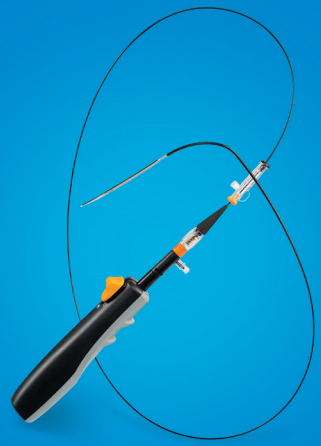
IMPRESSIVE ALONE. BETTER TOGETHER. YOUR NEW REALITY.

The REALITY Study, sponsored by the VIVA Physicians,[1] demonstrates how optimizing the combination of HawkOne™ Directional Atherectomy and IN.PACT™ Admiral™ Drug-Coated Balloon in treating peripheral artery disease can help achieve excellent patient outcomes in complex, long, heavily calcified lesions.[2]

92.6%
12-MONTH FREEDOM FROM CD-TLR*

8.8%
BAILOUT STENT RATE



HawkOne Directional Atherectomy

+

IN.PACT Admiral Drug-Coated Balloon

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*12-month data reported includes patients beyond the follow-up window.

[1] The REALITY Study was independently sponsored and conducted by the VIVA Physicians. The study prospectively enrolled 102 participants whose treatment outcomes were independently adjudicated by angiographic and duplex ultrasound core labs and a clinical events committee. The research was funded by Medtronic.

[2] Rocha-Singh K. Data presented at VIVA 2020.

HawkOne™ Directional Atherectomy System

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™ peripheral 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.

BRIEF STATEMENT
IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter

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 Physicians' 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.

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PERIPHERAL ARTERIAL DISEASE

Optimizing Revascularization Outcomes and Limb Preservation in Critical Limb Ischemia

Siddhartha Rao, MD, RPVI, Amputation Prevention Center of North Carolina, Cary, North Carolina

CASE STUDY

Use of the Versatile Medtronic SilverHawk DS Plaque Excision System to Recanalize the Pedal Arterial Loop for Maximal Luminal Restoration

Charles MT Jost, MD; Nachiket J. Patel, MD; Sam Dierks, BS; Samuel Jost, BS; Angie Aguilar, BA; Michael Barry, DO; Kirk D. Minkus, MD; Southwest Cardiovascular Associates, Mesa, Arizona

CRITICAL LIMB ISCHEMIA

Take Charge of CLI: Tools for Optimal CLI Revascularization

Paul Michael, MD, Wound Management & Limb Preservation Center, JFK Medical Center, Palm Beach, Florida

CASE STUDY

Optical Coherence Tomography in the Diagnosis and Treatment of Spontaneous Popliteal Artery Dissection: A Case Report

Astrid Serauto, MD; Oscar R. Rosales, MD

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Optimizing Revascularization Outcomes and Limb Preservation in Critical Limb Ischemia

Siddhartha Rao, MD, RPVI, Amputation Prevention Center of North Carolina, Cary, North Carolina

Today there are over 12 million patients with peripheral artery disease (PAD) in the United States.[1,2] The most severe form of PAD is critical limb ischemia (CLI). Presentations of CLI that require hospitalization lead to great morbidity and mortality, with 29% undergoing major amputation or death at 12 months.[3] Further, greater than 50% of patients with CLI who undergo major lower-extremity amputation have no revascularization performed in the year before amputation, adding to the mortality associated with this disease.[3,4] Revascularization not only saves the affected limb, but is associated with reduced readmissions and costs.[3] Revascularization, however, involves the need for advanced endovascular therapy skills and tools to improve outcomes. One such tool is the HawkOne Directional Atherectomy system (Medtronic). This device has the versatility to treat lesion morphologies above the knee, below the knee, and even into the pedal arch. Additionally, the low profile 6 French (Fr) options allow for treatment using alternative access sites. Directional atherectomy has also proven to be effective in preventing major limb amputation in CLI patients. In the DEFINITIVE LE trial, enrolling 800 subjects, the freedom from major unplanned amputation of the target limb at 12 months in CLI subjects was 95%.[5] In this article, three unique clinical scenarios are presented in which endovascular therapy prevented major amputations and improved patient outcomes.

Case 1

A white female in her early 40s presented with progressive right foot gangrene for six weeks (Figure 1, left). Significant comorbidities included type 2 diabetes, smoking, hypertension, hyperlipidemia, and dilated cardiomyopathy, with an ejection fraction of 40%. Arterial duplex presented no evidence of flow-limiting right femoropopliteal disease. Tardus-parvus waveforms were noted in all three tibial vessels. Toe pressures were not detected. The patient subsequently underwent a trans-metatarsal amputation since there was significant gangrenous tissue.

Right lower extremity angiography via antegrade right common femoral artery access showed severe, flow-limiting, 3-vessel tibial disease on the right side, with occluded distal anterior tibial and posterior tibial arteries (Figure 2).

The occlusions in the arteries were crossed with a Fielder FC wire (Asahi-Intecc) and directional atherectomy with a HawkOne S Directional atherectomy system (Medtronic) was performed through the occluded posterior tibial, through the pedal arch, and into the dorsalis pedis artery (Figure 3). Due to residual eccentric disease in the anterior tibial and dorsalis pedis arteries, atherectomy was performed with the same device from the anterior tibial into the posterior tibial via the pedal arch, followed by balloon angioplasty with a 2.5 x 220 mm Coyote balloon (Boston Scientific), resulting in 0% residual stenosis and restoration of normal flow in the pedal arch (Figure 4).

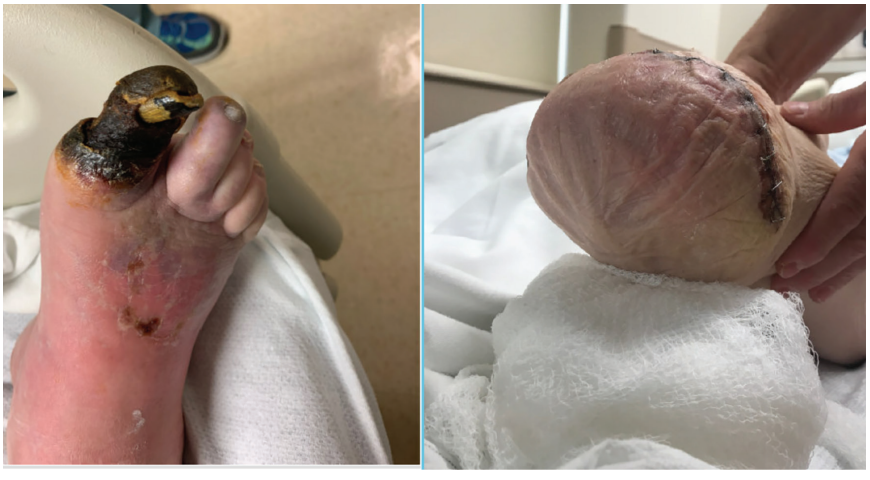

Figure 1. *Case 1:* **Image of the wound before and after amputation plus revascularization.**

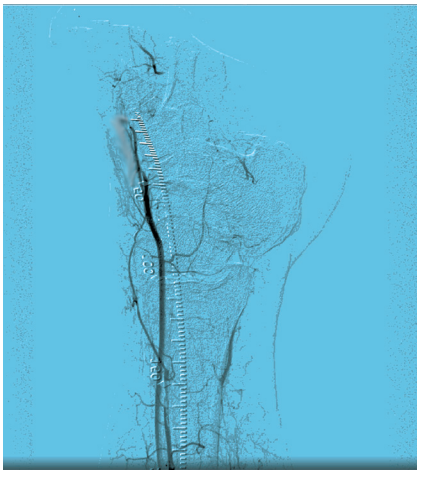

Figure 2. *Case 1:* **Angiogram prior to revascularization.**

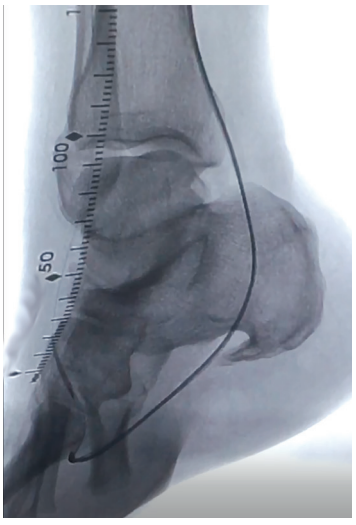

Figure 3. *Case 1:* **HawkOne S device (Medtronic) used to atherectomize the posterior tibial, pedal arch, and distal dorsalis pedis.**

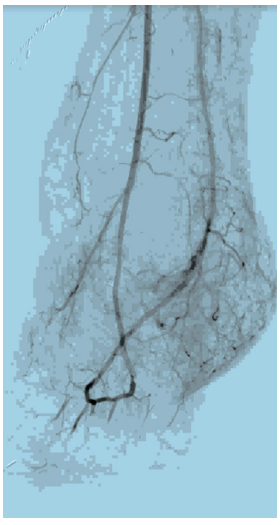

Figure 4. *Case 1:* **Final angiographic result.**

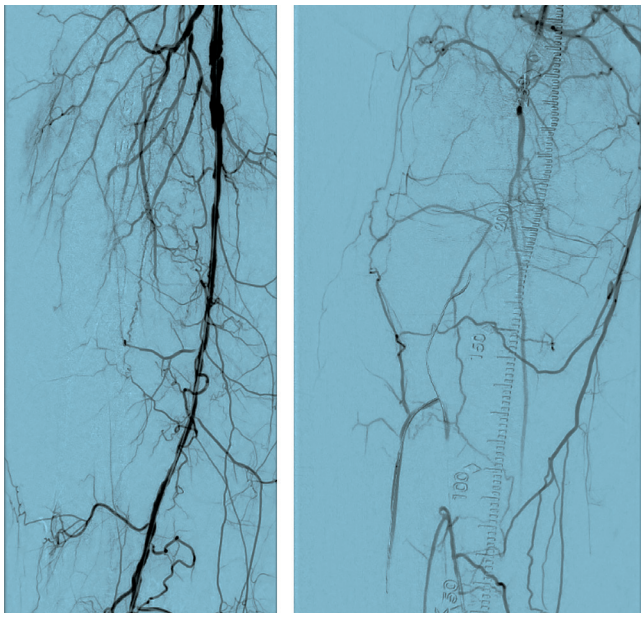

Figure 5. *Case 2:* **Angiogram prior to revascularization procedure.**

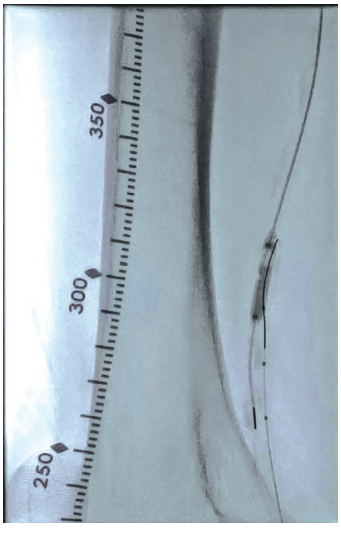

Figure 6. *Case 2:* **Enteer Re-entry system (Medtronic) deployed to cross lesion.**

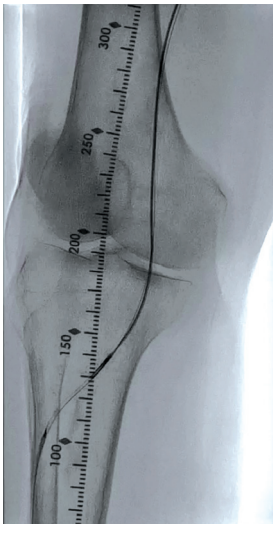

Figure 7. *Case 2:* **HawkOne M device (Medtronic) used to treat lesion.**

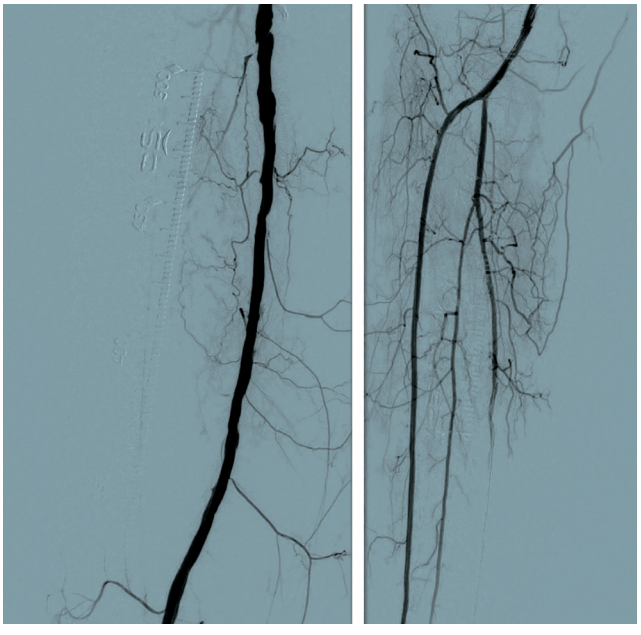

Figure 8. *Case 2:* **Final angiographic result.**

The patient was subsequently discharged home with a healthy surgical site (Figure 1, right) and was able to ambulate with a cane.

