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Endovascular TODAY

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OPTIMIZING CLI CARE

New visualization and interventional strategies for individualized treatment

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Contents

Why We Are Better Prepared to Fight CLI Than Ever Before

By Fadi A. Saab, MD, FACC, FSCAI, FASE

Recent publications have quantified the harm that critical limb ischemia (CLI) poses to the general population. The CLI Global Society has found more incident cases of death over 5 years after a CLI diagnosis than any type of cancer other than lung cancer,[1] and a recent study by Armstrong et al showed that the 5-year mortality for patients with diabetic foot complications was comparable to cancer.[2]

Despite posing a major threat to public health, treatment for CLI varies widely. Each year, approximately 150,000 amputations are attributed to CLI in the United States.[3,4] This is in part due to primary amputation still being considered a first-line therapy at some institutions,[1,5-9] with studies finding that most patients who had undergone primary amputation did not receive either diagnostic angiography or revascularization attempts before amputation.[8,9]

Although work is still needed to control CLI, physicians are better prepared than ever to fight CLI with new imaging equipment, low-profile tools, and techniques to tackle complex CLI cases.

NEEDS OF A CLI CENTER

The country is seeing an interest in the development of CLI centers with a focus on the complex multilevel, multivessel needs of the CLI patient. These complex cases require high-caliber imaging for fluoroscopy, intravascular ultrasound, and extravascular ultrasound.

An adequate selective digital subtraction angiogram is critical to map out a treatment strategy. However, it should be married with ultrasound to get the complete assessment necessary to adequately plan access, crossing, treatment, and closure.

Vascular sonography provides detailed real-time imaging of arterial and venous anatomy and surrounding structures. This provides significant benefits when incorporated into interventional procedures of the peripheral vascular systems, including increased safety, improved outcomes, and decreased radiation times for both patients and staff. Vascular sonographers are uniquely qualified to assist in this role, as they undergo extensive training to recognize vascular anatomy and pathology when performing diagnostic ultrasounds. Real-time imaging with ultrasound can do more than just increase patient safety; it can also improve patient outcomes. Fluoroscopy has long been utilized during interventions and is an invaluable tool. The use of ultrasound will never replace fluoroscopy; however, it can be another beneficial tool, working in tandem with fluoroscopy to improve patient outcomes. Real-time imaging of catheters and wires by an interventional sonographer can quickly and accurately identify when a wire is outside the vessel or engaged within a lesion. This gives the operator confidence when crossing difficult pathology, which has two significant benefits: limiting potential complications in the form of vessel perforation and increased speed in crossing lesions. This translates to safer, shorter procedures. Ultrasound use can also minimize the use of ionizing radiation in the form of fluoroscopy. This benefits not only the patient but all staff present.

Additionally, a broad spectrum of tools and devices must be available to the CLI operator. A wide variety of wires, catheters, balloons, drug-eluting technology, scaffolds, and atherectomy devices are a must to treat complex CLI arterial anatomy, which is fraught with chronic total occlusions that are dense, collagenous, and have varying degrees of calcification.

Finally, let's not forget experience and techniques. Having the right tools in your toolbox is only half the solution for success. The other half is having highly experienced operators and well-trained staff. An investment in the education and training of staff is necessary to ensure successful outcomes for your patients. ■

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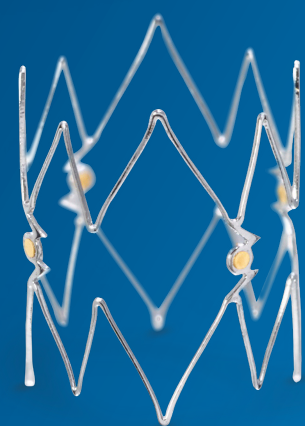

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The Four Pillars of IVUS for the Endovascular Treatment of CLI

Understanding the role of intravascular ultrasound in the treatment of critical limb ischemia.

By Serdar Farhan, MD, and Prakash Krishnan, MD, FACC

Critical limb ischemia (CLI) can be considered the end stage of atherosclerotic plaque progression along the lower limb arteries. Every year, nearly 2% of patients with peripheral artery disease (PAD) progress to CLI.[1,2] CLI is a major, potentially life-threatening condition, associated with a high risk of minor and major limb amputations, resulting in a significant increase in mortality.[3] Aside from the risk of major adverse cardiovascular and limb events, CLI management is associated with high health care costs.[3]

Revascularization by surgical bypass or endovascular intervention (EVI) is considered the cornerstone of CLI management to attempt limb salvage and prolong life.[4] Diagnostic peripheral angiography with fluoroscopy and digital subtraction angiography (DSA) is considered the gold standard for visualization of lower limb vasculature. Nevertheless, this imaging modality has its limitations in identifying of plaque morphology and geometry. Even when applying biplanar angiography, the actual dimension, depth, and anatomic characteristics of the plaque elude this imaging technique.

EVI of CLI is challenging due to the multilevel involvement and high frequency of chronic total occlusions (CTOs).[4] Furthermore, patients with CLI have comorbidities such as older age and chronic kidney disease and are thereby at high risk for EVI complications.[5] Because of these challenges in the interventional management of CLI, we recommend the use of intravascular ultrasound (IVUS) as an imaging tool to facilitate and improve the understanding of the atherosclerotic burden and vessel dimensions, thereby allowing for accurate device selection for EVI. Despite available evidence for improving procedural success and clinical outcomes of patients undergoing IVUS-guided coronary intervention,[6] similar studies in EVI are limited. Nevertheless, several retrospective studies have shown improved patency and reduction of reinterventions with the use of IVUS for EVI.[7-9] However, those studies were mostly performed as retrospective observational studies with no suitable comparator. Furthermore, in an analysis from the Nationwide Inpatient Sample (NIS) database, the use of IVUS was associated with nonsignificantly higher hospital costs but a significantly lower rate of postprocedural complications.[10]

Recently, four pillars of IVUS in PAD have been presented: visualizing plaque geometry, defining plaque morphology, vessel sizing, and guidewire orientation.[11] This article will highlight the importance of each pillar in the endovascular revascularization approach to CLI management. Furthermore, we want to discuss the importance of the confirmation of the four pillars.

THE FOUR PILLARS OF IVUS IN PAD

Visualizing Plaque Geometry

IVUS is superior to DSA in differentiating between eccentric and concentric plaque (Figure 1). Knowledge of plaque geometry may facilitate the selection of interventional devices, especially when performing atherectomy. Furthermore, orienting a directional atherectomy device toward the nonaffected side may eventually result in an adventitial cut and cause a higher degree of vessel trauma, affecting patency rate.[12] On the other side, identification of circumferential concentric plaque implies the need for pretreatment of the vessel with plaque modification devices to achieve optimal results.

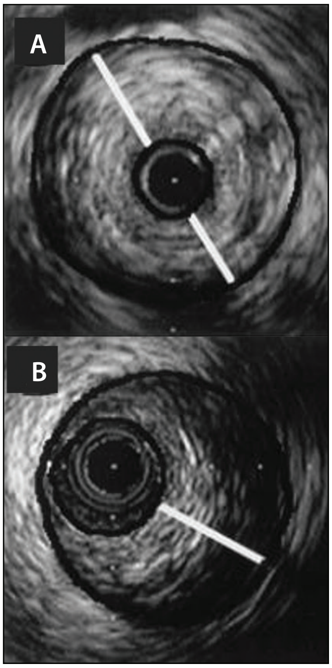

Figure 1. IVUS image of plaque geometry. Panel A represents a concentric plaque. Plaque burden is equal in thickness/volume 360° around the vessel. Panel B represents plaque burden that is higher on one side of the vessel and often includes an area of healthy vessel.

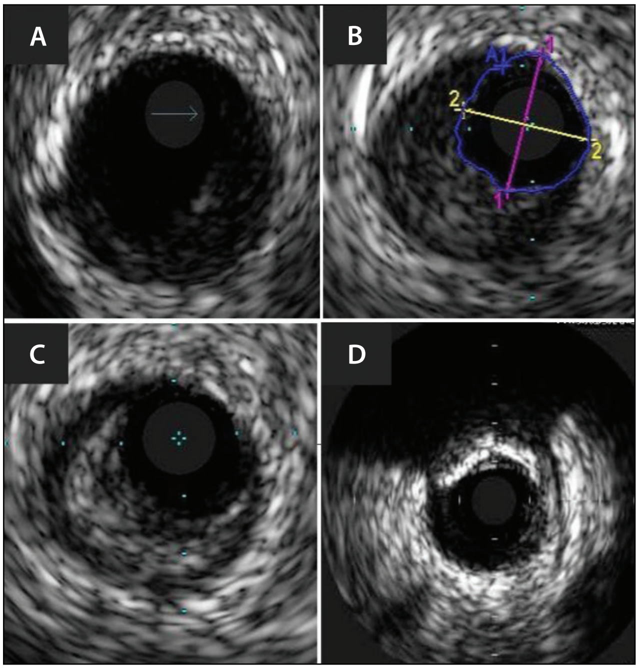

Figure 2. IVUS image of plaque morphology. Panel A represents a fatty plaque, which is the darkest gray (more echolucent) very compliant, gelatinous, and prone to shift. Panel B represents fibro-fatty plaque, which is dark gray, more structured than a fatty plaque but still compliant, and will shift with force. Panel C represents a fibrous plaque, which is the lightest gray (more echogenic) and tight network of plaque that is less likely to shift and therefore more likely to be noncompliant, especially in concentric lesions. Panel D represents a calcified plaque; calcium is highly echogenic, appearing bright white on IVUS with an acoustic shadow behind it.

