Lower Extremity CTO Crossing With the SABER™ Catheter

Two case reports showing initial experience with the SABER™ Catheter for the treatment of chronic total occlusions.

BY J.A. MUSTAPHA, MD

Chronic total occlusions (CTOs) represent a major obstacle for the treatment of lower extremity vascular disease. The SABER™ PTA Dilatation Catheter (Cordis Corporation) provides a new molded tip design, a dual-layer hydrophilic coating, and a low-profile body to enable a smooth crossing and a high burst pressure rating for the dilatation of tight lesions. An offering of 2- to 10-mm diameters and 20- to 300-mm lengths allows treatment of a wide range of iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal artery lesions.

SABER™ CATHETER CASE STUDY ONE

The patient was a 67-year-old obese man with a medical history of peripheral vascular disease, hypertension, tobacco use, and hypercholesterolemia. Three years before, the patient underwent right femoropopliteal bypass with a good outcome and complete resolution of his symptoms (Rutherford class 3 to Rutherford class 0).

At 8 months after surgical intervention, the patient developed recurrent lower extremity claudication, categorized as Rutherford class 3, with the right worse than the left. The symptoms continued, and the patient presented for evaluation. At presentation, the right lower extremity ankle-brachial index (ABI) was 0.74, and the toe-brachial index (TBI) was 0.53; for the left lower extremity, ABI was 0.99 and TBI was 0.81.

A diagnostic angiogram (Figure 1) was obtained via access of the left radial artery. This showed an occluded right SFA at the mid-segment that reconstituted in the distal popliteal artery at the level of P3 with three-vessel runoff (Figure 2). Further evaluation determined that the patient was not a suitable candidate for repeat vascular

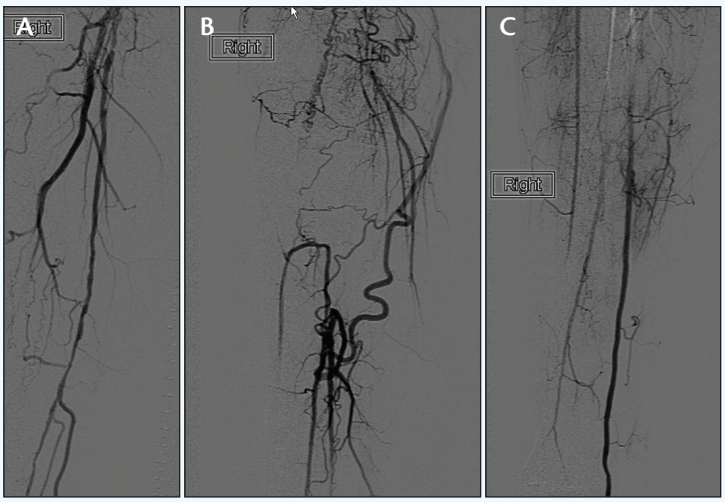

Figure 1. Initial diagnostic angiogram showing proximal superficial femoral artery (SFA) disease extending into the popliteal artery (A). Popliteal CTO reconstituting at the junction of the anterior tibial takeoff via the large genicular branch (B). Single-vessel tibial runoff via the posterior tibial artery (C).

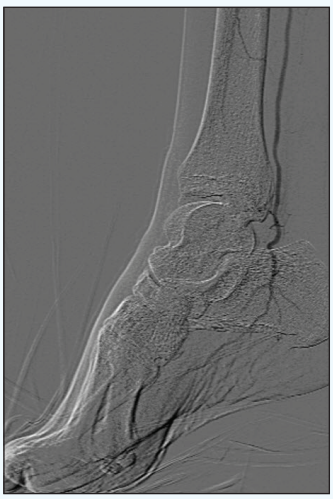

Figure 2. Preintervention runoff showing poor perfusion of the foot.

