DEBAS

First-in-man experience of self-expanding nitinol stents combined with drug-coated balloon in the treatment of femoropopliteal occlusive disease at 24-months[1]

Conclusions

- Primary Patency* (PP) of 88% and Freedom from clinically driven Target Lesion Revascularization (Fcd-TLR) of 88% confirm safety and efficacy of the combined Passeo-18 Lux and Pulsar treatment
- Significant improvement in Rutherford Becker (RB) category shows clinical improvement
- These long-term results confirm that combining Pulsar Self-Expanding Stent with Passeo-18 Lux Drug-Coated Balloon (DCB) is an effective therapy approach even in long and calcified lesions, achieving Drug-Eluting Stent (DES) like results

Study design

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

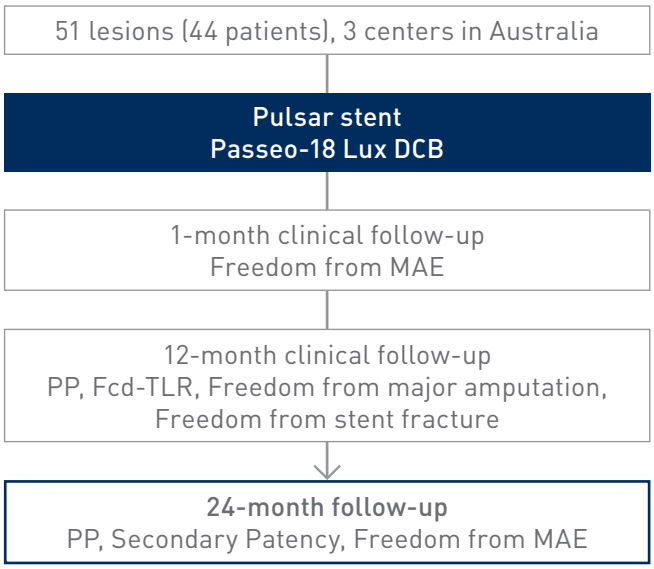
Endpoints

Primary endpoint

- PP* at 12 and 24 months.

Secondary endpoints (selected)

- Secondary patency at 12 and 24 months
- Freedom from Major Adverse Event (Freedom from MAE) at 12 and 24 months
- Fcd-TLR 12 and 24 months
- Freedom from major target limb amputation and death 12 and 24 months
- Freedom from stent fracture 6, 12 and 24 months



Patient characteristics	n = 44	
Age, yrs**	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%

Lesion characteristics	n = 51	(95.0% CI)
Lesion length (mm)	200 (IQR: 140-250)	-
Pre-procedure reference vessel diameter (mm)**	6.02 ± 0.33	(5.93-6.11)
Total occlusions	32	62.7%
Calcification, n (%)		
None or mild	17	33.3%
Moderate	22	43.2%
Severe	12	23.5%
TASC classification		
TASC B	2	3.9%
TASC C	23	45.1%
TASC D	26	51.0%
Rutherford Becker (RB) category		
RB3	21	41.2%
RB4	16	31.4%
RB5	14	27.4%
Pre-operative ABI	0.39 (IQR: 0.3-0.42)	

*Defined as the absence of >50% restenosis with an increase and no clinically driven re-intervention at the stented segment
**Data shown as mean ± SD
¤Coronary Artery Disease

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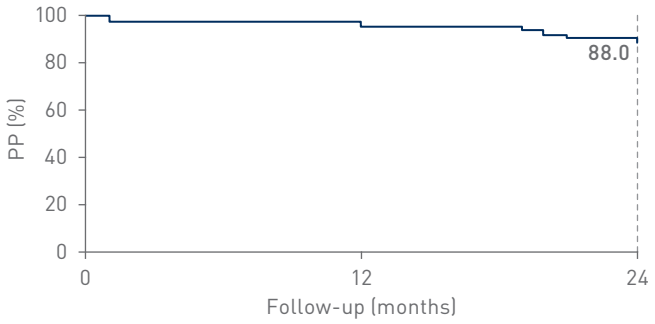
24-month PP