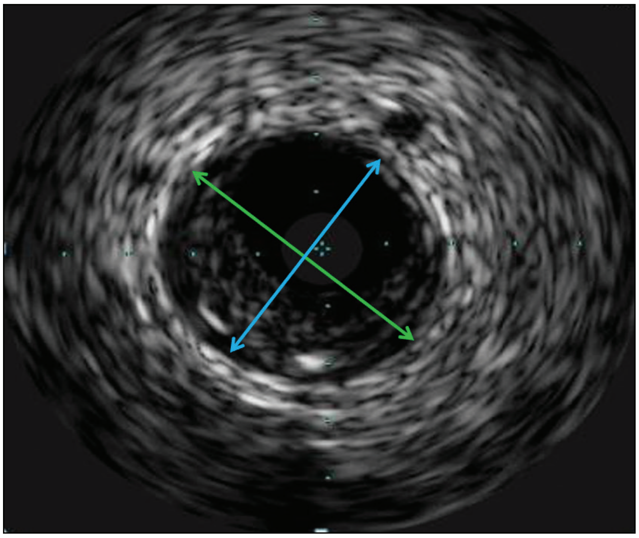

Figure 3. IVUS image with measurement of vessel dimensions. The green arrow indicates maximum and the blue arrow indicates minimum vessel diameter.

Plaque Morphology

The use of IVUS permits the examiner to distinguish between four subtypes of atherosclerotic plaque clearly. Atherosclerotic plaque can be divided according to fat and fibrous tissue content into fatty and fibro-fatty, fibrous, and calcified plaques (Figure 2). Softer plaques like fatty and fibro-fatty plaques are more easily dilated with plain balloon angioplasty (PTA) while bearing the risk of embolization on the other side. In such a lesion subset, an additional identification of the plaque's longitudinal extent improves the positioning of a scaffold to cover the entire affected segment. Fibrous and calcified plaques are more challenging to treat. Ex vivo IVUS analysis of amputated limbs confirmed that tibial arteries have a higher degree of fibrous and calcified plaque than popliteal arteries.[13] Early recoil has been described as one of the significant limitations of treating calcified tibial arteries.[14] Furthermore, IVUS allows identification of the depth and circumference of the calcium arch. Knowledge of these plaque qualities helps the examiner adequately select plaque modification tools such as orbital atherectomy or, more recently introduced, intravascular lithotripsy. Plaque modification permits a less aggressive PTA, thereby reducing the risk of barotrauma and dissection of the vessel with subsequent need for utilization of a vascular scaffold.

Vessel Sizing

Vessel sizing is paramount to select appropriate interventional devices (Figure 3). Lumen and vessel areas can be measured, and percent area stenosis and plaque burden can be calculated. Plaque burden has been associated with a high risk of subsequent events.[15] Furthermore, DSA, especially in the tibial arteries, does not permit the examiner to estimate vessel size. This limitation is frequently associated with either over- or undersizing balloons for PTA, resulting in either increased barotrauma and vessel injury or residual stenosis. Both conditions have been associated with a reduction of patency.[16]

Guidewire Orientation

EVIs for CLI are frequently performed in CTOs. In many cases, a subintimal crossing of a CTO lesion with reentry into the true lumen might occur. Using IVUS after wire passage, the examiner will quickly recognize the wire orientation and be able to make a suitable device selection (Figure 4). For instance, using an atherectomy device in such a lesion may cause substantial media or adventitia injury, which might affect the intervention site's patency.[12] On the other side, an intraluminal crossing of a CTO lesion has a tremendous plaque burden and may need methodic plaque modification before PTA or stenting.

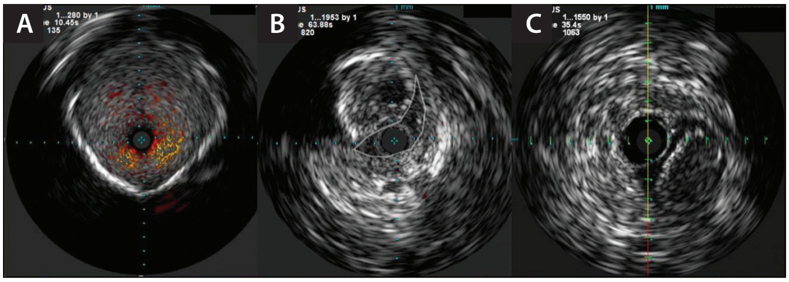

Figure 4. IVUS-guided guidewire orientation. Panel A represents an intraluminal position while panels B and C represent the subintimal orientation of the guidewire.

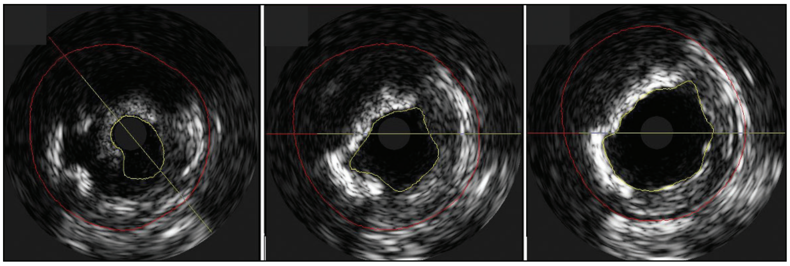

Figure 5. IVUS images of an atherosclerotic lesion comparing baseline with postatherectomy and post-percutaneous transluminal angioplasty apparel.

Postinterventional Imaging of the Treated Segment

The confirmation of the four pillars of IVUS-guided EVI is the postinterventional imaging of the treated segment (Figure 5). IVUS is superior to angiography alone in verifying the quality of the intervention. For instance, stent underexpansion, malapposition, or residual stenosis can be less frequently identified by angiography than IVUS.[17] Similarly, dissections and geographic miss can be better visualized by IVUS as compared with angiography.[17]

SUMMARY

EVI of CLI represents a challenge for the endovascular interventionalist. The use of IVUS to guide EVI in CLI appears to be a valuable tool to facilitate decision-making and eventually improve patient outcomes with CLI. Nevertheless, evidence from prospective, perhaps randomized, trials is desperately awaited to support the use of IVUS for EVI in patients with CLI. ■

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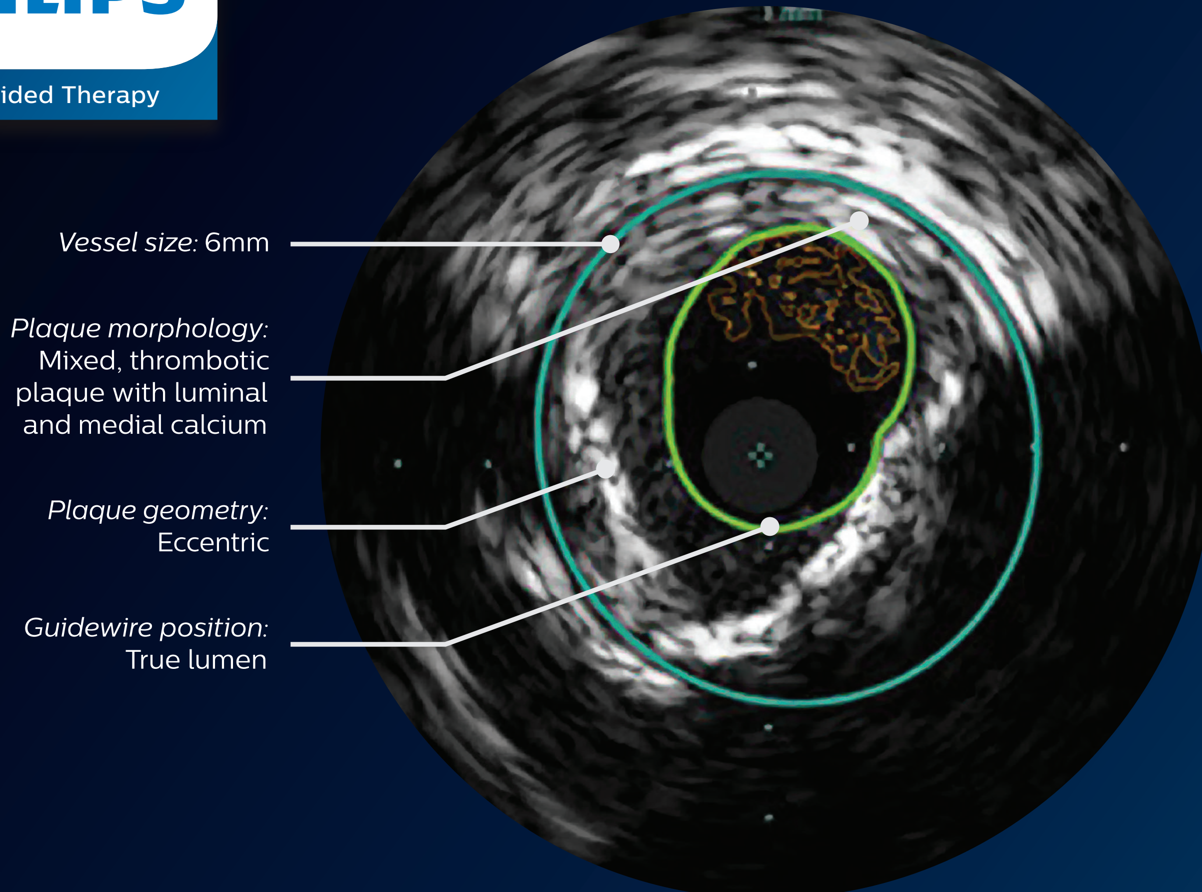

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Challenges of Calcium in Critical Limb Ischemia

Describing the prevalence of calcium in CLI, its impact on outcomes, and the use of IVUS to improve identification before intervention.