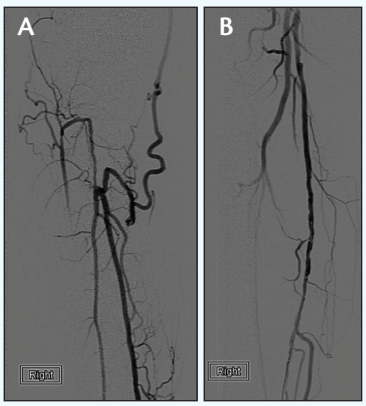

Figure 3. TAMI technique. Retrograde angiogram confirming the distal CTO reconstitution at the level of takeoff of the anterior tibial artery (A). Level of proximal CTO in the mid-popliteal artery (B).

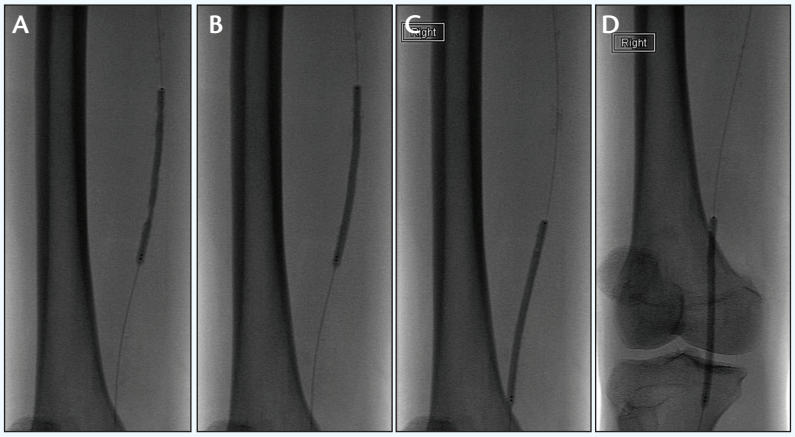

Figure 4. SFA 3-cm balloon angioplasty at 4 atm (A). SFA 5-cm balloon angioplasty, three inflations at 6 atm for a total of 114 seconds (B). Popliteal 3-cm balloon angioplasty at 4 atm for 35 seconds (C). Popliteal 4-cm balloon angioplasty at 2 atm for 47 seconds (D).

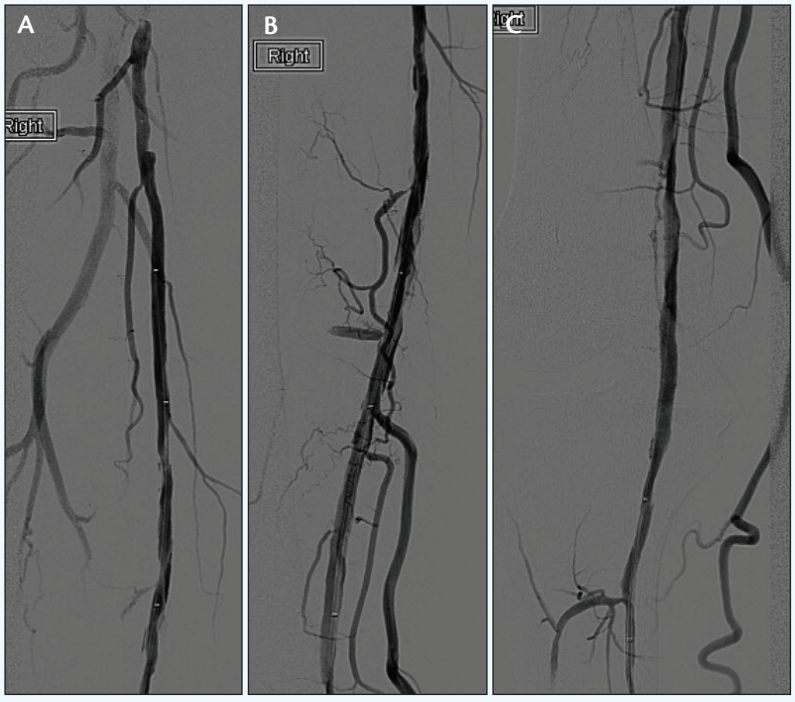

Figure 5. Post-PTA flow reconstitution in the SFA (A). Post-PTA flow reconstitution in the popliteal artery (B). Post-PTA flow reconstitution into the popliteal-tibial junction (C).

bypass intervention. In addition, access through the groin was prohibited due to several factors, including severely advanced pre-existing scar tissue, obesity, and the patient's inability to lie flat. Therefore, the decision was made to treat the right SFA via tibiopedal arterial minimally invasive retrograde access (TAMI) technique (Figure 3).

