

# Post-PTA Dissection: Clinical Impact, Identification, and Repair

Discussion on the prevalence of post-angioplasty dissections, guidelines for their identification, and the use of the Tack Endovascular System® for repair.

WITH EHRIN J. ARMSTRONG, MD, MSc; NICOLAS W. SHAMMAS, MD, MS, EJD;  
AND CHRISTIAN WISSGOTT, MD

## Post-Angioplasty Dissections: Current Evidence and Clinical Importance

By Ehrin J. Armstrong, MD, MSc

Dissection is the mechanism of action for balloon percutaneous transluminal angioplasty (PTA), the cornerstone of all endovascular intervention. PTA works through adventitial stretching and controlled dissection of the target lesion (Figure 1).<sup>1</sup> The extent of post-PTA dissection can widely vary, from local plaque rupture to severe flow-limiting dissection. The extent of dissection and the development of hemodynamic alterations in vessel flow are major determinants of both acute procedural complications (eg, need for bailout therapies) and future rates of restenosis. Understanding the prevalence, identification, and classification of dissections is therefore paramount to identifying optimal treatment strategies in both the superficial femoral artery (SFA) and infrapopliteal arteries.

### HIGH PREVALENCE OF DISSECTIONS

After balloon angioplasty of the SFA, the prevalence of any angiographic dissection has been reported to occur between 50% to 84% of the time.<sup>2,3</sup> Limited data are available regarding the prevalence of dissections after infrapopliteal balloon angioplasty, with reported rates of 15% to 30%.<sup>4,5</sup> However, the rates of post-PTA dissection are likely higher after infrapopliteal balloon angioplasty, with underreporting due to smaller reference vessel diameter and the presence of overlapping bones making identification more difficult.<sup>4</sup> For both SFA and infrapopliteal

disease, angiography also likely underestimates the prevalence of dissections relative to other imaging modalities. For example, initial studies utilizing intravascular ultrasound (IVUS) have demonstrated a much higher rate of dissections after balloon angioplasty.<sup>6,7</sup>

Current data suggest that drug-coated balloon (DCB) angioplasty is associated with rates of dissection similar to those of standard PTA, but it is difficult to extrapo-

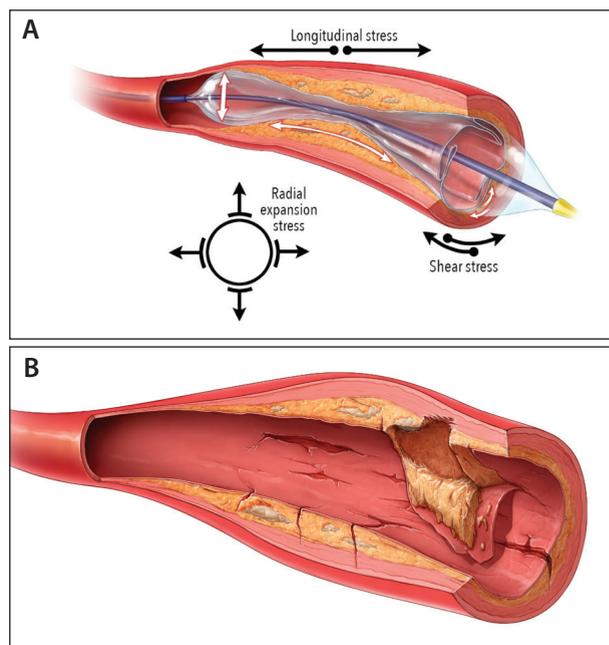


Figure 1. Mechanism of action for post-PTA dissection. Balloon angioplasty uses distortional stress to increase luminal gain (A). Resulting dissections range in severity (B), many requiring treatment.

late the results of these studies to real-world practice, where lesions tend to be longer, calcified, and more often occluded. In real-world registries, the rates of bailout stenting range from 20% to 40%,<sup>8,9</sup> suggesting higher rates of operator-determined severe dissections that necessitated stent implantation.

## OUTCOMES OF POST-ANGIOPLASTY DISSECTIONS

Recent data have demonstrated the clinical impact of dissections after PTA. In a large multicenter study, Fujihara et al studied 748 de novo SFA lesions.<sup>2</sup> After initial balloon dilation, 84% of lesions demonstrated some type of angiographic dissection. As a result, stent implantation was performed in the majority of lesions. Among the 193 lesions treated with balloon angioplasty alone, the association was studied between final dissection grade and subsequent restenosis. Severe dissections (characterized as type C or greater) occurred 42% of the time and were associated with significantly increased rates of restenosis and target lesion revascularization (TLR), with a stepwise relationship between dissection severity and outcomes.

