1. LIVECASE

- 68 Jahre, männlich
- CVRF: Hypertonie, HLP
- Stadium IIb Font. links, ABI links 0.6, rechts 0,9
- Schmerzfreie Gehstrecke: 120 Meter (Laufband, 3 km/h;12 % Steigung)
- Z.n. AFS Rekanalisation rechts 9/2013
- Links: subtotale „verkalkte“ SFA Stenose bei diffus arteriosklerotisch veränderter SFA
- Procedere: Cross over PTA

PEACE Registry

Pulsar Efficacy: an All Comers Registry
12 months outcome results of 118 patients with 151 stent implantations

Michael Lichtenberg
on behalf of the PEACE Registry Investigators

Study design and participating centers

Physician initiated multicenter all comers registry investigating the patency and clinical effectiveness of the Pulsar-18 SE stent system in symptomatic SFA and APOP disease

Principal Investigators

Dr. Michael Lichtenberg, Arnsberg

Prof. Guenther Wittenberg, Bielefeld

Participating centers

Prof. Birgit Hailer, Essen

Prof. Claus Nolte-Ernsting, Muelheim

Prof. Christiane Tiefenbacher, Wesel

Dr. Jawed Arjumand, Wuppertal

148 patients with SFA /APOP lesions in 6 clinical sites in Germany

BIOTRONIK 4F Pulsar - 18 SE Stent

↓

6 month follow up, clinical success, complications

↓

12 month follow up, clinical success, complications

Drop out: 30 patients
Decline for re-evaluation: 18 patients
Withdrew of consent: 5 patients
Death: 7 patients (not procedure associated)

Accepted by Journal of endovascular therapy

Registry design

PEACE

- **Primary / secondary endpoints**

  Primary patency of the Pulsar-18 SE stent at 6 and 12 months:

  Defined as a binary duplex ultrasound ratio (PSVR) < 2,5 at the stented target lesion(s)

  No clinically driven re-intervention within the stented segment(s)

  (freedom from target lesion revascularization)

- **Inclusion criteria:**

  Rutherford 2-5

  SFA – APOP Seg. III stenosis > 50 % with clinical indication for treatment

  No lesion length restriction

  No restriction of stent numbers

- **Exclusion criteria:**

  Instent re-stenosis

  Indication for drug eluting devices

Patients and lesions characteristics

Patients	N = 118
Male	64 (54.2%)
Age (Min/Max)	71,9 ± 9,6
Hypertension	109 (92.4%)
Dyslipidemia	82 (69.5%)
Current smoker	44 (37.3%)
Diabetes mellitus	37 (31.4%)
Obesity	48 (40.7%)
Renal Insufficiency	14 (12.1%)
Rutherford 2*	36 (30.5%)
Rutherford 3	54 (45.8%)
Rutherford 4	14 (11.9%)
Rutherford 5	13 (11.0%)
Ankle – brachial index	0.63 ± 0.16
Walking capacitiy (m)	74.4 ± 50.8

* One patient without classification because of missing data

Lesion characteristics	N = 118
Lesion length (mm)	111,5 ± 71,4
TASC A lesion	28 (23.4%)
TASC B lesion	29 (24.8%)
TASC C lesion	23 (19.4%)
TASC D lesion	38 (32.2%)
Implanted Pulsar-18 SE Stents	151
Stent per patient	1.28
Stent implantation length (mm)	122.7 ± 64.5
Total occlusion (CTO)	84 (56.7%)
Popliteal Segment (I-III)	22 (18.7%)

