EffPac - Trial: Assessment of the Effectiveness of DCB versus POBA in the SFA

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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 Heathcare, Spectranetics, W.L.Gore
- Master research agreements with Siemens Healthcare, GE Healthcare

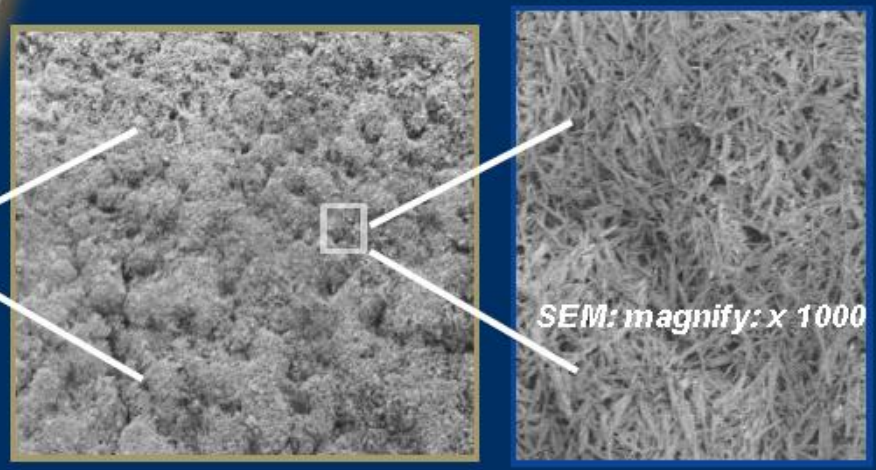
Paclitaxel-coated Balloon

Luminor35*

Dosage of uniform diameter nanodrops by direct **ultrasonic deposition**

- Ultrathin multilayer coating:
  - **DURABILITY**
  - Minimum drug loss
- **Homogeneous** distribution of drug
  - Accurate dosage

Control over **drug morphology**



SEM: magnify: x250

MICROCRISTALLINE paclitaxel

* Luminor® 35 Paclitaxel Eluting Peripheral Balloon Dilatation Catheter marked in European Union since 2013. (iVascular, S.L.U., Barcelona, Spain)

Paclitaxel-coated Balloon
Different Coating Technology

TRANSFERTECH

MICROCRISTALLINE paclitaxel

- Efficacy — **FAST** drug **TRANSFER**
- Safety — **MINIMUM** drug **LOSS**

EffPac-trial

Multicenter Randomized Controlled Trial to Assess the Effectiveness of Paclitaxel-coated Luminor® Balloon Catheter versus Uncoated Balloon Catheter in the Superficial Femoral and Popliteal Arteries to Prevent Vessel Restenosis or Reocclusion

EffPac-trial

Design:

Investigator-initiated, prospective, multi-centre trial and 2 arms randomised study

Objective

Safety and efficacy of the Luminor® paclitaxel drug-eluting balloon in inhibiting restenosis and in ensuring long-term patency

Sponsor:

University of Jena, Germany

Representative of the sponsor:

Prof. Dr. Ulf Teichgräber, Jena University Hospital

EffPac-trial

CoreLab

Dr. Ulrich Beschorner, coreLab Bad Krozingen GmbH, Germany

Data Management and Safety Board (DMSB)

Dr. Michael Werk, Martin Luther Krankenhaus, Berlin, Germany

Dr. Vicenc Riambau, Hospital Clinic de Barcelona, Spain

Prof. Dr. Wienke, University Halle-Wittenberg, Germany

Monitoring and SAE Reporting (VascuScience GmbH)

Dr. Christin Ott and Lars Mahler, Leipzig, Germany

Project Management

Tabitha Heller, Cornelia Eichorn, Nicole Brillinger, Dr. Andrea Rößler, University Jena, Germany

Producer of the Investigational Product

Life Vascular Devices Biotech, S.L., Barcelona, Spain

EffPac-trial
11 Participating Sites

01 Jena	PD Dr. R. Aschenbach, *Univ. Hosp. Jena*
02 Leipzig	Prof. Dr. Dierk Scheinert, *Univ. Hosp. Leipzig*
03 Bad Krozingen	Prof. Dr. Thomas Zeller, *Heart Center*
04 Hamburg	Dr. S. Sixt, *Angiologikum*
05 München	PD Dr. M. Treitl, *University Hospital*
06 Berlin	Prof. Dr. K. Brechtel, *„Ihre Radiologen"*
07 Sonnebrg	Dr. M. Thieme, *Medinos Clinic*
08 Karlsbad	Prof. Dr. E. Blessing, *SRH-Clinic*
09 Heidelberg	Dr. B. Vogel, University Heidelberg
10 Arnsberg	Dr. M. Lichtenberg, *Clinic Arnsberg*
11 Kusel	Dr. P. von Flotow, *Westpfalz Clinic*

