

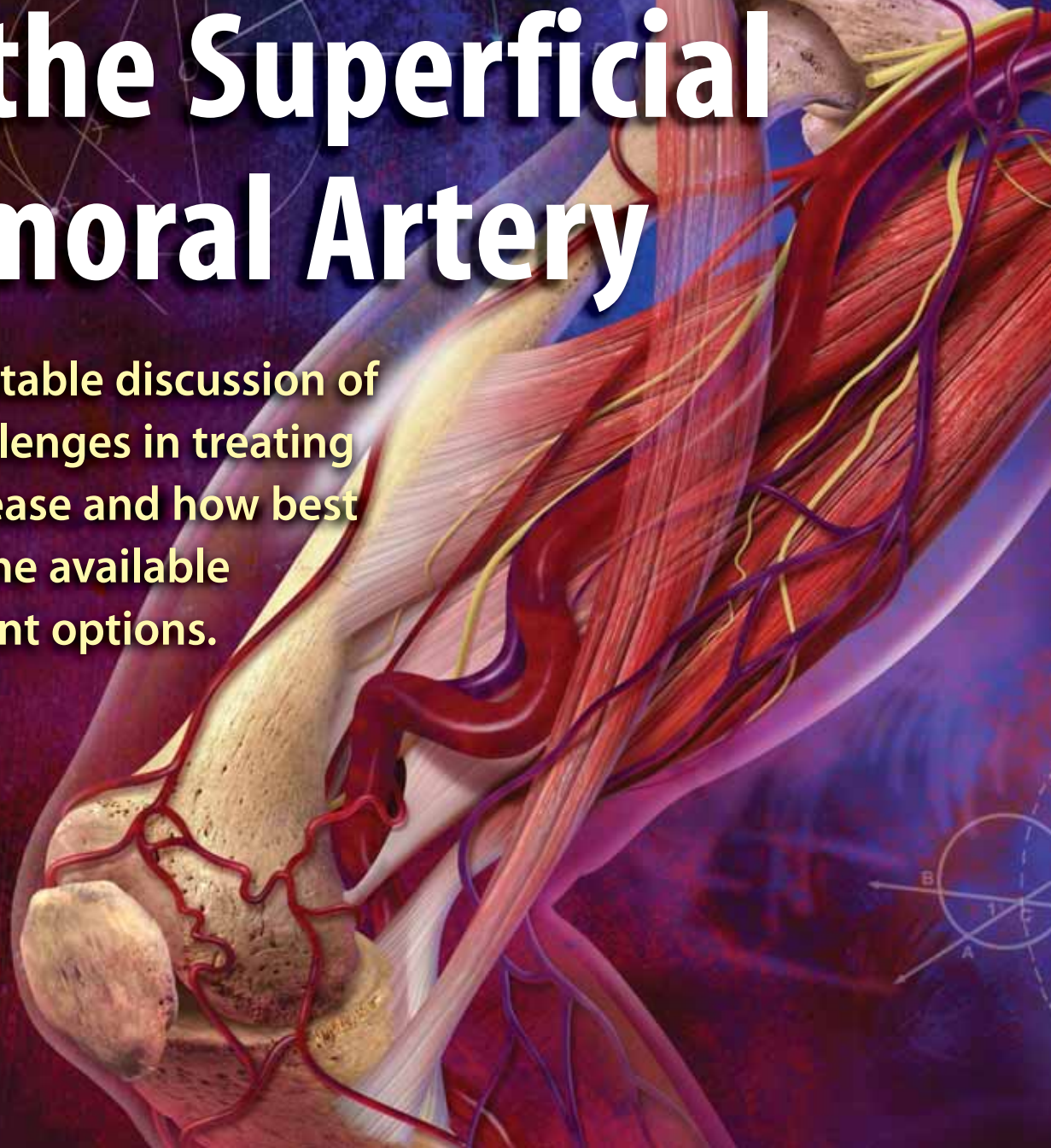
Endovascular

TODAY

September 2008

Endovascular Repair of the Superficial Femoral Artery

A roundtable discussion of the challenges in treating SFA disease and how best to use the available treatment options.



SFA Roundtable

The superficial femoral artery (SFA) has long presented endovascular specialists with a unique challenge. This vessel is subjected to various forces, such as compression, torsion, flexion, extension, and contraction, which have caused many treatments to fail. However, maintaining patency in the SFA has also been crucial for preserving patients' quality of life and limbs.

Numerous modalities now exist for treating the SFA. Self-expanding stents, covered stent grafts, angioplasty balloons, plaque atherectomy devices, and a variety of chronic total occlusion devices all provide endovascular specialists with a wide array of options. The question for many specialists is which tool in their vast armamentarium should they use on particular patients and lesions? Does one device treat all lesions best, or are other factors better indicators of which technology to use?

In April 2008, *Endovascular Today* gathered 12 top endovascular specialists from the fields of interventional cardiology, interventional radiology, and vascular surgery to discuss their recommendations for the optimum treatment of various lesions in the SFA.

As expected, their treatment protocols varied based on a number of factors, such as lesion length and characteristics, as well as patient variables such as run-off, anatomy, and comorbidities. In this supplement, we have attempted to synthesize the panel's recommendations for treating the SFA along with their suggestions for optimum use of the VIABAHN Endoprosthesis (W. L. Gore & Associates, Flagstaff, AZ). We look forward to continuing this important dialogue in the years ahead and would like to thank W. L. Gore & Associates for their sponsorship of this project.

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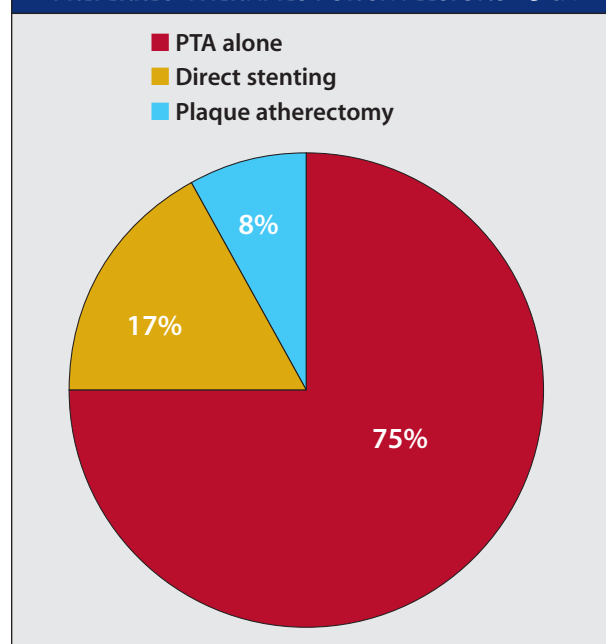
Short SFA Lesions: <3 to 5 cm

The ideal therapies for “short” lesions provoked the greatest amount of discussion and controversy among the panelists. Aside from differing opinions regarding the preferred method of treatment, the physicians noted that many additional variables must be considered, such as the condition of the SFA, the location of the lesion, its degree of calcification, and the patient’s associated symptomatology. The most important determining factor, however, was the length of the lesion. Many of the panelists were insistent that they generally treat lesions under 3 cm quite differently from those in the 3- to 5-cm range.

In order to limit the variables and forge a consensus, it was proposed that the panelists consider treating a hypothetical patient with lifestyle-limiting claudication and a stenotic, noncalcified lesion of 3 cm or less in an otherwise disease-free SFA. Although this hypothetical patient may rarely present for treatment, the majority of the panelists favored percutaneous transluminal angioplasty (PTA) alone if they achieved a favorable initial outcome (which some described as a “stent-like” result, and others referred to as having “good flow and angiographic result”). Many panelists also suggested that small, focal lesions (<5 cm) rarely result in lifestyle-

limiting claudication. Dr. Chopra noted, “If a patient comes to you with only one short SFA lesion, 99% of

PREFERRED THERAPIES FOR SFA LESIONS <3 CM



RECOMMENDATIONS FOR SFA LESIONS <3 CM

Device	Comments
PTA	Most of those who favored PTA concurred that they would proceed with adjunctive stenting if dissection, poor flow, or a persistent pressure gradient resulted after PTA A few panelists recommended long inflations of 2 to 4 or 5 minutes for optimal PTA outcome
Bare-metal stents	Useful for heavily calcified lesions Location remains an issue. Some stenting proponents were reluctant to stent around the proximal end of the common femoral artery (just above the common femoral artery bifurcation) or behind the knee due to concerns of stent fracture Be certain to land the stent from good segment to good segment
Stent grafts	When PTA alone is insufficient, two panelists opt for a stent graft to avoid the patency problems of bare-metal stents
Plaque atherectomy	Possible application for soft (noncalcified) plaque; particularly useful in locations less hospitable to stenting
Cryoplasty	Possible application for calcified plaque, but peak pressure (8 atm) may not be high enough
Scoring balloon	Possible application for focal calcified lesions toward the popliteal artery

the time, he does not need treatment. If that patient is symptomatic, then something else is probably going on. There are very few patients who have short [<5 cm single stenoses] who claudicate with lifestyle-limiting disease.”

Although PTA is the primary option the panelists employ in short, focal disease <3 cm in length, they also discussed several tips for the ideal applications of other devices that may be used. For lesions that were between 3 and 5 cm in length, the panelists noted that there were too many variables to recommend a single treat-

ment protocol. Although the percentage of panelists who favored stenting these lesions increased as compared to lesions <3 cm, there were many caveats, such as not stenting lesions behind the knee or near the proximal end of the SFA—locations that are exposed to excessive bending. The majority of the panelists deemed these lesions to be “moderate” in length, and they were generally persuaded by their own experiences and the data from the RESILIENT and ABSOLUTE trials regarding the superiority of stenting to PTA for these lesion lengths. ♦

Moderate Lesions: 5 to 10 cm

In stenotic lesions measuring 5 to 10 cm in length, the panel shared closer agreement about utilizing stents (bare metal or stent grafts) as the ideal treatment modality.

