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◆CLINICAL INVESTIGATION ◆

Endovascular Treatment of Infrainguinal Chronic Total Occlusions Using the TruePath Device: Features, Handling, and 6-Month Outcomes

Subhash Banerjee, MD[1,2]; Karan Sarode, MA[1,2]; Thomas Das, BA[2]; Omar Hadidi, MD[2]; Rahul Thomas, MD[1,2]; Ariel Vinas, MD[1,2]; Puja Garg, PhD[2]; Atif Mohammad, MD[2]; Mirza S. Baig, MD[1,2]; Nicolas W. Shammas, MD[3]; and Emmanouil S. Brilakis, MD, PhD[1,2]

[1]Veterans Affairs North Texas Healthcare System, Dallas, Texas, USA. [2]University of Texas Southwestern Medical Center, Dallas, Texas, USA. [3]Midwest Cardiovascular Research Foundation, Davenport, Iowa, USA.

Purpose: To report experience with a recently approved peripheral chronic total occlusion (CTO) crossing device in the superficial femoral (SFA), popliteal, and below-the-knee (BTK) arteries.

Methods: Thirteen patients (all men; mean age 68.6±7.9 years) from the *XL*PAD registry (*ClinicalTrials.gov* identifier NCT01904851) were treated between April 2012 and August 2013 with the TruePath device after an unsuccessful guidewire crossing attempt. More than half of the patients had diabetes mellitus. Most lesions were TASC classification type C (n=5) or D (n=6), with mean lesion length 169.8±83.3 mm; 12 lesions were de novo and severely calcified. Procedure success was defined as successful revascularization of the CTO. Technical success was placement of a guidewire beyond the distal CTO cap into the true lumen without the need for a re-entry device.

Results: All CTOs were successfully crossed using the TruePath, but 3 subintimal recanalizations required the use of a re-entry device (77% technical success). Eight lesions were stented, while the remaining were treated with balloon angioplasty and/or atherectomy. Average fluoroscopy time was 41.1±18.3 minutes, during which a mean 200.0±46.2 mL of iodinated contrast were used (radiation dose area product 211.2±202.6 Gy*cm^2). There were no periprocedural complications. Significant improvement was seen in the 6-month ankle-brachial index (p=0.018) and Rutherford class (p=0.019). The 6-month clinically indicated target vessel revascularization rate was 8%.

Conclusion: TruePath facilitated successful crossing of infrainguinal CTOs following an unsuccessful guidewire recanalization, with significant improvement in symptoms and no complications.

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Key words: peripheral artery disease, chronic total occlusion, superficial femoral artery, popliteal artery, balloon angioplasty, stent, recanalization device, crossing device

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Corresponding author: Subhash Banerjee MD, 4500 S Lancaster Road (111A), Dallas, TX 75216 USA. E-mail: *Subhash.banerjee@va.gov*

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Chronic total occlusions (CTOs) of the infrainguinal arteries are present in nearly 50% of all patients selected for endovascular treatment of lifestyle-limiting claudication or critical limb ischemia (CLI).[1] Since crossing of peripheral CTOs remains the most significant impediment to successful percutaneous revascularization, a number of dedicated peripheral CTO crossing devices have recently been approved for clinical use. However, there are limited published reports on features, technical handling, and procedural outcomes with these devices. This report describes the initial experience of operators participating in a registry involving a newly approved peripheral CTO crossing device and describes the device features and key aspects for optimal handling, along with device limitations and outcomes in the lower limb arteries.

METHODS

The *XL*PAD registry (*ClinicalTrials.gov* identifier NCT01904851) was established in April 2012 to evaluate the success and 6-month major adverse events associated with the use of the TruePath CTO recanalization device (Boston Scientific, Natick, MA, USA) following an initial failed guidewire attempt in the infrainguinal arteries of patients undergoing treatment for claudication or CLI. This report involves 13 patients (all men; mean age 68.6±7.9 years) treated at two centers for CTOs in the superficial femoral (SFA), popliteal, and below-the-knee (BTK) arteries. Demographics and baseline characteristics derived from the registry are shown in Table 1. Twelve patients had symptoms classified as Rutherford category 2/3. Most of the lesions (n=10) were in the SFA. Twelve lesions were severely calcified de novo CTOs and one was an in-stent reocclusion. The average CTO length was 128.0±81.1 mm (range 39–289), and the mean total lesion length was 169.8±83.3 mm (range 29–341). According to the TASC (TransAtlantic Inter-Society Consensus) classification, 5 were type C and 6 were type D.

