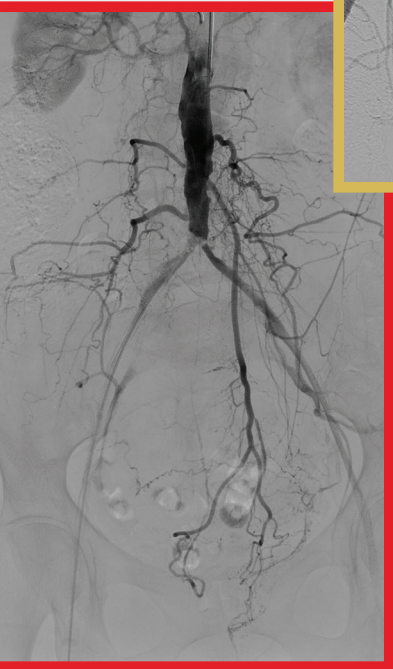
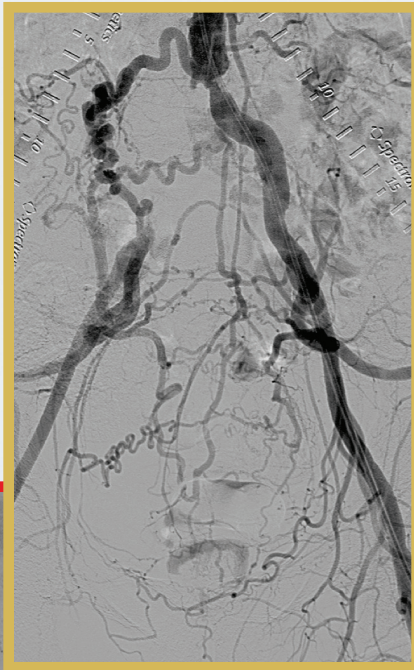


# Endovascular TODAY

February 2019



LOOKING AT THE

**FULL SCOPE  
OF PAD**

**CASES, TECHNIQUES,  
AND ECONOMIC  
CONSIDERATIONS FOR  
COMPLEX DISEASE.**

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# Current Challenges for the Modern Management of PAD

An overview of contemporary and emerging practices in peripheral artery disease.

BY FANNY S. ALIE-CUSSON, MD, AND JEAN M. PANNETON, MD, FRCSC, FACS

Peripheral artery disease (PAD) affects an increasingly high number of patients across the globe. Unfortunately, as our population ages, the incidence of PAD also increases and the burden of cardiovascular disease on health care costs is heavier than ever before. Luckily, the field of vascular intervention is in full effervescence with countless new devices and technologies emerging onto the market, further diversifying the available armamentarium to address this chronic and incurable condition.

PAD is a heterogenous disease process that affects patient groups differently; for example, younger patients and those who smoke typically present with inflow disease at the aortoiliac and femoropopliteal levels, whereas older or diabetic patients generally present with distal outflow disease at the tibioperoneal level. Symptomatology varies broadly from intermittent claudication (IC) to tissue loss, and the corresponding disease management also varies greatly. A generally accepted concept is that asymptomatic disease does not warrant intervention, and instead, optimal medical management should represent the mainstay of treatment for these patients. IC should be intervened upon when it is severe or refractory to conservative treatment. When indicated, determining the timing of intervention and navigating the wide array of therapeutic options present a great challenge for modern vascular specialists.

Multiple approaches, algorithms, and rationales to therapy have been proposed. The elderly comorbid patient with a short life expectancy has traditionally been the preferred endovascular patient, but indications for endovascular treatment are steadily becoming broader. The decision-making process in choosing between open or endovascular therapy is not clearly established and varies widely between practitioners and practice settings. Additionally, therapeutic approaches should be dictated by therapy goals, whether it be improvement of walking distance or resolution of rest pain and wound healing. Refractory IC is generally addressed via an endovascular approach first, with operative management reserved for more severe symptomatology. An important question

should be answered by the long-awaited BEST-CLI trial.<sup>1</sup> Hopefully, BEST-CLI will further define the optimal management algorithm for infrainguinal occlusive disease and allow for a more tailored therapeutic approach for patients with critical limb ischemia.

## ILIAC DISEASE

Endovascular treatment of inflow disease has been increasingly successful over the years and skilled practitioners are now tackling the most complex iliac lesions. The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Stent Graft) offers excellent primary patency rates in challenging aortoiliac occlusive lesions. In the VBX FLEX study, 32.1% of patients presented with TransAtlantic Inter-Society Consensus Classification II (TASC II) C/D lesions, and 42.5% of patients received kissing stents at the aortic bifurcation. The primary patency rate was 96.9% at 9 months with no significant difference in patency rates between TASC II A/B versus C/D lesions.<sup>2</sup> Figures 1 through 3 demonstrate the use of kissing VBX Stent Grafts for severe stenosis of both common iliac arteries at their origin with excellent angiographic results. These covered stents represent a safe option in managing high-grade, severely calcified or excentric lesions with an inherently higher risk of complications from recanalization as they allow for simultaneous management of dissections and potential ruptures.

## FEMOROPOPLITEAL DISEASE

Treatment for femoropopliteal disease is now steering away from the full-metal jacket era. Instead, a more comprehensive strategy to minimize stent complications while optimizing patency rates is employed with an As Low As Reasonably Achievable (ALARA) strategy. The body of clinical evidence supporting the use of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface for treating long lesions (> 10–15 cm) and chronic occlusions of the femoropopliteal segment continues to grow. The most recent study to evaluate the GORE VIABAHN Endoprosthesis performance in the superficial





Figure 1. Aortoiliac angiogram showing severe calcified bilateral common iliac artery ostial stenoses.

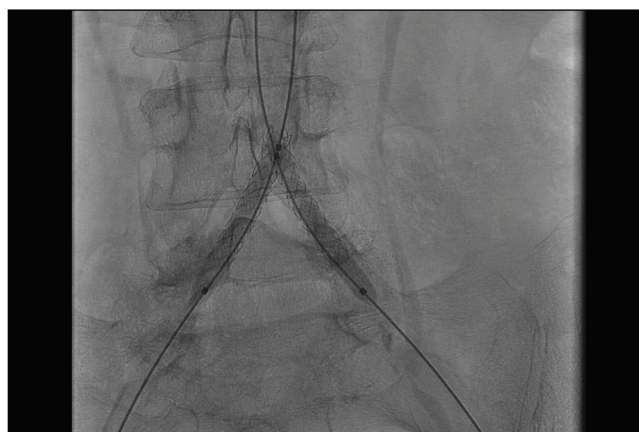


Figure 2. Deployment of bilateral common iliac artery GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis kissing covered stents.

femoral artery demonstrated a 12-month primary patency of 88% in lesions with an average length of 22 cm.<sup>3</sup> There are now five multicenter, prospective, randomized, or single-arm studies that have evaluated the heparin-coated GORE VIABAHN Endoprosthesis demonstrating an average 12-month primary patency of 75% in long (average lesion length, 22 cm), complex (n = 302 chronic total occlusions out of 422 limbs) lesions.<sup>3-7</sup> Data from the RELINE clinical trial support the use of the GORE VIABAHN Endoprosthesis for the treatment of in-stent restenosis (ISR) with a 75% primary patency rate and 80% freedom from target lesion revascularization (TLR) at 12 months

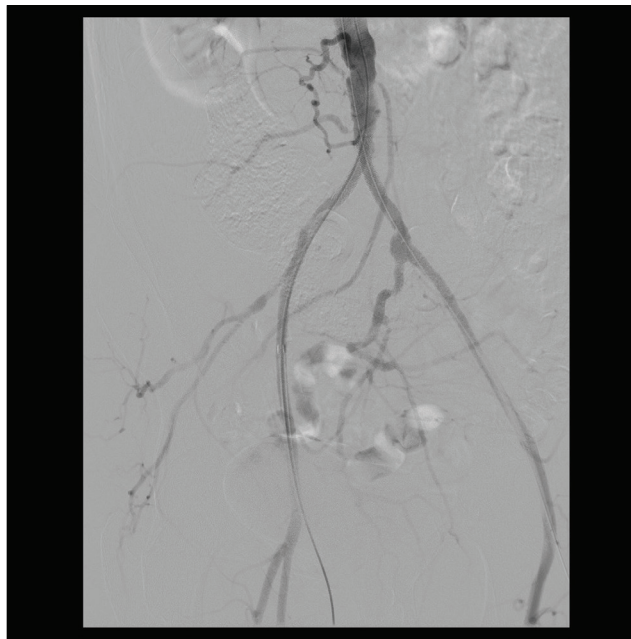


Figure 3. Excellent results can be seen on completion angiogram.

with a mean treated lesion length of 17.3 cm. In comparison, percutaneous transluminal angioplasty (PTA) was associated with a 28% primary patency rate and 42% freedom from TLR at 12 months.<sup>8</sup> However, edge restenosis, potential for acute limb ischemia by covering critical collateral branches, and stent thrombosis are caveats that need to be considered. Complete coverage of all diseased portions of the stented artery and avoiding oversizing of stent grafts may improve outcomes.

