

DEB in Challenging Lesion (CTO, Ca++)



“the miracle of healed foot”

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DEB in BTK Intervention

The optimal strategy for treating critical limb ischemia has not been clearly defined

1-year restenosis rate after balloon angioplasty of long lesions in BTK arteries may be as high as 70%

The use of drug-eluting balloon in BTK interventions is under evaluation

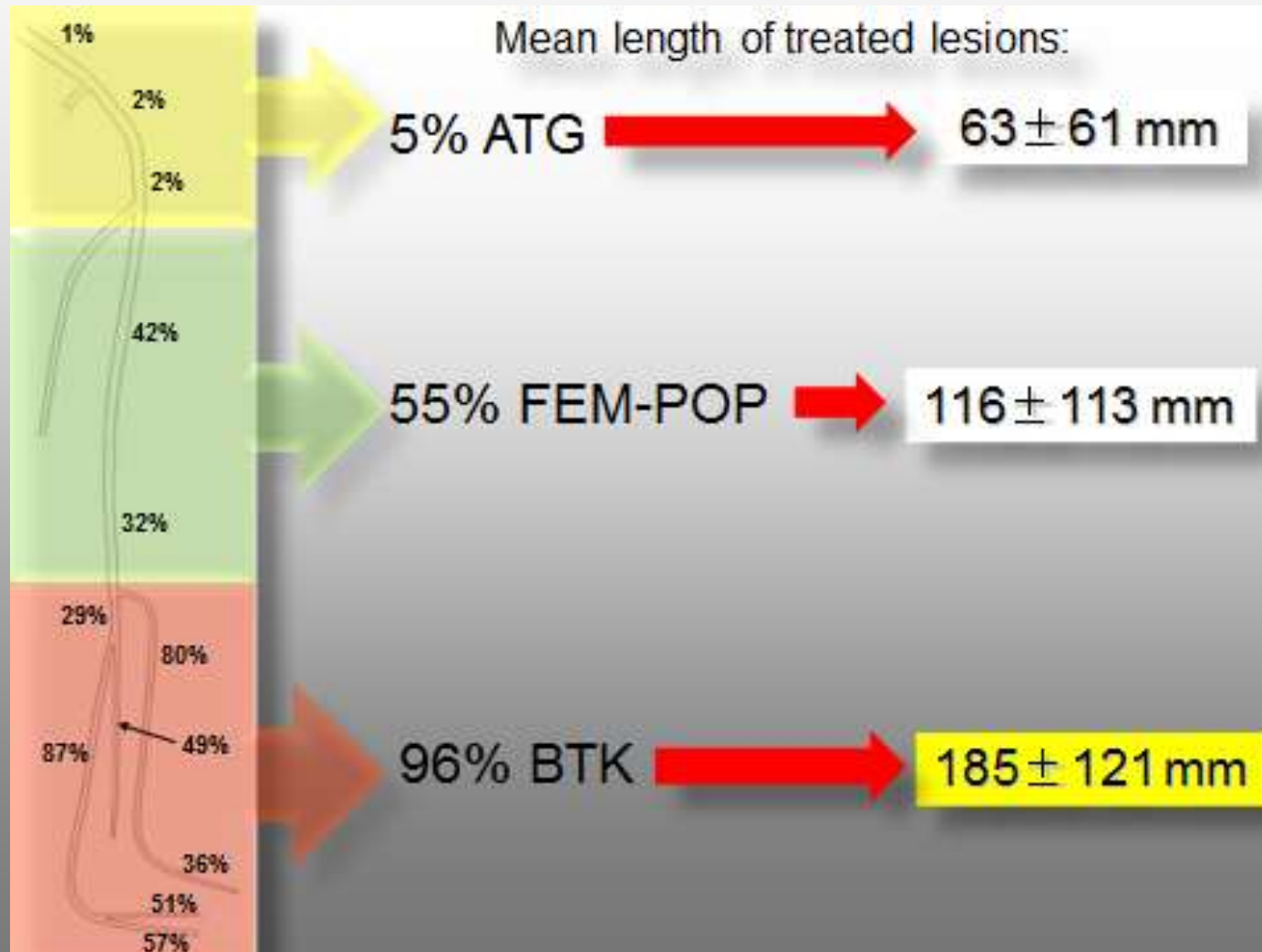
Data of DEB for CTO or calcified lesions are lacking

