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Treatment of infrapopliteal post-PTA dissection with tack implants: 12-month results from the TOBA-BTK study

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Abstract

Objectives: The Tack implant is designed for focal, minimal metal management of dissections. This study evaluated Tacks for treating postpercutaneous transluminal angioplasty (PTA) dissection in patients with below-the-knee (BTK) arterial occlusive disease.

Background: PTA is the most commonly used endovascular treatment for patients with occlusive disease of the BTK vessels. Post-PTA dissection is a significant clinical problem that results in poor outcomes, but currently there are limited treatment options for managing dissections.

Methods: This prospective, single-arm study evaluated patients with CLI and BTK lesions; 11.4% were Rutherford category (RC) 4 and 88.6% were RC 5. BTK occlusive disease was treated with standard PTA and post-PTA dissections were treated with Tack placement. The primary safety endpoint was a composite of major adverse limb events (MALE) and perioperative death (POD) at 30 days. Other endpoints included: device success; procedure success (vessel patency in the absence of MALE); freedom from clinically driven target lesion revascularization (CD-TLR); primary patency; and changes in RC. Data through 12 months are presented.

Results: Thirty-two of 35 (91.4%) patients had post-PTA dissection and successful deployment of Tacks. Procedural success was achieved in 34/35 (97.1%) patients with no MALEs at 30 days. The 12-month patency rate was 78.4% by vessel, 77.4% by patient, and freedom from CD-TLR was 93.5%. Significant ($P < .0001$) improvement from baseline was observed in RC (75% of patients improved 4 or 5 steps).

Conclusion: Tack implant treatment of post-PTA dissection was safe and effective for treatment of BTK dissections and resulted in reasonable 12-month patency and low rates of CD-TLR.

KEYWORDS

balloon angioplasty, critical limb ischemia, dissection, infrapopliteal arteries, peripheral artery disease, tibial artery

1 | INTRODUCTION

Within 1 year of diagnosis of critical limb ischemia (CLI), 25% of patients will require major amputation and most of the remaining patients will have nonhealed wounds [1]. Reversing limb threatening ischemia requires management of BTK occlusive disease. Over the years percutaneous transluminal angioplasty (PTA) has become the treatment of choice with comparable rates of limb salvage and amputation-free survival to bypass grafting [2–4]. This combined with the advantages of PTA, which include faster recovery, shorter length of

hospitalization, fewer major complications, and better patient acceptance have made PTA a reasonable treatment choice for many patients with CLI [4,5]. PTA depends upon mechanical dilatation of the artery and is associated with plaque fracture, intimal splitting and localized medial dissection. Localized post-PTA dissection is a common and expected adverse outcome associated with the angioplasty mechanism. The traditional approach to treating post-PTA dissection has been stent placement. In the SFA, stents acutely improve outcomes, but they have also been shown to induce chronic injury and inflammation leading to high 1-year restenosis rates ranging from 20% to 37% [6–9]. After BTK stenting, immediate technical and procedural success appear high, but so are the complication rates for clinically driven target lesion revascularization (CD-TLR) and amputation. Reported rates of CD-TLR are as high as 34% for bare metal stents and 30.5% for drug-eluting stents at 12 months [10,11]. Amputation rates range from 10.4 to 20% and 6.4 to 13.8% after placement of bare metal or drug-eluting stents, respectively [12,13].

The minimal-metal Tack® implant, is designed for focal treatment of post-PTA dissections with low outward force and reduced metal burden compared to stents, to reduce the likelihood of inflammation and intimal hyperplasia. In previous studies, including a multicenter investigation of 130 patients, Tack implants have been shown to be effective in treating post-PTA femoropopliteal dissections [14].

Herein we report the first, prospective, multicenter study evaluating the safety and efficacy of the Tack Endovascular System® for treating post-PTA dissections in the BTK arteries.

2 | MATERIALS AND METHODS

The TOBA-BTK (Tack Optimized Balloon Angioplasty Below the Knee) Study was an early phase prospective, first-in-human, single-arm, multicenter, open-label, nonrandomized study. The study was conducted in accordance with the Declaration of Helsinki. The local ethics committees at the participating sites approved the study protocol and all patients provided written informed consent prior to undergoing any study procedures. Patients that provided informed consent and met the study entrance criteria were considered enrolled.

The objectives of this study were to evaluate the safety and performance of the Tack Endovascular System for the treatment of dissections resulting from PTA of BTK lesions.

2.1 | Patients

A sample size of 35 was prespecified to ensure there would be at least 30 subjects followed for 12 months. In terms of safety assessments, a sample size of 35 provided an 80% chance to see at least one significant safety event if 4.5% or higher of subjects experienced the event. Patients were selected based on clinical and angiographic criteria as listed in Table 1. Patients were eligible for the study if they had the following: CLI; Rutherford Category (RC) score 4 or 5; reference vessel diameter BTK between 1.5 and 4.5 mm; lesion located in the arteries between the knee joint and the ankle; de novo target lesions with >70% stenosis; 1 or 2 tibial arteries requiring treatment with a total treated segment ≤15 cm; and angiographic evidence of a post-PTA dissection. Major exclusion criteria included: presence of extensive forefoot gangrene/ischemic ulcer that could not be resolved with transmetatarsal amputation; previous treatment failure of inflow arteries (iliac, superficial femoral, and/or popliteal); former below knee bypass; significant stenosis or occlusion of inflow vessels tract (proximal disease) not successfully treated (<30% residual stenosis and without complication) prior to BTK angioplasty; and the target lesion nondilatable by balloon angioplasty.