Case 2

A functional white female in her late eighties with history of type 2 diabetes, hypertension, and hyperlipidemia presented with progressive right hallux discoloration and early pre-gangrenous changes over a 2-month period. Arterial duplex suggested a right popliteal artery (P3 segment) occlusion, distal posterior tibial artery occlusion, and patent anterior tibial and peroneal arteries. Diagnostic angiography, performed through antegrade access into the right common femoral artery, revealed a diffusely diseased right superficial femoral artery (SFA) and occluded P2 and P3 segment popliteal artery, with 3-vessel tibial vessel reconstitution by collaterals (Figure 5). Antegrade crossing via the common femoral artery access and retrograde crossing of the popliteal occlusion via the anterior tibial led to the subintimal presence of the retrograde V-18 wire (Boston Scientific). A focal calcified lesion in the P2 segment of the popliteal artery prevented reentry at that level.

The decision was then made to reenter the true lumen of the SFA with an Enteer reentry wire (Medtronic) that was advanced from the retrograde route (Figure 6). Unfortunately, at that instant, the "roadmap" feature of the x-ray equipment failed. Since there was a need for image-guided reentry into the true lumen of the right SFA, a 6 x 20 mm EverCross balloon (Medtronic) was inflated in the SFA and under fluoroscopic guidance, this balloon was punctured with the retrograde Enteer wire, thus entering the true lumen of the SFA.

The Enteer wire was exchanged out for a V-18 wire that was subsequently externalized via the right common femoral artery sheath. Over an antegrade Fielder FC wire, intravascular ultrasound (IVUS) evaluation was performed with an .014-inch IVUS catheter, followed by directional atherectomy with a HawkOne M device (Medtronic) (Figure 7).

Sequential balloon angioplasty in the anterior tibial artery was performed with 2.0 mm and 4.0 mm Coyote balloon (Boston Scientific). Kissing balloon angioplasty of the popliteal artery, proximal anterior tibial, and tibioperoneal trunks was performed with long 3 mm balloons, followed by drug-coated balloon angioplasty of the right femoropopliteal segment with a 6 mm x 250 mm IN.PACT Admiral drug-coated balloon (Medtronic). There was restoration of normal flow in all treated segments (Figure 8), with a warm foot and a palpable dorsalis pedis artery at the end of the case.

Case 3

A white male in his early seventies with a history of type 2 diabetes presented with one year of claudication and a 2-month-old nonhealing ulcer at the tip of the right hallux with rest pain. Diagnostic angiography by a different physician revealed no evidence of right iliofemoral disease. The P3 segment of the right popliteal artery and the tibioperoneal trunk were occluded with recanalization of the mid peroneal artery via numerous collaterals (Figure 9, left). Antegrade crossing of the right popliteal artery was then attempted by this physician from the left common femoral artery and subsequently, in a different attempt, via right common femoral artery access, but was unsuccessful. The patient was then referred to me. The decision was made to attempt recanalization via a tibial approach. Right peroneal artery access was obtained under fluoroscopic guidance to advance a 6 Fr Prelude Ideal sheath (Merit Medical) in a retrograde fashion (Figure 10). A V-18 wire was advanced from the retrograde route and entered the subintimal space of the P3 segment of the popliteal artery. True lumen reentry was performed by advancing an Enteer wire with the aid of a 90 cm angled NaviCross catheter (Terumo) from the retrograde route. This wire was then exchanged out for a Fielder FC wire, followed by directional atherectomy of the right peroneal artery, right tibioperoneal trunk, and right popliteal artery, with a HawkOne M catheter advanced from the Prelude Ideal sheath, followed by balloon angioplasty with a 3.0 x 80 mm NanoCross balloon (Medtronic) and

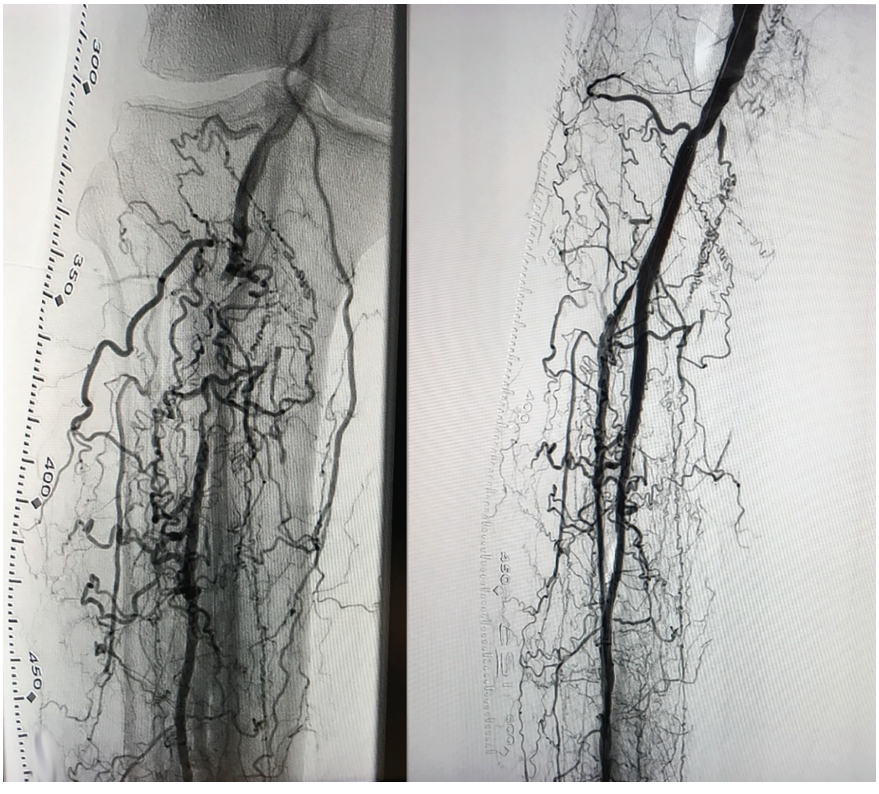

Figure 9. *Case 3:* **Before and after revascularization procedure.**

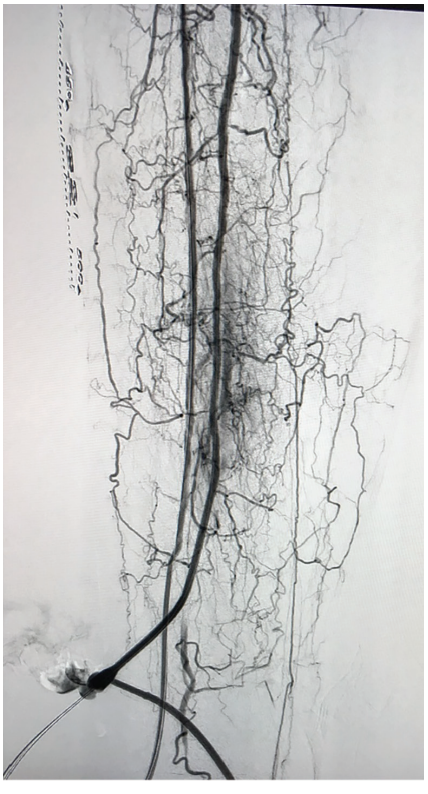

Figure 10. *Case 3:* **View of access site.**

a 4.0 x 80 mm IN.PACT Admiral drug-coated balloon in the popliteal. Residual popliteal artery disease was treated with a 6 x 80 mm EverFlex self-expanding stent (Medtronic), post dilated in the proximal segment with a 6 x 40 mm and a 4 x 40 mm EverCross balloon (Medtronic) in the distal segment. To maximize blood flow and aid healing, right dorsalis pedis artery access was obtained with ultrasound and a 4 Fr merit Prelude Ideal sheath was advanced into the right distal anterior tibial artery. A knuckled Fielder FC wire was advanced into the true lumen of the right anterior tibial artery and right popliteal artery, followed by balloon angioplasty with a long 3.5 mm NanoCross balloon (Medtronic). Final angiography showed a widely patent right popliteal artery, tibioperoneal trunk, and peroneal artery (Figure 9, right). The ostium of the right anterior tibial artery was pinched, but there was normal flow in the right anterior tibial artery. There was complete resolution of the rest pain by the end of the procedure.

Discussion

Long-term survival and cost metrics in critical limb ischemia management are improved with successful endovascular revascularization procedures. Primary major amputation results in shorter survival, higher risk of subsequent major amputation, and higher healthcare costs versus revascularization.[3] Use of the Medtronic HawkOne directional atherectomy system followed by drug-coated balloon angioplasty above the knee shows promising results for treating and optimizing the care of patients with severe PAD. In the DEFINITIVE AR clinical study, a multinational pilot study evaluating the effectiveness of directional atherectomy (DA) and anti-restenotic therapy (121 patients, 10 centers) demonstrated that vessel prep with DA prior to DCB resulted in increased technical success and fewer flow-limiting dissections compared to DCB alone. The DEFINITIVE AR clinical study suggests a trend towards improved patency using DA + DCB for both longer and severely calcified lesions.[6] The REALITY study will further evaluate this concept with HawkOne directional atherectomy (Medtronic), followed by IN.PACT Admiral DCB (Medtronic), to treat long, calcified femoropopliteal arteries.[7] ■

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Images courtesy of Dr. Siddhartha Rao. Individual results may vary.

Disclosure: Dr. Rao reports he is a consultant to Medtronic, CSI, and Intact Vascular.