TABLE 1
Demographics and Baseline Characteristics

Demographics, risk factors, anticoagulation	
Age, y	68.6±7.9
Men	13
Hypertension	12
Diabetes mellitus	7
Hyperlipidemia	10
Tobacco use	13
Chronic kidney disease	3
Coronary artery disease	11
Prior revascularization	10
Aspirin	13
Clopidogrel	13
Warfarin	0
Rutherford categories 2/3/4 (mean)	2/10/1 (2.9±0.5)
ABI	0.6±0.3
Lesion characteristics	13 lesions
SFA proximal/mid/distal	3/5/2
Popliteal artery	2
Anterior tibial artery	1
Multi-level SFA	10
TASC type B/C/D	2/5/6
In-stent reocclusion	1
Severely calcified	12
CTO length, mm	128.1±81.1
Total length lesion, mm	169.8±83.3
Number of runoff vessels	2.2±0.6

Continuous data are presented as the means ± standard deviation; categorical data are given as the counts.
ABI: ankle-brachial index, SFA: superficial femoral artery, TASC: TransAtlantic Inter-Society Consensus, CTO: chronic total occlusion.

Study Device

The TruePath device is intended to have all the functionality of a guidewire in terms of steering and guidance, along with an increased ability to cross difficult occlusions. The proximal end of the device consists of a control unit, which has audiovisual feedback indicators that monitor the tip as it is navigating within the lumen (Fig. 1). Distal to the control unit is the motor housing, which contains a detachment mechanism that enables the addition of extra length guidewires and also an adjustable "torquer" that generates 1:1 torque response. Attached to the distal end of the motor housing is a hollow 0.018-inch, 165-cm-long nitinol guidewire that can be extended up to 335 cm with additional wires. The last 130 cm of the guidewire is hydrophilic-coated, allowing smooth intraluminal navigation; the wire diameter tapers

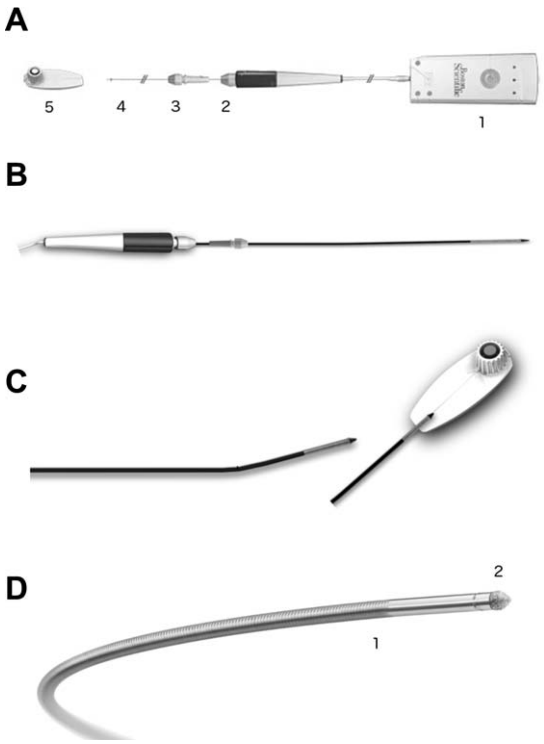

Figure 1 ◆ (**A**) The TruePath device features from proximal to distal end: (1) the control unit, (2) detachable housing, (3) adjustable torquer, (4) hydrophilic guidewire, and (5) distal tip reshaper (detached). (**B**) The torquer delivers 1:1 torque response, and attaches to a 165–cm–long, 0.018-inch nitinol hydrophilic-coated guidewire that tapers to 0.0096 inches over the distal 9 cm for optimized flexibility. (**C**) The distal tip reshaper bends the distal tip at a 15° angle. (**D**) The distal aspect of the device: (1) 3-cm radiopaque section and (2) 0.017-inch diamond-coated distal tip that rotates at 13,000 rpm.

along the last 9 cm (from 0.017 to 0.009 inches), providing greater flexibility toward the distal tip. The final 3 cm of the wire is a radiopaque section made of platinum tungsten coil and gold-plated distal tip housing. The highlight of the device is the diamond-coated distal tip, with a 0.017-inch profile that rotates at 13,000 rpm. In addition, the distal tip can be bent up to 15° to help avoid side branches and provisional subintimal re-entry. The TruePath is compatible with 0.018-inch catheters $\leq$135 cm long.

