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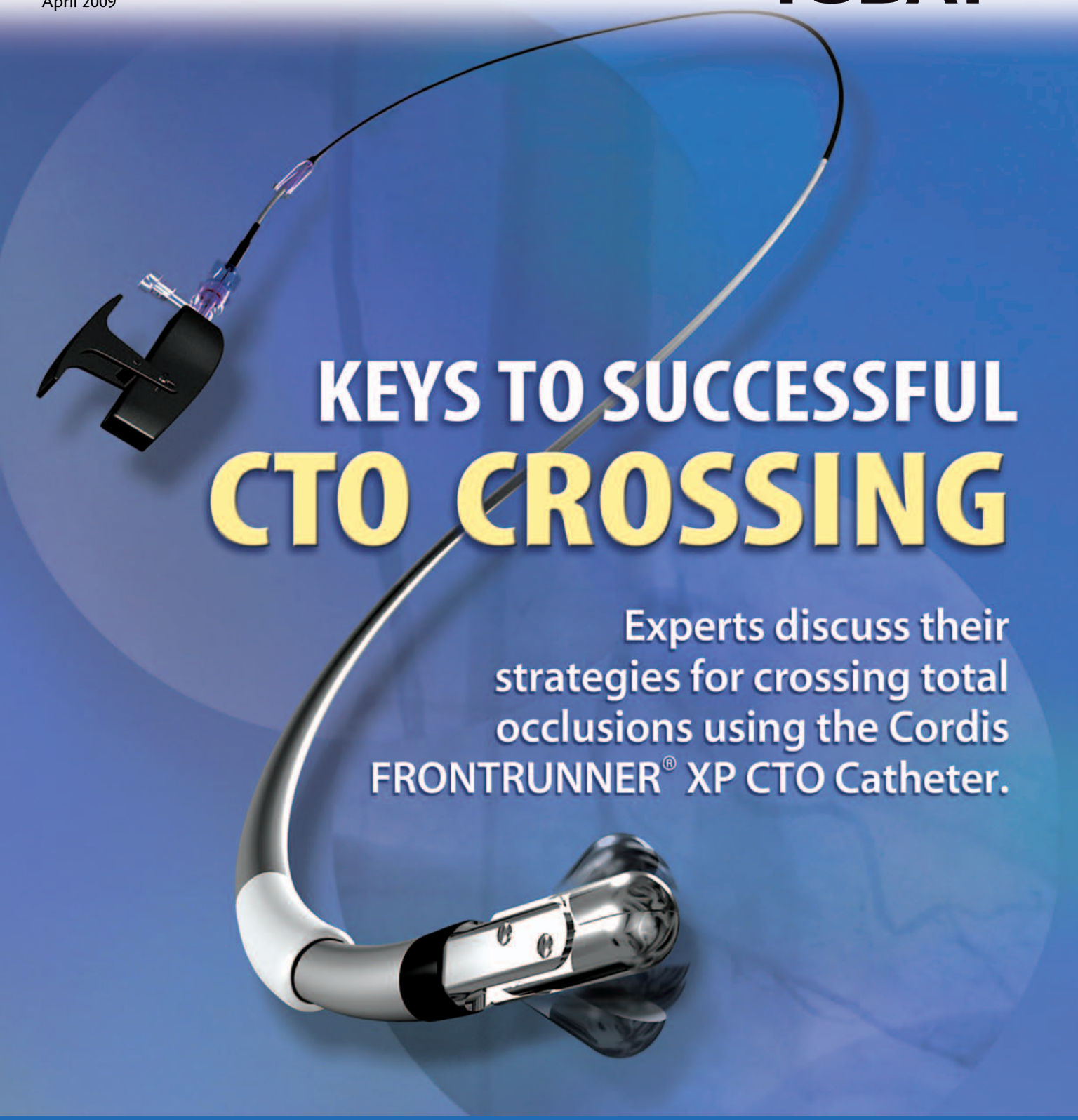

KEYS TO SUCCESSFUL CTO CROSSING

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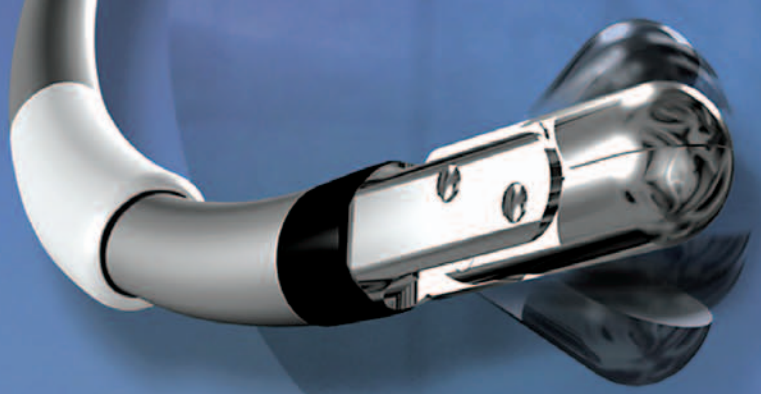

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New Strategies for Crossing Iliac CTOs

Two case studies demonstrate the utility of controlled blunt microdissection for the treatment of iliac CTOs in many patients.

BY PETER A. SOUKAS, MD, FACC, FSVM, FSCAI

The past decade has been witness to a dramatic shift from open to endovascular revascularization for occlusive peripheral arterial disease (PAD). The prevalence of PAD has increased to 15% to 20% in persons greater than 70 years of age.[1-3] Although percutaneous transluminal angioplasty (PTA) and stenting are effective for focal lesions in the iliac arteries, several factors have been identified that negatively affect the long-term results of PTA. These include diabetes mellitus, poor distal runoff, critical limb ischemia at the clinical presentation, and the length of the diseased segment.[4,5]

Another important predictor of procedural success is the presence of chronic total occlusion (CTO), which may be present in up to 20% to 40% of patients undergoing intervention for symptomatic PAD.[5,6] Historically, procedural success rates have been lower in the setting of CTO, primarily due to inability to traverse the occluded segment or to gain wire access into the true lumen of the reconstituted vessel. New technologies, including controlled blunt microdissection catheters and needle lumen re-entry devices, have significantly improved acute technical success rates and reduced the need for open surgical reconstructions.

We present two challenging cases of iliac artery CTO that were successfully treated using the new technology of controlled blunt microdissection. Suggested tips and techniques are then discussed.

CASE ONE

A 63-year-old man with a history of smoking presented to an outside hospital with unstable angina. His other risk factors included borderline diabetes mellitus, hypertension, and hyperlipidemia. Cardiac catheterization

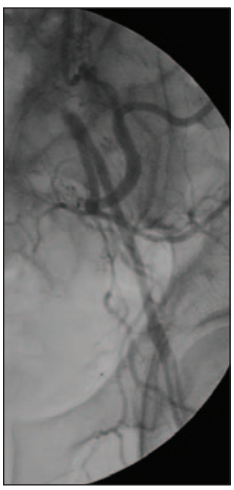

Figure 1. Baseline retrograde left femoral angiogram demonstrating proximal right common iliac CTO.

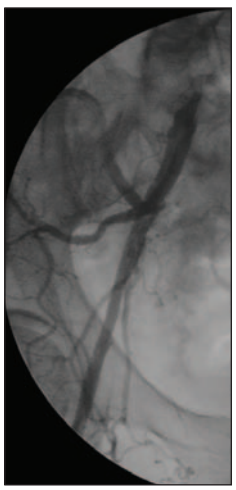

Figure 2. Baseline retrograde right femoral angiogram demonstrating proximal right common iliac CTO.

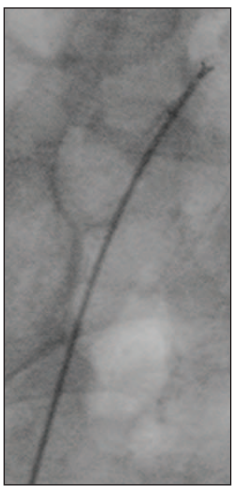

Figure 3. Retrograde traversal of right common iliac CTO with the FRONTRUNNER® XP Catheter (Cordis Corporation, Warren, NJ).

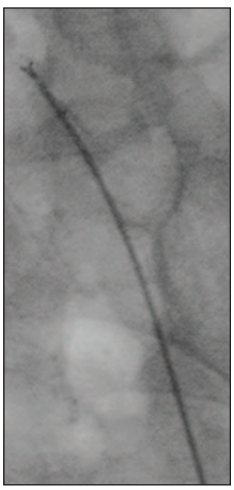

Figure 4. Retrograde traversal of left common iliac CTO with the FRONTRUNNER® XP Catheter.

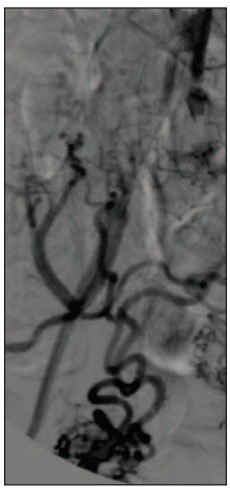

Figure 5. Angiogram through a 4-F support catheter documenting intraluminal position in the distal aorta.

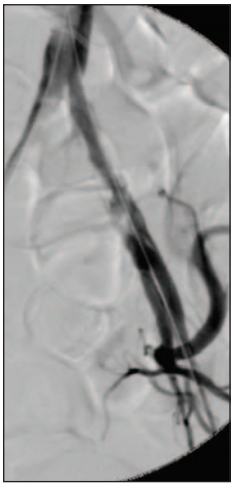

Figure 6. Angiogram through 4-F support catheter documenting intraluminal position in the distal aorta.

Figure 7. Focal severe "apple-core" stenosis of the distal aorta.

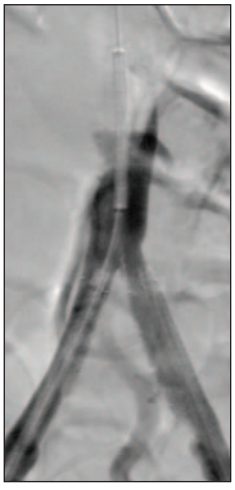

Figure 8. Distal aortic stent positioned before deployment.

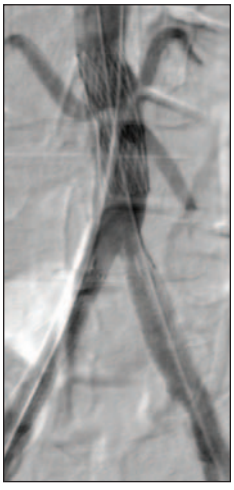

Figure 9. Distal aortic stent after deployment.

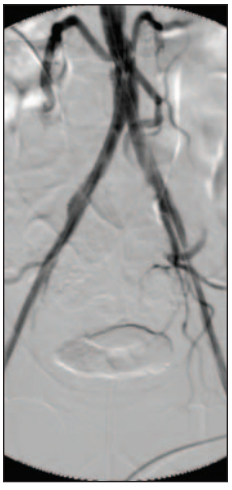

Figure 10. Final distal abdominal aortogram.

from a right femoral access was unsuccessful due to occlusion of the right common iliac artery. He was transferred to our institution, where cardiac catheterization from a right radial access revealed a 95% thrombotic lesion in the mid-left anterior descending artery and a diffuse 90% stenosis in the mid-right coronary artery. Both lesions were stented with drug-eluting stents. An abdominal aortogram revealed distal occlusion of the aortic bifurcation, involving both common iliac arteries, with patency of both external iliac and common femoral arteries.

