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Optimizing Endovascular Treatment for Multilevel Disease in Patients With CLI

By Laiq Raja, MD, FACC, FSCAI, and Lorie Henderson, APRN, MSN, NP-C

Critical limb ischemia (CLI) is a global epidemic associated with comorbid conditions that add to the complexity of the disease.[1] Patients often have extensive tissue loss due to misdiagnosis or infection from a previous hospital visit.[2] Many patients still have severe tissue loss even after endovascular or surgical treatment, at which point referral for a second opinion typically leads to a limb salvage approach. These cases are complex, pose significant challenges, and require great skill to treat the underlying lesions. In patients with diabetes, obstructive arterial disease related to CLI is characterized by multilevel lesions that can involve arteries below the knee, calcification, and chronic total occlusions (CTOs).[3-5] These types of complex lesion characteristics, in combination with comorbid conditions that are often present among patients with diabetes, can make revascularization especially challenging, which ultimately increases the risk of amputation, as seen in the following case.

PATIENT HISTORY

A 75-year-old woman with peripheral artery disease (PAD) was referred to our service by podiatry for treatment of CLI. Her medical history included insulin-dependent diabetes, hypertension, chronic renal insufficiency, and stable coronary artery disease. At presentation, she had a deep wound to the left great toe, which was being treated by wound care and podiatry. She had a palpable left femoral pulse, but her popliteal and tibial pulses were absent.

This case was unique because the patient was deemed to have no further endovascular or surgical options and was also referred to the orthopedic group for a below-the-knee amputation and subsequent hospice. In the United States, patients are commonly referred directly to an orthopedic surgeon for amputation before a full vascular evaluation can be performed. The additional referral to hospice after amputation showed a lack of hope or empathy for the patient. This case occurred prior to the full initiation of the

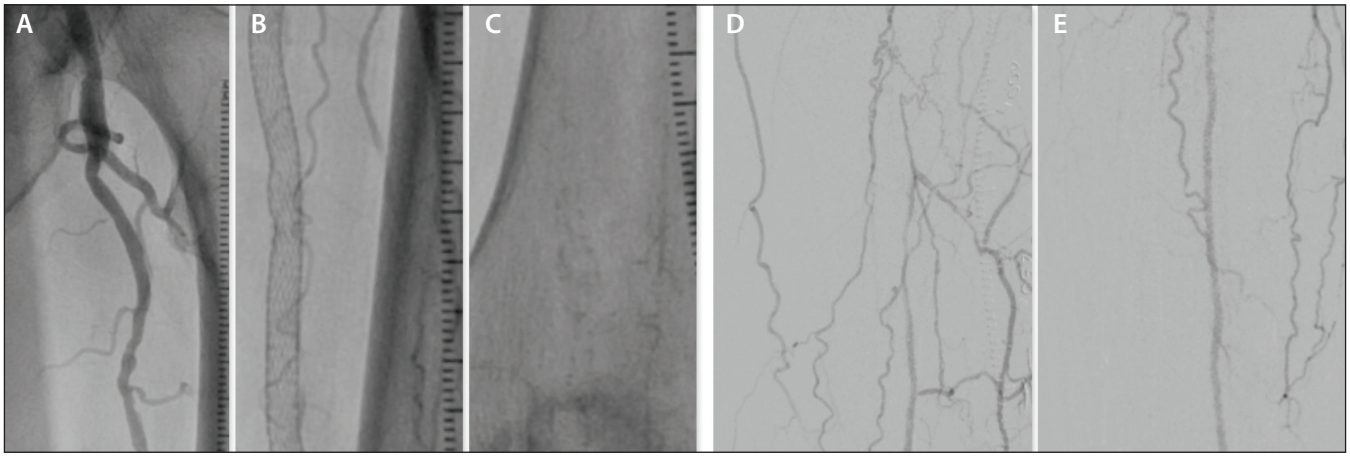

Figure 1. Preintervention angiograms showing the SFA bifurcation (A), SFA (B), site of the occlusion (C), and reconstituted peroneal artery through the collaterals (D, E).

