Update on the TOBA Trials of the Tack Device: Indications, Advantages in Improving Outcomes and Limitations

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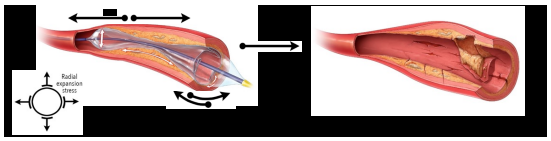
Conflicts

• InspireMD	*Research Funding (Co-PI)*
• MedAlliance/Cordis	*Advisory Board, Equity*
• Aveera	*Advisory Board, Equity*
• Protexa	*Advisory Board, Equity*
• Pulse Therapeutics	*Advisory Board, Equity*

Balloon Angioplasty = Controlled Dissection



Lesions with angiographically visible dissections have a
TLR rate 3.5 times higher
than lesions without visible dissection[2]

Current tools for dissection repair -*including stents*- have limitations

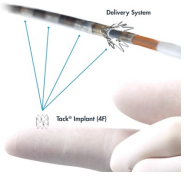
1. Losordo DW, Rosenfield K, Pieczek A, et al. How does angioplasty work: serial analysis of human iliac arteries using intravascular ultrasound. *Circulation* 1992;86:1845-1858. 2. Kokkinidis DG, Armstrong EJ. Emerging and future therapeutic options for femoropopliteal and infrapopliteal endovascular interventions. *Intervent Cardiol Clin* 2017;6:279-291.

Tack: Purpose-Built for Focal Dissection Repair

Multi-implant, minimal-metal designed for tapering vessels from SFA to ankle

Tack Implants
- Multiple pre-loaded nitinol implants
  - ATK: 6 implants
  - BTK: 4 implants
- 6mm or 8mm deployed length
- Each implant self-sizes to tapering anatomy
  - ATK: 3.5 – 6.0mm and 4.0 – 8.0mm RVD
  - BTK: 1.5 – 4.5mm RVD

OTW Delivery System
- Accurate (≤1mm) deployment
  - ATK: 6F/.035
  - BTK: 4F/.014



INTENDED USE: The Tack Endovascular System is intended for use for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissection(s).

CONTRAINDICATIONS: 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.

The Tack Endovascular System is CE Mark authorized under EC Directive 93/42/EEC.

Numerous Clinical TOBA Trials to Date (n = 820)

TOBA: Tack Optimized Balloon Angioplasty

1. Iosim et al. *J Vasc Surg* 2016 2. Gray WA, et al. *J Am Coll Cardiol Intv* 2019 3. Brodmann M, et al. *J Vasc Surg* 2020. 4. Brodmann M, et al. *Catheter Cardiovasc Interv* 2018. 5. Geraghty PJ, et al. *J Vasc Surg* 6. Geraghty PJ, et al. *J Endovasc Ther* 2020 7. Adams GL, et al. *J Endovasc Ther* 2022. 8. Adams GL, et al. *Journal of CLI* 2023.

Tack: Demonstrated Success in Dissection Repair

ATK		BTK
TOBA II	TOBA III	TOBA II BTK
Tack following POBA (n=90) or Lutonix® (n=123)	***Tack following*** IN.PACT™ Admiral™ (N=201)	***Tack following*** POBA (N=233)
Primary safety outcome: Freedom from any new-onset major adverse events at 30 days	**Primary safety outcome:** Freedom from MALE at 30 days + POD at 30 days	**Primary safety outcome:** Freedom from major adverse events at 30 days
Primary efficacy outcome: Primary patency at 12 months	**Primary efficacy outcome:** Freedom from MALE at 6 months + POD at 30 days	**Primary efficacy outcome:** Primary patency at 12 months
Endpoints Achieved[1] 86.5% ff CD-TLR 89.6% primary patency at 12 mo	**Endpoints Achieved[2]** 97.5% ff CD-TLR 95.0% primary patency 0.6% bail out stent rate 97.7% dissection resolution	**Endpoints Achieved[3]** 73.6% ff CD-TLR 94.7% target limb salvage (CLI pts) Continued, sustained improvement in ABI/TBI, Rutherford, EQ-5D-3L, WIQ and PAQ

1. Gray WA, et al. Treating post-angioplasty dissection in the femoropopliteal arteries using the Tack Endovascular System: 12-month results from the TOBA II study. *J Am Coll Cardiol Intv* 2019;12:2375-84. 2. Brodmann M et al. Treating post-angioplasty dissection in the femoropopliteal arteries using the Tack Endovascular System: 12-month results from the TOBA III IDE study. *J Vasc Surg* 2020;72(5):1636-1647. 3. Geraghty PJ, et al. Twelve-Month Results of Tack-Optimized Balloon Angioplasty Using the Tack Endovascular System to Treat the Knee Arteries (TOBA II BTK). *J Endovasc Ther* 2020;27(1):105-116.

