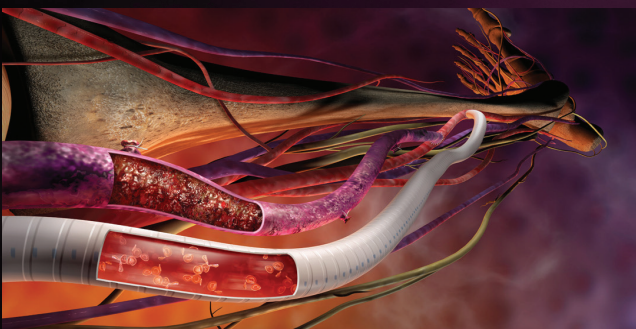
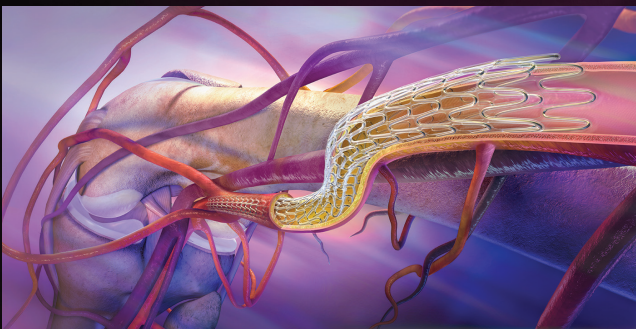
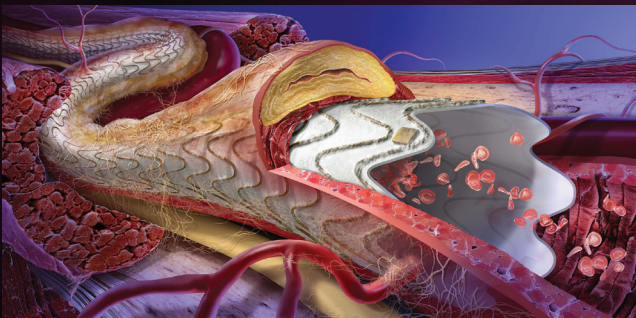
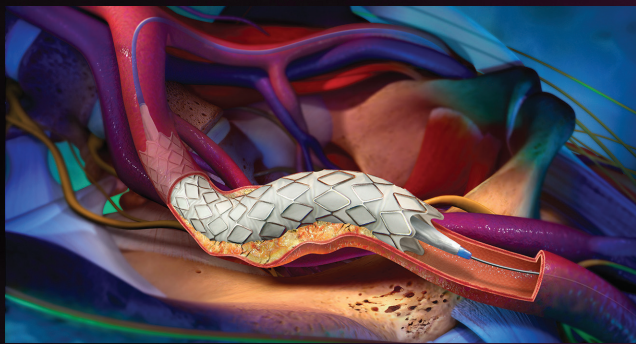


Endovascular TODAY

February 2018



MEETING THE NEEDS OF **COMPLEX PERIPHERAL ARTERY DISEASE**

The devices and
decisions needed for
optimizing outcomes.

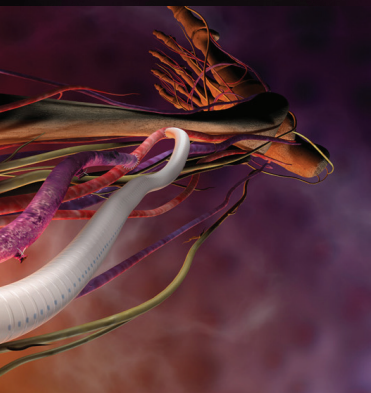
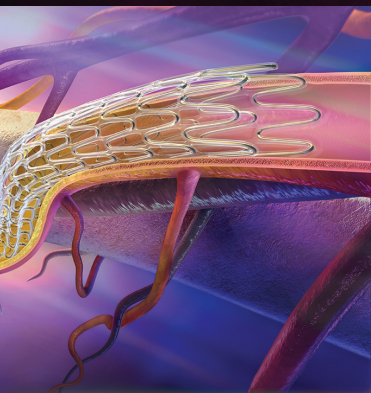
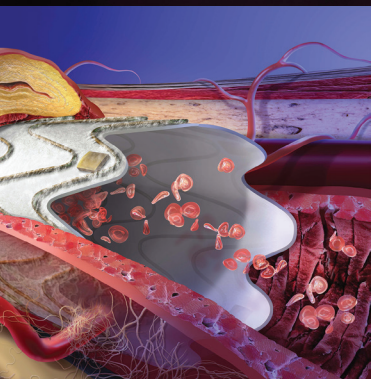
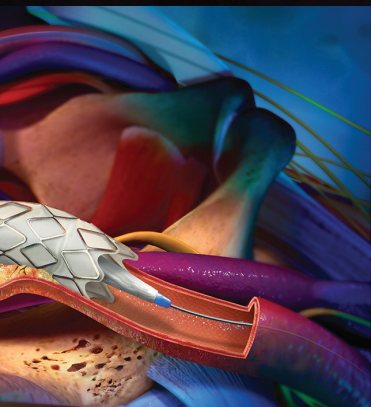


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The When and How of PAD Treatment: A Roundtable Discussion

A panel of PAD experts talk through the patient-specific factors and technical nuances that influence outcomes.

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WHEN TO TREAT

Dr. Gable: Let's first discuss the decision-making process for peripheral artery disease (PAD) as far as who you're going to treat and when you treat them.

Dr. Beasley: Each patient is considered on a case-by-case basis. For example, I had a patient the other day who could not walk from the concourse in the airport to his

car without stopping three times. He was fairly young and had an superficial femoral artery (SFA) occlusion—that is the kind of patient I want to treat. An older patient (75 or 80 years old) who has just a little bit of trouble because of SFA occlusions but has nice collateralization—that is the type who you want to start on a walking program and look at risk factor modification.

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Dr. Schneider: We treat all patients with PAD, but we just don't necessarily intervene on them all. We want to make sure we are treating the patients with asymptomatic PAD, not necessarily by offering them any interventions, but like you said—with risk factor modification and exercise programs that will hopefully make them better and prevent them from needing intervention.

Dr. Samson: In my belief, it is a shared decision-making. When you say, "What are we going to do for the patient?" it's not what we're going to do for the patient, but what the patient wants us to do for them. I think the most important thing is to understand exactly what the patient's goal is and then offer them the different treatment options we have and inform them as best we can.

Dr. Beasley: The rapport with the patient is really important. You have to gauge how intensely the patient is suffering or how much they want an intervention.

Dr. Schneider: Dr. Samson's point is important because with claudication, it's subjective. There are some patients who can walk just two blocks, but they're fine with that. Then there are some people who can walk two blocks, and it's a massive disability that has a major impact on their job and daily life. You can't know that unless you develop that relationship with your patient.

MEDICAL MANAGEMENT

Dr. Gable: Do you refer medical management out or keep it in your own practice? In either case, when do you follow up with the patient?

Dr. Beasley: I refer them to a cardiologist or internist.

Dr. Samson: If it's a first-time patient with stable claudication, it would depend on whether I'm going to treat them medically or if I'm leaving it up to the internist. If I'm taking over the medical management, which I do in a small group of people, I see them every 3 months. If they're under good care, I may see them in a year or 2 years.

Dr. Schneider: I do start patients on appropriate medications. If they're not on antiplatelet and statin, I'll start them myself. We communicate with their primary care doctor if they're not already on those medications and should be. We counsel for smoking cessation, too. It is individualized, so it may be 3, 6, or 12 months before I'll see them again. I reassure them that even if we're not going to intervene, we're going to follow them and make sure that they're not getting worse.

REST PAIN

Dr. Gable: What do you do for patients who present with true rest pain (foot with dependent rubor but no tissue loss or ulcerations)?

Dr. Schneider: First, you must differentiate whether the patient is asymptomatic, whether they have some claudication, or whether they have critical limb ischemia (CLI). Rest pain is technically CLI, and that's a critical decision point because for those patients with CLI, we're definitely going to consider an intervention to prevent limb loss. For elderly debilitated patients with many comorbidities, endovascular intervention is preferable, but for multilevel disease or disease that may not lend itself to endovascular intervention, we also have to consider surgical intervention.

Dr. Beasley: It may also be a combination of some other disease modalities—venous, sciatica, neuropathy. It's hard to gauge what is really pain. Figuring out if it's truly arterial is a diagnostic conundrum. I would proceed to do an angiogram and then determine if there was something significant that would tip my hand one way or the other.

Dr. Samson: I think this terminology of chronic limb ischemia is a misnomer. People are talking about chronic limb threat rather than chronic limb ischemia. Many people with clinical typical rest pain, assuming it is vascular related, can go years before they get to ischemia that will cause them to lose their legs. You have to assess the risk of converting a stable situation into true limb ischemia. However, I think for someone who is complaining of rest pain, most of us are going to intervene if we have a good option for intervention.

