Clinical Use of the Crosser® CTO Recanalization Catheter

An interventionist's perspective on the mechanism of action of the Crosser® Catheter and its practical application in the clinical setting.

BY JIHAD A. MUSTAPHA, MD

The Crosser® CTO Recanalization Device (Bard Peripheral Vascular, Inc.) is a catheter designed to treat peripheral chronic total occlusions (CTOs) by forming a new canal within a blocked artery to allow subsequent endovascular treatment options such as angioplasty and stenting. With the Crosser® Catheter, a specialized tip transmits high-frequency vibrations directly to the CTO, ablating the plaque. The Crosser® Catheter is designed specifically to work against resistance, particularly in CTO caps and plaque with highly calcified components. In this article, we review how the Crosser® Catheter performs based on our clinical experience and describe our treatment algorithm.

MECHANISM OF ACTION

The Crosser® Catheter uses a combination of mechanical vibration and cavitation to create a channel. Cavitation is a unique feature of ultrasound-based technologies such as the Crosser® Catheter. The Crosser® Catheter will repeatedly apply force to the CTO cap until it finds its way across the lesion:

- Via cavitation and erosion of the CTO cap , and/or
- By direct contact and penetration of the CTO cap as it creates its own new path.

The Crosser® Catheter mechanism of action selectively engages inelastic materials such as plaque. Elastic materials like the vessel wall absorb the impact of the device, thus reducing the risk of perforation. Angiographically, when the Crosser® Catheter comes in contact with a vessel wall, it appears to stand still. Operators should be able to recognize this feature by looking at the Crosser® Catheter in multiple views. If contact with the vessel is confirmed, then the interventionist should use the recommended Usher® or Sidekick® Support Catheter to redirect the Crosser® Catheter device to engage the center of the CTO cap. In our experience, the interventionist can achieve crossing with higher success rates and lower complication rates simply by visualizing the device and ensuring contact between the tip of the Crosser® Catheter and the target lesion.

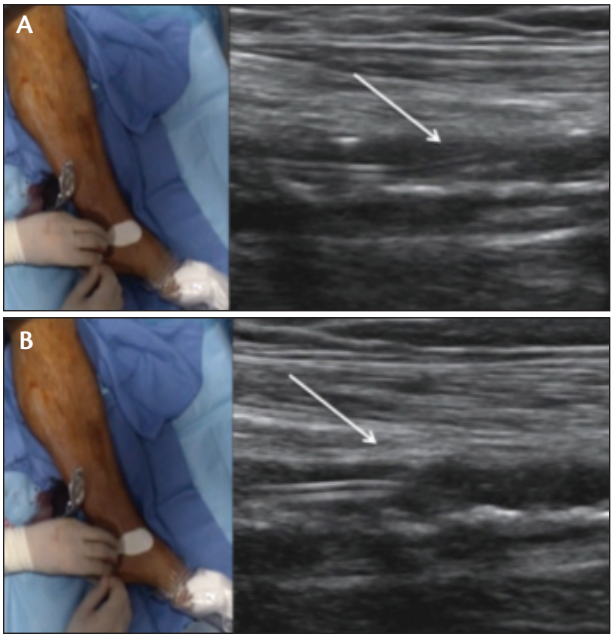

Figure 1. Tibial access sheathless with an angled Sidekick® Support Catheter rotated up (white arrow) (A). Tibial access sheathless with an angled Sidekick® Support Catheter rotated down (white arrow) (B).

