Check for updates

Received: 3 February 2023 | Revised: 7 June 2023 | Accepted: 28 July 2023

DOI: 10.1002/ccd.30800

ORIGINAL ARTICLE - CLINICAL SCIENCE

WILEY

Optimized drug-coated balloon angioplasty of the superficial femoral and proximal popliteal arteries using the Tack Endovascular System: Tack Optimized Balloon Angioplasty (TOBA) III 24-month results in standard and long lesions

Marianne Brodmann MD[1] | Christian Wissgott MD[2] | Klaus Brechtel MD[3] | Michael Lichtenberg MD[4] | Erwin Blessing MD[5] | Trisha Tarra PhD[6] | Thomas Zeller MD[7]

[1]Division of Angiology, Medical University Graz, Graz, Austria

[2]Imland Klinik Rendsburg, Rendsburg, Germany

[3]Interventional Radiology, Franziskus-Hospital Berlin, Berlin, Germany

[4]Vascular Center Arnsberg, Arnsberg, Germany

[5]SRH Klinikum Karlsbad-Langensteinbach, Karlsbad, Germany

[6]Philips North America, LLC, Cambridge, Massachusetts, USA

[7]Universitaets-Herzzentrum Freiburg – Bad Krozingen, Bad Krozingen, Germany

Correspondence
Thomas Zeller, Universitaets-Herzzentrum Freiburg – Bad Krozingen, Bad Krozingen, Germany.
Email: Thomas.Zeller@uniklinik-freiburg.de

Funding information
The study was funded by Intact Vascular, Inc., now a part of Philips Image Guided Therapy Corporation (Plymouth, MN).

Abstract

Objective: The Tack Endovascular System is a minimal-metal dissection repair device that is purpose-built to treat post-percutaneous angioplasty (PTA) arterial dissections in patients with peripheral arterial disease (PAD). The Tack Optimized Balloon Angioplasty (TOBA) III trial evaluated the safety and effectiveness of the Tack Endovascular System in patients with superficial femoral artery (SFA) and/or proximal popliteal artery (PPA) dissection after PTA with a drug-coated balloon (DCB). The objective of this study is to report the results in the standard- (SL) and long-lesion (LL) cohorts through 24 months.

Design: The TOBA III study was a prospective, multicenter, single-arm study including patients suffering from Rutherford category 2–4 PAD. Outcomes were assessed according to pre-specified lesion length in SL (≥ 20 mm and ≤150 mm) and LL (> 150 mm and ≤250 mm) cohorts. Follow-up was through 24 months.

Results: TOBA III enrolled 201 patients, 169 patients in the SL cohort and 32 in the LL cohort. At 24 months, the Kaplan–Meier estimates of freedom from major adverse events were 91.7% and 82.6% for the SL cohort and LL cohort, respectively. Kaplan–Meier estimates of freedom from clinically driven-target lesion revascularization (CD-TLR) were 92.3% in the SL cohort and 82.6% in the LL cohort. At 24 months, 78.8% of SL patients and 69.2% of LL patients experienced an improvement of >2 Rutherford categories (both cohorts $p < 0.001$). The baseline ankle-brachial index improved from 0.68 ± 0.18 to 0.93 ± 0.16 in the SL ($p < 0.001$) and from 0.62 ± 0.23 to 0.87 ± 0.15 in the LL cohort ($p < 0.001$) at 24 months.

Conclusion: The 24-month results of the TOBA III trial support the safety and effectiveness of the Tack Endovascular System in patients who required post-PTA

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes.
© 2023 The Authors. *Catheterization and Cardiovascular Interventions* published by Wiley Periodicals LLC.

dissection repair in the SFA and PPA following DCB angioplasty for claudication and rest pain. In both the SL and LL cohorts, Tack placement was associated with sustained freedom from CD-TLR through 24 months as well as sustained improvements in Rutherford categories, ankle-brachial index, and quality of life.

KEYWORDS
angioplasty, dissection, drug-coated balloon, peripheral artery disease, proximal popliteal artery, superficial femoral artery, Tack Endovascular System

1 | INTRODUCTION

Lower extremity peripheral artery disease (PAD) is associated with high morbidity and mortality and a lower quality of life (QoL).[1–3] The main treatment goals for patients with intermittent claudication are to relieve symptoms and reduce the risk factors that contribute to cardiovascular events.[4,5] However, there is no definitive treatment strategy for patients with superficial femoral artery (SFA) and/or popliteal artery disease.[6] Percutaneous transluminal angioplasty (PTA) is still a common approach for the treatment of symptomatic femoropopliteal stenosis or occlusion.[7,8] Angioplasty mechanically stretches the atherosclerotic artery, frequently inducing dissection that results in acute vascular injury.[9] Dissection may occur in up to 84% of femoropopliteal angioplasties.[10,11] In the short-term, dissection may reduce or obstruct flow, and, in the long-term, increase the rate of repeat target lesion revascularization (TLR).[11,12]

Treatment for dissections above-the-knee usually involves a secondary (prolonged) application of balloon angioplasty or scaffolding of the vessel wall with stent placement.[13] Stenting has improved acute PTA outcomes; although it may also induce chronic injury and inflammation which can lead to high rates of restenosis up to 37%.[14–16] The Tack Endovascular System (Intact Vascular, Inc.; now a part of Philips Image Guided Therapy Corporation) was purpose-built to treat post-PTA dissection without the need for stent implantation.[17,18] Tack implants are designed to exert low chronic outward force with minimal metal burden, which reduces the mechanical stress on the artery wall and minimizes neointimal hyperplasia that is commonly observed with traditional stents.[17–19]

The Tack Optimized Balloon Angioplasty (TOBA) III trial evaluated the safety and effectiveness of the Tack Endovascular System in patients with SFA and/or proximal popliteal artery (PPA) dissection after treatment with the IN.PACT Admiral drug-coated balloon (DCB; Medtronic) for Rutherford 2-4 PAD.[20] The 12-month results from the TOBA III trial demonstrated high rates of safety and efficacy, as previously published.[20] The device resulted in favorable patency, freedom from clinically driven-target lesion revascularization (CD-TLR), and dissection resolution rates in the pre-specified standard- (SL) and long-lesion (LL) cohorts.[20] Presented here are the 24-month follow-up results stratified into the SL and LL cohorts which include outcomes for CD-TLR, Rutherford classification, ankle-brachial index (ABI), and quality of life metrics.

2 | METHODS

2.1 | Study design

Detailed trial methodology and results through 12 months have been previously described.[20] Briefly, the TOBA III trial was a prospective, multicenter, single-arm study performed in patients that underwent PTA of the SFA and/or PPA with the IN.PACT Admiral DCB, and experienced dissection following angioplasty that was treated with Tack implants. The study was performed at 14 European sites. The study was approved by the appropriate medical ethics committee at each site and was conducted in accordance with the Declaration of Helsinki. The trial was registered at ClinicalTrials.gov (NCT028023). All patients provided written informed consent.

