

BIOFLEX PEACE

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

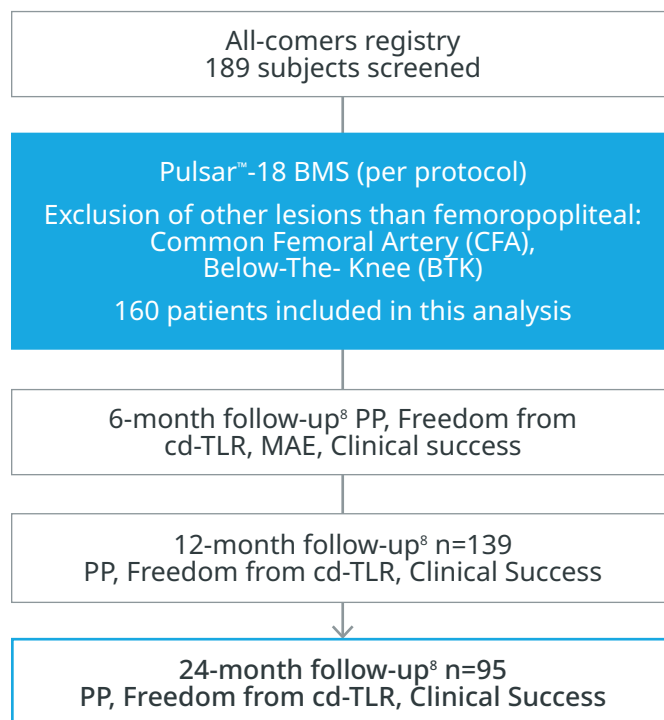
- 6-month Major Adverse Event⁷ (MAE) rate
- 12-month Primary Patency (PP)

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

	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	1	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

	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%

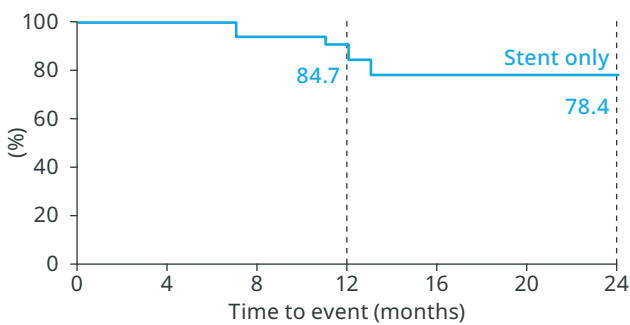
^{*}Data shown as mean±SD ^{**}Data shown as mean

24-month results in perspective

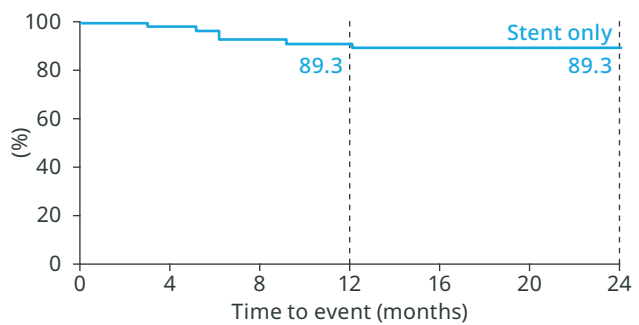
	A.L.L. (CM)	PP	FCD-TLR
BIOFLEX-PEACE (stent only group)	8.2	78.4%	89.3%
SUPERB (Supera™) ³	7.8	n/a	84.0%
4EVER¹²	7.1	72.3%	82.7%
RESILIENT (Lifestent™) ⁴	7.0	n/a	77.8%
ZILVER PTX (Zilver™ BMS provisional) ⁵	6.6	64.1%	76.7%
DURABILITY II (EverFlex™) ⁶	8.9	66.0%	75.3%

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

PP for stent only up to 24 months¹³

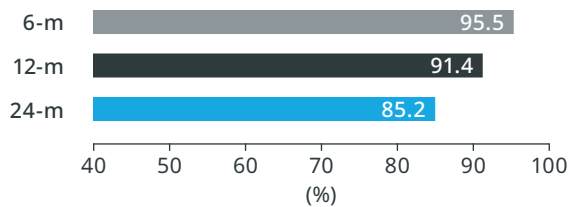


Freedom from cd-TLR up to 24 months¹⁴

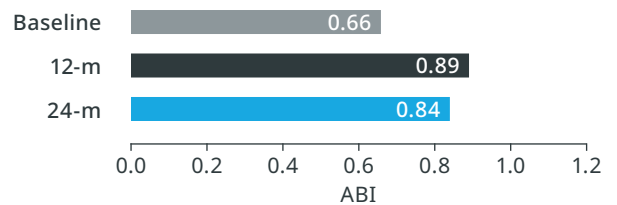


Full-Cohort outcomes

Freedom from cd-TLR

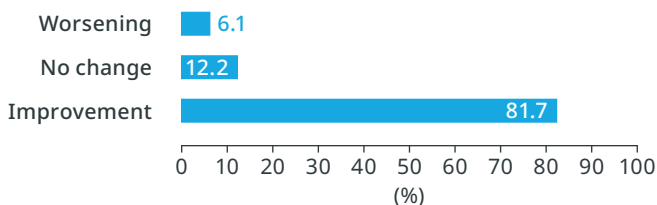


Clinical success – change in ABI

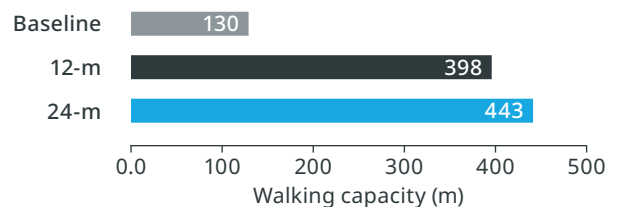


Clinical success – change in Rutherford

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



Pain free walking capacity up to 24 months



Coordinating clinical investigator: Dr. M. Lichtenberg, Arnsberg, Germany

References:

- 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 reintervention 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. *Catherization 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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