

# Specialty Crossing Devices: Understanding the Learning Curve

Technical pearls and new devices for crossing peripheral CTOs.

BY USMAN JAVED, MD, AND JOHN R. LAIRD, MD

Chronic total occlusions (CTOs) are frequently encountered during endovascular interventions. CTOs are reported in up to 40% of patients with symptomatic peripheral arterial disease.<sup>1</sup> In the lower extremities, CTOs are commonly encountered in the superficial femoral artery (SFA). Crossing these lesions may be challenging and lead to prolonged procedure time, increased operator and patient radiation exposure, higher contrast load, and periprocedural complications including perforation, dissection, loss of collaterals, and creation of an arteriovenous fistula. Revascularization of CTOs is usually hindered by failure to cross the lesion due to a variety of factors, such as the inability to keep the guidewire in the true lumen. Attempts to revascularize heavily calcified CTOs with traditional guidewire and balloon technologies fail in 20% of cases.<sup>2,3</sup> Understanding the vessel course and presence and location of collaterals is essential and allows the

interventionalist to adjust the procedural technique and increase procedural success.

Intraluminal recanalization of complex CTOs with standard wires and balloon catheter devices may be achieved in 40% to 60% of cases, depending on lesion morphology, location, and operator experience.<sup>3</sup> Although subintimal angioplasty using a hydrophilic wire has been readily adopted with procedural success rates approaching 80%, operator experience remains an integral aspect of technical success.<sup>4,5</sup> Use of newer CTO crossing devices may also facilitate more consistent distal entry and allow for a decrease in crossing time.<sup>2,3</sup> The available devices are designed to either remain in the true lumen or facilitate controlled subintimal tracking and reentry into the distal true lumen. Herein, we describe the clinical and technical aspects of the newest generation of peripheral CTO devices. A summary comparing these devices is shown in Table 1.

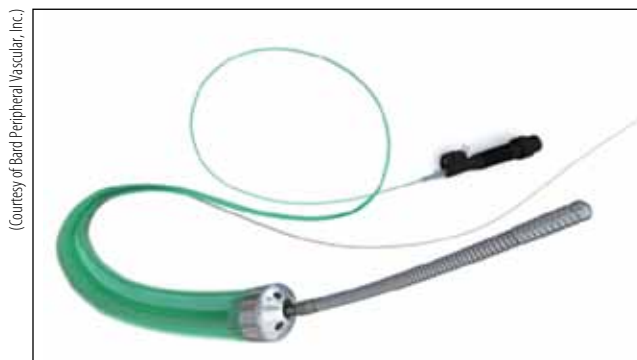


Figure 1. The Crosser catheter over a guidewire.



Figure 2. The TruePath Device, which has a diamond-coated tip that rotates on a 0.018-inch wire.

TABLE 1. COMPARISON OF VARIOUS PERIPHERAL CTO CROSSING DEVICES

Manufacturer	Bard Peripheral Vascular, Inc.			Avinger, Inc.			Boston Scientific Corporation	Covidien	
Device	Crosser 14	Crosser 18	Crosser S6	Wildcat	Kittycat	Ocelot <sup>a</sup>	TruePath	Viance <sup>a</sup>	Enteer <sup>a</sup>
Sheath compatibility (F)	5	6	5	6	5	6	5	5	5
Guidewire (inches)	0.014	0.014	NA	0.035	0.014	0.014	0.018	0.014	0.018
Working length (cm)	146	125	154	110	140	110	165	150	150
Crossing profile (mm)	1.1	1.5	0.6	2	1.5/1.7	2	0.4	0.89	1.42/1.56
Success rate (%)	83.5			89.3		NA	80	NA	NA
Safety rate (%)	98.8			95.2		NA	98.8	NA	NA

Abbreviations: NA, not available.  
<sup>a</sup>Not yet commercially available.

### THE CROSSER CTO DEVICE

The Crosser (Bard Peripheral Vascular, Inc., Tempe, AZ) is a unique system that is designed to achieve intraluminal penetration across long occlusions (Figure 1). This device has both a coronary and peripheral indication in the US. The system is comprised of an electronic Crosser generator, foot switch, high-frequency transducer, the FlowMate injector (optional), and Crosser catheter. It creates high-frequency vibrations propagated by a stainless steel tip that facilitates penetration of hard or calcified lesions. The peripheral system is available in both 0.014- and 0.018-inch guidewire versions. The Crosser S6 does not use a guidewire for its delivery. For the typical procedure with an over-the-wire catheter, the guidewire is advanced to the site of the occlusion. The Crosser is then passed over the guidewire until it contacts the occlusion. The guidewire is withdrawn while the device is activated and slowly advanced into the occlusion. Crossing of the lesion is confirmed by angiography, and the guidewire is then advanced into the distal lumen. The Crosser device is then removed. For additional tips, see the *Critical Technical Aspects of Using the Crosser Device* sidebar.

The basis for infrainguinal approval of the Crosser device was the PATRIOT trial.<sup>6</sup> In this study, a technical success rate of 84% was achieved in crossing peripheral CTOs. The average occlusion length was 117.5 mm, and 75% of the lesions were moderate to severely calcified.