Figure 1 describes the flow of patient enrollment. Patients underwent standard balloon angioplasty with a nondrug coated balloon, typically with a minimum of 5 mm of balloon length extending beyond each end of the lesion. The balloon was inflated to nominal pressure or higher if required to expand any residual waist on the balloon. Balloon inflation was typically maintained for a minimum of 30 sec. Post-PTA angiograms were assessed; if there was significant residual stenosis (i.e., >30%), the lesion was treated with repeat PTA at longer inflation times or increased pressure per clinician's judgment. If no dissection was observed on the initial post-PTA angiogram, oblique views were obtained to further evaluate the treatment site. Patients with evidence of dissection were enrolled for Tack treatment.

2.2 | Tack endovascular system

The Tack Endovascular System (Intact Vascular, Wayne, PA) consists of self-expanding nitinol implants, each measuring 6 mm in length. The short longitudinal length in combination with an open-cell design functions to minimize the amount of metal in contact with the artery. The Tack implant (Figure 2) is designed to treat dissections by exerting a low outward radial force upon the vessel wall to create focal tissue apposition.

Three independent Tack implants were provided preloaded onto a 4F delivery catheter with an outer diameter of 1.33 mm. Following angiographic identification of a dissection, the delivery catheter was loaded onto the same 0.014″ guidewire used during the PTA procedure and utilizing fluoroscopic guidance was advanced to the treatment site. Magnification was used for clear visualization during deployment. Based on the investigator's evaluation of the angiogram, Tacks were typically deployed at the proximal and distal edges of the dissection with additional Tacks being deployed and spaced at a minimum of 6.0 mm apart from end to end to ensure complete treatment of the dissection. After deployment across the dissected segment, post-Tack placement PTA was performed to secure each Tack implant and angiography was performed to verify acceptable acute vessel patency.

2.3 | Procedural angiography and postprocedure testing

The investigator performed evaluation of angiographic data for the determination of study enrollment at the time of the procedure. Angiographic images were sent to an independent core laboratory (Yale University School of Medicine Angiographic Core Laboratory, New Haven, CT) for blinded evaluation of the target lesions and outcomes. Dissections were adjudicated based on angiographic evaluation of intimal disruption utilizing the National Heart, Lung, and

TABLE 1 Inclusion and exclusion criteria

Inclusion	Exclusion
Clinical Criteria	**Clinical Criteria**
1. Age of subject is >18. 2. Subject or subject's legal representative has been informed of the nature of the study, agrees to participate and has signed the consent form. 3. Subject has critical limb ischemia (CLI). 4. Subject has Rutherford Clinical Category 4–5 5. Estimated life expectancy > 1 year. 6. Subject is able and willing to comply with all follow up visits.	1. The subject has a lesion on the plantar surface of the heel or over the Achilles tendon or has exposed calcaneus. 2. The subject has extensive forefoot gangrene/ischemic ulcer that cannot be resolved with standard metatarsal amputation. 3. Previous treatment failure of inflow arteries (Iliac, SFA and popliteal) 4. Subject with below knee bypass. 5. Subject has significant stenosis or occlusion of inflow vessel tract (proximal disease) not successfully treated (>30% residual stenosis and without complication) prior to BTK angioplasty and patient enrollment. 6. History of any open surgical procedure within the past 30 days. Endovascular procedures to treat inflow arteries the day of the procedure and prior to *Tack* placement are not considered surgical procedures. 7. Planned endovascular or vascular surgery within 14 days prior to the BTK procedure, except for treatment of the inflow vessels on the day of the procedure, or within 30 days following the BTK procedure on either limb. 8. Subject is permanently wheel-chair bound or bedridden. 9. Subject has an allergy to contrast medium that cannot be pretreated. 10. Episode of acute limb ischemia within the previous 30 days. 11. Subject is undergoing atherectomy in the target limb or cryoplasty or stenting of BTK treatment site. 12. Subject has a systemic infection with positive blood cultures/bacteremia within one week. 13. Subject has undrained pus or spreading wet gangrene in the foot that is not controlled at the time of revascularization procedure. 14. Subject in whom antiplatelet, anticoagulant, or thrombolytic therapy is contraindicated. 15. Myocardial infarction within 30 days prior to enrollment. 16. History of stroke within 180 days prior to enrollment. 17. Subject has acute or chronic renal disease (e.g., as measured by a serum creatinine of >2.5 mg/dL or >220 umol/L). 18. Subject is pregnant or breastfeeding. 19. Subject is participating in another research study of a device, medication, biologic, or other agent within 30 days, which could, in the opinion of the investigator, affect the results of this study. 20. Subject has other medical, social or psychological problems that in the opinion of the investigator would preclude them from receiving this treatment and the procedures and/or participating in evaluations pretreatment and posttreatment. 21. Subject has a known hypersensitivity or contraindication to nitinol.
Angiographic Criteria	**Angiographic Criteria**
1. Reference vessel diameter below the knee is between 1.5 mm and 4.5 mm (inclusive). 2. Lesion(s) located from the knee joint to the ankle. 3. De-novo target lesion(s) has stenosis >70%. 4. Either one [1] or two [2] different tibial arteries may be treated. The treated segment is defined as the total length of artery treated with PTA. The cumulative treated segment of tibial artery(ies) must be <15.0 cm. Lesions in the treated segment may be continuous or may have gaps present between stenoses and occlusions. 5. For a lesion to be included, the operator must be able to perform PTA with a resultant dissection Type A – F. 6. Any vessel intervened on must have distal reconstitution above the ankle. 7. Inflow Iliac, SFA and popliteal lesions can be treated during same procedure using standard angioplasty and/or an approved device. These inflow lesions must be treated first, prior to consideration of treatment of BTK lesions. The patient can be enrolled if the inflow lesions are treated with good angiographic results (must have <30% residual stenosis and no evidence of embolization).	1. Post-PTA, the vessel shows no dissections. 2. Target lesion is nondilatable by balloon angioplasty. 3. Maximum number of *Tacks* needed or anticipated exceeds 12.