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Use of the Versatile Medtronic SilverHawk DS Plaque Excision System to Recanalize the Pedal Arterial Loop for Maximal Luminal Restoration

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Current estimates suggest that peripheral arterial disease (PAD) may already affect up to 200 million people worldwide and approximately 8.5 million people in United States alone.[1,2] The nationwide epidemic of diabetes and renal failure, age, hypertension, hyperlipidemia, and smoking have become the definitive risk factors in identifying these patients. Many patients with PAD have arteries affected below the knee, and now, with longer length catheters and wires, we are seeing and regularly treating vessels below the ankle as well. However, there is limited data published[3] regarding the effectiveness of atherectomy below the knee or ankle. The DEFINITIVE LE study (**D**etermination of **EF**fectiveness of the SilverHawk Per**I**pheral Plaque Excisio**N** System (S**I**lverHawk Device) for the **T**reatment of **I**nfrainguinal **VE**ssels/**L**ower **E**xtremities) demonstrated a safe and effective technique providing high one-year patency rates (89.6%) in claudicant patients with infra-popliteal artery lesions treated with directional atherectomy.[4] In the critical limb ischemia (CLI) cohort of DEFINITIVE LE, the primary endpoint was freedom from major unplanned amputation of the target limb at 12 months, with a rate of 95%.[3] Treatment of the pedal loop is paramount in achieving a successful revascularization in CLI and claudicants, and will achieve the greatest long-term patency and the optimal benefit in avoiding partial limb amputation.[5] We present a case demonstrating use of directional atherectomy technology below the ankle for revascularization of the pedal loop to demonstrate that atherectomy + PTA may be more beneficial to PTA alone in maximizing patient outcomes.

Case Report

A 52-year-old nondiabetic female was evaluated for severe short distance claudication, lower extremity cramping, plantar surface neuropathy, toe color changes, cold feet and toes, poor pedal pulses, and chronic lower extremity throbbing pain and fatigue at rest (Rutherford class IV). Ultrasounds revealed multiple elevated arterial velocities in both legs, worse on the left. Lower extremity arteriograms were warranted for further endovascular evaluation. The left leg was addressed via antegrade approach due to a maximum usable catheter length of 132 cm. The distal left posterior tibial artery and lateral plantar artery demonstrated slower TIMI-I flow, with a diffusely narrowed lateral plantar artery and poor pedal loop representation. Delayed flow down the anterior tibial artery demonstrated mild to moderate narrowing of the distal anterior tibial artery and dorsal pedis artery (Figure 1). The revascularization procedure across the posterior tibial, lateral plantar, dorsal pedis, and anterior tibial arteries was performed successfully over a Gladius .014-inch wire (Asahi Intecc) without complications. The predilatation procedure at the pedal loop was performed from the lateral plantar approach by first positioning a 2.0 x 120 mm NanoCross Elite .014-inch OTW PTA balloon catheter (Medtronic) across the lateral plantar artery with the arc of the balloon in the middle of the pedal arterial loop. The distal aspect of the balloon was positioned in the dorsal pedis artery and the proximal aspect in the lateral plantar artery.

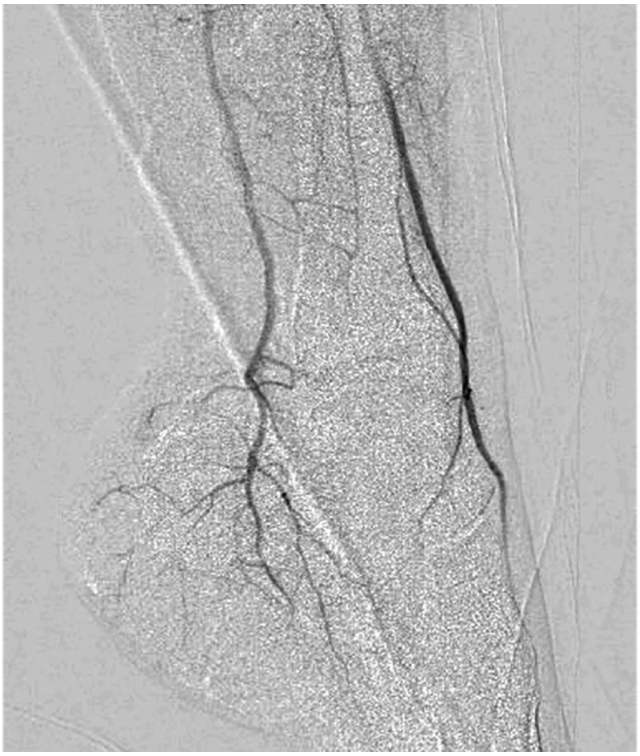

Figure 1. Initial distal arteriogram.

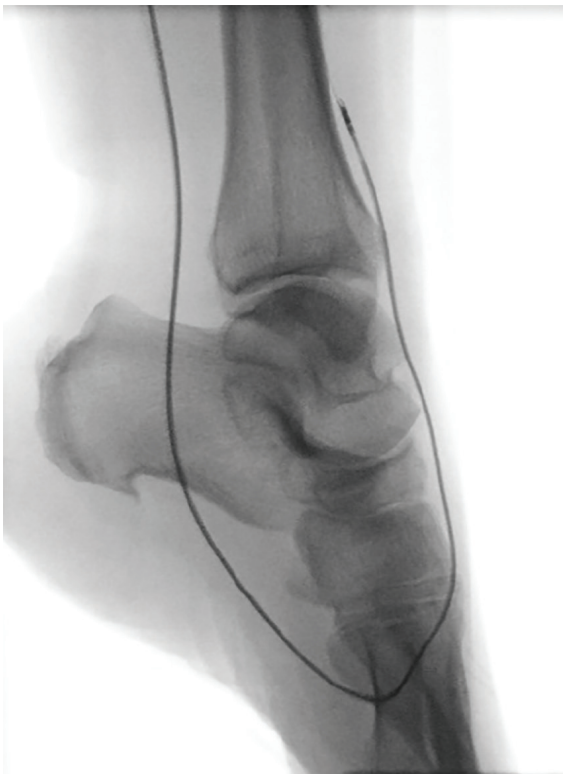

Figure 2. The SilverHawk DS atherectomy device (Kawarada Type 3 pedal artery disease was evident[6]).

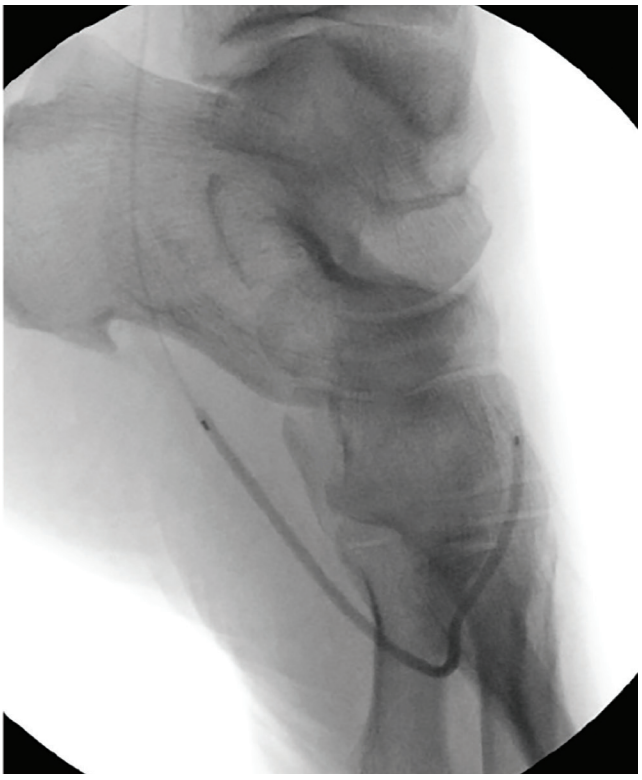

Figure 3. Post-atherectomy angioplasty throughout the treated pedal loop tract.

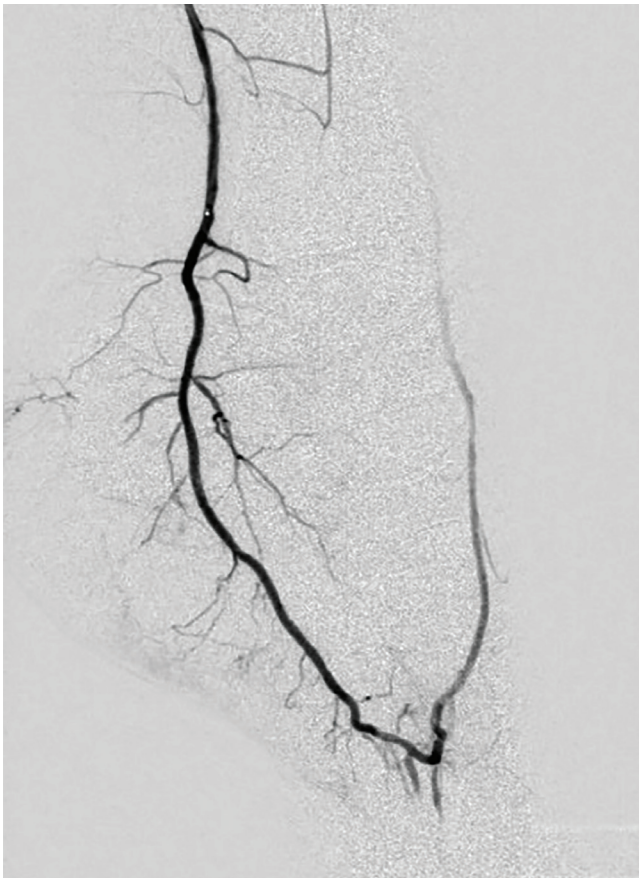

Figure 4. Final result: Restored pedal loop lumen and rapid flow and improved plantar surface tissue perfusion.

After the tract was predilated, the SilverHawk DS low-profile distal small vessel atherectomy catheter was advanced across the pedal loop once with blade closed for an initial "dry run" to see if the catheter would advance across the tract without significant resistance. The DS catheter can effectively treat a 1.5-2.0 mm artery diameter. This initial dry run (blade closed) was successful and the atherectomy device was advanced across the tract 3 times with the blade open, with the tip terminating at the distal anterior tibial artery with each pass (Figure 2). Directional atherectomy was followed by percutaneous transluminal angioplasty (PTA) of the pedal loop using a 2.0 x 120 mm NanoCross Elite PTA balloon inflated for 90-seconds at 8 atmospheres of pressure in the anterior tibial/dorsal pedis arteries, followed by the pedal loop, and then the distal posterior tibial/lateral plantar arteries. Nitroglycerine 200 mcg was injected into the area through the balloon catheter to further medically dilate the vessel, and a gentle injection through the balloon catheter tip demonstrated a widely patent, now symmetrically dilated tract, with a restored pedal loop perfusing the dorsal surface tissues, the metatarsal regions and toes, and the plantar surface tissues with excellent overall perfusion and rapid washout. Final angiography demonstrated successful post-treatment results and much improved arterial perfusion into the left foot across a now clearly patent and dilated pedal arterial loop (Figure 4). One week post procedure, patient indicated presenting symptoms were markedly improved, with noted improvement in toe color and skin temperature.

Discussion

As we continue to treat lower extremity PAD, chronic total occlusions, and CLI patients more distally, we must continue to explore the capabilities of available devices. In this case, we chose to test the efficacy of the SilverHawk DS atherectomy device beyond its typical distal reach and function, and advance further across the pedal loop and distal arterial vessels of the feet. The SilverHawk, TurboHawk, and HawkOne directional atherectomy devices (Medtronic) have proven to be versatile and effective in treating challenging atherosclerosis with resistive calcified plaque in most of the arteries of the lower extremities.[7] The SilverHawk DS device proved to be just as effective in removing plaque in the pedal loop compared to its use in the more proximal vessels, given a cooperative vascular setting. This case demonstrates a successful clinical outcome using existing directional atherectomy technology across the distal plantar and pedal loop arteries. ■

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**Images courtesy of Charles Jost, MD, and Kirk Minkus, MD. Individual results may vary.*

Disclosures: The authors report no conflicts of interest regarding the content herein.

