BIOLUX P-II

12-month results overview

Conclusions

- At 30 days clinical results show Major Adverse Event (MAE) composite of 0.0% for the Passeo-18 Lux Drug-Coated Balloon (DCB) vs. 8.3% compared to the control Percutaneous Transluminal Angioplasty (PTA) balloon
- At 6 months angiographic follow-up, Passeo-18 Lux demonstrated a Target Lesion Patency (TLP) of 82.9% vs. 73.9% compared to the control PTA balloon
- At 6 months, 59% of patients improved in Rutherford Classification (RC) in the DCB group vs. 47% in the control group. Improvement of RC 5 patients at 6 months was significant in the DCB group (p = 0.002*)
- The Passeo-18 Lux is safe in infrapopliteal lesions – demonstrated in a low amputation rate and no additional amputations beyond 6 months

Study design

- Prospective, multi-center, randomized controlled, First-In-Man study to assess the safety and performance of the Passeo-18 Lux DCB vs. the uncoated Passeo-18 balloon catheter in patients with stenosis and occlusion of the infrapopliteal arteries.

Endpoints

Primary endpoint

- 30-day MAE[1] rate
- 6-month TLP measured by Quantitative Vascular Angiography[2] (QVA)

Secondary endpoints

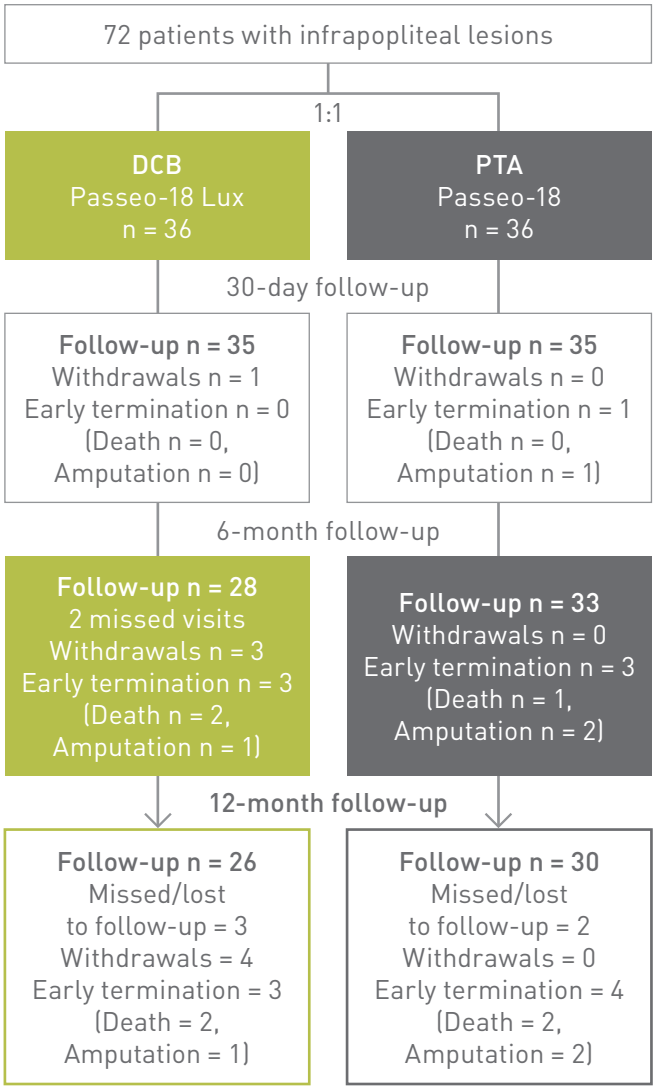
- 6-month change in RC
- 12-month Major Amputation rate

DCB lesion characteristics

	n = 50 lesions	Min - Max
Lesion length (mm)[2]**	113.1 ± 88.1	24.0 to 350.6
Diameter stenosis (%)[2]**	72.5 ± 25.4	31.0 to 100.0
RC 5 (n/%)	Patients n = 36	26/72.2

PTA lesion characteristics

	n = 54 lesions	Min - Max
Lesion length (mm)[2]**	115.0 ± 86.9	39.2 to 295.0
Diameter stenosis (%)[2]**	72.1 ± 23.2	30.0 to 100.0
RC 5 (n/%)	Patients n = 36	26/72.2



* p < 0.05 = significant
**Data shown as mean ± SD
PAOD = Peripheral Arterial Occlusive Disease; CLI = Critical Limb Ischemia; ABI = Ancle Brachial Index; SD = Standard Deviation

