◆ CLINICAL INVESTIGATION ◆

Recanalization of Femoropopliteal Chronic Total Occlusions Using the ENABLER-P Balloon Catheter System

Thomas Zeller, MD[1]; Antonio M. Kambara, MD[2]; Samuel M. Moreira, MD[2]; Eliyahu Atar, MD[3]; Alexander Chulsky, MD[3]; Yoav Turgeman, MD[3]; Sebastian Sixt, MD[1]; Gunnar Tepe, MD[4]; Aljoscha Rastan, MD[1]; and Maurice Buchbinder, MD[5]

[1]Herz-Zentrum, Bad Krozingen, Germany. [2]Dante Pazzanese, Sao Paulo, Brazil. [3]Emek Medical Center, Afula, Israel. [4]Klinikum Rosenheim, Rosenheim, Germany. [5]Foundation for Cardiovascular Medicine, La Jolla, California, USA.

Purpose: To evaluate the safety and effectiveness of a new system to facilitate intraluminal advancement of conventional guidewires through chronic total occlusions (CTO) of the superficial femoral artery (SFA) and popliteal artery.

Methods: The ENABLER-P Balloon Catheter System uses a unique balloon-anchoring mechanism and an automated balloon inflation device for steady, controlled advancement of a standard non-hydrophilic guidewire. The system was evaluated in 37 patients (22 men; mean age 67 years (range 41–87) with femoropopliteal CTOs averaging 86 mm in length (range 10–340). The device was used in a variety of occlusions, including heavily calcified, long, and fibrotic lesions. After successful guidewire recanalization facilitated by the system, occluded arterial segments were treated conventionally with balloon angioplasty, atherectomy, and stents as appropriate.

Results: The primary endpoint of successful crossing was achieved in 86% (32/37) of the overall study population. The average activation time for successful crossing was 5.3 minutes (range 0.4–22). Of the 32 cases successfully crossed with the ENABLER-P System, all but 1 was successfully recanalized. One (3%) device-related complication occurred when the wire was advanced into a side branch when treating a 300-mm-long flush ostial SFA occlusion; the resulting perforation was managed with a covered stent without further sequelae.

Conclusion: This novel system, which provides enhanced force to a standard guidewire tip for controlled intraluminal advancement, is a promising device for the treatment of peripheral CTOs.

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Key words: peripheral artery disease, superficial femoral artery, popliteal artery, femoropopliteal segment, chronic total occlusion, guidewire, angioplasty, balloon catheter, recanalization

Peripheral artery disease (PAD) is often characterized by complex high-grade atherosclerotic obstruction and eventual occlusion. Revascularization strategies include bypass surgery and endovascular techniques, such as balloon angioplasty, atherectomy, excimer laser ablation, and stent implantation.[1,2] All these modalities are aimed at improving tissue perfusion and thereby reducing or eliminating symptoms.

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Corresponding author: Prof. Dr. Thomas Zeller, Herz-Zentrum Bad Krozingen, Südring 15, D-79189 Bad Krozingen, Germany. E-mail: *thomas.zeller@herzzentrum.de*

Chronic total occlusion (CTO), defined as arterial obstruction lasting >30 days, is a frequent finding in patients with advanced PAD.[3,4] The most common percutaneous technique for crossing CTOs utilizes conventional hydrophilic or stiffened guidewires, which are navigated to the occlusion and then manually advanced by the operator, with or without dedicated support catheters. The success rates of endovascular CTO recanalization procedures are highly variable and largely dependent on lesion morphology[5–8] and operator experience. The main reasons for failure of CTO recanalization are the inability to cross the occlusion with a guidewire or the inability to re-enter the true lumen following subintimal tracking.[9,10]