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Take Charge of CLI: Tools for Optimal CLI Revascularization

Paul Michael, MD, Wound Management & Limb Preservation Center, JFK Medical Center, Palm Beach, Florida

Treating end-stage peripheral arterial disease (PAD), better known as critical limb ischemia (CLI), is a daily challenge and requires what basketball player Kobe Bryant refers to as a persistent "Mamba Mentality", defined as "constantly trying to be the best version of yourself." After attending the Amputation Prevention Symposium (AMP) meeting in Chicago for the first time, I realized how little I knew about CLI and how much more there was to learn if I was going to dedicate my career to amputation prevention. Passion and hard work alone do not make a CLI operator; it requires the development of advanced skill sets necessary to take care of these "forgotten" patients. Best treatment strategies for CLI patients remain unclear, but we do know that by combining advanced training with the formation of specialized vascular teams, techniques can be extended across the vascular care continuum to offer patients their best shot at amputation prevention, because saving limbs means saving lives.[1,2] To achieve this goal, CLI operators must first master interventional devices and advanced revascularization tools, a key take-home message of CLI education offered through conferences such as AMP. After performing thousands of CLI cases and trialing hundreds of devices, my diagnostic and treatment algorithm for amputation prevention therapy has been simplified into a basic formula: 1) Employ a radial-first diagnostic strategy; 2) Listen to the patient and the wound; 3) Plan the case; 4) Standardize alternative access; 5) Master multilevel, multivessel chronic total occlusion (CTO) crossing; 6) Use the right tool(s) for the job; 7) Employ non-radiation imaging modalities when needed; 8) Anticipate any complication; 9) Ensure wound-directed therapy. My guiding principle of CLI treatment is what I call "functional" revascularization, meaning that patients undergo purpose-driven therapy by a CLI team that focuses on achieving wound healing, with the end result encouraging a return to mobility, and ultimately, a functional quality of life for the patient.

Surgical and endovascular revascularization efforts frequently involve targeting infrapopliteal and inframalleolar lesions. These are particularly challenging because of their behind the knee and behind the ankle locations which receive excessive torsional stress and have variable reconstitution and morphology patterns. The ability to leave these vessels intact while maximizing outflow and future therapy options is of great importance. This creates a unique space for technology which can battle atherosclerosis and calcium in these territories, such as the versatile HawkOne directional atherectomy system. CLI "power tools", as I like to call them, are not only versatile, but have special applications.

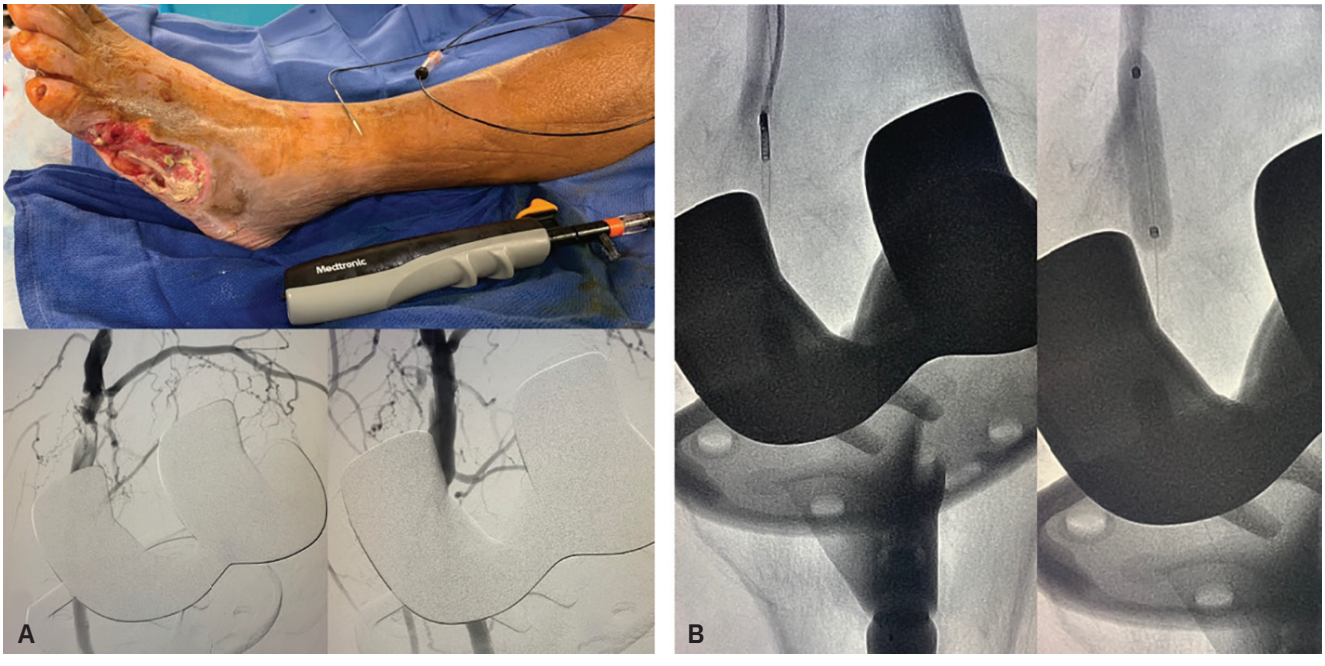

Figure 1A-B. Versatility of the 6 Fr HawkOne directional atherectomy system, demonstrating the IVUS image-guided "leave no metal behind" strategy and finishing with prolonged drug-coated balloon angioplasty.*

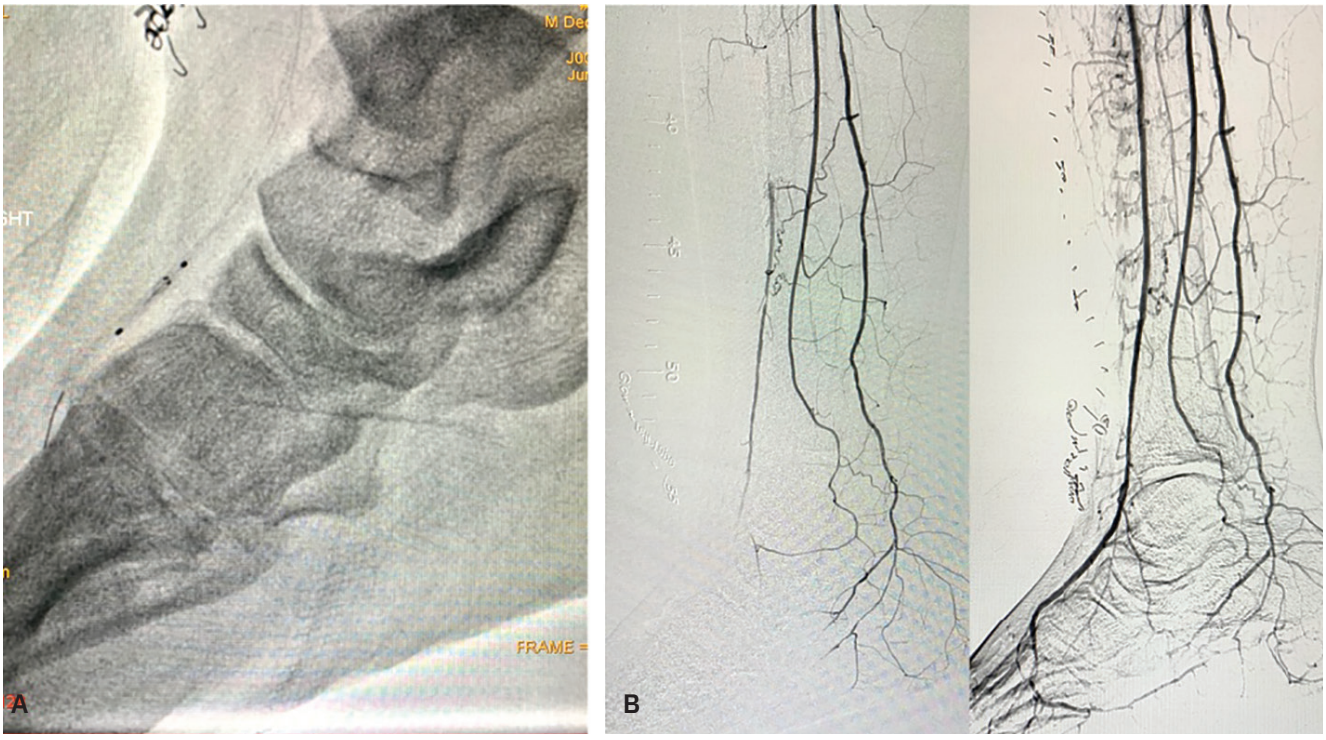

Figure 2A-B. Safe and effective placement of a Spider FX embolic protection device deep in the pedal circulation to ensure protection of viable tissue from embolization during pedal reconstruction.*

Additional examples include nitinol-caged balloons such as the Chocolate PTA balloon for controlled dilatation and limiting dissections, and the IN.PACT Admiral drug-coated balloon (DCB) for antirestenotic therapy. Extra-long balloons such as the Pacific Xtreme PTA balloons have become a major power tool in our CLI shop, given their 300 mm length and .018-inch platform. These extra-long balloons make cases efficient as well as reduce dissection potential with prolonged inflations. The Pacific Plus balloons give operators the ability to go down to a 2 mm PTA balloon diameter, all while maintaining an .018-inch platform, if required. The tapered 2.0 mm(proximal)/1.5 mm(distal) NanoCross Elite PTA balloon is a go-to workhorse for "around the pedal loop" angioplasty, giving it a special place among CLI power tools. With the ability to access pedal vessels quickly and cross lesions retrograde through the access needle using CTOP-guided therapy[3], the .018-inch 90 cm Trailblazer catheter technique has replaced sheath placement for many tibial access interventions. This involves advancing the .018-inch catheter over the wire directly through the skin in place of a sheath and quickly reversing access direction for antegrade intervention, followed by prompt removal of the Trailblazer support catheter. This CLI-fighting technique allows for direct visualization of arterial flow in the catheter and minimizes the puncture site size by eliminating the need for sheath placement when performed quickly.

With >95% of my current volume focused on limb salvage and amputation prevention, I need tools that offer predictable and safe results, with room for creative applications. The following cases demonstrate such applications and the "power tools" used to achieve a successful outcome.

Case Examples

Case #1

A 52-year-old diabetic gentleman presented through the emergency department with an occupational-related left foot wound. He was referred by the foot and ankle surgery team given his abnormal non-invasive findings and poor vascular physical exam, with a high suspicion for CLI. After initial angiography demonstrated a complex popliteal artery lesion compromising tibial inflow, an intravascular ultrasound (IVUS) catheter was used to assess true vessel sizing. Demonstrating its versatility, a 6 French (Fr) HawkOne M directional atherectomy device was used in the popliteal artery (Figure 1A) prior to prolonged inflation angioplasty with a 7 mm x 40 mm IN.PACT Admiral DCB (Figure 1B), all performed over a SpiderFX embolic protection device.

