How I do it: optimizing angioplasty using the Tack endovascular system in the management of chronic limb threatening ischemia

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ABSTRACT

Dissection occurring after percutaneous transluminal angioplasty (PTA) is associated with decreased vessel patency and an increased incidence of target lesion revascularization. Management of post-PTA dissection with the Tack Endovascular System (Philips, N.V., Amsterdam, Netherlands) has created an effective and durable treatment strategy for infrainguinal dissections. In this report, we discuss the indications and optimal methods for using Tack devices in post-PTA dissections. (J Vasc Surg Cases Innov Tech 2023;9:101206.)

Keywords: Peripheral arterial disease; Peripheral dissections; Tack

Percutaneous transluminal angioplasty (PTA) remains a primary tool for lumen creation and revascularization for limb salvage in patients with chronic limb threatening ischemia (CLTI).[1,2] The mechanism of PTA is adventitial stretching, medial necrosis, dissection, and plaque fracture.[3,4] Studies in both animal models and cadaveric models have shown that both vessel wall disruption and vessel wall stretching occur.[5-7] The prevalence of dissection after PTA varies from 7% to 84%, depending on the method used to evaluate the vessel after PTA.[8] Dissection occurring after PTA results in restenosis and worse clinical outcomes.[9] When left without treatment, post-PTA dissections have restenosis rates of 40% to 60% and a threefold increase in 6-month target lesion revascularization (TLR) compared with lesions without dissections.[10] Additionally, the severity of dissection significantly correlates with future vessel patency because severe dissections are associated with significantly lower patency rates and a higher incidence of clinically driven TLR.[11]

Post-PTA dissections have typically been managed with observation or prolonged balloon inflation or stent implantation. Although the dissection severity threshold for treatment (rather than observation) remains unclear, most clinicians have a working bedside threshold for treating post-PTA dissections that are severe enough they cannot be ignored. Prolonged angioplasty of a dissected segment has not been extensively studied. Prolonged angioplasty does not specifically treat the fundamental dissection and might not have any implications for long-term patency.[12] Stent implantation, although well studied, is not without potential issues. Stents can be associated with fracture or in-stent stenosis, which can negatively affect patency and limb salvage. Furthermore, stent sizing can be associated with early restenosis, especially when oversized. Additionally, for treatment of dissections in below-the-knee (BTK) lesions, no Food and Drug Administration (FDA)–approved stents are available. Some interventionalists might use coronary drug-eluting stents for these lesions, but this would be off-label use and those stents are prone to crushing, making them less durable. Thus, a more nuanced and adaptable therapy for post-PTA dissections is an unmet need for interventionalists.

THE TACK ENDOVASCULAR SYSTEM

The Tack Endovascular System is specifically designed to perform focal dissection repair after PTA. The Tack Endovascular System is available in a variety of sizes to address above-the-knee (ATK) and BTK post-PTA dissection (Fig 1). The Tack device was designed with an open cell geometry and short longitudinal length, minimizing the amount of metal in direct contact with the arterial lumen. The Tack stents are made of nitinol with radiopaque gold markers to aid in visualization. In contrast to conventional stents designed for the femoropopliteal segment, the Tack device can be deployed in a range of different vessel diameters and was designed to exert a lower outward force and exhibit a relatively flat force curve within the wide range of vessel diameters. This minimal biological footprint is designed to avoid the dramatic intimal hyperplastic response and subsequent