Dr. Schneider: In addition to a good examination, it is important to do good physiologic studies as well—ankle-brachial indices (ABIs) (though for diabetic and renal failure patients, ABIs may be falsely elevated), toe pressures, looking at waveforms, and making sure that intervention is truly appropriate. We get physiologic studies on everyone in whom we're going to intervene. You need to establish a baseline to support the diagnosis and then measure if you've had a treatment effect.

Dr. Samson: We should also involve the podiatrist in this decision tree, especially when you get into the chronic limb threat patient. Good podiatric care is critical.

TISSUE LOSS

Dr. Gable: How do you treat patients with tissue loss? Is there anything different you would use for diagnosis on your initial evaluation that you wouldn't have done for someone with just rest pain?

Dr. Schneider: When you have a combination of tissue loss or a wound and documented arterial insufficiency, that's where individualized treatment comes into play. By and large, they are going to get an intervention, whether it's surgical or endovascular. As part of our workup, when we're doing our arterial duplex examinations to assess the level of disease, we'll usually do vein mapping so we know whether they have a good autologous saphenous vein conduit. If I think I'm likely to intervene, I usually go straight to angiography with the possibility of doing the endovascular intervention at that time.

Dr. Beasley: We almost never do CTAs or MRAs. We'll make our decisions on the patient presentation in

combination with a wound care specialist and physiologic studies. Depending on renal status, I usually shoot an angiogram first from a contralateral approach on the uninvolved side to get an idea of whether there is significant SFA or tibial disease. We'll plan intervention 1 or 2 days later, likely going antegrade with a retrograde approach.

Dr. Samson: For proximal disease, I think CTA is essential. I image from the arch down because I am a believer in axillofemoral bypass grafts for people who have hostile aortas.

Dr. Schneider: There is value in CTA and MRA, especially when you are not sure about the anatomy or initial treatment approach based solely upon presentation and ultrasound studies. I prefer CTA because it helps me assess calcification when we're looking at the aortoiliac system, common femoral arteries, and profunda. You do have to take renal function into account because so many of our CLI patients have impaired renal function.



HOW TO TREAT | SURGICAL BYPASS

Dr. Gable: What comes into play when you are trying to choose between vein bypass and prosthetic bypass?

Dr. Schneider: It's primarily the quality of the vein. If you have a good 4 mm saphenous vein, nothing beats that, and I still prefer vein for infrainguinal bypasses. If you have a borderline-quality vein and it's an above-knee fem-pop, I'm probably going to choose a GORE® PROPATEN® Vascular Graft for that. There are a fair amount of data suggesting that the heparin-bonded GORE PROPATEN Vascular Graft has good patency for femoropopliteal bypass even below the knee. There are also a fair amount of data to suggest it's better than plain polytetrafluoroethylene (PTFE), so I tend to use the GORE PROPATEN Vascular Graft if I'm doing a prosthetic lower extremity bypass.

Dr. Samson: Our data showed that the GORE PROPATEN Vascular Graft is better than uncoated ePTFE grafts, and that has held up across multiple studies. However, the fact that it's better than standard ePTFE doesn't mean that suddenly we use this when we wouldn't have used ePTFE before.

As far as the above-the-knee popliteal, our prosthetic data show patients who are young do not do as well as patients who are older. If the patient is young, has excellent distal vessels, is not diabetic, and has a good

vein, definitely use vein above the knee. If the vein is bad, then there is no decision here. I would not use arm vein. If they are diabetic and have severe distal disease, even if they're young, I would use above-knee GORE PROPATEN Vascular Graft to save the saphenous vein for the future.

I would very rarely use saphenous vein from the other leg for bypass on an ipsilateral problem. If I had to use saphenous vein from the right leg to do an above-knee fem-pop on the left side, I wouldn't use vein, I'd use the GORE PROPATEN Vascular Graft.

Dr. Schneider: Our approach is almost identical. I still prefer vein whenever possible, especially if there is a good ipsilateral saphenous vein. I will also take contralateral saphenous vein, unless the opposite limb needs a bypass, too. For an above-the-knee fem-pop, however, I generally would not take a contralateral saphenous vein because the GORE PROPATEN Vascular Graft data for the fem-pop are good.

Dr. Samson: For below-knee fem-pops, we would use saphenous vein preferentially if there's a good saphenous vein, even if it means coming from the other side. If I don't have a good vein, the GORE PROPATEN Vascular Graft had an approximately 58% patency rate at 5 years, which is good for a below-knee procedure.

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INFECTION

Dr. Gable: If there is active infection, perhaps from a previous incision site, what is your choice of treatment?

Dr. Schneider: In a patient scenario like that, using a prosthetic there is going to be a potentially significantly elevated risk of graft infection. We are going to look for a vein, even arm vein, to try to get an adequate conduit to do an autologous bypass in a patient with infection.

Dr. Samson: A graft infection is a life-threatening condition. I would never put a prosthetic into a patient who is febrile or into a patient in whom I don't believe I've controlled the infection. The white blood cell count would have to be as close to normal as possible, the patient should be afebrile, and I've done everything I can to control the local infection.

Dr. Gable: It's been my experience that most of those patients, even though they're presenting acutely, can usually tolerate 1 or 2 weeks of antibiotics and any other treatment needed first.

VEIN PATCH USE/SURGICAL TECHNIQUE

Dr. Samson: I do not use vein patches for fem-pop bypass. However, for tibial arteries, I have started to use the Neville patch. I think the patch works because it makes the distal anastomosis so easy. Putting a little piece of vein into the artery first makes that junction of the ePTFE to the vessel so much easier technically.

Dr. Schneider: I completely agree. I don't always use patches for below-knee popliteal bypasses, and it depends on the vessel size. I do use patches for the tibial arteries, especially since it can be difficult to sew an ePTFE graft to the smaller tibial arteries. The vein patch widens the target and probably results in less trauma to the tibial artery.

Dr. Gable: We'll do that for small tibial vessels. For normal, good-size tibial arteries, I usually do not use a patch, but I'll make my anastomosis a lot longer (a couple of centimeters) than normal.

Dr. Samson: It's interesting how many referring physicians and vascular surgeons think of this operation as if it's this straightforward, easy procedure. However, there is so much to consider. How long an anastomosis do you make? What suture do you use? How do you handle the artery? How do you cut the artery? Do you start from the common femoral? Do you start from the SFA? There are so many different variations how you can do a fem-pop.

Dr. Schneider: You can't underestimate the technical aspects of these revascularizations. It has to be technically precise, and there are multiple steps and variables that go into conducting a proper operation with an optimal outcome. Bad technique leads to bad results, especially with tibial bypasses. In the small-caliber tibials, the toe of the anastomosis has to be perfect so that you don't restrict the outflow, which significantly increases the risk of graft failure.

Dr. Gable: Especially when you're talking about a prosthetic tibial with the size mismatch, it's paramount that every stitch is perfect.

COST CONSIDERATIONS

Dr. Schneider: There are cost-related downsides to both bypass and endovascular intervention. With bypass, you have the potential for wound morbidity, which can lengthen hospital stays and risk prosthetic graft infection. You also have patients who aren't discharged to home but to rehab facilities for several weeks to recuperate, even after a simple bypass with two incisions, especially if they are frail and have comorbidities. Those costs must be factored as well and may offset some of the added device costs for endovascular therapy.

Dr. Beasley: Also, not all surgeons have the same technical skills. If a surgeon does an above-the-knee bypass and it failed, you add significant cost to the situation to go back and either do a redo bypass or to try to salvage.

Dr. Gable: It's hard for me to ever argue against surgery because that's what I do, but there is consideration for time lost from productivity and work, or for patients who are retired, time until back to normal daily life. It's going to be a lot quicker with an interventional approach versus surgical approach. That's not a reason, in and of itself, to make for a choice of treatment, but it is a consideration.

Dr. Schneider: People use plain old balloon angioplasty instead of using drug-coated balloons and use bare-metal stents because they are less expensive. This is a real conflict in office-based labs, where profitability can affect clinical decision making. It is influencing the delivery of care in the United States and whether patients are getting what we all believe may be the optimal treatment or a less expensive, and possibly less effective treatment.

Dr. Gable: Hospitals are trying to be viable with Centers for Medicare & Medicaid Services (CMS) reimbursement alone, so any product on the market needs to be a viable option under CMS reimbursement.

