Intraluminal Recanalization of SFA CTOs

IVUS validation of center lumen crossing using the Crosser CTO catheter in peripheral interventions.

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Infrainguinal occlusive peripheral artery disease (PAD) has become the target of recent advances in endovascular techniques and procedures aiming to restore blood flow to the lower extremities without the conventional approach of bypass surgery. Chronic total occlusions (CTOs) of the lower extremities may be seen in up to 40% of patients with symptomatic PAD. Various methods for performing endovascular peripheral interventions have been developed for this subgroup of lesions, including subintimal angioplasty, blunt catheter dissections, laser light, and vibration 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 popliteal artery was dilated and subsequently found to maintain its patency for 9 years.[1] This approach has since been used in thousands of procedures worldwide.

Among the available literature, long-term patency rates using subintimal angioplasty vary considerably. Met et al summarized 23 cohort studies (n = 1,549) and reported an approximate 50% lower extremity patency rate at 1 year using this technique.[2] Generally, angiographic outcomes seem to improve as the practitioner gains experience with the intentional extraluminal technique, whereas other interventionists have not seen a significant improvement in their technical success or lower complication rates with added experience.[3-5] The increasingly complex nature of peripheral vascular disease that is presenting to our catheterization laboratories is a major limitation to this technique because the typical extended lengths and calcification of CTOs prevent crossing or re-entry into the true lumen. Current treatment modalities such as blunt microdissection, mechanical atherectomy, and subintimal re-entry devices have improved the success rate in these often challenging cases.

Thus, practically speaking, a method that would successfully gain access across CTOs of lower extremity vessels through central lumen crossing and limit the creation of subintimal dissection planes could potentially prevent some of the drawbacks of the PIER method. Maintaining an intraluminal course may also allow for alternative treatment strategies with a wide array of atherectomy options.

The Crosser catheter (Bard Peripheral Vascular, Tempe, AZ) is a CTO crossing catheter with a special-

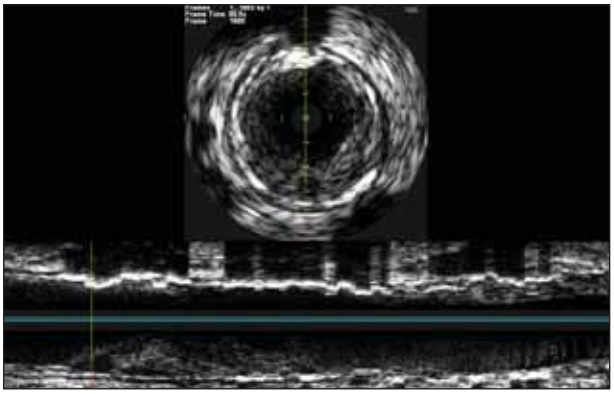


Figure 1. Proximal inlet of total occlusion as seen by intravascular ultrasound (IVUS). Note the echodense banded plaque in the tunica media extending to the internal elastic lamina.

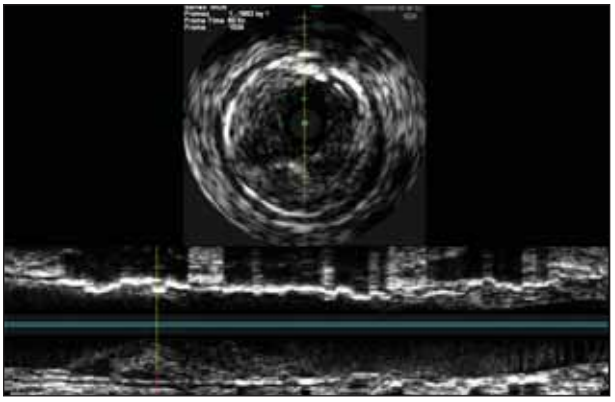


Figure 2. Midlesion image. Note the IVUS catheter remains relatively central during the crossing. Also of note is the cross-sectional area of the lumen that the Crosser created, ranging from 3.1 to 6.4 mm^2.