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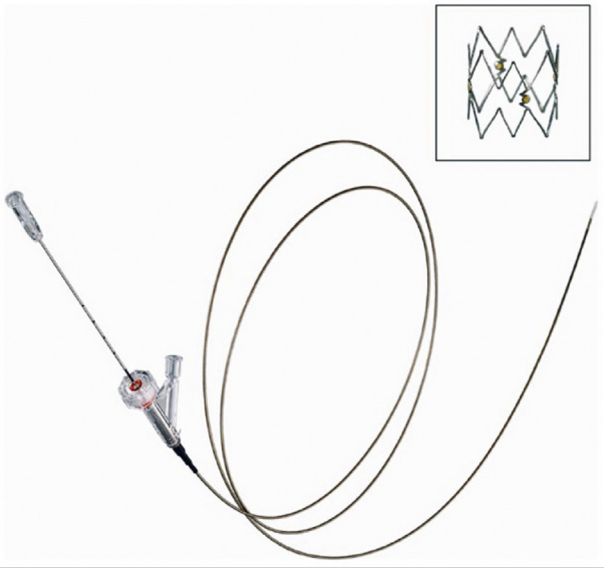

Fig 1. The Tack Endovascular System (4F).

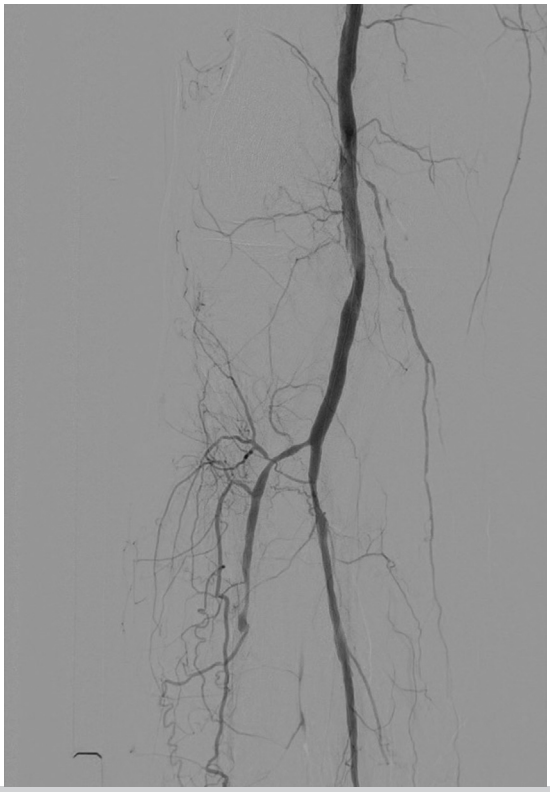

Fig 2. Post-percutaneous transluminal angioplasty (PTA) dissection of the popliteal artery.

in-stent stenosis associated with conventional stent radial force, material, cell design, strut thickness, and stent oversizing.[13-19] This allows for a more targeted, precise therapy to be delivered by the interventionalist, customized as the treated lesion requires and preventing the need for the excessive metal implantation that can occur with stenting. The Tack approach permits the vessel to retain as much of its natural configuration as

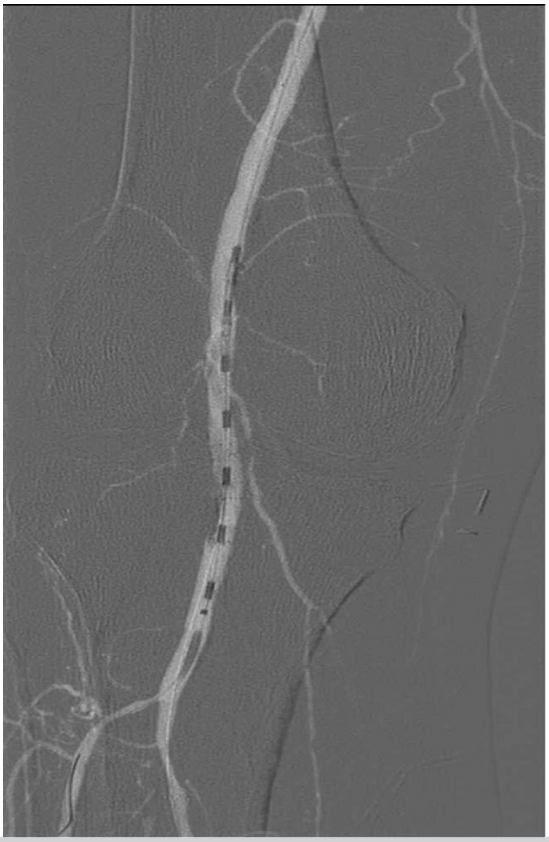

Fig 3. Fluoroscopic roadmap overlay with advancement and deployment of above-the-knee (ATK) Tack device for dissection treatment.