51.6 %

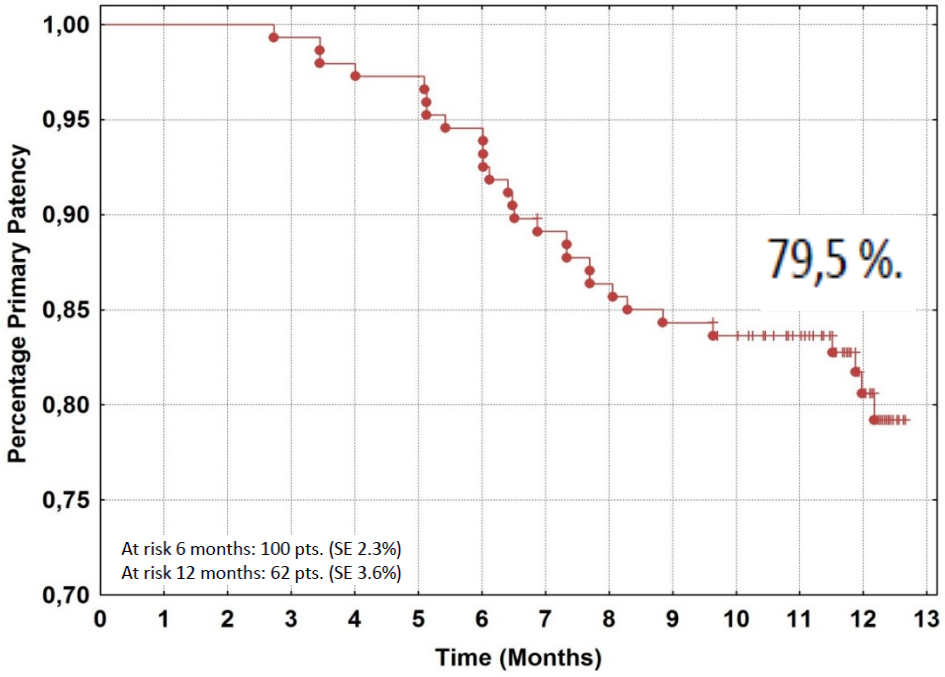
Effectiveness analysis

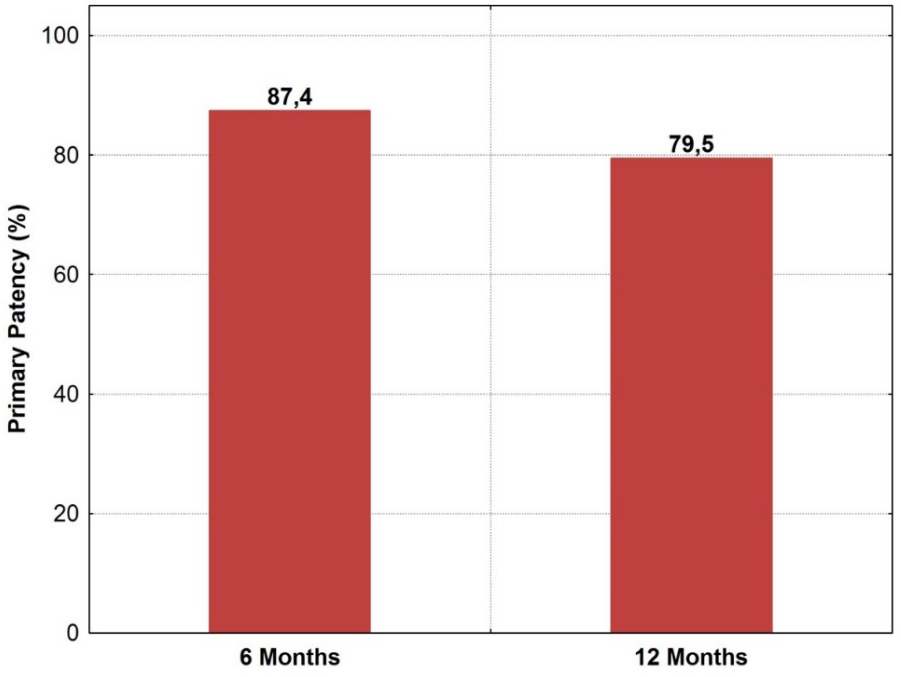
PEACE

Outcome measurement and effectiveness endpoint analysis	6 month follow-up	12 month follow-up
Overall primary stent patency	**87.4%**	**79.5%**
Freedom from target lesion revascularization (FTLR)	**93.2%** **(17/151)**	**81.0%** **(29/151)**
Diabetic patients primary patency	**86.0%** **(ns)**	**79.2%** **(ns)**
Lesion length > 100 mm primary patency	**82.9%** **(p = 0.089)**	**78.0%** **(ns)**
Primary patency after CTO recanalization	**89.2%** **(ns)**	**78.1%** **(ns)**
Popliteal segment (I – III) primary patency	**75.0%** **(p = 0.052)**	**71.4%** **(ns)**

PEACE

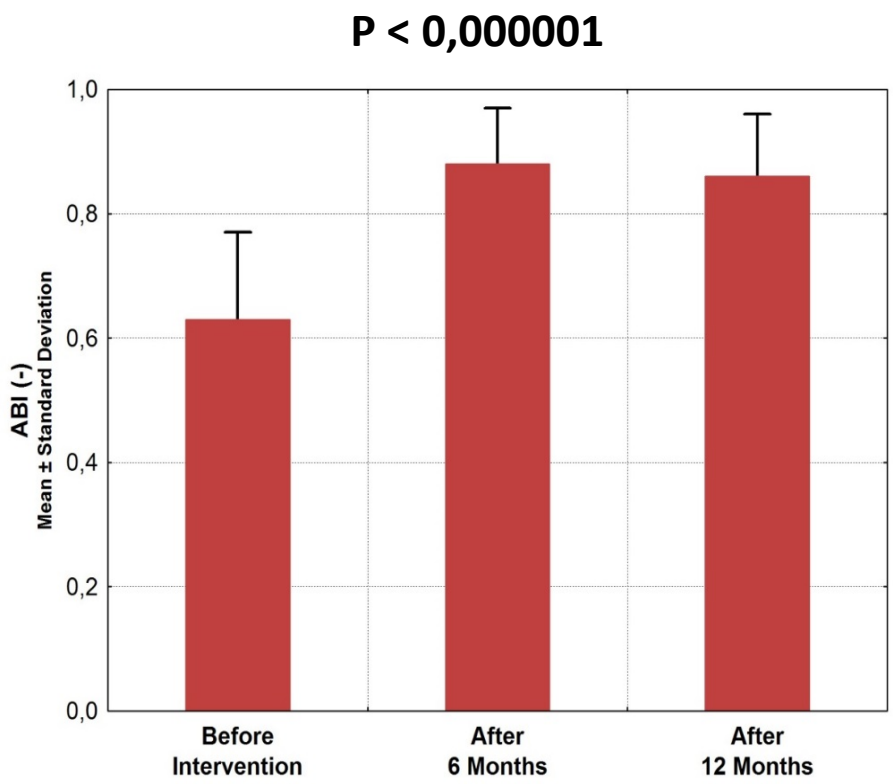
Primary patency analysis 6 and 12 months

