

The Evolution of True Lumen Re-Entry

An introduction to the OffRoad™ Re-Entry Catheter System.

BY DONALD L. JACOBS, MD

Endovascular treatment of chronic total occlusions of the peripheral arteries was initially accomplished using subintimal angioplasty. After the seminal description of the technique by Bolia et al,¹ the use of subintimal angioplasty was questioned as a useful technique for recanalization of totally occluded arteries. The patency of a subintimal tract was thought to be poor, and the technique raised the risk for propagation of the dissection into normal arteries beyond the occlusion. With improved wires and catheters, as well as the development of stents to address the acute technical and angiographic failure of subintimal angioplasty of total occlusions, the use of subintimal angioplasty increased.

However, as subintimal angioplasty became more accepted, it was repeatedly demonstrated that the primary reason for technical failure was the inability to get the wire and catheter to re-enter the true lumen beyond the occlusion. Failure to cross back into the true lumen continued to cause technical failure in 10% to 15% of cases.²⁻⁵ Various techniques were then developed to address this point of failure using standard wires, catheters, and balloons, but not until the development of specific re-entry tools was there any real advance in the ability to overcome this persistent limitation of subintimal angioplasty. This review describes the tools that have been developed and the evolution of these devices and techniques that now allow for increasingly high success in addressing the failure of spontaneous re-entry after the crossing of total occlusions of peripheral arteries.

PIONEER CATHETER

The first FDA-approved device specifically designed for true lumen re-entry was the CrossPoint TransAccess Catheter (TransSonic Systems, Inc., Ithaca, NY), which was released in August 2002. Shortly thereafter, the

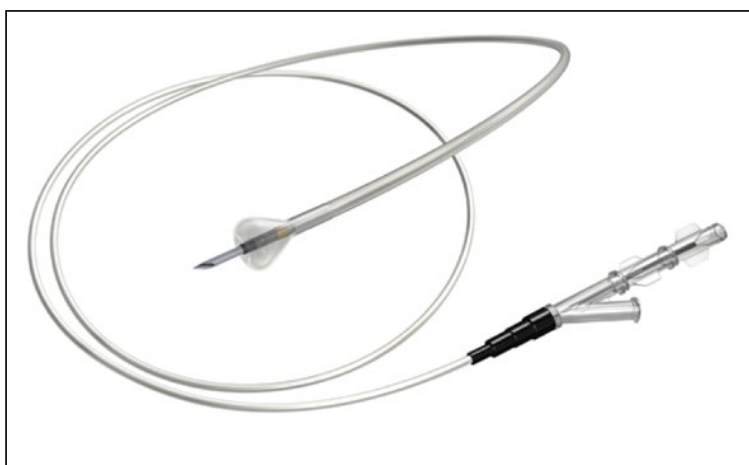


Figure 1. OffRoad catheter with balloon inflated and the needle hypotube advanced.

device was acquired by Medtronic, Inc. (Santa Rosa, CA) and renamed the Pioneer catheter. The device was a platform for placing a curved needle across the intima/plaque and into the true lumen such that a wire could be passed through the needle into the true lumen. The intravascular ultrasound (IVUS) integrated in the device allowed for real-time imaging of the subintimal tract to guide the operator in directing the needle deployment. IVUS imaging shows not only the catheter position in the dissection, but also the intimal layer of the dissection and the true lumen on the other side of the dissection. The color-flow capability of the IVUS also added an additional confirmation of the patency of the target vessel at the point of needle deployment. The Pioneer was a 7-F device that was very accurate at delivery of the needle to the right position based on the IVUS imaging.^{6,7} The bulk of the device and the sharp needle allowed for penetration of thick, calcified plaque, but also made the device difficult to track up and over the bifurcation and through occluded, calcified femoral vessels. This, combined with the need for capital investment in the Volcano Corporation (San Diego, CA) IVUS platform