DEB in BTK Intervention

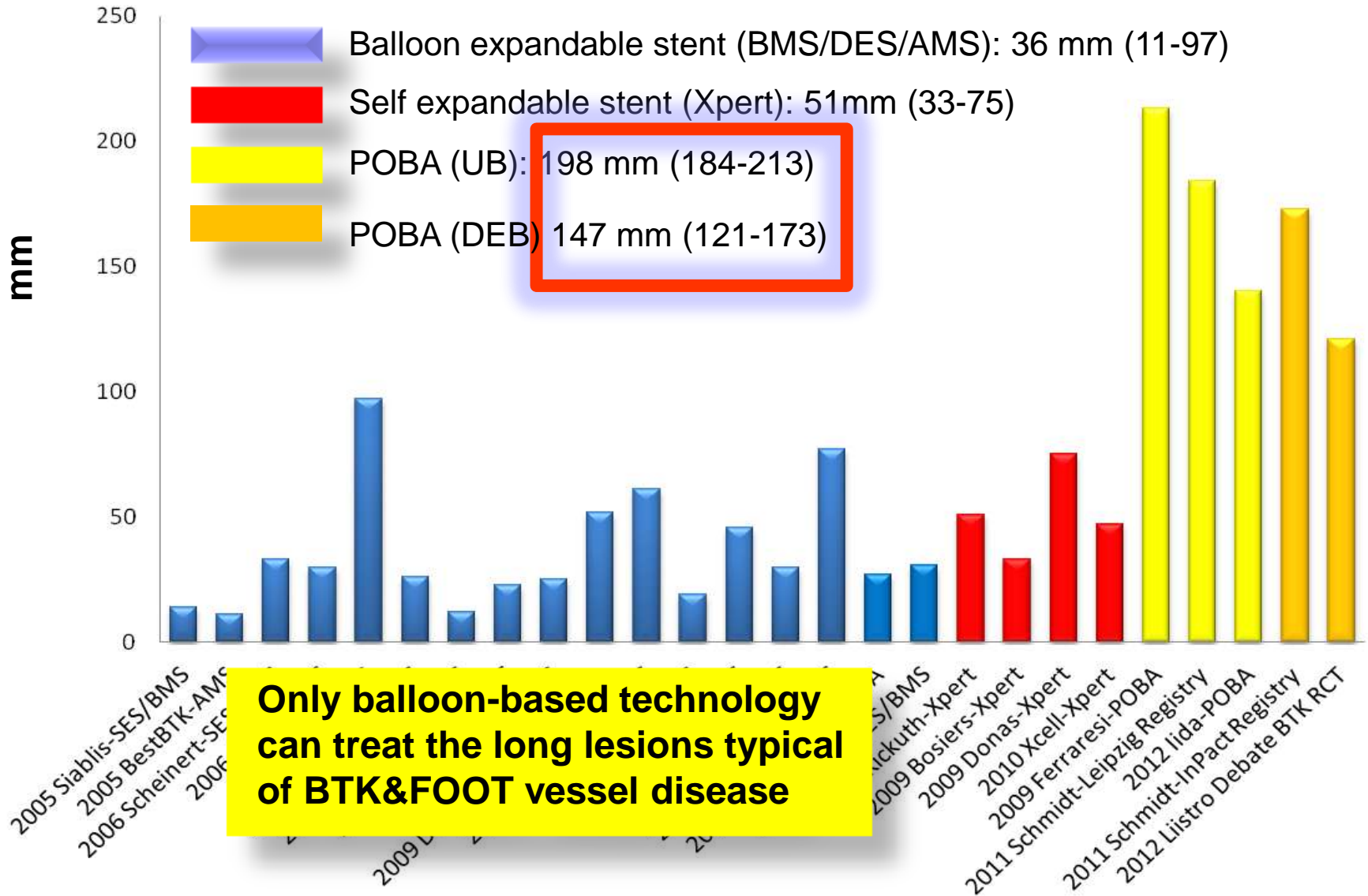
Rationale

- . Address root cause for development of restenosis**
- . Suited for long lesion**
- . Proven efficacy in SFA**
- . No foreign material left in place**