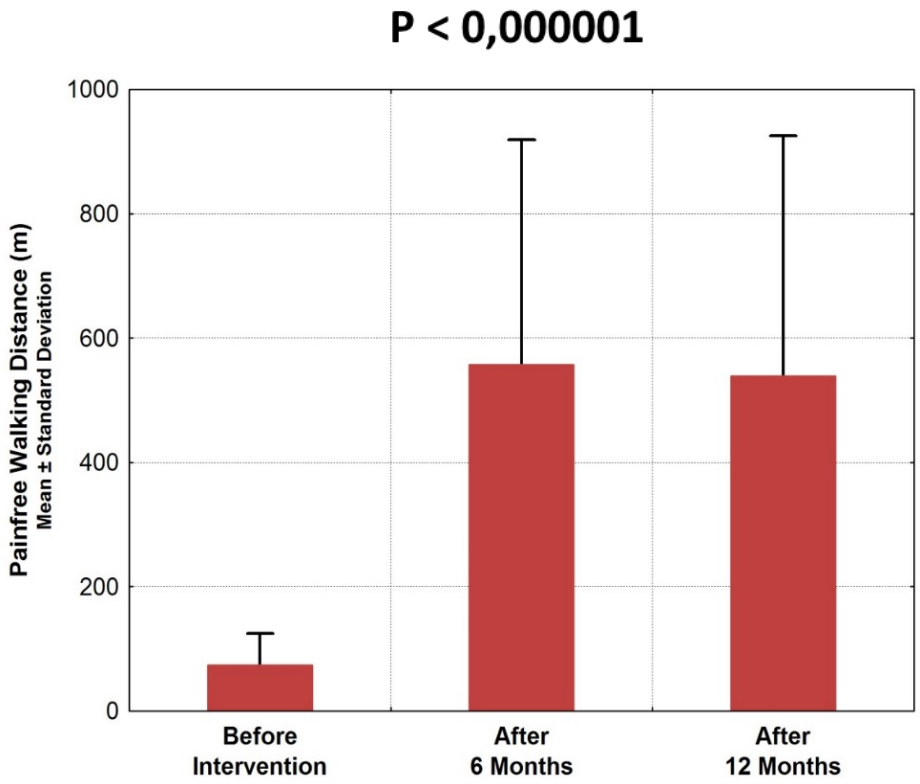




Clinical outcome

Ankle-brachial index / Painfree walking distance

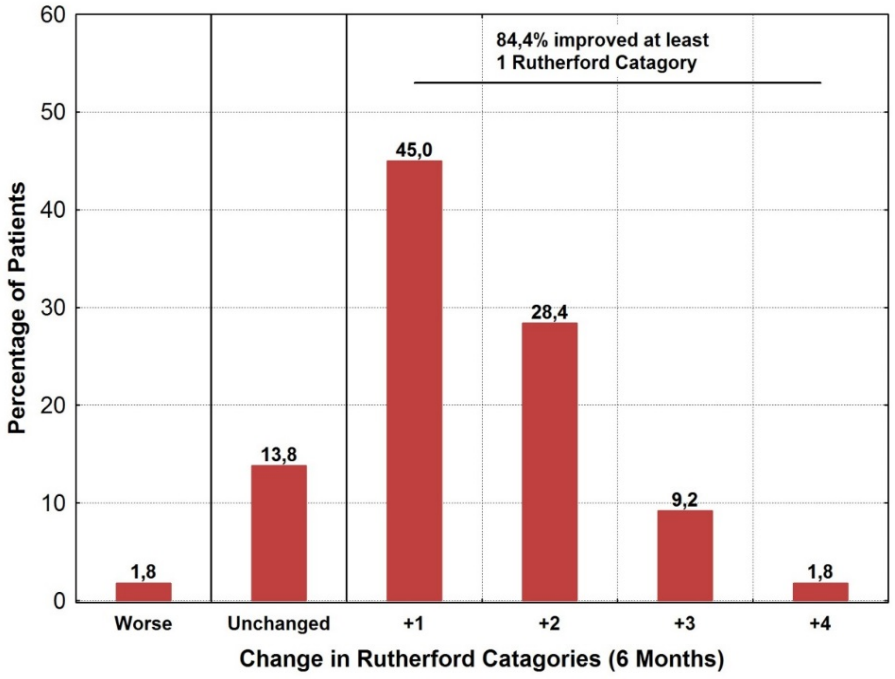


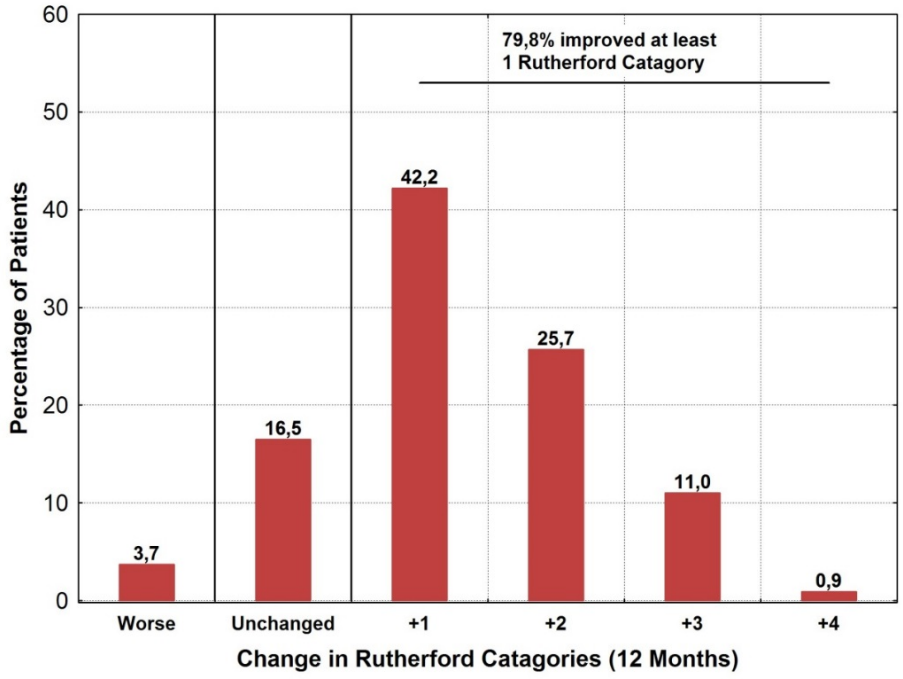


Clinical outcome

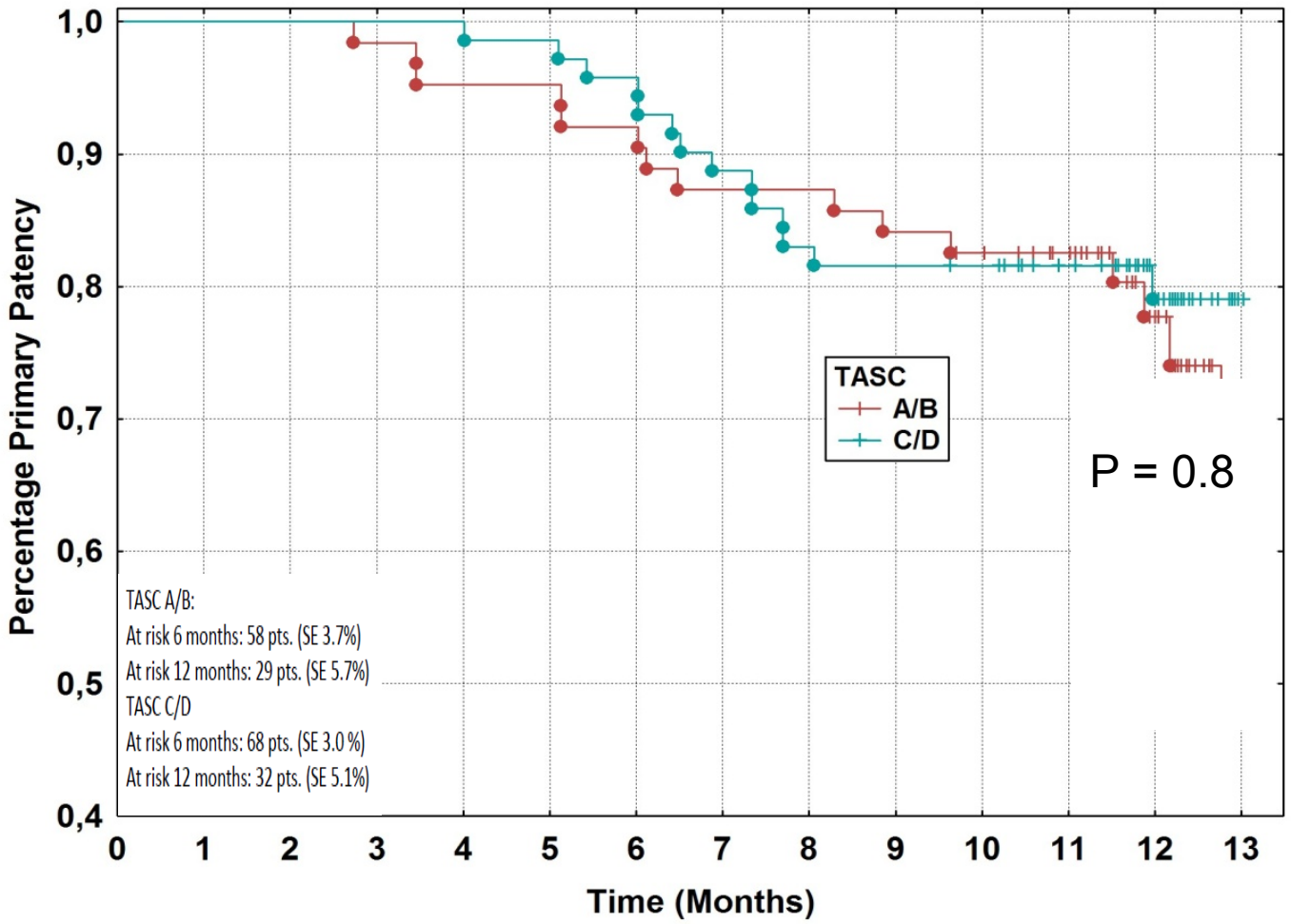
Rutherford category

P < 0,000001

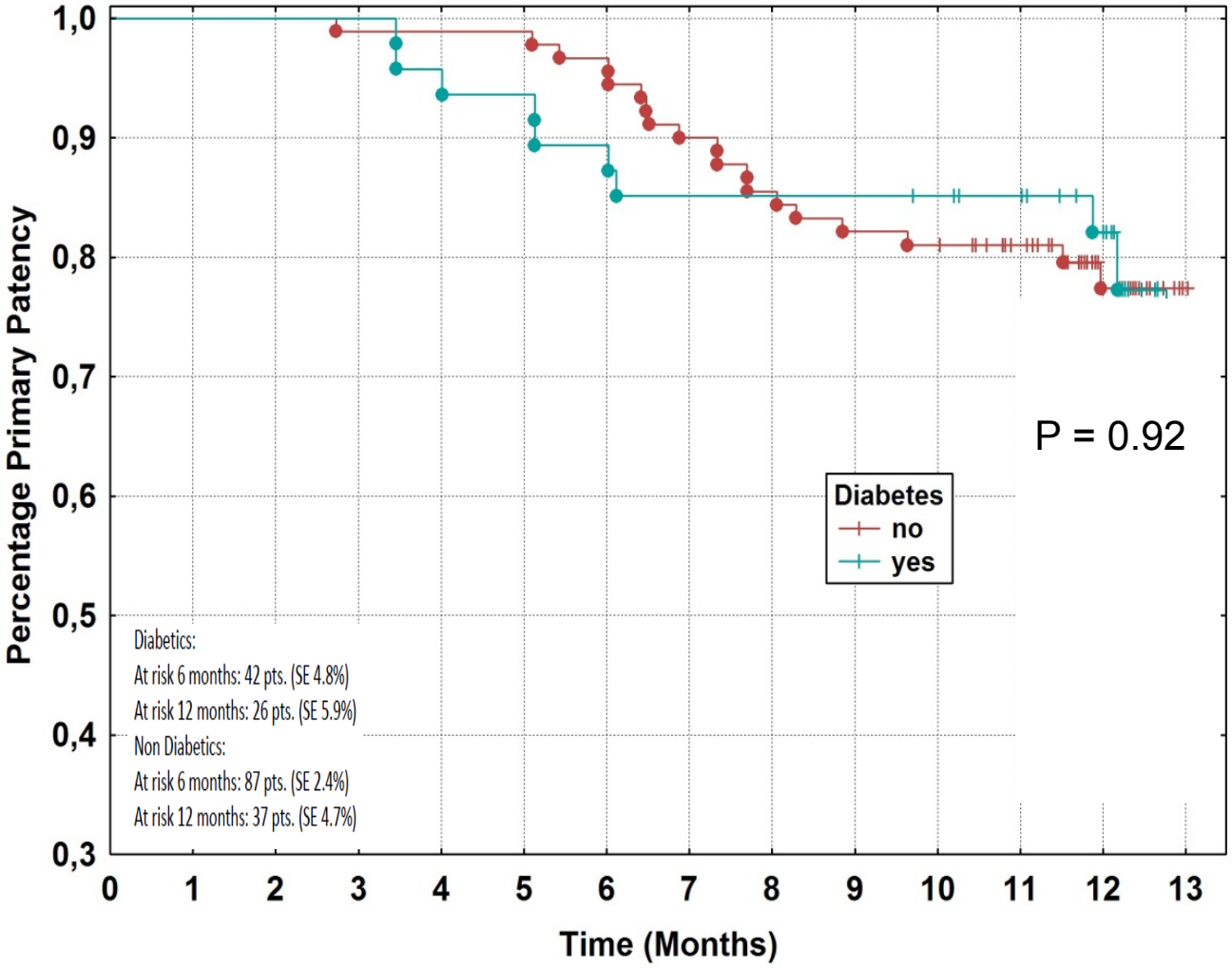




