BIOFLEX PEACE Registry
12 & 24-Month Results

Pulsar **E**fficacy: an **A**ll **C**omers R**E**gistry

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Disclosure

Speaker name: Michael Lichtenberg, MD

I have the following potential conflicts of interest to report:

- [x] Consulting: BIOTRONIK
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

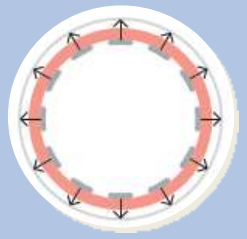
Properties of an ideal SFA stent

Low Chronic Outward Force (COF)

Chronic Outward Force is the force exerted on the vessel wall by a self-expanding (SE) stent to achieve its preset diameter. This can cause vessel injury, inflammation score and neointimal proliferation[a, b, c.]

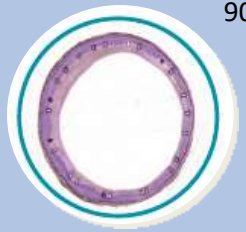
The higher the force exerted on the vessel wall the stronger the inflammatory response is.[a]

SE stent 1 mm oversized in vessel



Force exerted on vessel wall by SE stent to achieve its preset diameter

Vessel wall response on SE stent 1 mm oversizing showing neointima-hyperplacia at 90 days[d]



BIOTRONIK Pulsar-18

BARD Lifestent XL

Stent flexibility, Radial Resistive Force & Crush Risistance

- **High multidirectional flexibility**
- **Sufficient Radial Resisitive Force (RRF)**
- **Sufficient Crush Resistance (CR)**

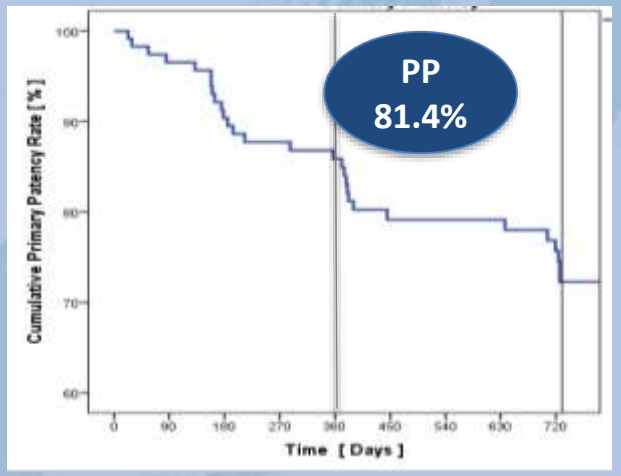
RRF
(resistance to **concentric** compression)

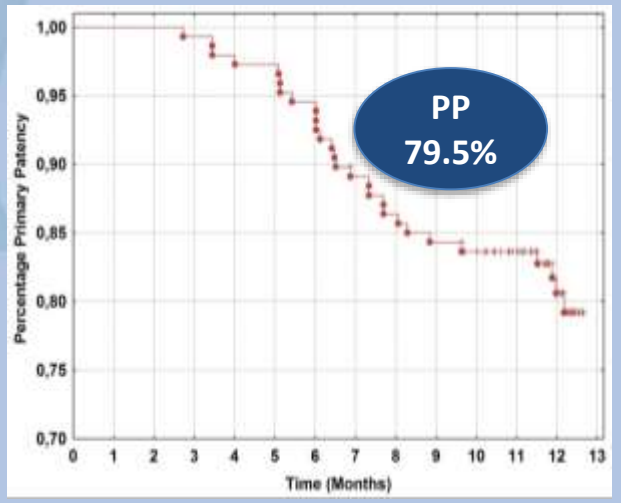
CR
(resistance to **eccentric** compression)

a As demonstrated in pre-clinical studies: Zhao HQ, et al. Late stent expansion and neointimal proliferation of oversized Nitinol stents in peripheral arteries. Cardiovasc Intervent Radiol. 2009 Jul. 32(4):720-6; b Freeman JW, et al. A link between stent radial forces and vascular wall remodeling: the discovery of an optimal stent radial force for minimal vessel restenosis. Connect Tissue Res. 2010 Aug; 51(4): 314-26; c Ballyk PD. Intramural stress increases exponentially with stent diameter: a stress threshold for neointimal hyperplasia. J Vasc Interv Radiol. 2006 Jul;17(7):1139-45; d Funovic M. oral presentation at LINC 2017 (As demonstrated in pre-clinical studies)