By Ehrin J. Armstrong, MD, MSc, MAS, FACC, FSCAI, FSVM

Although there have been many advances in the endovascular treatment of critical limb ischemia (CLI) in the past decade, calcification remains an important limitation in the success of lesion crossing, adequate lesion dilation, and long-term outcomes after angioplasty. Calcification is highly prevalent in patients with CLI, and its presence in both intimal and medial locations is associated with increased adverse outcomes. The use of intravascular ultrasound (IVUS) can more accurately determine calcium location and severity compared with angiography alone, thereby helping identify adjunctive therapies to improve procedural success and ultimately improve outcomes in this complex patient cohort.

PREVALENCE OF CALCIUM IN CLI

Patients with CLI have a significantly higher prevalence of calcium compared to patients with less severe manifestations of peripheral artery disease. In a cross-sectional cohort of patients where tibial artery calcification was assessed, CLI was associated with significantly higher calcification scores.[1] Increased tibial artery calcification was also associated with an increased risk of amputation. A subsequent study found that peripheral arterial calcification is associated with increasing ischemia categories, suggesting that calcification is an independent risk factor for lower extremity ischemia.[2]

In addition to calcification, patients with CLI often have concomitant mixed plaque morphologies in the infrapopliteal vessels, including diffuse thrombosis.[3] In these cases, calcium is also likely a mediator of plaque rupture and disease progression, as calcium is associated with an increased risk of in situ thrombosis from plaque erosion and rupture.[4] Therefore, both cohort and pathology studies emphasize the critical importance of calcium in mediating CLI development and progression.

ASSOCIATION OF CALCIUM WITH CLINICAL OUTCOMES

The presence of calcification significantly influences both acute procedural outcomes and long-term outcomes of endovascular intervention. Calcification is associated with an

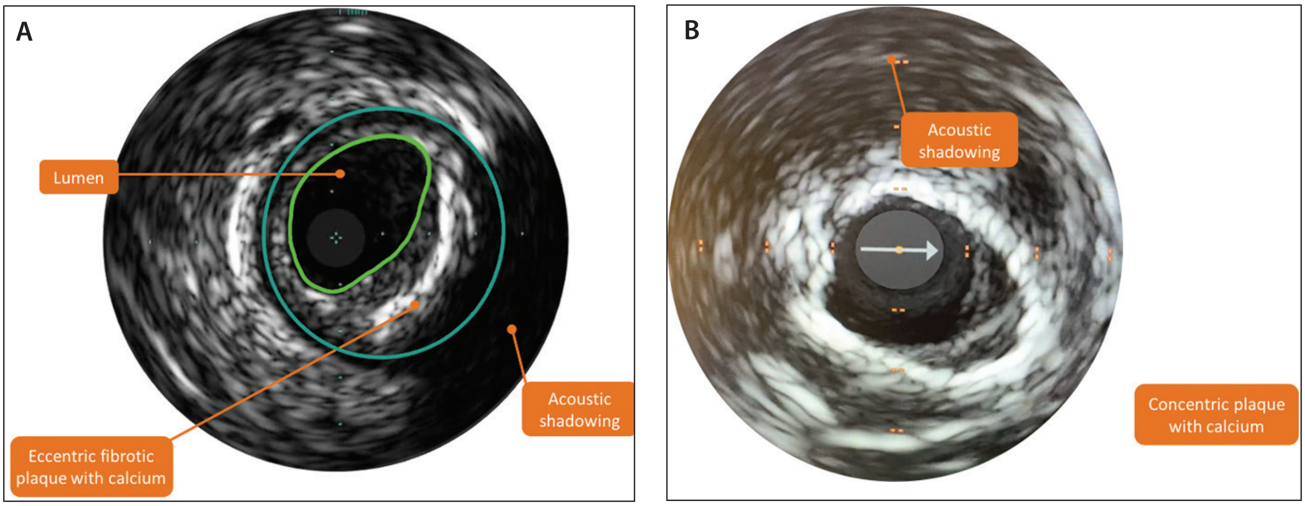

Figure 1. Eccentric and concentric calcification. IVUS can identify the location and depth of calcium in a lesion. In this example, the lesion contains eccentric calcium (A). Note the acoustic shadowing behind the sheet of calcium. In concentric calcification, the ring of calcium extends around the circumference of the vessel (B).

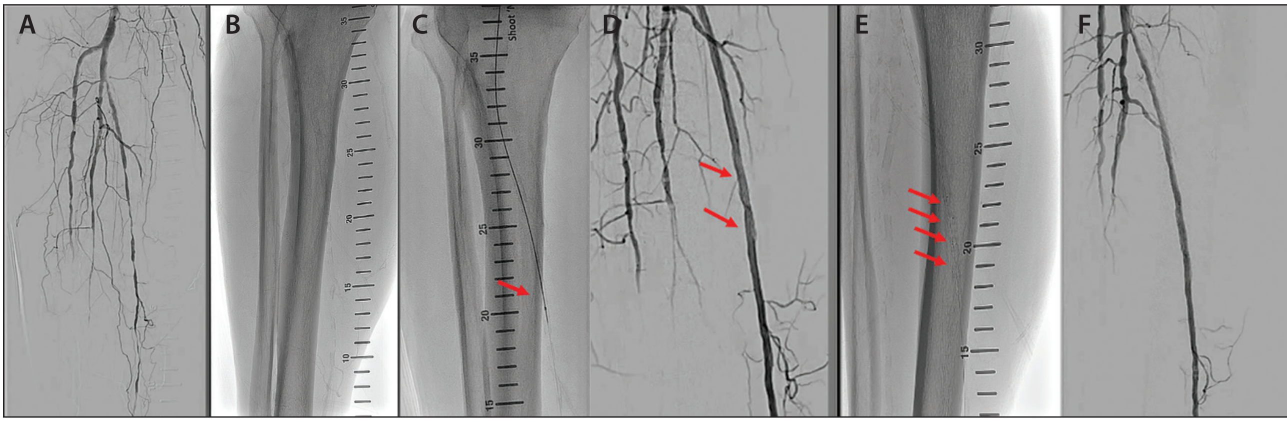

Figure 2. Atherectomy followed by Tack placement for dissection. A woman in her mid-80s presented with a nonhealing wound of the left heel. Baseline angiography revealed zero-vessel infrapopliteal runoff (A). Nonsubtracted images confirmed severe calcification (B). A 1.25-mm micro crown orbital atherectomy device was used in the posterior tibial artery (C). An area of severe dissection was identified after atherectomy (D). Four Tack implants were placed at the area of dissection (E). Final angiography revealed excellent luminal gain and no residual dissection (F).

increased likelihood of dissection due to greater shear forces, as well as inadequate luminal gain compared to noncalcified lesions. Typically, these dissections tend to occur at the interface between calcified and noncalcified segments. Multiple studies have demonstrated that vessel calcification is associated with worse outcomes after endovascular interventions.[5] In the case of drug-coated balloons, the presence of concentric calcification is associated with significantly decreased patency, potentially due to impaired paclitaxel diffusion through the calcium barrier.[6] Calcium is likely also a mediator of long-term restenosis after stent implantation, possibly due to smaller luminal diameters that are achieved.

Medial artery calcification (MAC) is defined as calcium deposited in the media/deeper wall of the artery. Historically, the relationship between MAC and outcomes was unclear, because MAC is not always associated with luminal encroachment. However, MAC was also recently shown to be a strong and independent predictor of major adverse limb events in patients with CLI.[7] The presence of MAC was strongly associated with so-called small arterial disease in the below-ankle segment, suggesting that patients with extensive MAC may require alternative endovascular approaches, including below-the-ankle angioplasty or deep vein arterialization.

IDENTIFYING CALCIFICATION IN INFRAPOPLITEAL VESSELS

Accurate identification of calcium prior to intervention is paramount to directing interventional approaches and the choice of adjunctive therapies. Multiple scoring systems have been developed to define calcium severity in the femoropopliteal segment.[8] The limitation of these scores is that they are all based on angiography. As a result, the location of calcium in the vessel (eg, intimal vs deep) cannot be determined by angiography alone. This distinction can be even more difficult when treating infrapopliteal vessels due to the smaller vessel size as well as the extensive bony overlap when imaging below the knee.

IVUS offers many benefits for the identification of calcium severity and location. Compared with angiography, IVUS provides important additional information, including the arc of calcium and delineation between intimal and medial calcium (Figure 1). In addition, IVUS can help with optimal vessel sizing. Recent studies have shown that the vessel diameter as assessed by IVUS is often 0.5 to 1 mm larger than by angiographic assessment. This increased luminal gain achieved with optimal balloon sizing likely translates into increased vessel flow and has the potential to improve rates of wound healing.[9,10]

TREATMENT OPTIONS FOR INFRAPOPLITEAL CALCIFICATION

Multiple therapies have been developed to assist with treatment of calcified lesions in CLI. Intravascular lithotripsy (IVL) is a recently developed therapy that couples the use of lithotripsy with balloon angioplasty. One advantage of IVL is that it can modify both intimal and deep calcium.

