

Dissections: Do they matter and how can they be managed

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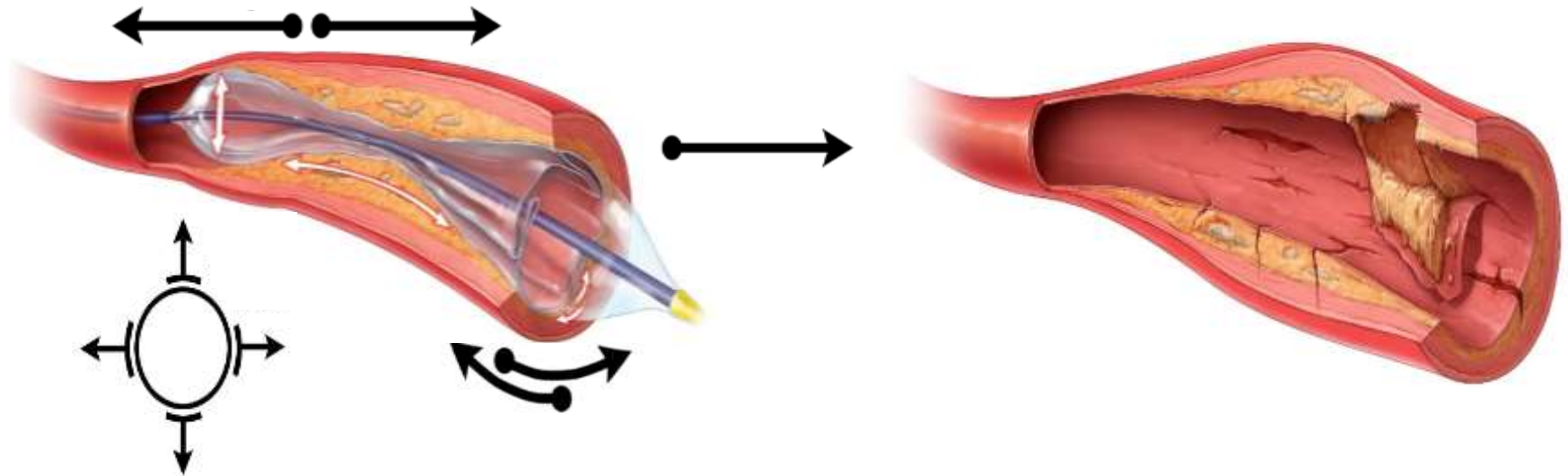


Thomas Zeller, MD

For the 12 months preceding this presentation, I disclose the following types of financial relationships:

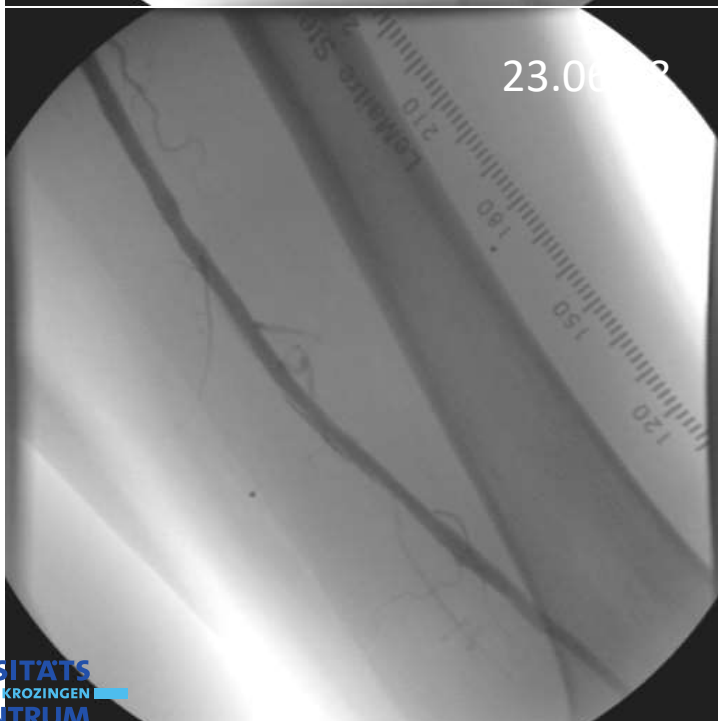
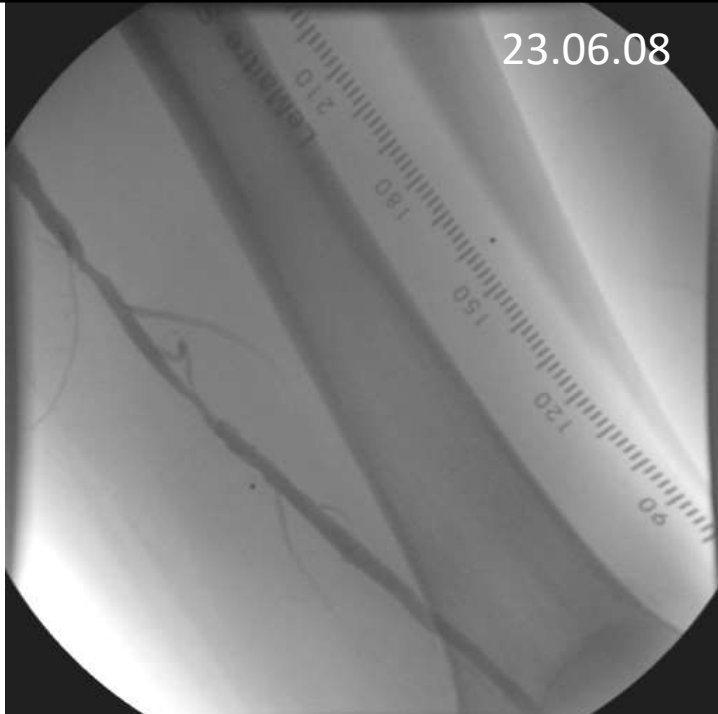
- **Honoraria received from:** Abbott Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Philips-Spectranetics, TriReme, Veryan, Shockwave, Biotronik, B. Braun
- **Consulted for:** Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Spectranetics, Veryan, Intact Vascular, Veryan
- **Common stock:** QT Medical

