EffPac-Trial: Effectiveness of Luminor® DCB vs. POBA in the SFA: primary endpoint and 12-months results

Ulf Teichgräber, MD, MBA
on behalf of the investigators

Teichgräber U, Aschenbach R, Scheinert D, Zeller T, Brechtel K, Thieme M, Blessing E, Treitl M, Lichtenberg M, von Flotow P, Vogel B, Werk M, Riambau V, Wienke A, Lehmann T, Sixt S

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Disclosure of conflict of interest

- Speaker name: Ulf Teichgräber, MD, MBA

- Potential conflicts of interest related to the presentation:
  - Research grant: iVascular, Endoscout

- Potential conflicts of interest not related to the presentation:
  - Consulting Fees, Honoraria, Research Grants, Advisory Boards: ab medica, Abbott Vascular, B.Braun Melsungen, Boston Scientific, Celonova, C.R. Bard, COOK, Endoscout, GE Healthcare, iVascular, Kimal, Maquet, Medtronic, Philips Healthcare, Siemens Healthineers, Spectranetics, W.L.Gore
  - Master research agreements with Siemens Healthineers, GE Healthcare

luminor

Paclitaxel coated balloon
(3,0 µg/mm²)

Fast deflation

Ultra low tip and crossing profiles

TransferTech

Innovative and UNIQUE nanotechnology coating

Complete balloon range dimensions

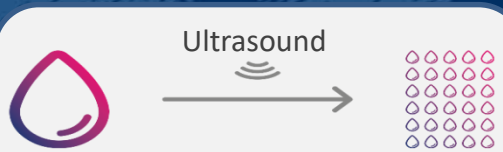
Luminor 35: 5-7mm Ø and 20-150mm length
Luminor 18: 2-8 mm Ø and 20-200mm length
Luminor 14: 1.5-4mm Ø and 40-200mm length

LINC Asia 2019 – U. Teichgräber et al. – EffPac-Trial: Effectiveness of Luminor® DCB vs. POBA in the SFA: primary endpoint and 12-months results

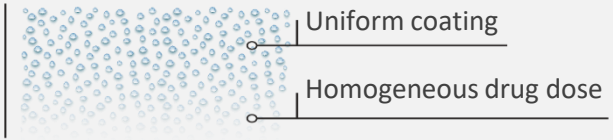
luminor

iVascular
therapies for living

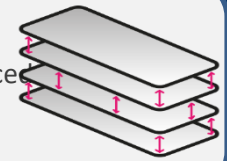
UNIQUE nanotechnology coating



Spray Technology
Dosage of uniform diameter nanodrops by ultrasonic deposition

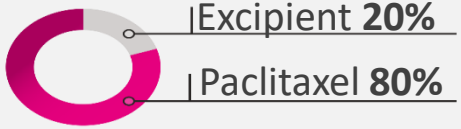


Multi-layer technology
- Coating durability during the proce
- No cracking



TransferTech

Proprietary nanotechnology dosage system for an **uniform, flexible** and **ultrathin coating**



Excipient
- Organic ester
- Biocompatible
- Lipophilic

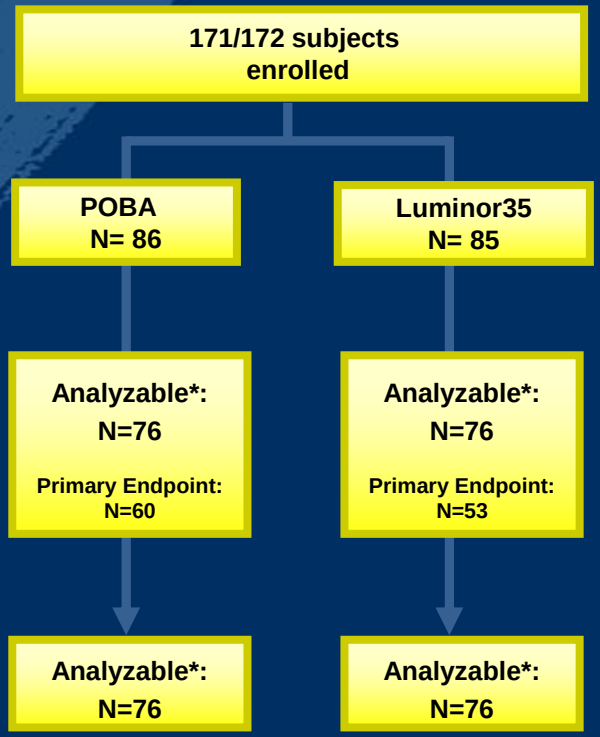
Paclitaxel
- Lipophilic
- Inhibition of stenosis
- Specific cellular receptors