The patient developed progressive buttock, thigh, and calf claudication, beginning after 100 yards and relieved with rest, and he admitted to erectile dysfunction. Exam

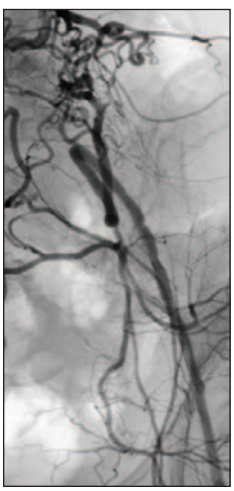

Figure 11. Baseline retrograde left femoral angiogram demonstrating proximal left common iliac CTO with extensive collateral network.

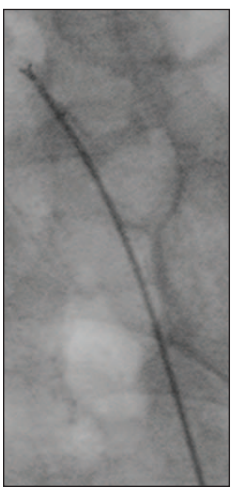

Figure 12. Retrograde traversal of left common iliac CTO with the FRONTRUNNER® XP Catheter.

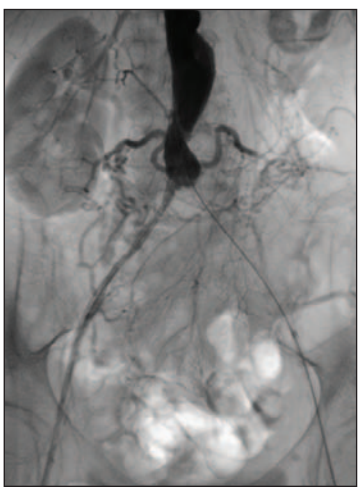

Figure 13. Distal abdominal aortogram demonstrating modest infrarenal abdominal aortic aneurysm (AAA) and left common iliac CTO.

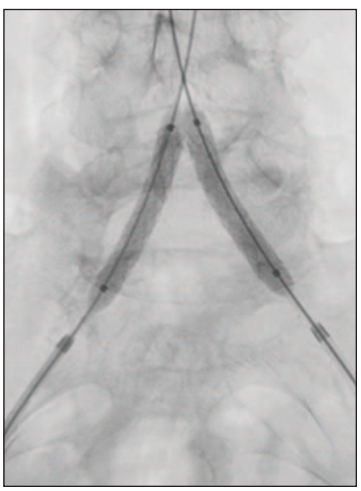

Figure 14. Kissing stents to the distal aortic bifurcation.

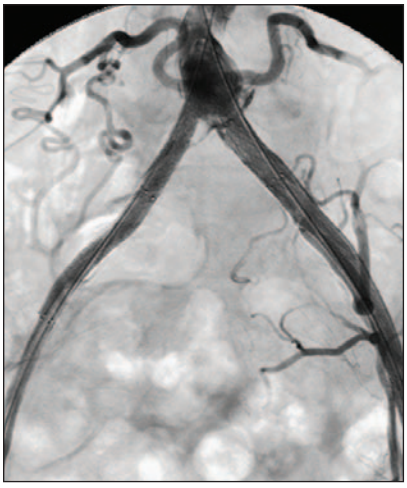

Figure 15. Final distal abdominal aortogram.

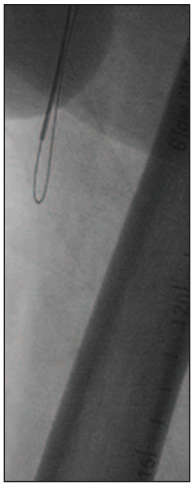

Figure 16. The looped Glidewire technique.

was notable for diminished 1+ femoral, popliteal, and pedal pulses. Resting ankle-brachial indexes (ABIs) were 0.73 on the right and 0.67 on the left, with monophasic Doppler waveforms bilaterally. Due to the patient's lifestyle-limiting intermittent claudication (IC), recent coronary stenting with requisite 1 year of clopidogrel, and inability to participate in cardiac rehabilitation, he was offered an attempt at percutaneous revascularization in lieu of aortobifemoral bypass.

Bilateral 6-F X 110-cm BRITE TIP® Interventional Sheaths (Cordis Corporation, Warren, NJ) were placed retrograde in the common femoral arteries (CFAs). Selective angiograms through the sheath sidearms confirmed occlusions of the common iliac arteries (CIAs), with patent external iliac arteries (EIAs) and CFAs (Figures 1 and 2). The CIA CTOs were quickly crossed using a 4-F straight Glidecath support catheter (Terumo Interventional Systems, Somerset, NJ) and a Cordis FRONTRUNNER® XP Catheter with controlled blunt microdissection (Figures 3 and 4). Angiography after the FRONTRUNNER® XP Catheter placement confirmed intraluminal placement (Figures 5 and 6).

Predilatation of the distal aorta and CIAs was performed with two 6- X 40-mm OPTA® Pro PTA Dilatation Catheters (Cordis Corporation). Two 9- X 60-mm Cordis S.M.A.R.T.® CONTROL® Iliac Stent Systems were then deployed in the common iliac and proximal external iliac arteries, taking care to avoid the aortic bifurcation. Abdominal aortography was performed to document the location of the aortic occlusion, and this "apple-core" lesion was located just superior to the bifurcation (Figure 7). A simultaneous 30 mm Hg resting gradient was documented across this stenosis. The right CFA sheath was upsized to an 8-F BRITE TIP® Sheath, and a hand-crimped stent was deployed across the lesion using a 10- X 40-mm OPTA® Pro Catheter (Figures 8 and 9). The stent was then postdilated with 12- and 14- X 40-mm OPTA® Pro Catheters with no residual resting gradient. Kissing balloon-expandable stents were then deployed across the distal aortic bifurcation. Final angiography confirmed an excellent angiographic result (Figure 10).

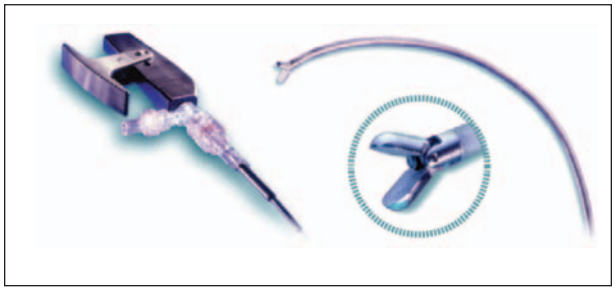

Figure 17. The FRONTRUNNER® XP Catheter with controlled microdissection.

The patient's recent 2-year follow-up visit confirmed 2+ femoral and pedal pulses, normal resting ABIs of 1 with no IC, and successful resolution of his erectile dysfunction.

CASE TWO

The patient was a 65-year-old woman with emphysema from long-standing smoking who underwent previous left upper lobectomy for lung cancer. Her history included hypertension, hyperlipidemia, and a known 28-mm AAA noted on a previous ultrasound. She presented with severe disabling claudication, worse on the left than on the right. Computed tomography (CT) angiography confirmed a left common iliac CTO, reconstituting at the bifurcation, along with a 30-mm AAA with mural thrombus. Resting ABI was 0.85 on the right and 0.69 on the left, with monophasic left common femoral artery waveform. Physical examination was notable for a small pulsatile aorta with normal pulses in the right leg, and the left femoral pulse was weak with a femoral bruit and only trace distal pedal pulses.

Retrograde femoral access was obtained with a 6-F BRITE TIP® Sheath. Angiography confirmed left CIA occlusion with reconstitution at the iliac bifurcation with a small-caliber CFA and moderate disease of the EIA (Figure 11). Controlled microdissection of the left CIA CTO was then performed with a FRONTRUNNER® XP Catheter using a 4-F, 65-cm straight support catheter (Figure 12). Abdominal aortography confirmed the AAA and proximal left CIA CTO (Figure 13). Retrograde

TABLE 1. DIFFERENTIAL DIAGNOSIS OF IC DUE TO AORTOILIAC DISEASE

Condition	Location	Prevalence	Characteristic	Effect of Exercise	Effect of Rest	Effect of Position	Other Characteristics
Thigh and buttock IC	Buttocks, hip, anterior thigh	Uncommon	Cramping, aching discomfort	Reproducible onset	Quickly relieved	None	Impotence May have normal pedal pulses with isolated iliac disease
Nerve root compression	Radiates down leg	Common	Sharp, lancing pain	Induced by sitting, standing, or walking	Often present at rest	Improved by change in position	History of back problems Worse with sitting Relief when supine or sitting
Hip arthritis	Lateral hip, thigh	Common	Aching discomfort	After variable degrees of exercise	Not quickly improved	Improved when not weight bearing	Symptoms variable History of degenerative arthritis
Spinal stenosis	Often bilateral buttocks, posterior leg	Common	Pain and weakness	May mimic IC	Variable relief but can take a long time to recover	Relief by lumbar spine flexion	Worse with standing and extending spine

femoral access was obtained on the right. Predilation of the left iliac was performed with a 6- X 40-mm OPTA® Pro Catheter with restoration of antegrade flow.

Kissing stents of the distal aortic bifurcation were then used with two balloon-expandable stents (Figure 14). A 7- X 60-mm S.M.A.R.T.® CONTROL® Iliac Stent System was deployed in the left CIA, and a 7- X 40-mm S.M.A.R.T.® CONTROL® stent was placed in the right CIA. Final angiography demonstrated an excellent angiographic result (Figure 15).

The patient had complete resolution of her claudication symptoms with normalization of both ABIs after the procedure. Normal ABIs were documented at 1-month and 2-year follow-up.

DISCUSSION

Most patients with PAD have limited walking ability and poor exercise performance; they will describe muscle discomfort in the lower limbs produced by exercise and relieved with rest. Typical IC occurs in only about one-third of patients.[7] Iliac disease may manifest as lower back, hip, or buttock discomfort, alone or in combination with the more common calf tightness. Because many patients with iliac disease are elderly, they may falsely attribute their symptoms to arthritis or spinal stenosis. The differential diagnosis of IC is summarized in Table 1.

Physical examination is notable for diminished femoral pulses, often with bruits, but pedal pulses may be preserved at rest. Similarly, the ABI may be normal at rest but drops significantly (> 0.1) after exercise. Therefore, rest and exercise ABI should be performed in patients with suspected aortoiliac disease. Beware of false ABI elevation in individuals with vascular calcification (eg, renal insufficiency or diabetes mellitus) who may have supernormal values > 1.4. Alternative testing (eg, pulse volume recordings, magnetic resonance angiography, CT angiography, duplex ultrasonography) should be performed to confirm the diagnosis and plan revascularization.

TREATMENT OPTIONS

The foundations of therapy for PAD include aggressive control of underlying risk factors, therapeutic exercise programs, and antiplatelet therapy. An initial trial of pharmacotherapy for IC using cilostazol, a phosphodiesterase III inhibitor, may be considered in patients with minor walking impairment, provided they do not have overt congestive heart failure.

For symptomatic patients who do not respond to conservative therapy, open or endovascular revascularization is warranted. Patients with multilevel disease should have their inflow corrected first, because this alone may resolve the patient's symptoms. The location, extent, and morphology of the disease must first be characterized to determine the optimal treatment plan. CT angiography and magnetic resonance angiography are commonly per-

formed before the procedure. At the time of diagnostic angiography, both resting and hyperemic pressure gradients are used to determine the hemodynamic significance of a given stenosis, 10 mm Hg resting or 15 to 20 mm Hg hyperemia after vasodilator stimulus.