Dissection: Mechanism of Action for Angioplasty



Lesions with dissections have a **TLR rate 3.5 times higher** than lesions without dissection¹

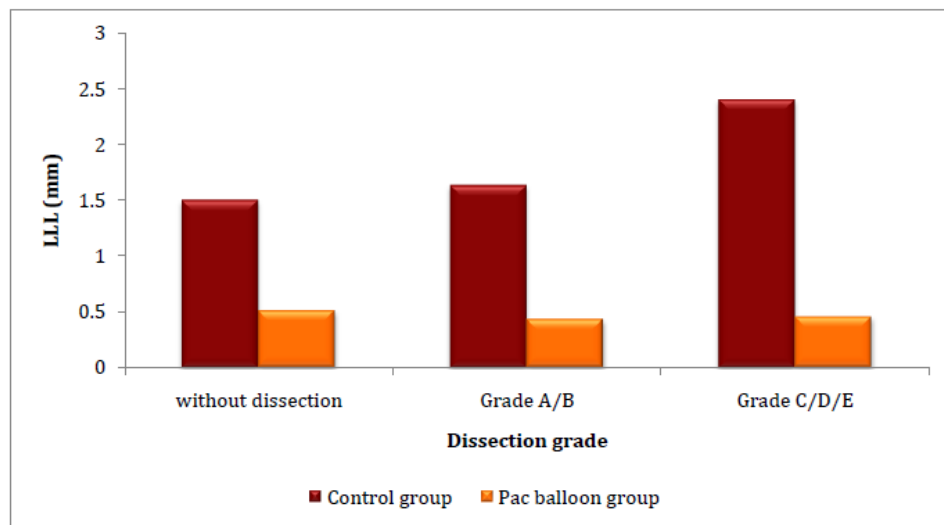
Current tools for dissection repair (stents) have limitations



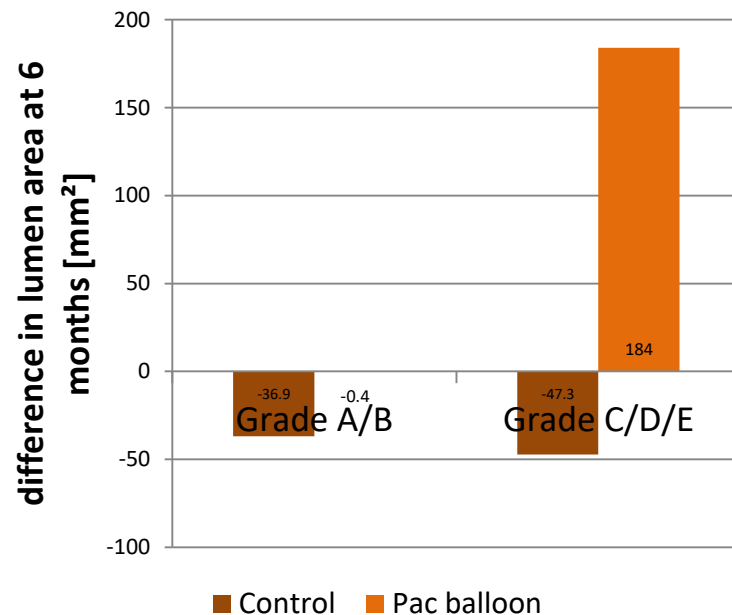
High-Grade, Non-Flow-Limiting Dissections Do Not Negatively Impact Long-term Outcome After Paclitaxel-Coated Balloon Angioplasty: An Additional Analysis From the THUNDER Study

Gunnar Tepe, MD, PhD¹; Thomas Zeller, MD²; Beatrix Schnorr, DVM³; Claus D. Claussen, MD⁴; Ulrich Beschorner, MD⁵; Klaus Brechtel, MD⁴; Bruno Scheller, MD⁶; and Ulrich Speck, PhD³

