

# Why DEB should be considered for BTK



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# Presenter Disclosure Information

**Name:** Andrej Schmidt MD

Within the last 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organizations listed below.

## Company

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*Biotronik*

*Boston Scientific*

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*C.R. Bard*

*Ev3*

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*Medtronic Invatec*

*Spectranetics*

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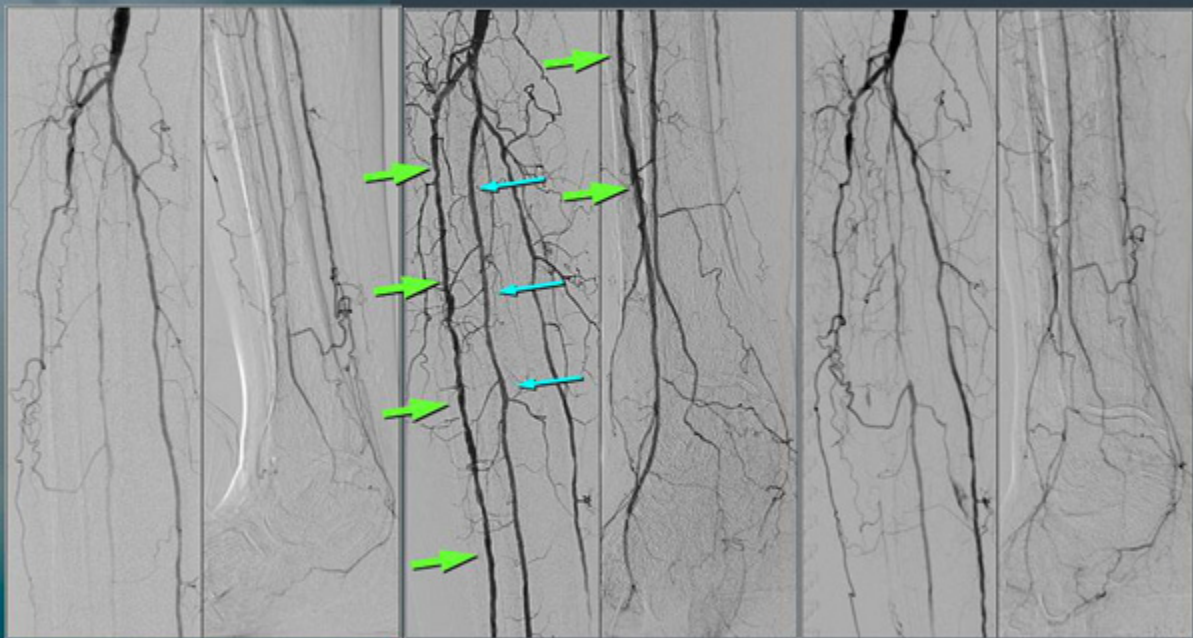
*Consultant*

*Consultant*

## Interventional Therapy BTK for CLI-Patients

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

# 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 %**
- Mean length of restenosis: **155 mm**

# Case example from the LACI-Trial



Before therapy



3 Months



6 Months

Extended patency is needed for wound healing

# Experience with Drug-Eluting Balloons BTK

- Prospective registry of patients with BTK-lesions
- Without industry-support
- In.Pact Amphirion Deep Paclitaxel-eluting balloon  
(Medtronic 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 %)	}	CLI 82.6 %
- Ruth 4	19 (17.4 %)		
- Ruth 5	70 (64.2 %)		
- Ruth 6	1 (0.9 %)		