HOW TO TREAT | DE NOVO LESIONS

ILIAC ARTERIES**Dr. Gable: How do you approach treatment of iliac disease?**

Dr. Samson: I usually use a bare-metal stent, but if I'm going to try to redo the bifurcation, I like to use covered stents because I know I'm going to want to come over from the other side at some stage, and I don't want to have to worry whether I'm going through previously implanted stent struts.

Dr. Schneider: Certainly for me a covered stent is the first-line approach for long iliac occlusions, as well as for heavily calcified eccentric plaque, where I think there's an elevated rupture risk. Covering that lesion up front is going to provide an additional layer of safety. Some data also show that patency of covered stents may be better than bare-metal stents for kissing stents at the bifurcation.

The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Stent Graft) is a game-changing device, because it is unique in marrying the properties of self-expanding and balloon-expandable covered stents in a single device. It can handle vessel tortuosity, has good radial force, and you can deploy it precisely. It also gives you the ability to flare the ends to different diameters, which can help in certain iliac anatomies.

Dr. Gable: For any type of significant calcification, especially in the bifurcation, I think a covered stent is the way to go.

SFA**Dr. Gable: What is everyone's usage of different products for de novo disease in the SFA?**

Dr. Schneider: If there is claudication and a long-segment SFA occlusion, even with some significant calcification, I'm going to do an angiogram and see if I can cross the lesion. If I can cross the lesion, then endovascular is still in the equation. If I cross the lesion but can't adequately predilate the lesion, then that's going to affect whether I'm going to use the GORE® VIABAHN® Endoprosthesis. I may opt for an alternative device that has more resistance against radial recoil in a heavily calcified lesion. If I can predilate adequately, then it's still a good case for the GORE VIABAHN Endoprosthesis. If I can't cross or predilate the lesion, then it's not a good endovascular candidate, so I stop and we bring the patient in for a bypass. For every case, there

is a plan A, plan B, and plan C, and you can make those decisions on the fly as long as they are all part of your algorithm.

Dr. Beasley: I say this as an interventionalist. We get to that point you just described, where there is four-quadrant calcification and even if you ballooned it, you know that you still won't get a nice enough dilatation to put a bare-metal stent in without the stent elongating. Even if you put a 7 mm balloon in and try to open it up, you still have that recoil. A lot of interventionalists will put in a good GORE VIABAHN Endoprosthesis or bare-metal stent hoping that they will get some long-term patency. I think the best case scenario for that patient is to abort and refer the patient for bypass.

Dr. Schneider: If you do the procedure correctly and the patient has appropriate anatomy for the device, it is equivalent to a prosthetic fem-pop bypass.¹ So for me, that is the first treatment option. Having appropriate anatomy for the procedure is important—you've got to be within the instructions for use with your sizing; you can't be oversized and you need to have reasonable runoff.² I rarely do above-knee fem-pop bypass unless a patient has already failed an intervention, and the lesion wasn't a good candidate for endovascular therapy in the first place.

Dr. Gable: When I talk to some interventionalists who use the GORE VIABAHN Endoprosthesis and end up saying they don't like it, a lot of them are just not sizing appropriately, they're not treating appropriately, they're ballooning outside of the device. I think if you do the procedure right, place the device to a vessel that is non-diseased, and adhere strictly to the sizing criteria and techniques of deployment, you will get reproducible results. If you don't do that, you will certainly see a failure of the device, but that is not really a failure of the device as much as it is a failure of the interventionalist.

Dr. Schneider: If you talk about the sweet spot for GORE VIABAHN Endoprosthesis use, it is cases where you have a complex clinical situation and challenging anatomy, especially a long occlusion, where you know most of the other endovascular alternatives are just not going to perform well. In those complex cases, there is clear justification for taking on the added cost of a covered stent.

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Dr. Gable: There is a lot of push now for DCB use in long lesions, and there are some reports of patency rates of 80% to 90% at 1 year. What do you all think of that?

Dr. Beasley: I think we need long-term DCB data. The mantra these days is “leave nothing behind.” We don’t know yet, but I want to see DCB long-term data with 2 or 3 year follow-up.

Dr. Schneider: It’s a selection thing. In a lot of the trials, lesions that couldn’t be adequately predilated were treated with stents. If the lesion is heavily calcified, scaffolding with a stent may be necessary and DCB may be less effective. I’m still selective about when I use a drug-eluting stent. If we do a predilation, and based upon the balloon inflation we see that the lesion is going to require scaffolding, then I’ll go straight to a drug-eluting stent. If I get a reasonable predilation, I’ll go ahead with the DCB. If there is a flow-limiting dissection or bad recoil, then I’ll spot stent as needed using a bare-metal stent because we have already delivered drug.

Dr. Beasley: I use laser atherectomy a lot, and then I would use DCB and spot stent if necessary.

Dr. Gable: We rarely use laser in our group. There is some limited atherectomy use (rotational or orbital) either in an isolated popliteal lesion or a focal calcific lesion near endpoint. I personally never use atherectomy; I just don’t believe in it. The published data on it are typically < 12 months. Until you can show me longer-term data, I’m not going to buy into it.

Dr. Schneider: If you look at the data, there is no added benefit that’s been demonstrated of atherectomy over other modalities. Maybe there is a role for improving drug uptake and modifying a vessel that is heavily calcified so that it will become susceptible to treatment with a drug strategy. This still hasn’t been clearly demonstrated. The complication rate is also radically different between balloon alone versus balloon with atherectomy. There are cases of distal embolization and perforation.

POPLITEAL SEGMENT

Dr. Gable: Does the GORE® TIGRIS® Vascular Stent play a role in any of your popliteal lesions?

Dr. Schneider: I don’t have a huge experience with the GORE® TIGRIS® Vascular Stent, but I do think that it is a good device for the popliteal.

There are some data starting to come out on that; it is an incredibly flexible device, and you don’t have the same concerns with covering the entire genicular network. It’s easy to deliver and deploy accurately.

Dr. Gable: I’ve used the GORE TIGRIS Vascular Stent and I think it’s a great flexible stent. I only use it on a < 8 cm lesion if I was going to use it anyway, or to treat the popliteal artery. I think the popliteal artery is going to be our sweet spot for the GORE TIGRIS Vascular Stent.

TIBIAL VESSELS

Dr. Gable: If you have lesions in the tibial vessels, and you’re going to treat endovascularly because the patient is a poor operative candidate, what is your treatment method?

Dr. Samson: I use laser atherectomy and a very low-profile balloon. I’ve never stented in the tibials.

Dr. Beasley: I would probably use a dual approach, antegrade and retrograde, to get through the occlusion. I would then use microportal atherectomy and then a low-pressure balloon. I can’t say I never stent, but it would have to be in the proximal third, in an area that was a raging dissection.

Dr. Schneider: Primarily low-profile balloon angioplasty for tibial lesions. I do some bailout stenting with coronary drug-eluting balloon-expandable stents for spot areas, especially at vessel origins, but I do not line the entire tibial vessels with them. At this point, I don’t think that there is a significant role for covered stents in tibial arteries.

SFA TREATMENT CONSIDERATIONS

DE NOVO LESIONS

LESION LENGTH

OCCCLUSIVE

CALCIFICATION

CAN A BALLOON BE DILATED?

CAN A STENT BE PLACED WITHOUT ELONGATION?

IN-STENT RESTENOSIS

STENT LENGTH

VESSEL SIZE

MULTIPLE AREAS OF RESTENOSIS

Dr. Gable: For tibial vessel disease, we will occasionally use low-profile laser atherectomy, and we will sometimes use coronary drug-eluting stents. Those are usually reserved for people who are not operative candidates. All those patients have either an angiogram or arterial duplex for follow-up. Surprisingly, the outcomes are good for the drug-eluting stents.

Dr. Schneider: I have started doing some tibial interventions in claudicants to try to improve runoff, but

only if it's a simple lesion that I think can be addressed with relatively low risk. If I have a focal, fairly tight tibioperoneal trunk stenosis, I'll hit that with a balloon and I think the risk is pretty low. If we're talking about crossing tibial occlusions and recanalizing occluded tibials, I'm not doing that routinely in claudicants.

I think that there is probably some role for atherectomy for a calcified eccentric lesion followed by angioplasty; and then if you don't get the result or you have a dissection, then I would put in a short coronary drug-eluting stent.



HOW TO TREAT | IN-STENT RESTENOSIS

Dr. Gable: What is your preferred method for treating in-stent restenosis?

Dr. Beasley: I think we are now able to prolong the inevitable, at least in years terms, with the GORE VIABAHN Endoprosthesis for in-stent restenosis. I have some patients who, years out after placing a GORE VIABAHN Endoprosthesis inside the stent, look pristine on ultrasound.

Dr. Gable: I go back and forth about debulking—currently, I do not. My preference is to reline with a GORE VIABAHN Endoprosthesis. If the original stent is 20 or 30 cm and the in-stent restenosis is only in a small section, then I may try to just use a DCB without debulking.

