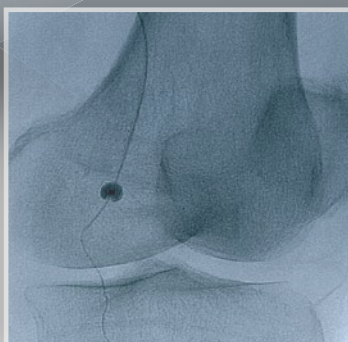
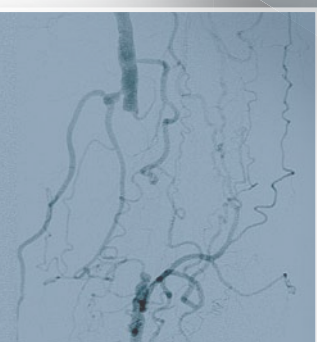


Endovascular TODAY

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MASTER THE CROSS



Leading endovascular experts describe the many techniques and tools required to conquer the challenges of CTOs in PVD.

FEATURING



Jon C. George, MD



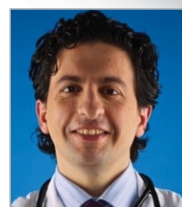
Richard Kovach, MD



Donald L. Jacobs, MD



James B. Park, MD



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MASTER THE CROSS

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Cover images courtesy of Donald L. Jacobs, MD

Techniques for Successful Crossing With the TruePath™ CTO Device

Best practices for treating vessels with chronic total occlusions.

BY JAMES B. PARK, MD, FACC

In terms of devices that treat chronic total occlusions (CTOs), the TruePath™ CTO Device (Boston Scientific Corporation, Natick, MA) offers the most versatility in managing a variety of lesion types and anatomical locations. For example, an intraluminal device such as the Frontrunner (Cordis Corporation, Bridgewater, NJ) serves its purpose, but when the interventionist is faced with a very hard, smooth proximal cap, it will not be easily traversed unless specific techniques are employed to make a “dent” in the cap. The TruePath device, however, is designed to “drill” through the proximal cap or occlusion regardless of composition, be it soft tissue, ulcerated plaque, mixed fibrocalcific, or extremely calcific. In addition, because of its 0.017-inch profile, it may traverse multiple levels over the length of a given CTO, including the distal cap.

RECOMMENDATIONS FOR USE

In addition to the specific lesion types for which it is suitable, the other useful aspect of the TruePath device relates to the anatomical locations where it can be used safely and effectively. Normally, when revascularizing or treating CTOs, my tendency is to assess where in the vascular tree a device is best used and where it should not be used. Given TruePath’s small size, it is safe and effective to use in various anatomies. For example, due to its proficiency in the calcified lesion/cap and its size, I find it to be the best intraluminal CTO device for below-the-knee lesions in the tibial/peroneal vessels.

Staying Intraluminal

Due to the lack of re-entry devices that we can use below the knee, it is extremely important to stay intraluminal or have the ability to come back to the luminal side with one device. Again, given its low profile,

when the TruePath CTO Device is used in the extraluminal area outside the vessel wall or the concomitant venous vessel, it will not produce a sizable perforation or fistula that will ultimately need treatment.

In the 52 cases that have been performed so far at our institution, there has not been a complication related to the device’s use for CTO in any of the vascular beds. This is of particular importance given the trepidation many operators feel when working below the knee, for fear of the patient developing compartment syndrome. Similar concerns exist when working in the pelvic space, such as in the iliac arteries, as well as the subclavian artery. Often, possible complications resulting from a perforation in these anatomies and the limited options to percutaneously correct them pose problems for interventionists. In addition to below-the-knee vessels, our experience with the TruePath device in the popliteal, superficial femoral artery (SFA), common femoral, iliac, and subclavian arteries leads me to believe that it is very useful in a variety of anatomic locations and types of CTOs.

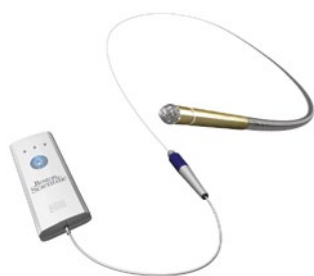
Techniques

The device is packaged with a short 3° bend at the distal tip, although a shaping tool is included with the device that, when used correctly, produces a 15° bend on the distal 5 mm of the tip. In my experience, putting a 15° bend on the tip is the best way to use the device so that when torquing the device, maneuvering throughout the length of the CTO is possible. Further, if advanced into a subintimal or extraluminal space, the device can be turned to a different plane or vector.

A supporting catheter may be used with the device, such as a straight 0.018-inch Quick-Cross Support Catheter (Spectranetics Corporation, Colorado Springs, CO). Spectranetics also makes a Quick-Cross support catheter in an angled configuration, which

BOSTON SCIENTIFIC TRUEPATH™ CTO DEVICE**Key features:**

- Diamond-coated tip
- 0.018-inch wire
- 165 cm
- 1:1 torque response
- No capital equipment



The TruePath™ CTO Device is designed to facilitate the crossing of chronic total occlusions (CTOs) within the peripheral vasculature. The device features a rotating diamond-coated tip designed to break through occluded peripheral arteries and facilitate the placement of conventional guidewires for treatment of peripheral lesions. The ultra-low 0.018-inch profile is approximately half the size of competitive devices and is engineered for optimal crossing. Once positioned, the distal tip rotates at 13,000 rpm to facilitate drilling through calcified lesions and other fibrous blockages. The TruePath device requires no capital equipment and is available with an optional extension wire to facilitate catheter exchange and increase the working length beyond 300 cm. The TruePath device is designed to function through an 0.018-inch support catheter, such as a Rubicon™ Support Catheter, and its tip can be angled to 15°. The TruePath CTO Device provides feedback to the user via audio and visual cues on the control unit. LEDs and audible signals are activated as the operator encounters increased resistance. Also, a built-in safety mechanism is included, so that when lesion resistance exceeds the device's drilling capacity, the audible and visual cues inform the operator to choose a different channel or withdraw the device.

I use to support my “push” to the end of the CTO device. Given that the device's cutting surface is covered with 15- to 20-μm diamond particles, my technique with TruePath is not unlike that used for the Rotablator™ Rotational Atherectomy System (Boston Scientific Corporation), another device with a diamond-coated cutting surface. Essentially, I let the device “do the work” by placing the tip on the cap and applying gentle forward pressure rather than being overly aggressive and ramming the device through the lesion. Sometimes, the interventionist needs to place consistent forward pressure on the TruePath device, especially for a severely calcified plaque/cap, but the operator may try to let the device almost drive itself.

Pressure and Steering

The interventionist will have to decide how much pressure he or she needs to put on the device, but for most lesions, aggressive forward pressure may not be needed. For the SFA, popliteal, and tibial vessels, if a patient has adventitial calcifications, it may help to guide the device by steering through the CTO, especially if the vessel is tortuous or does not sit in a “normal” plane, as seen on angiography or by fluoroscopy.

In addition to the 0.018-inch Spectranetics supporting catheter, the interventionist can use other catheters that are 0.018 inch or larger (eg, Rubicon™ Support Catheter [Boston Scientific Corporation, Natick, MA]), including a 0.035-inch catheter to help get to the beak, nub, or other planes that may be difficult to access due to the small angulation of the device itself at 15°. Making the bend of the TruePath tip any larger than 15° with other tools is not recommended, as this may compromise the tip's ability to rotate.

Controller

In addition to tactile feel and fluoroscopic guidance, the TruePath device also includes a hand-held controller with visual (three lights) and audio (“chirp”) feedback. The first light, a green light, indicates that the device is activated. The second light, another green light, indicates increased resistance at the device tip and that it is actively engaging hard or calcific tissue and is accompanied by a sustained audible tone. The third light, a red light, indicates significant resistance at the tip that is beyond the normal operating range and is accompanied by an audible, intermittent “chirp.” In my experience, prolonged activation of the third light and audible “chirp” may signal that the device has found a subintimal or extraluminal path. At first, given my lack of experience, I hesitated to use these features because I did not know what they meant clinically, but since my first case, I have learned to use and trust these indicators to help me understand where the end of the device might be in the vessel.

