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Does IN.PACt DCB Work in Long Femoro-popliteal Lesions

Faculty Disclosure

Thomas Zeller, MD

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

- **Honoraria received from:** Abbott Vascular, Angioslide, Bard Peripheral Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Cordis Corp., Covidien, Gore & Associates, Medtronic, Spectranetics, Straub Medical, TriReme, VIVA Physicians
- **Consulted for:** Abbott Vascular, Bard Peripheral Vascular, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Spectranetics, ReCor
- **Research, clinical trial, or drug study funds received from:** 480 biomedical, Bard Peripheral Vascular, Veryan, Biotronik, Cook Medical, Cordis Corp., Covidien, Gore & Associates, Abbott Vascular -DEV Technologies, Inc., Medtronic, Spectranetics, Terumo, TriReme, Volcano

Various Drug Concentrations and Excipients

DCB	Drug	Dose (µg/ mm^2)	Excipient
Lutonix™* Bard	Paclitaxel	2	Polysorbate & Sorbitol
InPact™* Medtronic	Paclitaxel	3	Urea
Freeway™* Eurocor	Paclitaxel	3	Shellac
Passeo 18 Lux™* Biotronik	Paclitaxel	3	N-butyryl-tri-n-hexylcitrate
Advance PTX™* Cook	Paclitaxel	3	None
Ranger™* Boston Scienfitic	Paclitaxel	2	Citrate Ester
Legflow™* Cardionovum	Paclitaxel	3	Shellac
Elutax™* Aachen Resonance	Paclitaxel	2	None

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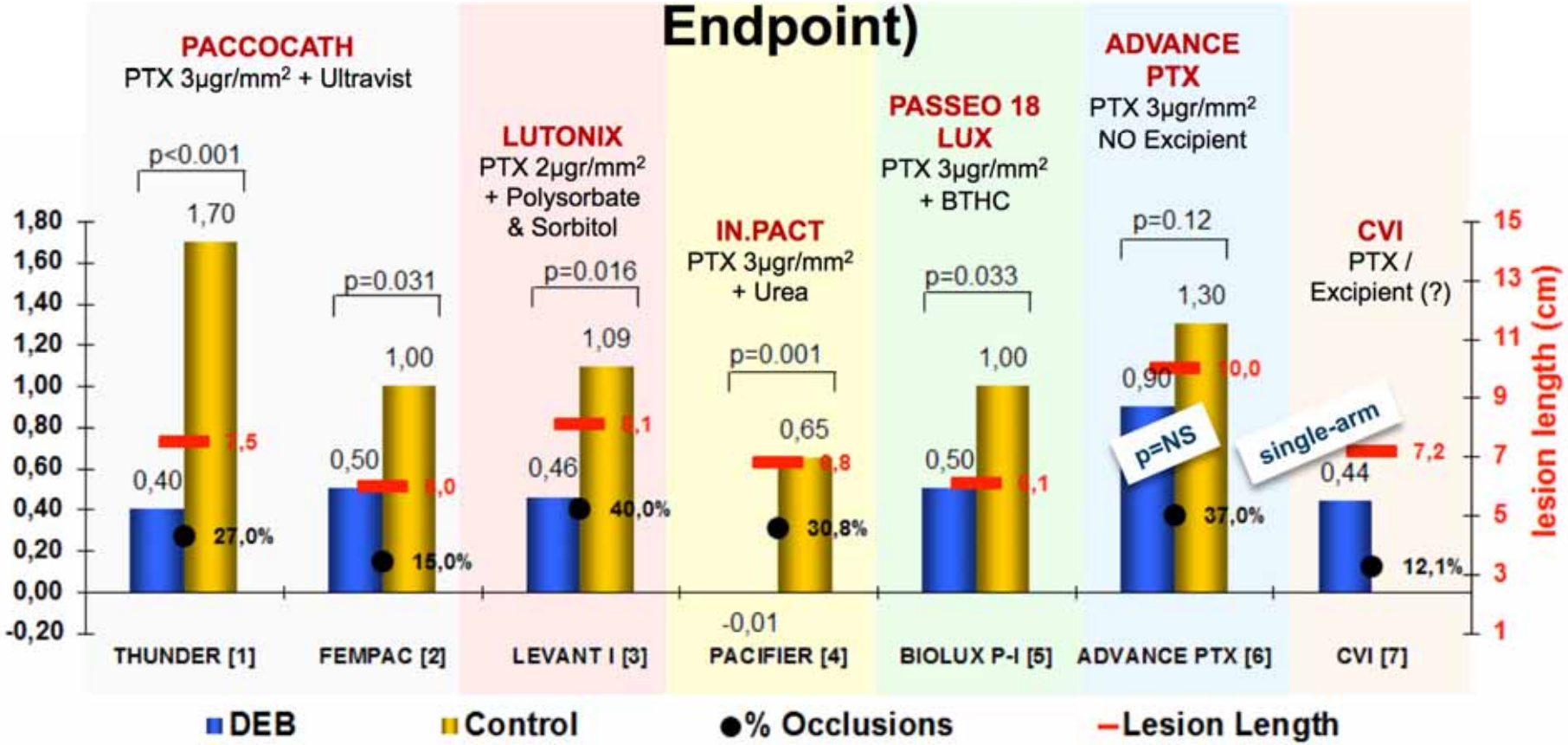
Schnorr Expert Rev Med. Devices (10(1) 105-114 (2013)