Tack ATK (TOBA II and TOBA III): Post-PTA Dissection Repair

TOBA ATK studies…

- Only studies to enroll **100% dissected arteries**
- Met all primary and secondary endpoints
- Demonstrate **92-98% dissection resolution** after POBA or DCB angioplasty
  - **No Tack implant fracture or embolization and extremely low stent rates (0-0.6%)**
- Report among the **highest-reported 12 month patency rates in the SFA**
  - TOBA II POBA: 89.6%
  - TOBA III DCB: 95.0%

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Tack BTK: TOBA II BTK

TOBA II BTK

Tack:

- The first BTK implant approved by FDA (April 2020)
- The only BTK implant with 36-month data

TOBA II BTK:

- Treatment with standard PTA + Tack for dissection repair only
- **100%** dissected vessels in a complex CLI population
- **100%** dissections were completely resolved per core lab

- **Dissection repair optimizes BTK angioplasty and results are durable to 36 months**
  - **69.6%** 3-year freedom from CD-TLR across all patients
  - **93.9%** 3-year limb salvage in CLI patients
  - **Sustained improvement** in Rutherford class, ABI/TBI
  - **Sustained improvement** in patient-reported quality of life and mobility

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Does this Success Extend to Patients with Complex BTK Lesions?

Eligible Patients	Patients enrolled in TOBA II BTK with complex lesion characteristics (n = 169) • Chronic total occlusion (n = 111) • Lesion length ≥ 115mm (n = 57) • Moderate to severe calcification** (n = 86)
Outcomes	• MALE + POD at 30 days (primary safety endpoint) • Amputation-free survival • Freedom from CD-TLR • All-cause mortality • Rutherford Clinical Classification • ABI/TBI

TOBA II BTK N = 233*

↓

Complex Lesions n = 169

*169/233 had core-laboratory-graded angiograms
**Calcium was graded based on angiographic evidence by a core-laboratory on a scale of 0-2 (0 = none/mild; 1 = moderate; 2 = severe)

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Demographics and Lesion Characteristics (Core Lab)

	All ITT (N = 230)	Long Lesion (n = 57)	Moderate to Severe Ca²⁺ (n = 86)	Chronic total occlusion (n = 111)
Mean Age	74.5 ± 9.9	74.0 ± 9.7	76.8 ± 8.5	74.2 ± 9.9
Female	33.0%	36.8%	23.3%	34.2%
Diabetes Mellitus	65.7%	64.9%	68.6%	70.3%
Current/Former Smoker	62.2%	63.2%	55.8%	64.0%
Hyperlipidemia	77.4%	68.4%	79.1%	77.5%
Hypertension	93.5%	96.5%	95.3%	94.6%
Proximal RVD (mm)	3.6 ± 1.0	3.5 ± 0.9	3.7 ± 1.0	3.5 ± 1.1
Distal RVD (mm)	2.6 ± 0.7	2.3 ± 0.5	2.7 ± 0.7	2.5 ± 0.6
Mean DS (%)	**85.8 ± 16.5**	**94.2 ± 12.1**	**84.8 ± 15.8**	**100 ± 0.0**
CTO	**48.3%**	**78.9%**	**41.9%**	**100.0%**
Moderate to Severe Ca²⁺	**37.4%**	**36.8%**	**100%**	**32.4%**
Mean Lesion Length (mm)	**82.2 ± 49.4**	**152.4 ± 26.5**	**81.2 ± 50.2**	**110.3 ± 47.1**

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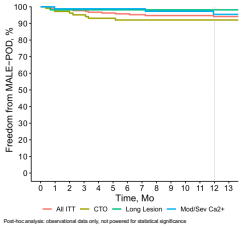
No Difference in **MALE + 30-Day POD*** Despite Increased Complexity



