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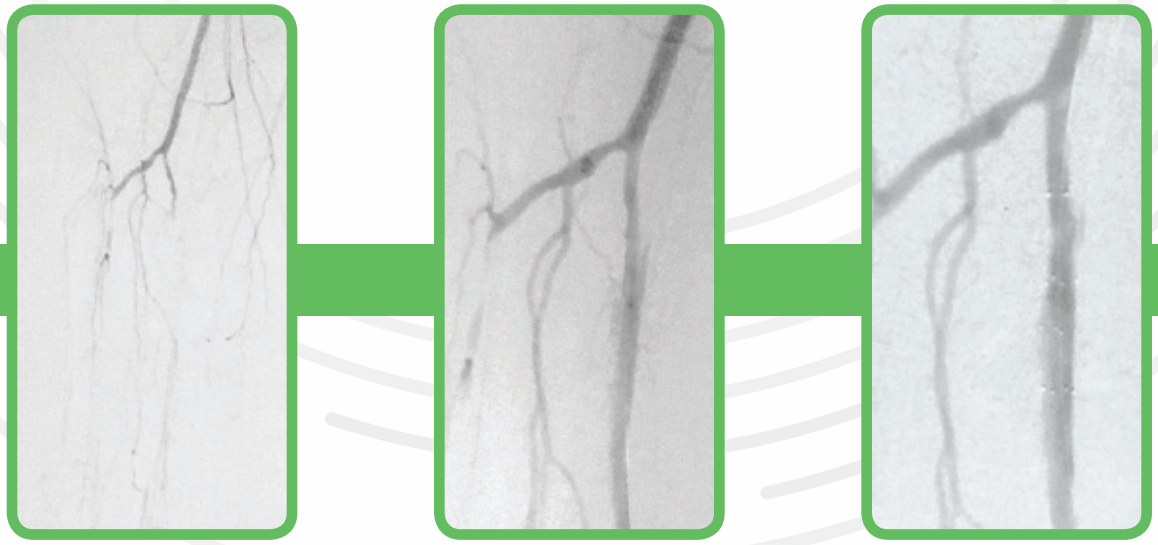
CLI CARE IN THE COVID-19 ERA

An Evolving Landscape



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CLI Care in the COVID-19 Era: An Evolving Landscape

An expert panel offers their insights and strategies for providing CLI care while navigating the COVID-19 pandemic.

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We are all aware of the unprecedented challenge that the global COVID-19 pandemic has provided for our communities, our patients, and health care providers. We face a rapidly evolving situation. My co-moderator, Dr. Ehrin Armstrong, and I are grateful to glean insights from our assembled panel of key clinicians who offer their perspectives on how to best optimize care for chronic limb-threatening ischemia (CLTI) under our current shared circumstance. We hope you find this discussion informative. We are all in this together.

– Dr. Andrew Holden

Dr. Armstrong: In Colorado, the concentration of COVID-19 patients was centered initially in ski resorts and then quickly spread to the Denver area. John, you are in the epicenter of the pandemic in the United States. How has COVID-19 impacted CLTI treatment in your area?

Dr. Rundback: Our hospitals in New Jersey have been dramatically impacted by COVID-19. Because of a need to preserve resources, elective procedures are not being performed. In addition, because the hospitals we work in are "in the news," patients don't want to go to them for fear of exposure to the novel coronavirus. We are medically managing all patients with claudication and borderline ischemic pain and delaying consults until the pandemic lessens. However, all patients are called either for formal telemedicine evaluation or, at the very least, to triage the severity of disease and determine if an in-person evaluation can wait. For borderline cases, we call the patients weekly to make sure they are stable.

Dr. Armstrong: Thanks, John for your interesting observations and strategies. Jay, how have you been managing CLTI patients in Florida?

Dr. Mathews: The COVID-19 pandemic has had many impacts, both seen and unforeseen, within our community. As expected, elective endovascular procedures have been halted, but we have also seen a significant decline in urgent/emergent procedures. This could reflect an understandable unwillingness on the part of patients who continue to self-isolate at home to come in for treatments, including those with CLTI. We have also seen impacts on the supply chain side of performing interventions. Vendors who would make sure that we had adequate inventory are no longer around to ensure that their product portfolio is available. It is challenging to be in the middle of a complex CLTI case and request a routine device only to find out it is unavailable.

Dr. Armstrong: That sounds challenging, Jay. Bryan, how has the pandemic affected your community?

Dr. Fisher: In middle Tennessee, this global pandemic has exacerbated the impact of CLTI. Unfortunately, many patients were already presenting late, with modifiable risk factors not being controlled. Although the existing economic and social disparities have increased the gap, the rate-limiting step in most cases is the patient's lack of desire to have procedures done in the hospital due to a perceived increased risk of getting the virus and potentially dying from it.

Dr. Armstrong: Thanks, Bryan. Scott, what unique challenges are you facing in Arizona?

Dr. Brannan: Our mission population is Native American critical limb ischemia (CLI) patients. The COVID-19 pandemic has hit the Navajo Reservation particularly hard, with approximately 1,200 cases and more than 40 deaths as of Spring 2020. The case fatality rate for the Navajo Nation has been 10 times higher than the rest of the United States. For other tribes, tribal members are often reluctant to leave the reservation because the incidence of infection on their reservations (Apache and Pima) are much lower. This is a microcosm of what we are seeing in the larger population in general. Many patients are more afraid of COVID-19 than they are of CLI.

Dr. Armstrong: Thank you, Scott. We know COVID-19 is a global problem. Michael, what is the situation for CLTI patients in Germany?

