Tack Optimized Balloon Angioplasty Below the Knee (TOBA-BTK): Twelve month results

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SCAI 2016
Orlando, FL | May 4-7, 2016

Translating Science to Practice

Poor BTK Treatment Options

- PTA
  - Standard treatment – POBA
  - Experimental treatment – DCB
  - Poor long-term outcomes
  - Dissection problems
- Stents
  - Off-label use of stents (BMS and DES)
  - In-stent restenosis
- Alternatives
  - Atherectomy
  - Invasive bypass surgery

High Technical & Procedural Success, but High Complications

HIGH…	PTA	DEB	BMS	DES
Technical & Procedural Success	78% - 100%	80% - 100%	93.6% - 100%	94.8% - 100%
Complication Rates @ 1yr	**3.4% - 51%**	**31%**	**41.7 – 63.3%**	**NR**

VARIED OUTCOMES @ 1 year	PTA	DEB	BMS	DES
Amputation Free Survival	71% - 100%	81.1%	78.3% - 98.5%	86.2% - 96%
Limb Salvage	84% - 100%	95.6%	88% - 100%	88.5% - 100%
Survival	68.4% - 94.8%	83.7% - 89.9%	74.7% - 87.5%	81% - 97%
Primary Patency	**37.9% - 82%**	**NR**	**40.5% - 94.7%**	**30% - 100%**
TLR	**13.5% - 47%**	**11.9% - 18%**	**5.3% - 34%**	**6% - 30.5%**
Amputation Rate	**0.0% - 20.0%**	**0.0% - 8.8%**	**10.4% - 20.0%**	**6.4% - 13.8%**

Debbie Barber, Canopy Medical LLC, Literature Review Report, September 2015

Current BTK Treatments for Dissections

Lack of effective treatment options

- BMS
  - Evaluated in shorter lesions (mean length 47mm[1], 18.9mm[2])
  - Multiple implants per lesion (1.2[2])
  - Stent fractures (1.2%[1])
- DES
  - Evaluated in shorter lesions (mean length 47mm[1], 15.9mm[2], 26.9mm[3])
  - Multiple implants per lesion (1.5[1], 1.1[2])
  - Stent fractures (0.9%[3])
  - Requires patients to be on long term anticoagulation

[1]Rocha-Singh, *Catheter and Cardio Inte* 80:1042-1051
[2]Bosiers, *J Vasc Surg*, 55(2):390-398
[3]Scheinert, *JACC*, 60(22):2290-5

A New Alternative for Dissection Repair Would…

- Leave minimum metal behind
- Minimize vessel inflammation
- Maintain normal vessel biomechanics
- Preserve future treatment options: *no bridges burned*

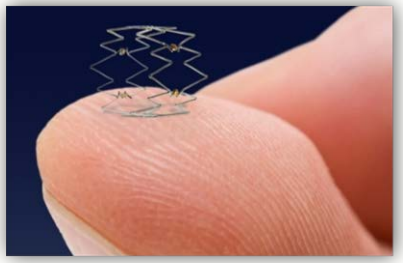
Tack Endovascular System™

Implant:

- Nitinol with Gold RO markers
- Unique anchoring system to prevent migration

Catheter:

- 4 Tack® implants per 4 Fr delivery system
- Pin-Pull delivery technique is highly familiar to clinicians
- Standard over the wire delivery system
- Design permits high accuracy Tack deployment



