

Drug-eluting Balloon or Stent for Infrapopliteal Lesions



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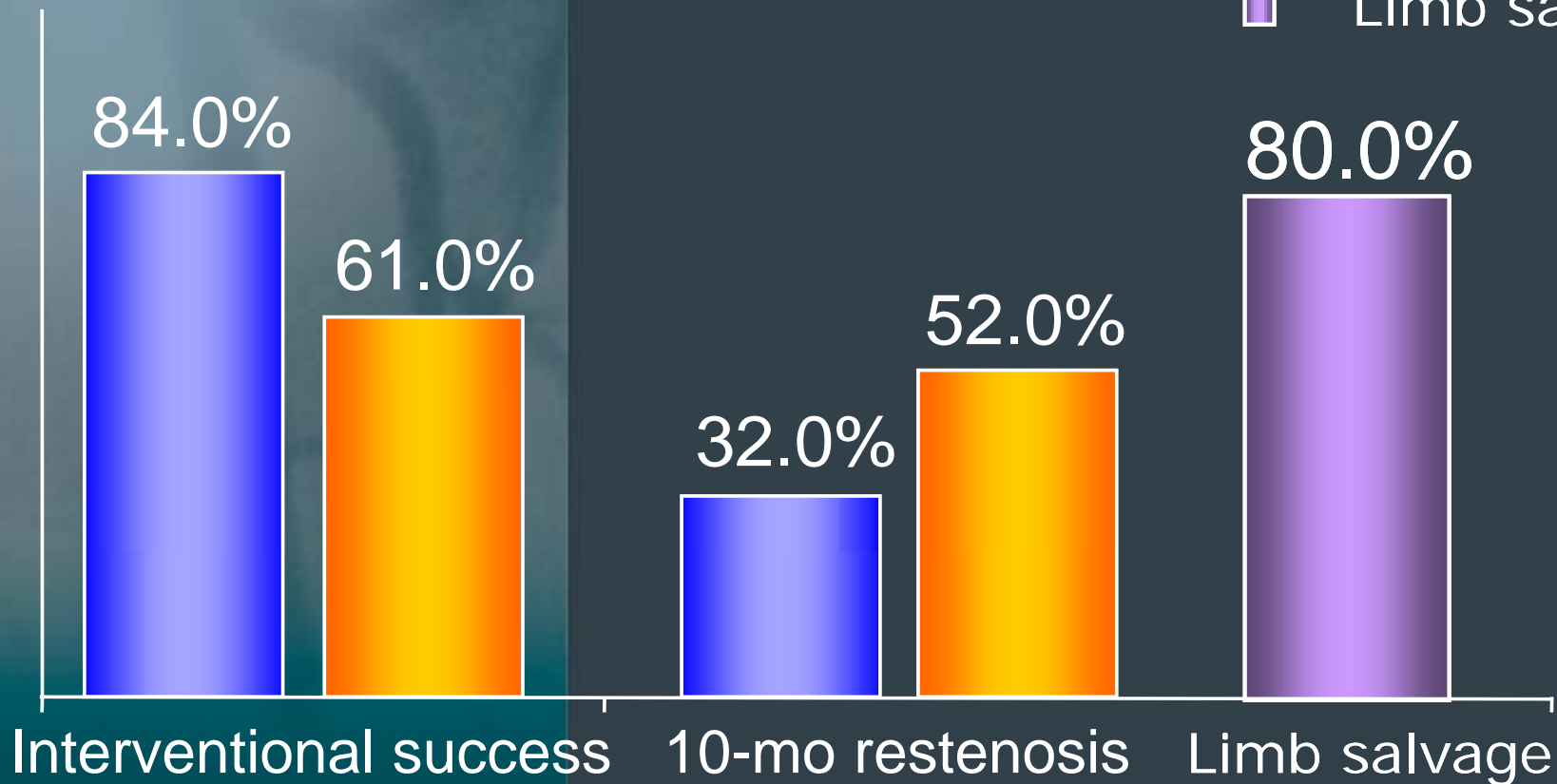
Interventional Therapy of the Critical Limb

- First Goal (for tissue loss):
 - To achieve a straight line flow to the foot
- Patency of the treated vessel:
 - Of secondary importance ?

Balloon-Angioplasty of Infrapopliteal Arteries in Critical Limb Ischemia

- 60 pat., 72 limbs, 12-24 Mo F/U
- Lesion-length 3.8 ± 3.0 cm

- Stenosis
- Occlusion
- Limb salvage



Soder et al, *J Vasc Interv Radiol* 2000

Case example from the LACI-Trial



Before therapy



3 Months



6 Months

Extended patency is needed for wound healing

Repeat interventions after POBA of BTK-lesions

In CLI-patients necessary in **50%**

Fernandez et al. *J Vasc Surg* 2010;52:834-42

Randomized Trials DES BTK

- YUKON:

- Yukon BMS vs. Sirolimus coated stent (no polymer)

- DESTINY:

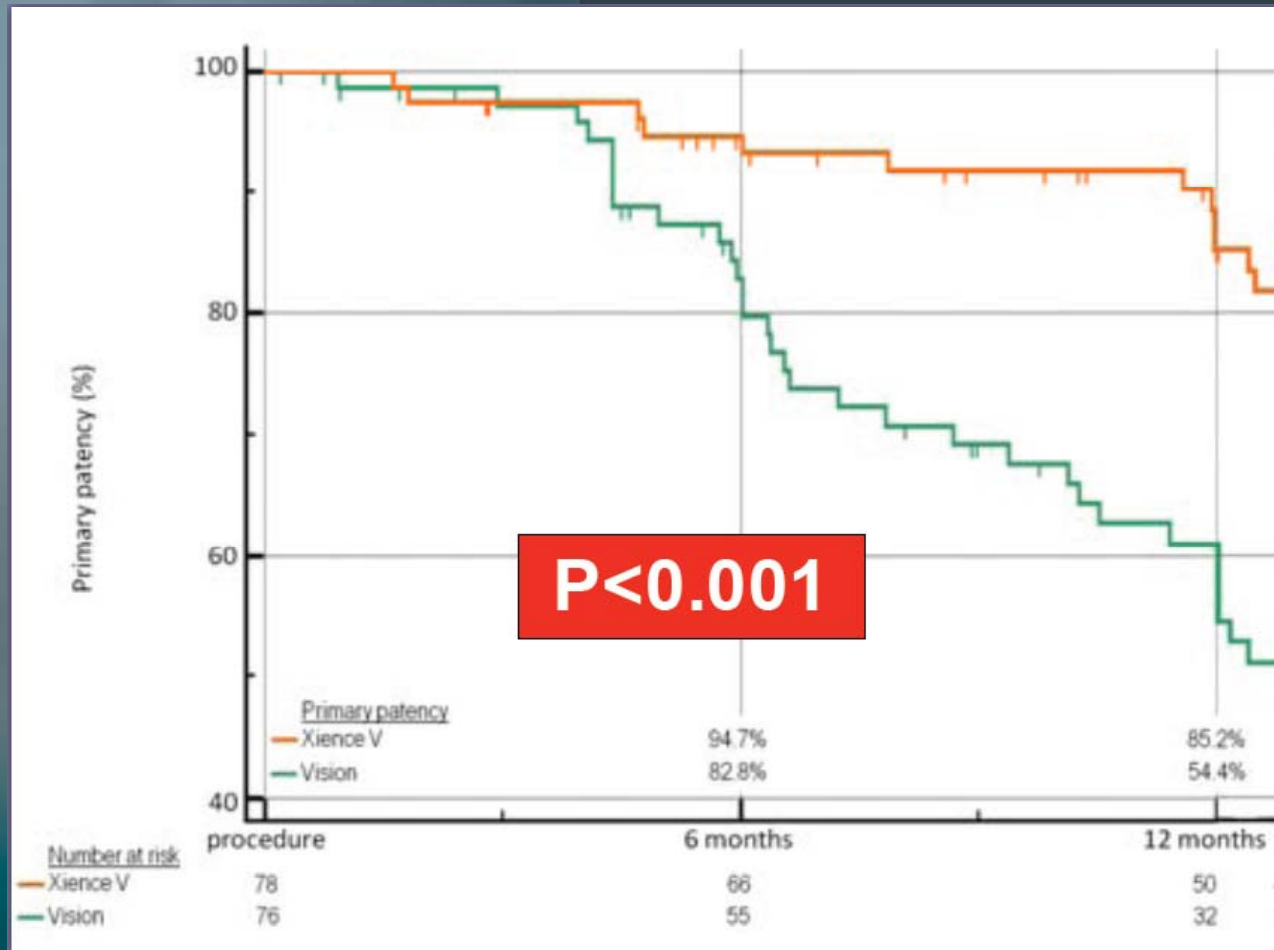
- BMS (Multilink Vision) vs. Xience V (Everolimus)