Blood Institute classification system [15]. Within a treated lesion, if there were multiple post-PTA dissections, only the most severe dissection was reported.

2.4 | Anti-platelet medication

Premedication was per investigator's clinical judgment or institutional practice and included a loading dose of aspirin 80–500 mg and clopidogrel 75–600 mg. Most patients remained on aspirin (median dose 100 mg) throughout the 12-month follow-up period. Clopidogrel (median dose 75 mg) was continued for 30 days postprocedure in 81% of the patients.

2.5 | Study endpoints

The primary safety endpoint of this study was a composite of major adverse limb events (MALE) and peri-procedural death assessed at 1-month postprocedure. MALE events included major amputation (amputation above the ankle) or reintervention in the target limb. Other primary endpoints included: device success and procedure success. Device success was defined as the achievement of successful delivery and deployment of Tack implant(s) at the intended target site(s) and successful withdrawal of the delivery catheter. Procedure success was demonstrated vessel patency as reported by the physician (visual estimate) without the occurrence of MALE + POD on the date of procedure. Secondary endpoints included all cause death, above ankle amputation, amputation free survival, clinically driven TLR and TVR, change in Rutherford Classification, luminal patency by Toe brachial index (TBI) and presence of Doppler signal.

Primary patency was defined as presence of a pulsatile Doppler signal in the treated artery, freedom from CD-TLR and freedom from major amputation (above the ankle). Presence of an audible Doppler signal was chosen to define primary patency in lieu of the need to