Figure 4: LLL by dissection grade

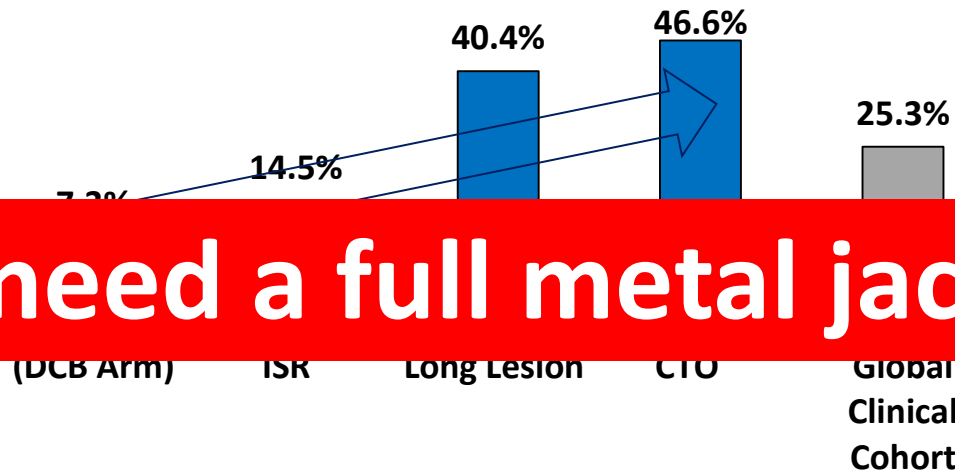


LLL: Late Lumen Loss



Do we Need Implants?

Bailout Stent Rates across DCB Trials



?Do we need a full metal jacket?

Sample Size	220	131	157	126	1406
Lesion Length [cm]	8,9	17,2	26,4	22,8	12,1
Total Occlusion	25,8%	34,0%	60,4%	100,0%	35,5%
Primary Patency (KM @ 360 days)	87,5%	88,7%	91,1%	85,3%	N/A

DCB Limitations: High rate of Provisional Stent

Tack Endovascular System[®]

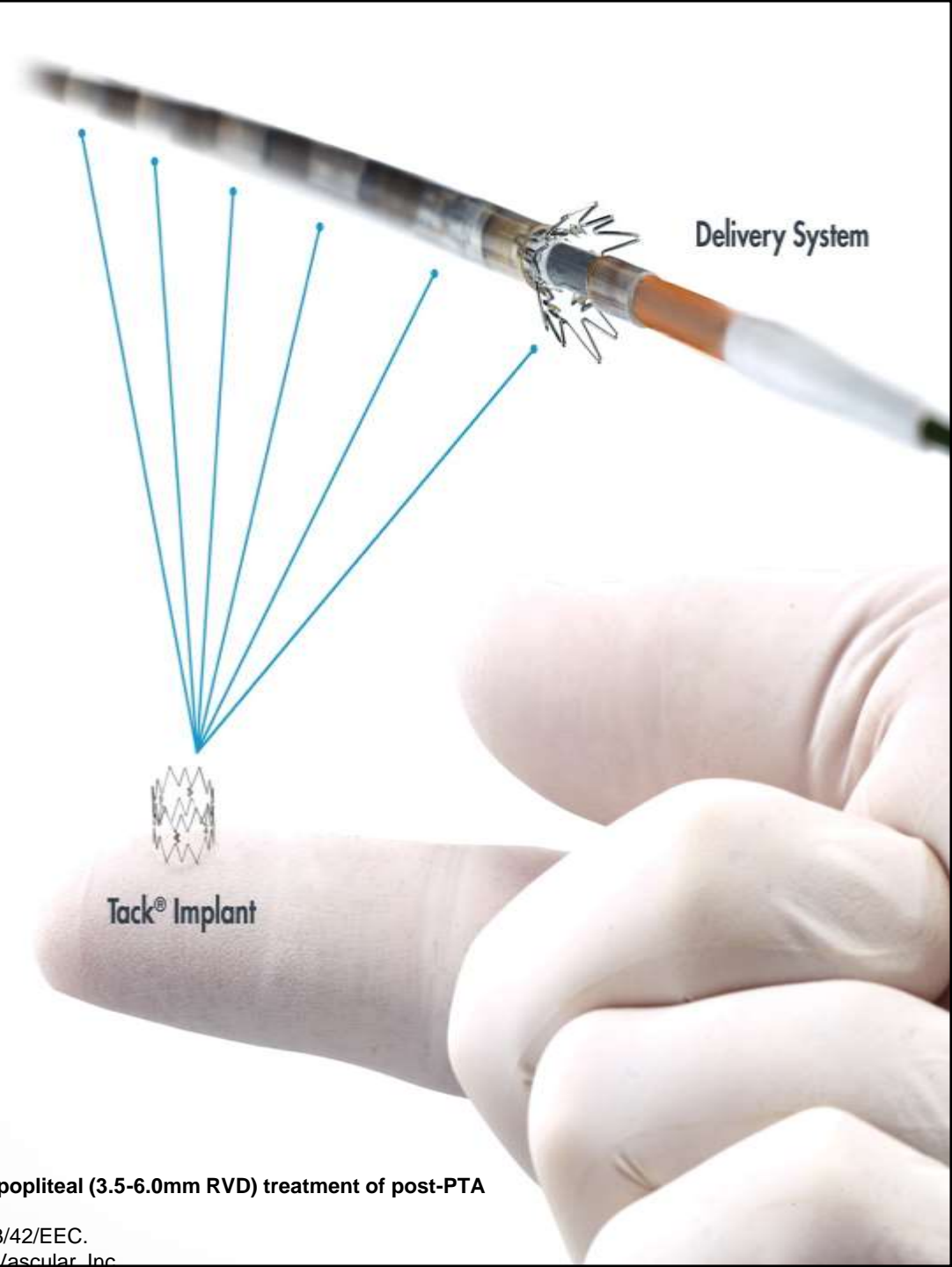
PURPOSE-BUILT. PRECISION REPAIR. PRESERVES OPTIONS.

