

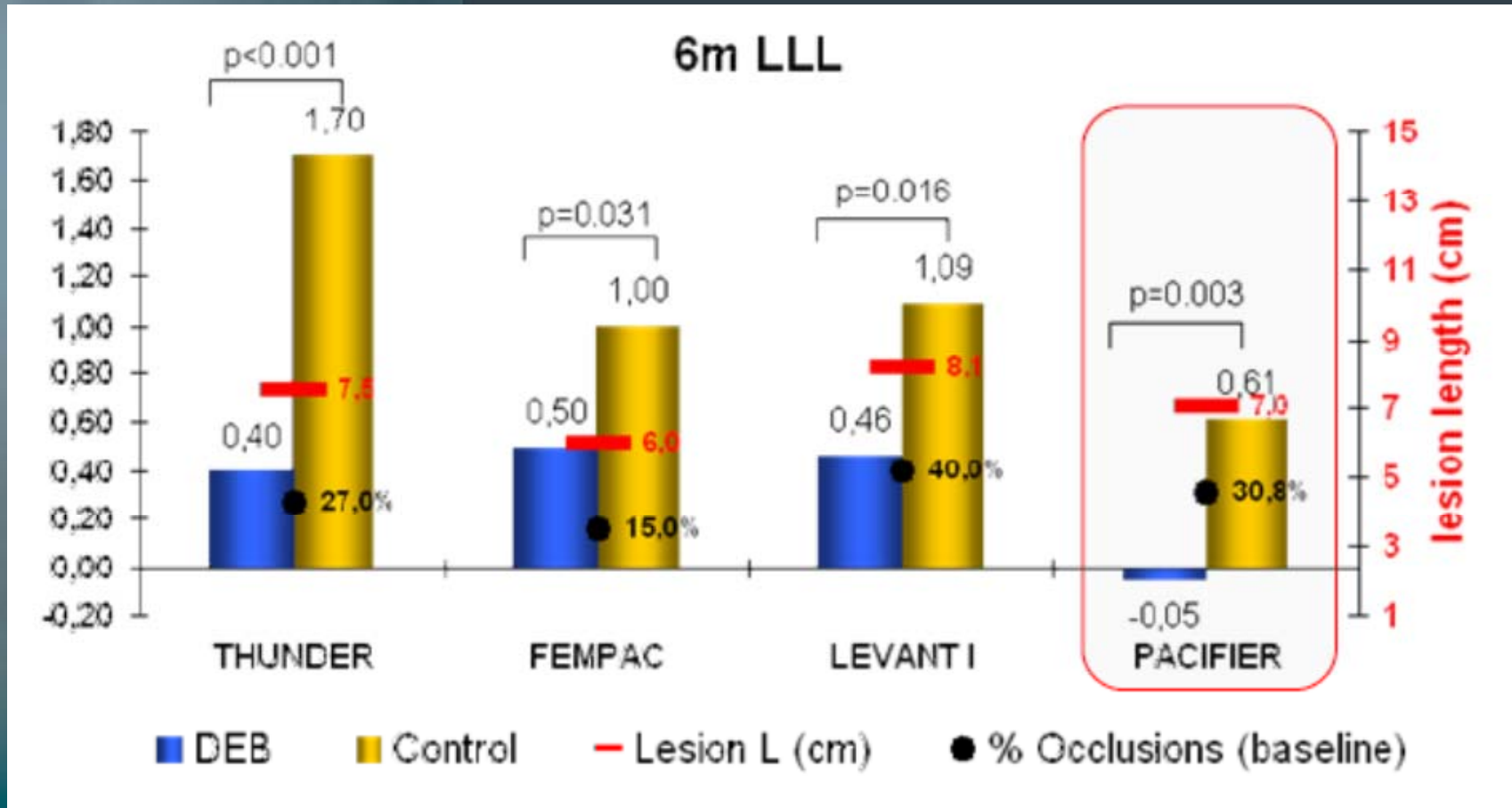
Drug-Eluting Balloon will be most Promising in Infrainguinal Arterial Disease



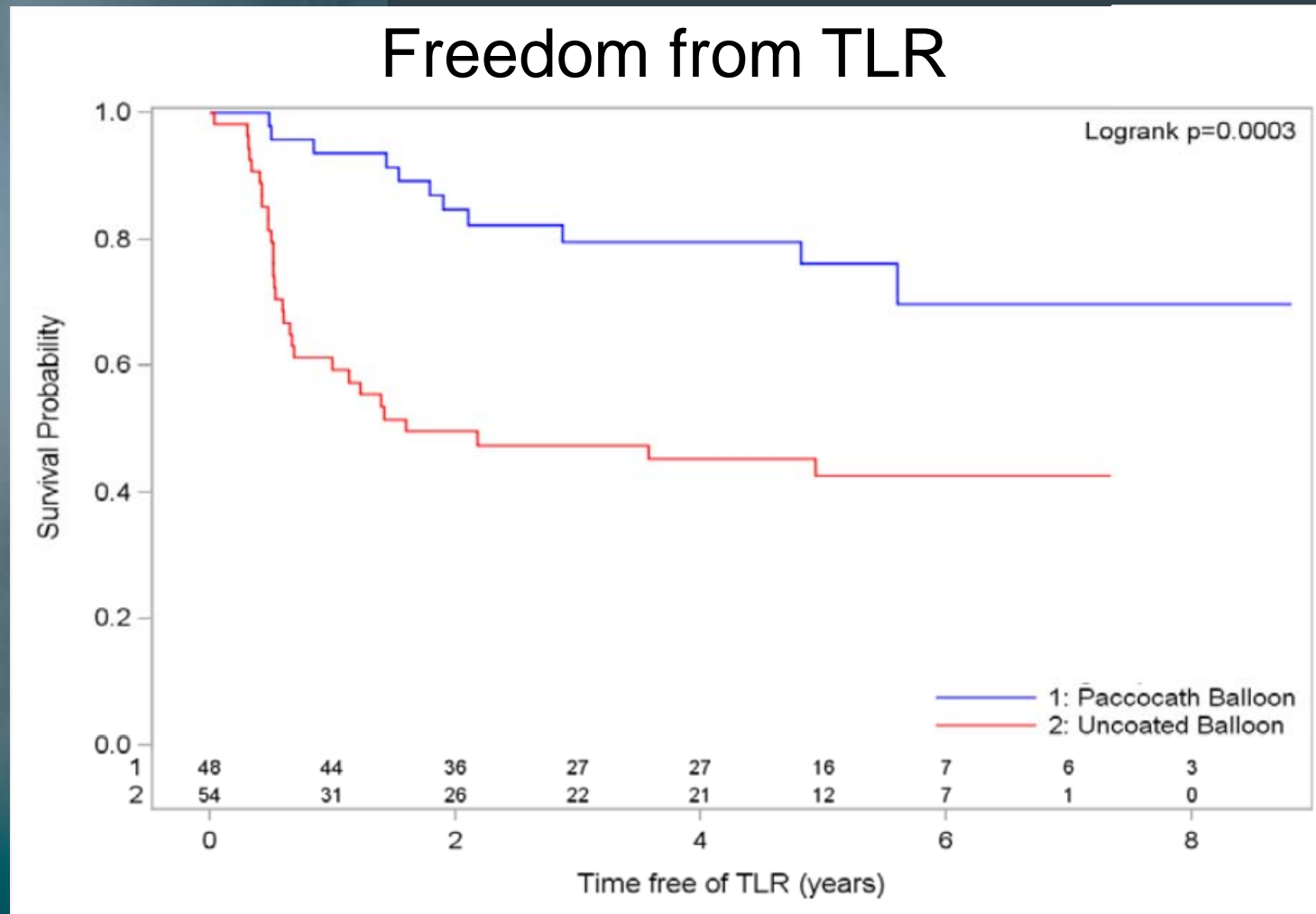
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Angiology, Cardiology and Vascular Surgery
Park Hospital Leipzig, Germany

Randomized Trials DEB vs. Conventional Balloon



THUNDER-Long-Term Results (5 Years)



