Techniques for Successful Crossing With the TruePath™ CTO Device

Best practices for treating vessels with chronic total occlusions.

BY JAMES B. PARK, MD, FACC

In terms of devices that treat chronic total occlusions (CTOs), the TruePath™ CTO Device (Boston Scientific Corporation, Natick, MA) offers the most versatility in managing a variety of lesion types and anatomical locations. For example, an intraluminal device such as the Frontrunner (Cordis Corporation, Bridgewater, NJ) serves its purpose, but when the interventionist is faced with a very hard, smooth proximal cap, it will not be easily traversed unless specific techniques are employed to make a "dent" in the cap. The TruePath device, however, is designed to "drill" through the proximal cap or occlusion regardless of composition, be it soft tissue, ulcerated plaque, mixed fibrocalcific, or extremely calcific. In addition, because of its 0.017-inch profile, it may traverse multiple levels over the length of a given CTO, including the distal cap.

RECOMMENDATIONS FOR USE

In addition to the specific lesion types for which it is suitable, the other useful aspect of the TruePath device relates to the anatomical locations where it can be used safely and effectively. Normally, when revascularizing or treating CTOs, my tendency is to assess where in the vascular tree a device is best used and where it should not be used. Given TruePath's small size, it is safe and effective to use in various anatomies. For example, due to its proficiency in the calcified lesion/cap and its size, I find it to be the best intraluminal CTO device for below-the-knee lesions in the tibial/peroneal vessels.

Staying Intraluminal

Due to the lack of re-entry devices that we can use below the knee, it is extremely important to stay intraluminal or have the ability to come back to the luminal side with one device. Again, given its low profile, when the TruePath CTO Device is used in the extraluminal area outside the vessel wall or the concomitant venous vessel, it will not produce a sizable perforation or fistula that will ultimately need treatment.

In the 52 cases that have been performed so far at our institution, there has not been a complication related to the device's use for CTO in any of the vascular beds. This is of particular importance given the trepidation many operators feel when working below the knee, for fear of the patient developing compartment syndrome. Similar concerns exist when working in the pelvic space, such as in the iliac arteries, as well as the subclavian artery. Often, possible complications resulting from a perforation in these anatomies and the limited options to percutaneously correct them pose problems for interventionists. In addition to below-the-knee vessels, our experience with the TruePath device in the popliteal, superficial femoral artery (SFA), common femoral, iliac, and subclavian arteries leads me to believe that it is very useful in a variety of anatomic locations and types of CTOs.

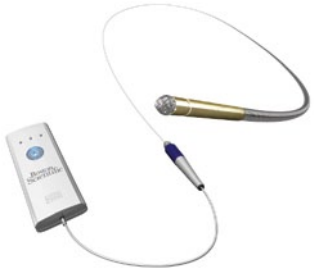
Techniques

The device is packaged with a short 3° bend at the distal tip, although a shaping tool is included with the device that, when used correctly, produces a 15° bend on the distal 5 mm of the tip. In my experience, putting a 15° bend on the tip is the best way to use the device so that when torquing the device, maneuvering throughout the length of the CTO is possible. Further, if advanced into a subintimal or extraluminal space, the device can be turned to a different plane or vector.

A supporting catheter may be used with the device, such as a straight 0.018-inch Quick-Cross Support Catheter (Spectranetics Corporation, Colorado Springs, CO). Spectranetics also makes a Quick-Cross support catheter in an angled configuration, which

BOSTON SCIENTIFIC TRUEPATH™ CTO DEVICE

Key features:
- Diamond-coated tip
- 0.018-inch wire
- 165 cm
- 1:1 torque response
- No capital equipment



The TruePath™ CTO Device is designed to facilitate the crossing of chronic total occlusions (CTOs) within the peripheral vasculature. The device features a rotating diamond-coated tip designed to break through occluded peripheral arteries and facilitate the placement of conventional guidewires for treatment of peripheral lesions. The ultra-low 0.018-inch profile is approximately half the size of competitive devices and is engineered for optimal crossing. Once positioned, the distal tip rotates at 13,000 rpm to facilitate drilling through calcified lesions and other fibrous blockages. The TruePath device requires no capital equipment and is available with an optional extension wire to facilitate catheter exchange and increase the working length beyond 300 cm. The TruePath device is designed to function through an 0.018-inch support catheter, such as a Rubicon™ Support Catheter, and its tip can be angled to 15°. The TruePath CTO Device provides feedback to the user via audio and visual cues on the control unit. LEDs and audible signals are activated as the operator encounters increased resistance. Also, a built-in safety mechanism is included, so that when lesion resistance exceeds the device's drilling capacity, the audible and visual cues inform the operator to choose a different channel or withdraw the device.

I use to support my "push" to the end of the CTO device. Given that the device's cutting surface is covered with 15- to 20-µm diamond particles, my technique with TruePath is not unlike that used for the Rotablator™ Rotational Atherectomy System (Boston Scientific Corporation), another device with a diamond-coated cutting surface. Essentially, I let the device "do the work" by placing the tip on the cap and applying gentle forward pressure rather than being overly aggressive and ramming the device through the lesion. Sometimes, the interventionist needs to place consistent forward pressure on the TruePath device, especially for a severely calcified plaque/cap, but the operator may try to let the device almost drive itself.