Dry-off
- Microcrystalline structure
- Optimal drug transfer to the vessel wall within 30-60s seconds

Trial Design and Endpoints

	Endpoints	Baseline	6 month	12 month	24 month
Efficacy	Primary	Vessel diameter (mm)	• Late Lumen Loss (LLL)	-	-
Efficacy	Secondary		• Freedom from Target Lesion Revascularization (TLR/TVR) • Patency* • Change of ABI, Rutherford stage, QoL (WIQ), EQ-5D		
Safety	Primary		• Major and minor amputation rate at index limb • Mortality, independently of cause		

Patient Flow



Recruitment completed on 31.12.2016

Randomization (1:1)

6 month follow-up

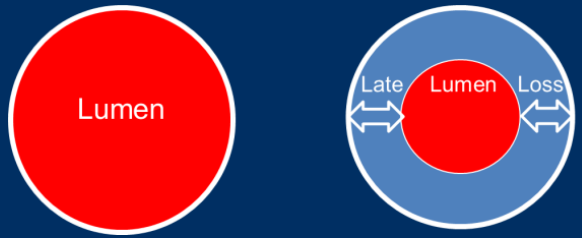
Data Lock: 31.08.2017

12 month follow-up

Data Lock: 31.01.2018

* Patients with data of at least one endpoint

Efficacy: Late Lumen Loss - LLL



*** LLL =** difference between the diameters (in mm) post-procedure minus 6 months follow-up

	LUMINOR®	POBA	Difference, 95% CI (LUMINOR® vs. POBA)	p value
LLL 6M (mm)*	0.14 [CI: -0.38; 0.67]	1.06 [CI: 0.54; 1.59]	-0.92 [CI: -1.36; -0.49]	<0.001

* Estimated LLL (Mean, 95% CI) from linear mixed model adjusted for center

Efficacy: Late Lumen Loss - LLL

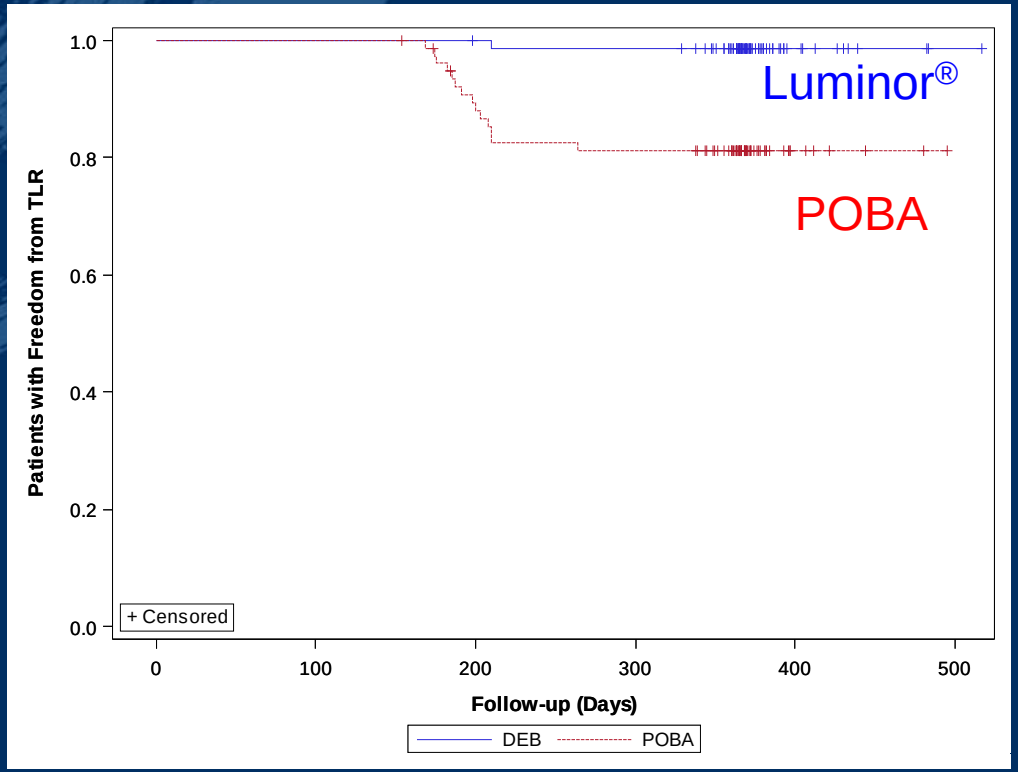
Study	Drug-coated balloon 6 mo LLL (mm)	Control 6 mo LLL (mm)	LLL Difference (mm)
THUNDER Tepe et al. 2008 Paccocath coating	0.4±1.2	1.7±1.8	-1.3
AcoArt I Trial Jia et al. 2016 Orchid (Acotec)	0.05±0.73	1.15±0.89	-1.1
EFFPAC 2017 Luminor (iVascular)	**0.14 [CI: -0.38; 0.67]**	**1.06 [CI:0.54; 1.59]**	**-0.92**
RANGER Bausback et al. 2017 Ranger DCB	-0.16±0.99	0.76±1.4	-0.92
LEVANT I Scheinert et al. 2014 Lutonix (Bard)	0.46±1.13	1.09±1.07	-0.63
BIOLUX P-I Trial Scheinert et al. 2015 Passeo-18 Lux (Biotronik)	0.51±0.72	1.04±1.0	-0.53
FEMPAC Werk et al. 2008 Paccocath DCB	0.5±1.1	1.0±1.1	-0.5
CONSEQUENT 2017 SeQuent Please (B. Braun)	0.35 [CI: 0.19; 0.79]	0.72 [CI: 0.68; 1.22]	-0.37

