

An Extreme Approach to CLI Revascularization

A useful technique for treating challenging cases of obstructive arterial disease below the knee and ankle.

BY LUIS MARIANO PALENA, MD

Lower limb ischemia is one of the most frequent complications in patients affected by long-term diabetes mellitus. It can be classified into subcritical limb ischemia, which manifests as rest pain and transcutaneous oxygen pressure (TcPO₂) > 40 mm Hg and critical limb ischemia (CLI), which manifests as chronic rest pain, gangrene, tissue loss, and/or TcPO₂ < 40 mm Hg.¹

In diabetic patients, CLI occurs because of progressive and diffuse obstructive atherosclerosis, most closely associated with tibial and foot arterial involvement. Revascularization is a fundamental therapy in patients with CLI, with the goal of achieving relief of rest pain and improving wound healing. In recent years, endovascular therapy has gained acceptance as a primary strategy for the treatment of infrapopliteal vascular lesions in patients with CLI. However, the standard approach and techniques for recanalizing below-the-knee (BTK) and below-the-ankle (BTA) arteries are not always feasible, with failure rates up to 20%. This is due to the obstructive pattern of the vascular disease, which is characterized by multilevel disease, calcifications, prevalence of chronic total occlusions (CTOs), and specific involvement of BTK arteries compromising distal runoff at the foot level.²

CLINICAL CONDITION

Patients with diabetes have a 12% to 25% risk of developing foot lesions,^{3,4} making diabetes the most important risk factor for limb amputation.^{5,6} Advanced atherosclerosis with extensive tibial and foot arterial lesions is a common concern in diabetic patients with CLI and skin wounds. Clinical manifestations range from intermittent claudication to limb-threatening ischemia, rest pain, nonhealing ulcers, and gangrene. Foot lesions may start as uncomplicated, but infection can develop, eventually involving soft tissue (cellulitis) and even bones (osteomyelitis), thus increasing the amputation risk.⁷

Diabetic foot ulceration needs a clear, descriptive classification system that can be used to direct appropriate therapy and possibly predict the outcome. The University of Texas Diabetic Wound Classification considers the pathogenesis and anatomical aspects of the lesions. Lesions are considered both for depth and the presence of infection and ischemia. The University of Texas Diabetic Wound Classification provides a strict correlation between the lesion's grade and stage and the risk of amputation.⁸ Knowledge about the risk of amputation is fundamental to setting up the procedure and taking on a clinically driven, extreme approach to management.

VASCULAR CONDITION

CLI is strictly correlated with multilevel and multivessel arterial disease with compromised circulation to the foot. The distribution of arterial disease in the diabetic population is reported as follows: overall, 5% had above-the-groin disease, 55% had superficial femoral artery (SFA) and/or popliteal artery disease, 93% had BTK disease, and 71% had foot disease. Of note, 77% of patients had two- or three-vessel BTK disease, and 50% of the patients had two- or three-vessel disease in the foot.⁹

Obstructive arterial disease related to CLI in diabetic patients is characterized by multilevel disease, specific involvement of BTK arteries, calcification, and prevalence of CTOs over stenosis.^{2,10,11} This pattern of obstructive arterial disease, in addition to the baseline clinical conditions (eg ischemic and infected ulcers/gangrene) in the diabetic patient population, makes revascularization therapy very challenging and increases the risk of amputation.

THE EXTREME APPROACH TO ENDOVASCULAR REVASCLARIZATION

Multiple technical strategies to successfully cross long occlusions in arterial segments below the groin, BTK, and BTA have been described. Recanalization can be performed



Figure 1. A diabetic patient with CLI. Antegrade access was achieved in the CFA, and diagnostic angiography showed stenosis in the proximal superficial femoral artery (A). Angiogram showing diffuse stenosis and short occlusion in the popliteal artery, occlusion of the anterior tibial and posterior tibial arteries at their origin, and patency of the peroneal artery (B, C). In the foot, only collaterals are identified (lateral tarsal branch and partial flow in the medial plantar artery), without flow in the main foot arteries or in the plantar arch (D). The patient presented with apical gangrene in the first and second toe and previous amputation of the third toe. The ulcers were classified as University of Texas Diabetic Wound Classification IIIC (E).