Using external ultrasound in conjunction with fluoroscopy while crossing a CTO (Figure 1) allows operators to see the tip of the support catheter and its vector direction, which one can then guide away from the vessel wall and direct into the center of the lumen. Once the support catheter is in the center of the CTO cap, the Crosser® Catheter

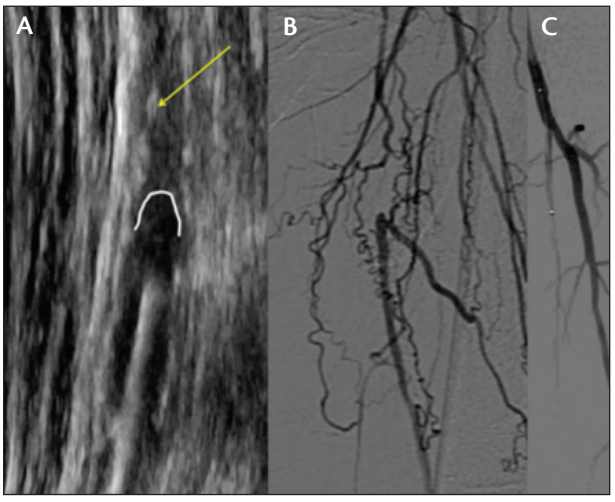

Figure 2. Extravascular ultrasound (EVUS) evaluation of the distal CTO cap defines the cap as retrograde concave and antegrade convex (white line) (A). This type of CTO is best approached from a retrograde access. The yellow arrow points to the plaque calcification (A). Angiographic evaluation of the CTO cap is consistent with the EVUS findings of antegrade convex and retrograde concave cap (B). Angiogram of the common femoral artery (CFA) and the superficial femoral artery (SFA) after retrograde crossing of the proximal SFA CTO (C).

is advanced, brought into contact with the surface of the CTO cap, and activated.

In the subsequent example, the Tibiopedal Arterial Minimally Invasive (TAMI) Retrograde Revascularization technique was used to treat a previously failed conventional antegrade crossing with a wire/catheter approach.[1] The previous failure site was at the distal cap. In Figure 2, it becomes clear why the distal cap was difficult to cross. The cap possesses an antegrade convex CTO cap, and the antegrade crossing tools were deflected away from the center of the vessel, leading to a failure to cross. Here the TAMI technique was started via a retrograde access approach in the posterior tibial (PT) artery. Initially, EVUS-guided PT mapping and access in the transverse view were performed. The access wire and sheath were advanced in a longitudinal view followed by sheath placement. Figure 3 shows the retrograde Crosser® Catheter and its support catheter in contact with the retrograde concave CTO cap. With the addition of EVUS, operators have the ability to view the progression of the forward motion of the Crosser® Catheter as it penetrates CTO segments.

The Crosser® Catheter slowly penetrates the distal CTO cap with slight forward motion guided by slight pressure of the operator's hands on the Crosser® Catheter (Figure 3). Gentle forward pressure on the shaft is sufficient to allow the device to move forward through the CTO. This method of slight forward pressure on the device followed by a period of waiting and allowing the Crosser® Catheter to do the work is shown in Figure 4. Under fluoroscopy, the small movements of the Crosser® Catheter tip may not be visible as the catheter tip advances approximately 20 µm. Although the catheter may appear to be standing still, the catheter is still vibrating against the plaque. Hence, we have seen success after letting the device "activate and wait" during times where there was not visible forward movement.

The distal CTO cap was successfully crossed, so the focus shifted to the proximal CTO cap. Both distal and proximal CTO caps were crossed from a single retrograde access. Although EVUS is an extremely viable tool to aid in access and crossing in complex CTO cases, angiography still plays an essential and required role, especially during real-time flow evaluation of long arterial segments. This is shown in Figure 5, which is taken after complete revascularization of the long superficial femoral artery/popliteal CTO.

CATHETER CHARACTERISTICS

The Crosser® Catheter is a straight catheter available in three different configurations: 14S, 14P, and S6. The device is recommended to be used in conjunction with a support catheter for more support, torquability, and steerability. The Sidekick® Support Catheter is used with the 14S and 14P configurations and is available in straight and angled configurations and tapered and untapered versions. The Usher® Support Catheter is available in straight and angled configurations and all versions are tapered to work with the S6 Catheter.