Dr. Schneider noted, “For the longer lesions, we know that angioplasty alone does not fare well.” This sentiment was echoed by most of our panelists, a few of whom recommended angioplasty solely for predilation or debulking purposes.

Most of our panelists (87%) opt to stent these moderate-length lesions, with 67% preferring bare-metal stents and 20% favoring stent grafts. Those favoring stent grafts in this setting prefer to use them in larger vessels (>4.5 mm in diameter) that show evidence of good runoff. One of the bare-metal stent proponents prefers using this procedure as the first treatment, leaving stent grafting available as a future option. In vessels with larger diameters, primary stent failure may be addressed through secondary treatment with a stent graft. Most agreed that smaller vessels <4.5 mm in diameter were unable to accommodate a stent graft and should be treated with bare-metal stenting.

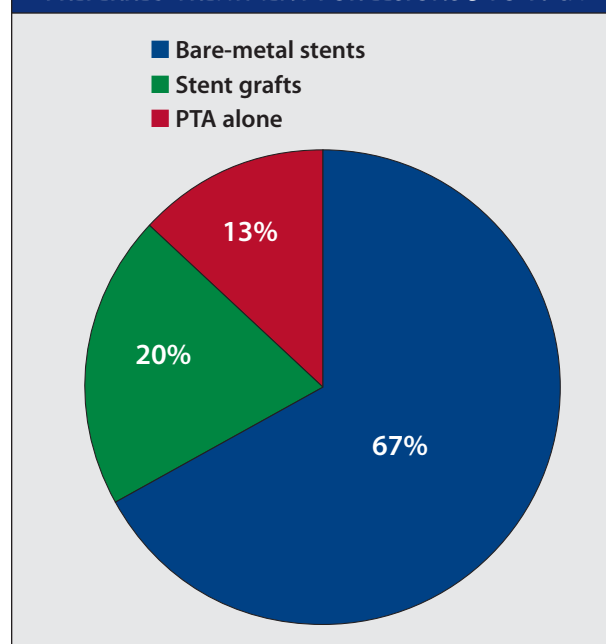
Dr. Bajwa delivered the final word on stenting moderate lesions, stating, “I use just one device. I think overlapping devices gives you a higher risk of fractures, and fracture is a marker of restenosis, both in coronary as well as in the peripheral circulation.”

Most utilized adjunctive therapies (atherectomy and cryoplasty) almost exclusively to prepare the vessel for stenting, and several panelists expressed the need for

more data to support the use of these therapies.

Another treatment variable the panelists noted pertains to the patient’s symptoms. Many of the panelists approach patients who have claudication differently than those with critical limb ischemia (CLI). Dr. Mewissen noted, “If a patient has CLI and clearly has a small vessel, I know that balloon angioplasty will not work, and I know that a bare-metal stent will give me at

PREFERRED TREATMENT FOR LESIONS 5 TO 10 CM



least 6 months of patency, during which I can achieve healing. The decision is easy for me.” Dr. Chopra advised that when treating CLI patients, he uses “whatever is necessary to open the vessels. First, I cross the occlusion. If I cannot use angioplasty alone to treat it, I will then use atherectomy. Once I get through, I try to cover the lesion and keep it open as long as possible. If there are additional lesions in the popliteal segment, I treat them and attempt to keep the runoff vessels open. If none of this is possible and the flow is still insufficient, I refer the patient to surgery.”

Dr. Motarjeme stated, “My protocol depends on what type of recanalization I am likely to achieve. Will I be intraluminal or subintimal? If I achieve recanalization and I am confident that I am intraluminal, I elect to perform atherectomy to remove as much old thrombus and plaque as I can, followed by balloon angioplasty and an evaluation. If the result at that time is anything less than perfect, I will likely place a stent. However, if I am confident that I am in the subintimal space, I will place the stent after balloon angioplasty is performed.”

Speaking as one of the three surgeons in the group, Dr. Gable made the important point that for certain patients, surgical intervention may be the optimal treatment. “If a patient has poor runoff, small vessels, and calcified lesions, there is still a surgical option, particularly if there is a venous conduit and the patient is a good surgical candidate,” he said.

The panel members who use embolic protection when treating SFA lesions tend to do so whenever utilizing atherectomy. “I firmly believe you need to use distal protection with practically every single atherectomy

case because the rate of distal embolization is 80% to 90%,” said Dr. Motarjeme. “We place a distal protection device in the popliteal artery, and we perform atherectomy over the entire length of the occlusion before PTA and stent graft placement.”

Predilatation also carries some risk of embolization. Due to the stent graft’s profile, stent-grafting chronic total occlusions (CTOs) may require predilatation not only to prepare the lesion, but also to properly position the device within the vessel. “In my opinion, all CTOs need predilatation,” said Dr. Mewissen, “and I think that step carries some risk of embolization. That is when I use protection.”

Distal protection should also be employed when there is low patient tolerance for distal embolization. For example, in a situation of one-vessel runoff, even a slight degree of downstream obstruction of flow could have disastrous consequences. Dr. Pershad said, “Even with balloon angioplasty, if the lesion is bulky and the runoff is marginal, [if embolization occurs] you could potentially have no runoff below the knee, making a procedure much more complicated. Those are instances in which I consider using embolic protection as a frontline and always in concert with intravenous GP IIb/IIIa therapies.”

Occluded stent grafts also present the possibility for embolization due to thrombus that may become dislodged during treatment. Similarly, distal edge restenosis of a stent graft that results in lack of flow within the device (and therefore possible thrombus) may also warrant embolic protection after lytics have reopened the occluded stent graft, due to concern that residual unstable material within the device might embolize. ♦

RECOMMENDATIONS FOR LESIONS 5 TO 10 CM

Device	Comments
PTA	Most panelists believed that patency rates do not justify its use in treating moderate lesion lengths
	Still useful in some cases for pretreatment or debulking prior to stenting
Bare-metal stents	Panelists favor their use in these lesions but concur that not all stents are the same. Fracture rates of the various stents vary greatly
	Almost always used if vessel is <4.5 mm in diameter
	Do not use multiple overlapping stents
Stent grafts	Useful in larger vessel diameters (>4.5 mm) if the device can be placed from healthy segment to healthy segment
	Pay close attention to potential runoff concerns
Plaque atherectomy	Some use for pretreatment, but there are insufficient data to support use in most vessels
Cryoplasty	Useful if needed to save the geniculate vessel

Long Lesions: 10 to 20 cm

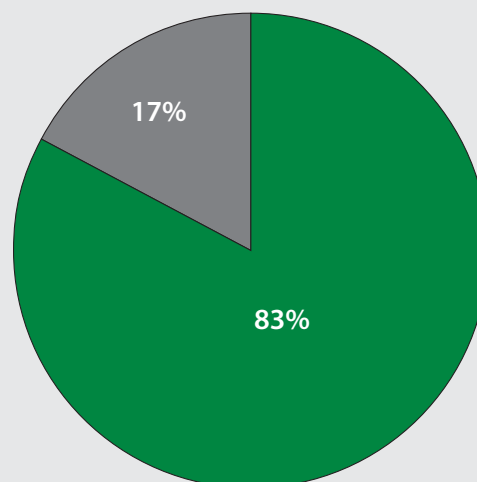
Lesions measuring 10 to 20 cm generated considerable consensus among the panelists, with 83% treating these lesions with a stent graft and the remaining 17% using a stent graft or a bare-metal stent, depending on factors such as lesion length, vessel diameter, and runoff.

The majority of roundtable participants agreed that stent graft placement is their treatment of choice for larger-diameter long lesions that do not extend behind the knee joint. “The longer the lesion, the better the stent graft looks compared to everything else,” said Dr. Saxon. This conviction was echoed by Dr. Schneider. “The patency of nitinol stents starts falling off dramatically as lesion length increases,” he said. “It seems that this isn’t the case with covered stents, in which the restenosis is limited to the edges, based upon the data we have available.”

Recommended adjunctive treatments for long lesions include atherectomy to create a favorable landing zone for the stent graft, if necessary. This “healthy-to-healthy” approach is recommended whenever undertaking a percutaneous SFA repair. A clear landing zone can be particularly important, however, when initiating the stent graft near or at the SFA origin. ♦

PREFERRED TREATMENT FOR LESIONS 10 TO 20 CM

■ Stent grafts
■ Stent grafts or bare-metal stents



PERSONAL RECOMMENDATIONS FOR LONG LESIONS

Physician	Recommendations
Dr. Bajwa	One of the only limitations of using stent grafts in long lesions is if the disease extends proximally into the common femoral segment, where the profunda is located, which for us is one of the indications to send the patient for surgery.
Dr. Chopra	Our protocol is to get through the occlusion using whatever it takes. Once past the occlusion, I attempt angioplasty, after which the result is never sufficient. It may look good initially, but there is a good deal of restenosis, and the patient will be back within months—if not weeks.
Dr. Coats	If I can get across the lesion, I will stent it using a stent graft, and use adjunctive procedures such as cryoplasty proximally or distally. If it is encroaching on the profunda origin, then I will attempt to use cryoplasty up high; if I have to cover collaterals distally, I will also use cryoplasty.
Dr. Gable	I almost always try to treat long lesions initially with a stent graft. I have not gone across the popliteal artery, but I have taken it down to the knee joint, and I have not had any issues. If I have to treat any proximal disease, I usually cover that with a stent graft rather than using cryoplasty, atherectomy, or anything else.

