12 months overview

BIOLUX P-I

Study design

Prospective, multicenter, 1:1 randomized controlled, trial to assess the safety and performance of the coated Passeo-18 Lux Paclitaxel releasing PTA balloon catheter versus the uncoated Passeo 18 balloon catheter for treatment of stenosis of the femoropopliteal arteries.

Principal investigator

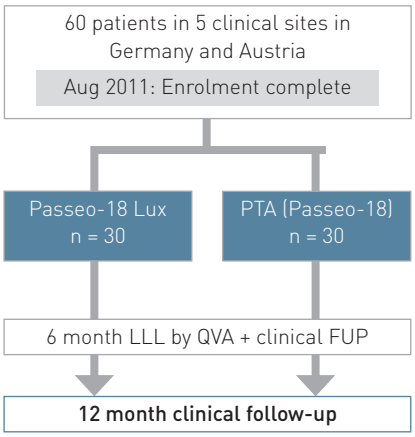
- Prof. D. Scheinert, Leipzig, Germany

Primary endpoint

- 6 month Late Lumen Loss in target lesion measured by Quantitative Vascular Angiography (QVA) by an independent corelab

Secondary endpoints

- 6 month binary restenosis
- 6 and 12 month TLR
- 6 and 12 month change in mean ABI and Rutherford class
- MAE at 6 and 12 months (procedure or device-related death or amputation, TL thrombosis, clinically driven TLR)



Baseline characteristics

Demographics	DRB n = 30 (n / %)	PTA n = 30 (n / %)
Age (Mean ± SD) yrs	70 ± 10	71 ± 10
Diabetes mellitus	11 / 37	9 / 30
Hypertension	23 / 77	21 / 70
Hyperlipidemia	18 / 60	19 / 63
Smoking	19 / 63	22 / 73
History of Peripheral Arterial Disease	18 / 60	20 / 67
History of previous PTA	17 / 57	18 / 60
Rutherford Classification		
Class 2 Moderate	7 / 23	9 / 30
Class 3 Severe	17 / 57	17 / 57
Class 4 Ischemic Rest Pain	4 / 13	2 / 7
Class 5 Minor Tissue Loss	2 / 7	2 / 7

Baseline lesion characteristics

Variable	No. of lesions (total) DRB n = 33 Mean ± SD	No. of lesions (total) PTA n = 35 Mean ± SD
Reference Vessel Diameter (mm)	4.6 ± 0.8	4.7 ± 0.9
Lesion Length (mm)	51.4 ± 47.2	68.5 ± 57.0
Pre Mean Lesion Diameter (MLD) (mm)	1.0 ± 1.1	1.2 ± 1.1
Pre Diameter Stenosis (DS %)	80.1 ± 21.3	73.3 ± 25.0

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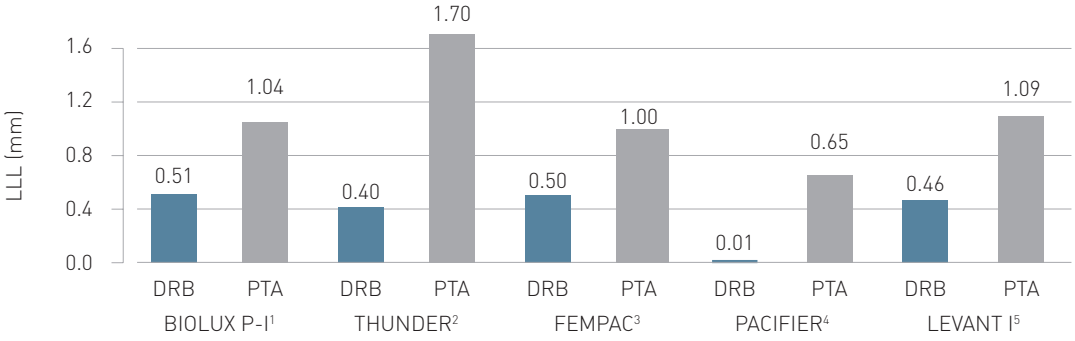
6 month follow-up

Variable (in segment)	DRB n = 26 Mean ± SD	PTA n = 26 Mean ± SD	p Value
Late Lumen Loss (LLL) (mm)[A]	0.51 ± 0.72	1.04 ± 1.00	0.033*
Binary Restenosis [n/%][B]	3 (11.5%)	9 (34.6%)	0.048*
Diameter Stenosis (%)[C]	36.5 ± 18.5	47.5 ± 20.1	0.048*

[A] Primary endpoint
[B] Secondary endpoint
[C] No endpoint

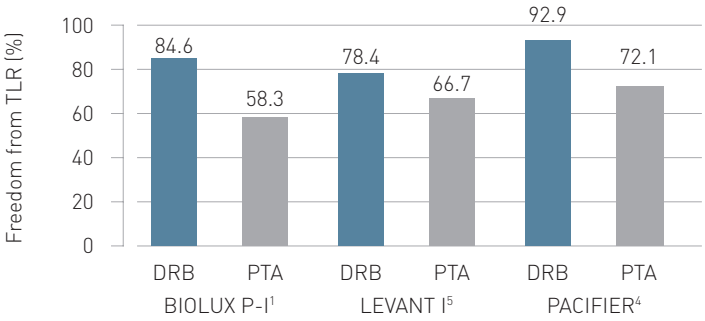
* $p < 0.05$ significant

6 month LLL compared to competitor peripheral DRB trials



12 month results (Kaplan-Meier estimates)

Freedom from Target Lesion Revascularisation compared to competitor trials



12 month improvement in Rutherford classification

DRB	PTA
72.0 %	65.2 %

Key messages

- In BIOLUX P-I, the Passeo-18 Lux drug releasing balloon demonstrated a significant reduction in LLL and binary restenosis at 6 months compared to the control PTA balloon.
- At 12 months freedom from Target Lesion Revscularisation was achieved in 84.6 % of DRB patients and 58.3 % of PTA patients.
- In addition, patients receiving treatment with Passeo-18 Lux showed greater improvement in Rutherford class compared to baseline (72.0 %) vs. those receiving treatment with PTA (65.2 %)
- It can be concluded that at 12 months, Passeo-18 Lux demonstrated significantly better clinical performance compared to the control PTA balloon, and in line with data from similar, competitor DEB randomised clinical trials.

References:
[1] BIOLUX P-I. Scheinert et al. Presented at LINC 2013; [2] THUNDER Tepe et al: N Engl J Med. 2008 Feb 14;358(7):689-99.
[3] FEMPAC Werk et al: Circulation. 2008;118:1358-1365.; [4] PACIFIER Werk et al: Circ Cardiovasc Interv. 2012 Dec;5(6):831-40
[5] LEVANT I: Scheinert et al. Presented at TCT 2010

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