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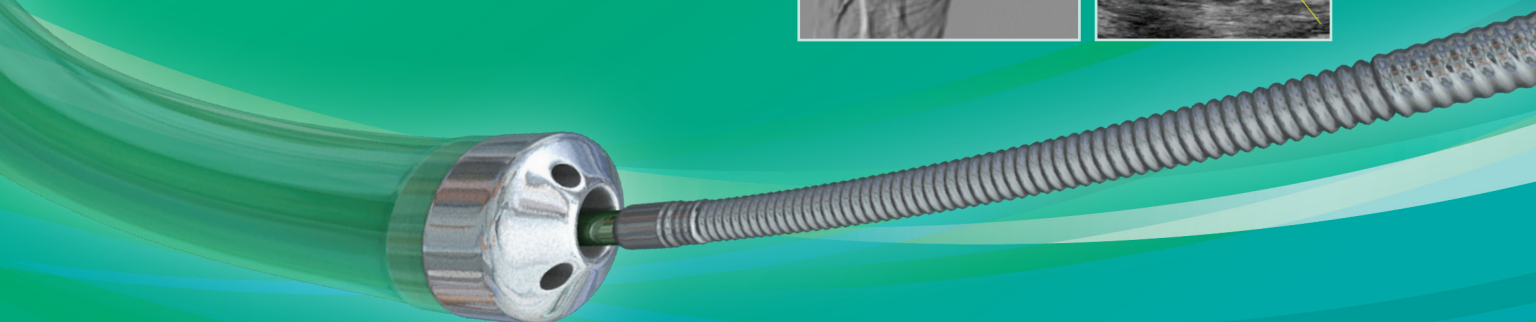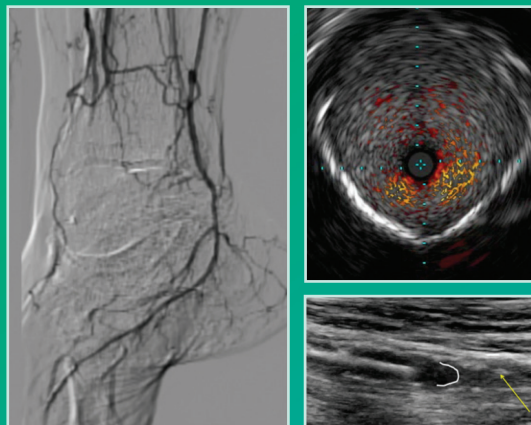## TODAY

SEEING IS
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An in-depth look at the science and clinical use of the Crosser® CTO Recanalization Catheter

SEEING IS
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JIHAD A. MUSTAPHA, MD
Chief Medical Editor
Director of Cardiovascular Catheterization Laboratories
Metro Health Hospital, Wyoming, Michigan

CONTENTS

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Therapeutic Ultrasound for CTO Recanalization

A behind-the-scenes look at catheter-delivered therapeutic ultrasound for CTO crossing using the Crosser® Catheter.

BY PENG ZHENG, PhD; JESSICA ROLL, BBME; BILL PARMENTIER, BS; JIM O'BRIEN, BS; AND ANGELA CRALL, MS

Therapeutic ultrasound has been used in a variety of medical applications such as lithotripsy and dentistry for several decades. Ultrasound in the frequency range from 20 to 45 kHz is often used in medical applications due to its unique feature of selective disruption of inelastic rigid materials. Since the 1960s, there have been several studies exploring the use of therapeutic ultrasound for vascular intervention. In 1965, Anschuetz and Bernard conducted an in vitro study on the effect of therapeutic ultrasound on atherosclerotic arteries and suggested its use for atherosclerotic plaque ablation.[1] That same year, Lane and Minot demonstrated that ultrasonic energy could defragment calcified plaque in cadaveric coronary arteries.[2] This work was the beginning of 4 decades of studies and development of therapeutic ultrasound for vascular interventions.

In 1974, Sobbe et al conducted the first published animal study using a wire transmission member to deliver ultrasonic energy to the lesion for vascular plaque disruption.[3] Starting in the 1980s, several studies focused on the development of a catheter prototype for initial clinical testing. In 1989, Siegel et al performed the first clinical study on patients with peripheral vascular disease using percutaneous catheter-delivered ultrasound for arterial recanalization.[4] The results from the initial pilot clinical study were very positive, with three of four chronic total occlusions (CTOs) recanalized and no evidence of arterial emboli, dissection, spasm, or perforation. A num-

ber of clinical studies were conducted in the 1990s and demonstrated promising results for CTO recanalization using catheter-delivered therapeutic ultrasound.[5-9]

In 1991, Demer et al performed an in vitro study on atherosclerotic cadaver arteries and found that the arterial distensibility was increased after 2 minutes of exposure to a therapeutic ultrasound catheter.[6] In 2001, Gunn et al published the results of a clinical study on 40 patients with single-vessel stenosed (not occluded) coronary arteries using catheter-delivered therapeutic ultrasound and standard percutaneous transluminal coronary angioplasty (PTCA) treatment. The results showed a 40% lower mean lesion yield pressure in the PTCA treatment in the group with ultrasound, suggesting improved distensibililty in atherosclerotic plaque with therapeutic ultrasound treatment.[10]

THE CROSSER® RECANALIZATION SYSTEM

Despite the initial success of using therapeutic ultrasound in arterial lesions and CTOs, the lack of trackability, large catheter profile, and insufficient CTO crossing efficacy limited the applicability of this technology. In the early 2000s, the Crosser® Recanalization System was developed by FlowCardia, Inc. to improve on the first-generation ultrasound device performance and provide a low-profile system with good trackability and an increased CTO recanalization success rate. The device was first evaluated in the coronary arteries. In the FACTOR (FlowCardia's

Figure 1. The Crosser® Recanalization System, including the Crosser® Generator, transducer and foot switch, and Flowmate® Injector.

Approach to Chronic Total Occlusion Recanalization) clinical study, the Crosser® System demonstrated a 60.8% crossing success rate in 125 patients with coronary CTOs.[11] With this early success, the device was further modified for use in the peripheral arteries. In the PATRIOT (Peripheral Approach to Recanalization in Occluded Totals) clinical trial, the Crosser® System was used to treat 85 patients with CTOs in peripheral arteries.[12] It successfully crossed 84% of guidewire-resistant CTOs with an average ultrasonic energy activation time of 126 seconds. The Crosser® System received CE Mark in the EU in 2004 and was cleared by the FDA in 2007 for CTO crossing.

The Crosser® System consists of a generator, transducer, foot switch, and catheter, and is used in conjunction with the Flowmate® Injector System, which provides saline irrigation (Figures 1 and 2). The Crosser® System was designed to facilitate crossing of CTOs using catheter-delivered ultrasonic vibrational energy at a frequency of 20 kHz.

The Crosser® Catheter is connected to the generator through a handheld transducer. The Crosser® Generator converts AC power into high-frequency electrical current, which then excites the piezoelectric crystals within the transducer, causing them to expand and contract. The piezoelectric crystals convert high-frequency current from the Crosser® Generator into ultrasonic energy. This energy is amplified, and the ultrasonic wave is propagated down the catheter via a core wire to the tip. Upon activation, the Crosser® Catheter tip advances approximately 20 µm with each stroke, initiating mechanical impact with the CTO material. In addition, saline is injected through the Crosser® Catheter via the Flowmate® Injector and exits through the small irrigation lumens in the catheter tip for cooling and cavitation.

The peripheral Crosser® Catheter portfolio includes rapid-exchange (RX) and over-the-wire (OTW) systems, along with a lower-profile system that does not use a guidewire for delivery. Each Crosser® Catheter includes a hub with irrigation port, hydrophilic-coated outer body over a transmission wire, irrigation outlets, and metal tip. The Crosser® Catheter 14S and 14P have a 1.1-mm tip and are compatible with 0.014-inch guidewires utilized for both above- and below-the-knee CTO crossing applications. The Crosser® Catheter S6 is a smaller-profile system that is not delivered over a guidewire with a 0.6-mm tip used in highly calcified lesions above and below the knee. The small tip focuses vibrational energy providing twice the efficiency of the Crosser® Catheter 14S, as shown in a bench occlusion model.[13†] Compared to first-generation ultrasonic CTO crossing devices, the Crosser® Catheters offer small catheter profile and improved trackability in the peripheral anatomy and are considered major improvements over the early catheter designs.

