



24-month results of All-Comers Registry¹

Conclusions

- 24-month results for Pulsar stent only group show Kaplan-Meier Freedom from Clinically-Driven Target Lesion Revascularization² (Fcd-TLR) of 89.3% in this All-Comers Registry, which is in line with published stent data^{3,4,5,6}
- The 24-month Kaplan-Meier Fcd-TLR of 85.2% of this full patient cohort are indicative of a long term positive trend
- Clinical success was maintained at 24 months with 81.7% Improvement in Rutherford Class ≥ 1

Study design

Prospective, multi-center, all-comers registry investigating safety and efficacy of the 4F Pulsar-18 stent in real world population in subjects with atherosclerotic disease of the femoropopliteal arteries

Endpoints

Primary endpoints

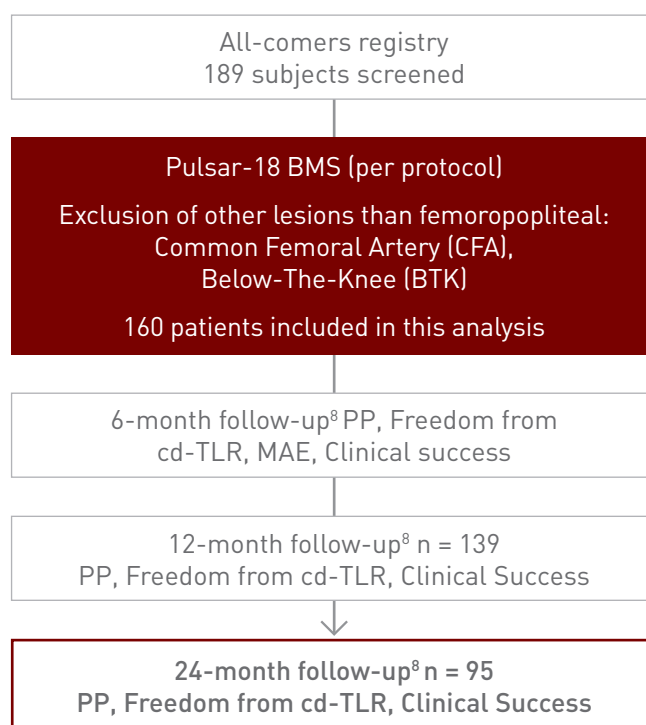
- 6-month Major Adverse Event⁷ (MAE) rate
- 12-month Primary Patency (PP)

Secondary endpoints (selected)

- PP at 6 and 24 months
- Freedom from cd-TLR at 6, 12 and 24 months
- Clinical success at 6, 12 and 24 months
 - Improvement of ≥ 1 Rutherford Class
 - Improvement in Ankle Brachial Index (ABI)

Patient characteristics

Patient characteristics	Total cohort n = 160	Stent only ⁹ n = 60/135
Age, yrs*	69.7 ± 10.5	70.3 ± 9.8
Male	99 61.9%	38 63.3%
Hypertension	141 88.1%	46 76.7%
Dyslipidemia	127 79.4%	42 70.0%
Smoking	115 71.9%	46 76.7%
Diabetes mellitus	53 33.1%	24 40.0%
Renal insufficiency	21 13.1%	7 11.7%
CLI ¹⁰	23 15.3%	9 15.8%
Rutherford		
0	1 0.7%	
n = 150	4 2.7%	
2	62 41.3%	
3	60 40.0%	
4	12 8.0%	-
5	9 6.0%	-
6	2 1.3%	
Ankle brachial index (n = 122)	ø 0.66	
Walking capacity (m) (n = 41)	ø 130.1	



Lesion characteristics

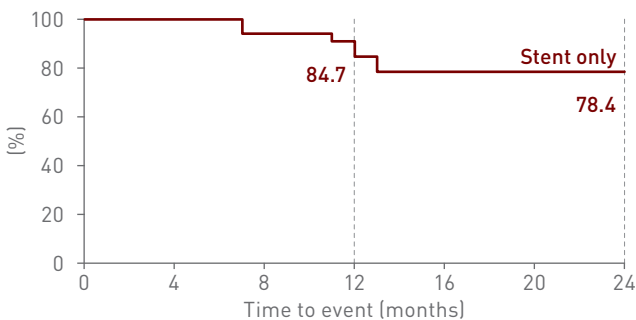
Lesion characteristics	Total cohort n = 186	Stent only ¹¹ n = 73/153
Lesion length [cm]*	11.6 ± 10.3	8.2 ± 7.9
Reference vessel diameter [mm]**	5.0	4.9
Stent diameter [mm]**	5.8	
TASC C lesion	34 18.3%	8 11.0%
TASC D lesion	40 21.5%	7 9.6%
Calcification Moderate & severe	78 41.9%	33 45.2%
Occlusion	35 18.8%	12 16.4%