- ACHILLES:

- Balloon vs. Cypher Select (Sirolimus)

DESTINY-Trial DES vs. BMS

Primary patency (angiographical at 12 months)



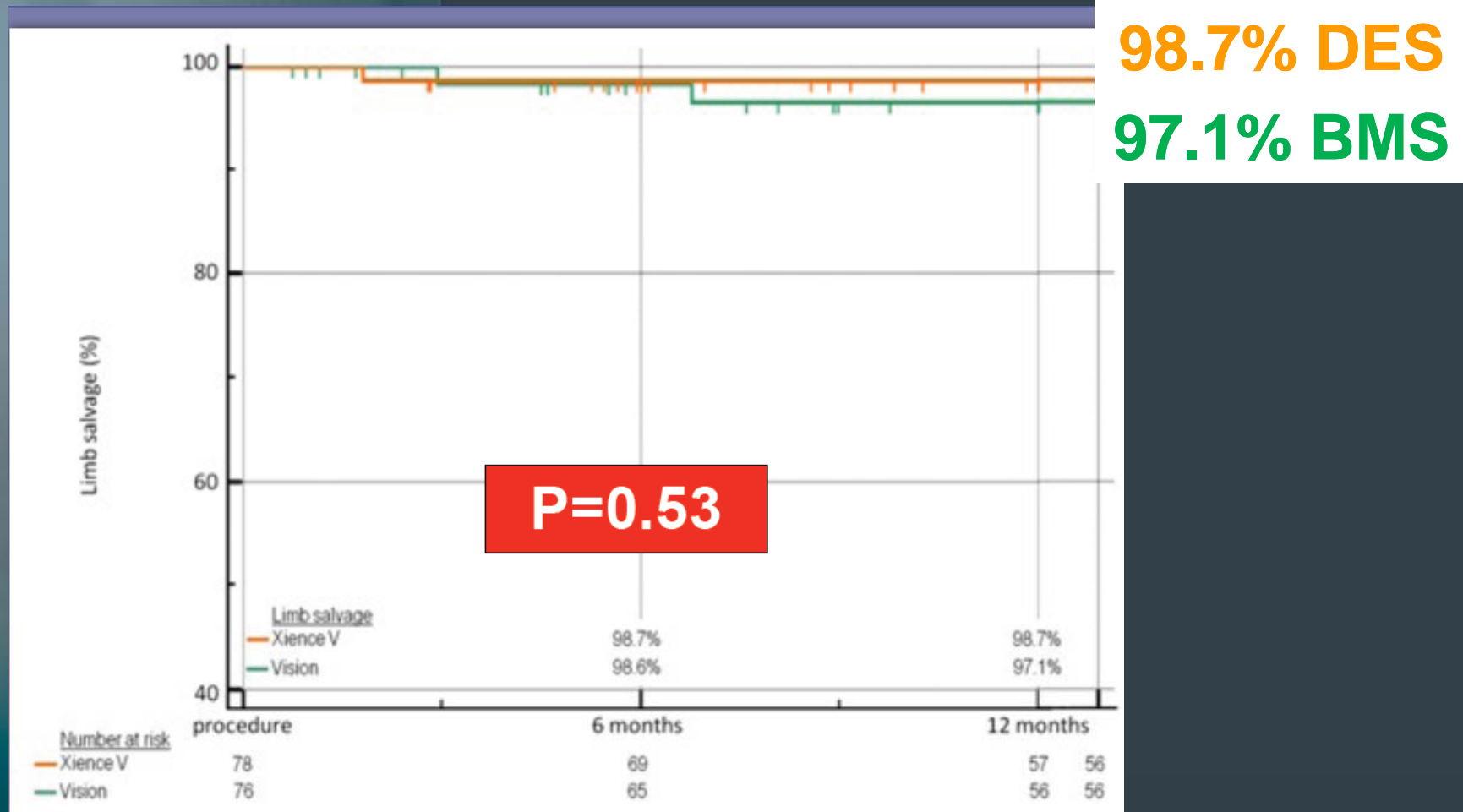
**85.2% for DES
(Xience V)**

**54.3% for BMS
(Multilink Vision)**

Bosiers et al. LINC 2011

DESTINY-Trial DES vs. BMS

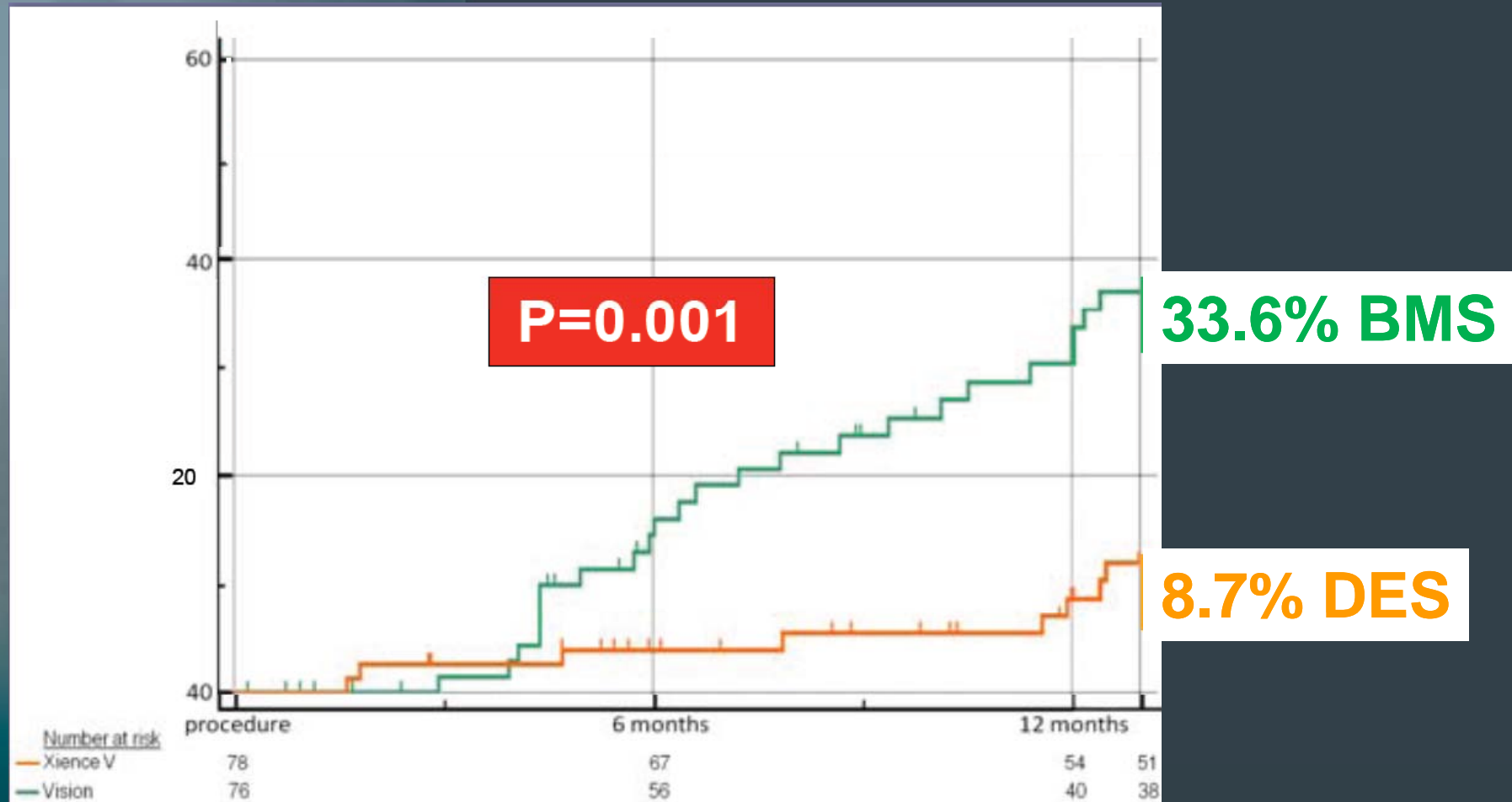
Limb-salvage at 12 months



Bosiers et al. LINC 2011

DESTINY-Trial DES vs. BMS

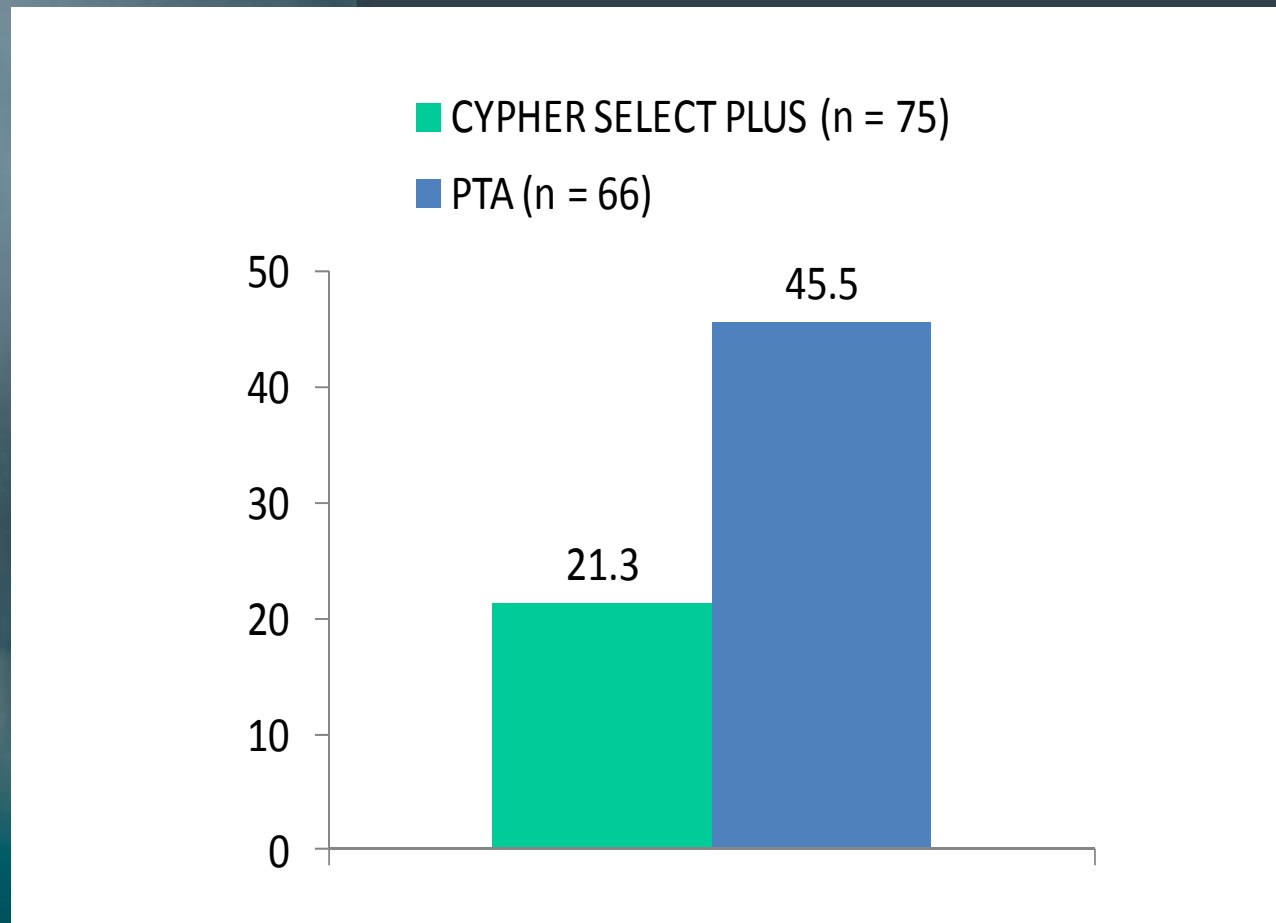
Reintervention rate



Bosiers et al. LINC 2011