DEB in SFA Evidence: Proof-of-Concept

7 Trials / 6 DEB Technologies; 6-month LLL (Primary Endpoint)



[1] G.Tepe et al. - NEJM 2008; [2] M.Werk et al. - Circulation 2008; [3] D.Scheinert - TCT 2012 oral presentation; [4] M.Werk et al. - Circulation CI 2012; [5] D.Scheinert – EuroPCR 2012 oral presentation; [6] D.Scheinert – LINC 2013 oral presentation; [7] S.Duda – EuroPCR 2013 oral presentation

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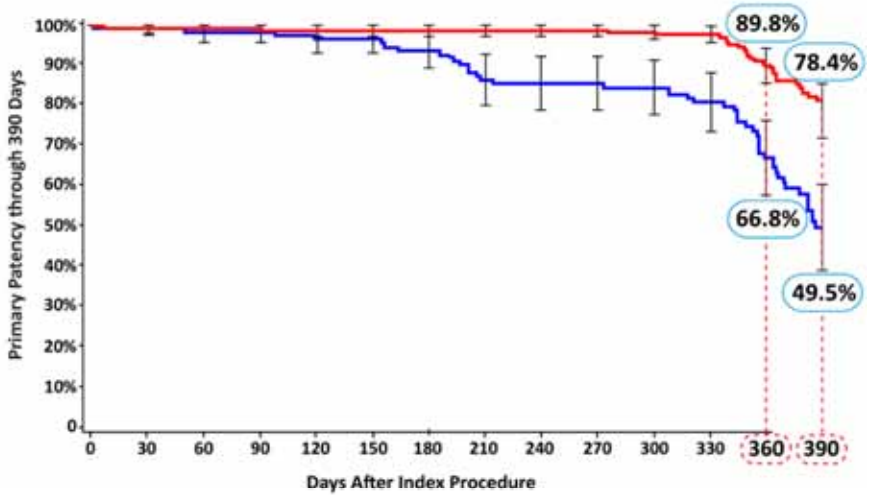
IN.PACT vs. PTA
IN.PACT SFA Pivotal RCT

Prospective ☑
Multicenter ☑
Randomized ☑
Corelab ☑
Peer-rev. Published ☐

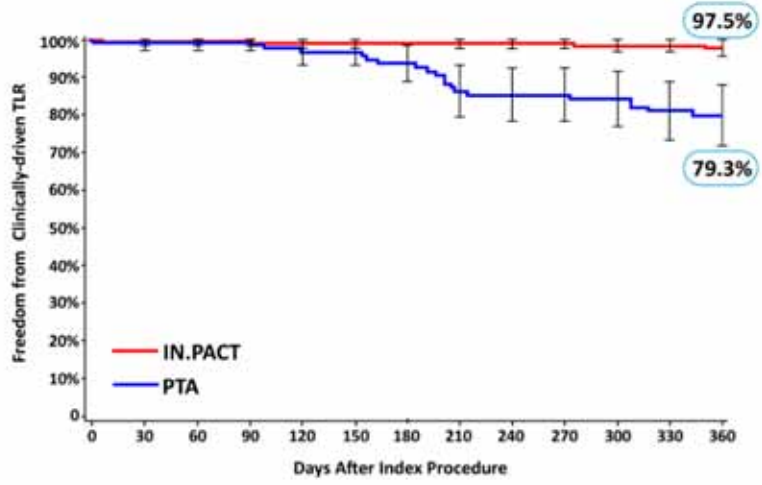
331 Patients RCT (IN.PACT Admiral vs. PTA)