Dr. Lichtenberg: This pandemic has had a significant impact on our daily routine within our vascular center. As in other centers, many elective patients cancelled their appointments and procedure dates because of the virus. The main reason cited was the fear of high infection risk within a clinic environment. Many patients also assumed that all hospitals were occupied by patients with COVID-19, with no capacity for other indications. As many other specialized vascular centers

in the area faced a total shutdown, we experienced an overflow of CLTI patients from areas outside of our normal referral pathways. As a consequence, we had to adapt and increase our working time within the labs to cope with this challenge.

Dr. Holden: Thanks, Michael. All of you report that patients are cancelling procedures and staying home. Ted, what are your thoughts on how to stay in contact with your patients?

Dr. Gifford: What is evident, now more than ever, is the importance of building a framework for clear and effective communication with our patients so that we can stay up to date should their clinical condition change while they are awaiting revascularization. Many of our patients are reliant on their regular surveillance visits, visiting nurses for wound care, and prompt specialty consultation for urgent referrals. As we deal with the COVID-19 crisis, we have to find a way to make sure that our patients know that we are thinking about them and that we are making plans to address their needs as soon as it is safe to do so. Telehealth via video conferencing has played a major role in maintaining that connection with the patients in our practice.

For patients with peripheral artery disease but without CLTI, we are reaching out through local news outlets to promote awareness and offer guidance about maintaining vascular health. We want to encourage our patients with claudication who are isolated at home to stay active and to try to go for daily walks. We also recognize the effect this crisis may have on our patients' efforts at smoking cessation and similarly are trying to support their efforts to stay tobacco-free.

Dr. Holden: Good insight for us all, Ted. Michael, you have some additional thoughts?

Dr. Lichtenberg: Yes, thank you. The most important mistake from the beginning of the crisis was not to educate patients on the importance of self-care for their chronic cardiovascular diseases and, if indicated, to immediately contact their vascular specialists. In Germany, the German Angiology Society recently started a media campaign, "Don't let the virus be responsible for your amputation." We hope that this campaign will help prevent a limb-threatening crisis from taking place at the same time as the pandemic.

Dr. Holden: That's a very interesting initiative. At Auckland Hospital here in New Zealand, we also limited our treatment indications to acute limb ischemia, rest pain, and tissue loss and used telephone calls as well as video conferencing to communicate with patients. Another important question we face is which patients are still being treated during this crisis?

Dr. Mathews: I currently serve as the Cath Lab Director for Manatee Memorial Hospital. Together with colleagues from other disciplines, we drafted our policy regarding procedures to be performed during the COVID-19 pandemic. We have allowed CLTI (Rutherford class 4–6) and, of course, our acute limb cases. Some colleagues at other centers in Florida have been forced to limit cases to Rutherford class 6 patients, which we thought was too extreme. Of course, our policies are subject to change depending on availability of personal protective equipment (PPE), which remain in short supply.

Dr. Gifford: For the most part, we have limited our treatment to patients who come to the hospital with acute limb ischemia or who present urgently to the emergency department (ED) with severe CLTI. If a patient comes into the ED with severe digital or forefoot gangrene or if the patency of their bypass is in imminent danger, we have continued to offer them interventions. Throughout this time of uncertainty, we have advised patients and their families that we may reach a point where resources are so precious that the only procedures being performed are truly life-threatening.

Dr. Lichtenberg: We are dealing with significantly sicker patients including severe CLI infection and no-option situations. We have never faced such a high number of CLI-associated sepsis patients needing intensive care unit support. Many of these emergency patients demonstrated poorly controlled diabetes in the weeks preceding their arrival and showed signs of severe dehydration.

Dr. Armstrong: Thanks for those commentaries. The current policy to triage patients and reserve treatment for those most at risk means some patients are not receiving treatment, at least in the short term. What are the most important implications of these patients not receiving treatment?

Dr. Rundback: CLI is non-elective. We have had two patients with CLI who refused revascularization and wound care for fear of COVID-19 and ended up with gas gangrene and major amputation. There are 300 to 500 amputations each day in the United States, and management by dedicated vascular specialists and CLI teams can lower this by 60% to 80%. We need to urge primary care physicians, podiatrists, as well as high-risk patients that ischemic rest pain and nonhealing lower extremity wounds require urgent and immediate attention.

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Dr. Mathews: I am concerned for many of these patients who have been deferred or "denied" treatment. Many of these patients who have a lower Rutherford class will later present with a far more severe status, which could have been avoided. These are patients who are not exercising and may have limited mobility.

Dr. Fisher: One obvious implication is not identifying patients with CLTI. Based on the literature, we know that patients with mild claudication are at very low risk for limb loss and the increased risk at Rutherford class 3 isn't staggering. However, patients with rest pain and/or wounds are at high risk. The implications of minor and major amputations are potentially devastating. Compound this with a global pandemic and resultant economic hardships and you have the dire and unfortunate circumstances that many of our patients go on to endure.

Dr. Brannan: Over time, cases will get harder to treat. Patency rates decrease. The absence of treatment can lead to amputation. The difference in terms of procedural outcome durability between a 90% stenosis versus a 1-month-old chronic total occlusion is astronomical. By delaying treatment for severe Rutherford class 3 disease, we are producing difficult to treat and rapidly reoccluding Rutherford class 4 disease.

Dr. Armstrong: Given the challenging situation, how can CLTI care and outcomes be optimized?