Choosing between endovascular and open techniques depends on several clinical and anatomic factors but also on the experience and skill of the local operators. The TASC treatment guidelines were recently updated (Tables 2 and 3). Patients with TASC D lesions are generally considered surgical candidates, but with newer technologies such as controlled blunt microdissection and needle lumen re-entry devices, these patients are now eligible for endovascular therapy.

Endovascular Therapy of Occlusive Aortoiliac Disease

For common iliac and distal aortic lesions, balloon-expandable stents are preferred due to their superior radial strength, more precise placement, and better radiovisibility. When one or both common iliac ostia are involved, balloon-expandable stents are used in a "kissing" fashion to avoid plaque shift from one iliac into the other but also to properly scaffold the plaque burden not commonly seen in the posterior wall of the terminal aorta. An acute technical success rate of 100% and a primary patency rate of 92% at 2 years has been reported by Mouanoutoua et al.[8] Self-expanding nitinol stents are preferred for external iliac disease due to a higher rate of dissection and for ectatic areas with discrepant vessel diameters. Self-expanding stents are also preferred for disease at the CFA junction near the hip joint to avoid stent fracture or compression that may be seen with balloon-expandable stents at this location.

Early reports confirmed very high acute technical and clinical success rates > 90% with iliac PTA, particularly for focal stenotic disease. Iliac occlusion recanalization rates are on the order of 80%, alone or with adjunctive thrombolysis. Estimated technical success rates of iliac PTA from weighted averages are 96% in claudicants with 5-year patency rates of 71%.[7] Factors negatively affecting patency include severity of ischemia, length of diseased segments, and poor-quality runoff vessels.

The strategy of PTA with provisional stenting versus primary stenting was prospectively evaluated in a randomized multicenter study.[9] PTA with provisional stenting had a similar outcome to primary stenting with regard to 2-year reintervention rates of 7% and 4%, with similar 5-year primary patency outcomes of 82% and 86%.[10] However, a meta-analysis by Bosch and Hunick comparing these two strategies found higher technical success rates with stenting. After including technical failures, the severity-adjusted 4-year primary patency rates were 54% for PTA and 61% for stenting in patients presenting with baseline occlusions, a 39% relative risk reduction for long-term failure.[11] This report uses data from older studies, and with newer techniques and stents available today, it is reasonable to expect better results with contemporary practice. A European randomized trial of primary iliac stenting with the Palmaz stent versus PTA demonstrated a superior stent 4-year patency rate of 94% compared with 69% for the PTA group.[12]

The most common failure modes for iliac occlusive disease are inability to traverse the CTO segment and inability to re-enter the true lumen with a wire from the subintimal space. Traditionally, many operators use a looped Glidewire (Figure 16) with a 4-F support catheter to cross the occlusion, hoping to re-enter the true lumen at the point of vessel reconstitution. This process is often time-consuming and may lead to excess contrast volumes and radiation exposures. The looped Glidewire technique may also result in wide subintimal dissection planes, with extension beyond the point of reconstitution and may rarely cause perforation. Ultimately, the procedure fails due to the interventionist's inability to wire the true lumen distally.

New technology, such as the FRONTRUNNER® XP Catheter, allows a controlled blunt microdissection through the occluded segment (Figures 17 and 18). The device uses a pair of rounded hinged jaws that are actuated in a "see-saw" fashion with a handle on the proximal end of the device. The jaws open to a diameter of 2.3 mm, and the crossing profile is 0.039 inch with the jaws closed. There is no guidewire lumen, but the distal shaft may be shaped. It is available in 90- and 140-cm lengths. Once the lesion is crossed, the companion Micro Guide radiopaque-tip hydrophilic catheter is advanced until the lesion is crossed. The FRONTRUNNER® XP Catheter is

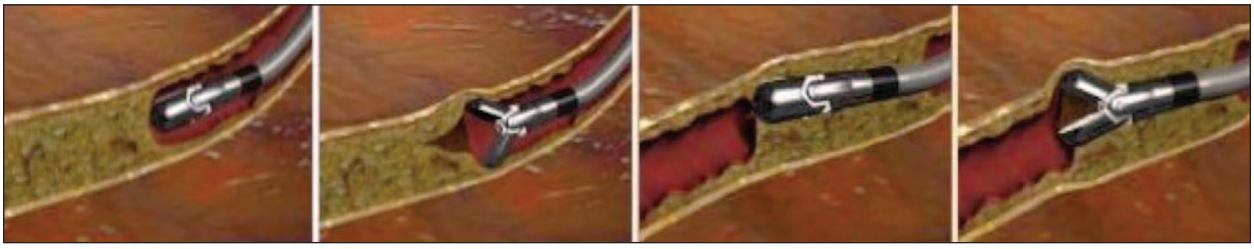

Figure 18. The FRONTRUNNER® XP Catheter mechanism of action.

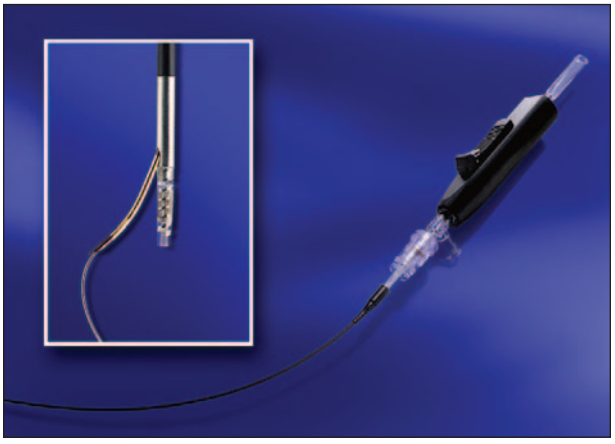

Figure 19. The Cordis OUTBACK® LTD® Re-Entry Catheter.

then replaced with a conventional guidewire to allow definitive therapy such as PTA or stenting.

The first report of controlled blunt microdissection by Mossop et al using a prototype catheter resulted in a high overall procedural success rate of 91% in treating iliac and lower limb CTO in 36 patients with 44 symptomatic occlusions that had failed conventional revascularization attempts. Successful recanalization was accomplished in 21 of 24 iliac CTOs (87.5%).[13] Importantly, the procedure was safe, with no perforations, distal embolizations, or arterial dissections, and only one complication of in-stent thrombosis within 24 hours of iliac recanalization that was successfully resolved with thrombolysis. In our early experience using the FRONTRUNNER® XP Catheter to treat lower extremity CTO, the FRONTRUNNER® Catheter was successful in 89% of cases, with or without adjunctive Glidewire use. In only 11% of cases we needed to use a needle lumen re-entry device such as the OUTBACK® LTD® Catheter or Pioneer (Medtronic, Inc., Minneapolis, MN).[14] Based on our cumulative experience, we now employ a strategy of "FRONTRUNNER® Catheter first" for CTO. Otherwise, successful traversal

TABLE 2. TASC II CLASSIFICATION OF AORTOILIAC LESIONS

Type A
1. Unilateral or bilateral stenoses of CIA
2. Unilateral or bilateral single short (≤ 3 cm) stenoses of EIA

Type B
3. Short (≤ 3 cm) stenosis of infrarenal aorta
4. Unilateral CIA occlusion
5. Single or multiple stenoses totaling 3 to 10 cm involving the EIA not extending into the CFA
6. Unilateral EIA occlusion not involving the origins of IIA or CFA

Type C
7. Bilateral CIA occlusions
8. Bilateral EIA stenoses 3- to 10-cm long, not extending into the CFA
9. Unilateral EIA stenosis extending into the CFA
10. Unilateral EIA occlusion that involves the origins of IIA and/or CFA
11. Heavily calcified unilateral EIA occlusion with or without involvement of the origins of IIA and/or CFA

Type D
12. Infrarenal aortoiliac occlusion
13. Diffuse disease involving the aorta and both iliac arteries requiring treatment
14. Diffuse multiple stenoses involving the unilateral CIA, EIA, and CFA
15. Unilateral occlusions of both CIA and EIA
16. Bilateral occlusions of EIA
17. Iliac stenoses in patients with AAA requiring treatment and not amenable to endograft placement or other lesions requiring open aortic or iliac surgery

Abbreviation: TASC, Trans-Atlantic Inter-Society Consensus.
Adapted from Norgren et al. J Vasc Surg. 2007;45:S5-S6.[7]

TABLE 3. TREATMENT OF AORTOILIAC LESIONS

- TASC A and D lesions: Endovascular therapy is the treatment of choice for type A lesions, and surgery is the treatment of choice for type D lesions.
- TASC B and C lesions: Endovascular treatment is the preferred treatment for type B lesions, and surgery is the preferred treatment for patients with type C lesions. The patient's comorbidities, fully informed patient consent, and the local operator's long-term success rates must be considered when making treatment recommendations for type B and type C lesions.

Adapted from Norgren et al. J Vasc Surg. 2007;45:S5-S67.[7]

of any subsequent CTO devices will be reduced, as they will simply follow the path of least resistance into the dissection planes created earlier by the Glidewire.

Controlled Blunt Microdissection Technique

For iliac CTO, it is recommended to access the ipsilateral common femoral artery using a short 6-F sheath with a radiopaque tip (eg, Cordis BRITE TIP® Sheath), unless the occlusion involves the distal external iliac artery, thus precluding sufficient arterial purchase. Obtaining contralateral access with angiography is helpful to discern the anticipated true course of the occluded iliac vessel and may be used to attempt antegrade access if the retrograde approach proves unsuccessful. Another benefit of retrograde CTO access is the lower likelihood of extending a dissection in this direction.

A 65-cm 4-F sheath is then advanced from the ipsilateral sheath to the funnel of the occlusion stump. The FRONTRUNNER® XP Catheter is delivered through the 4-F catheter, and the jaws are then actuated at the apex of the stump. The device is then advanced through the occlusion, along with the support catheter, until the CTO is successfully crossed. Angiography is then selectively performed through the 4-F support catheter, confirming intraluminal placement. If the path of the FRONTRUNNER® XP Catheter veers off the longitudinal axis of the presumed lumen and enters a side branch or large collateral, it may be removed and the distal end shaped to re-engage the center of the lumen. Alternatively, an angled 4- or 5-F catheter may be used to direct the FRONTRUNNER® XP Catheter away from the subintimal path or side branch. The end of the support catheter should be brought close to the jaws of the device to afford more pushability, especially when crossing a heavily calcified proximal CTO cap. Do not inject contrast through the support catheter to avoid persistent staining of the occlusion, thus impairing visualization.

Needle Lumen Re-Entry Technique

When either the controlled blunt microdissection or looped wire techniques fail to engage the true lumen, needle lumen re-entry devices such as the OUTBACK® LTD® Catheter usually result in successful access to the true lumen. The OUTBACK® LTD® Re-Entry Catheter is 120 cm in length, with a 5.9-F crossing profile and is 6-F sheath compatible (Figure 19). The device is delivered over a 0.014-inch wire and employs a 22-gauge needle near the distal tip of the catheter. Distal radiopaque markers are used to properly direct the needle toward the true lumen from the subintimal space. After advancing the cannula into the true lumen, a 0.014-inch wire is advanced into the true lumen, the device is exchanged out, and conventional PTA and stenting are performed.

