Treatment of Chronic Total Occlusions Using the Avinger Ocelot Crossing Catheter

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Abstract

Keywords

- ▶ peripheral arterial disease
- ▶ chronic kidney disease
- ▶ occlusion
- ▶ interventional radiology

Peripheral arterial disease is becoming more prevalent as the population ages. In addition, the severity of the disease seems to be progressing from simple narrowing of vessels to chronic total occlusions (CTOs). Treatment of CTOs of the infrainguinal peripheral arteries remains a challenge even for experienced endovascular specialists. Many crossing techniques have been described ranging from standard guidewire and catheter-based techniques including subintimal recanalization to specialized CTO crossing devices. One of the newest technologies, the Avinger Ocelot catheter (Avinger, Inc., Redwood City, CA), employs optical coherence tomography imaging on the tip of a rotating crossing catheter to allow visual confirmation of luminal passage. This article will review this new technology for crossing CTOs, review the results of the multicenter CONNECT II trial, and discuss the potential benefits of direct visualization while crossing occlusions.

Objectives: Upon completion of this article, the reader will be able to discuss the newer technologies now available for crossing chronic total occlusions (CTOs), including the Avinger Ocelot crossing catheter.

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It is estimated that peripheral artery disease (PAD) affects approximately 12 to 14% of the general population, and approaches 20% in patients 75 years of age or older. In addition, PAD is associated with higher cardiovascular morbidity and mortality.¹ Over 200,000 amputations are reported each year for patients with end-stage PAD in the United States

and Europe.² As the population continues to live longer, the prevalence of this disease is only expected to grow. Aggressive risk factor modification, smoking cessation, supervised exercise programs, and optimal medical therapy may prevent the development or slow down the progression of symptoms; however, without early diagnosis and risk factor modification, approximately 1 to 2% of these patients will develop critical limb ischemia (CLI). Without successful intervention, CLI patients have significantly increased morbidity with a 95% amputation rate at 1 year.³

Endovascular treatment of PAD continues to evolve. The days of focal iliac stenosis have been replaced with chronic total occlusions (CTO) of the iliac arteries, superficial femoral arteries (SFAs), and tibial arteries. In addition, symptomatology has progressed from simple claudication to nonhealing wounds, ulcers, and gangrene. As the complexity of diseases has progressed, new technologies have evolved to treat them. The Inter-Society consensus (TASC) II guidelines have recommended surgical intervention for severe PAD, including CTO, denoted as type C and D lesions.⁴ Bypass surgery has traditionally been the “gold standard,” with a 5-year limb salvage rate of nearly 80%.⁵ Recent advances in endovascular therapy

enable patients with CLI to be treated using minimally invasive techniques. With successful endovascular therapy rates reported as high as 97%, endovascular crossing options are becoming first-line treatments for patients across a wide health spectrum. Importantly, endovascular interventions are a safe alternative for nonviable surgical candidates as a result of their comorbidities, lack of suitable target vessels, or poor venous conduits.⁴

Ocelot Crossing Catheter

The Ocelot catheter (Avinger, Inc.; Redwood City, CA) is the first in class device to combine diagnostic imaging at the point of therapy. The Ocelot is an optical coherence tomography (OCT)-equipped CTO crossing catheter, using proprietary real-time OCT guidance for optimal intraluminal recanalization. OCT technology uses near-infrared light to optimize intravascular visualization, and has been extensively studied for coronary arterial circulation imaging as well as plaque characterization.⁶ Ocelot's optical image resolution is 10 μ m, and incorporates 1,024 A-lines per image. These capabilities enable differentiation between various healthy arterial structures including media and adventitia (layered structures), and diseased arterial walls including plaque (nonlayered structures). Either saline or contrast may be used via the local flush port to clear the imaging fiber when blood refracts the OCT image. Because the device is designed to function in occluded vessels, minimal flush (<1 mL) is adequate to displace blood artifact. Ocelot's working edge includes fixed spiral flutes with adjustable speed of rotation between 30, 45, and 60 rotations per minute.

The Ocelot catheter is an over-the-wire device that is compatible with a 6F sheath and a 0.014" guidewire. It has a working length of 110 cm and a crossing profile of 2 mm. A smaller version, the Ocelot PIXL, is compatible with a 5F sheath, is 135 cm in length, and has a crossing profile of 1.7 mm. The catheter has a distal tip with spiral wedges (► Fig. 1) that can rotate clockwise and counterclockwise to facilitate a corkscrew-like action, allowing for advancement of the catheter across a CTO. The distal tip is pre-shaped with a ~20-degree angle and contains radiopaque markers. The directional markers are used to orient the catheter during a CTO-crossing procedure in the event that fluoroscopy is used. When using the catheter, the operator guides CTO crossing by

positioning the middle marker over healthy tissue (layered structures) prior to advancement of the catheter. This orientation permits the catheter tip to engage the diseased segments, allowing for luminal crossing. Real-time, constant OCT imaging allows for reorientation of the middle markers over layered structures for the duration of lesion crossing (► Fig. 2). OCT not only guides safe and efficacious crossing but can also be used to diagnose plaque morphology that may help modify therapeutic decision making.