Tack[®] Implants

- Multiple pre-loaded implants on a single catheter
- **Adaptive Sizing[™]** self-sizes to tapering ATK and BTK anatomy
 - **ATK** 2.5 – 6.0 mm
 - **BTK** 1.5 – 4.5 mm
- Nitinol with gold radiopaque markers
- 6 mm deployed length

Delivery System

- **ATK: 6F / 0.035"** – 6 implants preloaded on an OTW delivery system
- **BTK: 4F / 0.014"** – 4 implants preloaded on an OTW delivery system
- Accurate (≤ 1 mm) deployment



Tack Endovascular System (6F) is FDA approved for SFA and proximal popliteal (3.5-6.0mm RVD) treatment of post-PTA dissections.

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

Tack Endovascular System[®] and Tack[®] are registered trademarks of Intact Vascular, Inc.

TOBA: Dissection Repair Clinical Trials

ATK

First in Human (N=11) ATK and BTK Safety, Feasibility
 Prospective, single arm
 2 Paraguay sites

JACC: Cardiovascular Interventions¹
 Safety, feasibility demonstrated SFA to Tibial

- 83.3% 12-month patency

TOBA (N=138) Prospective, single arm
 13 European sites

Journal of Vascular Surgery²

- 89.5% K-M freedom from
- 76.4% K-M patency
- 98.5%

TOBA II (N=213) Prospective, single arm
 33 US sites

Enrollment Complete
 IN.PACT™ Admiral™ DCB

92.1% complete resolution of dissection

Prospective, single arm
 European sites

Long lesion subset (≤250 mm)

BTK

TOBA BTK (N=35) Prospective, single arm
 6 Europe/New Zealand sites

Catheterization and Cardiovascular Intervention³

- 93.5% K-M freedom from CD- TLR
- 84.5% Amputation-free survival
- 78.4% K-M patency rate

TOBA II BTK (N=233) Prospective, single arm
 41 US and international sites

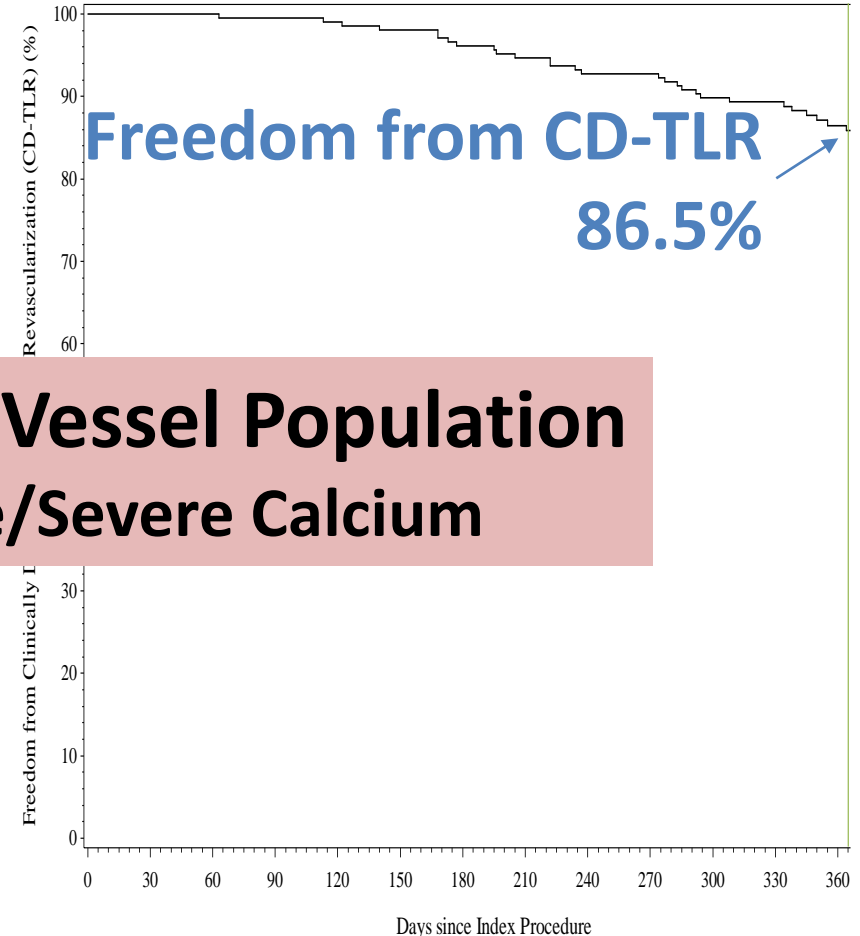
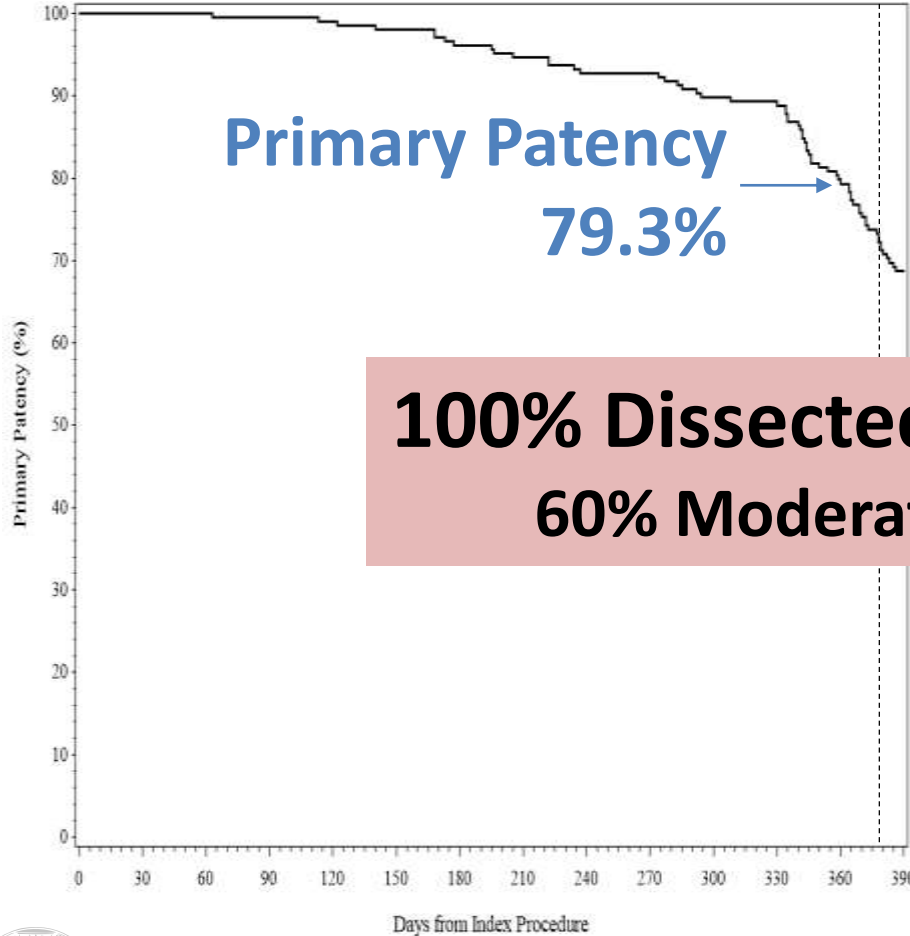
Enrollment Complete
 6-month primary endpoint

