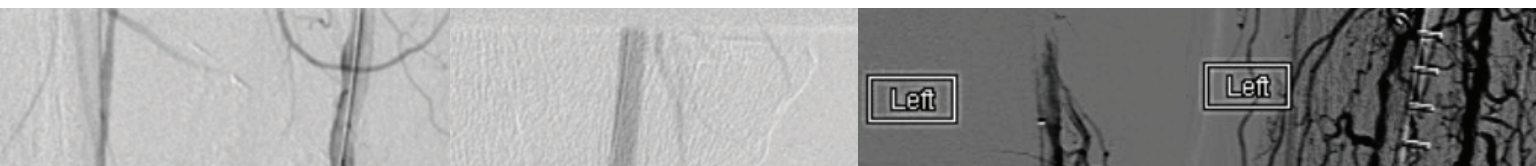


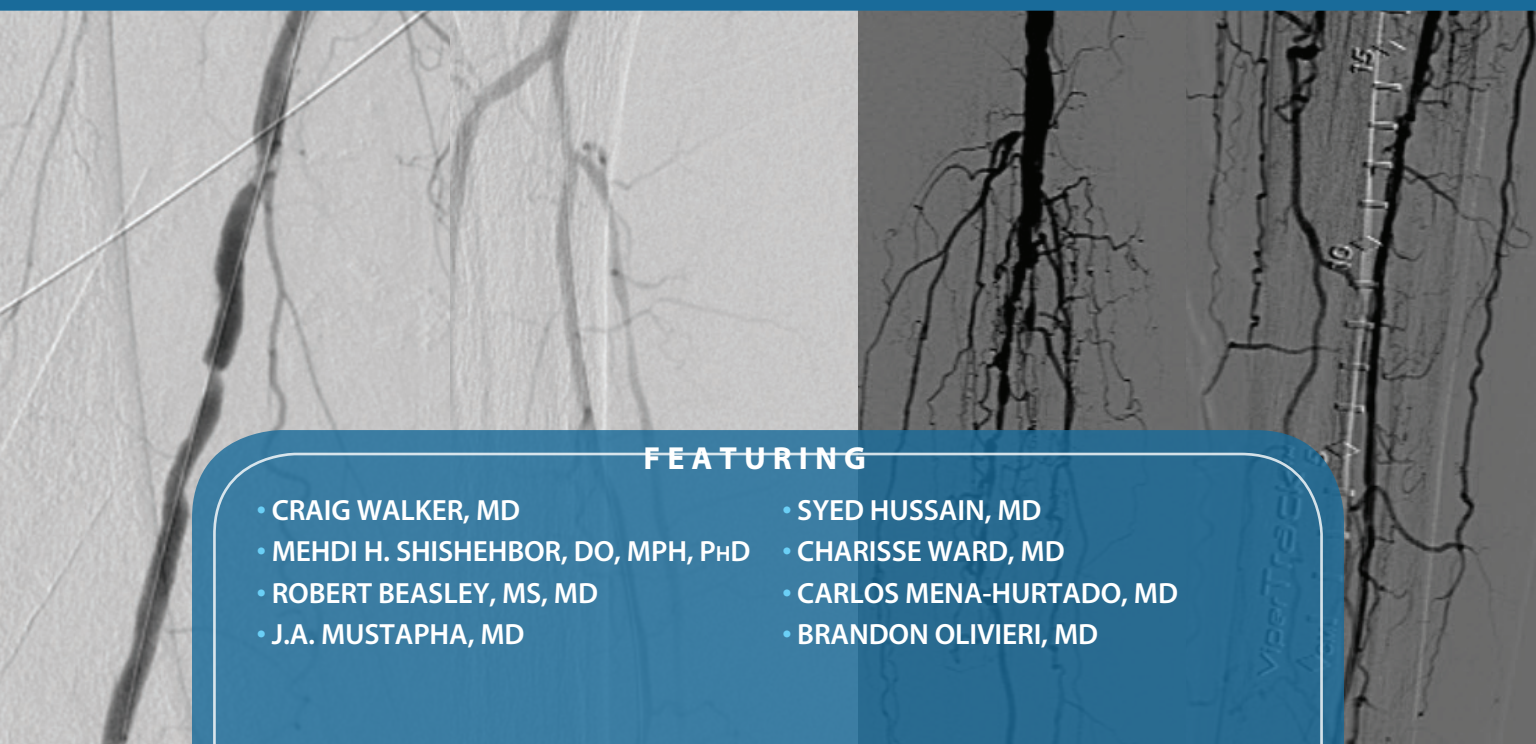
# Endovascular TODAY

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## NEW STANDARDS IN ANGIOPLASTY

Expert discussion and challenging case reviews show that we may be on the verge of a major transformation in angioplasty-centric therapy for lower extremity interventions.



### FEATURING

- CRAIG WALKER, MD
- MEHDI H. SHISHEHBOR, DO, MPH, PhD
- ROBERT BEASLEY, MS, MD
- J.A. MUSTAPHA, MD
- SYED HUSSAIN, MD
- CHARISSE WARD, MD
- CARLOS MENA-HURTADO, MD
- BRANDON OLIVIERI, MD

# NEW STANDARDS IN ANGIOPLASTY

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# Leaving Options Open in Lower Extremity Intervention

Experienced operators share what you need to know before adopting the Chocolate® PTA Balloon Catheter as a first-line therapy into your practice.

Endovascular Today sat down with expert interventionists Craig Walker, MD; Mehdi Shishehbor, DO, MPH, PhD; Robert Beasley, MD; J.A. Mustapha, MD; and Syed Hussain, MD, to discuss their clinical experience with the unique Chocolate® Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter and how it is changing their approach to treating lower extremity lesions. In April 2014, Cordis Corporation began distribution of this balloon, which is manufactured by TriReme Medical, LLC. The Chocolate® PTA Balloon Catheter is an angioplasty balloon that is constricted by a nitinol pressure shield,\* which ensures uniform cylindrical inflation. This unique design has facilitated lower rates of dissection, and the short-term outcomes point to the Chocolate® PTA Balloon as a viable option for standalone treatment of lower extremity lesions or as part of a combined treatment strategy with other interventional devices, such as atherectomy. This discussion explores how this balloon differs from standard angioplasty balloons, various operator techniques for sizing and inflation, and why this multispecialty panel is choosing the Chocolate® PTA Balloon Catheter first for peripheral arterial disease treatment.

## PANELISTS



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\*Nitinol constraining structure.

### What are some of the key attributes of the Chocolate® PTA Balloon Catheter?

**Dr. Walker:** The Chocolate® PTA Balloon is a PTA balloon catheter with a nitinol pressure shield, which constrains the balloon and enables uniform inflation. The Chocolate® PTA Balloon was designed to overcome the clinical challenges of torsional (twisting), radial (expanding) and longitudinal (lengthening) stress that can occur during angioplasty and that may result in bailout stenting or higher rates of TLR. When the device is inflated, the balloon expands the nitinol pressure shield to its preset diameter, then, the balloon inflates minimally around the nitinol struts, creating balloon pillows and grooves at the sites of the constraining struts. The nitinol pressure shield negates transmission of rotational forces as the wrapped balloon inflates. It protects against balloon elongation with inflation and facilitates balloon deflation. This design reduces the amount of shear stress applied to a vessel wall as the balloon elongates. By limiting balloon inflation diameter and therefore radial stress, it ensures that heterogeneous plaque, which has different levels of resistance to expansion, is uniformly dilated, avoiding overstretching certain parts of the vessel while understretching others.

**Dr. Shishehbor:** With standard angioplasty, the pressure is increased to get the entire balloon to expand across a lesion. The junction where the partial expansion and full extension meet is usually where dissections occur. My experience with the Chocolate® PTA Balloon has been that the nitinol pressure shield prevents unequal or heterogeneous inflation. It forces the balloon to homogeneously inflate, preventing dissection, which is helpful because you never want to have to place a stent that you didn't initially plan to. This feature allows me to be more aggressive with sizing, which can provide more acute luminal gain. This is important because there is a direct correlation between acute luminal gain and patency. The more you can gain lumenally acutely, the higher your patency rate will be downstream.

### How do dissection rates with the Chocolate® PTA Balloon compare to other balloons?

**Dr. Beasley:** The physics of this balloon allow you to take it up to its rated burst pressure without dissection. As mentioned previously, dissections can lead to additional, unplanned therapies or worse outcomes, thus increasing the overall cost of the procedure or increasing retreatment rates. The pressure shield does not cut

into the arterial wall; instead, it constrains the balloon and enables a uniform inflation by creating the mounds or pillows we've mentioned. The typical result is an excellent angioplasty result with no dissection.

**Dr. Mustapha:** The pillows and the grooves of the Chocolate® PTA Balloon allow the energy to dissipate and dissolve along the rest of the balloon without cutting into the vessel wall.

In the Chocolate BAR registry,<sup>2</sup> we showed a dissection rate of 3%, which is much lower than what we have seen in standard PTA balloons. Odink et al<sup>1</sup> showed a dissection rate up to 20% with standard angioplasty. The rate of dissection was 3% with the Chocolate® PTA Balloon versus 20% with standard PTA across the board, even with the 3.5-mm balloon.

**Dr. Walker:** At higher pressure levels, it behaves like an ultra-noncompliant balloon. The nitinol pressure shield absolutely limits balloon inflation at a certain point. Additional inflation is only at the pillow level, and that's minimal. Theoretically, the dissection is limited to the diameter of the pillow, not the length of the entire lesion.

### How would you describe your personal experience to date with the Chocolate® PTA Balloon?

**Dr. Beasley:** I have used more than 250 of these balloons, including many times in the tibial arteries. I have not encountered any issues getting through an occlusion after atherectomy. I perform atherectomy in almost all of my cases by using the 1.25-mm Diamondback system (Cardiovascular Systems Inc.). Even down into the pedal arteries, I don't have a problem crossing with the Chocolate® PTA Balloon Catheter.

**Dr. Mustapha:** I have been a high-volume user of the Chocolate® PTA Balloon and have performed a lot of procedures in the tibial and tibial-pedal vessels without atherectomy. The composition of the braided shaft of the Chocolate® PTA Balloon is a very important element. I find the pushability and trackability of the balloon and shaft together to be phenomenal. We compared the Chocolate® PTA Balloon to many other balloons, including a conventional balloon, and we were able to get the Chocolate® PTA Balloon to more lesions for many reasons. The taper angle at the tip of the balloon contributes to a low entry profile, and the coaxial composition of the shaft of the balloon contributes to what I've experienced as excellent pushability and trackability. The junction between the tip of the



catheter and the balloon has a variable angle instead of a high angle. Above and at the ankle, this balloon is phenomenal. Below the ankle, it is tricky, as is the case with any device.

**Dr. Hussain:** I have performed more than 50 cases with the Chocolate® PTA Balloon. Its profile is a little bit on the larger side because of the nitinol pressure shield itself, so there has been some difficulty getting this device across complete occlusions or through vessels that are somewhat tight or heavily calcified. However, once the Chocolate® PTA Balloon is at the lesion, the results have been very good. Many times, I have not had to place a stent after performing angioplasty.

### How do the radial, torsional, and longitudinal force of the Chocolate® PTA Balloon compare to other angioplasty balloons?