PERSONAL RECOMMENDATIONS FOR LONG LESIONS (CONTINUED)

Physician	Recommendations
Dr. Jones	My decision to use a bare-metal stent versus a stent graft depends upon vessel size and runoff. Also, I do not place stent grafts in patients with nonhealing ulcers, particularly in the diabetic population, if I am under the impression that they are actively infected and there is a potential risk for systemic septicemia.
Dr. Mewissen	Two things are important here: lesion location and patient symptomatology. For claudicants, if the lesion reconstitutes above the knee joint, then I would probably favor a stent graft, assuming the vessel size and the vessel diameter are all appropriate. If the claudicant's lesion is below the knee, we would still favor a below-knee bypass graft. However, if the patient has CLI, then the lesion location is irrelevant, and I cross the popliteal, usually with a bare-metal stent.
Dr. Motarjeme	For longer lesions—in particular 20-cm occlusions—we use stent grafts, but I firmly believe in debulking before placing the stent graft in order to be able to use the larger-diameter device. We use excisional atherectomy over the entire length of the occlusion, balloon it, and then place the stent graft and redilate it.
Dr. Park	I would recommend stenting as opposed to angioplasty, and if the lesions are longer (>15 cm) or if it is a CTO recanalization, I tend to favor stent grafts.
Dr. Pershad	These longer lesion lengths are one of the niche roles for stent grafts. Long lesions typically do poorly with any kind of therapy, and balloons and self-expanding stents are probably not going to cut it here. I cannot emphasize enough the importance of duplex surveillance in these patients after placing the stent graft. Most of the time, the disease is extensive and the problem of edge restenosis, if not treated at the time of duplex surveillance, can quickly make a good-looking SFA into one that is full of clot if the proximal edge shuts down. For patients I believe will be difficult to closely follow and who have disease at the ostium of the SFA, I would have very little hesitancy in sending for a vein or PTFE bypass procedure because I think edge restenosis is still an issue proximally.
Dr. Saxon	<p>I tend to prefer the stent graft. In our stent graft data, there is no difference in patency based on lesion length. As such, the longer the lesion, the better the stent graft looks compared to everything else. Although I believe stressing follow-up and duplex surveillance are important, the patency of a stent graft in our hands for long lesions is the same as the patency of a synthetic surgical bypass, so I am not sure I would send a patient for bypass because I suspect that the patient is going to be noncompliant with surveillance.</p> <p>One word about cost-effectiveness: There are several expensive adjunctive therapies that we can use in longer lesions, but we do not have any data that debulking leads to better long-term patency than nondebulking, or that cryoplasty is any better than balloon angioplasty. The only instance in which I routinely use any of the adjunctive therapies is for disease at the SFA origin, where I perform atherectomy to create a landing zone for a stent graft when necessary. I fear in the near future we will not get paid for these adjunctive therapies unless we do the necessary studies to prove their efficacy.</p>
Dr. Schneider	<p>As the lesion length increases, so too does my preference for stent grafts because the patency for nitinol stents begins to decline dramatically as lesion length increases. This does not seem to be the case with stent grafts, in which restenosis is limited to the edges based upon the data we have available.</p> <p>Longer lesions also create more difficulty in dealing with the forces of the SFA in terms of the risk of stent fracture. Moreover, in long lesions, it is more likely that overlapping nitinol stents will be needed, which will also increase the rates of stent fracture and restenosis.</p> <p>In terms of the role of surgical treatment, the determining factor is not only the lesion length, but also the pattern and location of the disease. If there is common femoral disease, it may involve the origin of the SFA, and many of those patients are probably better treated with a femoral endarterectomy. A hybrid procedure can then be performed to treat the rest of the SFA with a stent graft or a catheter technique.</p>
Dr. Soukas	<p>The location of the lesion significantly affects my decision regarding how to treat the patient and what specific stent to use. We do like to use atherectomy for the ostium of the SFA to give us a short stent-free zone. It is critically important to remember that the profunda is a vital vessel, and we have to be very careful not to jail it with a stent. For this reason, we tend to proceed with atherectomy for that 1- to 2-cm portion.</p> <p>If I am dealing with a diabetic claudicant with poor runoff and a small vessel, I might attempt a debulking procedure first. We have had a fair amount of success debulking with the laser, followed by a cutting balloon or perhaps cryoplasty. If we achieve a great result in someone who is not an ideal candidate for a stent, we might be satisfied with that particular result and not necessarily place the stent.</p>

Longest Lesions: >20 cm

In most cases involving stenotic and/or occluded lesions of 20 cm or longer, the panelists agreed that stent grafting is clearly the preferred frontline treatment. There were some caveats, including the usual requirement of sufficient runoff and a vessel diameter >4.5 mm. In addition, approximately half of the group indicated they might also refer patients for surgical bypass in certain situations, including the disease extending into the profunda or those involving unsuccessful percutaneous outcomes.

The group engaged in further discussion about the need for a proximal neck or “landing zone” approximately 1 to 2 cm long for placement of a stent graft in a long lesion. Dr. Bajwa stated that if no such landing zone is available, and if

disease extends all the way to the profunda or presents with a flush occlusion, he would send those patients for bypass surgery. In contrast, Dr. Chopra mentioned that in his experience, he has been able to adequately treat patients with insufficient landing zones by placing the stent graft flush with the profunda. Dr. Coats concurred. “Flush occlusions are the most difficult, obviously,” he said. “But if I can get across the lesion, I will use a stent graft.” When utilizing a stent graft with a flush occlusion, however, the potential for edge restenosis must be kept in mind. The proximal end of the device must be of ample diameter, stated Dr. Park. “You do not want to leave a very narrowed or strictured lesion right at the beginning of the device.” ♦

RECOMMENDATIONS FOR LONGEST LESIONS

Landing zone	Some panelists believe that a stent graft requires a 1- to 2-cm landing zone below the profunda, whereas others take the stent graft flush to the profunda. Note: the proximal end should have a sufficient diameter.
Multisegment disease	Some panelists believe in covering the entire segment, from healthy segment to healthy segment; one panelist argued for leaving “normal” segments alone within diffuse disease.
Diameter and runoff	As with all other lesion lengths, the panelists recommend not using a stent graft in vessel diameters <4.5 mm or patients with insufficient runoff.

Antiplatelet Regimen

There was a fairly strong consensus among the roundtable participants when it came to discussion of recommended antiplatelet regimens. Low-dose aspirin and clopidogrel appeared to be the pharmaceuticals of choice.

Most of the experts said they recommend baby aspirin indefinitely and maintain their patients on clopidogrel for at least 3 months. Others indicated they extend the clopidogrel regimen to 6 or even 12 months. Dr. Chopra recommends clopidogrel to his patients for life. Regarding the reimbursement challenges that he and Dr. Saxon cited for such long-term drug treatment, Dr. Chopra said, “For some patients, we secure samples to help keep them going.” Should that approach fail and a patient on the drug develops restenosis, warfarin may offer a viable alternative.

For patients who present with nonhealing ulcers and significant infrapopliteal arterial occlusive disease, Dr. Jones also prescribes cilostazol until healing has occurred.

In high-risk patients with acute limb ischemia or multi-level disease, he incorporates periprocedural intravenous GP IIb/IIIa inhibitors such as eptifibatide. Dr. Jones also commented that statins are still useful and important drugs. However, Dr. Soukas does not believe that cilostazol has been shown to add anything above and beyond acetylsalicylic and clopidogrel. “Clopidogrel, which has been shown in the CAPRIE trial to be superior to aspirin, would be expected to have particular benefit in patients with panvascular disease,” said Dr. Soukas. “Similarly, there are no data to suggest that GP IIb/IIIa inhibitors add any particular value for routine proton-pump inhibitor, and they may increase the risk of bleeding. There is also no evidence that switching to warfarin after stent graft failure on clopidogrel will prevent recurrent stent graft failure. It is more likely that the stent graft failed from proximal or distal edge restenosis, emphasizing the need for Duplex surveillance.” ♦

Posttreatment Protocol

The panel exhibited variance in their approaches to follow-up visit timing, from once in the first 6 months and twice yearly after that, to every 3 months. Follow-up is crucial to prevent early stent graft failure, which is seen in a small subset of patients. Regular monitoring can also more efficiently address potential restenosis and prevent graft blockage due to thrombus.

At the time of treatment, patients should be coached to keep all follow-up appointments, but also to call in should symptoms reappear at any time in between visits. When a stent graft fails, CLI is a much less likely occurrence than simply a return to baseline status including claudication.

Duplex surveillance can be crucial in following these patients; Dr. Gable and a number of other participants recommend them every 3 months. Ankle brachial index (ABI) measurements are also valuable. "You're not just fol-

POSTTREATMENT TIP

- Survey patients frequently for symptoms to ensure early detection of restenosis

lowing them for device failure," said Dr. Pershad. "You are also following them for progressive de novo disease."