2.2 | Eligibility

Patients were evaluated to be appropriate candidates for endovascular treatment of SFA and popliteal atherosclerotic lesions based on traditional standards of care. As described previously, dissections were classified by the National Heart, Lung, and Blood Institute (NHLBI) classification system.[20] Patients with types A (minor radiolucent areas within the coronary lumen during contrast injection with little or no persistence of contrast after the dye has cleared) through F (those that lead to total occlusion of the coronary lumen without distal antegrade flow) dissections after PTA with an IN.PACT Admiral DCB in the SFA or PPA was eligible for inclusion. Patients that did not experience dissection following PTA were excluded from the study. Participants were ≥18 years of age and met the inclusion and exclusion criteria previously described in Brodmann et al.[20] Eligible patients included those assigned to Rutherford class 2, 3, or 4, eligible for standard surgical repair if necessary, and ambulatory. The treated lesion was required to have a reference vessel diameter between 2.5 and 6.0 mm. The study enrolled two cohorts of patients based on lesion length as follows: SL (patients with target lesion

1522726x, 2023, 4, Downloaded from https://onlinelibrary.wiley.com/doi/10.1002/ccd.30800 by Bosnia and Herzegovina Hinari NPL, Wiley Online Library on [18/11/2025]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

length ≥20 mm and ≤150 mm representing TASC II A and B lesions), and LL (patients with target lesion length >150 mm and ≤250 mm representing TASC II C lesions). The LL cohort was an observational arm intended to allow for the examination of a subgroup of the whole study population for real-world observations and was not powered for statistical analysis.

2.3 | Study device

Patients underwent angioplasty with the use of an IN.PACT Admiral DCB followed by treatment with the Tack Endovascular System following post-PTA dissection. The Tack Endovascular System is available for commercial use in both Europe and the United States. The above-the-knee device system is a 6F (2.0 mm) delivery catheter containing six individual Tacks. Tack implants measure 6.0 mm in length and have an open-cell design that lowers the outward radial force compared with traditional stents.

2.4 | Procedure

Eligible patients received angioplasty based on the instructions for use of the Medtronic IN.PACT Admiral DCB that included vessel preparation with a standard uncoated balloon as previously described.[20] Patients were considered angiographically eligible for study device treatment if the target lesion had <30% residual diameter stenosis, thrombus was not present, and there was at least one dissection (type A–F) by visual estimate.[20] Dissections were graded by visual estimate at the time of the index procedure, followed by adjudication by the angiographic core laboratory (Yale Cardiovascular Research Group). The clinical decision to treat was made by experienced operators trained on the NHLBI classification system.[21] Patients were considered enrolled after the Tack Endovascular System was advanced through the introducer sheath. After deployment, standard balloon angioplasty was used to post-dilate the Tacks per protocol. Angiography was used to evaluate results following Tack placement. Calcium was core-lab adjudicated and was graded as "mild/none," "moderate," or "severe." Bail-out stenting was permitted in the event of persistent flow-limiting dissection not able to be treated with the Tack (or as otherwise required for the safety of the subject). Safety outcomes were adjudicated by an independent Clinical Events Committee (CEC).

2.5 | Endpoints, definitions, and follow-up visit schedule

Follow-up visits were scheduled at 1, 6, 12, and 24 months. The primary efficacy endpoint was primary patency at 12 months. Per protocol, primary patency information was not collected at 24 months.[20] The primary safety endpoint was freedom from major adverse events (MAEs) at 30 days which was previously reported.[20] MAEs were collected through 24 months and included index limb major amputations (above the ankle), CEC-adjudicated CD-TLR, and all-cause mortality. CD-TLR was defined as any target lesion re-intervention with angiographic evidence of >50% diameter stenosis and the presence of symptoms associated with the target limb, such as an increase in Rutherford classification or a decrease in ABI > 0.15. Other observational endpoints included change from baseline in ABI and Rutherford class, and QoL assessed by the EuroQol-5 Dimension 3-level (EQ-5D-3L). The 12-month outcomes were previously published.[20] Here, we report the outcomes through 24 months for MAEs, CD-TLR, Rutherford classification, ABI, and QoL metrics for the pre-specified SL and LL study cohorts.

2.6 | Statistical analysis

The intent-to-treat (ITT) population was analyzed in this study. The ITT population consisted of all enrolled patients who met all inclusion, none of the exclusion criteria (including angiographic criteria), and had the Tack Endovascular System advanced through the introducer sheath. Descriptive statistics were calculated for each variable. The median was used for instances in which the mean was an inappropriate measure of central tendency. Data and statistical analyses were performed using SAS 9.4 software (SAS Institute). Kaplan–Meier curves were used for the analysis of freedom from CD-TLR as well as individual components of the MAE composite.

3 | RESULTS

3.1 | Enrollment and follow-up

Between June 1, 2016 and May 2, 2018, the TOBA III trial enrolled 201 patients: 169 patients in the SL cohort and 32 patients in the LL cohort (Figure 1). Of these, 151 (89.3%) patients in the SL cohort and 26 (81.3%) patients in the LL cohort completed 24-month follow-up.

3.2 | Demographics and baseline characteristics

Baseline characteristics were published previously and were generally similar between the SL and LL cohorts (Table 1). The mean age was 66.7 and 63.7 years in the SL and LL cohorts, respectively. Males comprised 58.6% of the SL cohort and 59.4% of the LL cohort. Most patients in the SL (94.7%) and LL (100%) cohorts had symptoms of claudication (Rutherford 2 or 3). In the SL cohort, 5.3% were classified as Rutherford 4 with ischemic rest pain.

Procedural characteristics are shown in Table 2. In the SL cohort, there were 170 lesions and 301 dissections treated. In the LL cohort, there were 32 lesions and 83 dissections treated. The mean dissection lengths were 22 mm and 30 mm in the SL and LL cohorts, respectively. The most common dissection grade was B, which comprised 44.5% and 54.2% of the dissections in the SL and LL cohorts, respectively. Grade C or greater dissections accounted for 29.5% of the SL cohort and 26.5%

1522726x, 2023, 4, Downloaded from https://onlinelibrary.wiley.com/doi/10.1002/ccd.30800 by Bosnia and Herzegovina Hinari NPL, Wiley Online Library on [18/11/2025]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