DEB in BTK Intervention



Length of BTK treated lesion



DEB in BTK Intervention

5 Studies

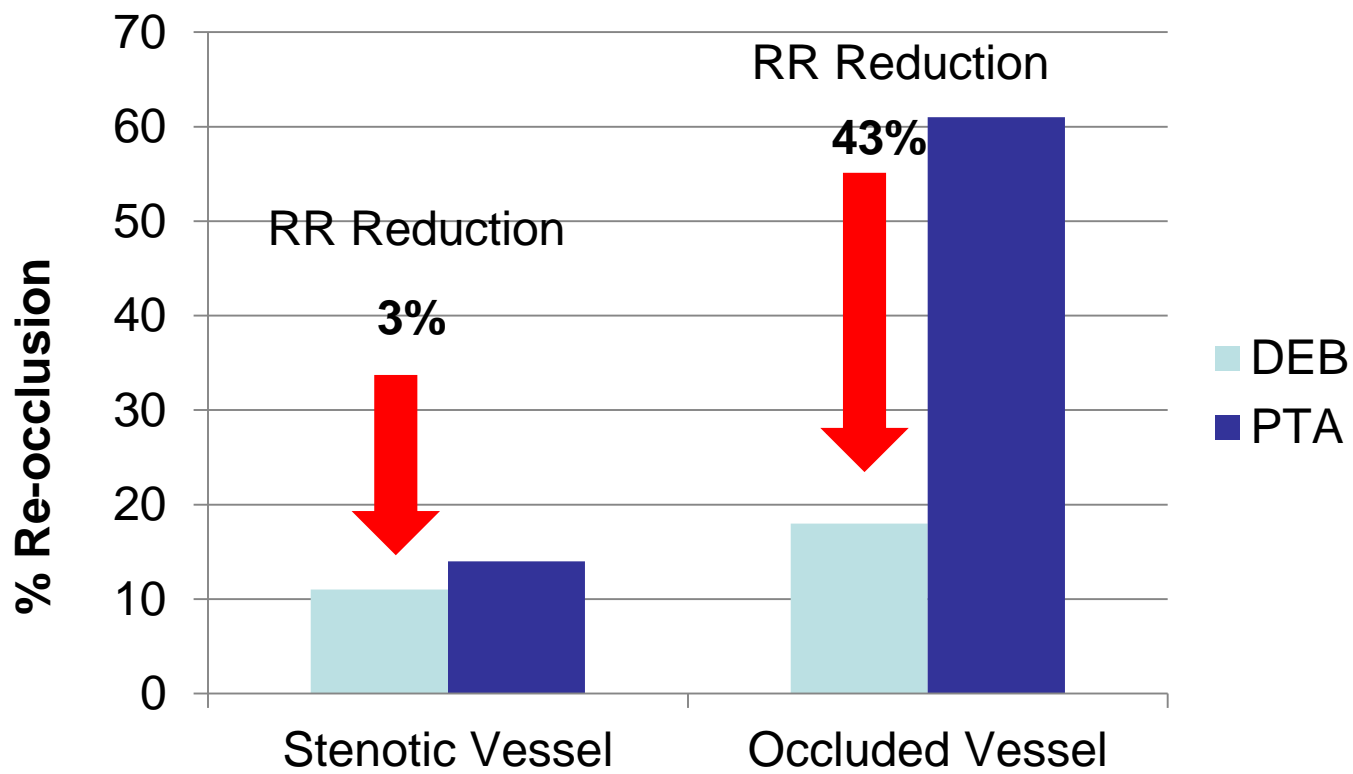
(2 published, 3 presented)

- 1 Single-center Registry DEB [1]
- 1 Single-center RCT DEB vs. PTA – Two years data [2]
- 2 Multi-center RCT DEB vs. PTA^[3,4]
- 1 Single-center RCT DEB vs. DES [5]