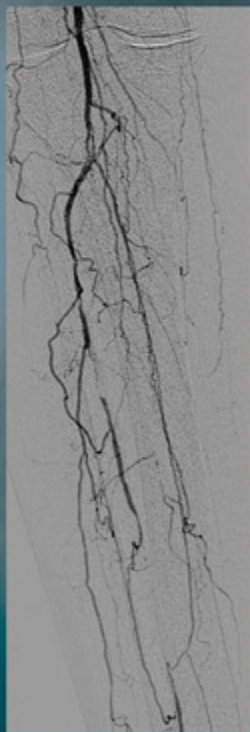


# Subgroup with 3-Mo Angio

## 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 %)

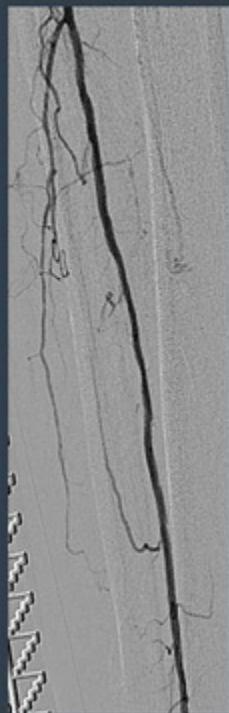
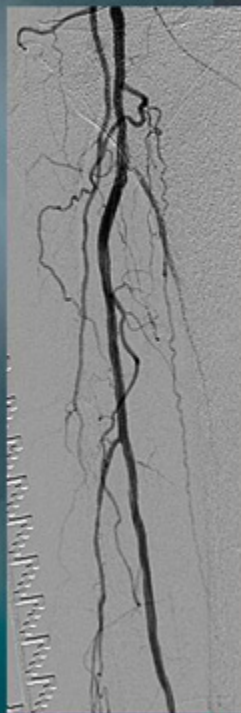
# Leipzig Experience with DEB BTK



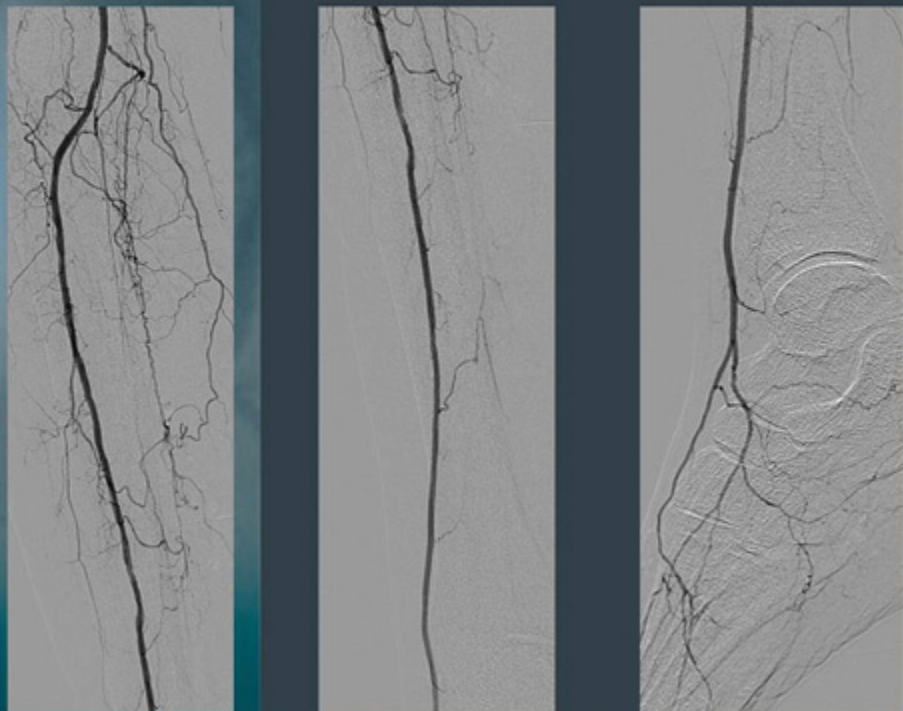
# Leipzig Experience with DEB BTK



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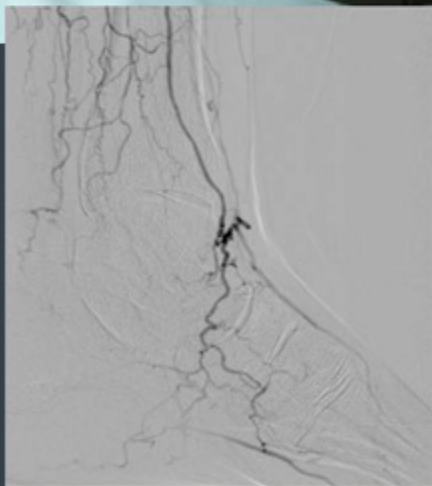
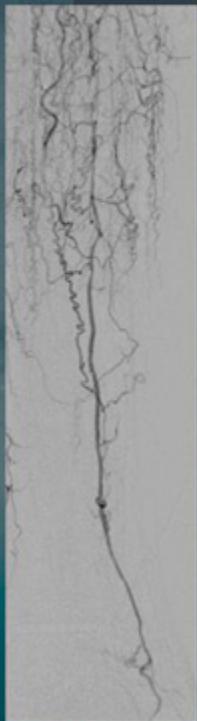


