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# Treatment Strategies for Femoropopliteal Chronic Total Occlusions

By Harry W. Donias, MD

A chronic total occlusion (CTO) is present in nearly 50% of all patients undergoing endovascular treatment of infrainguinal peripheral arteries.[1] The presence of a CTO has been associated with a lower procedural success rate, longer procedure times, and higher radiation doses and contrast loads.[2] As a busy cardiovascular surgeon in the southern United States who treats this patient population, I present a case that illustrates my treatment strategy when managing this difficult clinical challenge.

## CASE REPORT

A 61-year-old African American woman presented with complaints of bilateral lower extremity claudication in November 2018. She had a history of hypertension, non–insulin-dependent diabetes mellitus, breast cancer, gout, and she was an everyday smoker. Her in-office ankle-brachial index (ABI) was 0.62 mm Hg for the right leg and 0.39 mm Hg for the left leg. We discussed smoking cessation and a walking program, and she was given a prescription for pentoxifylline. As is my practice for these patients, a CTA of the abdomen and pelvis with runoff was ordered in anticipation of peripheral intervention to decrease potential procedure time, contrast load, and radiation exposure at the time of the procedure.

The patient's next visit was in early December, and the results of her CTA showed a series of lesions in the left leg: a high-grade lesion of the distal left common iliac artery (CIA), ≥ 75% stenosis of the mid-segment of the left external iliac artery (EIA), high-grade stenosis with near-occlusive changes at the origin of the left superficial femoral artery (SFA), multifocal stenotic changes with occlusion of the mid-SFA and reopacification of a small popliteal artery via collaterals, and multifocal stenoses of the runoff vessels and occlusion of the left posterior tibial artery. She had rigorously followed her exercise regimen since her last visit and was in the process of quitting smoking, down to two or three cigarettes per day. She reported that her legs were feeling better and opted to continue with conservative management.

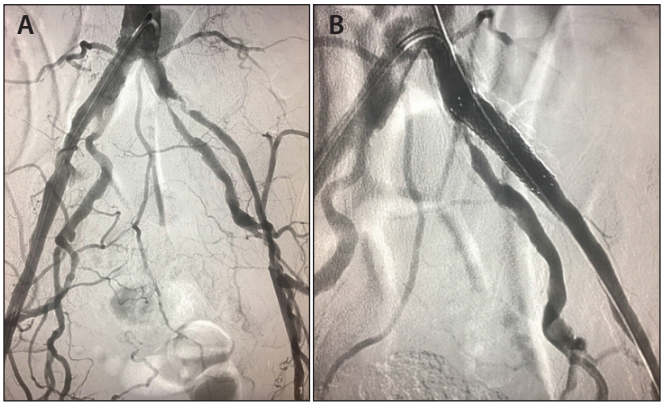


**Figure 1. Angiography revealed a tight lesion of the distal left CIA, a 70% lesion of the mid-EIA, and a 90% lesion at the orifice of the left internal iliac artery (A). The mid-EIA lesion was stented with an EverFlex™ self-expanding stent and postdilated with an 8- X 30-mm balloon (B).**

The next visit was in January 2019. Her in-office ABI was stable in the right leg at 0.62 mm Hg and was 0.53 mm Hg in the left leg. The patient had successfully quit smoking and agreed to endovascular intervention in the left leg.

At the time of the procedure, the right femoral artery was cannulated, and a 5-F sheath was placed. A Glidewire™* (Terumo Interventional Systems) and a renal bifurcation iliac catheter RBI (renal, bifurcation, iliac) catheter™* (Merit Medical Systems, Inc.) were advanced to the infrarenal aorta. Angiography was performed showing a tight lesion of the distal left CIA, a 70% lesion of the mid-EIA, and a 90% lesion at the orifice of the left internal iliac artery (Figure 1A). A 6-F sheath was placed in the left femoral artery and a Glidewire was able to cross the lesions of the left CIA and EIA. The patient was

systemically heparinized. An 8- X 27-mm Visi-Pro™ balloon-expandable stent (Medtronic) was deployed in the CIA with no residual stenosis seen. The lesion in the mid-EIA was then stented with an EverFlex™ self-expanding stent (Medtronic) and was postdilated with the 8- X 30-mm balloon (Figure 1B).