Ultrasound-guided retrograde access via the posterior tibial artery was obtained. The highly calcified, high-plaque-burden CTO of the SFA and popliteal was crossed using the Approach 25 wire (Cook Medical). The decision was made to perform orbital atherectomy of the right posterior tibial artery; tibioperoneal trunk (TPT); distal, mid, and proximal popliteal artery; and distal SFA.

Balloon angioplasty was then performed in the TPT (Figure 4), using a 3-mm X 250-mm SABER™ Catheter (Cordis Corporation); in the posterior tibial artery, using a 3-mm X 250-mm SABER™ Catheter followed by a 4-mm X 80-mm SABER™ Catheter; and in the SFA, using an initial 3-mm X 250-mm SABER™ Catheter followed by 5-mm X 100-mm SABER™ Catheters, with < 10% residual stenosis in all vessel segments (Figure 5). A unique feature of the SABER™ Catheter is its quick deflation and refolding time, which allows better pushability into a new area for repeat PTA. The balloon has a combination of low-profile characteristics involving both the balloon and the sheath, which make it a unique balloon for ease of delivery into hostile high-grade stenosis and CTOs.

Hemostasis was obtained using a tibial access hemostasis device. The patient was discharged home the same day without access or procedural complications.

SABER™ CATHETER CASE STUDY TWO

The patient was an 82-year-old man with a medical history of stage III chronic kidney disease, lower extremity edema, deep vein thrombosis, and osteomyelitis of the left toe. The patient presented from the wound clinic for further evaluation of a left lower extremity nonhealing ulceration of the left fourth toe with PVD symptoms consistent with Rutherford class 5. MRI results of the toe were consistent with osteomyelitis. Doppler results obtained during the visit showed reduced waveform at the dorsalis pedis (DP) and posterior tibial (PT) arteries. Noninvasive imaging was obtained. The results of the evaluation were as follows: left ABI, 0.75; left TBI, 0.28; right ABI, unable to be determined due to noncompressible arteries; right TBI, 0.45.

A diagnostic angiogram was obtained via access of the right common femoral artery (Figure 6A through 6C). This showed the proximally occluded AT, tandem lesions of the mid-AT (95%), then complete occlusion distally with