# Leipzig Experience with DEB BTK

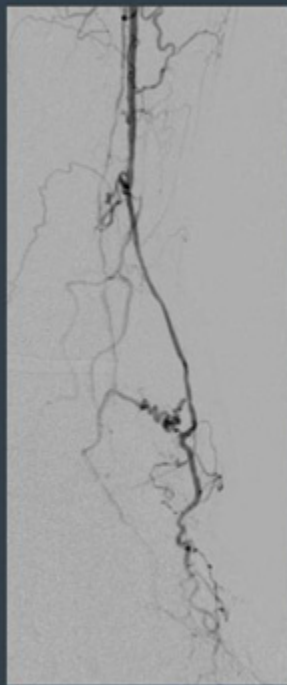
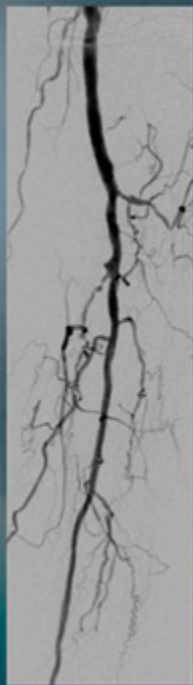


3-months follow-up angiography

# Rutherford 5 left

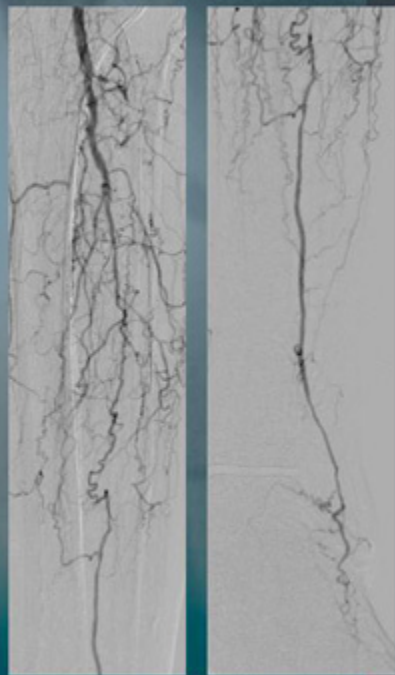


## After Balloon-Angioplasty

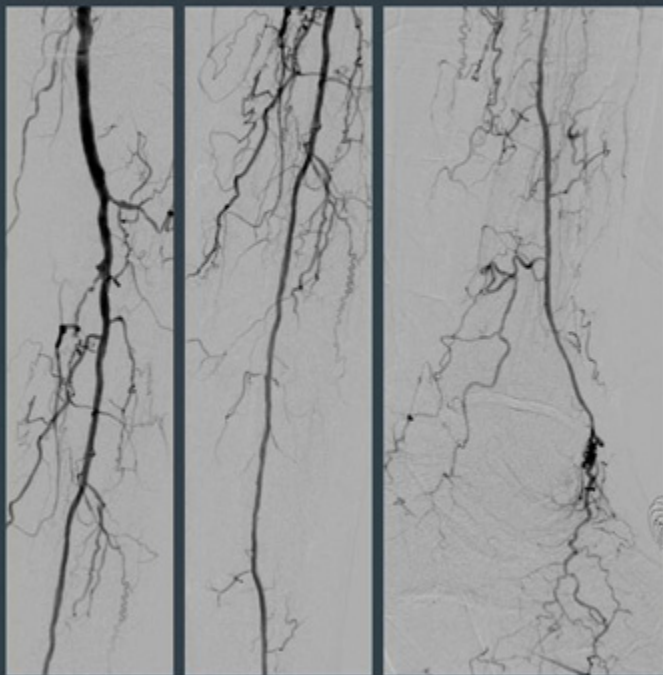


Non-coated balloon 2.5/150