Dr. Samson: If I have a very long stent that is showing multiple areas of stenosis, I'm going to do a fem-pop bypass. If it is a short segment, I don't see any reason why you wouldn't try another endovascular approach.

Dr. Schneider: It depends on the length of the lesion and the length of the stent that's in there. If it's relatively short (10 to 15 cm), we have data showing that DCBs are effective in that lesion length, so we may use a DCB-first approach. If it's an SFA full-metal jacket with diffuse in-stent restenosis, our preferred treatment is to reline completely with covered stents because we know that the data for covered

stents in long lesions is good compared to a lot of the other technologies. I have had a number of patients who are out 4 or 5 years with patent GORE VIABAHN Endoprostheses after recurrent failures with a bare-metal stent.

Dr. Gable: Do you have any best practices for optimized outcomes when using a covered stent for in-stent restenosis?

Dr. Schneider: The caveat is that it has to be an adequate-size vessel to begin with. If you're too oversized or dealing with small vessels, then it's not a covered stent approach. We don't debulk. We used to, and then we stopped, and we've had no difference in outcomes.

Dr. Gable: Do you think it makes a difference how far out at the end of the previous stent you put the GORE VIABAHN Endoprosthesis?

Dr. Schneider: You have to reline the entire stent. If you spot stent, the remaining uncovered nitinol stent will restenose again. We try to extend to get a normal artery landing zone, but that will be dictated by the patient's anatomy. ■

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Best Practices for Distal Bypass Using the GORE® PROPATEN® Vascular Graft

The patient and case dynamics to consider when utilizing a surgical approach to PAD.

WITH RICHARD F. NEVILLE, MD, FACS



What are the dynamics that you take into consideration when deciding whether to treat surgically or endovascularly?

When we're trying to decide whether bypass or an endovascular approach is appropriate, we take five particular things into consideration: (1) indications for the procedure: significant tissue loss or gangrenous changes would do better with bypass; (2) the patient's medical comorbidities, including their perioperative risk and life expectancy: high perioperative risk would do better with an endovascular approach, versus someone with a significant life expectancy who would undergo bypass¹; (3) the patient's arterial anatomy: long-segment TASC-D lesions in the femoropopliteal or tibial segments or significant calcified common femoral artery disease would tend towards bypass²; (4) the wound's angiosome: all other things being equal, I might do a bypass to get to the proper angiosome; and (5) previous failed endovascular therapy.

Once you decide to treat surgically, what is the next key decision you make?

The next decision point in planning a bypass is inflow, outflow, and the conduit. For distal bypass, I try to use the patient's own great saphenous vein if it's available, ipsilateral or contralateral. If the patient does not have the great saphenous vein available, my next choice is to use the GORE® PROPATEN® Vascular Graft, and I use a vein patch at the distal anastomosis.

I'm no longer using arm vein or lesser saphenous vein, except in young patients with a long life expectancy, and I'm no longer doing composite polytetrafluoroethylene (PTFE) and spliced segments of vein. The distal vein patch technique has proven superior to composite PTFE with spliced vein segments. I don't use much cryopreserved vein—I reserve cryopreserved conduit for infected situations.

How do you determine the distal anastomosis technique?

When using the GORE PROPATEN Vascular Graft, I suture the proximal anastomosis directly to the artery, unless the patient has significant femoral artery disease, in which case a femoral endarterectomy may be needed. For a femoral endarterectomy, we put a patch on the endarterectomy and then put the GORE PROPATEN Vascular Graft into the patch. The distal anastomosis is usually to a small tibial artery, and I think you need the distal vein patch. We suture the patch to the artery with 7-0 MEDLINE PROLENE® Polypropylene Sutures, and then we suture the GORE PROPATEN Vascular Graft to the patch with 6-0 MEDLINE PROLENE® Polypropylene Sutures.

What is the clinical benefit of using the distal vein patch and GORE PROPATEN Vascular Graft?

Use of the GORE PROPATEN Vascular Graft with a distal vein patch combines the antiplatelet, antithrombotic, and antihyperplastic characteristics of heparin bonding with the advantages of the vein patch technique. These advantages include hemodynamic and compliance optimization as well as technical ease of suturing to small, calcified tibial arteries.³⁻⁵

Another benefit is if the GORE PROPATEN Vascular Grafts thromboses when you have used the distal vein patch technique, the failure occurs between the graft and the vein, not between the graft and the artery, making secondary patency much easier to establish. If you took the GORE PROPATEN Vascular Graft right to the artery and the graft fails, then the clot that develops extends into the artery. Using the GORE PROPATEN Vascular Graft and distal vein patch technique, if the artery doesn't get thrombosed, I can expose the distal anastomosis under local anesthesia and reestablish flow and maintain secondary patency.

How might the treatment goals for your patients impact conduit selection and why?

The real goal is amputation-free survival. When using a graft to treat femoropopliteal disease, you can treat claudication and lifestyle, but for tibial bypasses, the goal is limb preservation and wound healing.

Are there other options you consider?

There are advanced endovascular techniques being developed that may impact this decision, but for right now I hold to my original indications.

DISTAL BYPASS BEST PRACTICES

What are the sources of vein patch that you use?

Despite long segments of vein that are atretic and suboptimal, there is usually a segment of saphenous vein that can be used—only 2 to 4 cm of vein is required. If not, then I've taken occluded superficial femoral artery and opened it longitudinally and performed an endarterectomy. You could also use superficial femoral vein.

I've rarely used lesser saphenous vein. We have not used arm vein. I do not use bovine pericardium for the patch; I've found that it leads to suboptimal results compared to a distal vein patch. There is also the AZIYO® CORMATRIX® ECM Vascular Repair Patch, which we have written about in other situations, but I would not use it in this setting.

When you make the distal anastomosis, what is your consideration for the venotomy site?

When we do the venotomy and construct the patch, we offset it to the proximal two-thirds of the patch. I want a third of the patch to be purely free of the PTFE.

What is the target artery diameter? Is there a limitation?

There is not a size limitation, but if we do a bypass to a very small tibial artery, we have come up with the Patchula technique, which adds a distal AV fistula to the anastomosis.⁶ If a target artery is < 1.5 to 2 mm, especially if arteriographic runoff is poor, I would consider a distal AV fistula.

What is the usual graft diameter?

I use a 6 mm graft. If I'm doing a fem-pop or a fem-fem, I use an 8 mm graft, but if I go below the knee, I use 6 mm.

Any tips on graft handling?

Surgeons probably know this, but I'll catch nurses sometimes who will ask if we want the graft soaked—you don't soak the graft. Also, keep the graft off the skin, we don't want contamination.

What is your wound care protocol?

There is no one protocol, there are so many choices out there. We strongly advise that you involve podiatry, plastic surgery, and your local wound care centers and come up with a protocol that works for your facility.

What is your approach to patient follow-up regarding dual antiplatelet therapy and surveillance?

I do try to anticoagulate these patients. We have unpublished data that shows that if you anticoagulate them, there is a statistical trend toward improved patency. We usually use warfarin; we have also used the new oral agents, because of the issues associated with warfarin.

CONSIDERATIONS WHEN DECIDING BETWEEN SURGERY AND ENDOVASCULAR INTERVENTION

1	2	3	4	5
INDICATIONS	COMORBIDITIES	ANATOMY	ANGIOSOME	CLINICAL HISTORY
Significant tissue loss or gangrene → bypass	High perioperative risk → endovascular intervention High life expectancy (> 2 years) → bypass	Long-segment TASC D lesion in femoropopliteal or tibial segments, significant calcification in common femoral artery → bypass	If the wound's proper angiosome is reachable → bypass	Previous failed endovascular intervention → bypass

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If patients cannot be anticoagulated for some reason, then we use dual antiplatelet therapy, aspirin 81, and Plavix. If the patient comes in on Plavix because of a coronary stent or another reason, then I don't add anticoagulation and use dual antiplatelet therapy.

For every patient, even those I may discharge on dual antiplatelet therapy alone, in the hospital I put them on 48 to 72 hours of heparin during the initial, immediate postoperative period to establish flow through the graft.

For follow-up, we use the standard guidelines and image the grafts at 3, 6, and 12 months and then annually. We are also working on a new technology using microsensor technology and a remote monitoring system that gives a second-to-second evaluation of the graft and works remotely through Bluetooth applications.

What are your long-term expectations regarding quality of life and patency?

We published a 300 patient series in the European *Journal of Endovascular and Vascular Surgery* that found 50% patency at 4 years, but amputation-free survival was in the 70% to 80% range.⁴ I tell my patients that if I do a bypass, there's a 50/50 chance it will be working over several years, but there's a 75% to 80% percent chance that we'll keep your leg and get the wounds to heal.