**Dr. Walker:** Radial force in this context is how much a balloon expands in diameter against an external restrictive force (the vessel obstruction). When a vessel is dilated, the goal is to make the balloon inflate uniformly at a very slow rate to lessen strain. The Chocolate® PTA Balloon inflates in a uniform cylindrical fashion. There is less strain, not only in terms of how fast you are inflating, but also because of the way you are interacting with the plaque. Strain is related to how rapidly a balloon expands. It is a major determinate of the creation of dissections.

When something is held in place for a longer period of time, it tends to retain that shape; this is what we call *plasticity*. In trials, we insisted on slow rates of inflation and holding the Chocolate® PTA Balloon's maximum dilatation pressure up for at least 60 seconds, but in addition, we also used balloons slightly larger than the reference vessel diameter. With that, one would historically have anticipated higher rates of dissection, but we did not see this. Instead, we saw very impressive luminal gain without flow-limiting dissections.

**Dr. Mustapha:** Torsional stress sometimes gets overlooked. Torsional stress is real; as a traditional balloon unfolds, it tears at the plaque. With the Chocolate® PTA Balloon Catheter, there is uniform distribution of both longitudinal and torsional force. A standard balloon will not give you that.

**Dr. Walker:** When a standard balloon inflates, it unwraps and makes contact with the vessel wall. It continues to torque as it inflates. A standard balloon also typically elongates during inflation, applying longitudinal vessel stress. Both of these forces create

potentially damaging vessel stress. If a balloon inflates not as a cylinder but as a dumbbell or dog bone, part of the balloon is constricted, part is not, and that is potentially problematic because of overstretching. By having an external restraining nitinol pressure shield, this effect is limited with the Chocolate® PTA Balloon Catheter. All balloons interact with the plaque and the lesion being dilated, so a noncompliant element allows interventionists to avoid overdilation of one part of the vascular obstruction while achieving full dilation of even the hardest parts of the lesion, particularly in long lesions.

**Dr. Mustapha:** A standard balloon elongates against the vessel wall, and if you inflate it too quickly, it can create a spiral dissection. The Chocolate® PTA Balloon Catheter decreases the risk of spiral dissections.

### What type of access are you employing when you use the Chocolate® PTA Balloon?

**Dr. Mustapha:** We have shifted to 90% ultrasound-guided common femoral artery antegrade access and 10% retrograde tibial access. Antegrade access allows you to reach the distal two-thirds of the tibial vessels that you may not otherwise be able to reach. In our critical limb ischemia (CLI) patients, we have shifted to 100% antegrade.

For those who do up-and-over intervention, the length is probably going to be an issue to treat BTK lesions. That needs to be addressed at some point, as this is where retrograde tibial access becomes valuable. The available lengths are 120, 135, and 150 cm.

**Dr. Walker:** I don't use an antegrade approach 100% of the time, but I do use it in a high percentage of cases. In a severely overweight patient, an antegrade approach is difficult at best. When feasible, I prefer an antegrade approach because it gives you better wire control and reach.

### In which patients or for which lesions are you primarily using the Chocolate® PTA Balloon Catheter?

**Dr. Mustapha:** We were fortunate to have the Chocolate® PTA Balloon early on, and we have had the chance to use it with simple lesions to severely calcified lesions. Initially, we didn't think that the Chocolate® PTA Balloon alone could tolerate some of the long, calcified lesions, so we did atherectomy first and then used the balloon. Eventually, we tried it without atherectomy, and we had great success in a broad range of

lesions. There isn't a lesion that I wouldn't attempt to treat with the Chocolate® PTA Balloon as a primary therapy at this point.

For patients with CLI with severely calcified lesions, which are a concern for perforations, I tend to perform atherectomy and follow with the Chocolate® PTA Balloon.

**Dr. Beasley:** I use the Chocolate® PTA Balloon Catheter in minimally calcified to heavily calcified tibial vessels in diabetic patients with CLI. I get excellent results with minimal dissection in those vessels. Across the popliteal and the posterior tibial segment, I rarely see dissection, which has cut down my fear of stenting in that location. I use the Chocolate® PTA Balloon across the common femoral, superficial femoral, and profunda bifurcation, and typically have no problems.

**Dr. Hussain:** I think the Chocolate® PTA Balloon Catheter is good for any patient. It works well in the diabetic population and for patients with CLI. I occasionally run into an issue with the crossing profile in heavily calcified lesions, but I have had very good outcomes with the Chocolate® PTA Balloon overall once it crosses the lesion. For patients with infrapopliteal disease and behind-the-knee popliteal disease, the Chocolate® PTA Balloon has been beneficial with excellent results.

The Chocolate® PTA Balloon gives you the option to go to very high pressures and not worry about the risk of dissection. We see a minimal number of flow-limiting dissections with this particular device. We tend to use it quite often in the tibial vessels and especially at the origins of these vessels. I refrain from using this device near the ankle or in the foot itself because these vessels are tortuous and in some cases, make it difficult to track the balloon catheter.

**Dr. Walker:** I routinely use the Chocolate® PTA Balloon Catheter in the popliteal segment, particularly for the P3 segment when disease extends into the infrapopliteal arteries. I have found that I can often dilate into the tibial-peroneal trunk or into the anterior tibial vessels with a balloon diameter larger than the infrapopliteal vessel without damaging that distal vessel, and end up with an acceptable definitive angiographic result. I have found the Chocolate® PTA Balloon very useful in lesions where other balloons rupture and frequently fail to dilate. The goal of PTA is "big lumen, little injury," and I think the Chocolate® PTA Balloon is a superior format for those areas.

## How does lesion length have an impact on your decision-making process?

**Dr. Shishehbor:** I believe balloons do much better in shorter than in longer lesions. In long lesions, unfortunately, nothing works well, but everything is relative. Longer lesions almost always have a very high restenosis or reocclusion rates. It is hard to rely on the balloon alone, especially in the SFA. Hopefully, drug-coated balloons will change that.

In the SFA, we tend to have a lower threshold to place stents in longer lesions (25–30 cm). In shorter lesions, I typically try to stay with balloon angioplasty alone, and the patency for shorter lesions (4–7 cm), in general, is not bad.

Below the knee, we have very limited options. Your only choice is to balloon. I may use drug-eluting stents for proximal tibial vessels if there is a dissection or something that I am not able to treat with a balloon.

## What are your technical tips for using the Chocolate® PTA Balloon, such as deployment, sizing, inflation times, etc.?

**Dr. Beasley:** I often use Chocolate® PTA Balloon dilation in conjunction with atherectomy. As for oversizing, my sizing is liberal—if I think it's a 5-mm vessel, I will typically use a 6-mm balloon. If I think it's a 3-mm tibial vessel, I'll use a 3.5-mm balloon. I use the 3-mm balloon all the way down to the ankle. I don't have issues with any patient population using this balloon.

**Dr. Walker:** For infrapopliteal applications, vessels 3.5 mm or smaller, I tend to oversize by 0.5 mm. Above the knee, or in vessels  $\geq 4$  mm, I oversize by at least 1 mm.

I inflate slowly, as I believe that it's the rate of rise that matters. At 30 seconds, we might get to half nominal, but I don't think we should do that in 1 second and wait 30 seconds. I'm trying to achieve a nice, cylindrical inflation and minimize strain. I also tend to inflate the balloon out for 3 minutes. That's taking into account plasticity and the fact that if we stretch something and hold it in that space for a period of time, it is more likely to retain that shape. This was traditionally done in the earliest days of angioplasty when we had no bailout mechanism. In many ways, we have lost the art of angioplasty. Now that we have bailout mechanisms such as stents, we are not as diligent about the balloon angioplasty component.

**Dr. Hussain:** I try not to overdilate with any standard angioplasty balloon due to the risk of dissection. With the Chocolate® PTA Balloon, I inflate relatively slowly for the vessel wall to accommodate the nitinol

constraining structure and achieve a uniform dilatation. About 2 atm every few seconds to nominal pressure is often the case when indeflating the balloon. I try to match the balloon to the blood vessel size as often as possible. I think this yields a better response and less dissection of the vessel wall.

**Dr. Shishehbor:** Before I was a big Chocolate® PTA Balloon user, I wouldn't put any balloons larger than 2.5 mm in diameter in the distal tibial vessels and near the ankle. Now, approximately 90% of the time, I'm putting a 3-mm Chocolate® PTA Balloon all the way to the ankle. You do have to tailor your decisions toward each patient, but in my own experience, I have not had any complications being more aggressive with sizing. I use a 3-, 3.5-, or sometimes a 4-mm Chocolate® PTA Balloon, even in the proximal tibial vessels. I have become much more aggressive with sizing, and I believe this is allowing more acute gain at the time of the procedure, which will then translate to patency.

**Dr. Mustapha:** I tend to oversize. We started initially with 1:1 balloon-to-vessel sizing, and we found that we needed a little bit more, so we increased to 1.1:1 sizing. We found much better results with this approach. You will not get the desired result if you match only 1:1. With the prolonged inflation, you get this nice step-up, step-down appearance (a common term used in the era of coronary stenting, meaning the typical images you see after deploying a stent).

With the Chocolate® PTA Balloon, we relearned that going slow and staying inflated longer gave us great results.

**Dr. Walker:** Our goal is the biggest lumen without dissection or injury. It has been shown by computer modeling that there is less deep injury with the Chocolate® PTA Balloon than with conventional balloons. Registries have shown angiographically that the Chocolate® PTA Balloon results in fewer dissections. We may need a study in which we use intravascular ultrasound to show true luminal gain and better evaluate dissection rate. It has certainly been our clinical impression that we have achieved greater luminal gains with lower rates of major dissections.

I started off sizing 1:1 as well, but based on some of what was observed in the BAR registry, in which we saw better outcomes without paying a price in dissection, we adopted larger sizing.

**Dr. Beasley:** I'll go to half nominal pressure, 30 seconds, and then I'll go up to nominal pressure. I'll usually give about another 1.5 to 2 minutes once I get

up to nominal pressure or crank it up to rated burst pressure, depending on the appearance. If I don't get a good, uniform dilatation, or if there is a little fleck of calcium or an area of calcification, I will take it up to rated burst pressure.

**Dr. Shishehbor:** When you use the technology, you have to understand how it works mechanistically. You have to allow the nitinol pressure shield to work. The teaching point is that you shouldn't rapidly go up to the minimal inflation pressure, which is 9 atm for BTK; you should go to about 4 atm, and that should take you about 30 seconds. That will allow the balloon to inflate, and it will allow the nitinol pressure shield to expand and get a uniform inflation. Once you get to that point, then you can increase the pressure to about 9 atm or 10 atm and leave it there for about 2 to 3 minutes.

### In which cases are you performing atherectomy before using the Chocolate® PTA Balloon?

**Dr. Walker:** It depends on where the lesion is, but I use atherectomy approximately half the time. For infrapopliteal, long, calcific lesions, I tend to perform atherectomy followed by the Chocolate® PTA Balloon. Although there are no randomized controlled data to cite for this approach it is my approach. I think in that area, we don't have a great stent alternative right now. We don't have long stents that work in the infrapopliteal space, so we look for a good primary angioplasty result. We're trying to keep a vessel open long enough to achieve healing, and if we do that, we typically achieve limb salvage.

I would prefer performing atherectomy and angioplasty rather than putting long stents in the infrapopliteal space, where we also lack positive data. Some of the stenting data in the SFA are pretty good. In some of those cases, I would balloon, and, if necessary, place a stent.