Runoff imaging was then performed on the left femoral artery, showing a high-grade lesion at the origin of the left SFA (Figure 2A) and a CTO in the mid-SFA extending to the popliteal artery (Figure 2B). This reconstituted in the behind-the-knee popliteal artery via collaterals and there was one-vessel runoff to the foot via the anterior tibial artery.

A long 7-F sheath was advanced from the right groin, across the newly stented CIA and EIA, and to the left femoral artery. To avoid entanglement in the newly placed stents, we used a 0.035-inch Glidewire with a preformed J-tip. The Glidewire and a TrailBlazer™ support catheter (Medtronic) were advanced through the tight lesion in the proximal SFA to reach the mid-SFA above the CTO. Interarterial nitroglycerin (1 mL; 200 µg) was administered via the TrailBlazer support catheter followed by 2 mg of tissue plasminogen activator to pretreat the CTO.

A selective SFA angiogram showed that the lesion was long and heavily calcified with mature well-formed collaterals. Based on these findings, we used the Viance™ crossing catheter (Medtronic) and advanced it through the Trailblazer™ catheter, with a 0.014-inch Hi-Torque Spartacore™* guidewire (Abbott Vascular) inserted into the Viance crossing catheter to lend support. The Viance crossing catheter successfully passed to the level of the popliteal artery but appeared to be in a subintimal plane. To regain luminal access, an Enteer™ re-entry catheter (Medtronic) was advanced over the 0.014-inch Hi-Torque Spartacore wire to the popliteal artery. Magnified images were taken from multiple planes before attempting re-entry. The images showed that the Enteer re-entry catheter was a short distance away from the popliteal artery wall, suggesting that we were not in the subintimal plane but had passed down a collateral. The Enteer re-entry catheter was withdrawn.

We again attempted to use the Viance crossing catheter to find the true lumen of the CTO. While the Viance crossing catheter, TrailBlazer support catheter, and Spartacore wire were eventually able to engage the true lumen of the CTO, we could not advance further than midway through the lesion. At this point, the TrailBlazer support catheter was left in place and the Viance crossing catheter and Spartacore wire were removed. The 0.035-inch Glidewire with the preformed J-tip was advanced through the TrailBlazer support catheter. The Glidewire and TrailBlazer support catheter traversed the remaining length of the CTO into the true lumen of the popliteal artery. An angiogram confirmed proper placement within the artery and facilitated placement of a 5-mm SpiderFX™ embolic protection device (Medtronic).

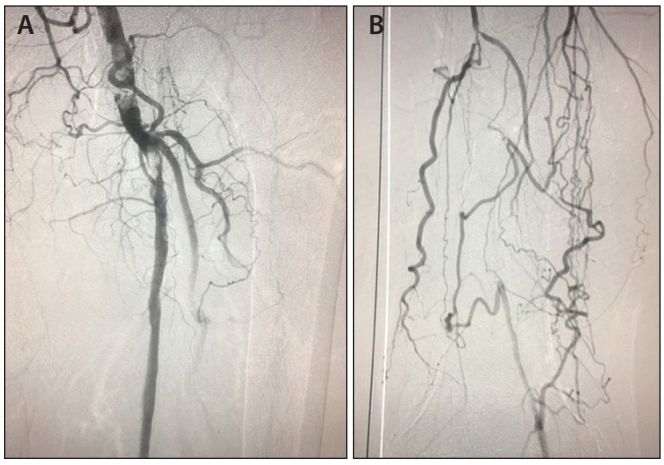


**Figure 2. A high-grade lesion was visible at the origin of the left SFA (A), as well as a CTO in the mid-SFA extending to the popliteal artery (B).**

