TOBA II 12-Month Results
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Medical University of Graz

TOBA II Study Design

Dissection: The Primary Mechanism of Angioplasty

Lesions with dissections have a TLR rate 3.5 times higher than lesions without dissection\(^1\)

Current tools for dissection repair (stents) have limitations

TOBA II Key Eligibility Criteria

Inclusion Criteria

- RVD 2.5 – 6.0 mm, inclusive
- De novo or non-stented restenotic lesion in SFA and/or P1:
  - 30 – 99% stenosis: length ≥20 – ≤150 mm
  - 100% occlusion: length ≤100 mm
- Presence of ≥1 patent (DS% <50) infrapopliteal vessel
- Post-PTA residual DS ≤30%
- Presence of at least one dissection Grade A to F

Exclusion Criteria

- Previous bypass in target limb
- Acute/sub-acute thrombosis and/or occlusion
- Post-PTA residual DS >30%
- Severe calcium

TOBA II Study Design

- Prospective, multi-center, single-arm, non-blinded study at 33 sites in US, Europe

213 subjects, all with post-PTA dissection following POBA (n=90) or Lutonix® angioplasty (n=123)

Primary Safety Endpoint: Freedom from the occurrence of any new-onset MAE(s) at 30 days

Primary Efficacy Endpoint: Freedom from any new-onset MAE(s) at 30 days

Delivery System
- 6F/0.035"
- 6 implants pre-loaded on a single catheter
- Designed for highly accurate (≤1mm) deployment

Tack Endovascular System®

Tack® Implant:
- Adaptive Sizing™ adapts to tapering diameter of vessel
- 2.6 – 6.0 mm SFA/PPA
- Nitinol with gold RO markers for visibility
- Unique anchoring system prevents migration
- 6mm deployed length

Tack® Optimized Balloon Angioplasty Study for Post-Dissection Repair of the Superficial Femoral and Proximal Popliteal Arteries (TOBA II)

Adaptive Sizing™ is a trademark of Intact Vascular, Inc.
Tack® Implant and Tack® are registered trademarks of Intact Vascular, Inc.

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**Key Baseline Patient, Lesion Characteristics (Intent to Treat Population)**

**Patient Characteristics**  
Mean ± SD (N) or n/N (%)

- Age (y) 68.2 ± 9.1 (213)
- Male gender 151/213 (70.9%)
- BMI 29.3 ± 6.1 (212)
- ABI in treated leg 0.76 ± 0.21 (200)
- Rutherford 2: 68/213 (31.9%), 136/213 (63.8%), 9/213 (4.2%)
- Diabetes mellitus: 92/213 (43.2%)
- Coronary disease: 128/211 (60.7%)
- Renal insufficiency: 19/213 (8.9%)
- Hypertension: 191/213 (89.7%)
- Hyperlipidemia: 184/211 (87.2%)

**Lesion Characteristics**  
Mean ± SD (N) or n/N (%)

- Target vessel: SFA 156/212 (73.9%), SFA and P1 15/211 (7.1%), P1 36/211 (17.0%)
- Target lesion length (mm): 74.6 ± 46.6 (210)
- PTA treated length (mm): 96.7
- Proximal RVD (mm): 5.3 ± 0.7 (211)
- Distal RVD (mm): 5.5 ± 0.7 (211)
- Total Occlusion: 49/211 (23.2%)
- Calcification: Moderate 113/211 (53.6%), Severe 12/211 (5.7%)
- Patent Run-Off Vessels: 0 6/207 (2.9%), 1 72/207 (34.8%), 2 86/207 (41.5%), 3 43/207 (20.8%)

**TOBA II Primary Endpoints Met**

211 subjects with post-PTA dissection following TOBA (n=90) or Lutonix® angioplasty (n=123)

**Safety**

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<tr>
<th>Safety</th>
<th>Population</th>
<th>Met/Not Met</th>
<th>p-value*</th>
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</table>
| 30-Day Freedom from MAE:  
  - Index limb amputation  
  - CD-TLR  
  - All-cause death | Intent to Treat (n=212) | MET | <0.0001 |

**Efficacy**

<table>
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<tr>
<th>Efficacy</th>
<th>Population</th>
<th>Met/Not Met</th>
<th>p-value*</th>
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</table>
| Primary Patency at 12 Months:  
  - Freedom from USC adjudicated CD-TLR and  
  - Freedom from core lab adjudicated DUS-derived binary restenosis (PSVR ≥ 2.5) | Intent to Treat (n=143) | MET | 0.0006 |
| Freedom from Tack fracture at 12 months | 100% (870/871) | MET | 0.0005 |

*Fisher’s exact test for one proportion, p-values and 95% CI are one-sided

**12-Month Results**

- Total number of dissections: 369
- Number of dissections per subject: 1.8 ± 0.9 (209)
- Mean dissection length (mm): 20.7 ± 21.4 (368)

**Pre-Tack: Dissection Severity**

- 92.1% of all dissections were completely resolved with Tack
- 69.4% of subjects had a dissection ≥ Grade C before using Tack

**Post-Tack: Dissections Resolved**

- 93.1% of all dissections were completely resolved with Tack
- 69.4% of subjects had a dissection ≥ Grade C before using Tack

**Tack Stability and Durability**

- Total number of Tack implants deployed: 871
- Number of Tack implants per subject: 4.1 ± 2.5 (213)
- Bailout stent rate: 6.5% (1/213)
- Freedom from Tack fracture at 12 months: 100%
- Freedom from Tack migration at 12 months: 99.9% (870/871*)

*Dissections were scored by core lab; certainty during index procedure

**Additional Information**

- TOBA II 12-Month Results: 99.5% core-lab adjudicated dissection rate
- Primary Patency 79.3%
- Freedom from CD-TLR 86.5%
- Total number of Tack implants deployed: 871
- Number of Tack implants per subject: 4.1 ± 2.5 (213)
- Freedom from Tack fracture at 12 months: 100%
- Freedom from Tack migration at 12 months: 99.9% (870/871*)

*Data from TOBA II: Tack, a System for the Treatment of Arterial Dissections, lipscombetal.com
TOBA II 12-Month Results

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TOBA II: Unique trial: first to enroll 100% dissected vessels
Successfully met primary safety and efficacy endpoints
Demonstrated that Tack effectively repairs dissections after POBA/DCB with:
- Minimal metal
- Low radial force
- Stable and durable design
- Preservation of future treatment options

Bailout stent rate 0.5%
High patency rate (79.3%) and high freedom from CD-TLR (86.5%)
Position Tack to be a clinically important treatment option for focal dissection repair after balloon angioplasty

All analyses calculated using the Wilcoxon Signed Rank Test
These analyses were not included in the overall Type I error control for the study