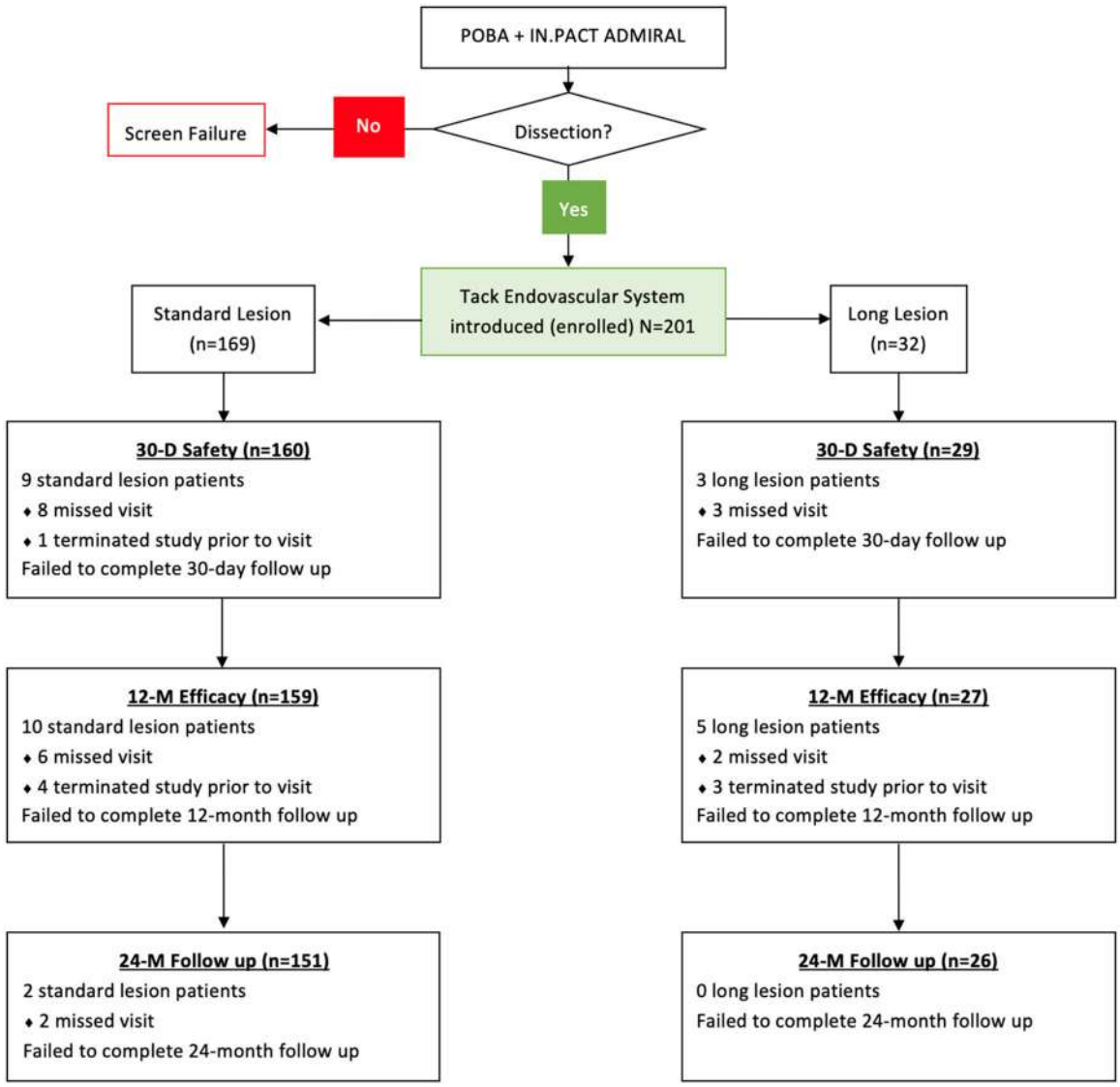


FIGURE 1 Patient flow diagram listing reasons for missed follow-up or study exclusion. POBA, plain old balloon angioplasty. [Color figure can be viewed at wileyonlinelibrary.com]

of the LL cohort. All patients received at least one Tack implant during the procedure, with a mean of 4.1 and 7.0 Tacks for the SL and LL cohorts, respectively. Only one patient, in the SL cohort, required bail-out stenting. Post-Tack implantation, 97.7% of the treated standard lesions and 98.8% of the treated long lesions had no remaining dissections per core lab review. The remaining dissections post-Tack were < Grade B for patients in both lesion cohorts.

3.3 | Outcomes through 24 months

At 24 months (720 days), the Kaplan–Meier estimates of freedom from MAEs were 91.7% in the SL cohort and 82.6% in the LL cohort (Table 3). One death occurred 10.3 months following the index procedure. The death occurred in the SL cohort and was attributed to acute cardiac insufficiency. Notably, the death was adjudicated by the CEC to be unrelated to either the device or the procedure. No major amputations were reported. Through 24 months, 17 (12/150 [8.0%] from the SL cohort and 5/26 [19.2%] from the LL cohort) TLRs occurred and were adjudicated by the CEC as clinically driven, with 8 of these events occurring in the first-year postprocedure. The Kaplan–Meier freedom from CD-TLR at 24 months (720 days) was 92.3% and 82.6% in the SL and LL cohorts, respectively, and freedom from CD-TLR rates was sustained at 92.3% and 82.6% throughout the follow-up window of 750 days (Figure 2).

3.4 | Clinical and functional outcomes through 24 months

Changes in the Rutherford category are depicted in Figure 3. At baseline, 22.5% and 37.5% of patients were Rutherford category 2,

1522726x, 2023, 4, Downloaded from https://onlinelibrary.wiley.com/doi/10.1002/ccd.30800 by Bosnia and Herzegovina Hinari NPL, Wiley Online Library on [18/11/2025]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

TABLE 1 Demographics and baseline characteristics.

Demographics and baseline characteristics	Mean ± SD (*N*) (min, median, max) or % (*n*/*N*) Standard-lesion cohort	Long-lesion cohort
Age at baseline (years)	66.7 ± 9.4 (169)	63.7 ± 8.8 (32)
Gender		
Male	58.6% (99/169)	59.4% (19/32)
Female	41.4% (70/169)	40.6% (13/32)
Ethnicity		
Hispanic or Latino	0.0% (0/169)	0.0% (0/32)
Not Hispanic or Latino	93.5% (158/169)	71.9% (23/32)
Unknown	2.4% (4/169)	0.0% (0/32)
Decline to answer	4.1% (7/169)	28.1% (9/32)
Race		
American Indian or Alaska Native	0.0% (0/169)	0.0% (0/32)
Asian	0.0% (0/169)	0.0% (0/32)
Black or African American	0.0% (0/169)	0.0% (0/32)
Native Hawaiian or Pacific Islander	0.0% (0/169)	0.0% (0/32)
White	95.3% (161/169)	78.1% (25/32)
Other	0.6% (1/169)	0.0% (0/32)
Unknown	0.6% (1/169)	0.0% (0/32)
Decline to answer	3.6% (6/169)	21.9% (7/32)
BMI	26.9 ± 4.7 (168)	27.0 ± 4.1 (32)
BMI > = 30	23.2% (39/168)	31.3% (10/32)
ABI in treated leg	0.68 ± 0.18 (168)	0.62 ± 0.23 (29)
Noncompressible	0.0% (0/169)	6.3% (2/32)
ABI in contralateral limb	0.91 ± 0.15 (160)	0.86 ± 0.17 (28)
Noncompressible	4.1% (7/169)	6.3% (2/32)
Rutherford Classification		
2	22.5% (38/169)	37.5% (12/32)
3	72.2% (122/169)	62.5% (20/32)
4	5.3% (9/169)	0.0% (0/32)

Abbreviations: ABI, ankle-brachial index; BMI, body mass index; SD, standard deviation.