In another study, Kobayashi and colleagues studied 319 de novo SFA lesions treated with balloon angioplasty.<sup>3</sup> After balloon angioplasty, 75% of lesions had evidence of angiographic dissection. In their analysis, mild dissections (< one-third of the vessel lumen) were not associated with restenosis among lesions < 100 mm, but even mild dissections were associated with restenosis if the treated lesion was > 100 mm in length. More severe dissections were associated with decreased primary patency independent of lesion length. These findings suggest that even mild dissections may affect vessel patency, especially among longer lesions.

The outcomes of dissections after DCB angioplasty remain an active area of investigation. Because most randomized trials excluded enrollment if initial balloon angioplasty resulted in a severe dissection, limited data are available on the natural history of dissections after DCB angioplasty without provisional stent placement. Although DCB angioplasty has been shown to reduce the rates of neointimal hyperplasia and restenosis, the biologic effect of paclitaxel on dissection healing is unclear. For example, the reduction in neointimal hyperplasia with DCB angioplasty may limit the association of small intimal tears with restenosis. Alternatively, the presence of paclitaxel likely has no

impact on torn tissue and plaque in the flow lumen, so it is unclear whether it has an effect on long-term patency and/or the potential for vessel thrombosis. Such hypotheses need to be confirmed in large cohort studies.

## FUTURE DIRECTION

Dissections occur after almost all balloon angioplasty procedures regardless of the type of balloon used. The prevalence and clinical outcomes of post-PTA dissections have only recently been described and have gained increasing prominence in the operator's decision of whether an acceptable acute result has been achieved. Emerging data suggest that all dissections matter and that dissections significantly impact clinical outcomes after infrainguinal endovascular intervention. The concept of leaving as little metal behind as possible is gaining ground given the neointimal hyperplasia associated with stenting; however, there is still a need for a better method of treating dissection. The development of novel therapies, such as the Tack Endovascular System® (Intact Vascular, Inc.), may create the opportunity for focal dissection repair without the disadvantages of conventional stent implantation.

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*Disclosures: Consultant/advisory board for Abbott Vascular, Boston Scientific Corporation, Cardiovascular Systems, Inc., Intact Vascular, Inc., and Philips.*

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## Identification and Classification of Dissections

By Nicolas W. Shammam, MD, MS, EJD

### IDENTIFICATION OF DISSECTIONS

Contrast angiography is often the sole imaging modality used in infrainguinal intervention. Angiography provides a two-dimensional silhouette of the vessel lumen, which is limited by planar angle, vessel tortuosity, and overlap of bone and other vessels. As a result, angiography has been shown to underestimate peripheral arterial intraluminal pathology, such as vessel diameter, degree of stenosis, calcium burden, and importantly, the presence and extent of vessel dissection.<sup>1-4</sup> Given the prevalence and clinical impact of postintervention dissection, better imaging techniques are required. IVUS and optical coherence tomography (OCT) have emerged as important modalities to define the exact number, length, depth, and circumference of dissections following PTA or atherectomy in infrainguinal arteries.<sup>5,6</sup> A study by Iida et al resulted in better clinical outcomes and improved freedom from reintervention and adverse limb events at 1 year following femoral arterial stenting when the procedure was guided by IVUS and not angiography alone.<sup>7</sup>

Another major challenge with dissections is that even once identified, their severity is underestimated. The TOBA study by Bosiers and colleagues found that physicians reported National Heart, Lung, and Blood Institute (NHLBI) dissection grades  $\geq$  C in only 25.8% of patients, compared with an independent core labora-