I do think we get better results with the Chocolate® PTA Balloon in densely calcified lesions as compared with conventional balloons because of the uniform inflation. Most balloons expand more in the softer parts of the lesion, and at the more densely calcific parts of long occlusions, they are restrained. Dissimilar amounts of dilation occur with conventional balloons, and therefore, different amounts of injury occur to the vessel.

**Dr. Beasley:** For above-the-knee claudicants, I don't always use atherectomy, because I am able to get through these lesions. I had a case recently in which the

patient had complete occlusion of her SFA and popliteal, and I got through the lesion fairly easily. I thought I was intraluminal, used the Chocolate® PTA Balloon, and had an awesome result. I couldn't convince myself to place a stent. I know that's anecdotal, but because I was fairly certain I was intraluminal, there was no reason to do atherectomy on this particular patient.

**Dr. Mustapha:** As previously mentioned, for patients with CLI and severely calcified lesions, which are at higher risk for perforation, I tend to perform atherectomy and then follow with the Chocolate® PTA Balloon.

### For thrombotic lesions, are you using thrombectomy or thrombolysis before deploying the Chocolate® PTA Balloon?

**Dr. Hussain:** In patients with long, chronic, thrombotic lesions, some interventionists have advocated treating first with thrombolysis to soften the thrombus, but I have not done that myself. I usually start with placement of a distal embolic protection device, perform atherectomy, and then perform balloon angioplasty. That has been my treatment for thrombotic disease.

**Dr. Mustapha:** We typically use Angiojet (Bayer) thrombectomy and almost always see irregularly shaped residuals. Given that, when we suspect an organized thrombus with high fibrin density, we therefore treat with the Chocolate® PTA Balloon and then lytics for underlying thrombus burden. Also, we, of course, place filters. There are usually two or three culprit areas of high-grade stenosis that actually started the process of acute thrombosis. We try to reduce the percent stenosis with the Chocolate® PTA Balloon first to allow increased flow velocity during lytic therapy.

**Dr. Walker:** It's been our experience—albeit some of the literature does not reflect this—that shorter courses of lytic therapy are associated with fewer bleeding complications. My personal experience is that when I can limit the length of lytic therapy to a few hours, the rate of major bleeds falls dramatically.

### How do you determine whether to perform angioplasty alone or angioplasty plus stenting?

**Dr. Shishehbor:** Once you have done angioplasty, regardless of what you have used—a standard balloon, a Chocolate® PTA Balloon, or a cutting balloon or scoring balloon—the decision to stent is a little bit challenging. Sometimes it's very subjective, and we are advocating that we need to be more objective.

Our own experience has been that the restenosis rates from those lesions are extremely high, especially if you have grade C or D or higher dissections. We advocate an objective assessment, which means measuring a pressure gradient at the end of your angioplasty in the SFA. If there is a significant gradient, approximately 10 mm Hg across the lesion in the SFA, then I think you need to do something else. The options are to go back with the balloon and do a prolonged inflation, stent, or use other novel devices that will be available soon, such as the Tack-It system (Intact Vascular), to maintain patency.

Because the field wants to move toward less stenting, people are willing to leave much more pronounced and larger dissections alone and not stent them, and we have not previously had a drug-coated balloon. Maybe when the data come out showing that because of a drug, even a moderate-sized dissection will remain patent, then I may change my approach.

**Dr. Mustapha:** Above the knee versus BTK are two different stories. With standard BTK angioplasty, there are a lot of data showing a high rate of restenosis due to a high percentage of dissection after angioplasty. Standard angioplasty does work, but with a high dissection rate that has a significantly high reocclusion rate.<sup>3,4</sup> The Chocolate BAR registry showed lower dissection rates versus standard angioplasty in the BTK arm.<sup>2</sup>

**Dr. Beasley:** The results from the Chocolate BAR registry show a 2% or 3% rate of immediate flow-limiting dissection above the knee. Those results sold me on the fact that this balloon works. The reinforcement of being able to oversize to achieve an excellent result far outweighs the economic problems that you might face using the balloon.

**Dr. Walker:** No one has ever shown that treating long-segment BTK disease with stenting is a good thing to do. The results were poor with longer bare-metal stents below the knee. Balloon-expandable stents (particularly drug-eluting) in very proximal sections are a reasonable option below the knee. In the distal segments, stents can be compressed and are probably not a good choice. Even if compressibility were not an issue, treating 30 cm of occlusion would take 10 of the longest stents, at a prohibitive cost. For above-the-knee therapy, I typically dilate with a balloon, then stent cases with suboptimal balloon results. There are many operators who routinely stent most SFA lesions. Even when stents are the final therapy, I strongly believe that good initial angioplasty is necessary to ensure



ideal stent expansion. Often, stents that appear fully expanded in anteroposterior projections show signs of compression in oblique angiographic views.

Despite stent data demonstrating improved primary patency as compared to PTA, stent placement has long-term negatives as well. These patients have to be on antiplatelet regimens. Long-term antiplatelet regimens are more problematic than we think. If these patients need their antiplatelet regimens reversed for GI bleeding or surgical procedures, stent thrombosis may occur. There are factors other than just looking at patency of a vessel. Stents may fracture. If diffuse in-stent stenosis occurs, it may be difficult to treat.

### Does your vessel prep differ if you are planning to stent after angioplasty?

**Dr. Shishehbor:** We rarely plan to stent. Our goal is to leave minimal metal in the artery if possible, and that's the direction of the field, with drug-coated balloons. The reason for this desire for less stenting is that long stents will occlude, and it is much more difficult to cross an in-stent occlusion. Treatment is more challenging because it requires more than standard angioplasty. You either have to place a drug-eluting stent or a Viabahn covered stent (Gore & Associates) inside it.

There is a lot of cost and difficulty in crossing an in-stent occlusion, so if there were a way for us not to have to put a stent, we'd rather go that route. Sometimes, of course, we don't have a choice.

**Dr. Mustapha:** Yes, if I am planning to stent a vessel, I tend to do an aggressive vessel preparation. I may start with a standard balloon first, prep the vessel, and stent it. I try using the Chocolate® PTA Balloon to eliminate a resistant or residual focal area before stenting.

**Dr. Beasley:** If I'm planning on stenting, I may use a Dorado balloon (Bard Peripheral Vascular), for example, to prep the vessel. But if there is uncertainty about whether I am going to stent, I have no qualms about picking up a Chocolate® PTA Balloon. If I definitely know I'm going to stent, then the Chocolate® PTA Balloon would not be the first choice.

**Dr. Walker:** I'd always use the same technique with this balloon because I think the mechanism by which we should dilate remains the same. If I absolutely know I'm going to stent, I would use a lower-cost balloon.

When I use the Chocolate® PTA Balloon, I'm hoping not to stent. There have been cases I've gone into thinking I potentially may need to stent, but I have found I often don't have to with the Chocolate® PTA

Balloon because of an excellent primary PTCA result. I am starting to evaluate with angiography and intravascular ultrasound. Previously, when we assessed conventional PTA with intravascular ultrasound in patients with good angiographic results, we found much smaller lumens than we thought we had achieved, and often there were significant dissections not identified by angiography. It has been my initial limited experience that when we follow the Chocolate® PTA Balloon with IVUS, our initial results are better.

The cases I know I'm going to definitely stent are the "rock piles" where I have crossed deeply subintimal and often have had to use a re-entry tool. In my experience with these, one must stent with devices that have great radial force.

### In which cases would you not elect to use the Chocolate® PTA Balloon?

**Dr. Shishehbor:** I don't see any major limitations with the Chocolate® PTA Balloon. For long, totally occluded lesions, it may be difficult to pass a longer Chocolate® PTA Balloon through the lesion, so you may need to predilate. If that's the case, I usually predilate with a much smaller balloon, such as a 2-mm balloon, especially if I am working below the knee, and then I can deliver the Chocolate® PTA Balloon. We've been able to deliver the Chocolate® PTA Balloon all the way to the foot, so delivery is not a problem.

**Dr. Walker:** I don't use the Chocolate® PTA Balloon when I'm doing pedal arch reconstruction because of balloon flexibility and the need to negotiate through very tortuous vessels of the foot. I routinely use the Chocolate® PTA Balloon in long-segment infrapopliteal disease. I think it has been transformative in terms of the outcomes of having fewer dissections and more predictable outcomes in that area without having to stent.

This balloon tracks fairly well. In very high-grade calcific lesions, particularly in areas of tortuosity, the nitinol pressure shield does tend to stop the balloon assembly from bending and tracking through long densely calcified occlusions at times. I have had more resistance in this type of situation, and I have had a couple of cases in which I've had to either predilate or consider atherectomy first. Outside of that, I have not had issues with tracking in straight segments of vessel.

**Dr. Mustapha:** The severe tortuosity in the transpedal loops and the high rate of spasm in the transtibial collaterals cause these areas to not be ideal places to use the Chocolate® PTA Balloon.

### Does the Chocolate® PTA Balloon have the potential to decrease procedural or retreatment costs?

**Dr. Shishehbor:** Unfortunately, I believe that many institutions, including ours, rely heavily on up-front economic cost cutting, and we are not sophisticated enough yet to look at the downstream effect of the decisions that we make upstream. For example, you may say, don't use the Chocolate® PTA Balloon because it costs more than a standard balloon. However, you then go into the lesion, you have more dissections, you end up using more stents, the patient has restenosis, and needs to come back for more procedures.

This is very challenging and complicated decision making in my opinion, and the field is not yet there in regard to understanding how to deal with these cost issues in terms of available data.

Unfortunately, the hospital does not have a lot of incentive, nor the physician, to try to use the best-quality device because they do not get paid for the best-quality device, but they do get paid for [treating] restenosis.

**Dr. Walker:** A balloon is a cost that cath lab managers identify, but it is actually a very small part of the total cost of admission and interventional treatment of that patient. Stents are expensive. I try to weigh those costs against other options. I think there are certain cases in which I may be inclined to stent first if I've had crossed deeply subintimally. In patients who I think will be noncompliant and will not take antiplatelet medications, I try to avoid placing a stent. There are many patients who leave the hospital and never take their antiplatelet drugs even with education about the need to take these to avoid stent thrombosis. When I am intervening below the knee, it's typically in a patient who is going to otherwise lose his or her limb if I don't get the vessel open. That's an area where I aggressively treat. Of course, above-the-knee disease is becoming a larger part of treating CLI patients who also have multilevel disease. In these cases, making sure we have a great long-term above-the-knee outcome is important.

**Dr. Beasley:** There is no doubt in my mind that the Chocolate® PTA Balloon has reduced the number of stents I place in the SFA and popliteal arteries, which does lower costs. If you reduce the number of stents, then you reduce the chance of in-stent restenosis. There is not a doubt in my mind that the Chocolate® PTA Balloon decreases the amount of stents I use.

**Dr. Mustapha:** When we look at the Chocolate BAR BTK data,<sup>2</sup> the target lesion revascularization and target vessel revascularization rates are much lower than other modalities, including stenting. Any decrease in target lesion revascularization and target vessel revascularization, reducing the number of potential reinterventions, results in an economic benefit.