* Data shown as mean ± SD
** Data shown as mean

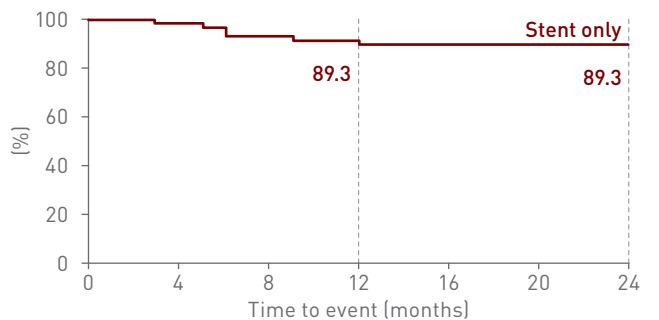
24-month results in perspective	A.L.L (cm)	PP	Fcd-TLR
BIOFLEX-PEACE (stent only group)	8.2	78.4%	89.3%
SUPERB (Supera) ³	7.8	n/a	84.0%
4EVER ¹²	7.1	72.3%	82.7%
RESILIENT (Lifestent) ⁴	7.0	n/a	77.8 %
ZILVER PTX (Zilver BMS provisional) ⁵	6.6	64.1%	76.7%
DURABILITY II (EverFlex) ⁶	8.9	66.0 %	75.3 %

Excellent outcomes after 24-months with Pulsar are comparable to Zilver PTX DES

PP for stent only up to 24 months¹³

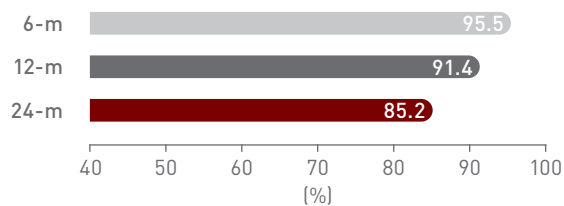


Freedom from cd-TLR up to 24 months¹⁴

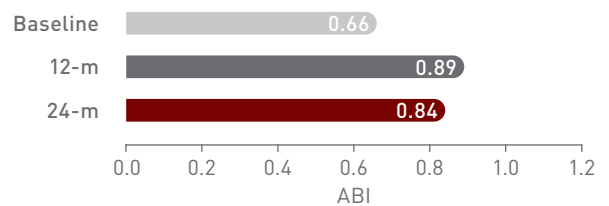


Full-Cohort outcomes

Freedom from cd-TLR

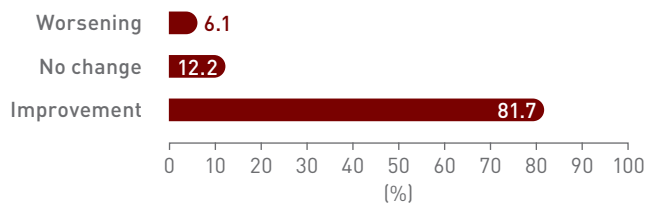


Clinical success – change in ABI

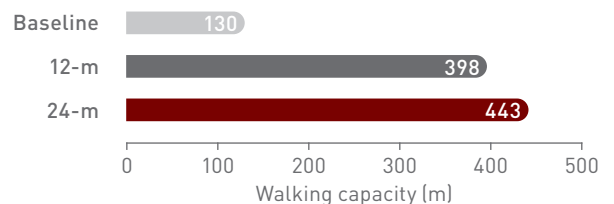


Clinical success – change in Rutherford

Improvement of ≥ 1 Rutherford class in 81.7% after 24 months



Pain free walking capacity up to 24 months



Coordinating clinical investigator

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1. Lichtenberg et al. Effectiveness of the Pulsar-18 self-expanding stent with optional drug-coated balloon angioplasty in the treatment of femoropopliteal lesions - the BIOFLEX PEACE All-Comers Registry. Vasa (2019), 1-9. doi_10.10240301-1526a000785; 2. Freedom from clinically driven Target Lesion Revascularization (Fcd-TLR) is defined as any re-intervention performed for $\geq 50\%$ diameter stenosis (visual estimate) at the target lesion after documentation of recurrent clinical symptoms of the patient; 3. Garcia LA et al. SUPERB Final 3-Year Outcomes Using Interwoven Nitinol Biomimetic Supera Stent. Catheterization and Cardiovascular Interventions 2017; 89:1259-1267; 4. Laird J et al. RESILIENT SFA nitinol stenting. JET 2012;19:1-9; 5. Dake et al. 2-year Zilver PTX Results for femoropopliteal Lesions. JACC 61, 24, 2013: 2417-27; 6. Rocha-Singh et al. DURABILITY II Three-Year Follow-up. Catheterization and Cardiovascular Interventions 2015; 86:164-170; 7. Major Adver Events (MAE) is the composite of device or procedure related death, major target limb amputation above the ankle, and target lesion revascularization; 8. Not for all subjects all measures are available; 9. For 135 patients and 153 lesions was recorded whether or not concomitant drug-coated balloon (DCB) angioplasty was conducted; 10. Critical Limb Ischemia (CLI) – Rutherford category ≥ 4 ; 11. Antonopoulos CN, Mylonas SN, Moulakakis KG et al. A network meta-analysis of randomized controlled trials comparing treatment modalities for de novo superficial femoral artery occlusive lesions. J Vasc Surg. 2017;65(1):234 -245 e11; 7; 12. Bosiers M. 4EVER 24 month results: long-term results of 4F Pulsar stent in femoropopliteal lesions. Presented at: CIRSE 2013; Barcelona, Spain; 13. PP estimates in this study might have been affected by selection bias concerning the DUS evaluation with just about half of the patients followed up from the 6th month; 14. It is a fact that different DCBs feature different outcomes, thus, our data obtained from the plus-DCB-group cannot entirely compete with results of controlled studies.

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