ACHILLES-Trial DES vs. POBA

- 12 months in-segment binary restenosis by QA



Scheinert et al. Charing Cross 2011

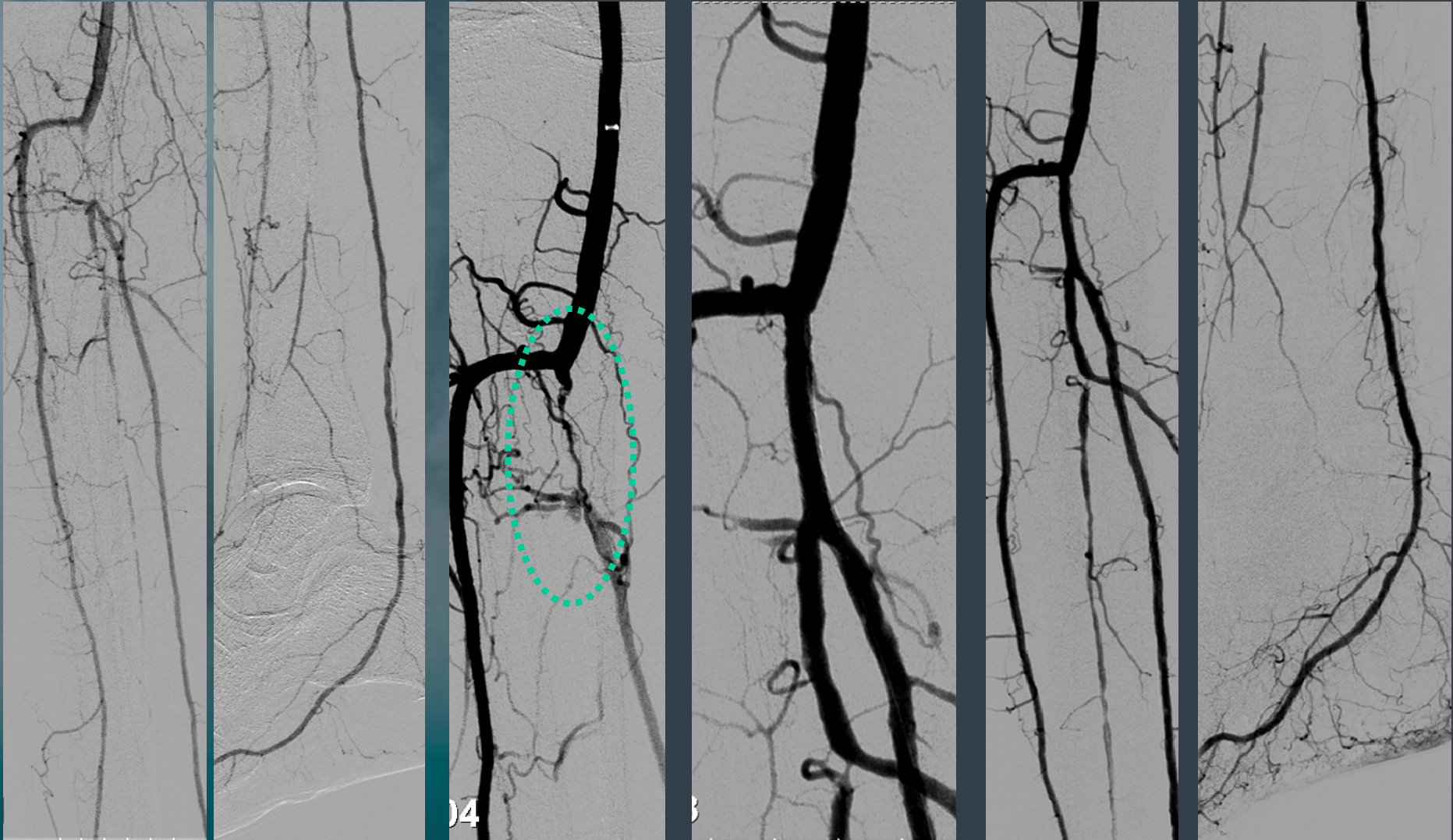
ACHILLES-Trial DES vs. POBA

- Safety endpoints at 12 months

	CYPHER	PTA	p-value
TLR	10.0%	16.5%	0.257
Index Limb Amputations	13.8%	20.0%	0.307

Scheinert et al. Charing Cross 2011

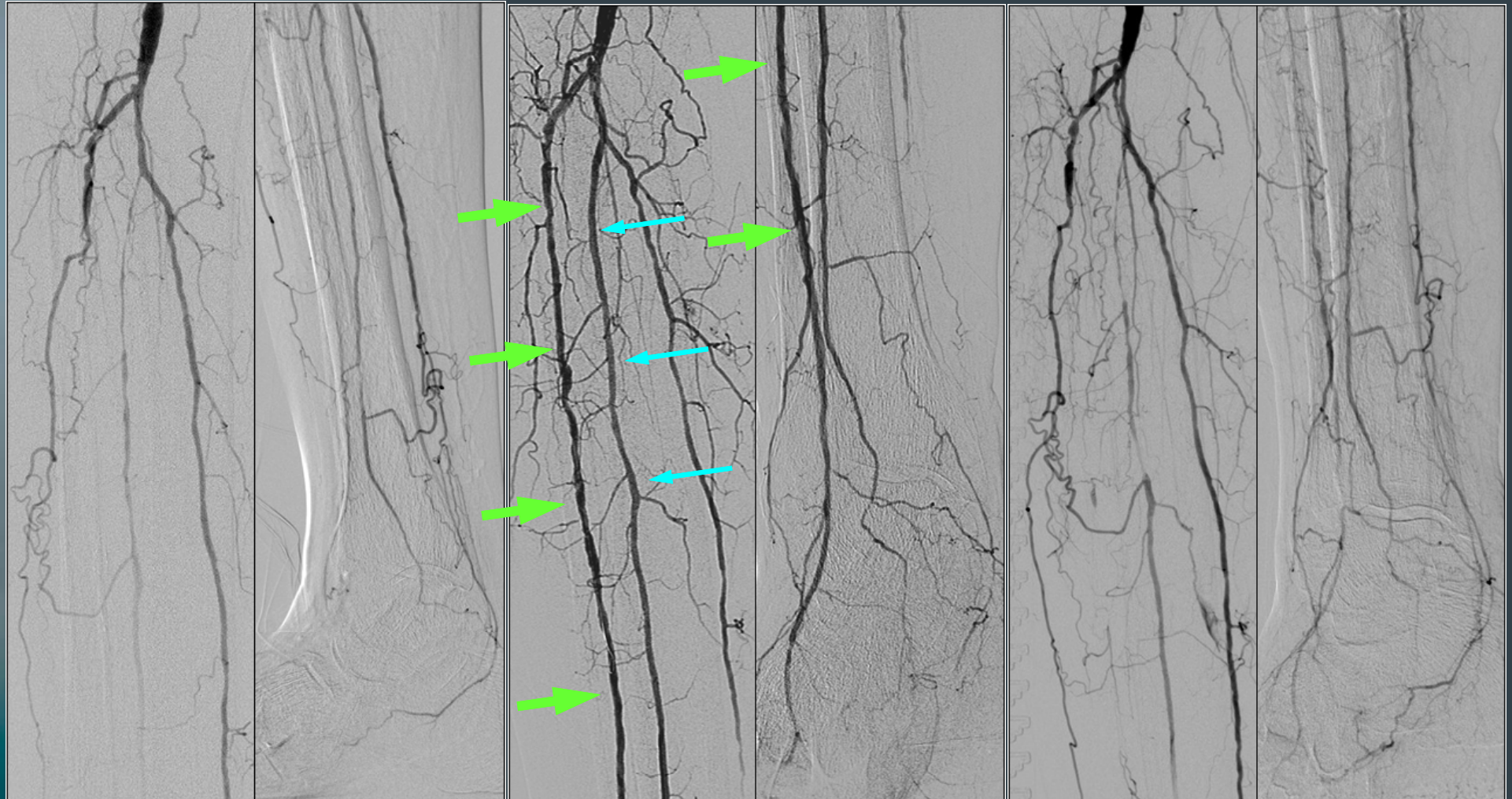
Drug-Eluting Stents Below-The-Knee



52 years, DM, Rutherford 5

Cypher 3,5/33mm

Standard-Therapy for long BTK-Lesions: 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 %**

Leipzig Experience with Drug-Coated Balloons BTK

- Prospective registry of patients with BTK-lesions
- In.Pact Amphirion Deep Paclitaxel-eluting balloon
(Invatec)
- Planned FU:
 - Angiography after 3 months
 - Clinical FU 3, 6 and 12 months

BTK-Lesions Treated with the PTX-Coated In.Pact Amphirion Deep

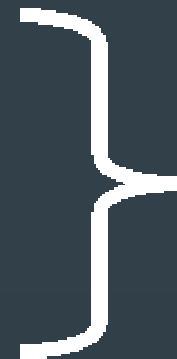
- 104 patients included (Jan 2009 – Feb 2010)
- 109 limbs treated with In.Pact Amphirion
- Clinical limb status