**Dr. Hussain:** When this balloon first came into my lab, I was skeptical, because I didn't have any data on it, and the cost was prohibitive for me. I never thought it would get through administration at a hospital to get it on the shelf. That took a little time. If you look at where and why you are using the Chocolate® PTA Balloon, I think the results have justified the cost certainly in certain locations. I think the Chocolate® PTA Balloon offers a huge cost benefit below the knee because it is an angioplasty catheter that gives an excellent result. Optimal therapy in this area is still lacking.

As we're maturing in the vascular field, a lot of what we do with CLI patients is not always about the patency, but more about the wound healing rate and limb salvage. Every time I go to a vascular surgery meeting, we talk about patency rates, but the thing we should be conscious of is whether the patient will keep his or her leg, even though the vessel may have gone down 6 months later. ■

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## THE CHOCOLATE® PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER

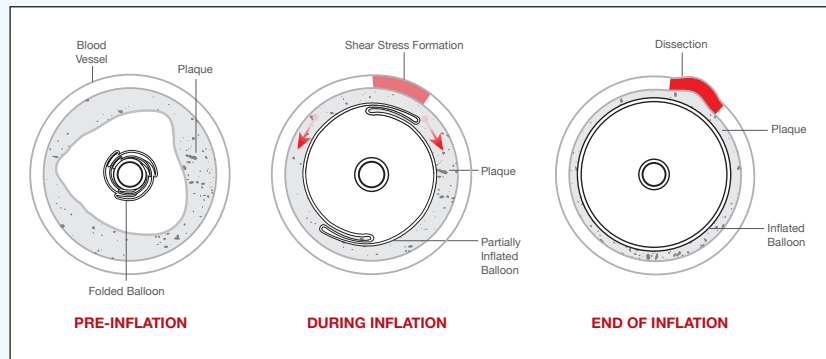
*The following section has been adapted from an article published by Charisse Ward, MD, and Carlos Mena-Hurtado, MD, in the May 2014 issue of Endovascular Today, available online at [bit.ly/EVTChocolate](http://bit.ly/EVTChocolate).*

The technique of balloon inflation during angioplasty is of paramount importance to the end result: underinflation can lead to elastic recoil, whereas over-inflation can lead to neointimal hyperplasia, either of which could result in restenosis. Achieving the best possible result with angioplasty entails minimizing strain on the vessel wall. The standard angioplasty balloon unfolds with inflation, resulting in the application of force in a nonuniform manner to the stenotic lesion. Uncontrolled expansion with the standard angioplasty balloon results in increased torsional (Figure 1), longitudinal (Figure 2), and radial (Figure 3) stresses that can strain the vessel wall and lead to increased incidence of dissection, elastic recoil, and abrupt vessel closure. However, a controlled dilatation technique can help to mitigate these challenges and ultimately achieve much better flow.

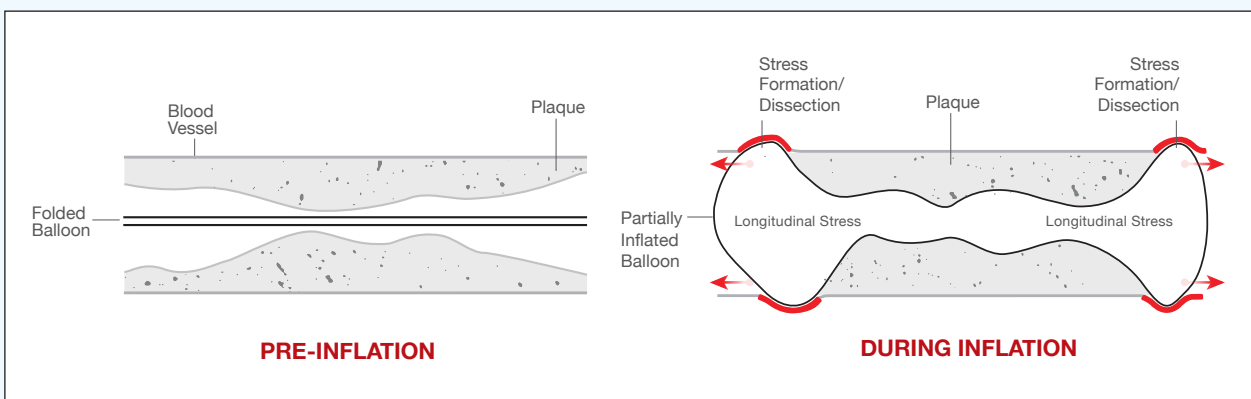
The Chocolate® Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter (manufactured by TriReme Medical, LLC, distributed by Cordis Corporation) is a novel balloon catheter with a mounted nitinol constraining structure specifically designed for uniform, controlled inflation and rapid deflation resulting in atraumatic dilatation without the need for cutting or scoring.<sup>1</sup>

The nitinol-constraining structure of the Chocolate® PTA Balloon cre-

ates balloon segments or “pillows” that make contact with the vessel and functions to minimize local forces. The “grooves” facilitate plaque modification (Figure 4). The distinctive pillows and grooves serve to minimize vessel trauma, reduce the rate of dissection, and lead to a decreased need for bailout stenting.<sup>1</sup> In addition, the Chocolate® PTA Balloon retains a cylindrical shape while deflating and facilitates lesion recrossing after multiple inflations.



**Figure 1. Torsional stress can be imparted on the vessel wall through a twisting motion when a plain balloon unfolds during inflation.**



**Figure 2. Longitudinal stress elongates the vessel wall when a plain balloon unfolds during inflation.**

The Chocolate® PTA Balloon Catheter is an over-the-wire balloon dilatation catheter that is compatible with 0.014- and 0.018-inch guidewires. It is available in sizes to treat both above- (ATK) and below-the-knee (BTK) lesions with balloon diameters of 2.5 to 6 mm, balloon lengths of 40 to 120 mm, and catheter lengths that range from 120 to 150 cm (Figure 5).

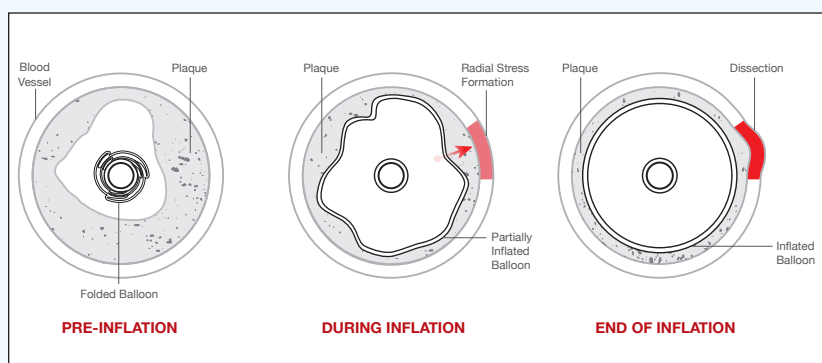
### CLINICAL RESULTS WITH THE CHOCOLATE® PTA BALLOON CATHETER

The Chocolate® Balloon Angioplasty Registry (BAR, Principal Investigator, J. A. Mustapha, MD) is a core-lab adjudicated registry with up to 500 patients from up to 40 centers. The interim data from the first

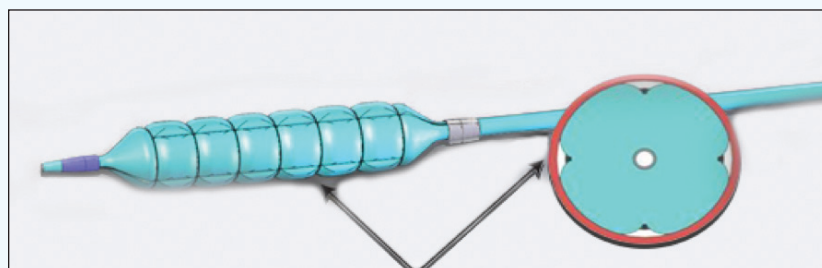
354 patients in the registry were presented at LINC 2014 by Tony Das, MD, and include 174 patients in the ATK cohort and 180 patients in the BTK cohort.

Only 2% of patients who underwent ATK interventions with the Chocolate® PTA Balloon Catheter had evidence of a flow-limiting dissection; 90% achieved < 30% diameter stenosis, and 94% achieved freedom from bailout stenting. At 6 months postintervention, 11% required TLR, 96% of patients had amputation-free survival, and 89% of patients were free of major adverse events.

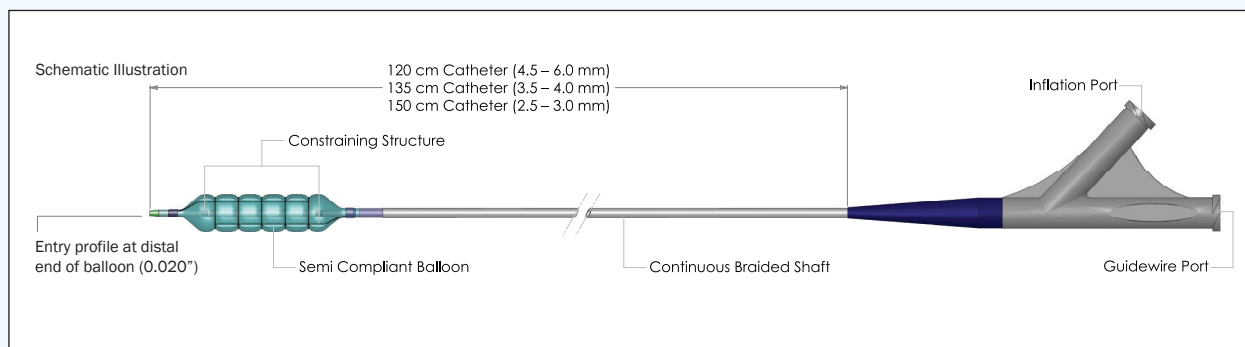
The success rate for BTK interventions was similarly impressive: 99% of patients treated with the Chocolate® PTA Balloon Catheter had no flow-limiting dissections, 94% achieved < 30% diameter stenosis, and 3% required bailout stenting. At 3 months, 7% of patients required TLR, the amputation-free survival rate was 97%, and freedom from major adverse events was 90%. ■



**Figure 3.** Radial stress outwardly expands the vessel wall when a plain balloon unfolds during inflation.



**Figure 4.** The Chocolate® PTA Balloon Catheter with distinctive “pillows” and “grooves” that serve to reduce vessel wall trauma.



**Figure 5.** The Chocolate® PTA Balloon Catheter design.

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# SFA and BTK Interventions With the Chocolate® PTA Balloon Catheter

This device allows operators to achieve excellent results with low rates of dissection, as demonstrated in these cases of high-grade stenosis.