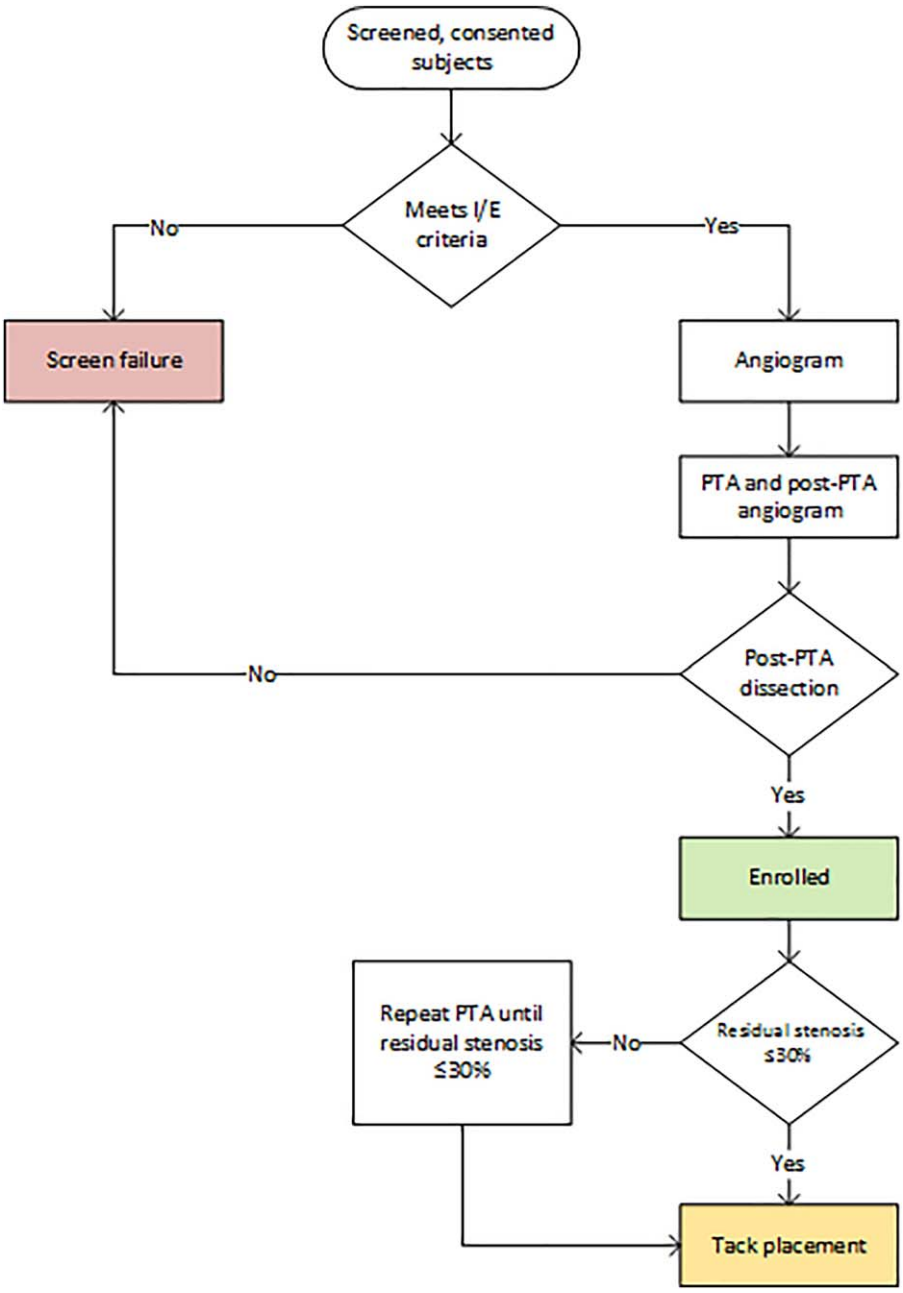

FIGURE 1 Tack implant. The Tack implant (right) is a self-expanding nitinol implant designed for the focal treatment of post-PTA dissection. The device is secured by pairs of anchors (left) located in the center of each implant. PTA, percutaneous transluminal angioplasty

determine degree of stenosis if present. An infrapopliteal stent study by Peregrin et al used similar measures of patency [16]. Primary patency was determined per patient and per vessel since multiple vessel treatment was permitted in the study. Primary patency was considered lost at the first occurrence of CD-TLR, major amputation or lack of an acceptable Doppler signal observed at the 1, 3, 6, or 12-month follow-up. In the per vessel analysis, CD-TLR and major amputation indicate lack of primary patency for all vessels within the patient. In the absence of CD-TLR and major amputation each vessel's patency is determined by whether a Doppler signal was audible at 30 days, 3, 6, and 12 months. Given no intervening CD-TLR or amputation, a missing Doppler evaluation could be determined to be patent given an audible signal present at a later follow-up.

Primary assisted patency was also assessed: if a vessel or patient lost patency but a revascularization occurred and the appropriate Doppler signal was present at subsequent visits, primary assisted patency was achieved.

2.6 | Statistical analysis

This was a first-in-human study for the use of Tack implants in BTK lesions and the primary intent of the analysis was to provide a

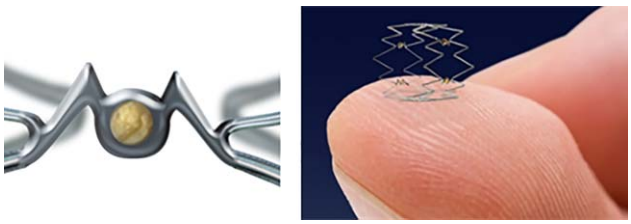

FIGURE 2 Patient enrollment flowchart. Patients were enrolled when a dissection was identified. Three patients did not receive Tack implants due to tortuous anatomy and/or small vessel diameter. I/E, inclusion/exclusion; PTA, percutaneous transluminal angioplasty; n, number

descriptive summary of the safety and efficacy of the Tack system. Descriptive data summaries including number, mean and standard deviation (SD) are provided for continuous variables. For categorical variables, the frequency of patients is provided along with percentages based on the number of patients with available data.

3 | RESULTS

Thirty-five patients with 36 lesions were enrolled across six sites. Baseline patient and clinical characteristics are detailed in Table 2. So as to not confound study results, patients were not treated with exercise therapy. Most patients were RC 5 (88.6%) with the remainder being RC 4. Common co-morbid conditions included hypertension (91.4%) and diabetes mellitus (77.1%) in accordance with such a cohort of CLI patients. Ankle brachial index (ABI) was 0.95 ± 0.42, demonstrating that ABI can be unreliable in patients with diabetes. TBI was 0.47 ± 0.28, and more representative of CLI.

Table 3 summarizes the angiographic and procedural characteristics and outcomes of the patient population as reported by the core laboratory. The severity of lesion calcification was adjudicated as none or mild in 36.1% of lesions, with moderate and severe calcification occurring in 61.1% and 2.8% of the lesions, respectively. The core lab adjudicated mean diameter stenosis was 72.3 ± 17.4% prior to treatment and 21.4 ± 10.3% post-PTA and prior to Tack implant. The worst dissection per lesion was Grade A in 21.2%, Grade B in 60.6% and Grade C in 18.2%. The number of Tacks required to treat the dissections was 2.6 ± 2.1 per target lesion. Procedure success was achieved in 34/35 (97.1%) patients. The patient that did not achieve procedure success required reintervention of a nontarget vessel in the treated

TABLE 2 Baseline patient demographic and clinical characteristics

Age (years)	**76.1 ± 9.3**
Men	18/35 (51.4%)
Hypertension	32/35 (91.4%)
Diabetes mellitus	27/35 (77.1%)
Current smoker	2/34 (5.9%)
Target limb	
Left	14/35 (40.0%)
Right	21/35 (60.0%)
Rutherford clinical category	
4	4/35 (11.4%)
5	31/35 (88.6%)
Ankle-Brachial index in target leg	0.95 ± 0.42
TBI in target leg	0.49 ± 0.30
Target limb pain symptoms	
No pain	17/35 (48.6%)
Pain on exercise	10/35 (28.6%)
Rest pain	10/35 (28.6%)

Values are mean ± SD or *n* (%).

