

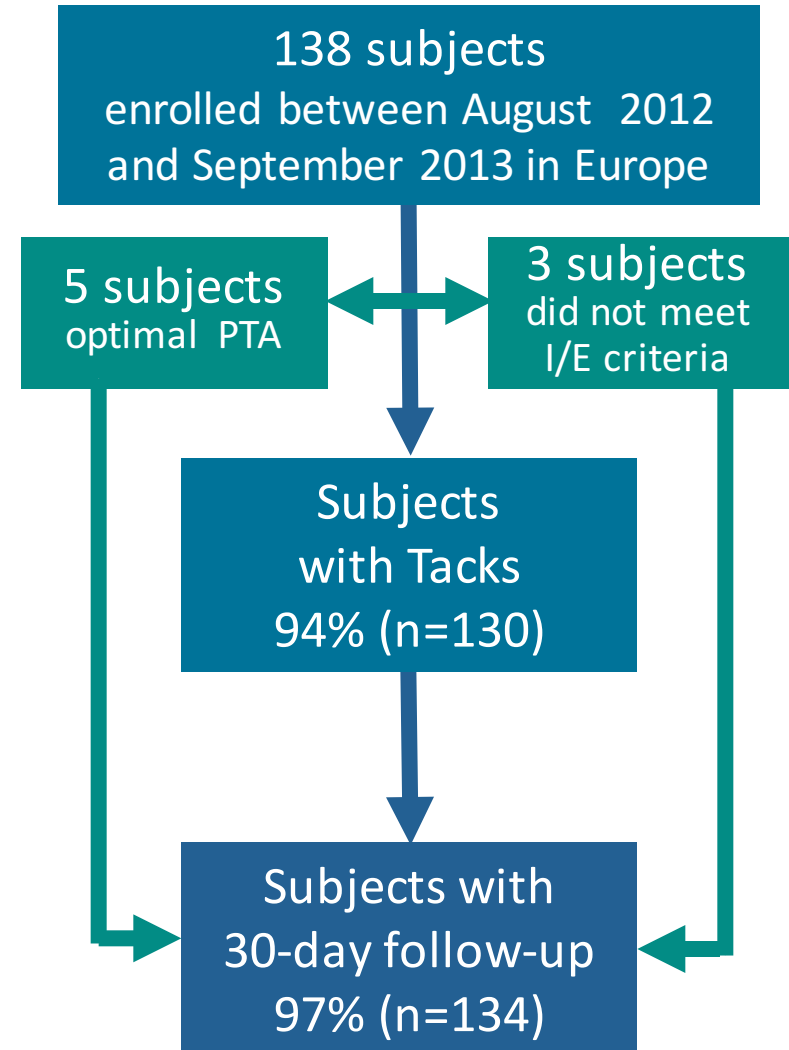


Tack Optimized Balloon Angioplasty (TOBA)



TOBA Study Summary

- **Design:** Prospective, single-arm, multi-center confirmatory trial for optimization of SFA and popliteal artery balloon angioplasty
- **Objective:** To collect confirmatory data in support of the safety and performance of the Intact Vascular Tack Endovascular System[®]
- **Intended Use:** The Tack Endovascular System is indicated for tissue apposition to optimize balloon angioplasty. Dissection or tissue flaps after angioplasty may be indicated for Tack[®] placement.





TOBA: Participating Sites

Principal Investigator	Clinical Site
Marc Bosiers	A.Z. St. Blasius Hospital, Belgium
Marianne Brodmann	Medical University Hospital, Austria
Jean-Paul DeVries	St. Antonius Hospital, The Netherlands
Hans Martin Gissler	Hochrhein-Eggberg Clinic, Germany
Jeroen Hendriks	Antwerp University Hospital, Belgium
Hans Krankenberg	Center for Cardiology & Vascular Intervention Andreas-Gruntzig-Haus, Germany
Lieven Maene	Onze-Lieve-Vrouwziekenhus Moorselbaan 164, Belgium
Patrick Peeters	Imeldaziekenhuis Imeldalaan 9, Belgium
Jens Ricke	Universitätsklinikum Magdeburg, Germany
Dierk Scheinert	Park-Krankenhaus, Germany
Robert Staffa	St. Anne's Faculty Hospital, Česká Republika
Christian Wissgott	Westküstenklinikum Heide, Germany
Thomas Zeller	Herz-Zentrum, Germany