Tepe, LINC 2012

Drug-Eluting Devices CE-marked in Europe

MEDRAD

Cotavance
CE approved

 Eurocor

Freeway
CE approved

 Aachen
Resonance

Elutax
SFA, BTK, AVF, Renal
CE approved

MEDTRONIC

IN.PACT ADMIRAL *IN.PACT PACIFIC* *IN.PACT AMPHIRION*

IN.PACT Range

Admiral 0.035" SFA

Pacific 0.018" SFA/BTK

Amphirion 0.014" BTK

All CE approved

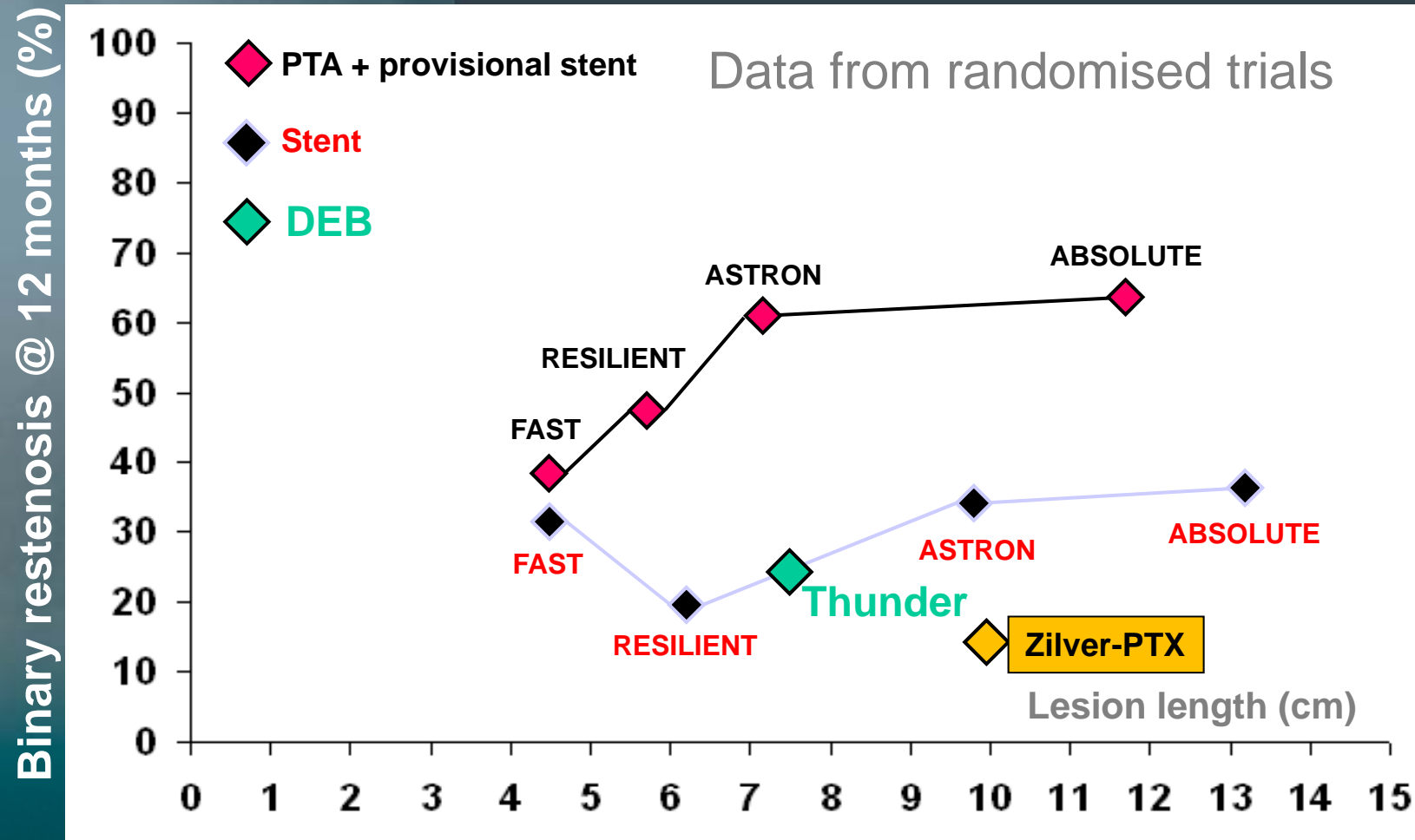
DEB:

DES:

Zilver-PTX (COOK)

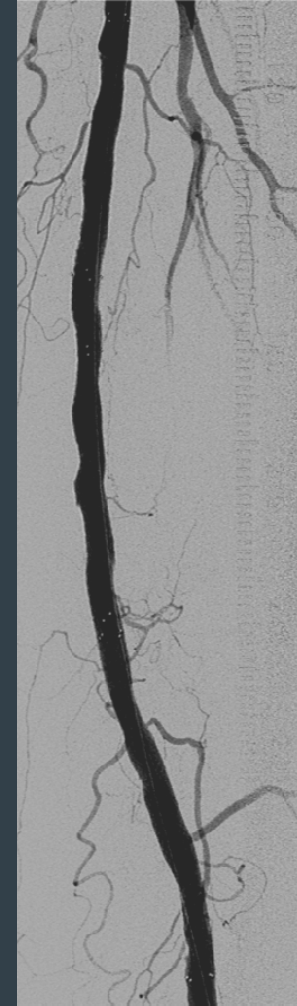
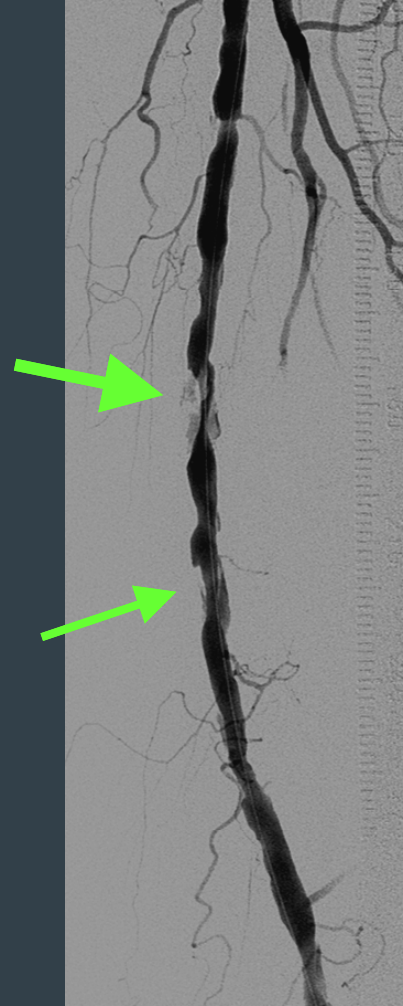
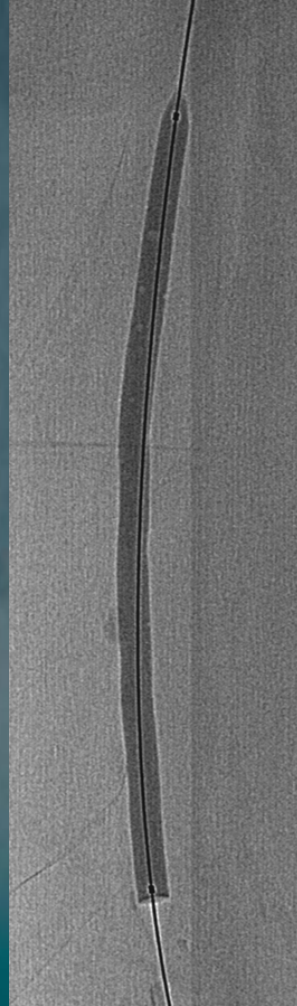
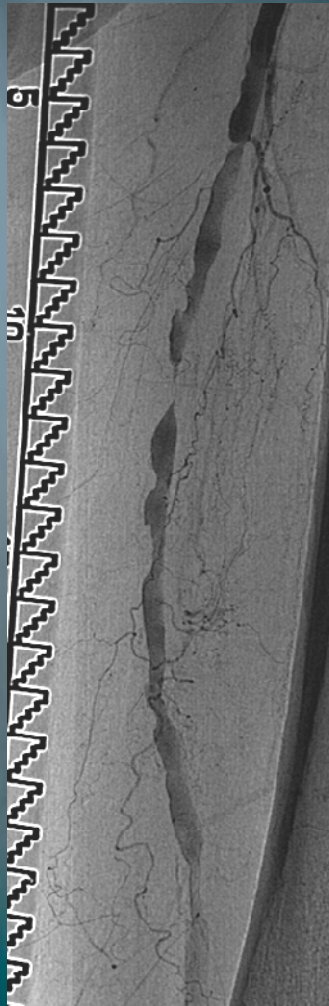
RCTs POBA vs. Stenting SFA

12 months restenosis vs. lesion length



Modified from Prof. Schillinger, EURO-PCR 2008

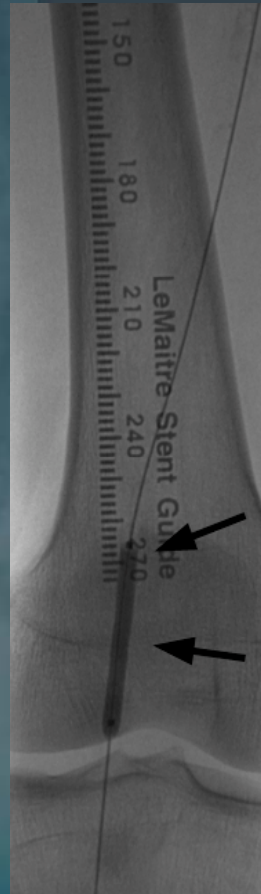
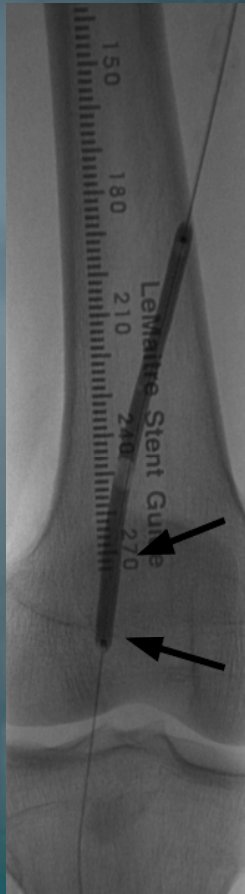
Recoil after Balloon-Angioplasty



