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Breaking Through the Challenge of Chronic Total Occlusions

BY STEPHEN B. WILLIAMS, MD, MPH

Chronic total occlusions (CTOs) may be present in 20% to 40% of patients undergoing treatment for symptomatic peripheral arterial disease.[1] The ability to successfully cross long total occlusions is directly related to acute procedural success. Lower procedural success rates are associated with longer occlusions, flush ostial occlusions, increased collaterals (especially near the proximal cap), heavier calcification, and the duration of occlusion. Inability to successfully cross is the most frequent reason for open surgical bypass.

Most long SFA occlusions begin with a proximal stump followed by varying degrees of distal vessel reconstitution by way of collaterals from the profunda femorus.[2] Intraluminal crossing may reduce the dissection plane of a long occlusive lesion, protect collaterals, and keep treatment options open. Subintimal crossing may extend re-entry and subsequent treatment options beyond the occluded segment, putting collaterals and potential "no-stent zones" at risk of complications of the interventional procedure.[3] Subintimal crossing may also increase the rates of complications such as perforation, dissection, embolization, and increased radiation and contrast exposure.

Intraluminal crossing is preferred in areas in which the operator wishes to avoid stenting, such as the common femoral artery, Hunter's canal, the popliteal artery, the iliac bifurcation, and areas with prominent collaterals. Below the knee, once a wire has crossed into the adventitia, it can be extremely difficult to re-enter the true lumen due to the medial calcium. In this setting, re-entry options are more limited, and intraluminal crossing is preferred.

The advent of endovascular CTO devices has enabled physicians to increase their crossing success and expand their interventional treatment options.

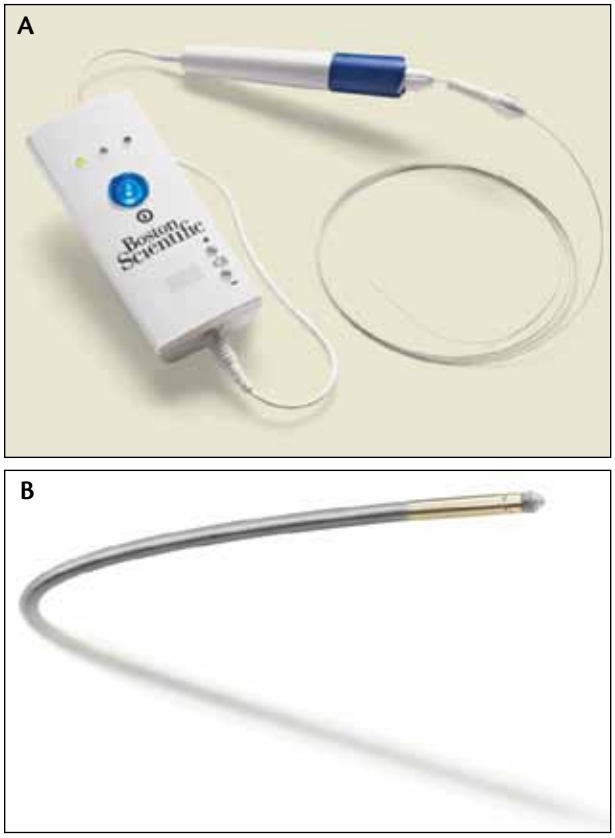


Figure 1. The TruePath™ CTO Device consists of a motor housing, control unit (A), and a diamond-coated tip rotating on an 0.018-inch wire (B).

The TruePath™ CTO Device has become an important part of our clinical armamentarium when addressing CTOs, particularly those with calcified proximal or distal caps that cannot be crossed or engaged with standard interventional techniques. I most frequently use this device as first line therapy for moderate-to-long total occlusions. The predominant advantage of the wire-based system is that it enables the support catheter to advance more readily than standard wire techniques. The 0.018-inch profile has also enabled us to approach lesions from the retrograde popliteal and pedal approach.

