Sponsored by Intact Vascular®, Inc.

Solving the Lower Extremity Challenge of "Too Much Metal"

Focal treatment after lower extremity PTA using the Tack-It Endovascular System™.

BY DIERK SCHEINERT, MD

If you must leave something behind, leave as little as possible to get the optimal result.

The current treatment paradigm for lower extremity occlusive disease relies on percutaneous transluminal angioplasty (PTA) to recreate luminal integrity. PTA increases the cross-sectional area of the artery via a subtotal rupture of the vessel that fractures the plaque, intima, and media down to the level of the adventitia. However, an uncontrolled pattern of expansion may result in vessel dissections (Figure 1) and cause irregular luminal defects or torn plaque hanging into the flow channel. The dissected plaque and vessel wall may create hemodynamic disturbances and generate thrombus. Balloon angioplasty in the superficial femoral artery (SFA), even in experienced hands in short lesions, has a 1-year patency rate of 28% to 37%.[1] Post-PTA dissections may be even more problematic when treating long lesions and occlusions.

As the field of endovascular intervention evolves, it has become clear that we need tools that permit us to customize therapies to the needs of our patients. Medical device manufacturer Intact Vascular®, Inc. (Wayne, PA) has developed a technology called the Tack-It Endovascular System™ (Tack), which is designed to create tissue apposition after angioplasty when focal treatment is needed to tack down dissections.

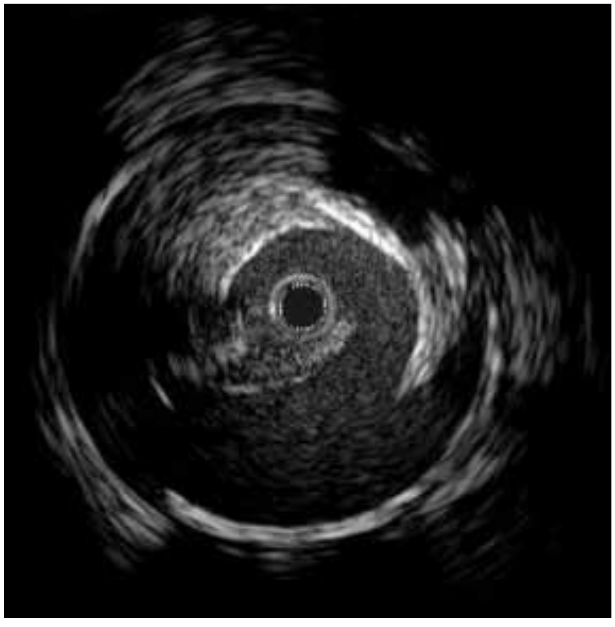


Figure 1. Intravascular ultrasound depicting dissection.

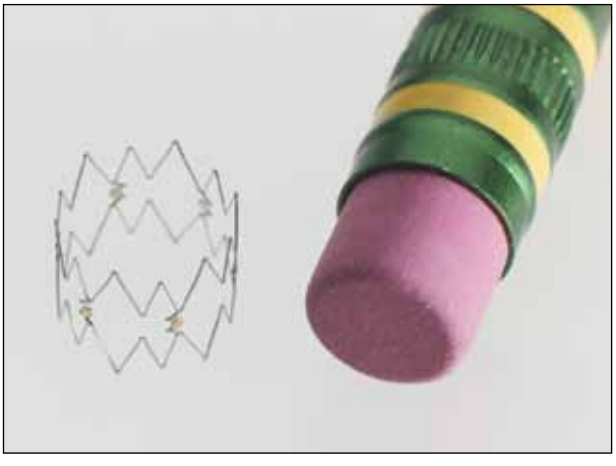


Figure 2. A 6-mm-length Tack compared to a pencil eraser.

THE TECHNOLOGY

The Tack is a circumferential, self-expanding nitinol device that is only 6 mm in length and has an open-cell design. It includes an anchor fixation feature that assists in maintaining proper position of the Tack and secures dissected tissue to create tissue apposition. Each Tack has six pairs of anchors and six radiopaque markers located along the center of the device (Figure 2). Four preloaded Tacks are crimped on the distal end of a 6-F delivery catheter. The Tack can expand to treat a

Sponsored by Intact Vascular®, Inc.