Patients will most likely be followed for life; the timing of office visits depends on physician comfort level as well as patient status. "Certainly, in the patients that get to 1 year without requiring reintervention, the incidence of failure after that point is pretty low," said Dr. Saxon. At the 12-month mark, some experts said that they decrease follow-up frequency in patients who are doing well to twice yearly with annual duplex imaging. Dr. Chopra continues to follow the majority of his patients every 3 months for life, with the exceptions being seen every 6 months. ♦

VIABAHN Endoprosthesis Placement Considerations

COLLATERAL MANAGEMENT

Precise placement of the VIABAHN Endoprosthesis is of primary importance, particularly in longer lesions or when disease spans segments that contain branching vessels. Unlike positioning metal stents, some panelists expressed concern that placement of stent grafts across collateral vessels can lead to occlusion. The panelists agreed that although an interventionist's intention should be to avoid crossing collaterals whenever possible, most of the SFA collaterals can be covered. A more important consideration for a successful outcome is to extend the stent graft from healthy segment to healthy segment. The panelists concurred that the profunda should not be covered because it serves an important role should the SFA reocclude. The panelists agreed that covering most SFA collaterals was not a concern. However, the one SFA collateral that generated discussion was the profunda-to-supragenicular collateral. One panelist believed that this collateral should not be covered. The other panelists agreed that although they would

try to preserve the supragenicular collateral, if that segment of the SFA is diseased, they would cover it. Dr. Soukas commented regarding one technique he employs with regard to the proximal landing zone in the proximal SFA. "I've often performed plaque excision atherectomy to have a stent-free zone to avoid the chance of jailing the profunda with the VIABAHN Endoprosthesis."

"I think it's most important to treat all disease," said Dr. Schneider. "If faced with the situation in which you need to decide between covering a collateral or leaving some residual disease, I would cover the collateral because I think the most important determinate of success is excluding the diseased segment. I have covered a lot of collaterals with the VIABAHN Endoprosthesis and have not had patients return with acute limb-threatening ischemia who require emergent care. I think that's very unusual."

Dr. Motarjeme noted, "Distally, I make sure that I have one collateral intact, and the larger the collateral, of course, the better it is. It doesn't mean that small collaterals cannot

get larger later, but I make sure that I leave a good collateral intact below the lower end of the VIABAHN Endoprosthesis.”

For cases in which there is a heavily diseased profunda, however, the treatment approach to collaterals must become more conservative. Such patients may be better managed surgically, said Dr. Saxon.

RESTENOSIS

In-stent restenosis is much less common with the VIABAHN Endoprosthesis than with bare-metal stents, whereas proximal-edge restenosis (and to a lesser extent, distal-edge restenosis) is the most common failure mode our panel experienced.

In order to prevent edge restenosis, our panelists recommended precise placement of the VIABAHN Endoprosthesis, taking care to place the device from healthy segment to healthy segment. According to Dr. Saxon, “damage in the artery outside of the device will predispose patients to edge stenosis, but the etiology of edge stenosis is poorly understood, likely multifactorial, and this problem is currently impossible to completely

prevent.” Dr. Pershad recommends using 1:1 balloon sizing and prolonged balloon inflations at the edges to prevent edge restenosis. It is critical to avoid dilating outside the stented segment (ie, geographic miss), to avoid edge restenosis. Several panelists stressed the importance of having both adequate inflow and outflow, and a few also noted that some patients are simply genetically predisposed to hyperplasia.

When edge restenosis occurs, most panelists agreed that the best course of action was to extend the VIABAHN Endoprosthesis past the restenosis to healthy tissue. They were in agreement that atherectomy should not be used inside the VIABAHN Endoprosthesis. If the stent graft is already flush with the proximal end of the SFA, most participants agreed that the patient should be referred to surgery.

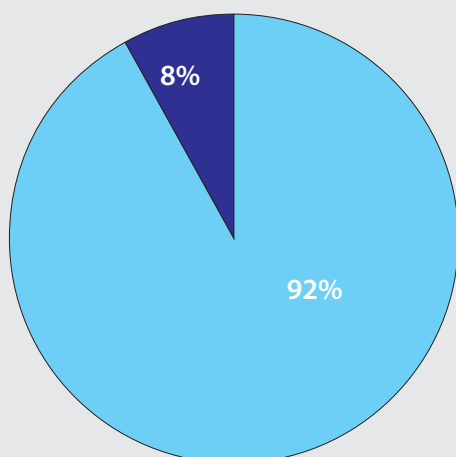
Most of the panel would treat edge restenosis more aggressively than in-stent restenosis of a bare-metal stent. Dr. Saxon noted, “Bare-stent multifocal in-stent restenosis is a very difficult issue to deal with, and part of the reason we don’t intervene early is that it is slowly progressive and difficult to fix.” Dr. Saxon further stated that he generally does not treat asymptomatic patients with stent graft edge stenoses when their ankle brachial indexes (ABIs) are normal until their systolic velocity ratios on duplex reach a threefold increase. In symptomatic patients or in those with a diminished resting ABI, he recommends intervening earlier, when the systolic velocity ratio has increased by 2 to 2.5 times.

TIPS FOR ADDRESSING COLLATERALS

- Most collaterals can be covered without concern
- Covering the SFA from healthy segment to healthy segment is crucial to success
- Do not cover the profunda

COVERING SFA COLLATERALS

- Attempt to preserve the profunda-to-suprageniculate collateral, but cover if diseased
- Always preserve the profunda-to-suprageniculate collateral



ACUTE THROMBOSIS

The incidence of acute thrombosis with the VIABAHN Endoprosthesis is rare. The majority of our panel reported experiencing acute thrombosis in <5% of their patients who presented with an occluded VIABAHN Endoprosthesis. The panelists were divided as to whether the risk of thrombosis was greater with bare-metal stents or the VIABAHN Endoprosthesis, with the majority finding the VIABAHN Endoprosthesis to be slightly more thrombogenic.

The causes of acute thrombosis were sited as poor runoff, edge restenosis, patients engaging in long plane rides, and activities such as gardening, when the patients’ legs were in a flexed position for extended periods of time.

Thrombus formation was not generally a problem except for patients who failed to attend follow-up appointments or if edge stenosis was not addressed. Most patients did not progress to acute limb ischemia but returned to their preintervention status. As Dr. Chopra noted, “We have done more than 200 VIABAHN Endoprosthesis cases, and we have not had one patient come to the emergency room like this with a stent graft shutdown. We also instruct our patients at the time of the procedure to come back immediately if their symptoms return. That is why we like to see

TIPS & TRICKS TO PREVENT STENT GRAFT RESTENOSIS

- Be sure to place the VIABAHN Endoprosthesis from healthy segment to healthy segment
- Ensure proper sizing for optimal results
- Be mindful to have adequate inflow and outflow
- To repair edge restenosis, extend the VIABAHN Endoprosthesis beyond the restenosis; if the endoprosthesis is flush with the proximal SFA, consider referring the patient for surgery

them every 3 months, and our patients are doing fine.” The majority of the panel found that even after 1 month of clotting, the clots in the VIABAHN Endoprosthesis were usually not organized but acted more like fresh thrombus and were easily handled by thrombolysis or thrombectomy.

The panelists were unanimous that their decision of the device they use to treat patients with lifestyle-limiting claudication is based on the length of occlusion, vessel diameter, and outflow.

To prevent stent graft thrombosis, the panelists cover the diseased vessel completely and always ensure adequate distal runoff before implanting a stent graft in the SFA. Dr. Saxon noted that patients must have adequate distal runoff and at least one tibial vessel (<50% stenotic to the ankle). Intervention should be considered to correct restenosis and prevent occlusion if duplex ultrasound surveillance detects a >50% restenosis. Also, patients should be cautioned not to sit or kneel in prolonged flexed positions for too long (>30 minutes).

PEARLS FOR USING THE VIABAHN ENDOPROSTHESIS

- Ensure adequate distal runoff; the patient needs at least one tibial vessel
- Cover the entire diseased vessel from healthy segment to healthy segment
- Monitor patients frequently for changes in symptoms, ABI, and velocity ratios
- Caution patients not to sit or kneel in flexed positions for long periods of time (>30 minutes)
- Be wary of edge restenosis and treat it should the patient become symptomatic or experience high velocity elevations
- Do not cover the profunda
- Use proper pre- and postprocedure imaging to ensure adequate sizing and hemodynamics

TIPS & TRICKS TO PREVENT STENT GRAFT THROMBOSIS

- Ensure adequate distal runoff; the patient needs at least one patent tibial vessel (<50% stenotic to the ankle)
- Monitor patients frequently for changes in symptoms, ABI, and velocity ratios
- Caution patients not to sit or kneel in flexed positions for long periods of time (>30 minutes)

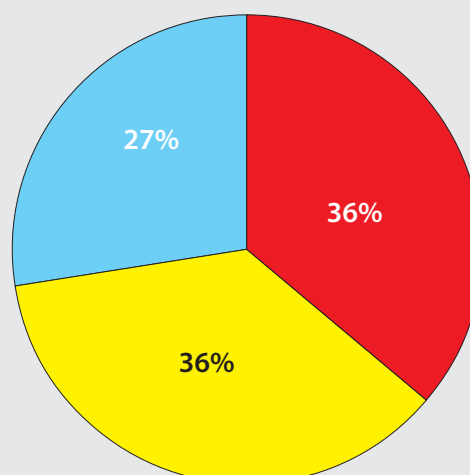
On those occasions when stent graft thrombosis does occur, intravascular ultrasound is useful to determine the cause of the stent thrombosis after recanalization with lytics.

Treatment

Should thrombus form in a stent graft, the panel uses a variety of techniques, including overnight thrombolysis, Power Pulse infusion with the AngioJet (Possis Medical Inc., Minneapolis, MN), or the Ekos system (Ekos Corporation, Bothel, WA), a combination of thrombolytics and ultrasound. Regardless of the treatment option selected, our panelists recommended crossing the occlusion and the stent graft to the distal runoff. Atherectomy devices were not recommended for

HOW OFTEN DO YOU SEE A PATIENT WITH AN OCCLUDED VIABAHN ENDOPROSTHESIS PRESENT WITH ACUTE LIMB ISCHEMIA?