The popliteal artery is more difficult to address via endovascular approaches given its location and the dynamic stresses to which it is exposed. Therefore, stent placement in this arterial segment is particularly prone to fracture due to insufficient flexibility and heightened breakability, inevitably leading to secondary complications. New generations of nitinol stents, such as the GORE® TIGRIS® Vascular Stent, are designed to adapt to the ever-changing anatomy of the distal artery with a higher resistance to fracture via an interconnecting heparin-bonded polymer mesh. Primary patency at 12 months was 81.5%.<sup>9</sup> More recent data have also shown its efficacy in combination with a GORE VIABAHN Endoprosthesis.<sup>10</sup>

Despite the ALARA strategy rationale, residual stenosis or dissection following PTA remain accepted indications for stent placement. Technology has fortunately evolved from standard laser-cut nitinol stents and their high fracture rates to more conformable interwoven nitinol stents, which are associated with better patency rates as well as a reduced incidence of stent fractures. Despite

this, ISR unfortunately represents one of the toughest challenges we face as endovascular practitioners. Multiple trials have supported the use of drug-coated balloons to improve patency rates in management of ISR, such as the FAIR trial,<sup>11</sup> with freedom from TLR rates of 96.4% with the MEDTRONIC IN.PACT Admiral Drug-Coated Balloon versus 81% with plain old balloon angioplasty ( $P = .0117$ ) at 6 months and 90.8% versus 52.6% ( $P < .0001$ ) at 12 months, respectively. The DEBATE-ISR trial showed similar results but, unfortunately, the difference did not persist at the 3-year mark.<sup>12</sup> Atherectomy devices, such as the SPECTRANETICS® EXCIMER Laser System, were also introduced as a potential solution to treat ISR by debulking the intimal hyperplastic tissue, thus improving luminal gain.<sup>13</sup>

Surgical bypass procedures still have an important role in certain instances, namely in younger patients with aortoiliac disease, long-segment femoropopliteal disease, severe tibial disease, or failed prior endovascular therapy. Autologous vein grafts are preferable, but another option would be expanded polytetrafluoroethylene (ePTFE) synthetic bypass grafts. Notably, the GORE® PROPATEN® Vascular Graft has been shown to offer promising results in infrainguinal bypass compared with standard ePTFE, with 74.5% overall primary patency at 5 years versus 56.2% for standard ePTFE grafts ( $P = .03$ ).<sup>14</sup>

## CONCLUSION

Modern endovascular technology is rapidly evolving, and outcomes are steadily improving. However, as we look ahead, multiple challenges remain, such as minimizing neointimal hyperplasia, refining our approach to tibioperoneal interventions, and managing ISR more effectively.

This supplement offers an up-to-date overview of the interventional management of complex PAD with a heavier focus on endovascular approaches. We hope to allow readers to have a better grasp on current available technologies and their evidence-based indications. ■

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### Fanny S. Alie-Cusson, MD

Fellow

Division of Vascular Surgery

Eastern Virginia Medical School

Norfolk, Virginia

aliecuf@evms.edu

Disclosures: None.

### Jean M. Panneton, MD, FRCSC, FACS

Professor of Surgery

Chief and Program Director

Division of Vascular Surgery

Eastern Virginia Medical School

Norfolk, Virginia

pannetjm@evms.edu

Disclosures: Consultant to Gore & Associates, research investigator, and honorary speaker.

# Treating a Long Chronic Total Occlusion in a Patient With CLI

A personalized treatment approach to a challenging case.

BY ERIK WEEKMAN, BS; VINAYAK SUBRAMANIAN, BS; IVY SMITH, BS;  
AND GEORGE L. ADAMS, MD, MHS, FACC, FSCAI

Critical limb ischemia (CLI) is associated with very high morbidity and mortality and is caused by inadequate arterial blood flow to the extremities. CLI is often associated with complex atherosclerotic disease including long chronic total occlusions (CTOs). Treating CTOs is technically challenging due to a variety of proximal and distal cap configurations and mixed lesion morphology.<sup>1,2</sup> These lesions are often long and cross multiple vascular beds. The following case presented such a challenge; a personalized approach is described for access, crossing, and treatment to provide the best outcome for this patient.

## CASE PRESENTATION

A 64-year-old woman with a history of hypertension, dyslipidemia, stroke, diabetes, and peripheral artery disease

(a stent had previously been placed in the distal left superficial femoral artery [SFA]) presented with nonhealing wounds of the plantar aspect of the left lower extremity.

Angiographically, the patient did not have significant disease in the distal aorta, bilateral iliac arteries, or common femoral artery (CFA) systems. In the left lower extremity, the SFA was occluded at its ostium and reconstituted at the proximal peroneal artery (Figure 1). This was the sole vessel to the foot; it reconstituted the posterior tibial artery at the ankle and supplied the plantar region of the foot, where the wounds resided.

## INTERVENTION

A 6-F, 45-cm sheath was placed to the level of the left CFA from a contralateral retrograde CFA access. The proximal cap of the left SFA CTO was probed with an 18-g CTO wire but was unsuccessful in entering the proximal segment of the SFA. Therefore, direct angiographic access of the left popliteal stent was performed with an 18-gauge needle and a stiff TERUMO GLIDEWIRE® Guidewire (Figure 2A). The stiff TERUMO GLIDEWIRE Guidewire was supported with an 0.035-inch TERUMO NAVICROSS® Support Catheter and the CTO was successfully crossed within the true lumen and into the left CFA. An angled COOK® CXI® Support Catheter was then placed into the left CFA from the 6-F sheath, and the retrograde stiff TERUMO GLIDEWIRE Guidewire was exchanged for an 0.014-inch, 18-g-tip load COOK® APPROACH® CTO Microwire Guide. The wire was then maneuvered into the COOK CXI Support Catheter and externalized in a flossing fashion (Figure 2B). Laser atherectomy was then performed with a 2-mm SPECTRANETICS® TURBO-ELITE Laser Atherectomy Catheter at 50/40 rate/fluency and 60/60 rate/fluency from the ostium of the left SFA to the mid aspect of the distal SFA stent. Because this was restenotic plaque, there was high suspicion for the presence of thrombus in the plaque. Laser atherectomy was the preferred modality for treatment in this case due

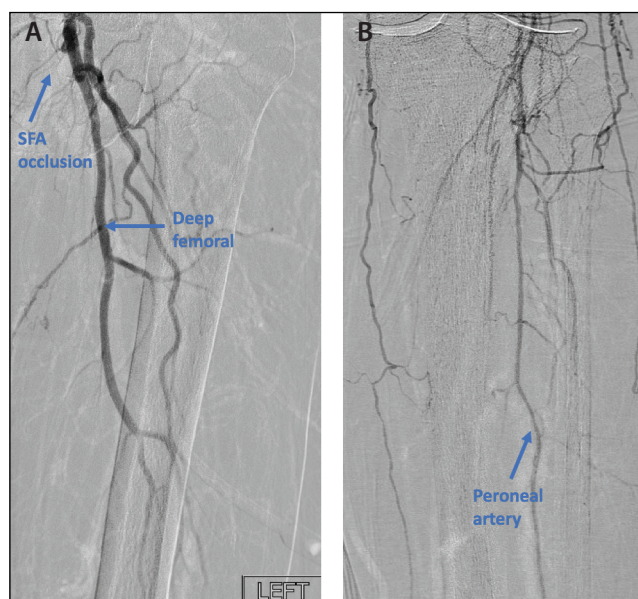


Figure 1. Flush occlusion of the SFA (A). Distal reconstitution of the peroneal artery (B).



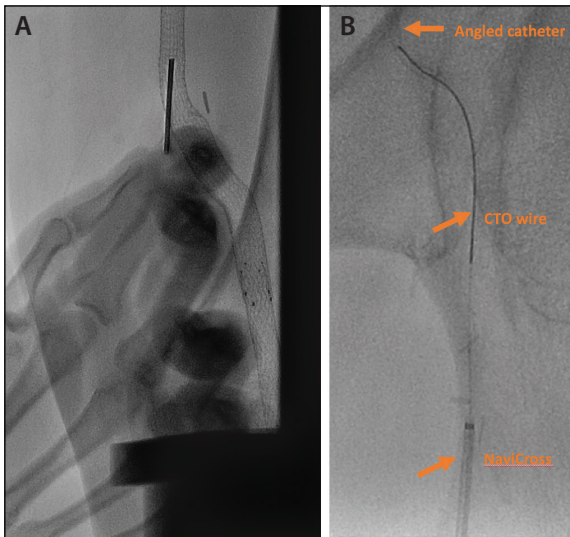


Figure 2. Angiography-guided (RAO 30°) access of the prior stent in the left SFA (A). Retrograde TERUMO GLIDEWIRE® Guidewire guided into angled COOK® CXI® Support Catheter to "floss" and externalize retrograde wire through the contralateral CFA access site (B).

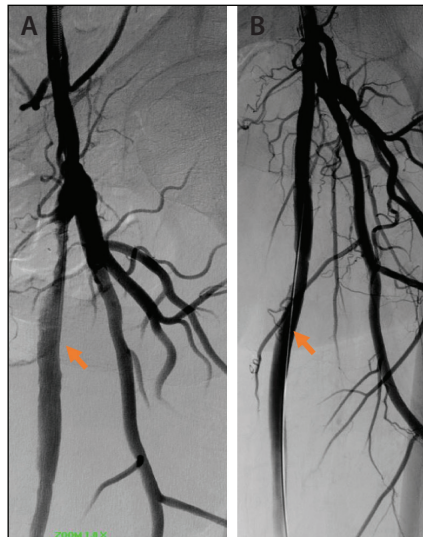


Figure 3. Preintervention SFA, homogenous plaque noted in the vessel (A). Postintervention SFA after placement of GORE® VIABAHN® Endoprosthesis (B). Soft plaque is successfully trapped by the stent.

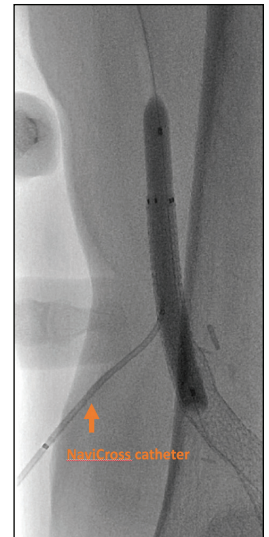


Figure 4. Internal tamponade of retrograde access site.