Dr. Rundback: We remain diligent in our outpatient practice, performing extensive distal tibial and pedal arch interventions, digital artery interventions, rendezvous procedures, multivessel revascularization, and distal deep venous arterialization, when needed. Our need for emergency transfer to a hospital has been and remains almost nonexistent. To assure this, we use some unique strategies. We address occluded segments before working on stenotic segments to establish more overall foot flow and avoid unplanned occlusions and clinical worsening. We call this strategy "protected intervention." We also believe in targeted and multivessel interventions whenever feasible to allow the greatest chance for clinical resolution and lower the chance for acute decompensation. Wherever procedures are performed, we are cognizant that we must avoid hospital admission for these patients at this time. We are also using more low-molecular-weight heparin at discharge; again, this is with the goal of preventing acute thrombosis. The recent VOYAGER data have also impacted our decision to prescribe more rivaroxaban and aspirin than we did before.

Dr. Gifford: If you're going to perform a procedure on an urgent or emergent patient, ideally favor something that may help the patient recover faster. In our practice, we have looked to some of the sister hospitals in our network if we need to do a short endovascular procedure as opposed to bringing the patient through our main tertiary center. Similarly, if you have access to an outpatient-based lab, that may be a better option to avoid potential COVID-19 exposure for both patients and health care workers. We want to avoid, whenever possible, a discharge to a nursing home after revascularization. Given the negative effect of COVID-19 on nursing home residents around the country, if an endovascular therapy may offer a shorter postoperative recovery for our patients, now is the time to favor that approach.

Dr. Lichtenberg: I suggest to be as effective as possible with revascularization treatment strategies to avoid prolonged hospitalization. Our mandate is not only to revascularize but also to take care of long-term patency. My personal strategy is to use an aggressive lesion debulking strategy especially in calcified long lesions followed by prolonged drug-coated balloon (DCB) angioplasty to avoid dissection and recoil.

Dr. Fisher: Each intervention has its own inherent risks. For this reason, we must place a greater emphasis on identifying patients at risk and work aggressively to control their modifiable risk factors. This starts with smoking cessation and includes addressing hypertension and hyperlipidemia and controlling blood glucose levels to ensure adequate wound healing in patients with tissue loss.

Dr. Holden: Thank you all for those perspectives. All of you have emphasized the importance of optimizing acute results in CLTI intervention, particularly during this pandemic. We are seeing some new treatment options, including the recently FDA-approved Tack Endovascular System® for a below-the-knee (BTK) application. So finally, which tools do you currently rely on to treat CLTI?

Dr. Fisher: The tools and options available for treating CLTI are exciting and continue to evolve. Drug-coated technology has been a game changer; however, enthusiasm has been somewhat tempered for now due to a concern of increased mortality risk. There is a strong argument that the benefit of vessel patency and perfusion to an ischemic tissue bed outweighs the, albeit very small, risk of death. The application of drug-eluting self-expanding stents BTK also has the potential to

address acute and chronic remodeling. Off-label balloon-expandable coronary drug-eluting stents have also been successfully applied in the proximal tibials where recoil can be addressed without a significant risk of crushing due to external forces. Finally, low-profile scaffolding BTK is one of the most exciting new modalities aimed at addressing dissection that can be clearly seen with intravascular ultrasound (IVUS). I am excited to see the new technology that continues to evolve in the space and look forward to applications below the ankle that represent the final frontier in the treatment of complex CLTI.

Dr. Rundback: The tools are the same as before, with the exception that new enrollment in our cell-based therapy trials is currently suspended. We continue to use the same devices we did before the pandemic, including laser atherectomy, orbital atherectomy, percutaneous transluminal angioplasty, DCBs, Supera peripheral stents (Abbott), and Tack® implants (Intact Vascular, Inc.) for dissection repair. Additionally, we use IVUS guidance for vessel sizing and endpoint evaluation, small-vessel microcatheters and balloons, and specialty wires as appropriate and individualized within our algorithm for each patient.

Dr. Brannan: Low-risk transportation to and from the procedures with PPE for both the driver and passenger has been crucial. Also, the Tack device for multifocal dissections helps reduce the number of visits required to fully treat CLTI and decrease frequency of reinterventions.

Dr. Mathews: Our toolbox for above-the-knee (ATK) disease is vast, but our BTK options remain limited. For ATK disease, I tend to do a lot of atherectomy, plaque scoring, and DCB therapy, with focal scaffolding using the Tack Endovascular System® (Intact Vascular, Inc.) for dissection or drug-eluting stents for areas with severe recoil. IVUS is very helpful in guiding this algorithm.

For BTK disease, I also use a lot of atherectomy and angioplasty. IVUS is an even more important tool for BTK CLTI patients. Chronic undersizing is a common problem in BTK interventions, which may impact outcomes. We also continue to enroll in several BTK technology trials despite the COVID-19 pandemic, as these include the CLTI population.

I look forward to BTK scaffolding options such as the recently approved Tack system for BTK arteries, which showed impressive results in the TOBA II BTK study. Despite the constraints of operating during a pandemic, I welcome any new technologies that can optimize outcomes and make treating CLTI patients even better.

Dr. Armstrong: We thank you all for taking time to discuss this important topic with us. Dr. Holden and I hope the readers have found this as interesting and educational as we have. ■

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CASE STUDY

Navigating BTK Revascularization in the Epicenter of a Pandemic

BY JOHN H. RUNDBACK, MD

CASE PRESENTATION

A 77-year-old woman with a history of diabetes mellitus, hypertension, and hyperlipidemia presented to her podiatrist with a history of a medial heel wound and was referred for revascularization. Due to concerns of COVID-19, she delayed seeking treatment until she had experienced progressive pain for nearly a month. Although revascularization is considered an essential hospital-based procedure during the ongoing pandemic, she was treated in our outpatient facility in northern New Jersey.

Intact Vascular's 4F Tack® implant designed for BTK interventions.

INTERVENTION

Antegrade femoral access was obtained using a 4-F sheath. Initial angiography of the infrapopliteal arteries showed segmental occlusion of the tibioperoneal trunk and proximal posterior tibial artery, and neither the anterior tibial nor peroneal arteries were patent (Figure 1). As the occlusion was unable to be crossed from an antegrade approach, transpedal access was obtained with successful guidewire rendezvous within the posterior tibial artery.