4EVER and PEACE

Two Trials Looking Into **4F** Self Expanding Stents in the SFA





With good initial results in standard lesions

4EVER[1] (Safety and Efficacy)

- Prospective, Multicenter, non-randomized trial, Belgium
- 120 pts
- **7.2 cm Mean Lesion Length**
- TASC (70% A, 22.5% B, 7.5% C, 0% D)
- 35.8% Diabetic, 41.7% curr. Smoker, 16.7% CLI, 20.8% CTO
- 81.4% PP and 89.3% fTLR at 12m

PEACE[2] (Registry)

- Prospective, Multicenter, non-randomized trial, Germany
- 148 pts
- 11.2 cm Mean Lesion Length
- TASC (18.7% A, 23.6% B, 19.4% C, 32.2% D)
- 31% Diabetic, 37% curr. Smoker, 68.7% CLI, 56.7% CTO
- 79.5% PP and 81% fTLR at 12m

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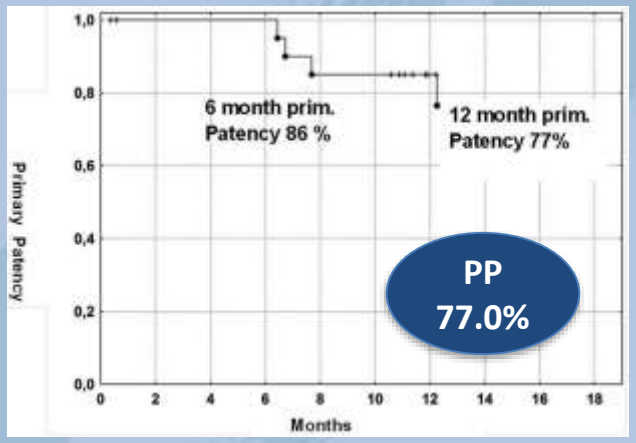
1.) Bosiers M. Journal of Endovascular Therapy 2013;20:746–756
2.) Lichtenberg M. Journal of Endovascular Therapy 2014;21:373–380

4EVER PEACE

TASC D registry

One Trial Looking Into **4F** Self Expanding Stents in long, complex lesions



...also for long, complex, TASC D, occlusions

TASC D[1] (Registry)

- Prospective, Single center, non-randomized trial, Germany
- 22 pts
- **24.5 cm Mean Lesion Length**
- TASC D 100.0%
- 72.7% Diabetic, 45.5% curr. Smoker, 100.0% CLI, 100.0% CTO
- 77.0% PP and 86.0% fTLR at 12m

4EVER	PEACE	TASC D

Equal Primary Patency and Freedom from TLR rates at 12 months in 3 independent trials with the same device.

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Pulsar in TASC D

1.) Lichtenberg M, Stahlhoff W, Boese D; J. Cardiovasc Surg 2013; 54: 433-9

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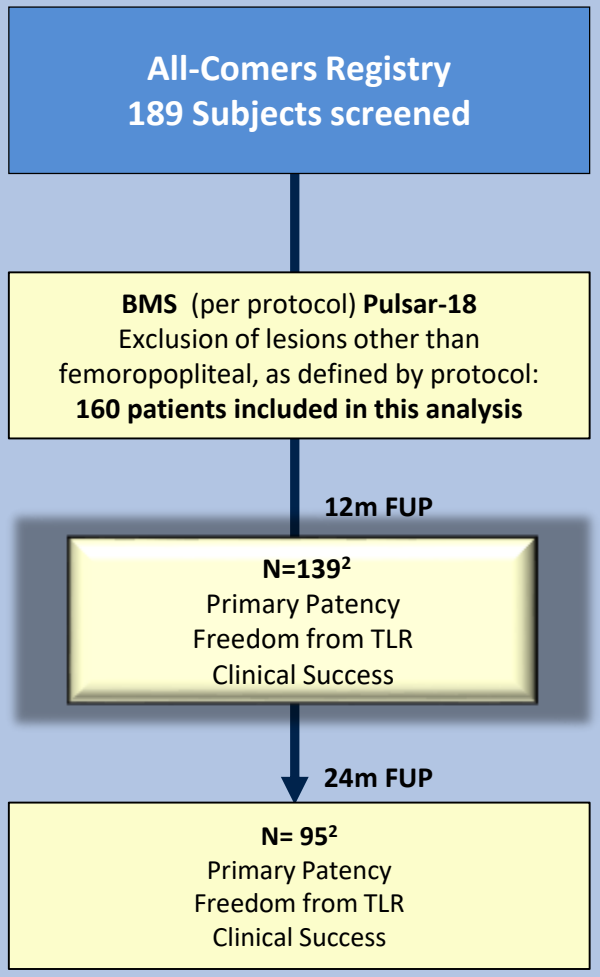
STUDY DESIGN:
All-Comers registry. Prospective, multicenter.
Treatment of femoropopliteal atherosclerotic lesions using the **4F, Pulsar-18** stent