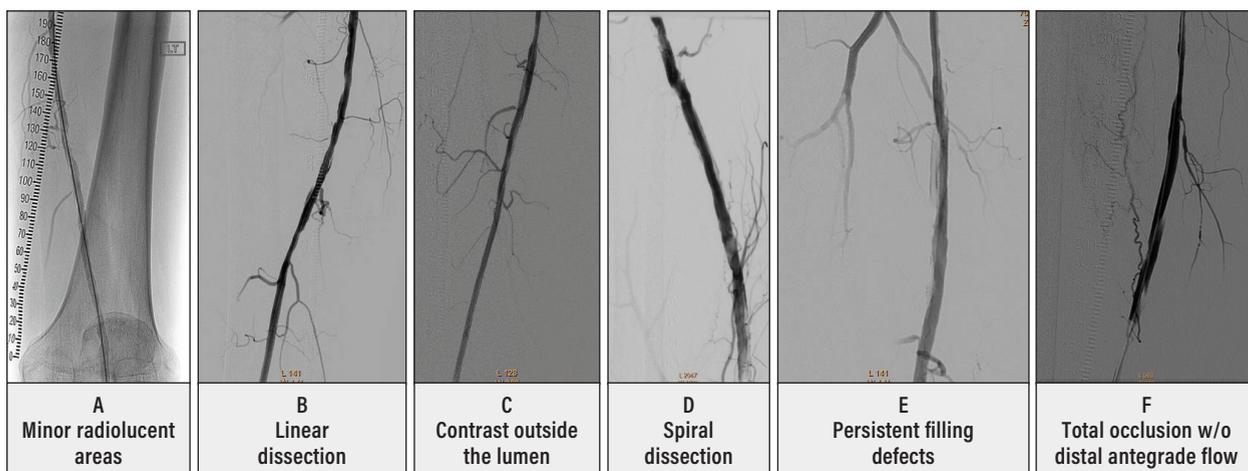
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tory analysis in which grades  $\geq$  C were present in 74% of patients.<sup>8</sup> This illustrates a significant gap in both the ability to recognize and classify the presence of dissections after intervention.

### CLASSIFICATION OF DISSECTIONS

Part of the difficulty is that despite the prevalent nature of dissections, there is not a dedicated dissection grading system for the lower extremity arteries. To date, most studies have utilized the NHLBI grading system, which was developed for coronary arteries more than 3 decades ago, to classify infrainguinal dissections.<sup>9</sup> In this system, dissections are graded A through F in increasing order of severity (Figure 1). Other angiographic categorization systems have also been proposed, including width of dissection as being either less than one-third or more than one-third of the vessel lumen.<sup>10</sup>

The NHLBI system, although useful for categorization, has several limitations. Initially developed for the coronary arteries, this system does not apply to the large



**Figure 1. Femoropopliteal dissection grading.** In the NHLBI grading system, dissections are graded A–F. An A dissection includes minor radiolucent areas; a B dissection is a linear dissection, typically on both sides of the vessel; a C dissection includes contrast outside of the flow lumen; a D dissection is a spiral pattern; an E dissection includes persistent filling defects; and an F dissection involves total occlusion without distal antegrade flow.

Courtesy of Prof. Marianne Brodmann.

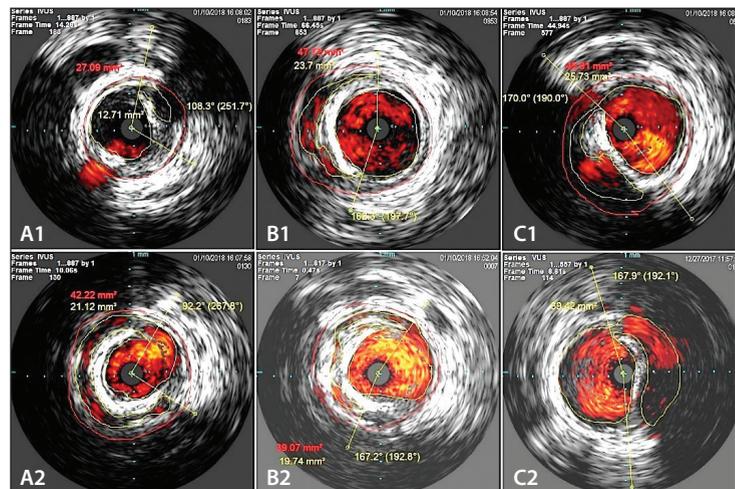
diameters and long lesions in the femoropopliteal arteries. There is a corresponding lack of consensus as to what constitutes a severe dissection, as demonstrated in recent DCB trials.<sup>11,12</sup> Although many physicians consider a grade C or greater dissection as severe, and therefore necessitating further treatment, additional data are necessary to determine the appropriate threshold for dissection treatment. Furthermore, the NHLBI system considers only the most severe dissection in a lesion, although multiple dissections may occur along a single treatment area. Notably, this classification does not account for other factors, such as length, depth, and arc of injury, that may be additive in the subsequent risk of restenosis. For these reasons, an updated and improved classification system is necessary for the study of dissections in the infrainguinal arteries. Pathologic studies have shown that deeper injuries into the media and adventitia correlate with loss of patency and increased TLR.<sup>13,14</sup> Wider dissections (> 50% of vessel circumference) are more likely to create flow limitation and loss of initial lumen gain. It is unclear whether wider dissections underappreciated by angiography contribute to loss of patency.