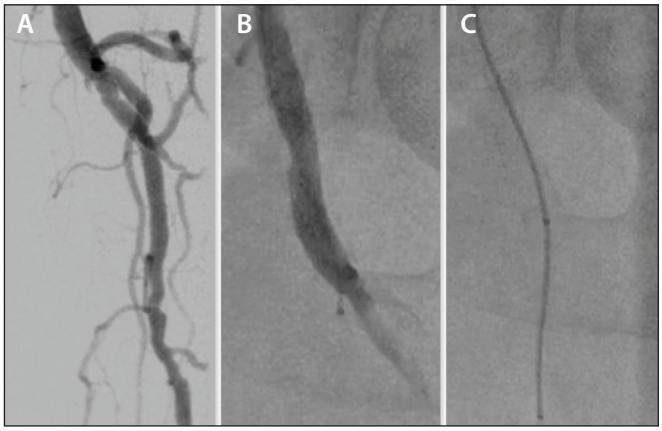

Figure 2. Identification of the SFA bifurcation: pushing through the proximal cap of the CTO in the SFA (A), at the site of the occlusion (B), and pushing through the proximal cap of the occlusion (C).

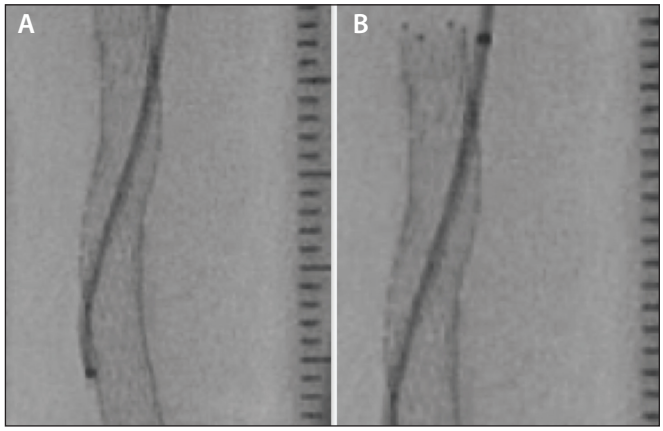

Figure 3. Traversing the stent in the SFA and deflection into the subintimal space (A, B).

CLI program at our institution. Currently, we have a system where referrals for amputations are flagged for review by the vascular interventional team, or the "CLI Team," which has significantly reduced amputation rates.

PROCEDURE

In the cath lab, right common femoral artery (CFA) contralateral access was achieved via a Glidesheath Slender™* sheath (Terumo Interventional Systems). A diagnostic angiogram revealed patent aortic and iliac arteries with moderate levels of plaque. A left lower extremity angiogram confirmed a CTO of the superficial femoral artery (SFA) at the bifurcation of the deep profunda artery and extending into the popliteal artery with reconstitution at the tibioperoneal trunk. Digital subtraction angiography (DSA) revealed a single runoff vessel—the peroneal artery—with CTOs in the anterior and posterior tibial arteries (Figure 1). Adding to the complexity of the situation, a totally occluded self-expanding stent was found in the mid-distal SFA. The presence of the stent showed that another interventionalist had already treated this patient, but the status of this previous care was unknown.

After the diagnostic angiogram, a Glidesheath Slender sheath was exchanged for a 6-F X 45-cm Destination™* sheath (Terumo Interventional Systems) and advanced over the iliac bifurcation into the left CFA using a 6-F Concierge™* Internal Mammary guide catheter (Merit Medical) as a telescope along with a stiff, angled Glidewire™* (Terumo Interventional Systems). DSA images were taken at various angles, which located the remnants of the SFA (Figure 2). The 0.035-inch stiff, angled Glidewire and an angled 0.035-inch NaviCross™* support catheter (Terumo Interventional Systems) were introduced to engage the nub of the occluded SFA. Under fluoroscopic guidance, a consistent strong push broke the proximal cap of the CTO, utilizing only the catheter and paying close

