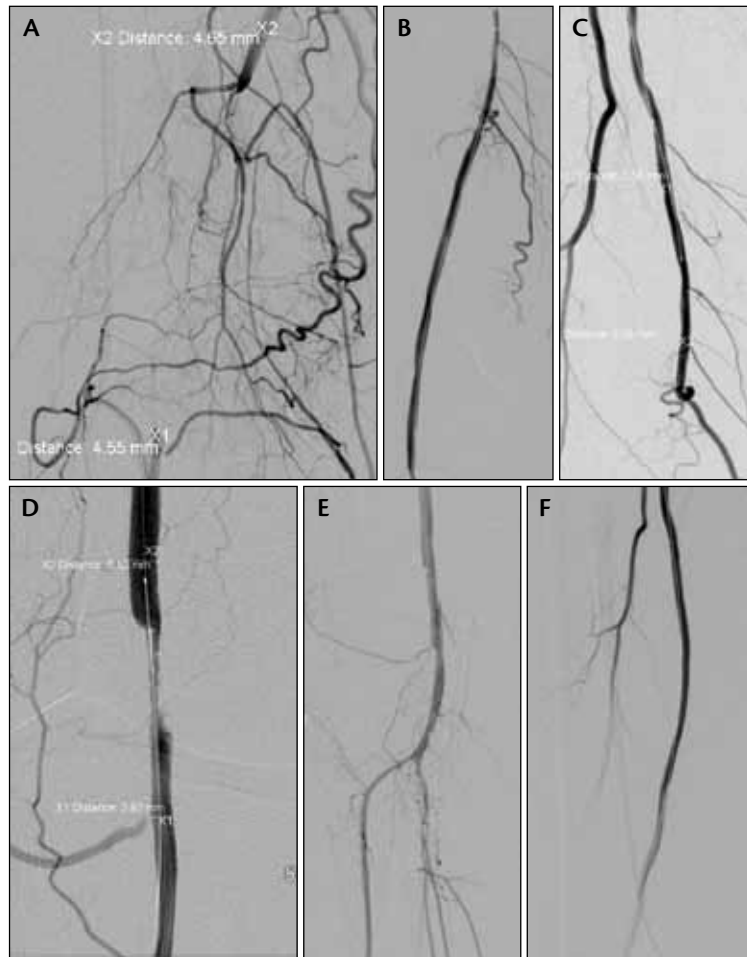
Interventionists routinely try to oversize self-expanding nitinol stents in the FPA by 1 or 2 mm, but is this really the optimal approach? In fact, there is a more basic issue: Are we accurately estimating the luminal diameter of the vessel we are treating? Because few of us routinely use quantitative techniques to measure vessels, many of us could be substantially and commonly overestimating the size of vessels and thus choosing stents that are too large.

Although we know that nitinol stents are relatively forgiving and that oversizing them does not lead to immediate technical failure, can we be certain that marked oversizing does not cause long-term vessel irritation and in-stent restenosis? Is it not possible that the chronic outward force of a too-large nitinol stent increases vessel injury and that the resultant inflammation promotes intimal hyperplasia and in-stent restenosis? Studies in animals have suggested that such a process can occur.<sup>7</sup> Therefore, exactly how to determine the device size that is most appropriate for treating a given vessel is an example of a poorly investigated aspect of endovascular treatment of FPA lesions with implantable devices. In order to achieve optimal outcomes with FPA stenting, however, the specific effect of device-to-vessel sizing on long-term patency must be understood.

## OUR RESEARCH AND OBSERVATIONS

Our group has been evaluating the failure modes of FPA stent grafts for several years. Our results with the first-generation GORE® VIABAHN® Endoprosthesis (W. L. Gore & Associates, Flagstaff, AZ), which did not have a heparin coating, indicated that patency with 5-mm devices was inferior to that of 6- and 7-mm devices;<sup>6</sup> therefore, we temporarily stopped using 5-mm stent grafts. However, the diminished patency with 5-mm devices may have been caused by several factors other than absolute device size.

Perhaps the treated vessels were too small or diseased; that is, maybe stent grafts simply fail more often when the vessel lumen is < 4 or 4.5 mm in size. Or, did we tend to oversize devices more frequently when treating smaller or diseased vessels, which led to a greater device-vessel lumen mismatch at the landing zones or ends of the device? In



**Figure 1.** Oversizing of a stent graft in a patient with a chronic total occlusion leading to early edge stenosis and occlusion. A measurement performed without calibration with a known reference length indicated that the vessel was approximately 4.5 mm in diameter (A). The lesion was treated with a 6-mm X 15-cm stent graft. Postprocedure angiography shows dramatic oversizing of the device relative to the native vessel (B). The stent graft occluded 4 months after implantation. During angiography, a wire with 1-cm markers was inserted, and calibration was performed. The vessel was determined to be approximately 3.6 mm in diameter (C). The stent graft was reopened using thrombolysis. Device-to-vessel mismatch and the development of a severe distal edge stenosis likely led to the occlusion of the device (D). A 4-mm self-expanding nitinol stent was used to treat the distal edge stenosis in the stent graft, and a 5-mm stent graft was placed to permit device extension proximally into a superficial femoral artery segment with a larger diameter (E, F).

avoiding use of 5-mm devices, we undoubtedly did oversize in some cases by placing 6-mm devices into small vessels, and this clearly caused some early occlusions (Figure 1). Our reviews of these various possibilities led to the idea that a more careful approach to vessel and device sizing might be important in achieving optimal outcomes.



## VIPER DATA

It is now clear that correctly sizing stent grafts relative to the proximal and distal landing zones is a critical issue when using these devices to treat FPA occlusive disease. The multicenter VIPER study (n = 119 limbs/patients) was a prospective, nonrandomized, single-arm, postmarketing evaluation of the heparin-coated GORE® VIABAHN® Device (5–8 mm). Although the results of this investigation have not yet been published, some preliminary data have been reported.<sup>8,9</sup> Most of the patients in the study had TASC C or D lesions, with a mean lesion length of approximately 19 cm. The overall primary patency rate at 1 year was 73%—a rate that is substantially higher than that in the earlier VIBRANT trial (a trial in which GORE® VIABAHN® Devices without a heparin coating or contoured edge were used, and no 5-mm devices were implanted because they were not yet available).<sup>10</sup> In the VIPER trial, neither device diameter, vessel size, nor lesion length appeared to have an effect on patency outcomes.

Data from the VIPER investigation do indicate, however, that patency was better in patients in whom the stent grafts were appropriately sized (ie, in accordance with the manufacturer's instructions for use) than in those in whom the device used was too large for the vessel treated. The 1-year primary patency rate for stent grafts that were oversized by < 20% at the proximal landing zone was 88%, whereas for devices that were oversized by more than 20% was 70%; this difference is significant.

The mechanisms by which a mismatch between device size and vessel luminal size might lead to stent graft failure remain unknown, although there are several possible explanations. For example, the mismatch may cause an infolding of the device that eventually results in acute occlusion or thrombosis. It is more likely that the mismatch produces turbulent flow and chronic vessel irritation at the end of the device, which in turn promotes the most common form of stent graft failure: the development of intimal hyperplasia or edge stenosis at the ends of the device.

## SUGGESTIONS FOR QUANTITATIVE VESSEL SIZING AND FUTURE RESEARCH

In the VIPER trial, in which only experienced interventionists participated, mismatches between device size and vessel size were found to be relatively common. This indicates that many of the sizing methods currently used during endovascular FPA interventions may not be providing information that is accurate enough. It seems to me that the best way to address this problem is to make much greater use of quantitative vessel analysis. I think that vessel evaluations employing quantitative angiography, endovascular ultrasonography, or both, should be considered in almost all patients with FPA disease who undergo endovascular therapy.

Quantitative analysis using calibration devices, such as wires and catheters with markers at known intervals, should become routine. When results are equivocal, endovascular ultrasonography should be contemplated. Such methods will produce much more accurate luminal measurements. The “eye-balling” technique for estimating vessel diameter is simply not sufficiently precise, especially in cases in which extensive disease has reduced the vessel lumen diameter available for device placement. Moreover, even when vessels are measured using the software built into many angiographic systems, the results can be erroneous if calibration against a known reference length is not performed (Figure 1).

Measuring vessels can add additional rigor and time to an endovascular procedure, but the results of the VIPER trial leave little doubt that, at least for stent graft implantation, careful quantitative analysis can contribute to excellent outcomes. Trials evaluating the importance of device-to-vessel mismatch for other treatment modalities are needed. Until those studies are performed, I think that we are obligated to slow down a bit and try to be more accurate in estimating vessel size during any FPA intervention, even if this approach has the potential to improve patency and other outcomes only minimally. The cost of a wire with 1-cm markers and the 10 minutes that careful vessel sizing may add to a procedure are insignificant compared with the expenditure of resources, cost, and amount of patient distress associated with any reintervention. Peripheral interventionists, get out your measuring sticks! ■

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# Techniques for Achieving Long-Term Secondary Patency

Occlusion failure modes for stent grafts, treatment approaches, and expected outcomes.

**BY CHARLIE C. CHENG, MD; LORRAINE CHOI, MD; ZULFIQAR CHEEMA, MD;  
AND MICHAEL B. SILVA JR, MD, FACS**

Recent advances in interventional devices and physicians' technical skills have allowed for treatment of severe peripheral arterial disease using endovascular therapy. Occlusion of the entire iliac or the superficial femoral arteries can be treated with balloon angioplasty and stenting. Bare-metal stents, either balloon-expanding or self-expanding, have been used in the past decades. However, there is decreased patency rates with the increasing length of arterial disease due to in-stent restenosis from intimal hyperplasia. Covered stents, or stent grafts, have been developed using polytetrafluoroethylene to "cover" any space between the metal struts of the bare-metal stents. This may reduce the impact of in-stent restenosis, and there are promising data suggesting increased patency rates for long-segment arterial disease using this "endovascular bypass." Good technical results are achieved by treatment of all diseased arterial segments.

Preservation of the collateral vessels should be attempted whenever possible; however, good technical revascularization with coverage of all diseased segments may be more important than preservation of every collateral vessel. With coverage of these collateral vessels, there is concern that thrombosis of the stent graft may lead to acute limb ischemia and limb loss. In our experience this is rarely seen, and most patients with failed or failing endovascular intraluminal grafts present with recurrent symptoms of claudication, rest pain, or non-healing wounds—conditions similar to those seen on initial presentation that were present prior to stent graft revascularization.

One of the failure modes for peripheral stents is occlusion caused by compromised flow through the device. Often, reduced flow leading to an occlusion is caused by progression of the disease in the native vessel proximal

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The decision to choose slow lytic therapy versus rapid removal depends on a patient's clinical status and the duration that the stent graft has been occluded.