- Never (return to pretreatment baseline)
- Rare (1 out of 20 failures)
- Uncommon (1 out of 10 failures)



use in the VIABAHN Endoprosthesis. Adding IIa/IIIb inhibitors (both locally and systemically) during thrombectomy or thrombolysis can also be helpful. Dr. Schneider recommended infusing “both the lytic and

the IIb/IIIa intra-arterially into the thrombus itself; I usually do that over a protection device in one setting on the table and then treat the stenosis once the clot is opened.” ♦

PEARLS FOR INCORPORATING SFA STENT GRAFTING INTO YOUR PRACTICE

- Maintain a strong clinical practice; seeing patients in the office first and following patients with a clinical focus is crucial for successful SFA treatments.
- Do not take SFA intervention lightly; have a healthy respect for the need to understand SFA flow characteristics and the nature of runoffs.
- Be sure the patient is fully anticoagulated during the intervention to prevent any thrombus formation, which can convert a straightforward case to a complex one.
- Device selection varies based on lesion lengths and characteristics:
 - PTA is generally beneficial only in the shortest of lesion lengths (<3 cm) and is not recommended for calcified lesions.
 - Bare-metal stents perform best in moderate lesion lengths and smaller diameters (<4.5 mm).
 - Stent grafts perform best in moderate to longer lesion lengths with diameters >4.5 mm.
 - Adjunctive therapies, such as atherectomy and cryoplasty, are useful in niche applications.
- Consider surgical options for patients with heavily calcified lesions or combined multisegment disease or for patients with chronic renal insufficiency.

REPORTED PATENCIES OF GORE VIABAHN ENDOPROSTHESIS / GORE HEMOBAHN ENDOPROSTHESIS (5–8 MM) IN THE SFA (UPDATED 8/10/08)

Author	Year	Journal Publication or Presentation	No. of Limbs	Lesion Length (cm)	Occlusions (%)	Primary Patency (y/%)				
						1	2	3	4	5
McQuade	2008	SVS Meeting, June 5–8.	50	25.6	NR	73	62			
Chopra	2006	AIM Symposium, November 13–16.	70	20	71	93	87	72		
Djelmami-Hani	2008	SCAI Meeting, March 29–April 1.	132	21	NR	80				
Coats	2006	<i>Endovasc Today</i> , 9:76-78.	83	NR	47	89				
Fischer	2006	<i>J Endovasc Ther</i> , 13:281-290.	48	10.7	87	80	73	71	64	62
Saxon	2007	<i>J Vasc Interv Radiol</i> , 18:1341-1350.	87	14.2	42	76	65	60	55	
Zander	2006	SIR Meeting, April 3.	31	16.6	NR	86	78	78	78	
Panetta	2005	<i>Endovasc Today</i> , August suppl:12-14.	41	30.4	90	86	77			
Alimi	2008	<i>Eur J Vasc Endovasc Surg</i> , 35:346-352.	102	11.7	NR	74	71	71		
Bleyn	2004	<i>Edizioni Minerva Medica</i> , 14:87-91.	67	14.3	100	82	73	68	54	47
Jahnke	2003	<i>J Vasc Interv Radiol</i> , 14:41-51.	52	8.5	83	78	74	62		
Turicchia	2003	<i>Osp Ital Chir</i> , 9:93-96.	16	10	50	80	80			
Railo	2001	<i>Ann Chir Gynaecol</i> , 90:15-18.	15	8	67	93	84			
Lammer	2000	<i>Radiology</i> , 217:95-104.	80	13.8	NR	79				
Verta	2008	<i>J Vasc Interv Radiol</i> , 19:493-498.	28	26	NR	44				
Saxon	2008	<i>J Vasc Interv Radiol</i> , 19:823-832.	97	7	21	65				
Average/Total			999	16	66	79	75	69	63	55

Case Reports

CASE STUDY 1

By Richard R. Saxon, MD, FSIR

A 62-year-old man presented with severe short-distance claudication of his left calf. The claudication was interfering with his activities of daily living. An exercise program was attempted for several months, but the symptoms failed to improve. He underwent a noninvasive vascular evaluation, and duplex ultrasound showed a long occlusion of the left SFA from near the origin to the adductor canal. Treatment options included continued conservative and medical management, open surgical femoral to popliteal bypass, or an endovascular intervention. The patient wanted more aggressive treatment and favored an endovascular approach with its associated lower morbidity and recovery time.

It was decided the patient might be a candidate for treatment with an “endovascular bypass” using a VIABAHN Endoprosthesis, and he was consented for possible enrollment in the VIPER trial (VIABAHN Endoprosthesis with Heparin Bioactive Surface for SuPERficial Femoral Artery Endoluminal Bypass). This trial is a postmarket single-arm study designed to assess patency and outcomes with the new heparin-bonded VIABAHN Endoprosthesis and to evaluate the 5-mm device size relative to other larger device sizes.

An aortogram and runoff arteriogram were completed showing a long occlusion of the left SFA (measuring approximately 33 cm in length) with minimal calcification and reconstitution at the adductor canal

(Figure 1). The inflow and outflow were widely patent and of adequate size with three-vessel runoff to the foot. Note the two large collaterals from the profunda reconstituting the SFA at the adductor canal, but also the plaque at the re-entry point of the second collateral (Figure 1C). In addition, the internal calibration of the angiographic equipment suggests that the SFA measures over 6.5 mm near its patent origin. This is an excellent landing zone for an endograft proximally, but from experience, this measurement seemed a bit too large.

The lesion was traversed with a 5-F angled catheter and straight hydrophilic guidewire without much difficulty. An 8-F sheath was placed over the aortic bifurcation, and a marker catheter was placed for calibration. After calibration, a repeat measurement of the proximal SFA landing zone measured 5.6 cm, and the distal SFA measured 6.4 mm (Figure 2). If the initial size of the proximal landing zone in the SFA (6.5 mm) had been accepted without calibration, a device much larger than the vessel would have been used (7 mm) for the proximal end of the stent graft. Such oversizing or mismatch may lead to the development of infolding, turbulent flow, and eventual proximal “edge stenosis.” Therefore, I believe that calibration and accurate measurement are imperative when performing an endovascular bypass using a stent graft.

The lesion was predilated with a 5-mm-diameter balloon, and two overlapping 7-mm X 15-cm-long stent grafts were placed from the distal SFA (past the two collaterals to normal-appearing vessel) back to the proxi-

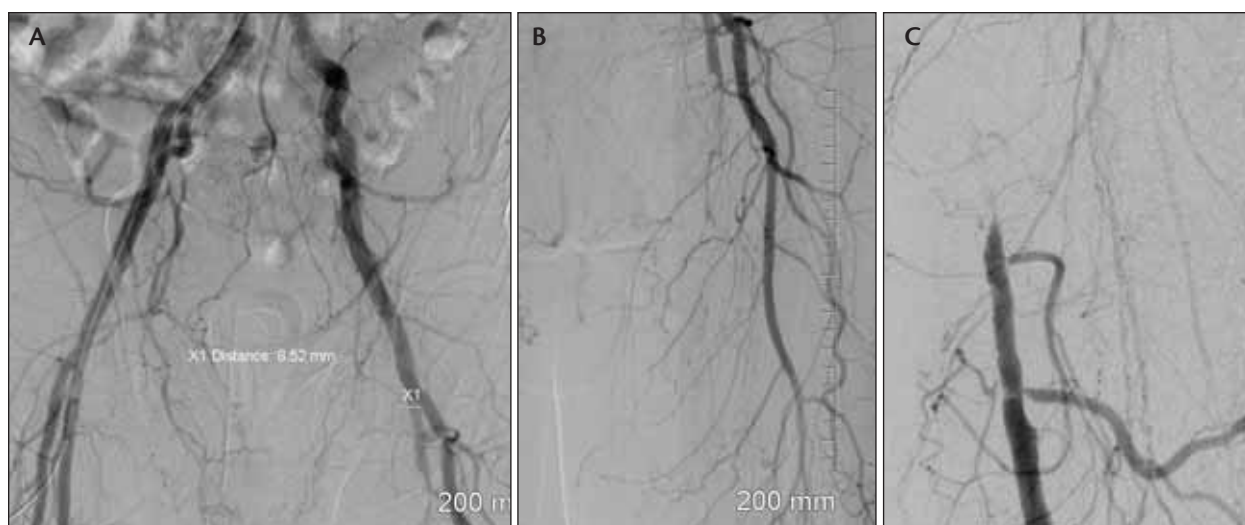


Figure 1. An aortogram and runoff arteriogram showing a long occlusion of the left SFA with minimal calcification and reconstitution at the adductor canal.



Figure 2. Oblique angiogram of the common femoral bifurcation with a marker catheter in place. Note that the SFA origin measures 5.6 cm after calibration, much smaller than the measurement on the initial angiogram.

mal SFA. Finally, a 6-mm X 10-cm device was placed to the origin of the SFA to complete the endovascular bypass. I do not believe that covering collaterals to the distal SFA such as these is of any significant clinical concern in the vast majority of cases. Although there are rare exceptions with clinical deterioration, if the endograft fails, the patient almost always goes back to baseline symptomatology. The entire length of the device was dilated with a 6-mm balloon, care being taken to dilate as little as possible outside of the device. An excellent final result was achieved without distal embolization (Figure 3).

The patient has done well over short-term follow-up. He is asymptomatic without complaint and remains clinically patent. Ultrasound follow-up as part of the VIPER trial is pending.