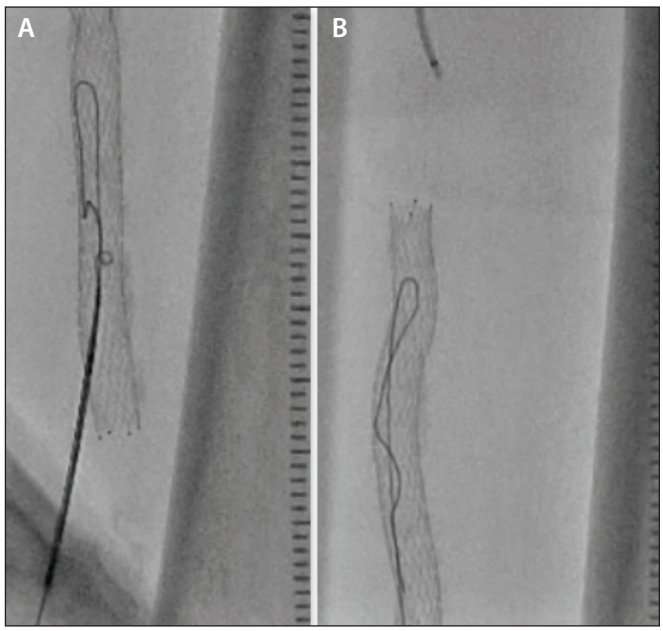

Figure 4. Addressing the occluded stent with direct stick of the SFA stent (A) and prolapsing the wire (B).

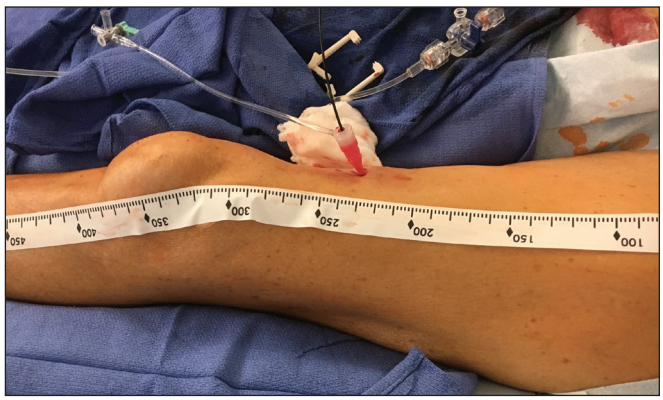

Figure 5. Insertion of a Glidesheath Slender sheath.

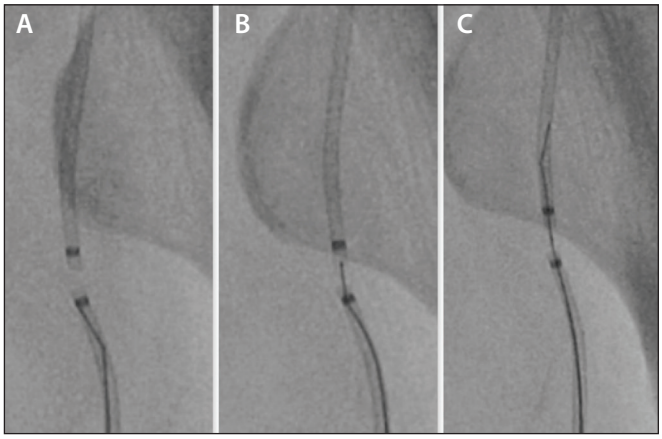

Figure 6. South-meets-north technique: two catheters meet (A); CTO wire is advanced toward the antegrade NaviCross support catheter as a wire is pushed out into the intimal space (B) and then into the lumen of the other catheter (C).

attention that the Glidewire remained inside of the catheter (Figure 2).

