The Tack-Optimized Balloon Angioplasty (TOBA) II Below-the-Knee Trial: 36-Month Results

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Abstract

PURPOSE: To report the 36-month results of the Tack-Optimized Balloon Angioplasty (TOBA) II below-the-knee (BTK) study for repair of post-percutaneous transluminal angioplasty (PTA) dissection(s) of the infrapopliteal arteries. **MATERIALS AND METHODS:** TOBA II BTK is a prospective, multicenter, single-arm evaluation of the Tack Endovascular System (Intact Vascular, Inc., now a part of Philips Image Guided Therapy Corporation) for post-PTA BTK dissection repair. Patients with Rutherford category 3 to 5 and a post-PTA dissection(s) of the mid/distal popliteal, tibial, and/or peroneal arteries were enrolled. The primary safety endpoint was a composite of major adverse limb events (MALE) and all-cause perioperative death (POD) at 30 days. The primary effectiveness endpoint was a composite of MALE at 6 months and 30-day POD. Outcomes are reported through 36 months. **RESULTS:** TOBA II BTK enrolled 233 patients with 301 post-PTA dissection(s); all patients received 1 or more Tack implant(s) (range, 1-16). Mean age was 74.4 ± 10.0 years and 67.4% were men. Most patients had critical limb-threatening ischemia (83.7%). Kaplan-Meier freedom from MALE at 36 months + POD at 30 days was 91.6%. Freedom from clinically driven-target lesion revascularization (CD-TLR) was 69.6%. High rates of target limb salvage (TLS; 95.0%) and amputation-free survival (AFS; 64.7%) were also reported. Improvements in quality of life (QoL), mobility, and Rutherford category were sustained through 36 months. **CONCLUSIONS:** The Tack Endovascular System for infrapopliteal dissection repair demonstrates durable freedom from MALE + POD and CD-TLR and high rates of TLS and AFS through 36 months. Improvements were also sustained in QoL, mobility, and Rutherford category.

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KEY WORDS: post-percutaneous transluminal angioplasty dissection, peripheral artery disease, critical limb-threatening ischemia

Peripheral artery disease (PAD) affects more than 200 million people worldwide,[1] and the incidence continues to increase with the growth of the aging population.[2] Treatment for PAD includes endovascular and surgical intervention;[2] however, below-the-knee (BTK) disease is particularly challenging to treat due to diffuse and multilevel disease.[3] Furthermore, patients often present with critical limb-threatening ischemia (CLTI), which manifests as pronounced rest pain, tissue loss, and ulceration.[4] When endovascular or surgical revascularization is not successful or is not indicated, patients with BTK disease face remarkably high rates of amputation and mortality.[5]

Percutaneous transluminal angioplasty (PTA) relies on mechanical dilatation and dissection of the vessel wall to initiate revascularization. However, post-PTA acute dissection occurs in 47% to 88% of BTK treatments[6,7] and is associated with infrapopliteal restenosis.[2,8-10] Prolonged secondary balloon inflation and the off-label use of coronary stents have traditionally been utilized to treat post-PTA dissections but are associated with high rates of restenosis at 1 year.[11-13]

The Tack Endovascular System (Intact Vascular, Inc., now a part of Philips Image Guided Therapy Corporation) was purpose-built to treat dissections that occur following PTA (**Supplemental Figure 1**). Tack implants are self-expanding and mitigate many of the issues associated with off-label coronary stent placement, such as the risk of fracture and in-stent restenosis. The implants are designed with an open-cell design,