PRINCIPAL INVESTIGATOR:
Dr. M. Lichtenberg (Arnsberg,DE)
CO-PI: Prof. C. Nolte-Ernsting (Mülheim, DE)

PRIMARY ENDPOINT:
6m Major Adverse Event (MAE) rate
12m Primary Patency

SECONDARY ENDPOINTS:
Primary Patency at 6 & 24m
Freedom from TLR at 6, 12 & 24m
Clinical success - improvement of ≥1 Rutherford Class
- improvement in ABI

Pre-defined sub-groups
Diabetic vs. non-diabetic
Lesion length ≤100mm vs. >100mm



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2 Not for all subjects all measures are available

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Patient demographics & Lesion characteristics at baseline

Patient demographics	N = 160
Male	99 (61.9%)
Age (mean (sd))	69.7 (10.46)
Hypertension	141 (88.1%)
Dyslipidemia	127 (79.4%)
Smoker (current or previous)	115 (71.9%)
Diabetes	53 (33.1%)
Renal Insufficiency	31 (19.4%)
CLI[3]	**23 (15.3%)**
Rutherford **(n=150)**	
0	1 (0.7%)
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 (mean) **(n=122)**	0.66
Walking capacity (mean in meter) **(n=41)**	130.2

Lesion characteristics	N = 186
Lesion length (cm) (n=185)	**11.6 ± 10.3**
Mean ref. vessel diameter	**4.97 mm**
Mean implanted stent diameter	**5.77 mm**
TASC A lesion	52 (27.9%)
TASC B lesion	60 (32.3%)
TASC C lesion	**34 (18.3%)**
TASC D lesion	**40 (21.5%)**
Calcification	
0 None	35 (18.8%)
1 Mild	73 (39.2%)
2 Moderate	43 (23.1%)
3 Severe	35 (18.8%)
Moderate & Severe	***78 (41.9%)***

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3 Rutherford classification 4-6 (23 out of 150 subjects)

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Stent oversizing mean **0.8mm**

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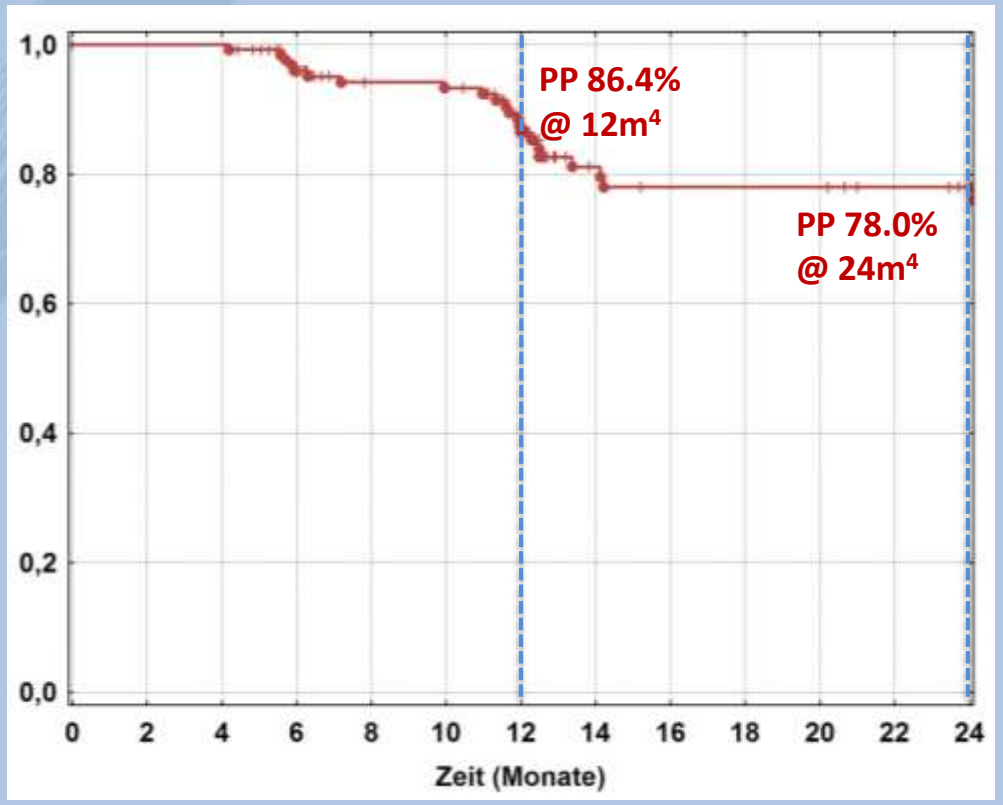
3 Rutherford classification 4-6 (23 out of 150 subjects)