In our experience, engaging the cap of the CTO in this way gives better control and reduces the chance of going subintimal. We closely watched the trajectory of the catheter as it traversed the CTO, constantly manipulating the angled tip in various degrees of motion and with consistent force applied throughout. We placed special attention on staying intraluminal within the stent itself, as occluded stents can create a very hard proximal cap that often deflects the catheter into the subintimal space. Unfortunately, that is exactly what occurred in this case (Figure 3).

We considered approaching the occluded stent in a distal retrograde fashion, but the usual distal retrograde access targets (anterior and posterior tibial arteries) were completely occluded and only the peroneal artery was visible by DSA. We determined the best approach was to do a direct stick to the occluded stent and prolapse an 0.018-inch wire with a solid body so that a Glidesheath Slender sheath could be introduced (Figure 4).

The puncture site was a few centimeters proximal and medial to the knee joint. As this was an anterior approach, with the patient lying in the supine position, there was no need to reposition the patient, reprep, or break sterility, which saved time and kept the procedure moving forward.

Once the Micropuncture™* introducer sheath (Cook Medical) was inserted (Figure 5), a second angled 0.035-inch NaviCross support catheter and stiff angled Glidewire were pushed through the occluded stent and aimed toward the antegrade NaviCross support catheter.

Both catheters were advanced to within a millimeter of each other, on the same plane. The retrograde 0.035-inch wire was exchanged for a 0.014-inch CTO wire with a heavy gram tip weight. Under fluoroscopic guidance, the wire was introduced from the retrograde catheter into the lumen of the antegrade NaviCross support catheter (we call this the "south-meets-north" technique; Figure 6).

The wire was advanced through the catheter and externalized out of the contralateral sheath, and the retrograde NaviCross support catheter was removed. Both ends of

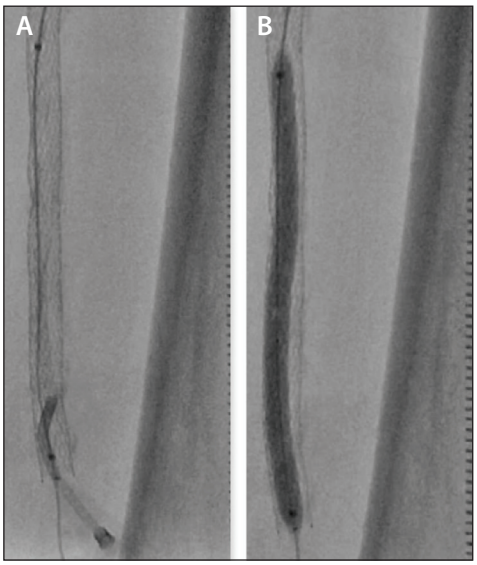

Figure 7. Hemostasis at the puncture site in the SFA. Advancing the balloon and positioning the balloon over the puncture site, identified by the intersection of the retrograde sheath (A). Inflating the balloon for 5 minutes (B).