Figure 2. The Crosser® Catheter 14S RX.

MECHANISM OF CROSSER® SYSTEM RECANALIZATION

The CTO crossing mechanism of the Crosser® Catheter is a combination of mechanical vibration and cavitation. Mechanical fragmentation is caused by the high-frequency vibration of the Crosser® Catheter tip impacting the calcified plaque. As shown in the high-speed video snapshots in Figure 3, the tip of the Crosser® Catheter vibrates a distance of approximately 20 µm at 20,000 cycles per second. This type of low-amplitude and high-frequency mechanical vibration enables the catheter tip to act like a vibrational "jackhammer" and ablate the calcified plaque into particles that are carried away by the bloodstream.

Cavitation is a key component of CTO recanalization using the Crosser® System. High-frequency vibration of the Crosser® Catheter creates strong negative and positive pressure cycles in the surrounding fluid. Cavitation bubbles are formed from the dissolved gas on the negative side of the pressure cycle when the catheter tip is retracting.[14,15] The bubbles quickly collapse on the positive side of the pressure cycle (Figure 3). The collapse of cavitation bubbles generates strong mechanical shock waves that erode the calcified plaque. In addition, microstreaming occurs as a secondary effect caused by the collapse of cavitation bubbles. When cavitation bubbles collapse, a jet-like ejection occurs, resulting in high-velocity fluid streaming, which also helps ablate the calcified lesion.[16] Cavitation-induced shock waves and microstreaming together create a localized region with intense shear stresses and break the internal fibrin structure of calcified plaque for mechanical penetration. Figure 4 shows the microscopic pictures of a Class 4 super-hard plaster stone (Bego USA) before and after
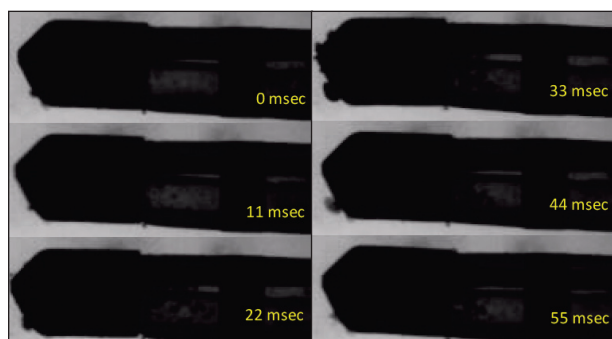
Figure 3. High-speed video snapshots of a Crosser® Catheter 14P tip vibrating in water with approximately 20 μm displacement. The catheter tip starts to move forward at 0 msec. Then it retracts around 22 msec, entering the negative side of the pressure cycle. Cavitation bubbles are generated from the dissolved gas. The cavitation bubbles collapse around 44 msec when the catheter tip starts to move forward again.

Crosser® Catheter activation.[13] The tip of the Crosser® Catheter was placed close but not in physical contact with the stone surface during activation. The strong erosion on the stone surface after activation demonstrates the effect of cavitation and microstreaming of the Crosser® Catheter.†

BIOEFFECT OF THERAPEUTIC ULTRASOUND-BASED CTO RECANALIZATION

The most distinctive feature of therapeutic ultrasound-based CTO recanalization is plaque ablation selectivity. Specifically, tissues with high collagen and elastin content are extremely resistant to ultrasonic disruption; however, tissues lacking these components can be very susceptible to disruption.[5,15] In 1965, Anschuetz and Bernard concluded that normal and atherosclerotic arterial tissue were more resistant to damage than other tissue types. Other early researchers observed that ultrasound destroys atherosclerotic plaque but leaves the adjacent vascular wall relatively unaffected.[1,18] Ernst investigated this theory further to determine whether high-intensity ultrasound could discriminate between fibrous or calcified plaque and normal arterial wall. The results of the study showed that ultrasonic disruption is inversely related to tissue elasticity—the time to perforate cadaveric arterial wall sites was significantly longer than the fibrous or calcified plaque sites.[18]

As an illustration, the bench demonstration in Figure 5 further shows the plaque ablation selectivity of the Crosser® Catheter. In this bench demonstration, the Crosser® Catheter successfully drills through a guidewire-resistant stone but does not penetrate a thin elastic membrane
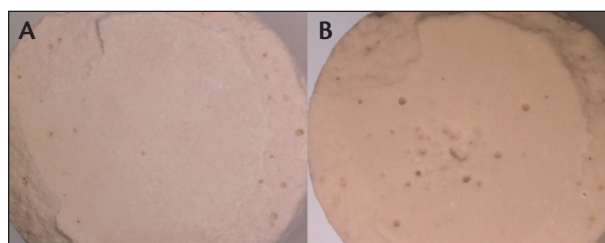

Figure 4. Microscopic pictures of a Bego stone surface before (A) and after (B) Crosser® Catheter activation. The tip of the Crosser® Catheter is placed close to the Bego stone surface but not in any physical contact during activation. The Bego stone is fabricated from a class 4 super-hard plaster with strong resistance to abrasion (Bego USA).[16]

layer of latex after crossing. The demonstration shows the effectiveness of the Crosser® Catheter on inelastic materials and also indicates that the elastic materials can absorb the impact of the ultrasonic vibration from the tip of the Crosser® Catheter.†

In addition to tissue ablation selectivity, researchers have also investigated the potential risk of peripheral embolization due to ultrasonic ablation of calcific lesions related to the size of resultant particles. Many of the studies on other therapeutic ultrasound devices show that more than 90% of debris particles after ultrasonic ablation are < 20 μm in size.[5,8,18] Microscopic analysis also reveals that a majority of them are cholesterol monohydrate crystals.[5] The small size of the resultant debris potentially reduces the risk of peripheral embolization when using therapeutic ultrasound for CTO recanalization. In a clinical study using a catheter-delivered therapeutic ultrasound device for coronary arterial obstruction, no evidence of arterial emboli, heart block, arterial perforation, dissection, or vasospasm was observed.[8]

In the previously discussed FACTOR (coronary) and PATRIOT (peripheral) clinical trials with the Crosser® Catheter, adverse events were tracked 30 days post-procedure, and rates were consistent with other published data on similar devices. In both trials, no Crosser® Catheter-related clinical perforations were found.[12]

SUMMARY

Therapeutic ultrasound for CTO recanalization has evolved from the 1965 in vitro study to today's standard clinical use status. Clinical studies in the past 50 years have demonstrated that this technique provides an effective treatment solution for plaque ablation. The use of therapeutic ultrasound by the Crosser® System provides the device tissue ablation selectivity and differentiates it from other competitive CTO devices. As ultrasound technology continues to evolve, physicians will be
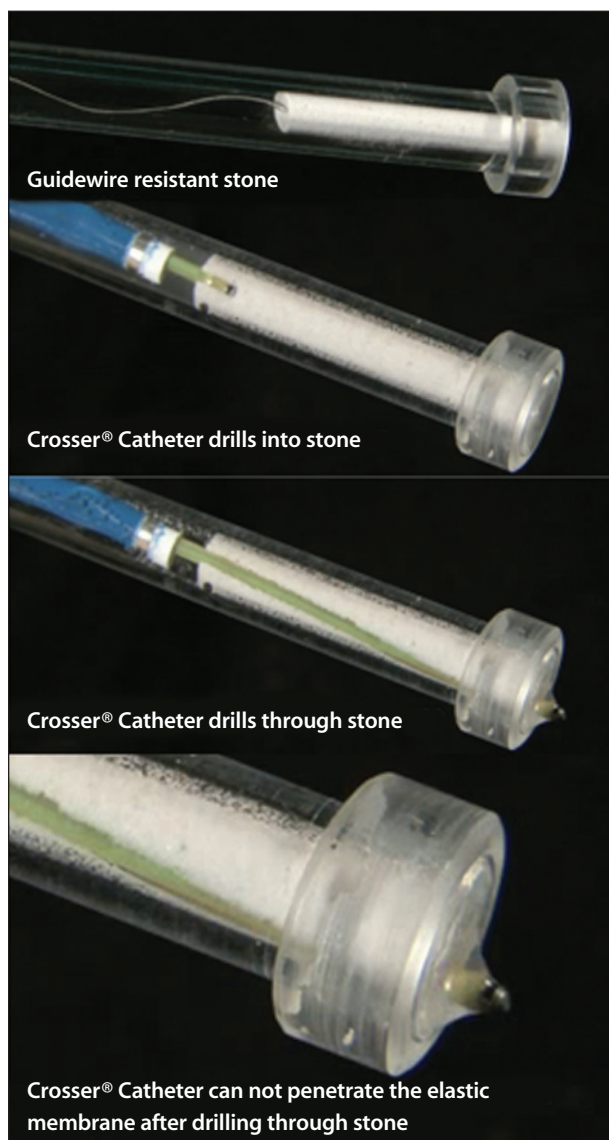
able to treat more patients with CTOs, and its use may broaden to other medical applications. ∎