Advancements in imaging technologies have improved CTO crossing techniques, rendering them more effective in some complex lesions. Long or heavily calcified lesions are often treated with subintimal angioplasty, a technique that has revolutionized the treatment of above-the-knee arterial occlusions.[11,12] While this type of procedure provides an effective alternative to surgical revascularization, it has significant limitations. Subintimal recanalization can often lead to uncontrolled distal dissection with involvement of the first popliteal segment, requiring extensive treatment and the stenting of longer segments than originally intended. Also, this technique may require the adjunctive use of somewhat unpredictable reentry devices.[13–15] Loss of supporting collaterals,[4] increased radiation exposure, and the hazard of renal failure have all been described as potential complications associated with such complex percutaneous interventions. In addition, aggressive guidewire manipulation through highly resistant plaque risks vessel perforation, which accounts for a significant percentage of failures to recanalize such arteries.

Dedicated CTO devices can facilitate guidewire crossing and provide more reliable procedural success with fewer complications. One such new device has been designed to facilitate CTO crossing by imparting increased tip force and better pushability to standard commercial non-hydrophilic guidewires. To study this mechanical advantage, aprospective, single-arm feasibility study [Accessing Peripheral Occluded LesiOns (APOLO)] was undertaken to evaluate a new system for endoluminal crossing of femoropopliteal occlusions.

METHODS

Study Design

The APOLO study was a first-in-man safety and effectiveness trial of the ENABLER-P Balloon Catheter System (EndoCross Ltd., Yokneam, Israel) performed by 10 operators at 4 clinical sites: Herz-Zentrum, Bad Krozingen, Germany; Dante Pazzanese, Sao Paulo, Brazil; Emek Medical Center, Afula, Israel; and Klinikum Rosenheim, Rosenheim, Germany. The protocol, approved by the centers' respective ethics committees, was designed to test the ability of the ENABLER-P system to facilitate guidewire crossing of arterial occlusions in the above-knee femoropopliteal segment. Patients were eligible for the study if they had chronic PAD (Rutherford-Becker categories 2–5) and occlusions up to 15 cm long in the superficial femoral artery (SFA) and proximal popliteal artery (PA). Patients were ineligible if they were taking oral anticoagulants, had a history of contrast allergy, or had undergone attempted treatment of the CTO within the prior 3 months (to prevent a guidewire from entering dissection planes created by prior recanalization attempts).

Safety was defined as a <10% rate of procedure-related or device-related serious adverse events (clinical perforation or major dissection requiring surgery, blood transfusion, or a >2-g/L drop in hemoglobin). Performance efficacy was based on successful crossing of the CTO without device-related adverse events. In addition, the durations of ENABLER-P System activation and the overall procedure (from catheter anchoring to catheter withdrawal) were measured. Results are presented for all enrolled patients and segregated according to those treated per protocol and those treated outside the protocol (extended use).

Study Device

The ENABLER-P Balloon Catheter system consists of 2 main components (Fig. 1): a

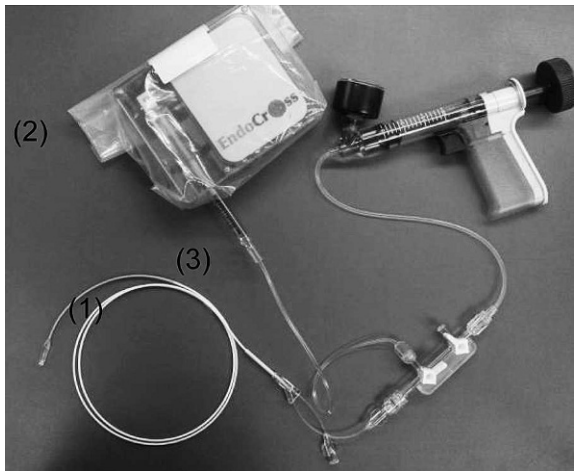

Figure 1 ◆ The ENABLER-P Balloon Catheter System is composed of an ENABLER-P Catheter (1) and a Pressure Control Unit (2) delivered in a sterile cover. A manual inflator is used to inflate the balloon to an anchoring pressure of 2 atmospheres (not part of the system), and a 1-mL syringe delivers the pressure from the control unit to the balloon (3).

specialized balloon catheter and a pressure control unit (PCU). The dual-lumen balloon catheter is designed to accommodate a 0.035-inch guidewire and can be used with 6-F or 7-F introducer sheaths. The noncompliant balloon, with radiopaque markers at the distal and proximal ends, has a ''grip tube'' within the distal portion of the central lumen that advances the guidewire.

