4EVER

Investigator-initiated trial investigating the safety of the full 4F EndoVascular trEatment appRoach of infra-inguinal arterial stenotic disease at 24-months[1]

Conclusions

- Pulsar stents are safe and effective for treating SFA disease with excellent performance and clinical outcomes:
  - Primary Patency (PP)* and Freedom from Target Lesion Revascularization (FTLR) are in line with other documented bare metal/passive coated stents in lesions with similar characteristics[2]
  - PP is in line with Zilver PTX (drug-eluting stent) despite longer average lesion length
  - Sufficient chronic outward force and compression resistance demonstrated by the favorable 24-month PP, even in calcified lesions and total occlusions

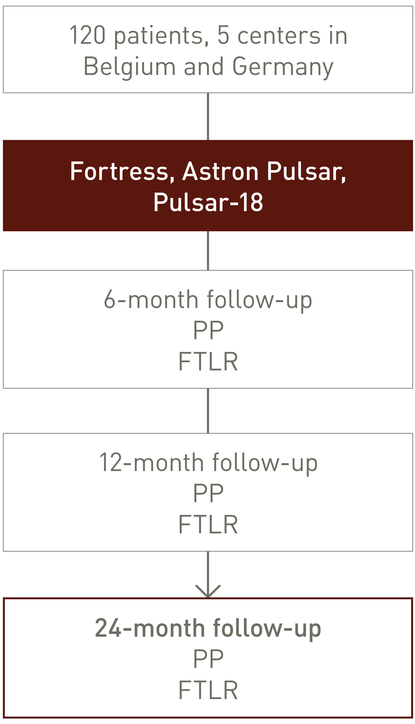
Study design

Prospective, non-randomized, multi-center, controlled study. 120 patients with 6, 12, 24-month follow-up. BIOTRONIK devices: Fortress, Astron Pulsar, Pulsar-18, Passeo-18 and Cruiser-18.

Endpoints

Primary endpoint
- PP* at 12 months

Secondary endpoints (selected)
- PP* at 6 and 24 months
- FTLR 6, 12 and 24 months
- Technical success
- Puncture site complication rate
- Stent fracture rate at 12 and 24 months
- Clinical success at 6, 12 and 24 months



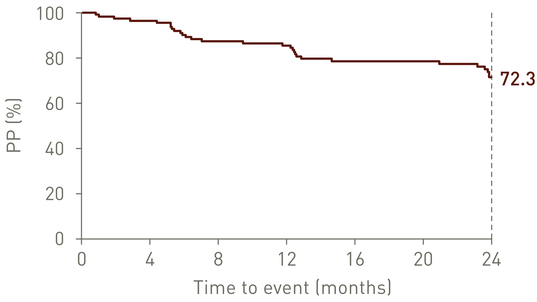
Patient characteristics	n = 120	
Age, yrs**	71 ± 9.7	47 - 90
Male	82	68.3%
Nicotine abuse (current)	50	41.7%
Hypertension (controlled)	78	65.0%
Diabetes mellitus	43	35.8%
Renal insufficiency	13	10.8%
Hypercholesterolemia	66	55.0%
Obesity	39	32.5%

Lesion characteristics	n = 120	
Lesion length (mm)**	71 ± 45.9	10 - 220
Popliteal involvement	5	4.17
Total occlusions	25	20.8%
Ulcerated lesion	3	2.5%
Calcified lesion	37	30.8%
Presence of thrombus	2	1.7%

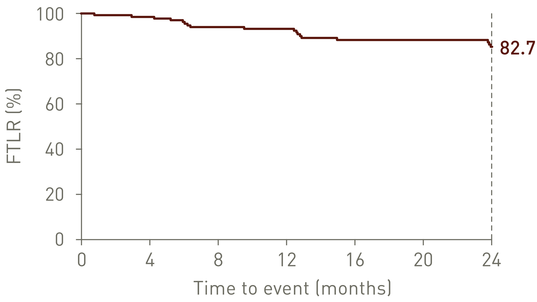
*Defined as freedom from >50% restenosis as indicated by duplex ultrasound PSVR < 2.5
**Data shown as mean ± SD

Results	12 months[1]	24 months[3]	p-value
PP (overall)	81.4%	**72.3%**	
Astron Pulsar	85.2%	76.2% (Δ -9.0%)	
Pulsar-18	73.4%	69.7% (Δ -3.7%)	
Calcified vs. non-calcified	80.2% vs. 82.0%	66.8% vs. 76.7%	0.659 0.485
FTLR	89.3%	**82.7%**	
Astron Pulsar	91.1%	82.3% (Δ -8.8%)	
Pulsar-18	25	85.1 (Δ -0.1%)	
Rutherford Classification change (+/0/-)	(2/3/91) of 96 patients	n/a	

24-month PP



24-month FTLR



24-month PP and FTLR in perspective

	A.L.L	PP	FTLR	Total occlusions
ZILVER PTX[4]	6.6 cm	74.8%	86.6%	32.8%
4EVER (Pulsar-18)[1]	**10.8 cm**	**69.7%**	**85.1%**	**32.6%**
4EVER (Astron Pulsar, Pulsar-18)[3]	**7.1 cm**	**72.3%**	**82.7%**	**20.8%**
STROLL[5]	7.7 cm	74.9%	80.3%	23.6%
DURABILITY II[6]	8.9 cm	66.0%	n/a	48.1%
SUPERA[7]	9.0 cm	84.7%	n/a	30.8%

Key points

No significant difference between calcified vs. non-calcified lesions at both 12 months and 24 months

Key outcomes

24-m
72.3%
PP

24-m
82.7%
FTLR

Principal investigator

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1. Bosiers M et al. 4-French -compatible endovascular material is safe & effective in the treatment of femoropopliteal occlusive disease: Results of the 4EVER Trial. J Endovasc Ther 2013; 20: 746-756; 2. Studies: DURABILITY II, SUPERA, STROLL and ZILVER PTX; 3. Deloose K. 4EVER 24m: Long-term results of 4F Pulsar stents in femoropopliteal lesions. Presented at: LINC; Jan 29, 2014; Leipzig, Germany; 4. Dake M et al. Sustained safety and effectiveness of paclitaxel-eluting stents for femoropopliteal lesions: 2-year follow-up from the Zilver PTX randomized and single-arm clinical studies. JACC. 2013; 61(24):2417-2427. doi: 10.1016/j.jacc.2013.03.034; 5. Bunte MC et al. Long-term clinical and quality of life outcomes after stenting of femoropopliteal artery stenosis: 3-year results from the STROLL study. Catheter Cardiovasc Interv. 2018 Mar 9. doi: 10.1002/ccd.27569; 6. Rocha-Singh KJ et al. A single stent strategy in patients with lifestyle limiting claudication: 3-year results from the Durability II trial. Catheter Cardiovasc Interv. 2015; 86(1):164-70. doi: 10.1002/ccd.25895; 7. Garcia LA et al. SUPERB final 3-year outcomes using interwoven nitinol biomimetic supera stent Catheter Cardiovasc Interv. 2017; 89(7):1259-1267. doi: 10.1002/ccd.27058.

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