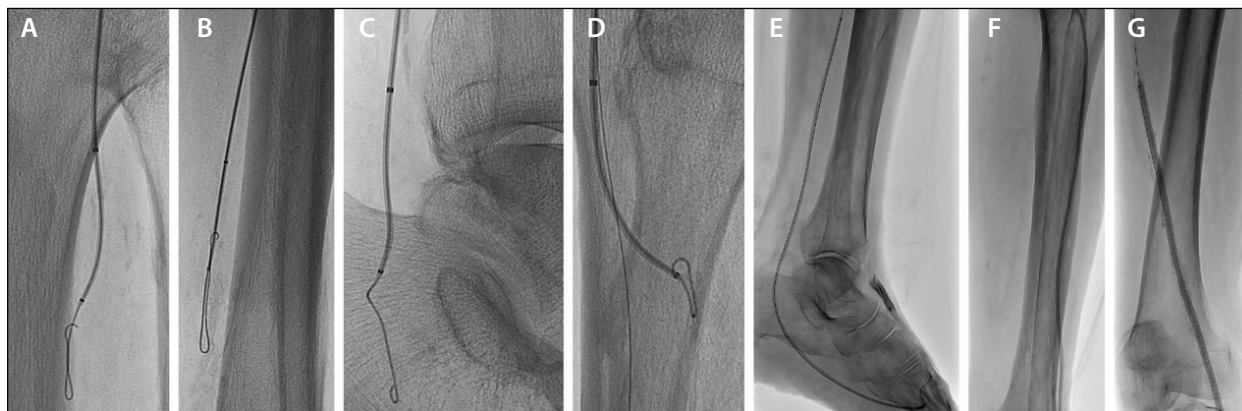


Figure 2. Endovascular therapy for the patient described in Figure 1. An extreme antegrade approach performed to recanalize posterior tibial and lateral plantar arteries using a NaviCross support catheter and 0.035-inch Radifocus half-stiff guidewire. The subintimal technique was used for a long CTO recanalization, and the plantar arch was considered the reentry point (A–C). The same strategy was used to recanalize anterior tibial artery and failed to recanalize the dorsalis pedis (D). Balloon angioplasty of the posterior and plantar arteries, the anterior tibial artery, and the popliteal and superficial femoral arteries (E–G).

using endoluminal, subintimal, and retrograde techniques (pedal-plantar loop technique, transcollateral and percutaneous retrograde access).^{2,12} To overcome the technical limitations and attempt to avoid technical failures, which may occur when foot arteries are occluded, novel revascularization techniques have been conceived, including transmetatarsal, transplanter arch, or antegrade pedal access.^{13–16} These technical strategies are valid tools for endovascular treatment of CLI; however, vascular specialists should perform the procedures based on clinical necessity. The higher the risk of amputation according to the University of Texas Diabetic Wound Classification, the greater the

indication for a clinically driven extreme approach to revascularization.

Our Experience

After local anesthesia in the groin, we start with an ultrasound-guided antegrade access in the ipsilateral common femoral artery (CFA). A 6-F sheath is deployed, and 5,000 units of unfractionated heparin is administered. The revascularization strategy is planned prior to surgery based on ulcer location, with the goal of providing a direct inline blood supply to the foot.

The first attempt to recanalize the vessels is made via the antegrade CFA route according to the standard