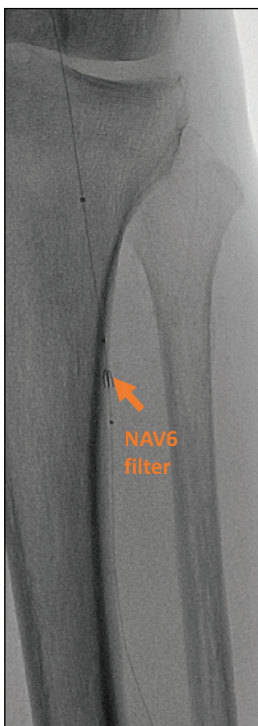


Figure 5. ABBOTT® EMBOSHIELD NAV6 Embolic Protection System deployed in the distal peroneal prior to protect sole outflow vessel.

to its indication for use with in-stent restenotic plaque.<sup>3</sup> This was followed by percutaneous transluminal angioplasty (PTA) of the SFA with a 4- X 200-mm balloon. On angiography, it was obvious that a large amount of thrombus was present at the ostium of the left SFA, so a 6- X 50-mm GORE® VIABAHN® Endoprosthesis was placed to prevent shifting of plaque to the lower extremity. The GORE VIABAHN Endoprosthesis was also used to ensure the stent was accurately placed in the SFA and prevent blocking the deep femoral profunda artery (Figure 3). This stent successfully trapped the thrombus and resulted in < 10% residual stenosis of the vessel. A second wire, an 18-g BOSTON SCIENTIFIC® VICTORY Guidewire, was then extended past the retrograde access site and internal tamponade was performed with a 6- X 40-mm balloon

for 3 minutes as the TERUMO NAVICROSS Support Catheter was removed from the distal SFA stent (Figure 4).

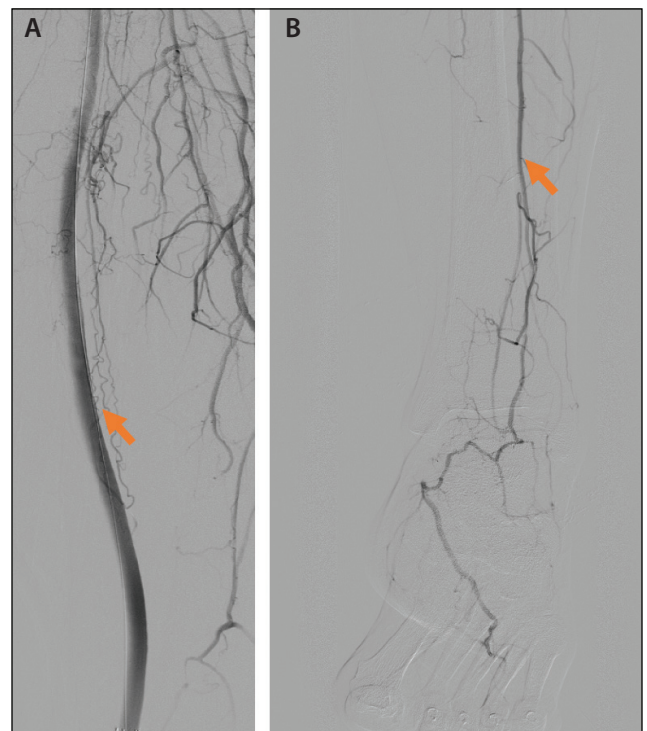


Figure 6. Postintervention. Revascularized distal SFA—popliteal (A). Direct inline flow to distal vascular bed from the peroneal artery (B).

The popliteal and tibioperoneal trunk occlusion was then crossed with the BOSTON SCIENTIFIC VICTORY Guidewire and exchanged for an 0.017/0.014-inch CSI® VIPERWIRE Advance-CSI-Diamondback-Guide-Wire, and a small ABBOTT® EMBOSHIELD NAV6 Embolic Protection Device was placed in the peroneal artery (Figure 5). The filter was placed to protect the sole vessel to the distal extremity and reduce the risk of distal embolization. PTA was performed with a 4- X 200-mm balloon. The filter was then removed. The intervention ultimately led to direct inline flow to the distal vascular bed (Figure 6).

## DISCUSSION

CLI is a complex disease and treatment remains technically challenging. There have been significant technical advancements in the treatment of complex peripheral artery disease, and care must be individualized to meet the patient's specific needs. The case described in this article illustrates the importance of understanding principles of access, crossing, and treatment and applying advanced techniques such as direct stent access to improve the chances of technical success. Furthermore, CTOs are a challenging entity and require an understanding of advanced crossing techniques such as retrograde crossing and flossing techniques. CTOs often have complex plaque morphology and are characterized by both homogenous and calcific plaque. In addition, in-stent restenotic disease is associated with the presence of thrombus, and the proper use of laser atherectomy to modify and treat the plaque is essential. Finally, it is important to realize that the distal lower extremity was only being perfused by one vessel, and protecting the vessel by trapping soft plaque with a covered stent and placing a filter is an important measure to prevent distal embolization and further complicating an already challenging case.

Ultimately, technical success in the treatment of complex peripheral artery disease is influenced by three tenants: (1) the skill and knowledge of the

interventionalist, (2) patience during the case, and (3) the nuanced use of the tools available to overcome the many challenges commonly encountered in the treatment of CLI. ■

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### Erik Weekman, BS

North Carolina State University  
Raleigh, North Carolina

*Disclosures: None.*

### Vinayak Subramanian, BS

UNC School of Medicine  
Chapel Hill, North Carolina

*Disclosures: None.*

### Ivy Smith, BS

UNC REX Healthcare  
Raleigh, North Carolina  
ivy.smith@unchealth.unc.edu

*Disclosures: None.*

### George L. Adams, MD, MHS, FACC, FSCAI

Associate Professor  
UNC School of Medicine  
Chapel Hill, North Carolina  
Director  
Cardiovascular and Peripheral Vascular Research  
UNC REX Healthcare  
Raleigh, North Carolina

*Disclosures: Consultant to Gore & Associates; Spectranetics, a Philips Company; and Cook Medical.*



# Treatment Challenges for Femoropopliteal Lesions

Discussion on managing complex peripheral artery disease, particularly in the femoropopliteal region, and a relevant case study to highlight specific challenges.

WITH M. CASEY BECKER, MD, FACC, FSCAI, FSVM



## TREATMENT APPROACH

**With the complexities associated with peripheral artery disease (PAD), there is not an agreed upon modern-day treatment algorithm. Given the multitude of PAD treatment options available, how do you make sense of it all?**

**Dr. Becker:** It is very important to factor in individual patient characteristics, both anatomic as well as clinical, when deciding the appropriate intervention to perform. I remain very committed to data-driven intervention, and I think that each year we gain more evidence supporting our interventions. Despite that, there is still great latitude in decision-making and gaps in evidence for a specific approach. Knowledge of the data and experience with multiple device techniques is paramount to tailor the therapy to a specific patient. Although it may be tempting to apply drug-coated balloon (DCB) technology to all my patients, that is clearly not feasible and is not data driven. In light of the recent meta-analysis by Katsanos et al that suggests higher mortality with paclitaxel therapies,<sup>1</sup> I am revamping my approach to these devices even more. It would be inappropriate to apply a certain standard size and type in most patients. A complete understanding of what the evidence shows and what it has failed to show, harmonized with good clinical experience and your own ability is key to patient care.

## What does your algorithm look like when treating PAD?

**Dr. Becker:** Assuming that the least-invasive approach provides the patient with the highest chance of freedom from adverse events and the lowest risk, then I typically allow the lesion and anatomy to drive my PAD treatment algorithm. Therefore, after diagnostic imaging, the patient's anatomy often dictates the best approach. For instance, short- to moderate-length lesions with low to moderate complexity are probably successfully

treated with DCBs. However, as the lesion complexity increases, that probability drops linearly. It is at this point we need to convert our thinking toward the best stent technologies, where we actually have a wealth of data to help guide the proper device and placement technique. When it comes to the femoropopliteal location, vascular mimetic technology like the GORE® TIGRIS® Vascular Stent has become my primary choice due to the resistance of the forces on elongation, extension, torsion, and compression, as well as fracture resistance.

## There has been a lot of discussion around the “leave-nothing-behind” approach over the last few years. In what clinical situations is this approach not necessarily enough?

**Dr. Becker:** An ideal situation is one in which we can apply DCB therapy and leave nothing behind. However, as we have clearly seen over the past couple of years, and with more data emerging at every meeting, the more complex lesions tend to have a higher rate of bailout stenting. Furthermore, most operators have become rather adept at assessing a lesion and its anatomy and deciding when it is reasonably futile to attempt DCB as a standalone therapy. It is in these situations, which are very common in clinical practice, that stent technology remains the primary endovascular tool. Then the question becomes: which stent performs best in this lesion subset and anatomic location? The GORE TIGRIS Vascular Stent delivers precise placement and expansion with optimal deployment in very challenging femoral popliteal lesions with excellent safety and efficacy data.