~2300 Tacks in ~830 Patients with Post-PTA Dissection and core laboratory/CEC adjudication



¹Schneider, *JACC Cardiovasc Interv* 2015
²Bosiers, *J Vasc Surg* 2016
³Brodmann, *Cathet Cardiovasc Interv* 2018

TOBA II 12 Month Kaplan-Meier Estimates



100% Dissected Vessel Population
60% Moderate/Severe Calcium

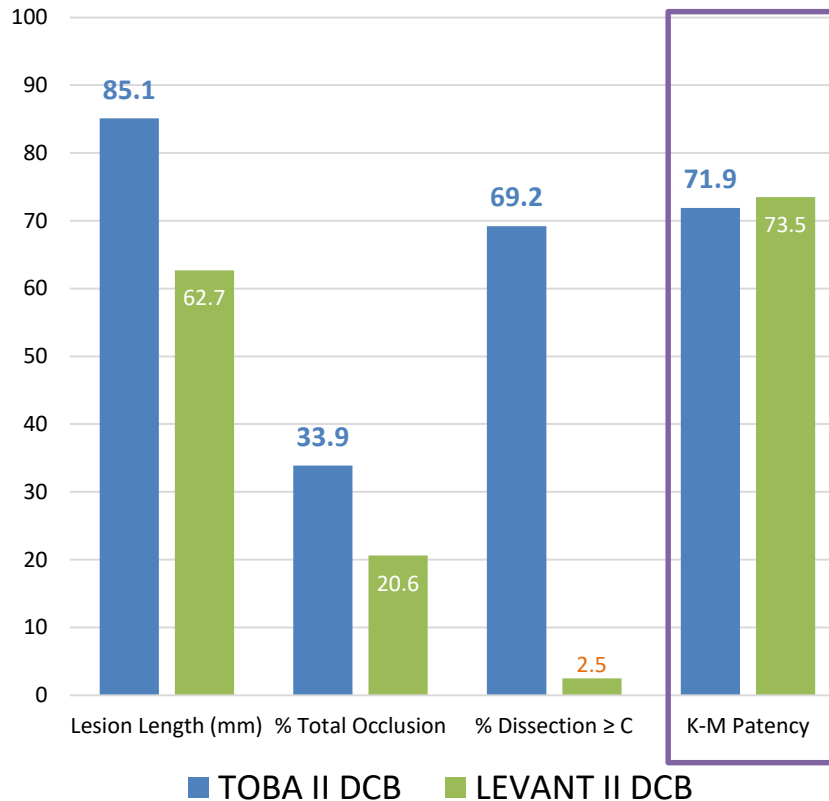
Dissections are site-reported (visual estimate during index procedure); 99.5% core-lab adjudicated dissection rate