Mechanical atherectomy devices that cut, capture, and clear are an important adjunctive therapy to debulk areas of calcification. The Phoenix atherectomy catheter (Philips) debulks below-the-knee calcium with a front-cutting directional head, then captures the plaque within the device shaft continuously clearing the debris. Phoenix shows promising benefits for the CLI population.[11]

Orbital atherectomy is another important adjunctive therapy that preferentially sands away calcification.

This results in differential sanding and improved vessel compliance in calcified lesions.[12,13]

Laser atherectomy may be an ideal choice for CLI disease as the photoablation mechanism of action can treat mixed morphologies, including calcium at the molecular level.[14] At higher frequencies, rigid materials like calcium respond well and result in improved vessel compliance.[15] Laser atherectomy also ablates accompanying diffuse thrombus.[15]

In addition to the use of adjunctive calcium-modifying technologies, specialty balloons may help improve the outcomes of balloon angioplasty. Multiple specialty balloons are available, and each seeks to increase luminal gain while minimizing dissection. The AngioSculpt balloon (Philips) consists of nitinol wires wrapped around a semi-compliant balloon. Upon inflation, the nitinol elements "score" the plaque with focal force, with enough power to open up calcium.[16,17] The Serranator balloon (Cagent Vascular) is a newer therapy that consists of a semi-compliant balloon with four embedded metal serrated strips along the length of the balloon. Recent studies have demonstrated the safety and potential efficacy of this device when treating calcified lesions.[18]

Because calcification is associated with higher rates of dissection, dissections may still occur despite use of these adjunctive therapies. In such cases, bailout therapies may be necessary to optimize the acute angiographic result and prevent early failure or subsequent restenosis (Figure 2). The Tack endovascular system (Philips) is available in a 4-F compatible system for use in infrapopliteal vessels as a tool for treating dissections after balloon angioplasty. In the TOBA II BTK study, use of the Tack implant to treat postangioplasty dissections was associated with excellent patency and freedom from major adverse limb events.[19]

CONCLUSION

Calcification remains a significant barrier to both acute and long-term success when treating patients with CLI. However, recent advances in imaging with IVUS have helped identify optimal techniques for treating calcified lesions. Concurrently, new therapies such as IVL, scoring balloons, and Tacks for dissection repair have recently made it possible to develop calcium-focused therapies for CLI. ■

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CASE REPORT

A Multimodality Approach to Critical Limb Ischemia and Limb Salvage

By S. Jay Mathews, MD, MS, FACC, FSCAI

CASE PRESENTATION

A man in his early 70s with a known history of diabetes, hypertension, and dyslipidemia presented with over a month of painful bilateral necrotic toes involving the digits of both feet (Figure 1). Imaging suggested supra-normal ankle-brachial indices bilaterally (> 2.0) with noncompressible vessels and monophasic waveforms in the bilateral infrapopliteal segments without high velocities.

TREATMENT OPTIONS

A comprehensive limb salvage plan was initiated between wound care, orthopedics/podiatry, cardiology, and vascular interventional services. Given his comorbidities, an endovascular-first approach was considered. The plan was to pursue staged revascularization bilaterally with subsequent debridement to determine the level of viability. Despite his significant tissue loss, there was hope to find viable tissue under the eschar.

COURSE OF TREATMENT

For brevity, we detailed the right-sided intervention. Imaging at the level of the popliteal artery was performed from an antegrade approach in the right common femoral artery. The patient was noted to have an anomalous anterior tibial (AT) artery and three-vessel occlusion (Figure 2A). Antegrade crossing with a 0.014-inch Command ES wire (Abbott) was subintimal. We opted to access both the posterior tibial (PT) and AT arteries with 4/5-F Slender sheaths (Terumo Interventional Systems) under ultrasound guidance (Figure 2B). We then crossed retrograde with the 0.014-inch Quick-Cross catheter (Philips) into the true lumen of the AT and PT arteries

Figure 1. The patient experienced painful bilateral necrotic toes on his right foot, which was the target of our described intervention.

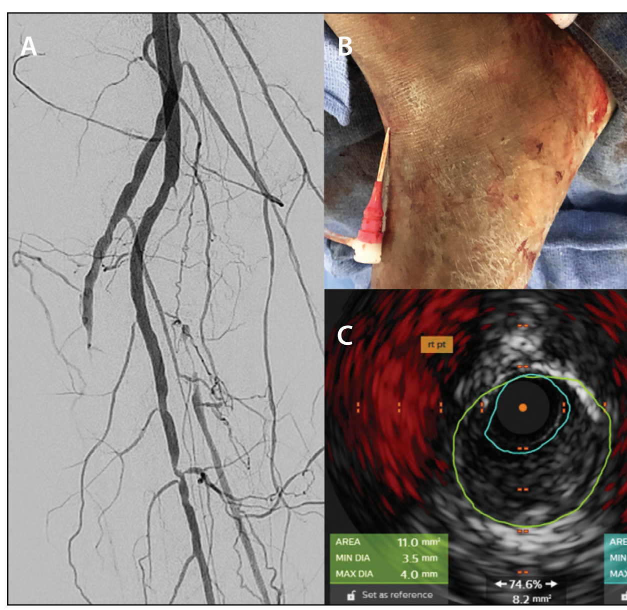

Figure 2. The patient presented with three-vessel occlusion (A). We opted to access both the AT and PT arteries (B). IVUS confirmed location in the true lumen as well as several dissections (C).

above. From the pedal access, laser atherectomy was performed in both the AT and PT arteries using a 1.4-mm Turbo-Elite laser catheter (Philips) at 60 mJ/mm^2/40 Hz, 60 mJ/mm^2/60 Hz, and 60 mJ/mm^2/80 Hz for four passes forward and backward. After this, we performed initial percutaneous transluminal angioplasty (PTA) using a 3- X 220-mm Coyote balloon (Boston Scientific Corporation) in both vessels. Intravascular ultrasound (IVUS) with the Visions PV .014P Rx (Philips) revealed that there were several areas of dissection, but we were in the true lumen. However, both vessels were close to 4 mm, and therefore our initial PTA was undersized (Figure 2C).

At this point, we reversed our access and wired antegrade into the occluded pedal loop with a Fielder XT wire (Asahi Intecc, USA), and the balloon occluded the pedal access sites, which allowed us to remove both sheaths and ensure no compromise of distal flow due to the access. The arch was crossed with a 3- X 150-mm Coyote balloon (Figure 3A), but there was severe recoil despite several prolonged inflations (Figure 3B). IVUS in the foot revealed severe medial calcium and severe plaque (not shown). We used a 0.9-mm Turbo-Elite laser catheter (Philips) at 60 mJ/mm^2/60 Hz, 60 mJ/mm^2/80 Hz, and 80 mJ/mm^2/80 Hz for four passes to debulk and modify the plaque. The lesion then yielded with a 3- X 40-mm AngioSculpt balloon (Philips) at high pressure (Figure 3C and 3D).

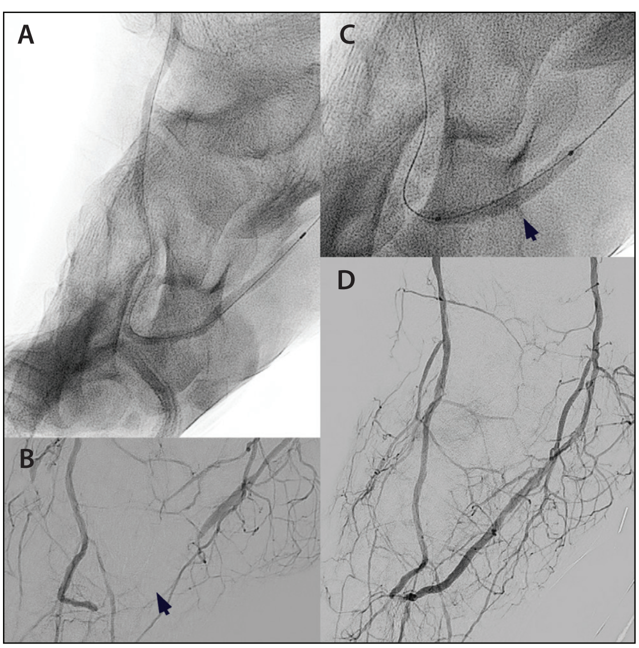

Figure 3. Reversed access to cross the pedal arch and perform PTA (A). Experienced severe recoil despite prolonged inflations (B). IVUS revealed severe medial calcium and plaque and drove decision to use Turbo-Elite laser catheter and AngioSculpt balloon to debulk and modify the plaque and gain yield of the lesion (C,D).

Three 1.5- to 4.5-mm below-the-knee (BTK) Tack implants (Philips) were placed in the distal AT artery and postdilated (not shown). Dissection in the proximal PT artery is shown (Figure 4A). Four BTK Tack implants were deployed in the proximal PT artery (Figure 4B) and postdilated with a 4- X 40-mm Coyote balloon. Final angiography showed no significant residual dissection in the proximal PT artery (Figure 4C). We closed the right common femoral arteriotomy site with a Perclose ProGlide system (Abbott) with excellent hemostasis.

Similar findings were found in the left limb, and the AT, PT, and pedal arch were revascularized 2 days later. Pulses were palpable in both the dorsalis pedis and PT territories. On postoperative day 3, the patient went to the operating room and had hydrosurgical resection of eschar of the necrotic digits with findings of viable bleeding tissue. No amputation was necessary. He was discharged to the wound care clinic for further treatment.