TABLE 2 Procedural characteristics.

Procedural characteristics	Mean ± SD (*N*) (min, median, max) or % (*n*/*N*) Standard-lesion cohort	Long-lesion cohort
Lesion type,[a,b]		
De novo	91.7% (155/169)	84.4% (27/32)
Restenotic	8.3% (14/169)	15.6% (5/32)
Target limb treated,[a,b]		
Left	53.8% (91/169)	65.6% (21/32)
Right	46.2% (78/169)	34.4% (11/32)

(Continues)

1522726x, 2023, 4, Downloaded from https://onlinelibrary.wiley.com/doi/10.1002/ccd.30800 by Bosnia and Herzegovina Hinari NPL, Wiley Online Library on [18/11/2026]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

TABLE 2 (Continued)

Procedural characteristics	Mean ± SD (*N*) (min, median, max) or % (*n*/*N*) Standard-lesion cohort	Long-lesion cohort
Approach[b]		
Ipsilateral	56.2% (95/169)	31.3% (10/32)
Contralateral	43.8% (74/169)	68.8% (22/32)
Target lesion length, mm	68 ± 42 (170)	154 ± 56 (32)
Balloon-treated length, mm	99 ± 43 (164)	215 ± 53 (30)
Baseline target lesion percent diameter stenosis[c]	82 ± 17 (170)	86 ± 18 (32)
Chronic Total Occlusion[c]	34.7% (59/170)	50.0% (16/32)
Presence of Thrombus[c]	2.9% (5/170)	0.0% (0/32)
Calcification[c]		
None-mild	64.1% (109/170)	68.8% (22/32)
Moderate	15.9% (27/170)	21.9% (7/32)
Severe	20.0% (34/170)	9.4% (3/32)
Total no of dissections visualized	1.8 ± 1.1 (167)	2.6 ± 1.0 (32)
Dissection length, mm[d]	22 ± 18 (301)	30 ± 25 (83)
Dissection type after PTA, before Tack[d]		
None	0.0% (0/301)	0.0% (0/83)
A	25.9% (78/301)	19.3% (16/83)
B	44.5% (134/301)	54.2% (45/83)
C	22.9% (69/301)	19.3% (16/83)
D	6.6% (20/301)	7.2% (6/83)
E	0.0% (0/301)	0.0% (0/83)
F	0.0% (0/301)	0.0% (0/83)
Most severe dissection per patient after PTA, before Tack		
None	0.0% (0/164)	0.0% (0/32)
A	14.0% (23/164)	0.0% (0/32)
B	40.9% (67/164)	56.3% (18/32)
C	33.5% (55/164)	28.1% (9/32)
D	11.6% (19/164)	15.6% (5/32)
E	0.0% (0/164)	0.0% (0/32)
F	0.0% (0/164)	0.0% (0/32)
Thrombus present (after PTA treatment)[d]	0.6% (1/170)	0.0% (0/32)
Average no of device systems used per patient,[a,e]	1.1 ± 0.3	1.4 ± 0.6

Note: Categorical variables are presented as percentages (*n*/*N*). Continuous variables are presented as mean ± standard deviation (*N*).

Abbreviations: ABI, Ankle-brachial index; ITT, intent to treat; PTA, percutaneous transluminal angioplasty; SD, standard deviation.

[a]Site-reported data.

[b]Reported by patient (*n* = 169 patients or *n* = 32).

[c]Reported by lesion (*n* = 170 lesions or n = 32).

[d]Reported by dissection (*n* = 301 dissections or *n* = 83).

[e]Each device system contains six independent Tacks.

1522726x, 2023, 4, Downloaded from https://onlinelibrary.wiley.com/doi/10.1002/ccd.30800 by Bosnia and Herzegovina Hinari NPL, Wiley Online Library on [18/11/2026]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

72.2% and 62.5% were Rutherford category 3, and 5.3% and 0% were Rutherford category 4 in the SL and LL cohorts, respectively.[20] Significant improvements in Rutherford class were sustained from baseline to 24 months in both the SL and LL cohorts ($p < 0.001$) with 82.5% and 80.8% of patients in the SL and LL populations classified as Rutherford 0 or 1 (Figure 3). There were no patients with critical limb ischemia at 24 months. In the SL cohort, improvement of >2 in Rutherford classification from baseline was observed in 78.8% of patients at 24 months, respectively. The LL cohort had a >2 improvement in Rutherford classification in 69.2% of patients at 24 months. Significant positive changes in measured ABI were also observed from baseline to 24 months in both the SL and LL cohorts ($p < 0.001$; Figure 4). In the SL cohort, significant positive changes in QoL (EQ-5D-3L) scores on mobility, usual activity, pain/discomfort, and visual analog scale (VAS) scales through 24 months ($p < 0.001$) were observed (Table 4). The LL cohort showed significant improvement in mobility ($p = 0.023$) and VAS ($p = 0.019$) through 24 months.

TABLE 3 Kaplan–Meier estimates of major adverse events through 24 months.

Safety	Standard-lesion cohort, %	Long-lesion cohort, %
Freedom from major adverse events	91.7	82.6
Freedom from amputation	100	100
Freedom from CD-TLR	92.3	82.6
Survival	99.4	100

Abbreviation: CD-TLR, clinically driven target lesion revascularization.

4 | DISCUSSION

The Tack Endovascular System demonstrated safety and effectiveness for repairing dissections following DCB angioplasty of the SFA and/or PPA for treatment of PAD. Per protocol, primary patency was not collected during the 24-month follow-up. Through 24 months of follow-up, the rates of MAEs were low. One patient death in the SL cohort occurred 10.3 months following the index procedure. The cause of death was acute cardiac insufficiency and was adjudicated by the CEC to be unrelated to either the device or the procedure. No major amputations were reported in either cohort. There were 17 CD-TLRs (12 SL patients and 5 LL patients) through 24 months, with eight of these events occurring in the first-year postprocedure. The Kaplan–Meier freedom from CD-TLR at 12 months (360 days) was 97.5% (SL cohort) and 96.8% (LL cohort).[20] The Kaplan–Meier freedom from CD-TLR was sustained through the 24-month window and was 92.3% and 82.6% in the SL and LL cohorts, respectively. Significant improvements in the Rutherford class were observed from baseline to 24 months in both the SL and LL cohorts and were associated with significant positive changes in measured ABI from baseline to 24 months in both cohorts ($p < 0.001$). Additionally, QoL improved from baseline to 24 months in areas such as mobility, and pain and discomfort ($p < 0.001$).