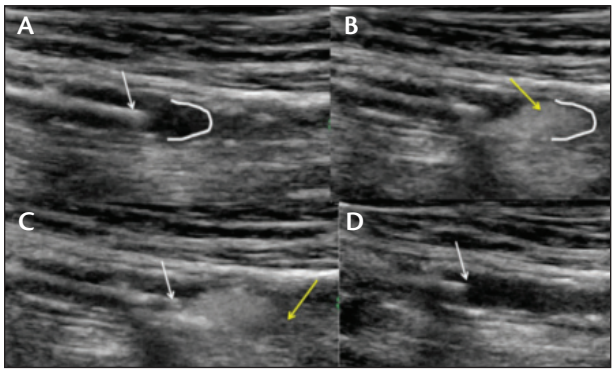

Figure 3. The white line shows the distal concave CTO cap. White arrow indicates the tip of the Crosser® Catheter (A). The action of the activated Crosser® Catheter can be seen downstream; note the configuration of the fluid (yellow arrow) to the concave CTO cap (white line) (B). The Crosser® Catheter penetrates and engages the CTO cap (white arrow); the yellow arrow shows the downstream microbubbles from activation (C). The Crosser® Catheter exiting the CTO cap after successful crossing (white arrow) (D).

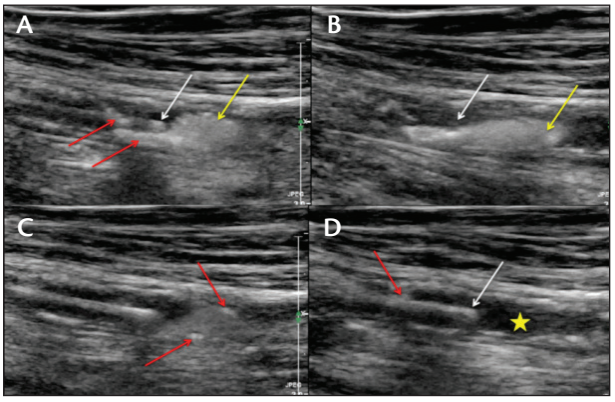

Figure 4. Plaque CTO calcification (red arrows); activated Crosser® Catheter engages the CTO plaque (white arrow); downstream irrigation flow into the CTO cap and plaque (yellow arrow) (A). The Crosser® Catheter crosses the CTO cap (white arrow) (B). This elongated appearance of the downstream irrigation flow from the catheter is typical for newly crossed CTOs (yellow arrow). The Crosser® Catheter generates ablative forces that migrate thru the cap between the calcified densities (red arrows) in the CTO cap (C). The Crosser® Catheter (white arrow) passes the proximal CTO cap (red arrow) into a patent arterial segment (star) (D).

CROSSER® CATHETER 14S AND 14P AND THE SIDEKICK® SUPPORT CATHETER

The Crosser® Catheter 14S and 14P feature a 1.1-mm diameter tip and are 0.014-inch guidewire compatible. The 14P is more flexible than the 14S and in our experience works best in the clinical conditions outlined below. The catheters are 5-F compatible on their own but are recommended to be used with the Sidekick® Support Catheter. The Sidekick® Support Catheter is labeled as 7-F compatible to permit contrast injection around the sheath. In our group's clinical experience, we have found that the support catheter fits easily through a 6-F Pinnacle™ Destination sheath (Terumo Interventional Systems).

The Sidekick® Support Catheter comes in both angled and straight configurations. Because the Crosser® Catheter does not have an angled tip, it is clinically intuitive to use a combination of an angled Sidekick® Support Catheter and a Crosser® Catheter. This combination provides operators the opportunity to maneuver the Crosser® Catheter within the target vessel when using fluoroscopy alone or when using ultrasound-guidance with fluoroscopy.

One of the unique features of the Sidekick® Support Catheter we have found is its high torqueability, allowing interventionists to direct the Crosser® Catheter in 360º rotations within the lumen as they see fit. Also, the additional support of the Sidekick® Support Catheter is extremely valuable, as it allows the tip of the Crosser® Catheter to change vector directions.