All authors are employees of Bard Peripheral Vascular, Inc. in Tempe, Arizona. Angela Crall may be reached at angela.crall@crbard.com.

†*Data on file. Bench test results may not necessarily be indicative of clinical performance. Different tests may yield different results.*

Figure 5. Bench demonstration of the plaque ablation selectivity of Crosser® Catheter. A plaster stone is used in this demo.

Guidewire resistant stone

Crosser® Catheter drills into stone

Crosser® Catheter drills through stone

Crosser® Catheter can not penetrate the elastic membrane after drilling through stone

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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,
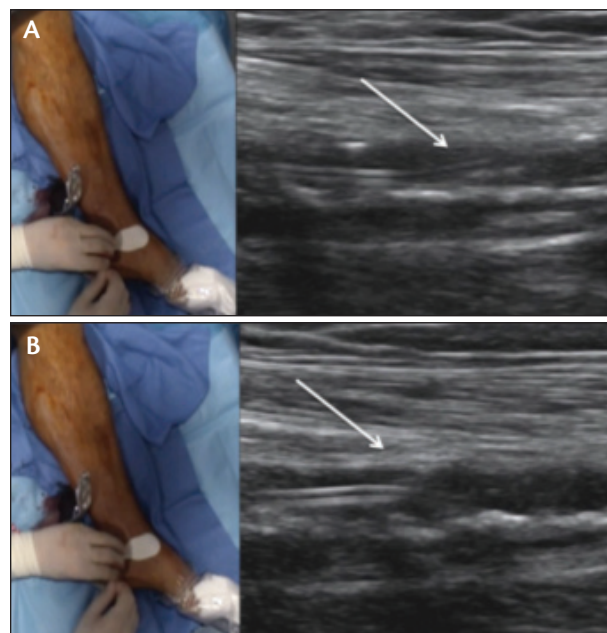

Figure 1. Tibial access sheathless with an angled Sidekick® Support Catheter rotated up (white arrow) (A). Tibial access sheathless with an angled Sidekick® Support Catheter rotated down (white arrow) (B).

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.

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
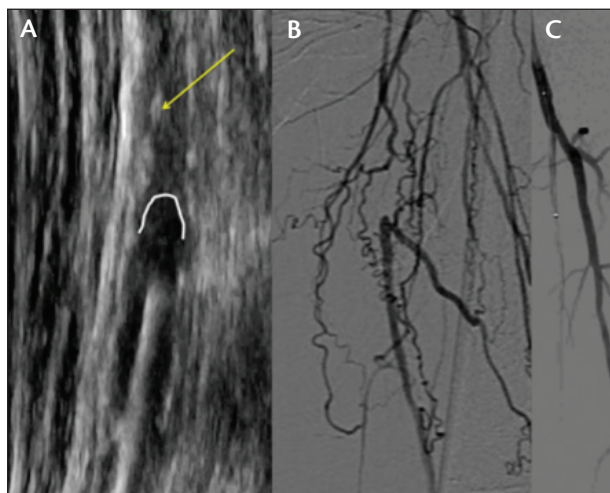
Figure 2. Extravascular ultrasound (EVUS) evaluation of the distal CTO cap defines the cap as retrograde concave and antegrade convex (white line) (A). This type of CTO is best approached from a retrograde access. The yellow arrow points to the plaque calcification (A). Angiographic evaluation of the 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.
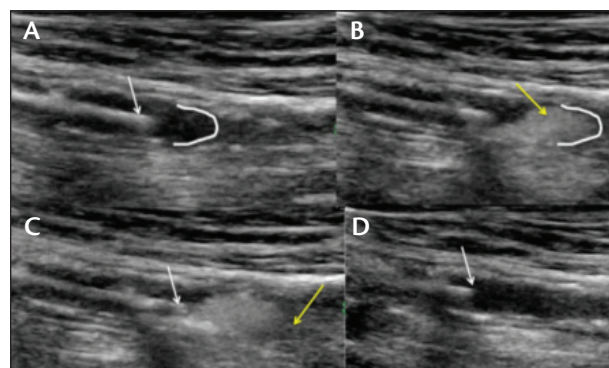
Figure 3. The white line shows the distal concave CTO cap. White arrow indicates the tip of the Crosser® Catheter (A). The action of the activated Crosser® Catheter can be seen downstream; note the configuration of the fluid (yellow arrow) to the concave CTO cap (white line) (B). The Crosser® Catheter 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 irr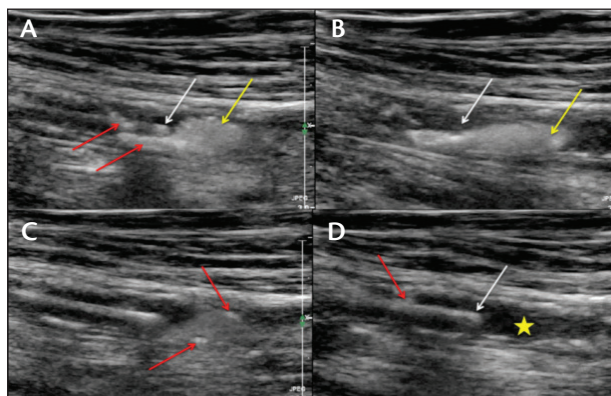igation flow into the CTO cap and plaque (yellow arrow) (A). The Crosser® Catheter crosses the CTO cap (white arrow) (B). This elongated appearance of the downstream irrigation flow from the catheter is typical for newly crossed CTOs (yellow arrow). The Crosser® Catheter generates ablative forces that 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 360° 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

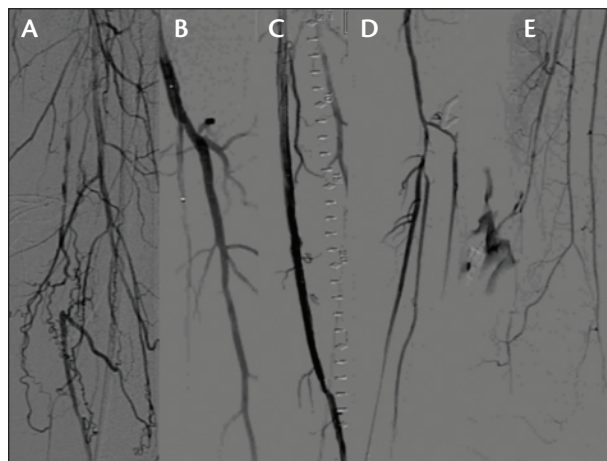Figure 5. Distal CTO cap reconstitution (A). Proximal CTO cap post retrograde Crosser® Catheter recanalization (B). SFA postintervention (C). Retrograde angiogram for the posterior tibial runoff (D). Post TAMI retrograde intervention angiogram with tibial-pedal runoff (E). The minor extravasation of 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. ∎

Jihad A. Mustapha, MD, is the Director of Cardiovascular Catheterization Laboratories, Metro Health Hospital, Wyoming, Michigan; and Clinical Assistant Professor of Medicine, Michigan State University CHM and COM, East Lansing, Michigan. Dr. Mustapha has disclosed he is a consultant for Bard Peripheral Vascular, Inc. Dr. Mustapha may be reached at jihad.mustapha@metrogr.org.