This guidewire advancement mechanism is unique to the ENABLER-P Balloon Catheter System. After the ENABLER-P catheter is advanced toward the occlusion, the balloon is manually inflated to anchor it against the vessel wall a few millimeters proximal to the lesion, which supports the guidewire within the central grip tube and maintains its intraluminal orientation (Fig. 2A). The PCU is then activated to set in motion an automated cyclical modulation of balloon pressure. As the pressure in the anchored balloon rises, the balloon elongates, and the grip tube tightens around the wire. As the pressure increases further (up to 6 atmospheres), the balloon elongation advances the gripped guidewire while the balloon remains in place (Fig. 2B). The balloon pressure is then lowered, and the balloon returns to its original state, releasing its grip on the guidewire while maintaining its anchorage to the vessel wall. With each inflation, the guidewire advances up to 3 mm. With continuous activation of the PCU, the cycle repeats 2.5 times per second until disengaged. The physician maintains control over the guidewire and is able to manually retract, advance, or torque the wire at all times.

Crossing Procedure

Patients were prepared for the catheterization procedure according to standard hospital protocols, including local anesthesia at the access site, insertion of an introducer sheath or a guiding sheath, and navigation with a 0.035-inch guidewire. Lesion access was obtained using the contralateral or ipsilateral antegrade approach unless a blunt ostial SFA occlusion prevented balloon anchoring proximal to the occlusion, then a retrograde approach was used. The ENABLER-P balloon catheter was inserted via the sheath over a conventional hydrophilic 0.035-inch guidewire and advanced to the target vessel (5–10 mm proximal to the lesion). Prior to inflation of the balloon and anchoring, the hydrophilic guidewire was exchanged for a standard non-hydrophilic guidewire (Cordis Emerald; Cordis, a Johnson & Johnson company, Miami Lakes, FL, USA), which protruded a few millimeters beyond the catheter tip. The balloon was inflated, and contrast was injected to verify its anchorage on the vessel wall. The PCU was then activated to advance the wire as described above. Following successful crossing of the guidewire, the ENABLER-P catheter was withdrawn, leaving the guidewire in place. Patients then underwent standard treatment including balloon dilation, atherectomy, and/or stenting as required. Patients were monitored for 24 hours or until discharge.

Patient Cohort

Thirty-seven patients (22 men; mean age 67 years (range 41–87) presenting with chronic PAD and a femoropopliteal occlusion were enrolled in this study. Twenty-two patients were treated per protocol, while 15 patients