# First Reocclusion after 6 weeks



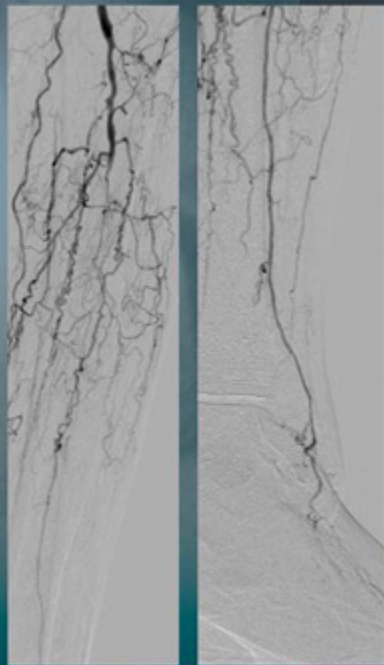
First re-occlusion



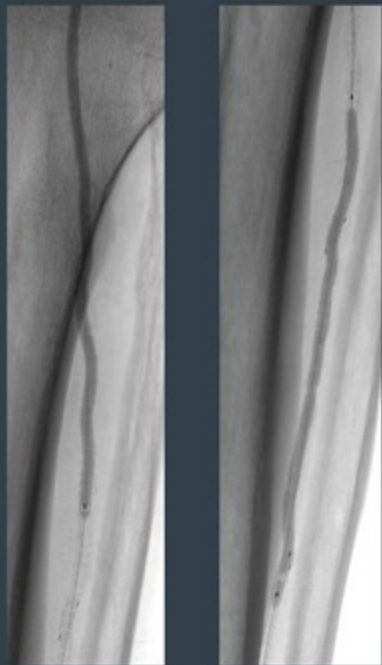
Second balloon-angioplasty



## Second Re-Occlusion after 4 Months

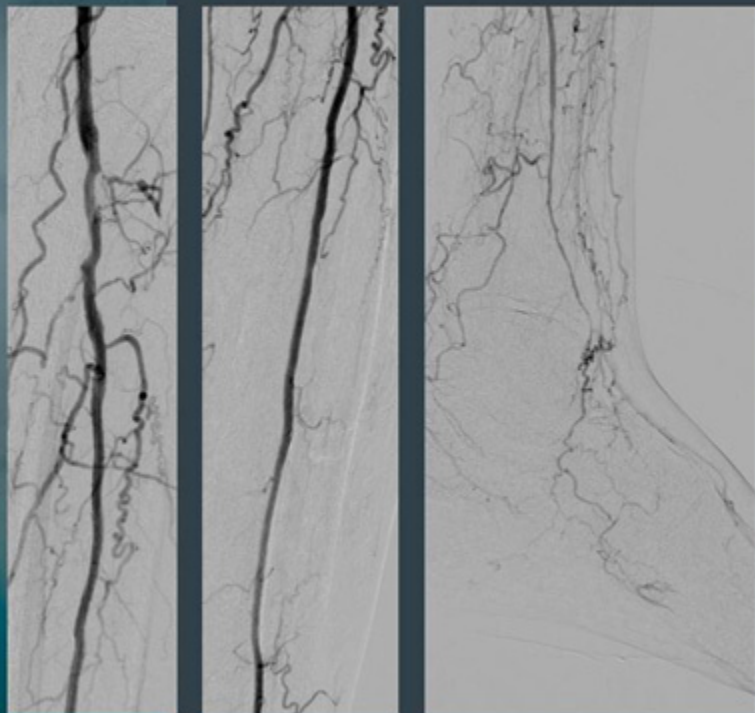


Second re-occlusion

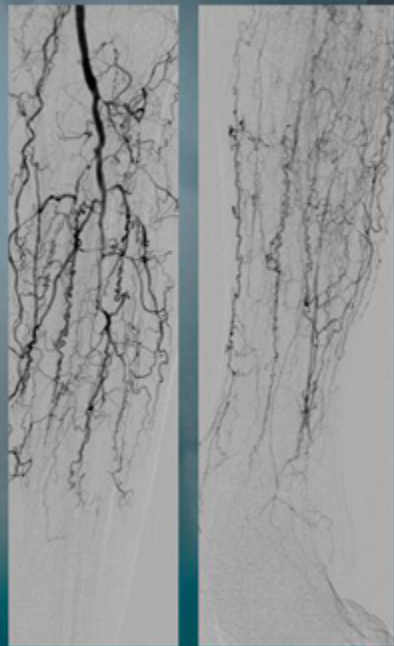


Stenting (3 x 4/80mm Maris Deep)