CONCLUSION

There are many endovascular treatment options that might be considered for this case. Our recently published results, as well as those in the literature, suggest that the patency of an endovascular bypass with the VIABAHN Endoprosthesis is roughly equivalent to prosthetic bypass with reasonable patency at four years, even in long lesions.^{1,2} Use of the VIABAHN Endoprosthesis seemed an excellent choice in this case due to the long length of the lesion (33 cm). Although there remain issues with edge stenosis with the use of the VIABAHN Endoprosthesis, patency appears independent of lesion length, whereas the incidence of in-stent restenosis with nitinol stents is likely to increase with lesion length.²⁻⁴ Therefore, for most lesions >10 to 15 cm in length with adequate vessel size, the VIABAHN Endoprosthesis remains our treatment of choice.

Due to issues with in-stent restenosis and edge stenosis, the future of endovascular intervention in the SFA is likely to include bioactive devices. The heparin-bonded VIABAHN Endoprosthesis is the first such endovascular device specifically designed for the SFA available in the US. There are no data currently on patency of the heparin-bonded stent graft. Theoretically, the patency may be somewhat improved relative to the device without heparin. There is literature on the use of the Propaten (W. L. Gore & Associates) heparin bonded vascular graft that suggests improved patency relative to a standard ePTFE graft for femoral to popliteal bypass.⁵

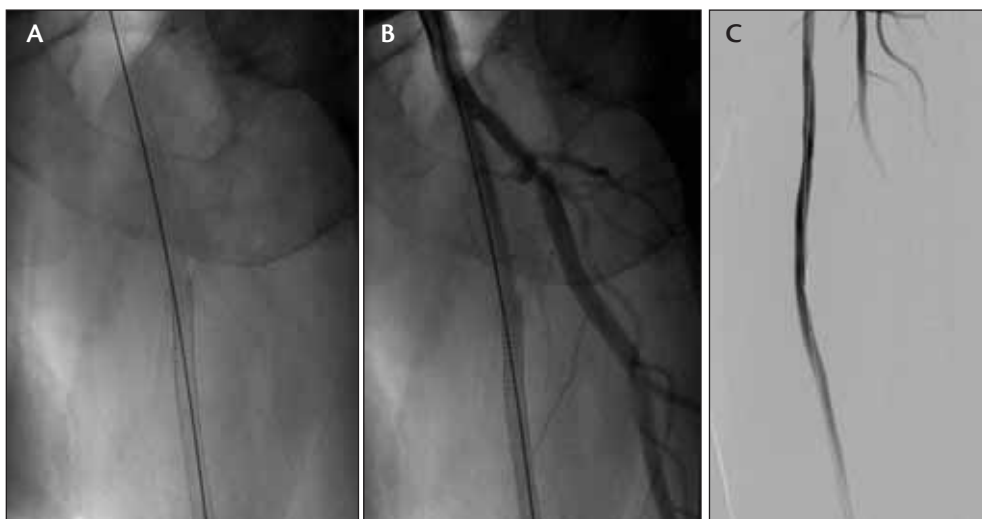


Figure 3. Final result.

The hope is that the heparin coating will not only decrease the incidence of acute thrombosis with the VIABAHN Endoprosthesis (approximately 2%–5% at 30 days) but might also affect the incidence of edge stenosis, the primary mode of failure. It might also improve the performance of the 5-mm device size in small vessels (in some series, there appears to be a substantially higher failure rate in small vessels using the 5-mm device). Hopefully, the VIPER trial will provide some insight into these issues and help to determine if there is a benefit to the heparin coating. ♦

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CASE STUDY 2

By Mark Mewissen, MD

Once determined that a patient is a candidate for endovascular intervention in the SFA, an appropriate device must be judiciously selected to best treat the lesion. For optimal treatment with a VIABAHN Endoprosthesis, several important anatomic landmarks that pertain to the diseased arterial segment must be carefully analyzed.

The patient was a 62-year-old man with lifestyle-limiting claudication of the right lower extremity. His ankle-brachial index was 0.6 at rest and 0.2 after exercise. An angiogram showed occlusion of the right SFA at least 1 cm distal to its origin and patency of the reconstituted popliteal artery at least 5 cm above the radiographic knee joint, giving adequate proximal and distal landing zones for treatment with the VIABAHN Endoprosthesis (Figure 1). For a 6-mm stent, the diameter of the landing zones should be no less than 4.8 mm and no less

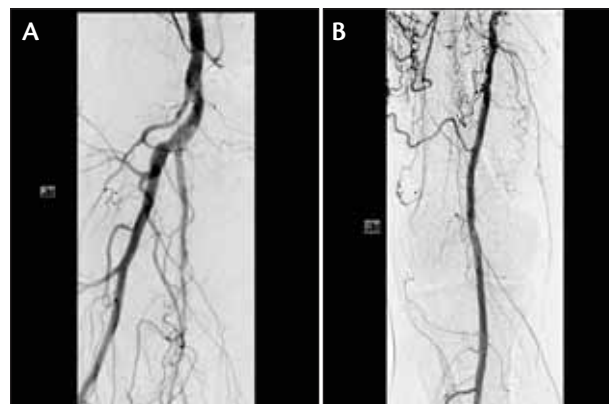


Figure 1. Preprocedure angiogram shows CTO of the SFA. The proximal SFA is patent, and the reconstituted popliteal artery is patent at least 5 cm to the radiographic knee joint. The profunda femoralis is patent.

than 4.2 mm for the 5-mm device.

As in the majority of endovascular interventions in the SFA, angiography was performed via a contralateral approach. The interventionist must be familiar with the catheters and guidewires necessary to safely navigate the aortic bifurcation and ultimately track a 7-F sheath to the level of the contralateral common femoral artery. Similarly,



Figure 2. Guidewire across the CTO.

the technique of crossing CTOs must be skillfully mastered to ultimately ascertain that the guide wire re-entry is intraluminal in the reconstituted distal arterial segment (Figure 2). It is important to ensure that there is not a subintimal dissection; deploying a stent in a dissection will jeopardize acute stent patency.

The distal landing zone of the stent is critical because it pertains to the covering or preservation of major collateral branches. The interventionist must always practice “no plaque left behind” and place the edges of the VIABAHN Endoprosthesis into “healthy” vessel. As shown in Figure 3, the major collateral that reconstitutes the distal SFA will not be preserved because there is no proximal landing zone and because the reconstituted segment is proximally diseased. Therefore, the next collateral must be clearly identified and preserved.

The profile of the device is such that balloon predilatation is necessary to ascertain its smooth tracking



Figure 3. The reconstituted proximal segment is stenotic (small black arrows) (A). The VIABAHN Endoprosthesis must be deployed between the collateral that has to be occluded and the collateral that has to be preserved (black arrow) (A). Nonsubtracted angiogram to help identify arterial landmarks, such as the collateral to be preserved (arrow) in relationship to adjacent bone landmarks, such as the medial cortex of the femur, the patella, the knee joint, etc. (B).

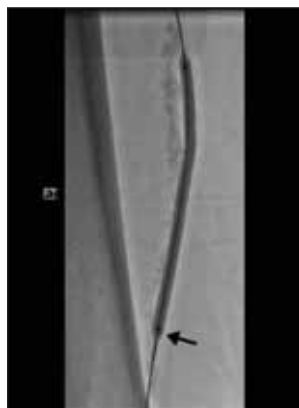


Figure 4. Predilatation: the balloon edges should not be inflated beyond the intended landing zone of the VIABAHN Endoprosthesis (arrow).

not inflated beyond those important landmarks (Figure 4).

Once deployed, balloon dilatation is performed to “seat” the stent graft, making certain that the edges are not dilated (Figure 5A and 5C). A high-pressure balloon is recommended to provide maximum stent expansion, particularly in heavily calcified segments (Figure 5B). In this case, two 15-cm X 6-mm VIABAHN stent grafts were deployed with a 1-cm overlap. Clearly, the VIABAHN Endoprosthesis should not be delivered proximal to the origin of the profunda femoralis.

and final positioning before deployment. The predilatation must be controlled so that the dilated segments will be entirely covered by the stent graft. The edges of the VIABAHN Endoprosthesis should not be deployed in an area that has previously been dilated because this is a set up for the future development of an edge stenosis. As a result, the interventionist must precisely and accurately identify the landing zones of the stent so that balloon edges are



Figure 5. Postdilatation with a high-pressure balloon (Dorado balloon, Bard Peripheral Vascular, Tempe, AZ) inside the stent, sparing stent edges (single arrow) and aggressive dilatation inside the stent (multiple arrows).



Figure 6. Final angiogram shows patency of the stent and preservation of the distal collateral branch (black arrow).

The final angiogram showed excellent patency (Figure 6), with intended preservation of the collateral branch. The patient was placed on clopidogrel, and so far he has done very well several months after the procedure. ♦

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CASE STUDY 3

By Ashish Pershad, MD

A 63-year-old man presented with left foot and calf pain at rest. The patient had been previously complaining of left leg and calf pain on ambulation, which over the last few days had progressed to pain at rest. He

denied any sensory or motor symptoms other than pain. On examination, his left foot was cooler than the right, and there were no palpable pulses in the left dorsalis pedis and posterior tibial arteries. However, a faint Doppler signal was obtained over both these vessels. Three months prior, his arterial duplex examination revealed a widely patent SFA with triphasic flow into the foot.

His past medical history was significant for having had a VIABAHN Endoprosthesis placed in his left SFA for a TASC D occlusion 6 months earlier. The indication for the procedure was lifestyle-limiting claudication at a distance of half a block. A few years preceding this, he had high-grade bilateral inflow disease that was treated with “kissing” balloon-expandable stents in the common iliac arteries. He was a nondiabetic lifelong smoker and had concomitant coronary artery disease, treated with a coronary artery bypass graft, and a small abdominal aortic aneurysm. He was on dual-antiplatelet therapy with aspirin and clopidogrel and was compliant with his medication regimen.