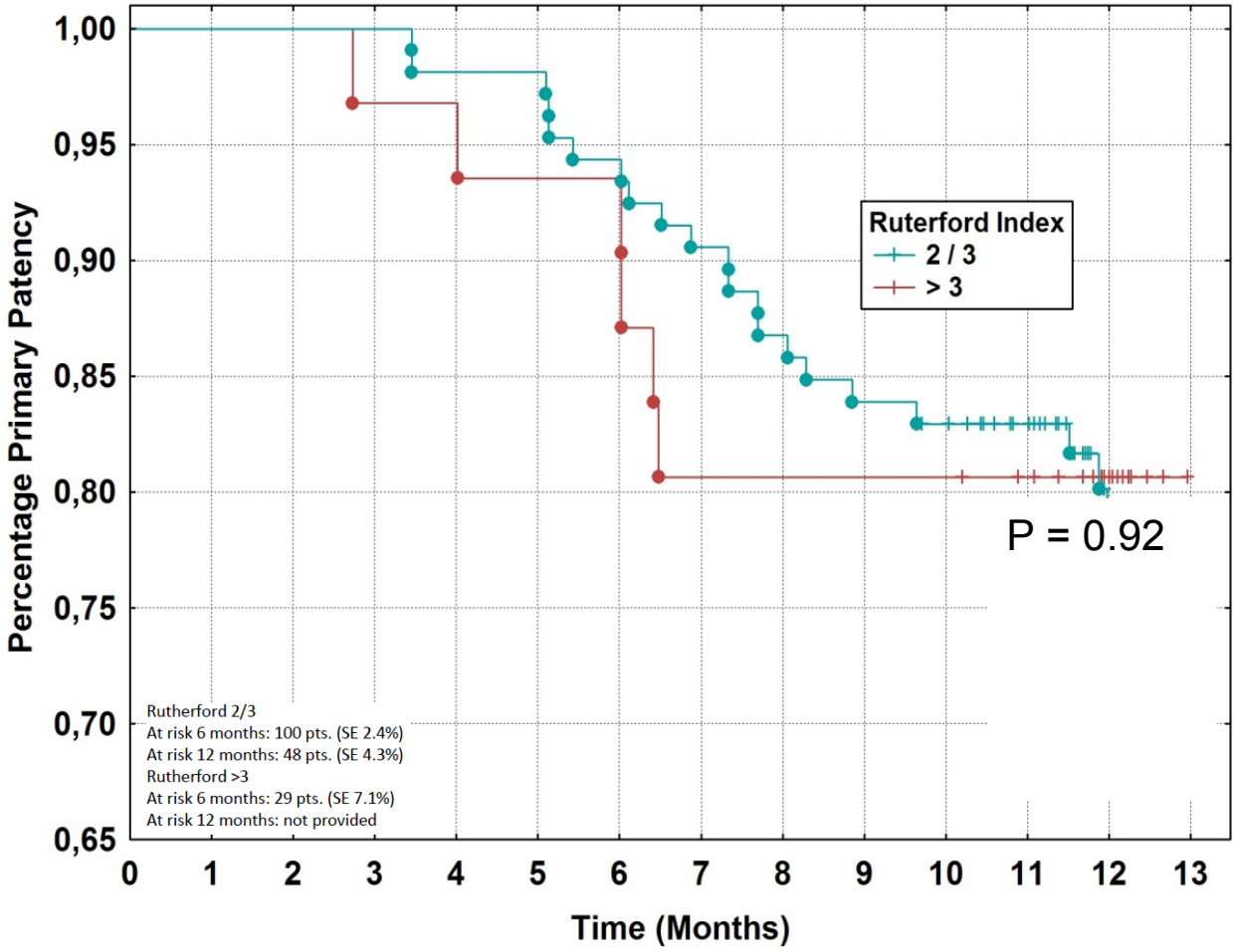
Subgroup lesion length



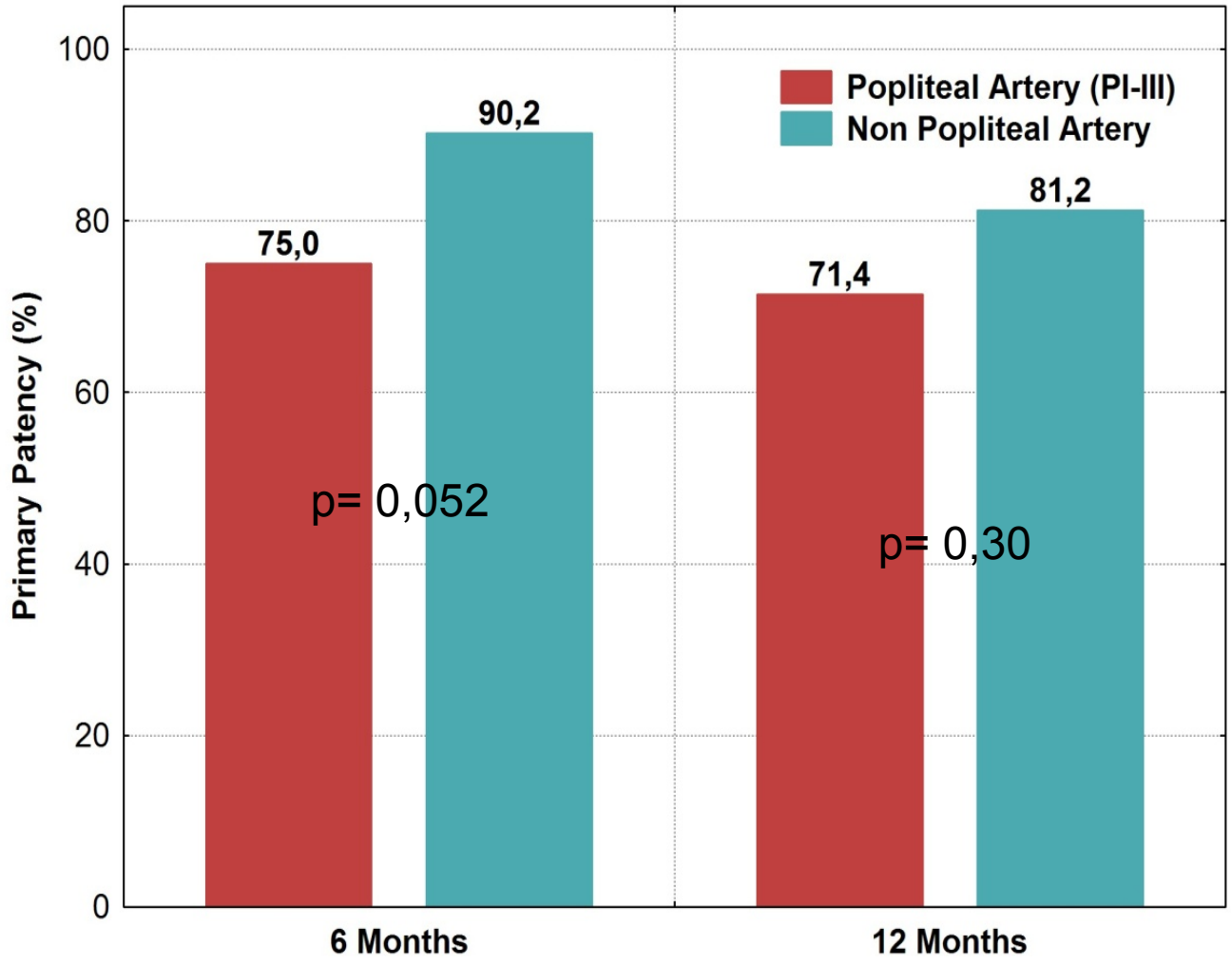
Subgroup Diabetes



Subgroup Rutherford category



Popliteal involvement (28/151 stents)



Conclusions

- **Safe nitinol stent device for even long SFA lesions**
  - Mean LL 111,5 mm, 51 % TASC C and D lesions