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or distal to the treated arterial segment. For bare-metal stents, there can also be reduced flow due to a compromised stent lumen from in-stent restenosis. For stent grafts, there can be stenosis caused by intimal hyperplasia at the device edges. All of these conditions may be better characterized once flow is restored through a thrombosed stent or stent graft. These conditions must be identified and treated to maintain stent graft flow and optimize secondary patency. The treatment strategy for device occlusion is therefore two-fold: removal of thrombus within the stent or stent graft to restore flow followed by treatment of the underlying flow-limiting disease. In this article, we discuss our strategies for treating thrombosed polytetrafluoroethylene stent grafts.

## TREATMENT STRATEGIES

There are a number of strategies for clearing thrombus from an occluded vessel or stent graft, from slow lytic therapy through a basic infusion catheter to more rapid removal by devices that are designed for mechanical thrombectomy. The first approach offers the advantage of reduced procedural time and cost and the theoretical advantage of a more subtle and manageable breakdown of the clot into smaller particles with less risk of distal embolization. More active clot breakdown and removal

**TABLE 1. COMPARISON OF TREATMENT OPTIONS**

	Slow Lytic Therapy	Rapid Pharmacomechanical Thrombectomy
<b>Agent</b>	25 mg of tPA	10 mg of tPA
<b>Materials</b>	Infusion catheter	Distal protection filter and AngioJet device
<b>Procedure</b>	<ul style="list-style-type: none"> <li>• Short-term infusion of 5 mg of tPA for 30 min, repeat with another 5 mg if there is progress</li> <li>• Long-term infusion of 1 mg per hour for 18–24 hours; you may need to repeat for another 24 hours</li> <li>• Treat the underlying cause</li> </ul>	<ul style="list-style-type: none"> <li>• Place distal filter if desired</li> <li>• Introduce 10 mg of tPA in 100 mL of saline for initial AngioJet infusion</li> <li>• Using the Power Pulse mode, run AngioJet through the length of the clot to permeate with tPA</li> <li>• Using the mechanical thrombectomy mode and run AngioJet through the length of the stent graft to remove all residual clots</li> <li>• Treat the underlying cause of stent graft thrombosis</li> </ul>
<b>Cost</b>	\$200 for 25 mg aliquot, overnight hospital stay(s)	Lytic costs, operating room time, AngioJet catheter, embolic protection filter

can be achieved using the mechanical thrombectomy devices, with the potential for a reduction in overall treatment time, reduced hospital stay, and less exposure of the patient to the bleeding risks associated with long-term lytic therapy.

The decision to choose slow lytic therapy versus rapid removal depends on a patient's clinical status and the duration that the stent graft has been occluded. Patients who present with clinical signs and symptoms of acute limb ischemia and threatened limbs require more rapid thrombus removal with reestablishment of distal circulation. On the other hand, patients with recurrent symptoms of chronic limb ischemia with stent grafts that have been stenosed for more than 2 weeks may have organized clots. These patients may benefit from slow lytic therapy using an infusion catheter placed in the thrombus within the stent graft for better "cleaning." In the following sections, we describe our techniques of lytic therapy in stent grafts (Table 1).

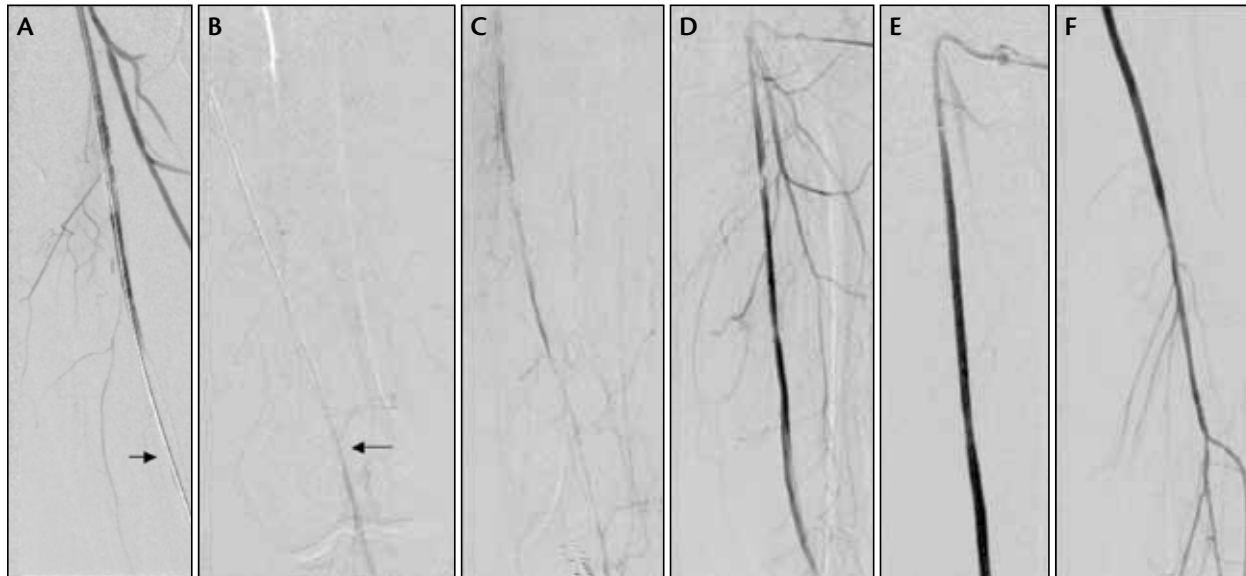
## SLOW LYTIC THERAPY

At our institution, this is the treatment of choice for treating arterial thrombosis. In most patients with thrombosed stent grafts, the clinical presentation is that of the recurrent symptoms of chronic limb ischemia that caused the patients to be treated initially. Arterial access and angiography from the abdominal aorta to the foot are performed as previously described. The thrombosed lesion is crossed and confirmed by angiography, and a wire is placed in the tibial artery that is providing the dominant outflow. Arterial access is achieved in the contralateral groin through the common femoral artery. A diagnostic flush catheter is

placed in the proximal abdominal aorta. Aortography with bilateral pelvic runoff is performed to identify any proximal, in-flow-limiting arterial lesions in the abdominal aorta or the iliac arteries. The catheter is then advanced to the ipsilateral ischemic leg using the standard "up-and-over" technique over the aortic bifurcation. Lower extremity angiography is performed from the groin to the foot. It is important that the status of the outflow in the popliteal and tibial arteries is known prior to any intervention.

For thrombosed stent grafts in the external iliac or superficial femoral (SFA) arteries, a sheath is placed up-and-over the aortic bifurcation, with the tip just proximal to the stent graft or in the distal common femoral artery. For thrombosed stent grafts in the common iliac arteries, access in the ipsilateral common femoral artery may be needed, with the sheath placed just distal to the stent graft in the retrograde fashion. Using the Glidewire and Glidecath devices (Terumo Interventional Systems, Inc., Somerset, NJ), the thrombosed stent is crossed. With the catheter distal to the external iliac or the SFA stent (or the catheter in the aorta for common iliac stents), angiography is performed to confirm true luminal position of the catheter. The 0.035-inch Glidewire is then placed distally in the dominant tibial artery that provides the best outflow to the foot (Figure 1A and 1B).

The Glidecath is exchanged over the wire for an infusion catheter with the appropriate length for the thrombosed segment (5, 10, 20, or 30 cm). A Touhy-Borst side-arm adaptor is connected to the end of the infusion catheter. Tissue plasminogen activator (tPA) is diluted in a 30-mL reservoir syringe containing 5 mg of tPA and 25 mL of normal saline. This reservoir syringe



**Figure 1.** Thrombosis of stent graft (black arrow) in the left SFA (A). Reconstitution of the above-knee popliteal artery distal to the stent graft (black arrow) (B). Partial recannulation of the thrombosed stent graft after initial thrombolytic therapy using 5 mg of tPA (C). Complete lysis of thrombus in the stent graft after overnight tPA therapy, with residual disease in the proximal bare-metal stent the following day after overnight tPA infusion (D). Successful endovascular treatment of the proximal bare-metal stent stenosis, with no residual thrombus in the stent graft (E). No residual thrombus in the distal stent graft and no arterial compromise (F).

is connected to a 1-mL tuberculin syringe via a three-way stop-cock. The third end of this stop-cock is then connected to the side-arm of the Touhy-Borst adaptor. Three milliliters of diluted tPA is infused immediately into the infusion catheter. The remaining tPA in the reservoir syringe is then slowly infused at a rate of 1 mL per minute. When the infusion has been completed, angiography is performed to assess the progress of thrombolytic therapy (Figure 1C). If progress is made and there is some flow of contrast in the stent graft, another infusion of 5 mg of tPA is repeated. Usually, this is not adequate for lysis of the arterial plugs at the ends of the stent graft but allows for a decrease of the thrombus load and the initiation of the lytic therapy.

This is followed by a slow, long-term infusion of tPA. The Glidewire is exchanged for an infusion wire, with its tip in the tibial artery that has the best outflow to the foot for simultaneous administration of tPA into the best outflow tract. The long-term infusion is partitioned into a portion for lysis of the lesion via the infusion catheter and a portion through the infusion wire to deliver lytic agent downstream to break down any potential distal embolization that may occur. We use an infusion rate of 30 mL per hour for the system: 20 mL per hour through the infusion catheter and 10 mL per hour through the distal infusion wire. After overnight infusion, angiography is performed to assess

the progress of thrombolysis (Figure 1D). Additional therapy using slow, long-term infusion can be provided if there is residual thrombus present.

Once the thrombus has been removed from the stent graft, the next step is to identify and treat the lesion that caused the stent graft to thrombose. If the offending lesion is not treated, the stent graft will likely thrombose again. The lesion could be in the native artery distal or proximal to the stent graft (caused by the natural atherosclerotic process). The lesion could also be at either end of the device (caused by intimal hyperplasia). These lesions are usually amenable to endovascular treatment options, such as percutaneous transluminal angioplasty, cutting-balloon angioplasty, bare-metal stents, or stent graft extension (Figure 1E and 1F).

Occasionally, in patients with chronic stent graft thrombosis, there is minimal residual thrombus after the initial lytic therapy with 10 mg of tPA (Figure 2A through 2F). This thrombus and the arterial plugs can be removed with the Angiojet catheter (Bayer Radiology and Interventional, Indianola, PA), using the mechanical thrombectomy mode as later described. The underlying cause is then treated (Figure 2G through 2K). This option allows for 1-day treatment and avoids the risk of bleeding from long-term thrombolytic therapy.



