TASC D II

Evaluation of the 4-French Pulsar-18 self-expanding nitinol stent in long femoropopliteal lesions (TASC D II) – 12-month results[1]

Conclusions

- At 12 months, results on all 36 patients show Primary Patency (PP)* rates of 85.4% and Freedom from clinically driven Target Lesion Revascularization (Fcd-TLR) rate of 87.5%
- Clinical benefit and improvement of patients quality of life measured by improvement in Rutherford Class (RC) of 1 or more in 97.1% of patients at 12 months; Ankle-brachial index (ABI) improved from 0.60 ± 0.10 before the intervention to 0.88 ± 0.08 at 12 months; and pain-free walking distance improved from 56.1 ± 34.9 m before the intervention to 654.2 ± 419.1 m at 12 months ($p < 0.0001$)
- This all-comers registry for long femoropopliteal lesions of (mean lesion length: 18.2 cm) proved a safe usage of Pulsar self-expanding stent. Diabetes and renal insufficiency had no negative impact on PP or TLR rate

Study design

Prospective, multi-center, investigator initiated registry to evaluate the 4-French Pulsar-18 stent for the treatment of long (>15 cm) femoropopliteal arteries.

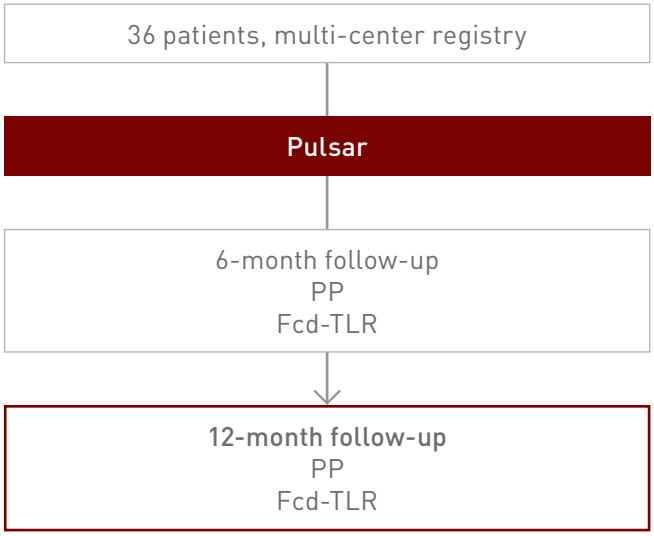
Endpoints

Primary endpoint

- PP* at 6 and 12 months, at the stented target lesion
- Fcd-TLR at 6 and 12 months

Secondary endpoints (selected)

- Improvement in resting ABI
- Improvement in pain-free walking distance improvement in RC
- Difference in PP* in diabetic and renal insufficieny patients
- Difference in PP* of single vs. overlapping stents



Patient characteristics	n = 36	
Age, yrs**	72.1 ± 10.6	
Male	18	50.0%
Hypertension	36	100%
Dyslipidemia	32	88.8%
Current smoker	21	58.3%
Diabetes mellitus	8	22.2%
Obesity	13	36.1%
Renal Insufficiency	4	11.1%
Rutherford Classification 2	6	16.6%
Rutherford Classification 3	19	52.8%
Rutherford Classification 4	5	13.9%
Rutherford Classification 5	6	16.6%
ABI**	0.60 ± 0.10	
Walking capacity (m)**	56.1 ± 34.9	

Lesion characteristics	n = 48	
Lesion length (mm)**	182.3 ± 51.8	
Chronic Total Occlusion (CTO)	46	95.8%
Popliteal segment (I–III)	3	6.3%
TASC D	48	100%

*Defined as no binary restenosis on duplex ultrasound (PSVR <2.5)
**Data shown as mean ± SD

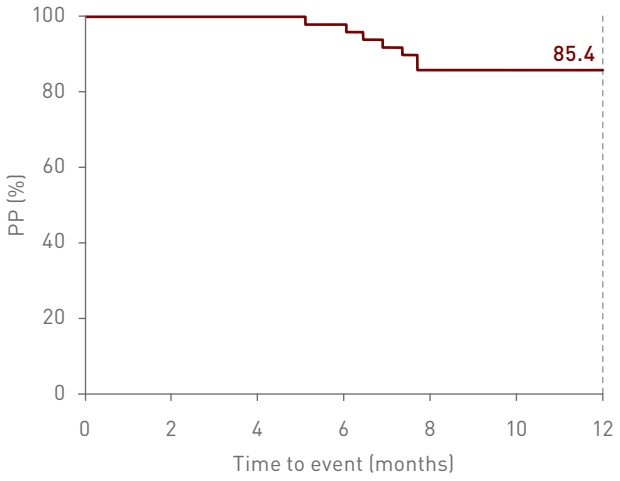
BIOTRONIK
excellence for life

12-month PP results

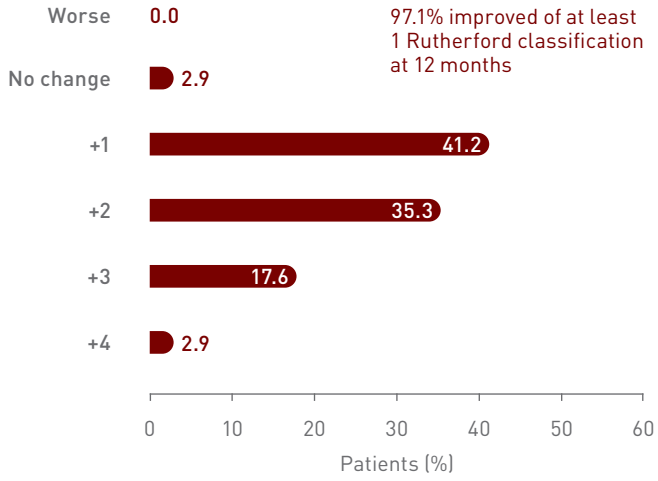
		p-value
PP		
Overall	85.4%	
Diabetic patients	81.1%	0.17
Overlapping stents	78.1%	0.07
Freedom from cd-TLR		
Overall	87.5%	

Clinical improvement	Baseline	12 months
ABI**	0.60 ± 0.10	0.88 ± 0.08
Pain-free walking distance**	56.1 ± 34.9	654.2 ± 419.1
Improvement in Rutherford Classification ≥ 1		97.1%

12-month PP



RC change at 12 months



Key outcomes

12-m
85.4%
PP

12-m
87.5%
Fcd-TLR

Principal investigator

Dr. M Lichtenberg, Klinikum Arnsberg, Germany

1. Lichtenberg et al. Evaluation of the 4-French Pulsar-18 Self-expanding Nitinol Stent in Long Femoropopliteal Lesions. Clin Med Insights Cardiol. 2015 Apr 8;8(Suppl 2):37-42. doi: 10.4137/CMC.S15224.

Dec_2018

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach,
Switzerland

Tel +41 (0) 44 8645111
Fax +41 (0) 44 8645005
info.vi@biotronik.com
www.biotronik.com

BIOTRONIK
excellence for life