# EffPac Trial

## First Luminor efficacy and safety outcomes at 3.5 years

Teichgräber Ulf, MD
on behalf of the investigators

Teichgräber U, Aschenbach R, 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, **Scheinert D**.

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Teichgräber et al. Trials (2016) DOI 10.1186/s13063-016-1657-x

Teichgräber et al. EuroIntervention (2019) DOI: 10.4244/EIJ-D-19-00292

Teichgräber et al. Radiology (2020) DOI: 10.1148/radiol.2020201370

# Disclosure

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:

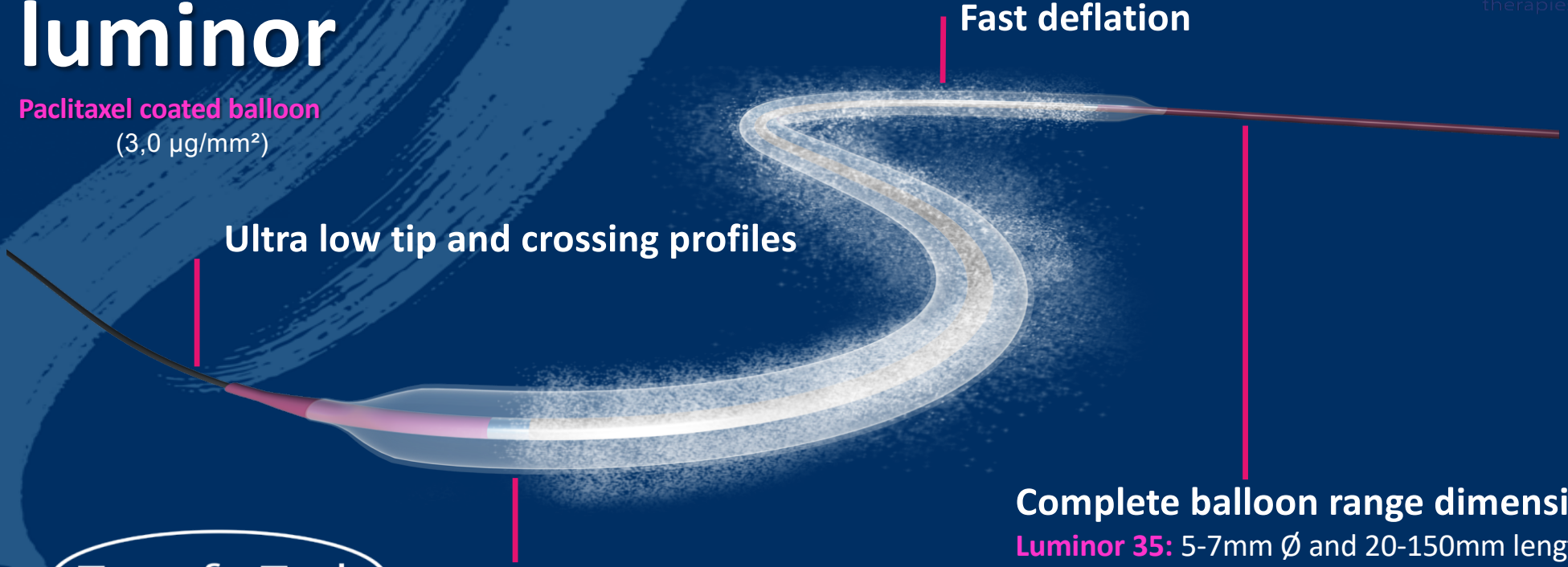
- Consulting Fees, Honoraria, Research Grants, Advisory Boards: ab medica, Abbott Vascular, B.Braun Melsungen, Boston Scientific, Celonova, C.R. Bard, Concept Medical, COOK, Endoscout, GE Healthcare, iVascular, Kimal, Maquet, Medtronic, Philips Healthcare, Siemens Healthineers, Spectranetics, W.L.Gore
- Master research agreements with Siemens Healthineers, GE Healthcare