BY BRANDON OLIVIERI, MD, AND ROBERT BEASLEY, MS, MD

Percutaneous balloon angioplasty has been the backbone of endovascular peripheral arterial disease therapy since it was first pioneered by Charles Dotter in 1964.<sup>1</sup> However, the sequelae of percutaneous angioplasty are inherent in its mechanism of action. Balloon inflation results in longitudinal and radial plaque redistribution, plaque extrusion, arterial expansion, and plaque rupture for its effect on luminal gain. Uneven application of this shear stress results in significant radial, longitudinal, and torsional vessel trauma.<sup>2-5</sup> This injury to the vessel wall may present itself acutely as a flow-limiting dissection or elastic recoil, often necessitating stent placement. Vessel wall trauma also results in the release of a significant amount of thrombogenic, mitogenic, and vasoactive factors, which likely contribute to late lumen loss via neointimal hyperplasia and vascular remodeling.<sup>4,5</sup>

The Chocolate® PTA Balloon Catheter (manufactured by TriReme Medical, LLC., distributed by Cordis Corporation) seeks to minimize vessel wall trauma, thereby theoretically decreasing both early and late lumen loss.<sup>6</sup> Composed of a nitinol pressure shield\* over a semicompliant balloon, inflation results in the formation of multiple alternating grooves and modules, or balloon pillows, allowing for a more controlled distribution of shear force despite variability in lesion morphology.<sup>6</sup> The Chocolate BAR registry demonstrated markedly reduced rates of dissection and bailout stenting compared to trials using normal percutaneous angioplasty alone in both above- and below-the-knee applications.<sup>7-10</sup>

The authors have found similar results and regularly use the Chocolate® PTA Balloon Catheter to achieve excellent angioplasty results, particularly in eccentric or heavily calcified lesions. In our experience, combining this technology with plaque-debulking atherectomy is particularly useful for achieving dissection-free maximum luminal gain, as demonstrated in the following cases.

## CASE STUDY ONE

A 79-year-old woman with a past medical history of hypertension, diabetes mellitus, and 65 pack-years of cigarette smoking presented with a chief complaint of progressively worsening severe right lower extremity claudication after ambulating approximately 1 block. The patient's symptoms were refractory to an exercise regimen started by her primary care physician. Her medications included lisinopril, aspirin, metformin, atorvastatin, and hydralazine. Physical examination of the lower extremities revealed hairlessness and nail hypertrophy. There was no carotid bruit or palpable abdominal aortic aneurysm, and pulses were palpable in the bilateral upper extremities. The bilateral femoral, left

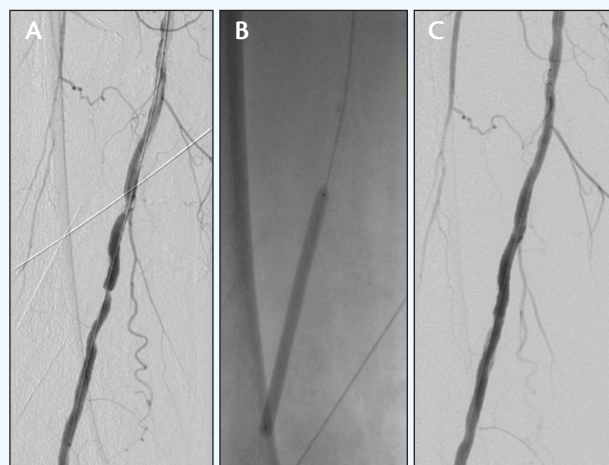
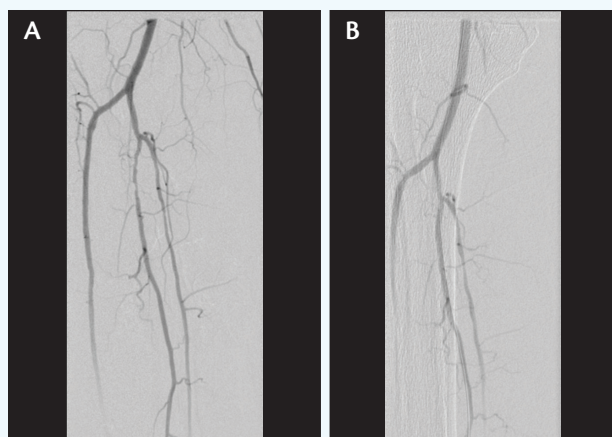


Figure 1. Diagnostic angiography of the right superficial femoral artery revealed multiple tandem high-grade stenoses of the right superficial femoral artery (A). Images obtained during plaque-modifying balloon angioplasty with the Chocolate® Balloon, applied with standard prolonged inflation times (B). Repeat angiography of the right superficial femoral artery revealed significantly improved vessel patency with no signs of dissection (C).

\*Nitinol constraining structure.



**Figure 2.** Diagnostic angiography of the right infrapopliteal arterial vasculature high-grade stenosis in both the distal right tibioperoneal trunk and proximal right peroneal arteries (A). Repeat angiography demonstrates dissection-free improved vessel patency with brisk flow down to the ankle (B).

popliteal, and left dorsalis pedis artery pulses were present. The right femoral pulse was palpable, but the right popliteal artery could not be detected on manual examination. The right dorsalis pedis and posterior tibials were not detected on evaluation with portable Doppler.

Lower extremity arterial Doppler ultrasound revealed high-grade stenosis of the right superficial femoral artery and right tibioperoneal trunk. The patient then underwent diagnostic lower extremity angiography for further evaluation, revealing two heavily calcified high-grade stenoses in the mid-right superficial femoral artery (Figure 1A) with additional high-grade stenosis in both the distal right tibioperoneal trunk and proximal right peroneal arteries (Figure 2A).

With this clinical scenario of lifestyle-limiting claudication refractory to medical management and an

exercise regimen, the decision was made to perform endovascular revascularization.

### Revascularization

Contralateral access was achieved using a combination of manual palpation and fluoroscopic guidance. A 6-F short sheath was placed across the iliac bifurcation, and the patient was systemically anticoagulated with unfractionated heparin. A microcatheter and a hydrophilic guidewire were used to navigate the severe right superficial femoral artery stenoses. Atherectomy was then performed using a 1.25-mm Diamondback 360 orbital atherectomy device (Cardiovascular Systems, Inc.). Balloon angioplasty was performed using a 6-mm outer-diameter over-the-wire Chocolate® PTA Balloon Catheter, inflating slowly to reach half nominal by 30 seconds, nominal by 1 minute, and holding at nominal for 2 minutes (Figure 1B). Follow-up angiography revealed widely improved vessel patency (Figure 1C).

Attention was then focused to the right infrapopliteal vasculature. A microcatheter and a 0.014-inch hydrophilic guidewire was used to negotiate the severe stenoses in the tibioperoneal trunk and proximal aspect of the peroneal artery. Next, atherectomy was performed using a 1.25-mm Diamondback 360 orbital atherectomy device. Balloon angioplasty was then performed using a 3-mm outer-diameter over-the-wire Chocolate® PTA Balloon Catheter. The inflation technique was used as described. A follow-up angiogram demonstrated wide patency and luminal gain with brisk flow down to the ankle (Figure 2B).

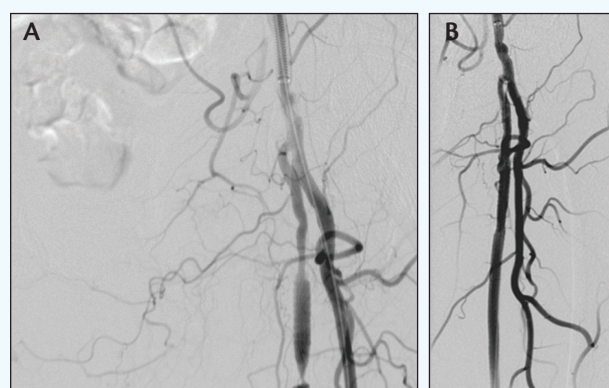
### Follow-Up

At 1-, 3-, and 6-month follow-up, the patient noted continued significant improvement in her lower extremity claudication and notes that she is now able to participate in activities with her grandchildren.

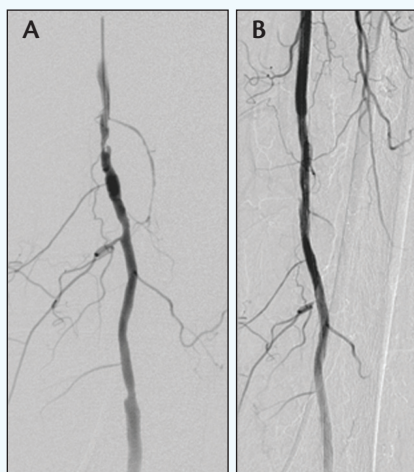
## CASE STUDY TWO

A 64-year-old woman with a history of hypertension, diabetes mellitus, and coronary artery disease presented to our clinic with progressively worsening two-block left lower extremity claudication that had begun to severely affect her ability to work. Her medications included lisinopril, aspirin, atorvastatin, metformin, and metoprolol. Physical examination of the lower extremities revealed hairlessness, nail hypertrophy, and mild coolness to the touch. There were no carotid bruits or palpable abdominal aortic aneurysms, and pulses were palpable in the bilateral upper extremities. The bilateral femoral, right popliteal, right dorsalis pedis, and posterior tibialis pulses were present. The left popliteal artery pulse was not palpable by manual examination. The left dorsalis pedis and posterior tibial pulses were 1+ on portable Doppler examination.

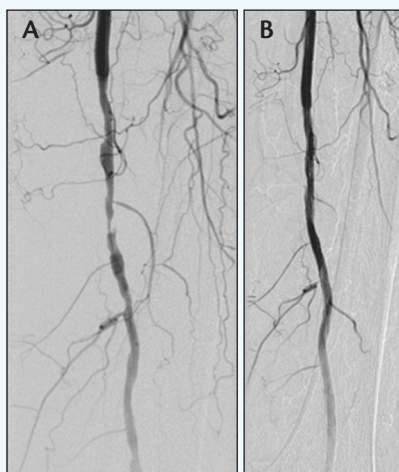
A lower extremity arterial ultrasound performed in



**Figure 3.** Diagnostic angiography of the proximal left superficial femoral artery revealed multiple tandem high-grade stenoses of the left superficial femoral artery with areas of subtotal occlusion (A). Repeat angiography after atherectomy and plaque-modifying balloon angioplasty demonstrated significantly improved vessel patency (B).



**Figure 4.** Diagnostic angiography of the mid-left superficial femoral artery revealed multiple tandem high-grade stenoses of the left superficial femoral artery with heavily calcified plaque (A). Repeat angiography after atherectomy and plaque-modifying balloon angioplasty again demonstrated significantly improved vessel patency (B).



**Figure 5.** Diagnostic angiography of the mid-distal left superficial femoral artery revealed multiple heavily calcified severe stenosis with areas of subtotal occlusion (A). Repeat angiography postintervention revealed a widely patent vessel with no evidence of dissection (B). Three-vessel runoff was noted to the ankle.

our office demonstrated high-grade stenosis of the left superficial femoral artery. Diagnostic lower extremity angiography revealed multiple tandem, highly calcified, high-grade stenoses with areas of subtotal occlusion extending along the length of the left superficial femoral artery (Figures 3A, 4A, and 5A).

Considering the patient's clinical scenario of lifestyle-limiting claudication, as well as her desire for intervention to attempt to improve her symptoms, the decision was made to perform endovascular revascularization.

### Revascularization

Contralateral right femoral arterial access was achieved using a combination of manual palpation and fluoroscopic guidance. A 6-F sheath was introduced and advanced across the iliac bifurcation, and the patient was systemically anticoagulated with unfractionated heparin. A microcatheter and a hydrophilic guidewire were used to navigate the severe left superficial femoral artery stenoses. Next, atherectomy was performed using a 1.25-mm Diamondback 360° orbital atherectomy device. Balloon angioplasty was then performed using a 6-mm outer diameter over-the-wire Chocolate® PTA Balloon Catheter. A repeat angiogram demonstrated significantly improved vessel patency with no evidence of dissection (Figures 3B, 4B, and 5B). The process was then repeated, using the same Chocolate® PTA Balloon Catheter, to treat multiple other high-grade SFA stenoses, retracting the device

through the sheath and reprep-ing it after treating each lesion. In the authors' experience, the device profile is slightly worsened after its initial use; however, the balloon retains total effectiveness after multiple uses.

