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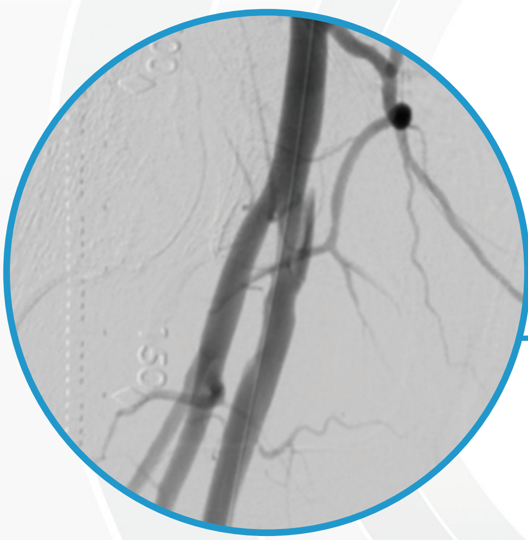
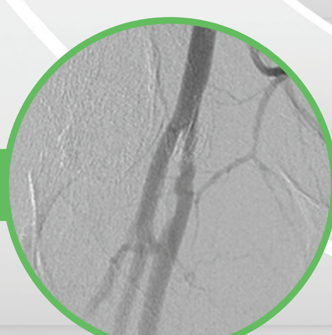
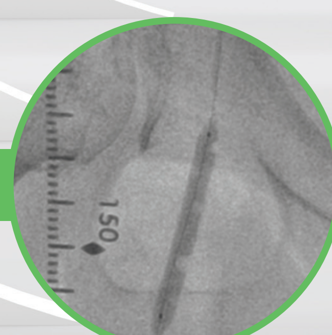
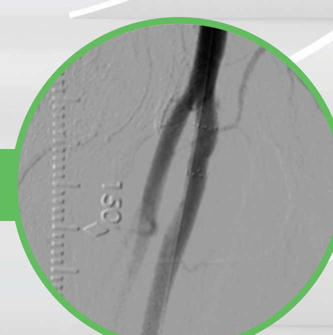


DISSECTION REPAIR.

A Critical Post-PTA Treatment for Optimized PAD Outcomes in ATK Interventions.







Post-PTA Dissection Repair in the Bifurcation Using the Tack Endovascular System®

BY MOHAMMAD LAIQ RAJA, MD

Atherosclerotic disease in the bifurcating femoral artery remains hostile anatomy for endovascular intervention. The angled ostia of the superficial femoral artery (SFA) and profunda make it difficult to place a stent without missing part of the target vessel circumference or jailing the other vessel. Even in friendlier territories, stenting can lead to inflammation and neointimal hyperplasia. Endovascular therapy in this area is largely composed of debulking and adjuvant balloon angioplasty.

For claudicants, durable patency decreases the risk of returning symptoms. For critical limb ischemia, restenosis is less of an issue. The aim is to restore adequate flow to allow wound healing with the expectation of repeat procedures, along with the notion that restenosis following nonimplant therapy is easier to treat than in-stent restenosis.

Dissections that arise from balloon angioplasty compromise clinical outcomes in both the short and long term. In the setting of limb salvage, dissection repair could be ideally achieved with a technique that allows for natural vessel movement and does not require high metal burden or complicate the potential for further treatment.

The Tack Endovascular System® (Intact Vascular, Inc.) is a first-of-its-kind dissection repair device that offers the advantage of focal treatment with minimal metal, treating only the area where dissections are present and avoiding covering portions of healthy tissue (Figure 1). The device consists of an over-the-wire delivery system preloaded with six self-expanding nitinol implants that can be deployed to treat multiple dissections using a single catheter and leaving behind 70% to 81% less metal than stents.[1]

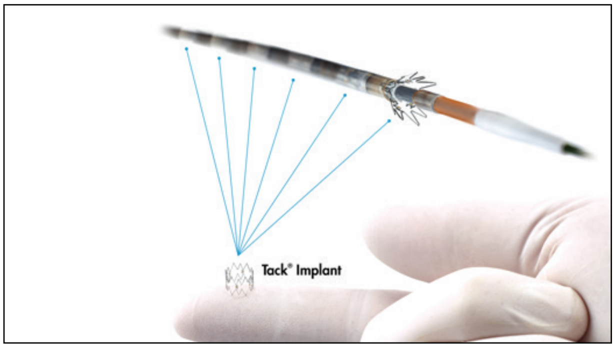


Figure 1. The Tack Endovascular System contains six preloaded self-expanding nitinol implants on a single catheter.