The device is advanced to the proximal CTO cap using a guide catheter or sheath (the TruePath is compatible with 0.018-inch catheters $\leq$135 cm long). Using the control unit, switching into "active mode" causes the distal tip to rotate, while "drilling mode" allows the device to pass through the proximal cap. The device then enters a non-rotating "passive mode" in which the position of the device and catheter can be readjusted in the true lumen, before returning to "active" and "drilling mode" to pass through the distal cap.

All crossing attempts with the TruePath device were made following an unsuccessful attempt lasting at least 10 minutes with a guidewire to either penetrate the proximal cap of the CTO and/or advance through half of the occluded segment. All cases involved a retrograde approach through the contralateral common femoral artery and a 45-cm, 6- to 8-F sheath. Adjunctive pharmacotherapy with antithrombin and antiplatelet drugs was at the discretion of the operator, as was the decision to perform balloon dilation, atherectomy, and/or stenting of the lesion.

Definitions

Lesion length was defined along the vessel segment having angiographic stenosis $>$70%, measuring the length of the CTO between the proximal and distal caps, often referred to as the critical lesion length of a CTO. A single CTO was defined by 100% angiographic occlusion or sequential occlusions separated by $\leq$2 cm in the SFA and popliteal arteries or a single occlusion separated by $\leq$1 cm with patent distal runoff in BTK vessels. Vascular calcification visible on angiographic views prior to contrast injection was classified as the presence of either isolated foci of calcification (mild), contiguous segments of calcification on one or alternating sides of the vessel (moderate), or contiguous calcification on both sides of the vessel (severe).[2] Angiographic data regarding lesion length and lesion characteristics were obtained from the analysis of diagnostic and procedural angiograms performed at the VA North Texas Clinical Angiographic and Ultrasound Core Laboratory.

Procedure success was defined as successful revascularization of the CTO. Technical success was defined as placement of a guidewire beyond the distal CTO cap into the true

TABLE 2
Procedure Characteristics and Outcomes

Procedure details	
Stent length, mm	114.7±40.2
Stent diameter, mm	6.2±0.41
Number of lesions stented	8
Subintimal re-entry device	3
IVUS guided	2
Post-procedure lumen diameter, mm	4.7±1.1
Reference vessel diameter, mm	5.0±1.2
Residual stenosis, %	12.1%±13.4%
Non-flow-limiting dissection	2
Flow-limiting dissection	0
Fluoroscopy time, min	41.1±18.3
Contrast volume, mL	200.0±46.2
Radiation dose area product, Gy*cm^2	211.2±202.6
Procedure duration, min	150.9±48.4
Heparin dose, units	8416±2056
Peak ACT, seconds	293.0±52.1
Outcomes	
Residual stenosis, %	12.1%±13.4%
Acute procedure success	13
Technical success	10
Rutherford category	1.7±1.2
ABI postprocedure/6 months	0.9±0.1/0.9±0.2
Dissection (non-flow-limiting)	2
Access site hematoma (>5 cm)	0
Amputation	0
Death	0
Repeat revascularization at 6 months	1

Continuous data are presented as the means ± standard deviation; categorical data are given as the counts.
IVUS: intravascular ultrasound, ACT: activated clotting time.

lumen of the targeted vessel, confirmed by angiographic contrast injection into the distal vessel. The need for a re-entry device indicated a technical failure.

Procedural safety was assessed by major adverse events reported from the day of the procedure through 30 days post procedure. These events included all-cause death, unplanned major amputation, perforation requiring endovascular or surgical intervention, unplanned surgical intervention, or large (>5-cm-diameter) access site hematoma. Continuous data are presented as the means ± standard deviation; categorical data are given as the counts.