### Follow-Up

At 1-, 3-, and 6-month follow-up, the patient noted significant improvement in her lower extremity claudication, allowing her to continue her work.

### CONCLUSION

Designed to reduce angioplasty-induced vascular trauma, the Chocolate® PTA Balloon Catheter has proven to be a useful tool in our peripheral arterial armamentarium. As demonstrated in these cases, the Chocolate® PTA Balloon Catheter enables the achievement of dissection-free maximum luminal gain in

difficult lesions. We look forward to new technological developments on the horizon, particularly with regard to the results of the ENDURE trial, which will examine infraginal revascularization outcomes using a drug-coated Chocolate® PTA Balloon Catheter.<sup>11</sup> ■

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*Robert Beasley, MS, MD, is Director of the Vascular/Interventional Radiology Lab and Evanesence Vein Center at Mount Sinai Medical Center in Miami Beach, Florida. He has disclosed that he is a consultant and trainer for Cordis Corporation and Cardiovascular Systems, Inc.*

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# Popliteal PTA and Transpedal Reconstruction Using the Chocolate® PTA Balloon

A case report detailing treatment of popliteal disease and diabetic foot ulcer.

BY MEHDI H. SHISHEHBOR, DO, MPH, PhD

An 82-year-old woman with diabetes mellitus and a bilateral midfoot collapse due to Charcot arthropathy and partial first ray amputations presented to the clinic with a left midfoot ulceration that had been present for 1 month and a heel ulcer present for 3 months (Figure 1).

The patient's medical history included coronary artery disease, hypertension, hyperlipidemia, and peripheral artery disease, as well as diabetes mellitus.

Pulse volume recording revealed severe distal superficial femoral artery (SFA) and popliteal disease with significant distal foot disease, as showed by flat tracing at the metatarsal and digit level (Figure 2). Diagnostic angiography revealed patent iliacs, common femoral artery, and SFA, with severe calcification of the popliteal artery with subtotal occlusion (Figure 3).

Diagnostic angiography revealed severe subtotal popliteal disease (Figure 4A). Lesions were prepared with a Diamondback 1.5-mm crown (Cardiovascular Systems, Inc.) with distal embolic protection. Percutaneous transluminal angioplasty (PTA) was per-

formed with a 6- X 80-mm Chocolate® PTA Balloon Catheter (manufactured by TriReme Medical, LLC, distributed by Cordis Corporation). The final angiogram showed a good result (Figure 4D).



Figure 1. The patient presented with a heel ulcer.

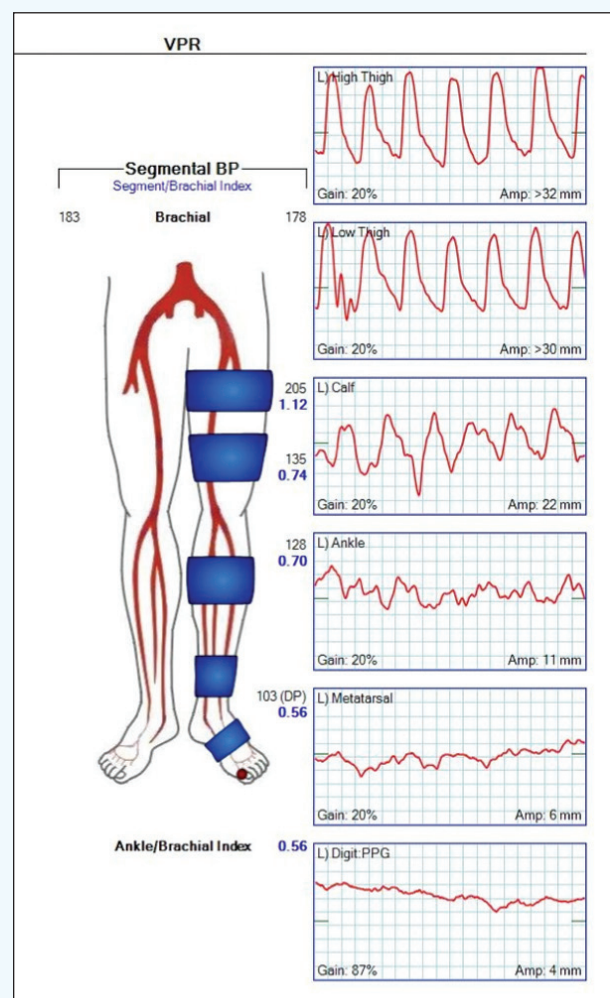
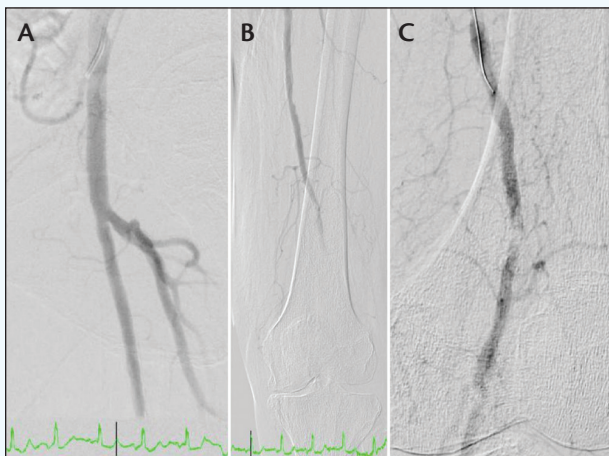


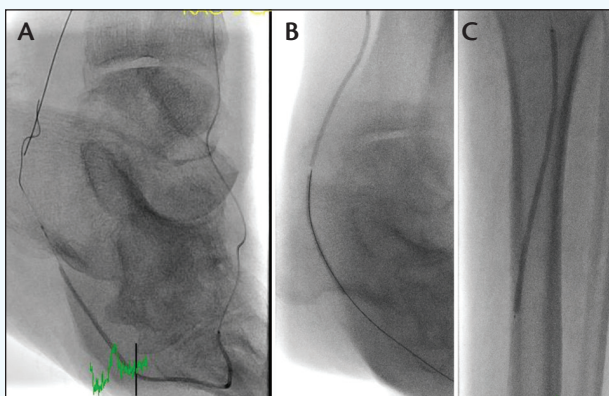
Figure 2. PVR revealed severe distal SFA and popliteal disease with significant distal foot disease.



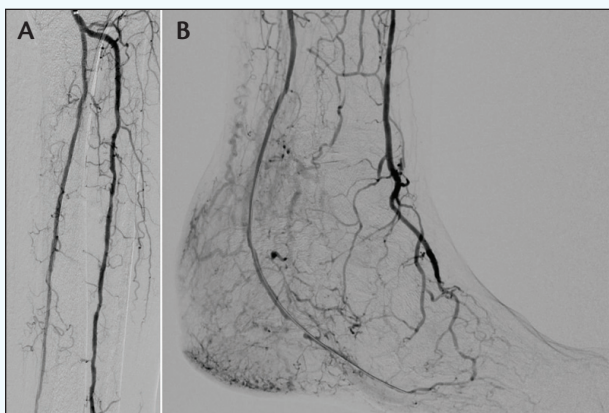
Complex retrograde transpedal reconstruction of the distal anterior tibial, pedal arch, and all of the posterior tibial artery was performed using a



**Figure 3.** Angiography revealed patent iliacs (A), common femoral artery, and SFA (B) with severe calcification and narrowing of the popliteal artery (C).

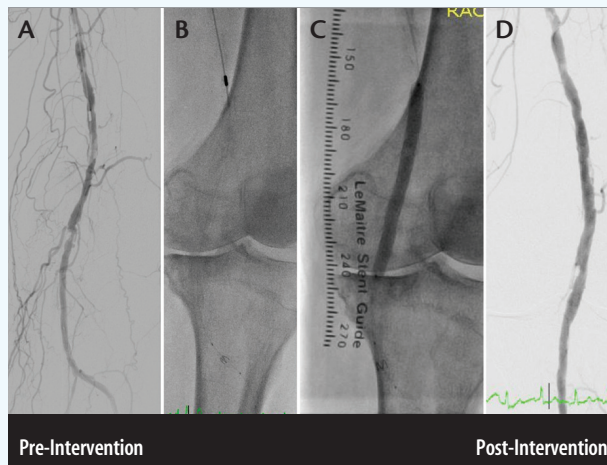


**Figure 5.** Complex retrograde transpedal reconstruction of distal anterior tibial artery and pedal arch (A) and Chocolate® PTA Balloon angioplasty of the distal (2.5 mm x 120 mm) (B) and proximal (3 mm X 120 mm) posterior tibial artery (C).

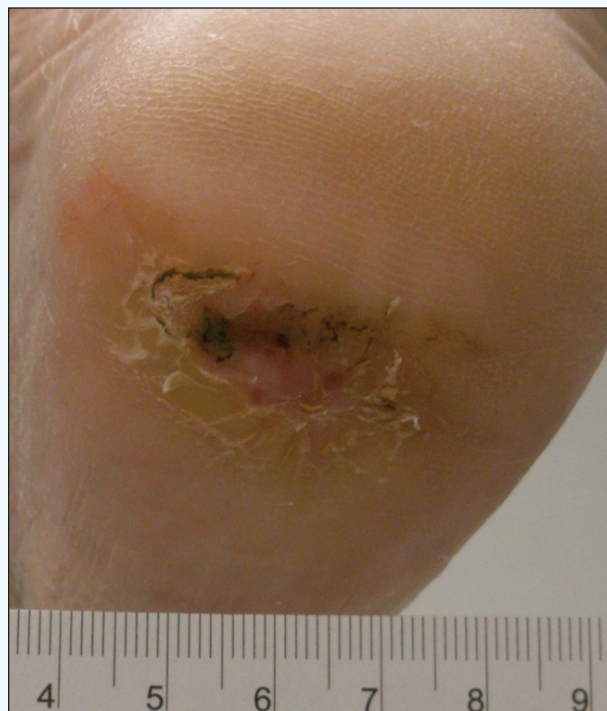


**Figure 6.** Excellent two-vessel runoff to the foot (A) with intact pedal arch (B).

2.5-mm X 120-mm, followed by a 3-mm X 120-mm, Chocolate® PTA Balloon (Figure 5). Revascularization resulted in excellent two-vessel runoff to the foot (Figure 6A) with an intact pedal arch (Figure 6B). After 4 months of aggressive wound care, the heel ulcer healed completely (Figure 7). ■



**Figure 4.** Diagnostic angiography revealed severe, heavily calcified subtotal popliteal disease (A). Atherectomy was performed using a Diamondback 1.5-mm crown (B). A 6-mm X 80-mm Chocolate® PTA Balloon was delivered without difficulty (C). The balloon was inflated slowly over 30 seconds to 4 atm and then to nominal pressure of 6 atm for 3 minutes. Final angiogram shows a good result (D).



**Figure 7.** Totally healed heel ulcer after 4 months.

# Covering Every Case: The SABER™ PTA Dilatation Catheter

A discussion with J.A. Mustapha, MD, and Craig Walker, MD, on how the SABER™ Catheter provides an important option for lower extremity endovascular therapy.

