BIOFLEX PEACE

24-month results of All-Comers Registry[1]

Conclusions

- 24-month results for Pulsar stent only group show Kaplan-Meier Freedom from Clinically-Driven Target Lesion Revascularization[2] (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 Event[7] (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)

All-comers registry
189 subjects screened

Pulsar-18 BMS (per protocol)

Exclusion of other lesions than femoropopliteal: Common Femoral Artery (CFA), Below-The-Knee (BTK)

160 patients included in this analysis

6-month follow-up[8] PP, Freedom from cd-TLR, MAE, Clinical success

12-month follow-up[8] n = 139 PP, Freedom from cd-TLR, Clinical Success

24-month follow-up[8] n = 95 PP, Freedom from cd-TLR, Clinical Success

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%

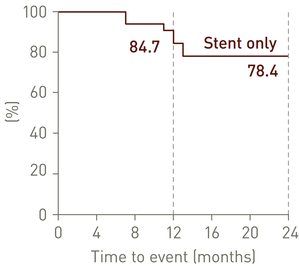
* Data shown as mean ± SD
**Data shown as mean

24-month results in perspective

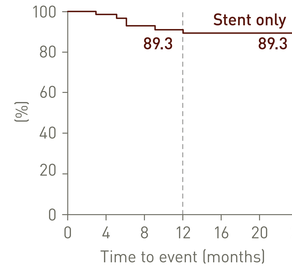
	A.L.L (cm)	PP	Fcd-FTLR
BIOFLEX-PEACE (stent only group)	8.2	78.4%	89.3%
SUPERB (Supera)[3]	7.8	n/a	84.0%
4EVER[12]	7.1	72.3%	82.7%
RESILIENT (Lifestent)[4]	7.0	n/a	77.8%
ZILVER PTX (Zilver BMS provsional)[5]	6.6	64.1%	76.7%
DURABILITY II (EverFlex)[6]	8.9	66.0%	75.3%

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

PP for stent only up 24 months[13]

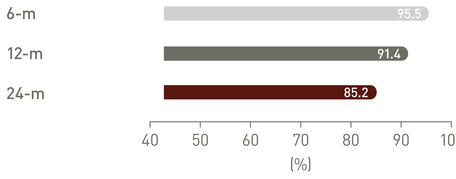


Freedom from cd-TLR up to 24 months[14]

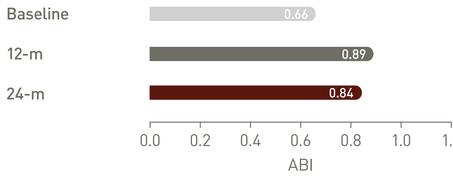


Full-Cohort outcomes

Freedom from cd-TLR

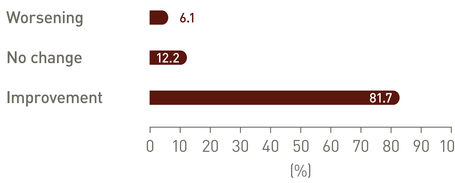


Clinical success – change in ABI

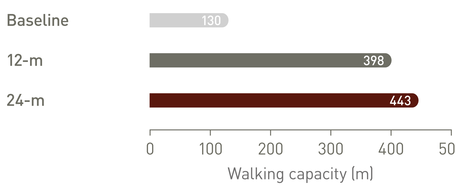


Clinical sucess – change in Rutherford

Improvement of ≥1 Rutherford class in 81.7% after 12 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 femoropoplíteal 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 ≥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 femoropoplíteal 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. Critial 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 femoropoplíteal 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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