Infrapopliteal vessel diameter is especially challenging to accurately assess angiographically. In this case,

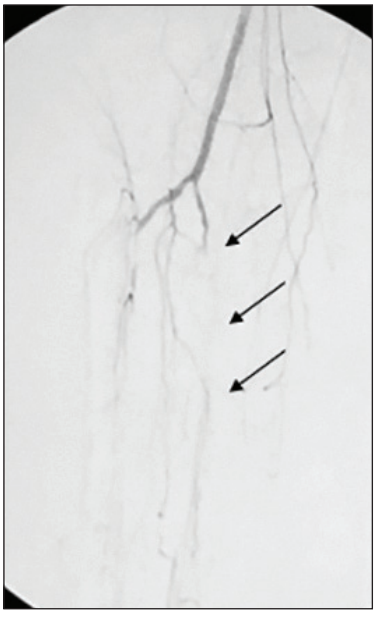

Figure 1. Baseline occlusion of the posterior tibial artery (arrows).

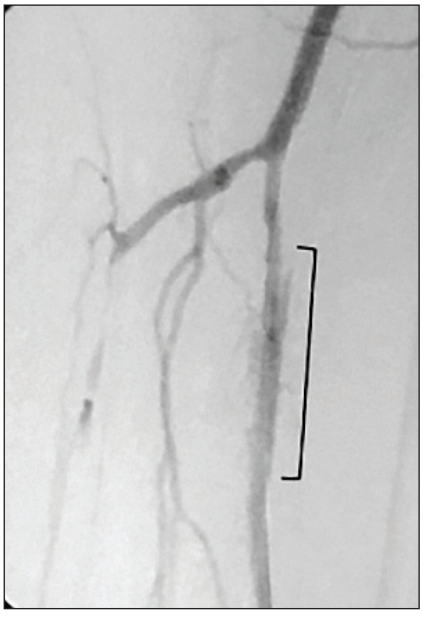

Figure 2. Post-PTA spiral dissection.

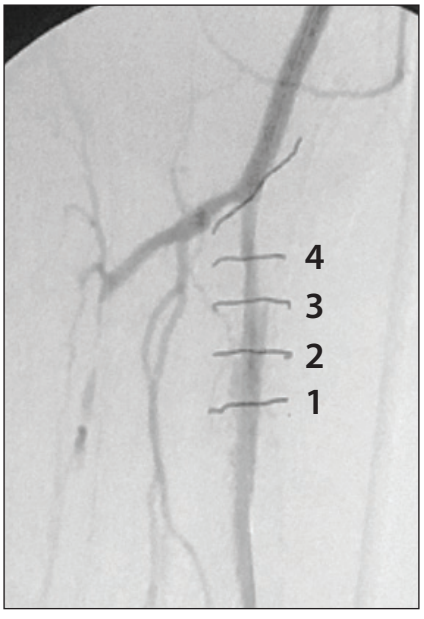

Figure 3. Treatment sites for Tack® implants are marked.

intravascular ultrasound was used to determine the vessel diameter to guide appropriate balloon sizing and ensure maximal lumen gain for wound healing.

Postangioplasty angiography revealed a severe spiral dissection (Figure 2). We decided to treat the dissection with the Tack Endovascular System® (4F) (Intact Vascular, Inc.), which was recently approved by the FDA for post-PTA dissection repair. The Tack Endovascular System contains four 6-mm implants preloaded onto a 0.014-inch guidewire-compatible catheter. These Tack® implants treat a range of vessel diameters from 1.5 to 4.5 mm, allowing for individualized treatment in multiple BTK vessels of varying diameter with a single delivery system. Before FDA approval, the off-label use of a coronary drug-eluting stent would have been the treatment of choice.

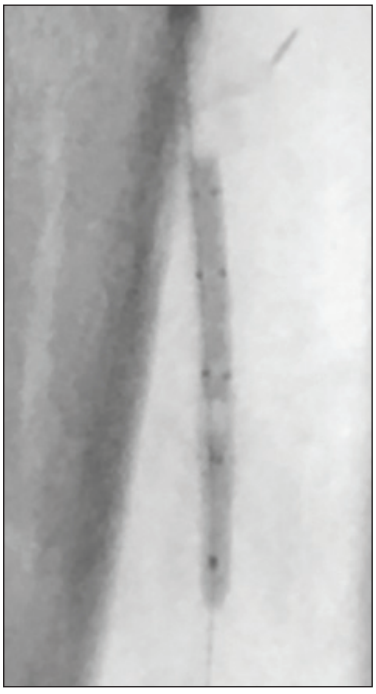

Figure 4. Postdilation of Tack® implants.

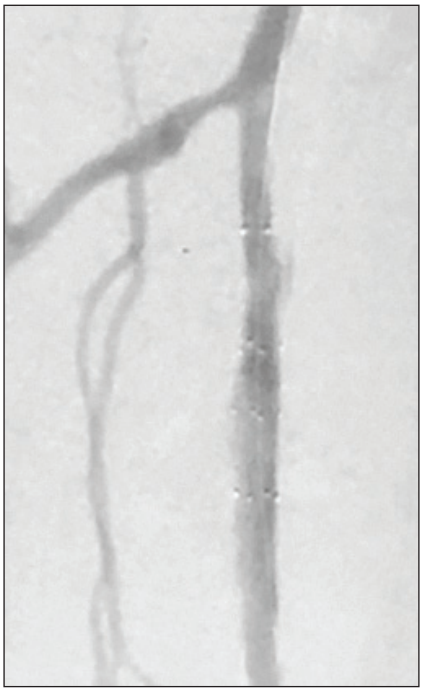

Figure 5. Dissection resolution.