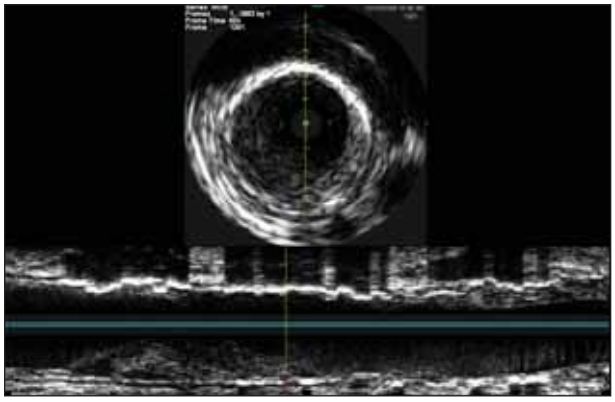


Figure 3. Exit point of the total occlusion. Note the clean periadventitial space and the lack of a dissective flap with immediate re-entry into the distal reference.

ized 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. The preliminary reports of the Peripheral Approach to Recanalization in Occluded Totals (PATRIOT) trial showed an 84% recanalization success rate of guidewire-resistant CTOs with no evidence of clinical perforations; in addition, it displayed an exceptional rapid lesion crossing time.[6] A similar safety profile was seen in coronary CTO cases in which the Crosser had no catheter-induced perforations.[7]

The purpose of our study was to assess the efficacy of the Crosser CTO catheter on maintaining central lumen crossing in isolated superficial femoral arteries (SFA), as well as one case involving SFA and popliteal artery CTOs using IVUS.

MATERIALS AND METHODS

To facilitate CTO crossing, an over-the-wire or rapid-exchange Crosser catheter was used. Once activated using a foot pedal, the mechanical vibration energy-delivering tip was slowly advanced, while a 0.014-inch guidewire was docked inside the catheter for support. The unit is then advanced through the entire length of the CTO. The catheter follows the contour of the vessel, which in most cases requires no steering. If calcified plaque is encountered and requires more catheter support or an acute angle is present, a MicroSheath XL (Bard Peripheral Vascular) straight or tapered can be used, respectively. Once the catheter tip has crossed through to the distal end of the blockage, the guidewire is advanced through the catheter to a distal vessel where it can be stationed while the catheter is removed.

Given the inherent limitations of angiography to identify the exact intra-arterial course of the catheter, IVUS was used to visualize actual true lumen passage versus subintimal tracking. The Eagle Eye Gold catheter (Volcano Corporation, San Diego, CA) is a 5-F–compatible imaging catheter that performs intravascular analysis of the culprit lesion measuring both grayscale images and virtual histology over a 0.014-inch guidewire. Manual as opposed to automated pullback was performed due to excessive lesion length. Images were

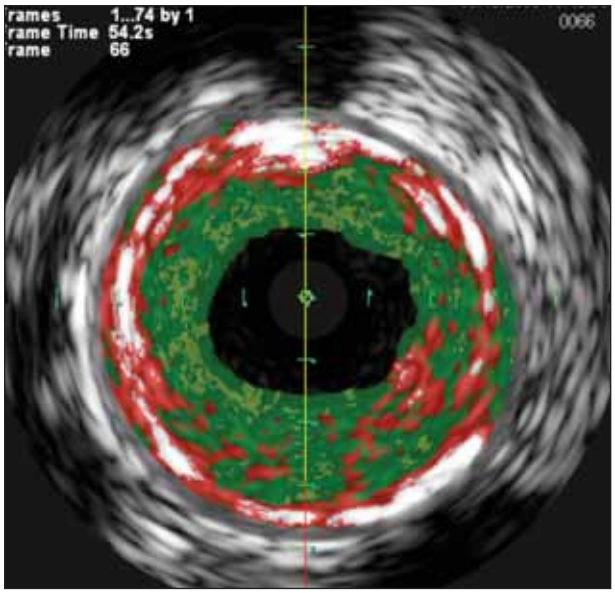


Figure 4. Virtual histology of Crosser lumen. Note the dense calcification of the tunica media that extends to the internal elastic lamina. Despite the appearance, no significant attenuation was detected in the far field consistent with a calcified plaque. The lumen at this point measured 6.4 mm^2.

recorded on DICOM format and stored on the s5i imaging system (Volcano Corporation) hard drive for subsequent analysis. All images were assessed independently by two experienced IVUS readers.

Seventeen consecutive patients undergoing percutaneous intervention of an SFA CTO using the Crosser device were studied using IVUS. Baseline demographic, angiographic, interventional, and IVUS data were collected. The frequencies of intraluminal and subintimal crossing were then calculated. The Crosser was used as the primary CTO crossing strategy. No intentional extravascular wiring was attempted before using the catheter.