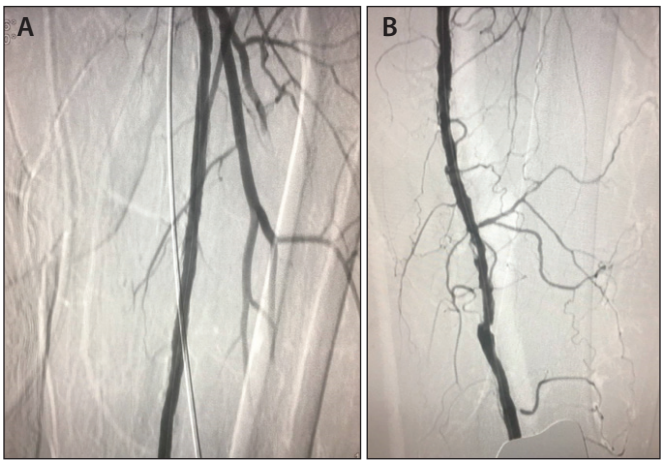


**Figure 3. Angiography after atherectomy and angioplasty showed remaining heavy calcification and luminal irregularity at the site of the CTO in the mid to distal left SFA (A), as well as one-vessel runoff to the foot via the anterior tibial artery (B).**

We performed directional atherectomy with the HawkOne™ LX directional atherectomy system (Medtronic) throughout the entire SFA and proximal popliteal arteries, followed by percutaneous transluminal angioplasty (PTA) of the entire SFA and proximal popliteal arteries with a 5- X 300-mm Pacific™ Xtreme PTA balloon dilatation catheter (Medtronic) over the SpiderFX filter wire. A completion angiogram showed a widely patent SFA, although it still had heavy calcification and luminal irregularity at the site of the CTO in the mid to distal left SFA (Figure 3A) and maintained good one-vessel runoff to the foot via the anterior tibial artery (Figure 3B).

We decided to stent the calcified area of the distal SFA to prevent restenosis. This was accomplished with a 7- X 120-mm EverFlex self-expanding stent. The completion angiogram now showed widely patent SFA and popliteal

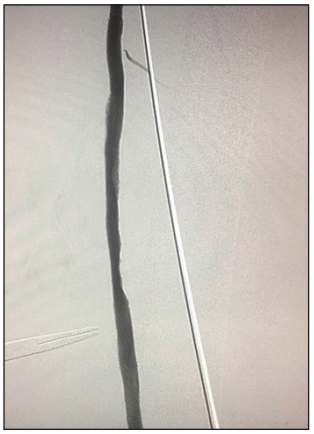

**Figure 4. Completion angiography after stenting of the distal SFA showed a widely patent SFA and popliteal arteries.**

arteries (Figure 4). The bilateral femoral sheaths were removed using MYNX™* closure devices (Cordis, a Cardinal Health company).

The patient was extremely happy at her follow-up visit. She no longer had any symptoms of claudication, was continuing her exercise program, and had successfully quit smoking.

## DISCUSSION

CTOs are defined as completely occluded arterial segments of ≥ 3 months duration. Femoropopliteal and infrapopliteal artery CTOs are present in up to 50% of patients with claudication or critical limb ischemia.[1,3] CTOs of the SFA, popliteal, or tibial arteries require interventions that are more technically challenging, with more periprocedural complications and lower rates of procedural success compared with lesions that are not completely occluded. Despite these challenges, the ability to successfully treat CTOs is nearly obligatory for an endovascular specialist.[4] CTOs are complex lesions that can widely vary among patients, and there is not a universal "right" way to proceed, more a series of choices dependent on both preprocedural characteristics and intraprocedural events, as shown in the algorithm in Figure 5.

