



# Tackling Challenges Below the Knee: Unveiling the Benefits of the Tack-Optimized Balloon Angioplasty (TOBA) II BTK System

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## Abstract

The Tack-Optimized Balloon Angioplasty (TOBA) II below-the-knee (BTK) study has emerged as a pivotal investigation in the realm of BTK interventions, specifically addressing post-percutaneous transluminal angioplasty (PTA) dissections of the infrapopliteal arteries. This commentary delves into the 36-month results of TOBA II BTK, showcasing the benefits of the Tack Endovascular System (Intact Vascular, Inc., now a part of Philips Image Guided Therapy Corporation) for repairing PTA-induced dissections in the challenging landscape of BTK disease.

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**Key words:** percutaneous transluminal angioplasty, peripheral artery disease, critical limb-threatening ischemia

Peripheral artery disease (PAD) poses a significant global health concern, affecting over 200 million individuals.<sup>1</sup> Treatment of below-the-knee (BTK) arterial disease poses different challenges than in more proximal lesions due to anatomic, physiologic, and technical limitations. Critical limb-threatening ischemia (CLTI) exacerbates the complexity, leading to high amputation and mortality rates when traditional revascularization methods fall short.<sup>2</sup> Percutaneous transluminal angioplasty (PTA), a prevalent technique, can cause dissections in BTK arteries, necessitating innovative solutions.<sup>3</sup>

Traditional strategies involving prolonged balloon inflation and off-label coronary stents have exhibited limitations with high rates of restenosis and associated complications.<sup>4</sup> The Tack Endovascular System (Intact Vascular, Inc., now a part of Philips Image Guided Therapy Corporation), a purpose-built technology designed to address post-PTA dissections, has emerged as a significant innovation in the treatment of PAD. This system's self-expanding, open-cell design offers advantages over traditional stents, minimizing the risks of fracture and in-stent restenosis while reducing the amount of metal left behind by 70%.

The Tack-Optimized Balloon Angioplasty (TOBA) II BTK trial is a prospective, multicenter, single-arm study focused on evaluating the Tack Endovascular System for repairing post-PTA BTK dissections. Enrolling patients with Rutherford category 3 to 5 and post-PTA dissections, the study employed a comprehensive

set of safety and effectiveness endpoints, with outcomes reported at 6, 12, 24, and 36 months.<sup>5-7</sup>

The study enrolled 233 patients with 301 post-PTA dissections, revealing promising outcomes. Kaplan-Meier freedom from major adverse limb events (MALE) at 36 months, coupled with perioperative death (POD) at 30 days, stood at an impressive 91.6%. Clinically driven target lesion revascularization demonstrated a 69.6% freedom rate. Noteworthy was the high target limb salvage rate of 95.0% and amputation-free survival at 64.7%. Patients with CLTI experienced substantial benefits, with 89.7% freedom from MALE + POD at 36 months.

Functional outcomes were equally compelling, with sustained improvements in quality of life, mobility, and Rutherford category through the 36-month follow-up. The Tack Endovascular System showcased its efficacy in addressing not only the anatomical challenges but also the broader spectrum of patient well-being.

The Tack Endovascular System's performance in the TOBA II BTK trial underscores its potential to revolutionize the management of BTK disease. The study's patient cohort, predominantly presenting with CLTI, showcased the system's ability to navigate complex scenarios, including moderate-to-severe calcium and total occlusions.

While traditional angiography served as the primary method for detecting dissections in this study, the iDissection study suggests that intravascular ultrasound (IVUS) could enhance diagnostic

accuracy.<sup>8</sup> Future research might explore the integration of IVUS to optimize BTK angioplasty further.

Comparative analyses with other investigational devices underscore the uniqueness of the Tack Endovascular System. It stands as the sole BTK implant with 36-month data, offering a valuable perspective on its sustained efficacy and safety.

## Conclusion

The TOBA II BTK study, spanning 36 months, establishes the Tack Endovascular System as a robust solution for infrapopliteal dissection repair post-PTA. Its durable freedom from adverse events, high rates of limb salvage, and sustained improvements in patient-centric outcomes position it as a promising intervention for BTK disease. The study's comprehensive insights contribute significantly to advancing the field, providing clinicians with a valuable tool to navigate the complexities of BTK interventions. As the only BTK implant with 36-month data, the Tack Endovascular System stands out as a beacon of innovation in the landscape of PAD management.

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