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Ocelot Catheter for the Treatment of Long SFA Occlusion

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Long saphenous femoral artery (SFA) chronic total occlusions (CTOs) are considered the "Achilles heel" of the lower extremity percutaneous interventions. Antegrade, retrograde, or transcollateral approaches, intraluminal or subintimal techniques with re-entry and specialized CTO devices using microdissection, vibrational energy, and laser have all been tried for the management of such challenging lesions with various success rates. Ocelot is the first CTO crossing device using real-time OCT technology. Its crossing catheter utilizes spiral wedges to corkscrew the CTO cap, while real-time OCT offers direct visualization to facilitate intravascular true-lumen orientation. The recently presented results of the CONNECT-II study demonstrated crossing success of 97% and freedom from major adverse events of 98%. We present one of the most challenging SFA CTOs with ambiguous proximal cap in the ostium of the SFA, heavy calcification and involving almost the entire length of the SFA. The Ocelot catheter assisted to the successful true-lumen recanalization of that complex lesion. © 2013 Wiley Periodicals, Inc.

Key words: peripheral arterial disease; chronic total occlusion; peripheral intervention; peripheral transluminal angioplasty

INTRODUCTION

Approximately, 40% of the patients with symptomatic peripheral arterial disease have chronic total occlusions (CTOs) of the saphenous femoral artery (SFA) [1]. Long SFA CTOs are considered the "Achilles heel" of the lower extremity percutaneous interventions and they are currently one of the most common reasons for surgical revascularization referrals. The TASC II classification categorizes them in the "Class D" sub-group where surgery is preferred over percutaneous intervention [2]. The increasing number of high-risk patients for surgery and the demand for more efficient and less morbid percutaneous procedures have resulted in the optimization of percutaneous techniques, accumulation of experience, and the FDA approval of newer devices for the transcatheter management of SFA CTOs.

Antegrade, retrograde, or transcollateral approaches, intraluminal or subintimal techniques with re-entry and specialized CTO devices using microdissection, vibrational energy, and laser have all been tried for the management of such challenging lesions with various success rates [1,3–5]. The main limitation of all those techniques is the inadequate real-time visualization of the selected crossing device during its advancement in the CTO.

Optical coherence tomography (OCT) technology utilizes near-infrared light to optimize intravascular visualization [6]. This newer technology offers ten times better spatial resolution than intravascular ultrasound (IVUS) and has been extensively researched in the coronary circulation [6].

Ocelot™ is the first CTO crossing device using real-time OCT technology. Its crossing catheter utilizes spiral wedges to corkscrew the CTO cap, while real-time OCT offers direct visualization to facilitate

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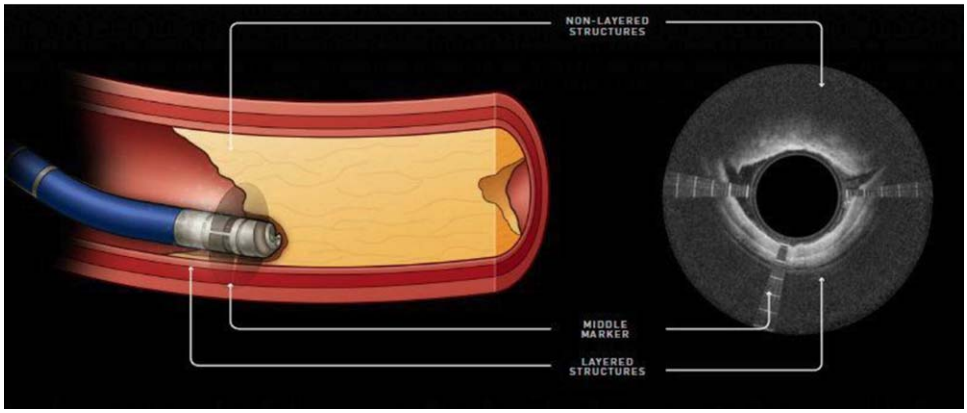

Fig. 1. Design of the Ocelot catheter and real-time OCT visualization (Permission granted from Avinger, Redwood City, CA). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

intravascular orientation. The catheter has a 2 mm crossing profile, 110 cm length, and it is compatible with 6 Fr sheaths and 0.014 guidewires (Fig. 1).