- Ruth 3 19 (17.4 %)

- Ruth 4 19 (17.4 %)

- Ruth 5 70 (64.2 %)

- Ruth 6 1 (0.9 %)

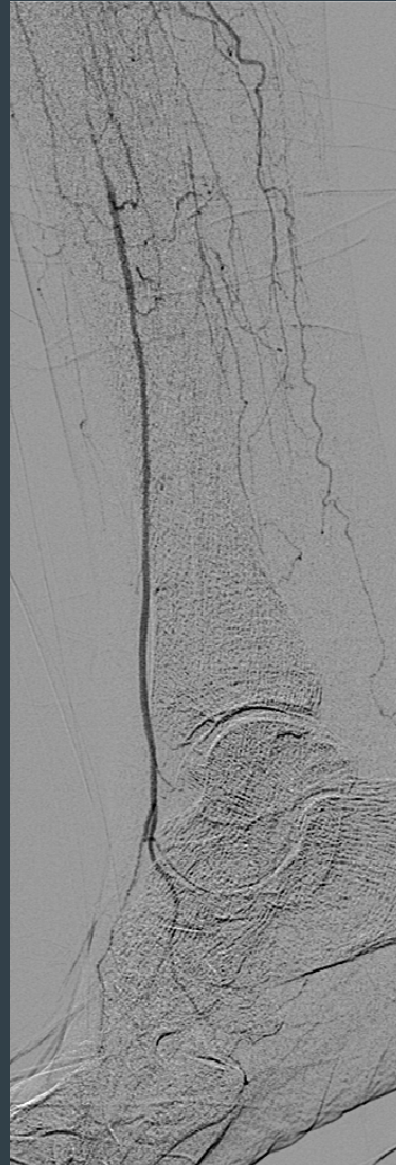


CLI 82.6 %

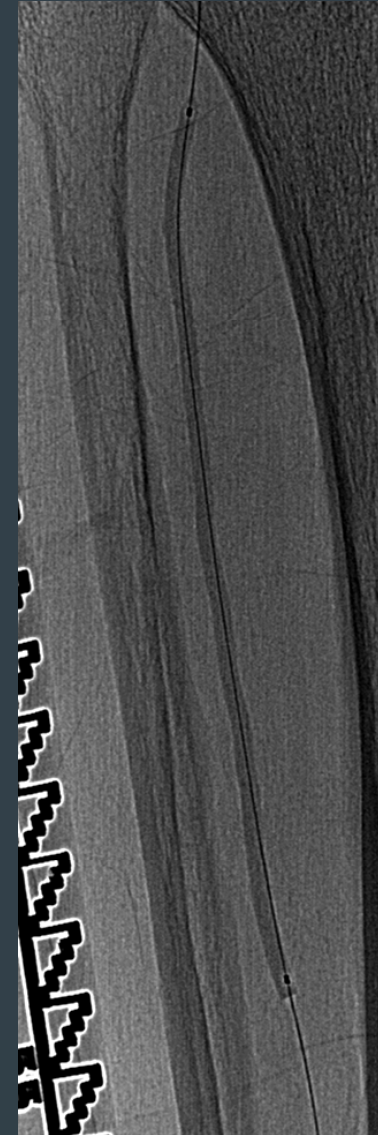
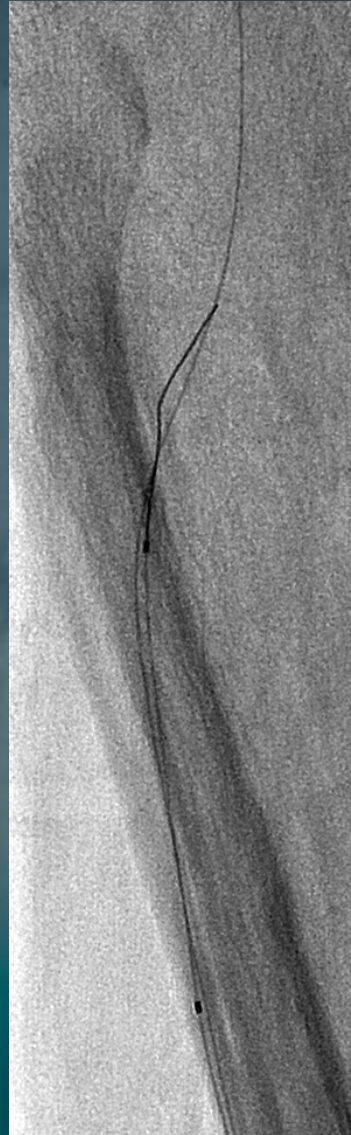
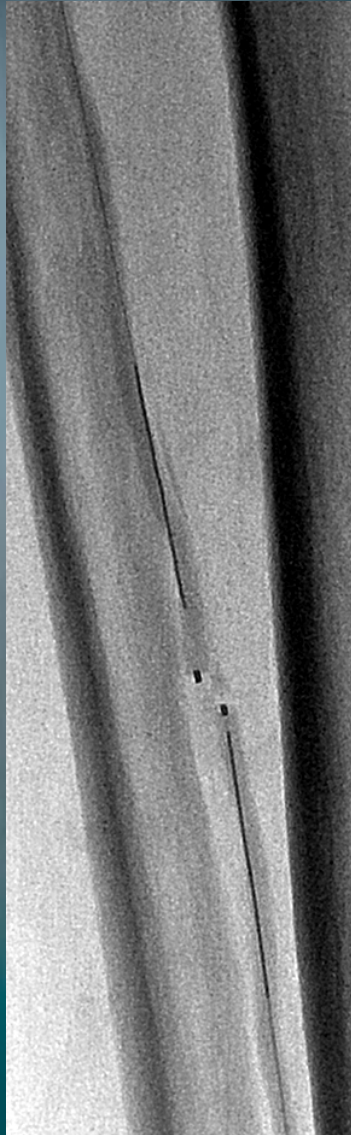
Subgroup with 3-Mo Angio 74 Patients / 84 BTK-Lesions with In.Pact Amphirion

- De-novo	55 (65.5 %)
- Restenosis	19 (22.6 %)
- In-stent restenosis	10 (11.9 %)
- Mean lesion-length	173 ± 87 mm
- Stenosis	32 (38.1 %)
- Occlusion	52 (61.9 %)