## What unique challenges does treatment of a proximal popliteal lesion present?

**Dr. Becker:** The femoropopliteal segment remains the most hostile arterial bed in the body. Much biomedical engineering work has gone into characterizing the multiple reasons that this area has a high rate of arterial sclerosis

and still remains quite hostile to endovascular therapy. The variation in sheer stress at this location combined with the extreme degrees of flexion, elongation, and tortuosity lead to a high degree of calcific arterial sclerosis. These factors make placement of most bare-metal stents (BMSs) extraordinarily challenging, which has been seen in multiple meta-analyses of trials involving BMSs at this location.<sup>2</sup> The GORE TIGRIS Vascular Stent, however, was purpose-built to hold up in this environment and has demonstrated fewer fractures than any other commercially available device out there. It is also noted that the GORE TIGRIS Vascular Stent showed no elongation and zero stent fractures with excellent safety and efficacy in this particular zone.<sup>3</sup>

## DEVICE SELECTION

### When you decide to stent, how do you choose which device to use?

**Dr. Becker:** If I am unable to perform successful DCB angioplasty (which may be a decision I make prior to or after dissection, and/or if recoil mandates it), I look to the lesion characteristics and pathology to help me select the proper prosthesis. Very short focal dissections or areas of recoil can usually be easily treated with implantation of a short BMS. Likewise, DCBs have great application here. However, as you approach the distal third of the superficial femoral artery (SFA) and enter the popliteal artery, data become more limited. What we know for sure is that traditional self-expanding BMSs have a very high rate of failure; so much so, that it has been rather taboo to revascularize the popliteal artery in that fashion. However, with the advent of vascular mimetic technology like the GORE TIGRIS Vascular Stent, we have shown that this is now a very successful strategy. When properly applying to the proximal popliteal, we have two vascular mimetic implant (VMI) technologies in the United States to utilize at this location: the GORE TIGRIS Vascular Stent and the ABBOTT® SUPERA® Peripheral Stent System. The strong advantage of the GORE TIGRIS Vascular Stent is that it is extremely simple to deploy, its size, and there is no elongation or compression. Many operators find deploying the ABBOTT SUPERA Peripheral Stent System in this location intimidating or are concerned about the stent elongation, which has the potential to impact the patency rates.

### Do your device considerations change when you are treating more complex lesions?

**Dr. Becker:** With regard to the SFA, it remains very clear that long, complex, occluded, and calcified lesions have poor long-term patency rates with BMSs. Even though we have seen better progress with drug-eluting stents and DCBs, there remains a high degree of bailout stenting and/or prosthesis failure in these most complex of lesions. In

this lesion subset, the GORE® VIABAHN® Endoprosthesis continues to demonstrate excellent results and safety.<sup>4,5</sup>

Therefore, when I approach a moderate to complex lesion, if I deem it not feasible to treat with DCB technology or I have the need for bailout stenting afterward, the GORE VIABAHN Endoprosthesis remains my first choice to revascularize these lesions. The robust dataset behind the stent as well as my personal clinical experience gives me great confidence in that strategy.

## CASE REPORT

An 82-year-old Caucasian male with claudication was referred to our service by his primary care provider due to nonhealing wounds involving the first three digits of his right foot. Further review of his medical history showed long-standing diabetes mellitus treated with insulin therapy, hypertension, hyperlipidemia, and coronary artery disease with two previous stent implantations. Although it was reported that the patient had stable claudication symptoms at 75 feet of ambulation, 7 weeks prior to presentation, the patient noted the eruption of ulceration on the aforementioned digits. At that time, the patient had been initiated on statin therapy, 325 mg of aspirin, and 50 mg of cilostazol twice daily. Despite referral to his local wound care clinic, the patient's lesions continued to progress, and he was referred to specialty care.

Initial clinical inspection revealed clear evidence of arterial insufficiency involving digits one through three on the right foot. Femoral pulses were 2+ bilaterally; however, the popliteal pulse on the right was markedly diminished. Ankle-brachial indices (ABI) were 0.51 on the right (anterior tibialis) and 0.72 on the left. Pulse volume recordings showed markedly diminished amplitude and blunting of the waveforms at the level of the right anterior tibialis. Given the patient's elevated creatinine at 2.13 mg/dL, it was decided to proceed to diagnostic aortography with lower extremity runoff and forgo CT angiography.

**“WHEN I APPROACH A MODERATE TO COMPLEX LESION, IF I DEEM IT NOT FEASIBLE TO TREAT WITH DCB TECHNOLOGY OR I HAVE THE NEED FOR BAILOUT STENTING AFTERWORD, THE GORE VIABAHN ENDOPROSTHESIS REMAINS MY FIRST CHOICE TO REVASCULARIZE THESE LESIONS.”**



Figure 1. Severe TASC-D lesion of the distal SFA extending into the P2 segment.

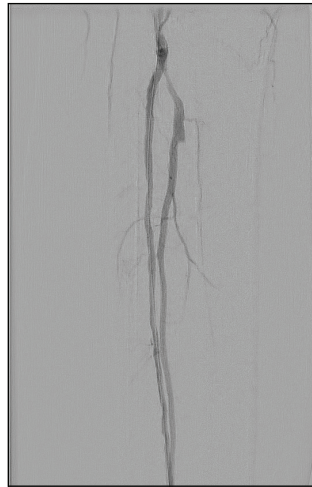


Figure 2. Two-vessel tibial runoff noted after reconstituting the artery.



Figure 3. Result after laser atherectomy with a 2-mm SPECTRANETICS® TURBO-ELITE Laser Atherectomy Catheter.

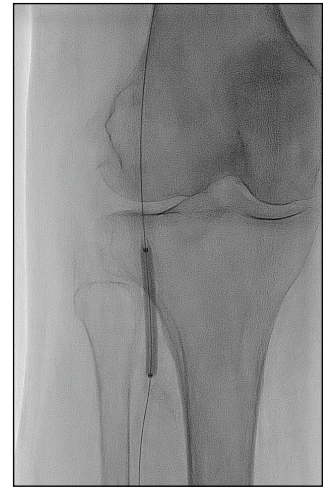


Figure 4. DCB therapy to the distal popliteal and tibioperoneal trunk.

Angiography revealed severe diffuse disease involving the distal third of the SFA becoming a total occlusion at the P1 segment of the popliteal artery (Figure 1). Reconstitution via genicular collaterals at the level of the distal tibioperoneal trunk was evident. The anterior tibialis had moderate diffuse disease, the peroneal artery was unaffected, and the posterior tibialis was totally occluded (Figure 2). A 6- X 45-cm destination sheath was taken across to the right common femoral artery. Unfractionated heparin was given to achieve an activated clotting time > 250 seconds. An ABBOTT® TREK® Coronary Balloon System and a TERUMO® GLIDEWIRE® ADVANTAGE Guidewire were used to navigate to the level of occlusion in the distal SFA.

At this point, a 0.035-inch SPECTRANETICS® QUICK-CROSS Support Catheter was used to support a 0.014-inch ABBOTT® HI-TORQUE COMMAND Peripheral Guidewire to traverse the occlusion through small micro channels that were evident. Achieving luminal purchase in the anterior tibialis, an exchange was made for an 0.014-inch VASCULAR PERSPECTIVES ASAHI Grand Slam Guidewire and laser atherectomy was performed with a 2-mm SPECTRANETICS® TURBO-ELITE Laser Atherectomy Catheter at 40/25 fluency/rate; a second pass was made at 60/60 fluency/rate (Figure 3).

Vessel predilatation was performed with a 5- X 100-mm SPECTRANETICS® ANGIOSCUPLT® PTA Scoring Balloon Catheter achieving full expansion at 12 ATM for 90 seconds. The P2-3 segment was then treated with a 5- X 80-mm SPECTRANETICS® STELLAREX Drug-Coated Angioplasty Balloon to 12 ATM for 2 minutes (Figure 4).

Following this, angiography confirmed an area of

dissection and acute recoil in the P1 and P2 segments of the popliteal artery (Figure 5). Therefore, it was deemed unlikely that the DCB result would yield satisfactory long-term results and, therefore, endovascular scaffolding with a prosthesis was deemed appropriate. Given the femoropopliteal location, VMIs provide the best option. An intravascular ultrasound (IVUS) probe was passed throughout the length of the lesion and the distal reference vessel diameter was deemed to be 5 mm. Therefore, a 5- X 100-mm GORE TIGRIS Vascular Stent was implanted from the distal P2 segment into the distal SFA across the adductor hiatus (Figure 6). Postdilation



Figure 5. Predilatation shows extensive dissection, making successful DCB treatment unlikely.

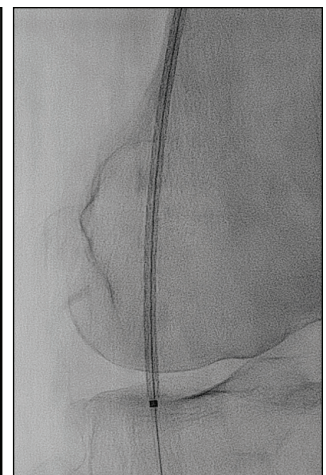
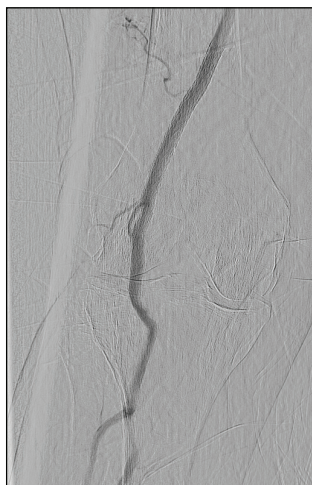


Figure 6. Precision placement of the GORE® TIGRIS® Vascular Stent to the P2 segment and across the adductor hiatus.





**Figure 7. GORE® TIGRIS® Vascular Stent precisely deployed across the adductor hiatus without any elongation or fore shortening.**



**Figure 8. Active flexion of the knee joint shows resistance to kinking.**



**Figure 9. Improved two-vessel tibial runoff at case completion.**

stress, which predispose to atherosclerosis and restenosis.<sup>6</sup> Fracture of nitinol self-expanding BMSs is commonplace in this location, resulting in poor patency rates of 55% to 65% after 1 year, thereby limiting their efficacy in this position.<sup>7,8</sup> VMIs, unique in their design and ability to conform to the vessel through highly malleable nitinol configuration, are better equipped to resist the flexion, extension, compression, and torsion of the femoropopliteal segment.<sup>9</sup> Not surprisingly, this translates to improved patency rates, freedom from

was gently performed with a 5- X 100-mm ABBOTT TREK Coronary Balloon System. Final angiographic imaging showed excellent stent placement and expansion (Figure 7). Active flexation of the joint showed the stent to flex and rotate mimicking the natural arterial anatomy (Figure 8). Excellent tibial outflow to the angiosome of the import was confirmed (Figure 9). The patient was administered 300 mg of clopidogrel and continued on 81 mg of aspirin. Three-month follow-up in the wound clinic revealed an ABl of 0.91 (anterior tibialis) and total resolution of the ischemic lesions.