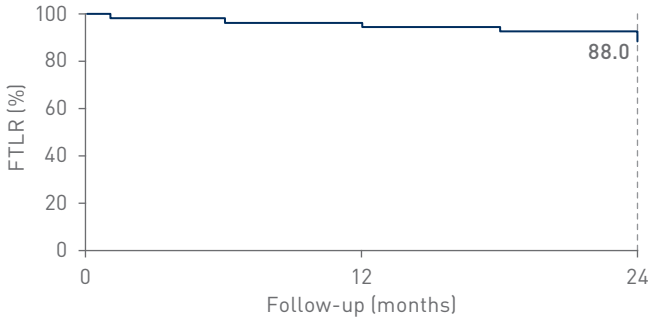
	12 months	24 months
PP	94.0%	88.0%
Left at risk	48	45

Baseline angiographic and interventional data

Variable	n = 51	(95.0% CI)
No. of crural runoff vessels		
One vessel	4	7.8%
Two vessels	18	35.3%
Three vessels	29	56.9%
Vascular access		
Femoral	41	80.4%
Retrograde tibial	10	19.6%
Mean lesion length**	200 ± 74.55	(167.09–208.01)
No. of stents implanted**	1.57 ± 0.70	(1.37–1.76)
Diameter of stents implanted**	6.21 ± 0.41	(6.10–6.33)
Length of stents implanted**	200 (IQR: 120–300)	n/a
No. of DCB used/patient**	2.45 ± 1.08	(2.13–2.78)
Diameter of DCB used/patient**	6.22 ± 0.42	(6.10–6.33)
Balloon inflation time (min)**	1.80 ± 0.27	(1.72–1.89)

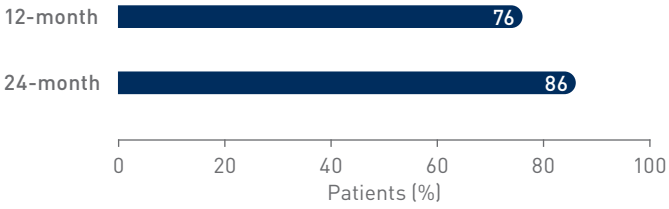
**Data shown as mean ± SD

24-month FTLR



	12 months	24 months
FTLR	94.%	88.0%
Left at risk	48	45

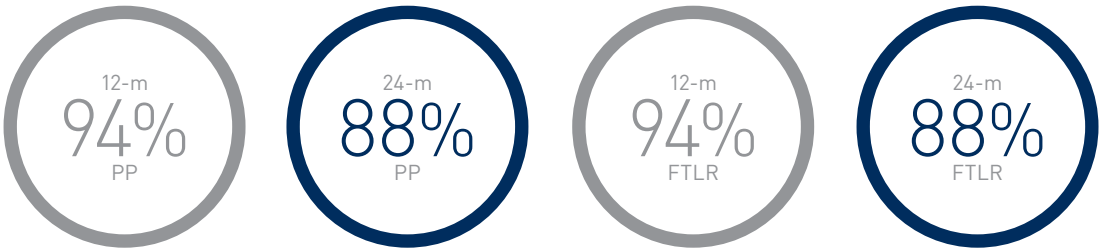
Improvement in RB category



Results

Follow-up	12 months	24 months
PP	94.0%	88.0%
Fcd-TLR	94.0%	88.0%
Freedom from major amputation	100%	98.0%
Freedom from minor amputation	96.1%	96.1%

Key outcomes



Principal investigator

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1. Mwipatayi P et al. First-in-man experience of self-expanding nitinol stents combined with drug-coated balloon in the treatment of femoropopliteal occlusive disease. Vascular 2018; 26(1):3-11.

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