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A patient presented with a Rutherford class V, nonhealing wound in the distribution of the posterior tibial (PT) artery. Angiography was performed and showed severe tibial disease (Figure 1). Multivessel tibial CTOs over 300 mm in length were also noted. The procedure was initiated with an antegrade selective angiogram showing severe proximal CTOs of the anterior tibial (AT) artery and the PT.

Figure 1. Antegrade selective angiogram showing severe proximal CTOs of the AT and PT arteries (A). Poor distal tibial runoff, a common finding in CLI patients (B). Note the absence of reconstitution of the PT and the faint reconstitution of the AT. The only artery with intact flow is the peroneal artery with intact anterior and posterior communicating arteries.

Poor distal tibial runoff and nearly absent flow in the pedal circulation are common in patients with critical limb ischemia. Note the absence of reconstitution of the PT and the faint reconstitution of the AT, making a decision to treat this type of anatomy very challenging, especially with the absence of target reconstitution of the distal CTO. The only artery with some intact flow was the peroneal artery, with intact anterior and posterior communicating arteries but no retrograde or antegrade flow into the PT artery. We chose to use the Crosser® Catheter due to our success rate and level of comfort with this device. In particular, this is the type of CTO where an operator will need to trust in the mechanism of action of the device. Figure 2 highlights this crucial point to remember while crossing the CTO cap with the Crosser® Catheter. Do not get discouraged if there is a lack of immediate forward movement of the Crosser® Catheter. As Figure 2 shows, the Crosser® Catheter penetrates the CTO cap, which can be seen if EVUS is being used.

With progressive advancement of the Crosser® Catheter into the complex long calcified CTO, the combination of mechanical disruption and cavitation allows the device to cross the disparate parts of the CTO. After successful revascularization of a long, 300-mm CTO, final fluoroscopic angiography was performed with direct runoff to the foot, which continues to be the gold standard during infrainguinal revascularization (Figure 3).
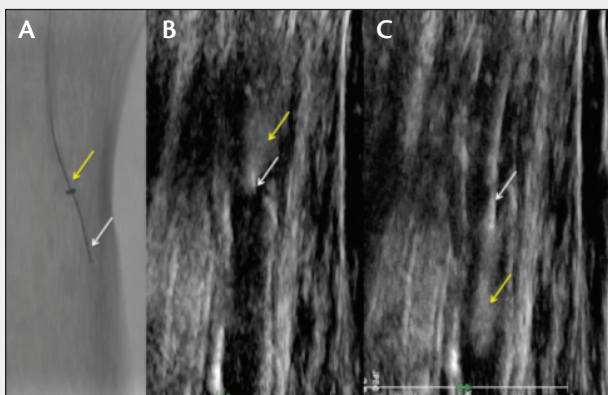

Figure 2. Fluoroscopic evaluation of an activated Crosser® Catheter (white arrow) with its angled Sidekick® Support Catheter (yellow arrow) (A). Fluoroscopy tends to provide no visual feedback, as shown here. Initial activation of the Crosser® Catheter (white arrow) at the cap initiates the generation of cavitation-induced microbubbles (yellow arrow), which are initially reflected back from the highly resistant CTO cap (B). The Crosser® Catheter (white arrow) advances through the CTO cap and the cavitation within the irrigation (yellow arrow) advances in front of the catheter (C).
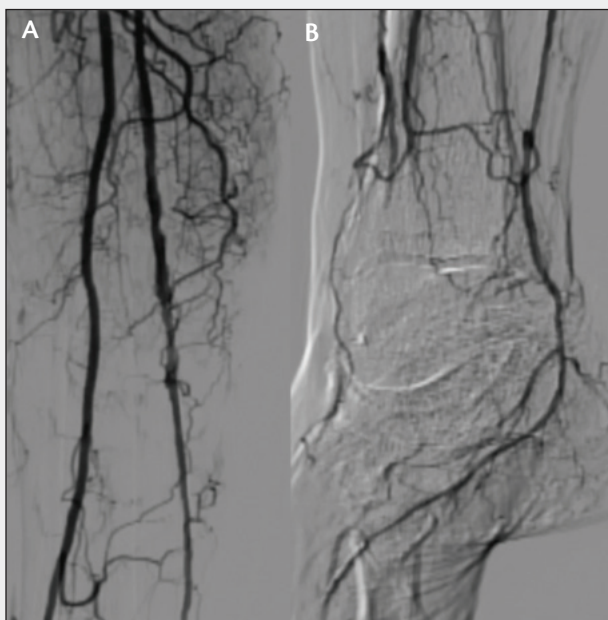

Figure 3. Postrevascularization of the PT artery with intact flow proximal, mid, and distal (A). Pedal runoff showing now intact pedal flow into the distribution of the PT artery (B).

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.
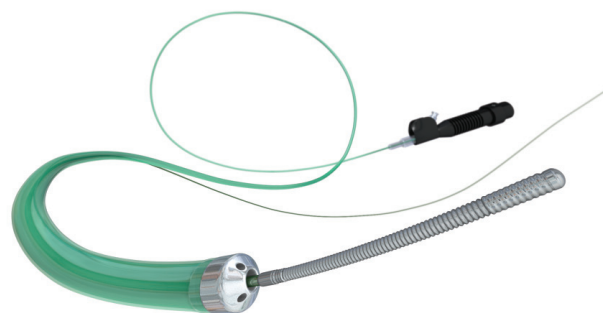

Figure 1. The Crosser® Catheter (Bard Peripheral Vascular, Inc.).

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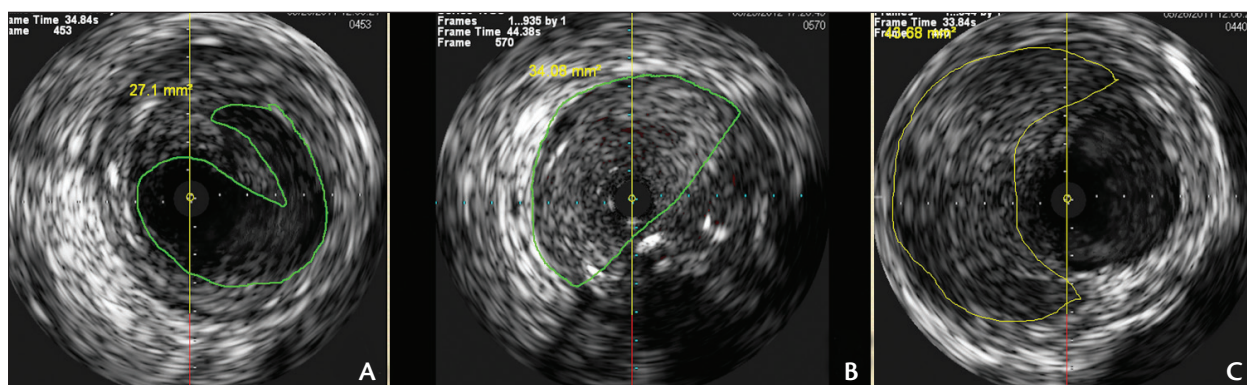
Figure 2. A 90° dissection with large intraluminal flap (T1) in proximal reference (A). An intralesional hematoma with characteristic "D" shape (T2) and an A2 orientation (B). A large extravascular hematoma in distal reference (T2) (C).