- **Primary Patency: 81.7% vs. 52.4% (p<0.001)**
- **Clinically driven TLR: 2.4% vs. 20.6% (p<0.001)**
- **No PTX related adverse Events**

Freedom from loss of Primary Patency



Freedom from clinically driven TLR



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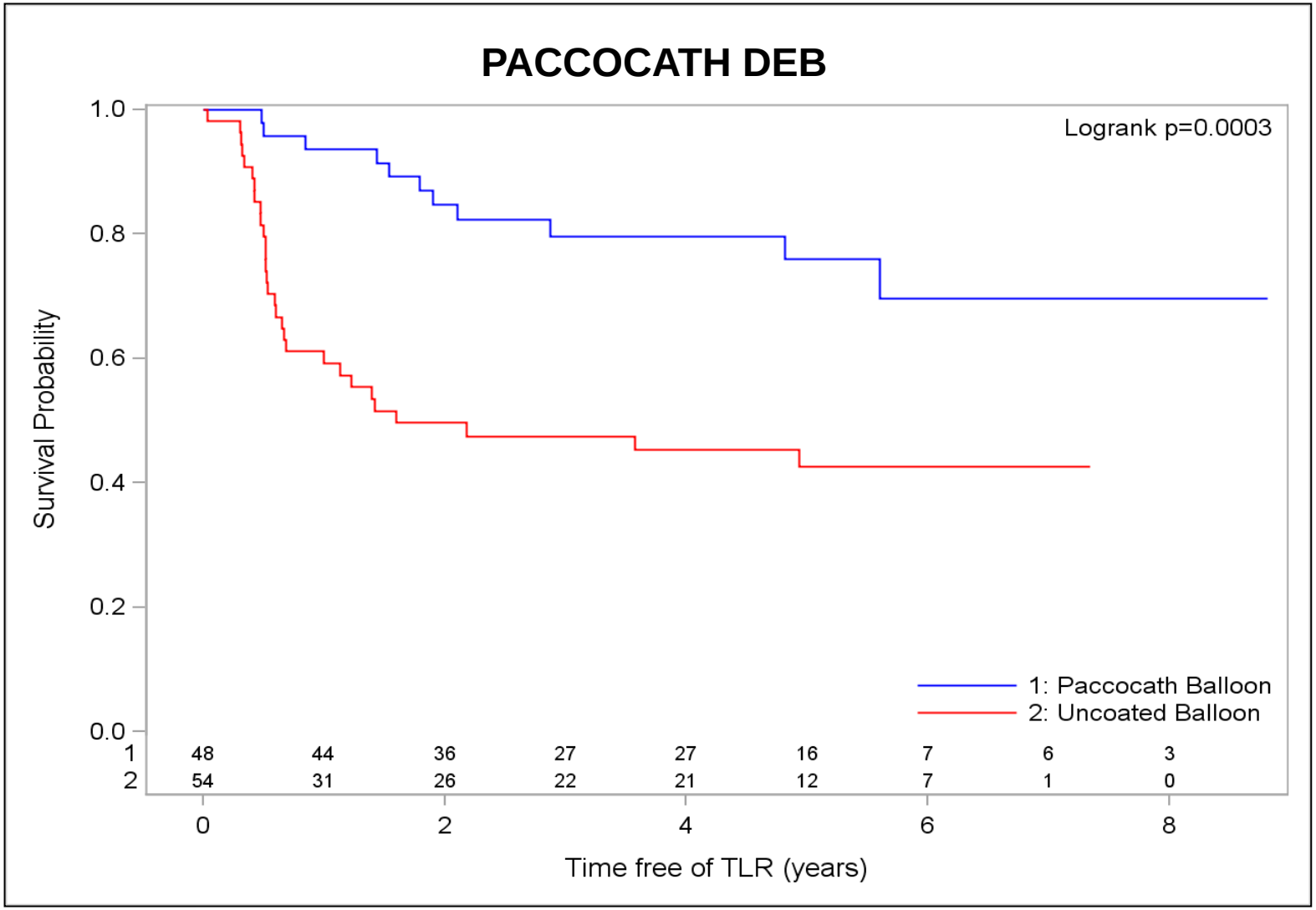
Tepe G et al. Circulation 2014