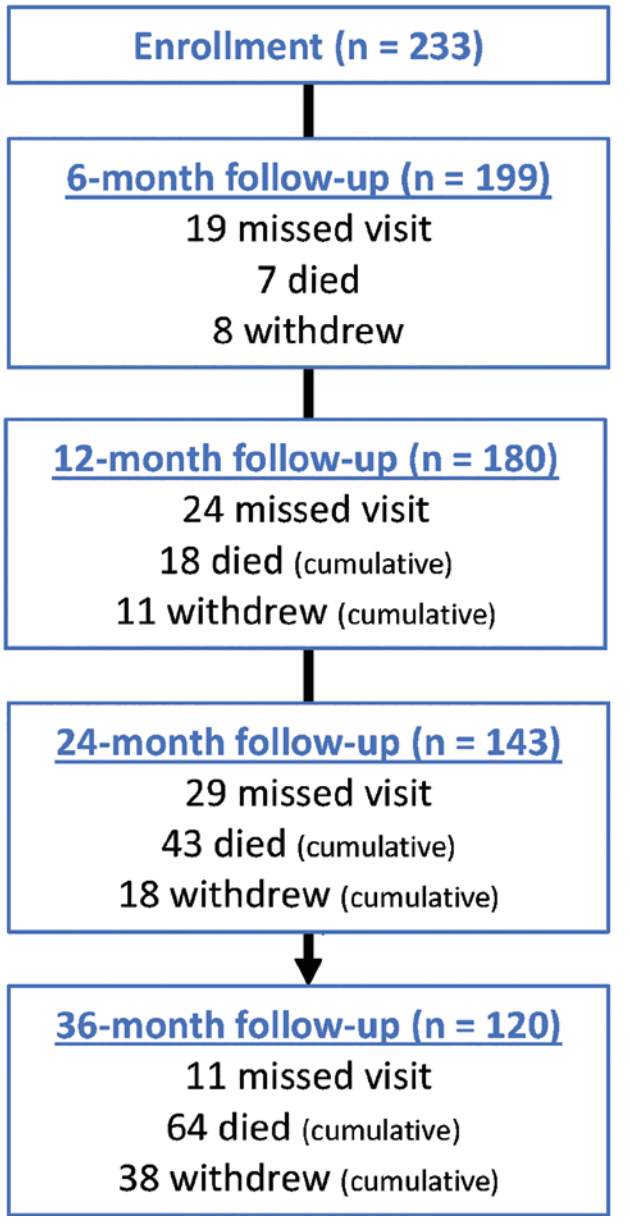

FIGURE 1. Patient enrollment and follow-up.

low outward radial force, and reduced metal burden relative to stents. The 4F Tack Endovascular System was specifically built for treatment of post-PTA dissections in BTK arteries.

The Tack-Optimized Balloon Angioplasty (TOBA) II BTK trial was designed to assess the 4F Tack Endovascular System for post-PTA dissection repair of the mid/distal popliteal, tibial, and peroneal arteries ranging from 1.5 mm to 4.5 mm in diameter. The 6-, 12-, and 24-month results demonstrated that Tack displays safety and efficacy along with improved functional outcomes in patients with BTK disease.[14-16] The objective of this study is to present the TOBA II BTK results through 36 months. Patients were stratified into intermittent claudication (IC) and CLTI cohorts.

Methods

Study Design

TOBA II BTK (NCT02942966) was an early phase prospective, single-arm, open-label, multicenter study performed at 41 sites throughout the United States, Europe, and New Zealand.[14] The study was single-arm as no appropriate comparator existed at the time of study design. Patients with angiographic evidence of a post-PTA dissection that required repair (per the operating physician's discretion) in the mid/distal popliteal, tibial, and/or peroneal arteries were enrolled. The study was conducted in compliance with the Declaration of Helsinki, International Conference on Harmonization E6—Good Clinical Practice, and ISO 14155, and it was approved by all relevant institutional review boards and/or ethics committees. All patients provided informed consent.

Eligibility

The TOBA II BTK eligibility criteria were previously described.[14–16] Briefly, patients with Rutherford category 3 to 5 ischemia were eligible if they required post-PTA dissection repair of the P2/P3 popliteal, tibial, and/or peroneal arteries, ranging from 1.5 mm to 4.5 mm in diameter, that would have otherwise been treated with prolonged angioplasty, off-label stent deployment, or bypass surgery.

Procedure

Procedural details were previously published.[14–16] In brief, the 4F Tack Endovascular System is pre-loaded with 4 independent Tacks. Following angiographic detection of a dissection using a core laboratory protocol, the delivery catheter was loaded onto the 0.014" PTA guidewire and was advanced to the treatment site. Patients were enrolled in the study after introduction of the Tack Endovascular System through the introducer sheath. Tacks were deployed in a distal-to-proximal direction and were post-dilatated. Vessel patency was confirmed by angiography. Bailout stenting was permitted.

Outcomes

Follow-up occurred at 6, 12, 24, and 36 months. Previous publications have reported results for the primary safety endpoint, a composite of major adverse limb events (MALE) and perioperative death (POD) at 30 days, and the primary effectiveness endpoint, freedom from MALE at 6 months + POD at 30 days as well as observational outcomes at 12 and 24 months.[14-16] In this study, we report the 36-month safety endpoint (freedom from MALE at 36 months and POD at 30 days) and additional observational endpoints (ie, clinically driven target lesion revascularization [CD-TLR], target limb salvage [TLS], and amputation-free survival