PATIENT PRESENTATION

A 41-year-old man presented with a 1-year history of right calcaneal ulcer, another wound on the second

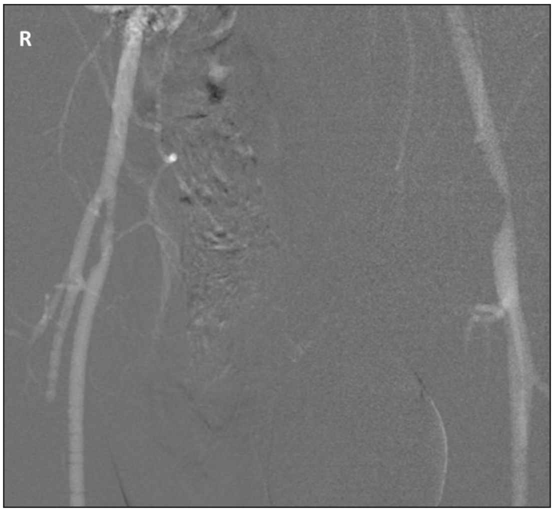


Figure 2. CO_2 angiogram revealed bilateral femoral disease.

Figure 3. Right femoral artery stenosis.

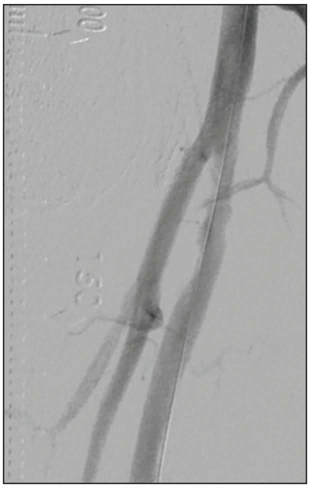


Figure 4. Postatherectomy shows no angiographic dissection.

Figure 5. Grade D dissection post-percutaneous transluminal angioplasty (arrows).

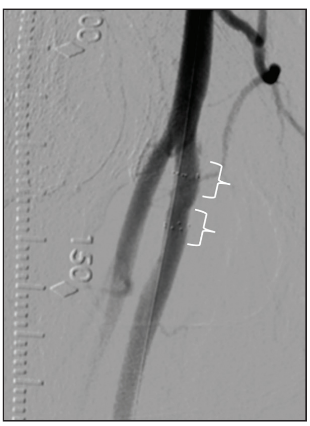


Figure 6. Two Tack implants (brackets) resolved the dissection.

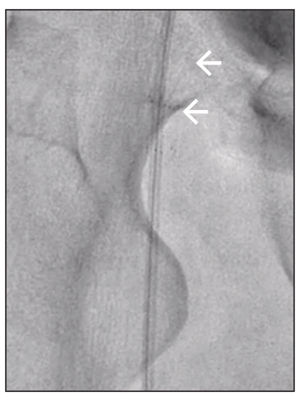


Figure 7. A 6-F sheath was successfully advanced through the Tacks (arrows) < 3 weeks later.

toe on his right foot for the past 3 months, and severe claudication. His risk factors included a strong family history for premature coronary death; he was status post five-vessel coronary bypass. He also had a history of hypertension, hyperlipidemia, and type 2 diabetes mellitus.

PROCEDURE

Upon examination, femoral pulses were normal on the right and moderately diminished on the left. Duplex ultrasound suggested severe inflow and outflow disease.