DISCUSSION

This case highlights several teaching points of the vessel preparation and treatment strategy employed in an angiosomal/"woundasomal"-directed limb salvage. The Philips portfolio leverages several key technologies that work well in these complex cases. Our algorithm, in general, follows a program of imaging, debulking, plaque scoring/modification, and drug therapies (above-the-knee [ATK]) and/or scaffolds (ATK/BTK). Utilizing IVUS upfront takes the guesswork out of anatomy and morphology and helps answer several questions including:

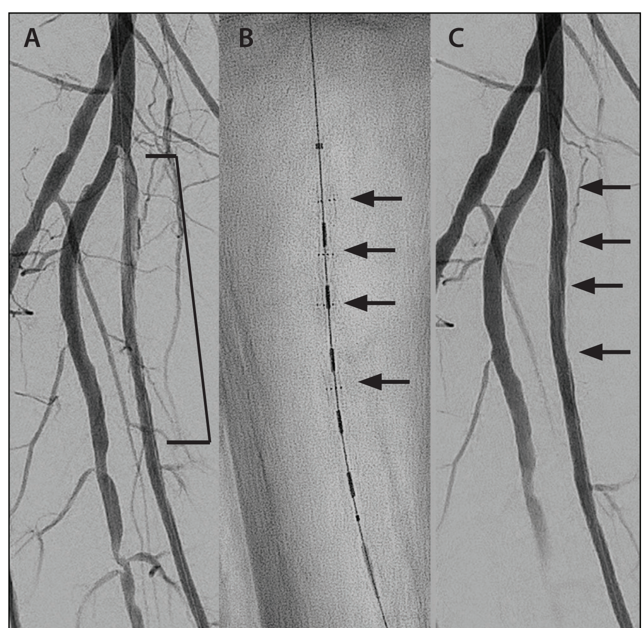

Figure 4. For the post-PTA dissection in the PT (A), four Tack implants were placed (B) to repair the dissection (C).

- Is there medial versus intimal calcium and is atherectomy needed (which type)?
- Is there soft plaque or thrombus that might require initial thrombectomy?
- What is the vessel size and is the treatment appropriate for its caliber?
- Are there dissections?
- Is the wire subintimal or in the true lumen?

Quick IVUS runs at different points of "image-guided" therapy can help plan the treatment strategy and potentially increase efficiency and improve outcomes. In this case, upfront IVUS was not possible due to dense occlusion, and we had to debulk and perform limited angioplasty prior to imaging, which was undersized relative to the vessel. Using appropriately sized treatments can prevent complications such as perforations or missed dissections. Acute vessel closure in infrapopliteal interventions may be related not only due to recoil from inadequately prepared vessels but also to pressurized dissections.

Laser atherectomy is possible in mixed morphologies, even in calcified vessels where traditional rotational or orbital atherectomy systems may be used. Many patients with BTK disease have more medial calcium, which affects vessel elastance and compliance. The acoustic wave generated by the laser pulse may modify this plaque. Moreover, the hydrophilic low profile of the 1.4- and 0.9-mm Turbo-Elite laser fibers permits easy crossing even in dense occlusions.

Utilizing plaque scoring with AngioSculpt allows for high-pressure angioplasty for difficult-to-yield lesions with minimal dissections, even when traditional angioplasty has failed. The helical nitinol scoring elements allow for 15 to 20 times focal force in plaque compared with conventional balloons.[1] If a scaffold like a drug-eluting stent is not needed ATK, I favor using Stellarex drug-coated balloon angioplasty (Philips) and spot-dissection stenting with Tack when there is no recoil. This keeps the metal-to-tissue ratio at a minimum and permits normal vessel dynamics. Unfortunately, with BTK intervention, drug-coated angioplasty options are limited and are likely to not be available in the United States. However, the 12-month data with targeted BTK dissection therapy using Tack implants (TOBA II BTK) are compelling, and Tack is the first approved scaffold for use in this space.[2] The investigators reported 100% dissection resolution, 81.3% 12-month Tacked segment patency, and 83.1% 12-month freedom from clinically driven target limb revascularization. For critical limb ischemia (CLI) patients in the study, a remarkable 96.1% had 12-month freedom from amputation and 89% achieved amputation-free survival.[2] Hopefully, we will continue to expand on the BTK therapy options to improve vessel patency and CLI outcomes. ■

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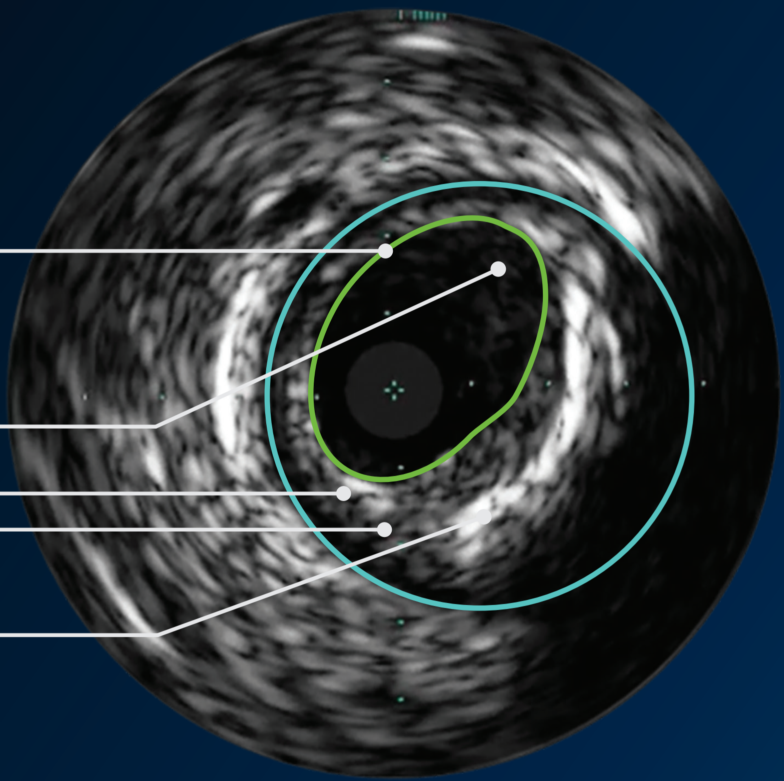

Clearly identifying plaque morphologies improves device selection.

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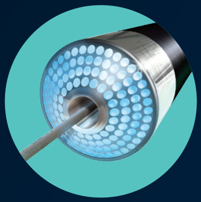

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Dissection Healing After Below-the-Knee Revascularization of CLTI Patients

Reviewing the 12-month TOBA II BTK data.

By Michael Lichtenberg, MD, FESC

Chronic limb-threatening ischemia (CLTI) is the most severe presentation of peripheral artery disease (PAD) and is associated with high rates of amputation and mortality. In patients aged > 50 years, 5% to 10% will develop CLTI within 5 years.[1] Patients with CLTI have a poor life expectancy with a mortality rate of 20% after 1 year and 40% to 70% after 5 years.[2] Only 40% of all patients are mobile 2 years after a below-knee amputation.[3]

CLTI manifests clinically as lower extremity ischemic rest pain and/or ischemic tissue. As a result of lower procedure-related complication rates, shorter length of stay, and faster recovery, infrapopliteal percutaneous transluminal angioplasty (PTA) has become widely accepted as primary therapy to establish a direct line of blood flow to the foot to assist wound healing and relieve rest pain, especially in patients at high perioperative risk.[4]

USE OF THE TACK ENDOVASCULAR SYSTEM FOR BTK DISEASE

Long lesions in small-diameter vessels with medial calcification add to the complex nature of PTA in the below-the-knee (BTK) arteries. The mechanism of PTA consists of plaque fracture, localized dissection, and permanent medial overstretching, often with dehiscence of the intima and media. Post-PTA dissection adversely impacts clinical outcome and can be a predictor for infrapopliteal restenosis.[5] If prolonged balloon inflation cannot resolve the dissection, stent implantation is the treatment of choice at present. However, in addition to the risk of in-stent restenosis and stent fracture, stents increase the stiffness of the vessel and may lead to chronic injury due to persistent outward force and friction between struts and artery walls. Thus, optimizing BTK PTA outcomes will provide durable vessel patency, reduce reinterventions, and promote limb preservation.

The Tack endovascular system (Philips) includes multiple, short 6-mm nitinol implants that can be deployed separately (Figure 1). It provides a targeted repair of dissected segments and preserves the flexibility of the artery. Preclinical data revealed less inflammation and neointima formation at 3 months with Tack implants compared to stents.[6] This is attributed to small dimensions, open-cell design, and the low outward force of the implants. Tack implants may effectively complement plain old balloon angioplasty (POBA) or drug-coated balloon angioplasty in case of dissections as a cautious strategy even compared to spot stenting. To avoid tissue irritation and inflammation, the outward force of Tack implants is relatively low. An open-cell design reduces the contact surface between metal and artery wall. In case of an irregular wall structure of the lesion, multiple short Tack implants might better guarantee for complete apposition than longer stents. Previous Tack-Optimized Balloon Angioplasty (TOBA) studies (Table 1) have offered promising technical success and safety.[7-12]

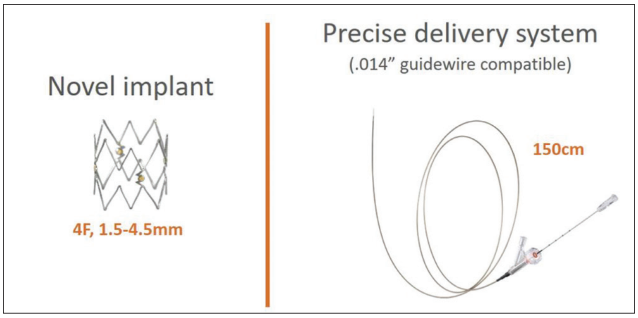

Figure 1. 4-F Tack endovascular system. Adaptive sizing self-sizes each Tack implant to vessel diameters ranging from 1.5 to 4.5 mm.