  - Overall primary patency 79,5 % after 12 months
  - FTLR 81 % after 12 months

- **Acceptable primary patency for popliteal interventions**
  - 71,4 % primary patency after 12 months

- Diabetes has no negative impact on this device
- CTO recanalization is no predictor for significant restenosis

Enough evidence > 12 months ?
Spot stenting, DEB, Atherectomy ?

Study	Stent	N	Mean Lesion Length, cm	12-Month PP, %	Fracture Rate, %
Astron 2009[14]	Astron ~~Pulsar~~	32	8.4	65.6	NR
FAST 2007[11]	Luminexx 3	101	4.5	68.3	12.0
Durability 2009[4]	Protegé	151	9.6	72.2	8.1
Complete SE 2012[15]	Complete SE	175	6.1	73.1	4.6
FACT 2008[16]	Conformexx	60	5.9	76.7	NR
Resilient 2010[5]	Life Stent	134	7.1	81.3	3.1
ZILVER-PTX-RCT 2011[17]	Zilver PTX	241	6.6	83.1	0.9
Supera 500 2013[12]	Supera	490	12.6	83.3	0.0
Misago 2 2012[18]	Misago	744	6.4	87.6	3.1
Current study 2013	EPIC	100	7.0	85.1	0.0

SFA: superficial femoral artery, PP: primary patency, NR: not reported.

