MEDTRONIC
MEDICAL AFFAIRS
CORNER

SPONSORED BY
Medtronic

Keeping it REAL: Revascularizing Extremities Against Limb Loss

By Paul Michael, MD, FSCAI

Limb salvage for amputation prevention is the most important therapeutic goal for patients with critical limb ischemia (CLI). If one were to ask for the definition of limb salvage, many answers may arise. Much of the literature and medical discussion surrounding limb salvage has traditionally been focused on the technical aspects of procedures; however, the requirement of interdisciplinary teams for successful outcomes has been recognized.[1] There have been tremendous technologic advancements, specifically in the areas of CLI and wound management. However, limb salvage is not a procedure but a process—a process that requires buy-in and participation on behalf of the physician, the patient, and the patient's support system to achieve true success. Limb salvage requires a functional outcome as well as an improvement in the quality of life.

Despite the incredible advancements in technologies surrounding peripheral artery disease (PAD) therapy, a significant gap has been left in the resources required to practice chronic disease management therapy in this complex population that is often afflicted by diabetes, hypertension, heart failure, chronic kidney disease, and malnutrition, to name a few. CLI is considered the end stage of PAD and requires a mode switch in the mentality required to take care of these patients, similar to a cancer treatment program. The United States population is accustomed to understanding how patients with cancer require a more comprehensive, integrated style of care given the complexities and logistics required to coordinate successful outcomes. Cancer education and screening are taught in as early as childhood levels of education in this country; self-examination and self-responsibility of disease awareness are also taught at this level. Having said that, it is clearly recognized that empowering a community to take responsibility for its own care begins at the earliest levels. However, the discipline to take ownership of this process is up to the patient.

A similar approach must be taken to combat such a devastating disease as CLI and prevent amputation, considering the extreme psychologic, physical, psychosocial, and emotional consequences of limb loss. In addition, the economic impact at the community and national level of limb salvage has been clearly demonstrated in the literature, supporting the need for organized care pathways that can help illuminate this preventable problem.[2,3] This is easily observed at the levels of social determinants of health contributing to the disparities of care outcomes in amputation prevention, where education and improved access to basic care can help close this gap. The gross majority of preventable amputation in this country is specifically related to one disease: diabetes.[4] Limb salvage patients are not only plagued by well-recognized chronic diseases but also by underrepresented risk factors contributing to unsuccessful functional outcomes. These include poor nutritional status, poor understanding of their disease state condition, poor access to pre- and posttherapy counseling, lower socioeconomic status, access to proper wound management therapy, and poor support systems. Appropriate management of both recognized and underrepresented risk factors can guide patients to a functional outcome that ultimately improves patient quality of life, better the community by improving health, and save overall health care costs. The role of disease navigators has long been recognized in the management of chronic disease to improve these outcomes at every level.

Endovascular education in CLI therapy is an important component in the community team approach that is required to improve functional outcomes related to limb salvage. I have been quoted many times saying, "I'm not in the artery-opening business, I'm in the wound-closing business." But in order to close CLI-related wounds, we must first know how to access, cross, open, and keep these precious vessels patent.

"I'm not in the artery-opening business, I'm in the wound-closing business."

The following case highlights the importance of choosing the right tool for the job when taking on a patient with challenging end-stage PAD.

CASE PRESENTATION

A patient in his mid-60s with diabetes mellitus, coronary artery disease, and hypertension presented with CLI and multilevel disease of the right superficial femoral artery (SFA), popliteal artery, and tibial vessels (Figure 1).

The patient underwent plain balloon angioplasty to treat these lesions, which was unsuccessful. In addition to his multivessel CLI disease, the patient presented late to the Wound Management & Limb Preservation Center due to the COVID-19 pandemic-related health care distancing and the fear of contracting contagion, limiting the access to care. This situation prevented him from achieving wound management therapy, and his rest pain worsened.

Given the proximal, long segment, right SFA disease and distal SFA chronic total occlusion (CTO), a contralateral left common femoral artery (CFA) approach was taken. The intervention was set up by placing a 6-F, 45-cm sheath in the proximal right CFA. A marker ruler, one of the most important tools in the CLI toolbox, was used to determine the zones of interest for directional atherectomy and angioplasty for efficient therapy delivery. Directional atherectomy was chosen to debulk the SFA and popliteal artery and allow for optimal drug-coated balloon (DCB) therapy delivery at the termination of the procedure without the need for excessive scaffolding in a stent-naive patient prone to restenosis. Successful directional atherectomy of the right SFA and popliteal artery was performed using a 6-F HawkOne™ directional atherectomy system (Medtronic), which was removed and exchanged for a TurboHawk™ SS-CL peripheral plaque excision system (Medtronic) to debulk the right posterior tibial artery down to the terminal portion at the level of the ankle (Figure 2).