OVERVIEW OF THE TRUEPATH DEVICE

The TruePath CTO Device (Figure 1) is designed to penetrate hard or calcified occlusions, creating a pathway through the occluded vessel via micro-dissection. The device consists of diamond-coated rotating tip, spinning at 13,000 RPM, on a 0.018-inch nitinol wire. The wire has a working length of 165 cm that tapers over the distal 9 cm to optimize flexibility (Figure 2). The tip of the device has a 3º angle, which can be shaped to a 15º angle. A support catheter or 0.018-inch balloon catheter is required to advance the TruePath CTO Device to the lesion.

Once the device is advanced to the lesion, it is activated and advanced through the proximal cap. Unique features of the TruePath CTO Device are the audible and visible cues providing feedback on the resistance encountered at the tip of the device. As increased resistance is experienced, LEDs and audible signals activate. The device incorporates a built-in safety mechanism when the resistance exceeds the operational range, allowing the operator to adjust the pressure used while advancing, or withdraw the device and redirect down a new channel.

The support catheter is advanced over the TruePath CTO Device through the lesion. Once the CTO has been crossed, the TruePath can be exchanged, or an extension wire is available to extend the working length of the TruePath wire to 335 cm.

Results from the ReOpen Study, a prospective, multicenter, single-arm study of 85 patients, have been presented and are pending publication.

STEPS OF THE PROCEDURE

When first engaging the proximal cap, extend the TruePath CTO Device 1 cm beyond the tip of the support catheter (Figure 3). Activate the TruePath CTO Device and slowly advance. It is important not to put too much pressure on the device as you advance to allow the drill to engage the lesion. Attempting to push, prolapse, or torque the device through the lesion works against the drilling mechanism.

As you advance the device through the lesion, advance the support catheter to maintain the consistent 1-cm distance between the support catheter and the tip of the TruePath Device. As with standard CTO wire techniques, the device will often cross more effectively by advancing both the TruePath and the support catheter as a unit.