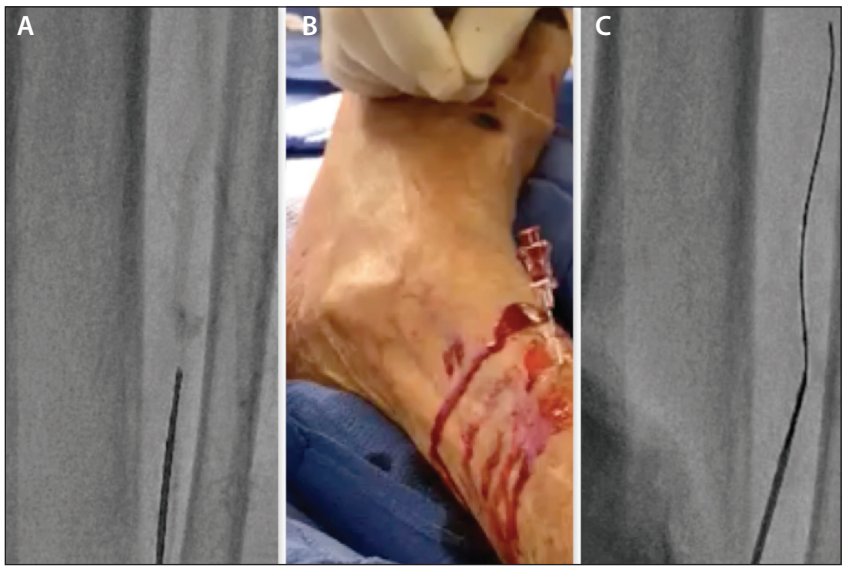

Figure 8. Cannulation of the peroneal artery under fluoroscopic guidance; roadmap through the antegrade sheath (A); micropuncture needle placement (B); advancement of the guidewire (C).

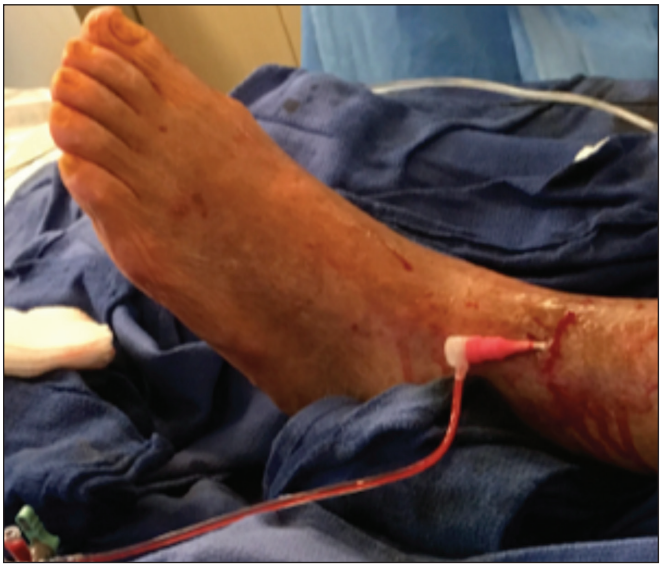

Figure 9. Insertion of the sheath into the peroneal artery.

the wire were externalized, giving outstanding control and support. The antegrade NaviCross support catheter was advanced distally toward the retrograde Glidesheath Slender sheath in the stent. The 0.014-inch CTO wire was exchanged back to an 0.035-inch stiff angled Glidewire, which was advanced distally past the sheath in the distal SFA, stopping near the end of the stent.

We removed the antegrade NaviCross support catheter and advanced a 4-mm X 80-mm EverCross™ percutaneous transluminal angioplasty (PTA) balloon (Medtronic) through the occluded SFA and into the lumen of the stent, centering the puncture site between the radiopaque markers. The micropuncture sheath was removed as the balloon was inflated to nominal pressure, creating hemostasis by internal tamponade, and held for a period of 5 minutes (Figure 7).

The balloon was removed and an angled NaviCross support catheter was reinserted to continue traversing through the distal CTO, which involved the distal SFA and popliteal artery. We made several attempts at crossing this part of the occlusion but were unsuccessful. When considering the peroneal artery as an alternative access strategy, the challenge is balancing safe access with avoiding complications that impair wound healing. It can also be difficult to visualize the artery with standard imaging techniques because of how deep the artery is in the interosseus space. Therefore, our approach is generally to access the artery under fluoroscopic guidance.

We created a roadmap with an injection through the antegrade sheath, and the micropuncture needle was advanced toward the opacified peroneal artery approximately 10 cm above the lateral malleolus (Figure 8).

Once accessed, an 0.018-inch X 80-cm Nitrex™ guidewire (Medtronic) was inserted and a Glidesheath Slender sheath was advanced into the peroneal artery, attached to TAMI solution (500 mL heparinized normal saline, 1,600 µg nitroglycerin and 5 mg verapamil)[6] at 100 mL per hour (Figure 9).

We performed a retrograde injection and saw that the peroneal artery was moderately diseased and totally occluded at the level of bifurcation, with an occluded posterior tibial artery and minuscule tibioperoneal trunk (Figure 10).

