12-month results overview

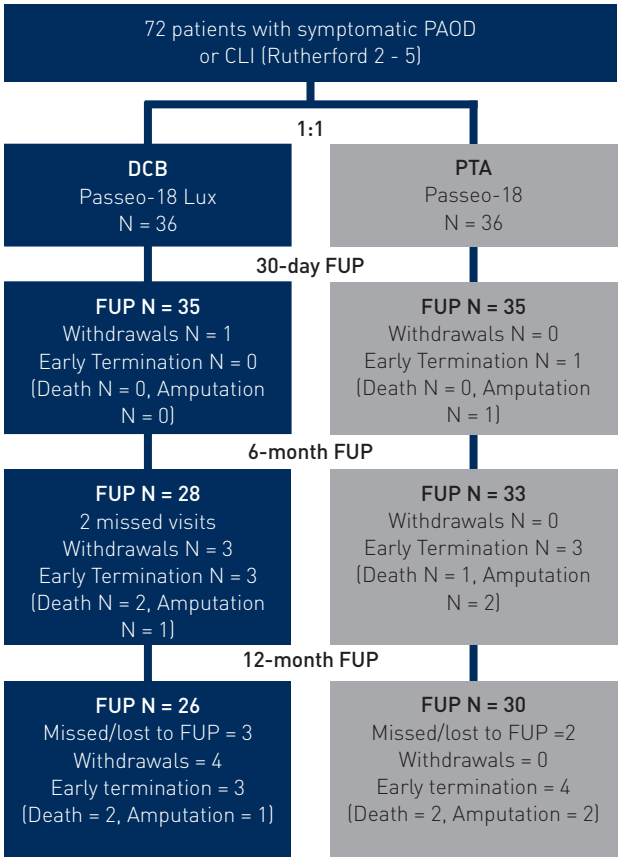
Conclusions

- 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 Percutaneus Transluminal Angioplasty (PTA) balloon
- At 6 months angiographic follow-up, Passeo-18 Lux demonstrated a **Target Lesion Primary Patency (TLP)** of **82.9 %** vs. 73.9 % compared to the control PTA balloon
- At 6 months, **59 %** of patients **improved in Rutherford Classification** in the DCB group vs. 47 % in the control group. **Improvement of Rutherford Class 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 180 days**

* (p < 0.05 = significant)

Study design

- **Design**
  Prospective, multi-center, randomized controlled, First-In-Man study to assess the safety and performance of the Passeo-18 Lux Drug-Coated Balloon vs. the uncoated Passeo-18 balloon catheter in patients with stenosis and occlusion of the infrapopliteal arteries.
- **Principal investigator**
  Prof. T. Zeller, Universitäts-Herzzentrum Freiburg, Bad Krozingen, Germany.
- **Primary endpoint**
  30-day Major Adverse Event[1] rate.
  6-month Target Lesion Primary Patency measured by Quantitative Vascular Angiography[2] (QVA).
- **Secondary endpoints**
  6-month change in Rutherford Class
  12-month Major Amputation rate



Key baseline demographics

	DCB		PTA	
	Lesion N = 50		Lesion N = 54	
	Mean ± SD	(Min - Max)	Mean ± SD	(Min - Max)
Treated length (mm)[2]	113.1 ± 88.1	(24.0 to 350.6)	115.0 ± 86.9	(39.2 to 295.0)
Diameter stenosis (%)[2]	72.5 ± 25.4	(31.0 to 100.0)	72.1 ± 23.2	(30.0 to 100.0)

	DCB	PTA
	Patients N = 36	Patients N = 36
Rutherford Class 5 (n/%)	26/72.2	26/72.2

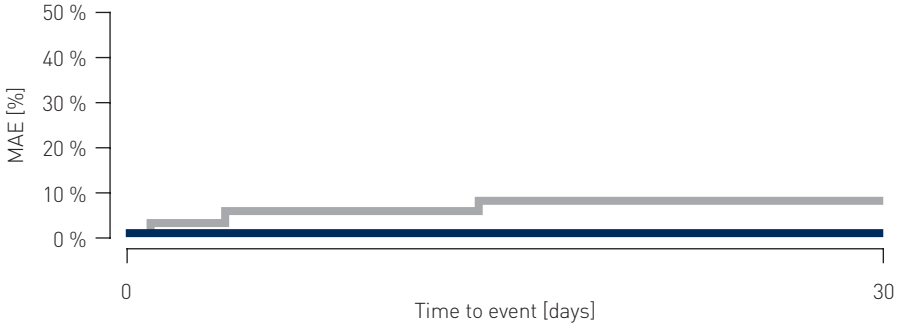
[1] MAE = all cause death, major amputation of target extremity, TLR, TVR, target lesion thrombosis, adjudicated by an independent Clinical Events Committee
[2] Assessed by an independent Core Laboratory