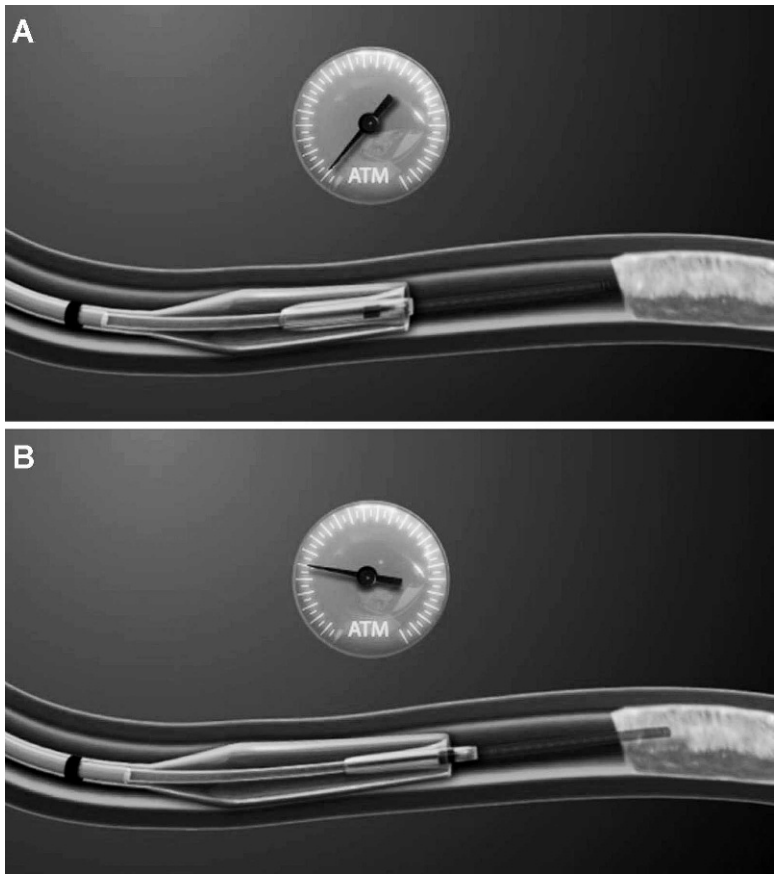

Figure 2 ◆ (**A**) Manual balloon inflation proximal to the target lesion anchors the catheter, which supports the guidewire and maintains intraluminal alignment. (**B**) System activation results in controlled balloon inflation-deflation, generating repeated cycles of the guidewire grip-advance-release mechanism.

had occlusions >15 cm long, which placed them in the ''extended use'' category for analysis. About 40% of the patients were current smokers (Table 1), and nearly a third (30%) had diabetes. The majority of the lesions were in the SFA (86%). Target vessel diameter was 4 to 6 mm and occlusion length ranged from 10 to 340 mm (average 86). Visual estimation by physicians during treatment classified 70% of the occlusions as moderately or severely calcified. Of the 37 occlusions treated, 21% were refractory to conventional guidewire attempts or had failed previous angioplasty attempts.

RESULTS

A contralateral approach was used in the majority (80%); 1 (3%) case was successfully recanalized using a retrograde popliteal approach (Table 2). Device success, defined as successful guidewire crossing, was achieved in 32 (86%) of the 37 cases. Although guidewire crossing using the ENABLER-P system was unsuccessful in 5 (14%) patients, recanalization was subsequently achieved in 3 of the 5 cases, resulting in an overall treatment success rate of 92% (34/37). Of the 32 cases successfully crossed with the ENABLER-P System, all but 1 was successfully recanalized.

In the 3 clinically unsuccessful cases, the interventions were not completed due to non-device-related adverse events: 2 perforations occurred during the use of conventional catheters following the removal of the ENABLER-P catheter and 1 dissection occurring during the use of a conventional guide-

TABLE 1
Baseline Patient Demographics and Lesion Characteristics

	Overall Experience (n=37)	Per Protocol (n=22)	Extended Use (n=15)
Demographics and risk factors			
Age, y	67.5 (41–87)	68.5 (41–87)	66.2 (54–84)
Men	22 (60%)	13 (59%)	9 (60%)
Diabetes	11 (30%)	7 (32%)	6 (40%)
Hypertension			
Controlled	31 (84%)	20 (90.8%)	11 (73%)
Uncontrolled	3 (8%)	1 (5%)	2 (13%)
Hyperlipidemia			
Controlled	23 (62%)	14 (64%)	9 (60%)
Uncontrolled	2 (5%)	1 (5%)	1 (7%)
Smoking	15 (40%)	9 (41%)	6 (40%)
Lesion characteristics			
SFA	32 (86%)	17 (77%)	15 (100%)
Popliteal	5 (14%)	5 (23%)	0
Length, mm	86 (10–340)	66 (10–150)	116 (30–340)
Calcification			
None	8 (22%)	4 (18%)	4 (27%)
Mild	3 (8%)	1 (5%)	2 (13%)
Moderate	14 (38%)	10 (45%)	4 (27%)
Severe	12 (32%)	7 (32%)	5 (33%)