TABLE 1. KEY FEATURES OF THE TACK DEVICE

- Four self-expanding nitinol Tacks preloaded onto a 6-F delivery catheter
- Open-cell design
- Anchor fixation designed to assist in maintaining proper position of the Tack and to secure dissected tissue to create tissue apposition
- One-size Tack accommodates arterial diameters from 2.5 to 5.5 mm
- Low outward force onto the arterial wall

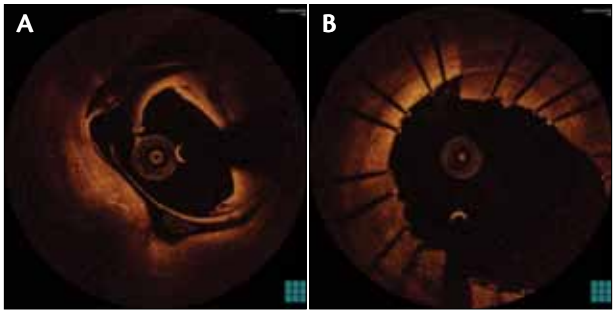


Figure 3. Optical coherence tomography of a post-PTA dissection (A) and tissue apposition achieved after Tack placement (B). (Images provided by Marianne Brodmann, MD, Medical University Graz, Austria.)

wide range of vessel sizes from 2.5 to 5.5 mm in diameter. Tacks are individually deployed and provide focal treatment only where needed. The device exhibits low outward force on the arterial wall and is designed to maintain the natural configuration of the artery. Use of the Tack maintains radial and longitudinal compliance of the vessel, enhancing the potential for positive remodeling and minimizing vessel injury. Key features of the Tack design are highlighted in Table 1. The intended result is an improved post-PTA arterial surface that is achieved with a minimal amount of foreign material (Figure 3).

The Tack received CE Mark approval in March 2012 and is indicated for tissue apposition to optimize angioplasty results in peripheral arteries ranging in diameter from 2.5 to 5.5 mm. Dissection, tissue flaps, or irregular luminal surface may be indicated for Tacking. The device is not currently available in the United States.

THE PROCEDURE

PTA of the target lesion is performed to the reference vessel diameter. The post-PTA result is evaluated angiographically for evidence of tissue dissection. If dissections are present and require treatment, the 6-F Tack-It Endovascular System™ is inserted past the treatment site on a 0.035-inch guidewire. The catheter is positioned in the treatment area, and the Tacks are released by pulling

Figure 4. Partially deployed Tack from the distal end of the delivery catheter.

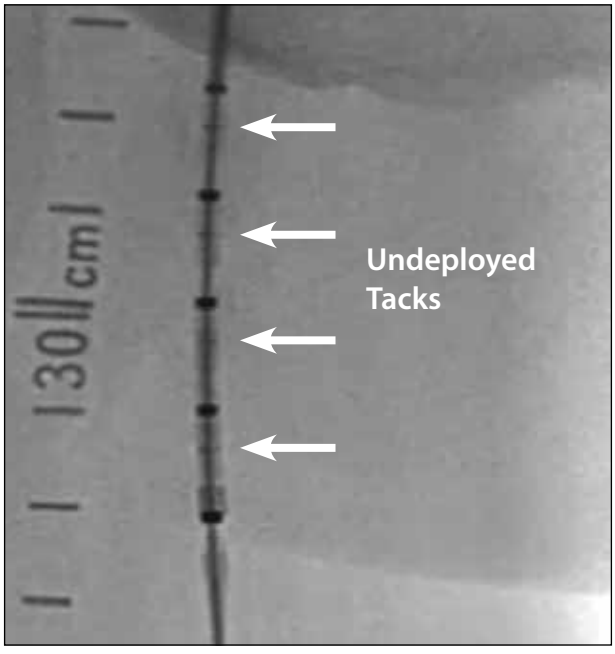
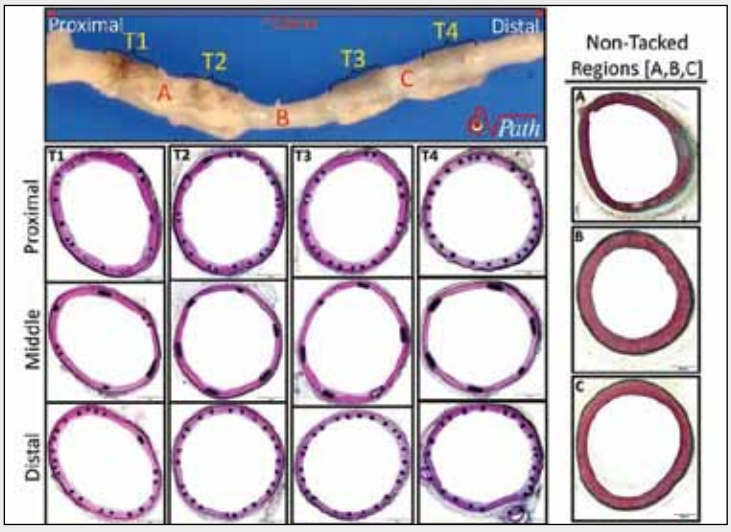