Bailout-stenting rate up to 40 % (Resilient)

After stenting

Case from Thunder-Trial



Intervention 8 / 2004
2 PTX-coated balloons;
5 x 100 mm and 4 x 40 mm

3 / 2005

3 / 2006

Tepe et al., *NEJM* 2008;358:689-99

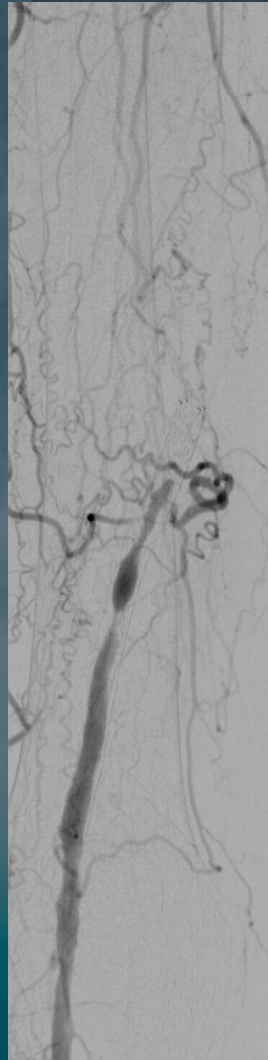
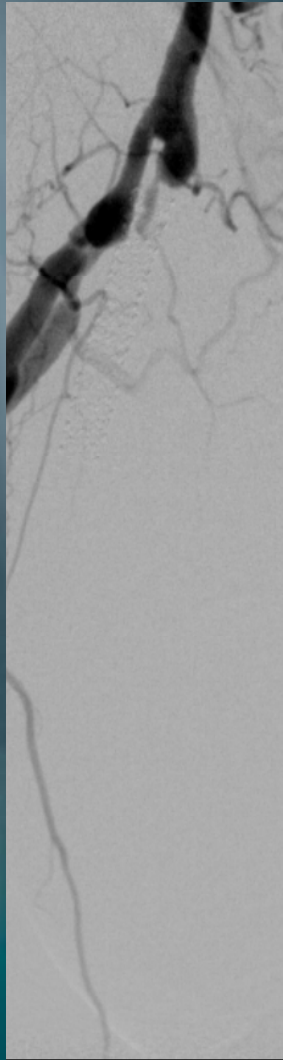
The Value of DEB for SFA Lesions

- In 4 RCTs DEB was significantly superior to non-coated balloons in SFA-lesions with regard to LLL.