Surgical Treatment of Iliac Occlusive Disease

Surgical techniques for occlusive aortoiliac disease include aortobifemoral bypass, endarterectomy, and axillofemoral extra-anatomic bypass. Although aortoiliac and aortofemoral bypass procedures are associated with 74% to 95% 5-year patency rates, respectively, they also involve an extensive abdominal incision with considerable 8.3% morbidity and 3.3% mortality rates.[15]

When data from trials with long-term outcome are combined, 873 patients with an iliac stent procedure enjoyed an acute procedural success rate of > 90%, with a 3 ± 1-year primary patency rate of 74% to 87% and a secondary patency of 84% to 95%, which compares favorably with reported surgical patency rates.[16] The 30-day mortality rate was 0.5%, compared with the weighted 4% risk with aortofemoral bypass. In a study specifically addressing iliac CTOs, Scheinert et al reported a success rate of 90%, a serious complication rate of 1.4%, with a 3-year primary patency rate of 78%, and a secondary patency rate of 86%.[17] Given the improved acute technical success rates with controlled microdissection and re-entry devices, it is now reasonable to consider most TASC C and some TASC D lesions for attempted endovascular therapy.

CONCLUSION

Occlusive aortoiliac disease often results in sympto-

matic hip, buttock, and anterior thigh claudication. Patients may have preserved pulses at rest, so provocative maneuvers, such as rest and exercise ABIs, should be performed. Noninvasive imaging, such as magnetic resonance angiography, CT angiography, or duplex ultrasound, may be used to confirm the diagnosis.

The mainstay of treatment is a strategy of primary stent placement, using balloon-expandable stents for common iliac lesions and self-expanding nitinol stents for external iliac disease. Although most iliac CTOs can be crossed using conventional wires, this may be a time-consuming effort with a 20% failure rate usually due to the interventionist's inability to cross the occlusion or failure to wire the true lumen. A strategy of using a controlled blunt microdissection catheter from the outset will result in greater acute success, saving time, contrast, and radiation exposure. When the wire is subintimal at the site of vessel reconstitution, a lumen re-entry catheter can quickly and safely secure true lumen access and result in a successful outcome. Surgery is reserved for endovascular failures, concomitant aneurysmal disease, and occlusions involving the common femoral arteries. ■

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Tackling SFA CTOs

Transcutaneous ultrasound-guided blunt microdissection: demystifying peripheral CTO crossings.

BY SUBHASH BANERJEE, MD; EMMANOUIL S. BRILAKIS, MD, PHD; AND TONY S. DAS, MD

Endovascular specialists who treat patients with advanced symptomatic peripheral arterial disease are commonly faced with long segments of complex TASC D or chronically occluded lesions, especially in the superficial femoral artery (SFA). SFA chronic total occlusions (CTOs), especially in the ostial location, present the greatest operator challenge. Standard guidewire recanalization of such lesions, with limited and unpredictable results, has largely been replaced by newer devices that have made the treatment of ostial SFA CTOs much more successful and predictable.

Generally, these lesions will require a contralateral common femoral arterial approach. The brachial and popliteal approaches are rarely needed. A 6-F or 7-F, 45-cm sheath placed proximal to the common femoral artery (CFA) bifurcation is optimal. A 30° to 50° ipsilateral lateral view will often help exclude overlaying branches. Probing the presumed SFA ostium with an angled Glide catheter (Terumo Interventional Systems, Somerset, NJ) is often revealing, and imaging the contralateral SFA origin can provide helpful clues to the origin of SFA at the site of CTO (Figures 1 and 2).

Crossing these CTO lesions, especially at ostial or proximal SFA locations, involves prolonged procedures with significant radiation exposure for the patient and operator, and require large iodinated contrast loads for the patient. Operator experience and comfort with the use of subintimal dissection techniques and true lumen re-entry devices is also crucial. All of the above factors limit the scope and success of traversing SFA CTO to modest 50% to 70% rates. The principle reasons for procedural failure are the inability to remain intraluminal during crossing the CTO segment, and re-entering the true lumen. There is also an associated risk of perforation, dissection, and creation of arteriovenous fistulas.

Engagement of the ostial or proximal SFA CTO nub using a combination of a Glide catheter and a Glidewire is often employed by operators first. The inability to engage and penetrate the CTO cap, or creation of a subintimal dissection plane, are frequent results of this approach. From this point onward, either most procedures are abandoned, or they are pursued with the subintimal dissection technique by operators skilled in the use of true lumen re-entry devices. Although there are some clear advantages of subintimal dissection, it is indisputable that a true lumen CTO crossing would be preferred because it is less complex and cumbersome and has a lower likelihood of procedural complications.

In this article, we describe a novel technique that com-

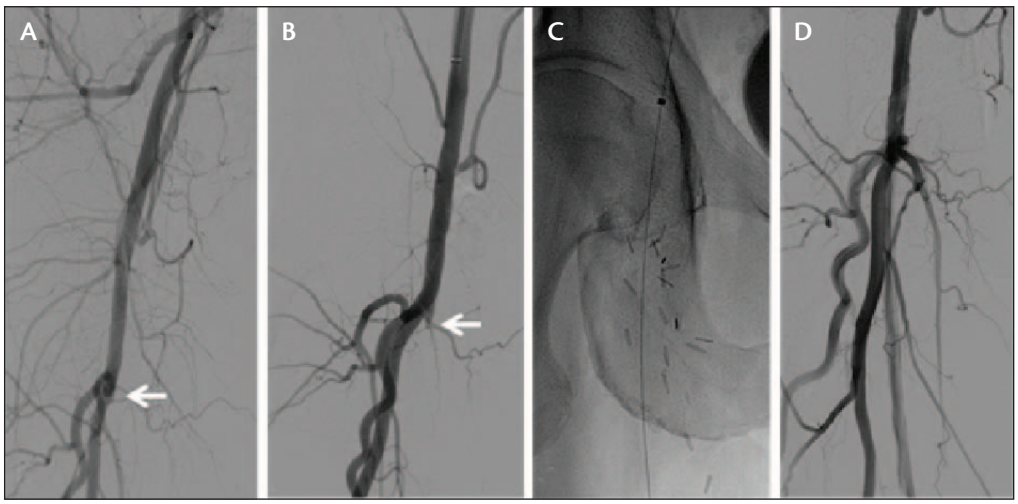

Figure 1. Locating an initially recognized no-nub SFA CTO (arrow, A) with 30° to 40° contralateral angulation (arrow, B). The lesion was crossed successfully (C) and treated interventionally with an excellent angiographic result without stent placement (D).

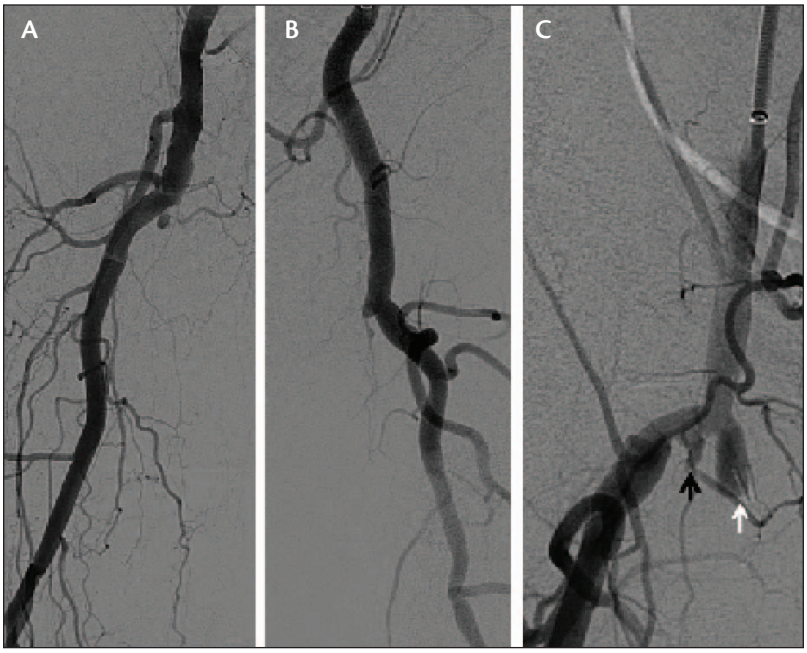

Figure 2. Imaging the contralateral SFA origin can provide helpful clues as to the origin of SFA at the site of CTO (A, B). In the presence of an occluded femoropopliteal graft (black arrow, C) the native SFA ostium is often located medially (white arrow, C).

bines blunt microdissection using the FRONTRUNNER® XP Catheter (Cordis Corporation, Warren, NJ) with transcutaneous ultrasound guidance for percutaneous endovascular crossing of long and complex infrainguinal CTOs.

TRANSCUTANEOUS ULTRASOUND-GUIDED CTO BLUNT MICRODISSECTION TECHNIQUE

This simple technique takes advantage of the fact that the entire length of the SFA is very well visualized with transcutaneous ultrasound. The ability to visualize the course of the SFA occluded at the ostium or proximally is critical in directing the engaging jaws of the FRONTRUNNER® XP Catheter through the CTO cap and into the true lumen of the occluded SFA. The ultrasound-reflective tip of the FRONTRUNNER® XP Catheter, along with its superior directional control, simplifies and demystifies CTO crossings of infrainguinal arterial segments. Traditionally, we approach an occluded SFA lesion from the contralateral CFA. The ultrasound probe is manipulated by the technician over the treatment limb, contralateral to the operator accessed extremity, without the use of any fluoroscopic imaging. For ostial or proximal SFA CTOs, ultrasound imaging of the CFA is performed first, followed by identification of the CFA bifurcation, profunda femoral artery, and the occluded SFA.

Color flow doppler imaging and doppler velocity recordings are then used to confirm the arterial and venous vessels and the site of SFA occlusion. The FRONTRUNNER® XP Catheter, loaded in the supporting 4.5-F Cordis Micro Guide Catheter, is then advanced to the site of the SFA occlusion under transcutaneous ultrasound-guided (TUG) blunt microdissection (Figure 3). The proximal CTO cap is engaged with the FRONTRUNNER® XP Catheter jaws open and advanced. The separation of the Micro Guide Catheter from the FRONTRUNNER® XP Catheter jaws can be manipulated to achieve the desired stiffness of the crossing device. Less separation between the Micro Guide Catheter and the FRONTRUNNER® XP Catheter jaws provides greater stiffness to the overall combined device.

In our opinion, it is important to emphasize that engagement of the proximal CTO cap with the open jaws of the FRONTRUNNER® XP Catheter under direct

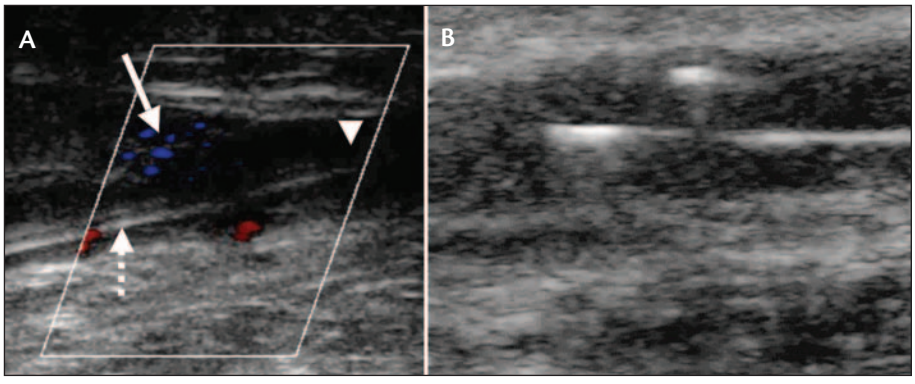

Figure 3. Transcutaneous ultrasound-guided CTO blunt microdissection technique (TUG-CTO). Ultrasound-reflective FRONTRUNNER® XP Catheter microdissection through an occluded superficial femoral artery (hatched arrow); common femoral artery (arrowhead); profunda femoral artery (white arrow) (A). The FRONTRUNNER® XP Catheter advanced through an occluded mid-transcutaneous ultrasound superficial femoral arterial segment.