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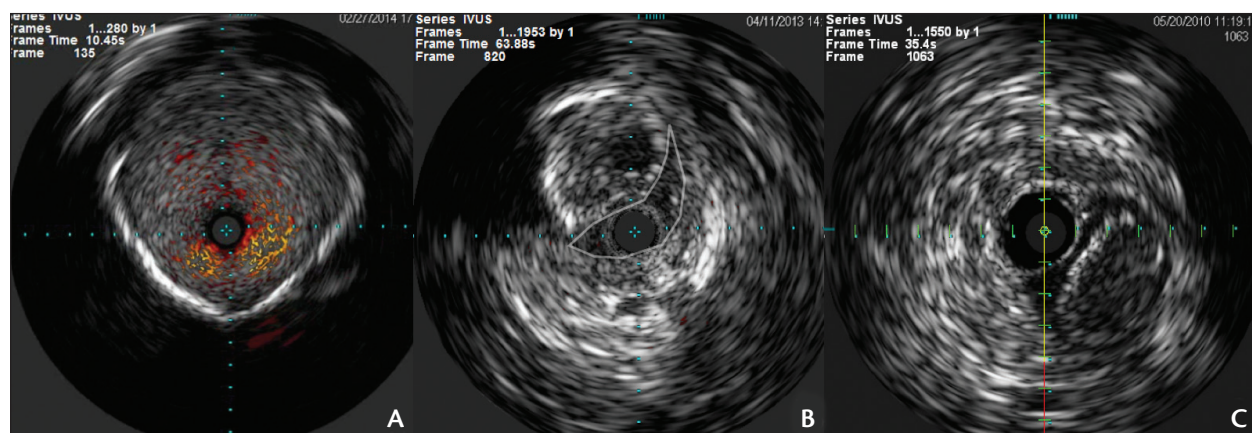
Figure 3. Anterior oblique orientation (intralesional) (A). A1 orientation (medial deflection); note the sickle-shaped lumen (B). A2 orientation (adventitial deflection); note the "snowman" appearance (C).

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.

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A closer look at recanalizing a restenotic occlusion.

BY FRANKLIN S. YAU, MD, RPVI

A 72-year-old woman with a history of type 2 diabetes, hypertension, hyperlipidemia, and peripheral vascular disease developed dry gangrene of the left great toe as well as rest pain over a 5-week period. She had a history of bilateral femoral stent placements and a 20 pack per year smoking history but quit 5 years ago. She did not have documented coronary artery disease or stroke and did not report chest pain, shortness of breath with exertion, or leg swelling. She had bilateral calf claudication at about one-half block.

Examination revealed a frail but alert woman brought in on a wheelchair. She had palpable femoral pulses on both sides but nonpalpable popliteal and pedal pulses. On the right side, she had 2-cm dry gangrene on the tip of her hallux. There was no drainage or surrounding erythema. She did have dependent rubor, which would resolve with leg elevation. Neurologic evaluation demonstrated decreased sensitivity to light touch in the feet bilaterally.

Ankle-brachial index was 0.55, with toe pressure of 17. Arterial duplex ultrasound confirmed right superficial femoral artery (SFA) stent occlusion with reconstitution of the popliteal artery above the knee. White blood cell count was 8.2, and creatinine was 1.1 mg/dL.

She underwent diagnostic peripheral angiography, which demonstrated an occluded right SFA stent with reconstitution of the above-knee popliteal artery. There was two-vessel runoff through the anterior tibial and peroneal artery (Figure 1).

We positioned a crossover sheath into the right SFA and administered therapeutic intravenous heparin. Initial attempts to cross the chronic total occlusion (CTO) with a Glidewire™ (Terumo Interventional Systems) and catheter were unsuccessful due to a calcified cap. Attempts at creating a subintimal plane only advanced our catheters outside the implanted femoral stent.

Our next maneuver involved using the Crosser® Catheter S6 (Bard Peripheral Vascular, Inc.) coupled with the Usher® Support Catheter (Bard Peripheral Vascular, Inc.). We positioned the Usher® Catheter at the center of the CTO cap. The Crosser® Catheter was able to successfully penetrate the calcified cap and continued intraluminally through the distal cap. The Usher® Catheter was advanced over the Crosser® Catheter into the reconstituted popliteal artery without difficulty (Figure 2).

We exchanged out for a 0.014-inch wire and performed mechanical atherectomy using a 2.4-mm Jetstream™ device (Bayer). Intravascular ultrasound revealed that the vessel size was 5.4 mm. We predilated the occlusion with a 5-mm Vascutrak® PTA Catheter (Bard Peripheral Vascular, Inc.) in

Figure 1. Diagnostic angiogram showing an occluded left SFA stent and extensive disease in the left SFA.

preparation for stent placement using a Lifestent® Vascular Stent (Bard Peripheral Vascular, Inc.). Completion angiography and intravascular ultrasound demonstrated no residual stenoses, dissections, occlusions, or embolizations (Figure 3).

Two-vessel runoff was preserved. Routine mechanical compression was performed, and the patient tolerated the procedure without immediate complications.

DISCUSSION

Restenosis is a common clinical scenario resulting from endovascular treatment with balloon angioplasty and intra-arterial stenting, with complications of arterial occlusion, elastic recoil, dissection, or residual stenosis. Restenosis due to endothelial injury from PTA progresses through three phases: acute vessel recoil, negative remodeling, and neoinitmal hyperplasia.[1] Although peripheral stenting can improve vessel recoil and negative remodeling, thrombus formation and neointimal hyperplasia are the primary causes of in-stent restenosis. Early reocclusions are usually the result of acute thrombosis, whereas late reocclusions are a result of neointimal hyperplasia.

Restenosis rates have been widely reported for balloon angioplasty of femoropopliteal lesions to be > 50% at 1 year, with the rate varying based on the type of lesion. One meta-analysis found that 3-year patency rates after PTA ranged from 61% in claudicants with stenosis to 30% for CLI patients with CTOs.[2] While stenting can mitigate vessel recoil and negative remodeling, in-stent restenosis occurs

Figure 2. The Crosser® Catheter and Usher® Support Catheter traverse the proximal and distal CTO caps.

Figure 3. Completion angiogram after successful treatment with atherectomy, balloon angioplasty, and stenting.

tions at approximately 20,000 cycles/sec at an amplitude of 20 μm to penetrate the hard calcified cap. It works like a small jackhammer. The mechanism of action maximizes its ability to penetrate inelastic surfaces such as calcium and minimizes its impact on elastic structures such as the vessel wall. Thus, the catheter is more likely to stay in the true lumen while avoiding perforation of the vessel. The PATRIOT clinical study demonstrated that the Crosser® Recanalization Catheter was successful in traversing CTOs that were unable to be crossed with a conventional guidewire.[7,8] Moderate to severe calcium was noted in 75% of these patients (n = 85), and no clinical perforations related to the Crosser® Catheter were observed. In addition, 15.3% of the patients had restenotic occlusions, having previously received endovascular treatment at the target lesion site.[8]

In our case, an occluded stent was resistant to a conventional guidewire and catheter method to cross the lesion. In addition, guidewire manipulation frequently creates a channel outside the occluded stent, thereby making successful secondary intervention challenging. The Crosser® Recanalization Catheter offered an elegant percutaneous solution to this difficult secondary intervention vascular case. ■

Franklin S. Yau, MD, RPVI, is a vascular surgeon with Vanguard Vascular & Vein in Dallas, Texas. Dr. Yau has disclosed that he is a consultant for Bard Peripheral Vascular, Inc. Dr. Yau may be reached at yau@thevanguardway.com.

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 the above case study for Bard's further use and distribution.

at a rate of 19% to 37% at 1 year.[3-6] Secondary interventions for nonocclusive restenosis include the use of repeat balloon angioplasty, cutting-balloon angioplasty, repeat stenting with either a bare-metal stent or covered stent, and atherectomy. Secondary interventions for CTOs can be more problematic. In our experience, restenotic occlusions tend to be quite fibrotic. In addition, the cap of the occluded lesion can sometimes be severely calcified, especially in patients with diabetes or end-stage renal disease.

In our experience, recanalization of a restenotic occlusion is usually more difficult than the treatment of a de novo TASC D lesion of an SFA that has not undergone previous intervention. Advancement of the wire and crossing catheter in the true lumen or the subintimal plane is usually difficult due to the fibrotic and sometimes calcified nature of the occlusion. Often, the wire and catheter enter the adventitial space outside the lumen and cannot be negotiated to remain inside the lumen.