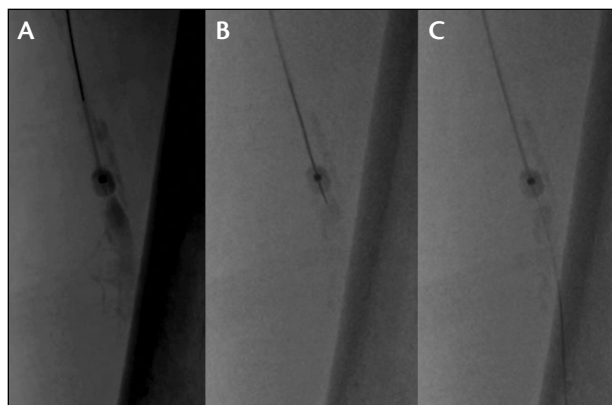


Figure 2. OffRoad inflated in the subintimal plane with centering of the balloon in the distal lumen that has static contrast in it (A). Advancement of the needle-tipped hypotube out of the catheter and into the true lumen (B). Advancement of the wire through the hypotube and into the distal true lumen (C).

and the high cost of the device, limited its utilization. However, its IVUS imaging accuracy and the excellent plaque penetration it provided made it particularly well-suited for use in the iliacs, where there is added comfort in limiting errant needle deployments in the retroperitoneum and often the need to penetrate thick plaque in the common iliac or distal aorta.^{7,8}

Medtronic released a second-generation device called the Pioneer Plus. This lower-profile, 6-F device improved infrainguinal trackability without any loss of its ability to penetrate plaque, but it remained considerably more expensive than other re-entry devices. In August 2013, the device was acquired by Volcano, the manufacturer of the IVUS components, and continues to be marketed as the Pioneer Plus catheter in the Volcano line of IVUS catheters.

OUTBACK CATHETER

In 2003, LuMend (Redwood City, CA) released a simple, 5-F, multipurpose-type angled guide catheter with an integral nitinol hypotube ending in a curved needle tip intended to be advanced from the end of the catheter to penetrate from the dissection plane to the true lumen. The needle was retracted in the guide catheter, and the device delivered over the wire to the point of true lumen re-entry. The wire was retracted back into the device, and the multipurpose angle of the catheter was manipulated to point the end toward the true lumen by fluoroscopic guidance. The needle could then be advanced to deploy it through the intima to the true lumen. An 0.014-inch guidewire could then be advanced through the hypotube into the true lumen.

With this first iteration of the device, the orientation of the catheter angle was the only directional guide to aim the needle.

This first-generation device was purchased by Cordis Corporation (Bridgewater, NJ) and marketed as the Outback catheter. Soon thereafter, the second-generation Outback LTD (Cordis) was released. This device used radiographic markers on the catheter that indicated the location of a fenestration near the tip of the catheter. This fenestration is the exit point for the hypotube, thus providing fluoroscopic guidance to the direction of the deployment of the curved-tipped hypotube. This modified device allowed for better tracking of the catheter and better directional control of the curved-needle deployment by having the needle exit the straight-configured catheter from the fenestration on the catheter about 12 mm from the tip. “L” and “T” markers were used to define when the catheter was positioned in a perpendicular and inline plane of the needle, respectively. Through imaging in two orthogonal views, the orientation could be confirmed to have the delivery catheter fenestration/needle exit site aimed at the desired point of re-entry into the distal true lumen target.

Technical success rates with the Outback LTD ranged from 64% to 88%.^{9,10} In my experience, the limitations of the device have been in tracking up and over tight bifurcations of the aorta in contralateral access, difficulty in tracking over the wire in calcified occlusions, and difficulty in penetrating calcified plaque at the re-entry site. Also, it has been reported anecdotally that users of the device were frustrated because it appeared that the device either rotated on deployment of the needle or deflected off of the thickened media at the desired point of re-entry. Angulation of the catheter by the aortic bifurcation and in iliac tortuosity can cause torsional forces that make the nitinol hypotube rotate as it exits the side fenestration of the distal catheter, such that the direction of the curved needle extension is not precisely defined by the orientation of the catheter markers. Failure on re-entry due to plaque resistance or orientation difficulty often requires several passages of the needle to achieve success. Although multiple needle penetrations of the adventitia may have been concerning to some clinicians learning the technique, there are no reported consequences of multiple deployments of the needle in the femoropopliteal vessels, as small perforations have not resulted in clinically relevant problems.