Both groins were prepped and draped, and right radial access was obtained for initial angiography. CO_2 angiography demonstrated a patent distal aorta and bilateral iliac arteries.

The left common femoral artery had a 90% stenosis, and the right limb had a 70% stenosis at the bifurcation (Figure 2) with severe tibial disease. With the need for extensive revascularization, it was decided to stage therapy over multiple procedures.

Because of the significant disease in the right femoral artery, antegrade access was abandoned.

Instead, a 5-F sheath was inserted only a few centimeters into the left common femoral artery, and the tip of the sheath was located distal to 90% stenosis. Angioplasty was performed with a 5- X 40-mm standard balloon. There was some recoil, but enough lumen was gained to place a 6-F, 65-cm sheath up and over into the right common femoral artery to proceed.

Selective angiography (Figure 3) and intravascular ultrasound images were obtained and showed a 70% to 80% stenosis composed of soft plaque, with 6-mm vessel diameter. Next, distal embolization protection was established in the mid-SFA, and directional atherectomy was used to debulk the distal common femoral artery. There was no visible dissection following atherectomy (Figure 4). Atherectomy was followed with angioplasty just across the bifurcation, using a standard balloon 1 mm smaller than the reference vessel diameter (5 X 40 mm).

Despite the use of a smaller-diameter balloon, angiography post-percutaneous transluminal angioplasty revealed a 10-mm grade C–D dissection with visible extraluminal contrast and staining of the dissected false lumen (Figure 5).

Two Tack® implants were deployed precisely at the desired location and postdilated per the instructions for use. The final angiogram showed a pleasing result with the dissection flap firmly apposed to the vessel wall with brisk flow (Figure 6). The patient returned for tibial intervention < 3 weeks later. Antegrade access was used with a 6-F sheath advanced through the Tacks with no movement of the implants (Figure 7).

DISCUSSION

In our practice, the Tack Endovascular System is used to treat type C and more severe dissections. It is ideal for spot treating, and the delivery system is precise and easy to use. Our patients receive ideal results with the least amount of metal left behind. ■

1. Bosiers M, Scheinert D, Hendriks JM, 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;64:109-116.

Mohammad Laiq Raja, MD
Interventional Cardiologist
El Paso Cardiology Associates
El Paso, Texas
rajamohammad@hotmail.com
Disclosures: None.

Optimized PTA With Tack Salvage Following Rendezvous Subintimal SFA CTO Recanalization

BY JOHN H. RUNDBACK, MD

PATIENT HISTORY

A 62-year-old man presented with a 2-month history of worsening bilateral calf pain (worse in the left leg) when walking one block. He complained of numbness in both feet when sleeping, which improved by dangling his legs. There were no leg or foot ulcers. Cardiovascular risk factors included an 8-year history of insulin-dependent diabetes mellitus, dyslipidemia, and hypertension. He denied coronary artery disease, cerebrovascular disease, renal impairment, or smoking history. Medications included insulin, losartan, omega-3 fish oil, gemfibrozil, and gabapentin. On examination, femoral pulses were intact and the popliteal, posterior tibial, and right dorsalis pedis pulses had audible Doppler signals. Pallor with elevation and mild dependent rubor were noted in both legs, and there were atrophic changes with hair loss and brittle nail beds. No edema or wounds were noted. Arterial imaging was performed and showed bilateral femoropopliteal occlusive disease.

PROCEDURE

The patient underwent left lower extremity angiography from a right femoral approach showing an approximately 20-cm-long chronic total occlusion (CTO) of the left superficial femoral artery (SFA) reconstituting the popliteal artery at the level of the adductor canal (Figure 1, arrow). Attempted antegrade puncture repeatedly resulted in collateral wire passage (Figure 2, arrows). Retrograde distal popliteal access was achieved that allowed for the insertion of a 5-F sheath and subintimal recanalization with a 5-mm balloon positioned at the SFA occlusion (Figure 3, asterisk). From the contralateral approach, an Outback Elite catheter (Cordis, a Cardinal Health company) was advanced adjacent to the balloon (Figure 3, open arrow) and successful puncture was performed into the retrograde balloon. Once the wire was externalized and through-and-through access was achieved, a 6-mm angioplasty was performed that resulted in restored arterial patency with multiple grade C and D

Figure 1. Left SFA CTO.