To place the Tack implants, lines were drawn on the fluoroscopy screen to mark the intended treatment sites (Figure 3); a radiopaque ruler or roadmap overlay could also be used to plan deployment. In the case of spiral dissection, it has been my practice with the above-the-knee 6-F systems (3.5–6.0 and 4.0–8.0 mm) to place one Tack at both the proximal and distal edges and place additional Tack implants between them.

Four Tacks were placed in the proximal posterior tibial artery, beginning with the distal implant and working proximally (Figure 4). The Tacks were deployed using a careful pin-and-pull technique. After deployment, we performed postdilation with a short-length balloon and low pressure to avoid creating additional dissection.

Completion angiography showed almost complete dissection resolution with no residual stenosis of the tibioperoneal trunk nor proximal posterior tibial artery (Figure 5).

CONCLUSION

In the midst of the COVID-19 pandemic, both in timing and geography, the delayed presentation of this patient could have led to limb loss. We believe in targeted intervention to allow the greatest chance for clinical resolution and to lower the chance for hospitalization. Optimizing angioplasty with the Tack Endovascular System allows us to be more aggressive in our efforts to maximize lumen gain for wound healing. ■

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CASE STUDY

Delayed Patient Presentation for CLI Revascularization Due to COVID-19

BY MICHAEL LICHTENBERG, MD, FESC

At our clinic during the COVID-19 pandemic, we are currently only treating patients with critical limb ischemia (CLI), and we are not intervening for claudication. As we often experience, patients with CLI present to the clinic later in the disease process; with COVID-19, patients are showing up even later. This was the situation in the following case.

CASE PRESENTATION

An 88-year-old man presented after several days of rest pain in his left leg. He had a history of chronic renal insufficiency as well as previous intervention in his right leg. Due to concerns about the COVID-19 pandemic, he delayed presenting to the hospital until the pain persisted over several nights.

INTERVENTION

A 4-F sheath was placed antegrade in the left femoral artery. Diagnostic angiography revealed severe calcium along the entire course of the superficial femoral artery into the distal popliteal artery, but without stenosis requiring treatment. Below the knee (BTK), the severe calcium continued with total occlusion of both the anterior and posterior tibial arteries (Figure 1A). The peroneal artery was also occluded and reconstituted distally; there was little flow to the foot and no flow to the forefoot (Figure 1B). It was decided to target the peroneal artery for primary intervention.

The sheath was then upsized to 5 F and a 0.014-inch guidewire was inserted through a 2- X 40-mm balloon as a support catheter for subintimal crossing of the occlusion (Figure 2). Using a balloon catheter for support allows for fewer device exchanges and the ability to perform immediate percutaneous transluminal angioplasty (PTA) after crossing. After several attempts, the peroneal occlusion was crossed, ballooned, and the guidewire was advanced just beyond the tibiotalar joint. The balloon was then exchanged for a 2.5- X 120-mm balloon for inflation along the vessel.

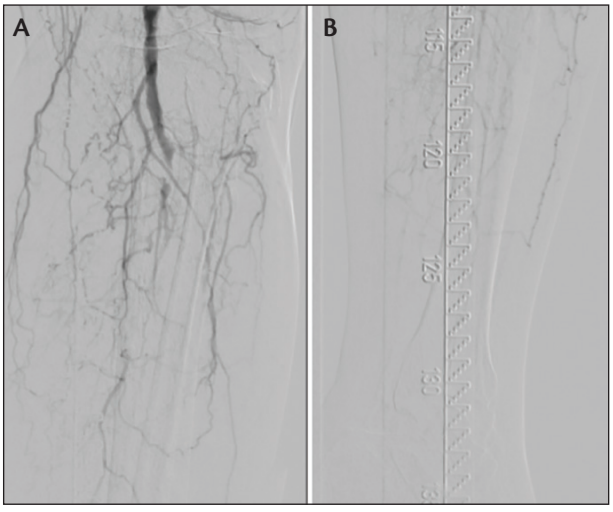

Figure 1. Baseline angiography showed extensive infrapopliteal disease.

As an aside, the issue of balloon undersizing for BTK intervention has been widely discussed, but there are very little data to show what impact it has on luminal gain. To properly size a balloon in the setting of chronic total occlusion, the large amount of calcium helps. If intravascular ultrasound is not used, then using the heavy calcium to measure reference vessel diameter with quantitative vessel analysis helps ensure the balloon is not undersized.

After a long inflation with the balloon, we evaluated the result. Dissections are very difficult to see in BTK arteries for several reasons. The severe amount of calcium in the vessel is one, but small vessel diameter and bone also cause challenges with visualization. In this case, I used multiple angles and magnification. In reviewing the post-PTA angiograms, several dissections were noted along the entire course of the vessel, but in particular, the proximal segment of the peroneal just distal to the tibioperoneal trunk (Figure 3).

In my patients, I have noticed that not treating all dissections clearly correlated with restenosis and

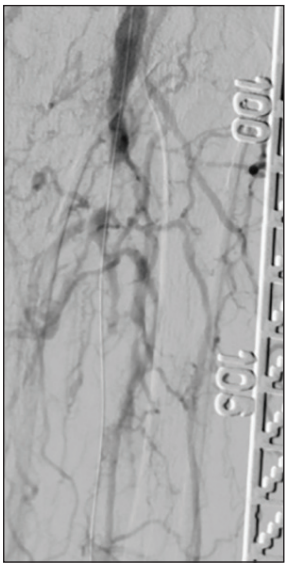

Figure 2. Occlusion was crossed with a 0.014-inch guidewire.