Primary Patency at 12m and 24 m

Kaplan-Meier analysis



Time point (m)	0	6	12	24
Patient at Risk (n)	128	117	82	40
Survival (%)	-	95.9	86.4	78.0

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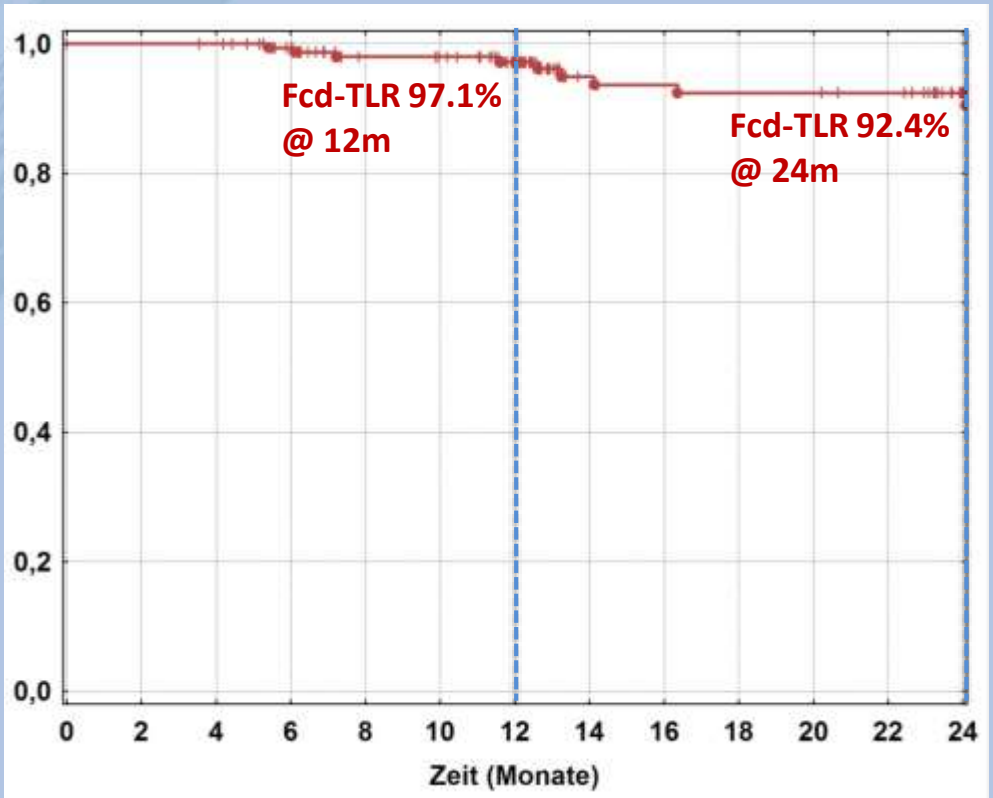
4 Imaging cohort of 127 subject, where duplex data was available

