

# BIOFLEX-COF

## 12-month Results of Full-Cohort BIOFLEX-COF (Chronic Outward Force)<sup>1</sup>

### Conclusions

- The first RCT\* to assess COF
- Low COF Pulsar group showed significantly lower restenosis rates than patients treated in the high COF LifeStent group at 12 months‡
- BIOFLEX-COF results suggest that COF impacts clinical outcomes and should therefore be an important factor in the choice of the stent

### Study design

Randomized controlled, investigator initiated, prospective, blinded trial investigating impact of COF on clinical outcomes in de novo Superficial Femoral Arterial (SFA) lesions

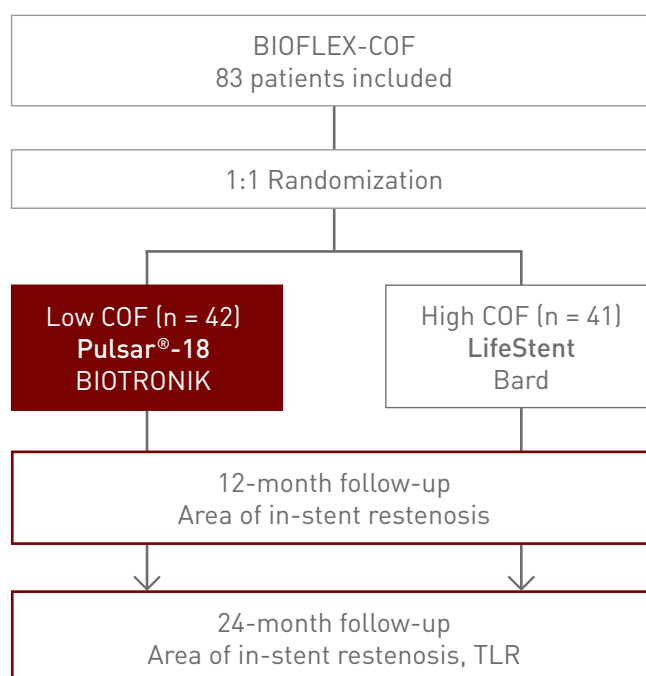
### Endpoints

#### Primary endpoints

- Area of in-stent restenosis at 12 and 24 months
- True lumen diameter

#### Secondary endpoints (selected)

- Device and procedure related adverse events at 24 months
- Target Lesion Revascularization (TLR) at 24 months



### Patient characteristics

	Pulsar n = 42		LifeStent n = 41		p-value
Diabetes	15	36.6%	21	51.2%	0.182
Smoker	18	42.9%	23	57.5%	0.185
Hypertension	41	97.6%	35	87.5%	0.079
Hyperlipidemia	38	90.5%	36	87.8%	0.696
Chronic heart disease	19	45.2%	10	24.4%	0.046
Myocardial infarction	10	23.8%	7	17.1%	0.447
Stroke	3	7.1%	5	12.2%	0.436
Arrhythmia	9	21.4%	6	14.6%	0.421
Chronic kidney disease	9	25.0%	6	22.2%	0.798
Contralateral PAD	17	48.6%	18	72.0%	0.070

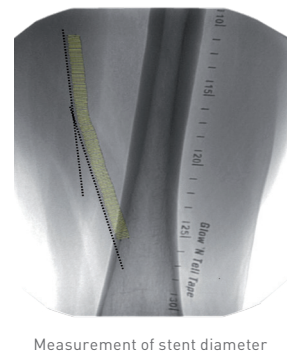
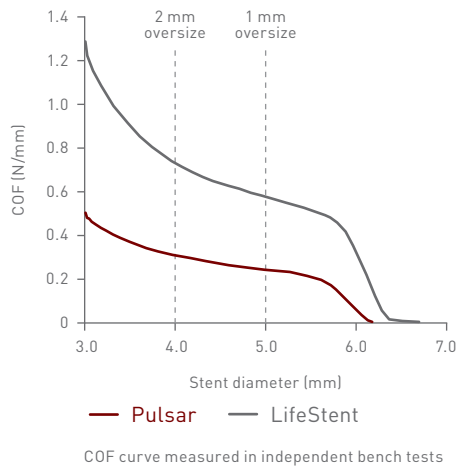
### Lesion characteristics

	Pulsar	LifeStent	p-value
Stented length (mm)	167	127	0.076
Stenosis (%)	91.5 ± 10.4	90.4 ± 10.1	0.406
Occlusion	17 [41.5%]	12 [29.3%]	0.248
Occlusion length (mm)	100.0 (70.0;227.5)	98.0 (35.0;145.0)	0.145

