intact®
vascular

TOBA BTK

TOBA BTK: Study Summary

- Thirty-five patients with CLI were treated with **uncoated** balloon PTA and post-PTA dissections were treated with Tacks
- Thirty-two of 35 (91.4%) patients had post-PTA dissection and successful deployment of Tacks
- Procedure success was achieved in 34/35 (97.1%) patients with no MAEs at 30 days
- Twelve-month patency rate was 77.4%; freedom from TLR was 93.5%
- Significant ($p<0.001$) improvement from Rutherford Category baseline (75% with a 4 or 5 step improvement)

TOBA BTK: Study Design

- Objective:
  - Pilot study to collect safety and performance data to support BTK use of the Tack Endovascular System®
- Design:
  - Prospective, single-arm, multi-center
- Population:
  - Subjects with CLI (RCC 4-5) and angiographic evidence of a post-PTA dissection

TOBA BTK: Study Design

Primary Endpoints:

- **Safety:** Composite of Major Adverse Limb Events (MALE) and Peri-Operative Death (POD) assessed at 1 month
- **Device Success:** Delivery and deployment of the study devices(s) at the intended target site(s) and successful withdrawal of the delivery catheter
- **Procedure Success:** Ability of the Tack® to demonstrate vessel patency as reported by the physician (visual estimate) without the occurrence of MALE + POD on the date of procedure

TOBA BTK: Study Design

Secondary Endpoints:

- Events assessed at 3, 6, 12 and 24 months:
  - All cause mortality
  - Amputation of the limb (above the ankle)
  - Amputation-free survival
  - Clinically-driven target vessel revascularization (CD-TVR)
  - Clinically-driven target lesion revascularization (CD-TLR)
  - Change in Rutherford Category from baseline
- Parameters assessed at 1, 3, 6, 12 and 24 months:
  - Maintenance of luminal patency of the target lesion by TBI (≤0.15 decrease) compared to the baseline TBI obtained prior to discharge
  - Doppler exam (presence of signal)

TOBA BTK: Participating Sites

Principal Investigator	Clinical Site
Marianne Brodmann	Medical University Hospital, Austria
Andrew Holden	Auckland City Hospital, New Zealand
Robert Staffa	St. Anne's Faculty Hospital, Česká Republika
Thodur Vasudevan	Walkato Hospital, New Zealand
Christian Wissgott	Westküstenklinikum Heide, Germany
Thomas Zeller	Herz-Zentrum, Germany

TOBA BTK: Study Results

Parameter	Safety Sample N=35	Performance Sample N=32
Device Success[1]	32/35 (**91.4%**) (77.6, 97.0)	N/A
Procedure Success[2]	34/35 (**97.1%**) (85.5, 99.5)	31/32 (**96.9%**) (84.3, 99.5)

[1]Delivery and deployment of the study devices(s) at the intended target site(s) and successful withdrawal of the delivery catheter

[2]Demonstrated vessel patency as reported by the physician (visual estimate) without the occurrence of MALE + POD on the date of procedure

TOBA BTK: Study Results

Parameter	30 Day	6 Month	12 Month
Amputation-free survival (above the ankle amputations)	100%	96.8%	**84.5%**
Freedom from CD-TVR	100%	93.5%	**93.5%**
Freedom from CD-TLR	100%	93.5%	**93.5%**
KM primary patency	100%	86.5%	**78.4%**
KM assisted primary patency	100%	94.6%	**89.2%**

TOBA BTK: Presentations

- **Six-month data presented at:**
  - Charing Cross 2016
  - European Congress of Radiology (ECR) 2016
  - LINC 2016
- **Twelve-month data presented at:**
  - Society of Coronary Angiography and Intervention (SCAI) 2016
  - EuroPCR 2016
  - New Cardiovascular Horizons (poster) 2016