Pressure and Steering

The interventionist will have to decide how much pressure he or she needs to put on the device, but for most lesions, aggressive forward pressure may not be needed. For the SFA, popliteal, and tibial vessels, if a patient has adventitial calcifications, it may help to guide the device by steering through the CTO, especially if the vessel is tortuous or does not sit in a "normal" plane, as seen on angiography or by fluoroscopy.

In addition to the 0.018-inch Spectranetics supporting catheter, the interventionist can use other catheters that are 0.018 inch or larger (eg, Rubicon™ Support Catheter [Boston Scientific Corporation, Natick, MA]), including a 0.035-inch catheter to help get to the beak, nub, or other planes that may be difficult to access due to the small angulation of the device itself at 15°. Making the bend of the TruePath tip any larger than 15° with other tools is not recommended, as this may compromise the tip's ability to rotate.

Controller

In addition to tactile feel and fluoroscopic guidance, the TruePath device also includes a hand-held controller with visual (three lights) and audio ("chirp") feedback. The first light, a green light, indicates that the device is activated. The second light, another green light, indicates increased resistance at the device tip and that it is actively engaging hard or calcific tissue and is accompanied by a sustained audible tone. The third light, a red light, indicates significant resistance at the tip that is beyond the normal operating range and is accompanied by an audible, intermittent "chirp." In my experience, prolonged activation of the third light and audible "chirp" may signal that the device has found a subintimal or extraluminal path. At first, given my lack of experience, I hesitated to use these features because I did not know what they meant clinically, but since my first case, I have learned to use and trust these indicators to help me understand where the end of the device might be in the vessel.

Periprocedural Imaging

With my experience in treating CTOs, viewing the fluoroscopic images gives me a good idea whether I am in the SFA space or not, even without adventitial calcifications to guide me while looking at the bony landmarks. I recall one particular case, however, when I consistently thought I was in the correct plane and direction, but the red warning light and "chirp" were activated, indicating that I was possibly outside the artery. I attempted to cross again, this time being mindful of the red warning light and "chirp," and the device

found a different pathway that did not appear to be the right direction, but the device soon passed easily through the distal cap. When looking at the lesion on angiography after revascularization, it clearly showed that at the end of the CTO near the distal cap, the SFA took a medial turn that we sometimes see in patients due to tortuosity. By trusting the TruePath™ CTO Device warning signals, the procedure was completed, without complication.

Using a Complete Toolbox

When treating CTOs, I never hesitate to use a combination of devices or to revert to the guidewire/guiding catheter technique using the subintimal space to move past the distal CTO to complete the case, especially in the SFA. I will sometimes then come back and re-use the TruePath CTO Device to return to the distal lumen or move through the distal cap instead of having to use a re-entry device.

In CTO work, the operator needs to be flexible and willing to use a variety of tools to achieve complete revascularization. When using the previously mentioned technique, the TruePath CTO Device gives the interventionist many options to achieve success while limiting complications.

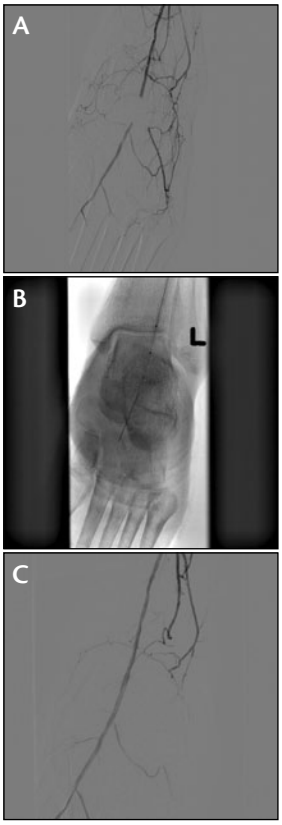


Figure 1. Pre- (A), intra- (B), and postprocedural (C) angiograms of a distal anterior tibial artery CTO.

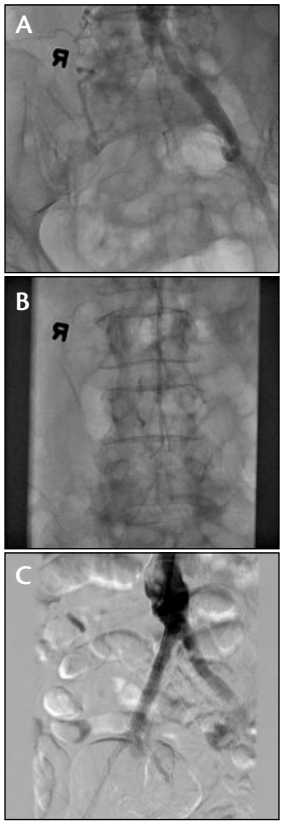


Figure 2. Pre- (A), intra- (B), and postprocedural (C) angiograms of an iliac CTO.