Case #2

This 67-year-old diabetic patient presented to the JFK Wound Management & Limb Preservation Center for a non-healing ulcer of the foot. Baseline angiography revealed an anterior tibial artery CTO compromising wound healing to the foot. This case highlights the routine workhorse utility of a highly maneuverable directional atherectomy device

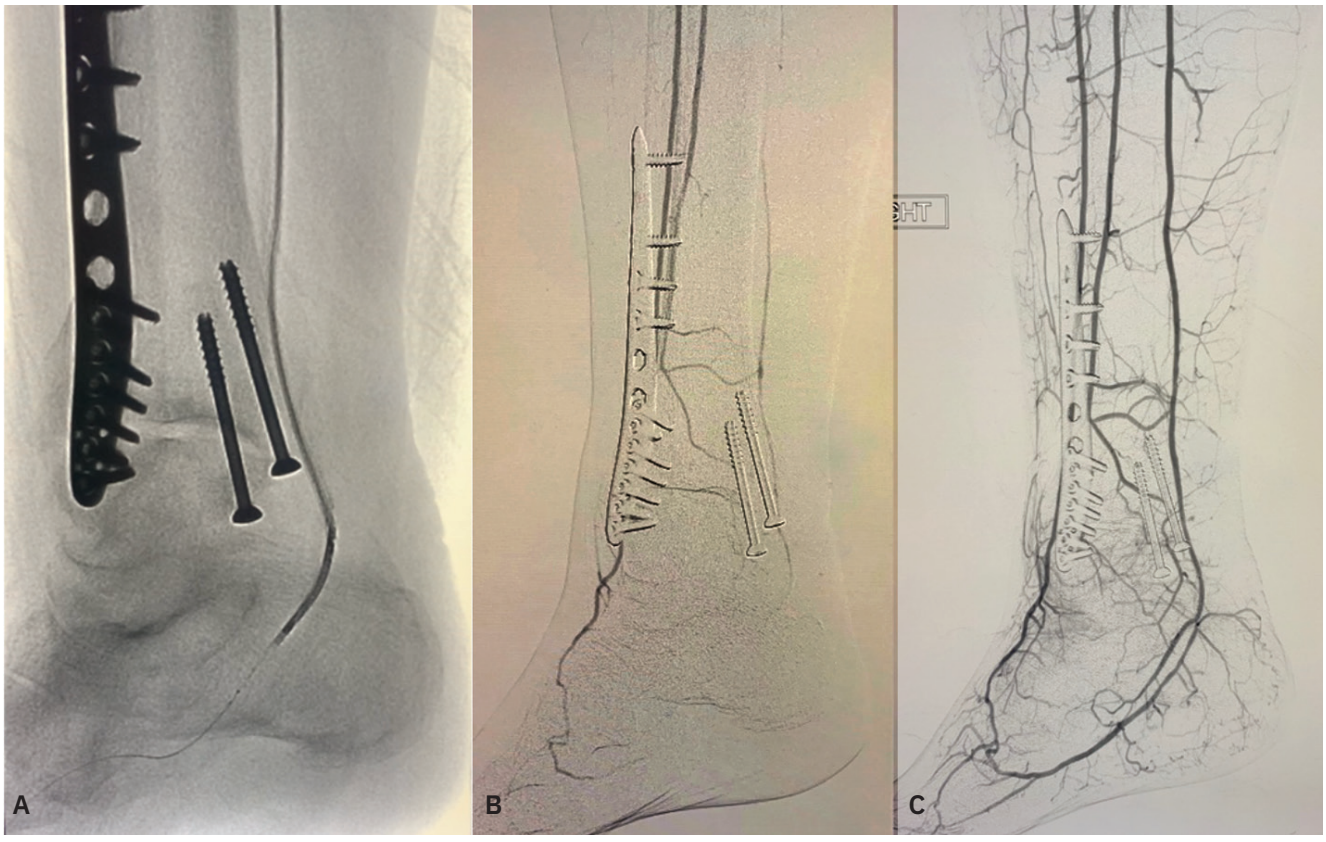

Figure 3A-C. Inframalleolar plaque removal using directional atherectomy with smooth deliverability demonstrated during this tibiopedal reconstruction.*

that can be easily used for tibial reconstruction. The ability to place embolic protection devices deep in pedal vessels allows one to confidently treat tibioperoneal vessels when needed, such as in Figure 2A, demonstrating safe placement of a filter in the dorsalis pedis artery to treat a long segment anterior tibial artery CTO with directional atherectomy using the TurboHawk SS-CL device (Figure 2B).

Case #3

This patient underwent foot and ankle surgery after a complex fracture from a motor vehicle accident. After hardware was implanted, this 62-year-old diabetic patient began to experience wound healing problems unrelated to hardware implantation. A baseline angiogram revealed chronic total occlusions of the anterior and posterior tibial arteries, requiring revascularization for wound-directed therapy (Figure 3A-C). Revascularizing tibiopedal vessels is of paramount importance to limb salvage and the ability to take devices beyond the inframalleolar level helps achieve this goal. There are many tools in our cath lab for tibial work, all of which have been taken below the ankle in antegrade and retrograde techniques. The TurboHawk SX-C, TurboHawk SS-CL, and HawkOne S devices are highly versatile, and can be maneuvered below the ankle in a flexible fashion to achieve atherectomy treatment goals (Figure 3A). I have incorporated intravascular

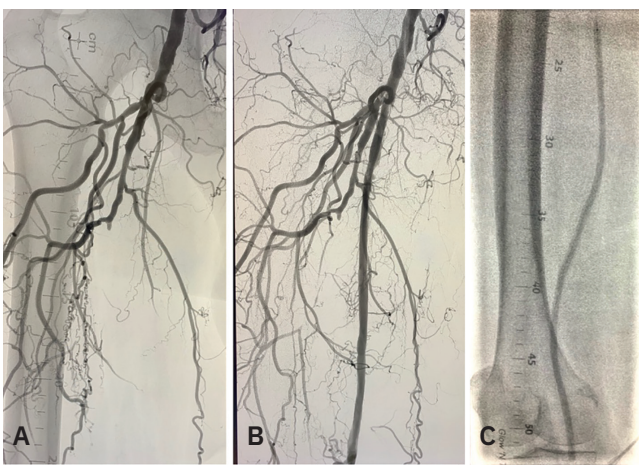

Figure 4A-C. Long segment CTO revascularization and the benefit of long deliverable balloons for prolonged and efficient CLI angioplasty.*

ultrasound (IVUS) into my CLI therapy algorithm to help accurately size and treat these typically underestimated vessels. CLI often presents a multi-vessel, multi-segment challenge where getting to the final tibiopedal destination involves crossing an obstacle course of iliofemoral and femoropopliteal CTOs. Long shaft, long length, and low profile equipment helps overcome these challenges when multi-segment therapy is required.

A LOOK AT THE DATA

DEFINITIVE LE[4,5]

The DEFINITIVE LE trial evaluated the safety and effectiveness of directional atherectomy as a frontline therapy for the treatment of PAD[4], including infrapopliteal artery lesions.

- Prospective, multicenter study, 800 patients at 47 centers in the U.S. and Europe
- Two cohorts: claudication (n=598) and CLI (n=201).
  - 1022 lesions (up to 20 cm in length) were treated with directional atherectomy.
  - Broad patient population: 52% diabetic, 45% female, and 75% claudicants.
  - A pre-specified hypothesis evaluated 12-month patency outcomes in diabetic and non-diabetic patients (77% and 78%, respectively).
  - Rate of bailout stenting was 3.2%.
- In CLI patients, the primary endpoint was freedom from major unplanned amputation of the target limb at 12 months, with a rate of 95%.
- Infrapopliteal lesions: of the 800 patients enrolled, 145 patients (189 infrapopliteal lesions) were included in the trial.[5]
  - Primary patency rate for infrapopliteal lesions was 89.6% in the claudication group and 78% in the CLI group.

DEFINITIVE LE demonstrated safety and efficacy at one year with the use of directional atherectomy in both CLI and claudication patients.

IN.PACT Global Study[6]

- Real-world registry evaluating the IN.PACT Admiral as a standalone therapy:
  - 86.3% freedom from clinically driven target lesion revascularization through 12 months in CLI subjects;
  - 98.6% of the patients were free of major target limb amputations through 12 months in CLI subjects.[6]

The use of IN.PACT Admiral drug-coated balloon facilitates the transfer of paclitaxel, an anti-restenotic drug, to the vessel wall where it has been measured to reside at therapeutic levels for 180 days.[7] The sustained presence of paclitaxel provides continuous antiproliferative activity that inhibits neointimal hyperplasia, which is a major contributing factor to restenosis after angioplasty.

Although directional atherectomy can be used as a standalone therapy, the luminal gain achieved may be sustained with the inclusion of anti-restenotic therapy. The use of directional atherectomy followed by the IN.PACT Admiral drug-coated balloon could be considered an effective treatment option in complex CLI cases to achieve a sustained treatment effect. ■

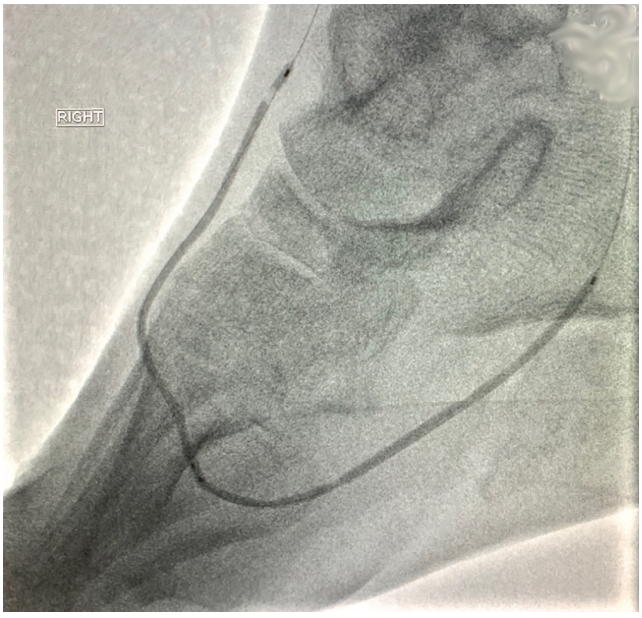

Figure 5. A 2.0(proximal)/1.5(distal) mm NanoCross Elite balloon in the process of reconstructing a pedal loop for maximal tissue preservation to yield a limb-sparing intervention.*

Case #4

This 71-year-old woman presented to the CLI team after multiple, failed revascularization attempts and was offered a palliative below-knee amputation for pain control. The CLI team offered her an intervention with revascularization of her long segment SFA CTO. Michael Jordan is famous for saying, "I've never lost a game, I just ran out of time." Time is an important factor in complex CLI cases. Tools that help revascularize faster for the "win" should be utilized. Long balloons (Figure 4), such as the .018-inch Pacific Xtreme PTA balloon catheter in up to 300 mm lengths, help save precious time and are routinely used in our lab from antegrade and retrograde approaches in treating long femoropopliteal lesions after directional atherectomy use (Figure 4B). When stenting the iliofemoral and femoropopliteal vessels is required from pedal access, having a versatile, low-profile 5 French delivery self-expanding stent comes in handy, and the Everflex self-expanding peripheral stent with Entrust delivery system performs well in these situations.

Case #5

This 66-year-old diabetic woman was referred by the foot and ankle residency team for ischemic digits and rest pain upon presentation to the emergency room. Her baseline angiogram revealed occlusions of her dorsalis pedis and plantar arteries. Pedal arch angioplasty (Figure 5) is frequently necessary with advanced tissue loss cases. Being able to preserve as much of the forefoot as possible prior to a debridement or transmetatarsal amputation optimizes chances for functional recovery.

BEHIND THE SCENES

Talking With the Operator

Cath Lab Digest talks with Paul Michael, MD, Medical Director, Wound Management & Limb Preservation Center, JFK Medical Center, Palm Beach, Florida.