TUG minimizes slippage or inadvertent entry of the device into the subintimal space; it is often observed with its closed jaws and frequent with the Glidewire-Glide catheter approach.

After breaking through the proximal CTO cap, the FRONTRUNNER® XP Catheter is advanced through the occluded segment of the SFA with its jaws closed, its tip directionally controlled away from the SFA walls through the center of the vessel, visualized in both longitudinal and cross sectional views under TUG. The FRONTRUNNER® XP Catheter, with its jaws closed, is then advanced across the distal CTO cap into the true lumen. The 4.5-F Micro Guide Catheter is then advanced over the FRONTRUNNER® XP Catheter, and distal true lumen access is confirmed by injecting diluted contrast through the Micro Guide Catheter under ultrasound or fluoroscopic guidance. The FRONTRUNNER® XP Catheter can then be exchanged for a 0.035-inch wire through the Micro Guide Catheter. After dilation and adjunctive interventional treatment, we routinely use TUG to confirm flow and doppler velocities through the stented segment. A bent leg transcutaneous ultrasound imaging and flow velocity recordings can also be obtained to assess possible flexure points along the stented SFA segment.

Thus, the TUG-CTO technique with the FRONTRUNNER® XP Catheter microdissection technique provides a simple, reproducible, and safe technique for the treatment of complex and long infrainguinal occluded arterial segments. ■

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Treating CTOs of the Tibial-Peroneal Vessels

Adapting the FRONTRUNNER® XP CTO Catheter, used more for proximal vessels in the SFA, for areas below the knee.

BY JAMES B. PARK, MD, FACC

Given the preponderance of endovascular procedures in the lower limbs, there has been rapid progression from treating TASC A and B lesions to more attempts at TASC C and D lesions.[1] When trying to revascularize the superficial femoral artery (SFA), which can often have chronic total occlusions (CTOs), we have, in the past, relied on the wire-loop method of using a Glidewire and Glide catheter (Terumo Interventional Systems, Somerset, NJ) to get to the stump of the lesions to go subintimal and used a pushing force to try to re-enter the luminal area distal to the total occlusion.[2] In the past, given the various techniques and wires/catheters used, the success rate ranged from 40% to 70% . In an attempt to completely revascularize patients, and in having the range of devices and techniques available to completely revascularize the patient, we have also used the re-entry devices, which have increased the success rate for such procedures.[3] We attempted to increase the ability to re-enter the distal lumen, which was past the total occlusion, via a device to help the operator reach the true lumen.

Catheters such as the Pioneer (Medtronic, Inc., Minneapolis, MN) and the OUTBACK® LTD® Re-Entry Catheter (Cordis Corporation, Warren, NJ) have decreased the chance for perforation and shorten the length of the vessel needing revascularization due to more accurate re-entry just distal to the end of the CTO or at the beginning of the visualization of the distal vessels via collaterals.[4,5] However, in trying to again completely revascularize the patient, we often encounter CTO of the tibial and peroneal vessels, which are a bit more problematic. In general, the features of the tibial vessels are less favorable for percutaneous revascularization via current methods. For instance, the tibial vessels tend to be more calcified, sometimes more tortuous, and often are very small in caliber to the more proximal vessels. These characteristics often pose a very significant problem for the operator trying to open up a CTO. In addition, the use of re-entry devices is difficult given the size of the vessel.

The use of hydrophilic wires or CTO wires is often successful, especially if the CTO is often a functional occlusion or of short duration. However, for many of these lesions, the wires eventually go subintimal, and once the interventionist has made a tract with these wires, it is often impossible to go down another path. In addition, if there are collaterals near the stump or beak of the CTO, these wires, given their caliber, often traverse into the collaterals and will not direct themselves to the end of the vessel.[6]

The FRONTRUNNER® XP Catheter (Cordis Corporation), originally developed and marketed as a CTO device in the coronaries, has been used since the acquisition by Cordis to work as a CTO device for the SFA (Figure 1). It is often successful in keeping the device intraluminal, thereby avoiding

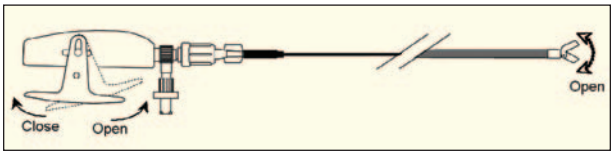

Figure 1. The FRONTRUNNER® XP Catheter.

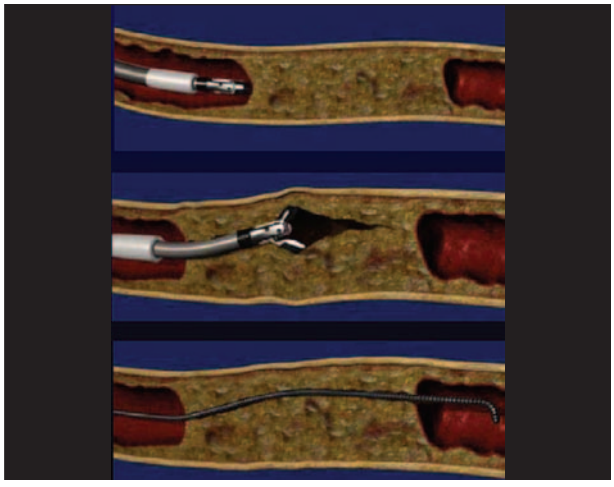

Figure 2. The FRONTRUNNER® XP Catheter facilitates placement of a conventional guidewire across stenotic lesions or CTOs in the peripheral vasculature by creating a pathway through the occluded vessel via blunt microdissection.

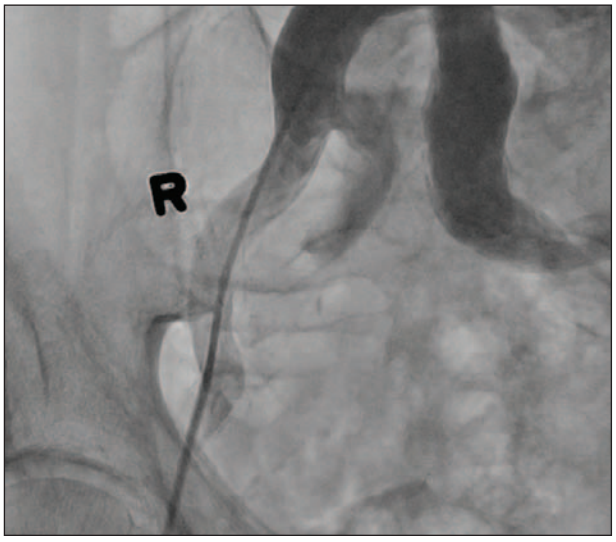

Figure 3. Aneurysmal iliac system.

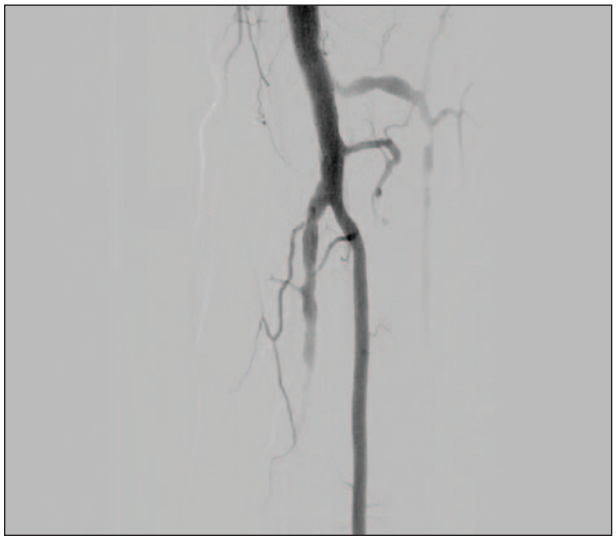

Figure 4. Occluded posterior and anterior tibial vessels.

the subintimal technique and reducing the use of re-entry devices and shortening the length the interventionist must revascularize via percutaneous transluminal angioplasty (PTA) and stenting. Often, with the use of these devices, the interventionist can get through the initial cap of the CTO and will encounter no further resistance in pushing the device down to where the vessel can be visualized again via collaterals. In addition, by using the jaws of the device to perform controlled blunt microdissection to get through the initial cap and areas of stenosis, we can often get through calcified and fibrocalcific areas easier than if we were to use the wire and catheter technique (Figure 2).[7,8]

In this article, we present a case study in using the FRONTRUNNER® XP Catheter to get through the CTO of the tibial vessels without using any other wires and staying intraluminal. It is this author's opinion that using the FRONTRUNNER® XP Catheter actually keeps the device more in the lumen, allowing for less chance to perforate or go subintimal given the rounded edge of the device and the matching of the size of the device-to-artery ratio. Although there might be hesitation in using the device below the knee given the device's size (0.039 inch with jaws closed; 2.3 mm with jaws open) and the relative small size of the vessel, I believe that this size ratio actually helps to get the device down through the CTO and to stay intraluminal. Because the device is relatively large compared to the vessel, it has less chance to go subintimal. In fact, there are many operators who successfully use the 0.035-inch Glidewires as their wire of choice for below-the-knee lesions, and I feel that it is this size ratio that allows these operators to be successful.

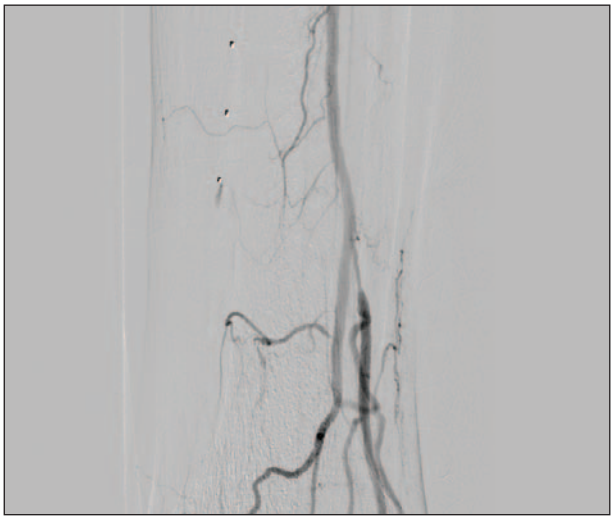

Figure 5. Distal vessel reconstitution via collaterals with good target.

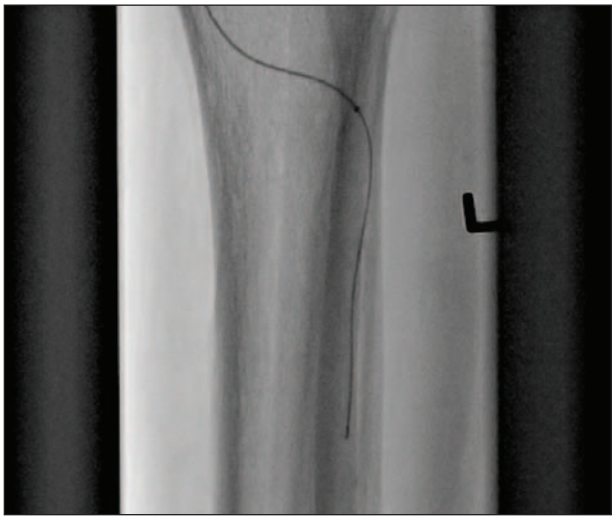

Figure 6. The FRONTRUNNER® XP Catheter in the anterior tibial artery.