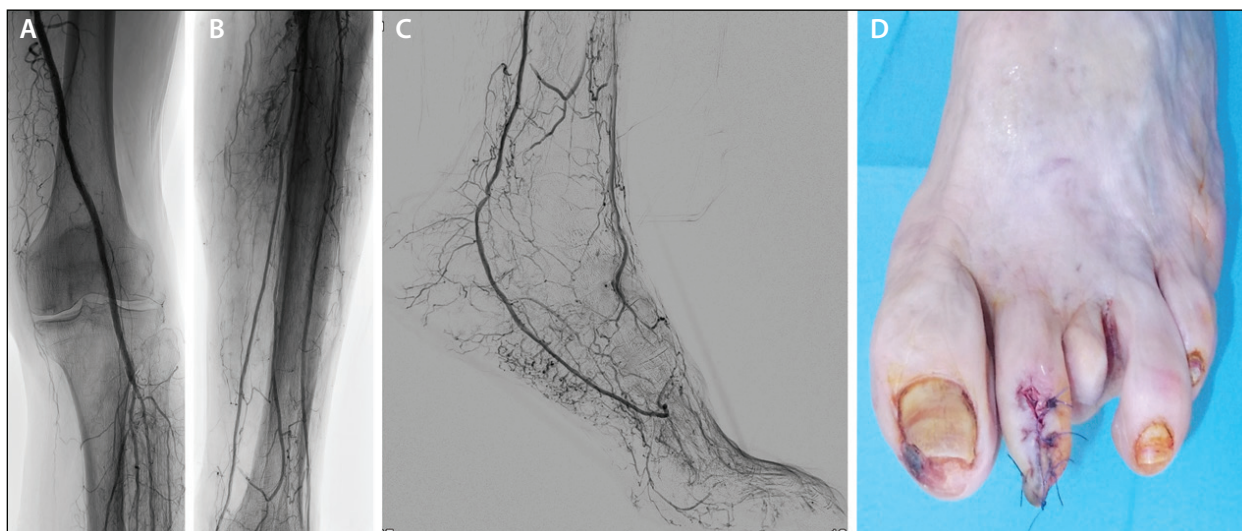


Figure 3. Angiographic and clinical results for the patient described in Figure 1. Angiogram showing patency and no flow-limiting dissections in the popliteal artery as well as patency of the posterior, anterior tibial, and peroneal arteries (A, B). Angiogram showing patency of the lateral plantar artery and direct brisk flow for the plantar arch and for the forefoot, as well as patency of the lateral tarsal branch on the dorsal circulation (C). Surgical treatment of the wound with apical amputation of the second toe (D).

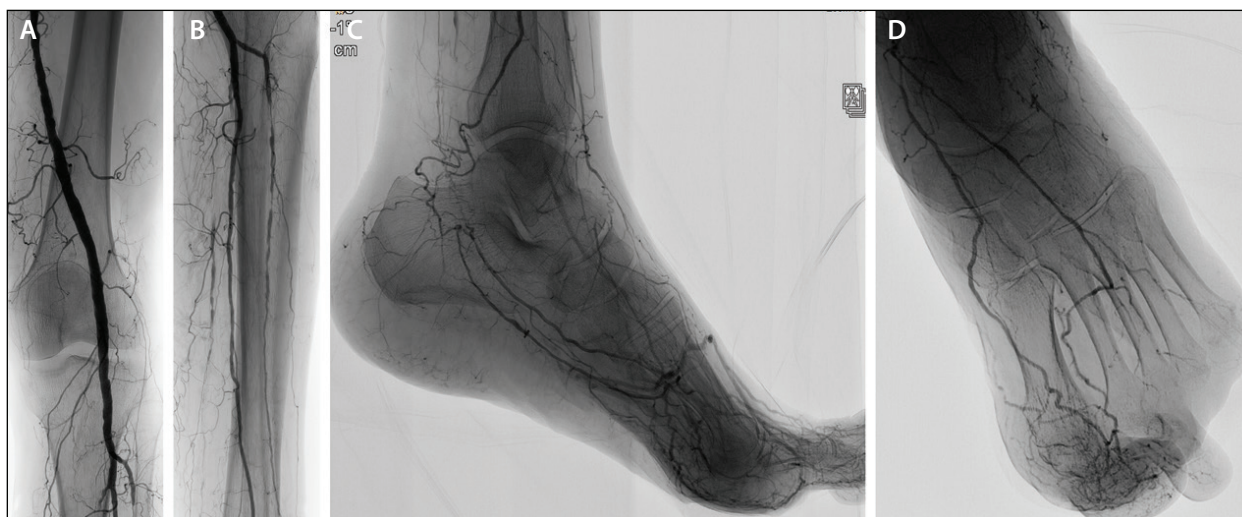


Figure 4. A diabetic patient with CLI. Diagnostic angiography shows patency of the femoropopliteal vessels and occlusion of the anterior and posterior tibial arteries with patency of the peroneal artery (A, B). In the foot, there is absence of the dorsal circulation and patency of plantar arteries and plantar arch, with a plantar dominance (anatomical variation) (C, D). The patient presented with previous amputation of the fourth and fifth toes and a class IIID ulcer in the first toe according to University of Texas Diabetic Wound Classification.

of care at our institution.¹² The step-by-step crossing strategy² is a useful approach for endovascular treatment of CLI, starting with the endoluminal approach as the first choice and shifting to the subintimal space when the endoluminal fashion fails and in cases of “desert foot” (ie, absence of main foot vessels). Retrograde options are considered when the antegrade approach fails. In this context, the extreme access

approaches are considered when no other options seem viable or other options have failed.