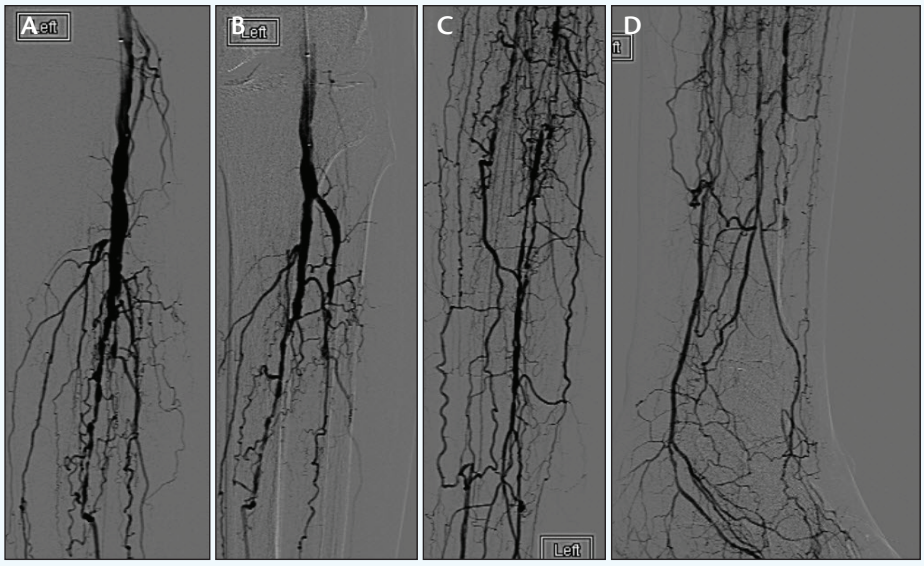

Figure 6. Anteroposterior angiogram of the proximal tibial artery showing total occlusion of the proximal tibial vessels (A). Oblique angiogram at 30º ipsilateral showing proximal tibial total occlusion, including proximal cap of anterior tibial (AT) total occlusion (B). Mid-to-distal reconstitution of the tibial vessel showing poor AT reconstitution via dense tibial collateral (C). Tibiopedal reconstitution via dense tibial collateral showing PT and AT runoff to the foot (D).

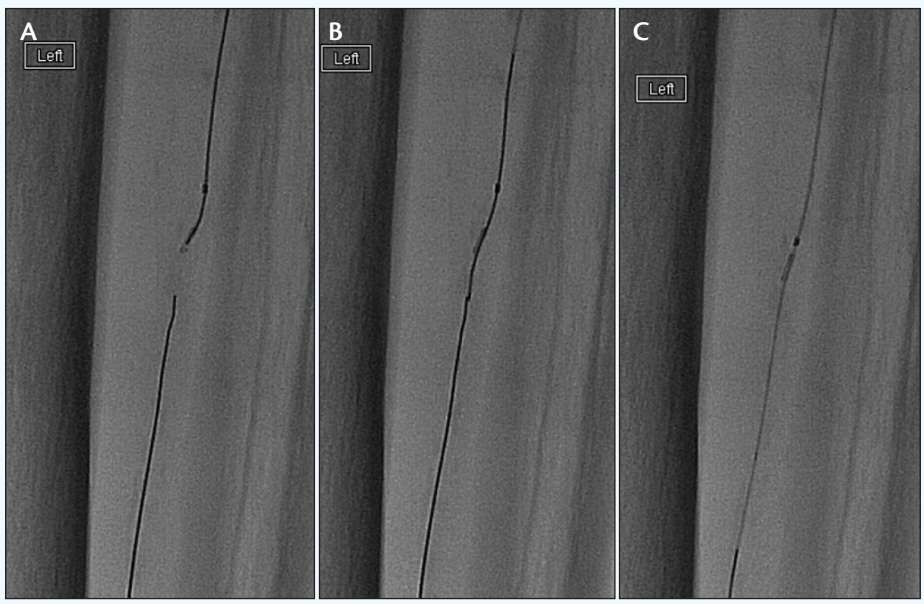

Figure 7. Retrograde CTO crossing wire maneuver toward antegrade recapturing catheter (A). Retrograde wire advanced into the antegrade capturing catheter (B). Axis reversal by advancing antegrade wire into the distal DP artery (C).

reconstitution in the DP below the ankle with weak flow and evidence of severe calcification (Figure 6D). Vessel diameter was 3.5 mm proximally, 3 mm at the midsection, and 2.5 mm distally, with a lesion length of 400 mm. The left PT showed total occlusion in the midsection that reconstituted distally above the posterior communicating artery with good runoff to the plantar arteries. The PT was severely calcified with a lesion length of 200 mm and diameter of 3.5 mm proximally, 3 mm at the midsection, and 2.5 mm distally. The left peroneal was occluded at the ostium and reconstituted distally with a lesion length of 200 mm. Therefore, the decision was made to pursue left lower extremity peripheral vascular intervention.

Ultrasound-guided antegrade access of the left common femoral artery was achieved. Additionally, a retrograde access site was also achieved in the left DP using ultrasound guidance. The CTO cap of the left AT was crossed with an Approach 25 wire (Cook Medical) in antegrade fashion (Figure 7). The wire was advanced into the mid-AT, where it was unable to advance further, and it appeared that the wire had gone subintimal on ultrasound evaluation. The decision was made to proceed with a second access site via retrograde access of the left DP using ultrasound guidance. This allowed successful crossing of the vessel and true lumen, and the Approach retrograde wire was advanced in the antegrade NaviCross catheter (Terumo Interventional Systems). Access was then reversed, with all therapy being delivered via the left common femoral artery in antegrade fashion. The retrograde DP artery sheath was then removed. Orbital atherectomy of the left AT and DP (proximal and mid) was performed, followed by balloon angioplasty using a SABER™ Catheter (Figure 8).