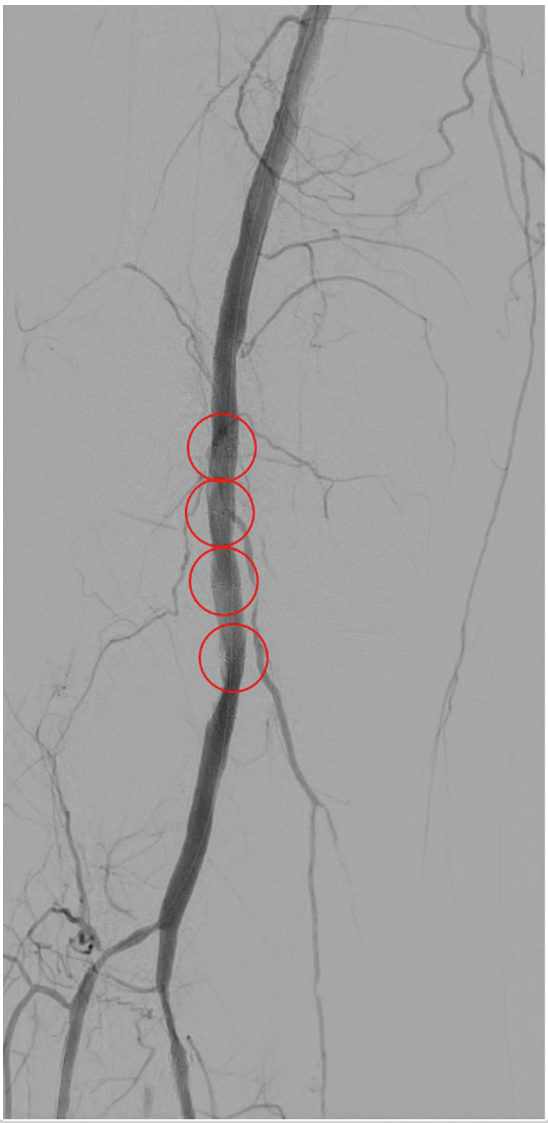

Fig 4. Completion angiography after above-the-knee (ATK) Tack deployment demonstrating successful popliteal dissection treatment.

possible. Furthermore, given the tapering nature of the vessels in the femoropopliteal and tibial vascular beds, Tacks are better suited than long stents given their range of diameter suitability. This, in turn, allows for the maintenance of normal vessel anatomy, because vessels treated with Tack devices maintain their flexibility compared with vessels treated with more rigid stent systems, which can be prone to fracture. Perhaps most importantly, the operator has the control to determine where exactly and how much metal is implanted to treat dissections, which, in turn, allows for preservation of both endovascular and open options in the future.

APPLICATION OF TACK SYSTEM

In our practice, a patient with CLTI will undergo lower extremity arteriography, whether for bypass planning or endovascular therapy. For patients without a suitable saphenous vein and those not deemed amenable to open bypass surgery, an endovascular strategy is pursued. A variety of techniques are used to traverse femoropopliteal or tibial lesions. However, ultimately, once successfully crossed, patients undergo some type of balloon angioplasty. Given the frequency with which post-PTA dissections occur, we perform angiography in at least two projections to evaluate for technical success. Increasingly, in lieu of multiple views and the potential increase in contrast administration associated with this, we are using intravascular ultrasound (IVUS) to assess technical success or the presence of luminal dissection.