Figure 5. Angiography showing the distal end of the delivery catheter with the Tacks between the radiopaque markers.

Sponsored by Intact Vascular®, Inc.

PATHOLOGY STUDY



An animal study using a Yucatan swine model was performed at the Skirball Cardiovascular Research Center in Orangeburg, New York, under the direction of Drs. Juan Granada and Greg Kaluza. The animals survived to 14 days. Histological assessment was performed by Drs. Renu Virmani and Frank Kolodgie at CVPath Institute in Gaithersburg, Maryland. These images show the Tack-It Endovascular System™ at 14 days in the right superficial femoral artery of the Yucatan mini swine model. The gross photograph in the top panel shows a series of Tacks (T1 through T4) well expanded against the arterial wall. The histologic sections of Tacks were prepared by Exakt grinding and then staining in toluidine blue-basic fuchsin. The low-power histologic images correspond to the proximal, middle, and distal regions of each of the four Tacks. Note that all of the Tack areas are well healed and incorporated by a thin layer of neointimal growth consisting mainly of smooth muscle cells and proteoglycan matrix. Images on the right (A through C) depict intervening segments between Tacks and show minimal or absent injury without neointimal response. Intervening histologic sections were embedded in paraffin and stained with Movat Pentachrome. (All images are courtesy of Renu Virmani, MD, CVPath Institute, Gaithersburg, Maryland.)

back on the delivery catheter sheath using a simple "pin-and-pull" technique (Figure 4). The catheter is repositioned to additional areas requiring treatment after each Tack deployment. If more than one Tack is required, the most distal Tack is placed first.

After inserting the desired Tacks, post-Tack angioplasty is performed using the same size balloon expanded to the reference vessel diameter to ensure that tissue apposition is achieved and to seat the anchors.

Figure 5 shows the distal end of the delivery catheter with the Tacks between the radiopaque markers.

LIMITATIONS

Tack placement may not be appropriate for the most heavily calcified lesions or recurrent fibrotic lesions that require high residual radial force.

PREVIOUS CLINICAL EXPERIENCE

A safety and feasibility study was performed in Asuncion, Paraguay. A total of 25 lesions in 11 subjects with 15 treated limbs were enrolled during a 4-month period from December 2009 to March 2010. The vessels treated included the common femoral, superficial femoral, popliteal, and tibial arteries.

The primary safety objective was the rate of major adverse events at 30 days, defined as the composite of death, device embolization, the occurrence of device-related surgery, device-related occlusion of the artery, or major unplanned amputation of the ipsilateral lower extremity. The secondary feasibility objective was the ability of using the Tack to secure vascular flaps. Feasibility was described as the ability to accurately place the Tack and to resolve post-PTA dissection prior to the conclusion of the procedure as demonstrated by angiography. Acute technical success was also included in the secondary feasibility objective, which was defined as patency in area of the Tack at the end of the procedure as demonstrated by angiography.

The results included:

