Welcome to the August 2014 issue of Vascular Disease Management. I have chosen to comment on Dr. Heuser’s case report, in which he utilizes the Ocelot device from Avinger to cross a totally occluded superficial femoral artery (SFA).

Great progress has been made in crossing chronic total occlusions (CTOs) in peripheral arteries. Wire technology has dramatically improved, giving clinicians wires with better torque, better tip penetrance, better shaft support, and lubricious coatings that allow true luminal and subintimal crossing of the vast majority of CTOs. Re-entry devices allow clinicians to regain intraluminal position when wires become trapped in the subintimal space. Dedicated crossing tools have been developed to help cross CTOs with the goal of true intraluminal crossing rather than subintimal crossing. It is reasoned that true luminal crossing may facilitate improved outcomes when atherectomy devices are utilized to remove plaque and possibly improve outcomes with drug-eluting balloons and stents. Intraluminal crossing may also lessen the risk of perforation and subintimal hemorrhage. Most of the dedicated crossing tools are directed fluoroscopically (with the inherent pitfalls of radiation exposure and only 2-dimensional imaging) but the Ocelot crossing device utilizes near infrared light with optical coherence tomography to direct the device via intraluminal cross-sectional imaging. This direct imaging potentially allows crossing with little or no x-ray exposure and it allows accurate real-time directional control of the device to ensure true luminal crossing.

The Ocelot device includes a 2 mm diameter catheter with a preset distal curve, distal flutes that can be rotated to facilitate crossing, a near infrared light located 1.5 mm from the catheter tip, a flush channel (to clear blood which may obstruct visualization), an .014” guidewire lumen, and a catheter rotation handle to direct the device. The device is 110 cm long. When connected to the light source, imaging is continuous. The device is advanced to the occlusion then directed through the occlusion by pointing the tip away from the “layered structures,” which represent the arterial wall and advancing the device in the direction of the “nonlayered structures” which represent the atheroma. There is a “starburst” effect upon entering the distal patent lumen. A guidewire is then placed distally, the device removed, and interventional treatment delivered.
In the Chronic Total Occlusion Crossing With the Ocelot System II (CONNECT II) trial, successful SFA CTO crossing was achieved in 97% of 122 SFA occlusions with a 2% major adverse event rate. These data are impressive because very few of the investigators had extensive experience with the device at the time of this trial. In CONNECT II, the device did occasionally enter subintimal space, requiring the use of a re-entry device. It would be interesting to know if investigators well beyond the learning curve would have further improved primary crossing success.

The entire field of image-guided intravascular crossing and treatment is intriguing. I clearly remember the first case that I observed when this device was utilized for crossing a totally occluded artery. I was impressed with the carefully directed crossing without x-ray exposure, but my thoughts rambled about the potential therapeutic possibilities to selectively treat the more diseased walls of a vessel while sparing the less diseased segments from injury. Will intravascular image-directed crossing and therapy be the future of intravascular intervention?

We will need to assess if devices like this will result in improved clinical outcomes and ultimately determine the appropriate clinical utility and cost effectiveness. I suspect that there will be iterative changes that improve performance, as this typically happens with all new devices. I anxiously await intravascular image-directed therapeutic devices to deliver directed therapy after successful intravascular crossing.

Reference