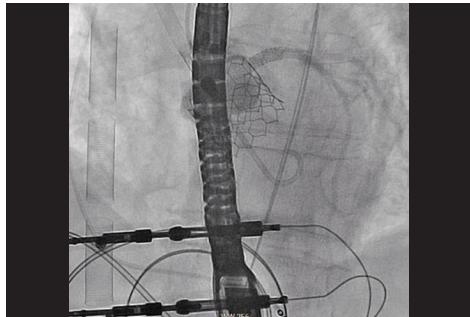


Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist



CASE REPORT

Left Main Coronary Artery Occlusion Following Transcatheter Aortic Valve Replacement

Monarch Shah, MD; Michelle Nabi; Shreya Patel; Riya-Aisha Patel; Pratik Patel, MD, FACC

We report herein a case of hemodynamic collapse immediately after transfemoral transcatheter aortic valve replacement (TAVR) using a balloon-expanding valve, resulting from extrinsic compression of the left main coronary artery by the native calcified leaflets. Due to early identification and immediate stent implantation in the left main coronary artery, the patient was successfully treated and had an uneventful hospital stay until discharge. Potential risk factors include shallow sinus of Valsalva, low coronary ostia height, heavily calcified aortic cusp and valve leaflets, and the use of balloon-expandable valves. However, a correct diagnosis of this complication can lead to a successful percutaneous treatment, as presented in this case.

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PERIPHERAL ARTERIAL DISEASE

Crossing Peripheral Chronic Total Occlusions Efficiently With the Crosser iQ™ CTO Recanalization System

Cath Lab Digest talks with Ehrin J. Armstrong, MD.

Can you tell us about your practice?

I am an interventional cardiologist at Adventist Heart and Vascular Institute. We have an extensive practice focused on limb salvage and limb preservation in patients with advanced peripheral artery disease (PAD). This includes patients with severe claudication, who have severe impairment in their quality of life and can't do their normal daily activities, and importantly, patients with wounds and rest pain who are at major risk of below-knee amputation. We have a large referral area that extends north of Napa Valley up to the border with Oregon, and treat a lot of people from rural areas who have extensive PAD and are at major risk for amputation. We do everything we can to revascularize their legs and improve their wound healing.

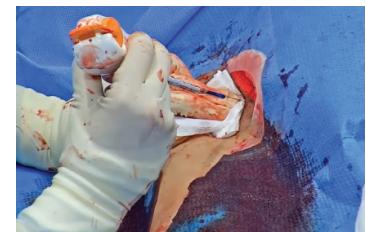


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CASE REPORT

Novel Approach in Percutaneous Large-Bore Arteriotomy Closure: Manta With Angiographic Guidance

Darren Jat-Lon Wong, MBBS; Yam Hong Wong, MBBS; Ka Hei Ho, MBChB; Ho Lam, MBChB; Ping Wa Yam, MBBS



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Crossing Peripheral Chronic Total Occlusions Efficiently With the Crosser iQ™ CTO Recanalization System

Cath Lab Digest talks with Ehrin J. Armstrong, MD.

What are some of the challenges you see when treating critical limb ischemia (CLI)?

One of the major challenges with CLI patients is that they often have severe advanced PAD, including multilevel PAD. The vast majority of these patients have severe femoropopliteal disease; in more than half of patients, there is the likelihood that we will have to get through a femoropopliteal occlusion. If you can't treat the femoropopliteal disease, you can't address the tibial disease that these patients are likely to have. In patients with CLI, it is paramount to get through an occlusion in the femoropopliteal segment to revascularize the rest of the leg.

Above the knee, we are typically dealing with a vessel that has a diameter in the range of five to seven millimeters, and there is often a mixed morphology above the knee, with variable levels of calcification and mixed plaque. We also have more treatment options with regards to reentry and crossing devices. In comparison, the vessel sizes below the knee are typically two to four millimeters and more often, there is a high percentage of concentric calcification. The amount of calcification below the knee that we encounter often means that it is difficult to penetrate the

patients, we need to cross a CTO to effectively revascularize their leg. It is important to do everything we can to maximize flow all the way down to the level of the tissue in the foot, and sometimes it does involve interventions below the ankle, within the pedal arch vessels, to maximize flow, which could help to improve limb preservation. CTOs represent some of the most difficult anatomy in peripheral artery disease. We now also have retrograde options, including pedal access or retrograde superficial femoral artery (SFA) access. The reason that we have developed all these different techniques like antegrade wire escalations, is because tools can still be unsuccessful when crossing challenging CTOs. Simply put, if you can't get a wire across, you are not able to deliver subsequent devices and the case will be unsuccessful. That's why devices like the Crosser iQ™ CTO Recanalization System (Becton, Dickinson and Company – Figure 1) are so important, to help increase the chances of crossing peripheral artery CTOs.