# Study Device

iVascular
therapies for living

## luminor

**Paclitaxel coated balloon**
(3,0 µg/mm²)



**Fast deflation**

**Ultra low tip and crossing profiles**

**Innovative and UNIQUE nanotechnology coating**

TransferTech

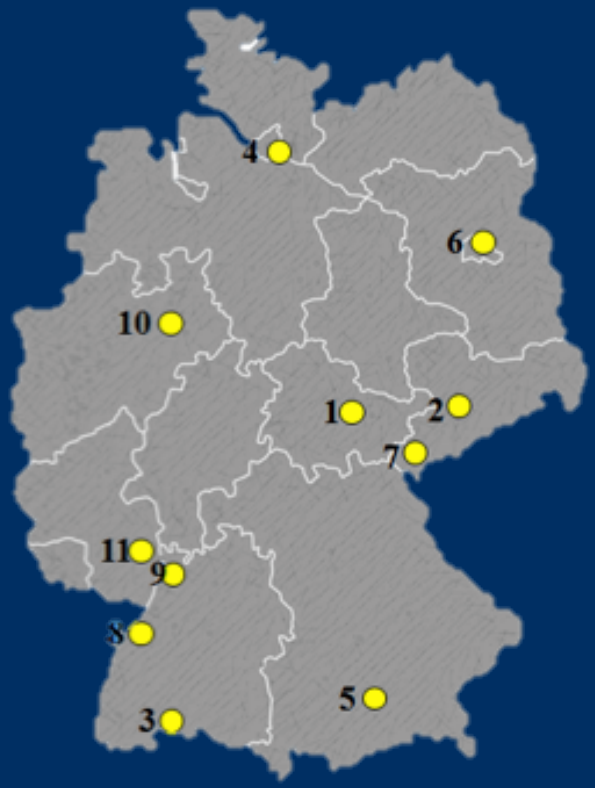
**Complete balloon range dimensions**

**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

# Study Design & Participating Sites

Investigator initiated, prospective, multicenter, randomized controlled trial

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



# Study Endpoints

**Primary Endpoint**

- LLL at 6 months

**Secondary Endpoints**

- Binary restenosis
- Primary patency
- Freedom from TLR
- Freedom from TVR
- Rutherford category
- WIQ-score
- ABI
- EQ-5D score