# RAPID PHARMACOMECHANICAL THROMBECTOMY

Rapid thrombectomy is recommended for patients who have acute limb ischemia with impending limb loss. In these cases, rapid removal of thrombus from the stent graft with reestablishment of distal perfusion to preserve

the limb is of the essence. Patients are taken emergently for arteriography and intervention. Ten mg of tPA is ordered from the pharmacy for thawing. Arterial access and angiography from the abdominal aorta to the foot are performed as previously described. The thrombosed lesion is crossed and confirmed by angiography, and a

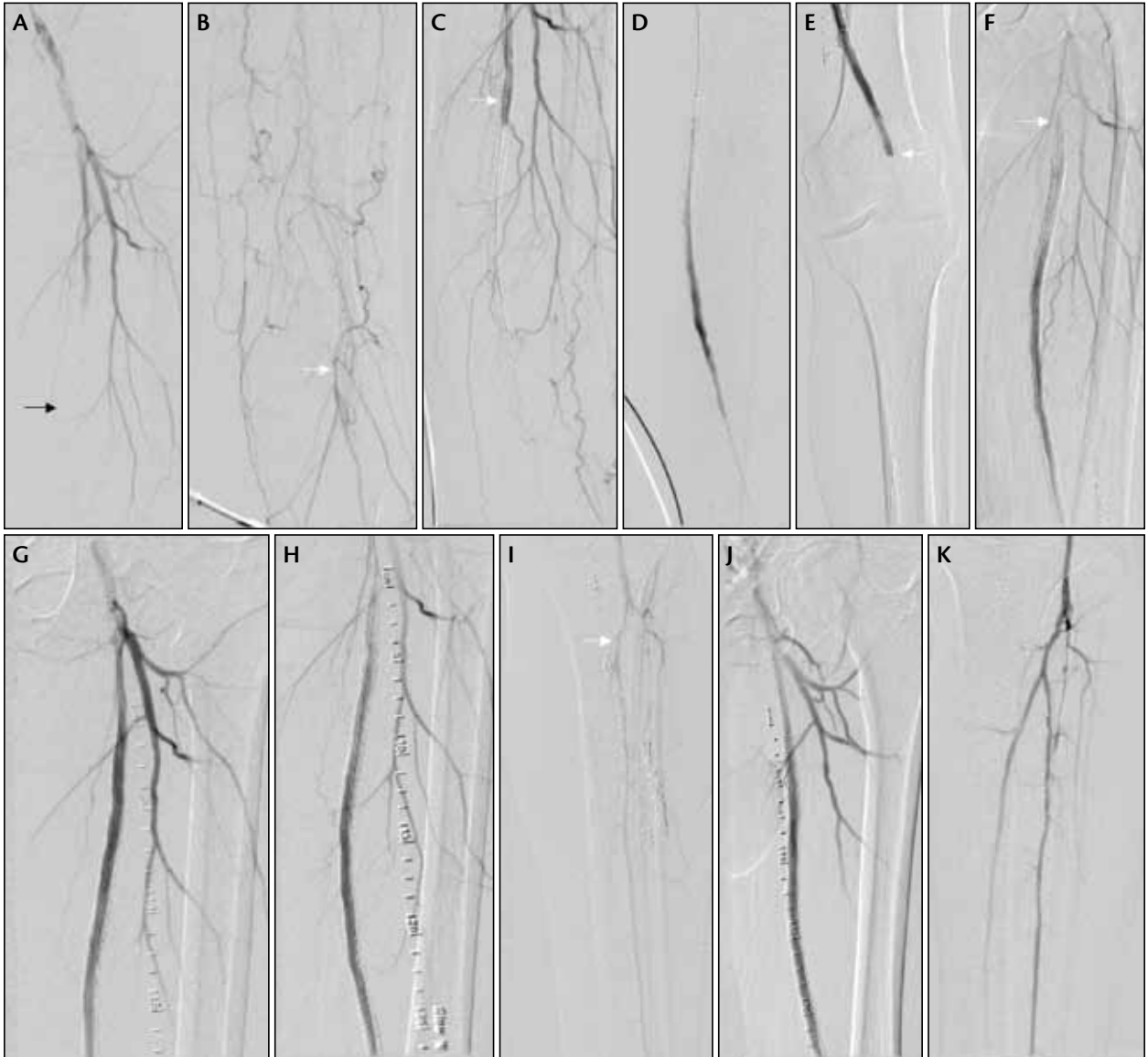


Figure 2. Occlusion of stents (black arrow) in the SFA (A). Distal occlusion of the stent graft, with reconstitution at the above-knee popliteal artery (white arrow) (B). Placement of an infusion catheter (proximal marker = white arrow) within the occluded stents (C). Partial recannulation of the thrombosed stents after initial thrombolytic therapy using 5 mg of tPA (D). Flow of contrast stopped abruptly at the distal arterial plug (white arrow) (E). Improved flow in stents after second round of 5 mg of tPA, with evident disease progression proximal to the stents (white arrow) (F). Resolution of the lesion proximal to the original stents after endovascular treatment, with improved flow (G). Resolution of the proximal lesion after endovascular treatment, with improved flow in the distal stent graft (H). Treatment of the outflow lesion in the proximal posterior tibial artery with orbital atherectomy and angioplasty (white arrow) (I). Completion angiography showing good flow through the stent graft after endovascular revision of the proximal SFA and distal tibial lesions (J). Completion angiography showing good flow in the proximal lower leg and resolution of disease in the proximal posterior tibial artery (K).

wire is placed in the tibial artery providing the dominant outflow.

A distal protection filter can be placed at the discretion of the interventionist. The Angiojet system is prepared according to the manufacturer's guideline, and the device is placed into the thrombosed stent graft. Ten mg of tPA is diluted into a 100-mL normal saline bag. Using the Power Pulse mode (this allows for infusion but not concurrent aspiration), the Angiojet catheter is advanced along the entire length of the clot to infuse the 10 mg of tPA. We wait 30 minutes to allow the thrombolytic process to take place. The Angiojet is changed to mechanical thrombectomy mode (simultaneous saline hydrolyzation of thrombus and aspiration of debris), and the catheter is advanced back and forth along the entire length of the thrombosed stent graft. It is important that the Angiojet catheter is used to treat the arterial plugs that are present at the proximal and distal end of the stent graft.

Arteriography is performed to assess the progress of thrombectomy. If contrast is not visualized within the stent graft, it is possible that the arterial plug is still present even though the thrombus has been removed from the stent graft. To visualize the lumen of the stent graft, a Glidacath device is advanced over the wire and placed within the proximal 1 or 2 cm of the stent graft. The Tuohy-Borst adapter is connected to the Glidacath device, and contrast is injected from the side-arm of the adapter. Any thrombus or arterial plug that is still present is treated with the Angiojet as needed until the maximum volume is reached according to the manufacturer's recommendations.

Once the result is adequate, the underlying disease is treated. This treatment paradigm offers the potential for complete treatment in the same day. Although the approach described in this article is not the standard

protocol suggested by the manufacturer, this stage-wise approach has been effective at our institution.

## CONCLUSION

Stent graft thrombosis can be effectively treated using the methods of thrombolysis described in this article. When the thrombus is cleared from the stent graft, the underlying disease process that caused the stent graft to fail can be treated. This treatment restores flow in the stent graft to original treatment conditions after the stent graft was initially placed for de novo disease, and may lead to similar outcomes that are seen from the de novo treatment. Additional studies are needed to evaluate the long-term outcomes of these approaches to maintaining secondary patency in stent grafts, although initial data from our institution appear promising. ■

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# Covered Stenting for Iliac Artery Occlusive Disease

Increasing evidence points to first-line use of covered stent grafts for complex iliac artery occlusive disease.

BY LEE J. GOLDSTEIN, MD, FACS, CWS

Interventionists are seeing increasingly complex iliac disease as patients age, diabetes becomes more prevalent, and smoking continues. As endovascular techniques continue to improve, patients can now be offered minimally invasive solutions for problems that were traditionally addressed with open bypass surgery. These interventions allow for inclusion of patients who were previously believed to be unfit for surgery, and excellent results can be accomplished with significantly less morbidity. Much of the severe iliac occlusive disease that is seen today has been seen before; however, we can now approach these challenges when treating older and sicker patients with less invasive but equally effective and durable therapies.

Initially, intravascular stenting in the iliac anatomy was questioned and was believed to be best reserved for “selective use” following balloon angioplasty.<sup>1</sup> As stent technology and techniques improved, complex iliac disease began to be successfully addressed with nitinol stents, with outcomes approaching those of open repair.<sup>2,3</sup> The gold standard of aortobifemoral bypass and femoral-femoral bypass was slowly challenged by creative endovascular recanalizations. Surgeons continue to pioneer complex reconstructions for TransAtlantic Inter-Society Consensus (TASC) C and D lesions by performing “hybrid” interventions composed of iliac stenting combined with common femoral and profunda open endarterectomy.<sup>4,5</sup>

## BACKGROUND AND EVIDENCE

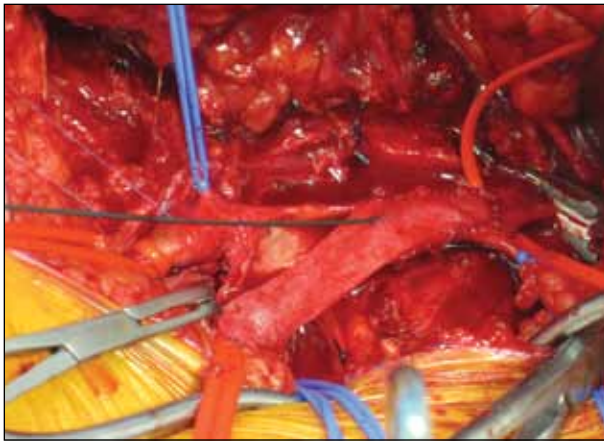
Initial reports of stent graft use in the aortoiliac anatomy were performed using off-label, homemade devices. These literal “stent grafts” were comprised of balloon-expandable stents coupled with prosthetic bypass grafts. Despite the rudimentary designs of these devices (requiring assembly and delivery systems as large as 14 F), tech-



**Figure 1. Successful wire crossing of a total iliac occlusion. Flush catheter angiography confirms intraluminal placement. Marker catheters are useful for measuring treatment lengths.**

nical success was excellent, with primary patency rates > 80% at 1 year.<sup>6-8</sup> Around the same time, Krajcer et al performed one of the earliest comparisons of bare-metal stents to stent grafts in the iliac position, finding good “technical and early success.”<sup>9</sup>

Seeing the potential for success in complex disease, interventionists devised increasingly creative approaches to treating difficult aortoiliac occlusive disease. Nelson et al demonstrated early effectiveness of hybrid recon-

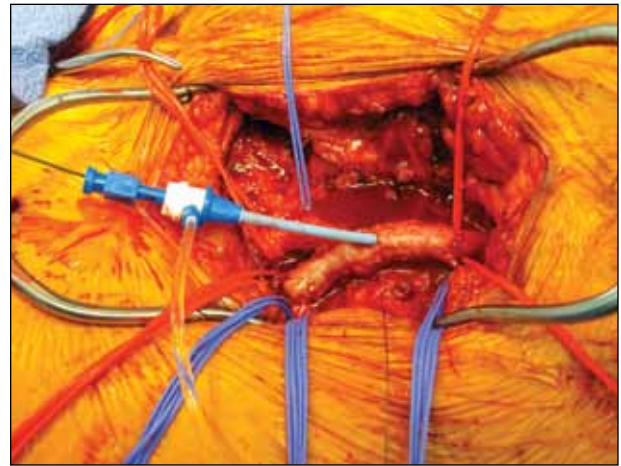


**Figure 2.** Patch angioplasty being performed following common femoral and profunda endarterectomy. A bovine pericardial patch has been brought down over the indwelling wire and is sewn onto the profunda orifice (inferior).

structions, employing common femoral endarterectomy and concomitant bare-metal iliac stent placement (both balloon-expandable and self-expanding).<sup>4</sup> Despite the novelty of this technique, and less-refined endovascular devices, this study achieved 1-year patency and a primary assisted patency of 84% and 97%, respectively.