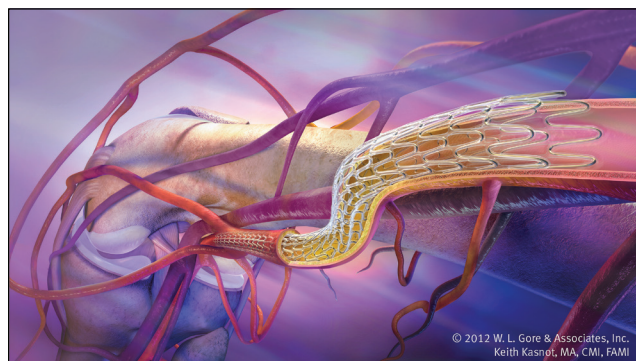
## DISCUSSION

The femoropopliteal arterial expanse has long posed a challenge for endovascular therapies. The notable presence of vessel tortuosity and curvature results in nonlaminar flow, mechanical strain, and a high variation in shear

fracture, and better long-term outcomes.

In the current United States marketplace, two VMIs predominate: the GORE TIGRIS Vascular Stent and ABBOTT SUPERA Peripheral Stent System. The GORE TIGRIS Vascular Stent utilizes two components: nitinol stent rings that are coated with expanded polytetrafluoroethylene and a fluoropolymer interconnecting structure with a heparin bioactive surface (Figure 10). The GORE TIGRIS Vascular Stent is designed to conform to the anatomy and allow vessel movement, minimize fracture risk, and permit axial compression while resisting stent elongation. Results of studies evaluating the GORE TIGRIS Vascular Stent in diverse populations show 90% freedom from target lesion revascularization (TLR) at 12 months in shorter lesions,<sup>10</sup> and 86% freedom from TLR at 12 months in a more high-risk population.<sup>11</sup> Despite complex lesion characteristics, the GORE TIGRIS Vascular Stent group had zero fractures at 3 years and no stent elongation as compared with the nitinol self-expanding BMS group, where fracture was documented in 28.8% of cases.<sup>3,12</sup>

Recent data from the SUPERB trial shows that at 2 and 3 years, freedom from clinically drive (CD)-TLR was 86.7% for minimal compression and 90.0% for moderate compression, respectively. In those stents deployed with minimal (10%–20%), moderate (20%–40%), or severe elongation (> 40%), freedom from CD-TLR was 84.1%, 87.4%, and 77.0% at 12 months, respectively. At 2 and 3 years, for those stents that had severe elongation freedom from CD-TLR was 63.4% and 42.3%, respectively. It is notable that only 36% of stents were able to be deployed



**Figure 10. GORE® TIGRIS® Vascular Stent.**

within the nominal range.<sup>13,14</sup> Therefore, although both prostheses offer excellent safety and efficacy, the GORE TIGRIS Vascular Stent and its ease of use often garners it more favor in my clinical practice.

In regard to the patient case described, the operator is faced with a complex lesion of the femoropopliteal region and must choose the best therapy. After crossing the lesion and performing diligent vessel preparation, it became clear that treatment with DCB would have a high likelihood of failure due to acute recoil and dissection—observed in upwards of 30% of TransAtlantic InterSociety Consensus (TASC) C-D lesions in this region.<sup>15</sup> Therefore, selecting the most appropriate stent becomes paramount for long-term success. Clinical trials of VMIs have demonstrated high patency and low fracture rates, making them ideal for this scenario. Furthermore, utilizing IVUS to properly size the prosthesis and precisely cover all diseased segments may also lead to better clinical outcomes.<sup>16</sup> Due to the implementation of innovative technology and improved operator experience, utilization of endovascular therapies as a first-line approach continues to rise in complex TASC C-D lesions of the SFA and popliteal arteries. A strong command of the clinical data and proper implant techniques associated with these devices is paramount.

## CONCLUSION

The femoropopliteal region remains one of the most hostile vascular environments and presents unique challenges to endovascular therapy. It is important to have familiarity with contemporary VMI technology and proper implant techniques to optimize clinical outcome in this region. As demonstrated by this case, careful and rigorous endovascular technique complimented by IVUS-guided deployment of the GORE TIGRIS Vascular Stent achieved excellent results. ■

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### M. Casey Becker, MD, FACC, FSCAI, FSVM

Peripheral, Structural, and Coronary Interventional Therapies Division

Saint Vincent Heart and Vascular Institute

President and Founder

Panvascular Consulting LLC

Erie, Pennsylvania

*Disclosures: Consultant to Gore & Associates.*

# Aortoiliac Occlusion in a Patient With Severe Claudication

Management with covered balloon-expandable stents provides another option for complex disease.

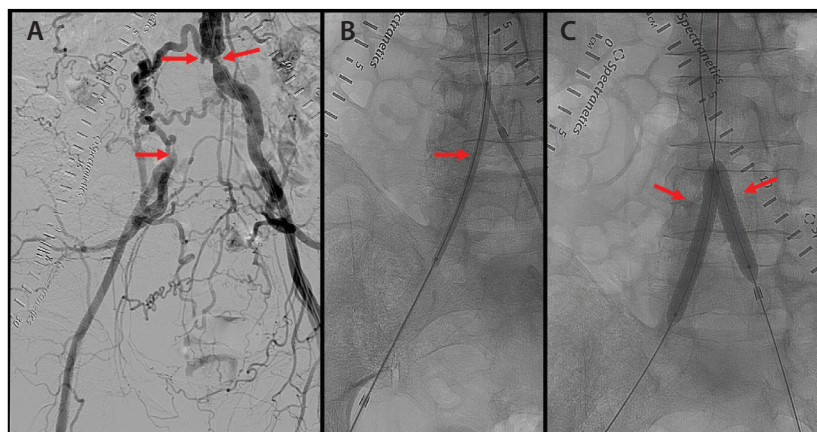
BY EHRIN J. ARMSTRONG, MD, MSc

**A** 64-year-old man with a past medical history of coronary artery disease and prior smoking presented with severe bilateral lower extremity claudication on exertion. Ankle-brachial indices (ABIs) demonstrated a right ABI of 0.75 and a left ABI of 0.85. The patient was initially treated with a walking program and optimal medical therapy, but he continued to experience severe lifestyle-limiting claudication. Therefore, he was referred for lower extremity angiography and possible endovascular intervention.

## TREATMENT

Aortoiliac angiography (Figure 1A) demonstrated a small- to moderate-caliber aorta with a focal 70% to 80% stenosis at the origin of the left common iliac artery and an occlusion of the right common iliac artery just after its origin. The distal right common iliac artery reconstituted just above the level of the right internal iliac artery. The ongoing bilateral external iliac and common femoral arteries were relatively free of disease and the patient did not have any obstructive infrainguinal disease.

The decision was made to proceed with endovascular repair of the iliac arteries. Bilateral 7-F sheaths were placed in the common femoral arteries under ultrasound guidance. The right common iliac artery occlusion was crossed from a retrograde approach with a straight stiff TERUMO GLIDEWIRE® Guidewire and the occlusion was then predilated with a 4-mm balloon (Figure 1B). A 7- X 59-mm GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Stent Graft) was deployed in the right common iliac artery and a 7- X 39-mm VBX Stent

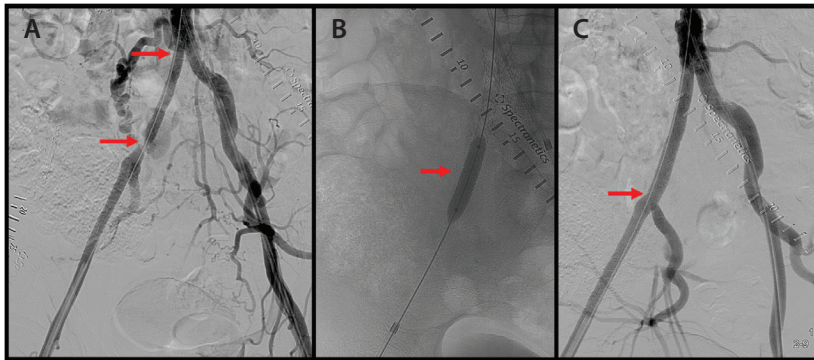


**Figure 1.** Baseline angiography revealed a small-caliber aorta with an occluded right common iliac artery (left arrows) and a high-grade stenosis of the left common iliac artery at its origin (right arrow). The ongoing external iliac arteries and bilateral internal iliac arteries were patent (A). The right common iliac artery occlusion was successfully crossed and then predilated with a 4-mm balloon (arrow) (B). After predilation, a 7- X 59-mm GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Stent Graft) was deployed to the right common iliac artery, and a 7- X 39-mm VBX Stent Graft was deployed to the left common iliac artery (arrows) (C).

Graft was deployed to the stenosis at the origin of the left common iliac artery (Figure 1C). These stents were simultaneously postdilated to 9 mm.

After stent deployment in the bilateral common iliac arteries, a residual stenosis remained in the distal right common iliac artery just proximal to the origin of the right internal iliac artery (Figure 2A). Therefore, an additional 7- X 29-mm VBX Stent Graft was deployed at nominal pressure and then postdilated to 9 mm in the right common iliac artery, while taking care to ensure that this stent did not impinge on the origin of the right internal iliac artery (Figure 2B). Final angiography revealed excellent stent expansion and no residual stenosis (Figure 2C). Bilateral ABBOTT® PERCLOUSE PROGLIDE®





**Figure 2.** After initial stent deployment, there was excellent stent expansion in the bilateral common iliac arteries, but a residual stenosis at the distal right common iliac artery near the origin of the right internal iliac artery (arrows) (A). A 7-X 29-mm VBX Stent Graft was deployed (arrow), while taking care to not occlude the internal iliac artery (B). Final angiography revealed excellent stent expansion and flow throughout the iliac arteries (C).