Although not reported for the peripheral interventions, a learning curve was identified for coronary interventions. In centers with greater or less than 10 cases, the success rate was 65% versus 56%, respectively, with decreased device activation time. However, procedure and fluoroscopy times were not reduced.<sup>7</sup> Available case series demonstrated a success rate of 41% to 75% in peripheral interventions with the Crosser device.<sup>8,9</sup>

### THE TRUEPATH CROSSING DEVICE

Recently approved by the US Food and Drug Administration, the TruePath device (Boston Scientific Corporation, Natick, MA) is designed to penetrate hard or calcified occlusions and create microdissection in CTOs to facilitate access to the distal true lumen (Figure 2). It is a 0.018-inch wire with a diamond-coated tip that rotates at 13,000 rpm. A support catheter is generally used to advance the TruePath to the lesion. The device is then activated and advanced across the lesion. It has a built-in safety mechanism with audible and visual alerts if excessive resistance is encountered. The working length is 165 cm, which can be extended up to 335 cm to allow for support catheter or balloon catheter exchanges. The tip may be bent up to 15° for added steerability. Please see the *Technical Tips for TruePath Use* sidebar for suggested procedural techniques.



**Figure 3.** Avinger, Inc. crossing devices. The Wildcat is designed to treat above-the-knee lesions (active mode) (A). The Kitty cat is designed to treat below-the-knee lesions or tight above-the-knee lesions (B).

TruePath was originally evaluated in the investigational device exemption ReOpen study in which a technical success rate of 80% and primary safety endpoint rate of 98.8% (84/85 not related to the device) was achieved. The mean lesion length was 166 mm, the fluoroscopy time was 29 minutes, and the device activation time was 8.2 minutes.

### AVINGER CTO DEVICES

The Wildcat device (Avinger, Inc., Redwood City, CA) was originally approved as a standard support catheter for peripheral interventions (Figure 3). This 0.035-inch catheter has a hydrophilic coating that facilitates tracking through complex lesions in the SFA. The rotatable

tip assumes both passive (wedges in) and active (wedges out) configurations. The tip is initially advanced to the lesion and rotated in the passive mode. For more fibro-calcified lesions, the active mode may be used to traverse the CTO. The tip may be rotated manually or with a handheld motorized unit. The 0.014-inch versions of this device (Kitty cat and Kitty cat 2 [Avinger, Inc.]) provide smaller crossing profiles and longer working lengths for tight above-the-knee lesions or tibial vessels. The Ocelot device (Avinger, Inc.) is the latest addition to the feline family that incorporates real-time optical coherence tomography built into the catheter to guide intraluminal crossing. The Ocelot is currently being evaluated in the CONNECT 2 study. For additional operating information, see the *Tips for Wildcat Device Use* sidebar.

Wildcat was evaluated in the CONNECT (Chronic Total Occlusion Crossing With the Wildcat Catheter) trial in which the technical success rate of crossing CTOs was 89.3%, with a primary safety rate of > 95%. The average lesion length was 174 mm, and approximately half of the lesions were moderately calcified. There are no data available pertaining to the learning curve with this device.

### VIANCE AND ENTEER PERIPHERAL CTO CROSSING AND REENTRY DEVICES

This is a novel peripheral CTO crossing system that was licensed from BridgePoint Medical, Inc. (Plymouth, MN) by Covidien (Mansfield, MA) and has yet to be approved by the US Food and Drug Administration for peripheral vascular use, pending submission for 510(k) clearance (Figure 4). The system is composed of a crossing catheter that facilitates both intraluminal or subintimal recanalization of the lesion and a reentry device to facilitate access to the distal true lumen. The crossing catheter has a working length of 150 cm and tracks over a 0.014-inch guidewire. It has a coiled shaft and an atrau-

#### CRITICAL TECHNICAL ASPECTS OF USING THE CROSSER DEVICE

- Use of cold saline for irrigation is essential to avoid excessive heating.
- Avoid using guidewires with polymer-coated distal ends.
- Do not exceed 5 minutes of activation time, as Crosser catheter malfunction may occur. After 5 minutes of activation time, the use of a second Crosser catheter is recommended.
- The use of a support catheter helps preventing kinking of the device in tortuous anatomy.
- Proper device selection should include a 0.018-inch device for SFA lesions and in-stent occlusion, as well as a 0.014-inch device for popliteal and infrapopliteal occlusions.
- Use gentle forward pressure when traversing occlusions. Let the device find its way.
- If significant resistance is encountered, back off and allow brief fluid infusion before additional slow advancement.

## TECHNICAL TIPS FOR TRUEPATH USE

- A support catheter is mandatory when using the TruePath device. A preshaped support catheter is preferred when this device is used in its straight configuration.
- For added support, the device tip should not be extended 1 cm beyond the support catheter.
- Shaping the device tip may help to access a vessel when it is “flush occluded” and will assist with device steerability through complex occlusions.
- The device should be shaped only once to avoid malfunction.
- Gentle forward pressure and slow device advancement is recommended.
- Additional 0.018-inch support or balloon catheters should be available in case the TruePath device successfully crosses the occlusion but the support catheter will not follow. Exchange for the low-profile balloon catheter can then be performed.

matic distal tip to prevent vessel exit. Using a torque device, the catheter is rapidly spun in either direction to facilitate advancement through the lesion. This crossing catheter will be available in two different levels of shaft stiffness for above- and below-the-knee interventions.