In the IN.PACT SFA trial, a primary patency rate of 78.9% and freedom from CD-TLR rate of 90.9% was reported 24 months

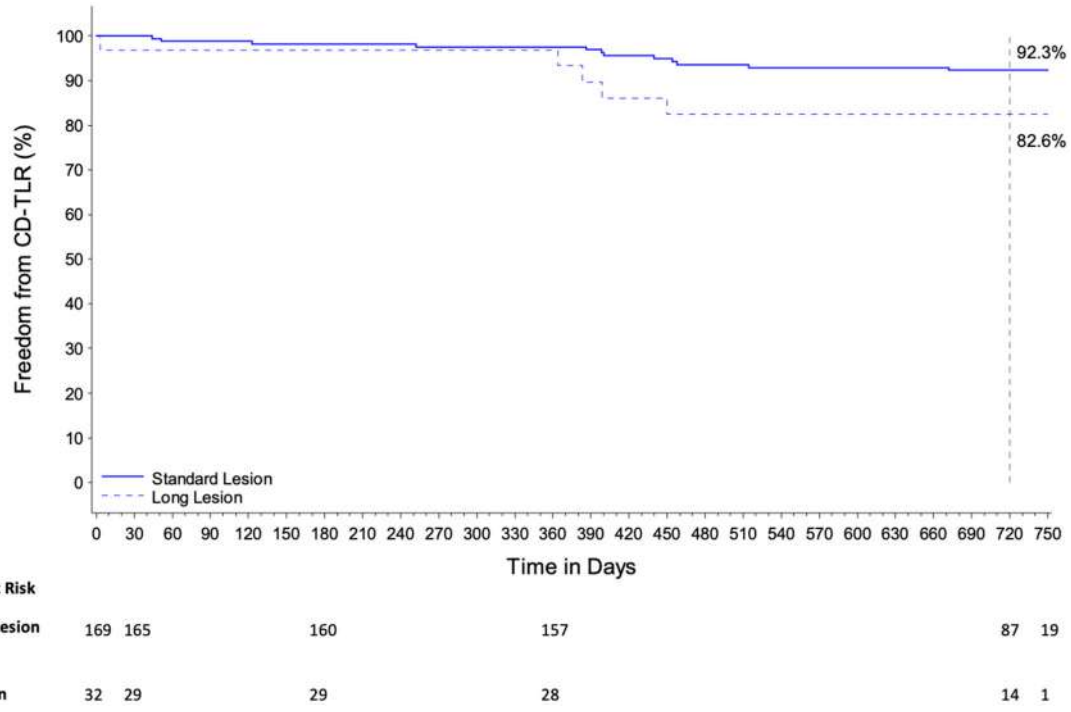
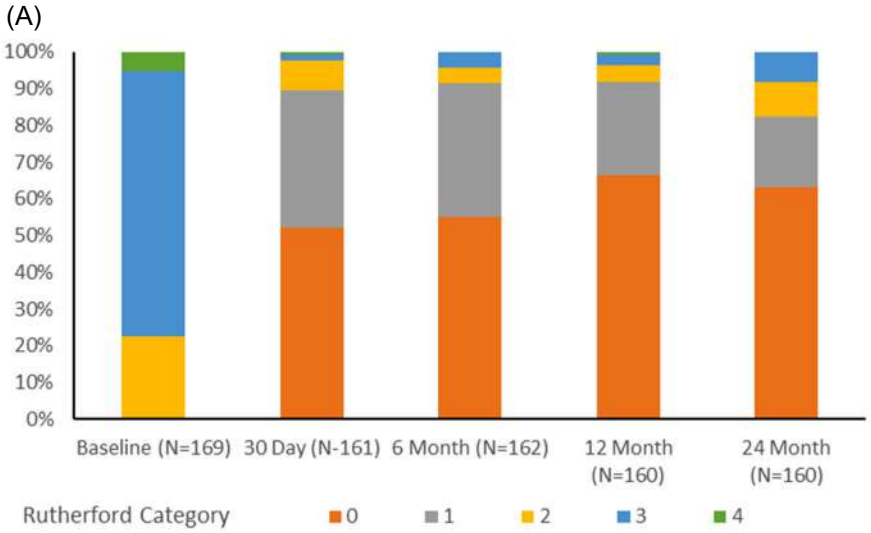


FIGURE 2 Kaplan–Meier curve for freedom from clinically driven target lesion revascularization (CD-TLR) in patients with standard- and long-lesions through 24 months. [Color figure can be viewed at wileyonlinelibrary.com]

1522726x, 2023, 4, Downloaded from https://onlinelibrary.wiley.com/doi/10.1002/ccd.30800 by Bosnia and Herzegovina Hinari NPL, Wiley Online Library on [18/11/2026]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License



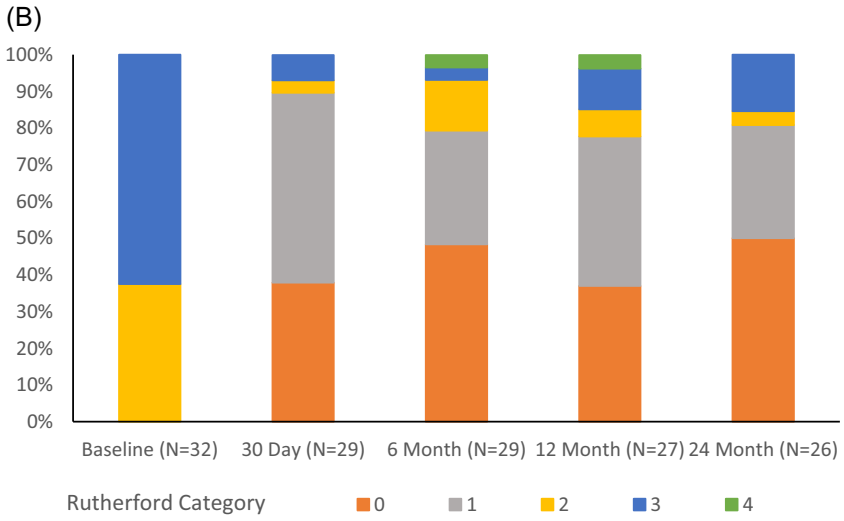


FIGURE 3 Change in Rutherford clinical category in (A) patients with standard-length lesions, and (B) patients with long-lesions through 24 months. [Color figure can be viewed at wileyonlinelibrary.com]