ENTEER CATHETER

In 2012, Covidien (Mansfield, MA) introduced the Enteer re-entry device. This device uses a flat balloon

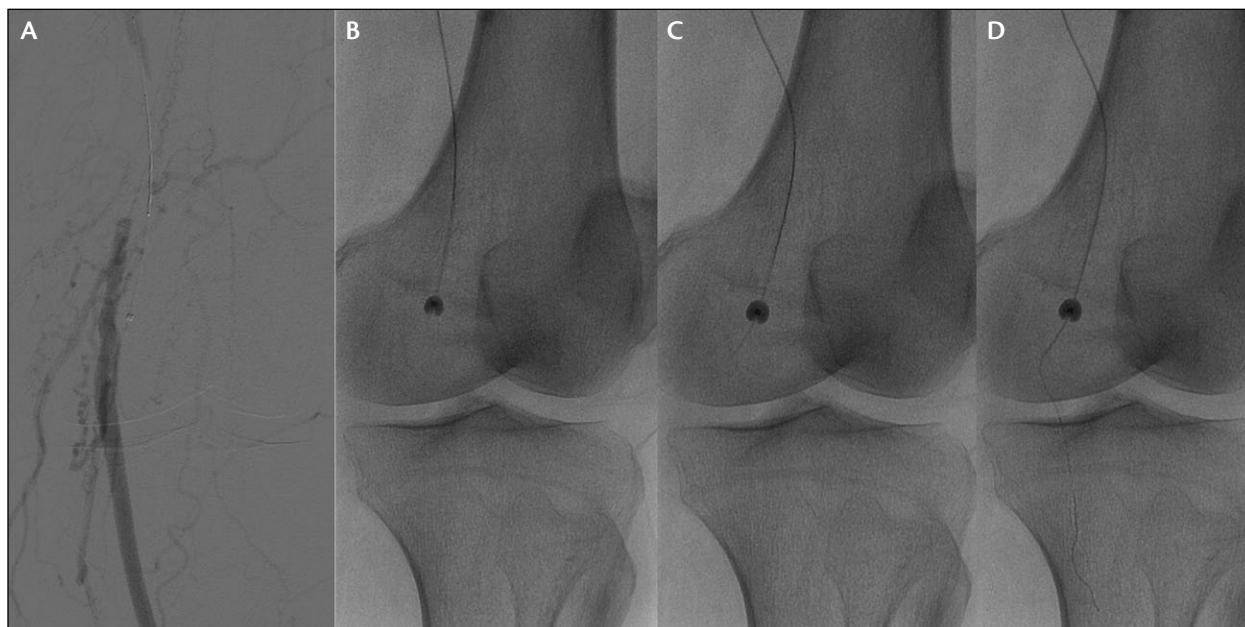


Figure 3. OffRoad balloon inflated with subtraction angiogram showing sinking toward the true lumen. OffRoad in the same position on fluoroscopy (A). OffRoad balloon inflated with forward pressure on balloon catheter that increases the angle of the catheter tip toward the center of the distal vessel (B). OffRoad with needle-tipped hypotube advanced through plaque to the distal true lumen (C). OffRoad with wire advanced through the hypotube to the distal true lumen (D).

with a side exit point of the lumen of the catheter in the midpoint of the flat balloon. Inflation of the flat balloon in a subintimal plane results in the balloon spontaneously orienting itself so the balloon “wings” are in the direction of the intimal plane. Then, the side hole in the catheter is pointed in either the direction of the adventitia or the intima. A blunt, stiff-tipped 0.014-inch wire is then directed out of the balloon side hole, aimed to penetrate the intimal/plaque layer to achieve re-entry. The device is small and easily tracked to the site of re-entry, and inflation of the balloon consistently provides orientation of the exit point of the catheter to the true lumen. However, the penetrating ability of a 0.014-inch wire tip is far less than the penetration afforded by the needle-tipped hypotubes utilized in other re-entry devices. Technical success rates for Enteer of 86% (18/21 cases) were reported in Covidien’s PFAST-CTO study as presented at VIVA 2012. No other postmarket studies with the device have been reported.