Martin Werner , JEVT 12/2013

4EVER	AstronPulsar/Pulsar-18	120	4,3/10,8	85,2/73,4	4,2
PEACE I	Pulsar-18	118	11,1	79,5	NR
TASC D Trial	Pulsar-18	22	31,5	77,0	NR

Bosiers et al. Results of the 4-Ever Trial. J Endovasc Ther 2013;20:746 - 756

Lichtenberg et al. : PEACE I all-comers registry: Patency evaluation after implantation of the Pulsar - 18 self - expanding nitinol stent in the superficial femoral and popliteal arteries. Journal of Endovascular Therapy (accepted)

Lichtenberg et al.: Superficial femoral artey TASC D Registry: Twelve-month effectiveness analysis of the Pulsar-18 SE nitinol stent in patients with chronic limb ischemia. J Cardiovasc Surg 2013;54:433-9

BIOFLEX PEACE Registry

All comers Registry evaluating the appropriate recanalisation in SFA occlusion
Standard of care evaluation for SFA recanalization

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Dr. Torsten Fuss (Suhl)

Dr. Ralf Langhoff (Berlin)

Prof. Dr. Sigrid Nikol (Hamburg)

Prof. Dr. Claus Nolte-Ernsting (Mülheim)

Prof. Dr. Andreas Saleh (München)

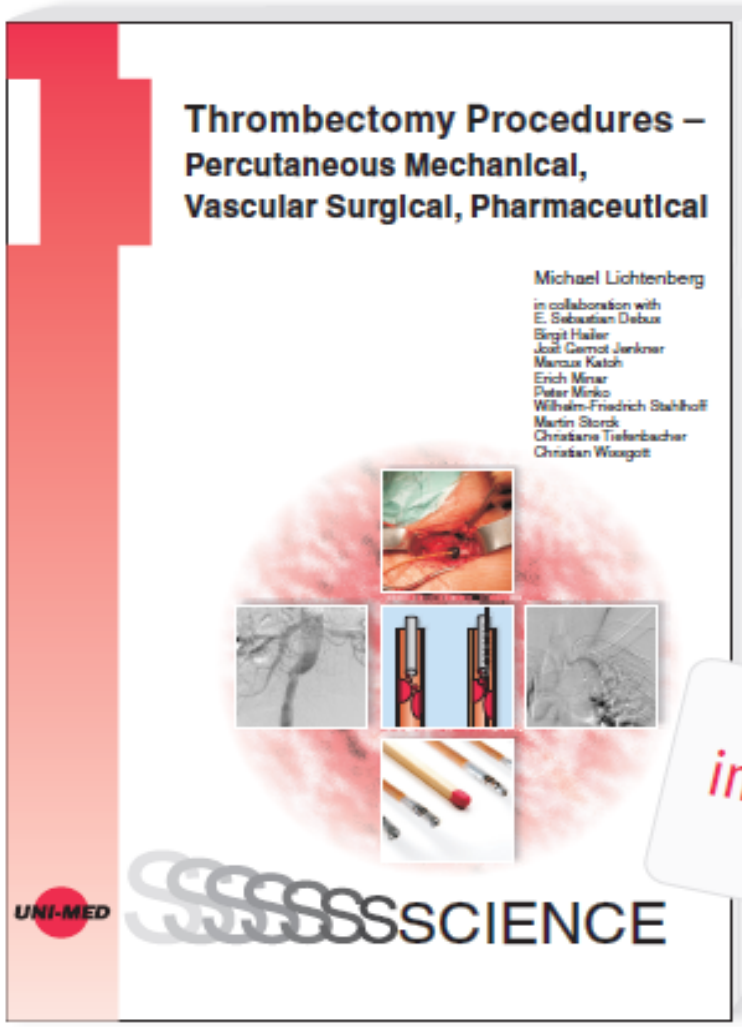
PD Dr. med. Ulrich Sunderdiek (Osnabrück)

Prof. Dr. Birgit Hailer (Essen)

500 patients with PAOD Rutherford 2 – 5 with SFA and APOP lesions
Primary Stent PTA plus/minus DEB postdilatation vs atherectomy plus Stent PTA plus /minus DEB

Objective: Evaluation of safety and performance of Pulsar-18 in treatment of subjects with atherosclerotic disease
Design: Prospective, non-randomized, multi-centre All Comers Registry with follow-up investigations at 6, 12 and 24 months
Indication: Subjects with infrainguinal atherosclerotic disease eligible for stent implantation

THANK YOU FOR YOUR ATTENTION













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