Suture-Mediated Closure Systems were deployed for hemostasis, and the patient was discharged home later the same day on a regimen including aspirin at 81 mg daily and clopidogrel at 75 mg daily. At 1-month follow-up, duplex ultrasound revealed patency of the common iliac arteries, and the patient reported that he did not experience any claudication and was now able to walk more than 2 miles per day.

## DISCUSSION

Covered balloon-expandable stents have a number of advantages in the treatment of complex aortoiliac disease. The randomized COBEST trial has demonstrated improved long-term patency of aortoiliac lesions when covered balloon-expandable stents are utilized instead of noncovered stents.<sup>1</sup> In the VBX FLEX Study, primary patency rates for the VBX Stent Graft were 96.9% at 9 months.<sup>2</sup> In addition, recently presented 24-month data on the VBX Stent Graft showed a 93.1% freedom from target lesion revascularization.<sup>3</sup>

Covered balloon-expandable stents have procedural advantages compared with noncovered stents. For example, the use of a covered stent can prevent any perforation that may occur during aortoiliac intervention.<sup>4</sup> Although perforation is a rare occurrence, it can be life threatening if not treated immediately. By using a covered stent in areas of high calcification or after subintimal crossing of an iliac chronic total occlusion, the likelihood of any significant perforation occurring is reduced or eliminated. Covered stents can also exclude plaque characteristics, including thrombus or calcification, that

may lead to embolization during a procedure. For all these reasons, covered balloon-expandable stents may be preferred for the treatment of complex aortoiliac lesions.

The VBX Stent Graft has a number of features that improve on previously available covered balloon-expandable stents, including an expanded size matrix, increased flexibility (data on file; W. L. Gore & Associates, Inc.; Flagstaff, AZ), and predictable deployment to the target lesion with excellent accuracy and minimal foreshortening.<sup>2</sup> In this case, the common iliac artery stents were deployed at 7 mm but were easily postdilated to 9 mm with no evidence of significant shortening. The residual stenosis in the distal right common iliac artery was also

easily treated with an additional VBX Stent Graft, which could be predictably deployed without altering flow to the right internal iliac artery. Both of these features of the VBX Stent Graft helped achieve an optimal procedural result, and the patient has done well during follow-up.

## CONCLUSION

Covered balloon-expandable stents have furthered the treatment options for patients with complex aortoiliac disease by providing improved patency and an optimal safety profile. As techniques continue to evolve, almost all patients with aortoiliac disease can be treated with endovascular techniques. ■

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### Ehrin J. Armstrong, MD, MSc

Associate Professor of Cardiology  
University of Colorado  
Aurora, Colorado  
ehrin.armstrong@gmail.com

*Disclosures: Consultant to Abbott; Boston Scientific Corporation; Cardiovascular Systems, Inc.; Gore & Associates; Medtronic; and Philips.*

# Best Practices for Lower Extremity Bypass

Surgical and endoluminal treatment considerations for femoropopliteal lesions.

WITH RUSSELL H. SAMSON, MD, FACS, RVT, DFSVS



## PATIENT CONSIDERATIONS

**What are the patient and case dynamics that you take into consideration when deciding whether to treat surgically or endovascularly for femoropopliteal lesions?**

I consider whether the patient is having a procedure for claudication or truly limb-threatening ischemia. For claudication, I will first try to do an endovascular procedure, assuming that the lesion is appropriate (< 25-cm long and ends at least 2 to 3 cm above the knee joint on angiography). I have not been happy with endovascular treatments of longer lesions, especially if they start at the origin of the superficial femoral artery. I am also somewhat suspect of an endovascular approach for heavily calcified lesions. However, if I have to cross the knee, I will perform an endovascular approach in extremely symptomatic patients who do not have an available saphenous vein with the proviso that there is at least some popliteal artery to land the distal end of the stent. The patient also must understand the downsides of an intervention for claudication and the potentially limb-threatening complications.

For most patients with moderate claudication and long, heavily calcified lesions or those extending to the knee joint, I will either try to convince the patient to follow a noninterventional approach or, if directed by a fully informed patient, I will do above-the-knee bypass.

For patients with limb-threatening ischemia, the dominant factors that I take into account—other than the lesion I am treating—are how quickly I need to restore adequate blood flow, the status of the saphenous vein, and the patient's long-term life expectancy. If the patient can tolerate a bypass operation and has poor runoff (eg, an isolated popliteal), I am more likely to go directly to bypass using saphenous vein.

In the majority of cases, however, the above-the-knee popliteal bypass will be with a GORE®

PROPATEN® Vascular Graft based on our data showing patency rates that are superior to standard expanded polytetrafluoroethylene (ePTFE).<sup>1</sup> However, in young, healthy patients who require a bypass, I am more likely to use saphenous vein because our data have shown inferior results in individuals under 60 years of age.

## How might the patient's treatment goals change your approach?

Under some circumstances, I will allow the patient to direct the type of treatment and even the choice of graft. For example, I recently had a patient who had extensive obligations that required him to be ambulatory after the procedure. He understood that there may only be a short-term treatment effect, but he was insistent on an endovascular treatment, which has fortunately worked well for this patient.

## As you know, there is often controversy around the idea of "saving a vein for later." Do you subscribe to this philosophy as it relates to above-the-knee bypass? In your opinion, when is this approach most appropriate for above-the-knee bypass cases?

I do believe in saving the saphenous vein for a future operation because the saphenous vein below the knee, especially to the tibial arteries, has superior patency rates compared to a prosthetic graft. In our practice, we use prosthetic grafts above the knee preferentially rather than the saphenous vein (except in younger patients and some of the scenarios outlined previously). Interestingly, we very rarely have had to perform a subsequent distal saphenous vein bypass. This may be explained by the more durable patency of heparin-bonded ePTFE. Further, heparin-bonded ePTFE above-the-knee grafts can be implanted quickly with just two small incisions, and patients return to normal activity more rapidly than those who have the saphenous vein as the conduit. This better suits their lifestyles.

**“SURVEILLANCE SAVES LEGS! OUR DATA HAVE PROVIDED US WITH CONFIDENCE THAT THE GORE PROPATEN VASCULAR GRAFT WILL PROVIDE GOOD 5-YEAR PRIMARY PATENCY APPROACHING 85%.<sup>1</sup>”**

### OUTCOMES AND FOLLOW-UP

#### **What are some of the key procedural best practices when using the GORE PROPATEN Vascular Graft to ensure optimal device performance?**

Preventing infection and wetting of the graft are key aspects of using the GORE PROPATEN Vascular Graft. Infection is controlled by applying BD® CHLORAPREP Applicator, a chlorhexidine gluconate and isopropyl alcohol solution, followed by wrapping the leg in 3M IOBAN Antimicrobial Incise Drape, thus preventing skin contamination. We use a SCANLAN® Vascular Tunneling System to prevent dragging the graft through tissue. Wetting occurs if the graft is filled with saline under pressure or if the proximal anastomosis is opened with the distal anastomosis still occluded. We also never infuse saline into the graft. We use 4-0 suture thread on a C1 needle, which decreases needle hole bleeding. We also routinely only use 15-mm arteriotomies and do not use vein patches for above-the-knee grafts.

#### **What is your approach to patient follow-up as it relates to dual antiplatelet therapy and surveillance?**

All patients are placed on 75 mg of clopidogrel for

life. We do not object to aspirin as well, but we do not routinely prescribe dual antiplatelet agents. Data suggest that vein bypasses would have prolonged patency if placed on warfarin, but we do not use warfarin or novel anticoagulants; we use clopidogrel for vein grafts as well. There is no science to support this, but it may also reduce cardiac complications. All patients are maintained on a statin. New data from the COMPASS trial suggest that perhaps we should be using low-dose rivaroxaban to decrease mortality and amputation, but I am awaiting further confirmation.<sup>2</sup>

We perform duplex ultrasound scans and measure ankle-brachial index (ABI) at 1, 3, and 6 months. ABI is measured every 6 months thereafter, with duplex ultrasound evaluation if we see evidence of stenosis in any part of the inflow, graft, or outflow. Although some insurers will not pay for such duplex ultrasound scans, we will do them at no charge if necessary. Surveillance saves legs! Our data have provided us with confidence that the GORE PROPATEN Vascular Graft will provide good 5-year primary patency approaching 85%.<sup>1</sup> ■

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#### **Russell H. Samson, MD, FACS, RVT, DFSVS**

Sarasota Vascular Specialists

Sarasota, Florida

Clinical Professor of Surgery (Vascular)

Florida State University Medical School

Tallahassee, Florida

rsamson@veinsandarteries.com

*Disclosures: Received financial compensation for this manuscript from Gore & Associates.*



# Stenting Lesions in Distal Anatomy

Perspective on a modern-day treatment algorithm.

WITH MARTIN WERNER, MD



## How would you define the modern clinical treatment algorithm for popliteal disease?

In the last few years, drug-coated balloons (DCBs) have changed how we treat popliteal lesions and a leave-nothing-behind treatment approach has evolved. I, along with many physicians, tend to use fewer stents. I try to avoid full-metal jackets and full-lesion covers with stents, and I only use stents in certain situations. However, we have learned from DCB trials, randomized trials, and other registries that there are always patients who need mechanical stabilization. This is the main disadvantage of DCBs. They do not give you the mechanical stabilization you need, particularly in calcified or long lesions. Depending on lesion length, you may need stents even when working primarily with DCBs.