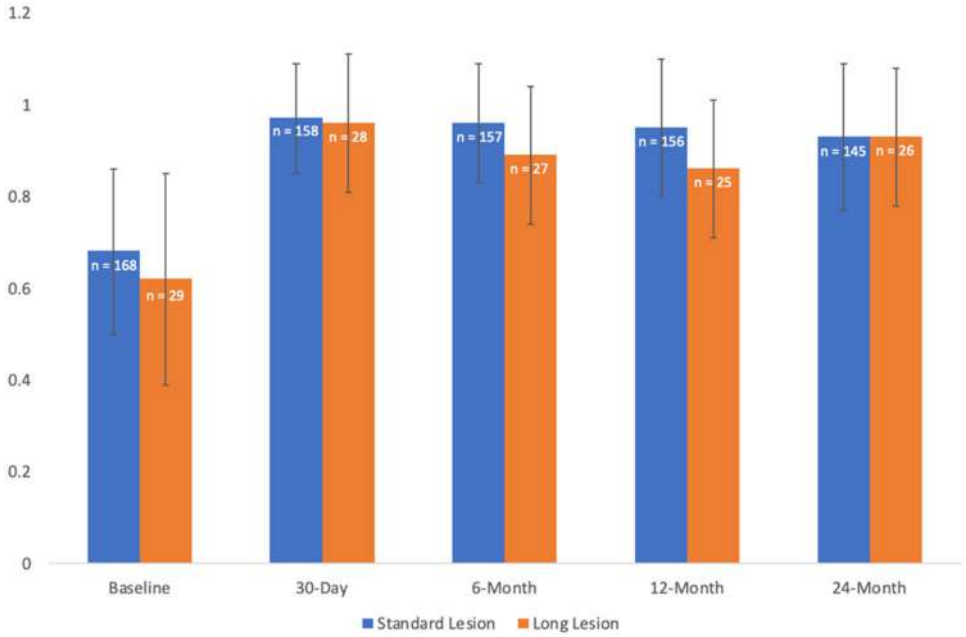


FIGURE 4 Change in ankle-brachial index (ABI) in patients with standard lesions and long-lesions through 24 months. [Color figure can be viewed at wileyonlinelibrary.com]

1527256x, 2023, 4, Downloaded from https://onlinelibrary.wiley.com/doi/10.1002/ccd.30800 by Bosnia and Herzegovina Hinari NPL, Wiley Online Library on [18/11/2026]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

TABLE 4 Change in EQ-5D-3L questionnaire in patients with standard-length and long-lesions through 24 months.

Parameter	Standard-lesion cohort, % (*n*/*N*)			Long-lesion cohort, % (*n*/*N*)		
	Baseline	12 Month	24 Month	Baseline	12 Month	24 Month
Mobility						
1 – No problems	16.8% (28/167)	80.1% (129/161)	80.5% (128/159)	28.1% (9/32)	70.4% (19/27)	69.2% (18/26)
2 - Some problems	82.6% (138/167)	19.9% (32/161)	19.5% (31/159)	71.9% (23/32)	29.6% (8/27)	30.8% (8/26)
3 – Extreme problems	0.6% (1/167)	0.0% (0/161)	0.0% (0/159)	0.0% (0/32)	0.0% (0/27)	0.0% (0/26)
p-Value*		**<0.001**	**<0.001**		**0.006**	**0.023**
Self-care						
1 – No problems	94.6% (158/167)	96.9% (156/161)	94.3% (150/159)	100.0% (32/32)	88.9% (24/27)	92.3% (24/26)
2 - Some problems	5.4% (9/167)	3.1% (5/161)	5.0% (8/159)	0.0% (0/32)	11.1% (3/27)	7.7% (2/26)
3 – Extreme problems	0.0% (0/167)	0.0% (0/161)	0.0% (0/159)	0.0% (0/32)	0.0% (0/27)	0.0% (0/26)
p-Value*		**1.00**	**1.00**		**0.25**	**0.50**
Usual activity						
1 – No problems	49.7% (83/167)	85.1% (137/161)	79.2% (126/159)	56.3% (18/32)	74.1% (20/27)	84.6% (22/26)
2 - Some problems	49.1% (82/167)	14.3% (23/161)	20.1% (32/159)	43.8% (14/32)	25.9% (7/27)	15.4% (4/26)
3 – Extreme problems	0.0% (0/167)	0.0% (0/161)	0.0% (0/159)	0.0% (0/32)	0.0% (0/27)	0.0% (0/26)
p-Value*		**<0.001**	**<0.001**		**0.23**	**0.11**
Pain/discomfort						
1 – No problems	19.2% (32/167)	66.5% (107/161)	63.5% (101/159)	25.0% (8/32)	48.1% (13/27)	50.0% (13/26)
2 - Some problems	61.7% (103/167)	26.7% (43/161)	32.1% (51/159)	62.5% (20/32)	44.4% (12/27)	42.3% (11/26)
3 – Extreme problems	19.2% (32/167)	6.8% (11/161)	4.4% (7/159)	12.5% (4/32)	7.4% (2/27)	7.7% (2/26)
p-Value*		**<0.001**	**<0.001**		**0.16**	**0.21**
Anxiety/depression						
1 – No problems	85.6% (143/167)	89.4% (144/161)	88.1% (140/159)	81.3% (26/32)	77.8% (21/27)	88.5% (23/26)
2 - Some problems	12.0% (20/167)	9.9% (16/161)	11.3% (18/159)	15.6% (5/32)	22.2% (6/27)	11.5% (3/26)
3 – Extreme problems	2.4% (4/167)	0.6% (1/161)	0.6% (1/159)	3.1% (1/32)	0.0% (0/27)	0.0% (0/26)
p-Value*		**0.083**	**0.23**		**1.00**	**0.38**

(Continues)

15227626x, 2023, 4, Downloaded from https://onlinelibrary.wiley.com/doi/10.1002/ccd.30800 by Bosnia and Herzegovina Hitari NPL, Wiley Online Library on [18/11/2026]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

TABLE 4 (Continued)

Parameter	Standard-lesion cohort, % (n/N)			Long-lesion cohort, % (n/N)		
	Baseline	12 Month	24 Month	Baseline	12 Month	24 Month
EQ-VAS						
At follow-up	62.0 ± 16.2 (167) (5.0, 60.0, 100.0)	77.6 ± 19.9 (160) (10.0,80.0,100.0)	78.0 ± 19.0 (159) (20.0,80.0,100.0)	58.9 ± 18.7 (31) (16.0, 60.0, 90.0)	69.8 ± 22.7 (27) (32.0,65.0,100.0)	71.6 ± 24.0 (26) (30.0,77.5,100.0)
Change from Baseline		15.9 ± 23.6 (158) (−35.0, 10.5, 70.0)	16.0 ± 23.7 (157) (−40.0, 15.0, 80.0)		13.6 ± 26.6 (26) (−43.0, 11.5, 60.0)	13.8 ± 27.1 (25) (−40.0, 10.0, 64.0)
p-Value[†]		**<0.001**	**<0.001**		**0.015**	**0.019**

Abbreviations: EQ-5D-3L, EuroQol-5 Dimension 3-level; EuroQol-VAS, Visual Analog Scale.
*Generalized McNemar's test.
†Wilcoxon signed rank test.