TOBA: Study Results

	Cumulative to 30 days (N=126) Subjects
Major Adverse Events (MAE)	0
Tack Embolization	0
Emergent Revascularization	0
TLR	0
Major Amputation	0

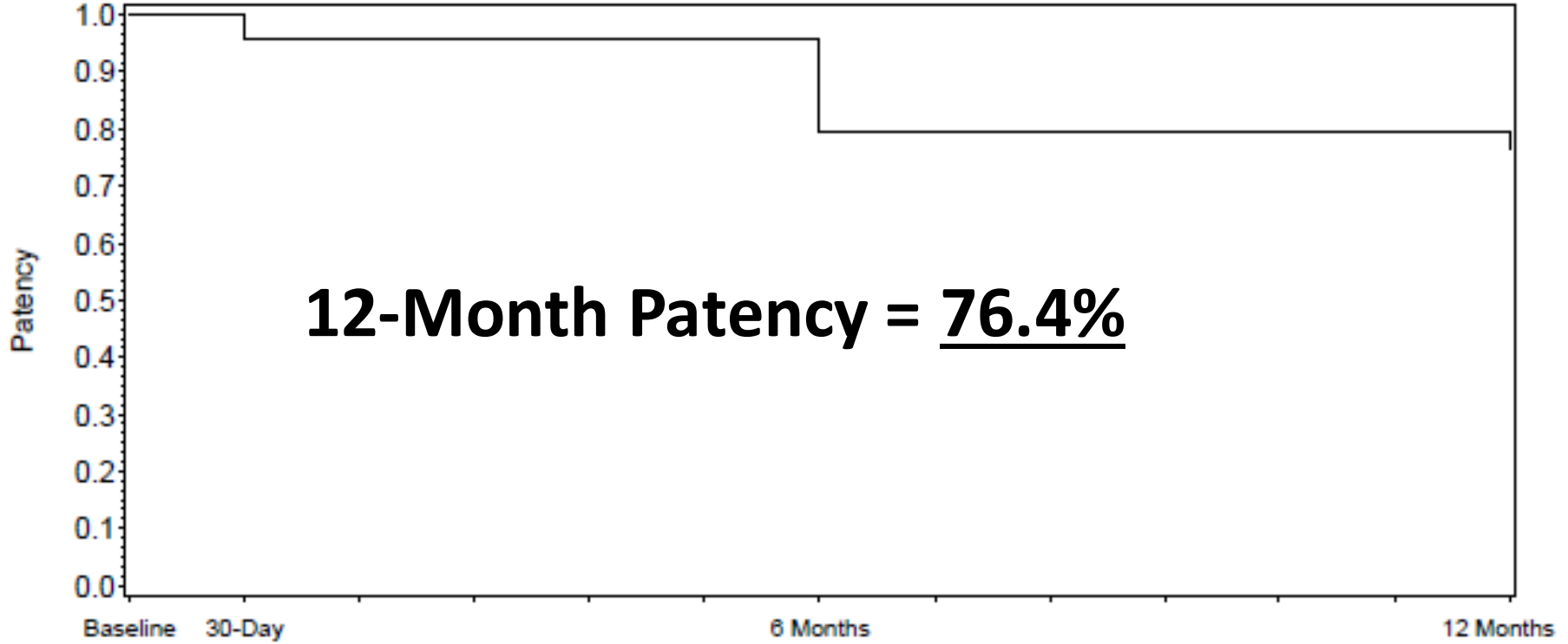
0.0% MAEs

98.5% Technical Success Rate

(only 2 out of 130 received bailout stents)



TOBA: Study Results



12-Month Patency = 76.4%

12-Month Freedom from TLR = 89.5%



TOBA: Presentations/Publications

- 30-day data presented at:
 - ▶ TCT 2013
 - ▶ LINC 2014
- 12-month data presented at:
 - ▶ LINC 2015
 - ▶ Slovakian Congress for Vascular Surgery
- 12-month data published in:
 - ▶ Bosiers M, Scheinert D, Hendriks JMH, et al. Results from the Tack Optimized Balloon Angioplasty (TOBA) study demonstrate the benefits of minimal metal implants for dissection repair after angioplasty. *Journal of Vascular Surgery* (2016).