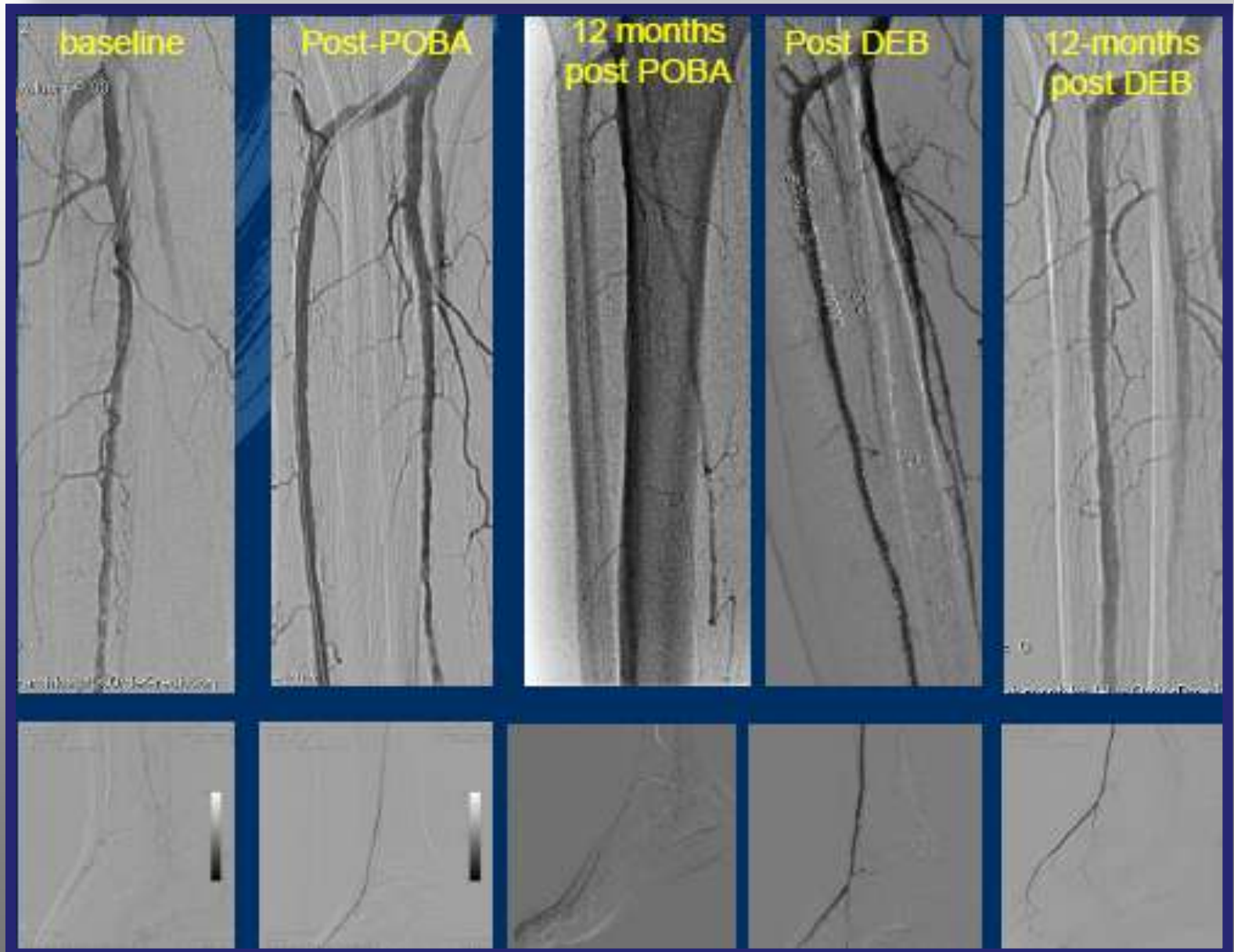
[1] Schmidt A, JACC 2011; [2] Liistro F, DEBATE-BTK Circulation 2013; [3] Brodmann M, BIOLUX-PII LINK 2014; [4] Zeller T, IN.PACT DEEP LINK 2014; [5] Kitrov PM, IDEAS-I LINK 2014.