In this particular patient, initial attempts at penetrating the calcified cap were unsuccessful; therefore, the Crosser® Catheter was used to treat this lesion. The Crosser® Catheter is a CTO recanalization system that uses a specialized catheter to transmit high-frequency vibra-

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Iliac Recanalization With the Crosser® Catheter

A case-based view on retrograde and antegrade approaches to challenging iliac artery revascularizations.

BY A. GEORGE AKINGBA, MD, PhD, AND LUONA SUN, MD

Peripheral artery disease (PAD) can present with acute, chronic, or acute-on-chronic symptoms, although chronic symptoms represent the most common presentation of PAD. Chronic symptoms of PAD are often a result of stenotic, occlusive, or a combination of both types of atherosclerotic lesions. As a result, chronic total occlusions (CTOs) are frequently encountered during endovascular interventions and have been reported in up to 40% of patients with symptomatic PAD.[1] The treatment of CTOs is challenging for the endovascular interventionist because CTOs present technical difficulties with maintaining central lumen wire positioning after lesion traversal. In the past, standard guidewire techniques were frequently used for crossing total occlusions. A review of femoropopliteal subintimal angioplasty found treatment failures occurred approximately 10% to 25% of the time, the most common reason for failure being the inability to re-enter the true lumen beyond the distal cap.[2,3] Because of the increasing prevalence of fibrocalcified plaque or multilevel or long occlusive lesions, CTO crossing devices are receiving greater popularity for recanalizing CTOs. Before the advent of CTO crossing devices, the approach of most vascular specialists was to treat long CTOs with bypass surgery. With the availability of these devices, we can offer additional treatment options, particularly for patients where an open surgical approach may not be feasible or recommended.

The Crosser® Recanalization System is designed to cross CTOs of the peripheral vasculature. For infrainguinal CTO treatment, the Crosser® Catheter 14S and 14P (Bard Peripheral Vascular, Inc.) are designed to facilitate the intraluminal placement of conventional guidewires via atherectomy. The Crosser® Catheter 14S and 14P have a 1.1-mm titanium tip and are compatible with 0.014-inch guidewires. The Crosser® Generator includes a transducer, which has piezoelectric crystals that convert amplified alternating current into high-frequency vibrational energy that is transmitted to the catheter tip. This vibrational energy disrupts and crosses through fibrocalcific plaque, creating a channel

for subsequent therapies. The Crosser® Catheter 14S and 14P come in 106- and 146-cm working lengths, and given the small footprint of the Crosser® Catheter, it is appropriately sized for use in small vessels, such as the tibial vessels. We have also found the Crosser® Catheter particularly useful in treating focal lesions in larger vessels such as the common and external iliac arteries. We are presenting two cases of iliac artery recanalization with the Crosser® Catheter that would otherwise have been addressed with open surgical techniques.

CASE ONE PRESENTATION

A 53-year-old man presented with a left great toe nonhealing wound and associated history of left lower extremity claudication after walking one-half block. On physical examination, his left great toe nail bed had a chronic ulcer and no palpable pedal pulses bilaterally. His ankle-brachial indices (ABIs) were 0.73 on the right and 0.33 on the left, and a CT angiogram showed on the left he had external iliac artery (EIA), common femoral artery (CFA), and proximal superficial femoral artery (SFA) occlusions with above-knee popliteal reconstitution. Based on these clinical findings, the patient was scheduled for a left lower extremity hybrid revascularization of his arterial inflow in the form of a left femoral endarterectomy plus profundoplasty, left EIA atherectomy, and stenting.

Description of Procedure

A vertical skin incision was made in the left groin. The left common femoral, superficial femoral, and profunda femoris arteries were exposed from the inguinal ligament to the primary branches of the profunda femoris artery. We then performed a left CFA and profunda femoris artery endarterectomy with a bovine patch repair in a standard fashion, after which we proceeded with the endovascular portion of this hybrid intervention. We used a 5-F micropuncture sheath assembly to retrograde-cannulate the left CFA through the patched artery just above its bifurcation in order to have adequate purchase for a larger access
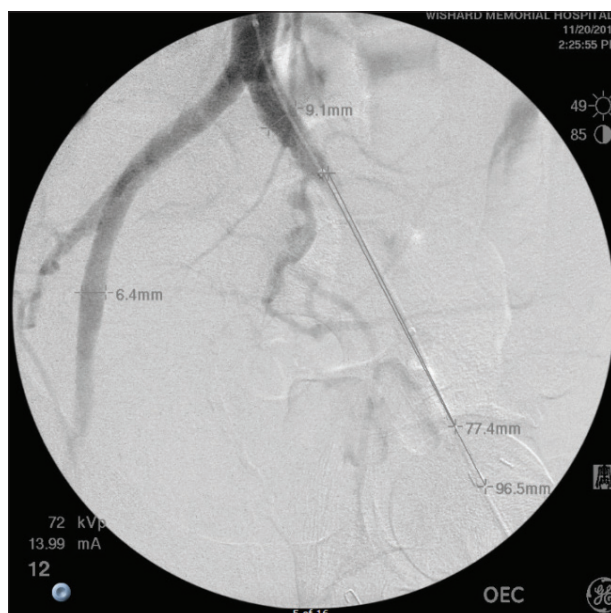
Figure 1. A postcrossing AIF angiogram demonstrating a long left common iliac artery CTO.

Figure 2. Completion angiogram showing normalized opacification through the iliac CTO.

sheath. Under fluoroscopic guidance, we then upsized to a 7-F access sheath using the Seldinger technique. We could only insert a portion of the sheath into the CFA secondary to the EIA CTO. We then proceeded to engage the Crosser® Catheter 14P at the distal cap of our EIA CTO lesion. Under fluoroscopic guidance, we then activated and advanced the Crosser® Catheter in a retrograde fashion across the distal and proximal caps of the iliac CTO lesion terminating with our catheter tip in the distal aorta.

We then confirmed intraluminal placement of our wire by performing aortoiliofemoral (AIF) angiography (Figure 1), which demonstrated adequate opacification of the distal aorta and contralateral iliac artery system, as well as outflow into the left hypogastric artery. This image identified the long, left common iliac artery CTO, and in the right anterior oblique magnified orientation, we were able to ascertain the critical dimensions of this left EIA lesion in order to select the appropriate-sized stents. Based on the length of the lesion, two self-expanding covered stents in the form of a 7- X 50-mm Viabahn™ Endoprosthesis (Gore & Associates) were selected for placement in an overlapping, telescoping fashion. The distal stent was placed first, with the most distal end at the level of the acetabulum. We then proceeded to telescope the more proximal end to the origin of the EIA in order not to cover the hypogastric vessel. This was done over a stiff V-18™ Guidewire (Boston Scientific Corporation).

A poststent angiogram was obtained, which showed improved opacification and flow through this segment with residual stenosis at the level of the inguinal ligament. We therefore placed a bare-metal self-expanding 7- X 40-mm

stent at this location. Poststent angioplasty was performed with a 7- X 80-mm Dorado® PTA Catheter (Bard Peripheral Vascular, Inc.), and completion angiography was performed that showed improved flow and normalized opacification through this segment with no residual stenosis and maintenance of flow through the left hypogastric and contralateral iliac artery system (Figure 2). A left lower extremity runoff angiogram was then obtained, which demonstrated adequate flow through the patch and profunda femoris artery branches in the proximal thigh. In the distal thigh, it showed reconstitution of the above-knee popliteal artery through large collaterals. The patient was noted to have an adequately opacified popliteal artery with an adequately opacified tibioperoneal trunk.

At 1- and 3-month follow-up, the patient was noted to have improvement in his claudication and complete left toe ulcer healing. His ABIs had improved from 0.33 (preoperative) to 0.70 at his 3-month postoperative evaluation, while his duplex study demonstrated a patent left EIA stent.