### THE iDISSECTION CLASSIFICATION SYSTEM

Ideally, an imaging-based dissection grading system should be both easily reproducible and quickly performed during interventional procedures. It should also accurately define the presence, depth, and extent of injury to effectively guide treatment. The recently published iDissection grading system was developed for this purpose.<sup>5</sup> It outlines six grades of dissections based on depth and circumference of injury as revealed on IVUS (Figure 2).

Although PTA increases luminal diameter via dissection and plaque compression, atherectomy has been used to modify vessel compliance and has been shown to reduce angiographic dissections when compared with PTA, reducing the need for bailout stent implantation.<sup>15-17</sup> Following atherectomy, it is thought that less inflation pressure is needed to expand the vessel wall to obtain a wider lumen, which creates less barotrauma. Despite lower adjunctive balloon pressure, the rate of bailout stenting due to suboptimal acute results, including dissection, still approaches 30%.<sup>16</sup>

The iDissection pilot study was designed to determine quantitative differences in postintervention dis-



**Figure 2. Intravascular ultrasound iDissection grading.** In the iDissection grading system, dissections are graded by both depth and arc of injury. A, B, or C denotes that the dissection extends into the intima, media, or adventitia. Injury that spans < 180° is labeled 1, and 2 denotes injury that involves ≥ 180°.

section number and severity on IVUS versus contrast angiography using the iDissection and the NHLBI grading systems, respectively.<sup>18</sup> Fifteen patients with de novo or nonstented stenotic lesions in the femoropopliteal arteries underwent atherectomy followed by adjunctive PTA. Atherectomy was performed with Jetstream (Boston Scientific Corporation) or B-laser (Eximo Medical Ltd), adjunctive angioplasty was performed with Lithoplasty (Shockwave Medical, Inc.) in one-third of patients, and DCB in all patients. Angiographic and IVUS imaging (Eagle Eye Platinum ST, Philips) of the same segment were performed at baseline, postatherectomy and postadjunctive PTA. All images were adjudicated by independent core laboratories.

Mean lesion length was 10.8 cm and treated length was 16.2 cm. Peripheral artery calcification scoring system (PACCS) grade 3 and 4 calcification was present in 20% and 40% of patients, respectively. Limb ischemia with ulceration was present in 26.7% of patients.

Postatherectomy intramural hematoma was present in 13% of patients on IVUS, yet not visualized on multiplanar angiography. Additionally, there were a total of 46 dissections on IVUS compared with eight dissections on angiography. These data challenge the widely held belief that vessel preparation with atherectomy does not produce dissections. After adjunctive PTA, IVUS showed 39 dissections to 11 with angiography, suggesting that adjunctive angioplasty does not mitigate the excisional trauma caused by atherectomy.

The iDissection pilot study demonstrated that IVUS revealed four to six times more dissections overall when compared with angiography, and nearly 40% of these dissections extended into the media and/or adventitia. Although longer lesions correlated with more dissections, there was no apparent predictor for dissections exceeding 180° in circumference. More research is needed to determine how these deeper and wider dissections may result from or interact with current therapies.

Precision imaging during endovascular therapy is critical to assess the severity of lower extremity occlusive disease, guide appropriate device selection, and secure a successful clinical outcome. The ability to identify the presence and extent of postintervention dissections will help design studies to more clearly investigate the role of dissections in clinical outcomes and how some technologies such as the Tack Endovascular System® might be utilized in dissection repair.