THUNDER

5-Year Outcomes – Freedom from TLR



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Tepe, Zeller TCT 2011

Femoro-Popliteal
TASC II C&D lesions

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IN.PACT in long SFA lesions: Leipzig Registry

Prospective ☑

Multicenter ☐

Randomized ☐

Corelab ☐

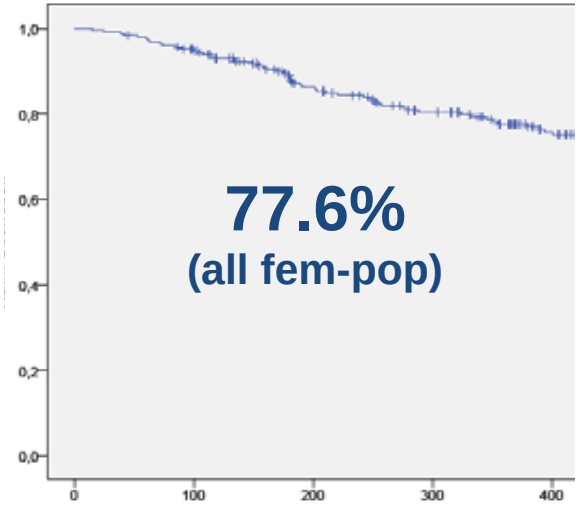
Peer-rev. Published ☐

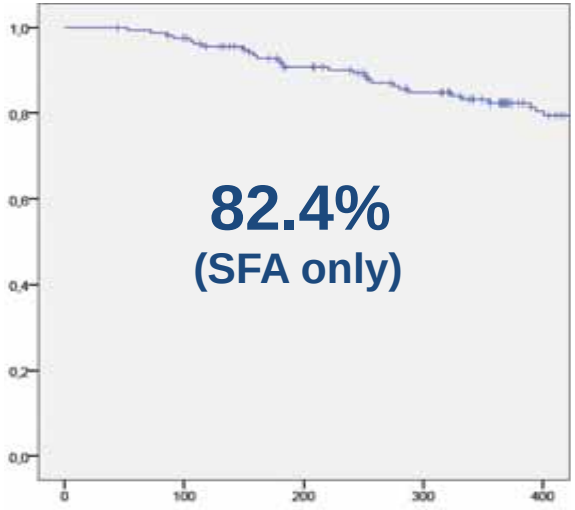
Real world 260-Patient Registry

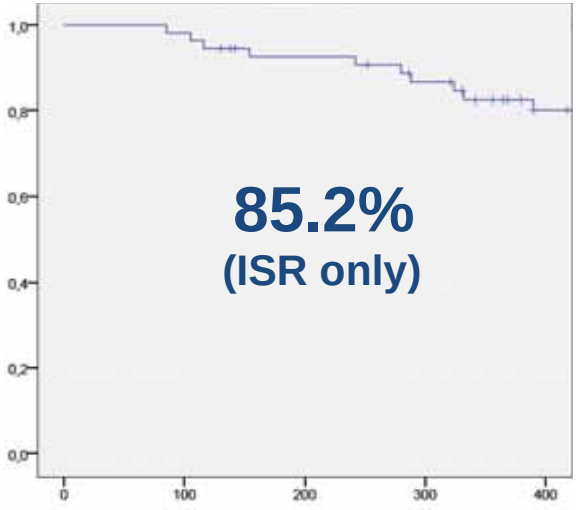
- High primary patency rates achieved overall in the full cohort and subsets
- 23.3% provisional stent rate

Lesions ~24 cm

1-year freedom from loss of Primary Patency (PSVR < 2.4)







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Propensity Score Analysis DES vs. DEB
Baseline Lesion Characteristics

Lesion		DEB	DES	*p*
N		131	97	
Location:	Proximal SFA	50.4% (66/131)	52.6% (51/97)	*0.743*
	Mid SFA	70.2% (92/131)	79.4% (77/97)	*0.119*
	Distal SFA	76.3% (100/131)	86.6% (84/97)	*0.052*
	P1	26.0% (34/131)	17.5% (17/97)	*0.131*
	P2	10.7% (14/131)	0.0% (0/97)	*< 0.001*
	P3	7.6% (10/131)	0.0% (0/97)	*0.005*
Mean Length (mean±SD)		194.4 ± 86.3	195.0 ± 64.5	*0.948*
Length Min / Max (mm)		100. 450	100. 350	
Restenotic lesions		51.9% (68/131)	44.3% (43/97)	*0.258*
Tot Occlusions		52.7% (69/131)	62.9% (61/97)	*0.123*
% Diameter Stenosis (mean±SD)		93.5 ± 8.6	95.4 ± 7.6	*0.073*
Calcification:	none	31.3% (41/131)	20.6% (20/97)	
	slight	25.2% (33/131)	48.5% (47/97)	*0.527*
	moderate	23.7% (31/131)	21.6% (21/97)	
	severe	19.8% (26/131)	9.3% (9/97)	