Continuous data are presented as the means (range); categorical data are given as the counts (percentage).
SFA: superficial femoral artery.

wire prior to insertion of the ENABLER-P catheter. Additional non-device-related events included vessel dissection (n=7), embolism (n=1), infection (n=1), puncture site hemorrhage (n=1), and hypertension (n=1).

In the subgroups, 2 attempts to deliver the wire in the per-protocol group were not technically successful. In 1, the wire could not penetrate the proximal cap, resulting in subintimal guidewire positioning; the patient was successfully treated with distal re-entry. In the other case, there was difficulty in crossing the distal cap. The ENABLER-P balloon catheter was removed, but vessel perforation occurred following adjunctive angioplasty. A subintimal approach was unsuccessful due to inability to re-enter the true lumen.

In the extended-use group, 3 wire crossings were unsuccessful. In 1, the balloon could not be anchored due to a large vessel diameter; in another, the guidewire entered a false lumen prior to balloon anchoring. The third case involved a device-related perforation in a 77-year-old woman who was enrolled (despite apparent protocol deviation) with a flush ostial SFA occlusion that measured 300 mm in length. The guidewire was advanced into a side branch in a curved segment of the proximal SFA, which was not immediately recognized. A covered stent was deployed to seal the perforation, and the patient was discharged without report of further complications.

The average duration of ENABLER-P system activation was 5.3 minutes (range 0.4–22), with a mean overall procedure duration from ENABLER-P catheter anchoring to withdrawal of 14.7 minutes (range 1–44).

DISCUSSION

Successful luminal crossing of peripheral CTOs continues to be a challenge in percutaneous revascularization procedures. Recanalization of complex disease is generally time-consuming, requires a high contrast load, and is often associated with increased radiation exposure when compared to other (non-CTO) endovascular procedures. Maintaining luminal

TABLE 2
Crossing Results

	Overall Experience (n=37)	Per Protocol (n=22)	Extended Use (n=15)
Successful guidewire crossing	32 (86%)	20 (91%)	12 (80%)
Crossing parameters			
Ipsilateral approach	6 (16%)	5 (23%)	2 (13%)
Contralateral approach	30 (81%)	17 (77%)	12 (80%)
Retrograde approach	1 (3%)	0	1 (7%)
System activation duration, min	5.3 (0.4–22)	5.3 (0.5–20)	5.3 (0.4–22)
Procedure duration,* min	14.7 (1–44)	12.7 (1–44)	17.3 (2–38)
Adverse events			
Procedure-related			
Dissection	7 (19%)	5 (23%)	2 (13%)
Perforation	3 (8%)	2 (9%)	1 (7%)
Other	4 (10%)	2 (9%)	2 (13%)
Device-related			
Dissection	0	0	0
Perforation	1 (3%)	0	1 (7%)
Other	0	0	0
Serious†			
Procedure-related	1 (3%)	0	1 (7%)
Device-related	0	0	0

Continuous data are presented as the means (range); categorical data are given as the counts (percentage).
* From ENABLER catheter anchoring to withdrawal.
† Perforation or major dissection requiring surgery, blood transfusion, or a >2-g/L drop in hemoglobin.

guidewire positioning distal to the occlusion is critical for overall procedural success.

A number of methods have been developed to facilitate guidewire crossing of CTOs, including mechanical crossing devices (e.g., Frontrunner[16,17]) and devices using various types of energy, such as radiofrequency (e.g., Crosser[18,19]) and the excimer laser.[20,21] A wide variation in success rates has been reported for these techniques to date.

