BIOFLEX PEACE

12-month results of full cohort

Conclusions

- Full cohort 12-month* results show Primary Patency (PP)[1] of 73.6%* and Freedom from clinically driven Target Lesion Revascularization (Fcd-TLR) of 96.2%* in this all-comers registry, which are in line with published study data for the Pulsar stent in controlled trials
- Clinical success of 80.8% (Improvement in Rutherford Class)
- Sub-group analysis has shown that patients treated with BMS and DCB have numerically higher PP than patients treated with BMS alone – a "Paclitaxel effect"
- Mean stent oversizing of 0.8 mm suggests that in the real-world, interventionalists are applying "minimal oversizing" to reduce the COF to least possible. Next step is to choose a stent design that reduces COF further

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

Principal Investigator

- Dr. M. Lichtenberg, Arnsberg, Germany

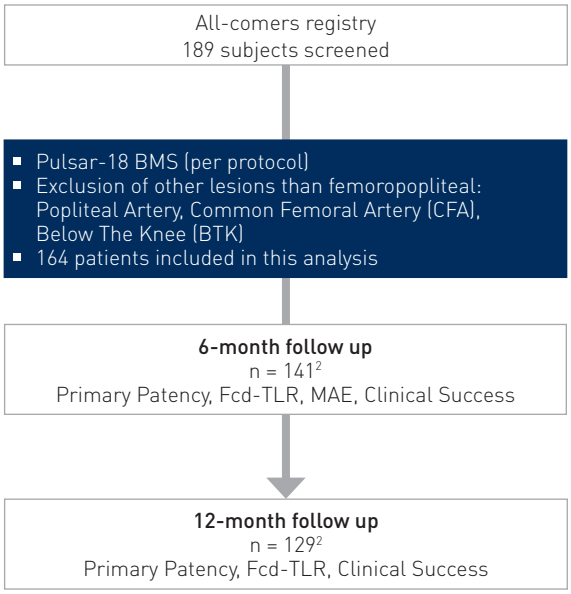
Endpoints

Primary endpoint

- 6-month Major Adverse Event (MAE) rate
- 12-month* Primary Patency[1]

Secondary clinical endpoints (selected)

- Primary Patency at 6 and 24 months
- Fcd-TLR at 6, 12* and 24 months
- Clinical success
  - Improvement of ⩾1 Rutherford Class
  - Improvement in ABI



Patient Demographics

		n = 164
Hypertension		146 (89.0%)
Dyslipidemia		131 (79.9%)
Smoker (current or previous)		119 (72.6%)
Diabetes		52 (31.7%)
Renal insufficiency		32 (19.5%)
Critical Limb Ischemia (CLI)[3]		**29 (18.7%)**
Rutherford (n = 155)	0	1 (0.6%)
	1	3 (1.9%)
	2	59 (38.1%)
	3	63 (40.6%)
	4	15 (9.7%)
	5	12 (7.7%)
	6	2 (1.3%)
Ankle brachial index (n = 129)		ø 0.66

Lesion Characteristics

		n = 178
Lesion length (mm) (n = 143)		119.2 ± 103.69
Mean ref. vessel diameter		5.03 mm
Mean implanted strut diameter		5.83 mm
TASC A lesion		46 (25.8%)
TASC B lesion		60 (33.7%)
TASC C lesion		35 (19.7%)
TASC D lesion		37 (20.8%)
TASC C/D lesions		**40.5%**
Calcification	0 None	29 (16.3%)
	1 Mild	71 (39.9%)
	2 Moderate	43 (24.2%)
	3 Severe	35 (19.7%)
	Moderate & Severe	78 (43.8%)

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12-month* Results

Population	Endpoint	Vessel	n (patients)	A.L.L. (mm) mean ± SD	%
Full cohort	Freedom cd-TLR	Femoropopliteal	125/130	119.1 ± 103.2	96.2%
Imaging cohort[4]	PP	Femoropopliteal	67/91	138.5 ± 111.7	73.6%