	Mean lesion length
Thunder	7.5 cm
FemPac	5.7 cm
Levant I	8.1 cm
Pacifier	7.0 cm

TASC A and B lesions

DEB or DES for Long SFA-Lesions

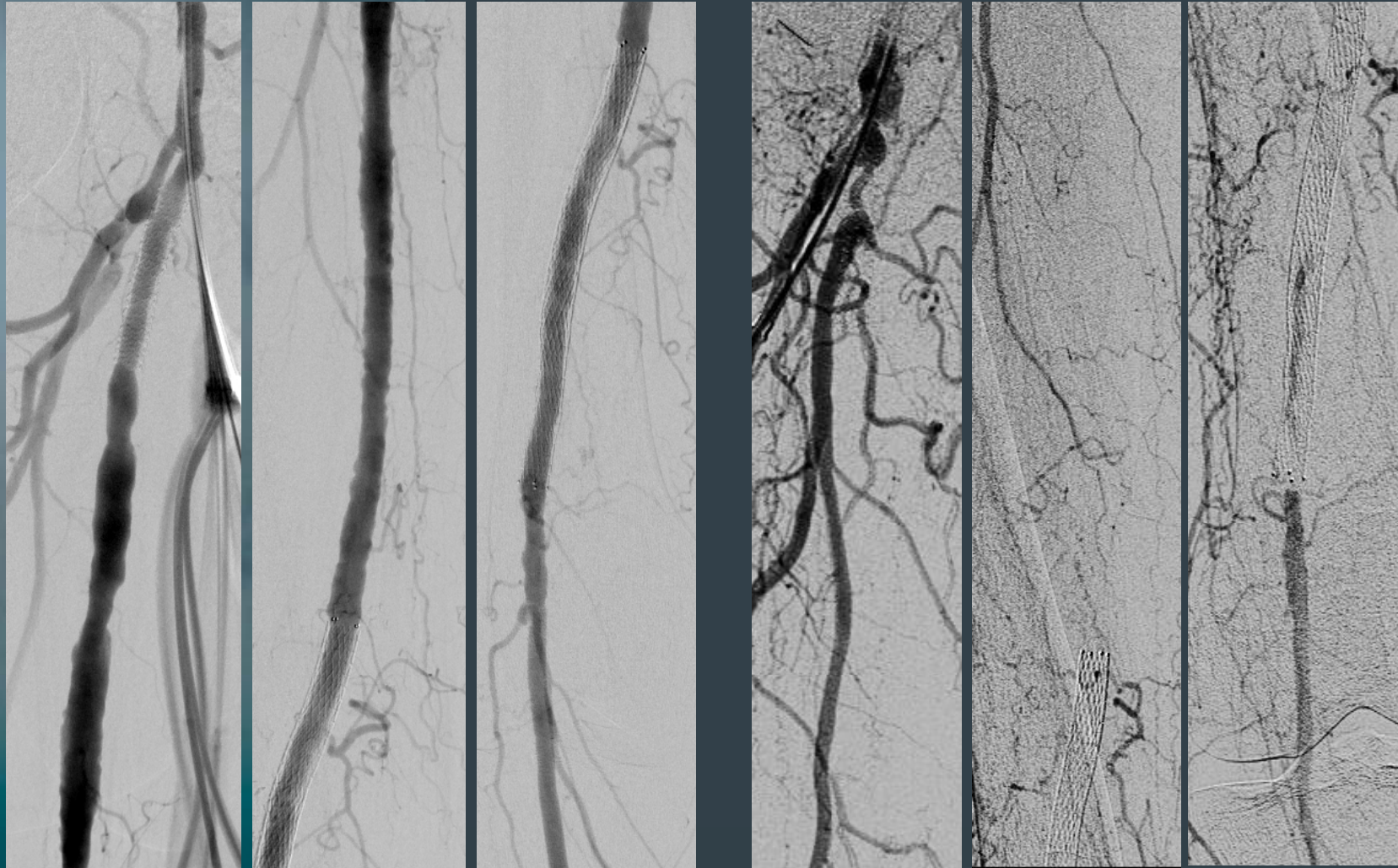


SFA reocclusion



3 x DEB 5.0/120

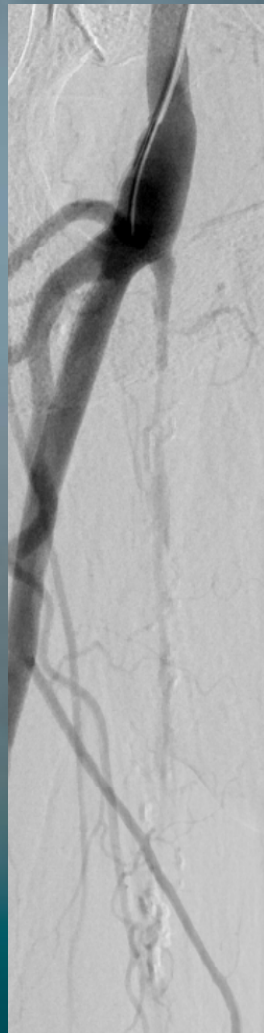
DEB or DES for Long SFA-Lesions



3-months result

9 months after DEB

DEB or DES for Long SFA-Lesions



Subintimal reca with Outback

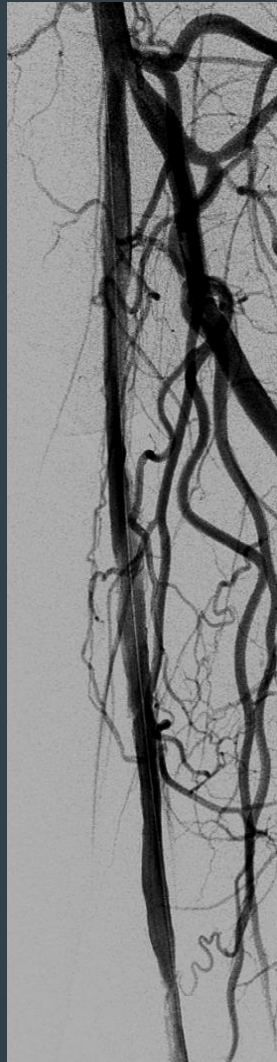