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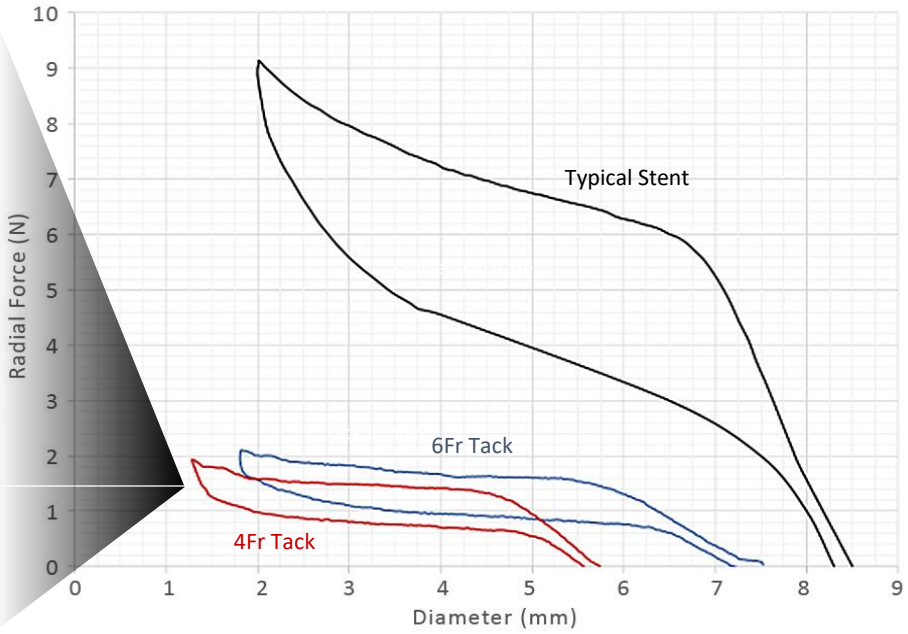
The Tack Endovascular System is Designed to Provide

Better Healing of Dissections

Low Radial Force minimizes inflammation

Radial force is constant across a wide range of diameters

Tack adapts to the vessel diameter – one size treats range of vessel diameters



Growing Clinical Experience

Study	Design	Status	Key Findings
FIM [1]	ATK & BTK - Safety & Feasibility Prospective, non-randomized 2 Paraguay sites n=11	Completed	Feasibility and 30 day safety demonstrated: SFA to Tibial • 83.3% 12-month patency
TOBA[2]	ATK - Prospective, single arm 13 European sites n=138	Completed	Presented 12-month results at LINC 2015 • 89.5% K-M freedom from clinically driven target lesion revascularization • 76.4% K-M patency rate • 98.5% technical success rate
TOBA II	ATK - Prospective, single arm 40 US and European sites n=210	Enrolling	Actively enrolling
TOBA BTK	BTK - Prospective, single arm 6 Europe/New Zealand sites n=35	Completed	Feasibility, 30 day safety & ease of use demonstrated. • 100% 30-day patency **12 month results NOW**

TOBA="Tack Optimized Balloon Angioplasty"
ATK=Above the Knee
BTK=Below the Knee

Total number Tack patients: **200+**
Total number of Tacks implanted: **680+**

[1] Schneider PA et al. *JACC: Cardiovasc Interv*, 8(2): 347-54.
[2] Bosiers M. Leipzig Interventional Course; 2015 Jan 27–30; Leipzig, Germany.

TOBA BTK Study

- 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 dissection post PTA

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

Primary Endpoints

- **Safety:** Composite of Major Adverse Limb Events (MALE) and Peri-Operative Death (POD) assessed at 1 month

- **Device Success:** The achievement of successful delivery and deployment of the study devices(s) at the intended target site(s) and successful withdraw 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.

Secondary Endpoints

- The following events will be 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 (TVR)
  - Clinically driven target lesion revascularization (TLR)
  - Changes in Rutherford Clinical Category from baseline
- The following parameters will be assessed at 1, 3, 6, 12, and 24 months:
  - Maintenance of luminal patency of the target lesion by TBI (≤0.15 decrease) as compared to the baseline TBI obtained prior to discharge
  - Doppler Exam (presence of signal)

Key Inclusion/Exclusion

Inclusion Criteria

- Rutherford 4 or 5
- RVD 1.5 – 4.5mm
- Lesion located between knee joint and ankle
- Denovo lesion ≥70% stenosed/occluded
- Up to 2 tibial arteries can be treated with cumulative length of ≤15cm
- Presence of post PTA dissection

Exclusion Criteria

- Stenosis or occlusion of inflow vessels not successfully treated
- Previous inflow vessel treatment failure
- Previous below the knee bypass
- Lesion on plantar surface of heel or Achilles tendon or exposed calcaneus

Challenging Patient Population

Subject Demographics

Subjects	Safety Sample (n=35)	Device Performance (n=32)
Age (Y)	76.1 ± 9.3	76.1± 9.5
Gender:		
Female	48.6%	43.8%
Male	51.4%	56.3%
Diabetes Mellitus	77.1 %	81.3%
Hypertension	91.4%	90.6%
Previous PVR	45.7%	43.8%
Current Smoker	5.9%	6.5%
Smoking History	29.4%	32.3%
Rutherford Category		
4	11.4%	12.5%
5	88.6%	87.5%