Can you tell us about your center?
I am medical director at the Wound Management & Limb Preservation Center at JFK Medical Center. We focus on all aspects of wound management and have been operational under this name for over a year. Our center has created a team of subspecialties (including foot and ankle surgery, plastic surgery, vascular surgery, interventional cardiology, infectious disease, endocrinology, vascular medicine, and dermatology) in order to create synergistic, total body wound care. By having a cardiovascular disease specialist working more deeply with the wound management team, we were able to create a more patient-centric approach to wound healing and limb preservation. We focus on achieving accelerated wound healing results through management of the underlying disease process, as well as providing advanced interventional solutions in our CLI patients. What makes us different and unique is that we assess all patient needs, everything from psychiatry to podiatry, and arteries to veins, and all at the same time.

Can you describe your patient population?
We have a multi-ethnic patient population, with many African American, Puerto Rican, Cuban, Afro-Caribbean, and Caucasian patients. Within our overall patient population, there is a group with extremely advanced hypertensive diseases. Our Afro-Caribbean population is very interesting and difficult to manage because of their advanced risk factors, mainly hypertension and diabetes. We have a large amount of CLI in our area.

Can you take us through what happens when a patient comes to the center?
Ninety-nine percent of the diagnosis is made in the initial visit with a visual assessment of the wound and a basic assessment of perfusion. In what we call the "pathway to angiography," patients routinely go from handheld Doppler straight to angiography. We have an extensive intake for wound patients with a standard protocol for photograph analysis of the wound. It also allows for the documentation of wound closure progression, done with graphical analysis and an advanced EHR system called WoundExpert. After the visual assessment of the wound takes place, a perfusion assessment is done with a handheld Doppler. If an ankle-brachial index (ABI) is necessary, it is done immediately. The handheld Doppler is used to reconstruct the presence or the absence of the tibial arteries and the pedal loop. We proceed within an algorithm depending on the assessment with the handheld Doppler. If it is inconclusive and good pulses exist, we will get a duplex, but most of the time, wound patients with compromised flow will go straight to an angiogram. We also do a physical exam assessment for venous disease so that any venous disease can be addressed at the same time. If a wound is present and the patient has not yet been established with a podiatrist, then we immediately arrange for them to see the foot and ankle specialist. All of the consults are coordinated and then patients start their care pathway.

Can you describe more of your work as an interventionalist from a revascularization perspective?
We do everything the patient needs to get the job done. We perform wound-directed therapy, but are also very aggressive in pedal reconstruction. Patients should have as complete a revascularization as possible for advanced wound management. We have the tools for that, which can be seen in our wound healing rates. We have over 98% success in limb salvage (obviously there is selection bias there) and a 99% success rate with chronic total occlusions. At a fundamental level, my revascularization algorithm begins with selecting the best strategy to provide inline and pressurized flow to the wound. This begins with the CLI diagnostic angiogram when possible, followed by an access strategy that maximizes successful crossing and revascularization.

How are patients typically referred to your center?
Our patients come from all over, including primary care, podiatry, and vascular surgery. When our center first launched, we spread the word in our physician community by giving talks to wound specialists — specifically, to foot and ankle surgeons that care for and are motivated regarding wounds, because there are many practices where wound patients kind of become a "nuisance" in a busy podiatry office. These patients really need specialized attention and that is best done at a wound management site with a focus on CLI. Our willingness to take over care for these patients encouraged buy-in from primary care, podiatry, and vascular surgeons, who can now refer these patients to our center, and remain confident that care is extended and patients remain part of their practice.

What do you see as the current state of CLI care?
We have a major need for better tools and better training. Becoming more and more advanced with technology will not do us any good, unless we can actually train physicians, staff, and industry personnel how to use these concepts in the wider community to benefit patients. Just like there are "access to care" issues, with CLI, there are "access to skill" issues. We need more education, and along with that, comes more awareness of the disease process. The goal is to simplify and standardize CLI care. It may involve adopting new technology, treating more patients, or taking the time to do a more complete job. I applaud companies like Medtronic for supporting training programs through our Wound Management & Limb Preservation Center, where operators, staff, and industry can experience a 360-degree care experience, from screening to salvage.

Any final thoughts?
We are in the wound closing business — the end goal is healing the wound and allowing patients to return to function. If that is the goal, and you are always striving to find the best way to avoid amputation, it will always lead you in the right direction. Tibial-pedal reconstruction with advanced wound management is the way to go. For me it began at AMP, where many more operators will also get their start. Anyone willing and motivated enough to put work into limb salvage will be greeted by grateful patients who know you chose their life over amputation. ■

The NanoCross Elite .014-inch OTW PTA balloon catheter is a specialty niche balloon for us, given its tapered 0.5 mm sizing, long length, and ease of use across the pedal arch. The 2.0(proximal)/1.5(distal) x 210 mm and 2.5(proximal)/2.0(distal) x 210 mm (Figure 5) are workhorse pedal balloons in our lab. ■

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**Images courtesy of Dr. Paul Michael. Individual results may vary.*

Disclosure: Dr. Michael reports he is a consultant to Abbott, Asahi Intecc, Boston Scientific, Medtronic, Philips, and Terumo.

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Optical Coherence Tomography in the Diagnosis and Treatment of Spontaneous Popliteal Artery Dissection: A Case Report

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Abstract: Spontaneous dissection of the popliteal artery is an uncommon event that if left untreated can lead to severe limb dysfunction and amputation. We report a case of atraumatic, non-aneurysmal dissection of the left popliteal artery in a 76-year-old woman after a flight to Europe who presented with progressive left lower-extremity claudication and nighttime left foot resting pain. Physical exam and non-invasive arterial examination were suggestive of left popliteal artery occlusion. Treatment was undertaken before irreversible ischemia developed and the patient underwent successful percutaneous transluminal angioplasty without complications. Optical coherence tomography (OCT) was used to confirm the presence of dissection and to guide interventional therapy. We intend to illustrate the novel application of OCT imaging in peripheral interventions.

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Key words: Dissection, popliteal artery, optical coherence tomography

Case Report

A 76-year-old woman with a history of hyperlipidemia and hypothyroidism developed new-onset left calf claudication immediately after a 13-hour flight from Houston to Rome. The patient did not have any prior history of peripheral artery disease, hypertension, coronary artery disease, Marfan's syndrome, fibromuscular dysplasia, ongoing smoking, atrial fibrillation, cardiomyopathy, clotting disorder, or knee trauma/surgery. Four weeks after the onset of the symptoms, she reported numbness, coolness in the left foot, and nightly left toes resting pain. Physical examination was notable for absent pulse of the left popliteal, posterior tibialis, and dorsalis pedis arteries. The left lower extremity motor and sensory functions were grossly preserved, and left foot coolness was apparent. An arterial Doppler ultrasound of the left lower extremity depicted monophasic flow in the distal popliteal and tibiopedal vessels. An urgent left lower extremity magnetic resonance angiography (MRA) demonstrated segmental atherosclerotic disease with mild to moderate stenosis of the left superficial femoral artery and proximal popliteal artery, distal popliteal artery severe attenuation, and extensive collateral formation that originated proximal to the attenuated segment and ended in the infrapopliteal vessels. In the axial plane, a dissection flap was apparent (Figures 1-2).

The patient was referred for invasive angiography. The vascular anatomy on the left lower extremity was unremarkable up to the distal popliteal artery where an apparent dissection plane was noticed with Thrombolysis in Myocardial Infarction 1 (TIMI-1) flow (Figure 3). The false lumen had compressed the true lumen with minimal antegrade flow. This initial angiography was obtained with

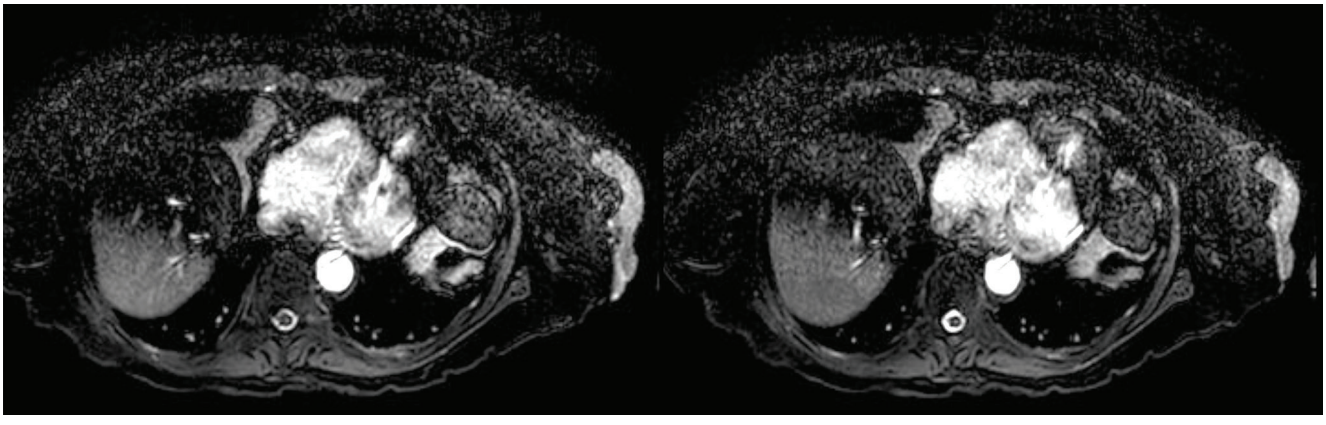

Figure 1. MRA of the left lower extremity (axial plane) demonstrating a dissection flap in the left popliteal artery in two consecutive angiographic cuts.

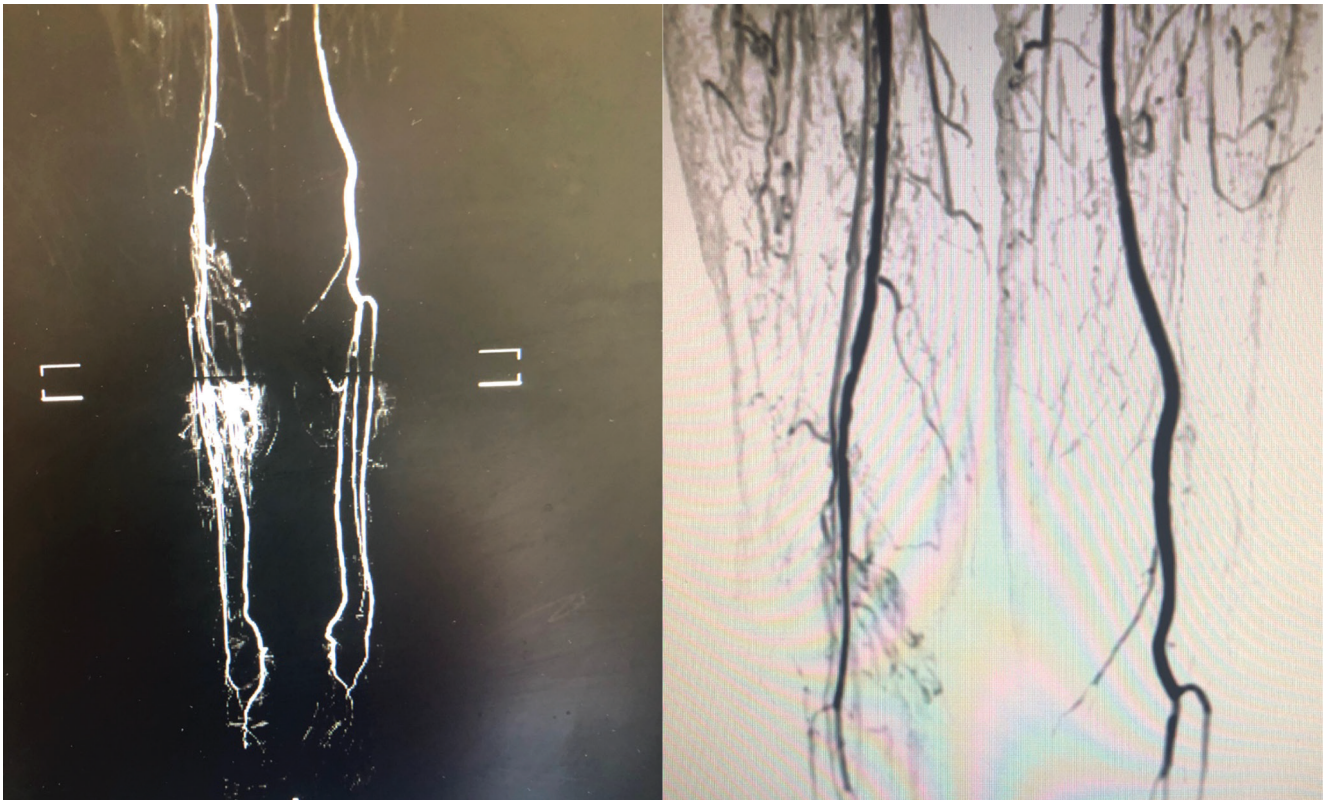

Figure 2. MRA of the left lower extremity (coronal plane) demonstrates moderate atherosclerotic plaques in the proximal and mid left popliteal artery. The distal left popliteal artery has signal attenuation, narrow lumen, and extensive collateral network.