CASE REPORT

A 77-year-old Caucasian female with prior history of coronary artery disease (CAD), hypertension, dyslipidemia, and tobacco abuse was referred with lifestyle-limiting left lower extremity Category 3 Rutherford intermittent claudication. The left lower extremity ankle-brachial index (ABI) was 0.5 and a subsequent CT abdominal angiogram with run-off showed a long 100% occlusion of left SFA from its origin to the distal end reconstituting via collaterals in the mid-segment of the adductor's canal. A selective left lower extremity angiogram confirmed the CTA findings.

Right-to-left cross-over was performed and a 6 Fr sheath was advanced to the left external iliac artery. Initial attempts to cross the ambiguous CTO with a 0.035 angled Glidewire (Terumo Interventional Systems, Somerset, NJ) supported by a 5 Fr Glidecath (Terumo Interventional Systems, Somerset, NJ) and an Asahi 0.014 Miracle Bros 12g guidewire (Abbott Vascular, Abbott Park, IL) supported by a 0.014 Quick Cross catheter (Spectranetics, Colorado Springs, CO) were unsuccessful. Using OCT guidance, the Ocelot catheter successfully advanced into the distal SFA and the Treasure 12 0.018 (Asahi, Santa Ana, CA) guidewire was advanced into the popliteal artery. Percutaneous transluminal angioplasty (PTA) was performed with a 5.0 mm × 200 mm × 135 mm Evercross peripheral balloon (Covidien, Plymouth, MN) and then stented with two 5 mm × 120 mm × 120 mm Supera self-expanding stents (IDEV, Webster, TX) (Fig. 2). Post-procedure ABI improved to 1.0 with progressive resolution of her claudication and a Rutherford category 0 (no claudication) at 1 month follow-up.

DISCUSSION

Endovascular interventions have evolved significantly over the last years, allowing interventionalists to switch to less morbid transcatheter procedures especially in patients deemed high-risk for surgery.

Long infrainguinal CTOs is the next frontier in peripheral vascular interventions. Newer techniques and devices provide the ability to recanalize most complex lesions. The main limitation is the inadequate contrast visualization when advancing stiffer devices inside long CTOs. Even experienced operators are unwilling to advance stiffer devices when visualization is suboptimal. Tracking in the collateral circulation or outside the vessel may result in vessel perforation and need for urgent surgical revascularization with threatened limb loss. Duplex-guided interventions have been previously described; however due to the need for additional personnel and expertise they have not gained wide acceptance [7].

Subintimal recanalization of the CTOs with re-entry has been associated with very low patency rates after stenting in the coronary circulation [8]. It is possible that true lumen recanalization may offer better patency rates in the peripheral arterial circulation; however, further research is needed to establish such statement. Real-time OCT provides assurance that the Ocelot catheter is located not only inside the vessel but in the true lumen. With OCT technology all three vascular layers can be determined (Fig. 3). A middle marker represents the tip of the Ocelot catheter which can be directed toward the layered segments. When entering in the subintimal space the catheter can be retracted

