

Interventional Treatment of the Common Femoral Artery – update on the PESTO Trial

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Disclosure

Speaker name: Thomas Zeller

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

Background PESTO – CFA Study

Surgical Endarterectomy

- *Technical success rate:* 90% to 98%
- *Primary Patency at 1 year:* up to 95%

But:

- *Mortality at 30 days:* up to 3.4%

**....endarterectomy is not an as „benign“
procedure as previously believed.....**

- Wound infection (deep) up to 2%
- Wound dehiscence up to 0.8%
- *Minor complications:* up to 20%
 - Incl. seromas, wound infection (superficial)

Wieker CM, et al. J Vasc Surg 2016
Nguyen BN, et al. J Vasc Surg 2015
Kang JL, et al., J Vasc Surg 2008

TECCO Trial:

Local complications: 26% vs. 6.4%

	<i>Surgery (N=61)</i>	<i>Stenting (N=56)</i>
Hematoma	3 (5)	0 (0)
Thrombosis	0 (0)	1 (1.8)
<u>Lymphorrhea</u>	2 (3.2)	0 (0)
Delayed wound healing	10 (16.4)	0 (0)
False aneurysm	0 (0)	0 (0)
<u>Arteriovenous fistula</u>	0 (0)	0 (0)
<u>Paresthesia</u>	4 (6.5)	0 (0)
Local infection	3 (5)	1 (1.8)
Vascular perforation	0 (0)	1 (1.8)



PESTO-CFA Study

Percutaneous Intervention versus Surgery in the Treatment of
Common Femoral Artery Lesions

A prospective, multi-centre, randomised study

PESTO-CFA Study

Percutaneous Intervention versus Surgery in the Treatment of Common Femoral Artery Lesions
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Title:	PESTO-CFA
Aim:	Non inferiority study comparing DCB based endovascular therapy and surgical therapy in the treatment of atherosclerotic CFA disease
Study design:	Prospective, multicenter, randomized, controlled study , 1:1 randomization Follow-up at 6 months, 1, 2 and 5 years
Patient recruitment:	320 patients. Study duration 6.5 years (recruitment time 18 months , follow-up 5 years)

Clinical Reality: Enrollment may last 4 years

PESTO-CFA Primary Endpoints

Primary Efficacy Endpoint

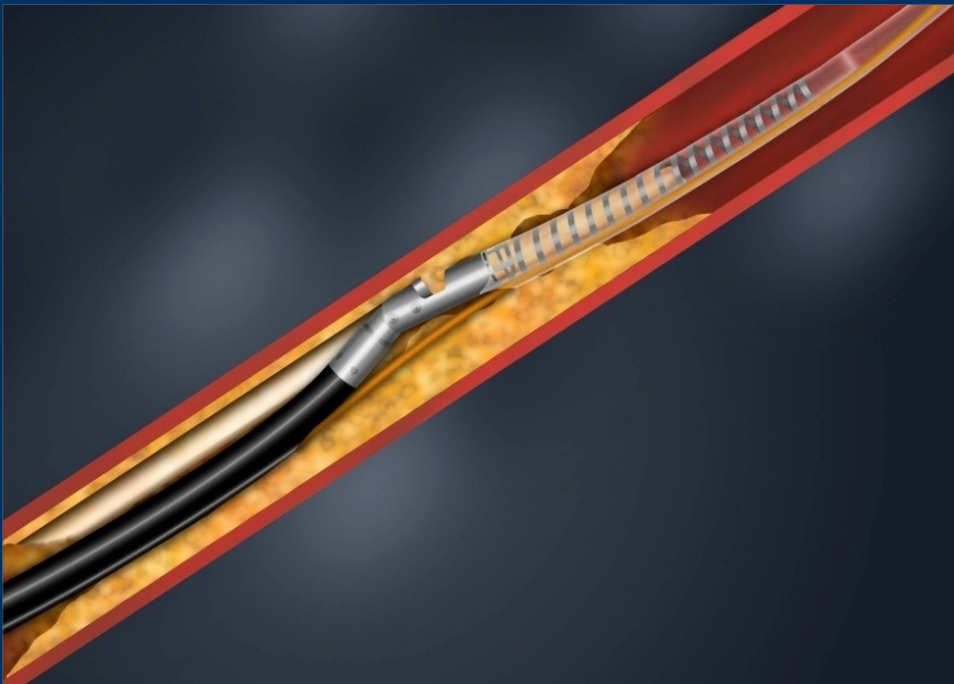
Primary patency without reintervention at 1 year based on duplex ultrasound PSVR 2.4