The same group then reported improved success using stent grafts compared to bare-metal stents for challenging iliac disease, namely TASC C and D lesions.<sup>5</sup> Self-expanding stent grafts were employed using both the Wallgraft endoprosthesis (Boston Scientific Corporation, Natick, MA) and the GORE® VIABAHN® Endoprosthesis (W. L. Gore & Associates, Flagstaff, AZ). Specific attention was noted in this study regarding the importance of addressing distal external iliac and common femoral/profunda occlusive disease via endarterectomy or another outflow procedure. This point has been referenced in several studies and appears to be critical in achieving long-term patency.<sup>4-6</sup>

The Dutch Iliac Stent trial, although less than a decade old, was one of the first randomized trials to critically examine the effectiveness of stent placement in the iliac anatomy.<sup>1</sup> The controversial conclusion asserted that angioplasty with selective stent placement resulted in a “better outcome for symptomatic success compared with patients treated with primary stent placement.”<sup>1</sup> The major problem with extrapolating the results of this study concerns the lesions included (ie, stenoses < 10 cm or occlusions < 5 cm), as well as the device employed (a hand-mounted, balloon-expandable, bare-metal Palmaz stent [Cordis Corporation, Bridgewater, NJ]). Today, these lesions would be classified as TASC II A and B lesions.<sup>10</sup> The following year, AbuRahma et al published



**Figure 3.** An 8-F interventional sheath is placed through the bovine pericardial patch angioplasty. Endarterectomy is routinely performed prior to stent placement.

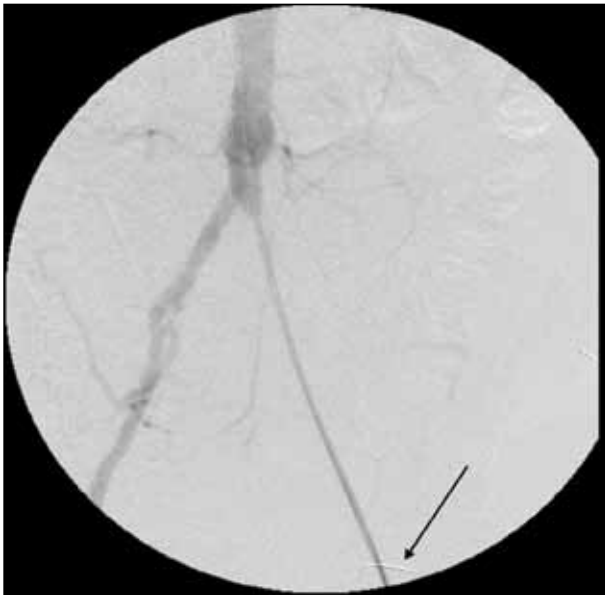
their experience for primary versus selective stenting, noting improved clinical success rates for primary stenting when specifically applied to TASC C and D lesions.<sup>3</sup> They concluded that “primary stenting should be offered to all TASC C and D lesions.”<sup>3</sup>

In the last 5 years, the data have continued to accumulate to support the use of stent grafts in the iliac anatomy (especially for TASC II C and D lesions). Chang et al published their long-term results, which demonstrated that hybrid reconstructions of the common femoral and iliac system have 5-year primary, primary-assisted, and secondary patencies of 60%, 97%, and 98%, respectively.<sup>11</sup> This study called specific attention to the improved primary patency rates seen with stent grafts versus bare-metal stents ( $87\% \pm 5\%$  vs  $53\% \pm 7\%$ ;  $P < .01$ ).

Sabri et al compared bilateral covered stent use to bare-metal stent placement in a “kissing” fashion at the aortic bifurcation, finding superior patency for covered stents at 2 years (92% vs 62%;  $P = .023$ ).<sup>12</sup> In 2011, COBEST (Covered Versus Balloon Expandable Stent Trial), a prospective, randomized, multicenter trial, provided strong data in support of covered stent placement for TASC II C and D lesions, with improved freedom from occlusion and restenosis with covered stent placement when compared to bare-metal stenting at 12 and 18 months (hazard ratio, 0.136; 95% confidence interval, 0.042–0.442).<sup>13</sup>

The increasing data in support of covered stenting in the iliac anatomy was strengthened by direct comparisons to open repair, demonstrating equivalent patency. Kashyap et al suggested that endovascular techniques “rivalled” open reconstruction, whereas Piazza et al found that extensive iliac and common femoral disease can be



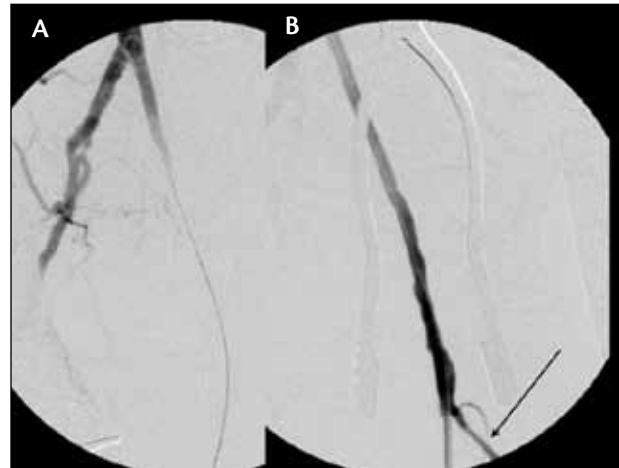


**Figure 4.** Angiography is performed via an indwelling introducer sheath prior to stent placement. A radiopaque marker has been placed (arrow) at the upper extent of the endarterectomy to aid in stent placement.

effectively treated with hybrid repair (femoral endarterectomy with iliac stenting) with “similar early and long-term efficacy” to open repair.<sup>14,15</sup> Piazza et al demonstrated particular effectiveness in intensive care unit and hospital stay lengths in TASC II C and D patients.<sup>15</sup>

### TECHNIQUE OF HYBRID ILIAC REPAIR WITH ENDOPROSTHESES

We have routinely been offering hybrid repair to our patients with diffuse unilateral iliac disease and common femoral involvement. As a rule, we employ general anesthesia but have utilized locoregional anesthesia in selected patients. We begin with open common femoral artery exposure via a vertical groin incision. Diffuse exposure of the distal external iliac artery, proximal superficial femoral artery (SFA), and proximal profunda is essential. Our practice, based on experience, has been to then access the occluded femoral artery with an 18-gauge introducer needle and attempt passage of a stiff Glidewire (Terumo Interventional Systems, Inc., Somerset, NJ) up into the aorta (Figure 1). Contralateral access and brachial access can be especially useful for imaging the aortic bifurcation and gaining wire access across challenging lesions. Retrograde subintimal recanalization can be accomplished using reentry devices should you get stuck in an aortic subintimal plane. Antegrade subintimal recanalization from a brachial or contralateral femoral approach is more easily handled with common femoral arteriotomy



**Figure 5.** Completion angiography demonstrating recanalization of the common and external iliac arteries. The newly recreated aortic bifurcation is widely patent (A), with distal outflow via the profunda femoris artery (B, arrow).

and direct exposure of the wire in the subintimal space during endarterectomy.

Standard surgical endarterectomy is then performed from the distal external iliac artery to the profunda. We have found that direct extension of the arteriotomy onto the proximal profunda is more effective in achieving good profunda outflow than proceeding to the proximal SFA. Robust profunda outflow is critical to success, especially if this is the only outflow vessel. If the profunda is severely diseased or diminutive in size, consideration should be given to concomitant distal outflow procedures (eg, femoropopliteal or femorotibial bypass). Preparation of the proximal SFA can aid in future endovascular interventions should they be required. Patch angioplasty is then performed using the preferred patch. Prior to implanting the patch, we utilize an 18-gauge needle to puncture the patch, bringing the wire out of the femoral arteriotomy and through the patch (Figure 2). Once the patch is implanted, we have wire access already through the lesion and exiting the patch.

Finally, we establish definitive inflow via stenting of the iliac system. Readers are cautioned against performing stenting prior to the endarterectomy, as stagnant blood within the freshly placed stents during the endarterectomy can result in stent thrombosis. A long (23-cm) introducer sheath is inserted over the indwelling wire, which is sized for the anticipated stent placement (Figures 3 and 4). Our standard approach is to insert 8-mm endoprostheses, exclusively employing covered stents for these complex lesions, and postdilating with an 8-mm balloon. A metallic marker is placed at the top of the patch angioplasty (or most proximal area of endarterectomy) on the

distal external iliac artery (Figure 4, arrow). This greatly aids in the positioning of the stent graft. Completion angiography is routinely performed to document adequacy of the repair and the outflow (Figure 5). Sheaths and wires are removed, and the patch is suture-repaired.

We have often implanted balloon-expandable covered stents for orificial lesions at the aortic bifurcation but find them to be limited in their lengths and flexibility. More commonly, we utilize the GORE® VIABAHN® Device, as it is the only covered stent graft that is approved for use in the iliac anatomy and affords several advantages over other products. When treating TASC II C and D lesions, especially chronic total occlusions of the entire common and external iliac segments, the GORE® VIABAHN® Device simplifies treatment, offering long-length (up to 15 cm) endoprostheses. We have also found the device to display excellent flexibility as one approaches the inguinal ligament in the distal external iliac artery (essential for hybrid reconstructions). Finally, the newest-generation GORE® VIABAHN® Device offers lower-profile delivery and a covalently bonded heparin surface to improve patency.

## CONCLUSION

Covered stent use in TASC C and D iliac lesions has a growing body of literature demonstrating its superiority to angioplasty with selective covered or bare-metal stent placement. Additionally, repair of complex lesions with hybrid approaches has long-term data demonstrating results that are equivalent to open surgery, with significantly less morbidity. These data point toward covered stent treatment of complex iliac occlusive lesions as a new standard of care. The GORE® VIABAHN® Device has the advantages of longer device lengths, flexibility when employed in the distal external iliac, low-profile delivery, and heparin-bonded surfaces. As our comfort level

increases and future devices emerge, interventionists and surgeons will likely continue to innovate with complex, minimally invasive techniques, combining endovascular and surgical approaches to address challenging iliac occlusive disease in older and sicker patients. ■

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# Treating TASC II D Lesions With the GORE<sup>®</sup> VIABAHN<sup>®</sup> Endoprosthesis

Examining the evidence for treating long SFA disease with stent grafts.

BY PETER A. SOUKAS, MD, FACC, FSVM, FSCAI

**T**he treatment of peripheral arterial disease has undergone a sea change in the last decade from invasive open bypass to percutaneous revascularization, thanks to the availability of new technologies. Acute procedural success rates have significantly improved with the availability of chronic total occlusion (CTO) traversal and reentry devices. Midterm results have also improved, chiefly due to endoluminal stents.

