Using IVUS to Guide Intraluminal Crossing of CTOs

An inside look at the anatomic advantages of central lumen crossing.

BY JAMES TOREY, PA-C; AND TOM DAVIS, MD

Chronic total occlusions (CTOs) of the lower extremities may be seen in up to 40% of patients with symptomatic peripheral artery disease.[1] Various methods for performing endovascular peripheral interventions have been developed for this subgroup of lesions, including subintimal angioplasty and intraluminal mechanisms such as blunt catheter dissections, laser light, and vibrational energy. Subintimal angioplasty, also known as PIER (percutaneous intentional extraluminal recanalization), was first described by Bolia et al in a case in which an inadvertent subintimal channel of a totally occluded femoral artery was dilated and subsequently found to maintain its patency for 32 months.[2]

Alternatively, intraluminal devices have been designed to facilitate crossing of the CTO within the existing lumen. The Crosser® Catheter is a central lumen CTO crossing catheter with a tip that transmits high-frequency vibrations at 20,000 cycles per second at a forward depth of 20 µm that is delivered directly to the occlusion (Figure 1). The PATRIOT (Peripheral Approach to Recanalization in Occluded Totals) trial showed an 84% recanalization success rate of guidewire-resistant CTOs with the Crosser® Catheter, with no evidence of device-related clinical perforations; in addition, it displayed an exceptionally rapid lesion crossing time.[3]

While no direct comparison has been made of subintimal versus intraluminal crossing, at our institution intraluminal techniques are our primary approach, with PIER utilized as a bailout option. Understanding the importance of remaining as intraluminal as possible during crossing lies with understanding the anatomic effect of subintimal crossing. By deflecting into the media or the adventitial space, several anatomic distortions become inherent as a cost. As described in this article, intravascular ultrasound (IVUS) is a powerful tool to visualize these potential costs.

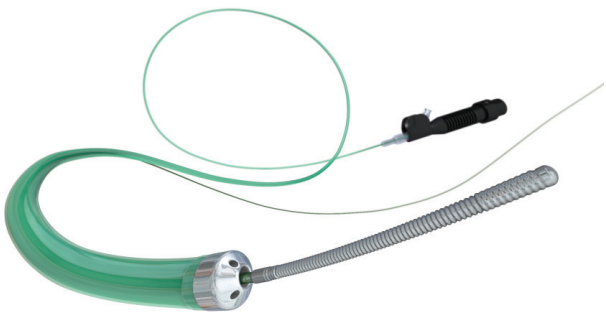

Figure 1. The Crosser® Catheter (Bard Peripheral Vascular, Inc.).

CENTRAL LUMEN CROSSING OF CTOs LOWERS DISSECTIVE EFFECTS

The process of deflecting into the subintimal space is a dissective process, as both the proximal and distal references experience tears into the medial plane that potentially compromise not only the anatomic integrity of the vessel but also impair or isolate the new lumen from the collateral circulation within this segment of the vessel. By utilizing central lumen crossing devices such as the Crosser® Catheter, these effects are potentially minimized.

By IVUS, we commonly see flow-limiting dissections and intramural or extravascular hematomas as a result of the PIER approach (Figure 2A). The hematoma is typically confined to a reference segment, but in the case of the superficial femoral artery (SFA), there are no significant side branches to limit its extension. Thus, the hematoma can travel and compress the entire length of the vessel, including the proximal or distal reference segment.

The characteristics of a hematoma are easily identifiable by IVUS: the base of the hematoma should be flush against the edge of the lumen (if intramural) or

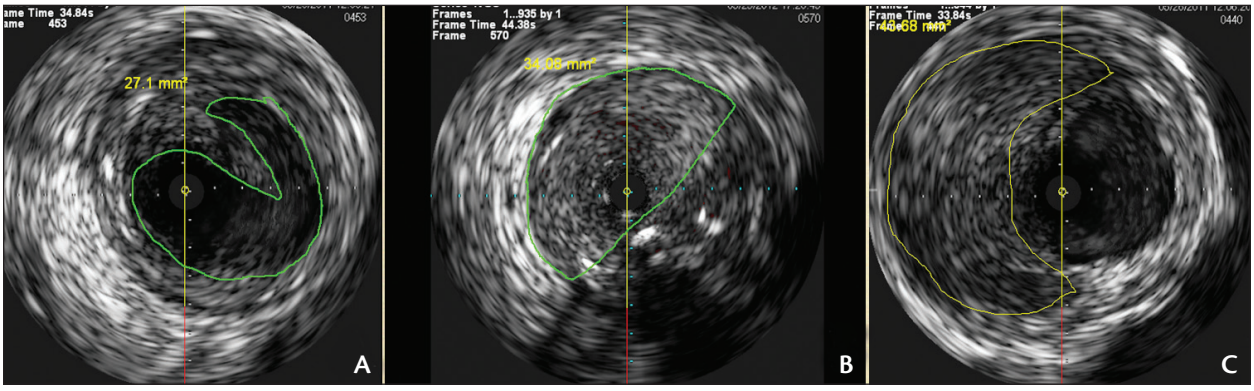

Figure 2. A 90° dissection with large intraluminal flap (T1) in proximal reference (A). An intralesional hematoma with characteristic "D" shape (T2) and an A2 orientation (B). A large extravascular hematoma in distal reference (T2) (C).

the edge of the adventitia (if extravascular) and extend outward in a "D" shape (Figure 2B). This will appear as a characteristic flattening effect on the inner edge. Intramural hematomas will maintain the size of the external elastic membrane in comparison to the segments of the vessel immediately proximal and distal to the hematoma. An extravascular hematoma will show compression of the external elastic membrane, with the hematoma initially growing to the size of the lost lumen it compressed and further growth only limited by the flow going into the hematoma and the space it occupies (Figure 2C).