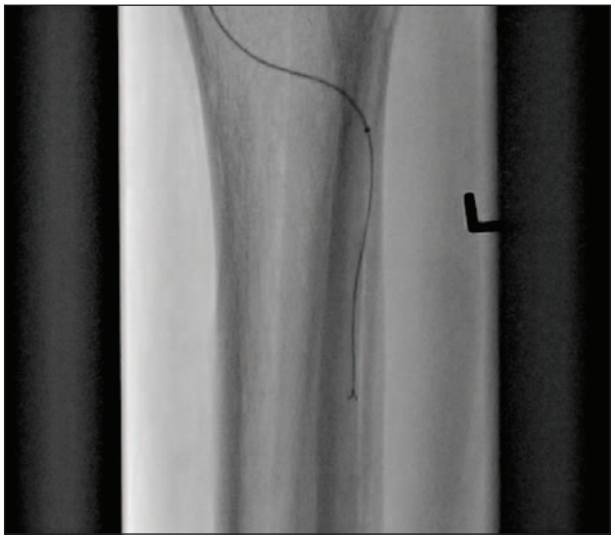

Figure 7. The FRONTRUNNER® XP Catheter with the jaws open.

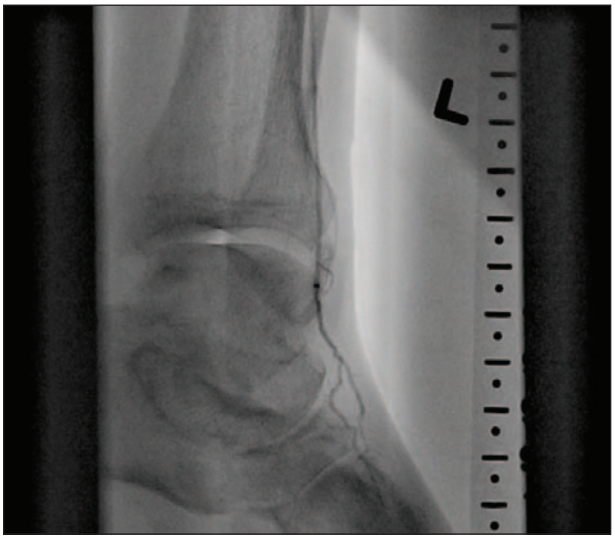

Figure 8. The distal dorsalis pedis artery after getting through the CTO.

CASE REPORT

A 76-year-old man presented with a history of diabetes, hypertension, and hypercholesteremia. He also has non-healing wounds on the left toe and heel, which needed revascularization. The patient had ankle-brachial indexes less than 0.6 bilaterally. His angiogram showed a totally occluded anterior tibial vessel with good distal target at the dorsalis pedis artery (Figures 4 and 5). On the first day, we attempted to go contralateral to use the FRONTRUNNER® XP Catheter to get through the CTO and were successful through the first third of the vessel, but we had to stop secondary to running out of the catheter length to complete the procedure. The FRONTRUNNER® XP Catheter is designed to be able to reach the ankle from the contralateral approach, but this patient had very tortuous and aneurysmal iliac vessels that used up the catheter length (Figure 3). The next day, via an antegrade approach, we reattempted to cross the CTO using the shorter FRONTRUNNER® XP Catheter, which was successful in getting into the distal anterior tibial (AT) vessel. Only one jaw opening was required (Figures 6 and 7); I was able to push the device with the support of the Micro Guide Catheter (which is the support catheter designed to be used with the FRONTRUNNER® XP Catheter) to the distal AT, where I was able to inject through the catheter to confirm that I was intraluminal (Figure 8). Thereafter, I was able to use a 0.014-inch Spartacore wire (Abbott Vascular) as my working wire to

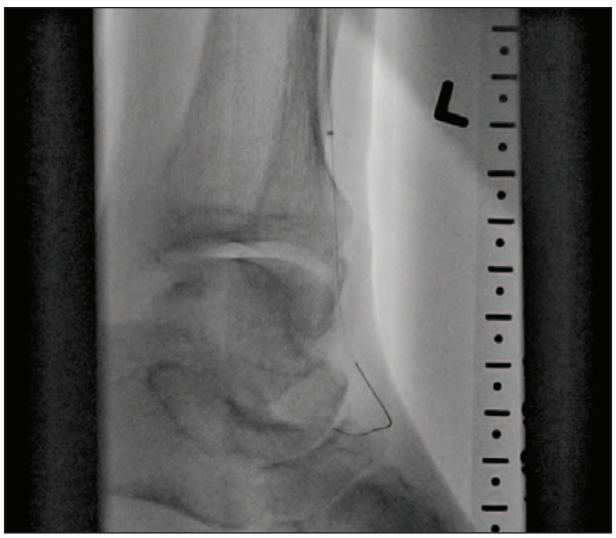

Figure 9. Wire in the distal vessel with balloon inflation in the lesion.

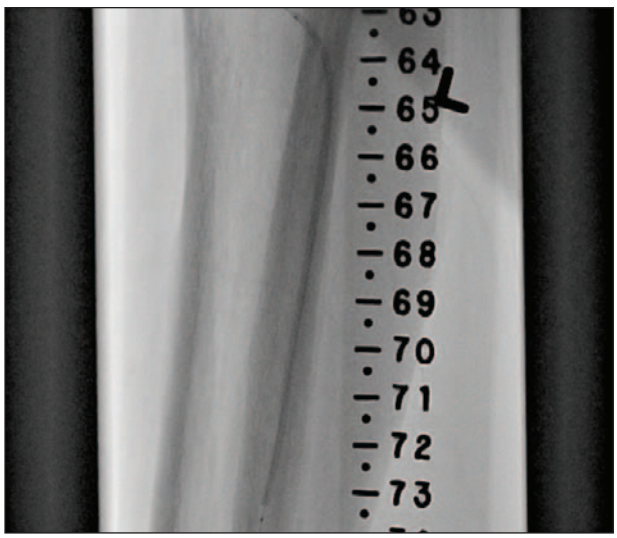

Figure 10. Balloon inflation in the proximal vessel.

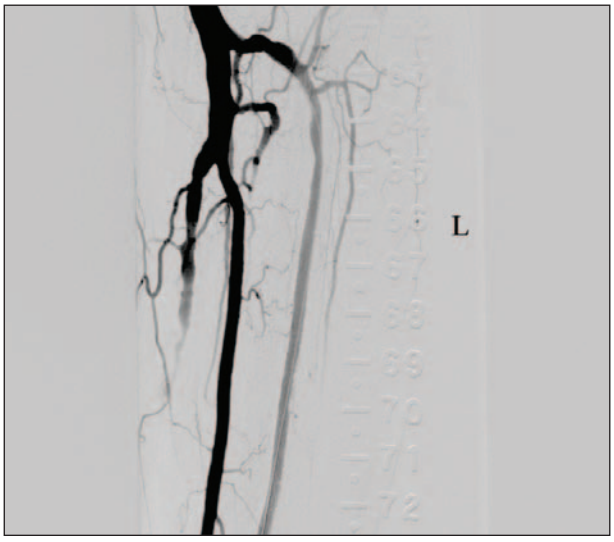

Figure 11. Final image of the proximal anterior tibial artery.

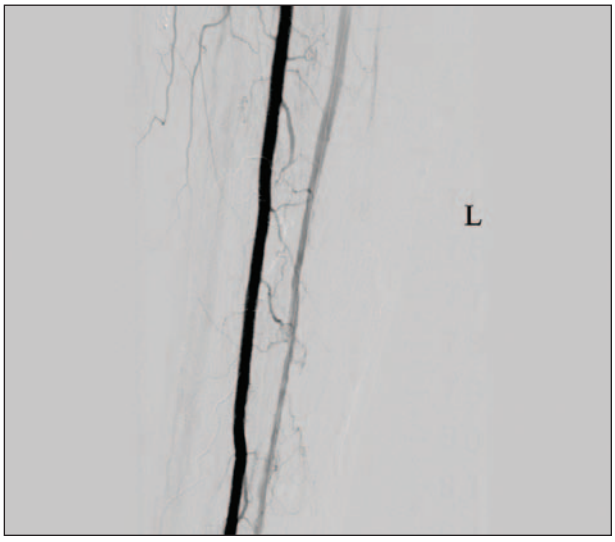

Figure 12. Midanterior tibial artery.

bring a peripheral below-the-knee balloon to perform the PTA followed by adjunctive interventional treatment (Figures 9 through 13).

DISCUSSION

Although there are a myriad of techniques and devices including different wires to use for CTO vessels, the FRONTRUNNER® XP Catheter seems to have an advantage over other devices in that it will try to keep the device intraluminal. Whether this has additional clinical benefit remains to be seen, but it does afford the operator an option to complete the procedure with less trauma to the vessel and might shorten the procedural time, particularly in the SFA when re-entry devices are used. In addition, for below-the-knee disease in the tibial and peroneal vessels, it might afford the opportunity to open these vessels when current technology is unable to complete the task or is inefficient in design.

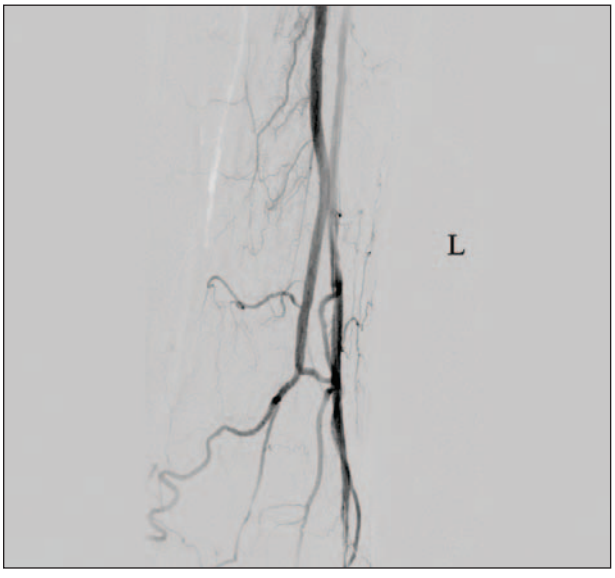

Figure 13. Distal tibial artery.

CONCLUSION

The FRONTRUNNER® XP Catheter can be used in a variety of clinical situations including CTO of the subclavian, iliac, superficial femoral, popliteal, and tibioperoneal arteries. However, surprisingly, it really might be most suited for the tibioperoneal arteries due to its ratio of size to the vessel. ■

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The FRONTRUNNER® XP CTO Catheter

One physician's experience using this device.

BY DAVID JESSUP, MD, FACC, FSCAI, RPVI

Saving time, improving efficiency, and increasing patient safety are always welcome developments in our practice, and recently, I have found that my total fluoroscopic and procedural time is reduced when I use the Cordis FRONTRUNNER® XP Catheter (Cordis Corporation, Warren, NJ) for infrainguinal vessels. Historically, I cross chronic total occlusions (CTOs) with a combination of wire and catheter techniques. I have discovered that the FRONTRUNNER® XP Catheter decreases my case time, thus allowing me to schedule an extra case every day. Decreased procedural time also translates into decreased patient discomfort and increased patient safety.

