BIOLUX 4EVER
24-month results

Conclusions

- BIOLUX 4EVER[1] results confirm safety and efficacy of combined use of Passeo-18 Lux and Pulsar-18, achieving similar outcomes compared to available drug-eluting stent data
- Results on 120 patients show Primary Patency[2] (PP) of 83.5% and Freedom from Target Lesion Revascularization (TLR) of 86.1%
- Results show an increased Primary Patency of 11 pp when compared to the 4EVER[3] trial, where BMS was used on its own, suggesting a positive effect of paclitaxel from the use of Passeo-18 Lux
- Combining Passeo-18 Lux DCB with low profile and low Chronic Outward Force (COF) Pulsar-18 BMS creates a win-win situation as shown in the 12 and 24 months data of BIOLUX 4EVER[1] and DEBAS[4]

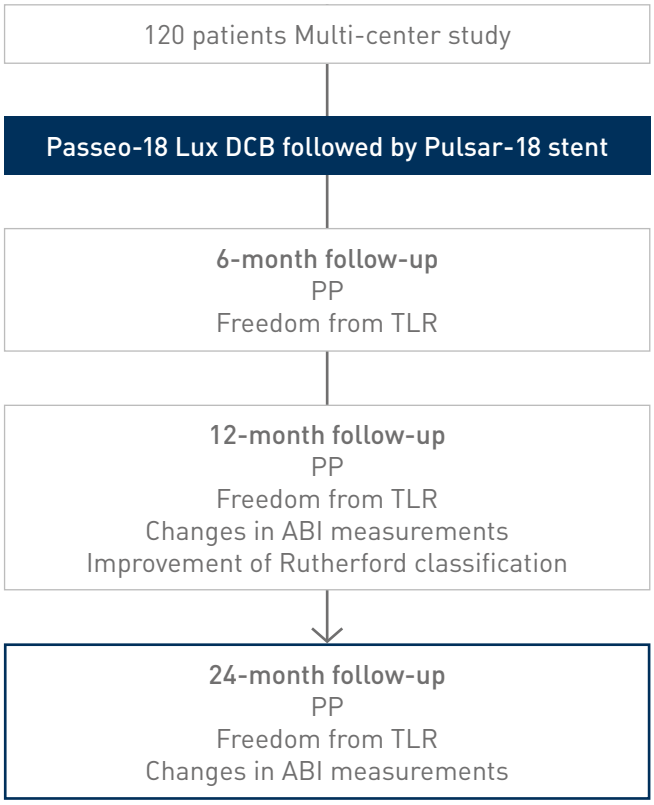
Study design

Prospective, multi-center, investigator initiated trial investigating the efficacy of endovascular treatment of femoropopliteal arterial stenotic or occlusive disease with a combination of Passeo-18 Lux DCB and the Pulsar-18 stent comparing with the 4EVER[3] trial results (Pulsar stents only).

Endpoints

Primary endpoints
- PP at 12 months

Secondary endpoints (selected)
- PP at 6 and 24-month follow up
- Freedom from TLR at 6, 12 and 24-month follow up
- Technical success[5]
- Clinical success at follow-up[6]



Patient characteristics n = 120

Male	79	65.83%
Age, yrs*	70.87	43.73-92.41 ± 10.52
Nicotine abuse	73	60.83%
Hypertension	76	63.33%
Diabetes mellitus	23	19.17%
Renal insufficiency	15	12.50%
Hypercholesterolemia	66	55.00%
Obesity	28	23.33%
Rutherford classification		
Category 2	38	31.67%
Category 3	62	51.67%
Category 4	20	16.67%

Lesion characteristics n = 120

Average lesion length (mm)*	83.33 mm	6.0-190.0; ± 49.49
Average reference vessel diameter (mm)*	5.26 mm	4.0-6.0; ± 0.59
Occlusion	40	33.33%
Calcified lesions	60	50.00%

* Data shown as mean ± SD

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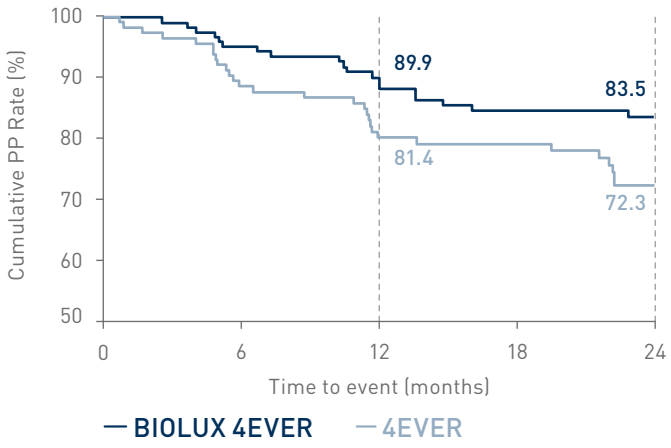
Procedural information[7] n = 120