TABLE 3 Angiographic, procedural characteristics, and outcomes

Characteristic	
Proximal lesion zone	
Anterior tibial artery	14/36 (38.9%)
Tibio-peroneal trunk	10/36 (27.8%)
Peroneal artery	6/36 (16.7%)
Posterior tibial artery	6/36 (16.7%)
Lesion length (mm)	51.4 ± 28.0
Proximal RVD (mm)	3.4 ± 0.8
Distal RVD (mm)	2.9 ± 0.8
Calcification	
None/mild	13/36 (36.1%)
Moderate	22/36 (61.1%)
Severe	1/36 (2.8%)
Total occlusion	8/36 (22.2%)
Approach	
Contralateral	3 (8.6%)
Ipsilateral	32 (91.4%)
Procedure time (min)	67.5 ± 37.4
Fluoroscopy time (min)	15.3 ± 10.7
Contrast media volume (ml)	124.8 ± 40.3
Tacks used	2.6 ± 2.1
Baseline dissection grade (prior to tack implant)[a]	
0	0 (0%)
A	7/33 (21.2%)
B	20/33 (60.6%)
C	6/33 (18.2%)
Dissection grade (after tack implant)[a]	
0	32/36 (88.9%)
A	1/36 (2.8%)
B	3/36 (8.3%)
% Pre diameter stenosis	72.3 ± 17.4
% Post diameter stenosis—prior to tack implant	21.4 ± 10.3
% Post diameter stenosis—after tack implant	23.3 ± 13.3
Device success	32/35 (91.4%)
Procedure success	34/35 (97.1%)

Values are mean ± SD or *n* (%).
RVD = reference vessel diameter; min = minutes; mm = millimeters; ml = milliliters.
[a]Reports most severe baseline dissection grade.

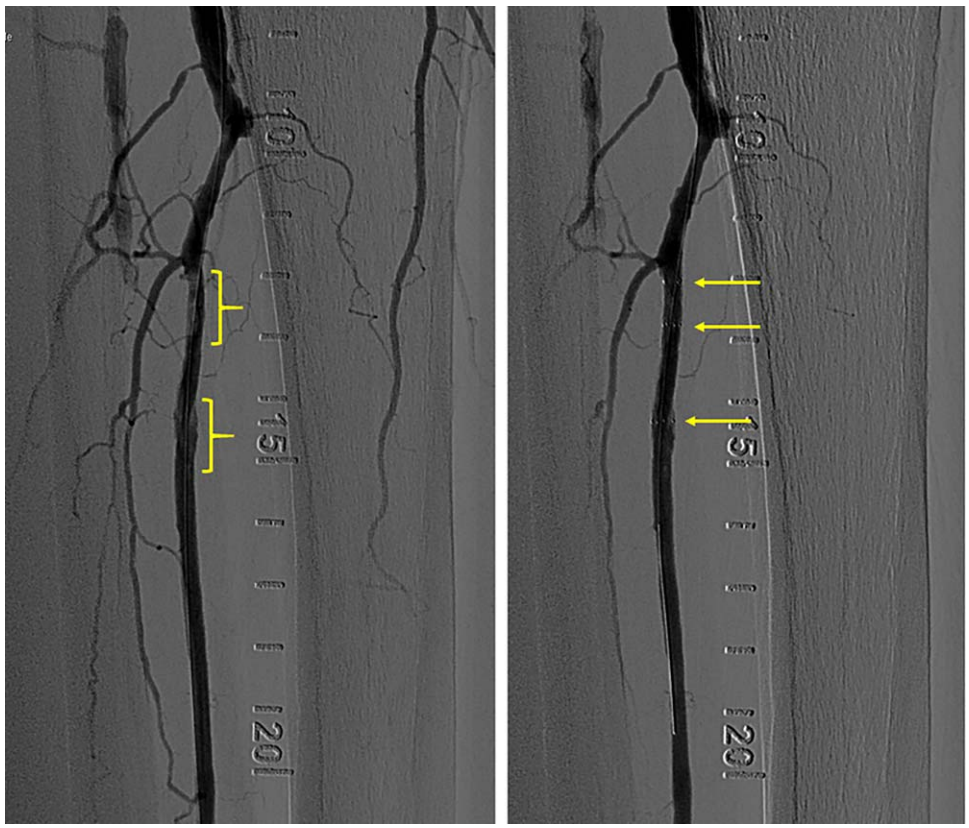

FIGURE 3 12 month primary patency per vessel. Primary patency was defined as presence of a Doppler signal, freedom from clinically driven target lesion revascularization and freedom from above the knee amputation. Primary patency presented as percent of vessels and 95% confidence intervals

limb. Device success was achieved in 32/35 (91.4%). In the three cases where device success was not achieved, the lesions were in the distal anterior tibial artery and the device was unable to be advanced to the desired position due to tortuous vessel anatomy and/or small vessel diameter. Figure 3 demonstrates an example of a post-PTA tibial dissection successfully repaired with Tack implants.

Major adverse limb event outcomes are summarized in Table 4. In the 30-day postprocedure period, no patients died, required limb amputation above the ankle, or required clinically driven TVR or TLR. At 12 months postprocedure, amputation-free survival was 84.5% (95% CI [66.6, 93.2]) and freedom from clinically driven TLR was 93.5% (95% CI [76.6, 98.3]).

Kaplan-Meier primary patency (Figures 4 and 5) was 78.4% (95% CI [58.4, 88.5]) per patient and 77.4% (95% CI [61.4, 88.5]) per vessel at 12 months. Primary assisted patency was 87.1% by patient and 89.2% by vessel at 12 months.

Changes in RC over time are displayed in Figure 6. At baseline, 11.4% and 88.6% of patients had an RC scores of 4 and 5, respectively. There was significant improvement in RC scores with 56.6% of the patients improving to RC class 0 or 1 at 6 months and 78.5% improving to RC class 0 or 1 at 12 months.