CROSSER® CATHETER S6 AND USHER® SUPPORT CATHETER

The Crosser® Catheter S6 is different from the 14S and 14P in that it has a smaller tip and cross-sectional area of 0.6 mm. It also has greater drill efficiency due to the fact that the same energy delivered from the transducer is now concentrated via a smaller cross-sectional tip area. To accommodate the reduction in cross-sectional area, the wire lumen of the device was eliminated. As such, the S6 should be maneuvered with the aid of its accompanying Usher® Support Catheter.

The Usher® Support Catheter is designed specifically to support the Crosser® Catheter S6. The tapered lumen of the Usher® Support Catheter accommodates the tapered outer shaft of the S6. In our experience, this combination provides the operators with excellent torque of the Crosser® Catheter tip, controlled pushability, and vector redirection of the S6 tip while engaged in a CTO. The use of a support catheter with the Crosser® Catheter S6 has been useful in tortuous and complex CTOs, including severely calcified plaque. The angled tip of the Usher® Support Catheter provides significant value in directing the tip of the S6, maximizing exposure to the surface area of the CTO cap.

CATHETER SELECTION IN OUR PRACTICE

When we use the 14S: The Crosser® Catheter 14S is the workhorse device that can be used in all peripheral CTO

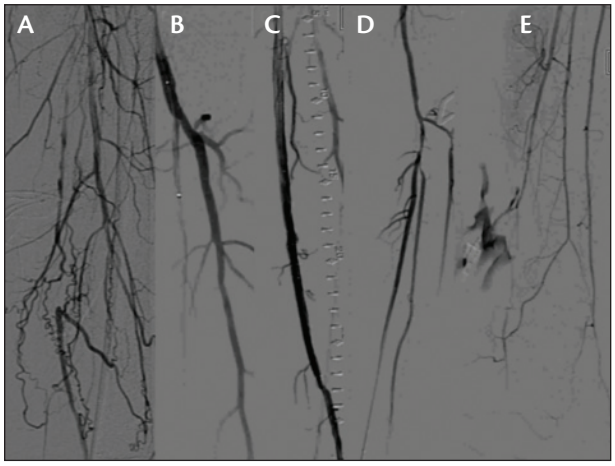

Figure 5. Distal CTO cap reconstitution (A). Proximal CTO cap post retrograde Crosser® Catheter recanalization (B). SFA postintervention (C). Retrograde angiogram for the posterior tibial runoff (D). Post TAMI retrograde intervention angiogram with tibial-pedal runoff (E). The minor extravasation of contrast from the tibial access site is not uncommon post downsizing of the access sheath from 5 F to 2.9 F.

segments, from the iliac arteries to, on rare occasions, pedal CTOs. The 14S has a stiffer support shaft than the 14P, allowing for higher pushability than the 14P.

When we use the 14P: Because the Crosser® Catheter 14P is more flexible it is able to track through more tortuous anatomy and we often utilize it in tortuous iliac CTOs or angulated tibial CTOs. It is also very effective in shorter CTOs.

When we use the S6: In comparison to Crosser® Catheter 14S and 14P, the S6 has a smaller tip and cross-sectional area with higher energy per sectional area. We have had a high success rate when using it in severely calcified lesions found in all vessels including the SFA, popliteal, and tibial.

OUR USE OF THE CROSSER® CATHETER

One of the most important and crucial steps in CTO crossing is engaging the CTO cap surface. In our experience, operators tend to aggravate the surface of the CTO cap during the attempt to engage it with a wire and catheter. This aggravation can lead to microdissections, specifically at the junction between the CTO cap surface area and the vessel wall. Whenever there is a dissection created at these junctions, they become a source of areas of lower resistance. This can create paths that other CTO devices will follow, especially when pushed, resulting in subintimal dissection during CTO crossing.