TOBA II Patency Observations

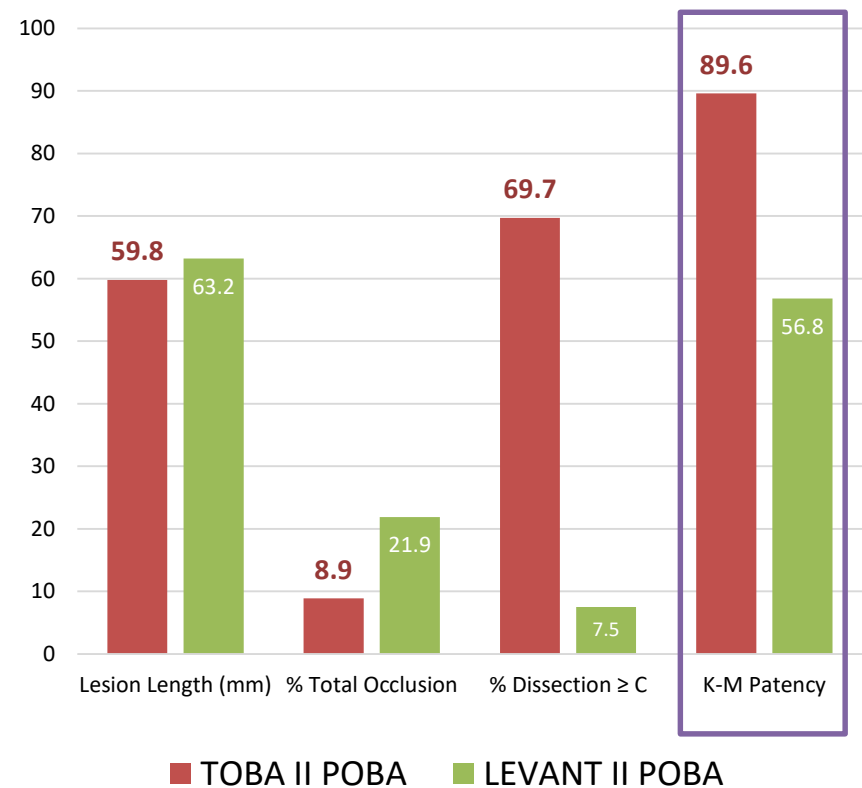
DCB-like patency in longer, more occluded and severely dissected vessels

Notably higher patency rate with POBA in severely dissected vessels

TOBA II DCB group and LEVANT 2 DCB arm¹



TOBA II POBA group and LEVANT 2 POBA arm¹



Observational data only • Patient populations and study methodologies differed • Not powered for statistical significance

TOBA III - Femoropopliteal dissection repair using the Tack Endovascular System following IN.PACT™ Admiral™ DCB

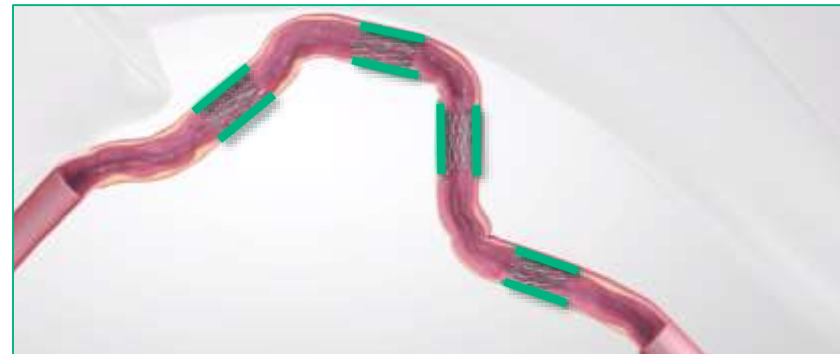
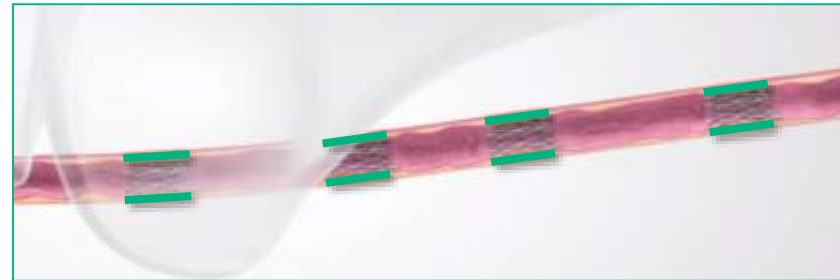
- **97.7% Dissection Resolution**
- **97.5% 12m K-M Freedom from CD-TLR**
- **95.0% 12m K-M Primary Patency**
- **0.6% Bail Out Stent Rate**

VascuFlex® Multi-LOC

- Multiple Stent Delivery System (MSDS)
- 6 individual stents on top of one delivery system:



- Stent-diameter: 5-8 mm
- Stent-length: 13 mm (6 / system),
- Delivery system: 6F-system (0.035" guide wire)
- Shaft lengths: 80 cm / 130 cm