Periprocedural Imaging

With my experience in treating CTOs, viewing the fluoroscopic images gives me a good idea whether I am in the SFA space or not, even without adventitial calcifications to guide me while looking at the bony landmarks. I recall one particular case, however, when I consistently thought I was in the correct plane and direction, but the red warning light and “chirp” were activated, indicating that I was possibly outside the artery. I attempted to cross again, this time being mindful of the red warning light and “chirp,” and the device

found a different pathway that did not appear to be the right direction, but the device soon passed easily through the distal cap. When looking at the lesion on angiography after revascularization, it clearly showed that at the end of the CTO near the distal cap, the SFA took a medial turn that we sometimes see in patients due to tortuosity. By trusting the TruePath™ CTO Device warning signals, the procedure was completed, without complication.

Using a Complete Toolbox

When treating CTOs, I never hesitate to use a combination of devices or to revert to the guidewire/guiding catheter technique using the subintimal space to move past the distal CTO to complete the case, especially in the SFA. I will sometimes then come back and re-use the TruePath CTO Device to return to the distal lumen or move through the distal cap instead of having to use a re-entry device.

In CTO work, the operator needs to be flexible and willing to use a variety of tools to achieve complete revascularization. When using the previously men-

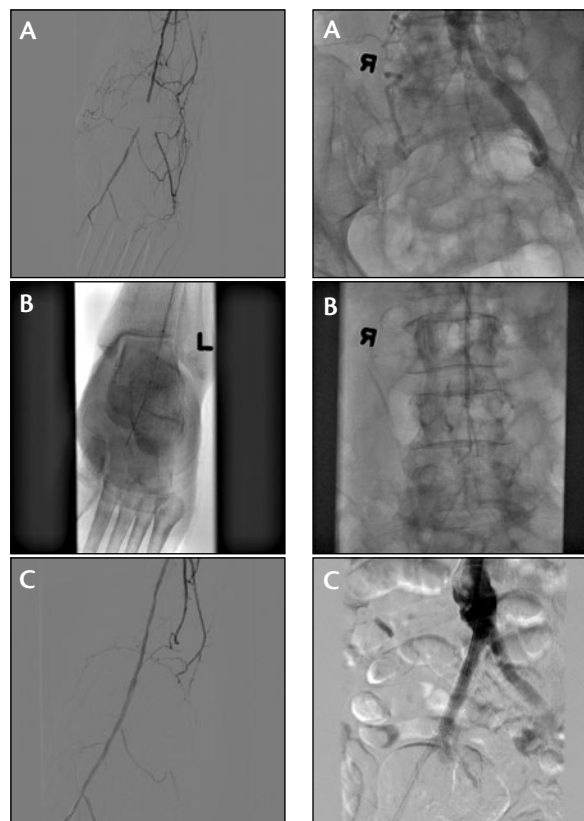


Figure 1. Pre- (A), intra- (B), and postprocedural (C) angiograms of a distal anterior tibial artery CTO.

Figure 2. Pre- (A), intra- (B), and postprocedural (C) angiograms of an iliac CTO.

tioned technique, the TruePath CTO Device gives the interventionist many options to achieve success while limiting complications.

APPLICATIONS OF THE TRUEPATH CTO DEVICE

Distal Anterior Tibial Artery CTO

Clinical scenario. This case (Figure 1) involved a distal anterior tibial artery CTO near the dorsalis pedis (DP) vessel in a patient with a toe wound that was not healing due to a lack of perfusion pressure. In cases such as this where the target lesion is very distal, there would be cause for concern for complications and/or failure rates, especially in a calcified vessel. In addition, the extreme distal nature of this lesion precluded the possibility of using a retrograde approach. In patients with wound healing issues, the correct angiosome vessels need to be revascularized, which are often completely occluded. These vessels need to be opened without surgery.

Solution. Using a 6-F, 90-cm Terumo sheath (Terumo Interventional Systems, Somerset, NJ) from the contralateral approach, with a 0.018-inch Spectranetics supporting catheter, I was able to come all the way from the right common femoral approach, and given the length of the 150-cm Spectranetics supporting catheter, we were able to get through the CTO using the TruePath device.

Iliac CTO Treatment From the Left Brachial Approach

Clinical scenario. The patient had a proximal or ostial CTO of the left iliac artery (Figure 2). Reconstitution was difficult to see, and retrograde cannulation of the left common femoral artery can be difficult. The patient was a thin elderly woman with severe claudication of the left buttock and left lower extremity. Given the size of the patient, having a sheath that is > 6 F in the brachial artery would pose significant risk. Also, due to the absence of a nub, other larger CTO devices would be difficult to use due to a lack of pushability by the supporting catheter or device.

Solution. I used a 6-F, 90-cm Terumo Destination sheath from the left brachial approach. Using the TruePath device and the Spectranetics supporting catheter, I was then able to get through the proximal cap and visualize that I was in the common femoral vessel. Using a 0.018-inch Steelcore wire (Abbott Vascular, Santa Clara, CA), I was able to revascularize using balloon-mounted stents on a 0.018-inch catheter through the 6-F sheath. Again, given the small size of the TruePath device, I was not as concerned about perforation of the iliac artery when trying to find the true lumen.

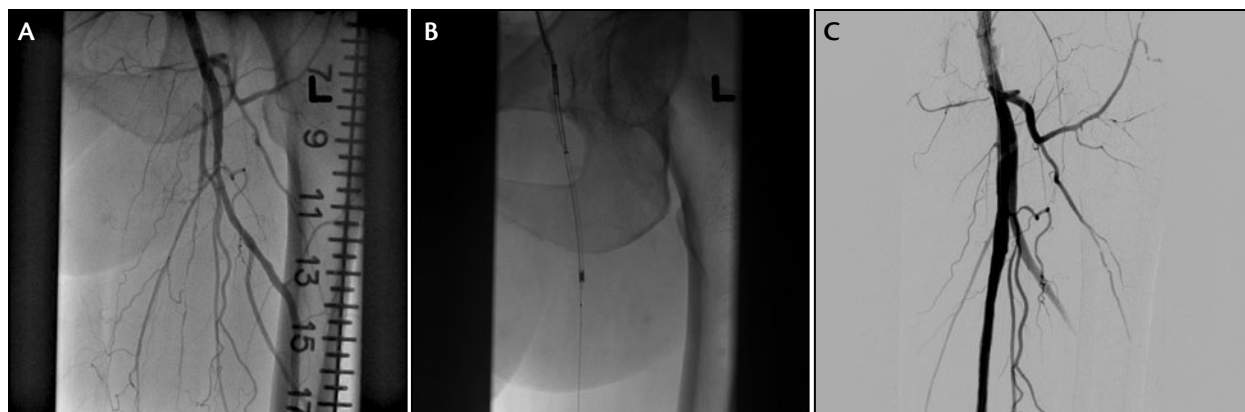


Figure 3. Pre- (A), intra- (B), and postprocedural (C) angiograms of a long CTO.

SFA CTO Treatment for a Long Diffuse Diseased Vessel

Clinical scenario. In this case (Figure 3), the patient had claudication, with a CTO greater than 200 mm in length. The ostial or proximal portion of the SFA was severely diseased, and there did not appear to be room to accurately place a self-expanding stent in the ostial portion of the SFA. In cases like this, atherectomy might be helpful at the ostium so that the interventionist would not have to stent to the ostium. This would indicate the need to be as intraluminal as possible. There might be concern that the length of the CTO and the vessel size would preclude the use of the TruePath™ device

Solution. A 7-F, 45-cm Terumo sheath from the contralateral common femoral artery can be used in case other devices (atherectomy, covered stents, etc.) need to be employed. With the TruePath device, we were able to stay intraluminal to revascularize using an atherectomy device in the proximal portion and stenting the distal portion.

CONCLUSION

In summary, the CTOs that we see in patients with peripheral artery disease are quite complex, especially

those with limb ischemia. Therefore, having purpose-built tools for CTOs, particularly in the tibioperoneal vessels, is extremely important. In addition, limiting complications while working on CTOs gives the operator more opportunities for success, which is exemplified by the TruePath CTO Device when treating complicated CTOs in all anatomical locations including the iliac, common femoral, superficial femoral, and popliteal arteries, in addition to the tibial vessels. ■

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

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

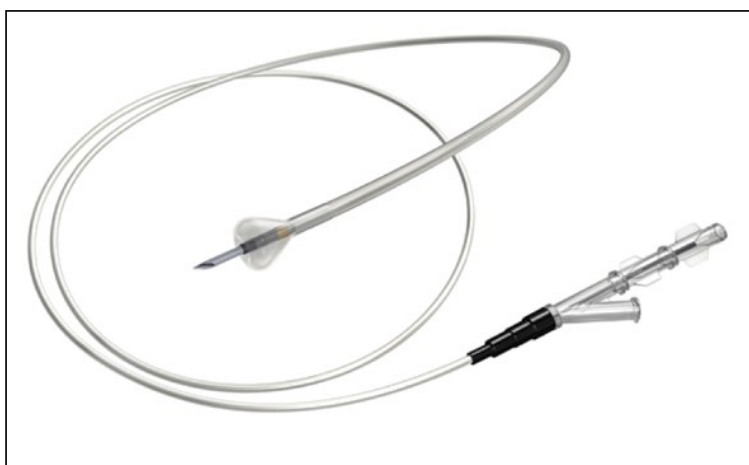


Figure 1. OffRoad catheter with balloon inflated and the needle hypotube advanced.