Efficacy: Target Lesion Revascularization (TLR)

	LUMINOR®	POBA	Relative Risk, 95% CI (LUMINOR® vs. POBA)	Number needed to treat (NNT)	p value
TLR 12M (%)	1.3 (1/76)	18.7 (14/75)	0.08 [0.01; 0.53]*	6	<0.001

*Relative Risk Reduction (RRR) = 91.8%, Cochran-Mantel-Haenszel estimate, adjusted for center

Efficacy: Target Lesion Revascularization (TLR)



Efficacy: Patency

	LUMINOR®	POBA	Relative Risk*, 95% CI (LUMINOR® vs. POBA)	Number needed to treat (NNT)	p value
Patency (%)	90.3 (65/72)	65.3 (47/72)	1.38 [1.14; 1.67]	4	<0.001

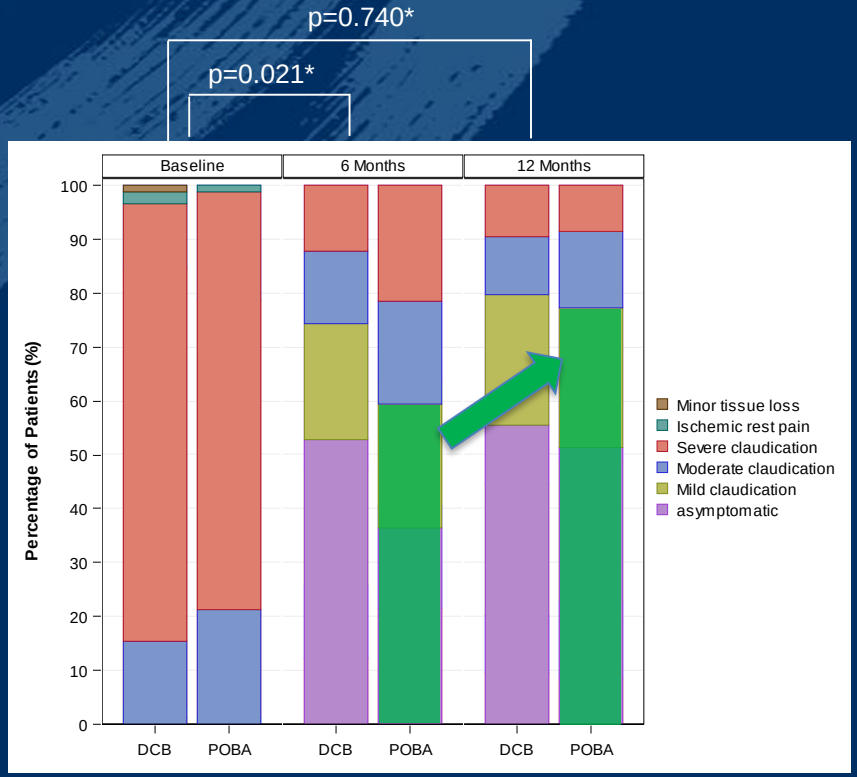
* Interpretation: Relative chance for patency is increased by 38% in the LUMINOR® group

Primary patency: Freedom from restenosis (determined by duplex ultrasound PSVR <2.5) and freedom from TLR at 12 months