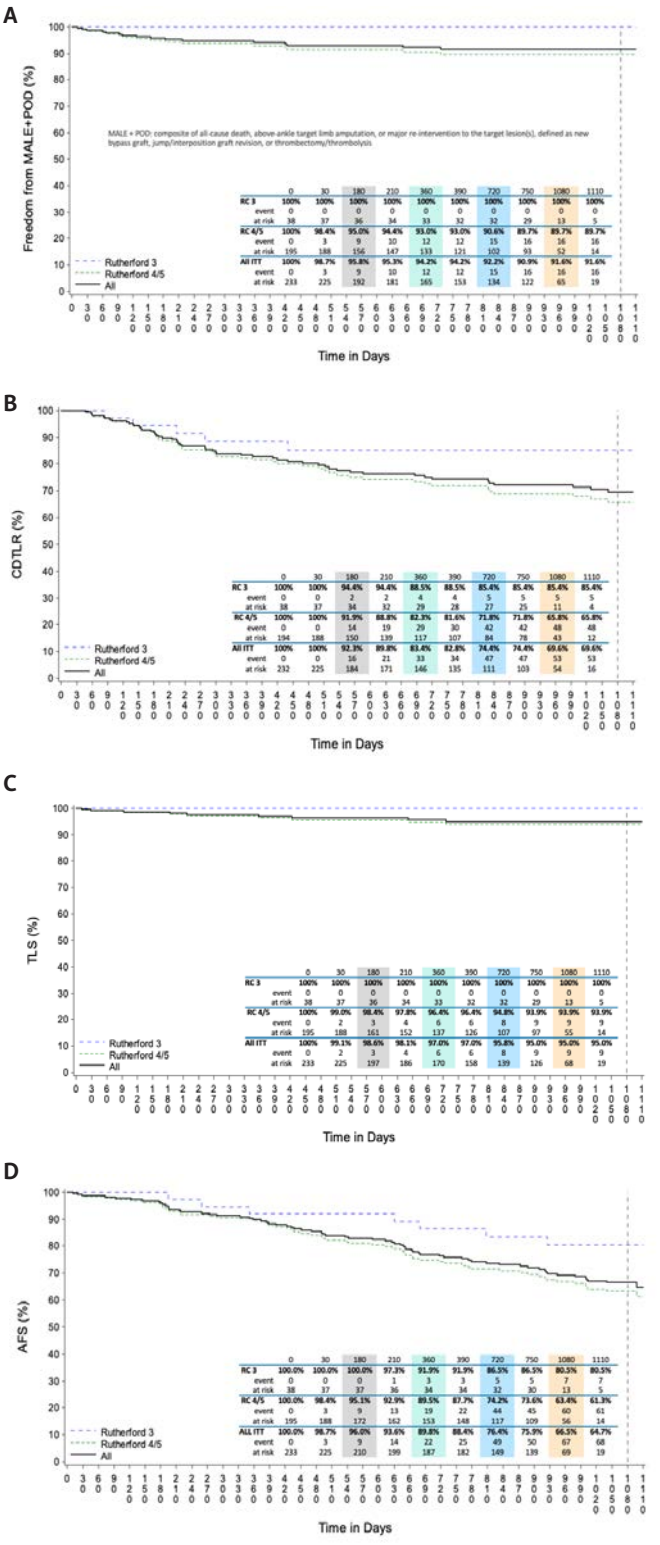

FIGURE 2. Kaplan-Meier curve for A) freedom from major adverse limb events + perioperative death in intent-to-treat (ITT) subjects through 36 months; B) freedom from clinically driven-target lesion revascularization in ITT subjects through 36 months; C) target limb salvage in ITT subjects through 36 months; D) amputation-free survival in ITT subjects through 36 months.

[AFS]). Functional outcomes at 36 months include improvement in Rutherford category, ankle-brachial index (ABI), tibial-brachial index (TBI), quality of life (QoL) as measured with the EQ-5D-3L, and mobility as measured by the Walking Impairment Questionnaire (WIQ).

An independent clinical events committee adjudicated safety outcomes, and study oversight was monitored by a data safety monitoring board. Independent core laboratories reviewed all angiograms, X-rays (Yale Cardiovascular Research Group) and duplex ultrasounds (VasCore, Massachusetts General Hospital).

Statistical Analyses

The statistical methods employed in the study were also reported in detail in prior publications.[14-16] Briefly, the intent-to-treat (ITT) population was comprised of all patients who had the Tack Endovascular System advanced through the introducer sheath. The ITT population was used for endpoint analyses. Continuous variables are reported as mean, standard deviation, and sample size. Alternative statistics such as median were considered if the mean was not appropriate. For categorical variables, the percentage of patients experiencing the event is presented along with the number of patients experiencing the event and sample size. Kaplan-Meier estimates were used to evaluate time-to-event data for freedom from MALE + POD, freedom from CD-TLR, TLS, and AFS. Statistical analyses were performed using SAS software (version 9.4).

Results

Enrollment and demographics

TOBA II BTK enrolled 233 patients at 41 sites who demonstrated angiographic evidence of a post-PTA dissection requiring repair (at the discretion of the physician) in the mid/distal popliteal, tibial, and/or peroneal arteries. Of these, 120 were included in the 36-month follow-up (**Figure 1**). Baseline patient, lesion, and angiographic characteristics were reported previously.[14-16] Briefly, the mean age was 74.4 ± 10.0 years and 67.4% were males. Most patients presented with Rutherford category 4/5 (83.7%). There was a high rate of diabetes (65.7%), total occlusions (47.6%), and smoking history (62.2%). The mean baseline target lesion length was 80 ± 49 mm. PTA was performed in 248 lesions and resulted in 301 dissections. Most (41.5%) dissections occurred in the anterior tibial vessels. The worst dissection per patient was grade A in 21.4%, grade B in 39.3%, grade C in 11.8%, grade D in 26.6%, and grade E in 0.9%. The mean number of Tacks deployed per patient for dissection repair was 4.0 ± 2.8 implants (**Supplemental Tables 1** and **2**).