Percutaneous transluminal angioplasty (PTA) has been shown to be effective for short ( $\leq 4$  cm) lesions, but primary patency rates are poor for longer lesions, occlusions, calcified vessels, chronic limb ischemia (CLI), and compromised distal vessel runoff.<sup>1-4</sup> For moderate-length lesions (5–10 cm), recent studies have demonstrated improved clinical outcomes with bare-nitinol stents (BNS) compared with PTA. BNS address the problems of flow-limiting dissections and early recoil, but at the expense of exaggerated neointimal hyperplasia and resultant in-stent restenosis (ISR).<sup>5-9</sup> Treatment of longer-length lesions with BNS has led to the vexing problem of stent fractures, which have been shown to negatively impact patency rates.<sup>10,11</sup> Moreover, most studies of BNS for longer lesions have consistently demonstrated reduced primary patency rates.<sup>12-15</sup>

To overcome the limitations of BNS for longer lesions, several investigators have reported promising results using endoluminal stent grafts.<sup>16-23</sup> The role of stent grafts and BNS for long superficial femoral artery (SFA) disease will be reviewed in detail, particularly in those patients with TASC II D lesions.

## TASC II CLASSIFICATION

To guide the therapy of patients with peripheral arterial disease, the TransAtlantic Inter-Society Consensus

Stent grafts offer a less-invasive alternative to the greater morbidity associated with open bypass in patients with long TASC II D lesions.

Document on the Management of Peripheral Arterial Disease (TASC) was published in January 2000. This document was updated in 2007 (TASC II).<sup>2</sup> The TASC II classification for femoropopliteal disease (Table 1) recommends bypass surgery for type D lesions, which include CTOs of the common femoral artery or SFA  $> 20$  cm involving the popliteal artery, and for CTOs of the popliteal artery and proximal trifurcation vessels. Although several randomized trials have confirmed superior patency rates for above-knee femoropopliteal bypass (AK-FPB) using greater saphenous vein compared with prosthetic grafts, polytetrafluoroethylene (PTFE) grafts are still widely used today for the AK position to allow preservation of the greater saphenous vein for future coronary artery bypass. Other reasons include lack of vein conduit and previous studies demonstrating equivalence of results.<sup>24-28</sup>

Limitations of open bypass surgery include the need for general anesthesia, longer length of hospital stay, lack of vein conduit, and greater morbidity, particularly in patients presenting with CLI. For example, in the PREVENT III trial for CLI patients undergoing open bypass surgery, 17.4% of patients experienced major morbidity at 30 days, including 4.2% graft occlusion, 4.7% myocardial infarction, 1.7% stroke, 3.4% infection, 1.8% major amputation, and major wound complica-

**TABLE 1. TASC II CLASSIFICATION OF FEMORAL POPLITEAL DISEASE<sup>a</sup>**

Type A lesions	<ul style="list-style-type: none"> <li>• Single stenosis <math>\leq 10</math> cm in length</li> <li>• Single occlusion <math>\leq 5</math> cm in length</li> </ul>
Type B lesions	<ul style="list-style-type: none"> <li>• Multiple lesions (stenosis or occlusions), each <math>\leq 5</math> cm</li> <li>• Single stenosis or occlusion <math>\leq 15</math> cm not involving the infrageniculate popliteal artery</li> <li>• Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass</li> <li>• Heavily calcified occlusion <math>\leq 5</math> cm in length</li> <li>• Single popliteal stenosis</li> </ul>
Type C lesions	<ul style="list-style-type: none"> <li>• Multiple stenoses or occlusions totaling <math>&gt; 15</math> cm with or without heavy calcification</li> <li>• Recurrent stenosis or occlusions that require treatment after two endovascular interventions</li> </ul>
Type D lesions	<ul style="list-style-type: none"> <li>• CTOs of the common femoral artery or SFA (<math>&gt; 20</math> cm) involving the popliteal artery</li> <li>• CTOs of the popliteal artery and proximal trifurcation vessels</li> </ul>
<sup>a</sup> Adapted from J Vasc Surg, 45, Norgren L, et al, TASC II Working Group Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II), S1–S70, Copyright (2007), with permission from Elsevier. <sup>2</sup>	

tion in 5.2%.<sup>29</sup> Primary graft patency at 1 year was only 61.5%, and event-free survival was 50%. Surgical bypass failure often results in acute limb ischemia, whereas endovascular procedures usually return patients to their preintervention symptom state.<sup>30</sup> Hence, many of these prohibitive surgical candidates are only eligible for treatment by endovascular methods.

## BARE-NITINOL STENTS

### Randomized Trials

Nitinol stents have become standard therapy for femoropopliteal disease due to their ability to tolerate the multiple mechanical forces at play in the hostile femoropopliteal bed and because of their ability to seal dissections and resist elastic recoil. In the US, the LifeStent (Bard Peripheral Vascular, Inc., Tempe, AZ) and EverFlex (Covidien, Mansfield, MA) are currently the only FDA-approved BNS, although other BNS are expected to gain approval soon. Several randomized BNS trials have recently been reported (Table 2). With the exception of the FAST trial, stenting provided superior patency rates compared with PTA.<sup>16–23</sup> The SUPER SL and VIBRANT trials showed no significant differences between different stent types.<sup>31,32</sup> Although these studies provide convincing evidence of the superiority of stenting over PTA, they are mostly limited to relatively short TASC A and B lesion subsets.

### Nonrandomized Trials in Long SFA Disease

Several nonrandomized retrospective studies have been published evaluating bare-metal stents, some of these in longer lesions. DURABILITY-200 reported a 1-year primary patency rate of 64.8% in 100 TASC II C

and D patients, with a mean lesion length of 24.2 cm.<sup>33</sup> Hu et al reported their single-center retrospective study on 165 limbs in 138 patients treated with BNS, with a mean lesion length of  $20.35 \pm 9.46$  cm (range, 10–32 cm) using 6-mm-diameter devices exclusively; 25.5% were TASC II B, 61.6% were TASC II C, and 51% were TASC II D lesions.<sup>34</sup> They reported remarkable primary patency rates of 92%, 78% and 62% at 1, 2, and 3 years but excluded patient lesions extending into the popliteal artery, and did not report on number of limbs at risk at each time.

Schoenefeld et al reported an 83.6% primary patency rate at a mean follow-up of 21 months in 103 patients who were treated with BNS using the Protégé EverFlex (Covidien).<sup>35</sup> The mean stent length was 15 cm. Lesions were classified as 36% TASC II C and 8% TASC II D, with a 4.7% overall stent fracture rate; however, lesion measurement methods were not listed. Baril et al specifically examined the outcomes of endovascular interventions in 74 patients (79 limbs) with TASC II D lesions.<sup>36</sup> Patients presented with CLI in 71% of cases, including 53% with tissue loss. The mean lesion length was 18.8 cm, 50.6% had single-vessel runoff, and 48% had stents placed in the popliteal artery. Primary patency at 12 and 24 months was 52.2% and 27.5%, respectively. The number of patients who underwent stenting is not listed, precluding evaluation of stent patency, which may explain the poor primary patency rates. Twenty-five percent of patients died during the 1-year follow-up period, underscoring the advanced comorbidity of patients presenting with TASC II D lesions.

The outcomes of consecutive nonrandomized patients with TASC II C and D SFA disease was reported by Dosluoglu et al in a single-center, retrospective analysis.<sup>37</sup> One hundred twenty-seven patients underwent AK-FPB (46 patients),



**TABLE 2. RANDOMIZED STUDIES OF BNS IN THE SFA (> 30 LIMBS)<sup>a,b</sup>**

Author	Study	Year	No. of Limbs	Lesion Length (cm)	1-year Primary Patency	Study Design
Krankenber <sup>7</sup>	FAST	2007	123	4.5	68%	Multicenter, randomized to PTA
Laird <sup>8,23</sup>	RESILIENT	2010	134	7.1	81%	Multicenter, randomized to PTA
Schillinger <sup>5,6</sup>	VIENNA (Absolute)	2006	46	11.2	63%	Multicenter, randomized to PTA
Ansel <sup>32</sup>	VIBRANT (bare metal)	2009	76	18	58%	Multicenter, randomized to the GORE® VIABAHN® Device
Dick <sup>9</sup>	ASTRON	2009	34	8.2	66%	Multicenter, randomized to PTA
Dake <sup>38</sup>	ZILVER PTX	2010	235	5.4	83%	Multicenter, randomized to PTA
Dake <sup>38</sup>	ZILVER	2010	62	5.3	73%	Multicenter, randomized to Zilver PTX
Sabeti <sup>39</sup>	Sabeti	2007	51	13.2	63%	Single-center, randomized to PTA
Duda <sup>31</sup>	SUPER-SL	2009	199	12.8	60%	Multicenter, SMART randomized to Luminexx
<sup>a</sup> Patient demographics, lesion characterization, and patency definitions may differ among studies. Randomized studies included with > 30 limbs in each arm.						
<sup>b</sup> Adapted from Gable DR. J Cardiovasc Surg. 2011;52:683–700. <sup>40</sup>						

PTA/BNS (49 patients) for TASC II C lesions, and PTA/BNS (44 patients) for TASC II D lesions. SMART stents (Cordis Corporation, Bridgewater, NJ) were employed. Mean lesion occlusion and stented lengths were 9.9/24.3 cm and 26.6/30 cm in TASC II C and D lesions, respectively. Twelve- and 24-month primary patency rates were 83%/80% and 54%/28% for the two groups, and the AK-FPB group patency rates were 81% and 75%, respectively. Despite the worse patency rates for TASC II D patients, the limb salvage rates were similar (88%, 88%, and 95% in for TASC II C, TASC II D, and AK-FPB groups, respectively).

The Zilver PTX (Cook Medical, Bloomington, IN) single-arm, real-world registry included 787 patients with a mean lesion length of 10 cm, in which 22% had lesion lengths > 15 cm, and 14% had ISR. Overall freedom

from target lesion revascularization was 91.1% at 1 year and 84.3% at 2 years. Subgroup analysis, however, showed a 1-year primary patency of 78% for ISR and 77% for long lesions (mean lesion length, 22.4 cm).<sup>38</sup> This study, like the others utilizing BNS for long lesions, demonstrates the inverse relationship of primary patency with increasing lesion length. Other studies have confirmed these findings of inferior patency results in TASC II D lesions.<sup>12–15</sup>

#### Stent Fracture

Although BNS provided an improvement in patency rates compared with PTA, it was at the cost of ISR due to proliferative intimal hyperplasia and stent fracture. This latter problem first came to light during the SIROCCO trials, in which 6-month fracture rates of 27%

**TABLE 3. RANDOMIZED STUDIES OF VIABAHN IN THE SFA (> 30 LIMBS)<sup>a,b</sup>**

Author	Study	Year	No. of Limbs	Lesion Length (cm)	1-year Primary Patency	Study Design
Saxon <sup>41</sup>	VIABAHN PMA	2008	97	7	65%	Multicenter, randomized, vessel patency
Ansel <sup>32</sup>	VIBRANT	2009	72	19	53%	Multicenter, randomized to the GORE® VIABAHN® Device
McQuade <sup>42</sup>	McQuade	2010	50	25.6	72%	Single-center, randomized

<sup>a</sup>Patient demographics, lesion characterization, and patency definitions may differ among studies. Randomized studies included with > 30 limbs in each arm.