RESULTS

Procedure success was achieved in all lesions, while technical success with the TruePath was obtained in 10 cases following an initial unsuccessful guidewire attempt. In 3 cases, the TruePath entered the subintimal space, and a re-entry device was used to gain true lumen access. In 2 lesions, intravascular ultrasound was used to confirm distal target vessel true lumen access. After successfully crossing the CTO, 8 lesions (all in the proximal and mid SFA) received self-expanding nitinol stents, while the rest were treated with balloon angioplasty and/or atherectomy. The mean stent dimensions were 114.7±40.2 mm long and 6.2±0.41 mm in diameter. Mean procedure duration was 150.9±48.4 minutes. The average fluoroscopy time was 41.1±18.3 minutes, during which a mean 200.0±46.2 mL of iodinated contrast were used (radiation dose area product 211.2±202.6 Gy*cm^2).

There were no periprocedural complications, though 1 patient had a small (<5 cm) access site hematoma. Average follow-up was 5.8±5.0 months (1 patient had <1 month follow-up), during which symptoms assessed by mean Rutherford category improved (2.9±0.5 to 1.7±1.3, p=0.019) and so did the ankle-brachial indices (ABI) (0.6±0.3 to 0.9±0.3, p=0.018). One (8%) patient experienced a stent thrombosis 1 month after the procedure, which required a clinically indicated repeat endovascular intervention. Of note, the patient initially had a TASC type D lesion and the longest CTO length of all at 341 mm.

DISCUSSION

The difficulty in crossing infrainguinal CTOs with a traditional guidewire has prompted the development of several crossing devices, which have been approved for clinical use in the US.[3] Inability to penetrate the proximal cap, navigate across side branches or bridging collaterals, and re-enter the distal true lumen are the more important mechanisms of failure.[3] Often, these devices have been deployed following repeated recanalization failures using traditional guidewires. Many devices have been shown to improve the success rate of CTO crossing by a moderate

TABLE 3
Recanalization Device Comparison

Device	Success	Location	Lesion Length, mm	Method of Use
Wildcat	75/84	SFA: 75 Popliteal: 9 BTK: 4	174.0±96.0	Post GW failure
Frontrunner[7]	40/44	Aortoiliac: 26 SFA: 16 Popliteal: 2	95.0±70.0	Post GW failure
Frontrunner[8]	21/22	SFA: 20 Popliteal: 2	180.0±101.0	Post GW failure
Crosser	56/73	Aortoiliac: 10 SFA: 26 FP: 10 Popliteal-tibial: 6 BTK: 21	131.0±89.0	Conditional upon adequate proximal stump characteristics
Safe-Cross	18/18	Iliac: 3 SFA: 14 Popliteal: 1	224.0±140.0	Post GW failure
Enabler	32/37	SFA: 32 Popliteal: 5	86.0	Primary
TruePath[14]	65/85	SFA: 61 Popliteal: 6 Tibial: 11 FP: 7	166.5±107.4	Post GW failure

Continuous data are presented as the means ± standard deviation if available; categorical data are given as the counts.
SFA: superficial femoral artery, GW: guidewire, BTK: below the knee, FP: femoropopliteal.

40% to 60% while at the same time decreasing procedure times and radiation exposure to the patient and operator.[4] However, the success of CTO recanalization with established devices cannot be conferred on new models, so each new CTO crossing device needs to be studied in the setting of an initial failed crossing attempt with a guidewire.[5]

There have been numerous published studies highlighting the efficacy of novel CTO crossing devices (Table 3) over the wire-catheter approach. Avinger's Wildcat catheter wields manually rotating wedges on the distal tip that channel through the occlusion. The CONNECT (Chronic Total Occlusion Crossing with the Wildcat Catheter) trial treated 84 lesions measuring a mean 174±96 mm long with this device after initially failing with a guidewire; 75 (89%) of these cases exhibited successful device crossing, but 15 (20%) necessitated the use of a re-entry device.[6] The Frontrunner XP from Cordis Endovascular utilizes a hinged jaw on the distal tip that can be manually opened, closed, and rotated to displace the occlusive material, permitting advancement to the distal true lumen. One clinical trial used this device in 44 procedures after an initial guidewire attempt was unsuccessful; 40 (91%) iliofemoral arteries with a mean lesion length of 95.0±70.0 mm were successfully crossed.[7] Another trial focusing on femoropopliteal arteries used the Frontrunner XP after initially failing with a guidewire, successfully crossing 21 (95%) of 22 TASC type D lesions with mean lesion length of 180.0±101.0 mm.[8]

Flow-Cardia's Crosser utilizes high-frequency vibrational energy to fragment fibrous calcifications characteristic of occlusions, leaving the arterial wall intact.[9] In a recent study, 56 (77%) of 73 peripheral CTOs averaging 131.0±89.0 mm in length were crossed successfully without the need for a re-entry device.[10] However, only the CTOs with an entry stump morphology amenable to Cross-

er catheter tip positioning were selected, which introduced selection bias.