Outcomes

At 36 months, freedom from MALE + POD was 91.6% in the total patient population (**Figure 2A**). In patients with IC (Rutherford category 3), 36-month freedom from MALE + POD was 100.0%. In patients with CLTI (Rutherford category 4/5), freedom from

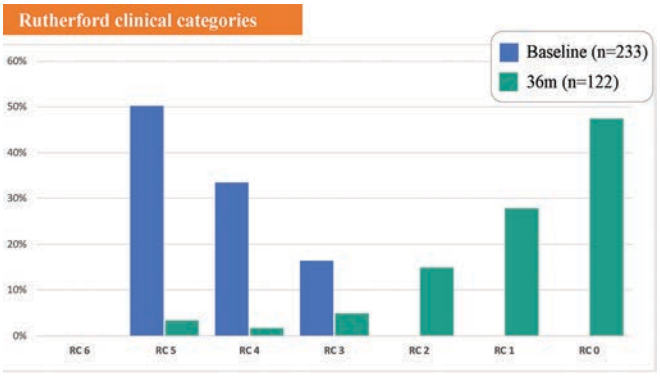

FIGURE 3. Sustained improvement in Rutherford category to 36 months (intent-to-treat population, site reported); *P*<.0001 baseline vs 36 months (Wilcoxon signed-rank test). m, month.

MALE + POD was 89.7% at 36 months.

The 36-month freedom from CD-TLR was 69.6% in all patients (**Figure 2B**). Freedom from CD-TLR in patients with Rutherford category 3 was 85.4%; in patients with Rutherford category 4/5, it was 65.8%.

The TLS rate at 36 months was 95.0% in all patients (**Figure 2C**). In patients with Rutherford category 3, it was 100% compared with 93.9% in patients with Rutherford category 4/5. The AFS rate was 64.7% in all patients (**Figure 2D**). In those with Rutherford category 3, it was 80.5% compared with 61.3% in patients with Rutherford category 4/5.

Functional Outcomes

Of the patients with 36-month follow-up, 70.4% improved 3 or more Rutherford categories and 48.3% improved 4 or more Rutherford categories (**Figure 3**) (*P*<.0001 compared with baseline). Improvements were sustained in both ABI (*P*<.0001) and TBI (*P*<.0001) throughout the 36-month follow-up window (**Figure 4**). Improvements were also sustained in self-care, anxiety, activity, and pain on the EQ-5D-3L (**Supplemental Figure 2A**) and in overall health on the Visual Analog Score (VAS) (**Supplemental Figure 2B**). Finally, improvements in mobility were sustained through 36 months on the WIQ (*P*<.0001) (**Supplemental Figure 3A**) and PAD-specific questionnaire (*P*<.001) (**Supplemental Figure 3B**).

Discussion

The Tack Endovascular System is a single catheter pre-loaded with self-expanding nitinol implants and is indicated for placement both above-the-knee (6 implants and a 6F delivery system) and BTK (4 implants and a 4F delivery system). Tacks adapt to tapering anatomy while keeping a constant radial force to treat multiple dissections. The first-of-its-kind implant treats dissections with precision, avoids stenting healthy tissue, and leaves behind 70% less metal than traditional stents to preserve future treatment options.[17] If left untreated, dissections can adversely affect vessel patency, target lesion revascularization rates, and patient outcomes.[6,18]

This study reports the 36-month follow-up data for patients treated with the Tack Endovascular System in the infrapopliteal arteries. The complex patient population was primarily comprised of patients with CLTI. Notably, site-reported moderate-to-severe calcium was present in 35.8% of lesions and total occlusions were present in 47.6% lesions. There were also high rates of diabetes

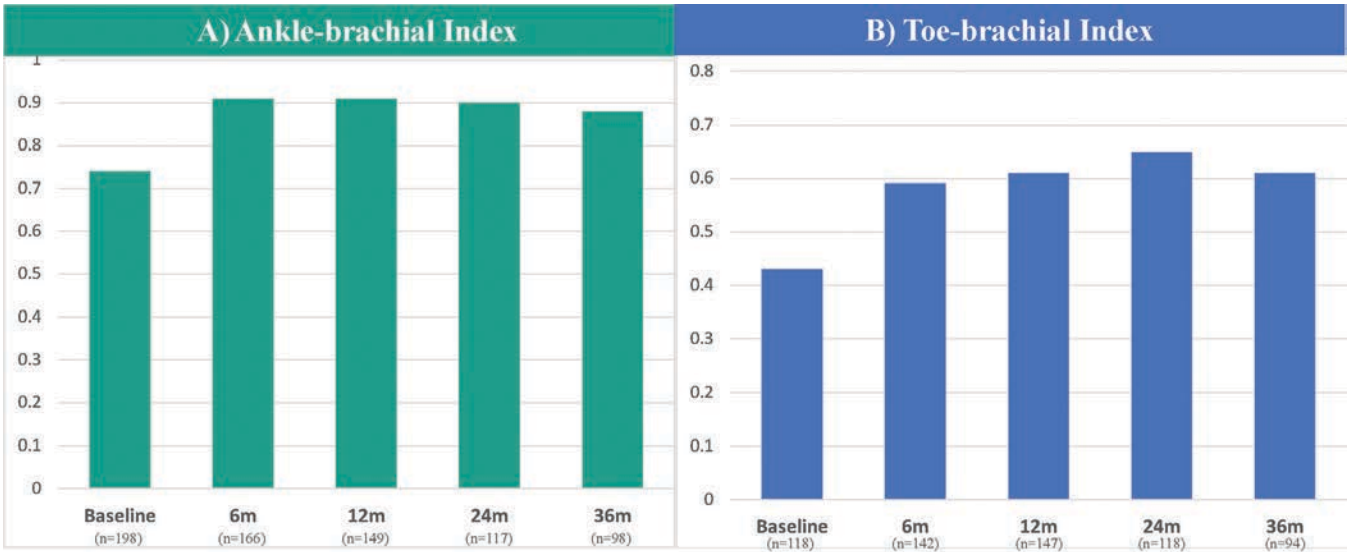

FIGURE 4. Sustained clinical improvement in A) ankle-brachial Index and B) toe-brachial Index to 36 months (intent-to-treat population, site reported); *P*<.0001 baseline vs 36 months (Wilcoxon signed-rank test). m, month.