3 x DEB 5.0/120

15 months result

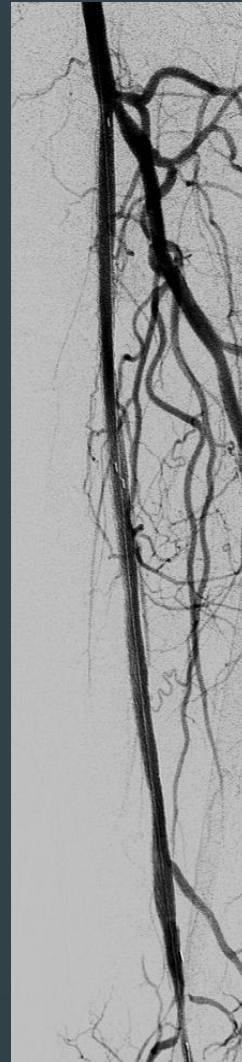
DEB or DES for Long SFA-Lesions



Outback-recanalisation



2 x 5,0/120mm DEB



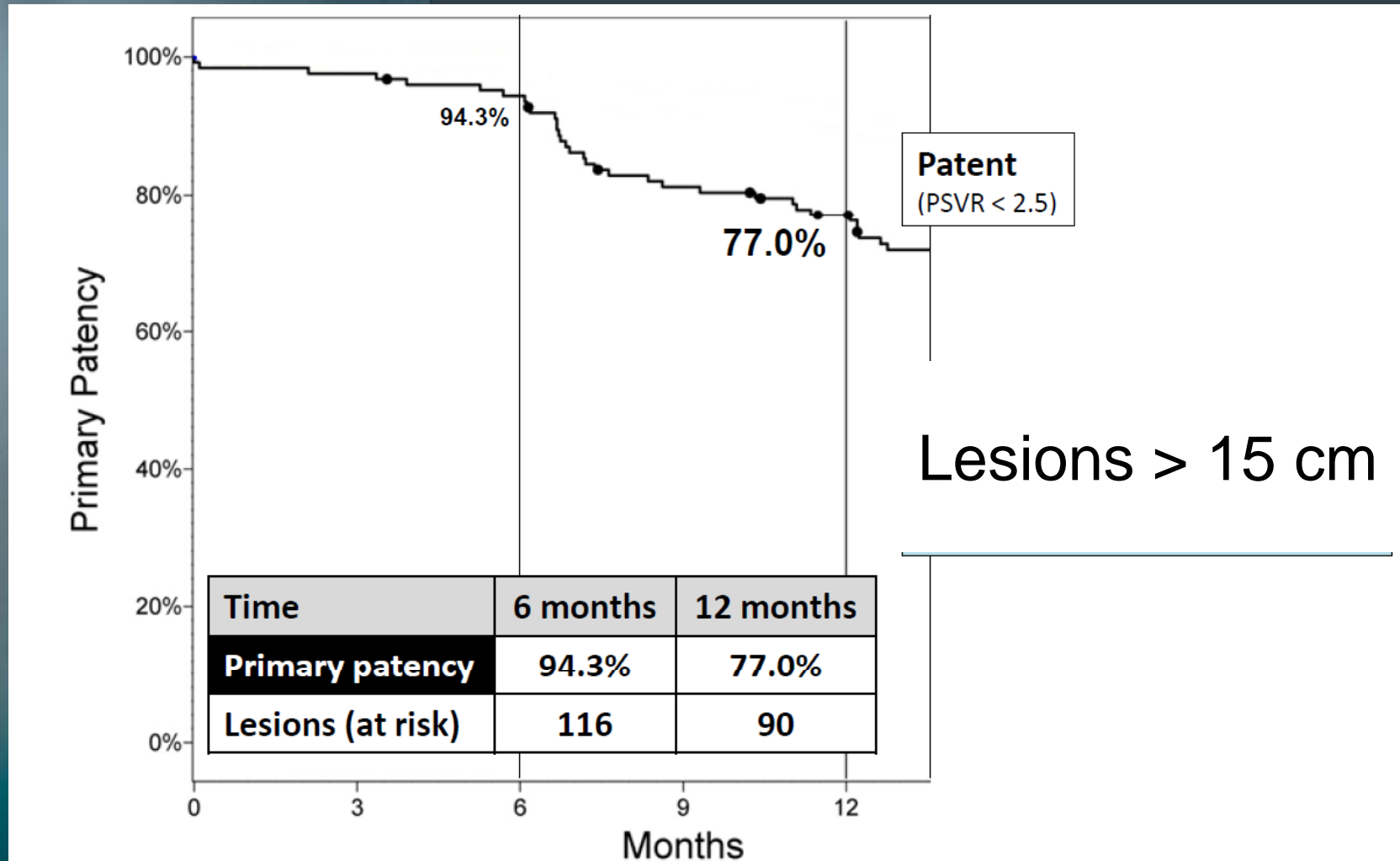
Bare-metal stents



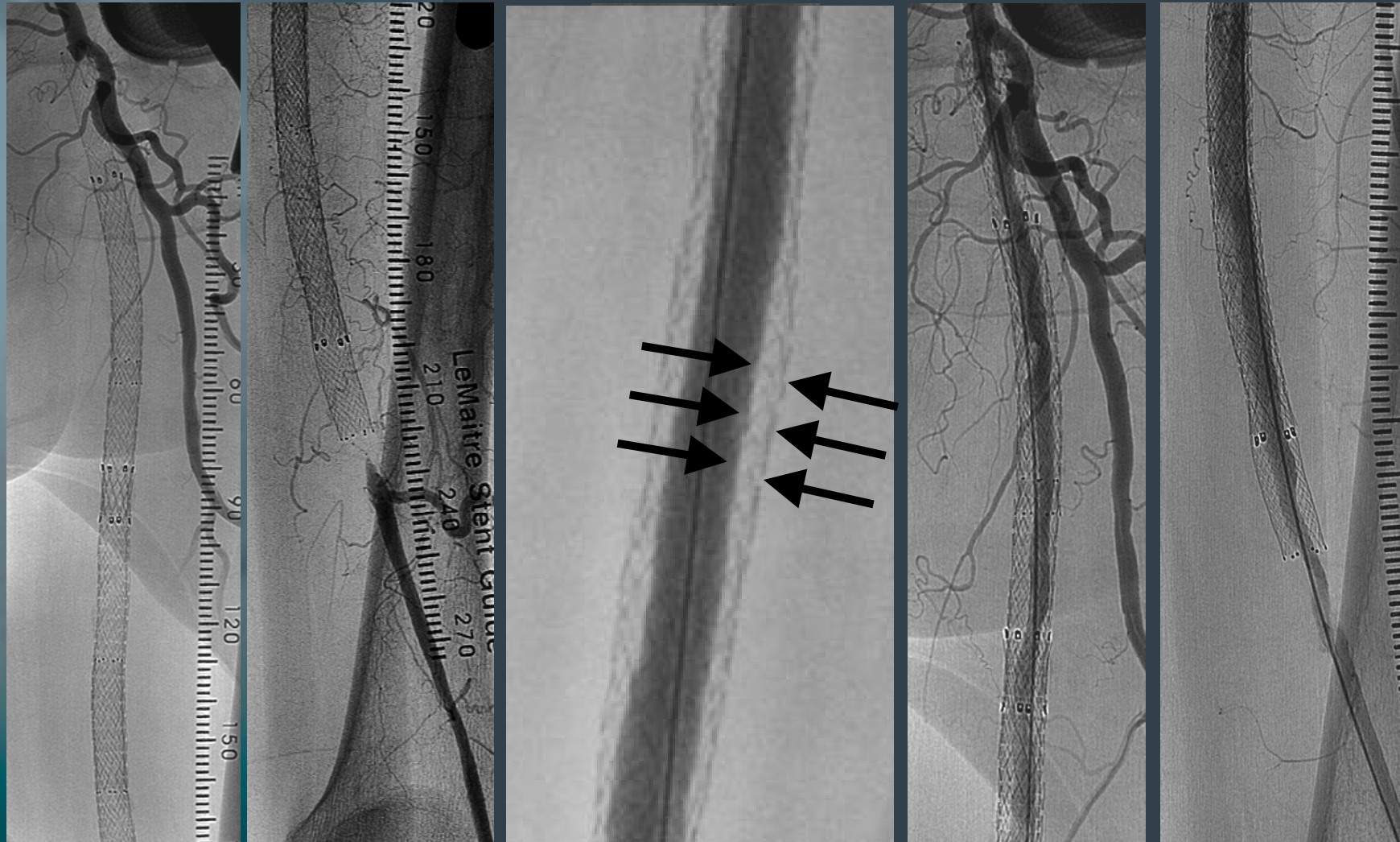
23 mo FU

Zilver-PTX for Long SFA-Lesions

Data from the single arm registry

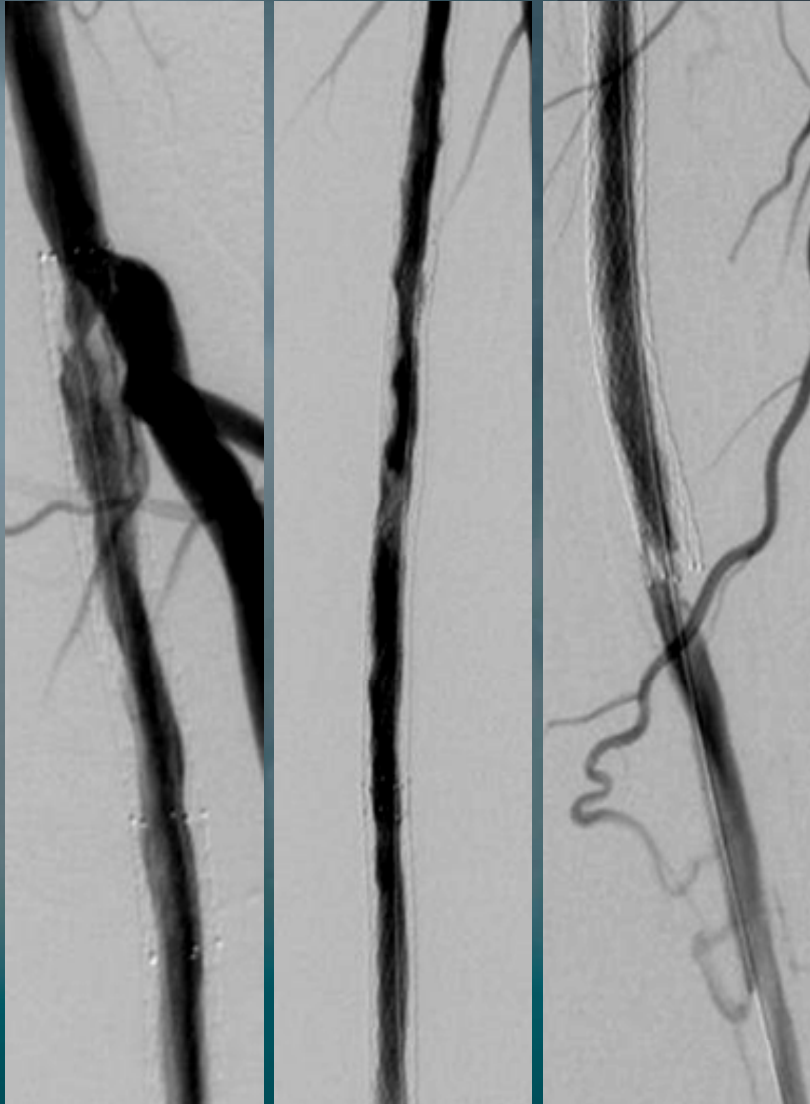


DEB or DES for In-Stent-Restenosis ?