Primary Safety Endpoint

Combined 30-day Endpoint:

- Peri-interventional/-operative complications including death, MI, major-/minor amputation of target limb
- Access site complications
- Thromboembolic events
- Index-procedure related infections

Endovascular Treatment



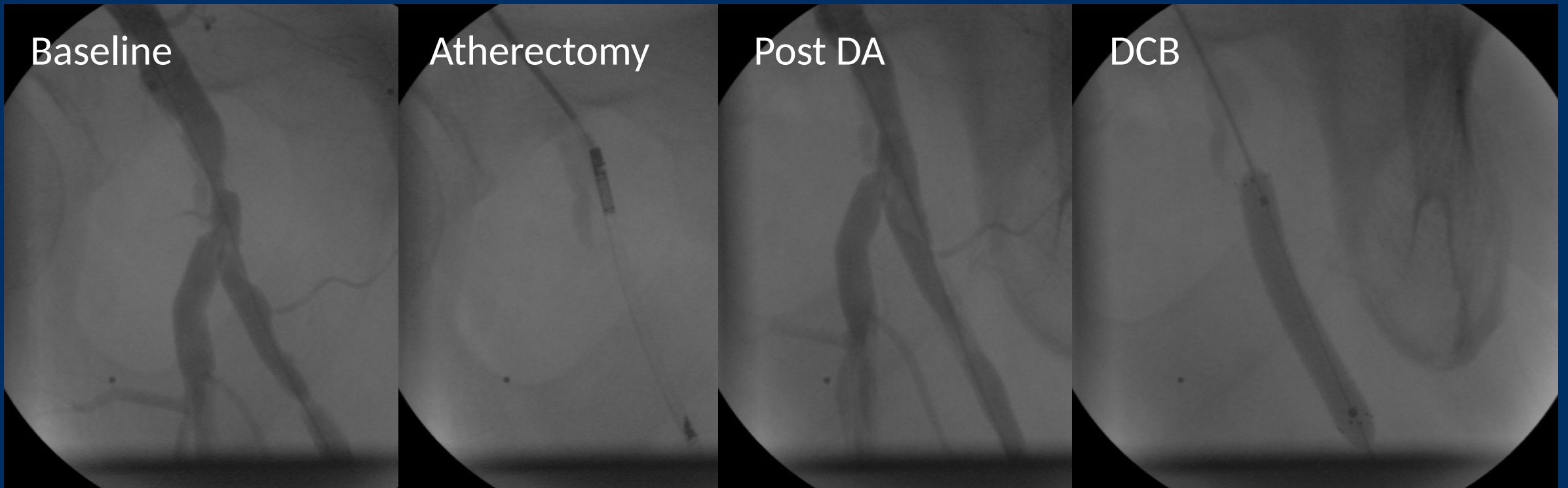
SilverHawk™ / TurboHawk™ / HawkOne™
peripheral plaque excision systems