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

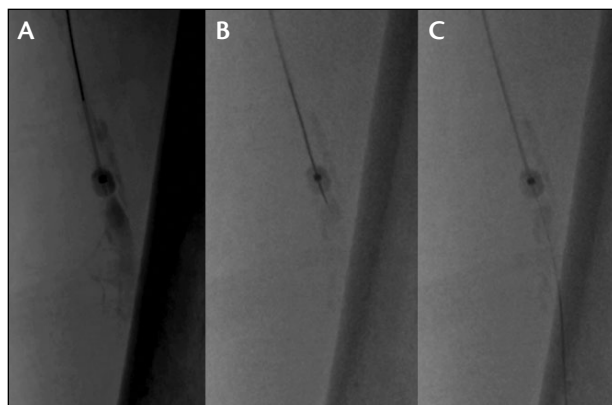


Figure 2. OffRoad inflated in the subintimal plane with centering of the balloon in the distal lumen that has static contrast in it (A). Advancement of the needle-tipped hypotube out of the catheter and into the true lumen (B). Advancement of the wire through the hypotube and into the distal true lumen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

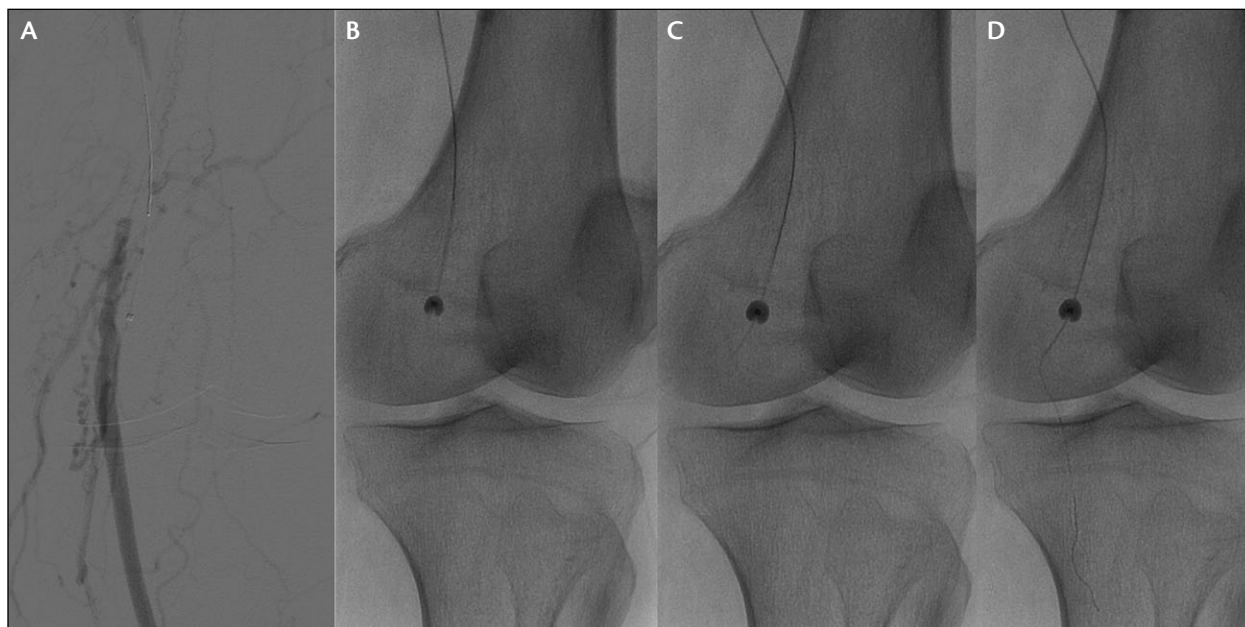


Figure 3. OffRoad balloon inflated with subtraction angiogram showing sinking toward the true lumen. OffRoad in the same position on fluoroscopy (A). OffRoad balloon inflated with forward pressure on balloon catheter that increases the angle of the catheter tip toward the center of the distal vessel (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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TAMI: A New Technique in Critical Limb Ischemia Revascularization

A novel use of the Boston Scientific TruePath™ CTO Device in the treatment of advanced peripheral vascular disease.

BY FADI SAAB, MD, FACC, FASE, AND J. A. MUSTAPHA, MD, FACC, FSCAI

The number of patients living with peripheral vascular disease (PVD) in the United States will continue to increase and will exceed 20 million by the year 2030.¹⁻⁵ But this epidemic is not isolated to Western countries. A recent analysis evaluating the prevalence of PVD in third-world countries shows an increase of 27%.⁶ The overall incidence of critical limb ischemia (CLI) and lower extremity arterial ulcers has been estimated at 1% to 2%.⁷

Endovascular revascularization of patients with PVD has evolved dramatically, and we now have a better understanding of the atherosclerotic process. Traditionally, therapy has been delivered through major arterial conduits, such as the common femoral artery (CFA), brachial artery, or even radial arteries. Arterial access may be challenging, depending on the patient's body habitus and any comorbidities, although a positive step forward by our industry partners is the fact that the crossing profiles of our peripheral vascular devices are becoming smaller. Tibiopedal arterial minimally invasive retrograde revascularization (TAMI technique) is a revascularization modality by which the operator obtains tibiopedal access and revascularizes the lower extremity via tibial access only.

The TruePath™ CTO Device (Boston Scientific Corporation, Natick, MA) was designed to penetrate hard or calcified occlusions with a diamond-coated tip that rotates at 13,000 rpm. This unique feature has gained significant interest in treating severely calcified CTOs, especially in patients with CLI who tend to have unusually high levels of dense calcium deposits in their CTO caps. In our practice, we have seen this device penetrate a dense calcific CTO cap under ultrasound. We believe the risk of perforations would be less in these dense, calcified lesions.

Our experience has led us to conclude that not all crossing tools are created equal, and each has a place in an algo-

rithmic approach to crossing complex CTOs. The TruePath device offers a unique advantage in dealing with bulky, calcified CTO caps, which tend to deflect away many crossing tools as once the CTO is penetrated, the body of the device can advance into the true lumen. The rotating tip will drill through the cap, engaging the device within the lesion, thus decreasing the chance of perforation or becoming immediately subintimal.

One highly differentiated feature of this device is its low, 0.017-inch profile, which allows it to be used via tibial retrograde access in sheaths as small as 2.9 F via an 0.018-inch support catheter, such as the Rubicon™ Support Catheter (Boston Scientific Corporation). This low-profile combination delivers robust energy to tackle complex CTOs from the retrograde approach.

We typically prefer to use the device with an angled, 0.018-inch support catheter, such as the CXI support catheter (Cook Medical, Bloomington, IN). This allows the operator to more easily direct the TruePath device where needed and deliver it to the target lesion. By rotating the 0.018-inch support catheter, the operator can obtain 360° access to the target. The simple maneuver of combining an angled catheter with a straight TruePath device adds significant value and enables a higher success rate for calcified CTO caps. If this combination does not work, the operator may choose to bend the TruePath tip for added steerability. A prepackaged shaping tool is included with the device, which allows the operator to impart a 15° angle to the tip.

In patients with severe disease before the lesion location, the operator may choose a 0.035-inch support catheter passed through a 4-F Precision sheath (Terumo Interventional Systems, Somerset, NJ). We typically utilize the NaviCross catheter (Terumo Interventional Systems) to direct the TruePath device. The device is then activated and advanced across the lesion. The working length

is 165 cm, which can be extended up to 335 cm with the addition of a wire extension to allow for support catheter or balloon catheter exchanges. In cases where the TAMI technique is used, the operator will advance the support catheter to the true lumen. Once adequate blood return is confirmed, a contrast injection will confirm the position. At this point, the operator may choose the modality of therapy.