What happens if it fails? What would you do next? Would you have done anything differently?

If the graft fails we usually (unless the patient doesn't want to or is medically unstable) try to reestablish secondary patency through local anesthesia with a small incision at the distal anastomosis, and I think it's much

easier to do that with the GORE PROPATEN Vascular Graft and vein patch technique than other prosthetic grafts.

If native vein occludes, it's hard to thrombectomize. The advantage to native vein is that the primary patency is better, but the disadvantage to native vein is that it is harder to reestablish secondary patency.

How does the GORE PROPATEN Vascular Graft design contribute to better outcomes for the patient?

The end-point covalent heparin bonding is the key. We think it's much better than standard PTFE. The graft handles well, and works especially well with vein patch. ■

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Approaching Complex PAD

Discussing patient considerations, best practices, and device placement techniques.

WITH ARUN CHERVU, MD, MBA, MHA, FACS



What types of cases do you see in your practice on any given day?

We see a combination of both claudication and critical limb ischemia (CLI) requiring urgent intervention. For claudicants, my first approach is to try conservative medical therapy including smoking cessation, medications, and an exercise program. Although it's not a structured exercise program, I give them an idea of what they need to do and try medications, including cilostazol. For some patients, I'm able to put off intervention for 6 months to a year, sometimes 2 years, and then do the appropriate intervention at that time.

We do a lot of peripheral artery disease (PAD) work, but there are always surprises, and it's really important to be ready for them. Then, we hopefully can treat the patient in one sitting rather than bringing him or her back at a separate time. That's why having a full armamentarium—covered stents, self-expanding stents, balloon-expandable stents—is an important part of taking care of the patient with PAD and complex PAD, which we're seeing more of.

What are some of the disease characteristics and comorbidities that move a PAD case from being simple to complex?

We have real difficulty with patients with end-stage renal disease; those are a very challenging group of patients. Diabetes is pretty standard in our patients, and congestive heart failure, stroke, and coronary artery disease are significant comorbidities.

It can be difficult to treat some of these patients, especially those with CLI and multilevel disease. Sometimes they require hybrid intervention—a combination with an iliac stent and a bypass. In an outpatient setting, it's sometimes hard to know what you're going to do. We can fix certain aspects of the disease, but then we need to move the case over to a hybrid OR setting.

What are the first signs of multilevel disease you see in a patient?

A lot of it starts with the history—how long they've had issues with claudication, how long they've had

issues with development of an ulcer. Then, the imaging is where you have an initial sense. We typically don't do CT scans, but if you do an aortic ultrasound or an arterial study, you start getting an idea of multilevel disease. You also can tell when you watch the patient walk.

What are some of the considerations when you have a patient with long-segment superficial femoral artery (SFA) disease?

One of the considerations always is whether to cover the collaterals. I don't think that debate is ever going to be completely settled one way or the other—you can make arguments for each side. One argument to cover them is that you are then providing a great bypass, so that you really never get rid of them. The other argument is that if you can save them, why not?

When it comes to complex, occlusive disease, what is your game plan?

Everyone handles chronic total occlusions differently. I prefer a simple MEDLINE KUMPE® Access Catheter or BOSTON SCIENTIFIC RUBICON® Support Catheter, and then I go through with the TERUMO® GLIDEWIRE® Hydrophilic Coated Guidewire and do balloon angioplasty. This works over 90% of the time. I have used a reentry catheter on occasion.

When do you make the choice to use a covered stent graft or a bare-metal stent?

In the SFA and popliteal space, the decision is not always easy because there are multiple characteristics to consider. The standard go-to is a self-expanding stent. You start thinking about using a covered stent for long lesions and in-stent restenosis (ISR) and a GORE® VIABAHN® Endoprosthesis in particular if you have a long occlusion (10–15 cm or longer). The VIASTAR randomized study demonstrated the advantages of the GORE VIABAHN Endoprosthesis compared to bare-metal stents in long lesions.¹ A lot of data have shown those patients do better at 1 year, 2 years, 3 years, and so on

with a GORE VIABAHN Endoprosthesis. The concern with patients with very significant plaque is whether you can dilate that area with a balloon or if atherectomy is needed to get rid of the lesion.

I also like using a GORE VIABAHN Endoprosthesis in the case of ISR. By physically preventing cells from infiltrating the lumen of the device, it addresses the underlying cause of the ISR. Plus, because it's ISR, the chance to "leave nothing behind" is not available. This approach is supported by data from the RELINE study (which remains one of the only randomized studies for any device in ISR), which demonstrated that the GORE VIABAHN Endoprosthesis is capable of durably treating ISR.² At 2 years, the primary patency was 60% for the GORE VIABAHN Endoprosthesis compared to only 10% for PTA. In my mind, this is where the GORE VIABAHN Endoprosthesis separates itself from paclitaxel therapies, which, as the DEBATE-ISR study showed, do not carry the 12-month benefits out to years 2 and 3.³

When do you choose a GORE VIABAHN Endoprosthesis to reline a failed bare-metal stent? Do you do anything else besides using a covered stent graft?

There are times when I will just do plain balloon angioplasty, especially if it's a short lesion (< 5 or 6 cm in length). If I've done balloon angioplasty once already and the restenosis returns, then I'm more likely to put in a covered stent.

Some physicians do atherectomy on ISR lesions, but I don't particularly love that concept. I don't want it to get stuck in the struts, especially proximally/distally.

The problem with ISR is intimal hyperplasia. A very short-segment ISR can be treated with balloon angioplasty. Some people use laser atherectomy debulking, but I think a lot of those patients come back very early, and that's where a covered stent has an advantage.

The advantage of a GORE VIABAHN Endoprosthesis for a long lesion is that you are covering the area of the disease in the intimal hyperplasia, and that really is better in the long run and hopefully will stimulate less reaction to the ongoing tissue in that area—the vascular endothelial cells.

What do you consider when you're trying to optimize stent placement?

Covering all diseased portions of the SFA is important when using the GORE VIABAHN Endoprosthesis. Leaving a diseased proximal SFA will more likely lead to early stent thrombosis. Optimizing stent placement to the origin of the SFA can be done using magnified

and oblique views to more accurately see the profunda and SFA origins. Intravascular ultrasound is a very helpful tool in selected cases. We have gotten better at sizing the stent grafts, which was a problem in the initial adaptation with GORE VIABAHN Endoprosthesis. Intravascular ultrasound or quantitative angiography has helped us get a better idea of sizing so that we are not oversizing > 20%.

It is important to know the length of the lesion to ensure you are intraluminal distally and sizing properly. Making sure you have good inflow and outflow is really important. We cover everything we balloon, and that's another important aspect—try not to balloon outside the device.

You have to be careful that you don't go between the stent and the arterial wall. These challenges can occur when you try to cross lesions, especially stent separation or stent fracture. It's very important to stay intraluminal.

There are a number of technical mishaps or hurdles that you need to avoid when stent fractures or a separation occur. You want to stay in the middle of the stent. You don't want to go through the stent interstices. It's helpful to get magnified views. Get multiple rotation views so you know that you're inside, and then try to put a catheter through. The catheter typically will not go if you are in the stent interstices, so that's really important because it's hard to crush the stent regardless of what you use, unless it's a small stent in a big artery.

What is your algorithm for follow-up and long-term surveillance, especially for covered stents?

I think the same algorithm applies for almost all stents. If I'm worried about something, I'll do an arterial study at 1 month, an ankle-brachial index, and an arterial duplex. If things seem reasonable, then I'll go out to 3 months, 6 months, 9 months, 1 year, and then every 6 months after that for at least another 1 or 2 years. It all depends on what you find. If there is severe recurrent stenosis, then we would want to reintervene to save the intervention we've done. We are looking at primary intervention, secondary intervention, primary patency, and secondary patency.

What outcomes or lifestyle changes do your patients experience after revascularization?

Patients come in with myriad symptoms prior to any intervention, and not all of it is straightforward claudication. Some people say their legs or buttocks ache. Some people say they are fatigued. Not everybody gives a classic history of, "My calf hurts when I walk half a block."

There are a couple of things that people report after revascularization. Some patients report that they have pain where they have had balloon angioplasty. They have pain in the calf or thigh. However, I would say in the majority of patients, those symptoms are gone, and they report that they're walking better within about a week. That's what we want to see—less pain when they walk in the calves and the thigh, depending on what you revascularize. Most patients are happy with the outcomes, and they tend to stay happy as long as there is no compromise of the arterial circulation. Quality of life is the reason we perform many of the cases. ■

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Disclosures: On the clinical trials and speakers bureau for Gore & Associates.