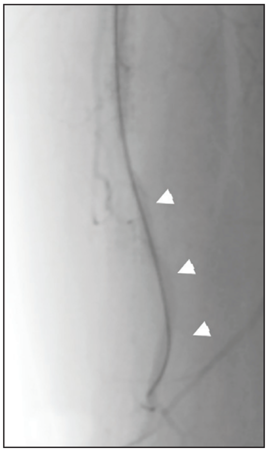


Figure 2. Antegrade access was unsuccessful.

dissections (Figure 4, curved arrows), which was confirmed with intravascular ultrasound (IVUS) (Figure 5, dissection marked with arrows). Using the Tack Endovascular System® (Intact Vascular, Inc.), a total of six Tack® implants were deployed and postdilated with a 6-mm balloon (Figure 5, Tacks marked with double arrows). Completion arteriography showed complete resolution of dissections with the restored unobstructed femoropopliteal flow (Figure 6).

DISCUSSION

Recanalization of femoropopliteal CTOs frequently results in intentional or inadvertent subintimal wire passage that results in dissection planes either after spontaneous wire reentry or the use of reentry or "rendezvous" techniques (as was used in this case). However, depending on the actual plane of wire passage, these dissections are often discontinuous (ie, areas of dissection separated by patulous uninterrupted arterial segments). These dissections may be flow-limiting and compromise acute results, and all grades of

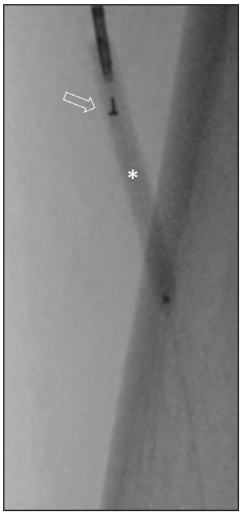


Figure 3. The lesion was crossed via contralateral retrograde access (arrows).

Figure 4. Post-PTA severe dissections (arrows).

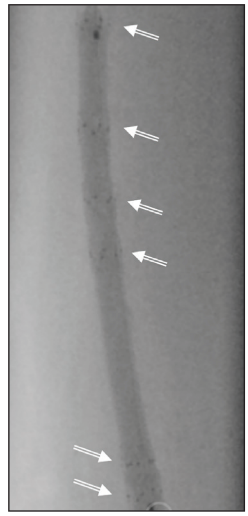


Figure 5. Six Tacks (arrows) were placed.

Figure 6. No residual dissection.

dissection are associated with a higher incidence of late failure and restenosis.[1] Although the placement of long-segment confluent stent scaffolds provides early resolution, long-term patency of most bare-metal stents is suboptimal,[2] and the use of drug-eluting stents has recently been subject to controversy regarding late mortality risk.[3] In our early experience, focal dissection repair using the Tack Endovascular System has the advantage of allowing targeted resolution of dissection areas with a low metal burden and vessel stress, because the Tack implants exert only low outward radial force through a dynamic range of vessel diameters.

IVUS can be a helpful adjunct for Tack-assisted optimized percutaneous transluminal angioplasty (oPTA) by showing the exact location of the dissection entry and exit, the arterial diameter (for best balloon selection), and the extent of the dissection. Because each Tack Endovascular System contains six Tack implants, Tacks can be individually and precisely deployed at needed sites and with uneven spacing.

Our workflow is to use IVUS and angiography to identify the entry and exit point as well as the length of dissections, then we mark these locations on the fluoroscopic monitor, and we deploy each Tack under high fluoroscopic magnification for targeted positioning and dissection repair with minimal Tacks. Should additional levels of dissection repair be needed, the process is repeated at high magnification with the image intensifier again centered over the region to be treated.