RESULTS

Procedures were performed between January 2009 and May 2009. Seventeen patients were analyzed. Four (23.5%) were men, and 13 (72.5%) were women. Ages ranged between 63 and 91 years with a mean of 73.5 ± 8.84. Twelve patients (70.5%) presented with Rutherford classification 3 or 4 (claudication/rest pain), whereas five (29.5%) presented with class 5 or 6 (minor or major tissue loss).[8] Twelve patients (70.5%) had a history of smoking. All patients were on antiplatelet therapy with aspirin, clopidogrel, or both. The entire cohort received intraprocedural intravenous heparin.

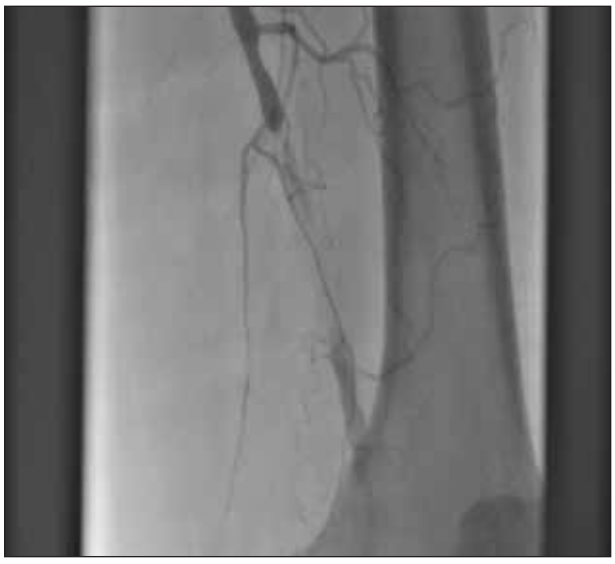
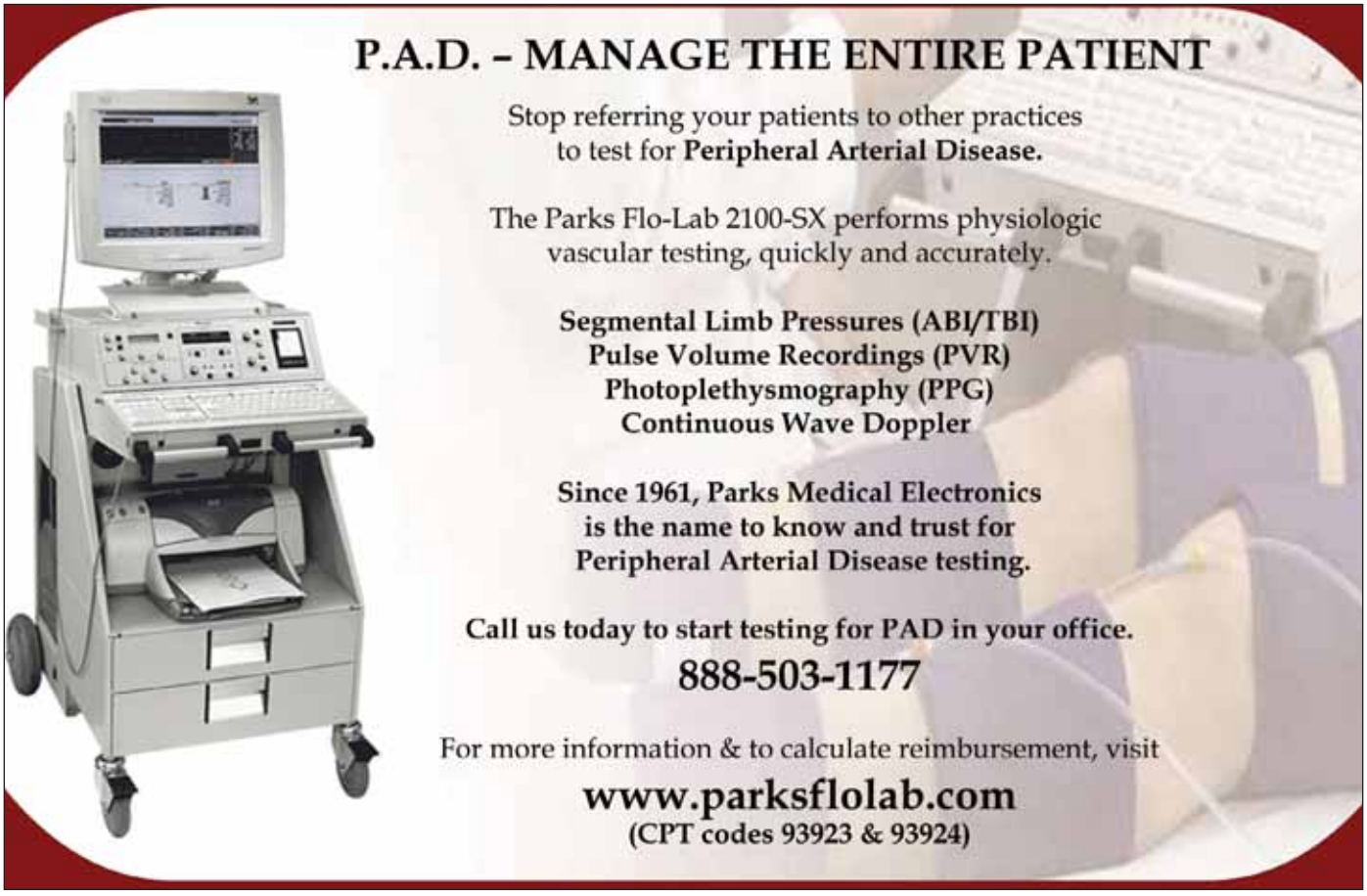