CASE TWO PRESENTATION

A 50-year-old woman with a history of anal squamous cell carcinoma status post neoadjuvant chemotherapy radiation followed by an abdominoperineal resection with an end colostomy presented with bilateral lower extremity rest pain and left great toe tissue loss. Her abdominoperineal resection procedure was complicated by wound dehiscence and a wound infection; therefore, the patient was noted to have a hostile abdomen. On physical exam, her bilateral femoral pulses were not palpable, and she had left great toe gangrene with adjacent rubor. ABIs were 0.33

on the right and 0.22 on the left. CT angiography showed the distal aorta and common iliac arteries were patent, as well as a patent origin of both external iliac arteries. The rest of the external iliac arteries were occluded with distal reconstitution at the level of the femoral arteries and three vessel runoffs bilaterally. Based on this clinical evidence, the patient was scheduled for an AIF angiogram and endovascular intervention through a left brachial access approach.

Description of Procedure

A 4-cm longitudinal incision was made at the level of the distal upper arm over the brachial pulse. The brachial artery was identified and exposed for 4 cm. We then proceeded to retrograde-cannulate the left brachial artery under direct visualization with a 5-F micropuncture sheath assembly with resultant good backflow of arterial blood. We then exchanged for a 5-F access sheath, selectively cannulated the distal aorta, and obtained an AIF angiogram. We exchanged the 5-F access sheath for a 7-F, 70-cm Ansel guide sheath (Cook Medical), which was advanced over a stiff wire into the distal aorta. The left common iliac artery was selectively cannulated, and a left iliofemoral angiogram in the right anteriolateral oblique orientation was then obtained in order to adequately define our proximal and distal CTO caps (Figure 3). This enabled us to obtain the critical dimensions of our CTO lesion. A Crosser Catheter® 14S was engaged at the proximal CTO cap in the proximal external
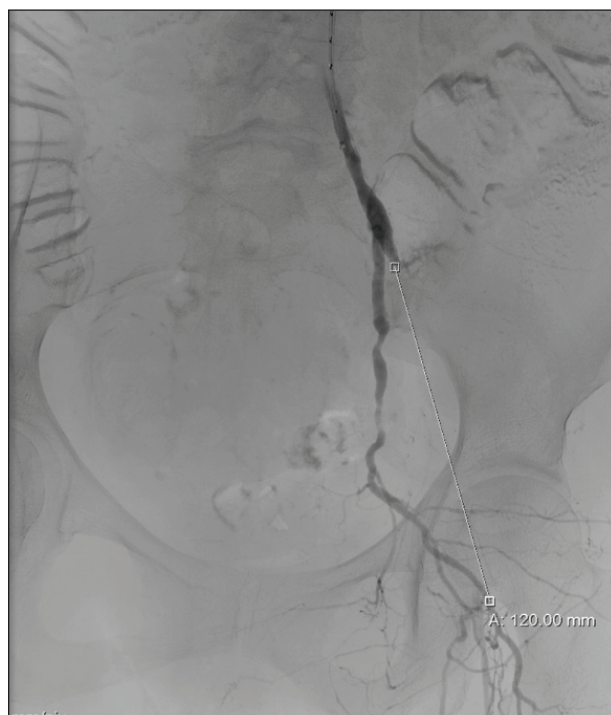

Figure 3. A left iliofemoral angiogram to define the proximal and distal CTO caps.

iliac artery (EIA), and under fluoroscopic guidance, we activated and advanced the Crosser® Catheter in an antegrade fashion across the proximal and distal caps of the left EIA CTO lesion, terminating this portion of the procedure with our catheter tip in the patent lumen of the left CFA. The left EIA and CFA lesions were predilated with a 6-mm X 120-mm Dorado® Balloon, and a postangioplasty angiogram was obtained that showed markedly improved flow and opacification through this treated segment. Based on our intent to primarily stent the left EIA CTO, we deployed a 6-mm X 80-mm stent across the left EIA lesion. The stent was postdilated with a 6-mm X 120-mm Dorado® Balloon, and a poststent angiogram was obtained that showed markedly improved flow and normalized opacification through the EIA and CFA (Figure 4A). A runoff angiogram demonstrated adequate flow and normal opacification of the infrainguinal arteries down to the ankle (Figure 4B).

After successful revascularization of the left lower extremity, we turned our attention to address the right EIA CTO lesion. In a similar fashion, a right iliofemoral angiogram was obtained to assess the critical dimensions of the right EIA and CFA lesion (Figure 5). We then proceeded to utilize the Crosser® Catheter 14S in the same antegrade fashion to traverse the right EIA and right CFA, as well as the proximal right SFA. A postcrossing traversal angiogram confirmed the device was intraluminal in the proximal right SFA. In a similar fashion to the contralateral side, the right EIA lesion was predilated and stented with a 6-mm X 80-mm stent. The stent was postdilated, and a poststent angiogram was obtained that showed markedly improved flow and normalized opacification through the EIA and CFA, as well as the proximal SFA segment (Figure 6). A completion angiogram for the right lower extremity was obtained, which showed adequate opacification of the right SFA in the proximal thigh as well as at the level of the distal thigh and above-knee popliteal artery (Figure 7).

At the patient's most recent clinic evaluation (1 month postoperative), she had complete resolution of rest pain and was now ambulating. Her ABIs had improved to normal (at 1+ bilaterally).

DISCUSSION

Revascularization of CTOs can be hindered by failure to cross the lesion due to a variety of factors, such as the inability to maintain the guidewire in the true lumen or inability to re-enter the true lumen with the guidewire.[4,5] Attempts to revascularize heavily calcified CTOs with traditional guidewire and balloon technologies fail in approximately 20% of cases.[4] In our experience, iliac artery CTOs provide a greater challenge for lesion wire traversal, as these vessels are fairly tortuous and often have a larger plaque burden compared to infrainguinal vessels. As such, knowledge of
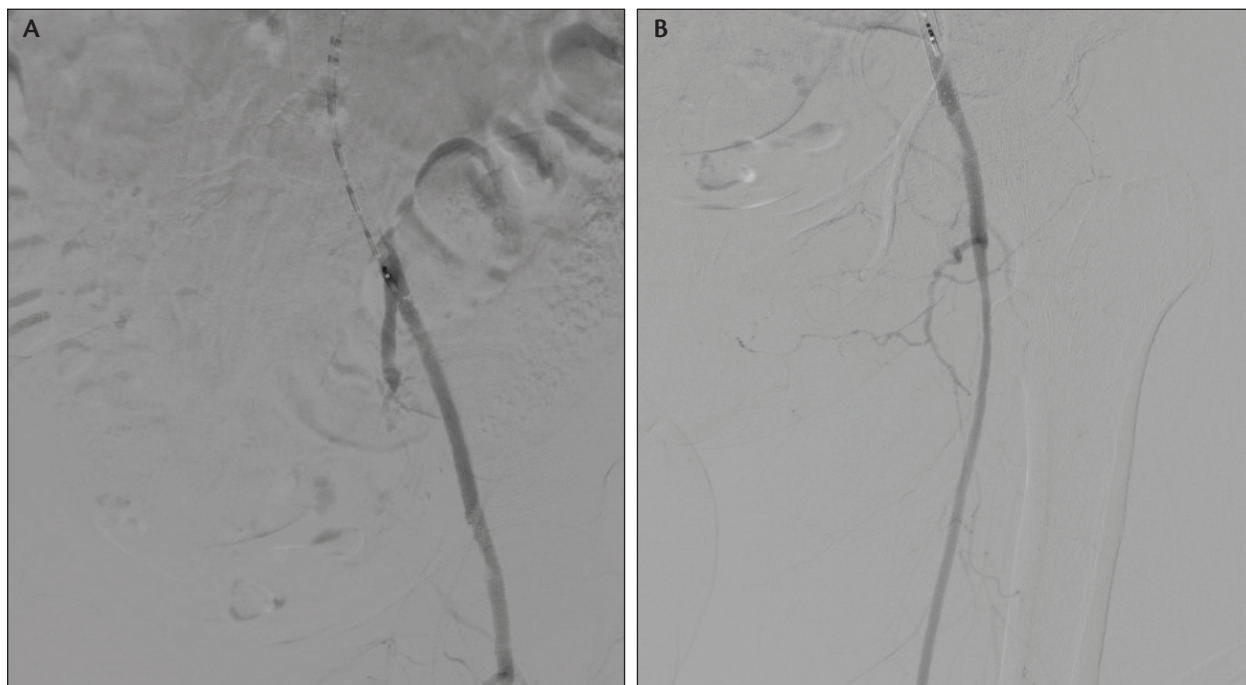
Figure 4. Completion left iliofemoral angiogram showing improved flow and normalized opacification through the EIA (A) and CFA (B) with good proximal SFA runoff.

the course of the iliac vessel as well as the orientation of the proximal and distal caps is very useful in improving the success of lesion traversal using the Crosser® Catheter. A CTO crossing device such as the Crosser® Recanalization System is designed to drill through the fibrocalcified lesion.[6] The addition of an angled 7-F Sidekick® Support Catheter (Bard Peripheral Vascular, Inc.) allows us to engage the proximal or distal cap in a perpendicular fashion to maximize central lumen Crosser® Catheter traversal of these tortuous vessels. Finally, after traversal of our distal cap, a tapered support catheter is used to dilate the recanalized channel and a run-off angiogram is obtained to ascertain appropriate re-entry into the center lumen of our distal target vessel. We then proceed with lesion pre- and postdilatation in addition to primary stenting of the iliac vessel.