Following the identification of post-PTA dissection (Fig 2), how best to treat the dissection is determined. The primary factors that prompt scaffold placement are luminal diameter reduction, spiral dissection morphology, flow impairment, and the length and number of dissections.[20] The DISFORM (diameter reduction, spiral shape, flow impairment, morphology) classification system is a useful tool for predicting adverse outcomes after PTA dissection and provides a method for standardized reporting and guided treatment management.[20]

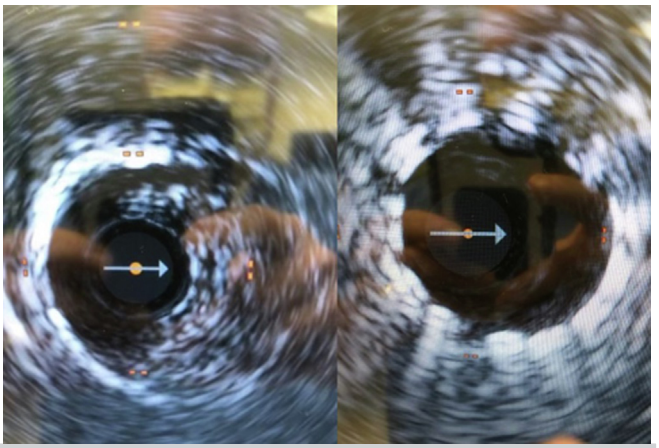

Fig 5. Intravascular ultrasound (IVUS) evaluation before and after Tack deployment in treatment of dissection.

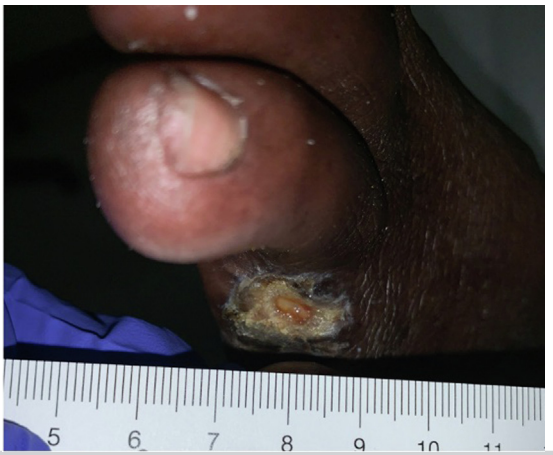

Fig 6. Photograph of nonhealing left fourth toe ulceration.