+

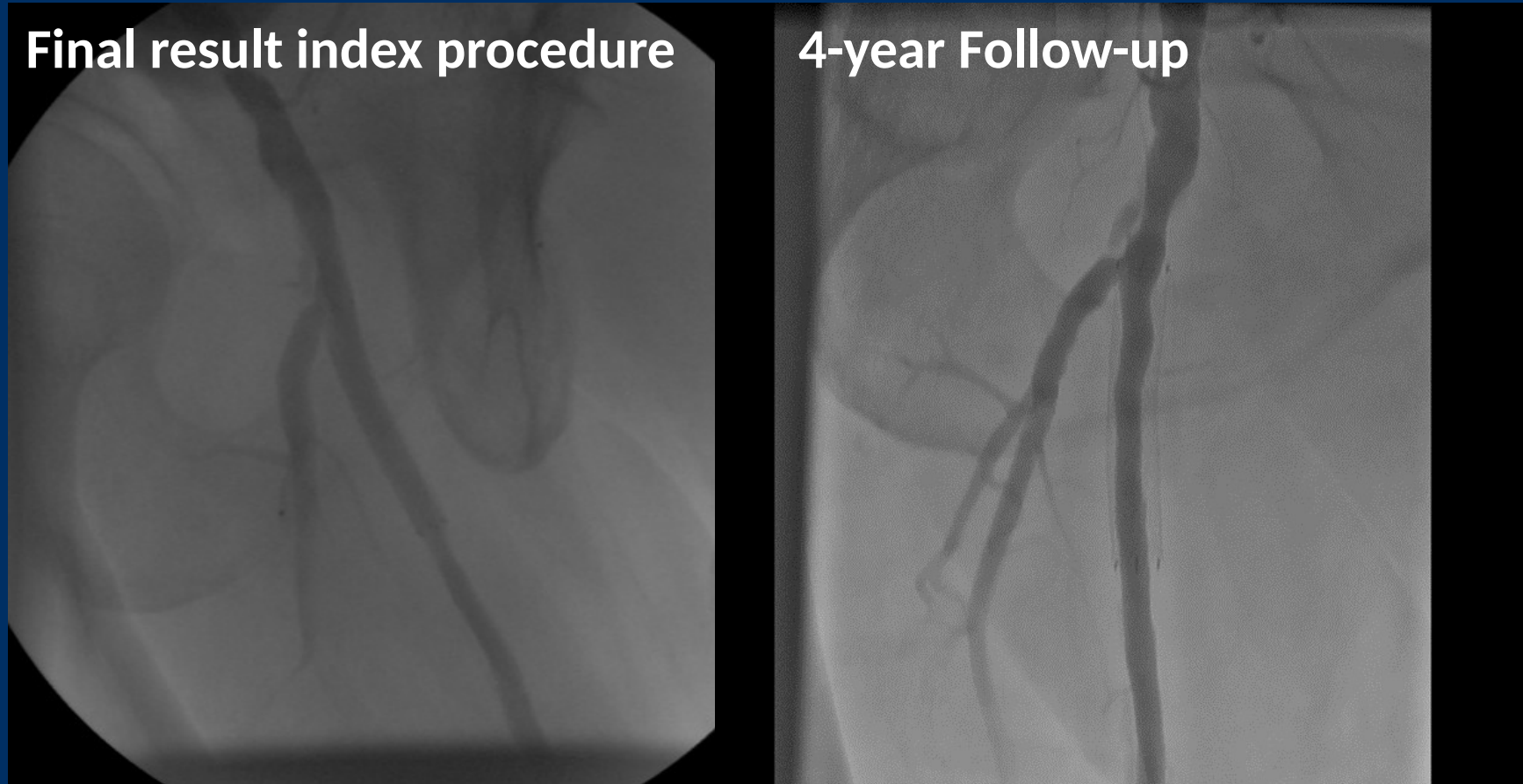


IN.PACT Admiral™ DCB

Case Example: Right CFA Stenosis



Case Example: Acute- and Long-term Result



CFA-Atherectomy Bad Krozingen

BASELINE CHARACTERISTICS	n=263 (%)
Age, yrs	70 ± 9
Male sex	180 (68.4)
Hypertension	238 (90.5)
Diabetes mellitus	91 (34.6)
Hyperlipidemia	237 (90.1)
Smoker	180 (68.5)
Coronary heart disease	132 (50.2)
Myocardial infarction	48 (18.3)
Stroke	32 (12.2)
Cerebrovascular disease	69 (26.2)
COPD	30 (11.4)
Renal failure*	64 (24.4)
Claudication	224 (85.2)
Critical limb ischemia	39 (14.8)

COPD – chronic obstructive pulmonary disease

* defined as clearance < 60 ml/min



Böhme T, Romano L, Macharzina RR, Noory E, Beschorner U, Jacques B, Bürgelin K, Flügel PC, Zeller T, Rastan A. Midterm Results of Directional Atherectomy for the Treatment of Atherosclerotic Common Femoral Artery Disease. EuroIntervention. 2020 Mar 17. pii: EIJ-D-19-00693. doi: 10.4244/EIJ-D-19-00693. [Epub ahead of print].