*Note: The Tack Endovascular System® has not been studied for the repair of dissections caused by atherectomy.*

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## Precision Dissection Repair With the Tack Endovascular System®

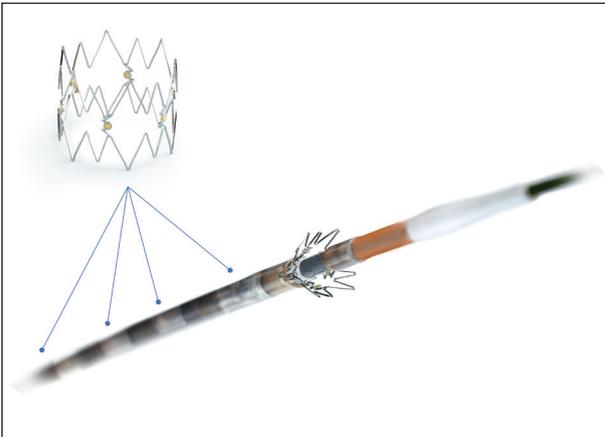
By Christian Wissgott, MD

### TACK ENDOVASCULAR SYSTEM®

The Tack Endovascular System® is purpose-built for the treatment of peripheral arterial dissections that

occur postangioplasty, whether above the knee (ATK) or below the knee (BTK). It is designed to offer focal treatment with minimal metal, optimizing PTA outcomes while preserving vessel mechanics and future treatment options (Figure 1).

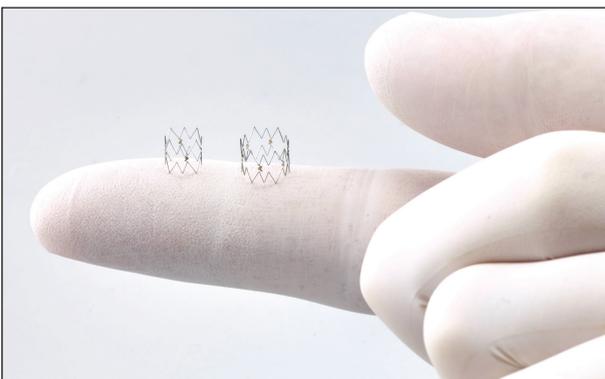
The system includes multiple preloaded, self-expanding nitinol Tack® implants on a single catheter designed for precise delivery to the treatment area. For ATK interventions, each of the six Tack implants can treat a wide range of vessel diameters from 2.5 to 6 mm. For



**Figure 1.** Designed for focal treatment of post-PTA dissections above and below the knee, the Tack Endovascular System® is preloaded with multiple implants on a single catheter.

BTK, there are four Tack implants that treat vessels from 1.5 to 4.5 mm in diameter. Both the ATK and BTK implants (Figure 2) are approximately 6 mm in length when deployed and feature gold radiopaque markers for increased visibility during fluoroscopy, as well as anchors that are designed to prevent migration.

The Tack implant's Adaptive Sizing™ technology offers the ability to treat multiple dissections within a single intervention, eliminating the need for precise device sizing and multiple catheter exchanges. A key Adaptive Sizing feature is the low radial outward force applied to the vessel wall by the Tack implant. This force remains relatively constant across a wide range of vessel diameters, allowing the Tack implant to fit a range of vessel sizes. This eliminates the need to precisely size the device to the diameter of the vessel. Compared with the much higher radial forces exerted by traditional stents, the Tack implant's low radial



**Figure 2.** BTK and ATK Tack implants. Approximately 6 mm in length, the Tack implant is a first-of-its-kind dissection repair device designed to treat only where dissections are present.

force does not activate the proliferative inflammatory response and neointimal hyperplasia that leads to in-stent restenosis. The metal burden of the Tack implant is 70% to 80% less than stents used to treat a similar dissection.<sup>1</sup> This avoids the need to cover healthy tissue, preserving normal vessel movement, and allows for additional treatment in the future with no bridges burned.

### CASE STUDY

A 67-year-old woman, Rutherford class 3, presented with an 18-cm lesion of the SFA including a 19-cm occlusion (Figure 3A). After predilatation and DCB angioplasty were performed, the post-PTA result was evaluated for the presence of dissection. The use of higher magnification and multiple angles with angiography is recommended, especially if intravascular imaging such as IVUS or OCT is unavailable. A grade D dissection was noted at the middle segment in addition to grade C dissections at the proximal and distal end (Figure 3B). To treat the dissections, the delivery system was advanced over the guidewire and positioned at each intended deployment site. Each Tack implant was released by withdrawing the outer sheath in "pin-and-pull" fashion, moving from the most distal dissection proximally. Six Tack implants were deployed (Figure 3C). The implants were then postdilated to seat the anchors and ensure apposition to the vessel wall, followed by final angiography (Figure 3D).