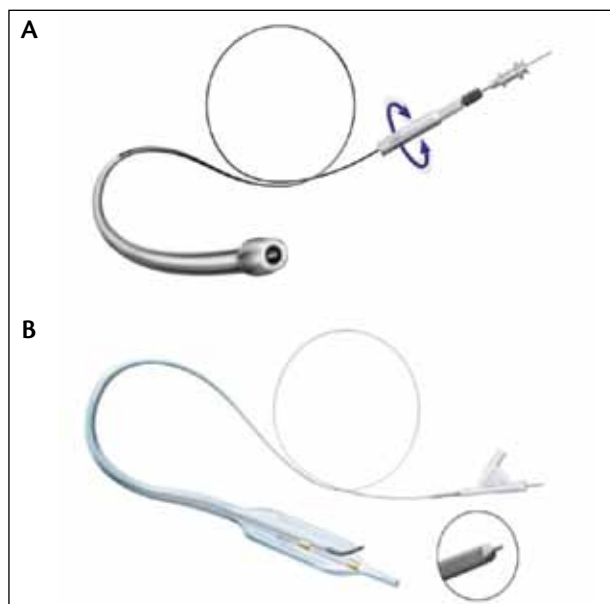
If the crossing catheter remains in the subintimal plane, the reentry device is used for directing, steering, controlling, and supporting a guidewire in order to access the distal true lumen. This is the only reentry device designed for below-the-knee use. The reentry system has two components: an orienting balloon catheter and a reentry guidewire. The balloon catheter has a 150-cm shaft length and is 0.018-inch wire compatible. The balloon is available in two sizes (3.75 X 20 mm and 2.75 X 20 mm) to facilitate reentry both above and below the knee. The balloon has a flat shape, which is designed to self-orient one of two 180° offset exit ports toward the vessel true lumen upon low-pressure inflation.

The location of the true lumen is determined with fluoroscopic guidance. When the balloon is at the desired reentry location, the primary guidewire is removed, and the barbed reentry guidewire is introduced. The 0.014-inch reentry guidewire is 300 cm long and is available in three levels of stiffness. The reentry barbed guidewire has an angled tip that is designed to be introduced through the appropriate exit port. Once the reentry wire is in the true lumen, the reentry balloon is removed followed by wire exchange and intervention.

The coronary versions of this system, the CrossBoss and Stingray devices (BridgePoint Medical, Inc.) have

## TIPS FOR WILDCAT DEVICE USE

- The catheter tip may be rotated clockwise, counterclockwise, or a combination of the two with a gentle forward pressure.
- Counterclockwise rotation is less aggressive and should generally be tried first.
- The device should not be rotated in one direction for prolonged periods of time to avoid tissue wrapping.
- Passive mode may be effective in softer occlusions and can be attempted before active mode.
- The active mode will be more effective in fibrocalcific lesions.
- If significant resistance is encountered at the proximal or distal cap, only gentle forward pressure should be applied, allowing the device wedges to do the work.
- If the catheter becomes subintimal, withdraw and try to reenter the true lumen or deflect the tip of the catheter and attempt reentry.
- KittyCat 2 has a larger profile (1.7 vs 1.5 mm) and longer working length (150 vs 140 cm) compared to the first-generation KittyCat.



(Courtesy of Covidien)

**Figure 4.** The Viance crossing catheter and Enteer reentry system. The Viance crossing catheter with torquing device and blunt tip help to advance the wire through the CTO (A). The Enteer reentry device is composed of a balloon catheter with an exit port that facilitates directing a barbed wire from the subintimal plane into the distal true lumen (B).

recently been reported to have a high success rate of 77%, with low complication rates.<sup>10</sup> Although data on peripheral interventions are not available, failure in the coronary experience was associated with smaller vessel size, severe calcification, severe tortuosity, and side branch involvement.

### CONCLUSION

The advent of these newer CTO crossing devices has the potential to facilitate recanalization of some of the most challenging occlusions. Further experience will be required to determine the best application for each of the newer CTO technologies. As with all emerging technologies, optimal technique and clinical experience (learning from the successes and mistakes of others) will be important to achieve the best results and hopefully shorten the learning curve. ■

*Usman Javed, MD, is with the Division of Cardiovascular Medicine and the Vascular Center, UC Davis Medical Center in Sacramento, California. He has disclosed that he has no financial interests related to this article.*

*John R. Laird, MD, is with the Division of Cardiovascular Medicine and the Vascular Center, UC Davis Medical Center in Sacramento, California. He has disclosed that he is a consultant/advisory board member for Abbott Vascular, Bard Peripheral Vascular, Boston Scientific, Covidien, and Medtronic. Dr. Laird may be reached at (916) 734-2028; john.laird@ucdmc.ucdavis.edu.*

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