CASE PRESENTATION

A 72-year-old woman with a medical history significant for coronary artery disease, diabetes, hypertension, and chronic kidney disease developed an ulcer involving the plantar and dorsal aspect of the right great toe. The distribution of the ulcer corresponded to both the anterior and posterior tibial arteries. The ulcer placed the patient at Rutherford class V. There were two attempts to revascularize the right lower extremity through a traditional left CFA retrograde approach and a right antegrade approach. Both attempts were unsuccessful, and the patient was recommended for a major above-the-knee amputation. Because of the heavy calcification and severity of the disease, revascularization via the TAMI technique was chosen.

The TAMI Technique

When the operator chooses the TAMI technique, the distal cap is usually engaged first. The TruePath device is extended 1 cm beyond the tip of the support catheter (Figure 1). The TruePath device is activated and slowly advanced. It is important that the operator does not put too much pressure on the device, as it is advanced to allow the drill to engage the lesion. Attempting to push, prolapse, or torque the device through the lesion works against the drilling mechanism. Applying significant pressure may advance the drill into a subintimal space or, in some cases, perforate the vessel. As the device is advanced through the lesion, the support catheter should be advanced to maintain the consistent 1-cm distance between the support catheter and the tip of the TruePath device. As with standard CTO wire techniques, the device will often cross more effectively by advancing both the TruePath™ and the support catheter as a system.

CTOs are complex and may require multiple catheter and wire exchanges. It has been our experience that penetrating the distal CTO cap is easier than penetrating the proximal cap.

CTOs are one of the last unconquered territories in the peripheral space, and crossing techniques continue to benefit from the advancement of many new devices, including the TruePath device.

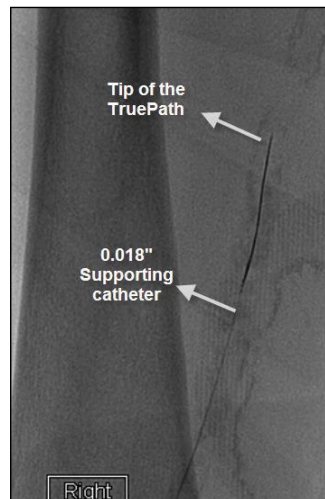


Figure 1. The TruePath™ tip engaging the distal CTO cap via the 0.018-inch catheter from retrograde access.

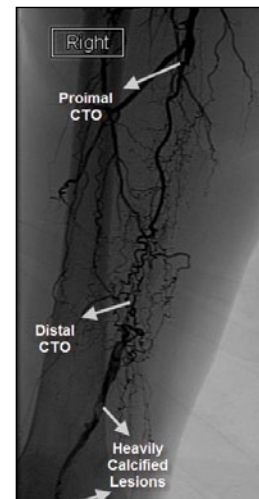


Figure 2. Diagnostic angiogram showing the proximal and distal CTO caps.

TruePath™ Operator Feedback

The TruePath device has audible signals that indicate the amount of resistance at the drill tip. The first two green lights signify whether the device is in active and drilling mode, respectively. When the resistance exceeds specifications, the third light, which is red, will illuminate, and the device will emit a “chirp.” In this mode, the tip oscillates to relieve pressure on the drive shaft. When the device enters this mode, the operator must determine what is causing the increase in resistance. Pushing too hard on the device as it advances can trigger this mode. Often, easing the forward pressure will allow the device to return to drill mode as the operator engages and advances in the lesion.

The tip overload mode can also be encountered while traversing the lesion. This mode can provide important feedback as to whether the device is taking a subintimal track, and it can allow the operator to redirect the catheter and device to stay in the true lumen. Upon hearing this feedback, the operator can take additional views and use calcium outlines to determine device position. We typically employ an angled support catheter to direct TruePath in case of tortuosity. The operator may choose an 0.018-inch or 0.035-inch support catheter, depending on the pedal sheath that is used.

STEPWISE TAMI PROCEDURE DESCRIPTION

A key to improving the chances for successful revascularization using the TAMI technique is having a detailed angiographic evaluation. This includes selective angiography of the limb that is being treated. Selective angiography will uncover vascular conduits that were



Figure 3. Patient position on the catheterization table with tibial access for the TAMI procedure.

thought of as nonexistent before. In our experience, the CTO segment is usually shorter than what originally was thought. In the current case, the patient was already recommended for amputation, and two attempts at revascularization failed prior to the current procedure. The patient underwent diagnostic angiography that showed a long CTO with severe calcification (Figure 2).

Step 1: Patient Placement. The patient was placed on the catheterization table in reverse fashion, with the head of the patient to the right of the operator to allow for antegrade and retrograde access (Figures 3 and 4).

Step 2: Access. With the presence of a vascular technologist, the tibial artery required for access is studied under ultrasound (US). We typically employ a hockey-stick-shaped probe. This probe employs a variable frequency between 7 and 15 MHz. Depending on the tibial vessel required for access, the leg is positioned accordingly. The operator is looking for the needle and aiming toward the tibial vessel. Identifying the tibial veins is very important, in order to avoid any venous sticks. A venous stick might predispose to access site complications, such as arteriovenous fistulas.

Step 3: Successful Arterial Cannulation. The needle trajectory is monitored under US guidance. After vessel puncture, the operator should observe the bright blood return. Pulsatile blood flow is never present.

Step 4: Access Wire Introduction. After introducing the access wire, a microsheath is introduced. The wire is introduced through the needle. The US technician will switch orientation from cross-sectional to longitudinal. At our institution, we use the Terumo Precision Microsheath and the Cook tibiopedal microsheaths (Cook Medical). The access wires have an atraumatic tip. The body of the wire is supportive and will allow the introduction of the



Figure 4. Operator and ultrasound technician position in relation to the patient.

sheath. The sheath is introduced, and depending on the anatomy of the patient, the tip of the sheath may be visualized under US, or a retrograde angiogram through the sheath may be obtained.

Step 5: Intra-arterial Medication. Once the sheath is secured inside the artery, full weight-based anticoagulation with heparin will be given (60–80 U/kg). Injecting heparin will create a burning sensation. Depending on the patient's blood pressure, 300 to 400 µg of nitroglycerin can be injected through the side arm of the sheath. Nitroglycerin may be injected at 5- to 10-minute intervals. Activated clotting time (ACT) is checked at 20-minute intervals. The ideal ACT target during these procedures is maintained between 200 and 250 seconds. Another option for treating the vessel with nitroglycerin every 5 to 10 minutes is using the TAMI solution (Table 1). Instead of frequent injections, the solution can be infused intra-arterially at a rate of 6 to 7 mL/min. The continuous infusion will decrease the chance of vasospasm and arterial thrombosis.

Step 6: CTO Crossing and Revascularization Strategy. Choosing the modality of therapy depends on the lesion being treated. The TruePath device requires a support catheter to help deliver the energy to the CTO cap (Figure 1). In our experience, working via a CXI 0.018-inch angled catheter (Cook Medical) or a NaviCross 0.035-inch angled catheter allows us to direct the tip of the TruePath without damaging the device or losing the ability to engage the CTO cap. After crossing the CTO cap, the support catheter must follow the tip. Once the CTO is crossed, an angiogram through the support catheter can confirm our position within the true lumen. In this example, after crossing, we choose to perform orbital atherectomy followed by balloon angioplasty (Figures 5 and 6). Final angiographic assessment should be performed via pedal access through the support catheter. The angiogram should include the tibial access site (Figures 7 and 8).



Figure 5. Orbital atherectomy of the popliteal and superficial femoral arteries.

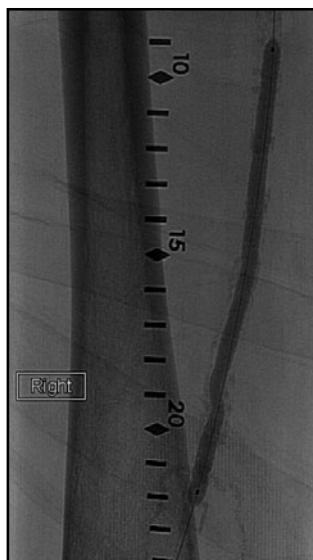


Figure 6. Balloon angioplasty of the SFA and popliteal arteries.



Figure 7. Final angiogram of the CTO segment of the SFA/popliteal arteries.



Figure 8. Final angiogram of the posterior tibial artery into the plantar vessels via tibial access.

Step 7: Hemostasis. At the end of the procedure, the sheath will be removed immediately. It is our practice to document an ACT before sheath removal. Currently, we are using the same hemostasis devices that are applied for radial access. One unique device is the Boa device (Lakeshore Medical Innovations, Byron Center, MI), which is basically a band with two parallel ridges that achieve hemostasis at the access site. The site is checked every 15 minutes. Once there is no visible bleeding, the hemostasis device is removed. Our patients will ambulate 30 minutes after hemostasis is achieved.