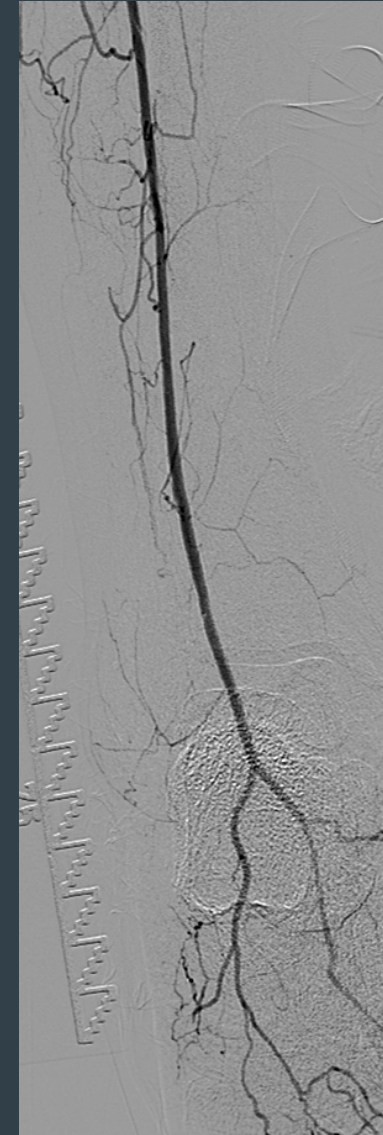
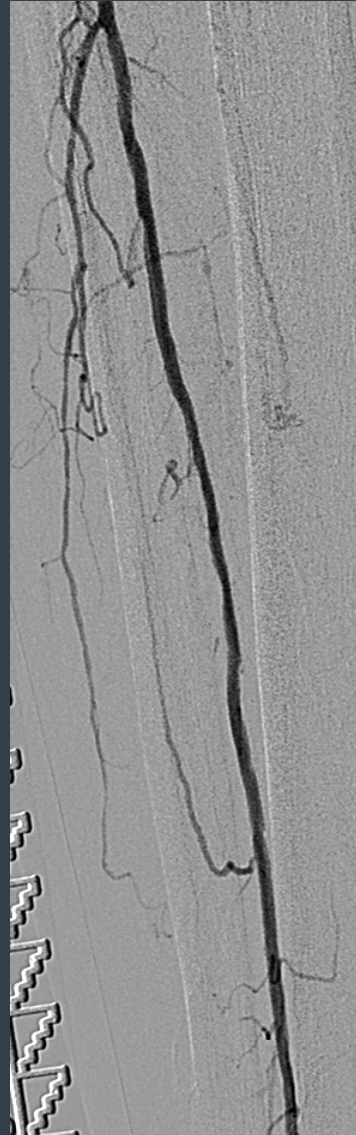
Leipzig Experience with DEB BTK



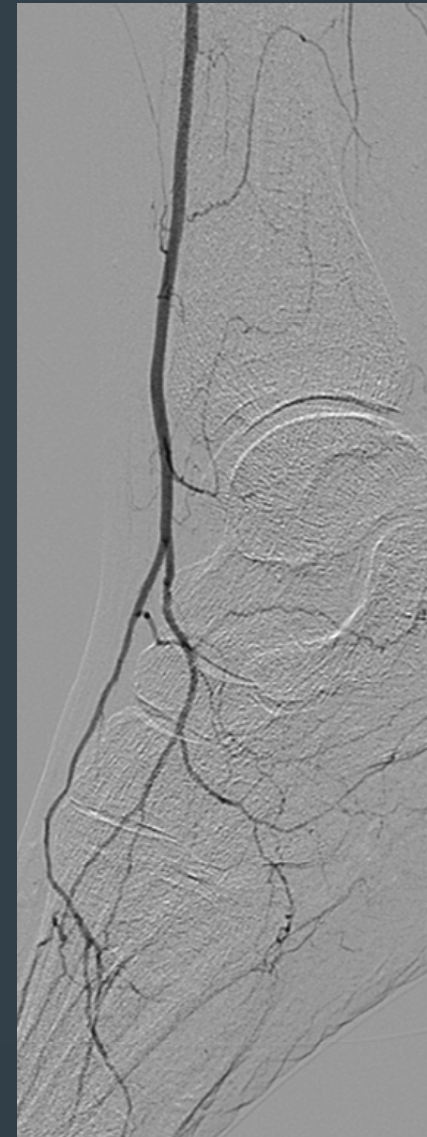
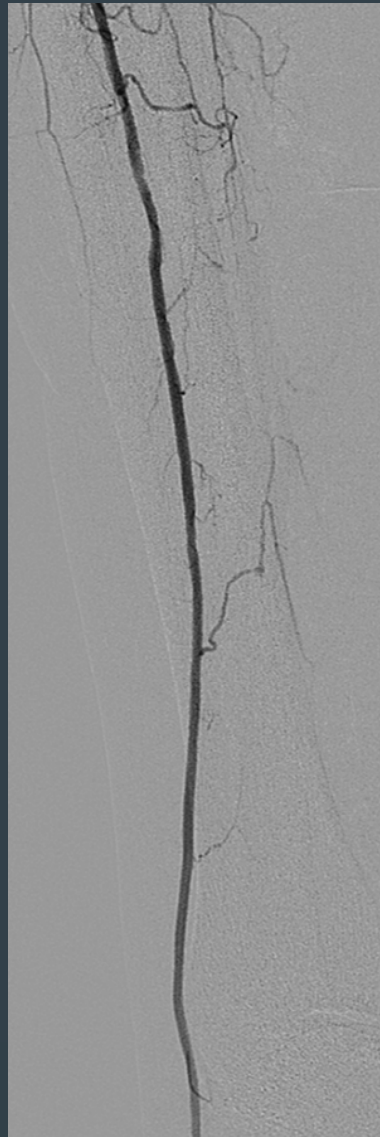
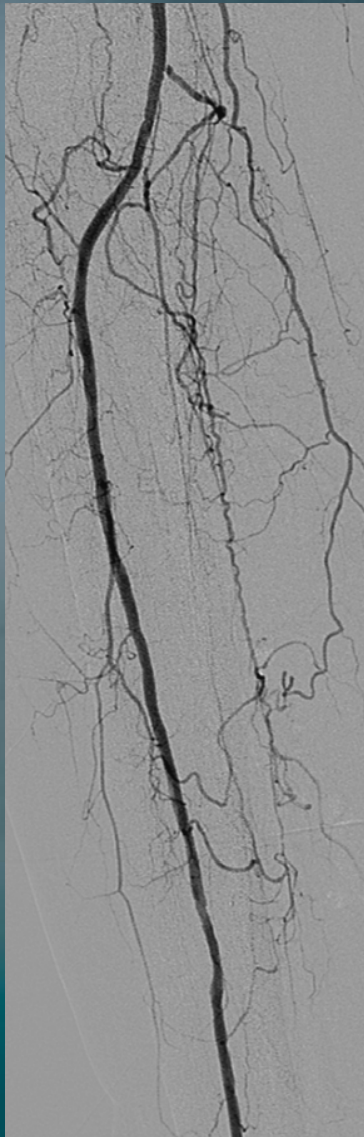
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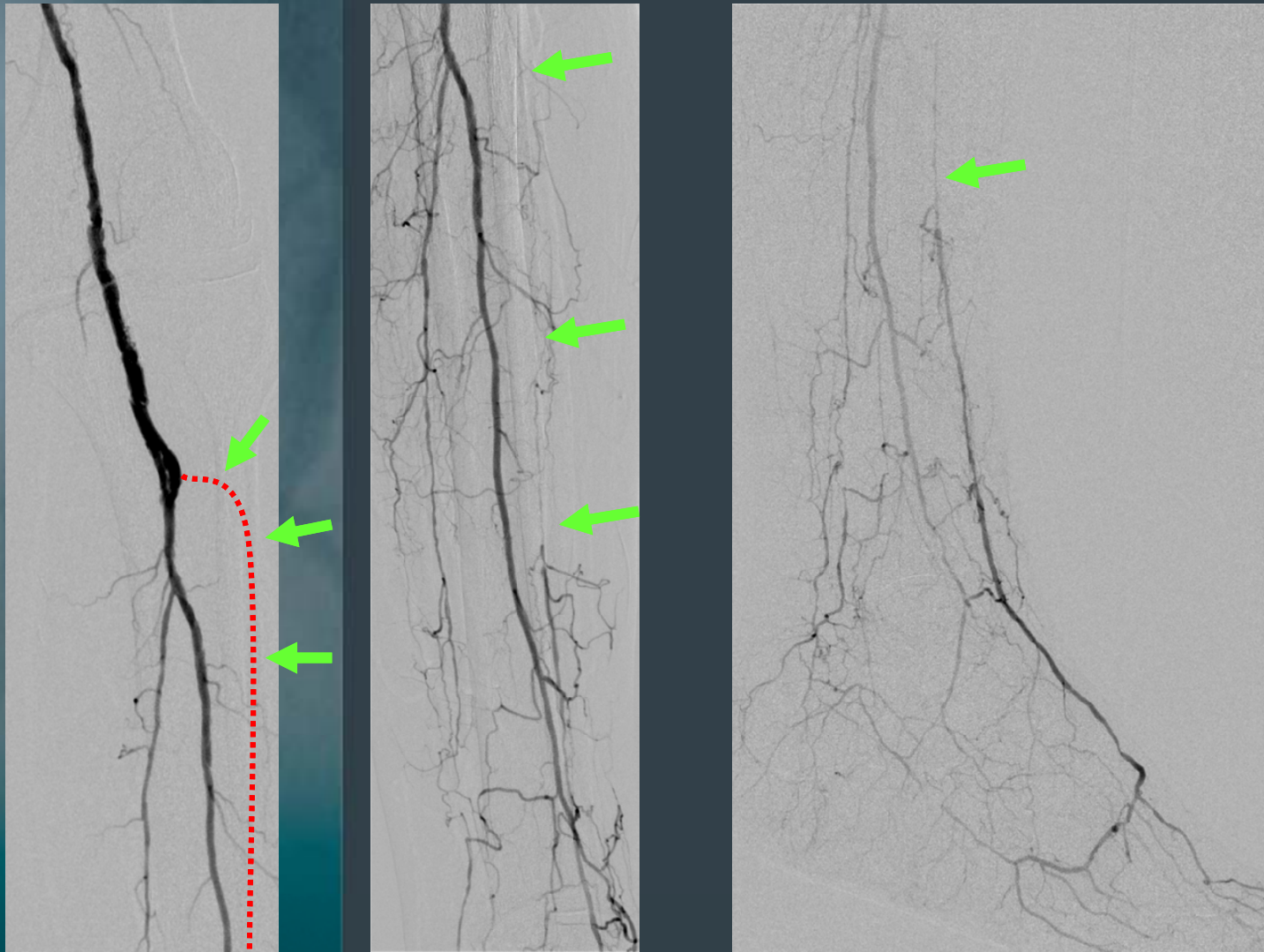