4 | DISCUSSION

The prospective multicenter TOBA-BTK (Tack Optimized Balloon Angioplasty-Below the Knee) study demonstrated the safety and feasibility of the utilization of the Tack Endovascular System for treating post-PTA dissections in patients with below-the-knee lesions and CLI. The primary technical endpoint of device technical success was achieved in 91.4% of patients. The primary safety endpoint of composite of MALE and peri-procedural death assessed at 1-month

TABLE 4 Major adverse limb events and death

Parameter	30 Days	3 Month	6 Month	12 Month
Amputation-free survival, composite of death/amputation	100% (NA, NA)	93.8% (77.5, 98.4)	93.8% (77.5, 98.4)	84.5% (66.6, 93.2)
Freedom from clinically driven target vessel revascularization	100% (NA, NA)	100% (NA, NA)	93.5% (76.6, 98.3)	93.5% (76.6, 98.3)
Freedom from clinically driven target lesion revascularization	100% (NA, NA)	100% (NA, NA)	93.5% (76.6, 98.3)	93.5% (76.6, 98.3)

Expressed as percent of patients and 95% confidence intervals.
NA = not applicable.

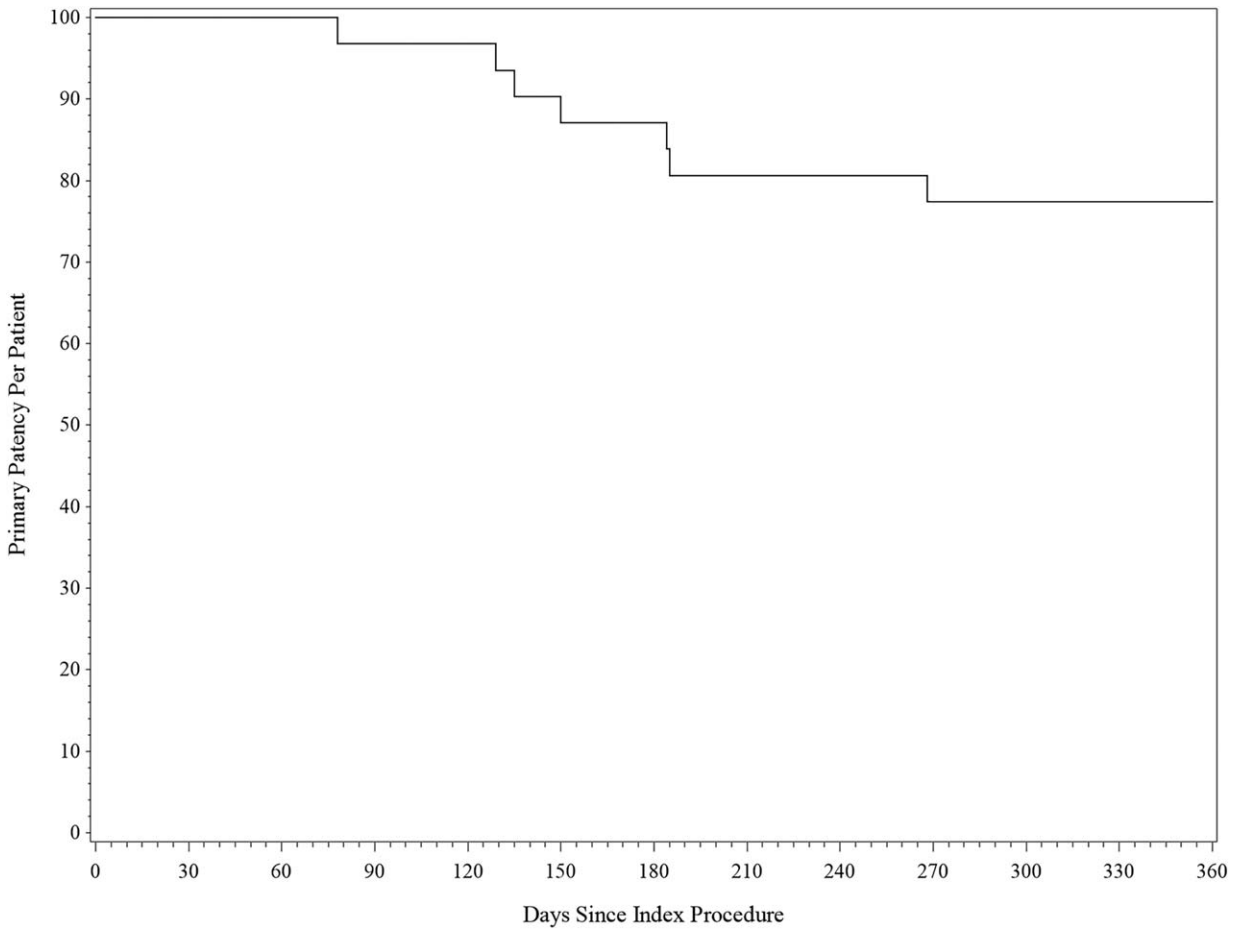

FIGURE 4 12 month primary patency per patient. Primary patency was defined as presence of a Doppler signal, freedom from clinically driven target lesion revascularization and freedom from above the knee amputation. Primary patency presented as percent of patients and 95% confidence intervals

postprocedure was achieved in 97.1% of patients. Twelve-month patency was 77.4% by patient and there were significant sustained clinical improvements in RC.