Our patient started with a monophasic posterior tibial pulse and ended with a palpable posterior tibial pulse. Eventually, the patient required toe amputation, and the limb was preserved.

DISCUSSION

Accessing major vascular conduits through the groin area has long been the traditional means of delivering therapy. The relationship between bony landmarks and the CFA is well established. Retrospective studies showed the benefit of fluoroscopy when trying to access the CFA.⁸⁻¹³ Anatomical variation with the CFA bifurcation is well documented. High bifurcation of the superficial femoral artery (SFA) and profunda has been documented in up to 35% of patients.¹⁴ US guidance has been shown to be an effective tool in difficult access cases.⁹ The use of US guidance has been particularly effective in facilitating vascular access, including femoral and tibial access in patients with CLI.¹⁵

In the past, the complexity of tibial vessel anatomy and disease in CLI patients prohibited operators from revascularization, but this is no longer the case, as clinicians understand the implications of amputation and the impact on patient morbidity and mortality. Mortality rates range anywhere from 40% at 2 years up to 70% by 5 years.¹⁶ Treating tibial vessels in CLI patients is one of the mainstays of limb salvage.

The use of ultrasound, fluoroscopy, and Doppler strategies offers a great advantage in cannulating the CFA. Despite the improvement in technical skills and access strategies, the use of lower-profile devices, and the judicious use of anticoagulation, complications still occur. These complications include hematomas, arteriovenous fistulas, pseudoaneurysm, nerve compression, and retroperitoneal bleed, to name a few. There are multiple risk factors that will increase the risk of these complications. Age, large sheath size, antiplatelet therapy, obesity, and above all, PVD are common risk factors in our patients.¹⁷⁻¹⁹ Groin complications causing bleeding or requiring blood transfusion are not a benign phenomenon; these are associated with significant morbidity and mortality.²⁰⁻²⁵

The idea of delivering therapy in high-risk CLI patients while decreasing the risk of access complication, bleeding, and transfusion is both challenging and compelling. A recent analysis examined the safety and feasibility of the TAMI approach, comparing a TAMI technique cohort to a traditional-access cohort.²⁶

TABLE 1. TAMI SOLUTION COMPOSITION

| |
|----------------------------------|
| 500 mL heparinized normal saline |
| 3,000 µg nitroglycerin |
| 2.5–5 mg verapamil |

Overall, the TAMI cohort patients had more comorbidities and a higher Rutherford class. Tibial vessels were clearly more fragile and of smaller caliber. The ability to use a CTO crossing device through a low-profile sheath is important in these cases. TruePath can be delivered through a 0.018-inch catheter, so the operator can capitalize on the unique features of the device without increasing sheath size, and subsequently, rates of complication.

The TAMI technique is unique in allowing the operator to access, cross, and treat patients with advanced peripheral vascular disease. With new technologies, such as the TruePath device, more and more patients may receive revascularization via tibial access. Despite the multiple comorbidities affecting these patients, a standardized approach was shown to be safe and effective. The TAMI approach should not be attempted in any patient without adequate lumen visualization allowing for tibial vessel cannulation.

The TAMI technique offers some advantages, such as a potential decrease in the rate of bleeding and the need for transfusions. Decreasing the rate of groin complications in cardiac patients undergoing angioplasty through a radial approach has also been correlated with a lower morbidity and mortality.²⁷

CONCLUSION

The TAMI technique is a novel approach to treating patients with advanced PVD and CLI. New technologies facilitating crossing of CTOs, such as the TruePath™ CTO Device, will allow more complex disease to be addressed without increasing the risk of complications. The TruePath Device is easy to use, with multiple built-in safety features and a low crossing profile. The TAMI technique is feasible because of the low crossing profile of newer endovascular devices. Use of the technique offers tremendous potential: improved patient safety, reduced contrast usage, and reduced radiation exposure to both the patient and operator. We believe that this approach, when chosen in the right subset of patients, will have a positive impact on patient outcomes. ■

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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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Wired for Success

Guidewire escalation and techniques for successful crossing of chronic total occlusions.

BY JON C. GEORGE, MD; TROY TRAYER, DO; AND RICHARD KOVACH, MD

Chronic total occlusion (CTO) of the coronaries has long been a known challenge for percutaneous coronary intervention. As the prevalence of peripheral arterial disease escalates, we are increasingly being confronted with complex superficial femoral artery (SFA) and below-the-knee CTO interventions. Our characterization of how CTOs develop is limited by the late stage of diagnosis and lack of data on the initial formative basis. Animal studies have attempted to develop a better understanding of the composition of CTOs. From these studies, we have theorized that the common initiating event is an acute arterial occlusion due to atherosclerotic plaque rupture with thrombus formation that triggers an inflammatory reaction. During the first 2 weeks of this process, an acute complex is formed that contains platelets and erythrocytes within a fibrin mesh with an influx of acute inflammatory cells.¹

During the intermediate stage at 6 weeks, negative arterial remodeling and disruption of the internal elastic lamina ensues, with intense neovascularization and CTO perfusion.² The subsequent 12- to 24-week time period demonstrates decreased microvessel formation and CTO perfusion with progressive gradual replacement of proteoglycans by collagen and calcium. The density of the fibrocalcific tissue is highest at the proximal and distal ends of the lesion: the proximal fibrous cap is characteristically composed of densely packed type I, III, V, and VI collagen, which is the initial barrier to the CTO,³ whereas the distal fibrous cap tends to be a thinner and softer, yet densely packed collagen structure (Figure 1). Within the main body of the CTO, organized thrombus and recanalization channels are observed (Figure 2) in 60% of lesions.² CTOs that are < 1 year old are usually composed of “soft” or cholesterol-laden foam cell lesions. In contrast, older CTOs typically contain “hard plaque” that is composed of fibrocalcific iron and hemosiderin deposits within the lesions (Figure 3).

GUIDEWIRE SELECTION

A foundational knowledge of the composition of CTOs is essential for the selection of an appropriate guidewire (Figure 4), which can consecutively increase success rates to cross CTOs, improve device delivery, control cost, and limit the risk of vascular injury.⁴ Although crossing a CTO alone may require a progressive escalation of guidewire choice,

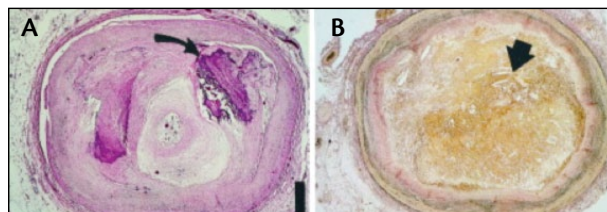


Figure 1. Hard or fibrocalcific CTO with extensive calcification (arrows; A). Soft or lipid-laden CTO intimal plaque with extensive cholesterol deposition (arrow; B).²

subsequent guidewire exchanges may be further required during the procedure to achieve optimal or safer device delivery. Ultimately, a fundamental understanding of guidewire selection (see *Peripheral Guidewires* insert at the end of this article) and performance characteristics (Table 1) is of paramount importance to successful completion of a complex endovascular CTO intervention.

First, the core diameter of the wire must be decided upon, which is the functional guidewire diameter with standard sizes of 0.014, 0.018, and 0.035 inches. Large-diameter wires, such as the 0.035-inch Magic Torque™ guidewire from Boston Scientific Corporation (Natick, MA) generally have greater rail support and can be used to straighten vessels and improve torque, whereas small-diameter wires have increased flexibility and trackability through tortuous segments. Second, the core material composition of the wire further corresponds to guidewire rigidity, torquability, and flexibility. Stainless steel is easier to torque and is more rigid, providing better columnar support compared to nitinol, which offers more flexibility and kink resistance. Meanwhile, hybrid wires have the benefit of high-tensile stainless steel shafts with nitinol tips to impart high torquability and columnar shaft strength with kink-resistant tips.