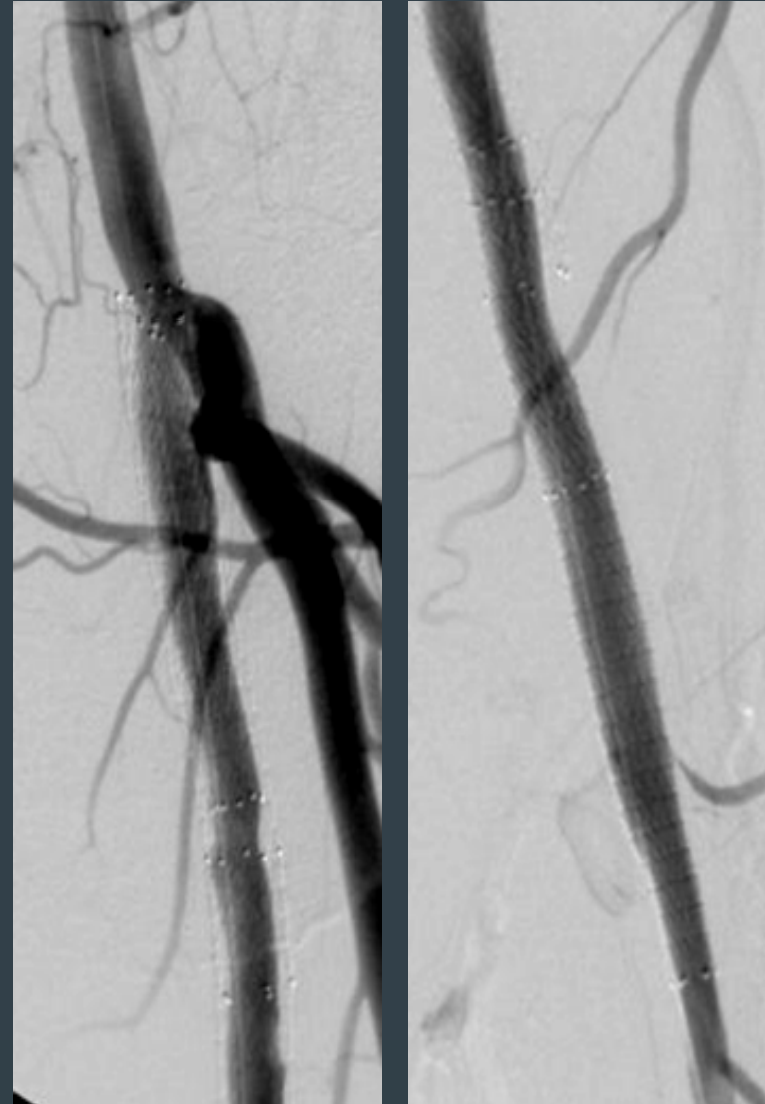


After balloon-angioplasty

Treatment of In-Stent-Restenosis



After ballooning

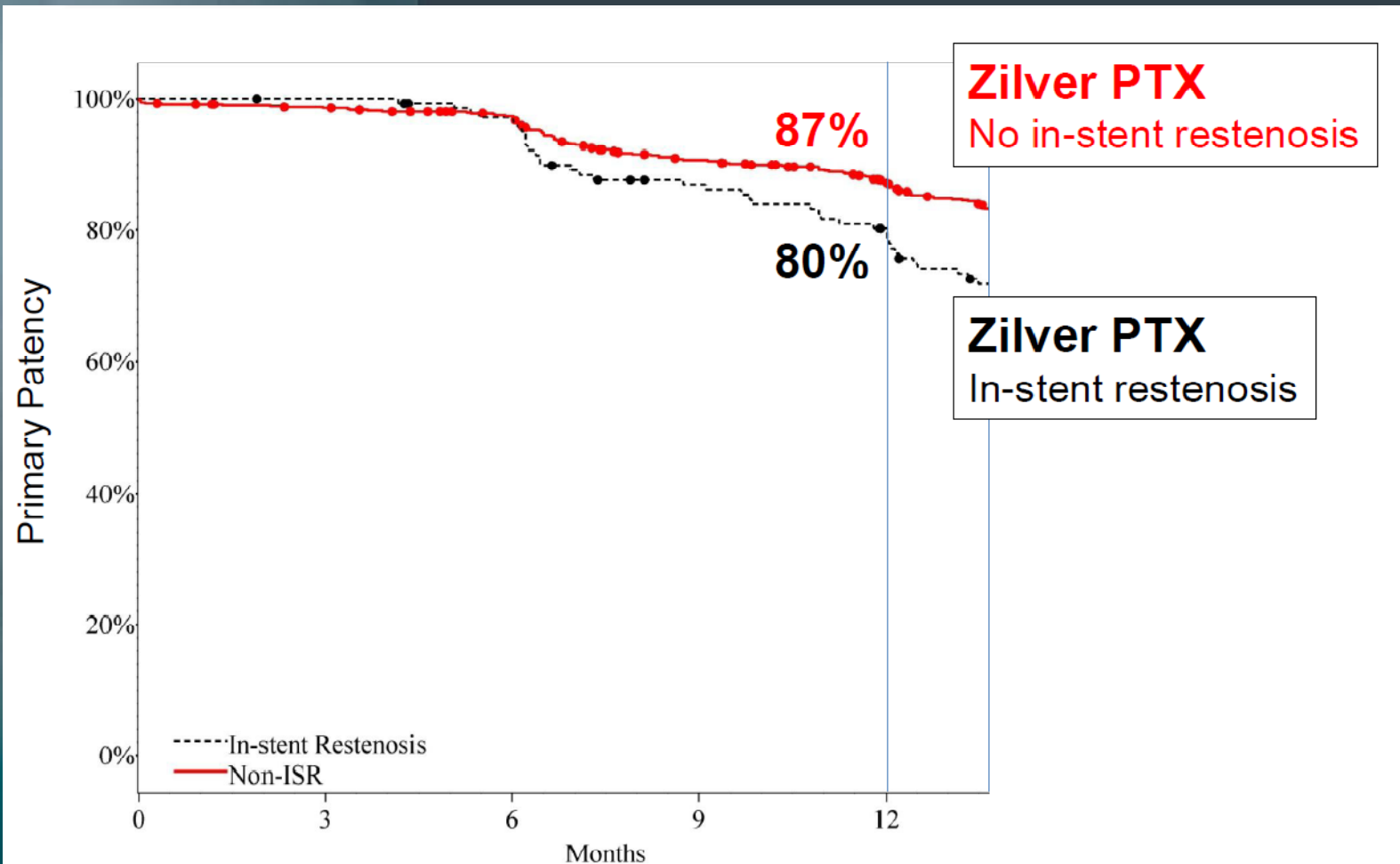


In-stent stenting

Zilver-PTX for ISR

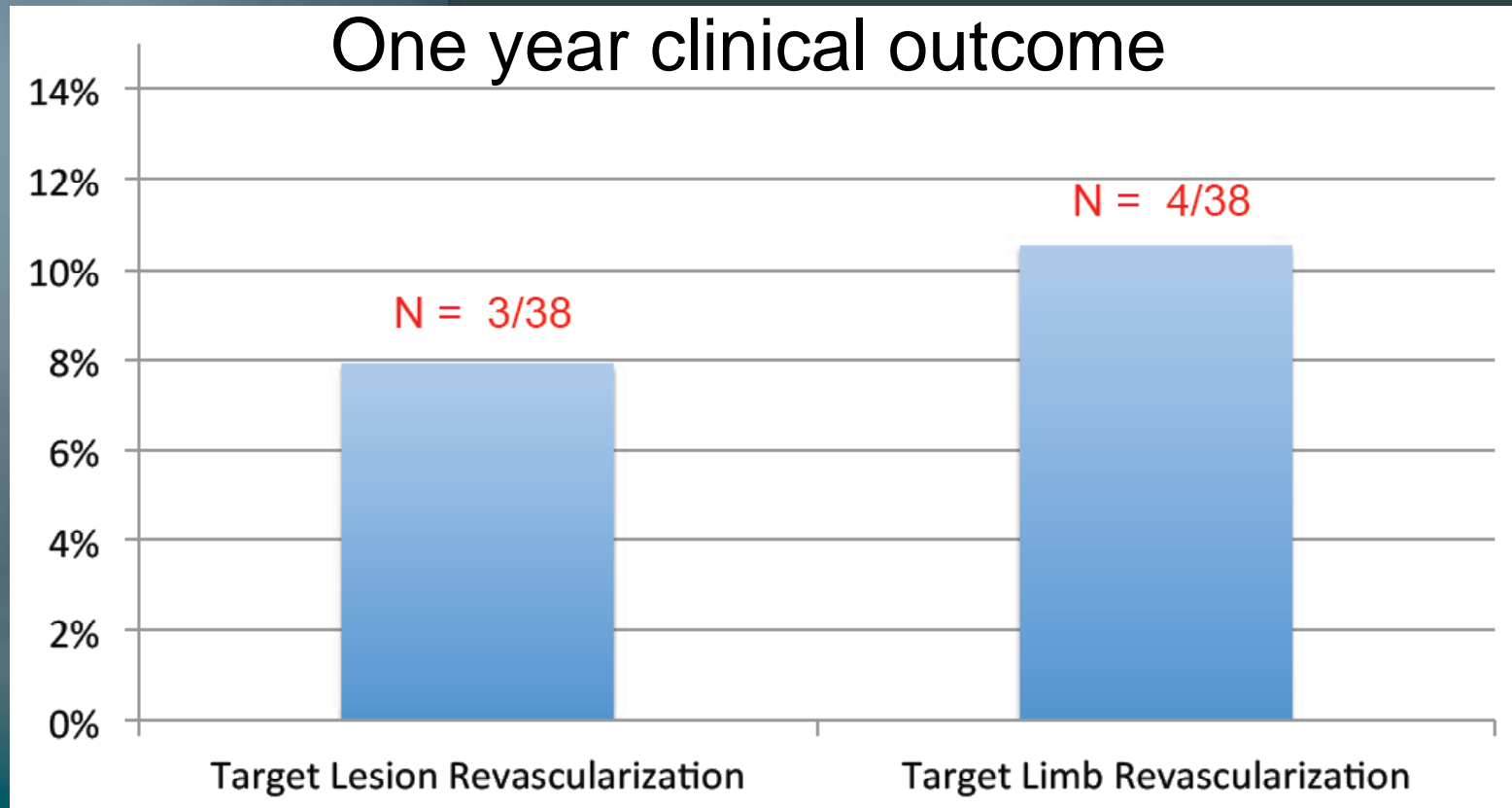
Data from the Single-Arm Registry

Primary Patency (PSVR < 2.5)



DEB for ISR of the SFA

39 ISR SFA, mean stent-length 181mm



Stabile, LINC 2012

Highly Calcified SFA-Lesions



- Cutting-balloon ?
- Scoring-balloon ?
- Atherectomy ?

Atherectomy + DEB ?

Standard nitinol-stent

DEB for SFA-Lesions

- Multicentric, italian registry
- PTA of femoropopliteal lesions n = 114
- In.Pact Admiral (Medtronic)

Lesion-length	76.3 ± 38.3 mm
Severe calcification	16.7 %
Moderate calcification	50.0 %
Stent-implantation	12.3 %
TLR at 12 months	8.7 %
Primary Patency at 12 months	83.7 %

How to Treat the SFA ?

Drug-eluting devices have proven to be superior compared to their non-coated counterparts.

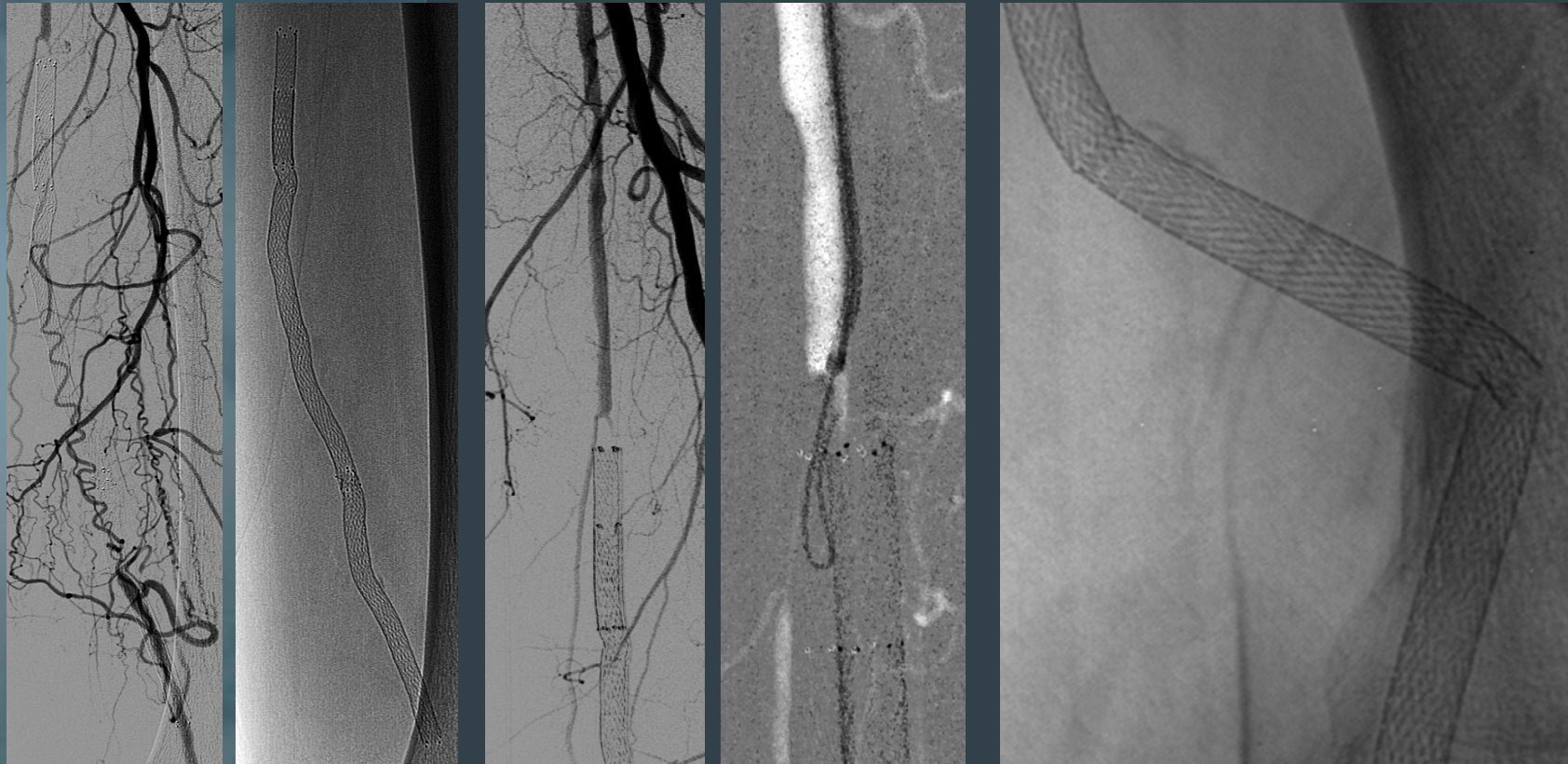
DEB or DES ?