An angiography was performed with concern that the SFA stent graft had thrombosed/occluded (Figures 1 and 2). The angiogram revealed that the SFA stent graft was indeed thrombosed, and the leg vasculature was maintaining its viability through a profunda femoral collateral. Reconstitution of the SFA occurred in the adductor canal with a moderate stenosis in the popliteal artery and a three-vessel runoff to the foot (Figures 3 through 5).



Figure 1. Stents are seen in both iliac arteries, extending all the way from the aortic bifurcation into the external iliac arteries. The use of the contralateral approach is therefore not possible in treating the SFA occlusion.

TREATMENT OPTIONS

Treatment considerations at this point include:

1. Femoropopliteal artery bypass procedure with autologous vein or polytetrafluoroethylene graft.
2. Attempt at recanalization of this stent graft with either pharmacological thrombolysis alone or with a combined mechanical and pharmacological strategy.

In this case, the option selected was the power-pulse spray technique using the AngioJet device.

The AngioJet Rheolytic Thrombectomy (RT) System uses a complex mixture of rapid fluid streaming and hydrodynamic forces to fracture thrombus, allowing extraction at the catheter tip using negative pressure (Bernoulli/Venturi principle). The AngioJet RT System includes a Drive Unit console, pump set, and catheter. The system is activated by depressing a foot pedal. Various RT catheters have been developed and tailored to specific clinical applications.

RT and conventional catheter-directed thrombolysis each have advantages and disadvantages, risks, and limitations. No single treatment modality has become the “gold standard,” and successful outcomes when dealing with subacute arterial thrombosis in the peripheral vascular system often require creative combination therapy.

The power-pulse spray technique initially described by Allie et al was used in this case.¹ The total SFA thrombotic occlusion was crossed using standard techniques with a .035-inch Terumo Stiff Shaft Glidewire (Terumo Interventional Systems, Somerset, NJ) from the

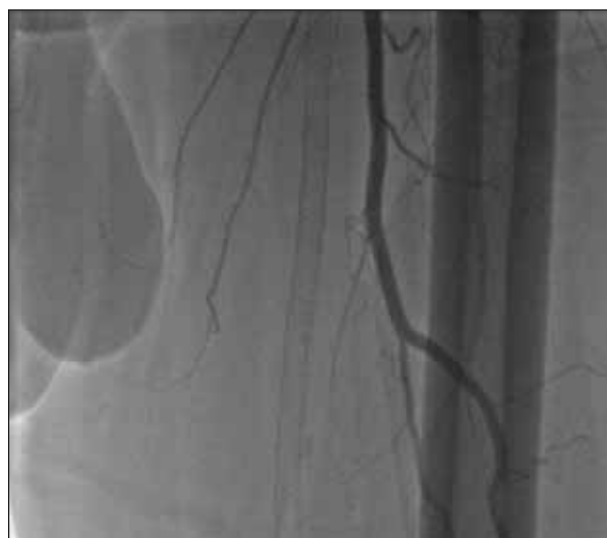


Figure 2. An anteroposterior image of the proximal SFA, demonstrating an occluded VIABAHN Endoprosthesis with prominent collaterals from the profunda femoral artery.



Figure 3. An anteroposterior image of the distal SFA, showing a reconstituted SFA at the level of the adductor canal beyond the stent graft with a moderate stenosis in the popliteal artery.

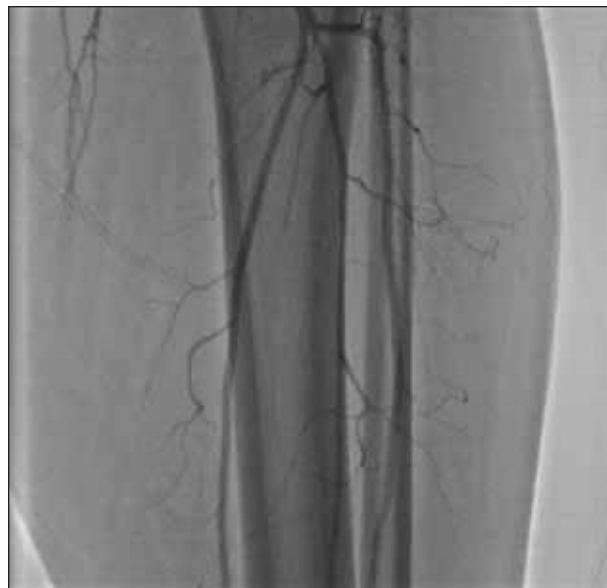


Figure 4. An anteroposterior image of the trifurcation below the knee, demonstrating three-vessel runoff to the foot.



Figure 5. An anteroposterior image of the distal SFA with a catheter in the popliteal artery, which was used to access the occlusion of the SFA.

popliteal artery because of the presence of kissing stents at the aortic bifurcation. This step was facilitated with a 5-F straight glide catheter (Terumo Interventional Systems). The wire was then positioned in the right external iliac artery.

Initially, the 6-F AngioJet RT System was set up and primed in its thrombectomy mode with normal saline.



Figure 6. An anteroposterior view of the distal SFA with a view of the culprit lesion at the distal edge of the stent graft.

A lytic bag was then created by adding 10 mg tenecteplase to 50 mL of normal saline and is then exchanged for the saline prime. A stopcock is added and closed to the outflow port RT catheter manifold, thus converting the RT system to its power-pulse spray mode. The RT catheter was advanced slowly, at 0.5 to 1 mm increments through the entire SFA stent graft,

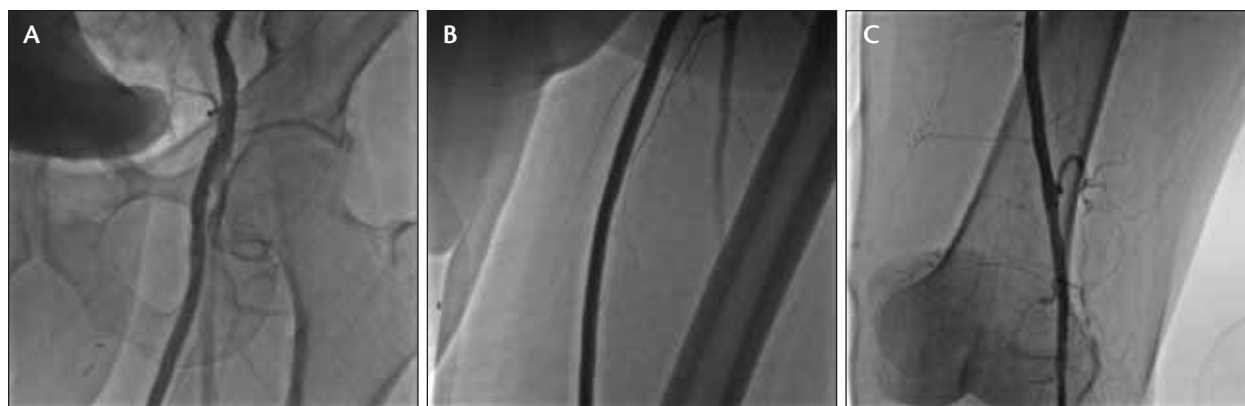


Figure 7. Final images of the proximal, mid, and distal SFA showing the clearance of thrombus and excellent angiographic appearance of the entire SFA.

using a single foot pedal pump/pulse per advanced increment. The RT system was set to deliver 0.6 mL volume of lytic solution per each pedal pump/pulse. The infused volume meter on the device unit console is set at zero at the initiation of the power-pulse spray mode, allowing calculation of the total thrombolytic volume and dose. A single antegrade and retrograde RT pass in the power-pulse spray mode was performed. The RT catheter was then removed. The concentrated pulsed thrombolytic was allowed to lyse for 15 minutes. The culprit lesion was identified at the distal edge of the graft and treated with a 6-mm PTA Fox balloon (Abbott Vascular, Santa Clara, CA) (Figure 6). The AngioJet catheter was reintroduced with a single antegrade and retrograde pass, followed by immediate angiography (Figure 7).

OUTCOME

The final outcome in this case was excellent with complete resolution of thrombus and no adverse effect of either distal embolization or bleeding related to the thrombolytic during the power-pulse spray infusion. This case illustrates the harmony of mechanical and pharmacological means in the management of thrombosed stent grafts in the SFA. The patient was discharged the following day with palpable pulses in the left foot. On 3-, 9-, and 12-month follow-up, he remains asymptomatic.

DISCUSSION

Management of thrombosed stent grafts in the SFA remains a challenging proposition. Management principles involve identifying the potential reason for the thrombosis, treating the thrombus-laden occlusion while minimizing the risks of distal embolization, and, finally, devising a strategy for preventing recurrence.

The most common reason for thrombosis involves a new de novo stenosis at either the proximal or distal edge of the stent graft. This finding highlights the need for regular surveillance with duplex imaging to pick these up before they become critical and impede inflow or outflow through the graft. This is akin to the concept of graft surveillance in surgically treated cases. All patients with stent grafts extending past the adductor canal need to be cautioned about prolonged flexion at the knee joint due to the potential for thrombosis of the stent graft.

The thrombosed graft itself can be treated using a combination of mechanical thrombectomy and thrombolysis as was described in the case report. An important point in the treatment involves concurrent use of antiplatelet agents such as glycoprotein IIb/IIIa inhibitors and using distal protection devices, especially if runoff to the foot is marginal because consequences of distal embolization can be devastating. After the graft has been treated, the anticoagulation regimen needs to be carefully evaluated. If the patient had the thrombotic event while being treated with aspirin and clopidogrel, then additional anticoagulation with warfarin may need to be strongly considered. ♦

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Considering the Surgical Option

Vascular surgeon Dennis Gable, MD, discusses TASC II and when surgical bypass is the best option.