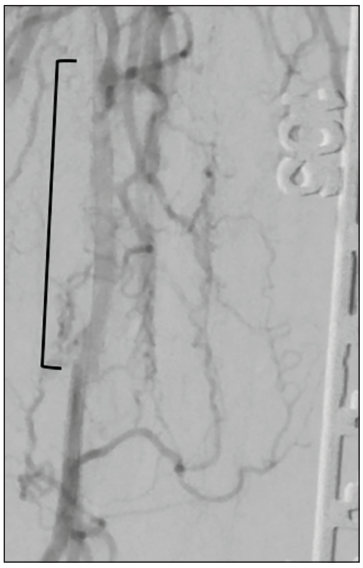

Figure 3. A 4-cm dissection was noted post-PTA.

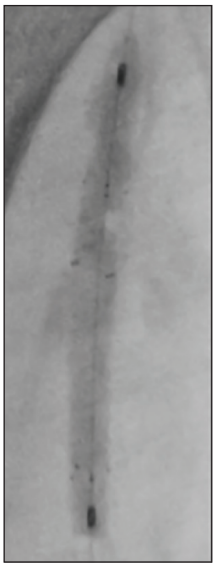

Figure 4. Post-dilation of Tack® implants

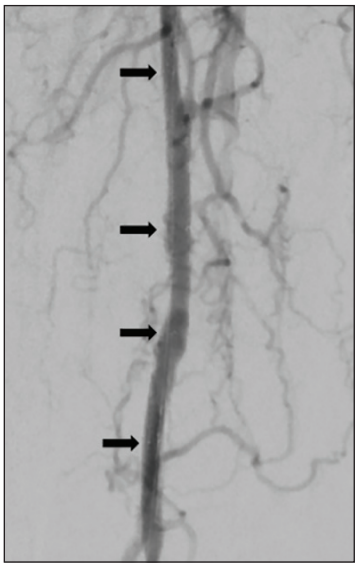

Figure 5. The long dissection was resolved with placement of four Tack implants.

early loss of patency. Later, what I learned from the TOBA II BTK trial is to heal all dissections to give the patient the best opportunity for healing.

When placing Tack® implants using the Tack Endovascular System® (4F) (Intact Vascular, Inc.), I feel the pushability and trackability of the catheter is very good, and deployment is accurate. The use of a radiopaque ruler or roadmap/overlay is helpful to get the implant precisely where I want. I can also get the Tack implants into the distal third of the vessel, where I wouldn't place a coronary stent. In this patient, several Tack implants were deployed and postdilated (Figure 4). After postdilating the Tack implants, the proximal peroneal artery had a nice result (Figure 5) and flow was restored to the forefoot, with brisk capillary refill at the end of the procedure.

CONCLUSION

When treating infrapopliteal disease in the setting of CLI, I feel there are two mandates. First, open the vessel, which is usually accomplished without too much difficulty. Second, provide a durable result in terms of patency, which is perhaps the most important mandate. This is particularly true in patients with tissue loss, such as patients with wounds or infections or those with a planned amputation. These patients depend on whatever flow we can provide for their healing. Overall, I feel that patency in CLI patients is directly related to mortality, so I prefer using Tack implants to give patients more time for healing. ■

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CASE STUDY

Tibial Artery Dissection Repair During the Pandemic

BY SCOTT M. BRANNAN, MD

CASE PRESENTATION

A 69-year-old man presented with bilateral lower extremity rest pain. He also had a history of right fourth toe amputation for a nonhealing ulcer. His risk factors included a history of diabetes, hypertension, hyperlipidemia, and chronic renal insufficiency. After initial concerns about being exposed to COVID-19, he agreed to intervention at our Modern Vascular outpatient center.

INTERVENTION

Antegrade access was obtained in the right common femoral artery. Baseline angiography revealed extensive multilevel disease. The posterior tibial artery had multiple high-grade stenoses and was occluded distally. The anterior tibial artery had diffuse disease along the entire vessel, and the peroneal artery was also severely diseased (Figure 1). The medial and lateral plantar arteries failed to opacify with prolonged image acquisition. The distal anterior tibial artery and dorsalis pedis artery opacified with delayed dynamics, but the pedal plantar loop was not identified.

To gain access to the pedal circulation, atherectomy was performed in the tibioperoneal trunk and into the posterior tibial artery using a Rotalink with 2-mm burr (Boston Scientific Corporation), followed by percutaneous transluminal angioplasty (PTA) with a 2.5- X 100-mm plain balloon. A guidewire was then advanced below the ankle. Atherectomy was also performed over a second guidewire seated in the anterior tibial artery, followed by PTA with a 3- X 220-mm balloon. Pedal circulation was then restored with a 2- X 100-mm balloon in the medial plantar and a 2.5- X 200-mm balloon in the lateral plantar.

With significantly improved distal outflow to the foot, the focus of revascularization shifted proximally to the tibial arteries. In Modern Vascular labs, intravascular ultrasound (IVUS) is used in most below-the-knee (BTK) procedures for both vessel sizing and to evaluate acute procedural success. In this case, an

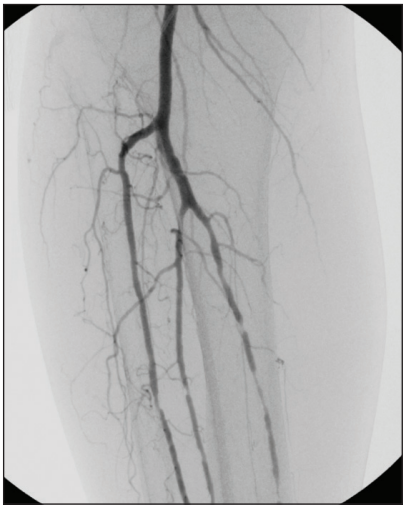

Figure 1. Baseline angiography showed occluded anterior and posterior tibial arteries.