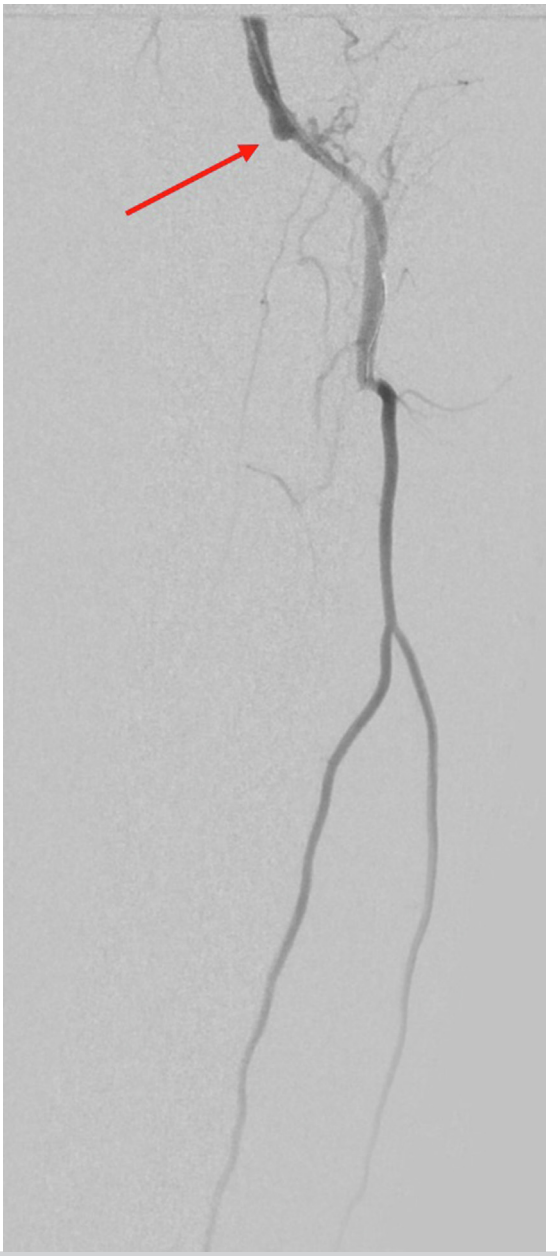

Fig 7. Left lower extremity arteriogram demonstrating severe tibial disease and long segment anterior tibial artery occlusion (*arrow* indicates anterior tibial artery origin).

We routinely use Tacks in the femoropopliteal and tibial segments unless patients have >50% residual stenosis in the treated segment after PTA. In such cases, additional angioplasty is performed to reduce the residual stenosis. Most often, we see this in the setting of severe eccentric calcification or very long segment spiral dissections.

For most patients with post-PTA dissections, the Tack device is the main tool we use to optimize the technical result. Once the decision to treat the dissection is made, using radiographic guidance, the Tack catheter is advanced into position using the gold radiopaque markers located in the center of the Tack (Fig 3). Deployed via a simple "pin and pull" mechanism, the Tacks can be accurately positioned to tack the dissection flap onto the luminal surface of the artery. Tacks are placed without overlapping and usually at intervals of 4 to 6 mm across the vessel segment in question. Short dissections (≤1 cm in length) are typically treated with a single Tack in the middle. Intermediate length dissections (1-2 cm) are treated with a Tack at the entry site, middle, and exit site of the dissection. Finally, longer dissections (>2 cm) are treated with Tacks at the entry and exit sites and spaced 4- to 6-mm apart across the dissected segment. Core laboratory-adjudicated studies of dissection have shown that dissections >2 cm are uncommon.[7,21,23] Following deployment, the Tacks are postdilated with a short balloon to secure each Tack to the vessel wall, seed the implant into place, and optimize Tack expansion. Next, completion angiography is

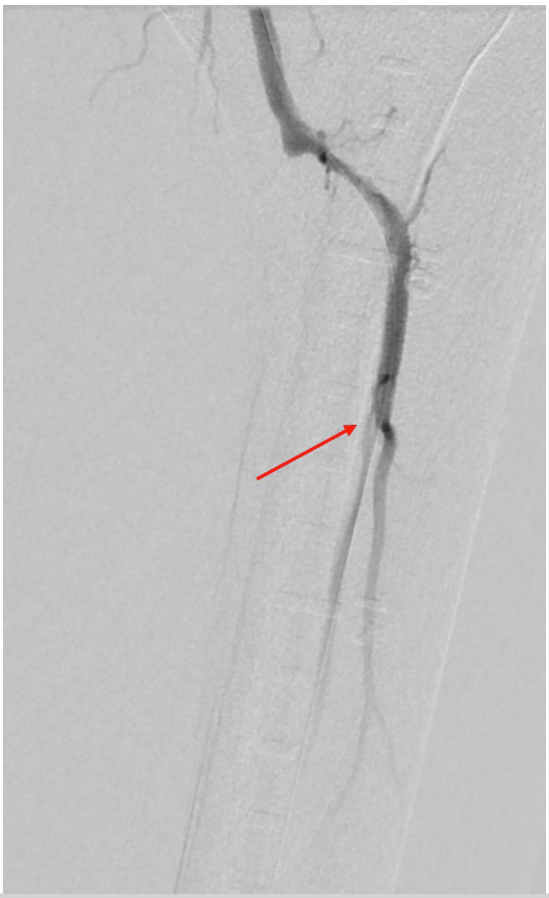

Fig 8. Post-percutaneous transluminal angioplasty (PTA) dissection of left anterior tibial artery (*arrow* indicates origin of dissection flap).