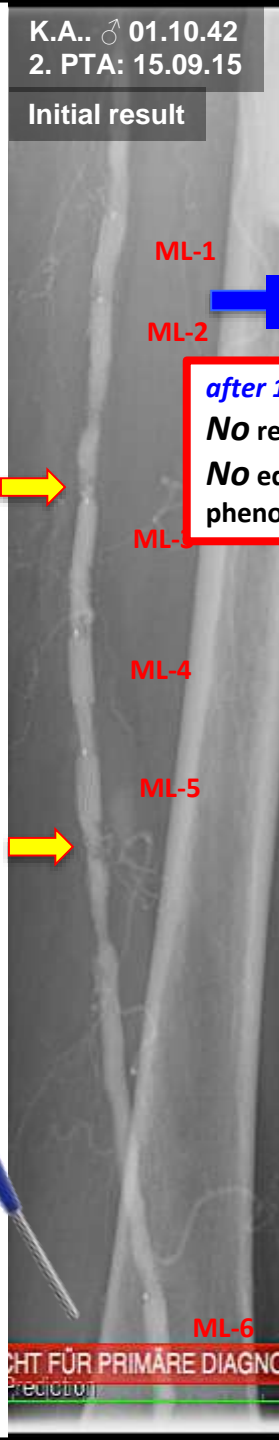
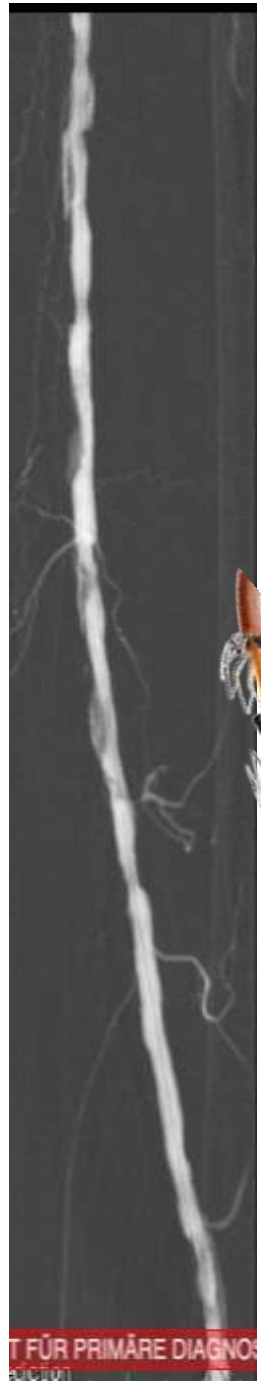
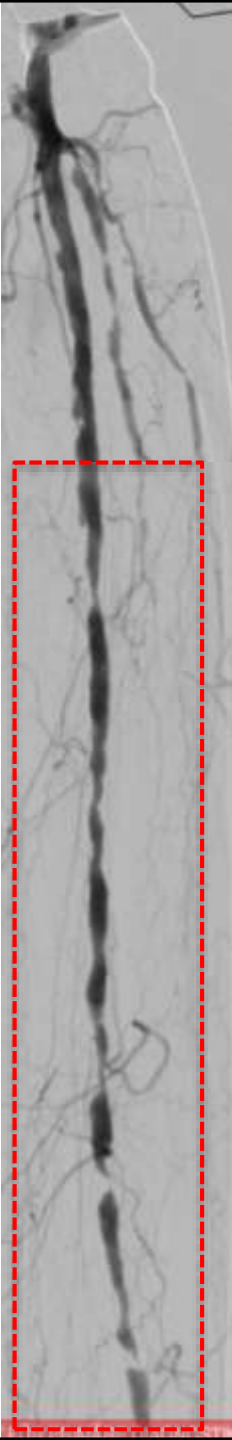


- Indication:
- pAVK → SFA and popliteal artery (p1-p3 segment)