DEBATE-BTK Study

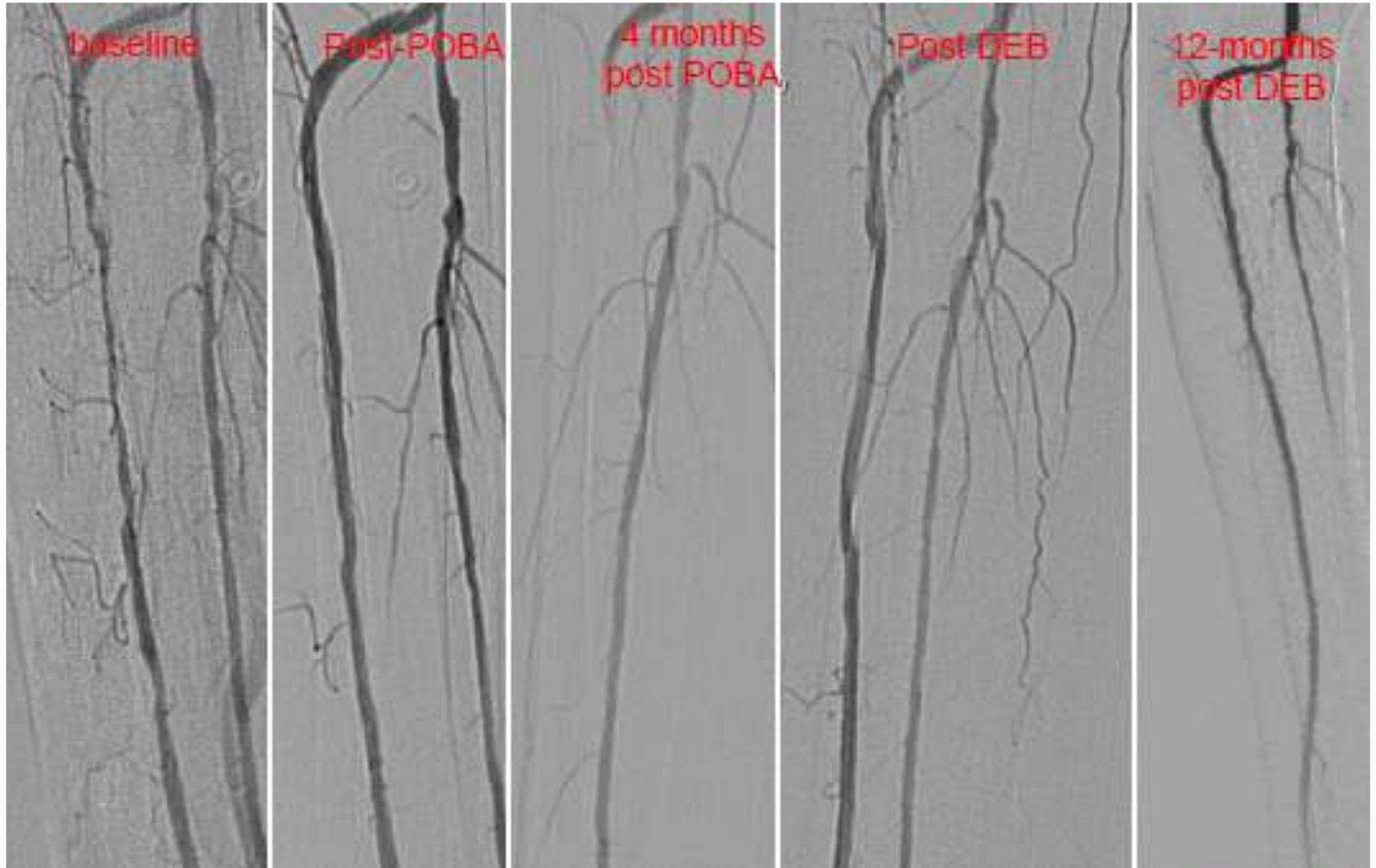
Reocclusion rate at 12 months



Occlusive Restenosis after POBA



Occlusive Restenosis after POBA



CTO of calcified PTA

- *64 yy old male*
- *type 2 DM, ESRD in hemodialysis*
- *Forefoot plantar ulcer*

Baseline angio



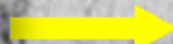


Target: calcified lesion of PTA
in patient with “desert” foot
(long history of diabetes and
hemodialysis)

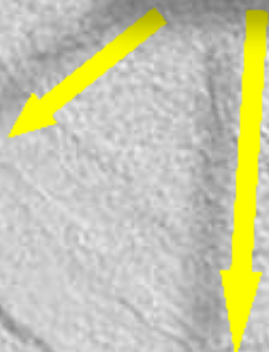
Failure of antegrade approach



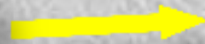
antegrade
wire



Med plantar
artery (occluded)



Lat plantar artery



NONAME.DD

Jun 07 2011
11:38:22

(File 5)

Seq: 2
FRAME = 79/90
MASK = 1

V: 4096 WL: 2048

Retrograde puncture of common plantar artery



Final DEB Treatment

Jun 07 2010
12:39:05

(FIL. 6)