The TruePath has audible signals that correlate to

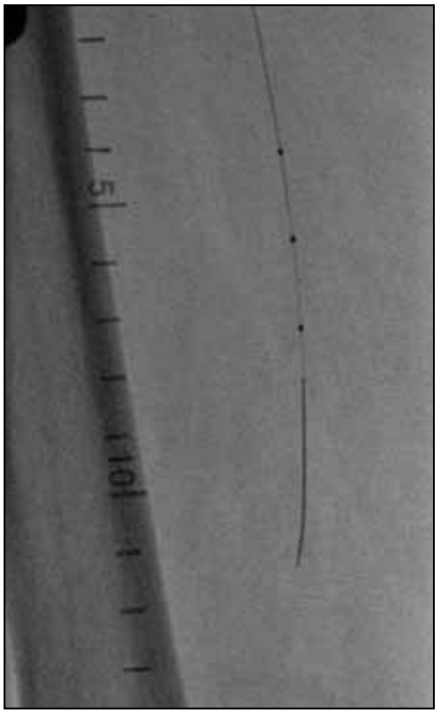


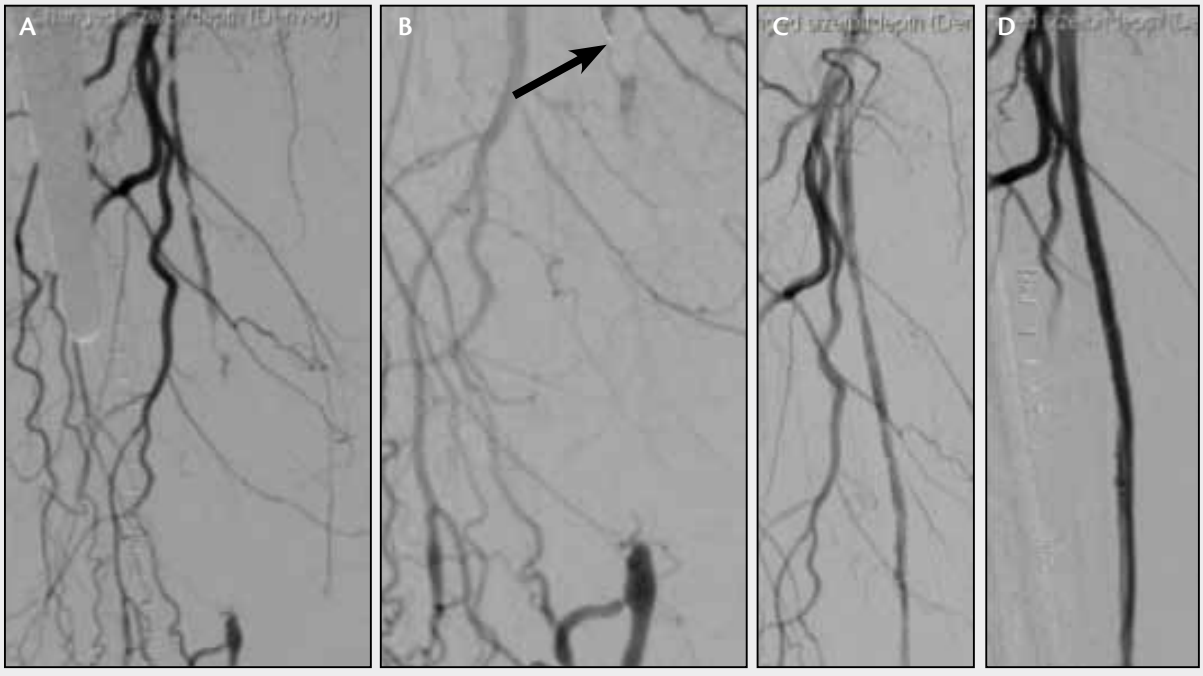
Figure 2. The TruePath CTO Device beyond the tip of the support catheter. A platinum tungsten coil and the gold-plated tip housing make up the radiopaque distal 3 cm of the TruePath Device.

Figure 3. The TruePath CTO Device extended 1 cm beyond the tip of the support catheter.

CASE 1

An 80-year-old woman with diabetes presented with claudication that progressed to Rutherford class IV. Angiography revealed diffuse SFA disease including a long total occlusion and three-vessel runoff (A).

The TruePath™ Device was advanced across the proximal cap (B), followed by the SFA CTO (C). Final angiography after successful balloon angioplasty and stenting showed a widely patent vessel and brisk flow (D).



the amount of resistance at the drill tip. The first two green lights signify whether the device is in active and drilling mode, respectively, with the tip spinning at 13,000 RPM. When the resistance exceeds specifications, the third light, which is red, will illuminate, and the device will "chirp." In this mode, the tip oscillates to relieve pressure on the drive shaft. When the device enters this mode, you must determine what is causing that increased resistance. Pushing too hard on the device as it advances can trigger this mode, and often just easing the forward pressure will allow the device to return to drill mode as you engage and advance in the lesion.