## What characteristics of the SABER™ PTA Dilatation Catheter differentiate it from other available balloons?

**Dr. Mustapha:** The true low profile of the entire balloon and the shaft make the SABER™ Catheter unique. Many balloons are described as being low profile. This is usually referring to the balloon itself. With the SABER™ Catheter, both the balloon and shaft have a low profile.

The second point to emphasize is the tremendous pushability of the shaft of the balloon, which enhances the already low-profile portion. The combination of its low profile and excellent shaft for pushability, makes it excellent for trackability. The combination of the balloon's low profile, pushability, and protractability make it an excellent balloon that will add a significant value to the therapy for infrainguinal vessels.

**Dr. Walker:** We are interested in getting the SABER™ Catheter. It's an 0.018-inch space wire balloon that comes in diameters from 2 to 10 mm. In particular, the 10-mm diameters are unique in terms of the 0.018-inch-based balloons. That allows us to use a smaller sheath to dilate fairly big vessels. The sizes up to 6 mm in diameter are up to 300 mm long. These longer balloons are important for long-segment disease.

I am interested in this concept of a dual-hydrophilic coating that provides durability and hydrophilicity, and therefore, diminished friction. The fact that the balloon itself is made of DURALYN® and therefore has highly controlled compliance is somewhat of a distinguishing characteristic due to the probability of not overdilating those segments.

## How do the inflation times of this balloon compare to others?

**Dr. Mustapha:** When I compared the deflation and inflation times of this balloon to others, I found that the deflation time of this balloon is significantly faster than other balloons. In my experience, the inflation time is similar.

## When would you use the SABER™ Catheter over the Chocolate® PTA Balloon?

**Dr. Mustapha:** It is well known that low-profile sheaths have a lower access complication rate. A 4-F sheath plays a major role when we access diseased vessels. The SABER™ Catheter allows use of large-diameter balloons, such as 5 or 6 mm, without having to change the sheath. This can mean the difference between failure and success, especially during a TAMI procedure.

The SABER™ Catheter is a phenomenal balloon when doing transtibial intervention because of its ability to track and its pushability. A third attribute that makes the SABER™ Catheter extremely attractive, and a scenario in which I might use it before the Chocolate® PTA Balloon Catheter is when we are doing transpedal loop revascularization. Other than that, if we have a larger-diameter sheath, the Chocolate® PTA Balloon Catheter is phenomenal in the majority of the same vessels that were mentioned in the earlier discussion. In addition, in vessels where we attempt to open with a traditional balloon and continue to have resistance, the Chocolate® PTA Balloon Catheter can be used to resolve the waist without an undue risk of complication. If there is evidence of moderate to severe calcification, we tend to go straight to the Chocolate® PTA Balloon Catheter, inflate it slowly, and keep it up for 2 minutes to simulate the same results in terms of low dissection and the low perfusion rate that we saw in the Chocolate BAR study.

## Would you employ the same technique for the SABER™ Catheter as you would Chocolate®?

**Dr. Mustapha:** Because we learned from the Chocolate BAR that inflating the balloon for more than 30 seconds and maintaining it for 2 minutes gives us such a good result, we're doing the same now with the SABER™ Catheter. ■



# Lower Extremity CTO Crossing With the SABER™ Catheter

Two case reports showing initial experience with the SABER™ Catheter for the treatment of chronic total occlusions.

BY J.A. MUSTAPHA, MD

Chronic total occlusions (CTOs) represent a major obstacle for the treatment of lower extremity vascular disease. The SABER™ PTA Dilatation Catheter (Cordis Corporation) provides a new molded tip design, a dual-layer hydrophilic coating, and a low-profile body to enable a smooth crossing and a high burst pressure rating for the dilatation of tight lesions. An offering of 2- to 10-mm diameters and 20- to 300-mm lengths allows treatment of a wide range of iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal artery lesions.

## SABER™ CATHETER CASE STUDY ONE

The patient was a 67-year-old obese man with a medical history of peripheral vascular disease, hypertension, tobacco use, and hypercholesterolemia. Three years before, the patient underwent right femoropopliteal bypass with a good outcome and complete resolution of his symptoms (Rutherford class 3 to Rutherford class 0).

At 8 months after surgical intervention, the patient developed recurrent lower extremity claudication, categorized as Rutherford class 3, with the right worse than the left. The symptoms continued, and the patient presented for evaluation. At presentation, the right lower extremity ankle-brachial index (ABI) was 0.74, and the toe-brachial index (TBI) was 0.53; for the left lower extremity, ABI was 0.99 and TBI was 0.81.

A diagnostic angiogram (Figure 1) was obtained via access of the left radial artery. This showed an occluded right SFA at the mid-segment that reconstituted in the distal popliteal artery at the level of P3 with three-vessel runoff (Figure 2). Further evaluation determined that the patient was not a suitable candidate for repeat vascular

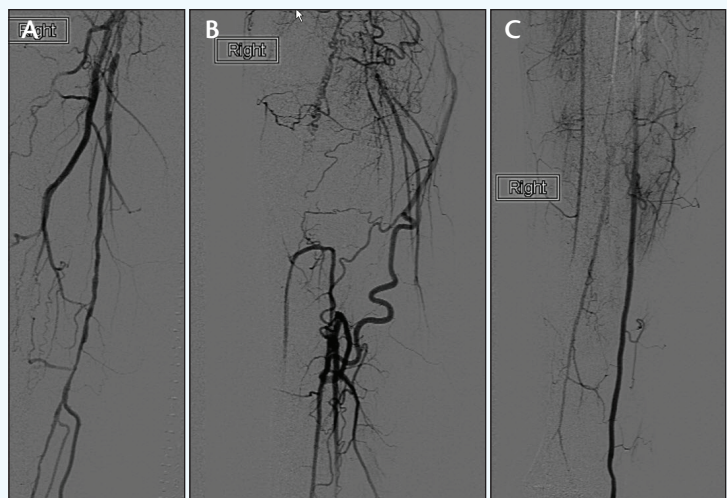


Figure 1. Initial diagnostic angiogram showing proximal superficial femoral artery (SFA) disease extending into the popliteal artery (A). Popliteal CTO reconstituting at the junction of the anterior tibial takeoff via the large genicular branch (B). Single-vessel tibial runoff via the posterior tibial artery (C).

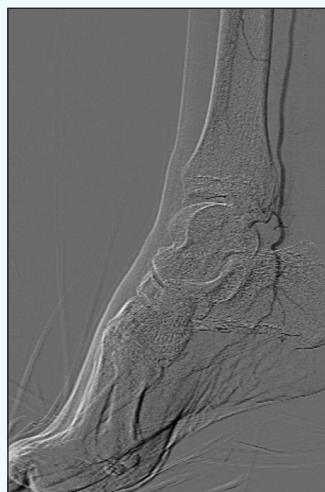


Figure 2. Preintervention runoff showing poor perfusion of the foot.

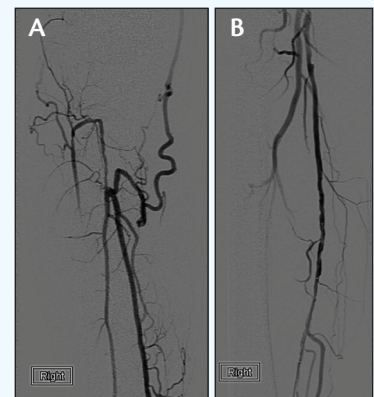


Figure 3. TAMI technique. Retrograde angiogram confirming the distal CTO reconstitution at the level of takeoff of the anterior tibial artery (A). Level of proximal CTO in the mid-popliteal artery (B).

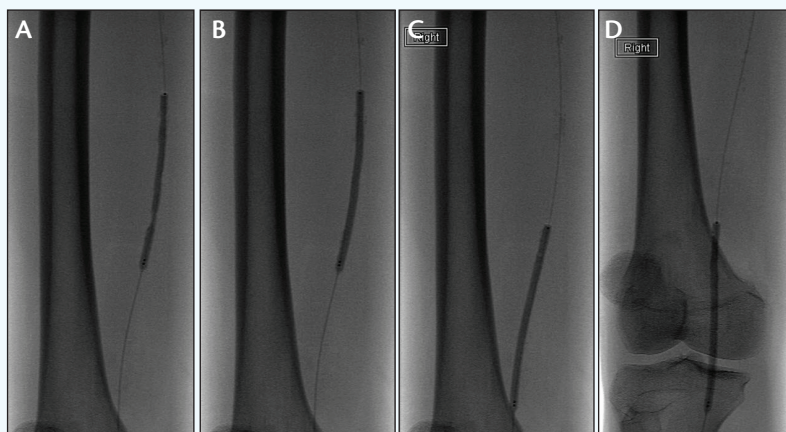


Figure 4. SFA 3-cm balloon angioplasty at 4 atm (A). SFA 5-cm balloon angioplasty, three inflations at 6 atm for a total of 114 seconds (B). Popliteal 3-cm balloon angioplasty at 4 atm for 35 seconds (C). Popliteal 4-cm balloon angioplasty at 2 atm for 47 seconds (D).

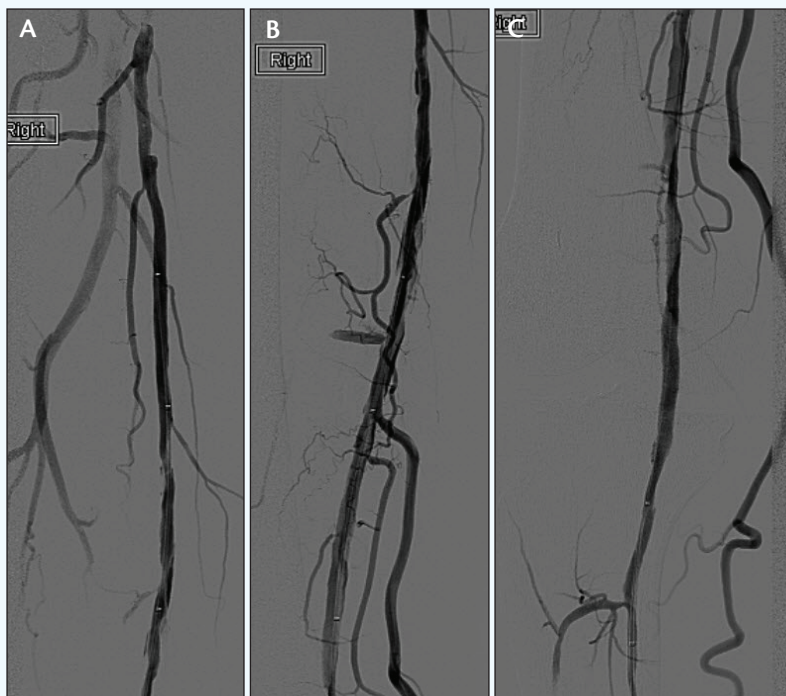


Figure 5. Post-PTA flow reconstitution in the SFA (A). Post-PTA flow reconstitution in the popliteal artery (B). Post-PTA flow reconstitution into the popliteal-tibial junction (C).

bypass intervention. In addition, access through the groin was prohibited due to several factors, including severely advanced pre-existing scar tissue, obesity, and the patient's inability to lie flat. Therefore, the decision was made to treat the right SFA via tibiopedal arterial minimally invasive retrograde access (TAMI) technique (Figure 3).