Seq 15
FRAME = 9 / 14

256WL128



Baseline angio



Final result



**Calcified and Diffuse
Disease of the Foot
Vessels**

Baseline angio



Baseline angio



**Calcified and diffuse
disease of the foot
vessels**

Pedal-plantar loop



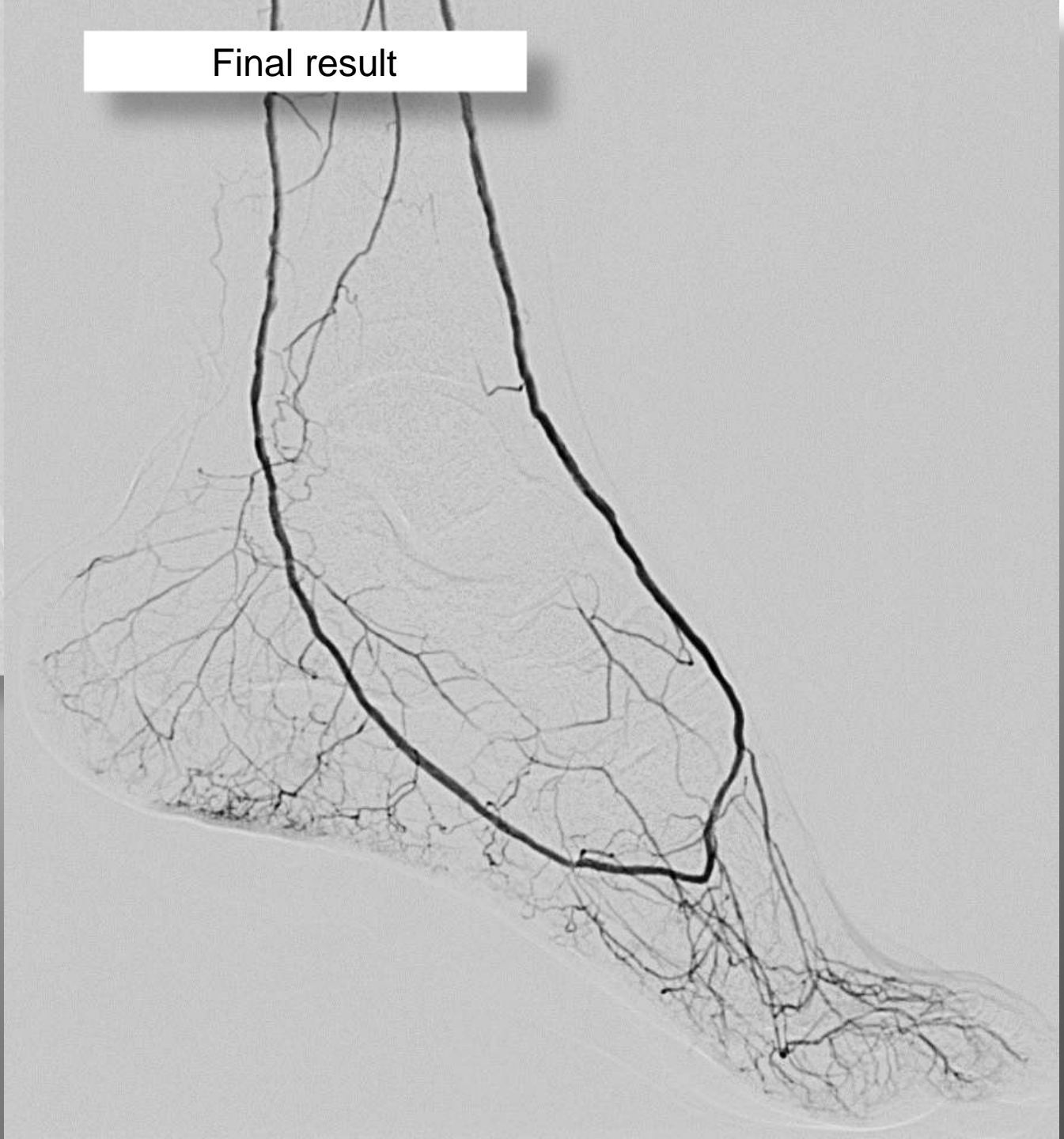
Final DEB treatment



Final result



Final result



DEB in BTK Intervention

- **In our clinical practice the use of DEB is reserved to specific subgroup of high-risk patients**
- **In order to expand the indications we need more consistent results from controlled clinical trials**
- **From a technical point of view, the deliverability of these devices needs to be improved**