K.A. ♂ 01.10.42
2. PTA: 15.09.15

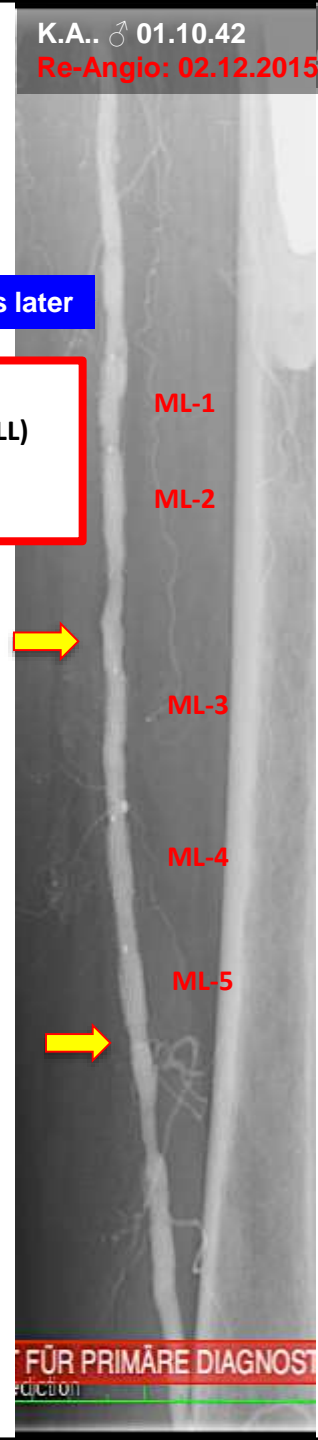
K.A. ♂ 01.10.42
Re-Angio: 02.12.2015⁵

Initial result



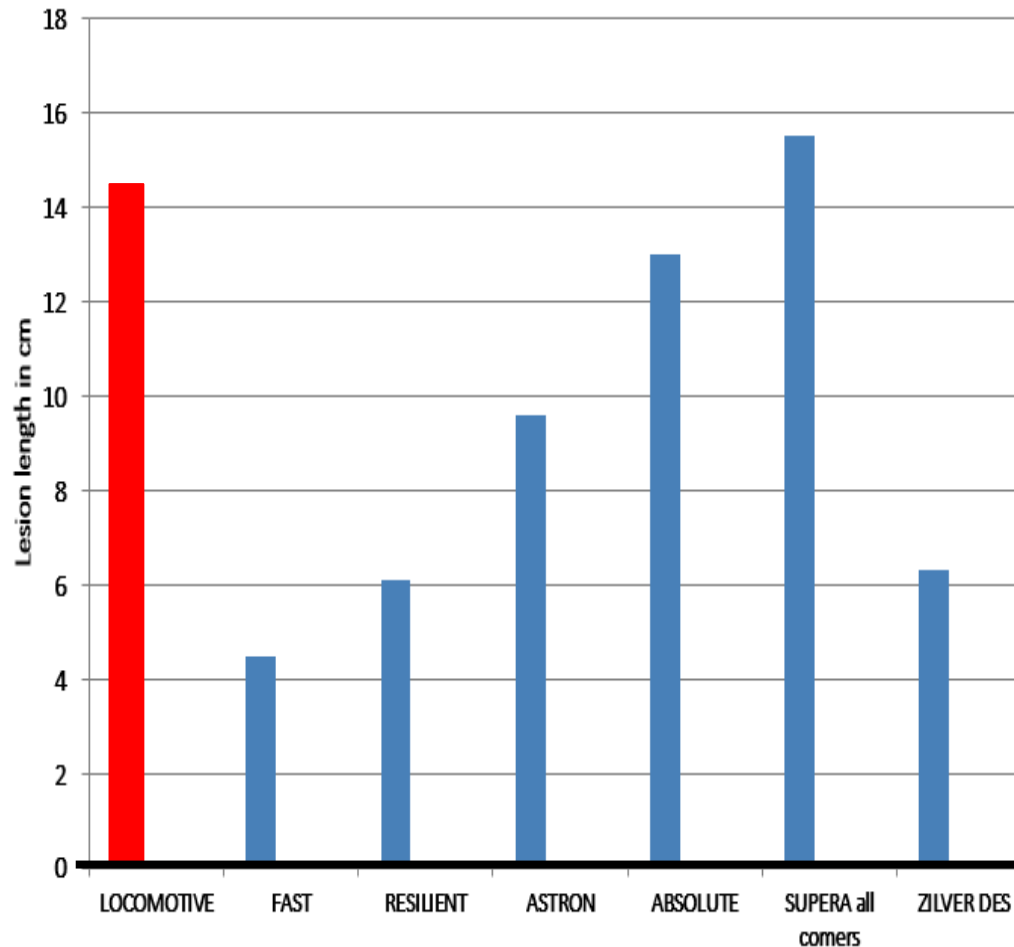
10 weeks later

after 10 weeks:
NO restenosis (LL)
NO edge phenomenon



LOCOMOTIVE Registry

Lesion Length: Comparison to Other Studies



LOCOMOTIVE Registry

12-month follow-up: Clinical outcomes

	All patients	CLI	No CLI	p-value
Patients	75	20	55	-
12 months				
Number of follow-ups Sonogr., clinical and telephone	75 (100.0%)	20 (100.0%)	55 (100.0%)	-
Duration to follow-up or event (months)	11.8±3.0	10.8±4.2	12.1±2.3	0.186
Primary unassisted patency², (diameter stenosis<50%)	54 (85.7%) n=63	14 (93.3%) n=15	40 (83.3%) n=48	0.334
All Target lesion revascul. = +3 after 6 month	7 (9.3%) n=75	1 (5.0%) n=20	6 (10.9%) n=55 (+3)	0.437

Tacks vs. „Mini-Stents“

- **Tack**

- Open cell
- Low compression force
- Low chronic outward force
- 6mm length
- One diameter only
- ATK and BTK indications

- **Multi-Loc**

- Closed cell
- High compression force
- High chronic outward force
- 13mm length
- 5 to 8mm diameter
- Femoro-popliteal indication only

Conclusion

- Long distant stent implantation is associated with
 - ➔ **Reduced patency**
 - ➔ **Increased fracture rate (1st & 2nd generation stents)**
 - ➔ **Impairment of vessel physiology and anatomy during leg motion (first & second generation stents)**
- Multiple short stents or Tacks might overcome the limitations of a full metal jacket
- Prospective studies are on the way or already published (LOCOMOTIVE, TOBA series)
- Head to Head studies against 3rd generation stents are warranted

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