

Low-Profile CLI Devices

The latest innovations in outflow treatment devices are expanding options for a growing CLI patient population.

BY GEORGE L. ADAMS, MD, MHS, FACC, AND MICHAEL J. POMPLIANO, BS

More than 1 million Americans currently suffer from limb loss secondary to vascular disease.¹ Nearly half of these individuals will die within 5 years, which is higher than the 5-year mortality rates for breast, colon, or prostate cancer.² To combat this devastating disease process, inline blood flow to critical limb ischemic wounds must be restored. Vascular specialists have long understood the importance of inflow circulation within arterial vessels above the knee, and these endovascular procedures have been well documented. On the contrary, the importance of outflow circulation, focusing on arterial vessels below the knee, is just now coming to light.

Current research into outflow procedures has shown tibiopedal interventions to not only increase the patency of inflow interventions but also increase limb salvage rates and decrease morbidity rates.^{3,4} As such, endovascular specialists are beginning to dedicate time to re-establish flow in the lower extremity tibial vessels, even with the increased complexity and time commitment of this procedure. However, endovascular devices have long focused on managing inflow (common iliac to the popliteal artery) rather than outflow (popliteal to the digital arteries). The main constraint of these inflow devices is their inability to reach blockages that are farther from the sheath and in treating smaller vessels (1–4 mm). This article reviews current long and low-profile outflow treatment devices and provides a perspective for future device development.

ARTERIAL ACCESS

The standard approach for addressing blockages in the legs is from a contralateral femoral approach. For many patients, however, standard access is not feasible, such as those who have steep iliac bifurcations in which a sheath cannot be advanced, contralateral femoral arterial occlusions that cannot be accessed, and long chronic total

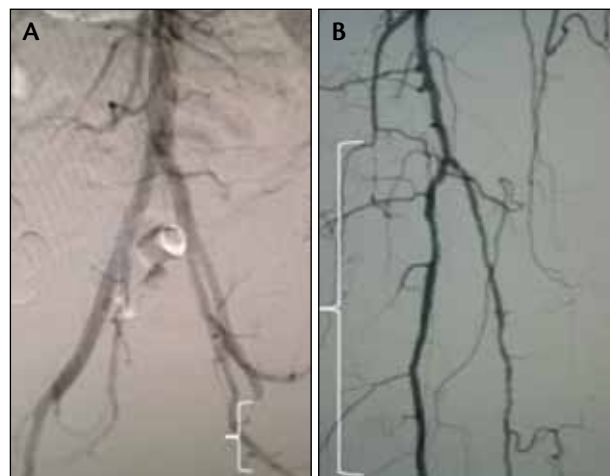


Figure 1. Left CFA occlusion (A) and a long right anterior tibial CTO (B).

occlusions in which the proximal cap cannot be crossed (Figure 1). The critical limb ischemia (CLI) population frequently has one or more of these obstacles, requiring endovascular interventionists to think outside the box in order to gain access to the occlusions. Brachial, popliteal, tibial, and even digital arterial access is becoming more frequent to treat this complex CLI population (Figure 2).

The size of digital, brachial, and popliteal arteries range from 0.5 to 4 mm, as compared to the approximate 6-mm common femoral artery (CFA). As such, the needles used to access these vessels are smaller (ie, a 21-gauge micropuncture needle compared to a standard 18-gauge needle), and the sheaths are lower profile with a better transition (ie, micropuncture and radial sheaths compared to the standard 6- to 7-F sheath). In fact, Cook Medical (Bloomington, IN) has developed a pedal access kit, which includes the Check-Flo hemostasis valve that attaches directly to the micro-



Figure 2. Brachial access (A), popliteal access (B), and anterior tibial access (C).

puncture introducer, allowing it to be used as an interventional introducer with a 2.9-F inner diameter. Additionally, pedal and arm access sites may decrease morbidity by allowing patients to sit up immediately after the procedure, as compared to a 2- to 4-hour supine position post-CFA access, and by reducing bleeding complications.^{5,6}

Mirroring the coronary realm, the future for radial access is that it may also come to the forefront for peripheral interventions. Radial access for coronary intervention has reduced access site bleeding, morbidity, and mortality and increased patient comfort as compared to the commonly used femoral access site.^{6,7} However, to utilize this access site for peripheral interventions, longer and smaller sheaths, wires, and treatment devices need to be developed. Currently, the longest sheath is 90 cm, the longest wire is 335 cm, and the majority of treatment devices reside on a 150-cm platform.

TREATMENT

Patients with CLI frequently have distal tibial stenosis affecting in-line blood flow to the wound. To address these small distal vessels, treatment devices need to have a longer shaft and smaller profile and be used in smaller-diameter sheaths.

Atherectomy

Atherectomy devices are commonly used in tibial vessels to modify and debulk various plaque morphologies. Many of these devices are built to go through larger sheath sizes and address above-the-knee blockages; however, some have the ability to treat tibial lesions through smaller sheath sizes. Such devices include the CVX-300 excimer laser (Spectranetics Corporation, Colorado Springs, CO), in which a 0.9-mm laser fiber can pass through a 4-F sheath, and 1.4- to 1.7-mm laser fibers can pass through a 5-F sheath. The shaft length for each of these laser fibers is 150 cm.