A previous evaluation of the Tack implant in femoropopliteal lesions showed similar safety and effectiveness results. A total of 130 patients were evaluated and device technical success was achieved in 98.5% of patients and the absence of new MAEs at 30 days was achieved in 100% of patients. Twelve-month freedom from CD-TLR was 89.5% and primary patency was 76.4%. As in the current study, there were significant sustained clinical improvements in ABI and RC [14].

Evaluations of strategies for revascularization of infrapopliteal lesions have indicated that the long-term patency is better in patients that receive tibial artery bypass when compared to PTA. Although the 12-month patency of infrapopliteal angioplasty is not as good as bypass ($58.1 \pm 4.6\%$ versus $81.5 \pm 2.0\%$; $P < .05$), the limb salvage rates are comparable ($86.0 \pm 2.7\%$ versus $88.5 \pm 2.2\%$; $P > .05$) [2,3]. Interestingly, this long-term patency has not been shown to correspond to an improved rate of limb salvage as both PTA and bypass were shown to have similar rates [2,3]. Given that limb salvage and reduced mortality are the desired outcomes in CLI associated with BTK disease, many treating physicians have opted to use PTA over bypass in this patient cohort. PTA has the advantage of better patient acceptance, lower health care utilization, and larger applicability when compared to bypass [4,5].

However, balloon angioplasty can have significant unfavorable effects to the vessel often resulting in dissection. The severity of dissection can range from mild disruptions of the vessel wall to severe flow limiting dissections [17]. The most common treatment for dissections is stenting. Stents are associated with failure, usually due to restenosis. Stent failure has been extensively studied in the femoropopliteal artery and many features of stents, including material, outward force, cell design, and strut thickness have been associated with poor outcomes [18–24].

The Tack system, with its shorter length and open cell design, addresses some of the challenges with stents including restenosis, metal burden and fracture [9,25–27]. In the previously published TOBA study, a mathematical model evaluation showed that metal burden was reduced by 81% by using Tacks to treat dissections when compared to stents [14]. In addition, the shorter length of Tacks should make them less susceptible to fracture, easier to cross for endovascular reintervention, and allow a placement location for a bypass graft reintervention.

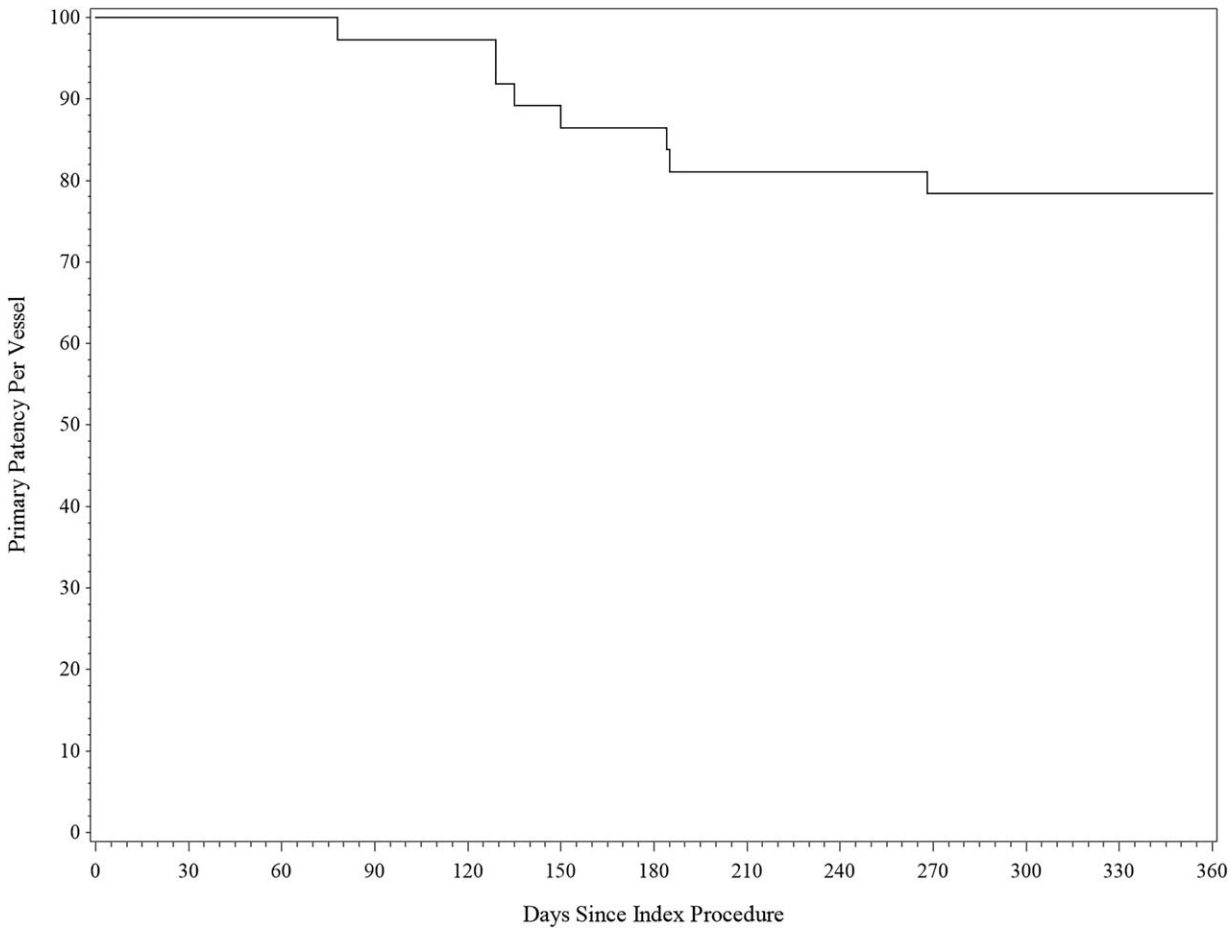

FIGURE 5 Rutherford category improvement. There was a significant ($p \leq 0.0001$) improvement in Rutherford Category score at all postprocedure time points through 12 months