3-months follow-up angiography

Leipzig Experience with DEB BTK

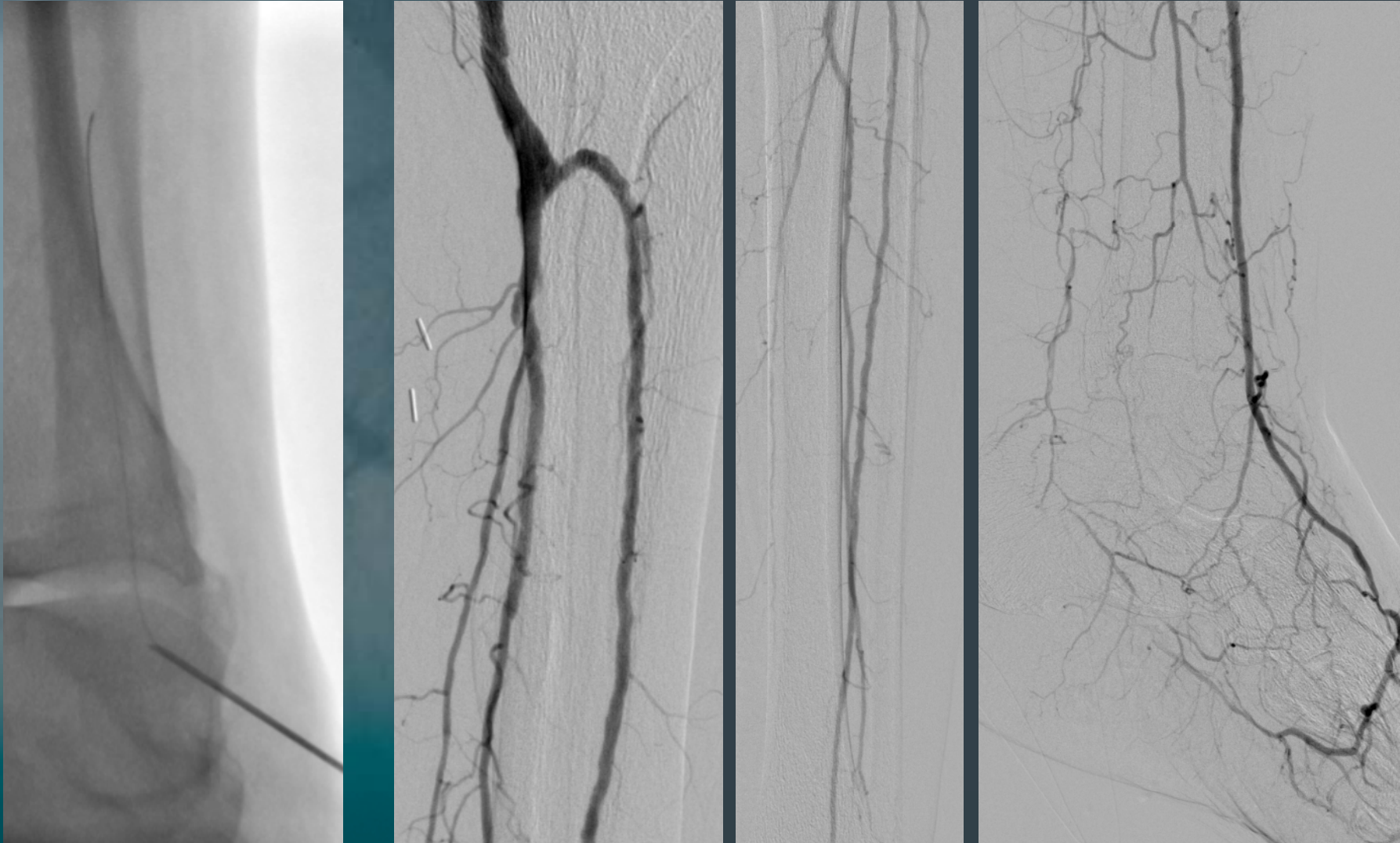
	POB BTK	DEB BTK
Lesion-length	183 mm	173 mm
Restenosis >50 % @ 3 Mo	69 %	27 %
61% restenosis reduction		
Length of restenosis	155 mm	64 mm