Third, core taper enables acute angulated vessel access and improved tracking. Abrupt or short tapers create support in shorter distances and have a greater tendency to prolapse compared to long, gradual tapers, which track well around bends but do not provide as much support in short distances. A core that extends to the tip of the wire (core to tip) increases the transmission of force, is more durable and steerable, improves tactile feedback, and is ideal for use in peripheral vessels. A core that does not extend to the tip (shaping ribbon) is delicate, flexible, easier to shape, can be

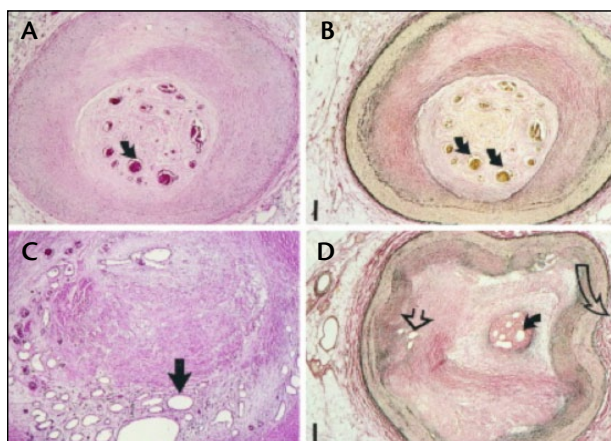


Figure 2. CTO lumen recanalization by large central neovascular channels (arrows; A, B). Extensive small, medium, and large intimal plaque neovascular channels (arrows; C). Central lumen, intimal plaque and adventitial neovascular channels formation (solid, open, and curved open arrows, respectively; D).²

easily prolapsed, and is ideal for navigating tortuous and distal anatomy such as the pedal arteries. Different levels of tip penetration (tip stiffness) provide the wire with more or less push force or “tip load” to cross challenging lesions. Guidewire covers are sleeves of polymer to enhance lubricity, resulting in less drag enhanced lesion crossing and smooth tracking in tortuous vessels. Straight tips or small angles increase tip penetration, while a secondary bend allows for a better angle to navigate tortuous segments.⁴

TECHNICAL TIPS AND CONSIDERATIONS

Intraluminal Crossing

Technical success in crossing long (> 10 cm) SFA occlusions ranges from 50% to 90%. The variability in success depends largely upon lesion length, calcification, distal vessel runoff, and operator experience. Based on the complexity and morphology of the peripheral CTO composition, an escalating guidewire approach needs careful consideration while attempting to cross the CTO. When choosing the first wire to cross this type of lesion from an antegrade approach, a soft wire should be introduced to determine whether the occlusion is an early thrombotic versus a late calcified chronic occlusion. If it is a thrombotic occlusion, then the soft-tipped wire should navigate across the lesion without overt resistance. However, if the wire meets resistance, the next consideration would be a hydrophilic polymer-coated wire, such as the V-18™ ControlWire™ (Boston Scientific Corporation), which allows the operator to direct the wire into a neovascularization microchannel within the CTO. If the operator does not have enough support to navigate through the microchannels, then upgrading to a stiffer core wire will allow the ability to torque through the “hard

plaque” or a high tip load wire to penetrate the hard calcific lesions. The Victory™ guidewire from Boston Scientific is one example of a high tip load guidewire with gram loads ranging from 12 g up to 30 g.

Once a thrombotic occlusion has been excluded and the decision to proceed to a stiffer wire has been made, then careful consideration of crossing techniques, guidewire size, and high tip load comes into play. The operator must first choose between intraluminal versus subintimal crossing for the proximal CTO cap. Finessing a guidewire through microchannels of the CTO may decrease the likelihood of severe dissections after balloon inflations compared to looping a guidewire through the proximal cap, which will routinely take a subintimal course. If finessing the guidewire through microchannels is unsuccessful, then guidewire escalation to the high tip load wires will afford further penetration into the CTO proximal cap but at the increased risk of forming subintimal dissection tracts if the guidewire tip does not penetrate the cap. Careful consideration of the appropriate high tip load wire will ensure increased intraluminal crossing success. Typically, an operator will want to start out with a 12-g tip load guidewire and only escalate to a higher tip load (such as a 30 g) if needed.

Subintimal Crossing

Once attempts at crossing have failed with the previous options, then a stiff hydrophilic wire with a crossing catheter, such as the Rubicon™ (Boston Scientific Corporation), will supply additional support to facilitate wire passage around the calcified proximal cap in the subintimal space, with the plan to re-enter the true vessel lumen in the distal segment of the CTO. The solid-core, hydrophilic wire possesses resilient properties that allow initial entry into the occlusive lumen,

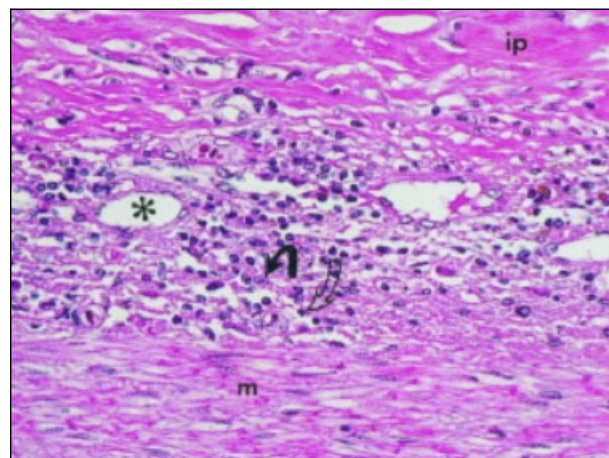


Figure 3. Dense cellular inflammation consisting of lymphocytes (open arrow) and macrophages (closed arrow) within the intimal plaque (“ip”) and media (“m”) of a CTO immediately adjacent to intimal plaque neovascular channels (asterisk).²

followed by purposeful creation of a wire loop to pass into the subintimal space.⁵ This re-entry technique involves advancing the support catheter past the proximal CTO cap into the subintimal plane and exchanging the larger-diameter stiff wire for a smaller-diameter stiff wire with a shallow bend to assist in navigating back into the true vessel lumen.

Alternative Access Points

Not all CTOs are the same, as the location of the proximal and distal CTO caps, as well as appearance and morphology, all play a major role in the decisions on how to successfully navigate the lesion. For example, a flush ostial SFA occlusion without a visible beak makes an antegrade approach difficult, because the plane of entry into the cap cannot be ascertained. In such cases, retrograde pedal, popliteal, or direct SFA access with guidewire crossing has improved success rates due to the morphology and often “softer” composition of the distal cap. The choice of access site depends on the length of the CTO, location of reconstitution, and distal vessel runoff.

The longer a CTO has been present imparts increasing complexity to the procedure. As the proximal cap hardens over time, retrograde access via a pedal or popliteal artery may be necessary. Once a retrograde sheath has been placed, this often allows for a softer, small-diameter guidewire to penetrate the thinner distal CTO cap and traverse the occlusion to the patent proximal vessel. When the wire is confirmed to be intraluminal

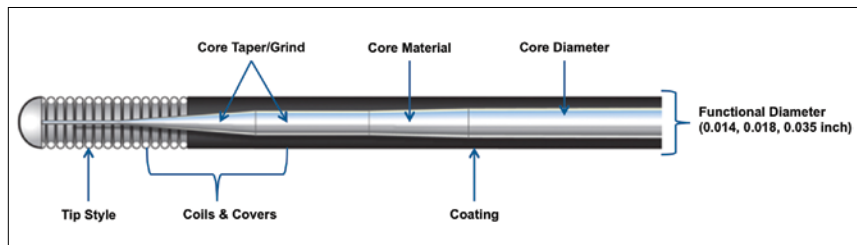


Figure 4. Guidewire composition.

proximal to the occlusion, varying techniques can be employed including finessing the wire retrograde into the antegrade sheath, or snaring the wire using a guidewire retrieval device, to externalize the wire through the femoral sheath and provide a railing for subsequent therapies. If the operator is unable to externalize the wire, then the retrograde access can be converted to a sheathless access to allow for entry of bulkier devices.

Advanced Wiring Techniques

More complex balloon and wiring techniques for challenging lesion subsets include controlled antegrade and retrograde subintimal tracking (CART) and reverse CART. The CART technique requires that the antegrade wire remain in true lumen at the proximal cap while the retrograde wire is advanced across the distal cap into a subintimal track, utilizing balloon inflation to dissect the subintimal tract until the retrograde wire can be advanced to the proximal wire location for externalization of the retrograde wire. Reverse CART is the same technique except in the reverse direction. Other complex techniques include inflation of a balloon in one subintimal track and puncturing the inflated balloon

TABLE 1. GUIDEWIRE CHARACTERISTICS: IMPACT ON CLINICAL PERFORMANCE

| Feature | Performance Characteristics | Clinical Relevance |
|---|--------------------------------------|---|
| Tip: Shape (straight, angle, J) | Steerability | Vessel access/selection, safety of positioning within vessels |
| Tip: Material | Shaping, shape retention | Durability and pushability |
| Tip: Taper | Tip stiffness | Lesion crossability, penetration power |
| Tip: Covers (coils, polymer sleeve) | Tactile feedback and torque response | Vessel access, lesion crossability |
| Core: Material (stainless steel, nitinol) | Torque (steering) and durability | Technique to advance/cross, wire durability |
| Core: Diameter | Support | Device deliverability/pushability |
| Core: Taper length | Trackability and support | Vessel access, device delivery/pushability |
| Coating (hydrophilic, silicon, PTFE) | Lubricity | Lesion crossing, smooth tracking of devices |

TIPS FOR OPTIMIZING WIRE SUCCESS

If the wire tip prolapses at the cap, use a wire with a higher tip gram load, or advance the support catheter near the tip.