\* RCT = Randomized controlled trial  
‡ mean restenosis defined as the average area of restenosis across a lesion assessed by CT-Angiography

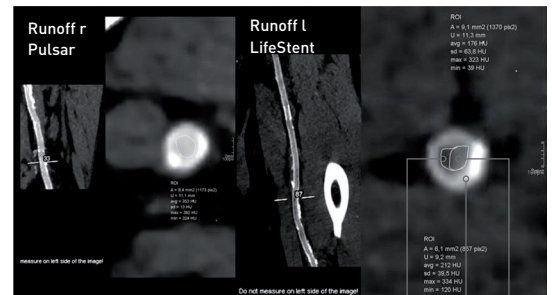
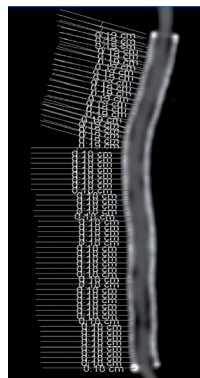
## Procedure<sup>2</sup>

- After successful lesion crossing, vessel diameter was measured with a ruler to select balloon and stent size
- Patients were randomized to low COF or high COF group
- High COF group received a stiffer LifeStent with maximal oversizing (according to IFU). Low COF group received a thin-strut Pulsar stent 1 mm smaller
- Difference in oversizing was determined the investigator to achieve highest possible difference in COF
- A completion angiography between two stent groups was performed in two planes to measure the diameter of implanted stent every 2 mm. The ratio between implanted stent diameter and nominal diameter results in amount of oversizing
- Identified oversizing was correlated to COF as measured in an independent bench test (iIB report)



## Follow up analysis<sup>2</sup>

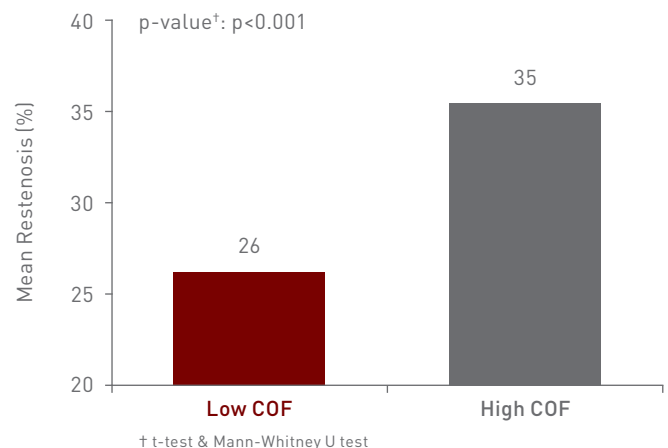
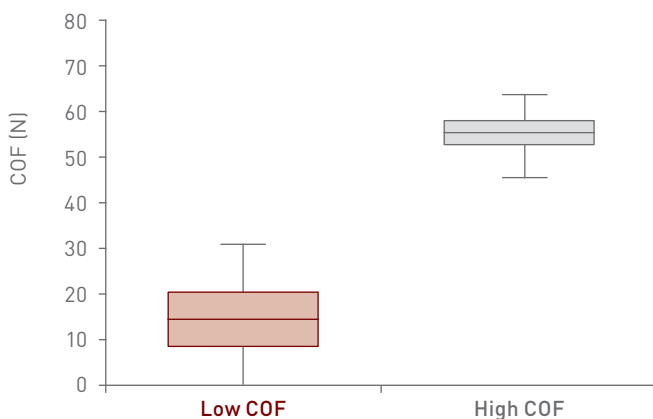
- Outcome evaluation based on Computed Tomography Angiography (CTA)
- Lesion diameter and area of restenosis was determined at every 2 mm across a lesion per patient
- All measured points were pooled in high COF group and low COF group
- The average of all data points is defined as mean restenosis and can be understood as the average loss of area lumen (in %)



Restenosis Blood flow Stent

## 12-month results

- Applied COF in LifeStent group was 4x higher compared to Pulsar group
- Mean Restenosis in high COF LifeStent group is 35% compared to 26% in the low COF Pulsar group
- The average area of restenosis was significantly higher in the high COF LifeStent group



## Principal clinical investigator

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1. Funovics M. Differences in clinical outcomes of low COF stent vs high COF stent proven in clinical practice. Presented at: CIRSE, Sep 8, 2019; Barcelona, Spain; 2. Wressnegger et al. Self-expanding nitinol stents of high versus low chronic outward force in de novo femoropopliteal occlusive arterial lesions (BIOFLEX-COF) trial: study protocol for a randomized controlled trial. *Trials* (2017) 18:594; DOI 10.1186/s13063-017-2338-0.

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