Procedure time (min)*	48.32	(6.0-120.0; ± 18.57)*
Access side	Femoral (100%)	
Cross-over performed	100	88.33%
Amount of contrast used (cc)*	92.62	(17.0-150.0; ± 35.68)
Technical success[6]	100%	

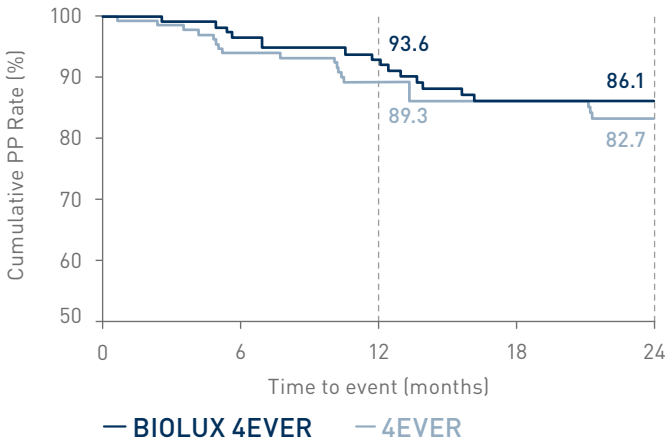
* Missing data of one patient

24-month PP[2]



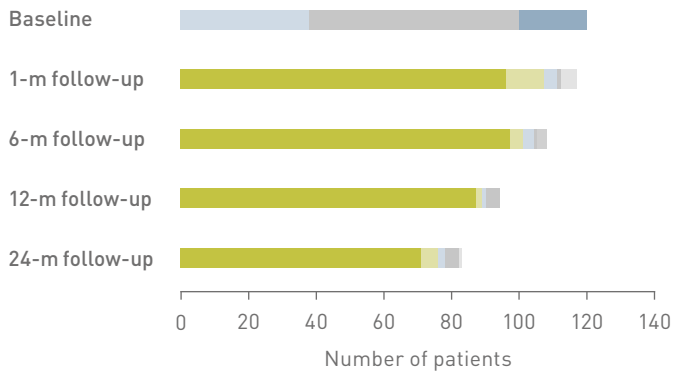
	Baseline	1-m	6-m	12-m	24-m
BIOLUX 4EVER (% PP)	100	100	94.9	89.9	83.5
4EVER (% PP)	100	-	-	81.4	72.3

24-month Freedom from TLR



	Baseline	1-m	6-m	12-m	24-m
BIOLUX 4EVER (% Freedom from TLR)	100	100	97.4	93.9	86.1
4EVER (% Freedom from TLR)	100	89.3	-	89.3	82.7

Improvement of Rutherford classification



	Baseline	1-m follow-up	6-m follow-up	12-m follow-up	24-m follow-up
Rutherford 5	0	5	3	0	1
Rutherford 4	20	0	0	0	0
Rutherford 3	62	1	1	4	4
Rutherford 2	38	4	3	1	2
Rutherford 1	0	11	4	2	5
Rutherford 0	0	96	97	87	71

Principal investigator

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1. Deloose K, BIOLUX 4EVER: combining Passeo-18 Lux DCB and Pulsar-18 BMS: 24-month results of full cohort. Presented at: Charing Cross; 2018; London, United Kingdom; 2. Defined as Freedom from >50% restenosis asindicated by an Peak Systolic Velocity Ratio (PSVR) <2.5 in the target vessel with no re-intervention; 3. Deloose K. The 4EVER Trial: 24-m results. Presented at LINC, 2014; Leipzig, Germany; 4. Mwipatayi P. DEBAS Study: First-in-man experience of self-expanding nitinol stents combined with drug-coated balloon in the treatment of femoropopliteal occlusive disease. Vascular 2018;26:3 -11; 5. Defined as the ability to cross and stent the lesion to achieve residual angiographic stenosis no greater than 30% and residual stenosis less than 50% by duplex imaging; 6. Defined as an improvement of Rutherford classification at 1, 6, 12 and 24-month follow-up of one class or more as compared to the pre-procedure Rutherford classification; 7. Bosiers M, The BIOLUX 4EVER study is a physician-initiated trial investigating the efficacy of endovascular treatment of femoropopliteal arterial stenotic disease with BIOTRONIK`s Passeo-18 Lux Drug-Releasing Balloon and BIOTRONIK`s Pulsar-18 Stent (comparing with the 4EVER trial results), ClinicalTrial.gov identifier NCT02211664 2017; 1-34.

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