Freedom from MALE + 30-day POD

	30 days	6 months	1 year
Tack following BTK POBA ALL ITT	98.7% (223/226)	95.8% (189/198)	94.1% (162/174)
Tack following BTK POBA Long Lesion	98.2% (54/55)	98.2% (49/50)	98.2% (40/41)
Tack following BTK POBA MOD/SEV CA2+	98.8% (83/84)	98.8% (68/69)	95.5% (52/55)
Tack following BTK POBA CTO	97.2% (105/108)	92.1% (87/95)	92.1% (74/82)

Post-hoc analysis: observational data only, not powered for statistical significance

*MALE + POD: composite of all-cause death, above-ankle target limb amputation, or major re-intervention to the target lesion(s), defined as new bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis

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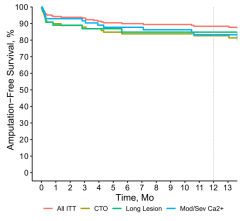
No Difference in **Amputation-Free Survival** Despite Increased Complexity



Amputation-free Survival

	30 days	6 months	1 year
Tack following BTK POBA ALL ITT	94.3% (213/226)	90.0% (179/201)	88.4% (155/180)
Tack following BTK POBA Long Lesion	89.0% (48/54)	84.8% (41/49)	84.8% (35/43)
Tack following BTK POBA MOD/SEV CA2+	93.0% (79/85)	87.8% (62/72)	83.2% (46/59)
Tack following BTK POBA CTO	89.9% (97/108)	83.8% (80/97)	82.6% (69/87)

Post-hoc analysis: observational data only, not powered for statistical significance

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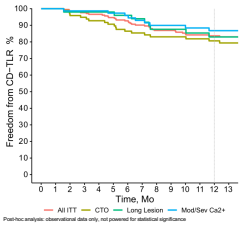
No Difference in **CD-TLR*** Despite Increased Complexity



Post-hoc analysis: observational data only, not powered for statistical significance

Freedom from CD-TLR

	30 days	6 months	1 year
Tack following BTK POBA ALL ITT	100% (223/223)	92.7% (182/197)	83.6% (144/176)
Tack following BTK POBA Long Lesion	100% (54/54)	96.0% (48/50)	83.0% (33/41)
Tack following BTK POBA MOD/SEV CA2+	100% (84/84)	95.9% (66/69)	86.8% (49/58)
Tack following BTK POBA CTO	100% (105/105)	86.5% (81/94)	80.6% (64/82)

*Clinically-driven target lesion revascularization, defined as any re-intervention (endovascular or surgical) to the target lesion(s) in subjects with recurrent clinical symptoms indicated by a worsening Rutherford classification (increase of one category or more) or procedure classification or a new or worsening wound. The designation of CD-TLR was corroborated by angiographic evidence of ≥50% DS at the time of repeat intervention and was adjudicated by the CEC

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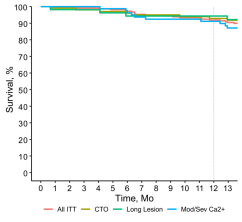
All-Cause Mortality Unchanged Despite Increased Complexity



Post-hoc analysis: observational data only, not powered for statistical significance

Freedom from All-Cause Mortality

	30 days	6 months	1 year
Tack following BTK POBA ALL ITT	99.6% (223/224)	97.2% (209/215)	91.9% (187/204)
Tack following BTK POBA Long Lesion	98.2% (54/55)	94.3% (49/52)	94.3% (44/47)
Tack following BTK POBA MOD/SEV CA2+	100% (84/84)	96.3% (78/81)	91.1% (69/76)
Tack following BTK POBA CTO	99.1% (105/106)	96.0% (95/99)	92.9% (86/93)

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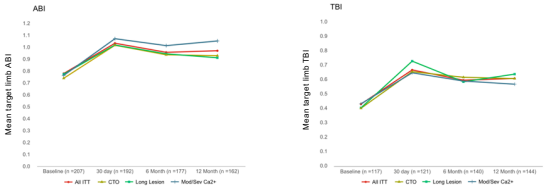
Similar Improvements in ABI/TBI



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SUMMARY

- Examination of outcomes in the 169 TOBA II BTK patients with complex lesions
  - Chronic total occlusion (n = 111)
  - Long lesion length ≥ 115mm (n = 57)
  - Moderate to severe calcification (n = 86)
- Similar outcomes were observed for each complex cohort compared with the entire ITT cohort through 1 year for:
  - Freedom from MALE + 30-day POD
  - Amputation-Free Survival
  - Freedom from CD-TLR
  - Freedom from All-Cause Mortality

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