- All-cause mortality
- Target limb amputation

# Key Eligibility Criteria

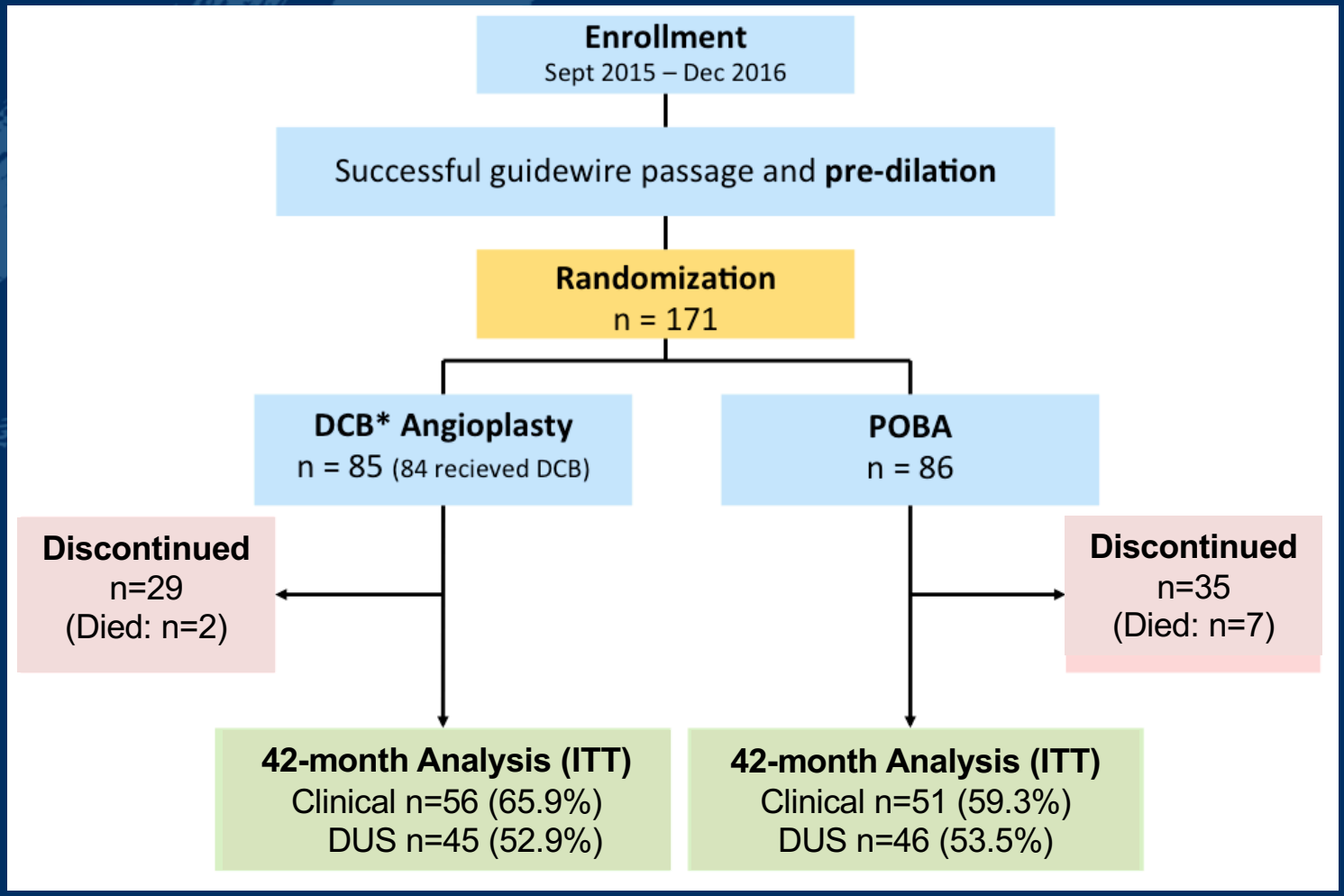
## Inclusion

- Rutherford category 2-4
- De-novo stenotic/restenotic or occluded (≥ 70%) SFA/prox. PA lesions
- Lesion length ≤ 150 mm
- 1 lesion/patient
- Successful pre-dilation

## Exclusion

- Previous TV surgery
- Major amputation TL
- Severly calcified lesions (PTA resistant)
- In-stent restenosis

# Patient Flow



# Baseline Patient Characteristics

| | **DCB** n = 85 | **POBA** n = 86 | P value |
|---|---|---|---|
| Age, years | 68.0 ± 7.5 | 68.1 ± 8.8 | p = 0.979 |
| Male, % | 60.0 | 69.8 | p = 0.239 |
| Diabetes, % | 36.5 | 40.4 | p = 0.681 |
| Hypertension, % | 87.1 | 84.9 | p = 0.850 |
| Hyperlipidemia, % | 70.7 | 68.6 | p = 0.144 |
| Current smoker, % | 40.5 | 43.0 | p = 0.856 |
| Critical limb ischemia, % | 3.6 | 1.2 | p = 0.613 |
| ABI | 0.73 ± 0.23 | 0.74 ± 0.23 | p = 0.929 |