(65.7%), smoking (62.2% current or former), and chronic kidney disease (24.6%). Despite the complex patients and lesions, all dissections were completely resolved per core lab adjudication. At 36 months, the TOBA II BTK trial demonstrates 69.6% freedom from CD-TLR across all patients and freedom from MALE + POD, TLS, and AFS rates of 89.7%, 93.9%, and 63.4%, respectively, in patients with CLTI. Thirty-six-month outcomes were further associated with sustained improvements in ABI/TBI, patient-reported QoL, mobility, and Rutherford category. Improvements in Rutherford category are particularly important, as those with Rutherford category 5 or higher show an increased risk of cardiovascular events and amputation, and a 5-year mortality rate of over 50%.[5] At baseline, 83.7% of patients began with a Rutherford category of 4/5; at month 36, approximately 5% of patients remained in this category.

The 36-month results presented in this manuscript are consistent with the TOBA II BTK 12- and 24-month follow-up results, which were published previously.[15,16] The primary effectiveness endpoint, freedom from MALE + 30-day POD, was 93.4%, 92.2%, and 91.6% at 12, 24, and 36 months, respectively, and improvements were sustained across all timepoints for scores measuring ABI, TBI, QoL (EQ-5D-3L assessment), WIQ, and EQ-VAS for overall health.

In this study, dissections were detected using an angiographic core laboratory protocol. However, the iDissection study demonstrated that dissections can be underdiagnosed if examined solely by angiography compared with intravascular ultrasound (IVUS). In a study of the infrapopliteal arteries (N = 20 patients), IVUS uncovered 3.8 times more dissections than revealed by angiography alone following treatment with PTA or orbital atherectomy. Furthermore, angiography underestimated the severity of dissections compared with IVUS. These data indicate that the use of IVUS may further optimize angioplasty by revealing BTK dissections that would go undetected when visualized by angiography alone.[19-20] IVUS may be especially valuable in identifying infrapopliteal dissections as detection is hindered by small vessel size.

Currently, the TOBA II BTK trial is the only BTK investigational device exemption study to be fully enrolled. Furthermore, to date, the Tack Endovascular System remains the only BTK implant with 36-month data. The Saval drug-eluting stent (Boston Scientific), Esprit bioresorbable stent (Abbott), and MicroStent (Micro Medical Solutions) each received breakthrough device designation from the FDA.[21-23] The SAVAL trial planned to enroll 301 patients in a 2-phase study to assess the nitinol self-expanding Saval paclitaxel-eluting stent vs PTA for the treatment of CLTI in BTK arteries.[21] The results of Phase A of the SAVAL study (N = 201) were recently released and showed that although there was high technical success, the primary safety (noninferior 12-month major adverse event-free rate) and effectiveness (superior 12-month primary patency) endpoints were not met. However, in-office follow-up will continue through 3 years, with vital status assessment through 5 years. The LIFE-BTK trial will assess the Esprit BTK everolimus-eluting resorbable scaffold vs PTA in 225 patients with infrapopliteal disease.[22] Finally, the STAND clinical trial will evaluate the self-expanding nitinol MicroStent compared with PTA for BTK disease in 177 patients.[23] It is important to note that while the 4F Tack BTK Endovascular System contains 4 tacks that are 6.0 mm in size, the Saval investigational stent length was 80.0 mm (2 stents were allowed to be placed per protocol) and the Esprit drug-eluting bioresborable scaffold is designed to cover lengths between 170 mm and 256 mm. The MicroStent is designed to be much smaller than a traditional stent and is available in lengths of 8 mm to 60 mm. However, at this time, the Tack Endovascular System remains the only scaffold that is FDA approved for use in the infrapopliteal arteries.

Limitations

TOBA II BTK was a single-arm study with a nonrandomized design due to the lack of a comparator device at the time of study design. Furthermore, although the study was originally designed to enroll Rutherford categories 3 to 6, the study only enrolled a small number of patients with IC before the protocol was amended to exclude these patients. However, because the results were consistent in this small patient population, we do not anticipate that larger enrollment of the Rutherford category 3 cohort would influence the interpretation of this study for patients with IC. Dissections were identified using an angiographic core laboratory protocol and may have gone undiagnosed without the use of IVUS. Finally, no patients with Rutherford category 6 were enrolled, and the results should be interpreted with caution in patients with CLTI and major tissue loss.

Conclusion

The TOBA II BTK study demonstrates safety and efficacy for post-PTA dissection repair in infrapopliteal lesions through 36 months. High rates of freedom from MALE + POD and CD-TLR, in conjunction with high rates of TLS and AFS through 36 months, were noted in patients with IC (Rutherford category 3) as well as CLTI (Rutherford category 4/5). Outcomes were associated with important and sustained improvements in Rutherford category, ABI/TBI, and patient-reported QoL and mobility, demonstrating that dissection repair with the Tack Endovascular System optimized BTK angioplasty with durable results through 36 months. Currently, the Tack Endovascular System is the only BTK implant with 36-month data and the only scaffold approved by the FDA for use in infrapopliteal arteries.