APPLICATIONS OF THE TRUEPATH CTO DEVICE

Distal Anterior Tibial Artery CTO

Clinical scenario. This case (Figure 1) involved a distal anterior tibial artery CTO near the dorsalis pedis (DP) vessel in a patient with a toe wound that was not healing due to a lack of perfusion pressure. In cases such as this where the target lesion is very distal, there would be cause for concern for complications and/or failure rates, especially in a calcified vessel. In addition, the extreme distal nature of this lesion precluded the possibility of using a retrograde approach. In patients with wound healing issues, the correct angiosome vessels need to be revascularized, which are often completely occluded. These vessels need to be opened without surgery.

Solution. Using a 6-F, 90-cm Terumo sheath (Terumo Interventional Systems, Somerset, NJ) from the contralateral approach, with a 0.018-inch Spectranetics supporting catheter, I was able to come all the way from the right common femoral approach, and given the length of the 150-cm Spectranetics supporting catheter, we were able to get through the CTO using the TruePath device.

Iliac CTO Treatment From the Left Brachial Approach

Clinical scenario. The patient had a proximal or ostial CTO of the left iliac artery (Figure 2). Reconstitution was difficult to see, and retrograde cannulation of the left common femoral artery can be difficult. The patient was a thin elderly woman with severe claudication of the left buttock and left lower extremity. Given the size of the patient, having a sheath that is > 6 F in the brachial artery would pose significant risk. Also, due to the absence of a nub, other larger CTO devices would be difficult to use due to a lack of pushability by the supporting catheter or device.

Solution. I used a 6-F, 90-cm Terumo Destination sheath from the left brachial approach. Using the TruePath device and the Spectranetics supporting catheter, I was then able to get through the proximal cap and visualize that I was in the common femoral vessel. Using a 0.018-inch Steelcore wire (Abbott Vascular, Santa Clara, CA), I was able to revascularize using balloon-mounted stents on a 0.018-inch catheter through the 6-F sheath. Again, given the small size of the TruePath device, I was not as concerned about perforation of the iliac artery when trying to find the true lumen.

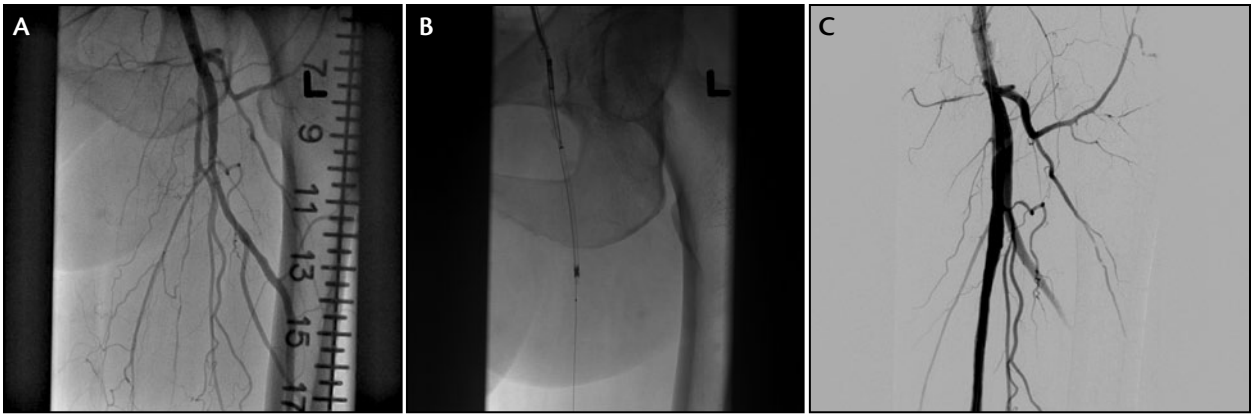


Figure 3. Pre- (A), intra- (B), and postprocedural (C) angiograms of a long CTO.

SFA CTO Treatment for a Long Diffuse Diseased Vessel

Clinical scenario. In this case (Figure 3), the patient had claudication, with a CTO greater than 200 mm in length. The ostial or proximal portion of the SFA was severely diseased, and there did not appear to be room to accurately place a self-expanding stent in the ostial portion of the SFA. In cases like this, atherectomy might be helpful at the ostium so that the interventionist would not have to stent to the ostium. This would indicate the need to be as intraluminal as possible. There might be concern that the length of the CTO and the vessel size would preclude the use of the TruePath™ device

Solution. A 7-F, 45-cm Terumo sheath from the contralateral common femoral artery can be used in case other devices (atherectomy, covered stents, etc.) need to be employed. With the TruePath device, we were able to stay intraluminal to revascularize using an atherectomy device in the proximal portion and stenting the distal portion.

CONCLUSION

In summary, the CTOs that we see in patients with peripheral artery disease are quite complex, especially those with limb ischemia. Therefore, having purpose-built tools for CTOs, particularly in the tibioperoneal vessels, is extremely important. In addition, limiting complications while working on CTOs gives the operator more opportunities for success, which is exemplified by the TruePath CTO Device when treating complicated CTOs in all anatomical locations including the iliac, common femoral, superficial femoral, and popliteal arteries, in addition to the tibial vessels. ■

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Results from case studies are not necessarily predicative of results in other cases. Results in other cases may vary.