Extreme antegrade approach. The extreme antegrade approach is usually performed by subintimal recanalization, after endoluminal failure, and is the preferred approach in cases without evident arterial wall calcifications and in extreme situations, with long CTOs involving tibial and foot vessels (ie, “desert foot”). This approach is considered

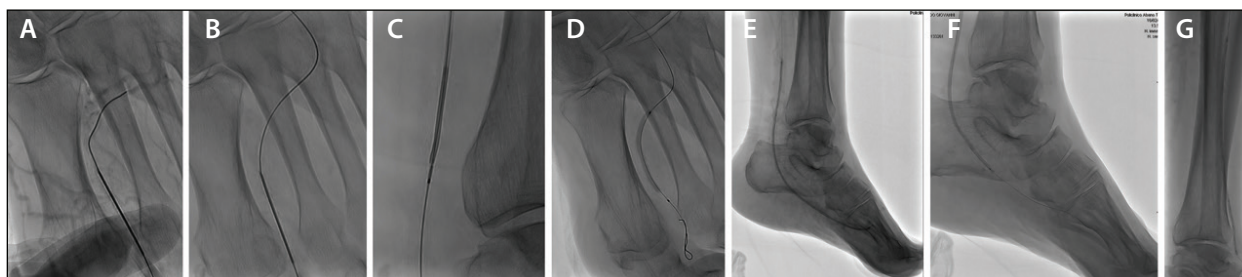


Figure 5. Endovascular therapy for the patient described in Figure 4. After an antegrade approach to recanalize posterior tibial artery failed, an extreme retrograde approach was performed via the first metatarsal artery access. Retrograde puncture of the first metatarsal artery was performed, followed by retrograde endoluminal wiring of the metatarsal artery, the plantar arch, and the lateral plantar artery. The antegrade catheter was connected at the distal posterior tibial artery level (A–C). After reverse access, a short balloon was used to obtain hemostasis at the level of the first metatarsal artery, and then definitive angioplasty of the lateral plantar, medial plantar, and posterior tibial artery was performed. The anterior tibial artery was also recanalized to improve the dorsal flow (C–G).

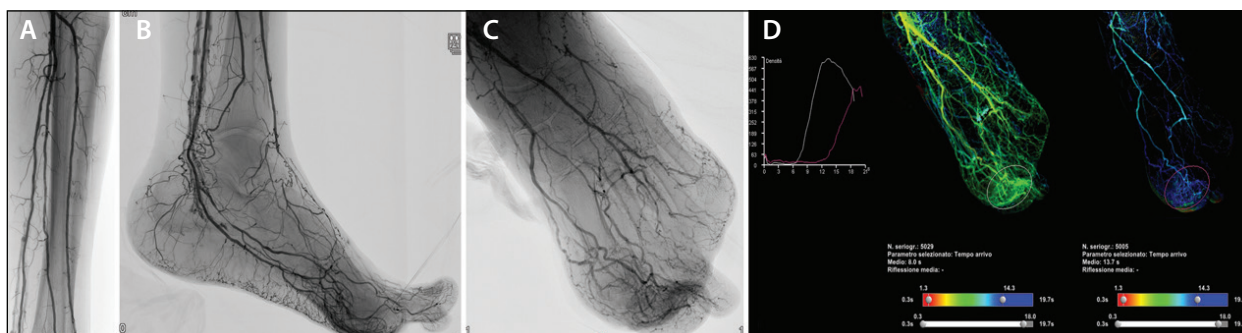


Figure 6. Angiographic and perfusion results for the patient described in Figure 4. Angiogram showing patency of the anterior and posterior tibial arteries, as well as the peroneal artery (A). Angiogram of the foot showing direct flow for both plantar arteries, the plantar arch, and the forefoot, with evident blush in the wound area (note the spasm in the proximal medial plantar artery and the small arteriovenous fistula in the proximal lateral plantar artery) (B, C). Perfusion angiography compared with diagnostic angiography before (right side, blue color) and after (left side, green color) the procedure and showing an evident improvement in terms of arrival time (seconds) and contrast medium concentration (density) as shown in the graph (D).

in an “extreme fashion” when there is no risk of damaging any other arteries, and it is used also in cases in which the plantar arch is the considered reentry point (Figure 1). This technique is often performed with a 0.035-inch guide-wire (Radifocus half-stiff, 1.5 J-tip, Terumo Interventional Systems) and a support catheter (NaviCross, Terumo Interventional Systems) (Figures 2 and 3).