Another novel treatment for occlusive infrainguinal vessels is the Safe-Cross from Intraluminal Therapeutics, which guides the interventionist through the occlusion by interpreting the infrared reflectivity of the material encountered within the artery and transmitting this audiovisual data.[11] A single-center study reported a 100% success rate in crossing all 18 CTOs averaging 224.0±140.0 mm long.[12] Lastly, the Enabler CTO crossing device from EndoCross uses a balloon anchoring mechanism for controlled advancement of a guidewire. Employed as the primary crossing device, this system was successful in traversing 32 (86%) of 37 femoropopliteal lesions averaging 86.0 mm in length.[13]

The efficacy of these devices for crossing peripheral CTOs, whether used in a primary or bailout strategy, and their cost-effectiveness have not been addressed in any large-scale published studies. Our study exhibits similar lesion lengths/locations, Rutherford categories, and TASC types compared to the aforementioned studies; however, ours contains a higher frequency of severely calcified lesions and a failed guidewire attempt in long infrainguinal CTO lesions. The average contrast volume of ~200 mL in our study reflects not only the complexity of lesions but also the imaging requirements to align the device for distal CTO reconstitution, as well as use of reentry devices and multiple stent implantations.

While using the TruePath in peripheral CTOs, our experience suggests that a gentle forward pressure on the device through the hand-held torquer facilitates easy advancement through the CTO. Following advancement of the TruePath, forward movement of the catheter provides greater support to the tip and facilitates crossing. The device tip should be shaped at an angle using a specially provided shaping tool if there is a large side branch at the proximal cap. Moreover, restrictive motion of the device or deviation into an extraluminal space is indicated by an audiovisual signal; at that point, the device can be easily retracted and advanced on a new path using the steerable torquer, with a minimal risk of vessel perforation. Figure 2 depicts advancement of the TruePath device through a CTO spanning the femoropopliteal segment and anterior tibial artery.

This initial experience with the TruePath device illustrates its efficacy in crossing primarily femoropopliteal CTOs resistant to conventional guidewire techniques. In this setting, the TruePath tracked into the subintimal plane in 3 cases. However, despite the prior guidewire attempt, it did not create a large subintimal space, facilitating the use of a re-entry device. In the recently published multicenter, nonrandomized ReOpen study,[14] the TruePath had a technical success rate nearly identical to ours. We believe the low-crossing profile of the device, potential ability to access microchannels in a CTO, along with the visual guidance provided by the controller unit may allow operators to limit device deviation into the subintimal or extravascular space.

Two potential shortcomings of the device are the power of its drill and steerability of the device, as it will tolerate only a 15° bend. However, using the TruePath in conjunction with an angled support catheter or a more supportive sheath might assist an operator in controlling the device. In the ReOpen study,[14] the TruePath had an excellent safety profile, achieving a 99% freedom from clinically relevant perforation.

Limitations

The cases in this series show that the TruePath may be effective in treating complex and technically challenging peripheral CTOs that cannot be crossed with traditional guidewire techniques. However, given the small number of patients and limited follow-up, a larger study is needed to test its utility in complex, multilevel CTOs. Additionally, previous crossing attempts had been made on all of the lesions before the TruePath was deployed, so this study does not provide information on the effectiveness of the device as an initial approach in crossing peripheral CTOs. The study also does not compare the effectiveness of subintimal angioplasty to intraluminal crossing of the CTO. Finally, these cases do not provide an assessment of