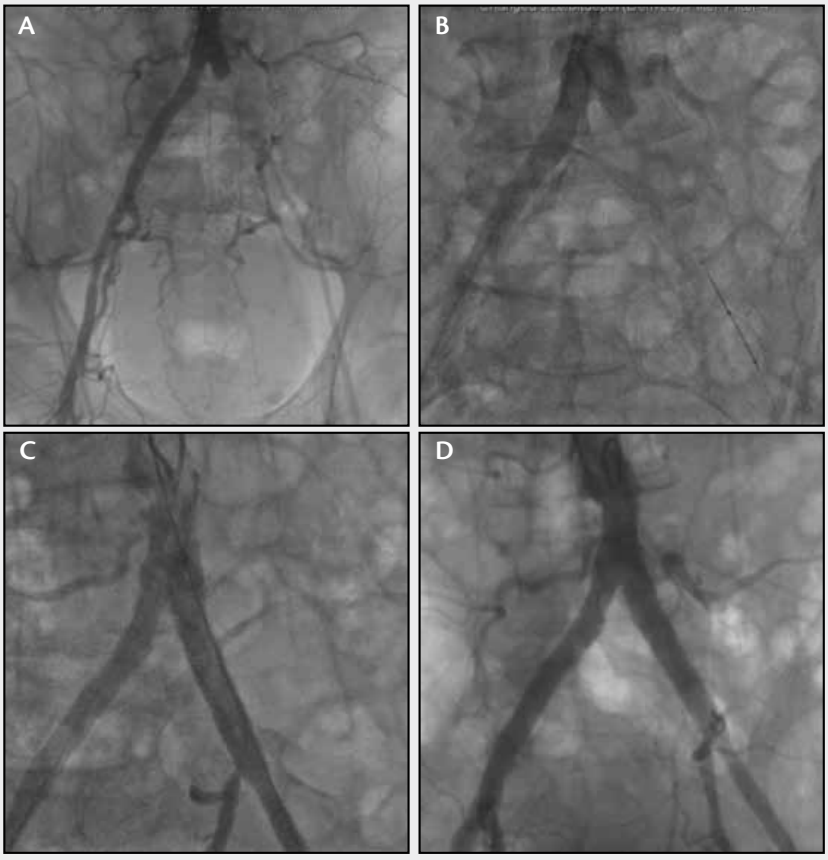
The tip overload mode can also be encountered while traversing the lesion. This mode can provide important feedback as to whether the device is taking a subintimal track, and it can allow the operator to redirect the catheter and device to stay in the true lumen. When I hear this feedback, I will take additional views and use calcium outlines to determine my position. Vessel tortuosity may require you to exchange for angled support catheters to direct the TruePath CTO Device through the true lumen channel. I have grown to respect the feedback from these alerts, and along with the tactile feel of the device, I use them to help determine if the device is taking a subintimal track. Within the body of the CTO, it can be difficult to find a course that does not trigger the oscillation mode; when this occurs, I may turn the device off and advance the device as a 22-g wire.

CTOs are complex and may require multiple catheter and wire exchanges, and the proximal and distal caps are usually the most difficult segments to penetrate. I often utilize the TruePath CTO Device to drill through calcified caps and then exchange it for a steerable crossing wire to traverse through tortuous vessels. Hydrophilic wires are useful in the mid-segment because they are less likely to perforate. The TruePath CTO Device can then be reintroduced to cross the distal cap. Unlike catheter-based technologies, this wire-based crossing device enables straightforward wire and device exchanges.

CASE 2

A 67-year-old man with active tobacco use presented with life-style-limiting (Rutherford class III) left buttock, thigh, and calf claudication. Baseline angiography revealed long common and external iliac chronic total occlusion (A).

After placing a 4-F sheath in the left common femoral artery, the TruePath™ CTO Device was advanced through the left external iliac (B). Crossing time through the lesion was less than 15 seconds. Two Express® LD Iliac balloon-expandable stents were placed in the left common iliac. Note patent hypogastric artery (C). Final angiography demonstrated patent common and external iliac arteries (D).



CTOs are one of the last unconquered territories in the peripheral space, and crossing techniques continue to benefit from the advancement of many new devices, including the TruePath CTO Device. ■

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Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary. BSC currently has no stents FDA-approved for use in the infrainguinal regions of the lower extremities.

All images courtesy of Stephen B. Williams, MD, MPH.

1. Rogers JH, Laird J. Overview of new technologies for lower extremity revascularization. Circulation. 2007;116:2072-2085.
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3. Jacobs, DL. True lumen re-entry devices facilitate subintimal angioplasty and stenting of total chronic occlusions: initial report. J Vasc Surg. 2006;43:1291-1296.

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