Figure 5. CTO of the Hunter's canal segment of the left SFA.



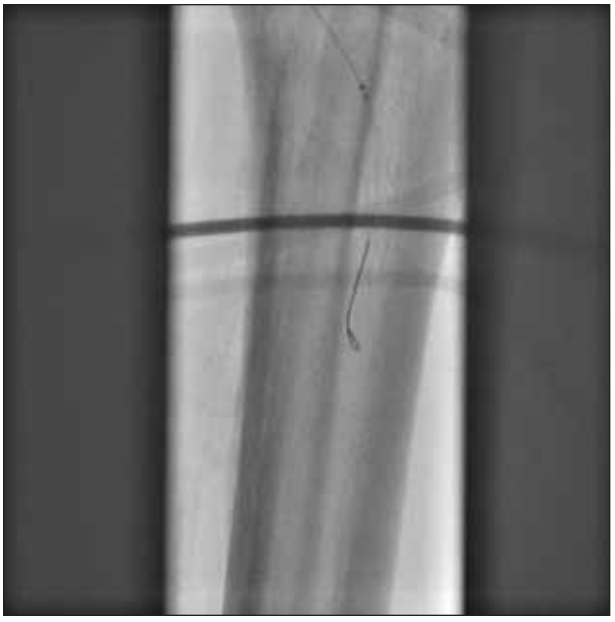


Figure 6. The Crosser catheter distal to the total occlusion.

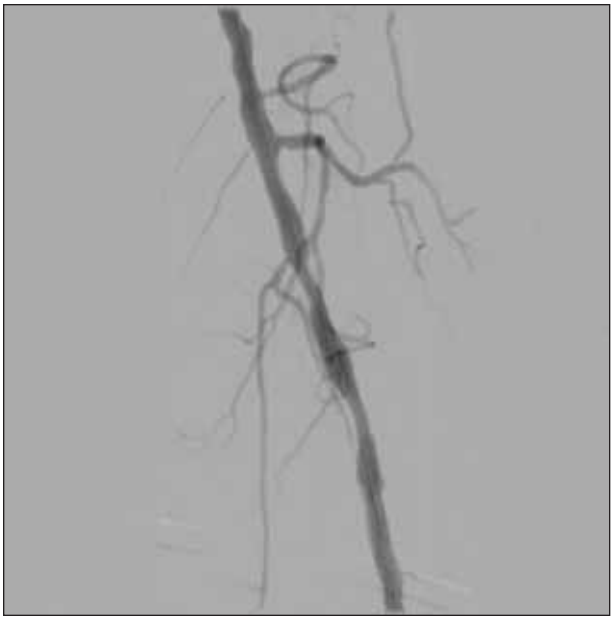


Figure 7. Right SFA after initial Pathway atherectomy.

All of the procedures were performed using the femoral access and contralateral approach. All lesions involved a CTO of the SFA, and one included the popliteal artery. Mean lesion length was 17.05 ± 10.75 cm, with 12 patients (70.5%) having a calcified entry diameter of 6.44 ± 0.89 mm. The Crosser catheter passed through 100% of the CTO lesions. Full intraluminal crossing was achieved in 14 of the 17 patients (82%). Three lesions had a partial subintimal crossing with two of the three lesions showing evidence of mild nonobstructive dissection and a small intramural hematoma. In all Crosser patients studied, there was immediate re-entry into the distal unaffected reference lumen without extension of total lesion length (Figures 1 through 3).

