DEBAS 24-month results

Conclusions

- The 88% Primary Patency[1] (PP) and 88% Freedom from Clinically Driven Target Leasion Revascularization (FCD-TLR) results confirm safety and efficacy of the combined Passeo-18 Lux and Pulsar-18 treatment
- Signifcant improvement in Rutherford Classification shows clinical improvement
- These long-term results confirm that combining Passeo-18 Drug Coated Balloon (DCB) with Pulsar Self-Expanding Stent (SES) is an effective therapy approach event in long and calcified lesions, achieving DES- like results

Study design

Prospective, feasibility study investigating safety and efficacy of Pulsar-18 and Pulsar-35 Self-Expanding Stents (SES) combined with Passeo-18 Lux Drug-Coated Balloon (DCB) in Severe Femoropopliteal Arterial Occlusive Disease

Principal Investigator

- Prof. Patrice Mwipatayi
  Royal Perth Hospital, University of Western Australia, Perth, Australia

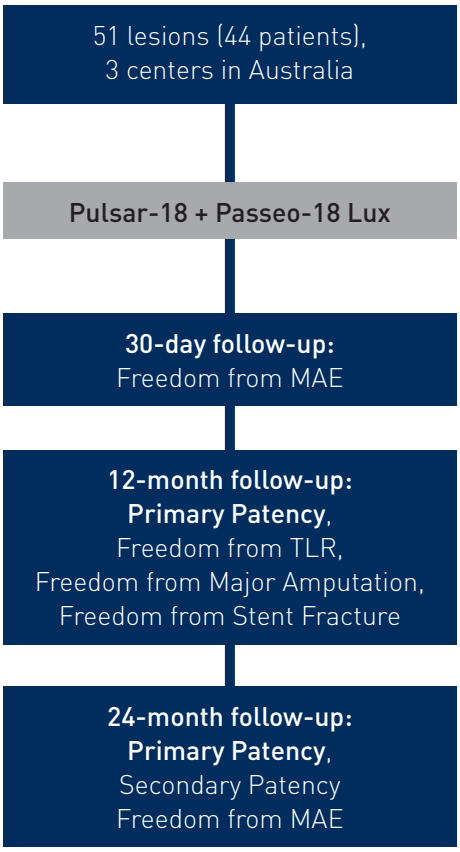
Endpoints

Primary endpoint

- PP at 12 and 24 months. Defined as an increase in the PSVR ⩾ 2.5 with no clinically driven re-intervention at the stented segment ± within 5 mm of each side of the stented area

Secondary clinical endpoints (selected)

- Secondary Patency at 1, 6, 12, 18 and 24 months
- Freedom from MAE at 12, 18 and 24 months
- Freedom from TLR 1, 6, 12, 18 and 24 months
- Freedom from Major Target Limb Amputation and Death 1, 6, 12, 18 and 24 months
- Freedom from Stent Fracture 1, 6, 12, 18 and 24 months



Patient characteristics

	n	%
Age (years)	67.6 ± 10.2	
Smoking	17	38.6
Diabetes	24	54.6
CAD	16	36.4
Hypertension	31	70.4
Hyperlipidemia	23	52.3
Indication for treatment		
Rest pain	18	35.3
Acute ischemia	3	5.9
Claudication	27	52.9
Ulcer / gangrene	14	27.4

Baseline data

	n = 51	% (95% CI)
Vascular access		
Femoral	41 (80.4%)	80.4 (0.66-0.89)
Retrograde tibial	10 (19.6%)	19.6 (0.11-0.33)
Mean lesion length	200 ± 74.55	(167.09-208.01)
Diameter of stents implanted	6.21 ± 0.41	(6.10-6.33)
Diameter of DCB	6.22 ± 0.42	(6.10-6.33)

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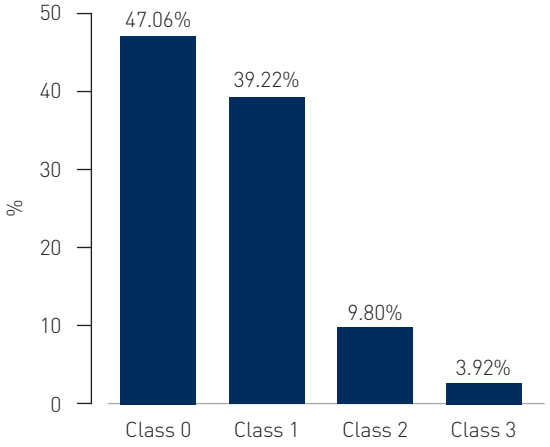
Lesion characteristics

	n = 51	% (95% CI)
Lesion characteristics		
Pre-procedure RVD (mm)	6.02 ± 0.33	(5.93-6.11)
Lesion length (mm)	200 (IQR: 140-250)	-
Total occlusions	32	62.7 (46-77)
Calcification, n (%)		
None or mild	17	33.3 (19-46)
Moderate	22	43.2 (29-58)
Severe	12	23.5 (13-38)
TASC classification		
TASC B	2	3.9 (1-15)
TASC C	23	45.1 (30-61)
TSC D	26	51 (36-66)
Rutherford Becker (RB) category		
RB3	21	41.2 (27-57)
RB4	16	31.4 (19-48)
RB5	14	27.4 (16-43)
Pre-operative ABI	0.39 (IQR: 0.3-0.42)	-

Results

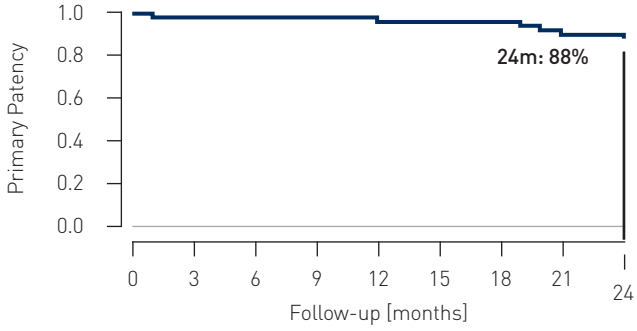
Follow-up (n)	12 months	24 months
Primary Patency	94%	88%
Freedom from CD-TLR	94%	88%
Freedom from Major Amputation	100%	98%
Freedom from Minor Amputation	96.1%	96.1%
Fracture Rate*	2%[2]	10%[3]

Rutherford score at 24 months follow-up



Key Message
Significant improvement in Rutherford Classification at 24 months.

Primary Patency at 24 months follow-up



Time	12 months	24 months
Patency	94%	**88%**
Patients (at risk)	48	**45**

Key Message
At 24 months Primary Patency rate is 88%.

DCB = Drug-Coated Balloon; PP = Primary Patency; RC = Rutherford Class;
CD-TLR = Clinically Driven-Target Lesion Revascularization

Source: DEBAS. Mwipatayi P. First-in-man experience of self-expanding nitinol stents combined with drug-coated balloon in the treatment of femoropopliteal occlusive disease. Sage Journals. 2017; 0(0) 1–9, 24-month data.

* Stent fracture was confirmed on plain X-ray screening of the implanted stents

1 Primary Patency (PP) is freedom from >50% restenosis in the target lesion as indicated by a duplex ultrasound peak systolic velocity ratio (PSVR) >2.5 or by visual.

2 All patients had a type II or III stent fracture

3 All patients had type III stent fracture

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach · Switzerland
Tel +41 (0) 44 8645111
Fax +41 (0) 44 8645005
info.vi@biotronik.com
www.biotronik.com

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excellence for life