How does the Crosser iQ™ CTO Recanalization System help to overcome these peripheral CTO obstacles?

CTO cases can be divided into two categories. The first involves difficulties in remaining true lumen. Other devices may get subintimal and get near the distal cap, but then it takes other additional devices, time, and cost to reach the true lumen of the ongoing vessel. By centering the wire and with its unique mechanism of action that automatically and selectively ablates the plaque while remaining atraumatic to elastic tissue, the Crosser iQ™ CTO Recanalization

System can help facilitate staying true lumen. The importance of that can't be understated, because once you get subintimal, it often adds another 20 or 30 minutes to the procedure time to get back into the true lumen. It also removes some of the other treatment options. Once you are subintimal, it becomes more difficult or can change the risk-benefit ratio for the use of atherectomy devices or other



Figure 1. Crosser iQ™ Ultrasonic CTO Device (Becton, Dickinson and Company).

vessel preparation tools that may help increase the long-term patency of the artery. The second category of cases involves CTOs with a very hard cap that may be difficult to penetrate, even with a standard wire. In each of these categories, the Crosser iQ™ CTO Recanalization System has an important role. First and foremost, it has a unique mechanism of action specifically designed to help you cross peripheral CTOs intraluminally. The Crosser iQ™ CTO Recanalization System uses a wire-based approach with the Recon™ Crossing Support Catheter and the device itself, which means it fits very easily into the standard workflow of the cath lab. The fact that you can integrate the crossing system with a support catheter is a major benefit. The device delivers ultrasonic energy by automatically adjusting its power output to help stabilize the distal tip of the catheter to assist in penetrating the CTO cap. The Crosser iQ™ Ultrasonic CTO Device's ability to cross a lesion from the antegrade approach has also helped to both speed up the case and increase the overall likelihood of my crossing success. In my experience, I have seen multiple cases where the cap of the CTO has been very hard and difficult to penetrate, even with a very high gram tip wire. I used the Crosser iQ™ Ultrasonic CTO Device and it had very good penetration capacity on harder caps. Once we got through the cap, I have been very impressed with how the device tracked through the chronically included mid segments of the occluded artery to ultimately reach the distal cap, often accomplished in just two or three minutes, which is quite efficient. For operators who are developing their practice, the Crosser iQ™ CTO Recanalization System is a device that can help increase their overall efficiency and is an important addition to our armamentarium for the effective treatment of patients with CLI who have peripheral artery CTOs.

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lesion with wires. There are also fewer ancillary devices that can be used below the knee because of the limitations of the vessel size itself.

Based on your experience, how frequently are you seeing peripheral CTOs in CLI patients?

Patients with CLI tend to have more advanced disease, and I would say that in 70%-80% of our