The oPTA strategy with Tack repair of dissections has been a particularly effective treatment approach in our office-based surgery lab. Early data suggest patency rates equivalent to other biomimetic stents and drug delivery technologies. As an alternative to drug-coated balloons (DCBs), oPTA with Tack deployment reliably resolves immediate postprocedural, dissection-related flow issues and provides a reimbursable, cost-judicious, and clinically reliable endovascular solution. In the TOBA II pivotal trial, primary patency at 1 year was 79.3% in a pooled population of 213 patients treated with either plain old balloon angioplasty or DCB, all of whom had post-PTA dissection (most of them severe).[4] Also, the dynamic range of Tacks (3.5–6-mm diameter) allows us to treat more than one arterial segment with a single device.

CONCLUSION

In our practice, the use of oPTA with the Tack Endovascular System is a clinically effective strategy for treating patients with complex peripheral artery disease lesions. The ability to treat multiple levels with one device, reliably achieve angiographic success, and feel comfortable with evidence-based results has made oPTA the first-line technique in our office-based surgery lab. ■

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2. Rocha-Singh KJ, Jaff MR, Crabtree TR, et al. Performance goals and endpoint assessments for clinical trials of femoropopliteal bare nitinol stents in patients with symptomatic peripheral arterial disease. Cath Cardiovasc Interv. 2007;69:910-919.
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4. Gray W. TOBA II 12-month results: Tack optimized balloon angioplasty. Presented at: Vascular InterVentional Advances (VIVA); November 5–8, 2018; Las Vegas, Nevada.

John H. Rundback, MD
Interventional Institute and Advanced Interventional & Vascular Services LLP
Holy Name Medical Center
Teaneck, New Jersey
jrundback@aivsllp.com
Disclosures: TOBA II/TOBA II BTK investigator and consultant to Intact Vascular.

Dissection Repair After Balloon Angioplasty of a Calcified SFA Lesion

BY EHRIN J. ARMSTRONG, MD, MSc

PATIENT PRESENTATION

A 67-year-old man presented with severe lifestyle-limiting claudication of the right lower extremity. The patient had a history of a right superficial femoral artery (SFA) endovascular intervention 4 years earlier with the placement of a nitinol stent in the distal SFA. He was compliant with medications, including aspirin, high-intensity statin, and an angiotensin-converting enzyme inhibitor. He also remained abstinent from smoking. Physiologic studies demonstrated an ankle-brachial index of 0.72, and a duplex ultrasound confirmed focal, severe stenosis of the mid-SFA, proximal to the previously implanted stent.

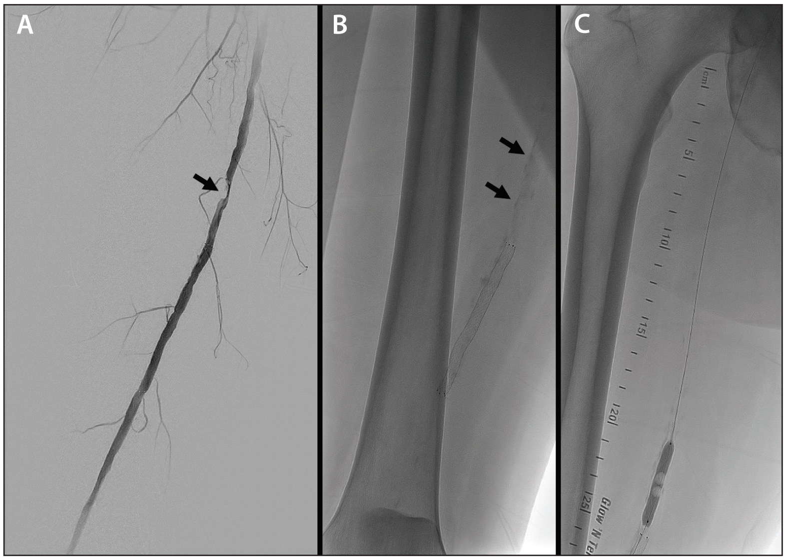

Figure 1. Mid-SFA stenosis (A); moderate-to-severe calcification (B); standard balloon angioplasty (C).