TOBA II BTK TRIAL

Recently, the 12-month outcome data of the TOBA II BTK trial demonstrated the efficacy and safety of the Tack endovascular system for the treatment of persistent dissection after POBA in BTK arteries.[12] TOBA II BTK was the first study to evaluate a BTK implant for post-PTA dissection repair (Figure 2). A total of 233 patients with Rutherford class 3 to 5 disease and lower extremity ischemia were included in this investigational device exemption trial. Baseline data collection included standard demographic data along with history and physical exam, laboratory testing, ankle-brachial index, toe-brachial

TABLE 1. TOBA DISSECTION REPAIR TRIALS				
ATK	TOBA (N = 138)	Prospective, single arm; 13 European sites	*Journal of Vascular Surgery*[7]	
			89.5% 12-m K-M freedom from CD-TLR; **76.4%** 12-m K-M patency rate	**98.5%** technical success
	TOBA II (N = 213) *Pivotal IDE*	Prospective, single arm; 33 US/European sites; POBA or Lutonix DCB (BD Interventional)	*JACC: Cardiovascular Interventions*[8]	
			86.5% 12-m K-M freedom from CD-TLR; **79.3%** K-M patency rate	**0.5%** bail-out stent; **92.1%** dissection resolution
	TOBA III (N = 201)	Prospective, single arm; 14 European sites; In.Pact Admiral (Medtronic)	*Journal of Vascular Surgery*[9]	
			97.5% 12-m K-M freedom from CD-TLR; **95.0%** K-M patency rate	**0.6%** bail-out stent rate; **97.7%** dissection resolution
BTK	TOBA BTK (N = 35)	Prospective, single arm; 6 European/New Zealand sites	*Catheterization and Cardiovascular Interventions*[10]	
			93.5% 12-m K-M freedom from CD-TLR; **84.5%** 12-m amputation-free survival	**78.4%** K-M patency rate
	TOBA II BTK (N = 233) *Pivotal IDE*	Prospective, single arm; 41 US/international sites	**6-m pivotal data in** *Journal of Vascular Surgery*[11] **12-m data in** *Journal of Endovascular Therapy*[12]	
			83.1% 12-m K-M freedom from CD-TLR; **89.3%** 12-m K-M amputation-free survival	**81.3%** 12-m K-M target lesion patency; **1.3%** bail-out stent rate **100%** dissection resolution

Abbreviations: CD-TLR, clinically driven target lesion revascularization; IDE, investigational device exemption; K-M, Kaplan-Meier, POBA, plain old balloon angioplasty.

index, Rutherford classification, Wound Ischemia and foot Infection classification, EQ-5D-3L quality-of-life questionnaire, and Walking Impairment Questionnaire. Patients underwent infrapopliteal intervention after successful screening, baseline data collection, and providing informed consent. These patients were eligible for enrollment during the index procedure if angioplasty resulted in dissection(s) of the P2/P3 popliteal artery segments, tibioperoneal trunk, anterior tibial, posterior tibial, and/or peroneal arteries that the investigator would have otherwise treated with repeat angioplasty or off-label stent deployment. Post-PTA dissections were identified using the angiographic core laboratory protocol, requiring imaging in at least two planes with ≥ 45° difference and use of magnification. Dissection(s) were graded by the operator using the National, Heart, Lung and Blood Institute classification system. Finally, patients were then eligible for enrollment if the investigator concluded that the dissection(s) required repair. A patient was enrolled when the Tack delivery system was advanced through the introducer sheath. Clinical follow-up was performed at 30 days and 6 and 12 months with planned follow-up to 36 months.

Half (50.2%) of patients were classified as Rutherford class 5, 33.5% as Rutherford class 4, and 16.3% as Rutherford class 3. The mean baseline target lesion length was 80 ± 49 mm, and PTA-treated length was 154 ± 110 mm. Moderate to severe calcium was present in 35.8% of lesions. Standard PTA was performed in 248 target lesions, resulting in 341 post-PTA dissections requiring repair. Most lesions were located within the anterior tibial (41.1%), posterior tibial (22.6%), and peroneal (21%) arteries. All patients were treated with at least one Tack implant, averaging 4 ± 2.8 Tacks per patient. The device success rate was 96.5%, and target lesion success and procedural success were 98.8% and 98.7%, respectively.

The angiographic core laboratory adjudicated 100% dissection resolution with Tack treatment. Safety analysis within the first 30 days reported three (1.3%) major adverse limb events (MALEs) and perioperative death occurrences (PODs); in total there were two above-ankle amputations and one patient death. The primary effectiveness endpoint, freedom from MALE at 6 months plus POD at 30 days, was 95.6% with a lower limit of the 97.5% confidence interval of 91.8%. Secondary outcome measurements included

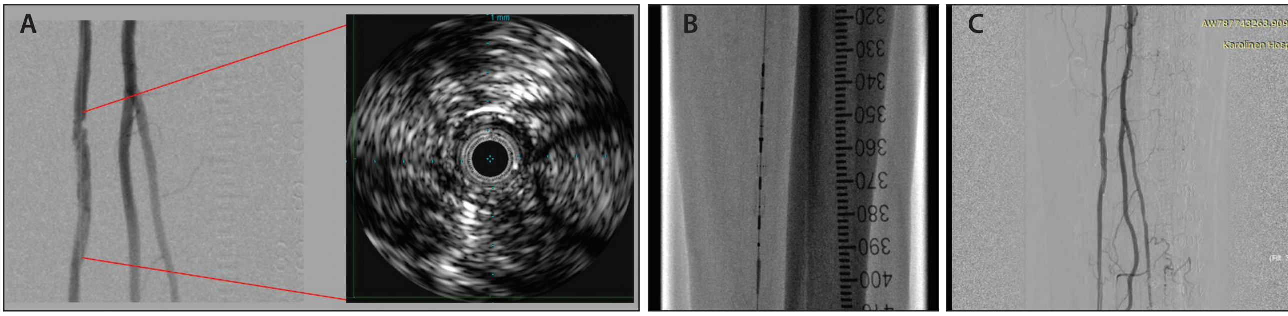

Figure 2. Persistent dissection with slow flow after recanalization of the posterior tibial artery with a 3- X 150-mm uncoated balloon. Intravascular ultrasound revealed a dissection and persistent high-grade stenosis (A). Implantation of two 4-F Tack devices (B). Complete healing of the dissection after Tack implantation with direct inflow and outflow (C).

12-month primary patency of the target lesions and Tacked segments including a 12-month Tacked segment patency of 81.3%. Kaplan-Meier estimate for target limb salvage at 12 months for all patients was 96.8%. Twelve-month Kaplan-Meier freedom from clinically driven target lesion revascularization was 83.1% in all patients, and 81.8% in CLTI patients. Kaplan-Meier freedom from clinically driven target vessel revascularization at 12 months was 82.7% and 81.4% in all patients and CLTI patients, respectively. At 12 months, Kaplan-Meier survival in all patients was 91.7% and 91.9% in Rutherford class 4/5 patients. Amputation-free survival was 89.3% overall and 89% in Rutherford class 4/5 patients. Rutherford class significantly improved between baseline to 6 months and was sustained through 12 months.

CONCLUSION

Previous analysis concluded that decreasing the rate of immediate technical failure (including recoil, dissection, and persistent stenosis) is integral to limb preservation and improving patency. Post-PTA dissection adversely impacts clinical outcome and can be a predictor for infrapopliteal restenosis.[5] Treatment options include the use of bare-metal or drug-eluting stents in an attempt to improve patency and reduce restenosis, depending on the location of the lesion. Especially in long persistent dissections and bifurcations, these scaffolds are not adequate to resolve immediate technical failures and could impact technical revascularization options after reocclusion. Based on the promising TOBA II BTK data, Tack implants may effectively complement angioplasty in case of dissections as a cautious strategy even compared to spot stenting. To avoid tissue irritation and inflammation, the outward force of Tack implants is relatively low. An open-cell design reduces the contact surface between metal and artery wall. In case of an irregular wall structure of the lesion, multiple short Tack implants might better guarantee for complete apposition than longer stents. Finally, Tack implants allow for bypass surgery at a later stage if required. ■

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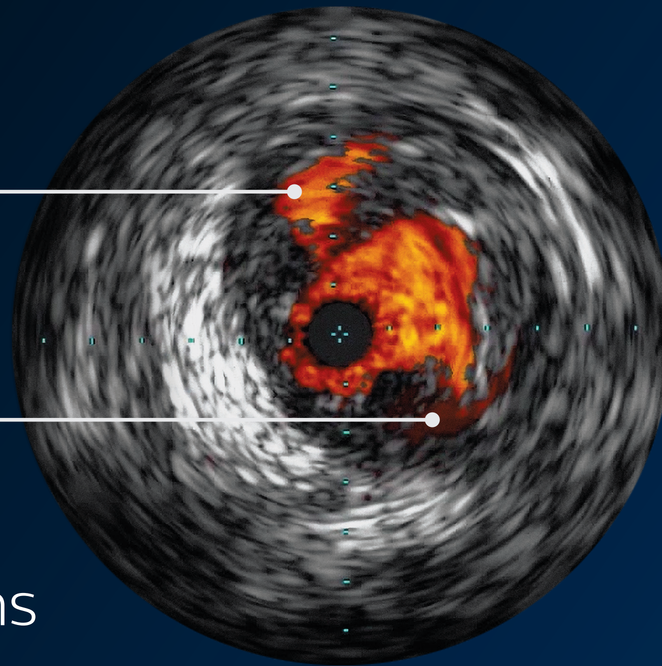
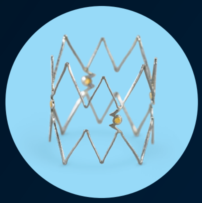


See post-PTA dissections clearly with ChromaFlo.
Repair dissections with Tack.

