BIOLUX P-I

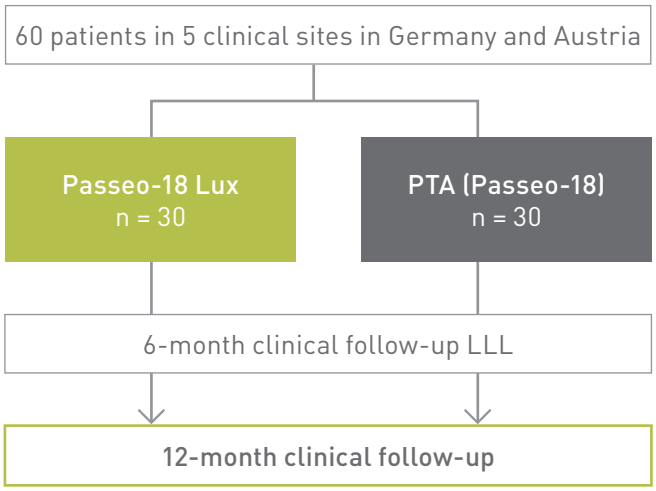
12-month results overview

Conclusions

- In BIOLUX P-I, the Passeo-18 Lux Drug-Coated Balloon (DCB) demonstrated a significant reduction in Late Lumen Loss (LLL) and binary restenosis at 6 months compared to the control Percutaneous Transluminal Angioplasty (PTA) balloon
- At 12 months freedom from Target Lesion Revascularization (FTLR) was achieved in 84.6% of (DCB) patients and 58.3% of PTA patients
- In addition, patients receiving treatment with Passeo-18 Lux showed greater improvement in Rutherford Class (RC) compared to baseline (72.0%) vs. those receiving treatment with PTA (65.2%)
- It can be concluded that at 12 months, Passeo-18 Lux (DCB) demonstrated significantly better clinical performance compared to the control PTA balloon, and in line with data from similar competitor DCB randomized clinical trials

Study design

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



Endpoints

Primary endpoint

- 6 month LLL in target lesion measured by Quantitative Vascular Angiography (QVA) by an independent core lab

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)

Patient characteristics	DCB n = 30 (n / %)	PTA n = 30 (n / %)
Age, 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
RC		
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

Lesion characteristics

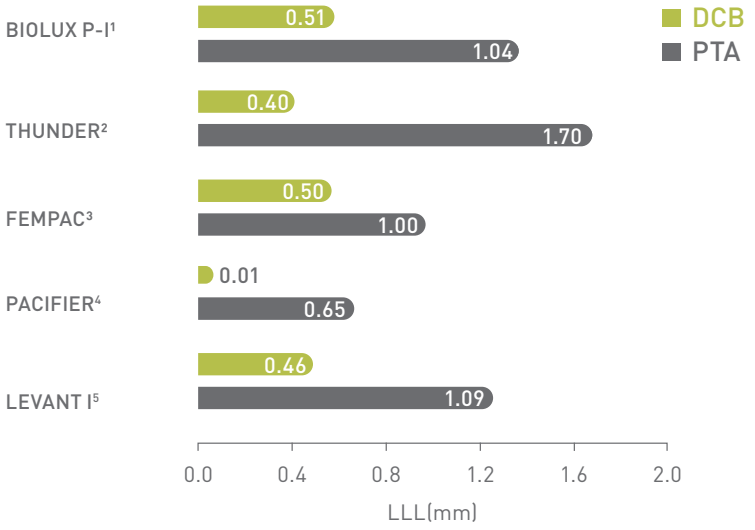
Variable	No. of lesions (total) DCB n = 33	No. of lesions (total) PTA n = 35
Reference vessel diameter (mm)*	4.6 ± 0.8	4.7 ± 0.9
Lesion length (mm)*	51.4 ± 47.2	68.5 ± 57.0
Pre mean lesion (mm)*	1.0 ± 1.1	1.2 ± 1.1
Pre diameter stenosis (%)*	80.1 ± 21.3	73.3 ± 25.0

6-month follow-up

Variable (in segment)	DCB n = 26	PTA n = 26	p value
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**

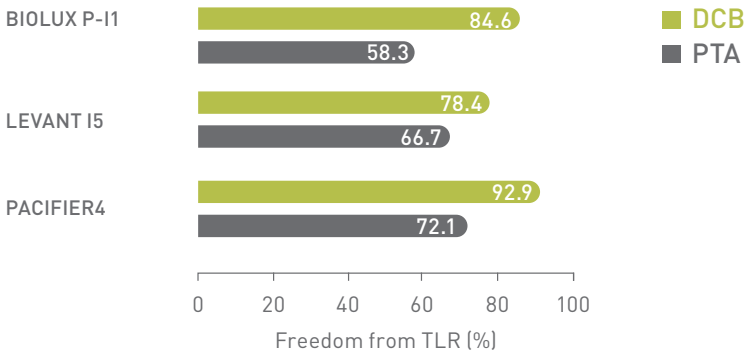
A. Primary endpoint
B. Secondary endpoint
C. No endpoint
*Data shown as mean ± SD
**p < 0.05 significant

6-month LLL compared to competitor peripheral DCB trials



12-month results (Kaplan-Meier estimates)

Freedom from TLR compared to competitor trials



12-month improvement in Rutherford classification	DCB	PTA
	72.0 %	65.2 %

Principal investigator

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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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