## Result after 3rd PTA + Stenting

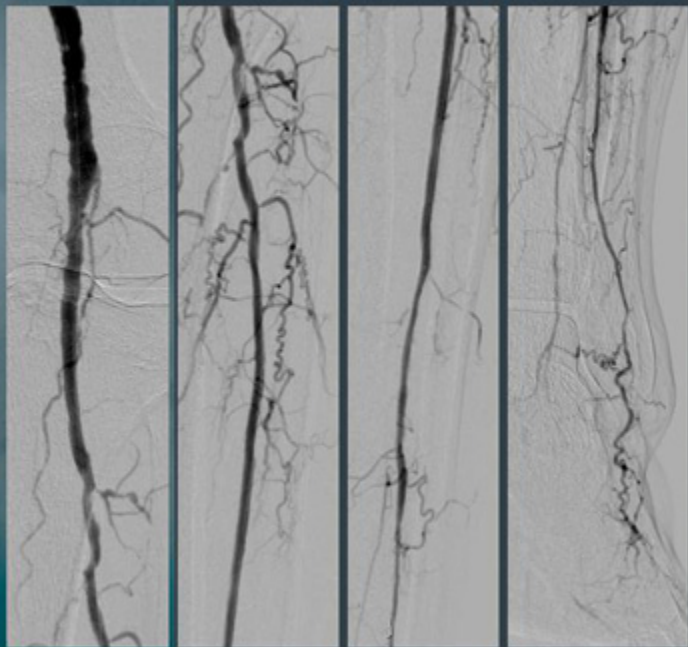


# Third Re-Occlusion (Stent-Reocclusion) after 5 months



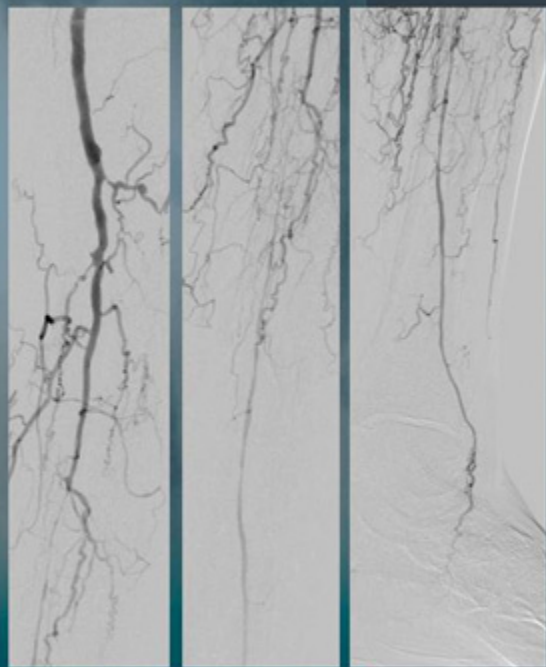
Third reocclusion

# Third Re-Occlusion (Stent-Reocclusion) after 5 months

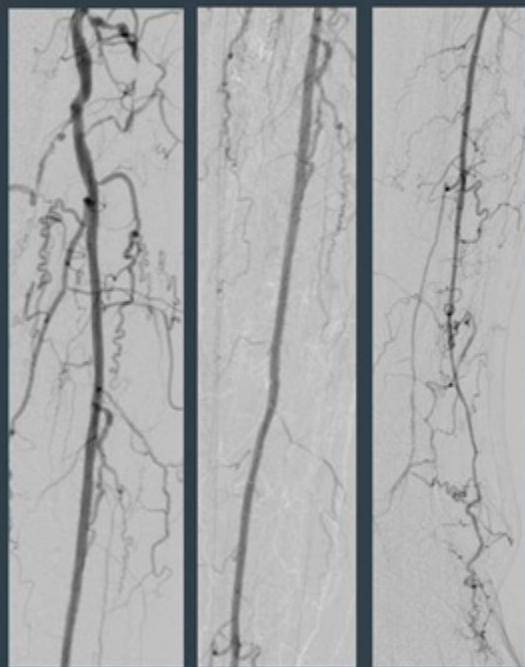


Fourth re-intervention (POB)