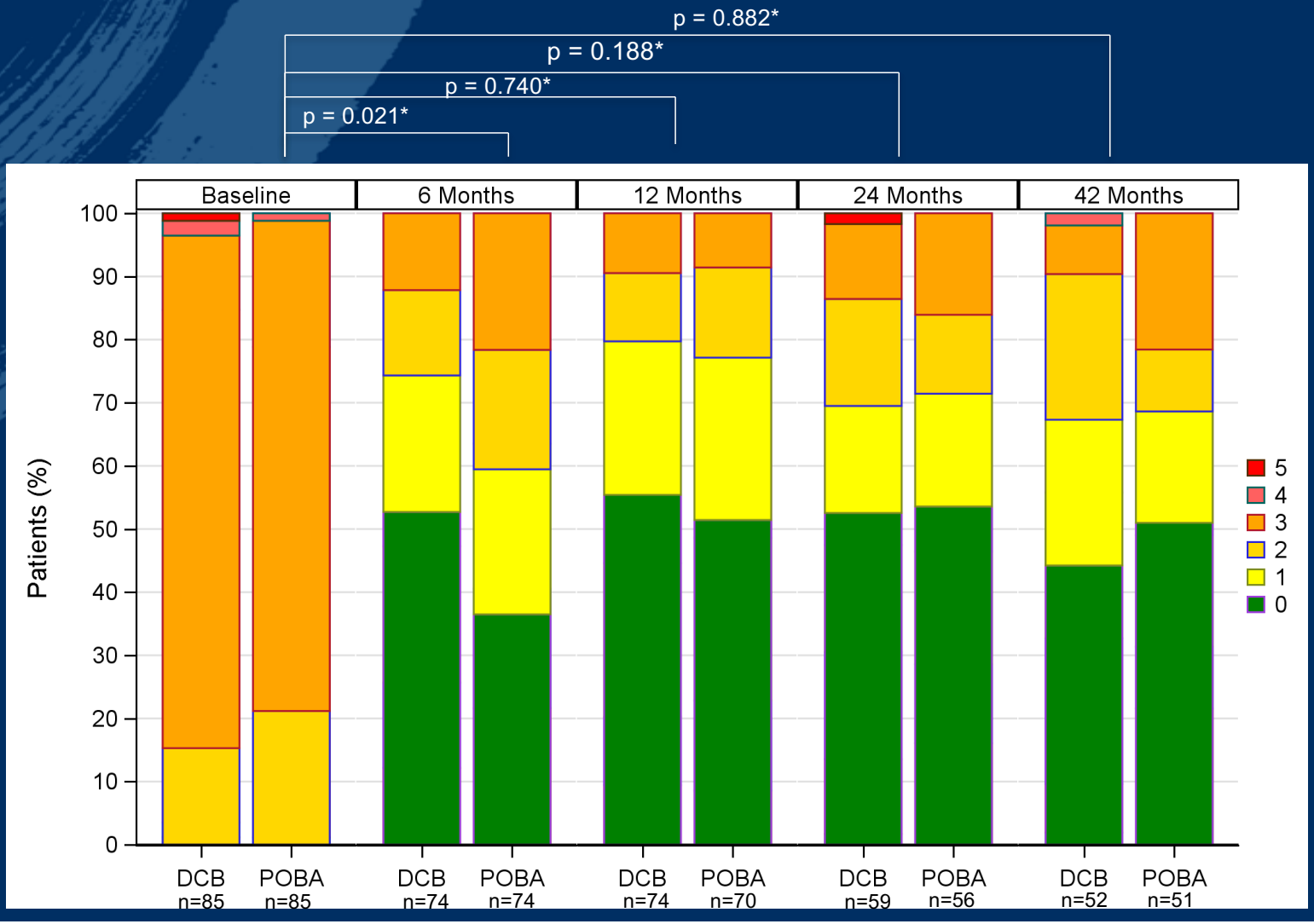
# Lesion and Procedure Characteristics

| | **DCB** (n = 85) | **POBA** (n = 86) | P value |
|---|---|---|---|
| Lesion length, mm | 59.1 ± 43.4 | 55.8 ± 39.1 | p = 0.732 |
| CTO, % | 20.2 | 25.6 | p = 0.492 |
| Calcification, %<br>Severe<br>Moderate | <br>3.6<br>42.2 | <br>11.6<br>44.2 | p = 0.232 |
| Mid / dist. popliteal artery, % | 18.8 | 14.0 | p = 0.248 |
| Pre-dilation, % | 98.8 | 98.8 | p = 0.993 |
| Dissection, % | 37.6 | 40.7 | p = 0.801 |
| Bailout stenting, % | 15.3 | 18.8 | p = 0.709 |