**“PREDILATION IS AN IMPORTANT PART OF OUR TREATMENT ALGORITHM. WE PREDILATE THE BALLOON FOR 60 SECONDS AND WE MEASURE THE BALLOON PRECISELY TO AT LEAST A RATIO OF 1:1 BALLOON-TO-VESSEL SIZING.”**

In our hospital, we first treat patients with standard balloon dilation to see how the vessel reacts. If the vessel opens up wide without dissections or recoil, we call this a *percutaneous transluminal angioplasty (PTA) responder*. The patient is then treated with DCBs. When a patient does not respond well to predilation, we call this a *PTA nonresponder* and will use a stent. In our daily practice, 80% of cases are PTA responders and around 20% are PTA nonresponders.

Predilation is an important part of our treatment algorithm. We predilate the balloon for 60 seconds and we measure the balloon precisely to at least a ratio of 1:1 balloon-to-vessel sizing. With this algorithm, we are able to define patients who need a stent and patients who will do well without one (Figure 1). Currently, there are no data on whether longer predilation time leads to less of a need for stenting, although my colleagues and I have found it to be true in our experience. From personal

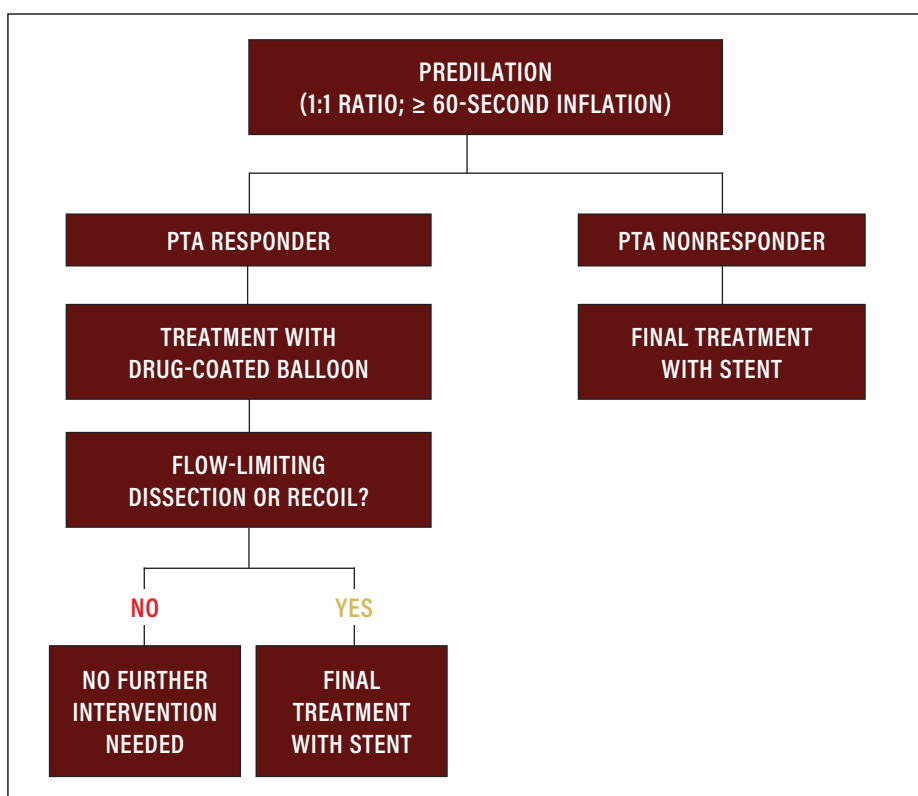


Figure 1. Treatment algorithm for lesions in the superficial femoral artery or popliteal artery.

experience, dilating for 10 seconds will not usually yield good results. The necessity of proper predilation is getting more attention in the scientific community and should be further scientifically investigated. Proper predilation is not only important before DCB treatment, but also before stent placement in order to achieve proper stent apposition of self-expanding stents in the superficial femoral artery (SFA).

### What factors led to your choice of the GORE® TIGRIS® Vascular Stent as your treatment method for popliteal disease?

Because of this stent's unique features, you can place the stent from the proximal SFA to the proximal segment of the popliteal artery, where there is a lot of vessel motion during leg movement. A few years ago, the popliteal artery was a "no stent zone." But with this modern generation of stents, you can cover those regions where previous-generation stents would have fractured. Our experience with the GORE TIGRIS Vascular Stent, as well as data from the GORE TIGRIS IDE Trial, show that there are no stent fractures with the GORE TIGRIS Vascular Stent in the femoropopliteal segment after 1 year.<sup>1</sup>

### What unique benefit does the GORE TIGRIS Vascular Stent provide as compared with other options?

The stent is not only composed of nitinol, but it also has expanded polytetrafluoroethylene interconnectors. This is unique to all the other competitors in that field, which are usually nitinol only. Another benefit is that, in our study, there were no device-related complications, no geographic misses, and no need to use a second stent in any of the patients.

### How did you structure the design of the Austrian TIGRIS Registry?

The GORE TIGRIS Vascular Stent has a maximum length of 10 cm, so we included patients who we were able to treat with one stent. Patients with lesions < 8 cm consented and were enrolled in the study if predilation did not show a good response. We enrolled 100 "PTA nonresponder" lesions in 97 patients and have 1-year follow-up available for all patients; 2-year follow-up is ongoing.

### What are the best practices necessary to achieve the outcomes you experienced?

First, always predilate, even when using a stent. Second, ensure that stents are appropriately sized. The GORE

TIGRIS Vascular Stent instructions for use recommends oversizing the stent just 5% to 20% relative to the artery. Analysis of the angiographic data shows that we accomplished that ratio. I have two techniques to ensure appropriate sizing. For the first technique, I use the balloon as a visual assessment. If I have a good impression from the balloon, that is enough for me to choose the stent size. If I am not sure, my second technique is to use quantitative measurements.

Third, confirm full-lesion coverage so there is no geographic miss or stent misplacement. The GORE TIGRIS Vascular Stent helped us achieve that because it does not jump forward or backward. It stays where you intend to deploy it. This feature makes it very easy to use.

### What were the most noteworthy conclusions from the study, for both physicians and patients?

We observed a 12-month primary patency rate of 92.9%. Freedom from target lesion revascularization at 12 months was 94.9%. Physicians should know this is a highly effective therapy for patients needing stenting in short lesions in the SFA or the popliteal artery—those segments that undergo a lot of motion. The few stents that had restenosis were easily treated, so secondary patency was 100% at 1 year. Hemodynamic and clinical improvement was evident for the vast majority of patients. The main message to take away from this study: If you need a stent in the SFA or popliteal artery, we have a very efficient and easy-to-use device right now.

Patients should know that there is no need to worry about stenting in the proximal popliteal artery. The GORE TIGRIS Vascular Stent is specifically intended for those flexible segments, so patients will be able to lead an active lifestyle. ■

1. Laird JR. Novel nitinol stent for long lesions in the superficial femoral artery and proximal popliteal artery: 24 month results from the TIGRIS Randomized Trial. Presented at VIVA 2016: Vascular Interventional Advances Conference; September 18-22, 2016; Las Vegas, NV.

#### Martin Werner, MD

Head of Department of Angiology  
University of Vienna  
Hanusch Hospital  
Vienna, Austria  
martin.werner@wgkk.at

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# A Physician Perspective on Collaborating With Your Hospital's Value Analysis Committee

Speaking with a physician leader at Atrium Health's Sanger Heart and Vascular Institute about advocating for physician device preferences and effectively communicating with key stakeholders.

WITH FRANK R. ARKO III, MD



## How has your organization changed in regard to decision-making as we move into the age of value-based care?

We are slowly moving into different reimbursement models for physicians, looking at quality outcomes as part of our way of paying them. Part of our pay structure involves value-based metrics. We look at our readmission rate on a yearly basis, and we try to put methods into place that will decrease that readmission rate. We also look at patient satisfaction with both our system and our physicians. Looking at these data, we are not afraid to make changes to make it fair for everyone involved.

Additionally, we have started to not just look at technologies at the time of implant; we also consider their indication and the potential long-term results. This helps us improve the quality of the procedure and long-term outcomes in order to decrease readmissions and secondary admissions.

## What role do physicians play in value analysis?

The value analysis committee works as a physician-administration dyad. From that team standpoint, we consider all available products. Within a 2-, 3-, or 4-year period, we'll go through a request for proposal (RFP) process with the varying manufacturers. As we sort through the data, we look at the quality of the data and the indication each device has for therapy and weigh out which devices need to be stocked. For instance, the RFP from one company that covers a broad range of devices may not include a stent that has indication for the popliteal artery, because they do not make one. In that case, we would include a device from another company that does have a popliteal artery stent. This goes to the

quality of patient care; we want to do what is right for the patient, and if we have information that says a stent has been studied for a particular indication we need, then we need to keep that stent.

Physicians need to be the advocates in situations like this because they are the most knowledgeable about disease processes and device indication. You need a physician who wants to be readily involved in that process. Oftentimes that is a nonpaying position, but it wields a lot of power and information that will allow you access to the devices and implants you need. If you abdicate full control of device selection to administrators, at some point, you will be told what you can and cannot use to treat your patients and lose the ability to care for them in the way you believe is best.

## What information does the committee usually expect from physicians?

The committee will ask physicians if one device is superior. When talking about plain old balloon angioplasty, as opposed to an antiproliferative or a stent, they will ask if one balloon is better than the others. At this point, there is not a significant difference in those types of commodities, so their selection is generally dictated by cost.