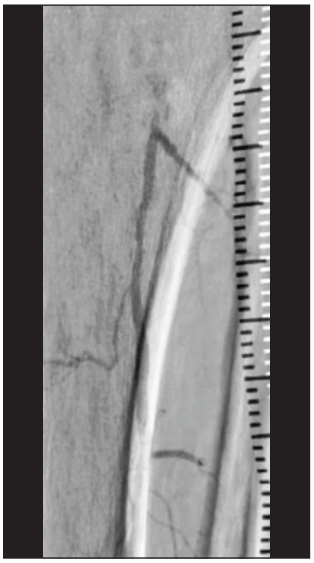

Figure 10. Retrograde injection through the peroneal artery sheath: evidence of occluded posterior tibial artery and small tibioperoneal trunk.

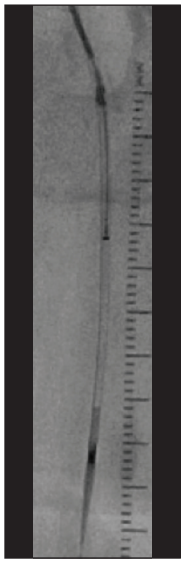

Figure 11. Directional atherectomy of the nonstented portion of the SFA.

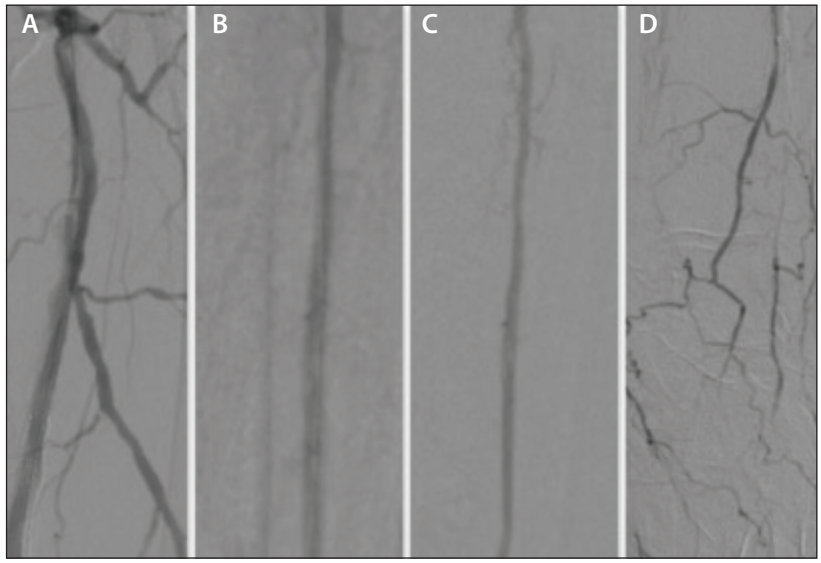

Figure 12. Final angiogram of the common femoral artery and proximal SFA (A), midproximal SFA (B), distal SFA, and peroneal artery (C). The peroneal artery giving collateral flow to the dorsalis pedis and posterior tibial artery (D).

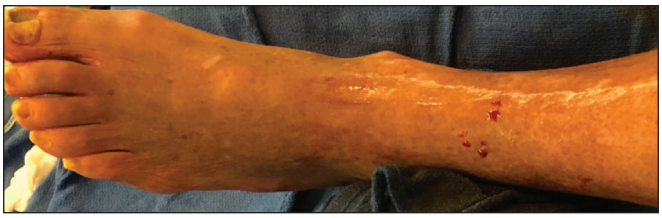

Figure 13. Cessation of peroneal artery puncture site bleeding after removal of the sheath.