A key attribute to assess in a hematoma is whether the hematoma communicates with luminal flow; in the case of an extravascular hematoma, this would constitute a form of perforation and would be considered high risk for subsequent pseudoaneurysm formation. High-flow hematomas (by grayscale IVUS) should appear black, and low-flow hematomas should be more solid in appearance, to the extent that it may be interpreted as a soft plaque on initial inspection.

CENTRAL LUMEN CROSSING AND COLLATERAL COMMUNICATION

Collateral loss is another potential drawback to subintimal crossings. Lipsitz et al reported in a study of 29 patients treated with subintimal angioplasty that 47% of the collaterals distal to and 26% of the collaterals proximal to subintimally treated CTOs of the lower extremity were lost after angioplasty.[4] It should be noted that this study found that the collateral loss was not clinically significant because the reocclusions were not typically presenting as a threatened limb. It is postulated that new collaterals can be formed in the new subintimal channel, and this may provide protection if the treated segment reoccludes.

The study, however, employed angiography to assess whether the collateral was preserved. Using IVUS, we see considerably more patent collaterals and more collateral loss than can be appreciated by angiography. We can also easily establish whether the collaterals connect to the subintimal lumen or the true lumen, which is now isolated from systemic flow, despite their angiographic appearance of being intact. In a crossing utilizing a central lumen crossing device, such as the Crosser® Catheter, it is common to see multiple collaterals communicate with the lumen that the catheter creates within the intraluminal space.

By using IVUS, we can accurately document collateral preservation and also isolate collateral compromise, which may guide strategies to debulk the site in order to re-establish flow in the compromised collateral.

CROSSER® CATHETER DESIGNED TO AUGMENT CHANCE OF INTRALUMINAL CROSSING

Axial orientation is a primary focus of our IVUS runs, documenting not only which plane the crossing takes but also attempting to optimize the crossing to make it as intraluminal as possible. In our experience, utilizing the Crosser® Catheter enhances our ability to achieve purely intraluminal crossings versus a standard guidewire approach with a significantly lessened risk of deflection into the medial or adventitial planes.

The appearance of an intraluminal crossing is fairly distinct; the IVUS catheter is seen medial to the border of the internal elastic lamina with the medial stripe seen clearly lateral to the catheter (Figure 3A). The position of the catheter can be purely eccentric or central within the vessel, as this bears little impact on the overall quality of the crossing. The emphasis is on the catheter being in the former lumen of the vessel, no matter its position.

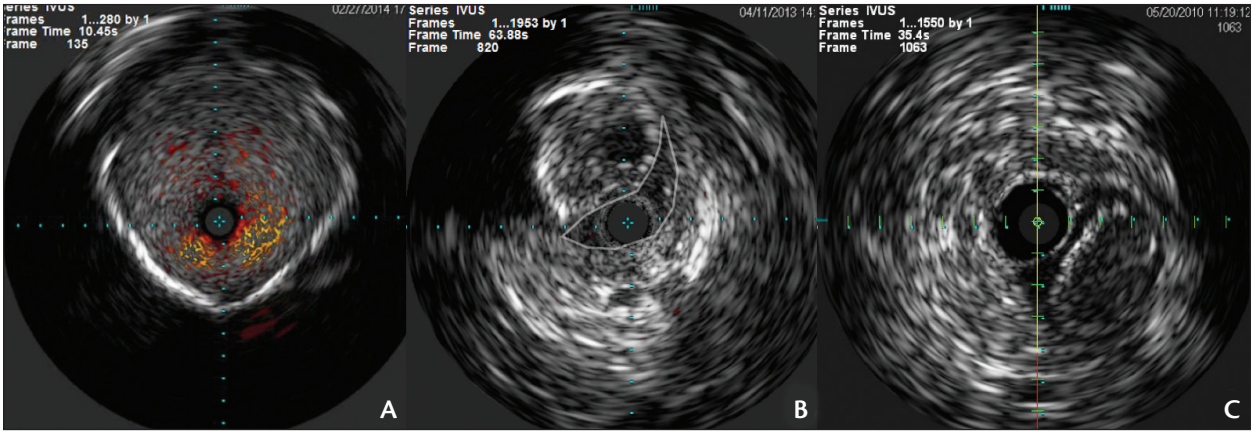

Figure 3. Anterior oblique orientation (intralesional) (A). A1 orientation (medial deflection); note the sickle-shaped lumen (B). A2 orientation (adventitial deflection); note the "snowman" appearance (C).