TREATMENT OPTIONS

Treatment options were discussed with the patient, including conservative management with a walking program and secondary risk factor reduction versus endovascular intervention. Due to the patient's severe continued claudication despite walking therapy, he opted for lower extremity angiography and possible intervention.

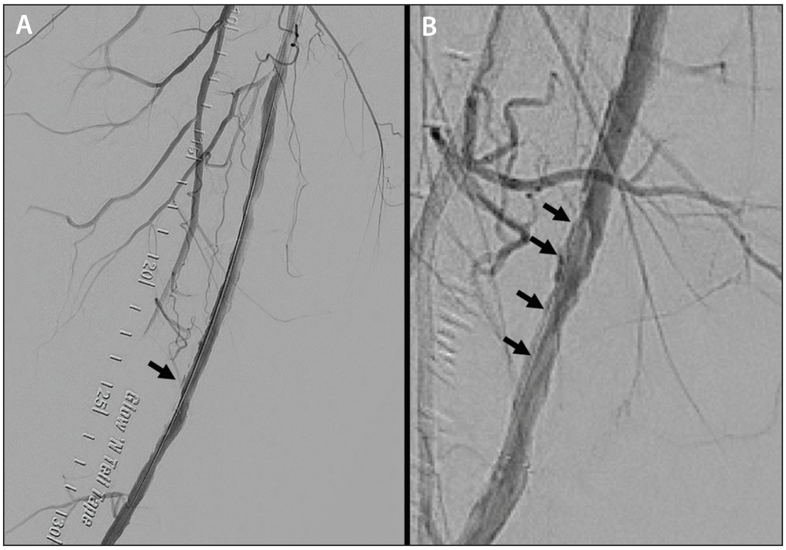

Figure 2. Panel A reveals a grade B dissection after percutaneous transluminal angioplasty, but an orthogonal view shows a severe, spiral dissection (B).

PROCEDURE

Right lower extremity angiography confirmed the presence of severe, focal stenosis in the mid-SFA (Figure 1A). Nonsubtracted images confirmed that the lesion was proximal to the previously implanted stent and that the lesion had moderate-to-severe calcification (Figure 1B). Based on the focal disease, balloon angioplasty was performed with a 5- X 40-mm balloon at 8 atm for 2 minutes (Figure 1C). After balloon angioplasty, angiography revealed a dissection in the mid-lesion segment (Figure 2A). The initial image of the dissection was consistent with a

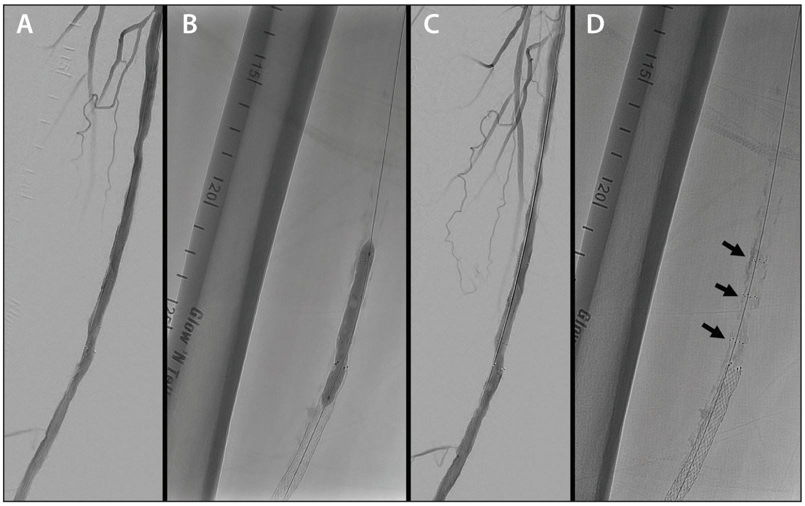

Figure 3. Three Tacks were placed (A) and postdilated (B). No residual dissection on the final angiogram (C). Panel D shows three Tack implants (arrows) in the mid SFA.

type B dissection. However, orthogonal imaging at high magnification revealed that the dissection spiraled around the lesion, consistent with a type D dissection (Figure 2B).