It is our recommendation to approach the CTO cap with a crossing device, rather than the wire, in order to avoid unnecessary aggravation of the CTO cap. In the case of the Crosser® Catheter, we advance a wire just proximal to the CTO cap. The support catheter is then advanced over the wire until just a few millimeters proximal to the CTO cap. Once in place, the Crosser® Catheter is advanced through the support catheter and becomes the first device to touch the surface of the CTO cap. Once contact is made, the operator generates a slight forward pressure on the device, which is usually reflected by seeing the support catheter push back from the CTO cap. Before activation, it is best to stabilize the support catheter and the Crosser® Catheter. The device is now ready for activation.

Upon activation of the device, there is no need to generate more forceful pressure on the Crosser® Catheter other than what was originally initiated. Additional pushing may result in the Crosser® Catheter tip sliding away from the center of the CTO cap onto the side, specifically the junction between the CTO cap and the vessel wall. Additional pressure can create an arc in the catheter shaft, which can be seen under fluoroscopy; this can lead the device away from the center of the cap. When this is seen, it is best to stop the activation of the Crosser® Catheter, pull it back, and readvance the support catheter. Reposition the Crosser® Catheter back on the center of the surface area of the CTO cap and reinitiate slight forward pressure of the Crosser® Catheter so that it is in complete contact with the surface of the CTO cap.

Once visualized, under fluoroscopy with or without ultrasound, activate the Crosser® Catheter and wait. It is best to continue to wait until motion is seen. Occasionally, you will find yourself waiting through multiple 30-second runs until the Crosser® Catheter finally penetrates the CTO cap. When using ultrasound, visualization of microbubbles where cavitation occurs and the constant burrowing of the Crosser® Catheter tip into the CTO cap gives the interventionist confidence that there is actual penetration of the CTO cap even when the Crosser® Catheter does not appear to be in motion under fluoroscopy. In our experience, patient waiting while the device crosses the cap increases the probability of crossing the CTO and lowers the probability of dissections. In our experience, perforation with the Crosser® Catheter is very low and tends to be associated with forceful pushing of the device.

CONCLUSION

In addition to fluoroscopy, EVUS provides direct visualization of the Crosser® Catheter S6, 14P, and 14S, allowing the operator to witness the fascinating science behind the device and its ability to accommodate the type of resistance it meets during the process of CTO cap crossing. Our experience with EVUS visualization of the Crosser® Catheter illustrates the device's ability to cross challenging lesions and should encourage operators to "activate and wait" more often than before. Using the Crosser® Catheter in the manner described has resulted in our high crossing success rates in CTOs. In addition, the device's selectivity for inelastic surfaces, such as plaque, coupled with the operator keeping the catheter properly aligned in the vessel has led to a low dissection rates in our practice. ■

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The opinions and clinical experiences presented herein are for informational purposes only. The results from this case study may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes. The physician has been compensated by Bard Peripheral Vascular, Inc. for the time and effort in preparing this article for Bard's further use and distribution.

1. Mustapha JA, Saab F, McGoff T, et al. Tibio-pedal arterial minimally invasive retrograde revascularization in patients with advanced peripheral vascular disease: The TAMI technique, original case series. Cathet Cardiovasc Interv. 2014;83:987-994.

SAFETY INFORMATION

Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contra-indications, Warnings, Precautions, Adverse Events, and Operator's Instructions. Caution: Federal Law (USA) restricts these devices to sale by or on the order of a physician.

CROSSER® CTO RECANALIZATION CATHETER

INDICATIONS FOR USE

The Crosser® Recanalization System is indicated to facilitate the intraluminal placement of conventional guidewires beyond peripheral artery chronic total occlusions via atherectomy. The Crosser® Catheter is only intended for use with the Crosser® Generator. Refer to the Crosser® Generator Manual of Operations for proper use.

CONTRAINDICATIONS

The device is contraindicated for use in carotid arteries.

WARNINGS AND PRECAUTIONS

• Never advance or withdraw the Crosser® Catheter without proper fluoroscopic guidance.

• It is not recommended to use the Crosser® Catheter over wires which have polymer-jacketed distal ends.