In 2007, the TransAtlantic Inter-Society Consensus (TASC) committee released the TASC II Guidelines. How do those guidelines affect your decision to treat a patient using surgery or endovascular therapies?

Dr. Gable: The TASC II Guidelines are just that—guidelines. When comparing surgery to endovascular therapy, however, these guidelines, which are based on previous studies and clinical data, must be considered before deciding on the correct treatment for each individual patient. We presented data at the SVS in June 2008, which will hopefully soon be published, in which we reclassified the lesions in our previous study comparing surgical bypass versus covered stent grafts using the original TASC criteria. Our mean lesion length treated was 25.6 cm. After reclassifying these lesions under TASC II, a number of the lesions were reduced to the TASC II B classification, but there were still a good number of TASC II C and D lesions that we successfully treated with an endoluminal bypass. The endoluminal results at 24 months were similar to the surgical results. I think that there are various criteria that need to be considered for TASC II D lesions before endovascular treatment is undertaken such as patient age, degree of calcification of the target vessel, limb runoff, and other comorbid conditions of the patient. Although I agree in theory that most TASC D lesions should be considered for surgical bypass, these more recent data suggest that some of these lesions may indeed be successfully treated with endovascular means. I do not think that it is necessary to perform surgical bypass simply because limitations that historically precluded use of an endovascular option are present.

What are the factors that would lead you to recommend surgery versus endovascular therapy to treat a patient?

Dr. Gable: If a patient has very poor arterial runoff, heavily calcified lesions, or combined multisegment disease, in my opinion, the treating physician should give stronger consideration for surgical bypass. Additionally, multiple previously failed percutaneous treatments would prompt me to give stronger consideration for surgical revascularization.

How do you determine that the level of calcification is too high to treat by endovascular means?

Dr. Gable: The answer is highly subjective. If I perform arteriography and see the vessel outlined with calcium, I would conclude that it is probably heavily calcified. If I perform arteriography and find an intraluminal filling defect that is not completely occlusive and calcified, I would suspect that the lesion is going to be heavily calcified. Both of these findings historically have resulted in decreased long-term patency for percutaneous treatment methods and therefore would give me cause to reconsider my options before proceeding.

What is the significance of multisegment disease?

Dr. Gable: By multisegment disease, I mean inflow and outflow disease, or multiple outflow segments being involved. This is not to say that interventionists cannot use endovascular options with these patients, but they must stop for a minute and ask, is there a better option for long-term patency? If an interventionist is stenting an inflow lesion and using atherectomy or PTA in the SFA and popliteal artery and stenting across the knee, might it not be better to just perform surgical bypass on that patient? In my opinion, it would be. However, if an interventionist does not have a good vein for bypass conduit, and the patient has ischemic rest pain or a limb-threatening ischemia, there may not be any other choice but to consider endovascular options unless prosthetic bypass is to be considered.

Does a critical ischemia situation factor into your determination with respect to treatment options?

Dr. Gable: Clinicians talk about that a lot, but to me, it does not make much difference. We will always try to do what we think is the best thing for the patient resulting in the best possible results. Whether or not the patient is a claudicant or has rest pain, we always try to offer the best long-term option given the patient's current situation. Why offer a lesser treatment for just a short-term result unless the patient has significant other comorbid issues? If a physician has a patient who only has claudication, yet would require the previously described treatments of stenting, atherectomy, PTA, etc., from the SFA to the tibial arteries, I believe he should rethink the treatment options. If that patient is only claudicating, there is a risk of making the patient worse than if the physician just left him alone and treated him conservatively. If that same patient had critical

ischemia, gangrene of the toe, tissue loss, or was Rutherford class 4, 5, or 6—and had no venous conduit to do a bypass—then the physician might consider the options of proceeding with endovascular therapy. Again, we should also remember that there is the option of a bypass with a prosthetic graft, although those results below the knee have historically not fared as well long term.

What are the other clinical considerations for surgical referral?

Dr. Gable: Another consideration is patients who have renal insufficiency and cannot tolerate a prolonged interventional procedure or use of contrast media. Similarly, patients that have prohibitive operative risks from a cardiac standpoint or who may have a short life expectancy may be considered more strongly for endovascular therapy.

How does lesion location have an impact on the surgical decision?

Dr. Gable: If patients have disease at the common femoral artery, most vascular surgeons would opt for bypass or endarterectomy. Endovascular therapy is a very poor option at that location, in my opinion, due to the anatomic constraints of placing a stent across the inguinal ligament and the proximity of the profunda femoris artery. Endovascular treatment in this location has never met with any real success and increases the likelihood of occluding the profunda outflow than would the surgical options. Distal endpoints and runoff must be considered before proceeding, and if the runoff score is poor or the vessels are badly diseased, consideration should be given preferentially to the surgical option.

What factors would cause you to choose endovascular therapy?

Dr. Gable: If the patient does not have a good saphenous vein for the surgical bypass, we would more strongly

consider endovascular therapy in some of the situations just described. Vein grafts have a variety of limiting factors: if we cannot obtain a saphenous vein, we can consider a composite vein graft or an arm vein graft. The patency rate will not be as high with those grafts as with the single, good-sized saphenous vein; nonetheless, these composite surgical grafts may still be a better alternative to endovascular therapy in some patients. Another issue to consider before using an arm vein graft is whether the patient might need dialysis access in the future. Interventionists want to be cautious before removing the arm vein graft in a patient who may require dialysis. If the anatomy was favorable for endovascular therapy with good runoff and mild to moderate calcification of the vessels, I would be more likely to consider endovascular therapy primarily, despite the length of an SFA occlusion or stenosis. Inflow stenosis—not occlusion—combined with SFA disease would not worry me quite as much as SFA disease and poor runoff.

Are there other contraindications for surgical bypass?

Dr. Gable: A contraindication for surgical referral would be if the patient is not a good surgical candidate overall. If the patient has poor cardiac function and we do not think that the patient will tolerate an anesthetic, then we would not want to take the patient to surgery. If the patient's life expectancy is <12 months, then surgical bypass may not be a good option. For example, if I was referred a patient who had gangrene of a couple of toes or the forefoot, had metastatic cancer, was not expected to live beyond a year, but was currently in decent shape, I would probably consider that patient more for endovascular treatment than for a bypass operation. Consideration for a "bridging" treatment in a patient that was currently not a good surgical candidate but hopefully would recover to the point of being able to tolerate a surgical procedure would also fall into a similar category. ♦

Preserving the Surgical Option

Endovascular treatment of the femoropopliteal arteries.
By Darren B. Schneider, MD

Endovascular therapies have supplanted open surgical revascularization for the management of many patients

with femoropopliteal occlusive disease. Early treatment failures have become less common due to advancements in endovascular techniques, device technology, and the use of antiplatelet agents. Nonetheless, not all patients can be successfully treated completely by

endovascular approaches, and late failures due to restenosis, thrombosis, or disease progression still occur with some regularity. Consequently, “preservation of the surgical option” remains an important consideration when performing vascular interventions.

Thrombosis, distal embolization, dissection, and rupture are risks of percutaneous interventions, and although they can usually be managed with endovascular techniques, surgical rescue may be occasionally needed. The best strategy to avoid complications is to prevent them from occurring by employing good technique. Therapeutic anticoagulation is essential during all femoropopliteal interventions to avoid thrombus formation. Use of embolic protection devices for lower extremity interventions remains controversial but may be advisable when performing atherectomy, thrombolysis, and mechanical thrombectomy, or when crossing or treating irregular, calcified lesions—procedures that may carry a higher risk for embolization. Also, patients with limited, single-vessel tibial runoff are less tolerant of embolization, and the use of embolic protection should be considered.

Surgical revascularization may become necessary if the percutaneous revascularization is technically unsuccessful or after late failure of endovascular therapy. Importantly, in the event of technical or late failure, percutaneous interventions should not make subsequent surgical revascularization more complicated or less durable. Converting a patient that could be treated with an above-knee femoropopliteal bypass to a patient that now requires a less durable reconstruction, such as below-knee femoral-popliteal bypass or, worse yet, a tibial bypass, is generally avoidable and antithetical.

The most common scenario when this is encountered is in the management of femoropopliteal occlusions. Usually, subintimal dissection is needed to traverse the occluded arterial segment, and re-entry to the arterial true lumen must be gained distal to the lesion. Ideally,

re-entry to the true lumen is gained as close to the point of distal reconstitution as possible because re-entry at a more distal point along the vessel may eliminate some surgical options. Fortunately, re-entry just beyond the occlusion can be gained in the majority of cases, but should re-entry become difficult, the subintimal dissection should not just be extended distally in the hope of finding another re-entry site. Under these circumstances, the catheter and wire should be pulled back and then readvanced in a different dissection plane that might allow proper re-entry. If re-entry remains elusive, then the use of a re-entry device such as the Outback (Cordis Corporation, Warren, NJ) or Pioneer (Medtronic, Inc., Minneapolis, MN) catheters may be used to re-enter the true lumen at the appropriate site. Direct popliteal or tibial puncture for retrograde crossing of occlusions is an alternative approach but is seldom necessary since re-entry devices have become available.

Deployment of stents or stent grafts too distally may also complicate subsequent surgical revascularization, if necessary. Avoid extension of stents or stent grafts all the way to the distal end of the below-knee popliteal artery, leaving room for a bypass to the popliteal artery rather than a tibial artery. Of course, all interventions should be tailored to the individual patient based upon the pattern of disease, comorbid conditions, and available surgical alternatives. Surgical options, when available, are more important to preserve in younger, fitter patients and may become a lower priority when managing elderly, debilitated patients lacking good surgical alternatives. ♦

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