Pioneer Plus Intravascular Guided Re-Entry Catheter

Simplifying chronic total occlusions.

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Revascularization of chronic total occlusions (CTOs), defined as a lesion that has impeded blood flow for a period of > 3 months, remains one of the most technically challenging medical procedures. Several techniques are available, and ultimate success is predicated on the skill of the physician, the type of device, lesion length, degree of calcification, and collaterals. Through the experience of Drs. Arko and Davis, we describe a powerful interventional device called Pioneer Plus (Philips Volcano), a true lumen re-entry tool that overcomes the limitations in traditional methods of CTO intervention.

With multiple techniques and a variety of products available, which crossing and re-entry devices have you used over the past year?

Dr. Arko: When faced with a heavily calcified CTO, I've been a big proponent of proactively going around the occlusion rather than through it. I explore and prod a bit to ascertain any channels or soft plaque, but won't spend too long on it and will default to a re-entry device when I run into problems. With some of the newer devices, I can do this with minimal harm to the delicate subintimal space and get back into the true lumen relatively easily. I've used both the Outback device (Cordis, a Cardinal Health company) and Pioneer Plus. With either device, we penetrate the subintimal plane near the proximal end, carefully working our way up past the occlusion and re-enter into the true lumen. The benefit of Pioneer Plus is that it is coupled with intravascular ultrasound (IVUS), and the increased visibility improves the likelihood of successful re-entry. No other re-entry device has this visibility.

Dr. Davis: If the angiogram indicates a CTO, I'll take the direct approach. First, I'll try just wires and then a couple of crossing catheters, either the Ocelot device (Avinger, Inc.), which has rotating tips that cut into lesions, or the Crosser device (Bard Peripheral Vascular, Inc.), which uses high-frequency vibrations to "microdissect" calcified plaque. These devices work most of the time to get me through. The specific composition and characteristics of the plaque are really what guides the wire. Soft plaque or

microchannels generally allow for intimal wire passage, whereas more fibrotic or calcific plaque tends to deflect and cause a more difficult central channel crossing, or worse, penetrate the luminal wall. I find that with CTOs, 10% to 15% of the time, the plaque morphology will necessitate a subintimal approach with a re-entry device. In this case, I'll usually use the Outback or Pioneer Plus device.

I used the Outback device principally when Pioneer Plus was not available. Similar to Pioneer Plus, I liked Outback because of the needle that can puncture and reorient back into the vessel. It also has a radiopaque marker to help mark re-entry from the subintimal space. Other re-entry devices don't have the needle, making it very difficult to get back into the true lumen. Approximately 15% of the time, re-entry devices don't get you back into the true lumen, resulting in technical failure. With the exception of the Pioneer Plus device, with added visualization to improve effectiveness and safety, you end up driving blind, potentially hazarding the membranes and boundaries of the vessel and risking suboptimal results when you start intervening.

What are your clinical scenarios for using a re-entry device?

Dr. Arko: Of all the endovascular interventions I undertake, I'll need a re-entry device approximately 6% or 7% of the time. I'll use these devices for CTOs of the superficial femoral artery and longer CTOs of the iliac arteries. Less often, I'll use the devices on patients with aortic dissections in which I need to fenestrate from the true to the false lumen and equalize pressure to a vessel.

Furthermore, these devices are often used as a last-chance option to help remove a CTO and hopefully save a limb. Coupled with IVUS, Pioneer Plus enables me to take a good look at the vessel before intervening. This provides a good overview of the size of the vessel and diseased environment, including boundaries and how to size the balloon or stent, all of which helps me to plan accurately and saves time on the remainder of the procedure.

Dr. Davis: After trying to stay within the intimal and save some cost, if I have any issues at all, I will opt for the re-entry device early on. A common benefit of all re-entry devices includes less trauma to vessel walls, less inflammation, and accordingly less restenosis. However, the Pioneer Plus re-entry device tends to work almost right away, foregoing other maneuvers that may or may not work, which results in increased procedural efficiency. Recently, one of my partners was using the Outback device and just could not get back into the lumen to complete the procedure. He was in there for more than an hour, which is time he will never get back.

Why is Pioneer Plus your device of choice for re-entry?

Dr. Arko: Not only does IVUS enable me to drive better and avoid damaging the vessel lining, but I can also obtain a comprehensive view of the lesion, including its size, morphology, and vessel boundaries. This preplanning information saves me time on the intervention side of the procedure. When I've finished intervening, I can then check how well the therapy has responded and if any adverse clinical events, such as major flow-limiting dissections, poor stent apposition, inadequate stent expansion, or incomplete coverage of the lesion, have occurred, which determines when the procedure is complete. With the touch of a button, ChromaFlo imaging (Philips Volcano) can also be activated for these preplanning and postassessments. ChromaFlo enables enhanced IVUS visibility and identification of dissections, branches, and plaque orientation in bifurcations and is especially appropriate while working in the peripheral arteries, the superficial femoral artery, and the iliac arteries, precisely where I need it. Unique to Philips Volcano, ChromaFlo is a blood motion detection technology that colors blood red and stands out in contrast to the IVUS grayscale.