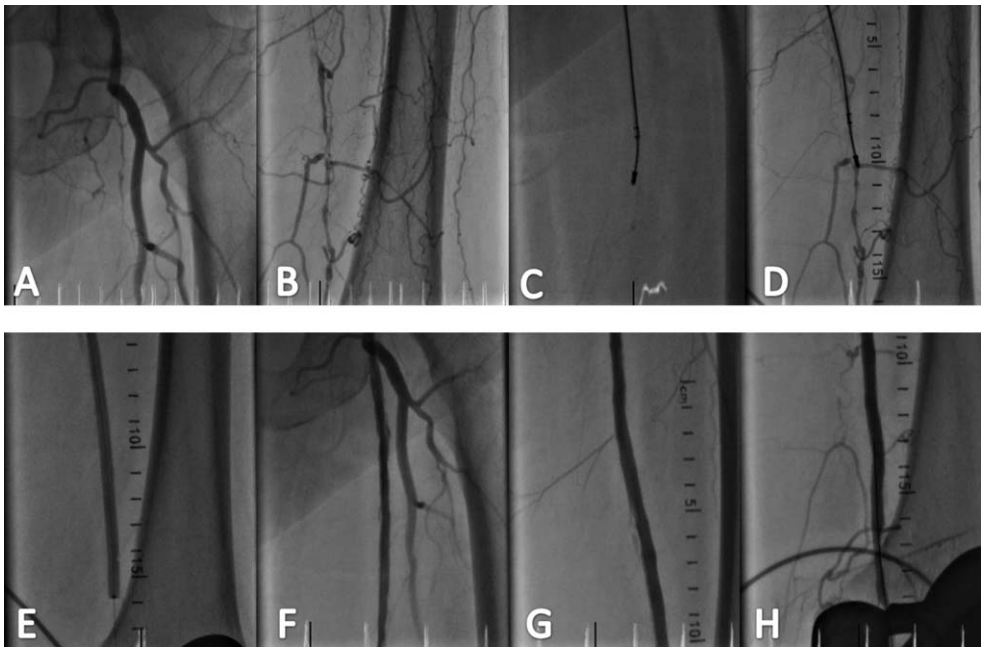

Fig. 2. Long SFA occlusion from its ostium (A) to the Hunter's canal (B). Advancement of the Ocelot catheter in the CTO to the distal end (D) of the CTO. PTA of the CTO with a long peripheral balloon (E) and stenting with two self-expanding stents. Optimal post procedure results (F, G, H).

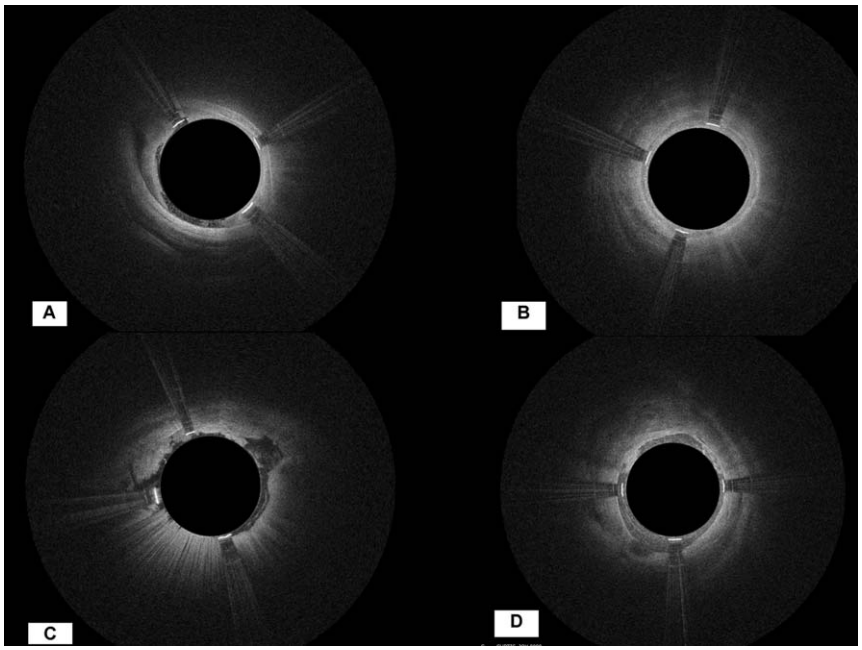

Fig. 3. A–D: OCT of the SFA through the Ocelot system. All three layers in different regions of the OCT. (A) Middle marker in the layered structures, (B) Middle marker is in the layered structures, (C) Middle marker is in nonlayered structures so it will be redirected toward the layered structures, (D) Middle marker is in non-layered structures.

and redirected, providing assurance that the CTO is tracked through the true lumen.

The CONNECT-II study has used the Ocelot catheter in 100 patients with long CTOs, most of them (97%) in the SFA. About 89% involved *de novo* lesions, 53% were calcified, and the attempted recanalization CTO length was 166 ± 93 mm. The use of Ocelot achieved crossing success of 97%, freedom from major adverse

events of 98% with a procedural time of 107 ± 58 min, contrast volume of 223 ± 145 ml and total fluroscopy time of 39 ± 29 min. At 30 days follow-up there was significant improvement in ABI and Rutherford class [9]. Furthermore, initial experience with the Ocelot catheter from a multicenter prospective study in Europe showed a 94% crossing success with absence of major adverse safety events [10].

Our case report represents one of the most challenging SFA CTOs with ambiguous proximal cap in the ostium of the SFA and involving almost the entire length of the SFA. The Ocelot catheter assisted to the successful true-lumen recanalization of that complex lesion.

CONCLUSIONS

Long SFA CTOs are common and represent the next important challenge for peripheral interventionalists. The newer Ocelot catheter, combining an effective CTO device with real-time OCT visualization assuring true-lumen tracking, offers promising results for the safer and more efficient percutaneous interventions. Our case represents an example of true-lumen recanalization of the entire SFA using that newer technology.

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