| Residual DS, %<br>post-angioplasty<br>post-treatment | <br>15.5 ± 16.7<br>7.5 ± 9.3 | <br>14.9 ± 16.2<br>8.3 ± 10.1 | <br>p = 0.807<br>p = 0.699 |

# Primary Endpoint – 6-Month LLL

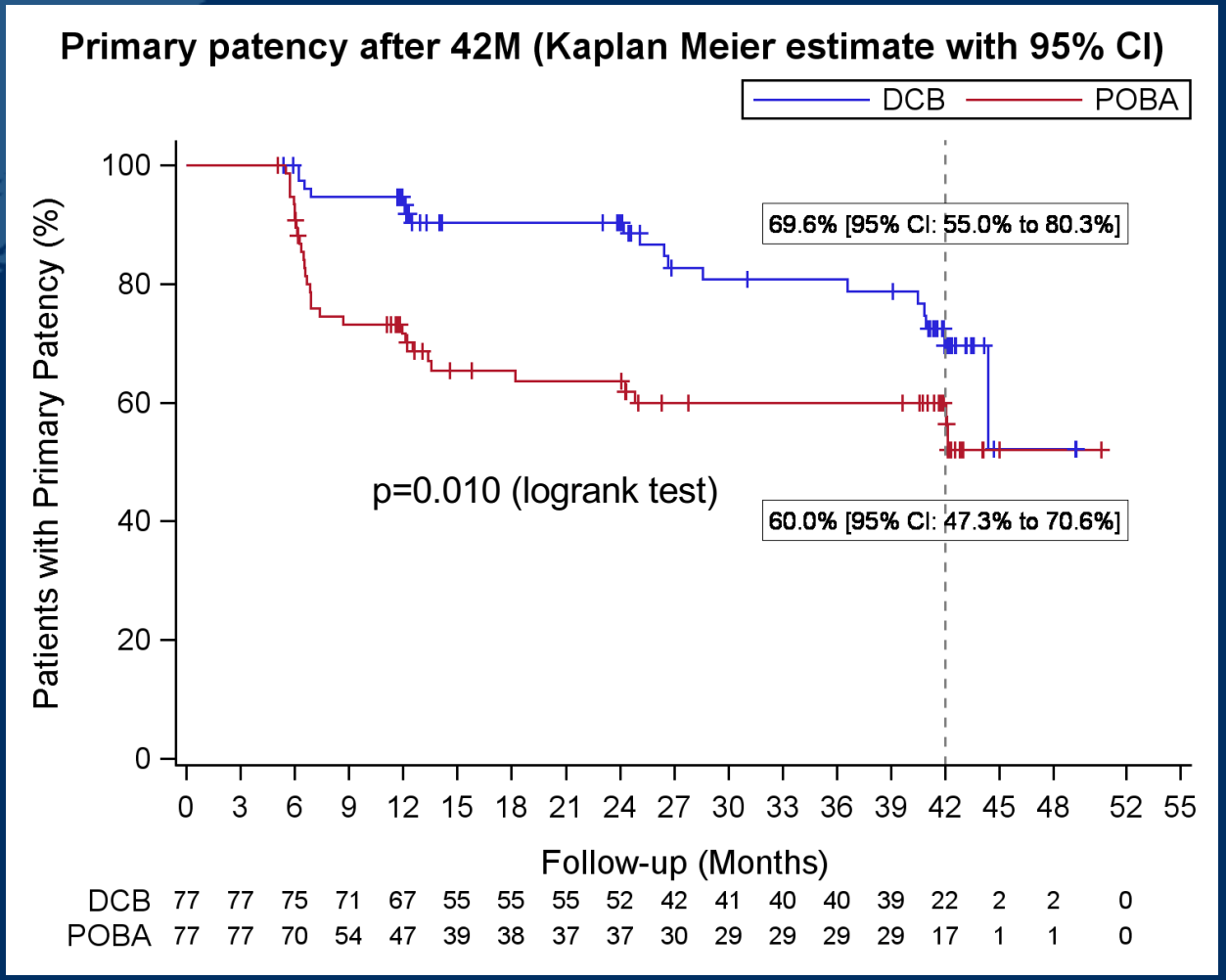
| Study | DCB<br>6-month LLL | Control<br>6-month LLL | Difference<br>DCB vs POBA (mm) |
|---|---|---|---|
| **THUNDER** Tepe et al. 2008<br>Paccocath coating | 0.4±1.2 | 1.7±1.8 | -1.3 |
| **AcoArt I** Trial Jia et al. 2016<br>Orchid (Acotec) | 0.05±0.73 | 1.15±0.89 | -1.1 |
| **EFFPAC** 2018<br>Luminor (iVascular) | **0.14** [CI: -0.38; 0.67] | **1.06** [CI:0.54; 1.59] | **-0.92** [CI:-1.364; -0.49]<br>p < 0.001 |
| **RANGER** Bausback et al. 2017<br>Ranger DCB | -0.16±0.99 | 0.76±1.4 | -0.92 |
| **LEVANT** I Scheinert et al. 2014<br>Lutonix (Bard) | 0.46±1.13 | 1.09±1.07 | -0.63 |
| **BIOLUX P-I** Trial Scheinert et al. 2015<br>Passeo-18 Lux (Biotronik) | 0.51±0.72 | 1.04±1.0 | -0.53 |
| **FEMPAC** Werk et al. 2008<br>Paccocath DCB | 0.5±1.1 | 1.0±1.1 | -0.5 |
| **CONSEQUENT** 2017<br>SeQuent Please (B. Braun) | 0.35 [CI: 0.19; 0.79] | 0.72 [CI: 0.68; 1.22] | -0.37 |