## Fourth Re-Occlusion, PTA with DEB

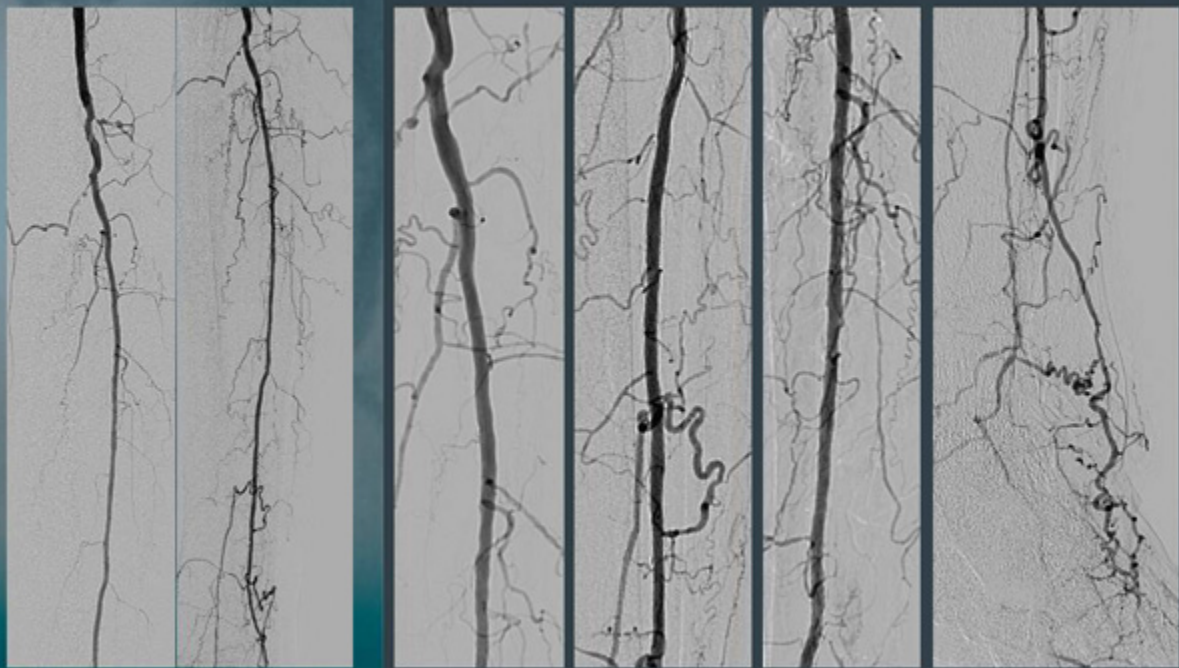


Fourth reocclusion



Fifth re-intervention (DEB)