<sup>b</sup>Adapted from Gable DR. J Cardiovasc Surg. 2011;52:683–700.<sup>40</sup>

Abbreviations: TVR, target vessel revascularization.

and 17% were observed. Scheinert et al followed three different BNS with serial x-rays.<sup>10</sup> Stent fractures were documented in 37% of treated limbs. Increasing stent lengths and vessel calcification predicted stent fracture (risk ratio, 5.55 for stent length > 160 mm; risk ratio, 3.91 for severe calcification), and primary patency was 41.1% versus 84.3% in those with and without fractures.

Iida et al examined the influence of stent fracture on long-term patency in 333 limbs treated with Luminexx (Bard Peripheral Vascular, Inc.) or SMART stents.<sup>11</sup> Primary patency at 1 year was 68% in those with stent fractures versus 83% in those without; fractures were found to be more common in CTOs and longer lesion lengths. The BNS group in the VIBRANT randomized controlled trial of the GORE® VIABAHN® Endoprostheses (W. L. Gore & Associates, Flagstaff, AZ) versus BNS documented an overall stent fracture rate of 30.8% and 42.9% in lesions > 15 cm in the BNS group, with a trend toward lower patency compared with the stent graft group.<sup>32</sup>

## COVERED STENT GRAFTS

### Randomized Trials

Compared with BNS, covered stent grafts create a barrier to the in-growth of neointimal tissue and exclude plaque and thrombus from the arterial lumen. The GORE® VIABAHN® Device, formerly known as Hemobahn, is the only FDA-approved covered stent for use in the SFA. It is composed of a 100-µm thick expanded PTFE graft with a single nitinol wire and without interconnecting struts, imparting great flexibility and fracture resistance. It is available in lengths of 2.5, 5, 10, and 15 cm in the US and 25 cm outside

the US. It was approved in the US in June 2005, and the new design incorporating a heparin-bound endoluminal surface was approved in September 2007, and a laser-cut proximal contoured edge was approved in January 2009. Several single-center studies have reported very good primary patency rates with the GORE® VIABAHN® Device, particularly in longer lesion subsets, and documented that primary patency was independent of lesion length.

Randomized studies using the non-heparin-bonded GORE® VIABAHN® Device are summarized in Table 3. Kazemi et al documented a 90% primary patency rate with the GORE® VIABAHN® Device at 1 year versus 57% in a group treated with the SilverHawk plaque excision atherectomy device (Covidien), despite a 50% adjunctive stent rate in the atherectomy group (however, this is not included in Table 3 because there were < 30 limbs).<sup>43</sup> Kedora et al and McQuade et al reported the 2- and 4-year results of a single-center, prospective, randomized controlled trial of the GORE® VIABAHN® Device versus a prosthetic AK-FPB in 86 patients (100 limbs).<sup>42,44</sup> The mean artery length treated by the GORE® VIABAHN® Device was 26 cm. There were no differences in patency or limb salvage rates, and 15% of patients were TASC II D. These remarkable patency rates were achieved without clopidogrel, now considered standard pharmacotherapy.

Saxon et al randomized 197 patients to the GORE® VIABAHN® Device versus PTA in a multicenter trial of lesions up to 13 cm in length (mean length, 7 cm).<sup>41</sup> Patients received aspirin, as clopidogrel was not yet available. The 1-year primary patency rate was 65% in the stent graft group versus 40% in the PTA group.

**TABLE 4. NONRANDOMIZED STUDIES OF THE GORE® VIABAHN® DEVICE IN THE SFA (> 40 LIMBS)<sup>a,b</sup>**

Author	Year	No. of Limbs	Lesion Length (cm)	Occlusions (%)	Primary Patency (%)			
					1 Year	2 Years	3 Years	4 Years
Lammer <sup>16</sup>	2000	80	13.8	NR	79	NR	NR	NR
Jahnke <sup>17</sup>	2003	52	8.5	83	78	74	62	NR
Bleyn <sup>45</sup>	2004	67	14.3	100	82	73	68	54
Panetta <sup>46</sup>	2005	41	30.4	90	86	77	NR	NR
Chopra <sup>47</sup>	2006	70	20	71	93	87	72	NR
Coats <sup>48</sup>	2006	83	NR	47	89	NR	NR	NR
Fischer <sup>19</sup>	2006	59	10.7	87	67	58	57	52
Saxon <sup>20</sup>	2007	87	14.2	42	76	65	60	55
Alimi <sup>21</sup>	2008	102	11.7	NR	74	71	71	NR
Djelmami-Hani <sup>49</sup>	2008	132	21	39	80	NR	NR	NR
Fritschy <sup>50</sup>	2010	96	NR	NR	76	70	67.7	NR
VIPER <sup>51</sup>	2011	119	19	56	73	NR	NR	NR
Lensvelt <sup>52</sup>	2012	56	18.5	NR	76	NR	NR	NR
Johnston <sup>53</sup>	2012	65	26	58	57	NR	NR	NR
<b>Average/total</b>		<b>1,094</b>	<b>17.3</b>	<b>67</b>	<b>79</b>	<b>71</b>	<b>66</b>	<b>54</b>

<sup>a</sup>Patient demographics, lesion characterization, and patency definitions may differ among studies. Nonrandomized studies with > 40 limbs included. Primary patency averages weighted by the number of limbs in the study.

<sup>b</sup>Adapted from Gable DR. J Cardiovasc Surg. 2011;52:683–700.<sup>40</sup>

Abbreviations: NR, not reported.

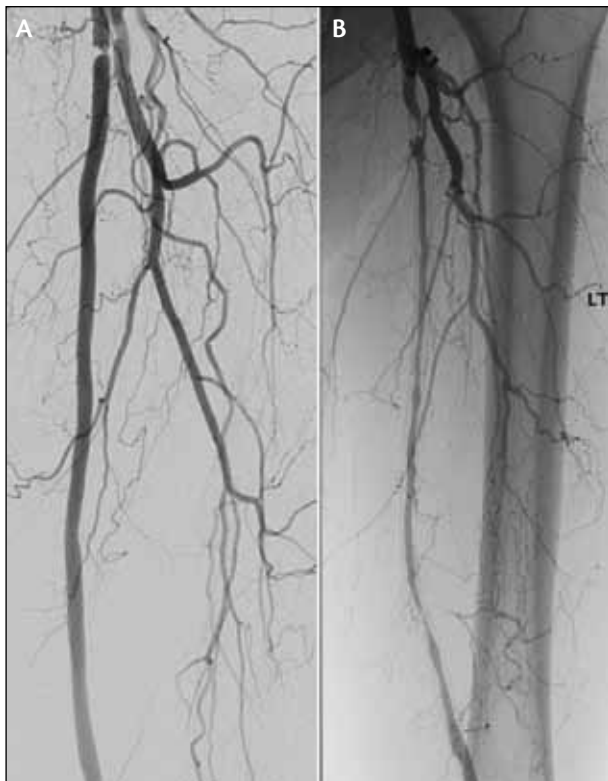
Patency rates were reported for the limb, not lesion, and defined failure as a peak systolic velocity ratio (PSVR) of > 2. Five of nine stent grafts > 12 cm were patent versus one out of six in the PTA group. TASC classification was not reported.

The VIBRANT trial is a multicenter, randomized study of the prior GORE® VIABAHN® Device (without heparin, contoured proximal edge; 5-mm device sizes available) versus BNS (multiple brands) in 148 patients (Rutherford classes 1–5), with a primary endpoint of primary patency at 3 years.<sup>32</sup> The mean lesion lengths were 19 and 18 cm, 40% were CTOs, and 62.5% of lesions demonstrated moderate to severe calcification (primarily TASC C and D lesions). Both groups had disappointing primary patency rates of 53% and 58%, respectively, but there were important differences in the patterns of restenosis: 93% of failed BNS had dif-

fuse ISR versus focal edge restenosis in 87% of the failed GORE® VIABAHN® Devices (Figure 1). This may explain why the GORE® VIABAHN® Device patients with restenosis with a PSVR > 3 had preserved resting ankle-brachial indexes of 0.93 versus 0.76 in the BNS group, and only 36% of these patients had claudication versus 71% of the BNS patients.

#### Nonrandomized Trials

Table 4 summarizes several of the nonrandomized studies employing the GORE® VIABAHN® Device. Early reports did not specify TASC criteria (TASC I not published until 2000), and many used short duration (≤ 1 month) dual-antiplatelet therapy, some with aspirin alone. Lammer et al examined 80 limbs with a mean device length of 13.1 cm; 62% were > 10 cm, and primary patency was 79% at 1 year with a 93% secondary patency rate.<sup>16</sup>

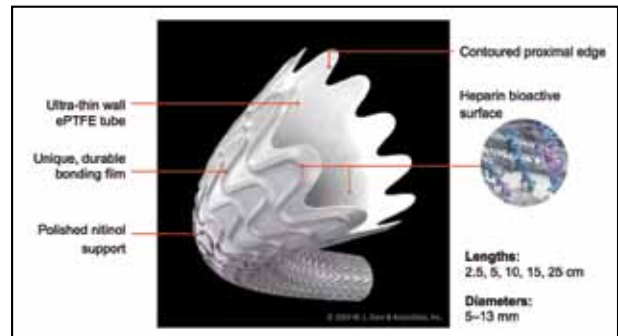


**Figure 1.** Patterns of SFA restenosis. The GORE® VIABAHN® Device demonstrating focal proximal edge stenosis (A) and BNS showing diffuse long-segment restenosis (B).

Jahnke et al reported a primary patency rate of 78%, with a mean lesion length of 10.9 cm in 52 patients, demonstrating patency independent of lesion length.<sup>17</sup> Fischer et al documented a 1-year primary patency rate of 78% in 60 limbs with 87% occlusions with a mean lesion length of 11 cm.<sup>19</sup> The 1- and 6-year primary patency rates were 80% and 57%, respectively.

Saxon et al reported on 87 limbs, of which, 81 were TASC II C and D lesions with a mean lesion length of 14 cm. The 1-year primary patency rate was 76%, and the secondary patency rate was 93%, with a lower patency rate in the 5-mm devices. Primary patency was independent of lesion length and type (stenosis vs occlusion). Further, 3.6% developed graft occlusion, and only one patient developed acute limb ischemia that required bypass. Alimi et al reported a similar 1-year patency rate of 74% and a 3-year patency of 71% in 102 limbs with a mean lesion length of 12 cm.<sup>21</sup> Twenty-three limbs were TASC D lesions.