However, physician involvement becomes more important when you look at long-term implants. An administrator may not consider certain factors, like the risk of stent fractures. For instance, a company will offer a first- or second-generation product with known failures for half the price than other companies. The administrators may not know or understand the complete picture on that device. Does it have a high risk of target lesion revascularization or fractures? Does the device have a limited indication for a certain arterial bed? The committee may not understand how a device works, what is considered



on- and off-label use, or how to interpret performance rates over time. It is important for physicians to speak up and use the available published data and experiential knowledge they have to make a strong argument as to why the hospital needs to go with a device that is more expensive but adds value in the form of lower associated rates of readmission or better-quality care. The device may have some incremental price increases, but if it causes no adverse events, the hospital is increasing value. These details are the physicians' responsibility to advocate, and it is important to develop a relationship with those administrators so that they can understand it.

### **What are the best approaches for a successful collaboration between physicians and the committee?**

Administrators need to be open to increasing their knowledge of the clinical consequences of certain devices and tools. Fortunately, our institution's administrators are good at working with physicians because they know they don't have that clinical knowledge. That may not necessarily be true at every institution. Physicians need to look at the clinical data and information, but then also be able to put on a business management hat. Different devices come out and physicians want to utilize them because they are new and unique, but they may not necessarily offer any value or outcome improvement. We need to be honest about that and not bring in every new device. The industry also plays a role. They must understand that they need to bring the data and information that will help the committee make the best choices for all parties involved.

### **How do you manage diversity of opinion among physicians about which devices to bring in?**

I want every physician to feel that they can treat patients the way they want to. You can't say that someone with a certain disease must be treated one particular way every time. In doing so, approximately 20% of patients will receive the wrong therapy. Physicians need to work as a team and ask what the best management is for a disease process.

### **How do you assess the differences between higher- and lower-cost items and procedures?**

Ideally, the cost per procedure per physician should be a bell curve; most physicians are at the top of the bell curve, with some who are cheaper and some who are more expensive. An administrator might look at that and ask for everyone to shift to the methods of the lower-cost individual. However, the committee needs to evaluate why the difference occurs. A physician at the higher end of the

curve may have more complex cases, and a physician at the lower end of the curve may have simpler cases. The more expensive physician could be overusing devices and implants, or that physician could be the world expert in a specific procedure that demands higher costs.

With the administration, we ask what we can do to lower the cost of more expensive procedures. Renegotiation of device price with the manufacturer is one step, but at times we cannot, so there are other ways to reduce cost and improve diagnosis-related group reimbursement.

For example, we lowered our cost for endovascular aneurysm repair (EVAR) first by getting the device price to something very reasonable. Asking what else we could do to decrease costs, we started performing EVAR percutaneously with almost all patients. With this method, we can treat the patient and discharge them the next day. We had better results than if the patient stayed for 2 days, and they had less pain when treated percutaneously. The next step was to look at the other EVAR procedural costs. If every patient is asleep in the operating room, then we need an anesthesiologist, an arterial line, and a Foley catheter. Our new method shifts very straightforward patients out of the operating room and into the catheterization laboratory, which saves nearly \$5,000 per case. There are a multitude of ways to consider cost, but it is important to have physicians and administration working together to give the best value to the patient.

### **When it comes to product selection, how is it determined if a new product is essential to the quality of care for your patients?**

First, we need a physician champion for the product. Then we evaluate the product with a short trial period, asking if this is something we want to utilize, how it worked in previous cases, and if it performed significantly better than other devices. If the trial period is successful, it goes to the value analysis committee. It can be helpful to speak to individuals on that value analysis committee beforehand, so you can develop some champions on the committee. It's important to come to the committee with an understanding of how the product will improve quality and outcomes based on the data. We ask if it is a novel device; if it is, will it increase costs but replace the need for other products? That is the algorithm that we look at to bring in a new product.

If a manufacturer has a new product available in a lower French size, it's unreasonable to charge twice the amount of money for an incremental improvement in the device. If that is the case, we will probably keep what we have already, unless the manufacturer wants to replace the old device and charge the same price.

However, if a device costs more but the data suggest a marked improvement, it is not as simple. Physicians must explicitly explain to the administration how the data are significantly better and will benefit patients. Utilizing that data, the goal is to reach a compromise between administration, physicians, and industry to bring in the best device for the patient at a reasonable price.

### What resources are used and who is responsible for gathering and interpreting product selection information? How does your hospital score that kind of information?

There is not a scoring system, per se, but it is related to how well the physician can make the argument to the administration. The physician and the device manufacturer are responsible for gathering the information. Researching any data, registries, and trials is helpful. Data on decreasing mortality, interventions, and complications on the procedures will also aid us in making our argument. When going to the committee, I would suggest that physicians have all this research summarized, so they can look at and present the big bullet points. Any physician can initiate bringing in a product for the trial period, but it is helpful to have someone at that top level to team up with.

### What advice would you give physicians and hospital administration for navigating the value analysis process?

Physicians, especially young physicians, should understand product cost. The more vested interest they have in the quality and value of a procedure, the more they will understand the need to evaluate whether a product offers value and improved outcomes for a patient or if it is just another tool in the toolbox. The business side of medicine should be instituted earlier in a physician's training because there's often a void when it comes to financial implications. The amount the United States spends on health care is increasing, and physicians need to become knowledgeable about this. The only way to solve the problem is to have physicians directly involved.

Physicians should build a relationship with administration by continuously trying to reduce procedure costs. The stronger the working relationship is with the physician and the administration, the easier it will be to bring in a device they believe in. Transparency between physicians and administration is also important. An institution can tell how costly each physician is for a specific procedure. Sharing those data with physicians is helpful because they can see where they are on the bell curve. No one wants to be the outlier, but if they do not know they are the outlier, it is hard to change. This transparency can improve the quality of care for patients.

**“RESEARCHING ANY DATA, REGISTRIES, AND TRIALS IS HELPFUL. DATA ON DECREASING MORTALITY, INTERVENTIONS, AND COMPLICATIONS ON THE PROCEDURES WILL ALSO AID US IN MAKING OUR ARGUMENT.”**

Institutions do not share these data as often as they should. My institution tries to develop a team approach to managing and caring for a patient, so the administrators share that information with the physicians. I think this team approach between physicians and administration is a fantastic way to develop better health care to deliver to patients, both from a clinical and an economic standpoint, as it allows both sides of the institution to utilize their respective expertise. Similarly, an engineer developing a medical device doesn't necessarily understand all the clinical implications, and a physician developing a device doesn't necessarily understand all the engineering components involved. Together, however, they can create a product that is markedly better than anything created by either one on their own. I think the same is true for the deliverance of health care with physicians and hospital administration.

### How do you think value-based care will evolve in the next 5 to 10 years?

It's evolving daily, so it is hard to say, but I am supportive of it and believe there will be more of it. I also think physicians need to be involved in institutional decision-making to make sure that value-based care is implemented in the best possible way for maintaining the care of the patient. Physicians must be vocal advocates for their patients. ■

#### Frank R. Arko III, MD

Chief, Vascular and Endovascular Surgery

Professor, Cardiovascular Surgery

Co-Director, Aortic Institute

Sanger Heart and Vascular Institute

Atrium Health

Charlotte, North Carolina

frank.arko@carolinashealthcare.org

*Disclosures: Consultant to Gore & Associates, Medtronic, Penumbra, Philips, and Cook Medical; does research for Gore & Associates, Medtronic, Penumbra, Silk Road, and Cook Medical.*

### **GORE® PROPATEN® Vascular Graft**

**INDICATIONS FOR USE:** GORE® PROPATEN® Vascular Grafts are intended for use as vascular prostheses for replacement or bypass of diseased vessels in patients suffering occlusive or aneurysmal diseases, in trauma patients requiring vascular replacement, for dialysis access, or for other vascular procedures. **CONTRAINDICATIONS:** A. DO NOT use the GORE® PROPATEN® Vascular Graft in patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of Heparin-Induced Thrombocytopenia (HIT) type II. B. DO NOT use any configuration of GORE® PROPATEN® Vascular Grafts with Removable Rings, Non-Removable Rings or Integrated Rings for coronary artery bypass or cerebral reconstruction procedures. C. DO NOT use GORE® PROPATEN® Vascular Grafts as a patch. If cut and used as a patch, GORE® PROPATEN® Vascular Grafts may lack adequate transverse strength. Refer to Instructions for Use at [goremedical.com](http://goremedical.com) for a complete description of all contraindications, warnings, precautions, and adverse events. **R only.**

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**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](http://goremedical.com) for a complete description of all contraindications, warnings, precautions, and adverse events. **R only.**

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### **GORE® VIABAHN® Endoprosthesis**

**INDICATIONS FOR USE IN THE U.S.:** The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery de novo and restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0–7.5 mm, in superficial femoral artery in-stent restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0–6.5 mm, and in iliac artery lesions up to 80 mm in length with reference vessel diameters ranging from 4.0–12 mm. The GORE® VIABAHN® Endoprosthesis is also indicated for the treatment of stenosis or thrombotic occlusion at the venous anastomosis of synthetic arteriovenous (AV) access grafts. **CONTRAINDICATIONS:** The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is contraindicated for noncompliant 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. Do not use the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface in patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to Instructions for Use at [goremedical.com](http://goremedical.com) for a complete description of all warnings, precautions, and adverse events. **R only.**

**INDICATIONS FOR USE UNDER CE MARK:** The GORE® VIABAHN® Endoprosthesis is a flexible, self-expanding endoluminal prosthesis for endovascular grafting of peripheral arteries. The GORE® VIABAHN® Endoprosthesis is also indicated for improving blood flow in symptomatic obstructions of peripheral veins. **CONTRAINDICATIONS:** 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. Do not use the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface in patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to Instructions for Use at [goremedical.com](http://goremedical.com) for a complete description of all warnings, precautions, and adverse events. **R only.**

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\* CBAS Heparin Surface. W. L. Gore & Associates Web site. <https://www.goremedical.com/cbas/references>. Accessed January 9, 2019.

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