comparative trials are needed

DEB for shorter lesions

DES for more complex lesions

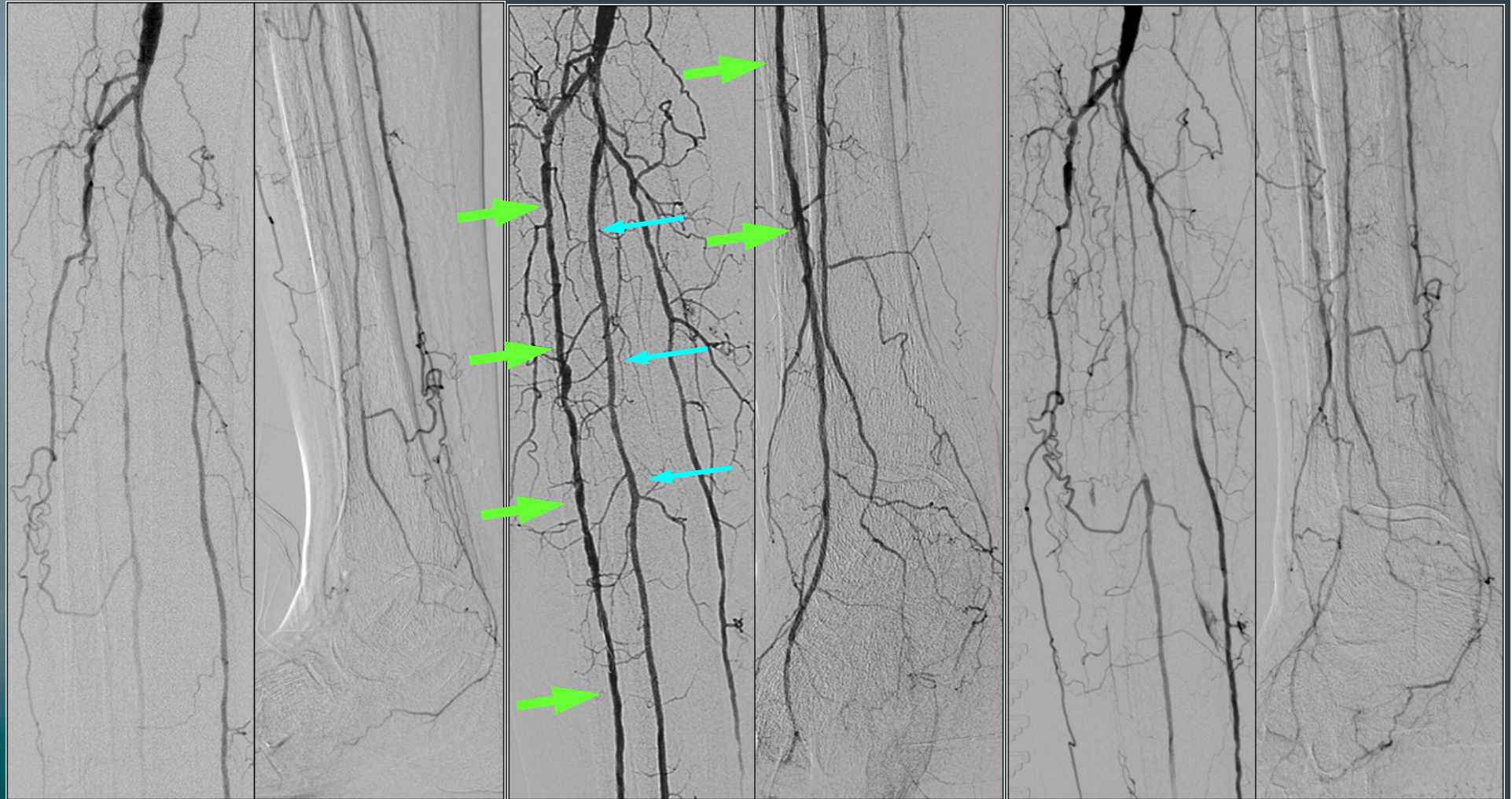
Comparative Trial of DES vs. DEB needed



ISR / occlusions can be difficult to treat

Follow-up should be long enough to recognize potential disadvantages of early SFA-stenting.

Angioplasty with Uncoated Balloons (POBA)



Occlusion ATA, Stenosis PA

After POBA both arteries

3-mo re-occlusion

3-Months Angiographical FU after POBA of long BTK-Lesions

- 58 CLI-pts. / 62 limbs
- Mean length of BTK-lesions: 183 mm
- Treatment with non-coated balloons
- Restenosis > 50 % after 3 months: **68.8 %**

In.Pact Amphirion for BTK-Lesions

Prospective registry of long BTK-lesions + DEB

104 patients, 109 limbs, 114 lesions

Critical ischemia in 82.6 %

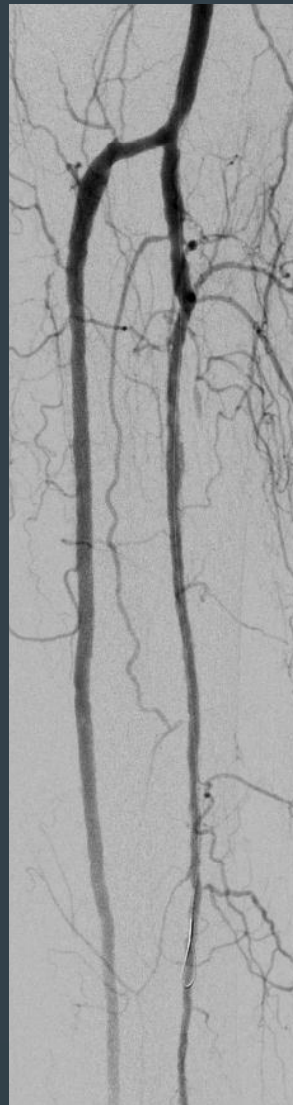
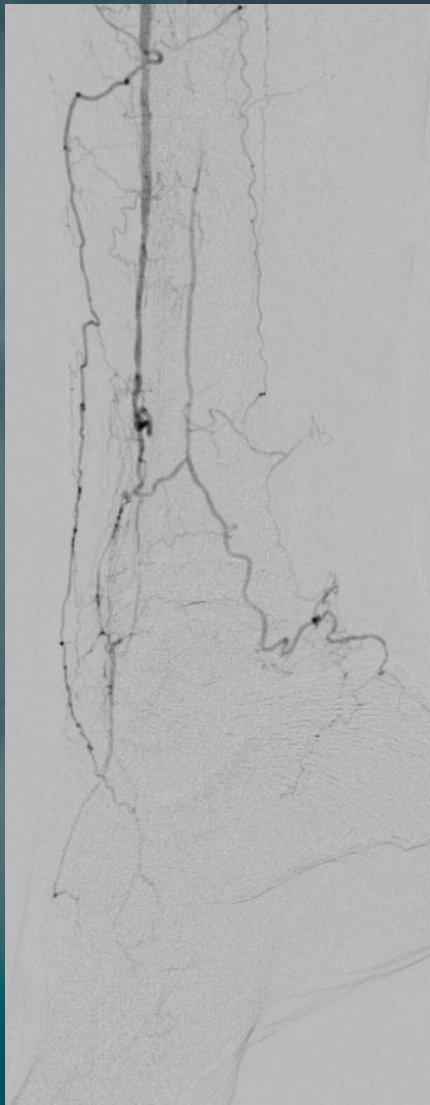
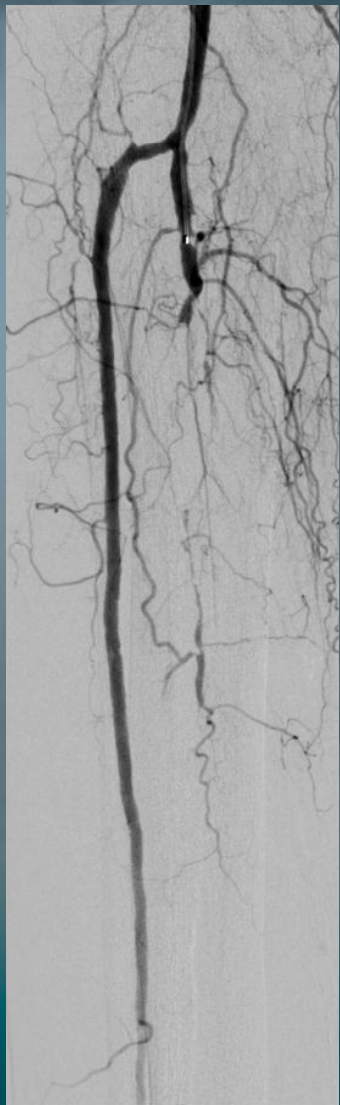
Mean lesion-length 173 mm

Follow-up schedule:

Angiography at 3 months

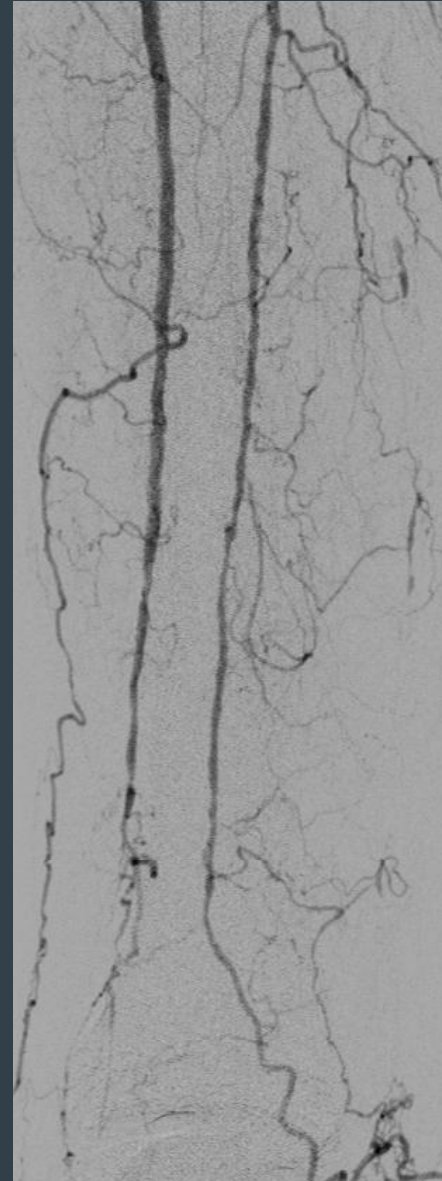
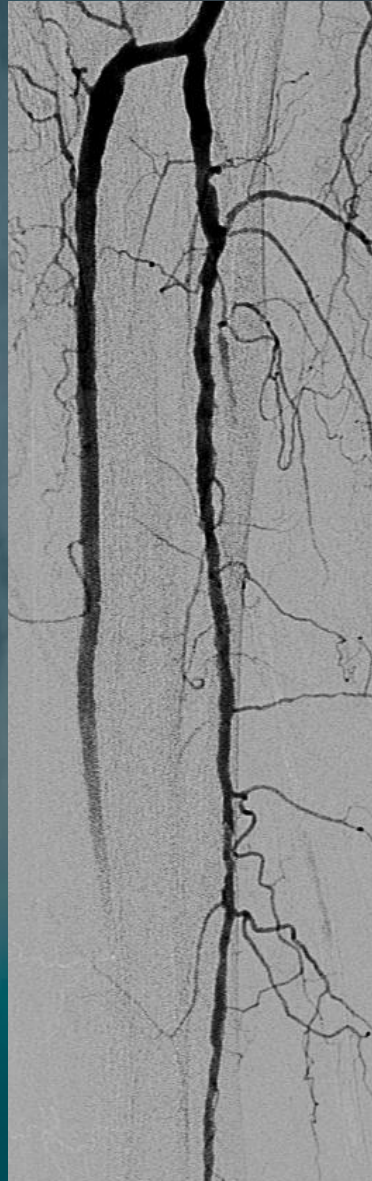
Clinical FU 3, 6 and 12 months

CLI right, Poor Run-Off

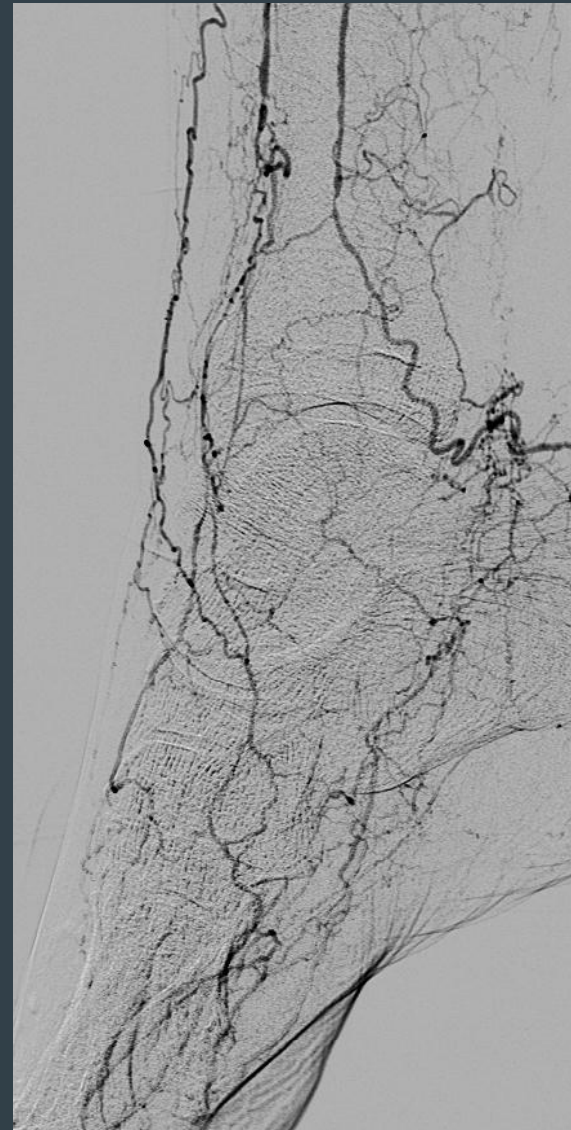
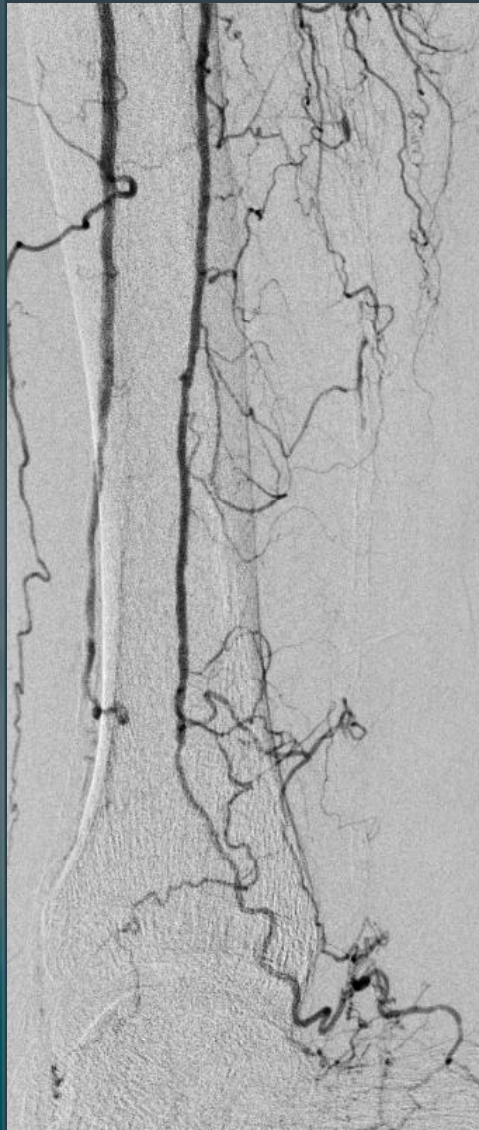
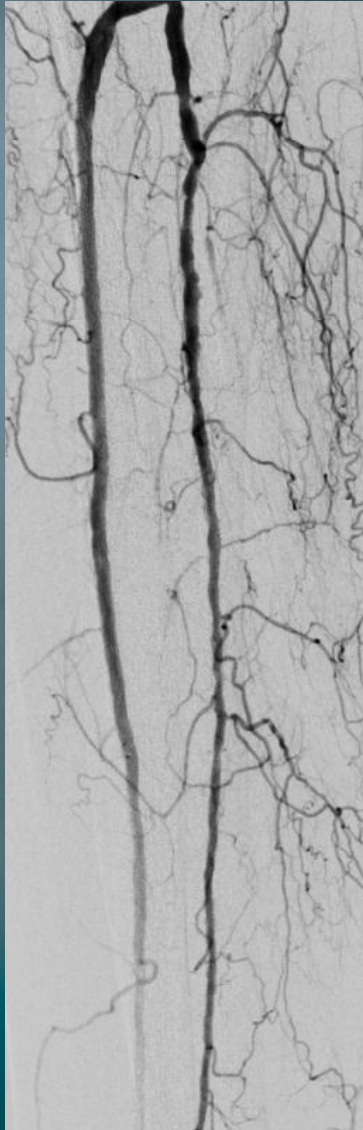


2.0/120 + 2.5/120mm In.Pact Amphiion

3-Mo FU after DEB of the Peroneal Artery



9-Mo FU after DEB of the Peroneal Artery



Drug-Eluting Balloons BTK

	POB BTK	DEB BTK
Lesion-length	183 mm	173 mm
Restenosis >50 % @ 3 Mo	69 %	27 %
61% restenosis reduction		
TLR-rate at 12-15 mo	50 %	17 %
65% TLR-rate reduction		

IN.PACT™ in BTK / CLI / Diabetics

- Preliminary results from a single center RCT of
- IN.PACT Amphirion™ vs PTA BTK in CLI diabetic patients
- Significant reduction in angiographic restenosis rate at **12 mo**

RCT DEB vs. PTA	In.Pact	PTA	p
# Patients	48	44	
Lesion length (mm)	121	116	0.07
12m RR (Angio)	27%	66%	0.0004
12m re-occlusion	16%	53%	0.0006

Will DEB Play a Role in BTK-Arteries ?

- No competitor for DES
- First angiographical results are very promising
- Clinical endpoints are more important, TLR-rate is one of them.