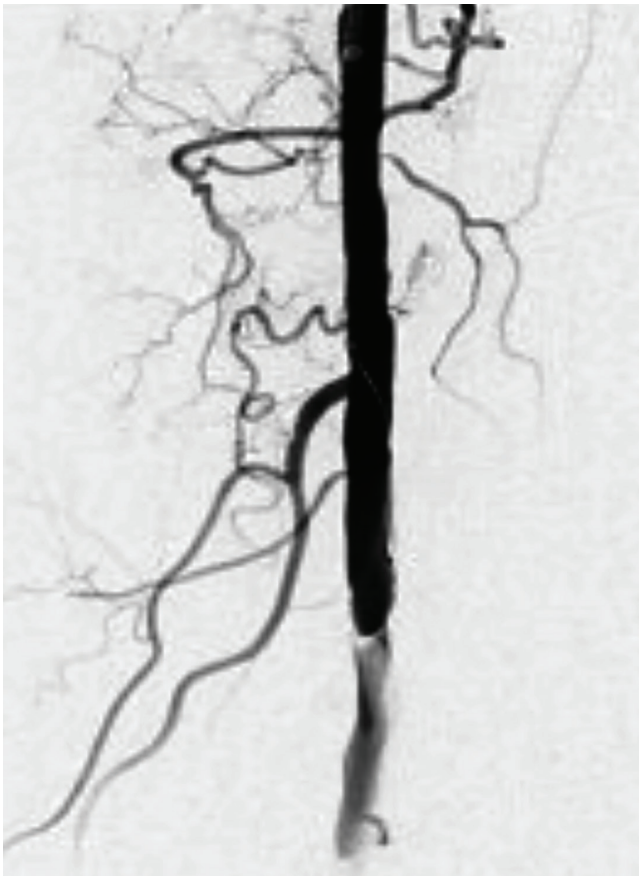

Figure 3. Dissection of the left distal popliteal artery with TIMI-1 flow.

a diagnostic 6 French (F) catheter positioned in the mid superficial femoral artery.

A 6F 70 cm sheath was advanced to the proximal left popliteal artery via contralateral femoral access. A .014-inch Luge wire (Boston Scientific) with the support of a 1.2 mm over-the-wire Mini-Trek balloon (Abbott Vascular) was advanced thru the dissection plane into the left anterior tibialis artery. Distal injection confirmed intraluminal crossing. The balloon was removed, a Spider distal protection device was placed in the distal popliteal artery (Medtronic) and OCT (Abbott Vascular) imaging was performed (Figure 4A-C). OCT images demonstrated an intimal tear of the left popliteal artery and very mild atherosclerotic disease. Thereafter, a 6 x 40 mm Chocolate balloon (Medtronic) was advanced to the site of the dissection and the lesion was dilated to 4 atmospheres (atm) for 3 minutes. Post PTA angiographic images showed TIMI-3 flow without evidence of dissection, perforation, or embolization (Figure 5). To our knowledge, there are no reported cases or series using OCT to confirm popliteal artery dissection.

Discussion

In 2013, our group described the application of intravascular OCT in peripheral arteries.[1] OCT provides a unique and detailed view of the vessel wall and vessel lumen. The diameter of most popliteal arteries, 4-6 mm, allows for OCT image acquisition while maintaining its ultra-high resolution properties. High quality image acquisition requires complete

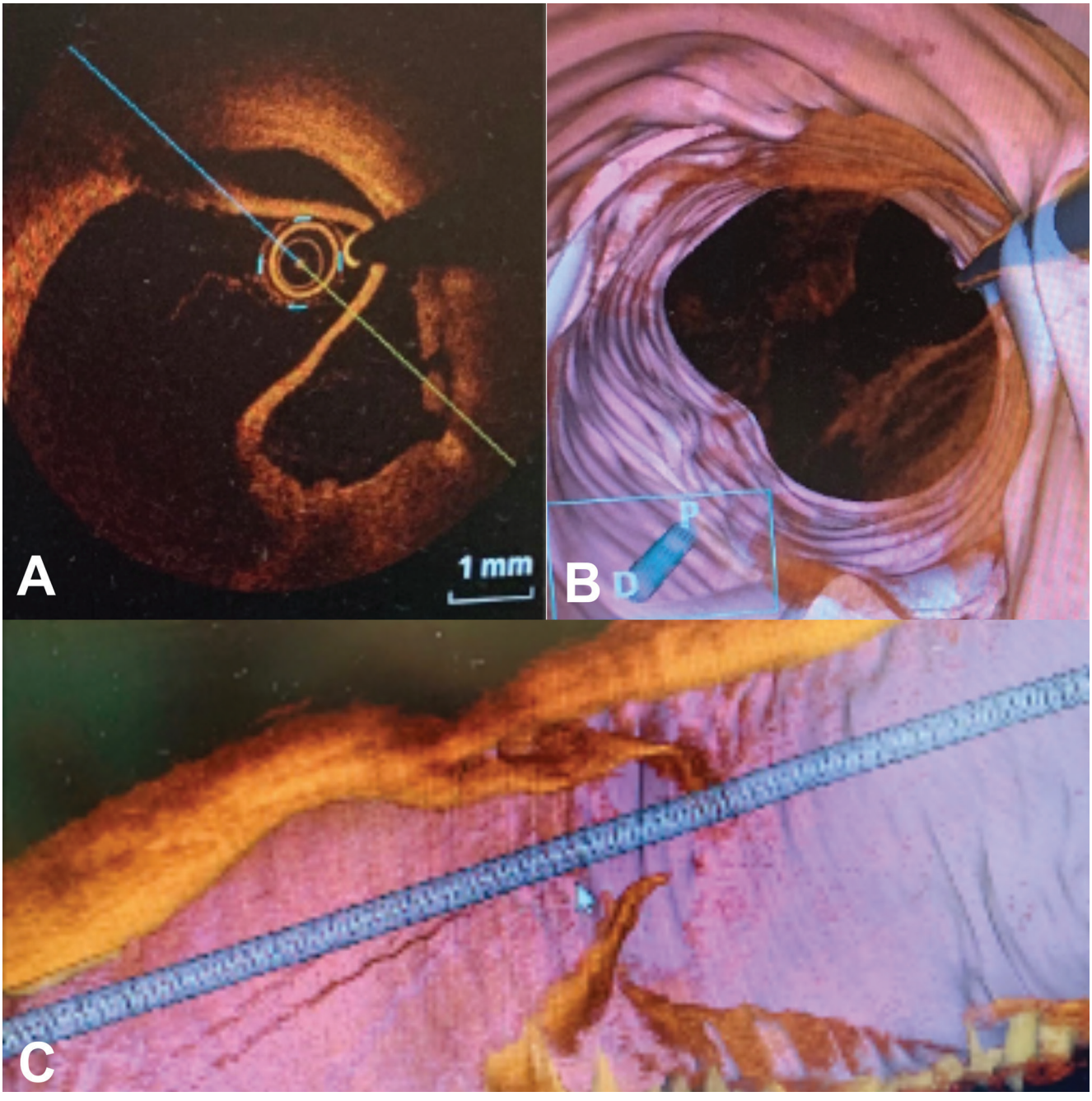

Figure 4A-C. Figure 4A depicts the wire in the true lumen and residual clot in the false lumen. The dissection flap can be seen in Figure 4B on 3D imaging reconstruction. Figure 4C illustrates the fenestrated dissection flap by the guide wire in a longitudinal display.

or near-complete opacification with contrast media injected at a rate of 2-4 mL/sec. A key technical aspect with regard to image acquisition in peripheral interventions is the close proximity of the distal sheath to the site of interest, ideally within a few centimeters. This was the rationale behind the utilization of a 70 cm sheath in this case.

Anatomically, the popliteal artery is a relatively short vascular segment subjected to movement and potent external forces, including compression, torsion, elongation, and flexion.[2] The patient in this case report had no known comorbidities associated with spontaneous arterial dissection. In the absence of significant focal atherosclerosis as demonstrated by OCT, one could hypothesize that focal dissection was the result of a transient increase in popliteal blood pressure due to prolonged sitting, which in turn caused elevation of the intima and a significant reduction in the diameter of the vessel true lumen, providing the mechanism for distal critical limb ischemia. Figures 4A-C illustrate the presence of a dissection flap, no significant atherosclerotic burden and a false lumen pouch with residual thrombus. The blind subintimal pouch with stasis of flow leads to thrombus formation, expansion of the false lumen, and compression of the true lumen. We

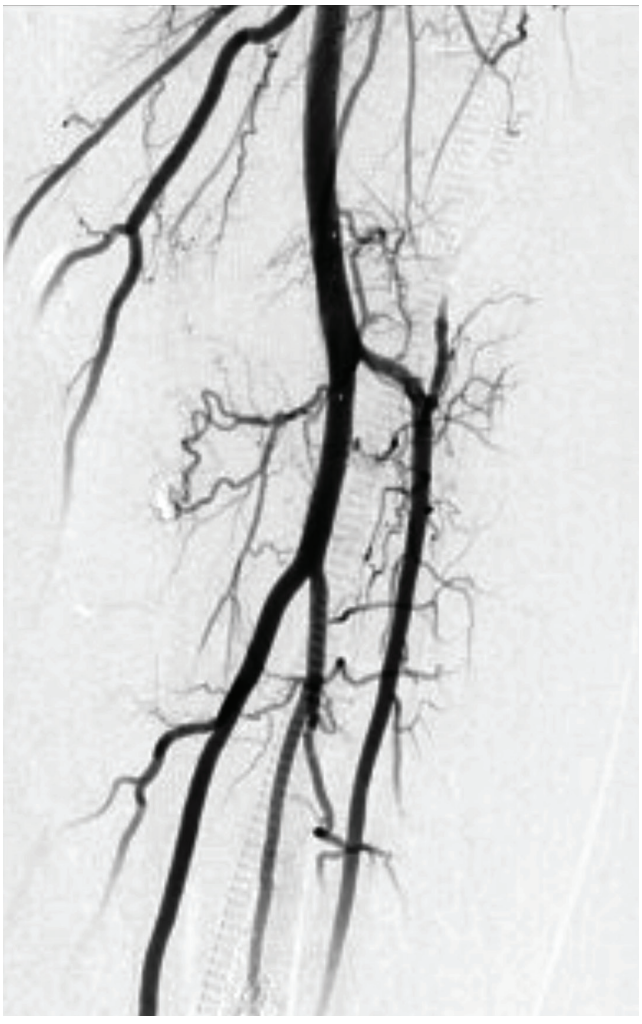

Figure 5. Post-PTA angiographic images depicting TIMI-3 flow.

can't comment on the presence of micro-fenestrations along the dissection flap since the crossing of the dissection flap with the wire and support catheter immediately improved antegrade flow. Similar OCT images and observations have been recently described by Jackson et al in 65 patients with spontaneous coronary dissection.[3]

The use of OCT to confirm wire placement in the true lumen was reassuring that a percutaneous intervention strategy with balloon angioplasty alone could restore linear TIMI-3 flow to the foot without extending distally a sub-intimal or false-lumen plane. The safe use of scoring balloons guided by OCT images to treat spontaneous coronary artery dissections was elegantly described by Yumoto in 2014.[4] OCT images, with their great resolution, frequently guide our selection and choice of the most appropriate interventional strategy in our peripheral cases and as in coronary cases, adds intravascular information not apparently revealed by angiography. We think that OCT has great potential in guiding best practices for vessel wall preparation in complex peripheral cases.