Ultrasound-guided retrograde access via the posterior tibial artery was obtained. The highly calcified, high-plaque-burden CTO of the SFA and popliteal was crossed using the Approach 25 wire (Cook Medical). The decision was made to perform orbital atherectomy of the right posterior tibial artery; tibioperoneal trunk (TPT); distal, mid, and proximal popliteal artery; and distal SFA.

Balloon angioplasty was then performed in the TPT (Figure 4), using a 3-mm X 250-mm SABER™ Catheter (Cordis Corporation); in the posterior tibial artery, using a 3-mm X 250-mm SABER™ Catheter followed by a 4-mm X 80-mm SABER™ Catheter; and in the SFA, using an initial 3-mm X 250-mm SABER™ Catheter followed by 5-mm X 100-mm SABER™ Catheters, with < 10% residual stenosis in all vessel segments (Figure 5). A unique feature of the SABER™ Catheter is its quick deflation and refolding time, which allows better pushability into a new area for repeat PTA. The balloon has a combination of low-profile characteristics involving both the balloon and the sheath, which make it a unique balloon for ease of delivery into hostile high-grade stenosis and CTOs.

Hemostasis was obtained using a tibial access hemostasis device. The patient was discharged home the same day without access or procedural complications.

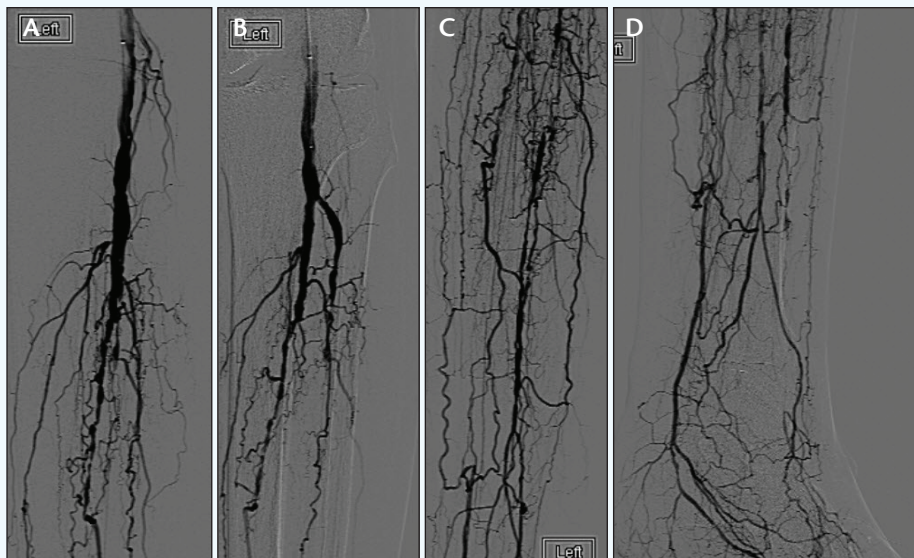
## SABER™ CATHETER CASE STUDY TWO

The patient was an 82-year-old man with a medical history of stage III chronic kidney disease, lower extremity edema, deep vein thrombosis, and osteomyelitis of the left toe. The patient presented from the wound clinic for further evaluation of a left lower extremity nonhealing ulceration of the left fourth toe with PVD symptoms consistent with Rutherford class 5. MRI results of the toe were consistent with osteomyelitis. Doppler results obtained during

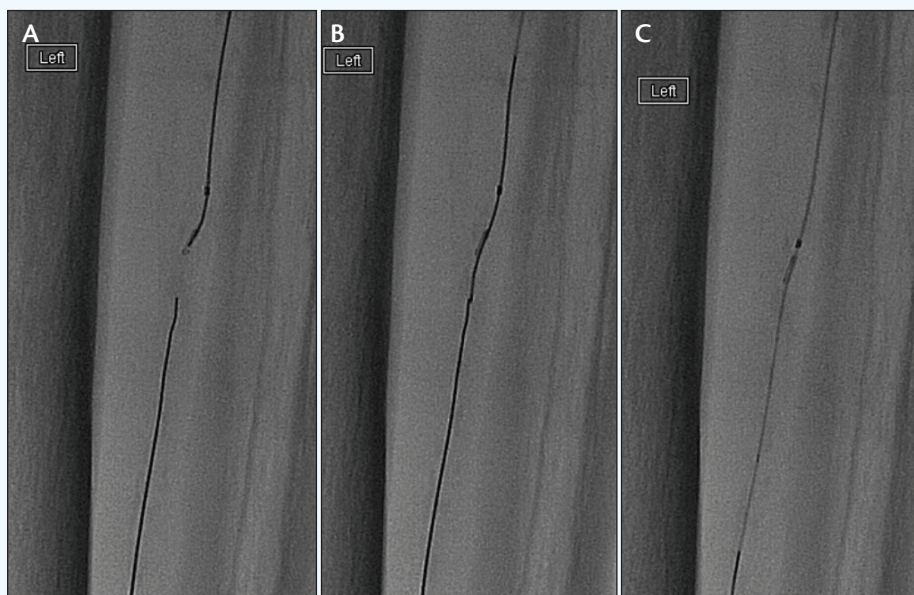
the visit showed reduced waveform at the dorsalis pedis (DP) and posterior tibial (PT) arteries. Noninvasive imaging was obtained. The results of the evaluation were as follows: left ABI, 0.75; left TBI, 0.28; right ABI, unable to be determined due to noncompressible arteries; right TBI, 0.45.

A diagnostic angiogram was obtained via access of the right common femoral artery (Figure 6A through 6C). This showed the proximally occluded AT, tandem lesions of the mid-AT (95%), then complete occlusion distally with





**Figure 6.** Anteroposterior angiogram of the proximal tibial artery showing total occlusion of the proximal tibial vessels (A). Oblique angiogram at 30° ipsilateral showing proximal tibial total occlusion, including proximal cap of anterior tibial (AT) total occlusion (B). Mid-to-distal reconstitution of the tibial vessel showing poor AT reconstitution via dense tibial collateral (C). Tibiopedal reconstitution via dense tibial collateral showing PT and AT runoff to the foot (D).



**Figure 7.** Retrograde CTO crossing wire maneuver toward antegrade recapturing catheter (A). Retrograde wire advanced into the antegrade capturing catheter (B). Axis reversal by advancing antegrade wire into the distal DP artery (C).

reconstitution in the DP below the ankle with weak flow and evidence of severe calcification (Figure 6D). Vessel diameter was 3.5 mm proximally, 3 mm at the midsection, and 2.5 mm distally, with a lesion length of 400 mm. The left PT showed total occlusion in the midsection that reconstituted distally above the posterior communicating artery with good runoff to the plantar arteries. The

PT was severely calcified with a lesion length of 200 mm and diameter of 3.5 mm proximally, 3 mm at the midsection, and 2.5 mm distally. The left peroneal was occluded at the ostium and reconstituted distally with a lesion length of 200 mm. Therefore, the decision was made to pursue left lower extremity peripheral vascular intervention.

Ultrasound-guided antegrade access of the left common femoral artery was achieved. Additionally, a retrograde access site was also achieved in the left DP using ultrasound guidance. The CTO cap of the left AT was crossed with an Approach 25 wire (Cook Medical) in antegrade fashion (Figure 7). The wire was advanced into the mid-AT, where it was unable to advance further, and it appeared that the wire had gone subintimal on ultrasound evaluation. The decision was made to proceed with a second access site via retrograde access of the left DP using ultrasound guidance. This allowed successful crossing of the vessel and true lumen, and the Approach retrograde wire was advanced in the antegrade NaviCross catheter (Terumo Interventional Systems). Access was then reversed, with all therapy being delivered via the left common femoral artery in antegrade fashion. The

retrograde DP artery sheath was then removed. Orbital atherectomy of the left AT and DP (proximal and mid) was performed, followed by balloon angioplasty using a SABER™ Catheter (Figure 8).

The left DP was treated using a 2.5-mm balloon, the mid to distal AT with a 3-mm balloon, and the proximal AT with a 3.5-mm balloon followed by a 3-mm balloon. All

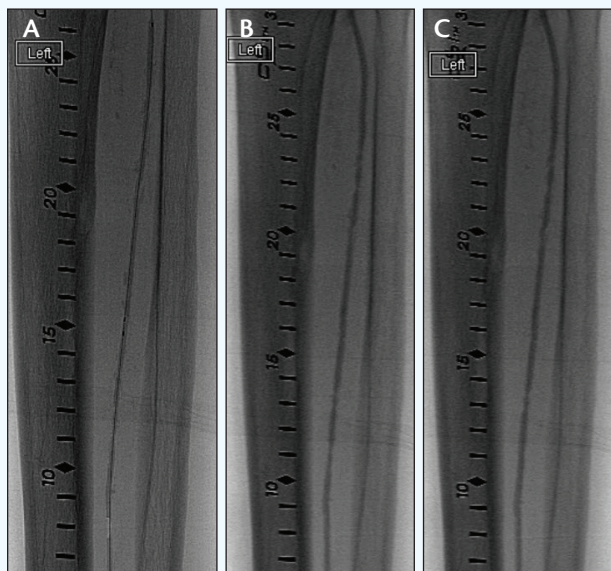


Figure 8. Multiple SABER™ Catheter inflations of the previously totally occluded AT with different sizes: 2.5 mm (A) and 3 mm (B, C).

balloons were 80-mm long. The total lesion length was 300 mm; all segments were severely calcified. Preintervention stenosis was 100%; postintervention stenosis was < 20% of vessel segments. Closure of the access sites was done via manual compression hemostasis (Figure 9). The patient was discharged the next day without access or procedural complications.

## CONCLUSION

In our initial experience, we see high promise for the SABER™ Catheter to be used as our go-to balloon. In the current era of complex CLI disease, low-profile devices such as the SABER™ Catheter add significant value for the area of the

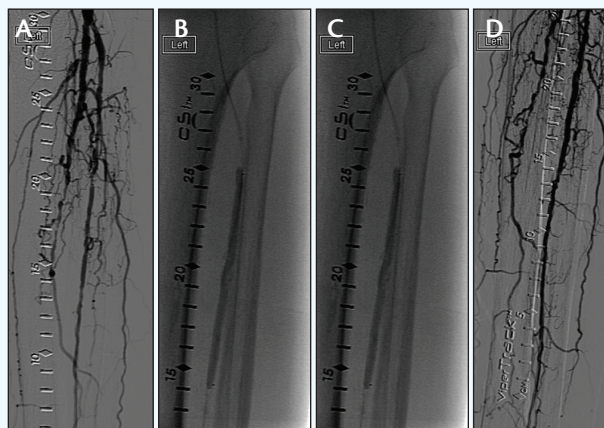


Figure 9. Post-PTA angiogram of previously occluded AT with residual stenosis (A). Additional SABER™ Catheter angioplasty of the proximal and mid-AT for residual stenosis as noted in A (B, C). Final angiogram runoff showing revascularization of the previously totally occluded AT artery with low-profile SABER™ Catheter (D).

vascular tree that has a significant unmet need. The SABER™ Catheter's combined unique characteristics of trackability, pushability, low profile, and 4-F compatibility make it a balloon that is highly effective, easy to use, and unique for utilization during TAMI procedures. ■

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