Freedom from cd-TLR at 12m & 24 m

Kaplan-Meier analysis



Time point (m)	0	6	12	24
Patient at Risk (n)	160	158	155	151
Survival (%)	-	99.3	97.1	92.4

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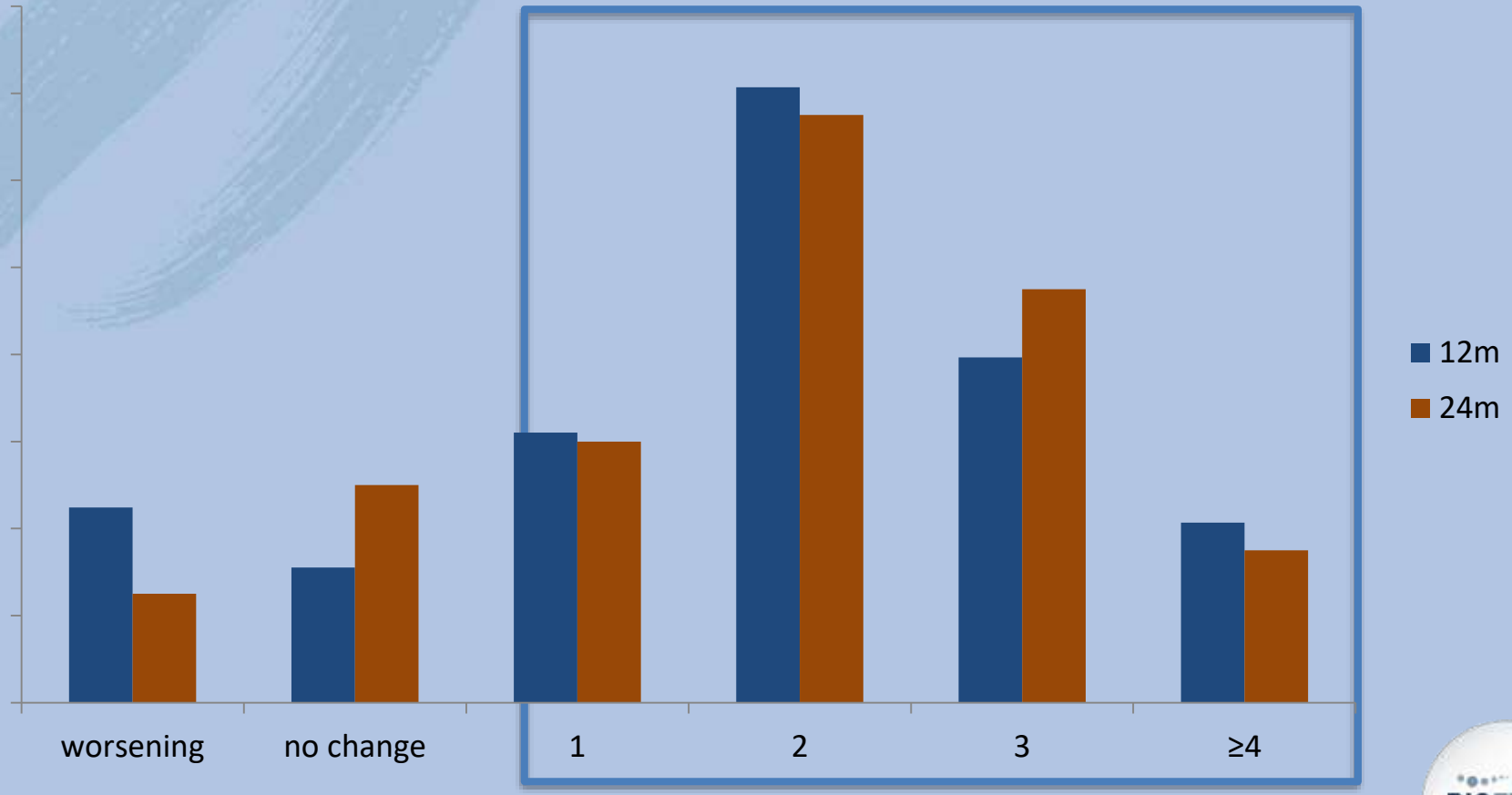
Change in Rutherford maintains at 12 & 24 months

Improvement of ≥1 Rutherford class in 81.0% of subjects after 12 months[5] and 81.3% of subjects after 24 month[6]