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Prior Presentations

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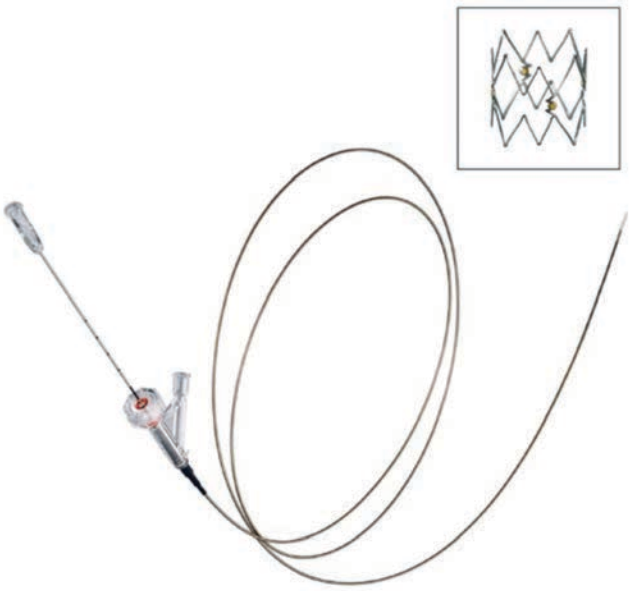
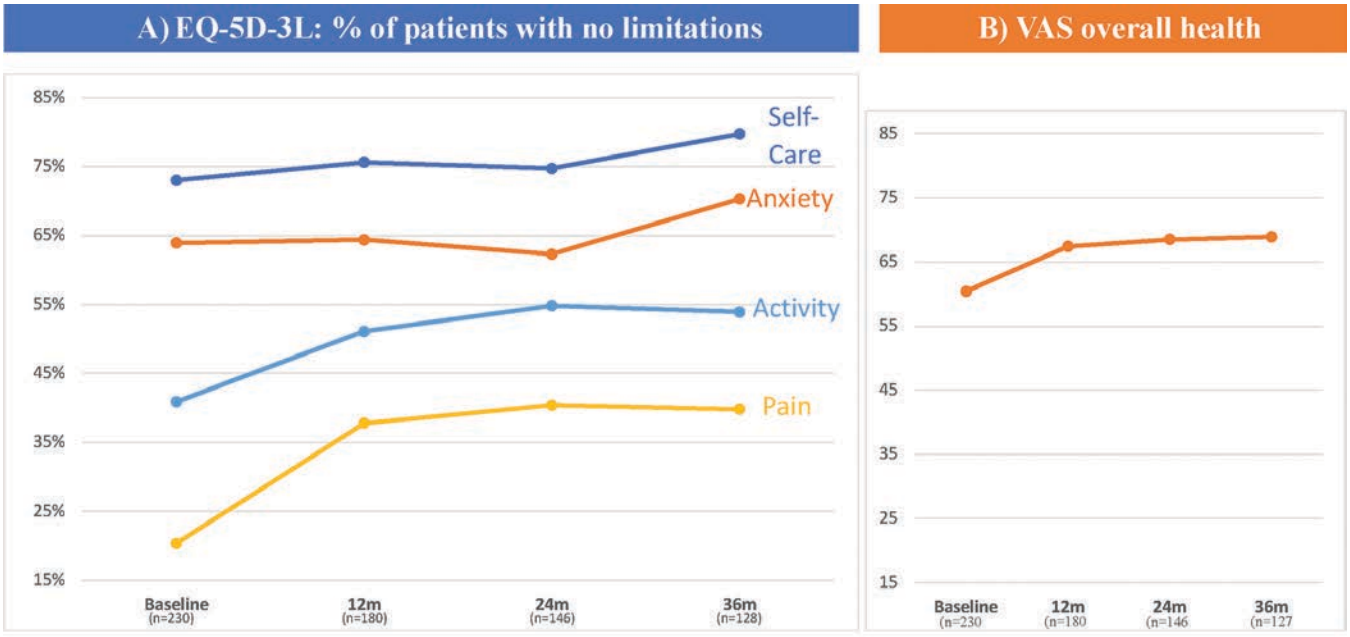
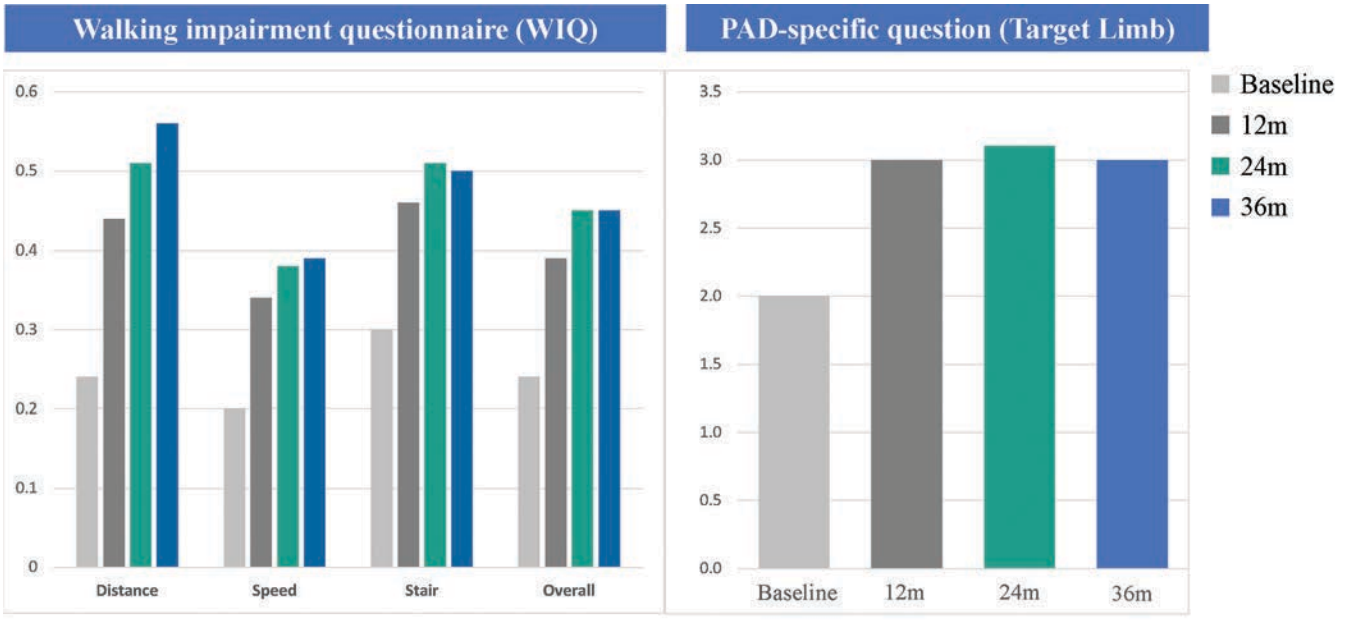
Supplemental Materials