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CASE REPORT

GORE® TIGRIS® Vascular Stent Implantation in Segmental Occlusion of the Popliteal Artery

Vascular-mimetic properties of this hybrid stent design contribute to high performance in a challenging vascular zone.

BY JACOB H. SHARAFUDDIN; BRIAN V. MILLER, MD; AND MEL J. SHARAFUDDIN, MD

A 70-year-old man presented to our office with a history of progressive intermittent claudication and bilateral common iliac artery stenting years earlier. He had failed prior conservative management including cilostazol and risk factor management, but had been unable to comply with a walking program due to debilitating pain. He underwent angiography with unsuccessful attempted endovascular intervention for segmental occlusion of the right popliteal artery at an outside hospital. He described his current symptoms as debilitating, with exertional right calf pain occurring at half a block. He denied having rest pain or tissue loss. His vascular risk factors included diabetes, smoking, hypertension, and hyperlipidemia. His past medical history was also remarkable for stage 3 chronic kidney disease and atrial fibrillation. His examination was remarkable for diminished distal pulses. Resting right ankle-brachial index (ABI) was 0.59 with blunted transmetatarsal pulse volume recording (PVR).

Management options discussed with the patient included continued best medical management and exercise therapy, bypass surgery, and endovascular intervention. The patient elected to proceed with an endovascular approach.

COURSE OF TREATMENT

Given the patient's history of chronic kidney disease, the bulk of the angiographic runs were performed using CO₂ with judicious use of diluted iodinated contrast medium.

A contralateral right transfemoral approach was used for access. The presence of the previously implanted ostial iliac stents posed some difficulties that were

overcome with the use of a tapered coaxial system and a flexible sheath, which enabled sufficient support for

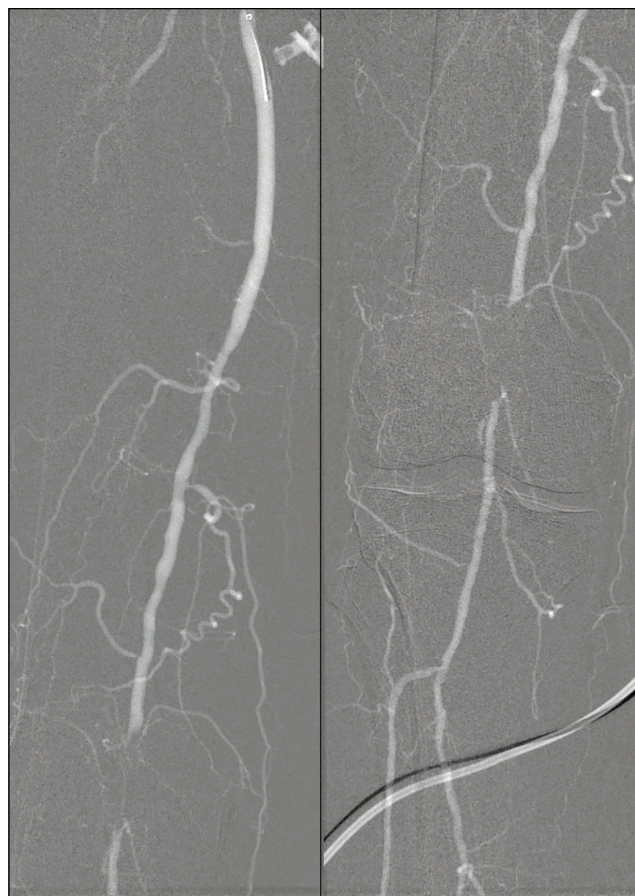


Figure 1. CO₂ angiogram of the right lower extremity showing diffuse moderate disease of the above-knee popliteal artery with segmental occlusion at the level of the patella.

planned traversal of the known chronic total occlusion and subsequent delivery of the interventional devices.

Angiography demonstrated a 4 cm occlusion of the distal above-knee popliteal artery with an adjacent long segment of moderate calcific atherosclerosis in the proximal popliteal artery (Figure 1). The popliteal occlusion was traversed using a COOK® CXI® Support Catheter and a coaxial TERUMO® GLIDEWIRE® Stiff Shaft Guidewire. Intraluminal position within the reconstituted segment was confirmed, and an ABBOTT TAD II Tapered Guide Wire System was used for the remainder of the intervention. The occlusion and upstream stenotic segment were predilated using a 6 mm COOK® ADVANCE® ENFORCER 35 Focal-Force PTA Balloon Catheter. Angiography demonstrated restored patency to the occluded segment, but multiple intimal defects persisted across the treated segment. We proceeded with stenting using a 6 x 100 mm GORE® TIGRIS® Vascular Stent distally, overlapped proximally with another 7 x 100 mm GORE TIGRIS Vascular Stent. The stented segment was postdilated up to 6 mm.

RESULTS

Completion angiogram showed complete resolution of the occlusion with no residual stenosis across the stented length. Angiography was also performed at a 90° knee flexion position, confirming maintained patency and excellent adaptation of the stented segment to the adjacent infolding of the geniculate popliteal artery without any kinking (Figure 2). Assessment of the runoff confirmed wide patency of the infrageniculate popliteal artery and preserved three-vessel runoff to the foot. At completion of the procedure, the patient had strongly palpable pedal pulses. Postprocedural ABI and PVR were normal. At clinical follow-up 1 month after the procedure, the patient reported complete resolution of his previous symptoms with normal ABI and PVR values (Figure 3). A widely patent stent was confirmed on duplex sonography.

DISCUSSION

The femoropopliteal artery is a highly dynamic vascular segment subjected to repetitive multidimensional stresses, with multiple folding points and regions subjected to dynamic extrinsic compression.¹ It also has a high prevalence of heavy calcification and total occlusions.

Our case illustrates the advantages of the GORE TIGRIS Vascular Stent for managing challenges encountered in the endovascular management of femoropopliteal artery occlusive disease. When compared to conventional nitinol stent designs, the dual-component design of

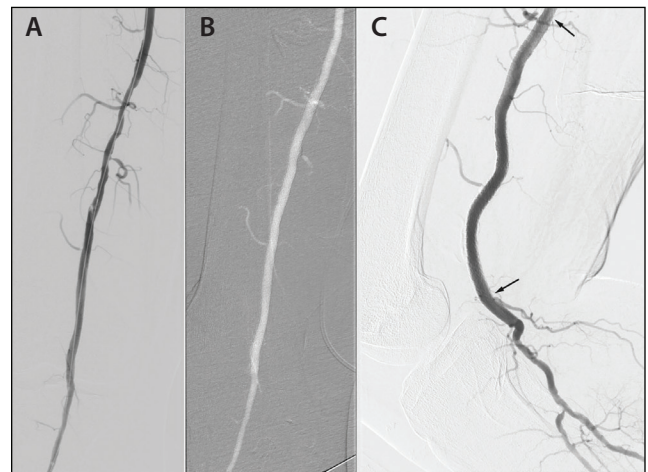


Figure 2. Residual irregularity in the popliteal artery after scoring balloon dilatation and deployment of the distal GORE® TIGRIS® Vascular Stent (A). Final angiogram after deployment of the proximal GORE® TIGRIS® Vascular Stent and postdilatation to show complete normalization of the popliteal artery lumen (B). Lateral angiogram (C) after knee flexion showing maintained patency and excellent conformation to the resulting infolding of the popliteal artery allowing gentle looping instead of kinking, which can be seen with conventional nitinol stents in Figure 4. Arrows indicate where the stent starts and ends.