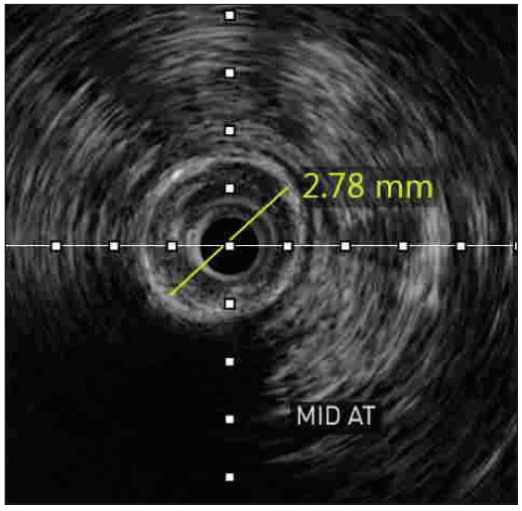

Figure 2. IVUS ensures accurate vessel diameter as shown in the anterior tibial artery.

Figure 3. Angioplasty of the posterior tibial artery.

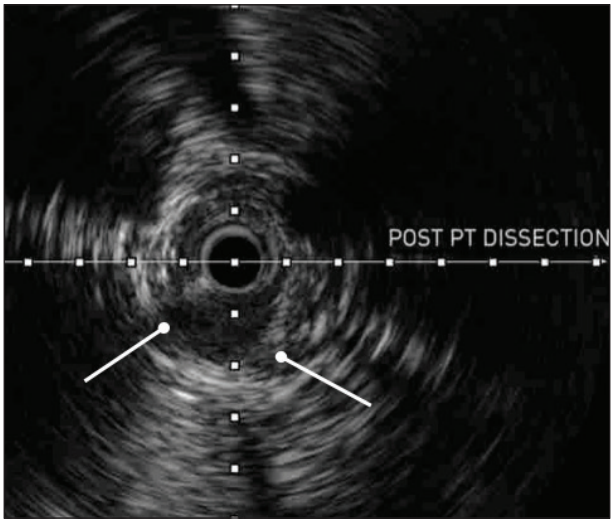

Figure 4. Post-PTA dissections are clearly visible on IVUS (lines).

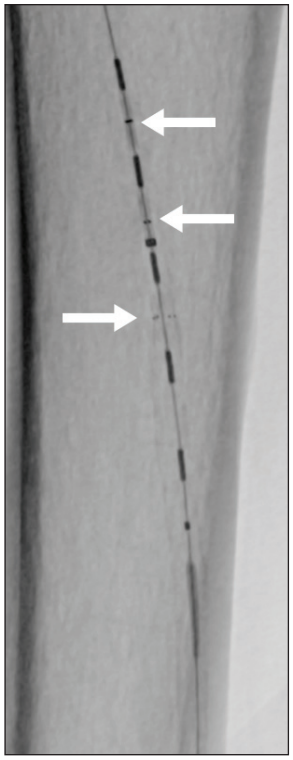

Figure 5. The Tack Endovascular System®. The second Tack® implant just deployed (bottom arrow) and two additional implants (top arrows) remain on the delivery system.

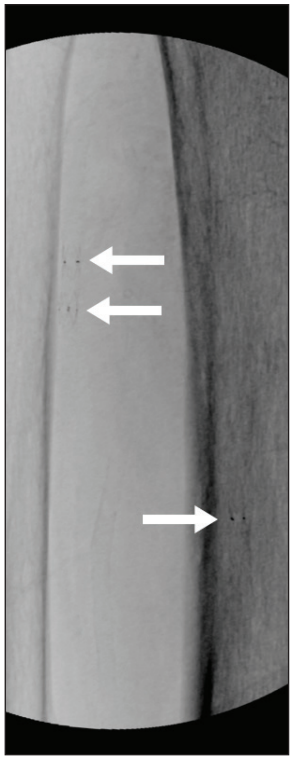

Figure 6. Multiple self-sizing implants on a single system can be used to treat dissections in different vessels.

Opticross 18 (Boston Scientific Corporation) was used to perform several cross-sectional measurements taken in the tibial arteries to ensure proper balloon size was selected (Figure 2).

In the tibioperoneal trunk through the distal posterior tibial artery, a 3.5- X 220-mm balloon was used to maximize the vessel lumen gained prior to the pedal intervention (Figure 3). Next, in the peroneal artery, PTA was performed using a 3- X 220-mm balloon. Finally, in the anterior tibial artery, additional angioplasty was performed with a 3- X 220-mm balloon.

IVUS was then used to assess the results of angioplasty. Figure 4 shows one of several post-PTA dissections identified in the posterior and anterior tibial arteries. There was no visible dissection in the peroneal artery. It was decided to repair the dissections using the Tack Endovascular System® (4F) (Intact Vascular, Inc.). This device was recently approved in the United States to repair post-PTA dissections in the mid/distal popliteal and infrapopliteal arteries with vessel diameters of 1.5 to 4.5 mm (Figure 5). The catheter contains four preloaded nitinol implants that exert low chronic outward force and are resistant to external crush. Because each implant individually self-sizes to the diameter range described, multiple areas of dissection can be treated with a single system, as in this case.

