12-month results overview

DEBAS

Conclusions

- At 12 months results on 51 patients show **Primary Patency (PP) rates of 92.2 %** and **Freedom from Clinically Driven Target Lesion Revascularization (CD-TLR) of 94.1 %**
- At 12 months **Freedom from Major Adverse Events (MAE) is 98.1 %** confirming safety of the treatment combination with Pulsar-18 and Passeo-18 Lux
- Significant **improvement in Rutherford Class (RC)** at 6 months and **sustained over time** shows clinical benefit and improvement of patients quality of life
- **The combined approach of Passeo-18 Lux Peripheral Drug-Coated Balloon (DCB) and Pulsar-18 Self-Expanding Stent is feasible and promising** and a potential future treatment option in complex, TASC C/D lesions.

Study design

Prospective, multicenter, investigator initiated registry to evaluate the outcome of the implantation of the Pulsar-18 stent followed by Passeo-18 Lux Drug-Coated Balloon in the femoropopliteal arteries.
Number of patients (n) 65 (12-month data available on (n) 51)

Principal Investigator

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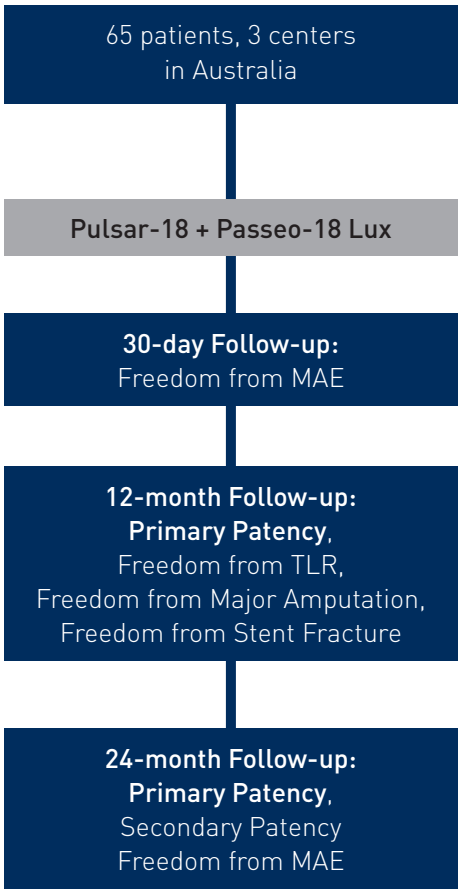

Endpoints

Primary endpoint

- Primary Patency at 12 and 24 months, defined as a binary duplex ultrasound ratio PSVR < 2.5 at the stented target lesion with no clinically-driven reintervention within the stented segment.

Secondary clinical endpoints (selected)

- Secondary Patency at 12 and 24 months
- Freedom from MAE at 12 and 24 months
- Freedom from Stent Fracture
- Freedom from TLR
- Freedom from Major Limb Amputation and Death

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Key baseline demographics

	Mean ± SD	Range
Total lesion lenght (mm)	187.55 ± 74.55	80 - 300

Rutherford Class	**n**	**%**
Class 3 Severe	21	41.2
Class 4 Ischemic Rest Pain	16	31.4
Class 5 Minor Tissue Loss	14	27.5

TASC	**n**	**%**
TASC A	0	0
TASC B	2	3.9
TASC C	23	45.1
TASC D	26	51

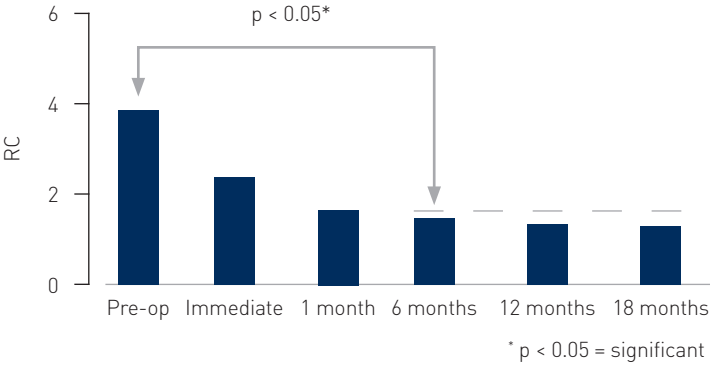
Calcification	**n**	**%**
None	1	2.0
Minimal	16	31.4
Moderate	22	43.1
Severe	12	23.5

Results

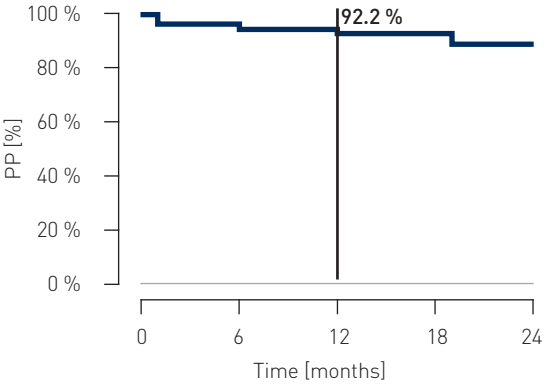
Follow-up (n)	**30 days (43)**	**6 months (40)**	**12 months (51)**
Primary Patency	100 %	100 %	92.2 %
Freedom from CD-TLR	100 %	100 %	94.1 %
Freedom from Major Amputation	100 %	100 %	100 %
Freedom from MAE*	100 %	-	98.1 %
Fracture Rate**	0 %	0 %	1.9 %

* Defined as clinically-driven target lesion revascularization, amputation of treated limb, or all-cause mortality.; ** Class II stent fracture

Rutherford Classification (RC)



Primary Patency (PP)*



* PSVR < 2.5

Key Message
Significant improvement in Rutherford Classification at 6 months and sustained over time.

Key Message
At 12 months Primary Patency rate is 92.2 % and sustained with 91.7 % at 18 months.

DCB = Drug-Coated Balloon; MAE = Major Adverse Event; PP = Primary Patency; RC = Rutherford Class; TLR = Target Lesion Revascularization

Source: Mwipatayi P. presented at LINC 2015

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