If the proximal segment of the tip buckles, use a wire with a higher tip gram load, a hydrophilic-coated wire, or advance a support catheter near the occlusion.



If the wire enters the subintimal space and fails to re-enter true lumen, shape/angle the guidewire tip to facilitate re-entry, change support to the wire tip by exchanging to a different catheter tip shape, or utilize a re-entry device.



If the wire crosses but the device fails to cross, change to a wire with higher rail support, advance the sheath closer to the occlusion, create a wiggle wire, or exchange for a lower-profile system.



with a high-tip-load guidewire from the reverse access to create a continuous path from true-to-true lumen. A variation of this technique involves balloon inflation in two subintimal tracks from the antegrade and retrograde approach at the same level to allow dissection of the two planes into a single communicating channel that can be wired in one direction to create a single lumen.

Re-Entry Challenges

Various re-entry strategies may need to be employed for successful revascularization of CTOs. Re-entry has the highest degree of success in lesions that reconstitute above the adductor canal, where the vessel is relatively large. If the occlusion does not collateralize until the popliteal artery or lower, re-entry becomes more challenging.

In SFA CTOs involving the adductor canal, a combination of antegrade and retrograde crossing is utilized, with a preference toward remaining intraluminal, as re-entry in this vascular location has its own challenges. When considering

a below-the-knee CTO, finesse from a retrograde approach is paramount to high success rates with a smaller-diameter, soft guidewire, highly torqueable guidewire, such as the Journey™ guidewire (Boston Scientific Corporation, Natick, MA) for navigating tortuous, small-caliber, and difficult-to-access anatomy while remaining intraluminal. If this technique is unsuccessful with a small-diameter guidewire, escalate the wire in a similar stepwise fashion as an antegrade approach by attempting a hydrophilic wire followed by a high tip load wire. If guidewire re-entry fails, the use of a niche device such as the OffRoad™ Re-entry Catheter System (Boston Scientific Corporation, Natick, MA) may facilitate the passage of the guidewire into the true lumen via an antegrade or retrograde approach.

CONCLUSION

As endovascular interventionists continue to treat peripheral arterial disease, CTOs will comprise a significant subset of infrainguinal disease. Although newer technologies aim to facilitate crossing of CTOs, the mainstay of endovascular interventions is wiring techniques and fundamentals of wire escalation (see the Tips for Optimizing Wire Success sidebar). The ultimate goal of procedural success and long-term patency is likely related to the success of crossing CTOs while preserving true vessel lumen. ■

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PERIPHERAL GUIDEWIRES






ACCESS GUIDEWIRES


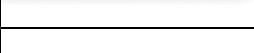



Designed to be flexible, have a soft atraumatic tip, and provide enough support to deliver diagnostic devices.

NAVIGATING GUIDEWIRES

Designed to be flexible, steerable, and provide excellent torque response to navigate tortuous anatomy.

| 0.014-inch Guidewires | | Clinical Scenarios | |
|-----------------------|--------------------|---|--|
| Navigating | Journey™ |  | Navigation of distal infrapopliteal arteries, acute angles, high tortuosity |
| Navigating | Thruway™ |  | Versatile access in renal arteries, visceral branches, infrapopliteal arteries |
| Crossing | V-14™ ControlWire® |  | Navigating and crossing tight stenosis in infrapopliteal arteries |
| Crossing | Victory 14™ |  | Crossing calcified lesions and tight stenosis in infrapopliteal arteries |
| Delivery Support | Platinum Plus™ |  | Extra device support where needed in infrapopliteal arteries |

| 0.018-inch Guidewires | | Clinical Scenarios | |
|-----------------------|-----------------------|---|--|
| Navigating | Thruway |  | Versatile access in renal arteries, visceral branches, infrapopliteal arteries |
| Crossing | V-18™ ControlWire® |  | Navigating and crossing tight stenosis in SFA, infrapopliteal arteries |
| Crossing | Victory 18 |  | Crossing calcified lesions and tight stenosis in SFA, infrapopliteal arteries |
| Crossing | ZIPwire® Small Vessel |  | Access and crossing in femoral, infrapopliteal arteries |
| Delivery Support | Platinum Plus |  | Extra device support where needed in SFA, infrapopliteal arteries |

| 0.035-inch Guidewires | | Clinical Scenarios | |
|-----------------------|-----------------------------|---|--|
| Access | Starter™ |  | Standard diagnostic and vessel access: available in Fixed Core, Moveable Core, Bentson, Newton, and Rosen |
| Navigating | Magic Torque™ |  | Contralateral access, catheter and sheath placement and exchange, Iliac/SFA navigation, vessel access off the aortic arch |
| Crossing | ZIPwire® Standard and Stiff |  | Access and crossing in femoral, popliteal arteries |
| Delivery Support | Amplatz Super Stiff™ |  | Contralateral access for tight aortic bifurcation or where extra support is needed, carotid artery access, and device delivery |
| Delivery Support | Back-Up Meier™ |  | AAA and where extreme device support is needed |

^aJourney has a hydrophilic coating with a 1.27-cm uncoated distal tip.

^bThe Platinum Plus 0.018 inch is available with hydrophilic coating or nonhydrophilic (Silicone) coating.

Thruway 0.014 inch has three distal radiopaque markers.

Platinum Plus is also available in 0.025-inch diameter.

Magic Torque has four distal radiopaque markers.

ZIPwire is also available in 0.025- and 0.038-inch diameter.

Amplatz Super Stiff and Starter are also available in 0.038-inch diameter.

CROSSING GUIDEWIRES

Designed to provide increasing tip stiffness and excellent torque response to cross lesions.

DELIVERY SUPPORT GUIDEWIRES

Designed to provide additional support for delivery of large devices and may aid in vessel straightening

| Tip Load (g) | Rail Support | Tip Coating |
|---|---------------|---------------------|
| 1.3 | Light | Hybrid ^a |
| 1.3 (short taper), 1.7 (long, extra-long taper) | Extra support | Nonhydrophilic |
| 3 (long taper), 6 (short taper) | Moderate | Hydrophilic |
| 12, 18, 25, 30 | Moderate | Hydrophilic |
| 7 | Extra support | Hydrophilic |

| Tip Load (g) | Rail Support | Tip Coating |
|------------------------------------|---------------|-------------------|
| 2 (short taper), 4 (long taper) | Extra support | Nonhydrophilic |
| 6 (long taper), 8 (short taper) | Moderate | Hydrophilic |
| 12, 18, 25, 30 | Moderate | Hydrophilic |
| 8 | Moderate | Hydrophilic |
| 4 (short taper), 5 (long taper) | Extra support | Both ^b |

| Tip Load (g) | Rail Support | Tip Coating |
|--------------|---------------|----------------|
| N/A | Moderate | None |
| N/A | Moderate | Hydrophilic |
| N/A | Moderate | Hydrophilic |
| N/A | Extra support | Nonhydrophilic |
| N/A | Super support | None |

Abbreviated Statements

Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

AMPLATZ SUPER STIFF™ GUIDEWIRE

Intended Use/INDICATIONS FOR USE: The Amplatz Super Stiff guidewire facilitates catheter placement and exchange during diagnostic or interventional procedures. Not intended for use in coronary arteries.

CONTRAINDICATIONS: None known.

MAGIC TORQUE™ GUIDEWIRE

Intended Use/INDICATIONS FOR USE: The Magic Torque guidewire facilitates placement of a catheter during diagnostic or interventional intravascular procedures. The wire can be torqued to facilitate navigation through tortuous arteries and/or avoid unwanted side branches.

Not intended for use in coronary arteries.

CONTRAINDICATIONS: None known.