# Clinical Improvement: Change of RBC - 42 mo



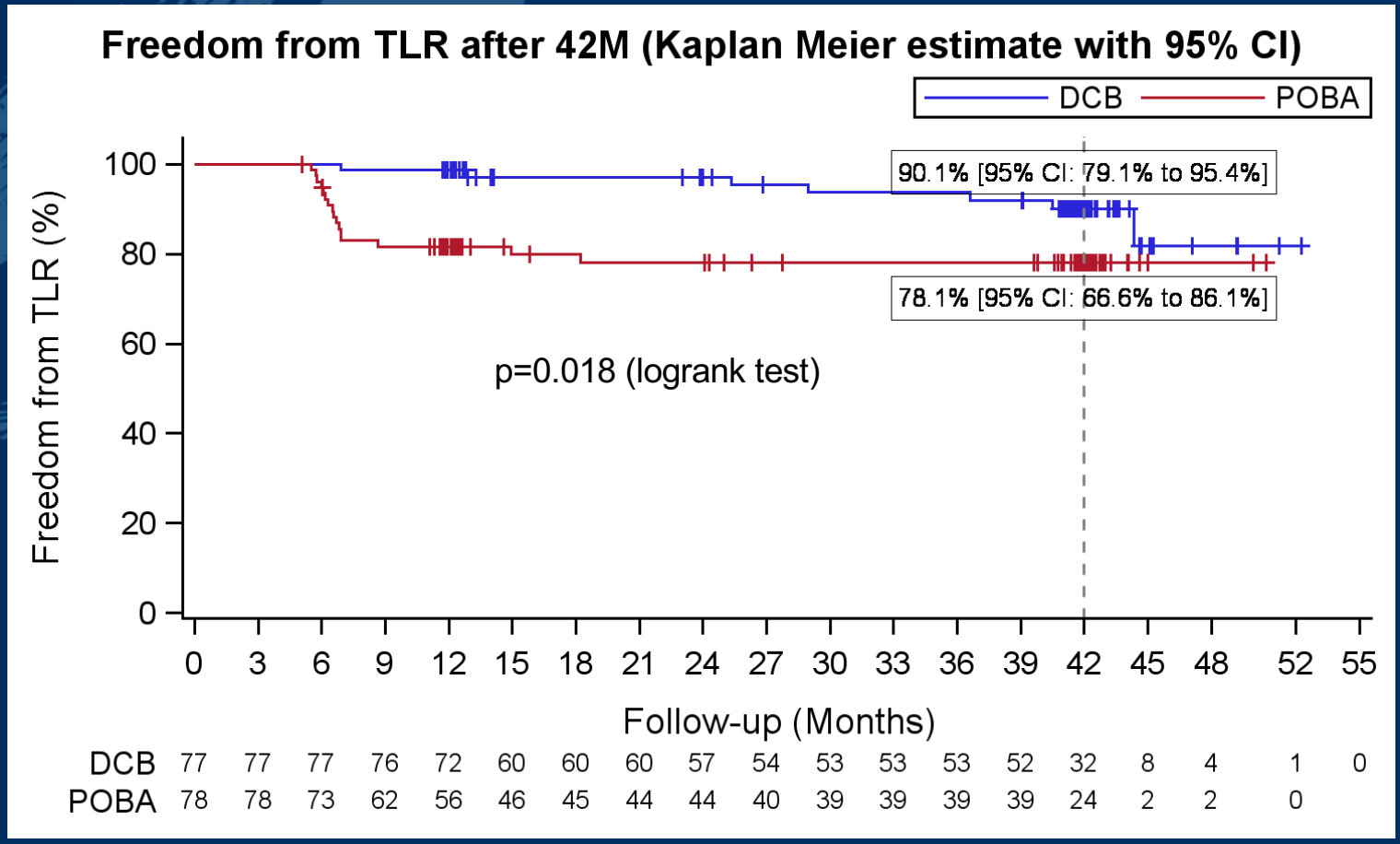

*P-value for difference in change from baseline to 42 months between DCB and POBA

# Primary Patency – 42 Months




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

# Freedom From TLR – 42 Months



# Safety – 42 Months

| | DCB | POBA | P value |
|---|---|---|---|
| All-cause mortality*, % | 2** (2.4) | 7*** (8.3) | p = 0.168 |
| Binary restenosis, % | 34**** (54.8) | 34**** (54.8) | p = 1.000 |
| TLR, % | 7**** (12.3) | 16**** (29.1) | p = 0.036 |
| Periprocedural complication, % | | | |
| Dissection | 32 (37.6) | 35 (40.7) | p = 0.801 |
| False aneurysm | 0 | 1 (1.2) | p = 1.000 |
| Thromb. embolization | 1 (1.2) | 0 | p = 1.000 |

* Survey of all randomized patients, DCB: n=82, POBA: n=84 (4 patients could not be reached, 1 patient has withdrawn informed consent)

** Two DCB patients died for unknown reason

*** Reasons: suicide, cardiac arrest (2x), cholangiocellular carcinoma, multiple organ failure, respiratory failure, unknown

**** including patients with an event (binary restenosis/TLR) at an earlier follow-up

# Conclusions

**At 3.5 years,** DCB angioplasty (Luminor-35®) of medium length SFA/PA lesions resulted in

- a significant clinical and hemodynamic improvement from baseline with lower TLR rate
- all-cause mortality similar to POBA
- significantly less need for TLR