MEDTRONIC
MEDICAL AFFAIRS
CORNER

SPONSORED BY
Medtronic

Treating Chronic Total Occlusions of the Superficial Femoral Artery

By Mark W. Fugate, MD, FACS

Crossing and treating chronic total occlusions (CTOs) in the superficial femoral artery (SFA) remains a significant challenge in the treatment of peripheral artery disease (PAD). When I encounter a CTO in practice, my procedural goal is to cross the lumen in a way that facilitates the use of directional atherectomy. I want to maximize luminal gain and limit dissections, all to avoid permanent implants. Data supporting this procedural choice comes from the DEFINITIVE LE study of 800 patients, where the bailout stenting rate was 3.2% and primary patency through 12 months was 78% in claudicants and 71% in patients with critical limb ischemia.[1]

The HawkOne™ directional atherectomy catheter (Medtronic) is a versatile device that can efficiently create channels and, if desired, provide additional vessel preparation. After vessel preparation, I use a drug-coated balloon (DCB) to provide the best long-term patency possible to limit the need for future reinterventions. Ultimately, my goal is to preserve treatment options and ensure that patients have the best chance of maintaining functional limbs long term.

Typically, the CTO intervention begins by preparing the patient's entire leg in the sterile field. This avoids taking extra time during the case to expose and prepare the foot or lower leg during the procedure. From there, I approach the CTO from a contralateral femoral approach with standard wire and catheter techniques. I find that most lesions are crossable, with good wire and catheter handling; a CTO crossing device is rarely required. If a lesion is particularly challenging, I tend to switch to a retrograde tibial approach sooner rather than later.

Retrograde crossing is often much easier. I use a standard micropuncture access under ultrasonography and then place a standard 0.018-inch wire, either a V-18™* ControlWire (Boston Scientific Corporation) or a Nitrex™ guidewire (Medtronic), with a "bareback" 0.018-inch TrailBlazer™ support catheter (Medtronic) without a sheath.

When I cross a CTO with the retrograde approach, tibial access is used solely for crossing, not for treatment. I sometimes find it beneficial to treat from retrograde tibial access, but I treat the majority of cases from contralateral femoral access. To perform sufficient atherectomy on lesions in the femoropopliteal artery and achieve the desired luminal gain, 7-F devices are typically required, but the tibial arteries are simply not large enough to accommodate that device size. Usually, I can cross and promptly redirect the 0.018-inch wire back through the 0.035-inch catheter already in place above the lesion. At that point, I exchange for a 0.014-inch wire or SpiderFX™ embolic protection device filter (Medtronic). Next, I remove the tibial access catheter; this procedural step helps avoid significant vessel complications. From there, I move into treatment with directional atherectomy and complete the treatment with DCBs.

The following case illustrates my CTO algorithm.

CASE PRESENTATION

A man in his late 50s presented with severe lower left leg claudication with numbness (Rutherford classification, 3) that interfered with his ability to work. His medical history included smoking (two packs per day), emphysema, and chronic obstructive pulmonary disease. His ankle-brachial index was 0.46, and the distal waveforms were monophasic. No previous PAD interventions were noted. Baseline angiography using a Tempo Flush™* 10-cm diagnostic catheter (Cordis, a Cardinal Health company) showed a 10-cm CTO in the SFA (Figure 1).

PROCEDURAL OVERVIEW

The right femoral artery was accessed with a 0.035-inch Bentson Starter™* wire (Boston Scientific Corporation), a 0.035-inch angled Glidewire™* (Terumo Interventional Systems), and a 0.035-inch TrailBlazer™ angled support catheter (Medtronic); however, the collaterals prevented crossing. The decision was made to achieve retrograde

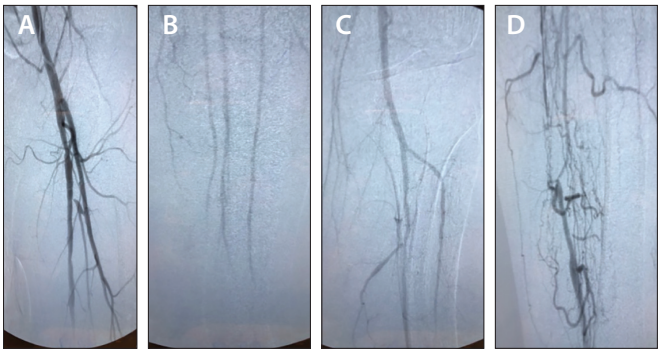

Figure 1. Baseline angiography of a CTO in the SFA.

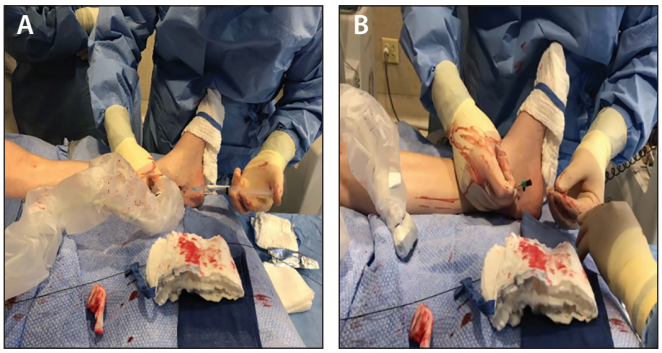

Figure 2. Gaining pedal access.