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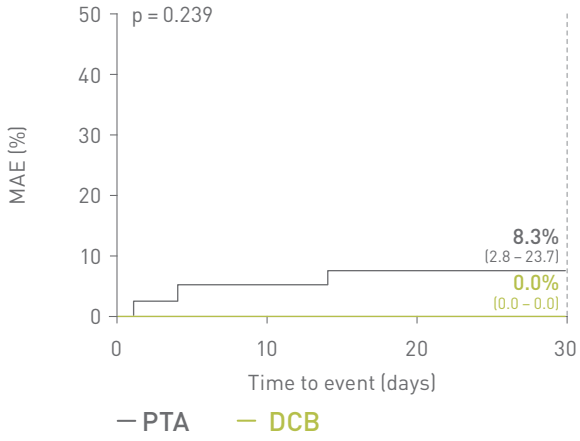
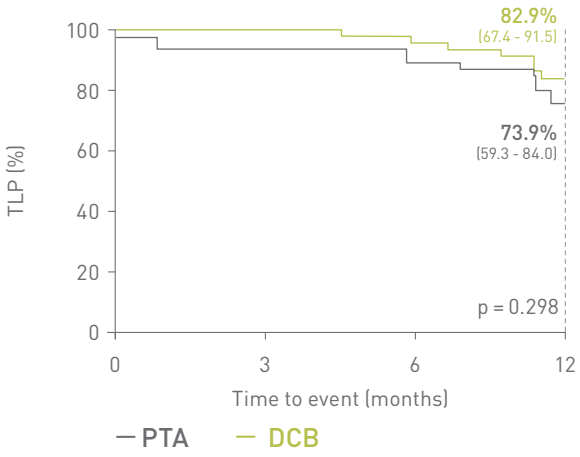
30-day MAE
(adjudicated by an independent CEC)

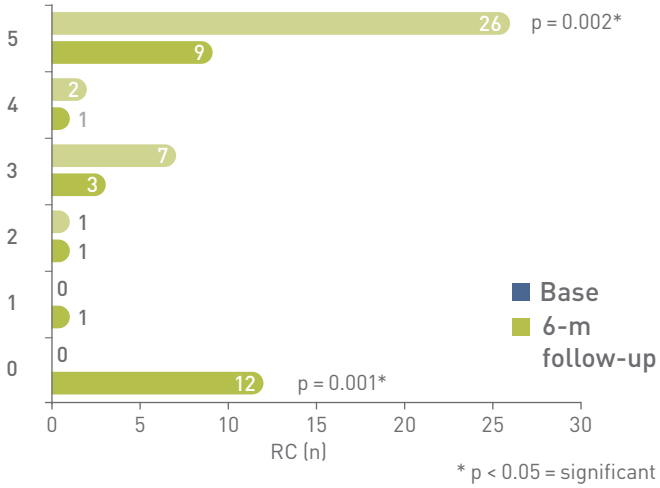


6-month TLP
(assessed by an independent Core Laboratory)

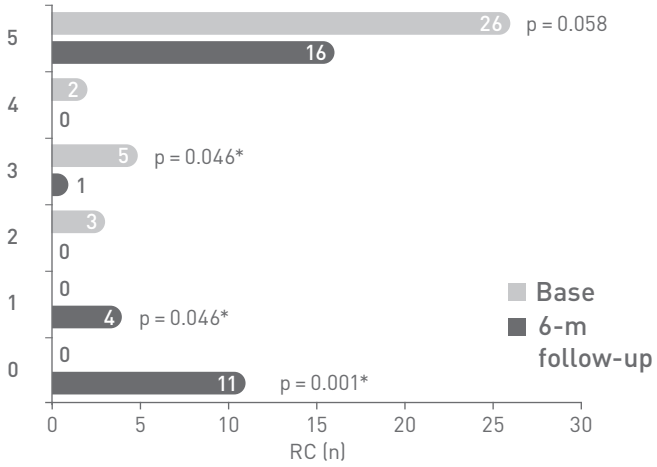


6-month change in RC

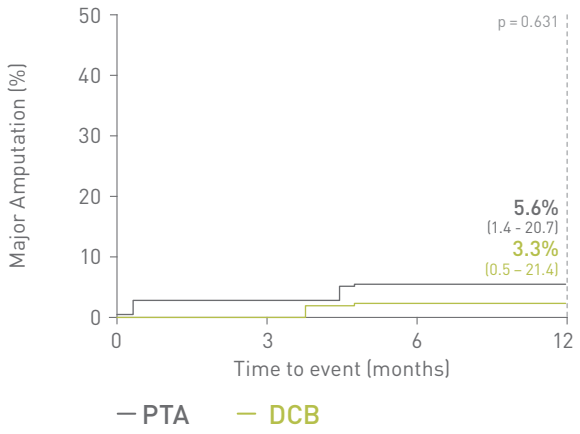
DCB at 6 months: Improvement: 59% Worsening: 0%



PTA at 6 months: Improvement: 47% Worsening: 6 %



12-month Major Amputations
(adjudicated by an independent CEC)



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1. MAE = all cause death, major amputation of target extremity, TLR, TVR, target lesion thrombosis, adjudicated by an independent Clinical Events Commi ttee. 2. Assessed by an independent Core Laboratory.

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