The TurboHawk SS-CL device was chosen for the distal tibial level because of the CTO, plaque morphology, and high rate of restenosis at the plantar bifurcation and the need for durable patency given the presence of

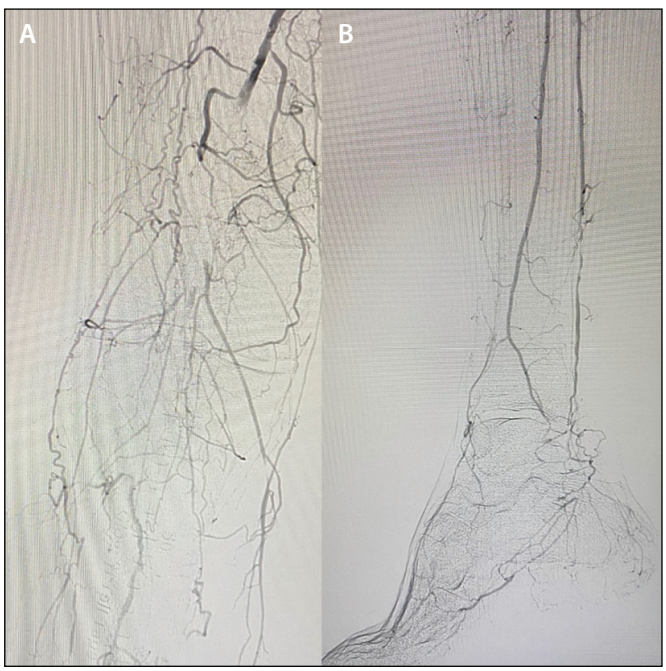

Figure 1. Initial angiogram showing stenosis of a long segment in the right SFA with distal SFA CTO as well as popliteal artery occlusion (A) and posterior tibial artery and plantar bifurcation restenosis (B).

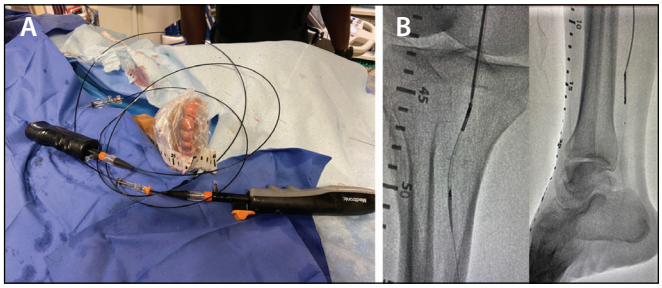

Figure 2. Directional atherectomy of the right SFA and popliteal artery (A) and the right posterior tibial artery (B).

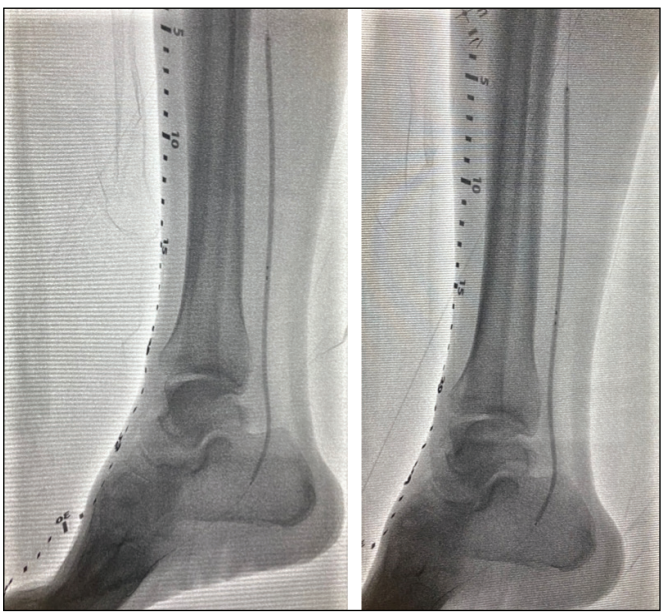

Figure 3. Balloon angioplasty of the right lateral plantar artery and posterior tibial artery.