SUPPLEMENTAL FIGURE 1. Tack implant and Tack Endovascular System (Intact Vascular, Inc., now a part of Philips Image Guided Therapy Corporation; 4F, 1.5 mm-4.5 mm reference vessel diameter).



SUPPLEMENTAL FIGURE 2. Sustained improvement in quality of life to 36 months measured by A) patient-reported EQ-5D-3L and B) visual analog score overall health (intent-to-treat population); m, month.



SUPPLEMENTAL FIGURE 3. Sustained improvement in mobility to 36 months measured by A) patient-reported Walking Impairment Questionnaire (WIQ) and B) the peripheral artery disease-specific question (target limb), (intent-to-treat population); *P*<.0001 baseline vs 36 m (Wilcoxon signed-rank test). m, month.

SUPPLEMENTAL TABLE 1. BASELINE CHARACTERISTICS FOR THE 233 STUDY PATIENTS WITH 248 BELOW-THE-KNEE TARGET LESIONS

Patient characteristics	Mean ± SD (N) or % (n/N)
Age (y)	74.4 ± 10.0 (233)
Male gender	67.4% (157/233)
Race	80.3% White 16.7% Black or African American
Rutherford category	3 16.3% (38/233) 4 33.5% (78/233) 5 50.2% (117/233)
TBI target limb	0.43 ± 0.23 (118)
Smoking history	62.2% (145/233)
Diabetes mellitus	65.7% (153/233)
Arterial hypertension	93.6% (218/233)
Coronary artery disease	56.1% (129/230)
MI	22.0% (51/232)
PCI / CABG	43.9% (101/230)
Chronic renal insufficiency	24.6% (57/232)
Lesion characteristics (core lab adjudicated)	
RVD (mm)	
Proximal	3.5 ± 1.0 (248)
Distal	2.6 ± 0.7 (248)
Lesion length (mm)*	
Baseline	80 ± 49 (248)
PTA treatment	154 ± 110 (238)
Pre-PTA DS%	85 ± 17 (248)
Total occlusion	47.6% (118/248)
Calcium (PARC)	
None/mild	63.1% (159/248)
Moderate	18.1% (45/248)
Severe	17.7% (44/248)
Distal target vessel	
P2/P3 (popliteal)	5.2% (13/248)
TP trunk	10.1% (25/248)
Anterior tibial	41.5% (103/248)
Posterior tibial	22.2% (55/248)
Peroneal	21.4% (53/248)

*Site-reported baseline lesion length: 116 ± 100 (277)
CABG, coronary artery bypass grafting; DS, diameter stenosis; MI, myocardial infarction; PARC, Peripheral Academic Research Consortium; PCI, percutaneous coronary intervention; PTA, percutaneous transluminal angioplasty; RVD, reference vessel diameter; SD, standard deviation; TBI, tibial-brachial index; TP, tibioperoneal.