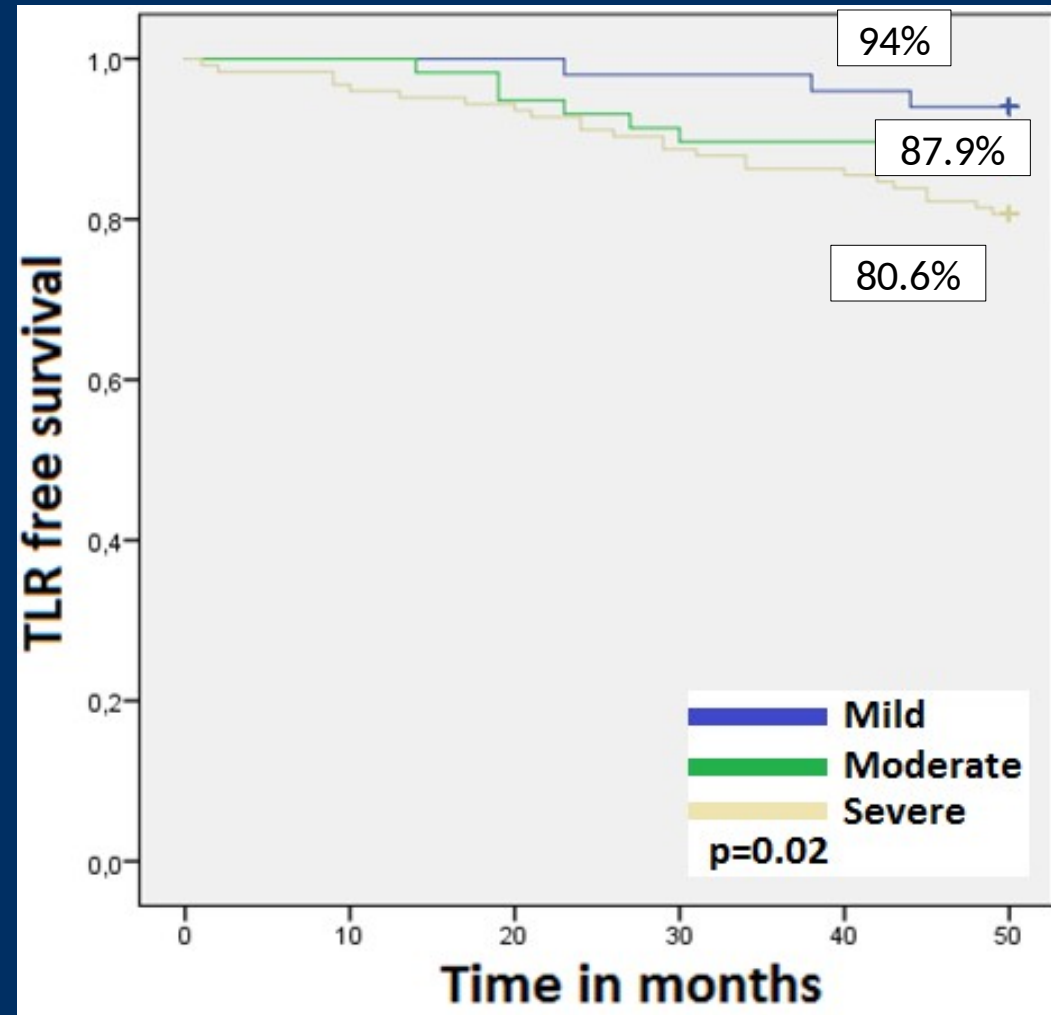
CFA-Atherectomy Bad Krozingen

RESULTS AT FU (29.8 ±20months)	
CD-TLR	37 (15%)
- Endovascular	20 (8.1%)
- Surgery (Aneurysm)	17 (6.9%)
Rutherford-Becker Class	
- Baseline	3.1 (±0.7)
- Follow-up	2.0 (±0.6; P<0.001)
ABI	
- Baseline	0.46 (±0.23)
- Follow-up	0.79 (±0.21, P<0.001)