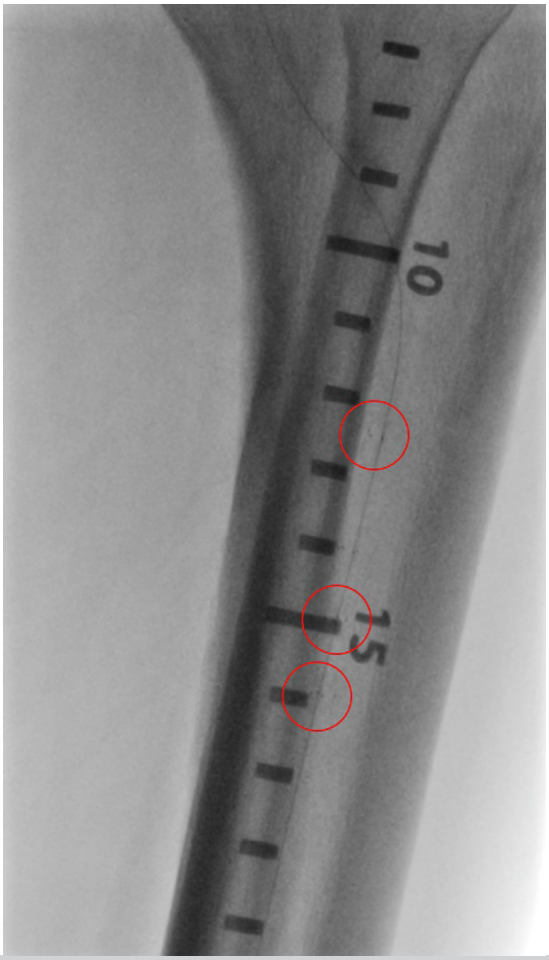

Fig 9. After deployment of three Tack devices at proximal anterior tibial artery.

performed to confirm resolution of the dissection (Fig 4). Additionally, IVUS can be used to assess the characteristics, length, and location of the dissection flap and assess the results after treatment (Fig 5). Tacks are indicated for the treatment of dissection that occurs after angioplasty. Clinical experience has shown that it can be used as an adjunct to numerous types of procedures during which a balloon is used to enhance the lumen gain, including PTA, drug-coated balloons (DCBs), intravascular lithotripsy, and various types of atherectomy.

ATK DEVICE

At present, two Tack devices are available for the treatment of ATK arteries. Both are deployed through a 6F sheath, contain six individual Tacks per catheter, and allow for the treatment of arteries ranging from 3.5 to 6 mm and 4 to 8 mm in diameter. Each catheter is delivered over a 0.035-in. wire, and each Tack implant is 6 mm in length.

The ATK Tack device has been studied extensively. The ATK device received FDA approval for use in the superficial femoral artery and popliteal artery after the TOBA II (Tack optimized balloon angioplasty study of the Tack Endovascular System in femoropopliteal arteries) study. This study was a prospective, multicenter, single-arm study that evaluated Tack device performance after angioplasty using PTA or DCBs, with the Levant 2 (Lutonix paclitaxel-coated balloon for the prevention of femoropopliteal restenosis) study as a guide. The TOBA II study, which included 213 patients with 369 dissections after PTA or DCBs, demonstrated that after Tack implantation, 92.1% of the dissections had resolved, and only one patient had required adjunctive conventional stenting. On average, four Tacks were required per patient. At 12 months, the primary patency was 79.3%, and the incidence of TLR was 86.5%. In addition, the ankle brachial indexes in the target limb and quality of life scores improved. Importantly, no amputations were reported during the follow-up period. These findings demonstrated that Tack usage was safe and effective in repairing dissection after either plain balloon angioplasty or DCB angioplasty.[21] Patients were required