When Philips IVUS ChromaFlo is on, dissections are easier to find. The Philips Tack endovasular system, is the first purpose-built minimal metal option for post-PTA dissection repair above- or below-the-knee. As an adjunct therapy to POBA and DCB procedures, dissection repair with Tack improves long-term patency and clinical outcomes.[1-3] See clearly. Treat optimally.



Tack endovascular system

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1. Gray WA, et al. Treating post-angioplasty dissection in the femoropopliteal arteries using the Tack endovascular system: 12-month results from the TOBA II study. J Am Coll Cardiol Intv 2019;12:2375-84.
2. Brodmann et al. Optimized drug-coated balloon angioplasty of the superficial femoral and proximal popliteal arteries using the Tack Endovascular System: TOBA III 12-month results. J Vasc Surg. 2020;S0741-5214(20)30330-X.
3. Geraghty PJ, et al. "Twelve-month results of Tack- optimized balloon angioplasty using the Tack Endovascular System in below-the-knee arteries." Jour of Endovas Therapy 27.4 (2020): 626-63

Intended use: The Tack endovascular system (4F, 1.5-4.5 mm) is intended for use in mid/distal popliteal, tibial and peroneal arteries, ranging in diameter from 1.5 mm to 4.5 mm, for the treatment of post percutaneous transluminal balloon angioplasty (PTA) dissection(s). The Tack endovascular system (6F, 3.5-6.0 mm US/ 2.5-6.0 mm EU and 4.0-8.0 mm) is intended for use in the superficial femoral and proximal popliteal arteries ranging in diameter from 3.5 mm to 6.0 mm US/ 2.5 to 6.0 mm EU and 4.0 mm to 8.0 mm for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissection(s).
Contraindications for use: The Tack endovascular system is contraindicated for the following: 1. Patients with residual stenosis in the treated segment equal to or greater than 30% after PTA. 2. Tortuous vascular anatomy significant enough to prevent safe introduction and passage of the device. 3.Patients with a known hypersensitivity to nickel titanium alloy (Nitinol). 4. Patients unable to receive standard medication used for interventional procedures such as anticoagulants, contrast agents and antiplatelet therapy. Prior to using the Tack endovascular system, please review the instructions for use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Tack endovascular system is CE Mark authorized under EC Directive 93/42/EEC. Tack endovascular system and Tack are registered trademarks of Intact Vascular, Inc. Adaptive sizing is a trademark of Intact Vascular, Inc.
Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

CASE REPORT

Enhanced Tack Placement Using IVUS in Severe Stenosis of the Proximal Anterior Tibial Artery

By John H. Rundback, MD, FAHA, FSVM, FSIR

Figure 1. Initial angiogram showing the proximal anterior tibial artery with multiple stenoses. The anterior tibial artery is the dominant wound supply.

CASE PRESENTATION

A man in his late 50s with prior lower extremity revascularization for femoropopliteal disease presented with a several-month history of a nonhealing lateral left foot wound after referral from his podiatrist. The patient's cardiovascular risks included insulin-dependent diabetes mellitus, hypertension, dyslipidemia, and a history of coronary artery disease with cardiac stenting 8 years ago. He denied cerebrovascular disease or renal dysfunction. Neuropathy in his lower extremities was reported. The patient's medications included clopidogrel, hydrochlorothiazide 12.5 mg, lisinopril, amlodipine, carvedilol, insulin glargine, metformin, and aspirin.

PROCEDURAL OVERVIEW

Initial angiography showed stenosis in the proximal anterior tibial artery, which was confirmed on distal angiography to be the wound supply and was therefore the target lesion for treatment (Figure 1). The posterior tibial artery had significant disease in the mid portion and a distal occlusion that was not directed toward the patient's wound.

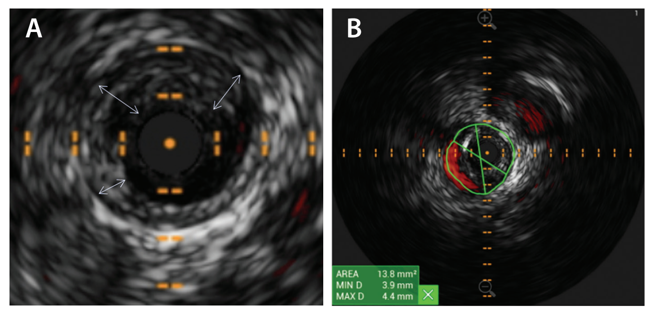

Figure 2. IVUS showing substantial plaque burden with severe stenosis in the proximal anterior tibial artery (double-headed arrows, A). Based on IVUS arterial sizing, 4-mm PTA was performed (B).

Intravascular ultrasound (IVUS) of the proximal anterior tibial artery showed substantial plaque burden with severe stenosis (Figure 2A, double-headed arrows) and allowed for "true" sizing. Based upon IVUS arterial sizing, percutaneous transluminal angioplasty (PTA) with a 4-mm X 24-cm balloon was performed (Figure 2B).

After PTA, patency was restored, but significant proximal dissection was confirmed in two oblique angiographic projections and with IVUS (Figure 3A-3E). Note the depth of the dissection extending to the adventitia in Figure 3D.

A total of four Tack implants (Philips) were deployed, with one each at the beginning and end of the dissection as identified on IVUS and two in the mid portion of the dissection (Figure 4). Angiography after Tack placement but prior to postdilation showed a smoother lumen and good Tack positioning. However, there were focal areas of residual luminal compromise due to dissection that were not completely covered with the initial Tack deployment (Figure 4B, arrowheads).

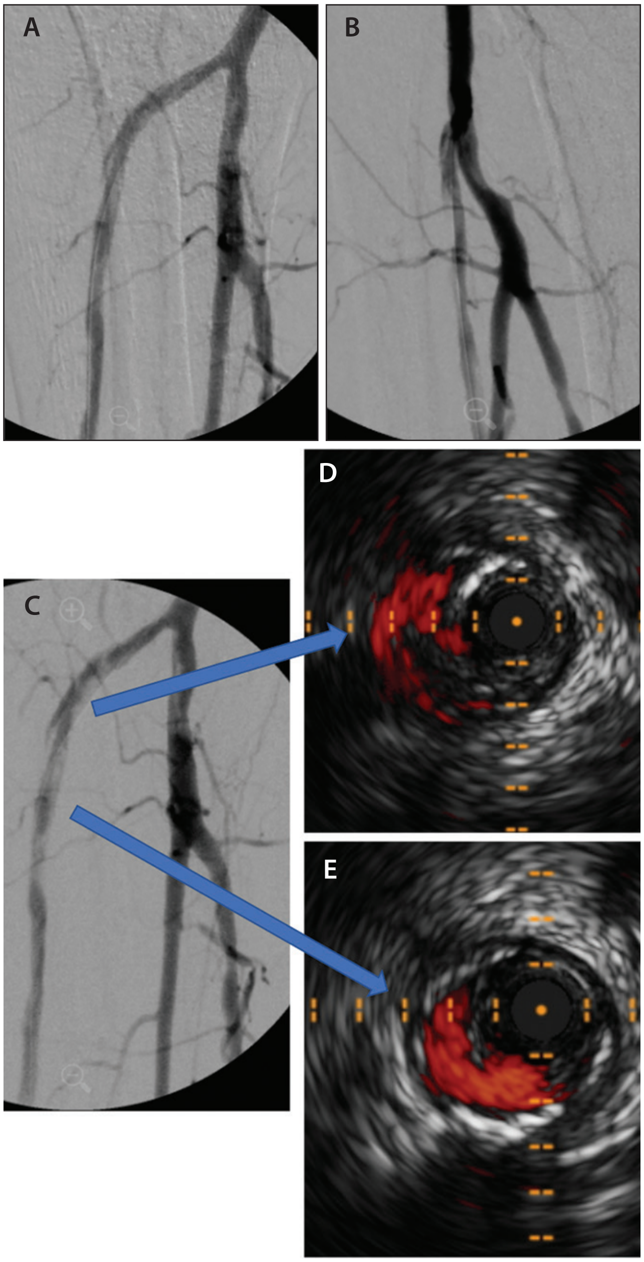

Figure 3. Angiogram showing restored patency (A). However, significant proximal dissection was shown in oblique projections (B, C) and IVUS (D, E). The depth of dissection into the adventitia is noteworthy (D).