MEIER™ STEERABLE GUIDEWIRE

Intended Use/INDICATIONS FOR USE: The Back-up Meier guidewire facilitates catheter placement and exchange during diagnostic or interventional procedures, including abdominal aortic aneurysm (AAA) endovascular graft procedures.

CONTRAINDICATIONS: Heavily tortuous vessels, previous diagnosis of severe vessel spasm

ZIPWIRE™ HYDROPHILIC GUIDEWIRE

INDICATIONS: The ZIPwire Hydrophilic Guide Wire is intended to facilitate the placement of devices during diagnostic and interventional procedures.

CONTRAINDICATIONS: There are no known contraindications.

STARTER™ GUIDEWIRE

Intended Use: Starter guidewires are designed for percutaneous vessel entry using the Seldinger technique to facilitate subsequent introduction(s) of an intravascular device.

PLATINUM PLUS™ GUIDEWIRE

Intended Use/INDICATIONS FOR USE: The Platinum Plus guidewire facilitates placement of a catheter during diagnostic or interventional intravascular procedures. The wire can be torqued to facilitate navigation through tortuous arteries and/or avoid unwanted side branches.

CONTRAINDICATIONS: Not intended for use in coronary arteries. Not intended for use in the neurovasculature.

THRUWAY™ GUIDEWIRE

Intended Use/INDICATIONS FOR USE: The Thruway Guidewire facilitates placement of a catheter during diagnostic or interventional peripheral intravascular procedures including but not limited to renal intervention. The wire can be torqued to facilitate navigation through the vasculature.

CONTRAINDICATIONS: Not intended for use in coronary arteries. Not intended for use in the neurovasculature.

V-18™ CONTROL WIRE™ GUIDEWIRE

Intended Use/INDICATIONS FOR USE: The V-18 Control Wire guidewire is available in 110, 150, 200 and 300 cm lengths. The wire can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters. This device is intended for peripheral use only. A torque device (pin vise) is included with each wire to facilitate directional manipulation of the guidewire. The 110 cm V-18 Control Wire guidewire is intended for general intravascular use including the placement of PTA balloon catheters requiring an 0.018 in guidewire in hemodialysis AV access procedures.

The 150, 200 and 300 cm V-18 Control Wire guidewire are intended for general intravascular use.

CONTRAINDICATIONS: Boston Scientific 110 cm Guidewires are not intended for use in the cerebral vasculature.

V-14™ CONTROL WIRE™ GUIDEWIRE

Intended Use/INDICATIONS FOR USE: Boston Scientific V-14™ ControlWire® Guidewire is intended to facilitate the placement and exchange of balloon dilatation catheters or other therapeutic devices during Percutaneous Transluminal Angioplasty (PTA) or other intravascular interventional procedures. The V-14 ControlWire Guidewire is not intended for use in the cerebral vasculature. The devices are provided nonpyrogenic, sterile, and intended for one procedure only.

CONTRAINDICATIONS: None known.

VICTORY™ GUIDEWIRE

INDICATIONS FOR USE: The Victory guidewires are intended to facilitate the placement and exchange of balloon catheters or other interventional devices within the peripheral vasculature during Percutaneous Transluminal Angioplasty (PTA) or other intravascular interventional procedures.

CONTRAINDICATIONS: The Victory guidewires are not intended for use in the coronary or cerebral vasculatures or in patients judged not acceptable for percutaneous intervention.

JOURNEY™ GUIDEWIRE

Intended Use/INDICATIONS FOR USE: Journey™ Guidewires are intended to facilitate placement and exchange of balloon dilatation catheters or other therapeutic devices during Percutaneous Transluminal Angioplasty (PTA) or other intravascular interventional procedures. The Journey Guidewires are not intended for use in the cerebral vasculature. The devices are provided nonpyrogenic, sterile, and intended for one procedure only.

CONTRAINDICATIONS: The Journey Guidewire is not intended for use in the cerebral vasculature.

The below stated Warnings, Precautions, and Adverse Events are encompassing of all above mentioned Guidewires, unless noted otherwise.

WARNINGS:

- While the guidewire is in a vessel, do not advance the movable core if the tip is in a curved shape. Never twist or force the core because excessive force may cause it to penetrate the coil and damage the vessel.
- Exercise care in handling of the guidewire during a procedure to reduce the possibility of accidental breakage, bending, kinking, or coil separation. Resulting guidewire fractures might require additional percutaneous intervention or surgery.
- Never advance the guidewire against the resistance without first determining the reason for resistance under fluoroscopy. Excessive force against resistance may result in separation of the guidewire tip, damage to the catheter or vessel damage. Care should be taken when advancing a guidewire after stent deployment. A guide wire may exit between stent struts when recrossing a stent that is not fully apposed to the vessel wall. Subsequent advancement of any device over the guidewire could cause entanglement between the guidewire and the stent.
- To prevent possible tissue damage, care should be taken when manipulating a device over a ZIPwire Hydrophilic Guide Wire during the device's placement and withdrawal. If resistance is felt during device placement, discontinue the procedure and determine the cause of resistance before proceeding. If the cause of resistance cannot be determined, remove the ZIPwire™ Hydrophilic Guide Wire and device as a unit to prevent possible damage and/or complications.
- When using a guide wire, potential exists for thrombus formation or emboli, arterial or venous wall damage and/or plaque dislodgment. The physician should be familiar with the literature concerning the complications of angiography.
- Do not manipulate or withdraw the ZIPwire Hydrophilic Guide Wire through a metal entry needle or a metal dilator. Manipulation and/or withdrawal through a metal entry needle or a metal dilator may result in destruction and/or separation of the outer polyurethane coating, requiring retrieval. A plastic entry needle is recommended when using this wire for initial placement.
- Do not use the ZIPwire Hydrophilic Guide Wire with devices that contain metal parts such as atherectomy catheters, laser catheters, or metal introduction devices as they may cause the ZIPwire Hydrophilic Guide Wire plastic coating to shear and/or sever the wire.
- Do not manipulate the ZIPwire Hydrophilic Guide Wire through a tightened rotating hemostasis valve, as this may result in damage to the wire.
- Do not reshape the ZIPwire Hydrophilic Guide Wire by any means. Attempting to reshape the wire may cause damage, resulting in the release of wire fragments into the vessel.
- A retrieving device, such as a gripper or basket forceps, can only be used after the ZIPwire Hydrophilic Guide Wire has been removed from the patient's vessel. Using a retrieval device while the ZIPwire Hydrophilic Guide Wire is in the vessel may cause the ZIPwire Hydrophilic Guide Wire to break.
- Do not attempt to use the ZIPwire Hydrophilic Guide Wire if it has been bent, kinked or damaged. Use of a damaged wire may result in damage to the vessel or the release of wire fragments into the vessel.
- Do not leave the wire in a prolapsed condition, as damage to the wire may occur.
- The Victory family of guidewires has distal ends of varying stiffness. Operate these guidewires carefully to minimize the risk of perforation or other damage to blood vessels.
- If the guidewire is removed and is to be re-inserted, it must be inspected for signs of damage (weakened or kinked segments) prior to re-introduction. Do not re-introduce if the guidewire is weakened or kinked.

PRECAUTIONS:

- Never attempt to straighten a J-tipped guidewire within a patient by advancing the movable core once it has been withdrawn.
- Do not withdraw the guidewire through a metal cannula needle. Withdrawal may damage the guidewire or coating.
- When using a movable core guidewire, the wire may become distorted to the extent of allowing the core to penetrate the guidewire coil and result in possible damage to the vessel. It is strongly recommended that when excessive resistance is incurred internally, the core wire should not be advanced.
- Do not attempt to straighten a wire that has been kinked or bent.
- Do not advance a kinked guidewire into a balloon catheter or guidewire to reduce the potential of wire breakage.

ADVERSE EVENTS: Potential adverse events which may result from the use of the device include but are not limited to: Air Embolism/Thromboembolism, Allergic Reaction, Amputation, Arteriovenous (AV) Fistula, Death, Delayed immune response, Embolism, Febrile reaction, Hematoma, Hemorrhage, Hemoglobinuria, Infection or Sepsis/ Infection, Myocardial Ischemia and/or Infarction, Pseudoaneurysm, Renal Failure, Stroke (CVA)/Transient Ischemic Attacks (TIA), Thrombus, Vessel Occlusion, Vessel Perforation, Dissection, Trauma, or Damage, Vessel Spasm, Wire Entrapment/Entanglement, Foreign body/Wire Fracture. Some of the stated potential adverse events may require additional surgical intervention.