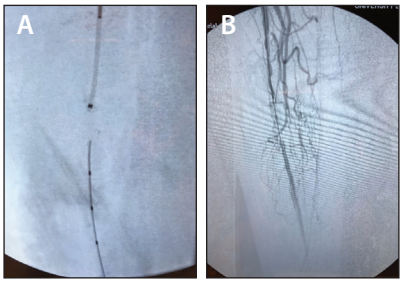

Figure 3. Flossing strategy.

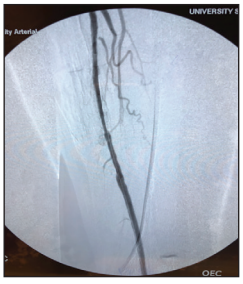

Figure 4. Angiography of the SFA after HawkOne atherectomy.

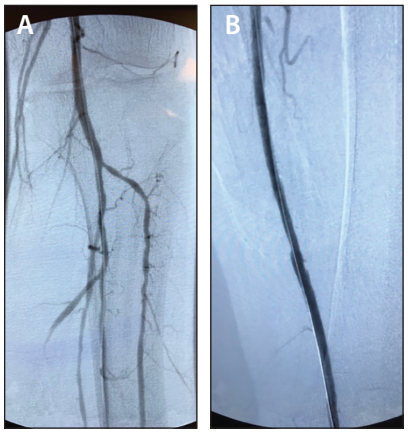

Figure 5. Final angiography after the DCB.

access. Because the patient's entire leg had already been prepared in a sterile field, switching to retrograde access was straightforward. An 0.018-inch V-18 ControlWire wire and a 0.018-inch TrailBlazer angled support catheter were used to access the pedal/posterior tibial artery (Figure 2).

The wire was maneuvered from the pedal approach through an 0.018-inch TrailBlazer angled support catheter into the proximal femoral 0.035-inch TrailBlazer angled support catheter that was already in place. A 0.035-inch wire crossed the lesion using the "flossing technique" (Figure 3).

Atherectomy was performed with a HawkOne™ LX directional atherectomy catheter (Medtronic) from an up-and-over retrograde common femoral approach over a 0.014-inch Thruway™* wire (Boston Scientific Corporation) (Figure 4). There were two insertions of the HawkOne device, with 8 to 10 passes on each insertion. After vessel preparation, a 5- X 150-mm IN.PACT™ Admiral™ DCB (Medtronic) was used to treat the SFA, resulting in flow to the foot (Figure 5).

DISCUSSION

PAD presents as a spectrum, from asymptomatic disease to critical limb ischemia and limb or tissue loss. Accordingly, I approach my treatment of PAD on a spectrum. With early detection and risk factor modification, patients can stay on the less severe end of the spectrum for longer periods. When intervention is indicated, directional atherectomy is a key part of my approach to limit permanent implants. This leaves more treatment options for the patient in the future and keeps them from progressing relatively quickly through the options of permanent implants, surgical bypass, and, ultimately, amputation. Interventionalists have so many tools and techniques at their disposal and relatively little clinical data to guide treatment decisions. In my practice, I have found that approaching PAD from the perspective of keeping patients and interventions on the lower end of the spectrum provides the best long-term outcomes in what is a treatable but ultimately incurable disease. ■

Mark W. Fugate, MD, FACS
Assistant Professor in Surgery
Department of Surgery
University of Tennessee College of Medicine
Chattanooga, Tennessee
mfugate2@gmail.com
Disclosures: Advisory board and speaker for Medtronic.

1. McKinsey JF, Zeller T, Rocha-Singh KJ, et al. Lower extremity revascularization using directional atherectomy: 12-month prospective results of the DEFINITIVE LE study. JACC Cardiovasc Interv. 2014;7:923-933.

Medtronic

IN.PACT™ Admiral™ Drug-Coated Balloon Reference 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.

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.

SpiderFX™ embolic protection device 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:
Lower Extremity (LE) Interventions- The SpiderFX embolic protection device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk™ Peripheral Plaque Excision System, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities. The vessel diameter at the filter basket placement site should be between 3.0 mm and 6.0 mm.

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

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

TrailBlazer™ Support 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: 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 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: 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.

Nitrex™ Guidewire 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 0.014 in. (0.36 mm) and 0.018 in. (0.46 mm) diameter NITREX nitinol guidewires are intended for use in the peripheral and coronary vasculature.
The 0.025 in. (0.64 mm) and 0.035 in. (0.89 mm) diameter NITREX nitinol guidewires are indicated for use in the peripheral vasculature.

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