Extreme retrograde approach. The extreme retrograde approach has previously been described in the literature.^{13–16} The access is created after administration of specific pharmacologic support to protect against spasms that compromise the puncture and wiring of foot arteries. We usually use nitrates (0.5 mg) injected intra-arterially through the CFA sheath, as well as verapamil (5 mg/2 mL), diluted to 10 mL with saline, with 9 mL of this solution injected intra-arterially as distal as possible, close to the foot. Local anesthesia is administered close to the target area at the dorsum of the foot, and 1 mL of the remain-

ing diluted verapamil solution, together with lidocaine, is injected into the subcutaneous tissue.

The most frequently used access site for the extreme retrograde approach is at the dorsum of the foot through the first dorsal metatarsal artery (Figures 4 and 5). By way of the dorsal branch of the first metatarsal artery, it is usually possible to reach the plantar arch, and across the arch, it is possible to recanalize the dorsalis pedis or lateral plantar artery (Figure 6).

Other extreme accesses. Other extreme accesses for the retrograde approach that can be considered are the plantar arteries (medial plantar and lateral plantar arteries), which can be easily punctured at the plantar bifurcations or in an extreme fashion more distally. Extreme antegrade pedal access involves wiring of the dorsalis pedis or lateral plantar artery, crossing the plantar arch, followed by retrograde recanalization of the opposing circulatory pathway of the foot. The puncture

is performed with a 21-gauge needle under fluoroscopic guidance with contrast medium injection and at the maximum magnification to identify the target vessel or under ultrasound guidance.

After arterial puncture, a 0.018-inch V-18 guidewire (Boston Scientific Corporation) is advanced into the artery through the needle, and the microsheath (Micropuncture pedal introducer set, Cook Medical) is deployed. After access creation, retrograde intraluminal wiring of the patent foot vessels and the plantar arch is performed, followed by intraluminal or subintimal recanalization of the occluded foot and tibial vessel and rendezvous technique to connect the antegrade and retrograde access. The procedure is completed with an antegrade approach, passing the guidewire beyond the puncture site, retrieving the microsheath, and inflating a balloon catheter, achieving hemostasis at the access level.

DISCUSSION

CLI is a frequent cause of amputation as a result of progressive obstructive arteriosclerosis of the infrapopliteal and foot arteries. Although endovascular intervention is recommended for the treatment of patients with severely symptomatic peripheral artery disease,^{10,17} crossing long CTOs in the BTK and BTA districts remains challenging in most patients, even when combining multiple technical strategies.¹² Different approaches have been proposed to solve this problem, such as the pedal-plantar loop technique, retrograde puncture, transcollateral technique, and advanced and extreme access.^{2,12-16} All of these techniques have proven to be safe and efficacious for managing challenging cases of CLI, achieving the expected outcome of revascularization—to reestablish an adequate blood flow to the wound area, allowing for healing and avoiding major amputations.

During the endovascular treatment of CLI, it is imperative to adapt the technical strategies and the procedure to the clinical indications and risk of amputation, according to the wound in the foot (University of Texas Diabetic Wound Classification).

Considering the description of the baseline clinical situation and the pattern of the obstructive arterial disease in diabetic patients with a CLI (BTK and BTA arterial involvement), the clinically driven extreme approach appears to be indicated in patients with catastrophic clinical situation at high risk of amputation (University of Texas Diabetic Wound Classification IIB to IIID), in combination with a particularly challenging vascular situation (desert foot, absence of main foot vessels, or anatomical variations in the vascular anatomy of the foot). In this context, patients are usually scheduled for surgical treatment of the foot

(preplanned minor amputations), and every effort should be pursued to improve the blood flow to the foot to achieve the surgical incision healing, avoiding new infections, and major amputation. The extreme approaches provide good clinical results in terms of limb salvage and amputation-free survival rates.¹³⁻¹⁵ However, vascular specialists need to know the risk of the extreme approaches. As published in the current literature, the extreme accesses increase radiation exposure and procedure time.^{14,15}

CONCLUSION

A decision to use the extreme approach to revascularization should be driven by clinical indications, not only by the vascular situation. These approaches are useful techniques for treating BTK and BTA arterial disease in CLI patients and should be reserved for extremely challenging cases with a clear clinical indication. ■

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Luis Mariano Palena, MD

Interventional Radiologist Unit
Foot & Ankle Clinic
Policlinico Abano Terme
Abano Terme (PD), Italy
marianopalena@hotmail.com
Disclosures: None.