Based on the cases we have presented and multiple other CTO crossing and atherectomy cases performed, we have found that an effective recanalizing device such as the Crosser® Catheter is a very useful tool for the vascular interventionist. Understanding the vessel course, location of collaterals, and CTO (proximal and distal) cap orientation is very important and allows the vascular interventionist to adjust the procedural technique accordingly in order to increase the likelihood of procedural technical success. Currently, we have also restricted our use of guidewire probing to only lesions that show evidence of a string-sign so as not to create a subintimal dissection plane, which, if
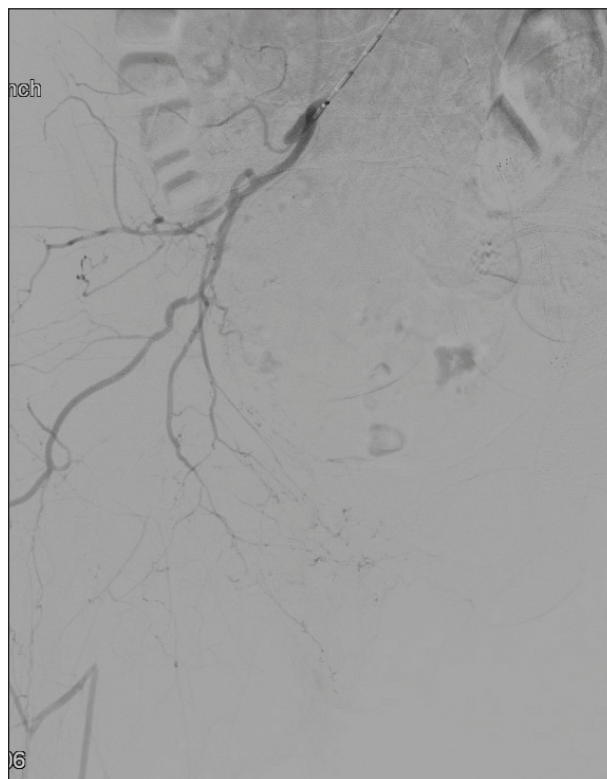

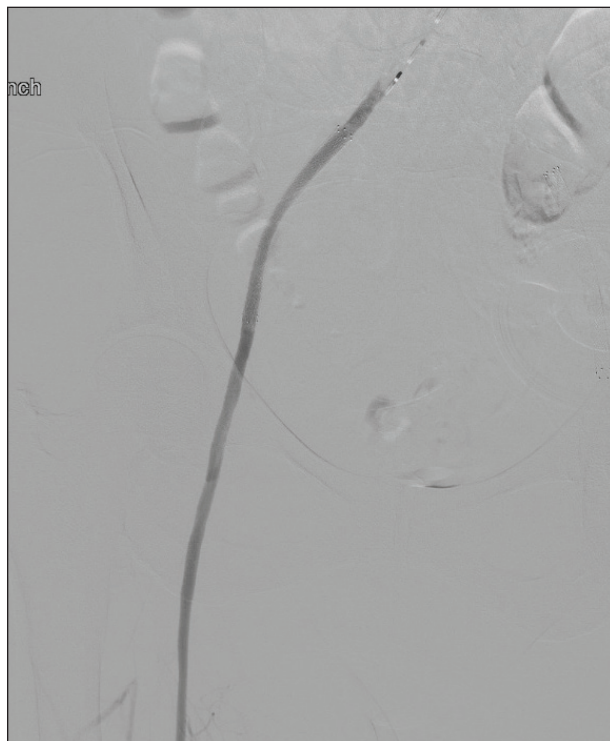**Figure 5. Right iliofemoral angiogram showing EIA and CFA CTO lesions.**

Figure 6. Right iliofemoral angiogram showing normalized opacification through the EIA and CFA, as well as proximal SFA segment.

Figure 7. A runoff angiogram for the right lower extremity showing adequate opacification of the right SFA in the proximal and distal thigh.

the interventionist is unsuccessful in re-entering the center lumen, likely becomes the path the Crosser® Catheter also takes, thereby eliminating our concurrent opportunity for successful center lumen lesion traversal. Our use of the Crosser® Catheter as a first-line therapy approach has resulted in our very high technical success rates of CTO traversal, irrespective of the arterial tree supplying the lower extremity.

CONCLUSION

The emergence of more sophisticated CTO crossing devices has increased the ability to recanalize some of the most challenging occlusions, such as highly calcified lesions in small- and large-caliber peripheral arteries using an antegrade or retrograde approach. The combination of the small-caliber Crosser® Catheter tip with an angled support catheter has allowed us to successfully tunnel through severely calcified plaque within the iliac vasculature, while maintaining central lumen positioning across our proximal and distal CTO caps. Further experience with these types of challenging lesions by multiple users and randomized controlled trials will be required in order to determine the long-term benefits and cost-effectiveness of crossing devices. ∎
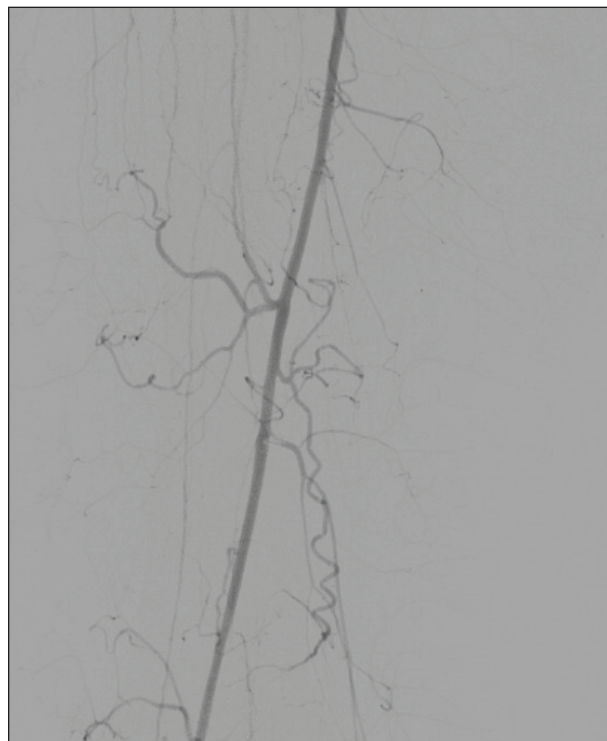
A. George Akingba, MD, PhD, is an Assistant Professor of Surgery, Biomedical Engineering, and Medicine, Indiana University School of Medicine in Indianapolis, Indiana. He has disclosed no financial interests related to this article. Dr. Akingba may be reached at (317) 880-3552.

Luona Sun, MD, is a research fellow for the Krannert Institute of Cardiology, Indiana University, School of Medicine, Indianapolis, Indiana. Dr. Sun has disclosed no financial interests related to this article.

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 physicians have prepared these case studies at the request of Bard Peripheral Vascular, Inc. 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 intra-luminal 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.