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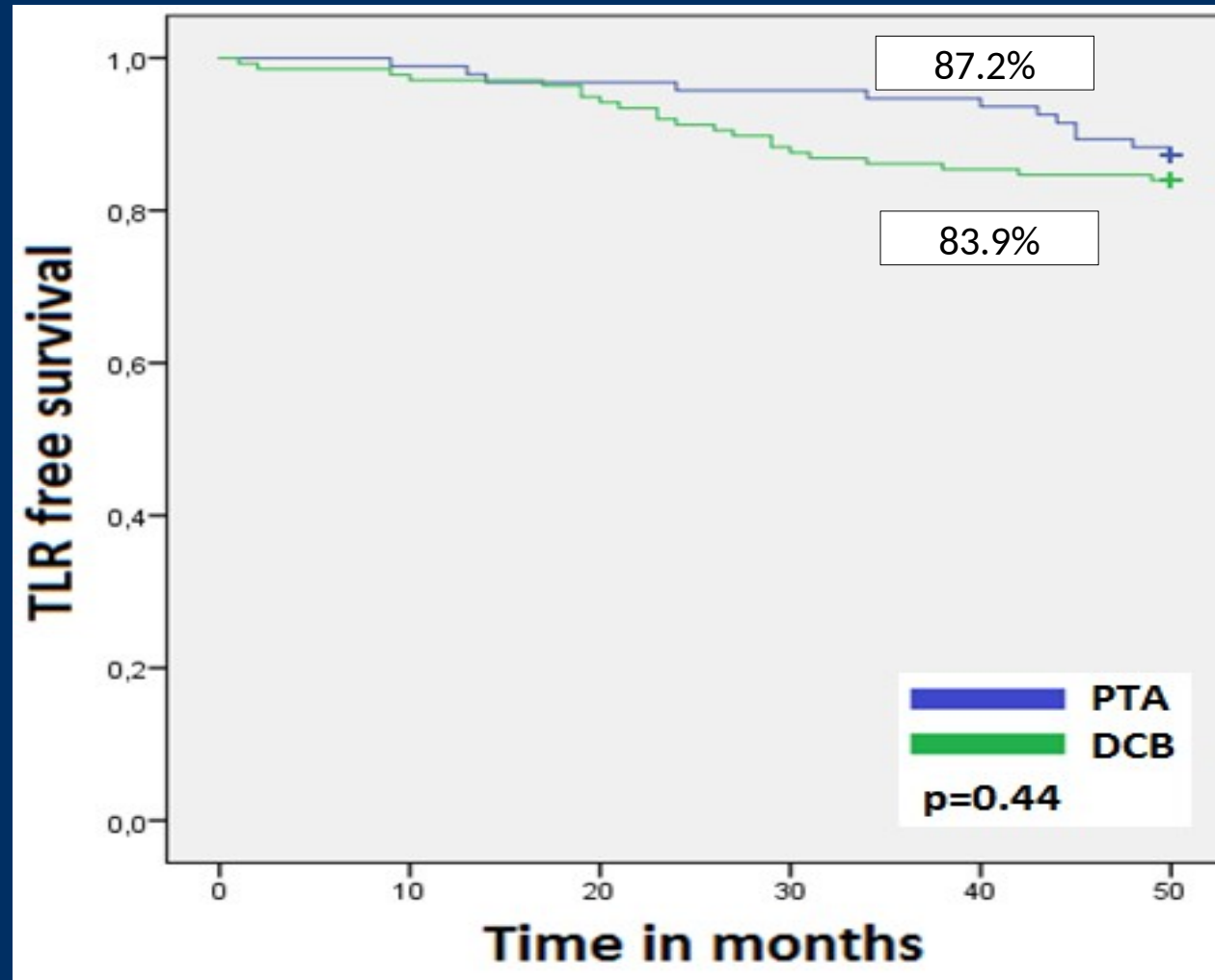
TLR-Free Survival: Target lesion calcification



Kaplan-Meier analysis of survival free from TLR depending on the degree of calcification
TLR - target lesion revascularization



TLR-Free Survival: POBA versus DCB



Kaplan-Meier analysis of survival free from TLR for patients treated with POBA and DCB following atherectomy
TLR – target lesion revascularization



PESTO-CFA Study

Enrollment Status January 11th 2021

PZ	PI	# Pat. random.	# Pat. enrolled	# Pat. ongoing	With-drawn	Death
001- Bad Krozingen	Prof. Dr. Zeller	50	45	33	4	3
002- Arnsberg	Dr. Lichtenberg	1	1	1	0	0
003- Bruchsal / Karlsruhe	Prof. Dr. Andrassy/ Prof. Dr. Storck	1	1	1	0	0
004- Karlsbad	Prof. Dr. Blessing	4	4	4	0	0
005- Münster	Prof. Dr. Torsello	8	8	8	0	0
006- LMU München	Dr. Czihal	N/A	N/A	N/A	N/A	N/A
006- Graz -A	Prof. Dr. Brodmann	N/A	N/A	N/A	N/A	N/A
07- Leipzig	Prof. Dr. Scheinert	26	24	22	1	1
08- TUM München	Prof. Eckstein	N/A	N/A	N/A	N/A	N/A
008- Radebeul	Dr. Fuß	0	0	0	0	0
009- Immenstadt	Prof. Dr. Ito	1	1	1	0	0
010- Sonneberg	Dr. Thieme	0	0	0	0	0
(011- Rosenheim)	Dr. Tepe	0	0	0	0	0
012- Aarau -CH	Dr. Rastan	0	0	0	0	0
		91	84	70	5	4

Interventional Treatment of the Common Femoral Artery – update on the PESTO Trial

- First multi-center trial to investigate the performance of endovascular treatment without a primary stent strategy vs. The „gold standard“ open surgical reconstruction of common femoral artery disease
- Investigator initiated study with support of an unrestricted grant by Medtronic
- Enrollment delayed, far behind the initial estimation
 - Referring physicians and patients are „preconditioned“ to a given revascularization strategy
 - COVID pandemic