Focal Restenosis after DCB BTK



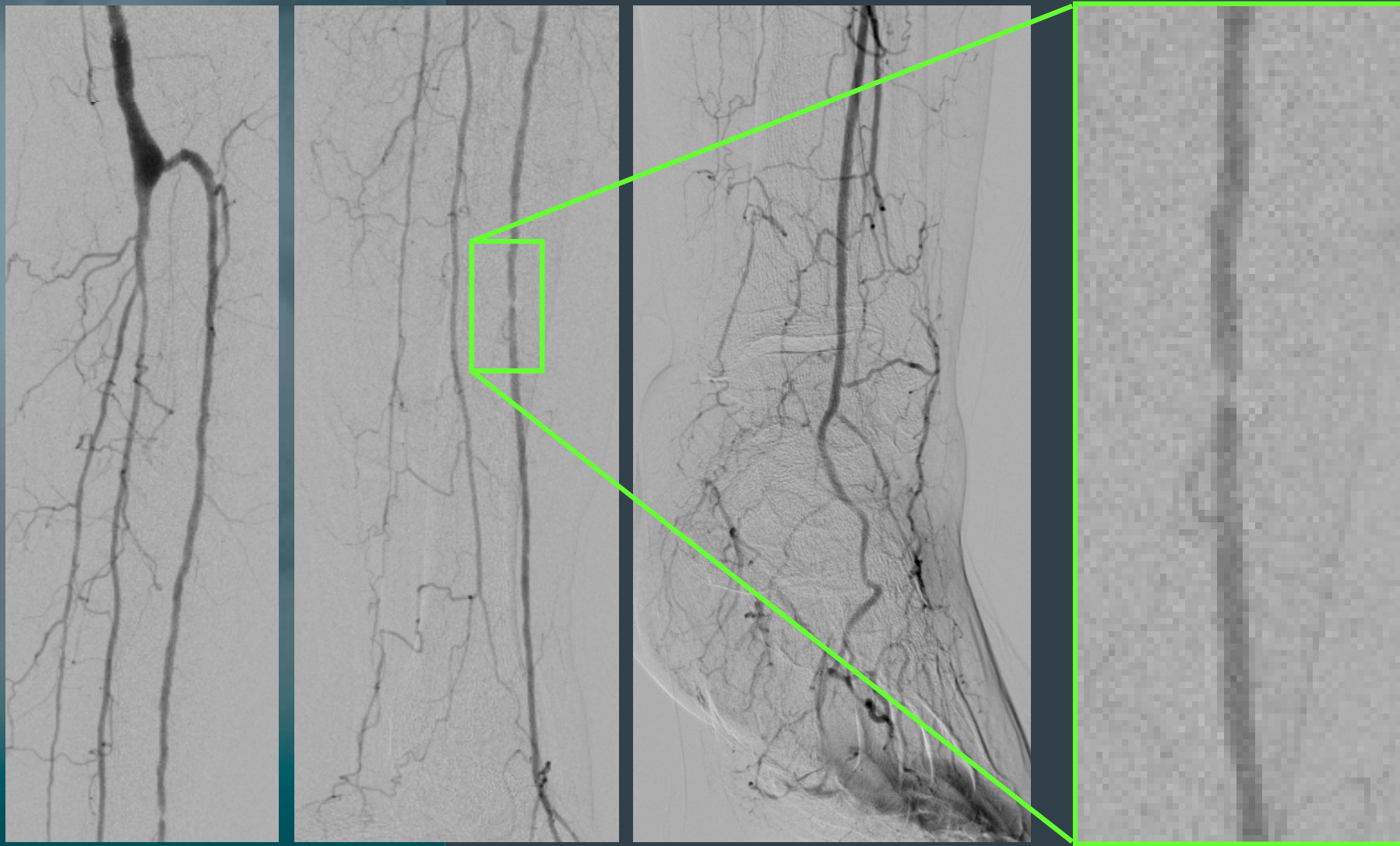
Occlusion left anterior tibial artery

Focal Restenosis after DCB BTK



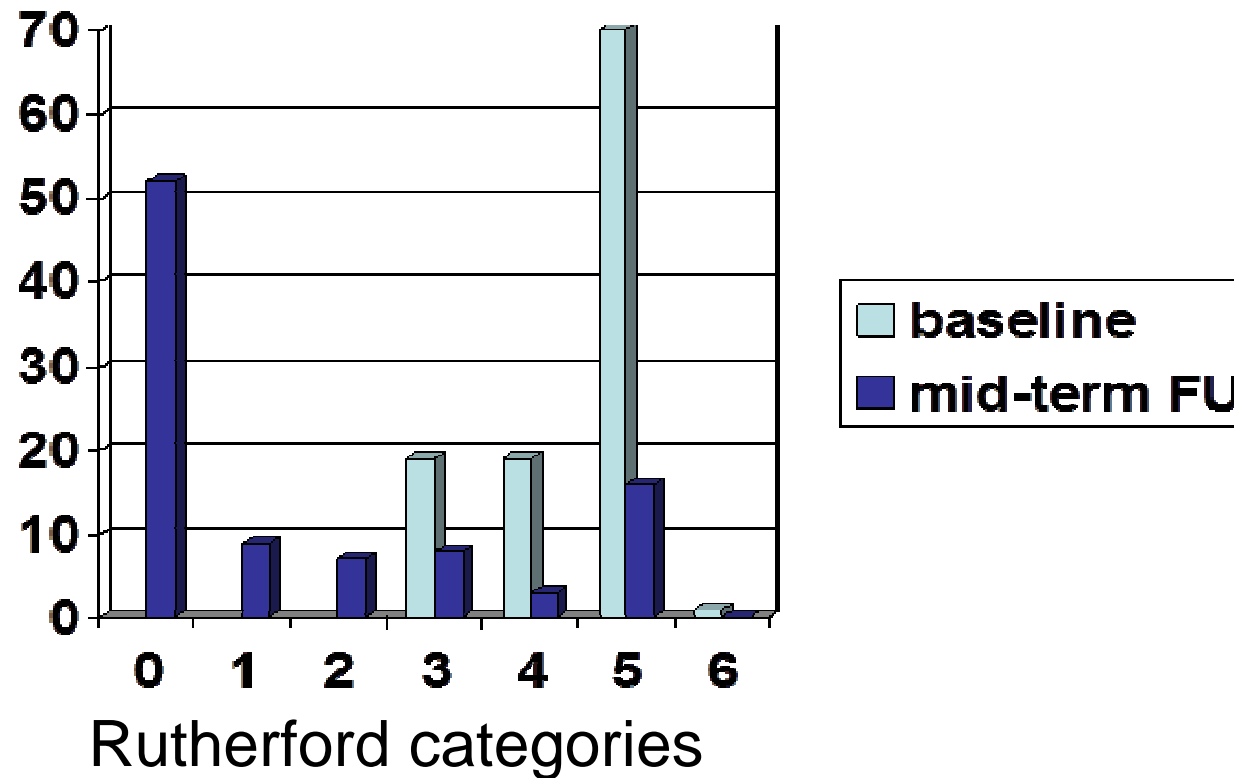
Retrograde recanalization, 3 x 2.5/120 In.Pact Deep

Focal Restenosis after DCB BTK



3-months angiogram

Mid-Term Follow-Up (309 days) (Entire patient-cohort with 109 limbs)



2 major amputation, one forefoot-amputation, no bypass-surgery
Complete wound-healing in 73 %

DES or DEB Below the Knee ?

- Drug-eluting devices in case of
 - Long healing time expected
 - Restenoses with clinically indicated TLR
- DES in shorter, proximal lesions
- DEB in longer and distal lesions

DES or DEB BTK ?



DES preferred in calcified lesions and bifurcational lesions ?

Do DES and DEB improve Clinical Results?

- Primary endpoints of randomized trials comparing DES with BMS/POBA was restenosis.
- Results from randomized trials comparing DEB with POBA (Piccolo, In.Pact Deep) not yet available.

Will DEB improve the results for Patients with BTK-Obstructions ?

- Limb-salvage
- Freedom of symptoms
- Time to healing
- Necessity for repeat revascularization