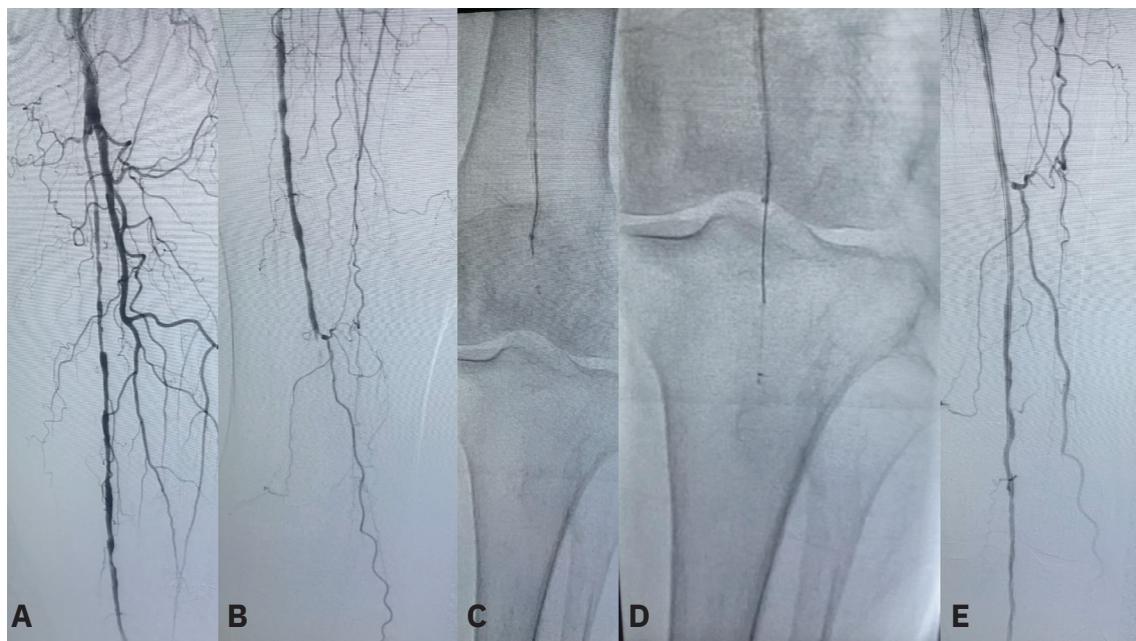


Figure 2A-E. A 75-year-old woman with rest pain and a nonhealing left great toe wound was referred for lower extremity angiography. (A) Baseline angiography demonstrated a diffusely diseased left superficial femoral artery. (B) The mid popliteal artery was totally occluded with a large collateral near the stump of the ongoing vessel. (C) The Crosser iQ™ Ultrasonic CTO Device (Becton, Dickinson and Company) was able to navigate into the ongoing cap of the occluded artery. (D) Magnified view demonstrates the luminal crossing of the device across the distal popliteal artery. (E) After initial angioplasty, there was excellent luminal gain and minimal dissection. The patient was subsequently treated with further adjunctive therapies (not shown).

When you are approaching the CTO, what are techniques and best practices you utilize?

The goal should be to advance the catheter just two to five millimeters per second, which allows time for the Crosser iQ™ Ultrasonic CTO Device to do its work at the front end of the cap and avoid displacing away from the chronically occluded segment into a sub plane. Another important technical tip is to maintain the support catheter in the range of 20 to 30 millimeters behind the Crosser iQ™ Ultrasonic CTO Device tip. Having the support catheter near the tip helps provide some additional force and can also provide directionality if you need to redirect the tip of the catheter while advancing. In all the cases I have done with the Crosser iQ™ CTO Recanalization System, I have been able to get through the CTO in under five minutes or I have been able to reach the distal cap in under five minutes. There have been some cases, even in the long segment CTOs over 300 mm, where we could get from the tip of the occlusion to the distal cap in under two minutes. Fluoroscopy offers only a two-dimensional view, so it can be hard to navigate in three dimensions, and in my experience, the Crosser iQ™ Ultrasonic CTO Device can be very helpful to make sure you are orienting in the right plane when crossing an occlusion.

Are collateral vessels often an issue with CTOs?

Collateral vessels are a major consideration, especially when dealing with femoropopliteal CTOs. The main reason is that the profunda femoral artery provides significant collaterals at the level of Hunter's canal in the proximal popliteal artery and frequently,

femoropopliteal occlusions will reconstitute at that level. If you can stay true lumen, then it is possible to reopen the SFA while still preserving the collaterals that feed into the popliteal segment. In comparison, if you are subintimal for a long time, then you may end up excluding those collateral vessels in the popliteal artery and thereby eliminating some of those collaterals, which has potential long-term consequences, as far as patient symptoms and if there is a restenosis in the future. The symptoms could be more severe if the collateral vessels have already been excluded. It is another reason why using a device like the Crosser iQ™ CTO Recanalization System and staying true lumen benefits patient outcomes long term. In a case where there has been some neo-angiogenesis and development of collateral vessels at the proximal cap, one of the primary difficulties is from a technique standpoint. Sometimes it can be difficult to direct a wire in a catheter into the occluded segment of the vessel because the wires will tend to redirect into the collaterals and anatomically, it can be very challenging to find the direction ahead. In my experience, the Crosser iQ™ CTO Recanalization System, because of the size of the tip and the directionality with the Recon™ Crossing Support Catheter, helps to preferentially engage the occluded segment of the vessel and cross the proximal cap, without being redirected into collateral vessels that lead you astray from your intended direction.

Do the proximal and distal CTO caps often differ from each other?

Proximal and distal caps can have different morphologies. We often speak of a concave or convex appearance to a cap. When a cap is convex from the antegrade standpoint, it is often difficult for a wire to engage the cap, because the wire will be deflected towards the side of the vessel, meaning you are more likely go subintimal. In comparison, a more convex or tapered cap means it is often easier to engage a wire. With regards to the differences between the caps themselves, proximal caps do tend to be harder than distal caps, probably due to the constant pressure of blood flow on the proximal cap that leads to a more tightly packed CTO proximally, whereas distally, the cap tends to be softer. This is a reason why sometimes retrograde crossing can be easier in certain circumstances, but I think it also emphasizes the value of using the Crosser iQ™ CTO Recanalization System, and its ability to engage the CTO cap. Because the device is designed to intraluminally cross unfavorable cap morphologies, it can help penetrate proximal caps and can accommodate for differences in plaque morphology.

If a CTO cannot be crossed, how do you proceed with treating the patient?