## 6-Months after DEB

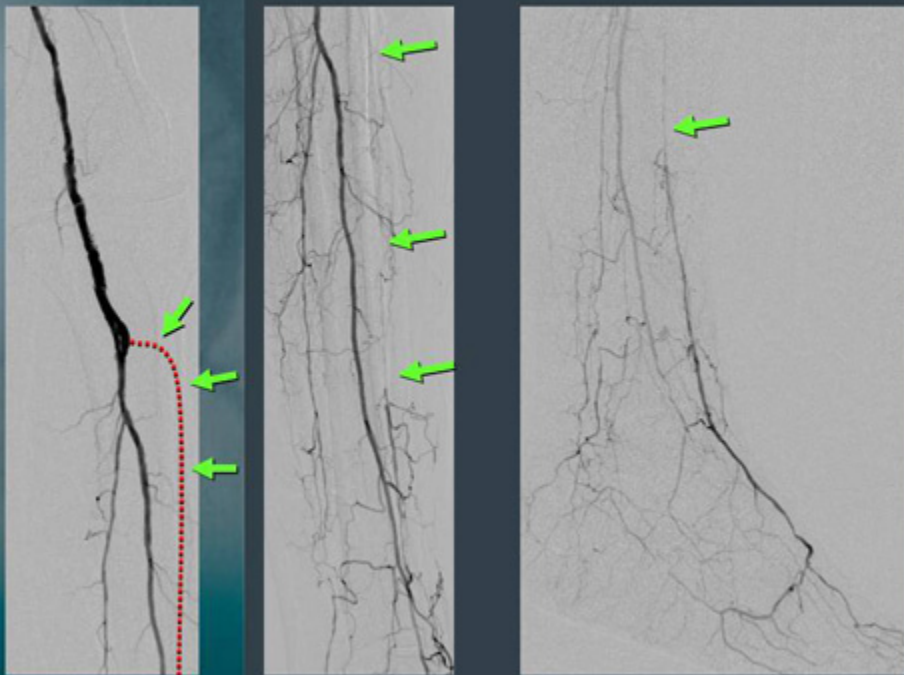


Wound completely healed

# Leipzig Experience with DEB BTK

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

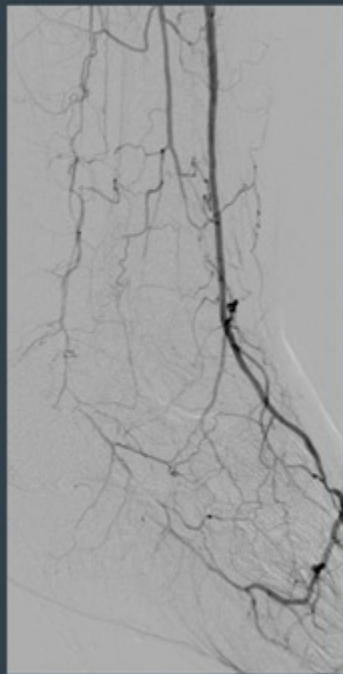
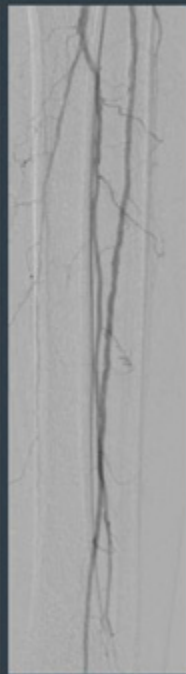
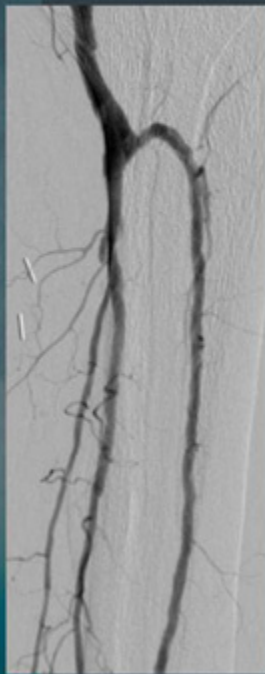
# Focal Restenosis after DCB BTK