Eight patients displayed a pattern of medial and internal elastic laminal calcification likely representing Monckeberg's sclerosis (Figure 4).[9] All eight patients with medial and internal elastic laminal calcification had successful intraluminal crossings. In these patients, there were no occurrences of periadventitial hematomas or evidence of flow-limiting occlusive dissections in the lesion proper or the reference segments. There was no angiographic evidence of distal embolization after lesion crossing. The final lesion treatment included rotational atherectomy with the Jetstream catheter (Pathway Medical Technologies, Kirkland, WA) followed by directional atherectomy using a SilverHawk catheter (ev3 Inc., Plymouth, MN) with or without balloon angioplasty (Figures 5 through 8). There were no acute clinical failures requiring reimaging before the patient's hospital discharge.

DISCUSSION

According to the Transatlantic Intersociety Consensus II (TASC II) recommendations, the standard of care for long arterial occlusions in the lower extremities is conventional surgical bypass. This approach, however, is marred by a significant rate of early morbidity (within the first 12 months) related to wound infections and cardiovascular complications.[10,11] Moreover, patients affected by life-threatening critical limb ischemia—often with diabetes—are typically not candidates for conventional surgical procedures; not only do they have extensive arterial wall damage that could jeopardize the distal anastomosis and have multiple comorbid conditions, but they often lack veins suitable for surgical conduits.

Due to these short-to-midterm limitations of surgery and frequent comorbidities of this patient population, an endovascular approach is a desirable option. Intraluminal crossing of the lesion is often difficult, forcing the operator to switch to a technical variation, such as subintimal angioplasty. The success of the subintimal angioplasty technique in totally occluded vessels is influenced not only by the length of the occlusion, severity of plaque calcification, and diffuse disease of the distal target, but also technical experience. The subintimal dissection approach may lead to suboptimal results as well as limit the use of newer

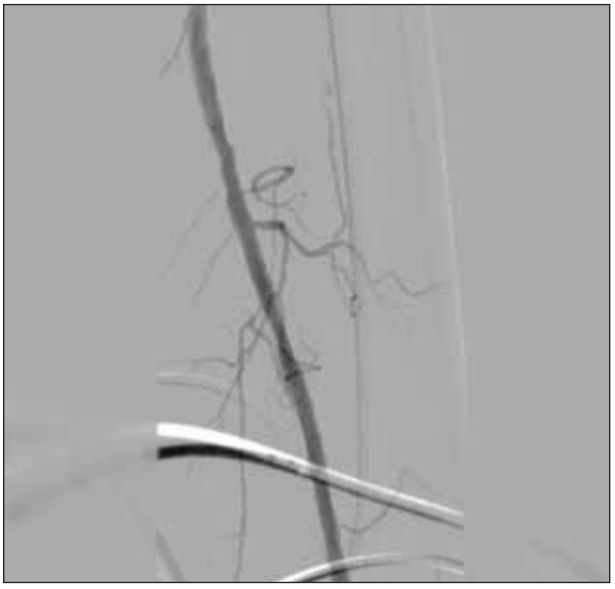


Figure 8. Final SFA image after SilverHawk atherectomy.

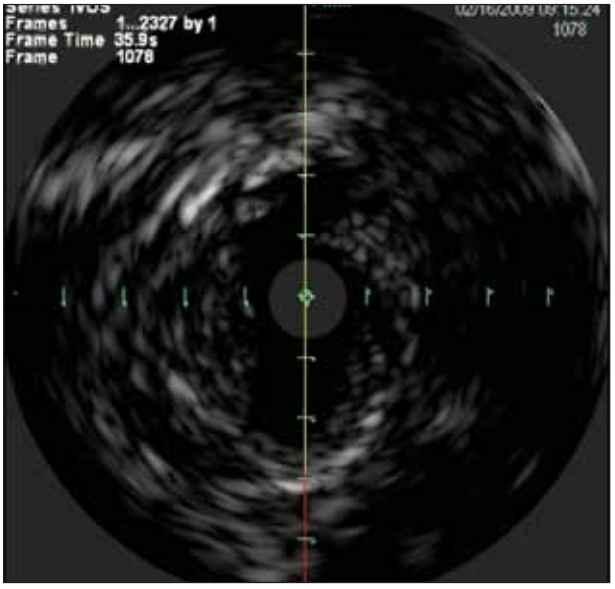


Figure 9. IVUS showing collateral preservation (at 12 o'clock) after Crosser passage.