Well, fundamentally, if you can't cross a CTO, you are not successful with treating the patient. For that reason, we have several techniques for dealing with CTOs, like previously mentioned, that include different antegrade wire escalation techniques, as well as reentry and crossing devices like the Crosser iQ™ CTO Recanalization System (BD). In addition, we have retrograde options too including pedal access or retrograde superficial femoral artery (SFA) access. Historically, studies have generally shown that with standard wire techniques, even in

Being able to treat the femoropopliteal CTO more efficiently and quickly with the Crosser iQ™ CTO Recanalization System than with other standard techniques allowed me to treat more of the tibial disease in a single setting.

the hands of experienced operators, the likelihood of crossing a CTO is moderate.¹ Using other tools such as retrograde access can also help in achieving successful recanalization.¹

The downside of having to use retrograde access is the amount of time that it takes and the fact that it is an additional access point. Devices that help maximize the efficiency and likelihood of assessment from an antegrade standpoint can improve the workflow in a case.

How has the use of the Crosser iQ™ CTO Recanalization System changed your treatment algorithm?

I use it as a frequent upfront device when approaching femoropopliteal CTOs. When I see a lesion that looks like it has a hard cap and a long segment occlusion, then I think the Crosser iQ™ Ultrasonic CTO Device is a great first tool to cross the occlusion, instead of committing upfront to using multiple wires and potentially, a reentry device. The Crosser iQ™ CTO Recanalization System has become an important part of my algorithm when considering an efficient way to cross a femoropopliteal occlusion.

What advice do you have for operators who might be interested in trying the Crosser iQ™ CTO Recanalization System?

It is easy to set up and use, and integrates easily into the cath lab workflow by using a support catheter and a wire within the device. I think it is a useful additional tool to work into your algorithm for crossing CTOs. You can set it all up on the table of the procedure in just two to three minutes total, so from the time of the decision to use the Crosser iQ™ CTO Recanalization System to getting across an occlusion, it has typically taken me under five to ten minutes.

What does the future look like for CTO treatment in the next few years?

We have made a lot of progress in treating CTOs. The development of additional techniques, such as the retrograde approach, has improved the success rate of crossing CTOs in my lab. Now we need additional training and education to disseminate those techniques to physicians, but we also need devices like the Crosser iQ™ CTO Recanalization System designed for efficient CTO crossing, because crossing a CTO is generally a time-consuming and difficult part of an endovascular procedure. In my opinion, if we can simplify certain aspects of CTO crossing, it may allow for additional time in the procedure to treat more distal arteries in one setting. If we can successfully and quickly cross occlusions in the femoropopliteal segment, then we can treat more multilevel disease within a single procedure, which helps with patient care and outcomes. Being able to treat the femoropopliteal CTO more efficiently and quickly with the Crosser iQ™ CTO Recanalization System than with other standard techniques allowed me to treat more of the tibial disease in a single setting. ■

This article is sponsored by Becton, Dickinson and Company (BD). Dr. Armstrong is a paid consultant of BD. See important Safety and Risk Information below.

Reference

1. Singh GD, Armstrong EJ, Yeo K-K, Singh S, Westin GG, Pevec WC, et al. Endovascular recanalization of infrapopliteal occlusions in patients with critical limb ischemia. *J Vasc Surg.* 2014; 59(5): 1300-1307. doi: 10.1016/j.jvs.2013.11.061

View the QR code below using your phone camera to learn more about the Crosser iQ™ CTO Recanalization System:



**Ehrin Armstrong, MD, MSc,
FACC, FSCAI, FSVM**

Medical Director, Adventist Heart and Vascular Institute, Adventist Health, Saint Helena, California



Crosser iQ™ CTO Recanalization System Safety and Risk Information:

Indications for Use: The BD Recanalization System (Console and Footswitch) and Crosser iQ™ Ultrasonic CTO Device are indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions.

Contraindications: The Crosser iQ™ Ultrasonic CTO Device is contraindicated for use in carotid arteries.

Potential Adverse Events: Bleeding which may require transfusion or surgical intervention. Puncture site hematoma, pain and tenderness. Hemorrhage. Embolism. Vessel 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. Other bleeding complications at access site.

Recon™ Crossing Support Catheter Safety and Risk Information:

Indications for Use: The Recon™ Support Catheters are single lumen catheters intended to create a pathway for other devices in the peripheral vasculature.

Contraindications: The Recon™ Support Catheters are contraindicated for use with cutting/scoring balloons, pediatrics, neonatal and neurovascular patients.

Potential Adverse Events: Hemorrhage. Hematoma. Ischemia. Hypertension/Hypotension. Vessel perforation/dissection. Allergic reaction to contrast medium. Vascular occlusion, thrombosis. Infection or fever. Vessel erosion, spasms. Embolism. Puncture site hematoma, pain and tenderness.

Please consult package insert for more detailed safety information and instructions for use.

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