Subintimal recanalization with distal re-entry has been proposed as a solution to the inability to achieve true luminal crossing of occluded vessels, particularly in long and complex lesions.[11,22] As Ko et al.[12] noted, studies have reported technical success rates ranging from 74% to 92%; however, the ability to re-enter the true lumen of the target vessel remains a limitation. These techniques may cause uncontrolled guidewire advancement distal to the target lesion, resulting in subintimal angioplasty or stenting beyond the occluded segment.[15] Re-entry can be relatively unpredictable and may occur distal to significant collaterals, which could jeopardize the limb if there is recurrent obstruction in the treated segment.

The use of re-entry devices may assist in achieving a true luminal position distal to the occlusion following subintimal guidewire advancement.[13,23,24] However, these devices have limitations, such as difficulty in tracking the device over the guidewire or through the lesion; a steeply angled aortic bifurcation might prevent these systems from crossing the bifurcation due to the stiffness of the catheter tip. Moderate to severe calcification at the site of re-entry is a significant predictor for re-entry failure.[14] The ENABLER-P Balloon Catheter System was developed to address some of these shortcomings by facilitating luminal crossing of CTOs using conventional guidewires.

The system's traditional catheter design with novel balloon technology, combined with a standard off-the-shelf guidewire, provides the physician with a familiar tool that does not interrupt the flow of the procedure and shortens the learning curve. When activated, the ENABLER-P technology mimics the

