Evaluation of the 4-French Pulsar-18 Self-expanding Nitinol Stent in Long Femoropopliteal Lesions (TASC D II) – 12-months results

Conclusions

- At 12-months, results on all 36 patients show Primary Patency (PP) rates of 85.4 % and clinically driven freedom from Target Lesion Revascularization (TLR) rates 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; 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-18 SE stent. Diabetes and renal insufficiency had no negative impact on primary patency or TLR rate

Study design

- Prospective, multi-center, investigator initiated registry to evaluate the outcome of the implantation of the Pulsar-18 stent in lesions >15 cm in the femoropopliteal arteries. Number of patients (n) 36

Principal Investigator

- Dr. M Lichtenberg, Klinikum Arnsberg, Vascular Center Arnsberg, Germany

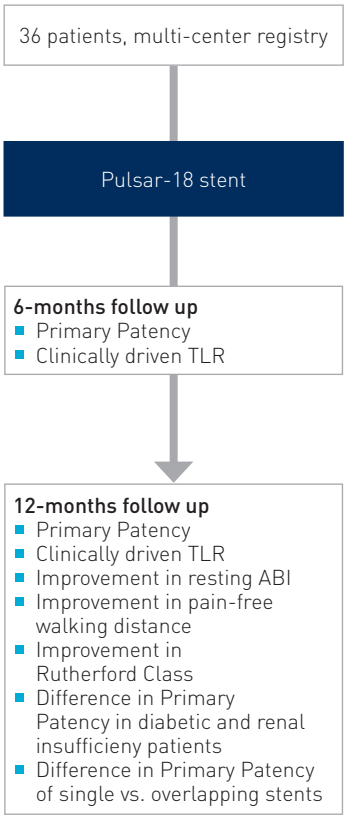
Endpoint(s)

Primary endpoint

- Primary Patency at 6- and 12-months, defined as a binary restenosis on duplex ultrasound (PSVR < 2.5) at the stented target lesion with no clinically-driven TLR (cd-TLR) within the stented segment

Secondary clinical endpoints (selected)

- Improvement in resting ABI
- Improvement in pain-free walking distance
- Improvement in Rutherford Class
- Difference in Primary Patency in diabetic and renal insufficieny patients
- Difference in Primary Patency of single vs. overlapping stents



Reference
Lichtenberg et al. Evaluation of the 4-French Pulsar-18 Self-expanding Nitinol Stent in Long Femoropopliteal Lesions. Clinical Medicine Insights: Cardiology 2014:8(S2) 37–42.

BIOTRONIK
excellence for life

Patient demographics

Diabetes Mellitus	22.2 %
Current smoker	58.3 %
Hypertension	100.0 %
Dyslipidemia	88.8 %
Rutherford Class 2	n = 6 [16.6 %]
Rutherford Class 3	n = 19 [52.8 %]
Rutherford Class 4	n = 5 [13.9 %]
Rutherford Class 5	n = 6 [16.6 %]

Lesion characteristics

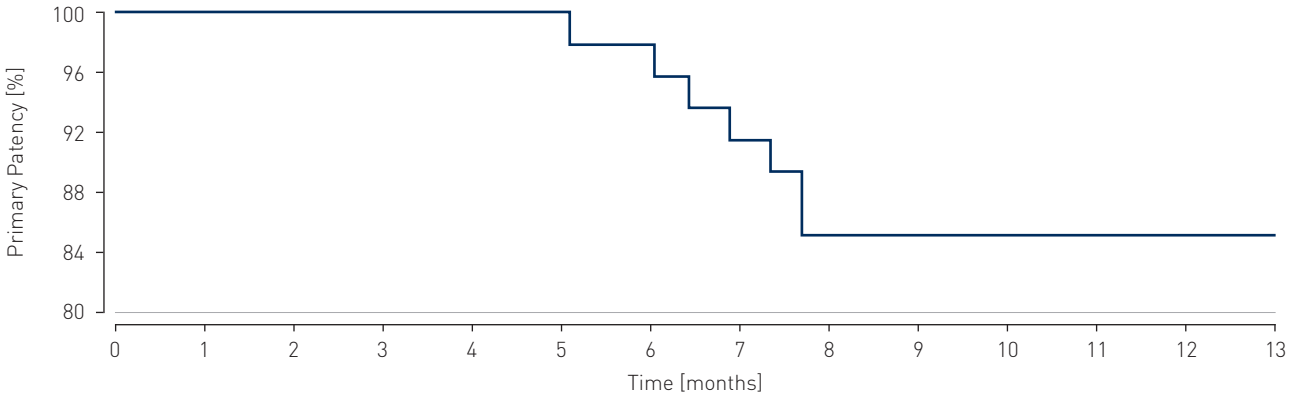
Average lesion length	18.2±5.2 cm [Mean ± SD]
Occlusion	95.8 %
Popliteal segment (I-III)	6.3 %
TASC D	100.0 %

12-months results

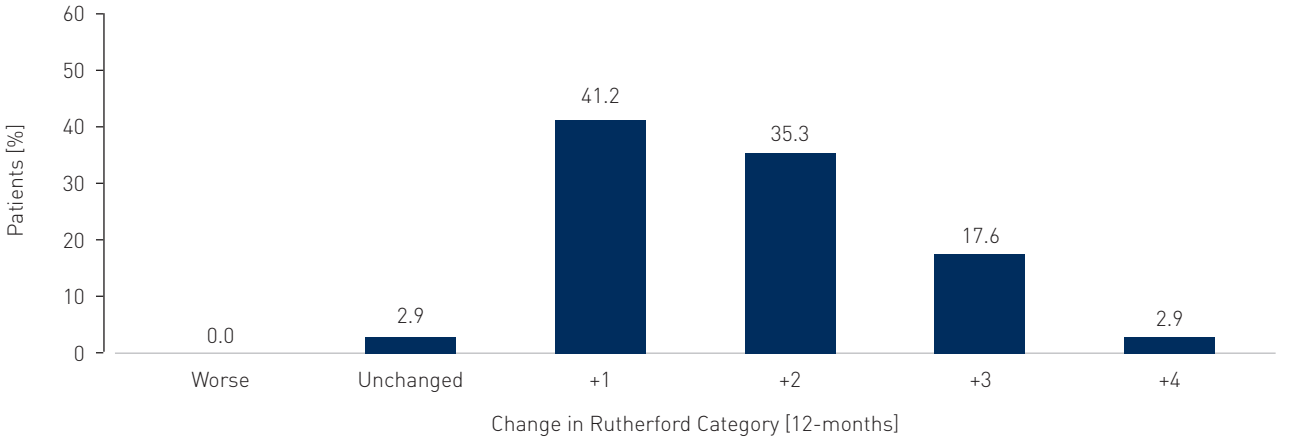
Primary Patency		**p-value**
Overall	85.4 %	
Diabetic patients	81.1 %	0.17
Overlapping stents	78.1 %	0.07
Freedom from cd-TLR		
Overall	87.5 %	

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

Kaplan-Meier estimates of overall Primary Patency



Clinical improvement by Rutherford Category after 12-months follow-up



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