### CLINICAL TRIAL PROGRAM

The Tack Endovascular System® has a strong clinical history with several studies completed or ongoing. The first ATK study, TOBA (Tack Optimized Balloon Angioplasty), studied the Tack Endovascular System® following standard angioplasty in 130 patients.<sup>1</sup> Results showed 74% of patients had dissections grade C or higher. Primary patency was 76.4% at 12 months with 89.5% freedom from clinically driven (CD) TLR. In our single-center TOBA cohort at Westküstenklinikum Heide, primary patency was 87.5% at 12 and 24 months, indicating no loss of patency between endpoints.<sup>2</sup> TOBA BTK studied the use of the Tack Endovascular System® in 35 patients with critical limb ischemia. The 12-month primary patency rate was 78.4%, with 93.5% freedom from CD-TLR and 84.5% amputation-free survival.<sup>3</sup>

TOBA II, a pivotal investigational device exemption (IDE) study, studied the Tack Endovascular System® after either standard or Lutonix 035 DCB (BD Interventional) angioplasty. The balloon choice was at the discretion of the operator. TOBA III, a post-

CE Mark approval study, investigated dissection repair with Tack implants after In.Pact Admiral (Medtronic) angioplasty, including a subset of patients with longer lesions between 15 and 25 cm. Both studies have completed enrollment. The 12-month data from TOBA II are anticipated to be released in late 2018.

TOBA II BTK is the pivotal IDE study of the Tack Endovascular System® in the treatment of patients with infrapopliteal disease and critical limb ischemia. The trial is enrolling rapidly in the United States, Europe, and New Zealand and will analyze primary end-points at the 6-month time frame.

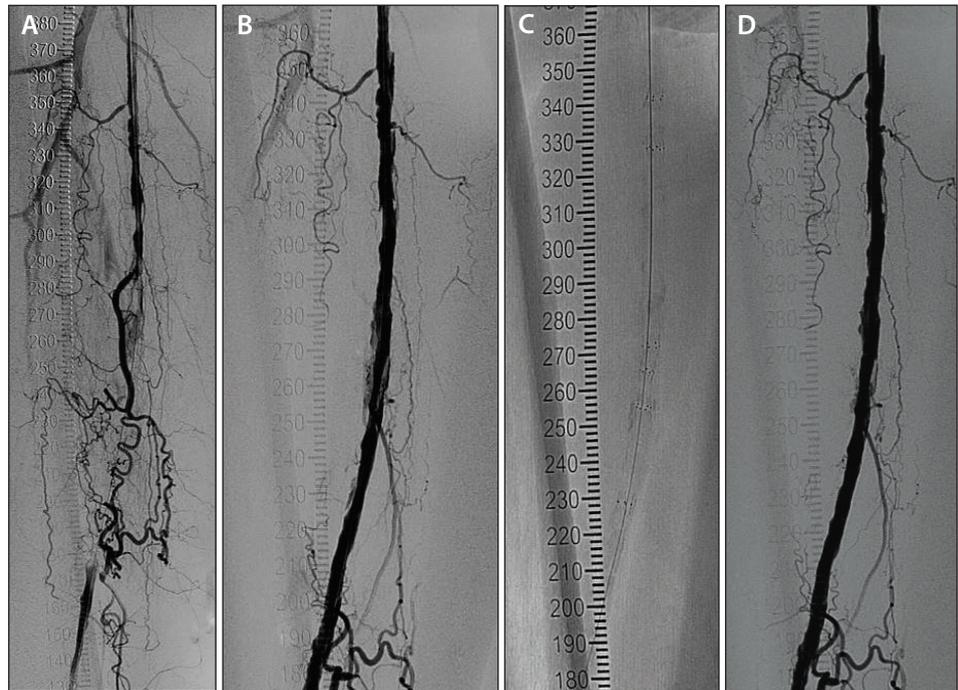


Figure 3. Case example from Westküstenklinikum, Heide, Germany. A long SFA occlusion (A) was treated with angioplasty, resulting in multiple severe dissections (B). Six Tack implants were placed with resolution of the dissections (C). The final angiogram after postdilatation of Tacks showed no residual dissection (D).

## CONCLUSION

With the Tack Endovascular System®, minimal metal and low radial force present a new scaffolding paradigm with focal treatment of postangioplasty dissections. In keeping with the progressive nature of peripheral artery disease, future treatment options, both endovascular or surgical, are preserved. ■

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