An angled 0.035-inch NaviCross support catheter was inserted through the retrograde peroneal sheath and approached the distal cap of the occluded peroneal artery, using the same motion previously described. The distal cap was successfully entered, and the catheter was advanced through the lesion into the popliteal artery toward the anterograde NaviCross support catheter that was located just distal to the SFA stent. Using the same south-meets-north crossing technique performed in the SFA, we brought each of the NaviCross support catheter tips to within a millimeter of each other. The wires were exchanged in both antegrade and retrograde catheters for 0.014-inch CTO wires. We introduced the antegrade wire into the lumen of the retrograde catheter, and subsequently externalized through the peroneal sheath. Once the wire was externalized, the rest of the procedure was completed from an antegrade fashion.

Predilation of the occluded SFA, tibioperoneal trunk, and peroneal artery was performed with a 3.5-mm X 150-mm NanoCross™ PTA balloon (Medtronic). Angiography after predilation showed successful recanalization of the entire SFA with multiple dissections (as expected) and persistent plaque burden.

The initial plan was to perform directional atherectomy with the HawkOne™ device (Medtronic) with a SpiderFX™ filter (Medtronic) placed in the distal tibioperoneal trunk to protect the remaining runoff vessel. Atherectomy (Figure 11) was successful in removing plaque from the SFA (outside of the stent) and popliteal artery.

This was followed by angioplasty with the Chocolate™* PTA balloon (Medtronic) to reduce the potential for flow-limiting dissections and, finally, angioplasty with the IN.PACT™ Admiral™ drug-coated balloon (DCB, Medtronic) to reduce the risk of restenosis. A final angiogram after DCB angioplasty showed excellent flow into the SFA and popliteal and peroneal arteries (Figure 12).

When removing the distal retrograde access sheath, manual compression was not an option due to the location of the peroneal artery deep in the interosseus membrane. To achieve hemostasis, we performed a balloon tamponade technique from an antegrade fashion, where a 2.5-mm X 120-mm NanoCross PTA was positioned just proximal to the peroneal entry site. The same 0.018-inch X 80-cm Nitrex guidewire was introduced into the retrograde peroneal sheath, and the sheath was removed. This maneuver was performed to allow the antegrade wire to bypass the puncture site going distally into the tibial artery. The PTA balloon was advanced forward and toward the puncture site, which was marked by the intersection of the retrograde access wire. The intersection was centered on the balloon, and the balloon was inflated to a pressure that occluded the artery while simultaneously removing the peroneal access wire, so that the blood trickle outside was interrupted. We typically hold pressure to 5 minutes at a time, then take a contrast image through the antegrade sheath to visualize any extravasation. In this case, it took two 5-minute rounds of inflation to achieve hemostasis.

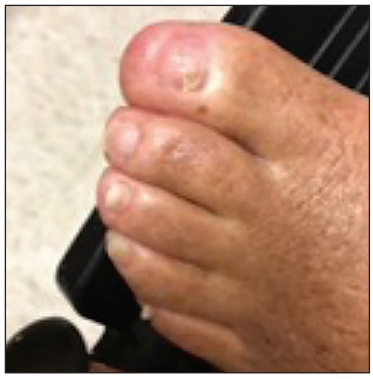

Figure 14. Healed wound after 3 months.

The final image showed a cessation of extravasation (Figure 13) and thrombolysis in myocardial infarction grade 3 flow to the foot with excellent collateralization of the dorsalis pedis and plantar arch artery through the anterior and posterior communicating branches of the peroneal artery.

The procedure was concluded with the long sheath being exchanged for a short 6-F sheath, and the patient recovered without any complications. The wound was completely healed at 3-month follow-up (Figure 14).

CONCLUSION AND LEARNING POINTS

The current case illustrates multiple strategies that can be used to treat patients with CLI with complex anatomy, including CTOs at multiple levels. These include the quick-thinking "fail fast" approach, a willingness to use the tibial arteries, the balloon tamponade technique to achieve hemostasis, and a multidisciplinary team approach to support the best possible outcomes after treatment.