Our treatment preference in distal popliteal artery occlusions has been balloon angioplasty due to the risk of

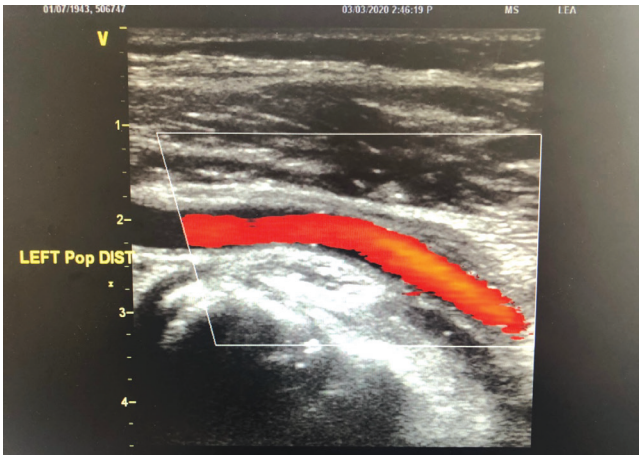

Figure 6. Doppler duplex of the left lower extremity 9 months after popliteal artery PTA demonstrates normal flow in the mid and distal popliteal artery with preservation of the lumen.

stent fracture by external forces at the knee joint. Popliteal artery stenting is usually reserved for flow-compromising dissection planes that fail angioplasty-alone strategies.

Nine months later, a follow-up arterial duplex ultrasound demonstrated the presence of normal triphasic flow in the proximal and distal popliteal artery with preservation of the lumen (Figure 6). The patient remains active and free of symptoms. ■

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Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. They report no conflicts of interest regarding the content herein.

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Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician.
Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device.

HawkOne™ Directional Atherectomy System

The HawkOne™ peripheral 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. This content is available electronically at www.manuals.medtronic.com.

TurboHawk™ Plaque Excision System

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 (LS-C and LX-C only).

SILVERHAWK™ Plaque Excision System

The SilverHawk™ Peripheral Plaque Excision System is intended for use in atherectomy of the peripheral vasculature. The catheter is NOT intended for use in the coronary, carotid, iliac or renal vasculature.

Medtronic directional atherectomy products are contraindicated for use in patients with in-stent restenosis.

IN.PACT™ Admiral™ Drug Coated PTA Balloon Catheter Brief Statement FTSOP113326-32 Rev. 1H

This content is available electronically at www.manuals.medtronic.com.

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 femoro-popliteal 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.

Chocolate™ PTA balloon catheter
The Chocolate PTA balloon catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, poplite-al, infra-popliteal, and renal arteries. This content is available electronically at www.manuals.medtronic.com.

Enteer™ Re-entry Guidewire
Indications for Use: The Enteer™ Re-entry Guidewire is intended to facilitate placement of balloon dilatation catheters or other intravascular devices during percutaneous transluminal angioplasty (PTA). The Enteer Guidewire is not to be used in cerebral blood vessels. When used as part of the Peripheral System, the Enteer Guidewire is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.

EverCross™ 0.035" PTA Balloon Catheter
Indications for Use: The EverCross™ 0.035" OTW PTA Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, 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.

EverFlex™ Self-expanding Peripheral Stent System
Indication: The EverFlex™ Self-Expanding Peripheral Stent System is intended to improve luminal diameter in the treatment of symptomatic de novo or restenotic lesions up to 180 mm in length in the native superficial femoral artery and/or proximal popliteal arteries with reference vessel diameters ranging from 4.5 mm-7.5 mm. The EverFlex Self-Expanding Peripheral Stent System is indicated for improving luminal diameter in patients with atherosclerotic disease of the common and/or external iliac arteries up to and including 100 mm in length, with a reference vessel diameter of 4.5 mm-7.5 mm. The Protege EverFlex Self-expanding Biliary Stent System is intended as a palliative treatment of malignant neoplasms in the biliary tree.

Contraindications: Use of the EverFlex™ Self-Expanding Peripheral Stent System is contraindicated in patients with known hypersensitivity to nickel titanium and in patients contraindicated for anticoagulant and/or antiplatelet therapy, patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.

Potential Adverse Events: Potential adverse events which may be associated with the use of a stent in the SFA and proximal popliteal arteries include, but are not limited to: Allergic reaction, Amputation, Artery perforation or rupture, Bleeding requiring transfusion, Infection, Pseudoaneurysm, Restenosis, Stent collapse or fracture, Stent migration, Surgical or endovascular intervention, Thrombosis/occlusion of the stent.
See the Instructions for Use provided with the product for a complete list of warnings, precautions, adverse events, and device information.

NanoCross™ Elite 0.014" PTA Balloon Catheter
Indications for Use: The NanoCross™ Elite 0.014" Over-the-Wire PTA Balloon Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, 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.

Trailblazer™ Support Catheter
TrailBlazer™ Support Catheter are percutaneous, single lumen catheters designed for use in the peripheral vascular system. TrailBlazer™ Support Catheters are intended to guide and support a guide wire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Trailblazer™ Angled Support Catheter
TrailBlazer™* Angled Support Catheters are percutaneous, single lumen catheters designed for use in the peripheral vascular system. TrailBlazer™ Support Catheters are intended to guide and support a guide wire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

SpiderFX™ Embolic Protection Device
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. This content is available electronically at www.manuals.medtronic.com.

The Pacific Xtreme™ PTA balloon dilatation catheter
The PACIFIC XTREME™ PTA Balloon Dilatation Catheter in 150 mm, 200mm, 250mm and 300 mm balloon length is intended to dilate stenoses in femoral, popliteal and infrapopliteal arteries.

The Pacific™ Plus PTA balloon catheter
The Pacific™ Plus PTA Catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infrapopliteal and renal arteries; and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Warning: Prior to use, refer to the Instructions for Use supplied with these devices for indications, contraindications, side effects, suggested procedure, warnings and precautions.

Warning: Do not exceed the rated burst pressure.

Caution: Larger models of the Pacific™ Plus PTA catheter may exhibit slower deflation times, particularly on long catheter shafts.

Potential Adverse Events: Possible adverse events associated with use of the Pacific™ Plus PTA Catheter include, but are not limited to, complications related to puncture such as, but not limited to, local hematoma, infection and hemorrhage; dilatation related complications including, but not limited to, dissection, perforation and restenosis; angiography related complications such as, but not limited to, hypotension, drug/allergic reactions and death.

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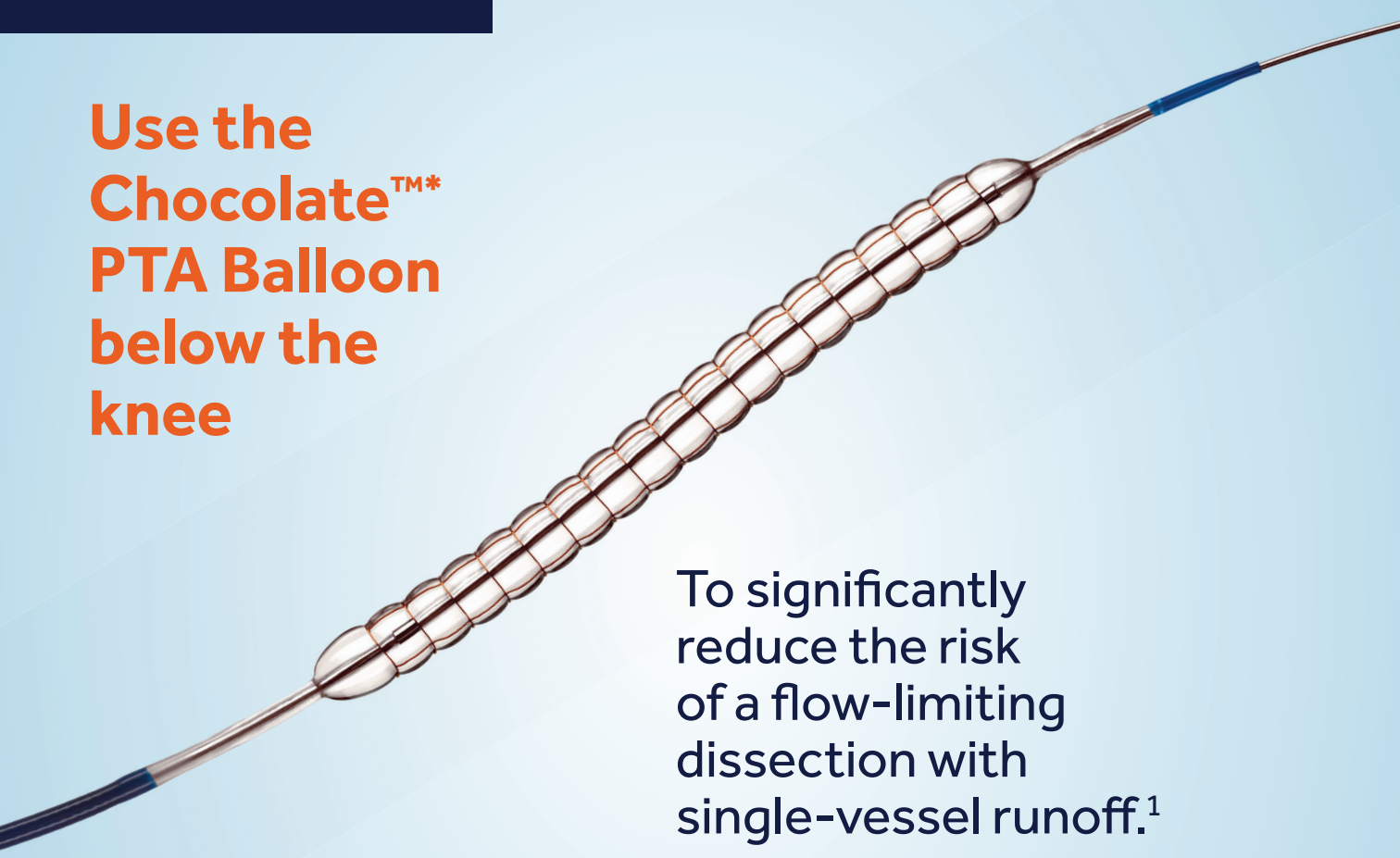

To significantly reduce the risk of a flow-limiting dissection with single-vessel runoff.[1]

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[1] Data on file with Medtronic. CLR782: Final Study Report: The Chocolate BAR by TriReme Medical, LLC.

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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, iliofemoral, popliteal, infra-popliteal, and renal arteries.

Medtronic