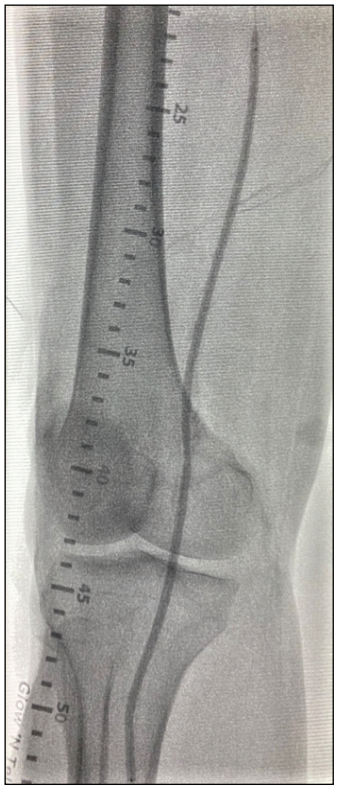

Figure 4. Balloon angioplasty of the proximal posterior tibial artery and SFA.

a plantar wound. After directional atherectomy, balloon angioplasty of the right lateral plantar artery was performed using a 1.5- X 40-mm balloon. The posterior tibial artery was treated with a series of tapered NanoCross™ Elite balloon catheters (2.5-/2- X 210-mm, 3-/2.5- X 210-mm; Medtronic) (Figure 3). The proximal posterior tibial artery was treated with a 4- X 300-mm Pacific™ Xtreme balloon catheter (Medtronic) extending into the SFA (Figure 4).

For the popliteal artery and SFA, a 5- X 300-mm and then a 6- X 300-mm Pacific Xtreme balloon were used, followed by 6- X 150-mm IN.PACT™ Admiral™ drug-coated balloon (Medtronic) to the terminal and mid-right SFA (Figure 5).

Prior to the intervention, the patient had no inline flow to the right foot and a plantar wound in the setting of diabetes. Postintervention, after directional atherectomy, prolonged angioplasty inflations with long balloons, and antirestenotic DCB therapy, the patient had brisk inline flow to the SFA and popliteal artery with two-vessel tibial outflow to the wound site, completing wound-directed therapy (Figure 6).

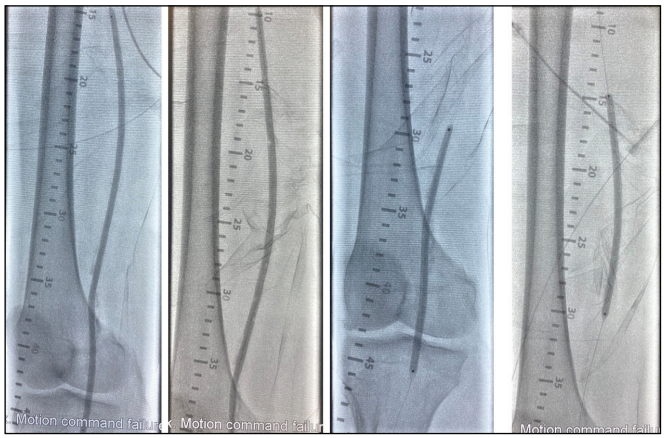

Figure 5. Plain balloon angioplasty followed by IN.PACT Admiral DCB angioplasty in the femoropopliteal artery.

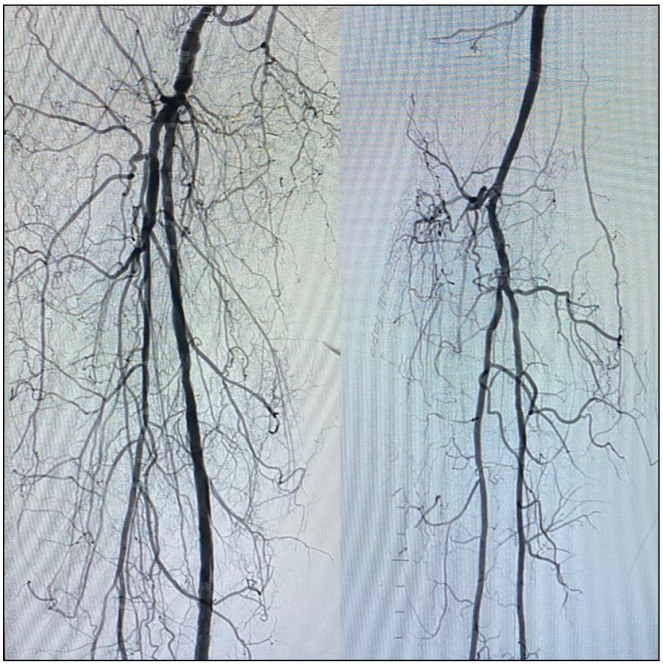

Figure 6. Completion angiograms showing successful revascularization with "leave nothing behind" strategy.