The left DP was treated using a 2.5-mm balloon, the mid to distal AT with a 3-mm balloon, and the proximal AT with a 3.5-mm balloon followed by a 3-mm balloon. All

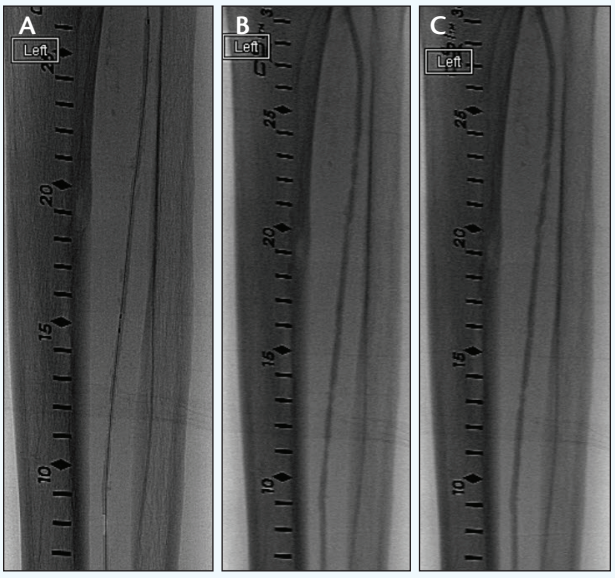

Figure 8. Multiple SABER™ Catheter inflations of the previously totally occluded AT with different sizes: 2.5 mm (A) and 3 mm (B, C).

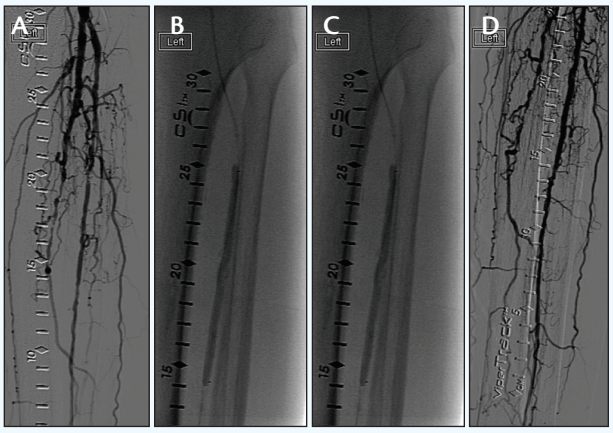

Figure 9. Post-PTA angiogram of previously occluded AT with residual stenosis (A). Additional SABER™ Catheter angioplasty of the proximal and mid-AT for residual stenosis as noted in A (B, C). Final angiogram runoff showing revascularization of the previously totally occluded AT artery with low-profile SABER™ Catheter (D).

balloons were 80-mm long. The total lesion length was 300 mm; all segments were severely calcified. Preintervention stenosis was 100%; postintervention stenosis was < 20% of vessel segments. Closure of the access sites was done via manual compression hemostasis (Figure 9). The patient was discharged the next day without access or procedural complications.

CONCLUSION

In our initial experience, we see high promise for the SABER™ Catheter to be used as our go-to balloon. In the current era of complex CLI disease, low-profile devices such as the SABER™ Catheter add significant value for the area of the vascular tree that has a significant unmet need. The SABER™ Catheter's combined unique characteristics of trackability, pushability, low profile, and 4-F compatibility make it a balloon that is highly effective, easy to use, and unique for utilization during TAMI procedures. ■

J.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. He has disclosed that he is a consultant for Cordis. Dr. Mustapha may be reached at jihad.mustapha@metrogr.org.