A more recent report from Farraj et al confirmed a 1-year primary patency rate of 80% in 30 patients with claudication, with a mean lesion length of 15.4 cm.<sup>54</sup> The authors avoided implants in heavily calcified ves-



**Figure 2.** The GORE® VIABAHN® Device with Heparin Bioactive Surface.

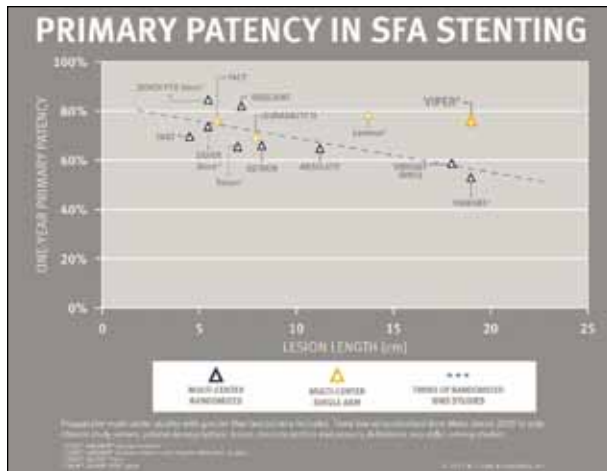
sels resistant to dilatation and did not implant any 5-mm devices. Only one patient with stent thrombosis presented with acute limb ischemia, which was treated with bypass.

### STUDIES EVALUATING THE CURRENT GENERATION OF THE GORE® VIABAHN® DEVICE

Despite the very long lesion lengths treated in VIBRANT, the primary patency rate for the GORE® VIABAHN® Device fell below the range reported in most series. A few recent studies sought to assess the effects of the new proximal contoured edge and heparin bonding in this device. The proximal contoured edge allowed for improved device apposition with less infolding, resulting in better accommodation of oversizing and improved flow dynamics, with the hope of reducing the incidence of proximal edge stenosis. The heparin bonding was added to reduce the risk of stent graft thrombosis and improve patency, as has been demonstrated in expanded PTFE grafts used in surgical bypass procedures.<sup>55-58</sup>

VIPER was a prospective, multicenter trial that utilized the new GORE® VIABAHN® Device (Figure 2) in 80 of 120 patients, with a mean lesion length of 19 cm, 56% being CTOs and 61% of lesions having moderate-to-severe calcification.<sup>51</sup> The preliminary 1-year overall primary patency rate presented in the fall of 2011 was 74%, with a secondary patency rate of 92%. Angiographic core lab analysis demonstrated excessive device oversizing (> 20%) at the proximal edge in a number of cases. In devices that were oversized by < 20%, the primary patency was 91% on the proximal edge and 87% when oversized < 20% on the distal edge. Unlike previous studies in which the 5-mm device was associated with inferior patency rates, this was no longer the case in VIPER. Patency was again shown to be independent of lesion length (< 20 vs





**Figure 3.** The relation of primary patency and lesion length. BNS demonstrate a reduction in primary patency rates with increasing lesion length. The VIPER trial demonstrated high patency rates with the GORE® VIABAHN® Device, independent of lesion length. Adapted from Dr. Thomas Zeller, LINC 2012, Leipzig, Germany.

> 20 cm). The remarkable improvement in VIPER relative to VIBRANT occurred despite nearly identical mean lesion lengths, incidence of CTOs, vessel calcifications, and number of runoff vessels. As illustrated in Figure 3, longer lesion lengths (typical TASC II D lesions) are associated with substantial primary patency loss with BNS, but patency with the current-generation GORE® VIABAHN® Device is preserved and independent of lesion length.

Perhaps the most important lesson to be learned from the VIPER trial is the importance of proper vessel sizing, particularly to avoid oversizing the device by > 20%. Please see the *Top 10 Technical Considerations in Using the GORE® VIABAHN® Device* sidebar on page 4.

In a single-center study in Europe published by Lensvelt, similar efficacy results (primary patency, 76%) were reported using the latest-generation GORE® VIABAHN® Device in 18.5-cm lesions.<sup>52</sup> The ongoing VIASTAR trial, a prospective, randomized, multicenter study, will evaluate the performance of the latest GORE® VIABAHN® Device relative to bare-metal stents in long lesions. Preliminary results have been presented, and patency results are in general agreement with those from the VIPER trial in long (approximately 20 cm) lesions.

## CONCLUSION

Studies of BNS show a progressive loss of primary patency and a high incidence of stent fracture with increased lesion lengths. Covered stent grafts, in contrast, have good primary patency rates that are

independent of lesion length and show great fracture resistance. The previous-generation stent graft was found to have equivalent patency to prosthetic femoropopliteal bypass for long SFA occlusive disease. In the VIPER trial, despite a mean lesion length of 19 cm, the new-generation GORE® VIABAHN® Device with proximal contoured edge and endoluminal heparin bonding was shown to provide excellent patency results, especially when devices were not oversized > 20% at the proximal edge. Stent grafts offer a less-invasive alternative to the greater morbidity associated with open bypass in patients with long TASC II D lesions. It is expected that future device improvements, such as treatment of the stent graft edges with paclitaxel, may further improve long-term patency rates. ■

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# Collateral Arteries: To Cover or Not to Cover?

Our center's experience using the GORE® VIABAHN® Endoprosthesis for treating long, diffuse SFA disease.

BY AMIR MOTARJEME, MD

The GORE® VIABAHN® Endoprosthesis (W. L. Gore & Associates, Flagstaff, AZ) was approved by the FDA for the superficial femoral and popliteal artery application in June 2005. This device, previously known as *Hemobahn*, has been in use in Europe since 1996. The results of the international trial study group reported by Lammer et al<sup>1</sup> showed a 1-year patency rate of 91% for iliac and 79% for the superficial femoral arteries (SFAs). The 1-year patency of the multicenter randomized postmarket approval study, conducted in the United States, was superior to percutaneous transluminal angioplasty but much lower at 65%.<sup>2</sup> The published articles both in Europe and the United States have shown a wide range of results, from 49% at 6 months by Deutschman et al<sup>3</sup> and 58% at 1 year by Bray et al<sup>4</sup> to several reports of patency rates between 78% to 82%.<sup>5-7</sup>

Although study endpoints and patient populations were diverse, this variability in clinical study outcomes in several independent studies is in need of scrutiny. Several technical considerations to optimize outcomes for the GORE® VIABAHN® Device in the SFA have been identified over the years, including avoiding oversizing, treating all of the disease, and prescribing appropriate antiplatelet therapies (please see the *Top 10 Technical Considerations in Using the GORE® VIABAHN® Device* sidebar on page 4.) One of the significant controversies that remains is the treatment of collateral arteries. In reviewing 18 articles published from 2000 to 2010, 10 authors have no concern and made no comment as to treatment of the collateral arteries. Four authors recommended not covering the collateral arteries distal to the occlusion at any cost and suggested treatment with bare-metal stents and cryoplasty.<sup>3,8-10</sup> The others believe that it is more important to cover the entire diseased area even if the collateral arteries have to be sacrificed.<sup>11-13</sup>

## BIOLOGY OF COLLATERAL VESSELS

The body provides a natural system of preexisting collateral arteries. These vessels can dramatically increase their lumen size to provide enhanced perfusion to

TABLE 1. DEMOGRAPHICS

	Group 1	Group 2
No. of patients	30 (100%)	30 (100%)
Male	12 (40%)	25 (83%)
Female	18 (60%)	5 (17%)
Claudication	18 (60%)	24 (80%)
CLI	12 (40%)	6 (20%)
Diabetes mellitus	10 (33%)	14 (46%)
CAD	15 (50%)	23 (77%)
Current smoker	22 (73%)	16 (54%)
History of smoking	1 (> 1%)	10 (33%)
Age	38–88; average, 68 y	51–91; average, 71 y

TABLE 2. LESION CHARACTERISTICS

	Group 1	Group 2
No. of patients	30 (100%)	30 (100%)
CTO	73%	63%
Stenoses	27%	37%
Calcification	46%	36%
De novo	50%	40%
Previous stents	27%	23%
Length (7–40 cm)	21 cm	24 cm
Patent distal arteries (0–3)	2	2

**TABLE 3. TREATMENTS**

	Group 1	Group 2
No. of patients	30 (100%)	30 (100%)
Debulking	16 (53%)	17 (57%)
Balloon dilatation	30 (100%)	30 (100%)
No. of stent grafts (average no. of stent grafts per patient)	52 (1.7)	63 (2.1)

**TABLE 4. PRIMARY PATENCY: COVERED COLLATERALS VS NONCOVERED COLLATERALS**

	6 Months	12 Months	18 Months	24 Months	30 Months	36 Months
Noncovered collaterals	86%	66%	60%	57%	54%	50%
Covered collaterals	93%	86%	83%	80%	NA	NA

Abbreviations: NA, not available.

ischemic regions. This process is termed *arteriogenesis*.<sup>14</sup> During this process, the collateral artery's diameter can increase up to 20-fold and restore circulation up to 30% in coronary arteries and 50% in peripheral arteries.<sup>15</sup> Also, during arterial occlusion, there is a steep gradient causing shear force, which in turn stimulates the vascular endothelial growth factor that can cause collateral growth (Figure 1). This should not be mistaken for angiogenesis, which is the sprouting of capillaries that results in a capillary network. These capillary tubes lack vascular smooth muscle cells and are not surrounded by mural cells; therefore, they are fragile and prone to rupture.

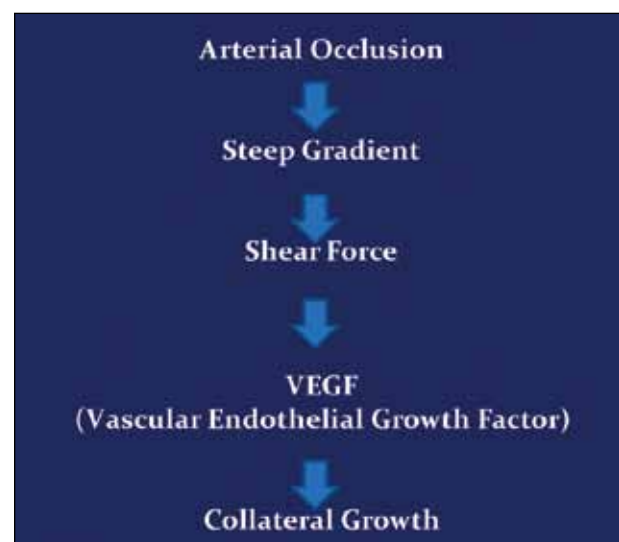
### THE COMPETITIVE FLOW CONCEPT

Although they can help to improve limb function in patients with peripheral artery disease, collateral arteries have a negative impact on parallel vessels, functioning as a competitive flow. The competitive flow occurs through the collateral arteries to perfuse the tissue distal to a graft or an artery compromised by a critical stenosis. Therefore, this competitive flow may lead to thrombosis when the flow velocity of the collateral arteries exceeds the velocity of the artery or graft. The hypothesis is that a lack of competitive flow prolongs the patency of an intraluminal stent graft in the SFA. This fact is well known in the coronary circulation in extraluminal coronary bypass grafts<sup>16</sup> but has not been explored in the peripheral arteries.