More importantly, the patient is now on his way to functional wound healing, allowing him the chance to return to work, gain his mobility back, and take charge of his health care condition through education on the importance of diabetic foot care maintenance, healthy lifestyle living, and risk factor control through a community team approach that is focused on saving limbs and lives. ■

1. Musuuza J, Sutherland BL, Kurter S, et al. A systematic review of multidisciplinary teams to reduce major amputations for patients with diabetic foot ulcers. J Vasc Surg. 2020;71:1433-1446.e3. doi: 10.1016/j.jvs.2019.08.244
2. Joret MO, Osman K, Dean A, et al. Multidisciplinary clinics reduce treatment costs and improve patient outcomes in diabetic foot disease. J Vasc Surg. 2019;70:806-814. doi: 10.1016/j.jvs.2018.11.032
3. Barshes NR, Chambers JD, Cohen J, Belkin M; Model To Optimize Healthcare Value in Ischemic Extremities 1 (MOVIE) Study Collaborators. Cost-effectiveness in the contemporary management of critical limb ischemia with tissue loss. J Vasc Surg. 2012;56:1015-1024.e1. doi: 10.1016/j.jvs.2012.02.069
4. Armstrong DG, Boulton AJM, Bus SA. Diabetic foot ulcers and their recurrence. N Engl J Med. 2017;376:2367-2375. doi: 10.1056/NEJMra1615439

Paul Michael, MD, FSCAI
Medical Director, Wound Management & Limb Preservation Center
JFK Medical Center
Palm Beach, Florida
Medical Director, Palm Beach Heart & Vascular
Boynton Beach, Florida
drpaulmichael@gmail.com | @drsavealimb
Disclosures: Consultant to Abbott, Asahi Intecc, Boston Scientific Corporation, Medtronic, Philips, and Terumo Interventional Systems.

Medtronic

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.
CAUTION: Federal (USA) law restricts this product for sale by or on the order of a physician.

TurboHawk™ peripheral plaque excision system Reference Statement

Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device.
Indications for Use: The TurboHawk peripheral plaque excision system is intended for use in the atherectomy of the peripheral vasculature. The TurboHawk catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculature.
The TurboHawk catheter is indicated for use in conjunction with the SpiderFX™ embolic protection device in the treatment of severely calcified lesions (LX-C only).
CAUTION: Federal (USA) law restricts this product for sale by or on the order of a physician.

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.
CAUTION: Federal (USA) law restricts this product for sale by or on the order of a physician.

IN.PACT™ Admiral™ Paclitaxel-coated PTA balloon catheter Brief Statement

Indications for Use:
The IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions with lengths up to 360 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.

Contraindications

- The IN.PACT Admiral DCB is contraindicated for use in:
- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure.

Warnings

- **A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients.**
- Use the product prior to the Use-by Date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT Admiral DCB.
- Do not exceed the rated burst pressure (RBP). The RBP is 14 atm (1419 kPa) for all balloons except the 200 and 250 mm balloons. For the 200 and 250 mm balloons the RBP is 11 atm (1115 kPa). The RBP is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety and effectiveness of using multiple IN.PACT Admiral DCBs with a total drug dosage exceeding 34,854 µg of paclitaxel in a patient has not been clinically evaluated.

Precautions

- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents.
- The safety and effectiveness of the IN.PACT Admiral DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure or following treatment failure has not been evaluated.
- The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the *Instructions for Use* (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events
- Vessel preparation using only pre-dilatation was studied in the clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT Admiral DCB.
- This product is not intended for the expansion or delivery of a stent.

Potential Adverse Effects

- The potential adverse effects (e.g. complications) associated with the use of the device are: abrupt vessel closure; access site pain; allergic reaction to contrast medium, antiplatelet therapy, or catheter system components (materials, drugs, and excipients); amputation/loss of limb; arrhythmias; arterial aneurysm; arterial thrombosis; arteriovenous (AV) fistula; death; dissection; embolization; fever; hematoma; hemorrhage; hypotension/hypertension; inflammation; ischemia or infarction of tissue/organ; local infection at access site; local or distal embolic events; perforation or rupture of the artery; pseudoaneurysm; renal insufficiency or failure; restenosis of the dilated artery; sepsis or systemic infection; shock; stroke; systemic embolization; vessel spasms or recoil; vessel trauma which requires surgical repair.
- 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.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Pacific Xtreme™ PTA balloon dilatation catheter Reference Statement

Important Information: Prior to use, refer to the Instructions for Use supplied with these devices for indications, contraindications, side effects, suggested procedure, warnings and precautions.
Indications for Use: The Pacific Xtreme PTA balloon dilatation catheter in 150 mm, 200 mm, 250 mm and 300 mm balloon length is intended to dilate stenoses in femoral, popliteal and infrapopliteal arteries.
CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.
Test data is on file at Medtronic Inc. Bench test results may not be indicative of clinical performance.