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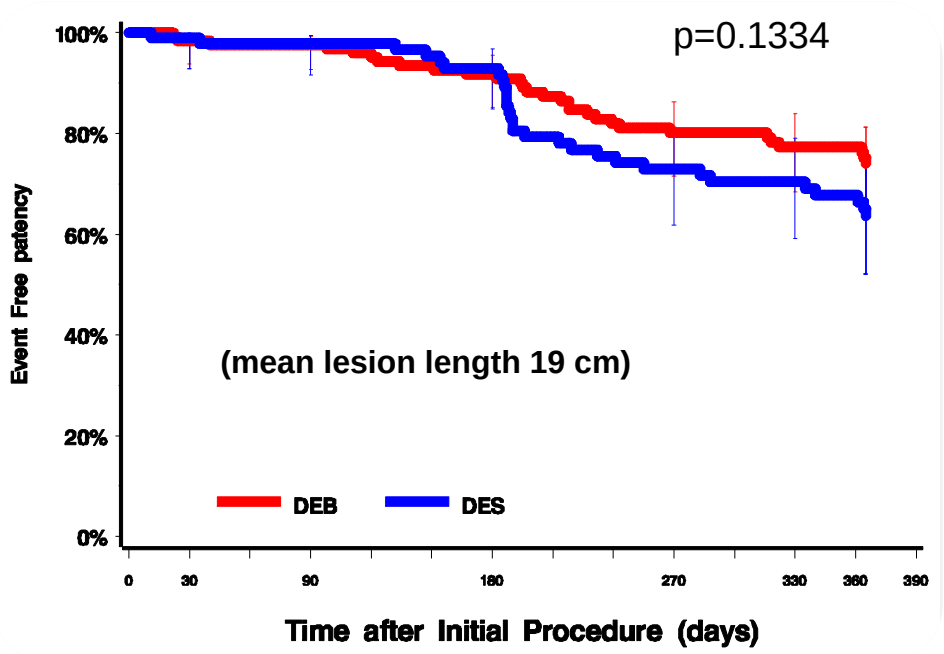
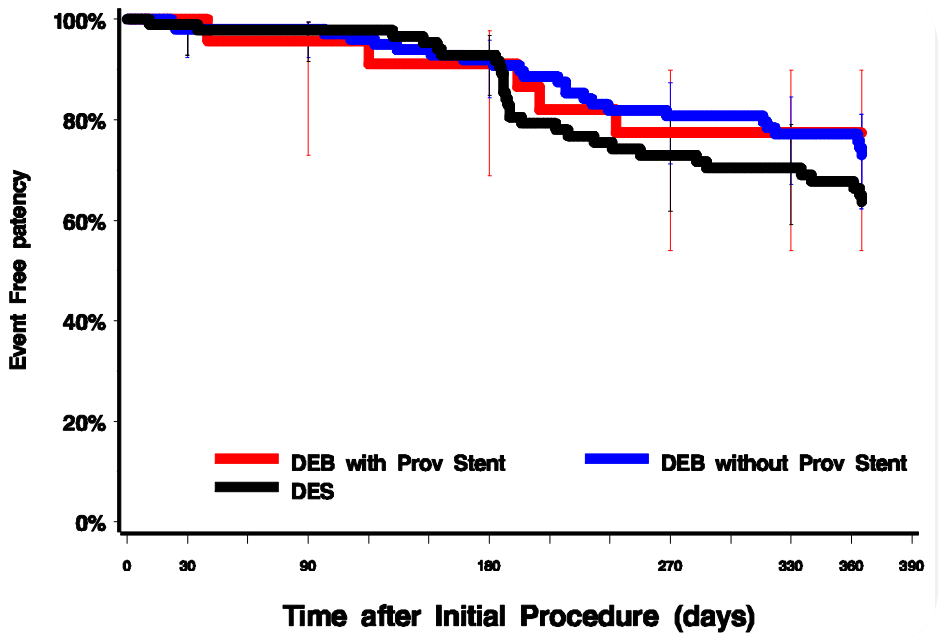
12-month Primary Patency