EFFPac-trial
Design

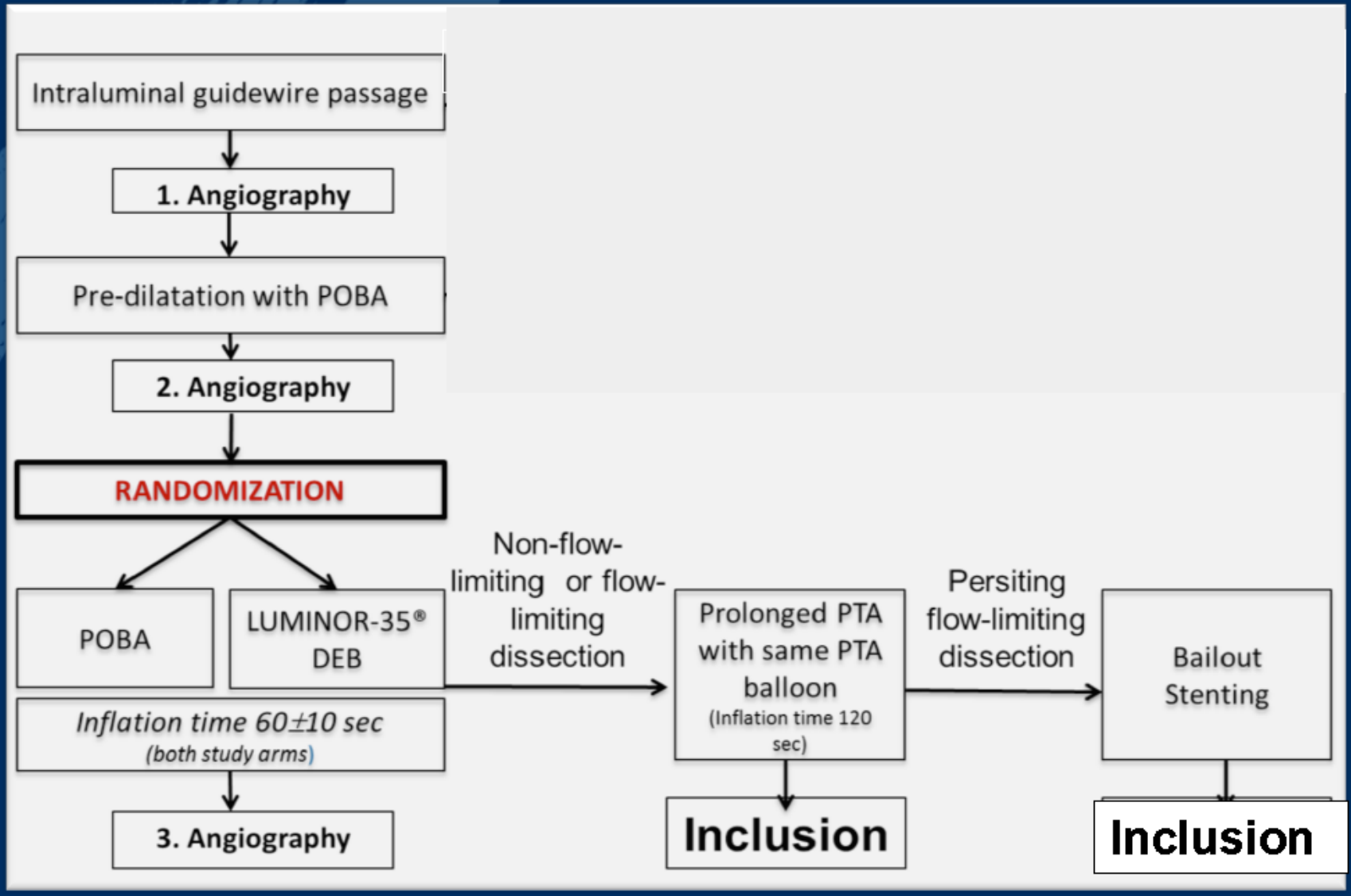
Major Inclusion Criteria

- Age ≥ 18 years
- Subject must agree to undergo the 6-month angiographic and clinical follow-up (at 12 month post-procedure)
- Peripheral vascular disease Rutherford class 2-4
- De novo stenotic/ re- stenotic lesion or occlusive lesions in the superficial femoral (SFA) and/or popliteal arteries (PA)
- ≥70% diameter stenosis or occlusion
- Target lesion length: ≤15 cm (TASC II A and B)
- ≥one patent infrapopliteal run-off artery to the foot
- If the index lesion is re-stenotic, the prior PTA must have been >30 days prior to treatment in the current study