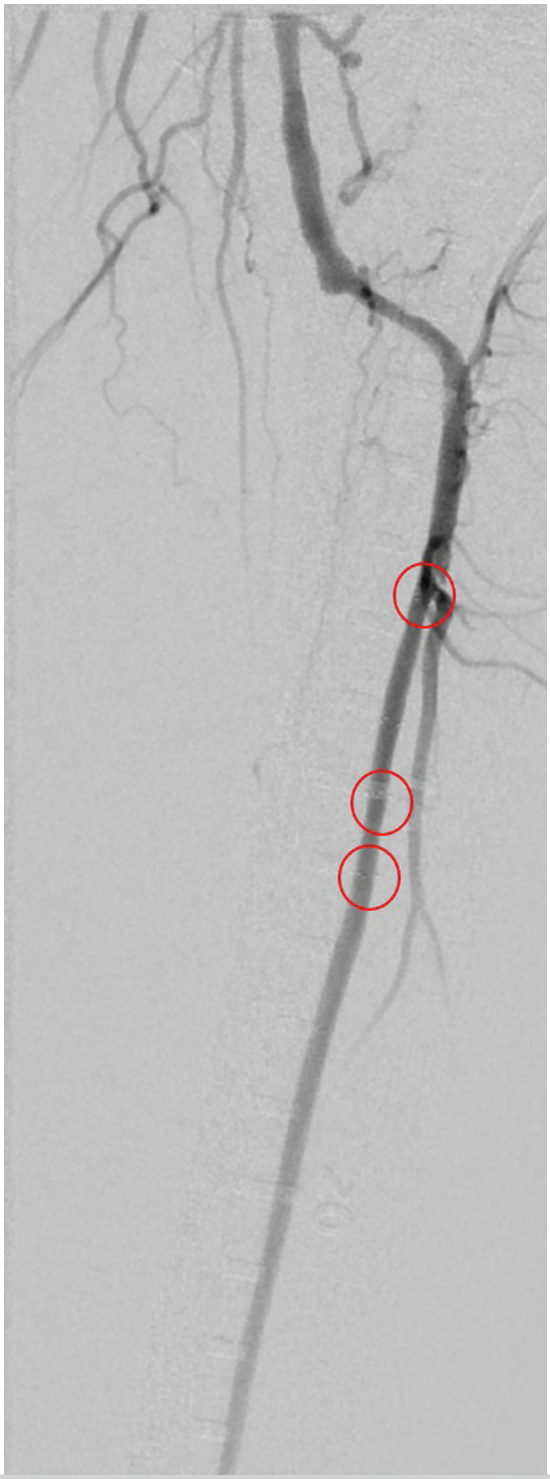

Fig 10. Completion angiogram demonstrating successful dissection treatment after Tack placement (*circles* indicate position of stents).

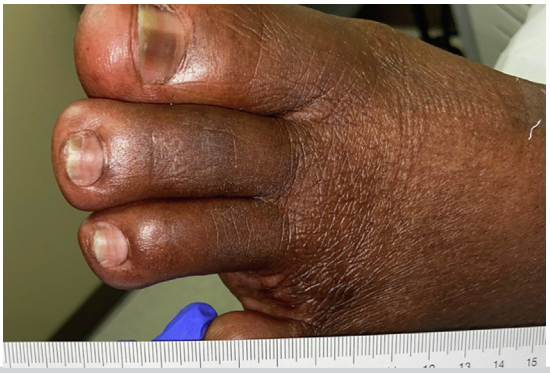

Fig 11. Complete healing after revascularization.

to have a dissection to be included in the study, and when a dissection could not be identified, it was considered a screening failure. Compared with the results of the Levant 2 study, the patients who subsequently underwent Tack placement for dissections had improved results despite having longer lesions, more occlusions, and more severe dissections.