Three additional Tacks were strategically deployed at areas of residual arterial narrowing, and postdilation was performed with a new 4-mm X 4-cm balloon for 30 seconds. Completion angiography showed complete dissection resolution and restored arterial patency without residual stenosis or recoil (Figure 5). ■

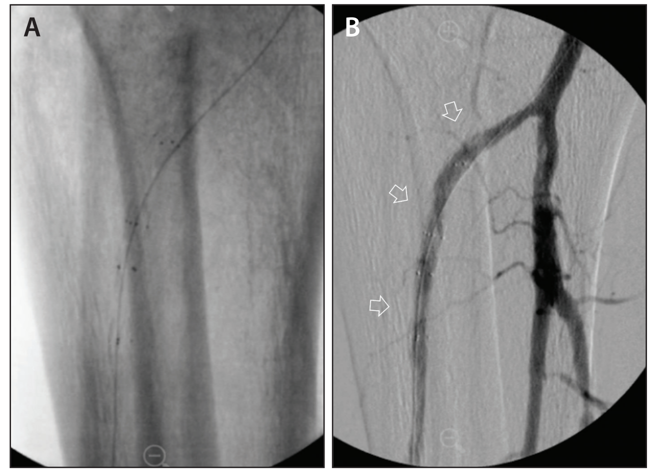

Figure 4. Angiogram showing four Tack placements at the beginning and end of the dissection and two in the mid portion (A). Focal areas of residual luminal compromise were identified due to dissection not completely covered by the initial Tack deployment (arrowheads, B).

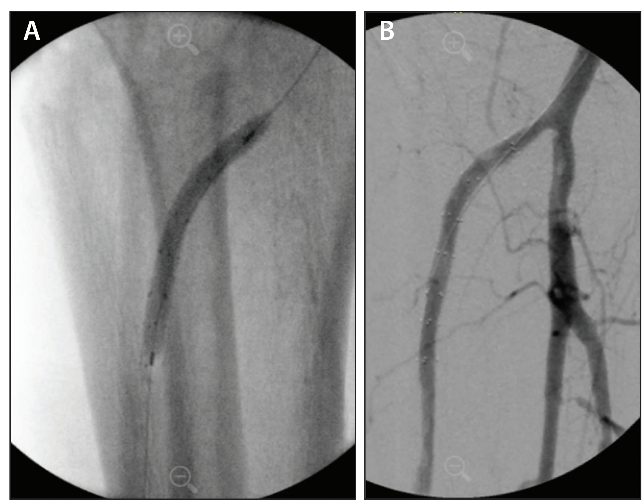

Figure 5. Three additional Tacks were deployed to address residual arterial narrowing and postdilation was performed with a new 4-mm PTA balloon for 30 seconds (A). A completion angiogram showed complete resolution of dissection and restored patency without stenosis or recoil (B).

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CASE REPORT

Treatment of Severe Calcific CLI With Atherectomy, Scoring Balloon Angioplasty, and the Tack Endovascular System

By Edward D. Gifford, MD, FSVS, RPVI

CASE PRESENTATION

A woman in her mid 60s with prior history of end-stage renal disease on dialysis, diabetes mellitus on insulin, hypertension, and prior left transmetatarsal amputation presented with extensive Rutherford class 5 right digital gangrene. On physical examination, the patient had nonpalpable pedal pulses with monophasic dorsalis pedis (DP) artery Doppler signals. Noninvasive studies demonstrated a minimally pulsatile ankle pulse volume recording with flat transmetatarsal and digital waveforms.

PROCEDURAL OVERVIEW

The patient was taken to the operating room for angiography and possible intervention. Contralateral groin access was achieved. Initial angiography demonstrated popliteal artery occlusion of the P2 segment with an eccentric calcific lesion (Figure 1A). Distally, the patient had long-segment stenosis with multifocal occlusion of the proximal anterior tibial artery and occluded peroneal and posterior tibial arteries (Figure 1B). In the foot, the primary outflow was a diminutive DP artery. After heparinization and sheath access, initial attempts were made to cross the lesion antegrade. Using a 0.018-inch Quick-Cross catheter (Philips) and a 0.014-inch hydrophilic tip wire, we successfully navigated past the popliteal occlusion and into the distal popliteal artery. The proximal anterior tibial artery was accessed, but we were unable to cross the long-segment lesion in the proximal anterior tibial artery via an antegrade approach. Pedal access of the DP artery was then obtained, and the lesion was successfully crossed retrograde with a 0.014-inch guidewire and a 0.018-inch Quick-Cross catheter. Through and through wire access was obtained.

Focal atherectomy of the eccentric calcific occlusion at the P2 popliteal artery was then performed with a 2.2-mm Phoenix atherectomy device (Philips). Two passes were completed without difficulty, with noted

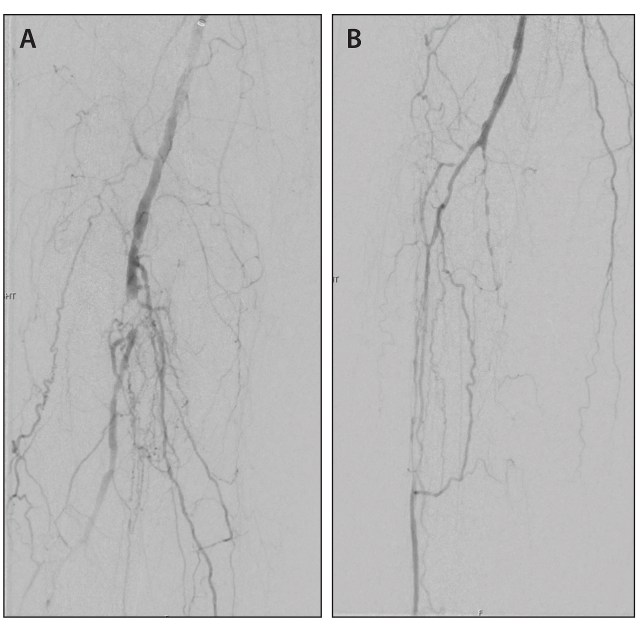

Figure 1. Pretreatment images show the eccentric popliteal occlusion (A) as well as the extensive proximal tibial disease (B).

Figure 2. Significant improvement in luminal diameter and flow in popliteal artery following Phoenix atherectomy and use of Angiosculpt scoring balloon.

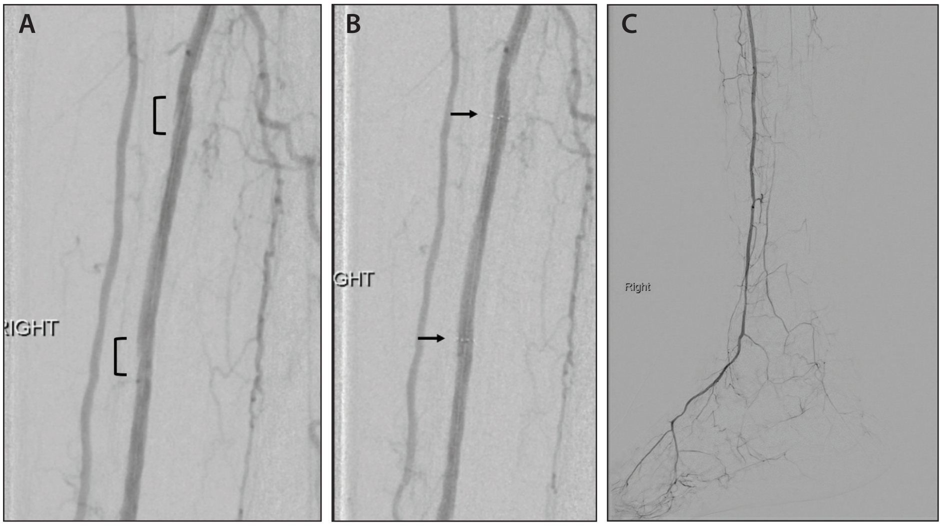

Figure 3. Post-tibial angioplasty showed two grade B dissections (A) successfully treated with two 4-F Tack implants (B). Completion angiogram of the popliteal artery and foot show in-line flow to the DP (C).

improvement in luminal gain and distal filling. AngioSculpt PTA Scoring balloon catheter (Philips) was then inflated to 5 mm, followed by drug-coated balloon angioplasty with prolonged inflation. Significant improvement was noted in the luminal diameter and flow, with minimal residual plaque and no evidence of dissection (Figure 2).

Attention was then turned to the anterior tibial artery lesion. Plain balloon angioplasty with sustained inflation was performed to 2.5 mm. Subsequent angiography demonstrated a widely patent anterior tibial artery. There were two areas of focal grade B dissection (Figure 3A). We suspected these may represent entry/reentry points from our retrograde access. Given the limited patency of primary balloon angioplasty below the knee, we elected to place two 4-F, 6-mm Tack implants (Philips) at the areas of dissection (Figure 3B). Completion angiography demonstrated brisk filling of the DP in the foot (Figure 3C).

Follow-up noninvasive studies demonstrated substantial improvement in pulsatility with a widely patent popliteal and anterior tibial arteries. The patient successfully underwent podiatric transmetatarsal amputation with complete healing at most recent follow-up.

DISCUSSION

Current management strategies for severe calcific disease of the infrageniculate arteries are limited by durability and patient fitness. In this case, we felt this patient was not a candidate for open bypass given her comorbid conditions. To decrease the need for bailout stenting of the popliteal artery, luminal gain with the front-cutting Phoenix atherectomy device and AngioSculpt scoring balloon resulted in excellent vessel preparation for subsequent drug-coated balloon angioplasty. In the tibial vessels, use of the 4-F Tack device allowed us to improve the long-term patency of traditional below-the-knee plain balloon angioplasty by targeting focal dissections. ■

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