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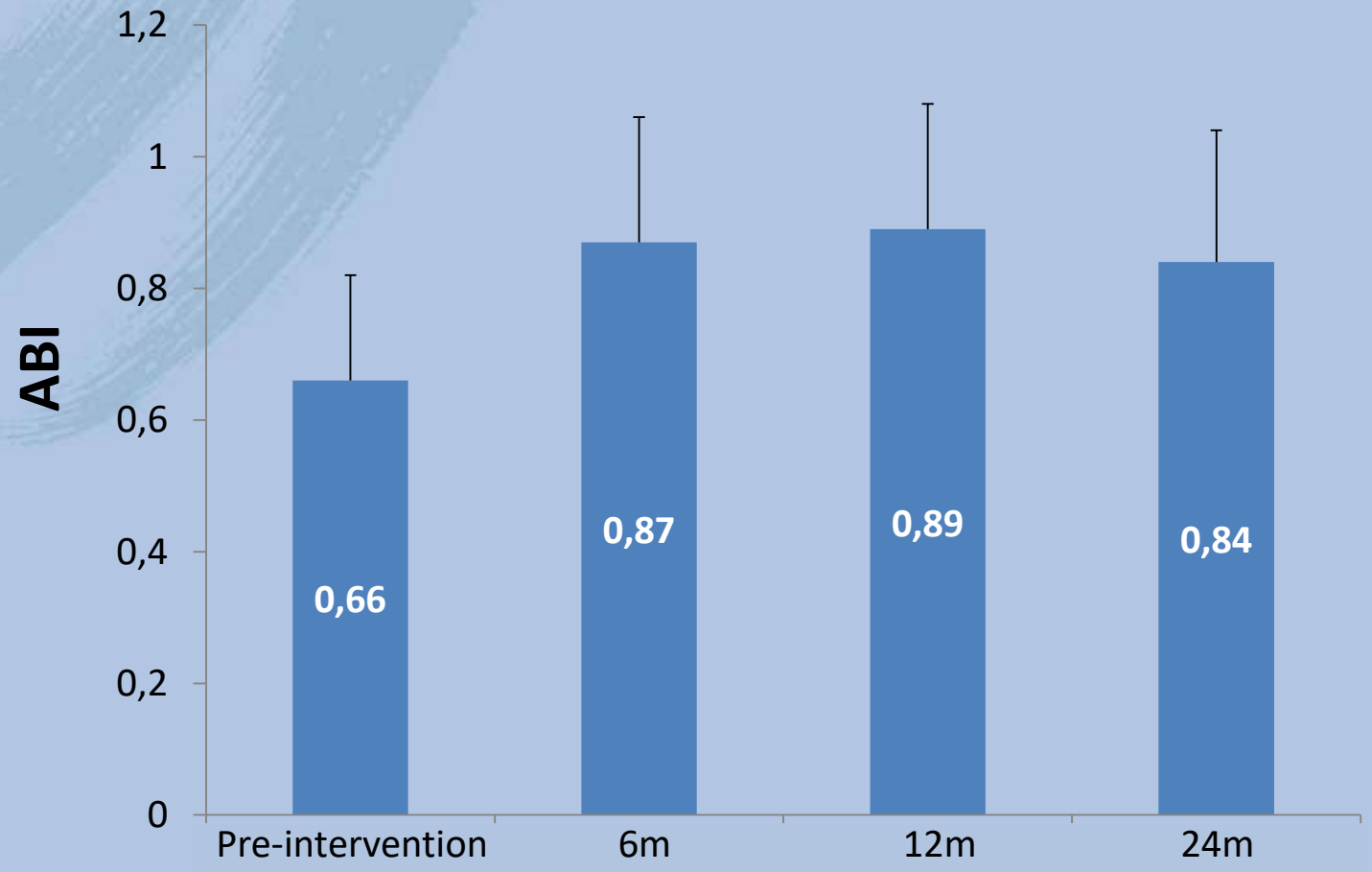
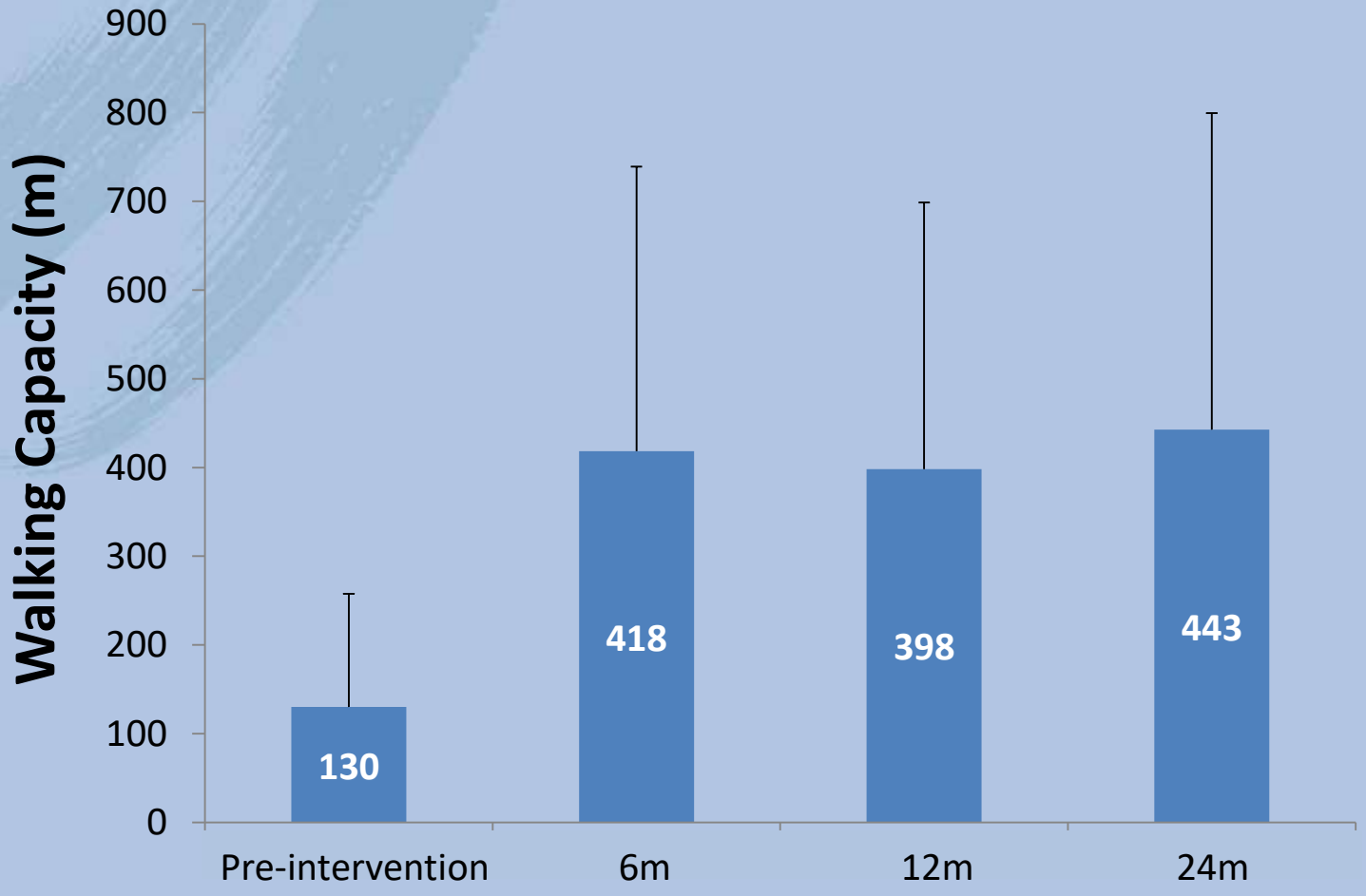
5 Data available for 116 subjects; 6 Data available for 80 subjects

Change in ABI up to 24 months



Pain Free Walking Capacity up to 24 months



Conclusions

- **The 12m Kaplan-Meier (K-M) Primary Patency of 86.4%**[6] and **Freedom from cd-TLR of 97.1%** are in line with published study data for the Pulsar stent
- **The 24m K-M Primary Patency of 78.0%**[6] and **Freedom from cd-TLR of 92.4%** of this full patient cohort are indicative of a long term positive trend
- **Clinical success of was maintained at 12 & 24m with 81.0% & 81.3%** (Improvement in Rutherford Class ≥1)
- **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

6 imaging cohort