The Diamondback atherectomy device (Cardiovascular Systems, Inc., St. Paul, MN) can also treat calcified tibial lesions. The 1.25- to 1.75-mm Diamondback crown can be

placed through a 5-F nontapered sheath and can extend out to 165 cm. The TurboHawk and SilverHawk devices (Covidien, Mansfield, MA) can also be used to treat smaller tibials, with a 150-cm working length; however, these devices require at least a 6-F sheath. The Jetstream G3 SF (Bayer, Indianola, PA) combines atherectomy and aspiration in one device. The 1.6- and 1.85-mm catheters can be used in tibial vessels with a treatment length of 150 cm and also require a 6-F sheath.

Balloon Angioplasty

Balloon angioplasty is a commonly used treatment strategy for patients with below-the-knee lesions. The majority of these peripheral balloons can travel through a 4-F sheath and reside on a 135- to 150-cm shaft. The smallest balloon diameter on the market is the 1.25-mm Slek OTW catheter (Cordis Corporation, Bridgewater, NJ), which is used for tight calcified stenosis through the distal tibial or digital arteries. The balloon with the longest shaft is the Advance 14LP catheter (Cook Medical) at 170 cm. The balloon is beneficial in tall patients with standard access, transcollateral treatment, and arm access cases when the blockage may reside as far away as the midtibial arteries (Figures 3 and 4). Recently, the Advance Micro 14 catheter (Cook Medical) gained US Food and Drug Administration approval. This balloon is especially helpful in pedal access cases when treatment can occur from the pedal access site rather than having to perform a flossing procedure. It can travel through a 3-F sheath, has a shaft length of 50 cm, and the smallest balloon size is 1.5 mm.

Below-the-Knee Stenting

Below-the-knee stenting is rare and usually reserved for significant vessel recoil or flow-limiting dissection after balloon angioplasty, whereas the majority of peripheral stents are used for above-the-knee lesions with larger diameters. However, the Xpert stent (Abbott Vascular, Santa Clara, CA) is a self-expanding stent that can pass through a 4-F system,



Figure 3. The transcollateral approach, wherein a posterior tibial artery occlusion is accessed via the peroneal artery collateral.

treat vessels as small as 2 mm, and has a shaft length of 135 cm. Typically, even though not currently indicated, drug-eluting coronary stents are placed in tibial vessels. These stents pass through a 5-F sheath, can be as small as 2.25 mm in diameter, and usually reside on a 145-cm shaft. Drug-eluting stent placement in tibial vessels has been shown to decrease restenosis rates compared to balloon angioplasty and bare-metal stenting.^{8,9}

CONCLUSION

Approximately 8 to 12 million Americans suffer from peripheral arterial disease (PAD). Advanced age, diabetes, and renal insufficiency predispose these patients to PAD, and these comorbidities are growing at epidemic proportions in the United States.^{10,11} Approximately 40% of PAD patients will develop intra-arterial chronic total occlusions and subsequently develop CLI, resulting in multiple complex lesions or blockages that partially inhibit or obstruct distal perfusion.¹² Until recently, restoring distal perfusion has been hampered by the lack of long, low-profile tools. These tools continue to evolve with novel access sites and techniques, which effectively treat outflow. It has become apparent that without successful outflow intervention, CLI may lead to limb amputation, morbidity, and mortality.¹³ ■

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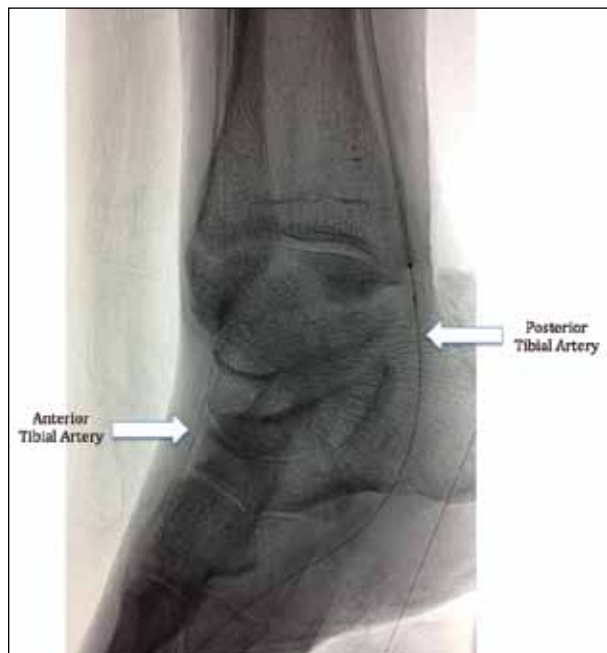


Figure 4. Treating both the anterior tibial and posterior tibial arteries from a contralateral femoral approach.

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