

BERN

Evaluation of 4F Pulsar efficacy in long segment (> 120mm) complex femoropopliteal arteries differentiating Critical Limb Ischemia (CLI) vs Intermittent Claudication (IC)¹

Conclusions

- Primary Patency (PP)* and restenosis rates of the 4F Pulsar stent are comparable with data from literature for stenting of long femoropopliteal obstructions

Study design

Single center, retrospective registry with 12-month follow-up.

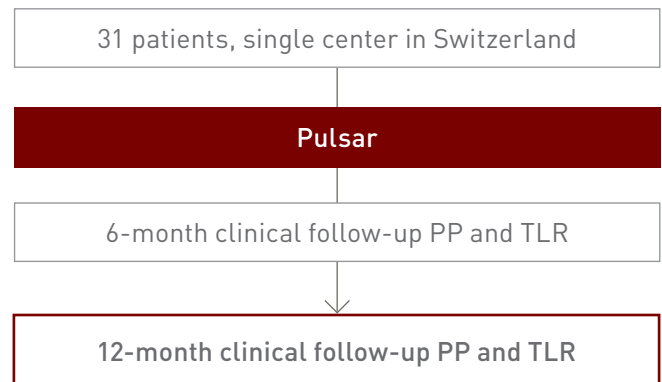
Endpoints

Primary endpoint

- PP*
- Stratified for CLI vs. IC

Secondary endpoints (selected)

- Freedom from Target Lesion Revascularization (FTLR)
- Technical success
- Procedural complications



Patient characteristics

	Total n = 31	IC n = 18	CLI n = 13	p-value
Age, yrs**	73.3 ± 10.1	72.2 ± 10.3	74.7 ± 10.1	0.9
Male	71.0%	72.2%	69.2%	1.0
Hyperlipidemia	71.0%	61.1%	84.6%	0.2
Diabetes mellitus	35.5%	27.8%	46.2%	0.5
Arterial hypertension	80.6%	77.8%	84.6%	1.0
Coronary heart disease	51.6%	50.0%	53.8%	1.0
Creatinine** (mmol/L)	81.9 ± 21.66	81.5 ± 19.9	82.5 ± 24.75	0.4
Cerebrovascular disease	16.1%	16.7%	15.4%	1.0
Current smoker	61.3%	66.7%	53.8%	0.71

Lesion characteristics

	Total n = 31	IC n = 18	CLI n = 13	p-value
Lesion length, (mm)**	163.5 ± 32.5	153.9 ± 34.0	176.9 ± 25.9	0.05
Primary intervention	77.4%	77.8%	76.9%	1.00
Re do intervention	22.6%	22.2%	23.1%	1.00
Stenosis	9.7%	5.6%	15.4%	0.56
Occlusion	90.3%	94.4%	84.6%	0.56
Acute limb ischemia	9.7%	11.1%	7.7%	1.00

*Defined as freedom from >50% restenosis as indicated by duplex ultrasound without re-intervention at the stented segment
 **Data shown as mean ± SD

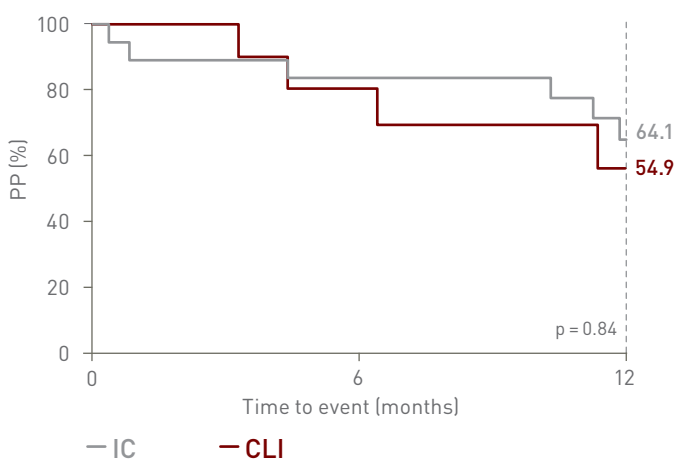
12-month results	Total	IC	CLI	p-value
PP	61.1%	64.1%	54.9%	0.84
Freedom from TLR	77.8%	85.9%	64.0%	0.43

