EuroSciCon

3rd Edition of World Congress & Exhibition on

Vascular Surgery

May 24-25, 2018
London, UK

Luboš Kubíček, J Vasc Endovasc Therapy 2018, Volume 3
DOI: 10.21767/2573-4482-C1-002

# POST-PTA DISSECTION REPAIR ABOVE AND BELOW THE KNEE

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**Objective:** Angioplasty often results in dissections and remains a significant problem. Dissections are typically managed with stents, which are associated with high rates of in-stent restenosis. Two tack optimized balloon angioplasty (TOBA) studies evaluated the safety and efficacy of a novel implant for dissection repair in both above and below the knee lesions. The Tack combines low outward force with minimal metal to provide focal treatment for dissections.

**Methods:** TOBA was a prospective, single-arm study evaluated patients with Rutherford Category 2-4 caused by lesions of the superficial femoral and popliteal arteries. Patients were treated with standard balloon angioplasty, and post-PTA dissections were treated with Tacks. The primary endpoints were device technical success (ability of the Tack implants to resolve post-PTA dissection) and device safety (absence of new-onset major adverse events). TOBA BTK, a separate study, evaluated patients with CLI and infrapopliteal lesions. The primary safety endpoint was a composite of MALE and POD at 30 days. Device success and procedure success were also assessed.

**Results:** In TOBA, Tacks were used in 130 patients with post-PTA dissections (74.0% grade C). Technical success was achieved in 98.5% of patients with no major adverse events at 30 days. Twelve-month patency was 76.4%, and freedom from TLR was 89.5%. Significant improvement from baseline was observed in Rutherford clinical category and ankle-brachial index at 12 months ($p<0.0001$). In TOBA BTK, 32 patients received dissection repair with Tacks. Freedom from MALE and POD at 30 days was 97.1%. Twelve-month patency was 78.4% and freedom from CD-TLR at 12 months was 93.5%.

**Conclusions:** Tack implant treatment of post-PTA dissection was safe and resulted in low rates of TLR both above and below the knee. Tack treatment represents a new, minimal metal paradigm for dissection repair that can safely improve the clinical results associated with PTA.

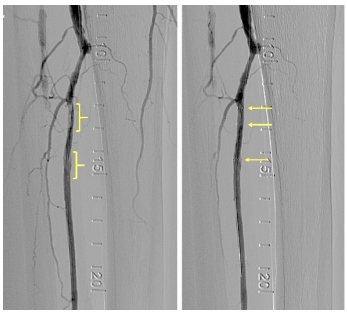

**Figure 1:** Example of resolved BTK Post-PTA dissection. Left: Two dissections (brackets) resulted from angioplasty. Right: Three Tack implants (arrows) were placed.

## Recent Publications

1. Werk M, Albrecht T, Meyer D R, et al. Paclitaxel-coated balloons reduce restenosis after femoro-popliteal angioplasty: evidence from the randomized PACIFIER trial. Circ Cardiovasc Interv 2012; 5: 831-40.
2. Kiguchi MM, Marone LK, Chaer RA, et al. Patterns of femoropopliteal recurrence after routine and selective stenting endoluminal therapy. J Vasc Surg 2013; 57:37–43.
3. Al-Nouri O, Krezalek M, Hershberger R, et al. Failed superficial femoral artery intervention for advanced infrainguinal occlusive disease has a significant negative impact on limb salvage. J Vasc Surg 2012; 56:106–10.
4. Tosaka A, Soga Y, Iida O, et al. Classification and clinical impact of restenosis after femoropopliteal stenting. J Am Coll Cardiol 2012; 59:16–23.
5. 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; 64:109-16.

## Biography

Luboš Kubíček received his MD degree from Faculty of Medicine, Masaryk University in Brno (Czech Republic) in 2011. He is a fifth-year postgraduate student in vascular surgery, university teacher, clinical researcher and vascular surgeon at 2nd Department of Surgery of St. Anne's university hospital in Brno, Czech Republic. His main research interests are: rupture risk prediction of abdominal aortic aneurysms, thermographic imaging in vascular surgery, systemic enzyme therapy in chronic wound healing and he is also involved in several international clinical trials, both drug research and interventional trials. He is also author or co-author of several grant project proposals and in this time, he is involved in two research grant projects.

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