SUPPLEMENTAL TABLE 2. LESION AND PROCEDURAL CHARACTERISTICS

Parameter	Mean ± SD (N) (Min, Median, Max) or % (n/N)
Target limb treated[a]	
Left	43.8% (102/233)
Right	56.2% (131/233)
Inflow lesions treated[a]	35.6% (83/233)
Ipsilateral iliac artery	3.6% (3/83)
Common femoral artery	1.2% (1/83)
Superficial femoral artery	63.9% (53/83)
Proximal popliteal artery	8.4% (7/83)
P1 / SFA / Iliac	1.2% (1/83)
P1 / SFA	21.7% (18/83)
Number of lesions treated per patient[a]	
1	92.2% (212/230)
2	7.8% (18/230)
Number of distal runoff vessels[b]	
Absent	0.0% (0/244)
1	28.3% (69/244)
2	46.7% (114/244)
3	25.0% (61/244)
Total occlusion[b]	47.6% (118/248)
Calcification[b]	
None/mild	64.1% (159/248)
Moderate	18.1% (45/248)
Severe	17.7% (44/248)
Proximal reference vessel diameter (mm)[b]	3.5 ± 1.0 (248) (1.7, 3.3, 8.1)
Distal reference vessel diameter (mm)[b]	2.6 ± 0.7 (248) (1.2, 2.5, 5.5)
Most proximal target lesion location[b]	
Mid popliteal	12.1% (30/248)
Distal popliteal	12.1% (30/248)
Anterior tibial	33.9% (84/248)
Posterior tibial	12.9% (32/248)
Tibioperoneal trunk	18.1% (45/248)
Peroneal	10.9% (27/248)

TABLE CONTINUES

SUPPLEMENTAL TABLE 2. LESION AND PROCEDURAL CHARACTERISTICS

Parameter	Mean ± SD (N) (Min, Median, Max) or % (n/N)
Most distal target lesion location[b]	
Mid popliteal	4.0% (10/248)
Distal popliteal	1.2% (3/248)
Anterior tibial	41.5% (103/248)
Posterior tibial	22.2% (55/248)
Tibioperoneal trunk	9.7% (24/248)
Peroneal	21.4% (53/248)
Baseline target lesion percent diameter stenosis (%)[b]	85 ± 17 (248) (31,92,100)
Target lesion length[b]	80 ± 49 (248) (8,71,237)
Injured lesion length[b]	154 ± 110 (238) (13, 120, 438)
Thrombus present (after PTA treatment)[a]	0.0% (0/230)
Target lesion residual diameter stenosis post-PTA, pre-Tack (%)[b]	27.9 ± 12.1 (248) (0.0, 26.9, 90.4)
Presence of one or more dissections[a]	99.6% (229/230)
Number of dissections per subject[a]	1.4 ± 0.6 (229) (1.0, 1.0, 4.0)
Dissection length (mm)[c]	24 ± 18 (341) (3, 19, 104)
All dissection types post-PTA, pre-Tack[c]	
None (no dissection)	0.0% (0/341)
A	24.9% (85/341)
B	38.7% (132/341)
C	10.3% (35/341)
D	25.5% (87/341)
E	0.6% (2/341)
F	0.0% (0/341)
Most severe dissection per subject post-PTA, pre-Tack[a]	
None (no dissection)	0.0% (0/229)
A	21.4% (49/229)
B	39.3% (90/229)
C	11.8% (27/229)
D	26.6% (61/229)
E	0.9% (2/229)
F	0.0% (0/229)

TABLE CONTINUES

SUPPLEMENTAL TABLE 2. LESION AND PROCEDURAL CHARACTERISTICS

Parameter	Mean ± SD (N) (Min, Median, Max) or % (n/N)
Most severe dissection per subject, post-Tack[a]	
None (no dissection)	100.0% (229/229)
A	0.0% (0/229)
B	0.0% (0/229)
C	0.0% (0/229)
D	0.0% (0/229)
E	0.0% (0/229)
F	0.0% (0/229)
Number of Tacks deployed per subject[a]	4.0 ± 2.8 (230) (1.0, 3.0, 16.0)
Number of Tacks used to treat each dissection[c]	2.6 ± 1.6 (341) (1.0, 2.0, 12.0)
Number of Tacks deployed per target lesion vessel and segment[d]	
Popliteal artery	10.4% (96/918)
Proximal	0.4% (4/918)
Mid	4.6% (42/918)
Distal	5.4% (50/918)
Anterior tibial artery	44.4% (408/918)
Proximal	19.5% (179/918)
Mid	15.1% (139/918)
Distal	9.8% (90/918)
Tibioperoneal trunk	10.9% (100/918)
Peroneal artery	17.5% (161/918)
Proximal	13.3% (122/918)
Mid	2.2% (20/918)
Distal	2.1% (19/918)
Posterior tibial artery	16.9% (155/918)
Proximal	11.1% (102/918)
Mid	4.1% (38/918)
Distal	1.6% (15/918)
Post-dilatation performed[a]	99.6% (232/233)
Final residual diameter stenosis (%)[b]	24 ± 9 (248) (5, 4, 100)
Bailout stent placed[a]	1.3% (3/233)
Bailout stent placed in tacked segment[a]	0.4% (1/233)
Any adverse events during procedure[a]	4.7% (11/233)

P1, proximal popliteal artery; PTA, percutaneous transluminal angioplasty; SD, standard deviation; SFA, superficial femoral artery
[a]variable reported per patient; [b]variable reported per target lesion; [c]variable reported per dissection; [d]variable reported per Tack implant