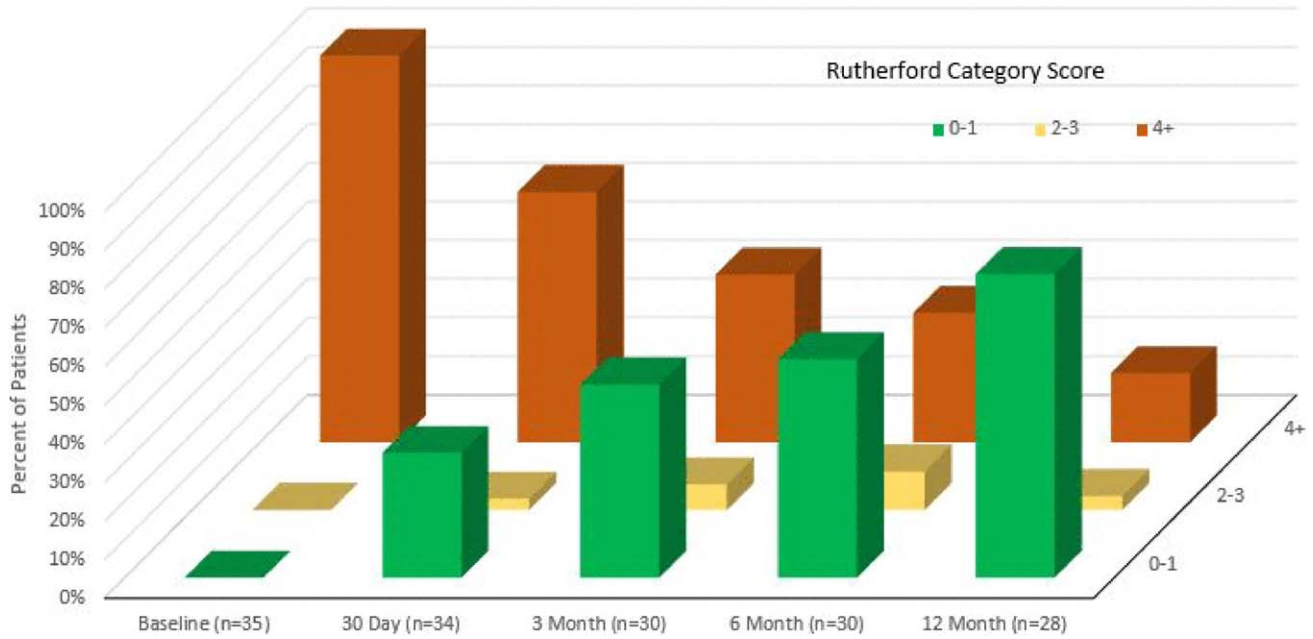

FIGURE 6 Example of resolved post-PTA dissection. Two dissections (arrows) resulted from balloon angioplasty (top). Three Tack implants (arrows) were placed (bottom)

Published data indicate that untreated post-PTA dissections, not just flow-limiting dissections, are associated with reduced patency. In one study, the 6-month TLR rate was 10.5% for patients without dissections and 33% and 44% for patients with grade A-B and C-E dissections, respectively [28]. Although post-PTA dissection is a well-known and widely reported feature of vascular intervention, accurate assessment of the severity and the clinical sequelae of dissections at the time of the procedure have proven difficult. In this clinical trial, all dissections were treated in an effort to reduce the negative consequences associated with untreated dissections. The predicate TOBA study data support the concept that treatment of femoropopliteal dissections has a beneficial effect on clinical outcomes [14]. In patients with CLI caused by infrapopliteal lesions, the Tack Endovascular System appears to be a feasible alternative to stenting post-PTA dissections.

5 | LIMITATIONS

This study was conducted as a first-in-human evaluation of infrapopliteal lesions in a small number of patients. As such, it was a single arm study and there was no contemporary comparator group. This study, along with the previously published TOBA study in above the knee lesions, has shown the applicability of this treatment in patients with short lesions in two anatomic areas. The broad applicability of these results requires further studies. All patients were treated with nondrug coated balloons, so it is not known if there could be additional benefit of combining DCB with Tack devices. Using the data obtained in the TOBA and TOBA BTK studies, TOBA II (NCT 02522884) and TOBA III (NCT02802306) were designed to evaluate Tacks in combination with DCB angioplasty and in longer lesions. TOBA II BTK was designed to further investigate the use of the Tack implant in the BTK arteries (NCT02942966).

6 | CONCLUSION

Treatment of post-PTA dissections in the BTK arteries was safe and effective and resulted in reasonable 12-month patency and low rates of CD-TLR. Treatment with Tack implants may represent a reasonable alternative to stenting for post-PTA dissection repair.

INSTITUTIONS AT WHICH THE WORK WAS PERFORMED

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