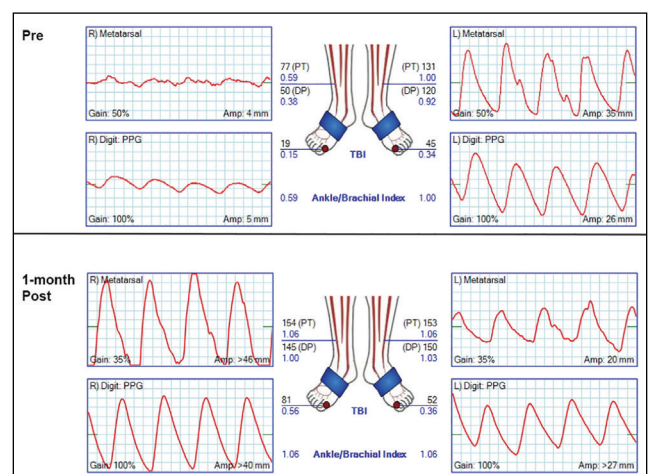


Figure 3. Noninvasive assessment 1 month after right popliteal artery stenting shows normal ABI and PVR values.

the GORE TIGRIS Vascular Stent markedly enhances its ability to dynamically adapt to the vascular anatomy, mimicking the physiologic behavior of the native target artery (Figure 4).² In addition, when compared to other vascular mimetic-type stents, it has the distinct advantage of extremely accurate deployment and long-axis adaptability with the lack of foreshortening or elongation. Other key advantages of this implant include

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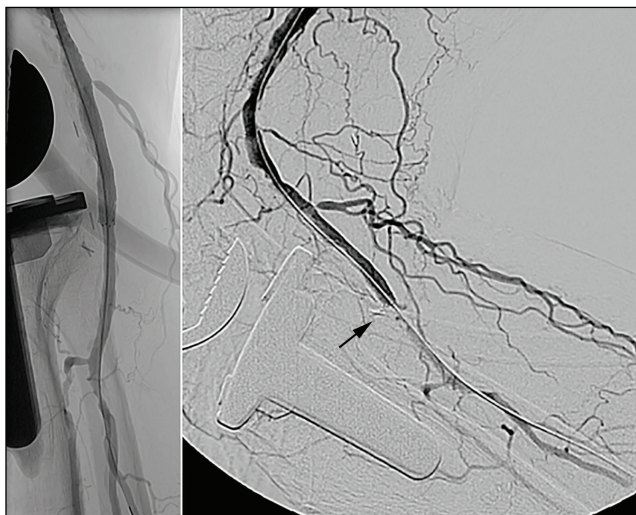


Figure 4. Inability of a conventional nitinol stent (BARD® LIFESTENT® Vascular Stent System) to accommodate the infolding of the popliteal artery, resulting in kinking on knee flexion.

high resistance to fracture and heparin-bonding to the interconnecting fluoropolymer mesh, providing local thromboresistance.³ These features represent the basis for the value of GORE TIGRIS Vascular Stent in the treatment of vascular segments associated with high mechanical stresses, particularly the popliteal artery.

Contraindications to the implantation of the GORE TIGRIS Vascular Stent, as with other nitinol stents, include failure to adequately predilate the stenotic lesion prior to stent deployment, very small target vessel diameter, poor distal runoff, or inability to stent a lesion without caging a vital branch.

The importance of overcoming a resistant stenosis prior to deployment of the GORE TIGRIS Vascular Stent cannot be overstated, especially in the setting of heavy calcification or the presence of fibrotic recoil. Our practice has been to routinely predilate lesions in

the popliteal artery segment using a scoring or cutting balloon to ensure optimal deployment of the stent. This approach is very effective even in the presence of heavy calcification and obviates the need for lesion prepping using atherectomy devices. ■

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IVUS for GORE® TIGRIS® Vascular Stent Placement During Knee Flexion

Intravascular ultrasound confirms the shape-maintaining abilities of a GORE® TIGRIS® Vascular Stent placed in the popliteal artery during leg flexion.

BY PROF. J. IAN SPARK, MD, FRACS, FRCS, AND RICHARD B. ALLAN, DMU, BHLTHSc (Hons)

The superficial femoral artery (SFA) and popliteal artery are a hostile environment for endovascular treatment due to high rates of more advanced atherosclerotic disease and a complex range of forces during normal leg movements.¹⁻³ Although stenting has been shown to be superior to plain angioplasty, restenosis rates are still unacceptably high.^{4,5} Conventional nitinol stents are not well suited to these conditions due to their relative rigidity and lack of compliance, which result in an increased risk of kinking and fracture.^{6,7} Mimetic stents are designed to mimic the flexibility found in the SFA and popliteal arteries and manage the extreme forces routinely found in these arteries. A number of mimetic stents are now available that utilize a range of design solutions, providing alternative options for the interventionalist.

The GORE® TIGRIS® Vascular Stent is a hybrid design that provides greater flexibility by combining a nitinol wire frame and a heparin-bonded interconnecting expanded polytetrafluoroethylene lattice. Results of studies evaluating the GORE TIGRIS Vascular Stent have been encouraging, with 90% freedom from target lesion revascularization (TLR) at 12 months in shorter lesions,⁸ 86% freedom from TLR at 12 months in a more high-risk population (70% of patients with critical limb ischemia [CLI], 74% with occlusions, and a mean lesion length of 114 mm),⁹ and no reported cases of stent fracture.¹⁰

We suspect the stent's kink resistance plays an underreported role in these positive clinical outcomes. Intravascular ultrasound (IVUS) has been shown to be superior to digital subtraction angiography (DSA) in assessing vessel and stent characteristics¹¹⁻¹⁷ and is therefore an ideal imaging modality to assess the stent's ability to maintain its shape when subjected to knee flexion. As far as we are aware, this is the first report of IVUS evaluation of the performance of a

GORE TIGRIS Vascular Stent in the popliteal artery. Key parameters to assess stent performance are maintenance of normal stent lumen and shape during knee flexion. Reduction in stent lumen area and eccentric lumen shape are associated with an increased risk of in-stent restenosis (ISR) in the coronary arteries,¹⁸ and the MUSIC quantitative criteria have been created to identify inadequate stent expansion in the coronary arteries.¹⁹ The stent lumen area ratio (minimum stent lumen/mean reference lumen) and stent lumen symmetry ratio (minimum stent lumen diameter/maximum stent lumen diameter) can be used to provide objective assessment of the adequacy of stent deployment. It should be noted that there are no validated criteria to evaluate stent expansion using IVUS in the peripheral arteries, although a recent retrospective analysis suggests that a stent lumen area of < 15.5 mm² may be associated with increased incidence of restenosis.²⁰

CASE PRESENTATION

A 68-year-old man, a former smoker with a past medical history of ischemic heart disease, hypertension, and type 2 diabetes, presented with a deteriorating left ankle ulcer, SFA/popliteal stenotic disease on duplex ultrasound (peak systolic velocity [PSV], 322 cm/s), and extensive severe calcific disease in the distal SFA and P1/2 popliteal segments on CTA (Figure 1).

Initial diagnostic angiography and IVUS confirmed diffuse disease with extensive calcification and multiple areas of stenosis in the distal SFA and the P1/2 segments of the popliteal artery. Reference vessel diameters (RVDs) were obtained using DSA quantitative vessel analysis (RVD, 5 mm) and IVUS (RVD, 5.6 mm), and 6 mm balloons were used based on the IVUS lumen measurements. The vessel was treated using a standardized angioplasty technique of 3 minute inflation with a 6 mm ABBOTT® ARMADA 35 LL Percutaneous

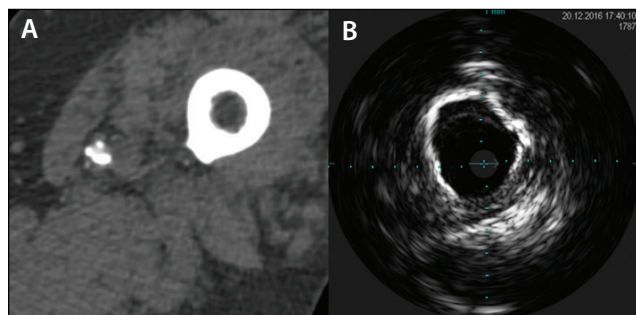


Figure 1. CTA image showing a calcified artery at the adductor canal (A). IVUS image at the same level showing calcification extending around at least 270° of the circumference, consistent with a grade 3B lesion as described by Fanelli et al²⁴ (B).

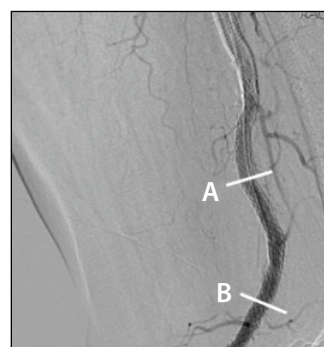


Figure 2. DSA image of the popliteal artery with the knee flexed after GORE® TIGRIS® stent deployment. The bars labeled A and B indicate the levels of the IVUS images featured in Figures 3 and 4.

Transluminal Angioplasty Catheter, followed by a 1 minute inflation of 6 mm MEDTRONIC IN.PACT® Admiral Drug-Coated Balloons, with a 10 mm overlap between balloons over a 280 mm length from the mid-SFA to just below the knee joint. The use of a long inflation time for plain balloon angioplasty has been recommended to reduce the incidence of flow-limiting dissection and residual stenosis.²¹⁻²⁴ We believe that the additional time taken for

a more thorough initial vessel preparation is rewarded with a lesser need for repeated dilatation, particularly in heavily calcified arteries.