Based on the significant dissection after balloon angioplasty, using the Tack Endovascular System® (Intact Vascular, Inc.), three Tack® implants were implanted at the site of the dissection (Figure 3A). The Tacks were postdilated with a 5-mm balloon (Figure 3B). Final angiography revealed no residual dissection and an excellent angiographic result.

RESULTS

The patient was discharged home later the same day. At 1-month follow-up, the patient reported complete resolution of his claudication symptoms with high levels of physical activity. Duplex ultrasound also confirmed a patent SFA with no evidence of restenosis or Tack migration.

DISCUSSION

Dissections occur after almost all balloon angioplasties and result from longitudinal stress, radial expansion stress, and shear stress exerted on the atherosclerotic plaque.[1] Despite the prevalence of dissections, few data have historically been available regarding the natural history of dissections and which dissections should be treated. Recently, data from a Japanese study demonstrated that any dissection ≥ grade B was associated with an increased risk of restenosis after balloon angioplasty.[2] These data suggest that dissections are often undertreated and that more aggressive treatment of dissections may improve patency after an endovascular intervention.

Treatment options for dissections include prolonged balloon angioplasty, stent implantation, or Tack placement. Small studies have demonstrated that extremely long duration of balloon angioplasty (mean, 7.8 minutes) may reduce dissection severity compared with balloon inflations of 3 minutes.[3] Stent implantation remains a treatment option for dissections but has the disadvantage of leaving a heavy nitinol burden behind, with the attendant risk of in-stent restenosis. In comparison, the Tack Endovascular System is purpose-built for the repair of dissections after balloon angioplasty. Each Tack is 6 mm long and the delivery system comes preloaded with six Tacks. This system makes it possible to treat discontinuous areas of dissection with a single delivery system.

In the current case, orthogonal imaging confirmed a severe dissection at the site of balloon angioplasty. This case emphasizes the importance of high-quality imaging and the use of multiple views to identify dissections. Intravascular ultrasound can also be considered for further dissection characterization.[4] Rather than placing an additional stent, the placement of three Tack implants made it possible to effectively treat the areas of dissection while minimizing the extent of nitinol implant. Based on data from the recent TOBA II trial, similar lesions (focal, moderate-severe calcium) treated with plain old balloon angioplasty reported 89.6% primary patency at 12 months.[5] These impressive results demonstrate that balloon angioplasty, when optimized with Tack implantation, can be durable and provide long-term symptom relief for patients with severe claudication. ■

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3. Horie K, Tanaka A, Taguri M, et al. Impact of prolonged inflation times during plain balloon angioplasty on angiographic dissection in femoropopliteal lesions. J Endovasc Ther. 2018;25:683-691.
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5. Gray W. TOBA II 12-month results: Tack optimized balloon angioplasty. Presented at: Vascular InterVentional Advances (VIVA); November 5–8, 2018; Las Vegas, Nevada.

Ehrin J. Armstrong, MD, MSc
Associate Professor of Cardiology
University of Colorado
Aurora, Colorado
ehrin.armstrong@gmail.com
Disclosures: TOBA II/TOBA II BTK investigator and consultant to Intact Vascular.

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INTENDED USE: The Tack Endovascular System (6F) is intended for use in the superficial femoral and proximal popliteal arteries ranging in diameter from 3.5mm to 6.0mm for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissection(s) type(s).

CONTRAINDICATIONS FOR USE: The Tack Endovascular System is contraindicated for the following:
1. Patients with residual stenosis in the treated segment equal to or greater than 30% after PTA.
2. Tortuous vascular anatomy significant enough to prevent safe introduction and passage of the device.
3. Patients with a known hypersensitivity to nickel-titanium alloy (Nitinol).
4. Patients unable to receive standard medication used for interventional procedures such as anticoagulants, contrast agents and antiplatelet therapy.

Prior to using the Tack Endovascular System, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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