After TOBA II, the TOBA III (Tack optimized drug coated balloon angioplasty study of the Tack Endovascular System in femoropopliteal arteries) was performed. TOBA III was a prospective, multicenter trial that evaluated the combination of the IN.PACT Admiral market-leading DCB (Medtronic) in the treatment of femoropopliteal disease with the Tack device used for focal dissection repair. The study enrolled a total of 201 patients and was composed of two groups: standard-length lesions (≤150 mm) and long arterial lesions (>150 mm but <250 mm). The standard-length patient group had 95% primary patency at 12 months. The long lesion subset of patients had 89.3% patency at 12 months with a 0% bailout stent rate.[22] That study demonstrated the safety and efficacy of Tacks in longer, more challenging lesions.

BTK DEVICE

The BTK device is deployed through a 4F sheath and contains four individual Tacks per catheter. This device is suitable for the treatment of arteries 1.5 to 4.5 mm in diameter, and the device is deployed over a 0.014-in. wire.

Like the ATK device, several clinical trials have evaluated the performance and safety of the Tack BTK device. The initial, promising results of the TOBA BTK study prompted the prospective, multicenter TOBA BTK II study. In this U.S. pivotal trial, 233 patients were enrolled, and 84% had CLTI. In that study, the mean balloon length was 15 ± 11 cm, with nearly 50% being total occlusions. After angioplasty, 341 dissections were identified that required the implantation of 918 Tacks. On average, 4.0 ± 2.8 Tacks were used to treat each patient, resulting in 100% dissection resolution. Only one patient required bailout stenting. At 12 months, freedom from major adverse limb events was 93.4% and patency of the tacked segments was 81.3% of patients. The limb salvage rate at 12 months was 96.8% for all patients, with a 68.5%

wound healing rate. The average ankle brachial index improved from 0.74 ± 0.27 to 0.91 F0B1 0.19 at 12 months, with improvement in the walking impairment questionnaire scores compared with before the procedure.[23]

CASE REPORT

We present the case of a 60-year-old man with a history of type 2 diabetes, hyperlipidemia, coronary artery disease, chronic kidney disease, and hypertension, who presented to the emergency room with a nonhealing left fourth toe amputation site (Fig 6). Arterial noninvasive testing demonstrating noncompressible tibial arteries bilaterally. The left toe pressure was 22 mm Hg. Left lower extremity arteriography revealed no aortoiliac or femoropopliteal disease; however, extensive tibial disease was present (Fig 7). The patient underwent recanalization of the long segment anterior tibial artery occlusion. Subsequently, arteriography and IVUS were performed and demonstrated a hemodynamically significant dissection in the proximal portion of the recanalized anterior tibial artery (Fig 8). Three BTK Tacks were deployed precisely in the dissected segment, successfully treating the dissection (Figs 9 and 10). The dehisced amputation subsequently healed after debridement (Fig 11). Follow-up at 1 month and 6 months demonstrated stable improvement, with a toe pressure of 81 mm Hg and 92 mm Hg, respectively.

CONCLUSIONS

Endovascular therapy continues to evolve and adapt in an effort to optimize the effectiveness and durability of endovascular interventions. Balloon angioplasty remains a primary tool of endovascular therapy, especially for BTK therapy. Given the frequency of dissection after PTA and its negative effects on patency and clinical outcomes, an effective and durable solution is crucial for advancement of endovascular therapy. The Tack Endovascular System is the first device of its kind and has met that challenge. At present, it is the first and only device approved by the FDA for the treatment of post-PTA dissection and the only on-label implant for repair of BTK arteries. The technique of focal dissection repair with the Tack device allows for precision placement with minimal metal, resulting in the ideal device for both ATK and BTK dissections. It is suited to the repair of dissections in vessels of various sizes and locations, facilitating spot treatment and avoiding the deployment of metal in potentially nondiseased portions of a vessel. In our clinical practice, we have adopted the use of these devices and have experienced excellent results both intraoperatively and during follow-up consistent with prior clinical trials.

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