Mean Length (mean±SD)	194.4 ± 86.3	195.0 ± 64.5	*0.948*
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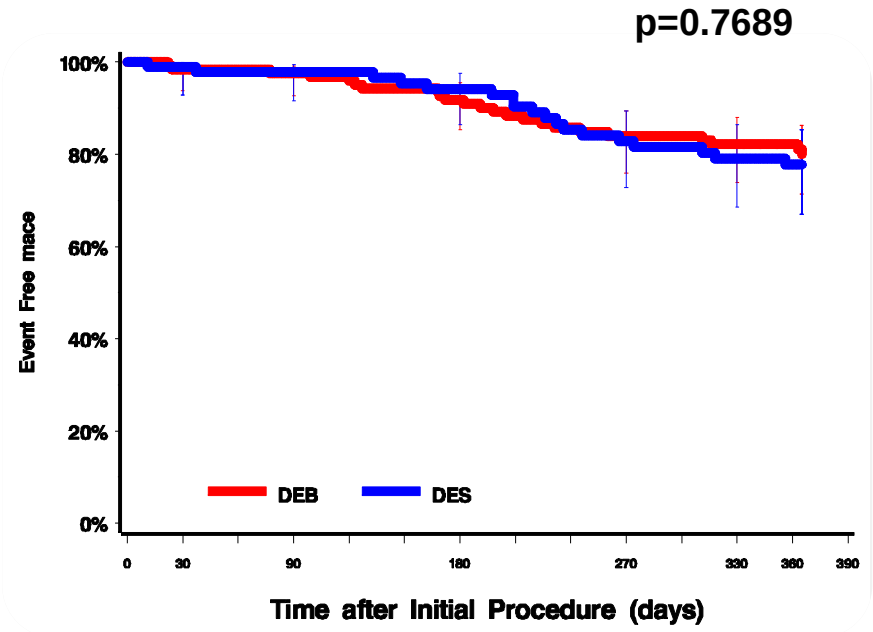
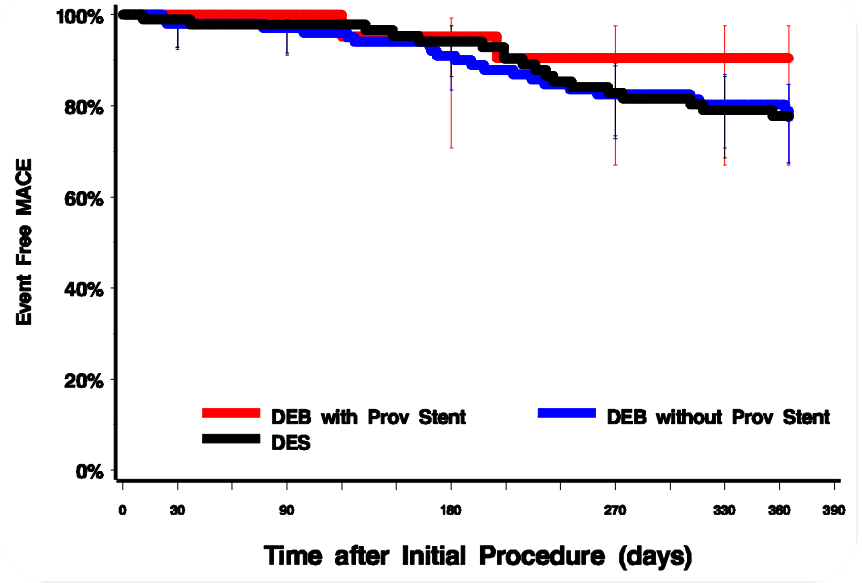
Zeller T et al. JEVT 2014;;21:359-368

12-month Freedom from Death and TLR*





* Clinically Driven TLR

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Zeller T et al. JEVT 2014;;21:359-368