The Cordis FRONTRUNNER® XP Catheter is particularly well designed to allow me to maintain an intraluminal course. The steerable, metal, rounded distal tip allows more pushability than a typical 0.035- or 0.038-inch Glidewire (Terumo Interventional Systems, Somerset, NJ) and is much more directable than the back end of a cored wire. The actuating jaws create a larger channel and can dissect a thick, fibrous cap that would otherwise deflect a 0.035-inch hydrophilic wire into the subintimal space. The hydrophilic shaft means that when I get through a stenosis with the FRONTRUNNER® XP Catheter, I am usually able to advance the FRONTRUNNER® Catheter through to the native lumen. Instead of creating an intentional subintimal dissection plane with vessel recanalization that occurs with standard wire techniques, the FRONTRUNNER® XP Catheter follows the lumen more frequently and allows more controlled vessel re-entry.

The combination of a FRONTRUNNER® XP Catheter with an OUTBACK® LTD® Re-Entry Catheter (Cordis Corporation) is especially potent. Although the Medtronic Pioneer catheter (Medtronic, Inc., Minneapolis, MN) is available in my peripheral laboratory, the OUTBACK® LTD® Catheter uses a smaller sheath size (6 F for the OUTBACK® LTD® Catheter versus 7 F for the Pioneer catheter); subsequently, not only do I reduce my procedure time by not requiring the Volcano IVUS system (Volcano Corporation, Rancho Cordova, CA), but I also increase patient safety by using a smaller sheath size (a real problem in patients of smaller stature). By decreasing the overall procedure time, patient safety is improved. I find that I can routinely stay out of the popliteal space when utilizing the FRONTRUNNER® XP and the OUTBACK® LTD® Catheters together, and I feel comfortable tackling the difficult TASC II C stenosis knowing that the patient will have a more favorable result.

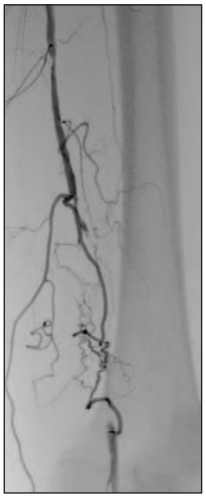

Figure 1. Diagnostic angiography confirmed the presence of a distal left SFA stenosis that reconstituted in the supragenicular popliteal space.

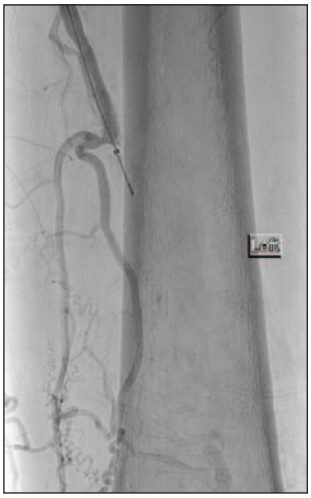

Figure 2. The FRONTRUNNER® XP Catheter crossing the proximal cap. Note that the actuating jaws are closed, but the FRONTRUNNER® XP Catheter's dome-shaped distal tip engaged the proximal cap and crossed it without difficulty.

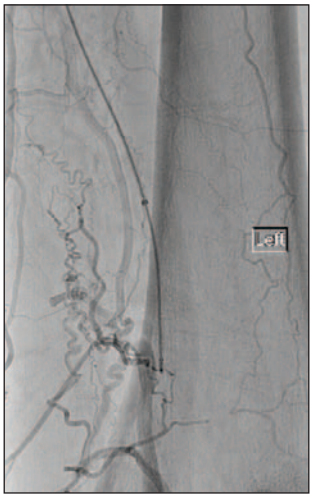

Figure 3. The FRONTRUNNER® XP Catheter engaged in the distal SFA subintimal dissection plane. The dissection plane did not extend into the main popliteal artery.

The FRONTRUNNER® XP Catheter performs particularly well in CTOs. Before switching to the FRONTRUNNER® XP Catheter, I had difficulty maintaining intraluminal position when crossing the chronically occluded segment. The Terumo Glidewire would cross either an easily recognized spiral dissection or a difficult-to-visualize plane dissection, which would only become recognizable once a balloon would fail to cross. Often, 0.014-inch coronary CTO wires lack the pushability of a 0.035-inch system, and it is no surprise that the Asahi Confianza Pro 12-gram 0.009-inch hydrophilic wire tip (Abbott Vascular, Santa Clara, CA) deforms with advancement. I prefer using the combination of a Confianza Pro 12-gram 0.014-inch CTO wire and the FRONTRUNNER® XP Catheter. The FRONTRUNNER® XP Catheter is excellent at blunt dissection and starting the channel from the proximal cap. It also is quite good at maintaining an intraluminal course. A 0.014-inch CTO wire allows me to "fine-tune" intraluminal lesion crossing in the event that the distal tip becomes deflected subintimally, as I will discuss in this article.

The FRONTRUNNER® XP Catheter has several positive aspects that make it especially suitable for occlusions. By placing a slight, 30º angle on the distal tip, I am able to torque the device and steer it in the direction of the native vessel. The easy-to-steer distal tip also lets me redirect the device away from the vessel wall, avoiding trauma there. Often, I do not need to use the actuating jaws for blunt dissection to cross long segments of occlusions, but having the ability to microdissect a particularly difficult, fibrous stenosis is reassuring.

Other practical techniques I have used with the FRONTRUNNER® Catheter include having a technologist tightly grip and pin the supporting Cordis 4.5-F Micro Guide Catheter as it exits a Cook 6-F Raabe sheath (Cook Medical, Bloomington, IN), which also facilitates the FRONTRUNNER® XP Catheter passage by preventing the Micro Guide Catheter from backing out when I am advancing the FRONTRUNNER® XP Catheter. I will often have the technologist provide forward pressure with the Micro Guide Catheter when a lesion is particularly demanding. I am comfortable allowing the peripheral lab technologist to provide aggressive forward support because, with the Micro Guide Catheter being shorter than the FRONTRUNNER® XP Catheter, I know that the technologist cannot outrun the FRONTRUNNER® XP Catheter that I am manipulating with the Micro Guide Catheter and cause more vessel trauma.

Once across the occlusion, advancing the 4.5-F Micro Guide Catheter is usually easy due to its hydrophilic coating. The integrated system allows this catheter to cross easily over the FRONTRUNNER® XP Catheter. Occasionally, when the 4.5-F Micro Guide Catheter fails to follow the FRONTRUNNER® XP Catheter, opening the actuating jaws of the distal tip of the FRONTRUNNER® XP Catheter can provide an anchor and allow me to rail the 4.5-F Micro Guide Catheter across the lesion. Also, the actuating jaws of the FRONTRUNNER® XP Catheter open to 2.3 mm, with which I can create a larger channel by opening the jaws and withdrawing the FRONTRUNNER® XP Catheter to the distal tip of the Micro Guide Catheter. If this does not work, I will recross the lesion with a Confianza Pro and exchange this wire for an Asahi Grand Slam (Abbott Vascular) using a 0.014-inch Spectranetics Quick-Cross (Spectranetics Corporation, Colorado Springs, CO). Once across, I feel comfortable using cutting balloon angioplasty (Boston Scientific

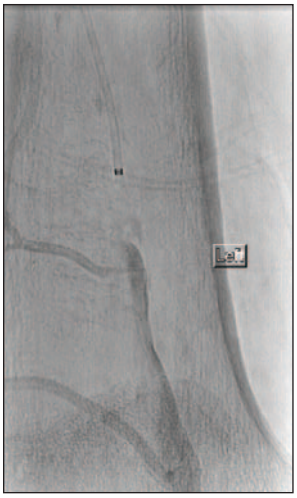

Figure 4. After pulling the FRONTRUNNER® XP Catheter back, I redirected the Confianza Pro 12 into the native lumen and was able to readvance the FRONTRUNNER® XP Catheter more distally. The Micro Guide Catheter is now engaged in the true lumen.

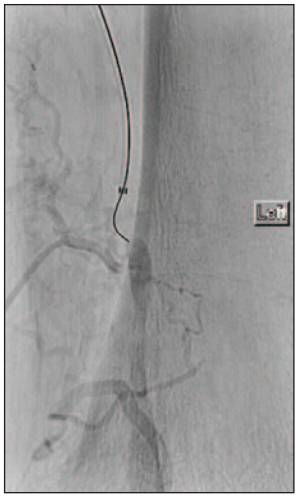

Figure 5. The thick, fibrous distal cap is not allowing the Confianza Pro 12 to cross. Previously, I was unable to cross using the FRONTRUNNER® XP Catheter.

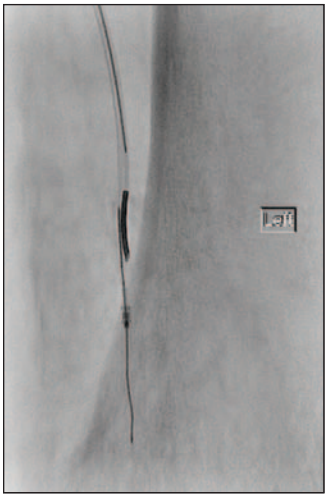

Figure 6. The OUTBACK® LTD® Catheter was not available at the time; Volcano IVUS was used for controlled re-entry (needed to upsize sheath from 6 to 7 F, adding considerable time and increasing the risk of groin complications).

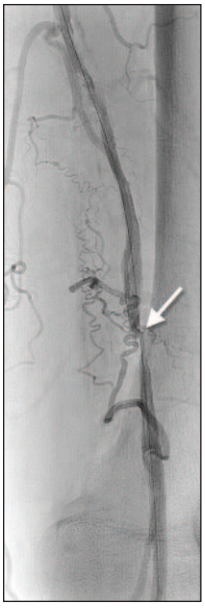

Figure 7. Postangioplasty result clearly shows the distal SFA re-entry site.

Corporation, Natick, MA) or scoring balloon angioplasty (AngioSculpt, AngioScore, Inc., Fremont, CA) with a lower risk of distal embolization than if I had used standard wire techniques and crossed the lesion subintimally

Overall, I am not comfortable tackling the long infraingunal/superficial femoral artery (SFA) CTO without having a combination of the Cordis FRONTRUNNER® XP Catheter and the OUTBACK® LTD® Re-Entry Catheter, both of which are available in my laboratory.

CASE REPORT: HIGHLY CALCIFIED DISTAL CTO SFA

A 67-year-old man with significant lifestyle-limiting claudication presented with an ankle-brachial index of 0.57 at rest that decreased to 0.23 with 55 toe raises. Duplex ultrasound illustrated a totally occluded SFA with reconstitution at the distal SFA. Diagnostic angiography confirmed 70% mid-SFA stenosis followed by a totally occluded, moderately calcified distal SFA (Figure 1). Having failed a 3-month outpatient exercise program, the patient desired to proceed with an endovascular approach.

A totally occluded and calcified distal SFA represents the most complicated of TASC II C SFA lesions. There is a strong desire not to cross into the popliteal space and subsequently inhibit future surgical options. Furthermore, the fibrous, calcified plaque morphology lends itself to subintimal dissection, thus further complicating the procedure with the risk of extending the dissection into the popliteal space. Optimally, the physician's desire is to maintain an intraluminal crossing that can be well managed without stenting.