PAOD = Peripheral Arterial Occlusive Disease; CLI = Critical Limb Ischemia; FUP = Follow Up; ABI = Ancle Brachial Index; SD = Standard Deviation

BIOTRONIK
excellence for life

30-day Major Adverse Events (MAE)

(adjudicated by an independent Cinical Events Committee)

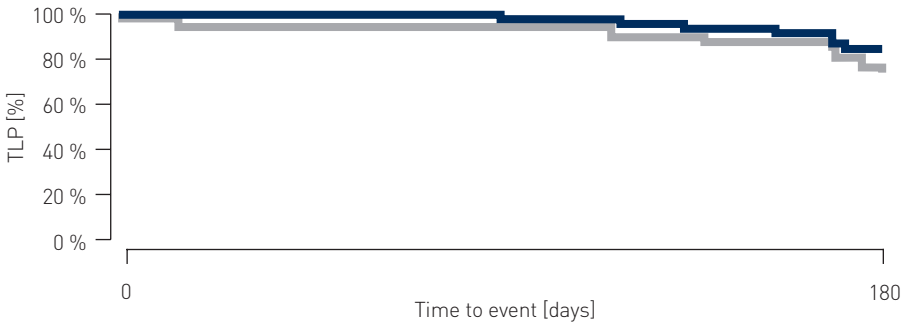


PTA 8.3 % [2.8 – 23.7]
DCB 0.0 % [0.0 – 0.0]

p = 0.239

6-month Target Lesion Primary Patency (TLP)

(assessed by an independent Core Laboratory)

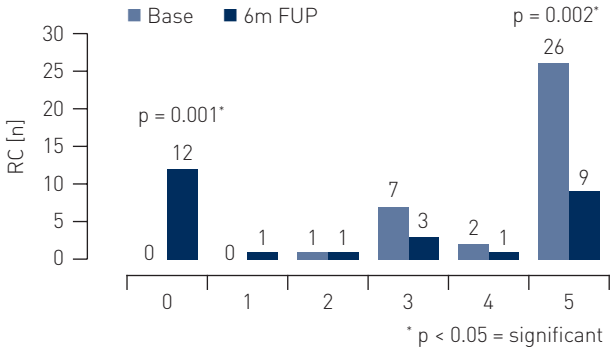


DCB 82.9 % [67.4 - 91.5]
PTA 73.9 % [59.3 - 84.0]

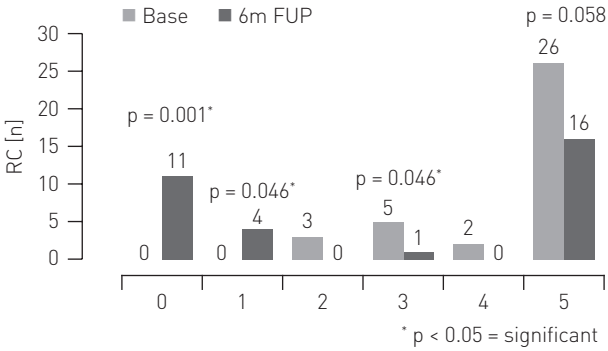
p = 0.298

6-month change in Rutherford Classification (RC)

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

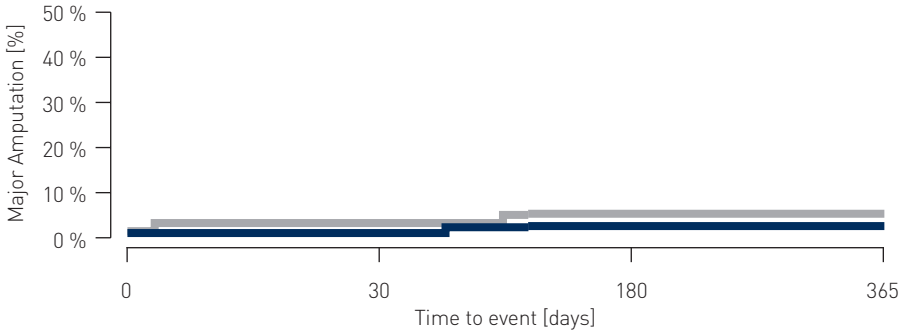


PTA at 6 months:
Improvement: 47 %
Worsening: 6 %



12-month Major Amputations

(adjudicated by an independent Clinical Events Committee)



PTA 5.6 % [1.4 - 20.7]
DCB 3.3 % [0.5 – 21.4]

p = 0.631

BIOTRONIK
excellence for life