Complex Lesions

Baseline Core Lab Lesion (Safety Sample)

- Broad anatomical distribution
- >60% moderate/severe calcification
- 1/5th of patients had total occlusions
- Lesion lengths up to 8cm
- ~80% Grade B+ dissections

Most Proximal Lesion Location	
Tibial Artery Anterior	38.9% (14/36)
Tibio-Peroneal Trunk	27.8% (10/36)
Peroneal Artery	16.7% (6/36)
Tibial Artery Posterior	16.7% (6/36)

Calcification	
None/Mild	36.1% (13/36)
Moderate	61.1% (22/36)
Severe	2.8% (1/36)

Characteristics	
Lesion Length (mm)	51.4 ± 28.0 (34)
Proximal RVD (mm)	3.4 ± 0.8 (36)
Distal RVD (mm)	2.9 ± 0.8 (36)
% Diameter Stenosis Pre-PTA	72.3 ± 17.4 (36)
Total Occlusion	22.2% (8/36)

Dissection Grade	
Grade A	21.2% (7/33)
Grade B	60.6% (20/33)
Grade C	18.2% (6/33)

Excellent Safety and Performance

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

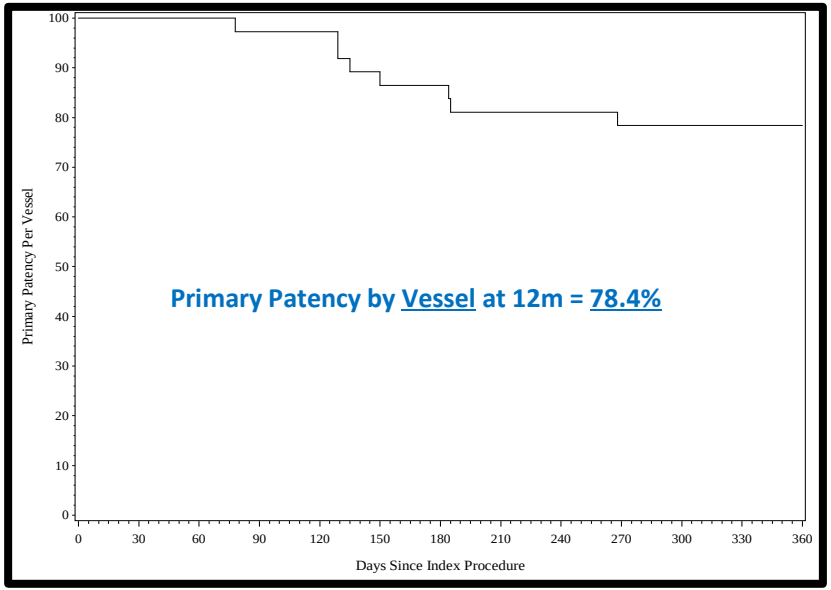
Positive Acute Results

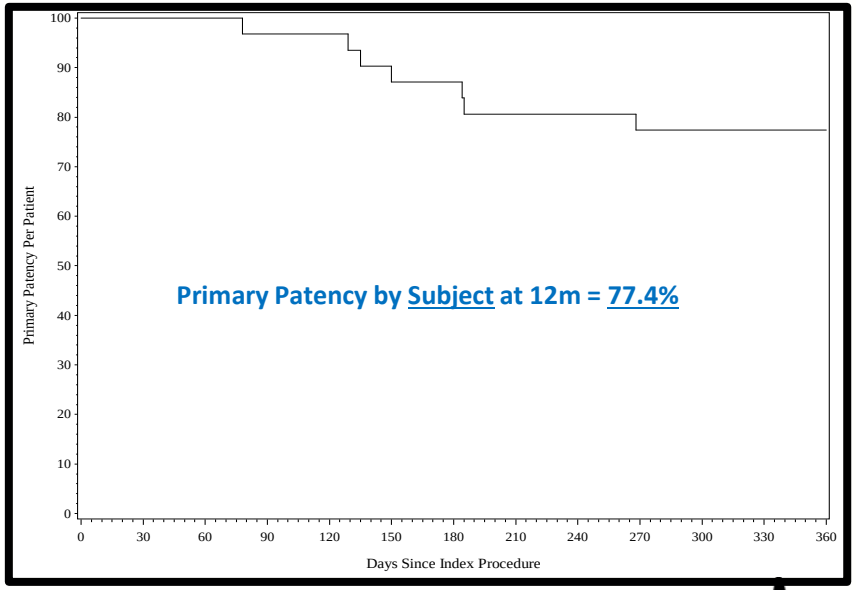
Safety Profile

Primary Safety Endpoint at 30 Days	Safety Sample	Perf. Sample
Composite Primary Safety Endpoint	1/35 (2.9%)	1/32 (3.1%)
Major Amputation	**0/35 (0.0%)**	**0/32 (0.0%)**
Re-intervention	1/35 (2.9%)	1/32 (3.1%)
Death	0/35 (0.0%)	0/32 (0.0%)