• When using the Crosser® Catheter 14S or 14P with the MicroSheath® XL Support Catheter Tapered, the Crosser® Catheter can be advanced approximately 15cm from the tip of the support catheter before resistance is encountered due to the taper on the Crosser® Catheter aligning with the taper on the support catheter. A taper lock-up marker (single marker on the Crosser® Catheter shaft) is located 127cm from the distal tip for the 146cm Crosser® Catheter and 87cm from the distal tip for the 106cm Crosser® Catheter. The taper lock-up marker can be used as an indicator that the tapers on the catheters are nearing alignment; advance the Crosser® Catheter slowly. Do not continue to advance the Crosser® Catheter if resistance is encountered.

• When using the Crosser® Catheter in tortuous anatomy, the use of a support catheter is recommended to prevent kinking or prolapse of the Crosser® Catheter tip. Kinking or prolapse of the tip could cause catheter breakage and/or malfunction.

SIDEKICK® AND USHER® SUPPORT CATHETERS

INDICATIONS FOR USE

The Sidekick® and Usher® Support Catheters are single lumen catheters intended to create a pathway for other devices in the peripheral vasculature.

CONTRAINDICATIONS

The Sidekick® and Usher® Catheters are contraindicated for use with cutting/scoring balloons, pediatrics, neonatal and neurovascular patients.

WARNINGS AND PRECAUTIONS

• When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Movement of the product without fluoroscopic guidance may result in damage to the product or vasculature or cause vessel perforation.

• Manipulating or torquing a product against resistance may cause damage to the product or vasculature or cause vessel perforation. Never advance, withdraw or torque a catheter which meets resistance.

• Verify compatibility of the product's inner and outer diameters and lengths with other devices before use.

• Refer to package label for tip shape for the Sidekick® and Usher® Catheters. Do not attempt to manipulate or re-shape the tip configurations.

VASCUTRAK® PTA DILATATION CATHETER

INDICATIONS FOR USE

The Vascutrak® PTA Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post dilatation of balloon expandable stents, self-expanding stents, and stent grafts in the peripheral vasculature.

CONTRAINDICATIONS

The Vascutrak® PTA Catheter is contraindicated where there is the inability to cross the target lesion with a guidewire and for use in the coronary or neuro vasculature

DORADO® PTA DILATATION CATHETER

INDICATIONS FOR USE

Dorado® Balloon Dilatation Catheters are recommended for Percutaneous Transluminal Angioplasty (PTA) of the renal, iliac, femoral, popliteal, tibial, peroneal, and subclavian arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post-dilatation of balloon expandable and self expanding stents in the peripheral vasculature. This catheter is not for use in the coronary arteries.

CONTRAINDICATIONS

None known

LIFESTENT® VASCULAR STENT SYSTEM

INDICATIONS FOR USE

The LifeStent® Vascular Stent System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions up to 240mm in length in the native superficial femoral artery (SFA) and proximal popliteal artery with reference vessel diameters ranging from 4.0-6.5mm.

CONTRAINDICATIONS

The LifeStent® Vascular Stent System is contraindicated for use in:

• Patients with a known hypersensitivity to nitinol (nickel, titanium), and tantalum.

• Patients who cannot receive recommended anti-platelet and/or anti-coagulation 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.

ADVERSE EVENTS

As with most percutaneous interventions, potential adverse effects include: Bleeding which may require transfusion or surgical intervention, Hematoma, Perforation, Dissection, Guidewire entrapment and/or fracture, Hypertension / Hypotension, Infection or fever, Allergic reaction, Pseudoaneurysm or fistula Aneurysm, Acute reclosure, Thrombosis, Ischemic events, Distal embolization, Excessive contrast load resulting in renal insufficiency or failure, Excessive exposure to radiation, Stroke/CVA, Restenosis, Repeat catheterization / angioplasty, Peripheral artery bypass, Amputation, Death or other bleeding complications at access site.