OFFROAD CATHETER

In 2009, S.I. Therapies, Ltd. (Caesarea, Israel) proposed a unique re-entry device to address some of the concerns of existing devices. The device is composed of a balloon catheter combined with a needle-tipped hypotube. This simple, stable re-entry technology was trialed in selected centers in Europe, was purchased by Boston Scientific

Corporation (Natick, MA) in 2011, and gained FDA approval in November 2013. The balloon catheter allows for anchoring and directional control. The flexible, laser-cut stainless-steel hypotube with a straight needle tip is advanced out of the balloon catheter end to penetrate the intima and plaque distal to the total occlusion to achieve true lumen re-entry.

The balloon catheter is 0.035-inch guidewire-compatible and is tracked to the point of desired re-entry, distal to the occlusion. The balloon is conical-shaped, semicompliant, 5.4 mm in diameter, and tipless. When inflated in the subintimal plane at the point of desired re-entry, the balloon’s conical shape deflects off of the (relatively stiffer) media and adventitia toward the (relatively softer) intima, thus directing the sharp, needle-tipped hypotube to penetrate through the intima and allow for passage of a 0.014-inch guidewire into the distal true lumen (Figure 1).

The OffRoad™ re-entry catheter system provides ease of use by tracking over a 0.035-inch guidewire, which is the standard wire for crossing most femoropopliteal occlusions. The balloon tracks across tight bifurcations. Inflation of the balloon in the dissection plane allows for sinking and slight angulation of the bell-shaped balloon to point the distal catheter tip at the middle of the distal vessel (Figure 2). The self-centering aspect reduces the complexity of imaging and repeated rotational adjust-

ments to orient the catheter before hypotube advancement. The anchoring aspect of the balloon and the pushability of the laser-cut, needle-tipped hypotube allow for improved penetration of the distal plaque to gain access to the distal true lumen. The stability of the balloon also provides for precise feedback from the hypotube while penetrating the distal plaque. The OffRoad™ re-entry catheter system is unique in that it comes in two working lengths (70 and 100 cm); these allow the operator to select the appropriate catheter length when working with antegrade or contralateral femoral access. In the Re-ROUTE clinical trial, Boston Scientific reported an 84.8% (78/92) technical success rate for the OffRoad device.¹¹

Although the ability to penetrate calcified plaque has improved, the device is not able to overcome severe calcification. Inflation of the balloon at a point of severely calcified plaque can deflect the balloon so as to prevent the sinking of the balloon and self-centering, such that the angle of the needle tip is not to the center of the distal vessel. In such instances, repositioning the balloon catheter at a site with less calcification will allow for the catheter to self-center in the distal vessel. If there is only a slight adjustment needed in the balloon-centering angle, applying forward pressure on the balloon catheter will typically cause it to increase the angle of the balloon tip to the catheter shaft and allow for an increase in the angle of the hypotube deployment toward the center of the distal vessel (Figure 3).

SUMMARY

The increased technical success afforded by re-entry tools has been critical in allowing advancement in the overall endovascular approach to complex peripheral vascular disease. In addition to providing for significantly increased technical success in complex CTO cases, added accuracy is afforded to the intervention. A re-entry device allows for limitation of dissection of the vessel distal to the occlusion and can preserve critical collaterals and vessel branch points. It can also limit the extent of the intervention and allow for preservation of options if recurrent stenosis or occlusion should occur in the treated segment. Despite the added cost of an unreim-

bursed re-entry device, the increase in technical success by using such a device allows the cost of unsuccessful re-entry cases to be recouped through reimbursement for the additional successful interventions; this maintains overall lab reimbursement and efficiency. Advancements with new devices have allowed for their broader application and increased technical success, and have reinforced the fact that re-entry devices have become essential tools in the treatment of complex CTO of the peripheral arteries. ■

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Results from case studies are not necessarily predicative of results in other cases. Results in other cases may vary.

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