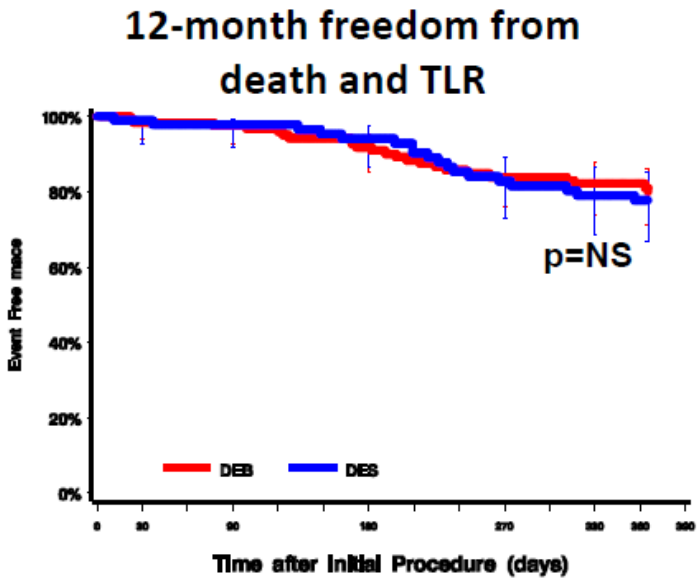
IN.PACT vs. DES in long SFA lesions

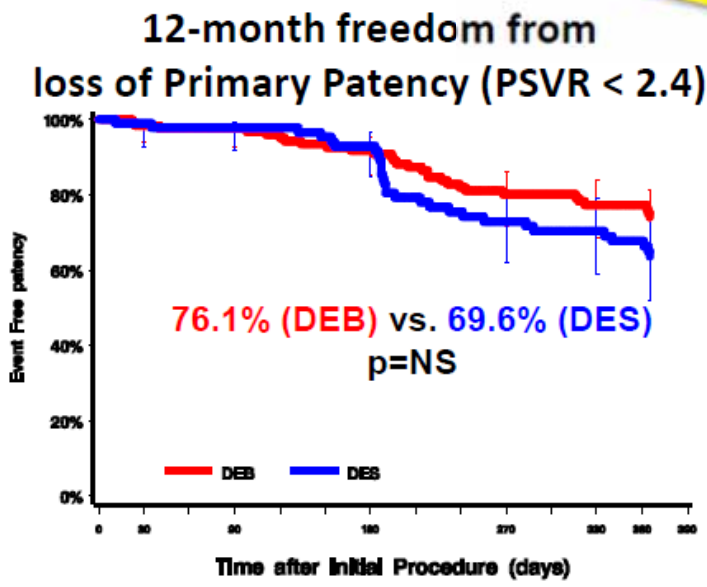
Prospective ☐
Multicenter ☑
Randomized ☐
Corelab ☐
Peer-rev. Published ☐

228-Patients Retrospective, Propensity score analysis

- Non significant difference between IN.PACT DCB and Zilver PTX in long SFA lesions
- provisional stent rate post DCB =

Lesions ~19 cm





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IN.PACT GLOBAL Study

Largest Real-World, independently adjudicated fem-pop Study

All-comers (RC-2-3-4)

- ☑ Bilateral disease
- ☑ Multiple lesions
- ☑ SFA and Popliteal
- ☑ TASC A
- ☑ TASC B
- ☑ TASC C
- ☑ TASC D
- ☑ Ca^{++}
- ☑ ISR

- **1500 Patients**
- **67 Sites in EU, Mid-East, Latin America, Asia**
- **Independent Adjudication by Clinical Event Committee**
- **Corelab adjudicated (450-patient imaging cohort of Long lesions, ISR and CTOs)**
- **Patient monitoring: up to 5 years**

Steering Committee: G.Tepe, M.Bosiers, P.Gaines, D. Dai-Do, A.Razuk, G. Ansel

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IN.PACT SFA and IN.PACT Global 12-months Results Summary

	IN.PACT SFA (DCB Arm) N=220	IN.PACT Global N=655
CD-TLR	2.4%	**8.7%**
CD-TVR	4.3%	9.5%
Thrombosis	1.4%	3.8%
Target Limb Major Amputation	0.0% (0)	0.3% (2)

	IN.PACT SFA	IN.PACT Global
Lesion Length	8.9 cm	**12.2 cm**
CTO	25.8%	35.8%
ISR	0.0%	21.4%
Baseline RC > 3	5%	15%

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IN.PACT DCB in Long Femoro-Popliteal Lesions
Conclusions

- Robust level 1 evidence regarding short-term performance of DCB in TASC A & B femoro-popliteal lesions
- Potential to become standard of care for SFA treatment even in long lesions; however, Level 1 data are still pending
- No DEB class effect, objective data needed for each individual DCB

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