One of our teaching philosophies when performing complex endovascular intervention is "fail fast," a strategy that saves time, resources, and patient discomfort when an operator is unsuccessful with a current course of action. This is compared with the "we'll bring them back" ideology. Many times, patients with CLI may not get another chance before infection or severe tissue loss forces the surgeon to amputate. In our experience, the "fail fast" mentality means we always have plans B, C, and D in mind, ready to

change course as circumstances require,thus increasing the chances of successfully crossing an occlusion, restoring in-line flow, and ultimately delivering a positive outcome for all parties involved.

Utilization of tibial vessels is also vital to the successful treatment of patients with CLI who have complex, multilevel CTOs. We strongly advocate the use of ultrasound-guided access and highly recommend that all operators become more comfortable with its use in retrograde tibial access. Tibials are your friends; use them.

The balloon tamponade technique is a reliable form of achieving hemostasis when handling multiple delicate retrograde access sites. There is a real-time response associated with the deliberate action, and the operator can repeat the tamponade until complete hemostasis is achieved. Although this approach adds time to the procedure, the avoidance of adverse events, such as bleeding, is worth the additional effort.

The mission of our practice is to produce the best possible outcomes for every patient with PAD and CLI. We achieve this with a multidisciplinary team approach that begins with the intervention and leads into a follow-up strategy that integrates the patient, caregiver, and referring and treating physicians. At the center of the circle is a patient liaison who closely monitors the patient for healing, manages coordinated care from all specialists, and ensures regular communication among all parties. The approach requires close and regular follow-up so that if there is a bump in the healing process, the patient can promptly return for evaluation and additional therapy if needed. All working together toward a single unified goal: wound healing and limb preservation. ■

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- Potential complications of peripheral balloon catheterization include, but are not limited to the following: balloon rupture; detachment of a component of the balloon and/or catheter system; failure of the balloon to perform as intended; failure to cross the lesion.
- Although systemic effects are not anticipated, potential adverse events that may be unique to the paclitaxel drug coating include, but are not limited to: allergic/immunologic reaction; alopecia; anemia; gastrointestinal symptoms; hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia); hepatic enzyme changes; histologic changes in vessel wall, including inflammation, cellular damage, or necrosis; myalgia/arthralgia; myelosuppression; peripheral neuropathy.
- Refer to the Physician's Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time.
- Please reference appropriate product Instructions for Use for a detailed list of indications, warnings, precautions and potential adverse effects. This content is available electronically at www.manuals.medtronic.com.

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HawkOne™ directional atherectomy system Reference Statement
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Indications for Use: The HawkOne directional atherectomy system is intended for use in atherectomy of the peripheral vasculature. The HawkOne catheter is indicated for use in conjunction with the SpiderFX™ embolic protection device in the treatment of severely calcified lesions. The HawkOne catheter is NOT intended for use in the coronary, carotid, iliac or renal vasculature.
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Chocolate PTA balloon catheter Reference Statement
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Indications for Use: The Chocolate PTA balloon catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries.
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SpiderFX™ embolic protection device Reference Statement
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Indications for Use:
Lower Extremity (LE) Interventions
- The SpiderFX embolic protection device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk™ Peripheral Plaque Excision System, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities. The vessel diameter at the filter basket placement site should be between 3.0 mm and 6.0 mm.

Carotid Interventions
- The SpiderFX embolic protection device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 7.0mm.

Saphenous Vein Graft (SVG) Interventions
- The SpiderFX embolic protection device is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/debris). The device also acts as the guidewire while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.0mm to 6.0mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral vasculature.

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Indications for Use: The 0.014 in. (0.36 mm) and 0.018 in. (0.46 mm) diameter NITREX nitinol guidewires are intended for use in the peripheral and coronary vasculature.
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EverCross™ PTA balloon catheter Reference Statement
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Indications for Use: The EverCross 0.035" OTW PTA dilatation catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.
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NanoCross™ Elite 0,014" OTW PTA balloon catheter Reference Statement
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Indications for Use: The NanoCross Elite 0.014" OTW PTA balloon dilatation catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.
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