### STUDY DESIGN

To evaluate this hypothesis, we arranged a comparative study of 60 patients with long diffuse SFA disease

treated with covered stents in two groups reflecting our shift in treatment strategy from early in our use of stent grafts. In group 1, the patients (treated early in our use of stent grafts) with distal collateral arteries reconstituting the distal run-off were not covered. In group 2, patients included those who were treated more recently in which the distal collaterals were covered. The study was limited to patients who primarily had long-segment SFA disease, mostly from the origin down to the adductor canal. The lower two-thirds of the popliteal arteries were spared even if they had mild stenosis of < 50%. The proximal device was extended to the origin of the SFA unless the proximal portion of the SFA was free of disease.


**Figure 1. Arteriogenesis.**



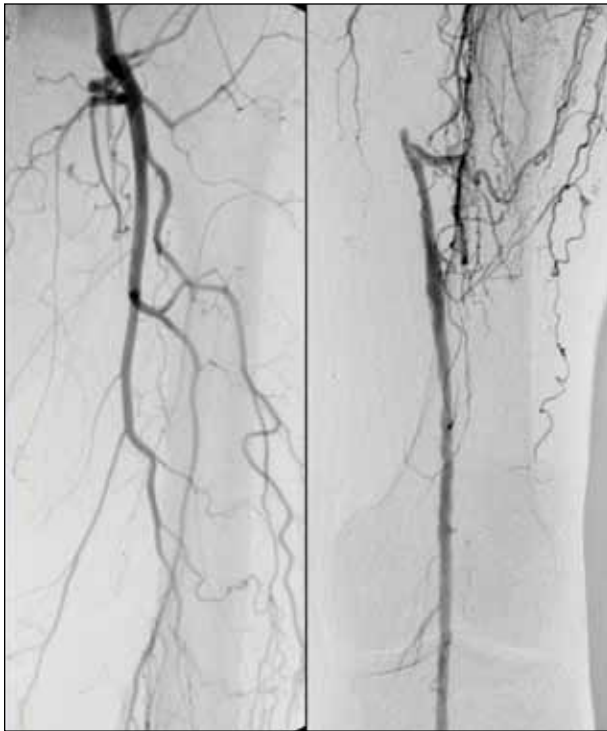


Figure 2. A 57-year-old man complaining of claudication of the left leg.

### DEMOGRAPHICS AND MEDICAL HISTORY

Despite the differing time period of treatment between the groups, there was no significant change in demographics. There were more men in group 2 (25 in group 2 vs 12 in group 1). Also, there were 18 claudications and 12 incidents of critical limb ischemia (CLI) in group 1 whereas there were 24 and six in group 2, respectively.

Of the patients in group 1, 33% were diabetics—in group 2, 46%. Furthermore, 50% of patients had coronary artery disease in group 1 versus 77% in group 2; 73% of the patients were smokers at the time of treatment in group 1 whereas only 54% were smokers at the time of treatment in group 2. The patients were 38 to 88 years of age, with a median age of 68 years in group 1; however, they were 51 to 91 years of age in group 2, with a median of 71. Total occlusion was seen in 73% of group 1 and 63% in group 2. Calcification was seen in 46% of group 1 and 63% in group 2.

There were de novo lesions in 50% of group 1 and 40% of group 2. The length of occlusions ranged from 7 to 40 cm, and the median for group 1 was 21 cm and 24 cm in group 2. Patent distal arteries ranged from zero to three, with a median of two in both groups (Tables 1 and 2).

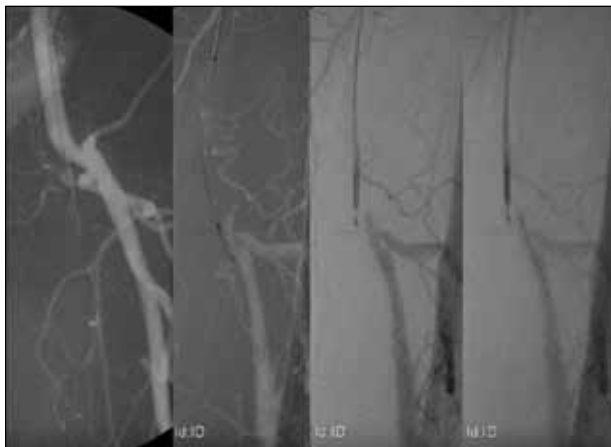
### PROCEDURE

All patients had arterial duplex sonography and resting ankle-brachial indexes assessed before treatment and



Figure 3. Atherectomy and percutaneous transluminal angioplasty of a predecided segment followed by implantation of a covered stent.

complete diagnostic angiography at the time of treatment. A contralateral transfemoral approach was used in all patients. The total occlusions were recanalized with a Quick-Cross catheter (Spectranetics Corporation, Colorado Springs, CO) or a similar catheter with a Glidewire device (Terumo Interventional Systems, Inc., Somerset, NJ). An Outback re-entry device (Cordis Corporation, Bridgewater, NJ) was used in cases with extraluminal passage of the wire. Approximately 53% of the patients in group 1 and 57% in group 2 underwent excisional atherectomy for debulking prior to balloon dilatation. All patients underwent balloon dilatation with a 5- or 6-mm balloon catheter matching the reference vessel size. Further, 60% of the patients had a 5-mm SFA that



**Figure 4.** Recanalization of an occluded SFA using a hydrophilic wire and a catheter. An Outback catheter was used for reentry.

was consequently dilated with a 5-mm balloon catheter and stented with a 5-mm GORE® VIABAHN® Device.

A total of 52 stents were used in group 1 and 63 in group 2. Ninety percent of the patients had GORE® VIABAHN® Devices extended up to the origin of the SFA. The segment to be treated was predetermined and was not deviated from. No atherectomy or percutaneous transluminal angioplasty was performed outside of the predetermined segment. The GORE® VIABAHN® Device was extended 1 cm below the predetermined segment to ensure that no treated segment was left uncovered. Mild stenosis of the popliteal artery (< 50%) was not treated (Table 3). In CLI cases, angioplasty and/or stenting of the infrapopliteal arteries was performed after implantation of the GORE® VIABAHN® Device. During the procedures, heparin was used to maintain an activated clotting time of 250 seconds, and postoperatively, all patients were treated with 80 to 350 mg of aspirin daily along with 75 mg of clopidogrel.

Any patient who was on warfarin for other reasons prior to the procedure was kept on this medication in addition to aspirin and clopidogrel. Patients were followed at our office at 6 weeks and 6 months postprocedure, then at 6-month intervals. Patients with CLI were seen every 3 months until their ulcers were healed. At each visit, complete arterial duplex sonography and assessment of resting ankle-brachial indexes were performed before physical examination. All of the patients in both groups have completed a 2-year follow-up evaluation. None of the patients were lost to follow-up or died.

## RESULTS

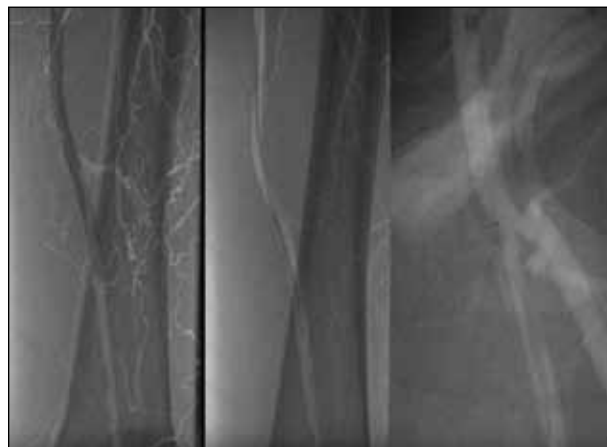
The primary success rate was 100% in both groups for diffuse stenoses, as well as total occlusions. No significant



**Figure 5.** Atherectomy for debulking.

complications were encountered, including no incidence of acute limb ischemia. There were three small hematomas and ecchymosis at the puncture sites in each group. No distal embolization was seen, but there were tiny visible pieces of atheroma captured by distal protection devices in the majority of the atherectomy cases. Distal protection devices were used in every single case that employed atherectomy. There were four graft thromboses in group 1 and two in group 2 within the first 6 months, with a patency rate of 86% in group 1 and 93% in group 2. At 12, 18, and 24 months, the patency rate was 66%, 60%, and 57% in group 1, respectively, versus 86%, 83%, and 80% in group 2, respectively.

Although at 6 months there was no significant statistical difference between group 1 and 2, as time elapsed, the difference between the patency rates of the two groups widened (Table 4). All thrombosed endoluminal grafts were successfully rescued by thrombolysis using an EkoSonic endovascular system (Ekos Corporation, Bothell, WA) and tissue plasminogen activator. The



**Figure 6.** Balloon dilatation and alignment of the GORE® VIABAHN® Devices.

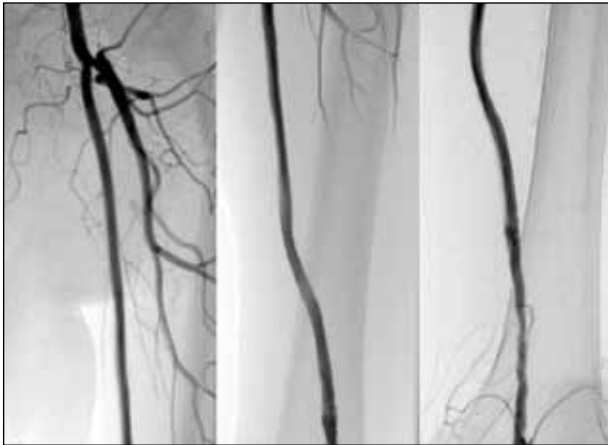


Figure 7. Postprocedure arteriography.

underlying cause of thrombosis was generally related to distal edge stenosis, which was often treated using a short GORE® VIABAHN® Device. Proximal edge stenosis was rarely seen, likely due to our liberal treatment of the proximal SFA.

Based on these very promising results, the following are our recommendations for improving the patency rate of endoluminal grafting (Figures 2 through 7):

- Debulk the diseased SFA segment.
- Avoid percutaneous transluminal angioplasty of the popliteal artery.
- Cover the immediate collateral arteries to eliminate competitive flow.
- Do not leave any treated segment uncovered.
- Extend the GORE® VIABAHN® Device to the origin of the SFA if any disease is present.
- Do not oversize the grafts.

In addition to these techniques, the latest device configuration with the heparin bioactive surface may have contributed to the excellent patency results in group 2. Also, coverage of collateral vessels may correlate strongly with more liberal treatment of diseased arterial segments. Further study is warranted to quantify the relative effects of those factors. Nevertheless, it appears that the latest GORE® VIABAHN® Device and the current treat-

ment algorithm employed at our institution, including coverage of distal collateral vessels, can lead to excellent patency results.

## CONCLUSION

The GORE® VIABAHN® Device is suitable for percutaneous endoluminal implantation in long-segment diffuse stenoses and total occlusion of the SFA and has been shown to be as effective as surgical femoropopliteal above-the-knee synthetic grafts.<sup>10</sup> In properly selected cases and with improved techniques, a patency rate of 80% out to 5 years is well within reach. ■

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