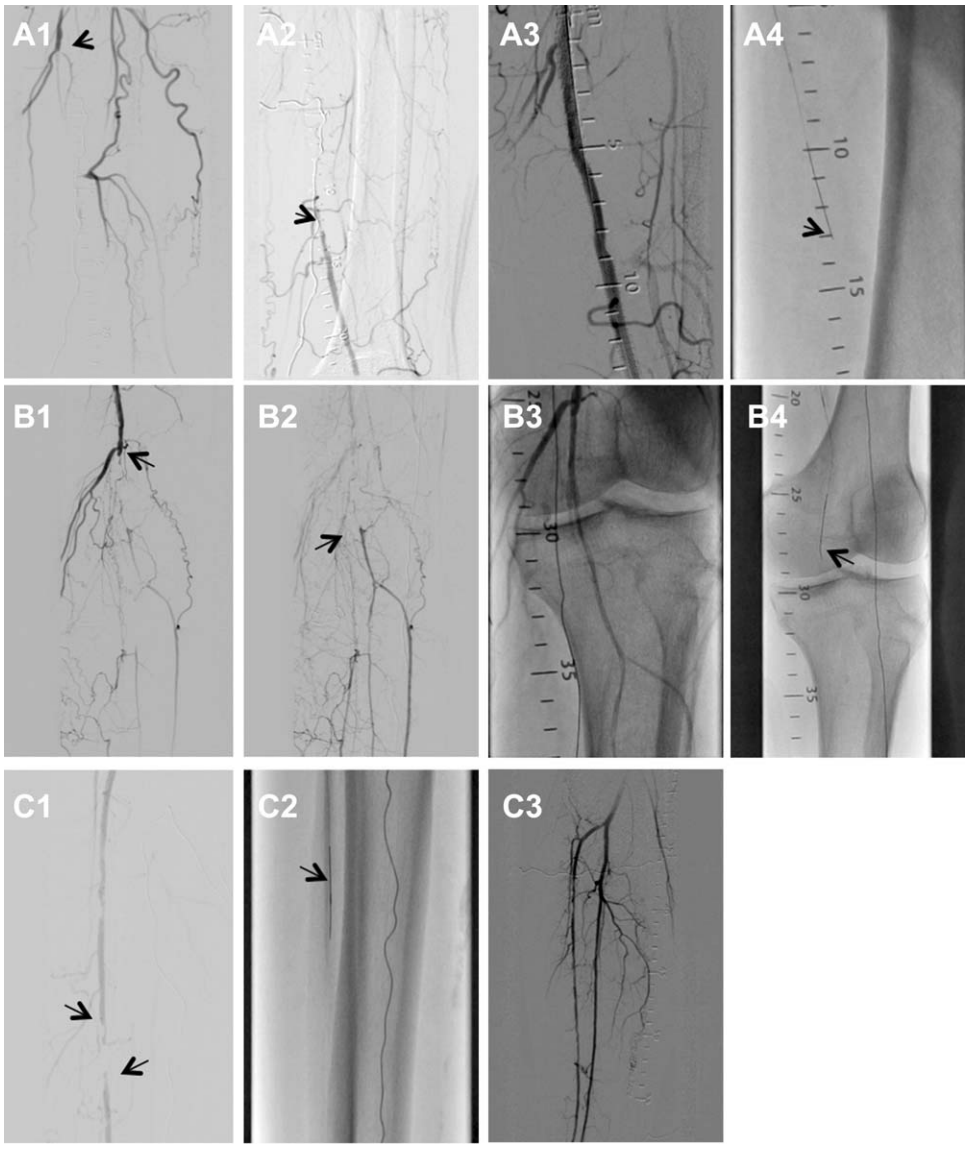

Figure 2 ◆ The arrows indicate (**A1**) the proximally occluded left SFA and the (**A2**) distal reconstitution of left SFA occlusion. (**A3**) The TruePath device is advanced through the occluded segment and (**A4**) the final angiographic result after stent deployment (arrow). The arrows indicate (**B1**) the proximally occluded popliteal artery and (**B2**) distal reconstitution. (**B3**) The TruePath device is advanced through the occluded segment and (**B4**) the final angiographic result after stent deployment (arrow). (**C1**) The arrows indicate the proximal occlusion and distal reconstitution of the anterior tibial artery. (**C2**) The TruePath device is advanced through the occluded segment and (**C3**) the final angiographic result after revascularization.

the TruePath device compared to other CTO crossing devices and techniques.

Conclusion

This report highlights the ability of the TruePath peripheral CTO crossing device to facilitate successful crossing of infrainguinal CTOs following an initial unsuccessful guidewire crossing attempt. Patients experience significant improvement in symptoms, and there were few complications. Overall, these cases suggest that the TruePath CTO device provides another safe and effective option for

crossing peripheral CTOs after conventional guidewire techniques have failed.

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