One of the first trials to evaluate the Ocelot catheter was the CONNECT II study. This study was a prospective, multicenter, nonrandomized study including 17 sites in the United States and Europe designed to evaluate the safety and effectiveness of the Ocelot catheter in CTO crossing. Patients were required to have CTOs in the SFA or the popliteal arteries less than 30 cm in length with a target vessel greater than 3 mm in diameter. The study met its endpoints with the Ocelot alone successfully crossing the occlusion (72%) or in conjunction with an additional device (25%), for a total successful crossing rate of 97%. The authors of the initial study also described a fairly steep learning curve, with initial cases taking longer and reasonable expertise gained only after 10 procedures.⁷ The authors noted that the radiation dose, contrast dose, and procedure times all dropped significantly after the first 10 cases had been completed.

Case Report

In this author's experience, the benefits have been similar to those noted in published studies. During the early learning curve, fluoroscopy is utilized as a safety confirmation that the pathway seems appropriate. In addition, contrast injection is utilized in a similar fashion to help confirm correct positioning. Over time, the operator's comfort level with interpretation of OCT imaging allowed for significantly less use of contrast material. More importantly, for some high-volume

Fig. 1 Drawing of the Ocelot catheter, demonstrating the distal tip that can rotate to facilitate a corkscrew-like action, allowing for advancement of the catheter across a CTO.

Fig. 2 Real-time, constant optical coherence tomography imaging. This not only guides safe crossing but can also be used to diagnose plaque morphology that may help modify therapeutic decision making.

operators, the radiation exposure during crossing of a long occlusion has dropped to nearly zero in many cases. A potential secondary benefit that this author has noted is a significant decrease in the need for adjunctive devices. This includes less use of re-entry devices, less use of atherectomy devices, and a significantly decreased need for adjunctive stent placement when compared with subintimal recanalization techniques.

An example of a typical superficial femoral artery occlusion from the author's institution is demonstrated in ► **Fig. 3**.

Discussion

Percutaneous crossing of infra-inguinal arterial CTOs is dependent on evolving guidewire and catheter technology. Guidewire therapy often rests on the premise of intentional extraluminal (subintimal) crossing, as originally described by Bolia et al.⁸ Medical device companies have continued to

develop and improve catheters for attempted true lumen crossings of CTOs in peripheral arteries. These include the Crosser (Bard Peripheral Vascular, Inc., Tempe, AZ), TruePath (Boston Scientific Corp., Natick, MA), the Frontrunner XP (Cordis Corp., Bridgewater, NJ), the CrossBoss (BridgePoint, Plymouth, MN), and the Wildcat catheter (Avinger, Inc.). All of these technologies rely on standard fluoroscopic guidance with intermittent injection of contrast material to evaluate the true lumen position.

In the midst of an expanding armamentarium of devices, there is a developing concern over radiation and contrast exposures during increasingly complex and lengthy procedures. On top of the normal concern to limit radiation exposure to patients using the ALARA principle (As Low As Reasonably Achievable), many studies are now addressing the expanding risks of radiation exposure to the primary operator and laboratory staff. Some studies have demonstrated a higher radiation risk to the operator during peripheral

Fig. 3 Single-plane angiogram from a 79-year-old man with poorly healing wounds in the great toe and second toe. The patient also had severe claudication with calf pain beginning at less than 50 feet of ambulation. The procedure was performed from a contralateral femoral arterial approach (a). A 6F sheath was placed, and the origin of the superficial femoral artery was engaged with the Ocelot catheter using oblique fluoroscopy (b). The remainder of the crossing was performed with 0.2 minute of fluoroscopy and no iodinated contrast material. Contrast was utilized after successful crossing to confirm good position within the popliteal artery lumen, as demonstrated in the figure. Angioplasty was subsequently performed first with 5 and 6 mm angioplasty balloons. The result after angioplasty was quite good, and no stents or adjunctive procedures were necessary (c).

interventional procedures than cardiac catheterization procedures.⁹ In addition, many severely compromised vascular patients may require repeat interventions, leading to additional exposure to both radiation and contrast material. These patients often have medical comorbidities such as advanced age, diabetes, coronary artery disease, and chronic kidney disease that put them at a higher risk of complications related to repeated exposure to iodinated contrast material.

Interventional Radiologists have always understood the value of 'seeing'. Our specialty is based on our ability guide small instruments into the body percutaneously using any number of imaging modalities. We have grown from Charles Dotter's initial use of fluoroscopy to treat arterial blockages to our current use of ultrasound, magnetic resonance imaging and computed tomography to guide a myriad of interventional procedures. While many of these procedures can be done without imaging, imaging is slowly becoming the standard for many procedures such as vascular access. The Avinger Ocelot is the first device designed to cross chronic total vascular occlusions while "seeing" the inside of the vessel. As with early experience with standard real-time ultrasound guidance, there is a learning curve necessary to obtain the requisite skill in mastering the device; In particular, as with many other products designed for CTOs, the device also appears to have limitations in its ability to cross densely calcified plaques. Once the learning curve is mastered, the Ocelot has the ability to decrease radiation dose, decrease the use of iodinated contrast material, and allow a much higher incidence of true lumen crossing of the occlusion.

Conclusion

Revascularization of peripheral vascular disease continues to evolve toward more aggressive endovascular techniques. Companies continue to develop new and improved devices to allow the endovascular specialist to treat more complex occlusive disease, including long segment CTO. The CONNECT II trial demonstrated how OCT-guided CTO crossing may be a

benefit to patients, care providers, and healthcare institutions by allowing greater procedural success with less radiation, less contrast, and improved technical success all while lowering complication rates. Further studies will clearly be necessary to validate the early results and successes of the Ocelot catheter.

Disclosures

L. E. S., MD, is a paid consultant and medical advisor for Avinger, Inc.

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