Major Exclusion Criteria

- Severely calcified target lesions in the SFA/PA resistant to PTA
- Previous intervention or surgery in the target vessel
- Major amputation in the same limb as the target lesion
- Acute myocardial infarction within 30 days before inter-vention
- Renal insufficiency with a serum creatinine >2.0 mg/dL at baseline
- Platelet count <50 G/l or >600 G/l at baseline

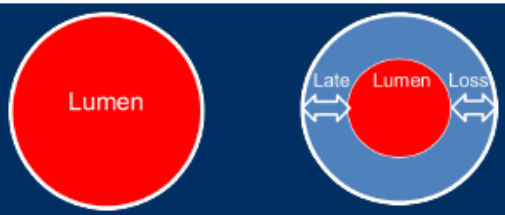
Study Design



Trial Design and Endpoints

Endpoints		Baseline	6 month	12 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	

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



Study Design

Recruitment completed on 31. Dec. 2016

Baseline Patient Characteristics

	LUMINOR®	POBA
Age	67.3 ± 10.5 (82)	67.8 ± 8.9 (83)
Male	61.0% (50/82)	68.7%(57/83)
Rutherford Clinical Category		
1	0% (0/82)	1.2% (1/82)
2	18.3% (15/82)	23.2% (19/82)
3	78.1% (64/82)	74.4% (61/82)
4	2.4% (2/82)	1.2% (1/82)
5	1.2% (1/82)	0% (0/82)
Diabetes	37.8% (31/82)	41.0% (34/83)
Hypertension	86.6% (71/82)	85.5% (71/83)
Hyperlipidemia	71.6% (58/81)	68.8% (55/80)
Smoking Status		
never smoked	16.3% (13/80)	16.8% (14/83)
previous smoker	45.0% (36/80)	39.8% (33/83)
current smoker	38.8% (31/80)	43.4% (36/83)
ABI		
left	0.88 ± 0.26 (65)	0.87 ± 0.27 (69)
right	0.83 ± 0.24 (67)	0.86 ± 0.29 (70)

Interim analysis of preliminary data

Baseline Angiographic Data

	LUMINOR®	POBA
Lesion Length (cm)	6.0 ± 4.4 (82)	5.5 ± 4.0 (83)
Total Occlusion	20.0% (16/80)	25.3% (21/83)
Calcification		
none/mild	53.1% (43/81)	45.8% (38/83)
moderate	43.2% (35/81)	43.4% (36/83)
severe	3.7% (3/81)	10.8% (9/83)
Diameter Stenosis (%)	87.8 ± 9.8 (82)	90.1 ± 8.9 (83)
Reference Vessel Diameter (mm)	5.5 ± 0.6 (80)	5.4 ± 0.7 (83)
# of Patent Run-off Vessel		
0	0% (0/82)	1.2% (1/83)
1	22.0% (18/82)	21.7% (18/83)
2	40.2% (33/82)	32.5% (27/83)
3	37.8% (31/82)	44.6% (37/83)
Target Lesion Location		
1	12.1% (12/99)	11.3% (11/97)
2	26.3% (26/99)	25.8% (25/97)
3	34.3% (34/99)	37.1% (36/97)
4	12.1% (12/99)	13.4% (13/97)
5	13.1% (13/99)	9.3% (9/97)
6	2.0% (2/99)	3.1% (3/97)

Interim analysis of preliminary data

Procedural Characteristics

	LUMINOR®	POBA
Pre-dilatation Performed	100% (82/82)	98.8% (82/83)
Post-DCB Dissection	36.6% (30/82)	41.0% (34/83)
Application of Stents	13.4% (11/82)	18.3% (15/82)
Post-procedure Diameter Stenosis	15.8 ± 16.8 (82)	14.9 ± 16.2 (83)

Interim analysis of preliminary data

Trial results @ 6 months follow-up
Report of primary endpoint: LLL

Jena, Thuringia, Germany