Multiple variables have been associated with failure to cross a CTO, including long lesion length, failure to penetrate the proximal cap, inability to navigate side branches or bridging collaterals, and inability to re-enter the distal true lumen. Dense fibrous caps and heavy calcification that often characterize CTOs have also been associated

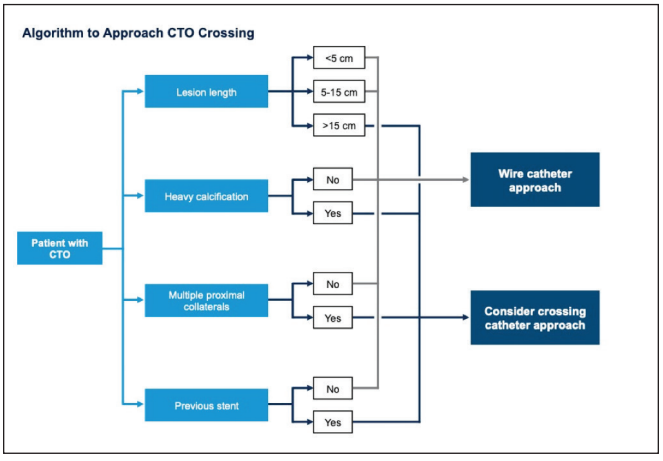


**Figure 5. Treatment algorithm for crossing CTOs with varying characteristics.**

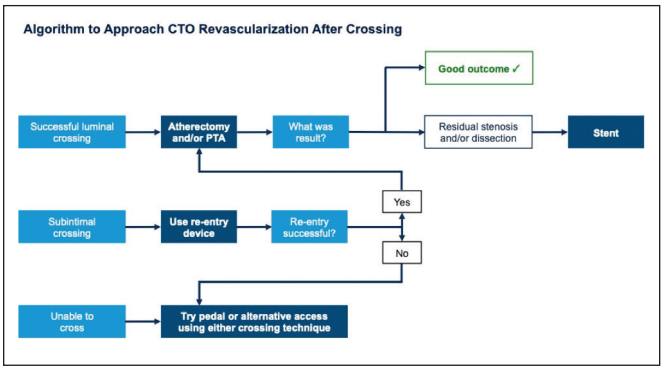


**Figure 6. Treatment algorithm for revascularization after crossing a CTO.**

with failure to cross.[1,2] When I encounter a CTO with one or more of these characteristics, I tend to choose a Viance crossing catheter versus a traditional wire catheter. When starting with the Viance crossing catheter, you can always change course and convert to the wire catheter technique if needed, as happened in this case. But the opposite is less true; using the crossing catheter after failing with a wire catheter is less successful. This is supported by a study that showed how a guidewire could cross 96% of CTOs after a Viance crossing catheter failed, but that a Viance crossing catheter could only cross 50% of CTOs after a guidewire failed.[1] If the only way to cross the CTO is in the subintimal plane, I use a re-entry device to access the true lumen.

Once across the lesion and in the true lumen, I generally perform vessel prep with directional atherectomy before proceeding with PTA (Figure 6). This treatment strategy is beneficial because it removes plaque, improves luminal diameter, and leaves nothing behind in the native artery, preserving future treatment options if restenosis occurs. The DEFINITIVE LE study demonstrated that treatment with directional atherectomy was safe and effective through 12 months.[5] If the completion angiogram shows residual stenosis or a clinically significant dissection after intervention, I place a stent to cover the area of concern.

Multiple techniques are often required to cross a CTO, as in this case, where the crossing catheter was needed to pass the proximal cap and traditional wire catheter techniques were used to cross the remainder of the CTO. In cases where the lesion cannot be crossed in an antegrade fashion, the next step is to proceed with pedal or alternative access for a retrograde approach. We would use similar crossing catheters or wire catheter techniques, depending on the characteristics of the lesion.

Above all, the most important thing to remember is that CTOs are challenging but manageable. There are multiple tools and strategies for the interventionalist to use, and there is no universal "right" way to approach each unique case. ■

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**HawkOne™ peripheral 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™ 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.