postprocedure in patients (mean lesion length 8.9 cm) treated with the IN.PACT Admiral DCB for femoropopliteal lesions, with a bailout stent rate of 7.3% (16/220)[22] Although primary patency was not collected through 24 months in TOBA III (per protocol), freedom from CD-TLR rate in the SL cohort (lesion length 6.8 cm) was comparable (92.3%) compared with IN.PACT SFA, with the placement of only one bailout stent (1/169; 0.6%).[20,22] Both studies reported no device- or procedure-related deaths and no amputations 24 months after treatment.[22]

TOBA III included lesions up to 250 mm long, which allowed device assessment in patients with LL that are typically excluded from clinical trials.[20] This cohort was small and not powered for primary analysis, but had a primary patency rate of 73.1% after 12 months, suggesting that the Tack Endovascular System has efficacy in long lesions.[20] Patients with long lesions had high device and procedure success. Freedom from CD-TLR was sustained through 24 months in the LL cohort and there were also sustained improvements in Rutherford class, ABI, and QoL through 24 months in this subgroup.

The IN.PACT Global study was a large prospective, multicenter, single-arm trial evaluating the IN.PACT DCB in patients with lifestyle-limiting claudication and/or ischemic rest pain due to atherosclerotic disease of the femoropopliteal artery that in part included complex lesions typically excluded from clinical trials.[23] This study reported a freedom from CD-TLR rate of 83.3% after 24 months in patients with a mean lesion length of 12.1 cm and a bailout stent rate of 21.2% (373/1,761).[23] TOBA III patients with LLs (mean length 15.4 cm; no bail-out stent placement) had a similar freedom from CD-TLR rate of 82.6% after 24 months. The IN.PACT Global study reported a mortality rate of 7.0% at 24 months, although a CEC determined that none of the deaths were device- or procedure-related.[23] Here, we report only one patient death after 24 months in the SL cohort that was not related to the device or the procedure and no deaths in the LL cohort. These data demonstrate that TOBA III LL cohort findings are similar to those reported in the LL cohort of the IN.PACT Global study; and, although direct comparisons cannot be made, it is important to note that enrollment of patients exclusively with dissections renders the TOBA III patients particularly challenging from a treatment perspective.[23]

The Tack Endovascular System is the first purpose-built device to optimize PTA following vessel dissection. The Tack device is designed to facilitate the apposition of dissection flaps to the luminal surface. Individual Tacks are only 6 mm in length with an open-cell design.[24] Compared with traditional stents, Tacks offer many advantages, including a reduced metal burden and limited outward radial force. Traditional stents may lead to chronic injury and inflammation with high restenosis rates.[16,25,26] The use of traditional stents can also limit future treatment options as stented segments of arteries are not viable sites for surgical bypass. Conversely, dissection repair with Tack can preserve future treatment options if reintervention is necessary.

4.1 | Limitations

The Tack Endovascular System is a first-of-its-kind device with no appropriate comparator device or technique. Accordingly, TOBA III

1522726x, 2023, 4, Downloaded from https://onlinelibrary.wiley.com/doi/10.1002/ccd.30800 by Bosnia and Herzegovina Hinari NPL, Wiley Online Library on [18/11/2025]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

was a single-arm study with no active control. Additionally, the study used the NHLBI classification system for dissections. This system is limited to the angiographic appearance of a single worst dissection without providing context around multiple dissections, length of dissection, or hemodynamic impact on luminal integrity. Although Tack demonstrated favorable results in the LL cohort, definitive conclusions cannot be drawn about the effectiveness of the Tack Endovascular System for these lesions as this study was not powered to detect effectiveness in this cohort. Furthermore, improvement in clinical results measured by changes in Rutherford Clinical Category was determined by the investigator and may therefore be subjective. Finally, although similar to many contemporary trials such as IN.PACT SFA and LEVANT 2, most of the enrolled patients were claudicants and the number of patients with critical limb-threatening ischemia was small.

5 | CONCLUSION

In the present study, the Tack Endovascular System showed sustained benefits in CD-TLR, Rutherford classification, ABI, and QoL metrics through 24 months in both the SL and LL cohorts. These results support the use of the Tack Endovascular System to treat post-PTA DCB dissections type(s) A through F in the SFA and PPA in diameter up to 6.0 mm. A randomized controlled trial is required to definitively determine if the Tack Endovascular System is superior to traditional methods (e.g., stenting) for post-PTA dissection repair.

ACKNOWLEDGMENTS

The authors thank Heather Gorby for writing assistance. The study was funded by Intact Vascular, Inc., now a part of Philips Image Guided Therapy Corporation (Plymouth, MN). Open Access funding enabled and organized by Projekt DEAL.

CONFLICT OF INTEREST STATEMENTS

Marianne Brodmann reports honoraria received from: Abbott Vascular, BIBA Medical, Biotronik, Boston Scientific Corp., Cook Medical, Medtronic, Philips-Spectranetics, and Shockwave and is a consultant for Boston Scientific Corp., CSI, Medtronic, Philips-Intact Vascular, Shockwave, Bayer, Cagent, Reflow Medical, Biotronik, Cagent, and Reflow Medical. Christian Wissgott reports honoraria received from Philips, Veryan, and Inspire MD and is a consultant for Philips-Intact Vascular, Inspire MD. Klaus Brechtel reports no disclosures. Michael Lichtenberg is a consultant/advisory board member for Abbott Vascular, Bard, Boston Scientific, Cook Medical, W.L. Gore & Associates, Medtronic, Cordis, a Cardinal Health Company, and Philips. Erwin Blessing reports honoraria received from Abbott Vascular, Biotronik, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Philips-Spectranetics, and Shockwave and is a consultant for Boston Scientific Corp., CSI, Medtronic, Philips-Intact Vascular, and Shockwave. Trisha Tarra is an employee of Philips. Thomas Zeller reports honoraria received from Abbott Vascular, BIBA Medical, Biotronik, Boston Scientific Corp., Cook Medical, Efemoral, Gore & Associates, Medtronic, Philips-Spectranetics, Shockwave, and Veryan, is a consultant for Boston Scientific Corp., CSI, Gore & Associates, Medtronic, Veryan, Philips-Intact Vascular, Shockwave, Bayer, Vesper Medical, VentureMed, and ANT, and reports institutional Grants for research, clinical trial, or drug studies received from Bard Peripheral Vascular, Veryan, Biotronik, Cook Medical, Gore & Associates, Medtronic, Philips, Terumo, TriReme, Shockwave, Med Alliance, Intact Vascular, B. Braun; CSI, Boston Scientific, University of Jena, Pluristem, Philips, PQ Bypass, Surmodics, Alative Solutions, and Reflow Medical.