This exceptionally challenging case illustrates how the blunt dissection techniques of the FRONTRUNNER® XP Catheter can be combined with the Confianza Pro 12 coronary guidewire to cross this difficult lesion. Using blunt microdissection, the proximal cap was crossed (Figure 2), but highly calcified plaque deflected the FRONTRUNNER® XP Catheter (Figure 3). By exchanging out the FRONTRUNNER® XP Catheter for a Confianza Pro 12 using the Micro Guide Catheter, I was able to create another channel. Steering the FRONTRUNNER® XP Catheter into this channel, the process was repeated several times, and ultimately, the FRONTRUNNER® XP Catheter was successful in crossing the lesion but was deflected by the distal cap (Figure 4). I was unsuccessful in trying to cross the distal cap using the Confianza Pro 12 (Figure 5). Because the OUTBACK® LTD® Re-Entry Catheter was not available at the time, I needed to exchange the 6-F sheath for a 7-F X 55-cm Raabe sheath (Cook Medical) and used an alternative re-entry catheter to successfully enter the distal SFA (Figure 6). After angioplasty, the re-entry site is clearly visualized (Figure 7), and flow-limiting dissection had occurred. A 7- X 100-mm self-expanding nitinol stent was deployed with an excellent result (Figure 8).

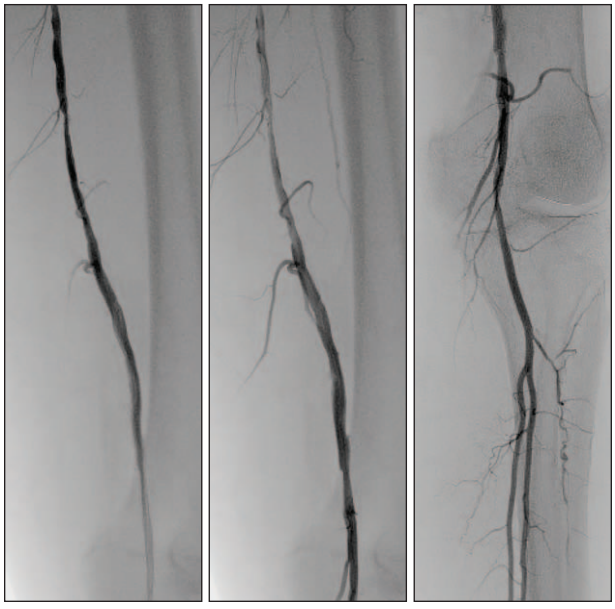

Figure 8. Excellent final result with TIMI 3 flow and no distal embolization.

CONCLUSION

Difficult peripheral cases require patience, time, and the right equipment. Although TASC II A and B lesions can usually be successfully managed with standard wire and catheter techniques, when approaching a TASC II C stenosis, it is best to have devices specifically designed to aid in intraluminal crossing techniques as well as re-entry techniques. The FRONTRUNNER® XP Catheter has multiple features designed to aid the physician in crossing CTOs. Having a re-entry catheter available is a necessity, especially when the potential exists to propagate the dissection into the popliteal artery. I would not have attempted this case if I did not have both a crossing and re-entry technology I believed in available in my laboratory. ■

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Lower Extremity Occlusions in Today's Practice

How should we interpret the BASIL trial in the real world?

BY PETER SCHNEIDER, MD

Chronic total occlusions (CTOs) represent one of the biggest challenges to endovascular operators. The strategy, equipment, and technique have all improved, and I expect they will continue to get better. In the not-too-distant past, the inability to cross an occlusion was a common occurrence. As we become more aggressive in attacking occlusions, our results are improving. The enhanced management of occlusions has helped to make endovascular techniques competitive with open surgery.

THE BASIL TRIAL

The BASIL trial, a multicenter controlled trial from 27 UK sites, randomized 452 patients with severe limb ischemia to surgery (n = 228) or angioplasty (n = 224). The primary endpoint was amputation-free survival. The hospital costs associated with a surgery-first strategy were about one-third higher than those with an angioplasty-first strategy. Intervention was more cost-effective than surgery with less early morbidity and shorter hospital stays. At the end of follow-up, 248 patients were alive without amputation of the trial leg, 38 were alive with amputation, 26 were dead after amputation, and 130 were dead without amputation. Six-month amputation-free survival was not significantly different between groups (48 vs 60; hazard ratio, 1.07; 95% confidence interval, 0.72–1.6). However, surgery was associated with a higher rate of early morbidity at 30 days (57% vs 41%; difference, 15.5%; 95% confidence interval, 5.8–24.8).[1]

The BASIL trial had a high number of interventional failures. Approximately 20% of interventional cases could not be treated because the lesion could not be crossed or re-entered. Some of these patients may have benefited from treatment with the FRONTRUNNER® XP or the OUTBACK® LTD® Catheters (Cordis Corporation, Warren, NJ) (Figure 1). The BASIL trial was published in 2005, but it began randomization several years before that, and our tools have changed immensely over that time. From 2000 until now, there have been new devices, changes in technique, and added tricks for the treatment of CTOs, such as a wider choice of wires, a better understanding that tibial disease can be addressed endovascularly, new entry and re-entry devices, the rebirth of laser treatment to bore a hole through a challenging occlusion, new low-profile stents, and a broader acceptance that CTOs can be crossed almost routinely. In 2009, the rate of failure to revascularize is less than 5%, so long as patients are properly screened regarding medical illness, history, and lesion morphology. The incidence of crossing failure relies on patient selection. We still do not have very good tools for dealing with a few anatomic morphologies, such as heavy calcification. In patients with diffuse, heavily calcified lesions, the best results will likely be from bypass.

BASIL was certainly a necessary study and one that has influenced practice, but it did not specifically state a preference for one treatment over another. The way the BASIL trial should be interpreted in the day-to-day clinical world is that surgery and endovascular treatment are complementary. It is not typically either/or; the populations that benefit more from each of these therapies are different. Some patients are going to be too ill for surgery, and endovascular treatment will be the preferred option almost no matter how bad their disease pattern is. Other patients desire endovascular intervention, but their disease morphology is so poor (eg, heavy, diffuse calcification; bulky common femoral disease; or long, multiseg-

Figure 1. The FRONTRUNNER® XP Catheter enables controlled crossing of CTOs for stenting and angioplasty procedures by creating a pathway through the occluded vessel via blunt microdissection.

ment occlusions crossing one or more joints) that surgery is preferred over endovascular intervention. Patients with a longer life expectancy and good autologous vein should be considered for surgery. However, many limb salvage patients have other problems that limit life expectancy and suitability for open surgery.

NEW TASC II 2007 GUIDELINES

The TASC guidelines, developed to provide an international consensus on the management of peripheral arterial disease, provide recommendations for endovascular or surgical therapies in specific patients with a variety of lesion morphologies. The TASC Working Group initially consisted of members from 14 North American and European societies representing the fields of vascular surgery, interventional radiology, angiology, and cardiology, as well as experts in health economics and epidemiology. This group produced the original TASC recommendations, which were published in 2000.[2]

The TASC II Working Group included members from 16 societies, not only from North America and Europe, but also from Japan, Australia, and South Africa. In 2007, the TASC II guidelines were published, recommending endovascular therapy as the treatment of choice for type A and B lesions.[3] TASC II recommends interventional treatment of occlusions ≤ 15 cm in length in the femoropopliteal arteries for TASC type B patients. In these patients, endovascular therapy is now the preferred treatment, whereas in the 2000 guidelines, there was not a firm recommendation. TASC II also recommends endovascular therapy as the treatment of choice for type A and B aortoiliac lesions. In comparing the first set of guidelines to the second, over the course of 7 years, there was significant movement toward expanded management of a variety of disease morphologies—including occlusions—using endovascular techniques. Many endovascular specialists from a variety of disciplines routinely consider minimally invasive options for TASC C and TASC D lesions as well.

SFA CTOs

There has been steady progress in the last 5 to 7 years in the field of treating CTOs in the superficial femoral artery (SFA). We are much better at crossing these lesions; the problem is that we are still having trouble keeping them open. The patency rates for various types of reconstruction after recanalizing an occlusion are all over the map. Intermediate and long-term patency is more dependent on the length of the lesion than on the method that is used to recanalize it. However, in terms of initially opening these occlusions and considering these patients candidates for endovascular treatment, we have made significant progress. SFA occlusions in patients who have heavily calcified disease, especially with medial calcification—a rim of calcium that outlines the artery, even on a plain x-ray or on a plain fluoroscopic view—are still a major challenge. These are the cases that present a challenge for re-entry into the true lumen. The calcium in the wall at the site intended for re-entry works against the operator and prevents re-entry into the true lumen.

A second challenge with SFA occlusions is preserving the collaterals. This has to do with where and how you re-enter, but typically, if you are performing an SFA recanalization, you do want to preserve the collaterals, because if reconstruction fails at a later time, you do not want the patient to present in a worsened condition than when he initially presented. It is extremely important to preserve the collaterals and the re-entry options. If the collaterals are damaged during re-entry or are covered and a second intervention becomes necessary, it may be more difficult. The occlusion is usually longer than when it was initially treated (Table 1).

TABLE 1. INDICATIONS FOR SURGERY AND ENDOVASCULAR TREATMENT OF CTOs

Indications for Surgery[a]
- Super-long bypass
- Limited runoff (isolated patent segment of single artery in the foot)
- Revascularization across one or multiple joints (eg, knee and ankle)
- Extremely heavy calcium burden (ie, diffusely calcified vessels)

Relative Contraindications for Surgery
- Congestive heart failure and renal failure combined
- Hypercoaguable states

Indications to Consider Primary Amputation
- Septic shock or life-threatening infection
- Exposed calcaneus or other major vital structure

[a]The patients with disease morphologies indicated for surgery represent only approximately 15% of the patients in my practice. Some of these patients may not be appropriate candidates for surgery, and medical management may be recommended.

CROSSING TIBIAL OCCLUSIONS

Our ability to cross tibial occlusions was improved by coronary catheters being adapted for use in the tibial arteries. We now have better, low-profile, small-caliber sheaths that are long and sleek and can be placed directly

into the popliteal artery or the origin of the tibial artery. Many patients with tibial artery occlusive disease have diabetes and renal insufficiency. Therefore, we use carbon dioxide (CO_2) angiography quite often. CO_2 is used as the contrast, usually for the aortoiliac and femoropopliteal segment, until we get to a point when the CO_2 does not give us an adequate understanding of the anatomy. CO_2 is very good for ruling out disease and demonstrating normal or mildly diseased anatomy. When CO_2 gas collides with the occlusive lesions, it fragments into smaller bubbles, and the images become less clear. If this is the case, we go to very diluted contrasts—sometimes contrast that is diluted to 20%. One of my partners, Nic Nelken, MD, has been studying this. It is not unusual in the setting of combined use of CO_2 and very diluted contrast to be able to do a complex limb revascularization with less than 10 mL of contrast being administered. Patients with renal insufficiency do need extra attention. We have them come to the hospital a few hours early for a bicarbonate drip and treat them with acetylcysteine.

The use of CTO guidewires and stiff CTO support catheters, and the step-by-step laser technique has made it possible to cross most tibial occlusions.

CONCLUSION

Lower extremity occlusions in the femoropopliteal and tibial segments remain a challenge, but significant progress has been made in the past few years. This improvement is demonstrated by the change in TASC recommendations between 2000 and 2007, showing that more severe lesions and extensive occlusions are considered for endovascular therapy. We are better at achieving recanalization and reconstruction of CTOs, but long-term patency in many settings is still lacking. The BASIL trial was a useful study but does not provide all the answers. There were many initial technical failures of intervention, which are less likely with current technology. With longer-term follow-up to several years, the surgical arm has shown a trend toward lower risk of limb loss, suggesting that surgery be more heavily considered in patients with long life expectancy. The BASIL trial findings reinforce the complementary nature of open and endovascular treatment of critical limb ischemia. ■

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