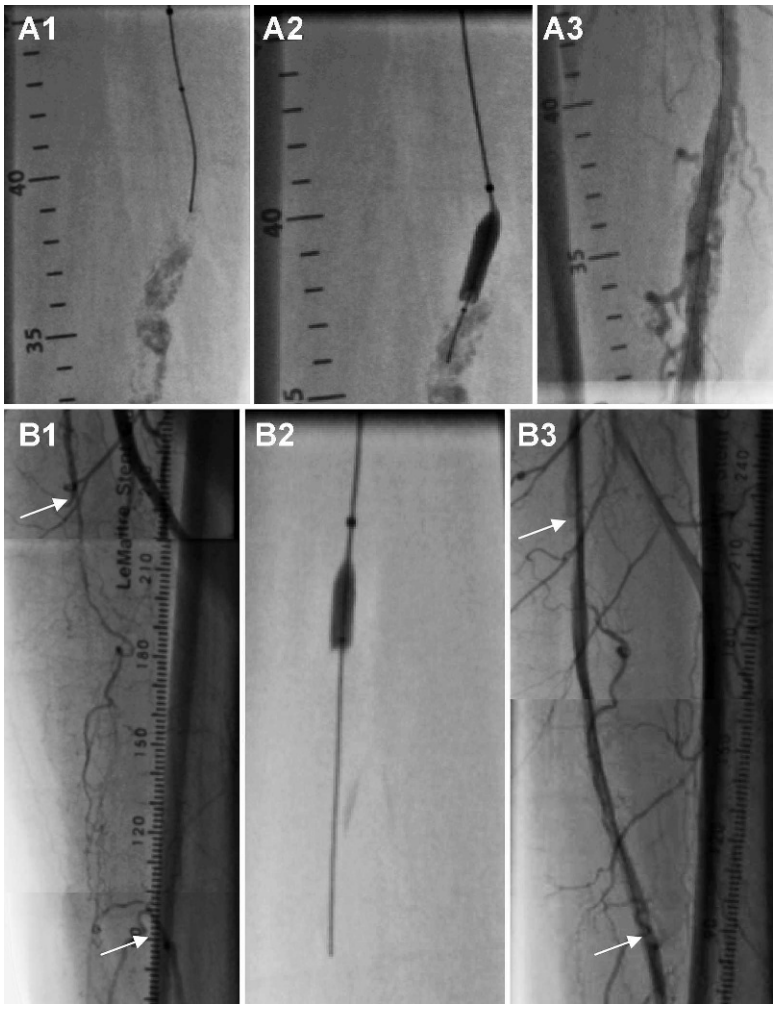

Figure 3 ◆ Occlusions treated with the ENABLER-P Balloon Catheter System. (**A1**) A 40-mm, highly calcified SFA occlusion has a 0.035-inch guidewire advanced by the ENABLER-P Balloon Catheter System. (**A2**) The distal marker band protrudes from the balloon tip during the balloon elongation phase. Blood flow is restored after dilation with 4-mm and 6-mm balloons. The system was activated for 8 minutes. (**A3**) Once 90% of the occlusion was successfully traversed with the ENABLER-P Balloon Catheter System, the operator switched to a 0.018-inch guidewire to successfully cross the remainder of the occlusion. (**B1**) A 100-mm SFA occlusion in which the ENABLER-P Balloon Catheter System was anchored 50 mm proximal to the occlusion due to severe stenosis of the vessel. Arrows indicate the proximal and distal occlusion caps. (**B2**) The remote anchoring did not impact the effectiveness of the device, and the occlusion was crossed with 3 minutes of system activation. (**B3**) Result after balloon angioplasty.

gripping, advancing, and releasing motion of the physician's fingers on the guidewire at the access site, with the additional benefit of applying enhanced force in close proximity to the occlusion. The mechanism provides controlled repetitive movements, preventing guidewire thrusting that may result from aggressive guidewire manipulation and lead to perforation or dissection. Unlike other CTO crossing devices that utilize radiofrequency or laser energy, the traditional balloon technology inherent in the ENABLER-P system eliminates the need for any capital equipment investment. Moreover, the technology is potentially less expensive compared to current crossing devices.

Study physicians using the ENABLER-P balloon system reported that the intraluminal position was maintained as the guidewire progressed through the lesion, even in curvilinear and challenging anatomies. Distal true luminal positioning was achieved without the need for re-entry devices. This luminal alignment, coupled with the significantly enhanced tip force and controlled wire advancement, facilitated successful crossing of severe and complex lesions, including long, highly calcified, and highly fibrotic lesions (Fig. 3).

As with traditional balloon dilation catheters used to treat vascular narrowing, the size of the ENABLER-P balloon should approximate that of the target vessel. Otherwise, the balloon cannot anchor properly to the vessel wall, as was illustrated by 1 case in which the system was ineffective because the balloon diameter was too small. In the same manner, the importance of an adequate anchoring zone for the ENABLER-P balloon was highlighted by the single device-related perforation that occurred during the treatment of a 300-mm flush ostial SFA occlusion. When faced with an ostial occlusion, a retrograde approach may be applied, as was successfully performed during the revascularization of a 180-mm SFA occlusion treated via the popliteal artery. If the target vessel is severely stenosed, predilation of the stenosed segment proximal to the occlusion may assist in establishing an appropriate anchoring zone.

Limitations

The study population was small and nonrandomized, and no control group was specified in the study design. Although one fifth of the patients treated in this study had failed prior standard treatment, the ENABLER-P system was used as first-line treatment in the majority of cases. This was consistent with the study design, which did not seek to assess the system as a secondary tool following standard guidewire failure because these attempts often lead to subintimal entry that may reduce the effectiveness of the device. Finally, of the 10 operators who took part in the study, most had done fewer than 5 cases with the device and so could be considered novel users. This bias could have been detrimental were it not for the ease of use and the short learning curve of the ENABLER-P Balloon Catheter System.

Conclusion

In this first-in-man experience, the ENABLER-P Balloon Catheter System appears to be safe and effective for the recanalization of femoropopliteal occlusions. The results of this small observational study demonstrate that the ENABLER-P Balloon Catheter System is a unique and promising device for the treatment of complex CTOs in peripheral arteries.

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