Occlusion left anterior tibial artery

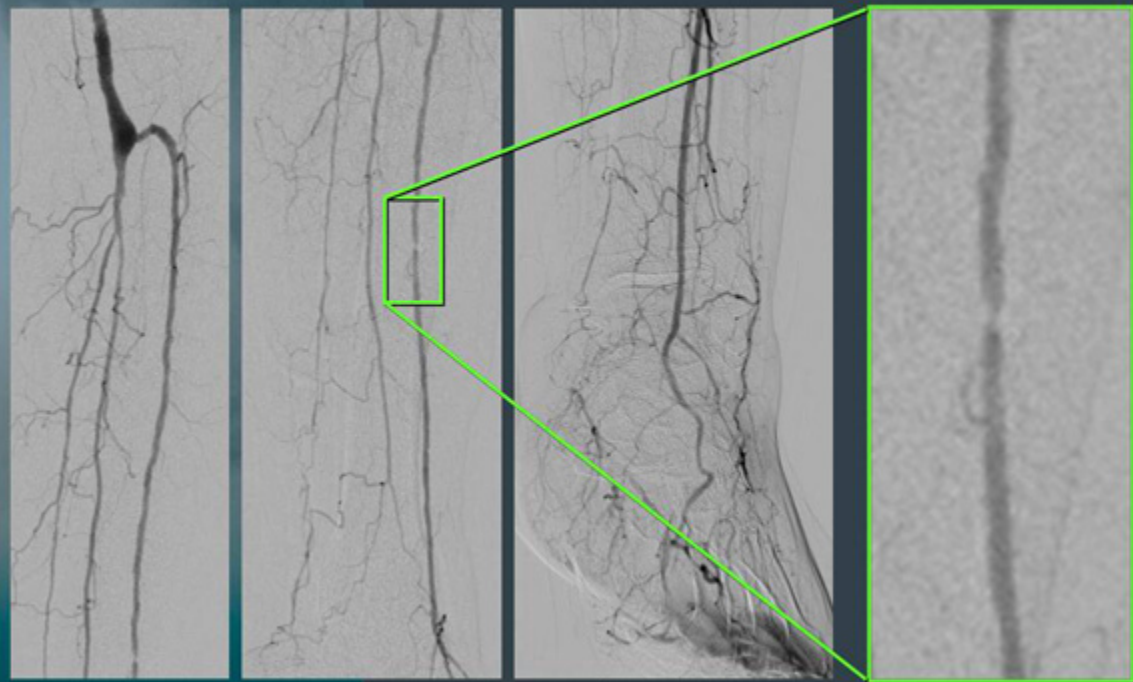


# Focal Restenosis after DCB BTK



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

# Focal Restenosis after DCB BTK



3-months angiogram

## Riskfactors for Restenosis after DEB

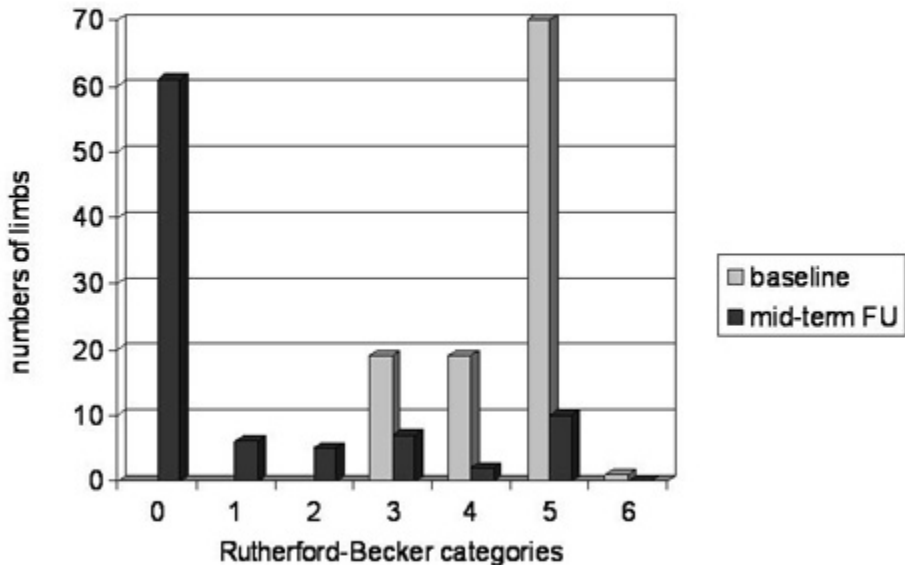
		Tibial			
	Apop (P3)	Prox.	Mid.	Distal	Foot
n treated segments	11	54	45	37	13
Restenosis-rate	9.1%	9.3%	20.0%	18.9%	<b>38.5%</b>

No involvement of foot-arteries in the POBA-series

## 12.5 Months Follow-Up (Whole Cohort)

- Mortality 16.3 %
- Amputation 4 (3 BTK, 1 forefoot)
- Angiography available in 3/4 patients 7-21 days prior to amputation showing a patent treated artery !
- Clinical improvement 91.2 %
- Complete woundhealing 74 %
- Re-intervention-rate 17.3 %

# Mid-Term Follow-Up (378 days) (Entire patient-cohort, )



# Plane Balloon Angioplasty BTK in CLI-Patients

- 101 Diabetes-patients (106 CLI)
- Rutherford 5 = 33; Rutherford 6 = 74
- Isolated infrapopliteal lesions
- Lesionlength: **213 mm**
- Limb-salvage at **2.9 years** **93 %**

# Plane Balloon Angioplasty of Tibial Arteries in CLI-Patients

- 111 CLI-patients
- 1-year FU:
  - Primary patency rate (Duplex) 33 %
  - Limb salvage rate 75 %
  - Re-intervention rate 50 %

„Re-intervention inevitable part of the treatment of CLI-patients with BTK-lesions using POBA.“

# The Value of DEB BTK

- Randomized trials DEB BTK:
  - PICCOLO:
    - Paccocath vs. bare balloon
  - IN.PACT Deep:
    - In.Pact Amphirion PTX-eluting balloon vs.
    - Uncoated Amphirion Deep balloon  
(Medtronic Invatec)



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

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

## Open Questions using DES or DEB BTK

- Which patients should be treated using drug-coated devices ?
- Can we expect a difference between Diabetes- and non-Diabetes patients ?
- Will restpain-patients especially benefit ?

## Open Questions using DES or DEB BTK

- DES:
- Selfexpanding or balloon-expandable ?
- Will DEB be effective in calcified lesions ?
- Will DEB be effective after subintimal PTA ?

## Open Questions using DES or DEB BTK

- Will the use of DES and DEB expand angioplasty of BTK-lesions to claudicants ?
- Which anticoagulation would you recommend after DEB ?