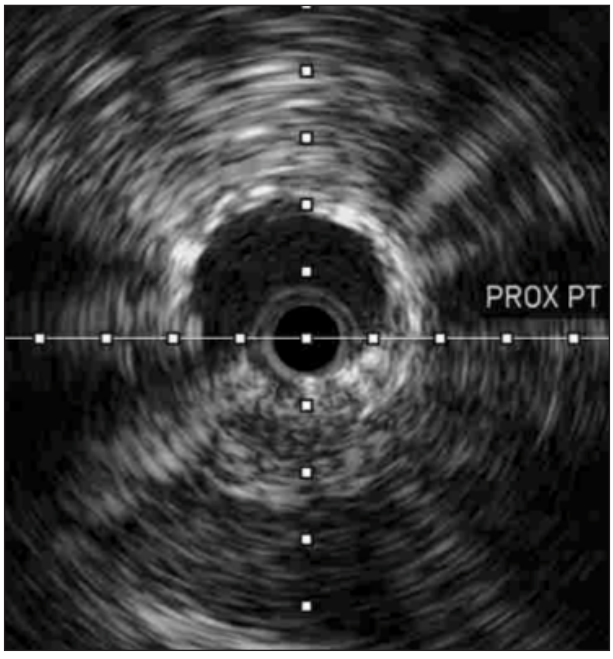

Figure 7. IVUS image showing dissection resolution with the Tack® implant.

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We deployed Tack® implants in both the posterior tibial artery (proximal and distal segments) and the proximal anterior tibial artery using the same system (Figure 6). These implants were then postdilated per the manufacturer's instructions for use.

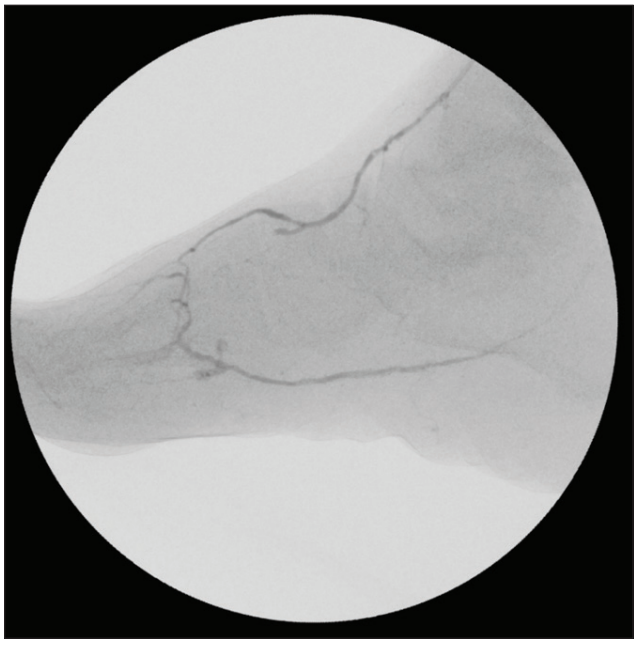

Figure 8. Angiography demonstrated flow restored to the level of the forefoot.

IVUS revealed apposition of the tissue flaps to the vessel walls, confirming complete resolution of the posterior tibial artery dissection (Figure 7). Final angiography showed restored flow to the forefoot (Figure 8).

CONCLUSION

The Tack Endovascular System (4F) allows us to scaffold areas where off-label coronary stents are prone to crush, and its short length does not constrain vessel movement. There is an inherent inventory and economic advantage to having a single device that can be used to treat multiple vessels of varying diameters. This helps to reduce the number of visits required to fully treat chronic limb-threatening ischemia and may decrease the frequency of reinterventions. ■

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Disclosures: Consultant to Intact Vascular, Inc.

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INTENDED USE: The Tack Endovascular System (6F, 3.5–6.0 mm, 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 and 4.0 mm to 8.0 mm for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissection(s).

The Tack Endovascular System (4F, 1.5–4.5mm) 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 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.

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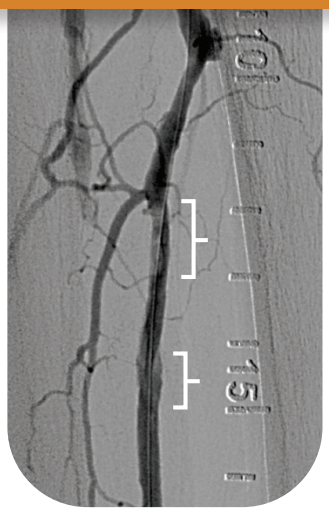
Endovascular TODAY

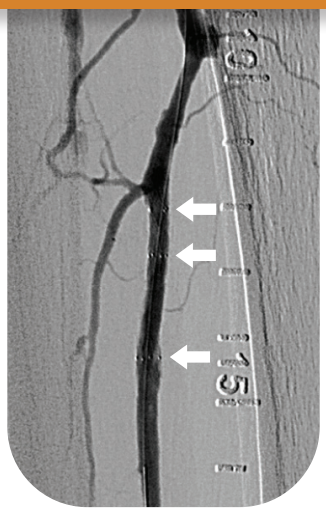
Announcing FDA Approval

of the first ever vascular implant for below-the-knee post-PTA dissection repair

The Tack Endovascular System® (4F) is a purpose-built, minimal-metal solution for precision repair of post-PTA dissections in below-the-knee (BTK) vessels. As an adjunct therapy to balloon angioplasty, Tack optimized PTA repairs BTK dissections with high rates of patency and freedom from CD-TLR, ultimately preserving future treatment options.



PRE-Tack® Implant



POST-Tack Implant

PURPOSE-BUILT.
PRECISION REPAIR.
PRESERVES OPTIONS.

Tack Endovascular System®
Dissection Repair Device

To learn more about the clinical evidence supporting the use of the Tack Endovascular System (4F) for BTK post-PTA dissection repair, visit **intactvascular.com/clinical-studies/toba-ii-btk/**

#DissectionsMatter

www.intactvascular.com

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