**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.

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

**Visi-Pro™ balloon-expandable peripheral stent system Reference Statement**
**Indications:**
- The Visi-Pro™ balloon-expandable peripheral stent system is indicated for improving luminal diameter in patients with atherosclerotic disease of the common and/or external iliac arteries up to 100 mm in length, with a reference vessel diameter of 5 to 10 mm.
- The Visi-Pro™ balloon-expandable biliary stent system is intended as a palliative treatment of malignant neoplasms in the biliary tree.

**Contraindications:**
- Use of the Visi-Pro™ balloon-expandable peripheral stent system is contraindicated in patients with known hypersensitivity to stainless steel or its components; patients contraindicated for anticoagulant and/or antiplatelet therapy; patients who exhibit persistent acute intraluminal thrombus of the proposed lesion site; perforation at the angioplasty site; aneurysm of the artery to be treated.

**Potential Adverse Events:**
- Potential adverse events which may be associated with the use of a stent in the Iliac arteries include, but are not limited to: Abrupt or sub-acute closure , Allergic reaction to 316L stainless steel, Allergic reaction to device materials or procedure medications, Amputation, Aneurysm, Angina, Arrhythmia, Arterio-venous fistula, Artery injury (e.g., dissection, perforation or rupture), Bleeding requiring transfusion, Contrast medium reaction/renal failure, Death, Device breakage, Embolism, Failure to deploy stent, Fever, Gastrointestinal bleeding due to anticoagulation, Hematoma, Hypertension/Hypotension, Infection, Inflammation, Intraluminal thrombus, Myocardial infarction, Pain, Partial stent deployment, Pseudoaneurysm, Renal insufficiency, Restenosis, Sepsis, Shock, Stent collapse or fracture, Stent migration, Stent misplacement, Stroke, Surgical or endovascular intervention, Thrombosis/occlusion of the stent, Transient increase in glomerular filtration rate, Transient ischemic attack, Venous thromboembolism, Vessel spasm, Worsening claudication or rest pain.
- See the Instructions for Use provided with the product for a complete list of warnings, precaution, adverse events and device information.

**CAUTION:**
- Federal (USA) law restricts these devices to sale by or on the order of a physician.

**EverFlex™ self-expanding peripheral stent system Reference Statement**
**Indication:**
- The EverFlex™ self-expanding peripheral stent system is intended to improve luminal diameter in the treatment of symptamotic 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 Protégé™ 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.

**CAUTION:**
- Federal (USA) law restricts these devices to sale by or on the order of a physician.

**Pacific Xtreme™ PTA balloon dilatation catheter Reference Statement**
- Important Information: Prior to use, refer to the Instructions for Use supplied with these devices for indications, contraindications, side effects, suggested procedure, warnings and precautions.

**Indications for Use:**
- The Pacific Xtreme™ PTA balloon dilatation catheter in 150 mm, 200 mm, 250 mm and 300 mm balloon length is intended to dilate stenoses in femoral, popliteal and infrapopliteal arteries.

**Caution:**
- Federal (USA) law restricts these devices to sale by or on the order of a physician.
- Test data is on file at Medtronic Inc.
- Bench test results may not be indicative of clinical performance.

**Viance™ catheter Reference Statement**
- Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

**Indications for Use:**
- The Viance™ catheter is intended for use with a guidewire to access discrete regions of the peripheral vasculature. When used as part of the peripheral system, the Viance catheter 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.

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

**Enteer™ re-entry catheter reference statement**
- Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

**Indications for Use:**
- The Enteer™ re-entry catheter is indicated for directing, steering, controlling and supporting a guidewire in order to access discrete regions of the peripheral vasculature. When used as part of the Peripheral System, the Enteer Catheter 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.

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

**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.

**CAUTION:**
- Federal (USA) law restricts these devices to sale by or on the order of a physician.