Postangioplasty angiography and IVUS revealed residual stenosis, and IVUS imaging revealed that all landing zones had significant plaque burden between the residual stenotic lesions. Therefore, the entire length of the treated vessel was stented. A 280 mm length of vessel was treated with three stents: 6 x 100 mm and 6 x 80 mm GORE TIGRIS Vascular Stents and a 6 x 120 mm BARD® LIFESTENT® Vascular Stent System (deployed from above the adductor canal to the mid SFA), with 10 mm of overlap between stents. BARD® LIFESTENT® Vascular Stent System was used in the segment proximal to the adductor canal because there were no appropriately sized GORE TIGRIS Vascular Stents available at the time of treatment. Postdeployment dilatation of the stents was performed with 6 mm plain balloons.

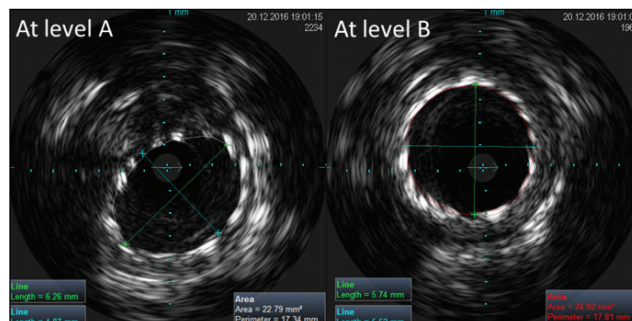


Figure 3. IVUS images of the GORE® TIGRIS® Vascular Stent at levels A and B as indicated in Figure 2 with the knee extended. Image A shows the area of minimum stent lumen and maximum eccentricity, and image B is representative of stent expansion seen through most of the stented artery. See Table 1 for the measurements and ratios at these levels.

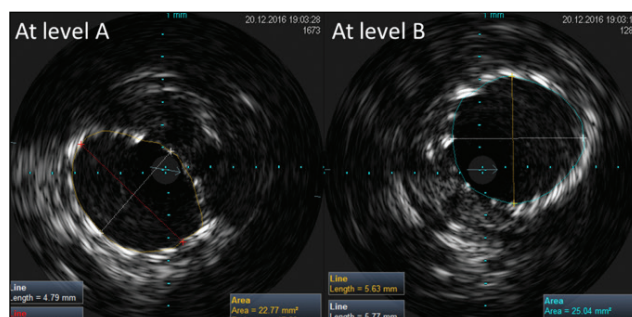


Figure 4. IVUS images of a GORE® TIGRIS® Vascular Stent at levels A and B as indicated in Figure 2 with the knee flexed. No change is seen at these levels compared to the knee in extension (Figure 3). See Table 1 for the measurements and ratios at these levels.

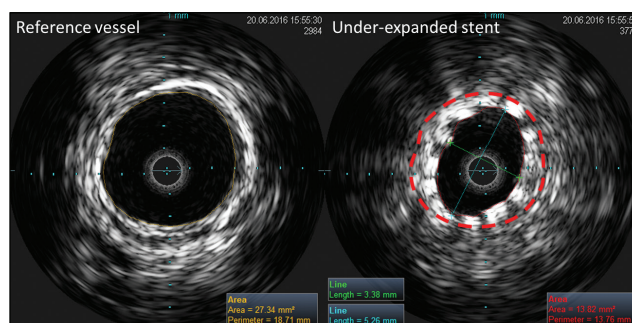


Figure 5. IVUS images of a conventional nitinol stent in the distal SFA demonstrating an under-expanded stent (right) in comparison to the proximal reference vessel (left). The red dashed line indicates the reference lumen size (27.3 mm²) that should have been achieved if optimal stent expansion had occurred. Note the significantly reduced stent lumen (stent lumen area, 13.8 mm²; stent lumen ratio, 0.51) and eccentric stent lumen (stent symmetry ratio, 0.64).

TABLE 1. IN-STENT IVUS MEASUREMENTS WITH KNEE EXTENDED AND FLEXED AT TWO LEVELS WITHIN THE STENTS*

		Stent Lumen Area (mm ²)	Lumen Ratio [†]	Stent Symmetry Ratio [‡]
Level A	Knee extended	22.79	0.91	0.78
	Knee flexed	22.77	0.91	0.76
Level B	Knee extended	24.92	0.99	0.96
	Knee flexed	25.04	1.00	0.98

Note: MUSIC study¹⁹ optimal stent expansion criteria is stent lumen ratio ≥ 0.8 and stent symmetry ratio ≥ 0.7 .

*As shown in Figure 2.

[†]Stent lumen ratio = stent lumen/(proximal reference lumen + distal reference lumen)/2.

[‡]Stent symmetry ratio = minimum lumen diameter/maximum lumen diameter.

Postdeployment angiography performed with the knee extended and in flexion showed no kinking or stenosis (Figure 2). IVUS was then performed with the knee extended and flexed, and measurements of the stent lumen were obtained at 5 mm increments. Stent lumen area and stent lumen symmetry were analyzed using the MUSIC study criteria (Table 1).¹⁹ IVUS with the leg extended showed good results with no areas of underexpansion and no change seen during knee flexion. In addition, the stent lumen was $> 15.5 \text{ mm}^2$ throughout the stented segment. Lumen area and stent symmetry were optimal with the knee extended and flexed (Figures 3 and 4), with a circular lumen area apparent through most of the stent length (Figures 3B and 4B). There was an area of mildly eccentric lumen (Figures 3A and 4A) in the area of maximum calcification. This was most likely due to the significant calcification (Figure 1) rather than artery movement, as the lumen shape was unchanged with knee flexion. The lumen shape was well within the acceptable range and demonstrated the stent's ability to resist compression by a highly calcified lesion.

There were no immediate postprocedural complications, and follow-up to date at 6 weeks has been normal (duplex ultrasound PSV ratio was 1.3 at the 6 week surveillance scan).

DISCUSSION

In this case, using objective criteria, IVUS demonstrated that the GORE TIGRIS Vascular Stent maintained good lumen size and symmetry, with good stent apposition, in a highly calcified popliteal artery. The flexible design of the GORE TIGRIS Vascular Stent coped easily with the range of forces applied to it during flexion with no deformation, kinking, or compression during knee flexion. Figure 5 shows a conventional nitinol stent placed using the same technique as in the case presentation in a patient with similar disease to illustrate how a poorly expanded, eccentric stent appears on IVUS. IVUS also allowed better matching

of the balloon and stent size to vessel dimensions and identified disease-free areas for landing the proximal and distal ends of the stents.

Data From 42 Patients Treated With the GORE TIGRIS Vascular Stent

We have used the GORE TIGRIS Vascular Stent to treat 42 patients with complex lesions (CLI in 61% of cases, occlusion in 53% of cases, popliteal location in 82% of cases, and a mean lesion length of 122 mm), with 12 month freedom from clinically driven TLR of 93% (unpublished data). We believe our excellent clinical outcomes with the GORE TIGRIS Vascular Stent are related to its flexibility and kink resistance, more accurate lesion assessment by IVUS, and the long and careful vessel preparation used prior to stent placement. The addition of IVUS allows for optimum sizing of the stent, and for treatment of the entire diseased segment.

It is clear that IVUS provides more accurate measurement of vessel lumen and lesion length and better assesses the adequacy of stent placement compared to DSA. A combined imaging approach provides a more comprehensive assessment of stent performance than angiography alone. Trials of coronary endovascular devices have required IVUS assessment as part of study design for some time, and it is time for peripheral vascular trials to follow suit. IVUS assessment during flexion may be prudent in trials of popliteal artery stenting to identify whether kinking or changes to lumen shape are occurring under conditions of maximum stress.

CONCLUSION

In this case, the GORE TIGRIS Vascular Stent performed well in a calcified popliteal artery. The combination of the GORE TIGRIS Vascular Stent, IVUS imaging, and careful and rigorous endovascular technique can deliver excellent results in one of the most hostile vascular environments. ■

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GORE® TIGRIS® Vascular Stent

INDICATIONS FOR USE IN THE U.S.: The GORE® TIGRIS® Vascular Stent is intended to improve luminal diameter in patients with symptomatic de-novo or restenotic lesions or occlusions in the native superficial femoral artery (SFA) and proximal popliteal artery (PPA) with reference vessel diameters ranging from 4.0 – 6.5 mm and lesion lengths up to 240 mm. **CONTRAINDICATIONS:** The GORE® TIGRIS® Vascular Stent is contraindicated for non-compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilatation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system. The GORE® TIGRIS® Vascular Stent is contraindicated in patients with contraindication to antiplatelet and/or anticoagulation therapy. DO NOT use the GORE® TIGRIS® Vascular Stent in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to *Instructions for Use* at goremedical.com for a complete description of all contraindications, warnings, precautions, and adverse events. **Rx Only**

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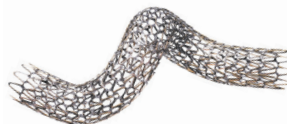
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