The appearance of the overall vessel shape should be round and consistent with the reference segment external elastic membrane cross-sectional area.

It should be noted that within a total occlusion, the plaque is often seen as echolucent and fragmented or web-like in appearance. With the ChromaFlo™ (Volcano Corporation) option on, it is also not uncommon to see extensive microchannels of flow within the total occlusion that have multiple communications with collaterals.

Diffuse calcific changes that can be noted within the occlusion appear as bright plaques, which obliterate all imaging behind the lesion and are often the nidus for deflection into the medial plane. Despite this, in several of our cases, the Crosser® Catheter maintained an intraluminal orientation through a 360° wall of intralesion calcification.

In comparison to an intraluminal crossing, a medial deflection of the IVUS catheter has a distinct appearance. When devices enter the space within the media, both the lateral and medial edges of the crossing will displace, creating a tear that resembles a "sickle-shaped" lumen (Figure 3B). By the TAPE method (tears, axial [vs nonaxial], preservation [collaterals], and extension [treatment lesion length]), this orientation would be graded as an A1 orientation and is the standard orientation for an optimal PIER crossing.[5] Reentry devices and wiring techniques work well within this space and are relatively straightforward and timely procedures.

A deeper deflection into the adventitial space or periadventitial area has a distinct appearance resembling a "snowman" or "figure 8" appearance (a small circle riding on top of a larger circle). The IVUS catheter rides in the smaller circle that is free of disease while the truly diseased vessel is seen adjacent to the lumen the IVUS catheter rides in. By the TAPE method, this orientation would be graded as A2 and is an undesired orientation for a PIER crossing. The distance between the false channel and true vessel can be significant in an A2 orientation, making reentry into the distal reference difficult or unfeasible, even when facilitated by reentry devices. Repeated attempts to enter the distal reference can cause substantial collateral loss to the segment and injury to the vessel wall, which could make this segment an unsuitable target if vascular bypass is opted for in the future.

INTRALUMINAL CROSSING AUGMENTS SUBSEQUENT INTERVENTION

Atherectomy in the lower extremities has been shown to be effective in removing significant amounts of plaque with low dottering effects.[6,7] In the TRUE (Tissue Removal by Ultrasound Evaluation) study, we saw an average increased lumen size of 64.3 mm^3 in the worst 20-mm segment, with an average plaque loss within that segment of 56.6 mm^3. This means that 88% of the lumen gain was directly due to plaque removal. The overall vessel size expanded by only 1% in the study, whereas the lumen was increased by 43%. The 1-year target lesion revascularization (TLR) rate in this study was 11% (n = 2/18).

In our experience, these impressive numbers are enabled by the atherectomy device being used intraluminally. The potential advantages of atherectomy are lessened in a subintimal crossing secondary to the crossing being purely eccentric and abutting the adventitial edge in a PIER approach. A purely eccentric and A1 orientation can lead to excision of the adventitia, either by central cutting atherectomy devices or directional atherectomy. In a study last year, the presence of adventitial tissue in the tissue excised from directional atherectomy

led to a pronounced increase in restenosis, with a 96.4% 1-year restenosis rate for patients who had adventitia in the sample analyzed and a 14.9% restenosis rate in those who did not.[8]

Uniform expansion by balloon-based devices (either percutaneous transluminal angioplasty or stent) also benefits from being intraluminal. Proper vessel preparation is important for SFA stenting and expansion. A purely eccentric orientation, which all PIER approach crossings constitute, has an inherent expansion disadvantage over a more concentric and intraluminal orientation.

CONCLUSION

The initial method of CTO crossing may have important implications on the amount of vessel injury that then guides further interventional strategies. Subintimal crossing is an accepted practice but is not without potential consequences. Vessel perforation, embolization, dissection, hematoma, compromise of important collaterals, and prolonged lesion treatment length are inherent pitfalls to be aware of with subintimal CTO crossings. The overall complication rate of the subintimal approach ranges between 6% and 17% due to the differing definitions.[9-13] Vessel injuries may contribute to an accelerated vessel healing response and restenosis.

Utilizing central lumen crossing catheters, such as the Crosser® Catheter, may help minimize the anatomic sequelae of an infrainguinal CTO crossing and augment the ability to optimally treat the segment either by balloon-based intervention, atherectomy, stenting, or a combination thereof versus a standard PIER approach. The initial benefit at this point is substantial, especially in patients undergoing atherectomy. The long-term benefits of intraluminal versus subintimal crossing have yet to be established and require further investigation. ■

James Torey, PA-C, is with the Department of Internal Medicine, Division of Cardiology, St. John Hospital and Medical Center in Detroit, Michigan. Mr. Torey has disclosed that he has no financial interests related to this article.

Tom Davis, MD, is Director of the Cardiac Catheterization Lab at St. John Hospital and Medical Center in Detroit, Michigan. Dr. Davis has disclosed that he is a consultant for Bard Peripheral Vascular, Inc. Dr. Davis may be reached at (313) 343-4612; tpdavis60@aol.com.

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

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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.