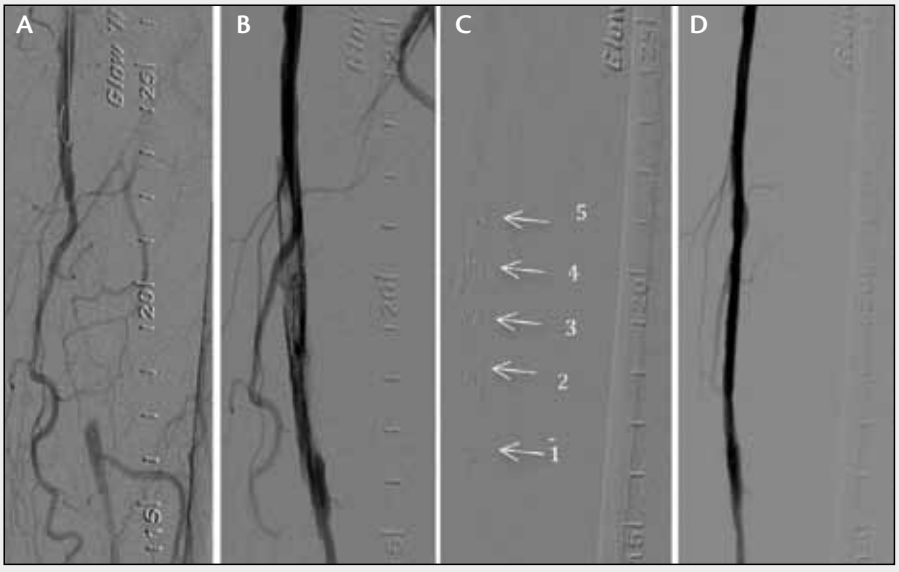
- 100% technical success in all of the treated lesions
- 96% (48/50) successful placement of the Tack(s)
- 95% of lesions were patent at 3 months
- No Tacks migrated or embolized

There was one death that occurred before discharge, which was possibly related to the procedure. The subject had a history of cardiovascular disease, myocardial infarction, and renal failure. One death occurred

Sponsored by Intact Vascular®, Inc.

CASE EXAMPLE

This patient was enrolled as part of the ongoing TOBA study and treated at Park Krankenhaus in Leipzig, Germany.



A 70-year-old man presented with left leg claudication after walking 50 meters. The subject had a history of diabetes, hypertension, and Rutherford clinical category 3. He underwent angiography that revealed an occluded SFA (A). The proximal reference vessel diameter of the mid-SFA was 4.8 mm, and the lesion length was 60 mm. The occlusion was treated with PTA that resulted in dissection (B). Five Tacks were placed (C), with successful resolution of the dissected areas (D). The total procedure time was 35 minutes. No adverse events occurred at the 30-day follow-up period, and the patient had a reduction in Rutherford clinical category from 3 to 1. The patient was able to walk 2,000 meters pain-free.

between the 1- and 3-month follow-up visit. The subject died at home. One subject was lost to follow-up. Seven of the eight remaining subjects, with a total of 18 treated lesions, had an angiogram at the 12-month follow-up period. Of these 18 lesions, the angiographically based patency rate was 83.3% (15/18). One subject with a single lesion had a severe recurrent stenosis at 3 months postprocedure and underwent a repeat revascularization. Two subjects had a single lesion with > 50% stenosis exhibited on angiography at the 12-month evaluation. No treatment was required.

CURRENT CLINICAL STUDIES

Our center, along with others in Europe, is participating in a postmarket study to confirm the long-term clinical performance of the Tack. The Tack Optimized Balloon Angioplasty (TOBA) trial is enrolling as many as 138 subjects at up to 15 centers in Europe. Patients with lesions of the SFA or the popliteal arteries who undergo balloon angioplasty and experience suboptimal PTA results due to dissections are treated with Tack placement as determined by the operator. The subjects are followed at 30 days, 6 months, and 12 months with a clinical assessment including duplex ultrasound. A subset of subjects is also undergoing angiography at 6 months.

CONCLUSION

PTA produces uncontrolled dissections that may benefit from focal treatment with the Tack-It Endovascular System™. The Tack is designed to create tissue apposition with a minimal amount of metal and low outward force to allow natural arterial flexibility and low neointimal response. Long-term clinical evidence is needed in order to confirm the clinical benefits of this novel technology. ■

Dierk Scheinert, MD, is Director, Center of Vascular Medicine, Angiology & Vascular Surgery at Park Krankenhaus in Leipzig, Germany. He has disclosed that he serves on the advisory board and is a consultant to Abbott, Angioslide, Atheromed, Biotronik, Boston Scientific, Cook Medical, Cordis, Covidien, CR Bard, Gardia Medical, Intact Vascular, Medtronic, TriReme Medical, TriVascular, and Upstream Peripheral Technologies. He has also disclosed that he is a stockholder and consultant to Idev.

1. Rocha-Singh K, Jaff MR, Crabtree TR, et al. Performance goals and endpoint assessments for clinical trials of femoropopliteal bare nitinol stents in patients with symptomatic peripheral artery disease. Cath Cardiovasc Interv. 2007;69:910-919.