BERN registry in perspective

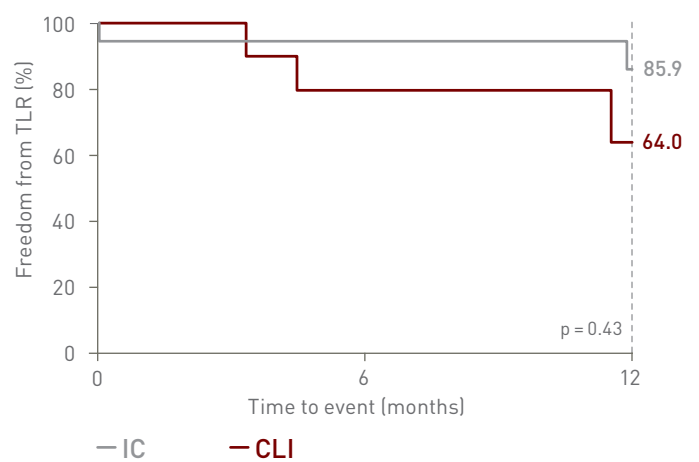
	IC	CLI	Average lesion length	Clinical endpoints	12-month clinical outcomes
BERN n = 31	58.1%	41.9%	16.4 cm	PP FTLR	61.1% 77.8%
Durability-200 (EverFlex) ² n = 100	71.0%	29.0%	24.2 cm	PP FTLR	64.8% 68.2%
REAL-FP ³ n = 511	76.0%	24.0%	15.1 cm	PP SP	79.8% 90.4%
Retrospective data analysis ⁴ n = 95	65.0%	35.0%	15.7 cm	PP AP SP	63.0% 70.0% 78.0%

AP = Assisted Patency SP = Secondary Patency
 REAL FP = REtrospective multicenter AnaLysis for FemoroPopliteal stenting registry (No. UMIN000002726)

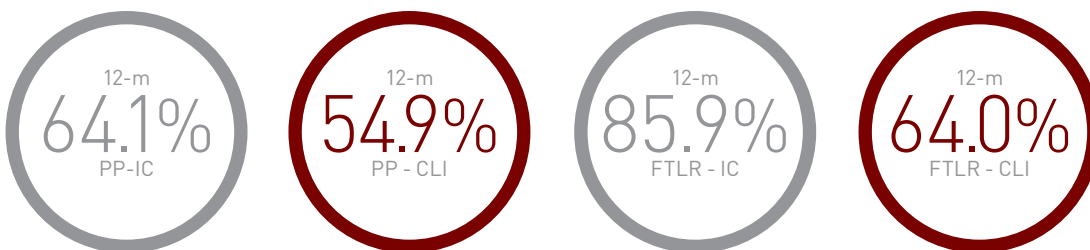
12-month PP



12-month Freedom from TLR



Key outcomes



Principal investigator

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1. Baumann FJ. Treatment of long-segment femoropopliteal obstructions: initial experience with a 4-F compatible self-expanding nitinol stent and review of the literature. J Cardiovasc Surg 2012;53(4):475-80; 2. Bosiers M et al. Results of the Protégé EverFlex 200-m-long nitinol stent (ev3) in TASC C and D femoropopliteal lesions. J Vasc Surg. 2011;54(4):1042-50; 3. Soga et al. M. Mid-term clinical outcome and predictors of vessel patency after femoropopliteal stenting with self-expandable nitinol stent. J Vasc Surg. 2010;52(3):608-15; 4. Ihnat DM et al. Contemporary outcomes after superficial femoral artery angioplasty and stenting: the influence of TASC classification and runoff score. J Vasc Surg. 2008;47(5):967-74.

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