12-month Results in Perspective

Study	Device	A.L.L.	PP	Fcd-TLR
BIOFLEX PEACE*	**Pulsar-18**	**11.9 cm**	**73.6%**[5] **(67/91)**	**96.2% (125/130)**
4EVER	Pulsar-18	10.8 cm	73.4%	85.2%
PEACE	Pulsar-18	11.2 cm	79.5%	81.0%
RESILIENT	Lifestent (C.R. Bard)	6.2 cm	81.3%	87.3%
ZILVER FLEX (PTX study)	Zilver Flex (Cook Medical)	6.3 cm	73.0%	77.0%
ZILVER PTX	Zilver PTX DES (Cook Medical)	6.6 cm	83.1%	90.5%
DURABILITY II	EverFlex (Medtronic)	8.9 cm	77.2%	n/a
SUPERA	Supera (Abbott)	9.0 cm	84.7%	n/a
DURABILITY	EverFlex (Medtronic)	9.6 cm	72.2%	79.1%
ABSOLUTE	Absolute (Abbott)	10.1 cm	63.0%	n/a

BIOFLEX PEACE 12-month data supports 4EVER and PEACE data in similar lesion length with comparable data to 6F BMS devices and Zilver PTX DES.

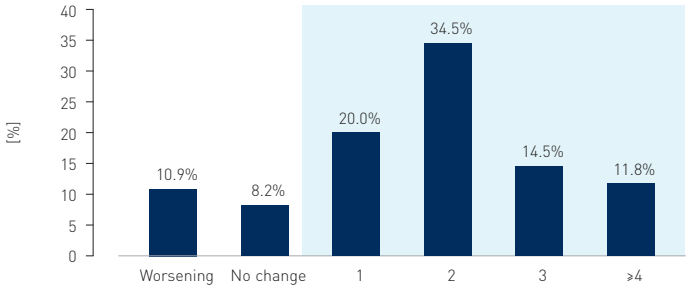
Treatment Regime Influences Outcome?

Lesions	n = 178
Stent only	113 (63.5%)
Stent + DCB	48 (27.0%)
Stent + other device (thrombectomy, atherectomy, scoring balloon etc.)	17 (9.6%)

	Population	Endpoint	Vessel	n (lesions)	A.L.L. (mm) mean ± SD	%
Stent	Full cohort	Freedom cd-TLR	Femoropopliteal	89/90	121.2 ± 113.1	98.9%
	Imaging cohort[4]	PP	Femoropopliteal	38/54	137.3 ± 112.7	**70.4%**
Stent + DCB	Full cohort	Freedom cd-TLR	Femoropopliteal	34/35	99.8 ± 80.6	97.1%
	Imaging cohort[4]	PP	Femoropopliteal	23/28	94.6 ± 84.7	**82.1%**

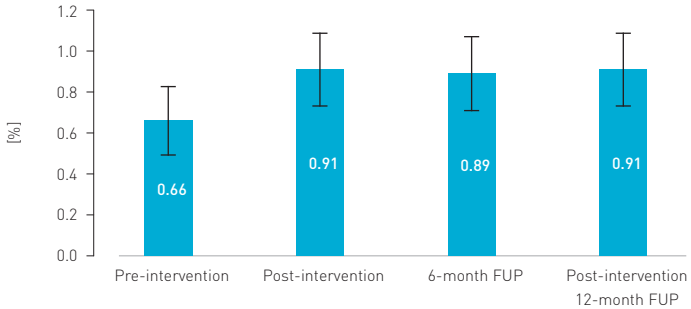
Clinical Success – Change in Rutherford

80.8% of subject show improvement of ≥1 Rutherford Class after 1 year[6]



Reference: Lichtenberg M., presented at Charing Cross Symposium April 2017

Clinical Success – Change in ABI



* 395 day results
1 Defined as freedom from >50% restenosis with no clinically-driven reintervention
2 Not for all subjects all measures are available
3 Rutherford classification 4-6 (29 out of 155 subjects)
4 Duplex data available. Duplex imaging was performed upon need and investigators discretion
5 Imaging cohort
6 Data available for 110 subjects

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