atherectomy devices. Lastly, the entry and re-entry of the occlusion with the subintimal wire approach had been plagued with considerable periadventitial hematomas and/or vessel perforations.[4,12-17]

In our experience with the subintimal angioplasty approach, IVUS often shows extensive flow-limiting dissections at the inlet and outlet of the affected segment with evidence of either intraluminal or extravascular hematoma showing phasic systolic compression of the residual lumen. There have been no consistent variables, such as traditional cardiovascular risk factors, to predict where the PIER technique may be less successful.[18] Ouriel et al suggested that calcification in the wall of occluded vessels may predispose to subintimal failure.[19] Thus, some lesions may not be ideally approached via the subintimal technique but may necessitate ancillary devices for effective and minimally traumatic crossings. The Crosser catheter, which has a titanium, smooth-edge tip, is designed to recanalize resistant or calcified obstructions in blood vessels via mechanical and cavitational effects. Although 82% of our lesion crossing was purely intraluminal, three of the 17 patients (18%) studied showed diversion to the intimal/medial interface secondary to central lumen calcification. Despite this, no studied patient displayed a flow-limiting dissection, and both intraluminal and extravascular integrity appeared intact and unchanged in comparison with the reference segments. There was no significant hematoma or vessel distortion in any Crosser patient and no evidence of lumen compression.

Also noteworthy is the focal entry and exits of the Crosser. A benefit is seen with this catheter by not causing extension of the current lesion length. On subintimal angioplasty approaches, the re-entry may occur several centimeters distal to the recanalization point, which results in a significantly longer treatment segment.

Additionally, all patients showed signs of the created lumen having a connection with the collateral circulation in the occlusive segments, which may potentially allow for improved long-term results and limb viability. These collaterals are typically occluded and compressed using the subintimal angioplasty technique, as the new false lumen, which typically requires balloon-based intervention and stenting, seals off the collaterals that connect into the previous true lumen (Figure 9).

Lastly, we noted a pattern of medial and internal elastic laminal calcification that was scattered throughout the study segment in 53% (8 of 17) of the studied patients. This pattern is consistent with pathologic descriptions of Monckeberg's sclerosis but may be indicative of other pathologic processes, because Monckeberg's sclerosis is described as a small vessel disorder.[8] By IVUS, the scattered nature of the calcific deposits in the tunica media was reflected with a unique appearance showing echodense-banded plaques in the tunica media extending to the internal elastic membrane (Figure 1). Despite a highly echodense band being present, there appeared to be no discernable attenuation defect in the periadventitial

space behind it. In every instance, virtual histology showed the tunica media appearing as being fully calcified. What makes the appearance noteworthy is that every instance in which this Monckeberg pattern emerged by IVUS, the patient had a full intraluminal crossing with the Crosser catheter. Additional pathologic verification must be established before recognition of this pattern can be defined.

The intent of this article is to report the success rate of central lumen crossing using a specialized CTO crossing catheter. Clinical outcomes were not reported because this was not the authors' intent. Multiple atherectomy devices were used after passage through the lesion, and the clinical outcomes would not be representative of the Crosser catheter in isolation. With multiple strategies for endovascular interventions available (ie, percutaneous transluminal angioplasty/stenting vs debulking/percutaneous transluminal angioplasty), the search for the ideal approach to total arterial occlusions is ongoing. In the meantime, the tools and techniques that are currently available must continue to be tested to show superior outcomes to allow the best chance for successfully treating peripheral vascular occlusive disease.

Our results from this feasibility study will be tested in a prospective trial called the CENTRAL (Crosser Enters the Right Arterial Lumen) trial. This ongoing, 100-patient, United States multicenter trial will attempt to confirm the catheter's ability to maintain central lumen crossing through CTOs in the SFA. It will include 30-day symptom follow-up data.

CONCLUSION

In our preliminary experience from a large community hospital, the Crosser CTO catheter has a high success rate of intraluminal CTO recanalization with excellent preservation of the periadventitial space. The Monckeberg's sclerosis pattern appeared to provide a favorable characteristic to true lumen crossing and protection from vessel injury. Further investigation is needed to validate this interesting finding. Lastly, we will wait for the results of the CENTRAL trial to confirm our findings and demonstrate that this device may improve the success rate of intraluminal recanalization in these technically challenging lesions. ■

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