Positive KM Primary Patency Rates

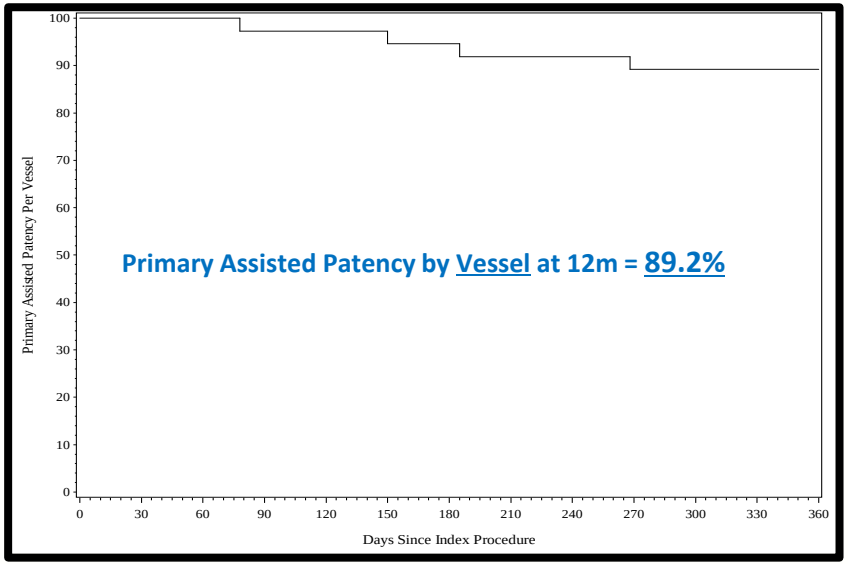
by Vessel and Subject

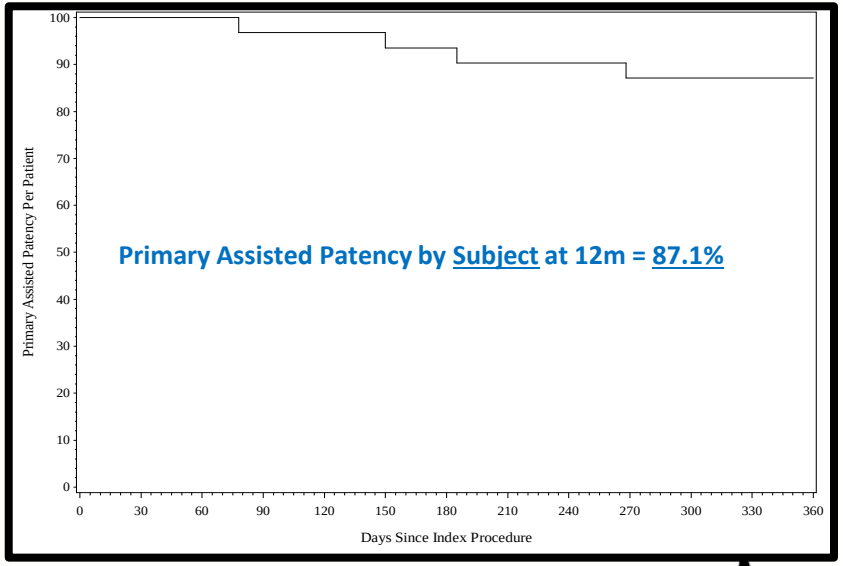




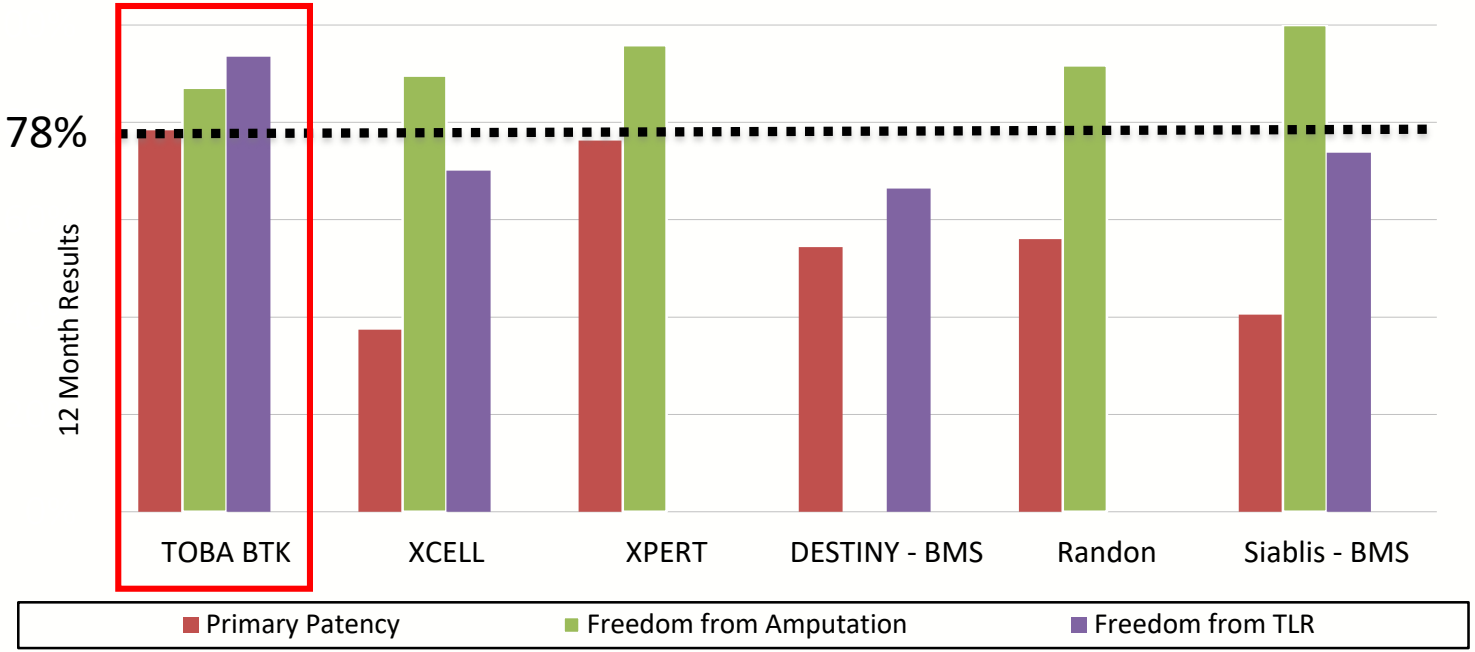
Excellent KM Primary Assisted Patency

by Vessel and Subject





TOBA BTK v. BMS Literature



Positive 12 Month Observational Data

Parameter	30 Day	3 Month	6 Month	12 Month
Amputation-free survival (above the ankle amputations)	100%	96.8%	96.8%	84.5%
Freedom from CD-TVR	100%	100%	93.5%	93.5%
Freedom from CD-TLR	100%	100%	93.5%	93.5%

TOBA BTK: Key Takeaways

- The **Tack Endovascular System** demonstrated strong clinical results:
  - 78.4% 12-month primary patency
  - 89.2% 12-month assisted primary patency
  - 93.5% freedom from TLR
  - 84.5% amputation free survival
  - 97% freedom from death
  - 87.1% freedom from major amputation

TOBA BTK: Key Takeaways

- "**Tacking**" represents a new paradigm for managing dissections with
  - Minimal metal
  - Minimal outward force
  - Minimal injury to vessel
- Tacking preserves future treatment options
  - No bridges burned

What's Next.....

- TOBA BTK
  - 24 month follow-up data in late 2017
- TOBA II BTK
  - International pivotal study in development
  - Projected start in 2017