DATA AVAILABILITY STATEMENT

Requests to access the data from qualified researchers trained in human subject confidentially protocols may be made through the Philips IGT Medical Information portal: https://www.usa.philips.com/healthcare/resources/landing/medical-information-services-inquiry

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ORCID

Marianne Brodmann http://orcid.org/0000-0001-6493-3799
Trisha Tarra http://orcid.org/0000-0002-8476-0837

REFERENCES

1. Muluk SC, Muluk VS, Kelley ME, et al. Outcome events in patients with claudication: a 15-year study in 2777 patients. *J Vasc Surg*. 2001;33(2):251-258.
2. Maksimovic M, Vlajinac H, Marinkovic J, Kocev N, Voskresenski T, Radak D. Health-related quality of life among patients with peripheral arterial disease. *Angiology*. 2014;65(6):501-506.
3. Wu A, Coresh J, Selvin E, et al. Lower extremity peripheral artery disease and quality of life among older individuals in the community. *J Am Heart Assoc*. 2017;6(1):e004519.
4. Ratchford EV. Medical management of claudication. *J Vasc Surg*. 2017;66(1):275-280.
5. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC guideline on the management of patients with lower extremity peripheral artery disease. *JACC*. 2017;69(11):e71-e126.
6. Davies MG, Waldman DL, Pearson TA. Comprehensive endovascular therapy for femoropopliteal arterial atherosclerotic occlusive disease. *J Am Coll Surg*. 2005;201(2):275-296.
7. Kayssi A, Al-Atassi T, Oreopoulos G, Roche-Nagle G, Tan KT, Rajan DK. Drug-eluting balloon angioplasty versus uncoated balloon angioplasty for peripheral arterial disease of the lower limbs. *Cochrane Database Syst Rev*. 2016;(8):CD011319.
8. Zeller T. Current state of endovascular treatment of femoropopliteal artery disease. *Vasc Med*. 2007;12(3):223-234.
9. Losordo DW, Rosenfield K, Pieczek A, Baker K, Harding M, Isner JM. How does angioplasty work? Serial analysis of human iliac arteries using intravascular ultrasound. *Circulation*. 1992;86(6):1845-1858.
10. Fujihara M, Takahara M, Sasaki S, et al. Angiographic dissection patterns and patency outcomes after balloon angioplasty for superficial femoral artery disease. *J Endovasc Ther*. 2017;24(3):367-375.
11. Kobayashi N, Hirano K, Yamawaki M, et al. Simple classification and clinical outcomes of angiographic dissection after balloon angioplasty for femoropopliteal disease. *J Vasc Surg*. 2018;67(4):1151-1158.
12. Tepe G, Zeller T, Schnorr B, et al. High-grade, non-flow-limiting dissections do not negatively impact long-term outcome after

1522726x, 2023, 4, Downloaded from https://onlinelibrary.wiley.com/doi/10.1002/ccd.30800 by Bosnia and Herzegovina Hinari NPL, Wiley Online Library on [18/11/2026]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

paclitaxel-coated balloon angioplasty: an additional analysis from the THUNDER study. *J Endovasc Ther*. 2013;20(6):792-800.
13. Voûte MT, Stathis A, Schneider PA, et al. Delphi consensus study toward a comprehensive classification system for angioplasty-induced femoropopliteal dissection. *JACC: Cardiovasc Interv*. 2021;14(21):2391-2401.
14. Laird JR, Katzen BT, Scheinert D, et al. Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: twelve-month results from the RESILIENT randomized trial. *Circ: Cardiovasc Interv*. 2010;3(3):267-276.
15. Bosiers M, Torsello G, Gißler HM, et al. Nitinol stent implantation in long superficial femoral artery lesions: 12-month results of the DURABILITY I study. *J Endovasc Ther*. 2009;16(3):261-269.
16. Krankenberg H, Schlüter M, Steinkamp HJ, et al. Nitinol stent implantation versus percutaneous transluminal angioplasty in superficial femoral artery lesions up to 10 cm in length: the femoral artery stenting trial (FAST). *Circulation*. 2007;116(3):285-292.
17. Schneider PA, Giasolli R, Ebner A, Virmani R, Granada JF. Early experimental and clinical experience with a focal implant for lower extremity post-angioplasty dissection. *JACC: Cardiovasc Interv*. 2015;8(2):347-354.
18. Vanderland M, Ooi YS, Gray WA. Device profile of the Tack Endovascular System® for the treatment of peripheral arterial disease: overview of safety and efficacy. *Expert Rev Med Devices*. 2021;18(8):717-726.
19. Gray WA, Cardenas JA, Brodmann M, et al. Treating post-angioplasty dissection in the femoropopliteal arteries using the Tack Endovascular System: 12-month results from the TOBA II study. *JACC. Cardiovasc interv*. 2019;12(23):2375-2384.
20. Brodmann M, Wissgott C, Brechtel K, et al. Optimized drug-coated balloon angioplasty of the superficial femoral and proximal popliteal arteries using the Tack Endovascular System: TOBA III 12-month results. *J Vasc Surg*. 2020;72(5):1636-1647.e1.
21. National, Heart, Lung, and Blood Institute. *Coronary Artery Changes After PTCA: Manual of Operations, NHLBI PTCA Registry*. National Heart, Lung, and Blood Institute; 1985:6-9.
22. Laird JR, Schneider PA, Tepe G, et al. Durability of treatment effect using a drug-coated balloon for femoropopliteal lesions. *JACC*. 2015;66(21):2329-2338.
23. Micari A, Brodmann M, Keirse K, et al. Drug-coated balloon treatment of femoropopliteal lesions for patients with intermittent claudication and ischemic rest pain: 2-year results from the IN.PACT global study. *JACC: Cardiovasc Interv*. 2018;11(10):945-953.
24. Bosiers M, Scheinert D, Hendriks JMH, et al. Results from the Tack Optimized Balloon Angioplasty (TOBA) study demonstrate the benefits of minimal metal implants for dissection repair after angioplasty. *J Vasc Surg*. 2016;64(1):109-116.
25. Schillinger M, Sabeti S, Loewe C, et al. Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. *N Engl J Med*. 2006;354(18):1879-1888.
26. Schillinger M, Minar E. Restenosis after percutaneous angioplasty: the role of vascular inflammation. *Vasc Health Risk Manag*. 2005;1(1):73-78.

How to cite this article: Brodmann M, Wissgott C, Brechtel K, et al. Optimized drug-coated balloon angioplasty of the superficial femoral and proximal popliteal arteries using the Tack Endovascular System: Tack Optimized Balloon Angioplasty (TOBA) III 24-month results in standard and long lesions. *Catheter Cardiovasc Interv*. 2023;102:701-712. doi:10.1002/ccd.30800

1522726x, 2023, 4, Downloaded from https://onlinelibrary.wiley.com/doi/10.1002/ccd.30800 by Bosnia and Herzegovina Hinari NPL, Wiley Online Library on [18/11/2025]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License