I also think Pioneer Plus with onboard IVUS improves outcomes because (1) it facilitates re-entry and completion of the procedure, (2) I can eliminate a multitude of other procedures that I would otherwise have to do, decreasing my cost, (3) I can potentially reduce the amount of radiation to the patient, operator, and individuals who are also on the case, (4) it speeds up the total length of the procedure, and (5) when I've completed the procedure, I can evaluate how well I've done. Did I appropriately size the balloons and/or the stent in relation to the lesion? And more importantly, did I get the lumen big enough to garner a nice outflow?

Dr. Davis: Certainly the main benefit of the Pioneer Plus is the visibility that IVUS and ChromaFlo affords. You can see exactly where you are and where you're going, whether you've injured the media, and you can get a better sense of how calcified it is and where you have soft microchannels to penetrate—having information like that saves me procedural time. Without Pioneer Plus, I can spend extra time, sometimes up to an hour, trying to get back in and/or performing an alternative access. With Pioneer Plus, I just pull it off the shelf, put it in, and literally get back to where I need to be within minutes, and then move on.

You're basically getting two devices for the price of one and with increased quality, speed, and better outcomes. But it's not always about price. Sometimes, it needs to be about quality. We look at a device and the cost, but what we need to ask is, "What's the benefit to the patient with the increased cost?" If we're improving that long-term outcome, then we're okay with utilizing a device that may add some cost to the procedure.

There are other benefits to using Pioneer Plus. Many times, the distal cap can't be visualized very well angiographically. The distal cap may be 1, 2, or 3 cm above where the collateral comes in to form the cap. With ChromaFlo, you clearly see the red image of blood and the microchannels, so you don't have to go past the collateral to get back in. This prevents extending the lesion longer than it needs to be.

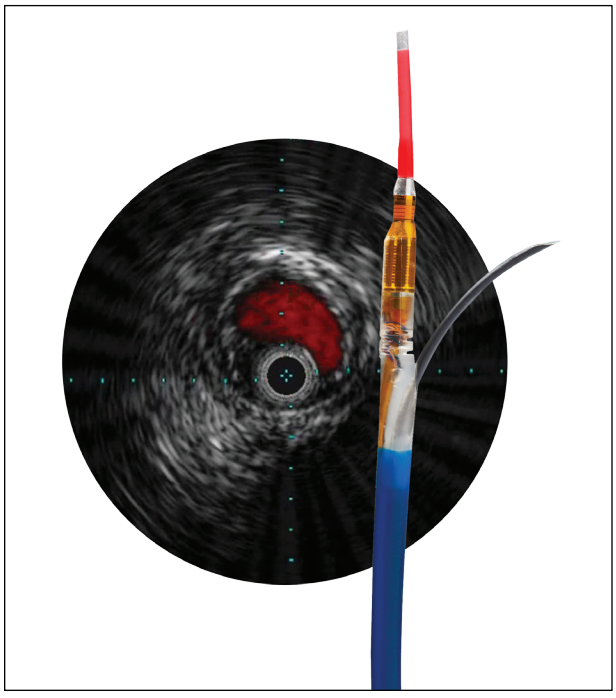
What are the economic advantages of using Pioneer Plus?

Dr. Arko: In lieu of doing a multitude of procedures for a difficult re-entry, you have the ability to save yourself time, depending on the physician's proficiency and the quality of the devices (approximately 5–60 min). Because of the variability of these aspects, including plaque morphologies, success rates vary broadly. In contemporary trials, they'll range anywhere from 50% among unselected sites to > 90% with dedicated operators in single centers. I attribute much of my success and ability to save time to the IVUS imaging offered by Pioneer Plus. I believe the Pioneer Plus device with the onboard IVUS is also reimbursable in the many office-based labs that are performing these types of procedures.

Dr. Davis: For the 10% to 15% of cases that I can't cross back into the true lumen, Pioneer Plus saves me that time. By decreasing the procedure time—up to an hour in some cases—it's a lot of additional time I can put toward that patient…and the next. When you're trying to wire things yourself and get back into a true lumen, the media is disrupted by constant, continuous wiring, and I think you cause a lot more perivascular trauma to the vessel. With the additional vessel trauma, it's more likely you're going to have inflammatory responses and restenosis. That alternative opportunity cost is priceless!

What advice do you have for a colleague regarding re-entry procedures?

Dr. Arko: If you're having a difficult time with re-entry or you have a lot of CTOs in your patient practice, and you're utilizing some of the other techniques and devices, Pioneer Plus can speed up that process by allowing you to see what's going on inside the vessel, which is going to save you time. You can set the depth of the needle to ensure you don't poke back through the outer lumen wall, as you don't want to poke, prod, puncture, and tear, especially when all you have to guide you is two-dimensional angiography. Instead of wasting time and trying to save money with these devices, you can just go right to Pioneer Plus where you have the confidence of entering into the true lumen. You want to look inside the vessel and send the wire down the appropriate lumen as quickly as possible rather than injuring that vessel. That's number one. Secondly, if you review the current literature, when you add IVUS to help guide your peripheral procedures, the long-term outcomes in patency of those stents are much better. Those would be the two pieces of advice.



The Pioneer Plus device is the first-and-only re-entry device with IVUS capabilities.

Dr. Davis: I think the peripherals have gained a lot of steam lately, much to the credit of IVUS. And now that it's reimbursed in outpatient office-based labs, this work is trending higher and with better outcomes. On the venous side, IVUS is almost an imperative for stenting. The visuals and information will put you head and shoulders above other devices. No other device can visualize the vessel, and none of them can visualize when you're in the media. ■