Efficacy: Improvement of Rutherford

	after 6 months*		after 12 months**	
Improvement of Rutherford-Becker	Paclitaxel-Coated Balloon (n=74)	Standard Angioplasty Balloon (n=72)	Paclitaxel-Coated Balloon (n=74)	Standard Angioplasty Balloon (n=68)
Deterioration of 1 stage	1 (1.4)	0 (0.0)	1 (1.4)	1 (1.5)
No improvement	10 (13.5)	18 (25.0)	6 (8.1)	7 (10.3)
Improvement of 1 stage	9 (12.2)	15 (20.8)	13 (17.6)	12 (17.6)
Improvement of 2 stages	21 (28.4)	19 (26.4)	17 (23.0)	21 (30.9)
Improvement of 3 stages	33 (44.6)	20 (27.8)	37 (50.0)	27 (39.7)

Efficacy: Improvement of Rutherford

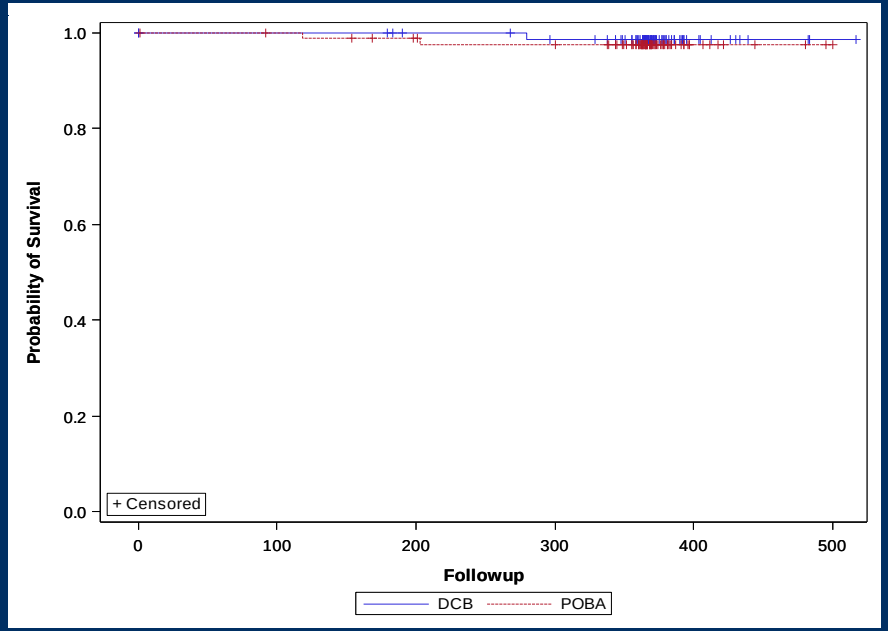


* Cochran-Mantel-Haenszel method was applied to compare the change of RBC at 6 and 12 months to baseline between DCB- and POBA-group

Safety: Mortality after 12 months

	LUMINOR®	POBA	p value
Death (%)	1.2 (1*/85)	2.3 (2*/86)	1.000

* Not related to device or procedure



Safety: Amputation after 12 months

	LUMINOR®	POBA	p value
Minor Amputation (%)	0 (0/85)	1.2 (1/86)	1.000
Major Amputation (%)	0 (0/85)	0 (0/86)	1.000

Classification of SAEs*

*to the causality to study procedure and investigational device/control product

SAE		Procedure		Total
		related	not related	
Investigational device (DCB)	related	2**	0	2
	not related	0	53	53
	Summe	2	53	55
Control product (POBA)	related	0	0	0
	not related	10	63	73
	Summe	10	63	73
	Summation	12	116	128

**thrombosis and persisting claudication

Classification of mortality

Mortality		Procedure		Total
		related	not related	
Investigational device (DEB)	related	0	0	0
	not related	0	1*	1
	Total	0	1	1
Control product (POBA)	related	0	0	0
	not related	0	2**	2
	Total	0	2	2
	Summation	0	3	3

* Exact cause of death: unknown; patient was multimorbid and suffered of severe lung disease (COPD) and emphysema, a coronary heart disease and abused of alcohol.
**Aortic and mitral valve infection with septic shock and suicide.

Safety: conclusions

When EffPac trial was initiated in 2015, POBA was the golden standard as comparative device to drug-eluting balloon catheters and LLL was imperative as primary endpoint to demonstrate technical efficacy.

A head-to-head study between two Paclitaxel-coated balloon catheters is necessary today and would bring more evidence about efficacy and safety of DCBs.

Conclusions

The LUMINOR® Paclitaxel-coated balloon catheter demonstrates to be clinical highly effective and safe in inhibiting restenosis compared to POBA

The innovative coating technique matters and is shown not only in the patency, LLL and TLR data, but also in an improvement of the Rutherford stage

The results of the study allow direct comparison to other already-completed RCTs applying Paclitaxel-coated DEB from different manufacturers in the same target vessel

PCR online

The 24-months results will be presented at the EuroPCR on May, 22nd 2019 in Paris

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