

# DEB will be the Future for BTK Lesions



**GB Danzi, MD**  
*Milan - Italy*

# BTK Intervention: Drug-Eluting Balloon

1. Pattern of disease in CLI patients
2. Targets in CLI revascularization
3. Lesion length in BTK-CLI-PTA
4. Restenosis in BTK vessel PTA

# Our last 1000 CLI patients

- 84% DM
- 17% ESRD-HD
- Mean age 72 yy



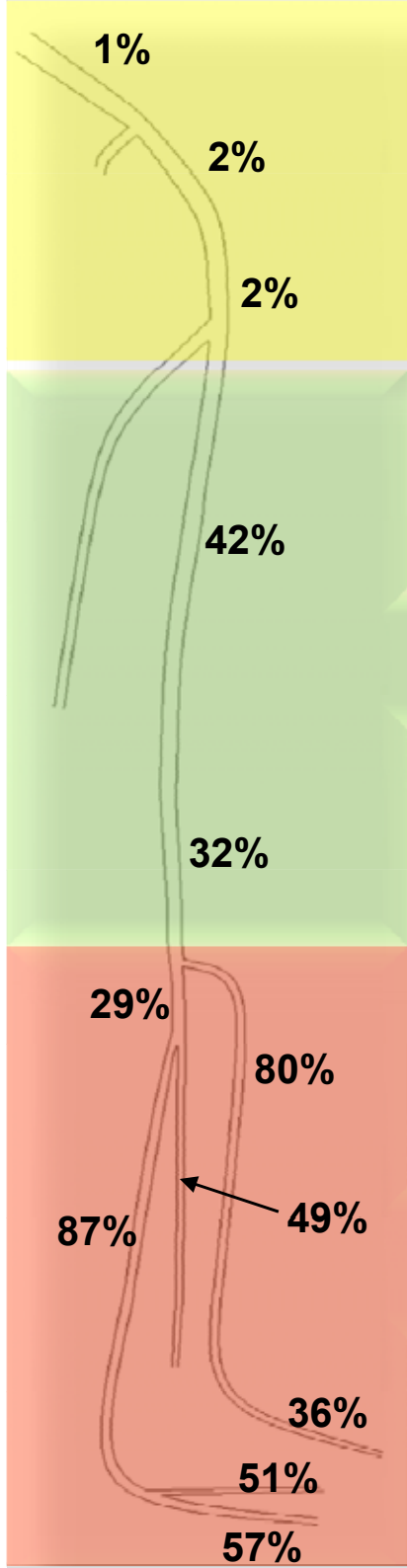
**5% ATG**

**55% FEM-POP**

**96% BTK**

TPT	<b>29%</b>
0 BTK vessel	<b>4%</b>
1 BTK vessel	<b>14%</b>
2 BTK vessels	<b>42%</b>
3 BTK vessels	<b>40%</b>

<b>0 FOOT vessel</b>	<b>26%</b>
<b>1 FOOT vessel</b>	<b>23%</b>
<b>2 FOOT vessels</b>	<b>33%</b>
<b>3 FOOT vessels</b>	<b>18%</b>



5% ATG

55%

96% BTK

**In our society we are facing an epidemic of OLD-DM-ESRD-CLI patients characterized by multilevel disease & extensive involvement of BTK & FOOT vessels**

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# Targets in BTK-CLI revascularization

## 1. Complete revascularization

- 1 vessel better than 0
- 2-3 vessels better than 1
- Tibials better than peroneal

DIABETICMedicine

DOI: 10.1111/j.1464-5491.2007.02167.x

### Original Article

**When is a technically successful peripheral angioplasty effective in preventing above-the-ankle amputation in diabetic patients with critical limb ischaemia?**

E. Faglia, G. Clerici, J. Clerissi\*, M. Mantero, M. Caminiti, A. Quarantiello, V. Curci, T. Lupattelli\* and A. Morabitot

Cardiovasc Intervent Radiol (2010) 33:720–725

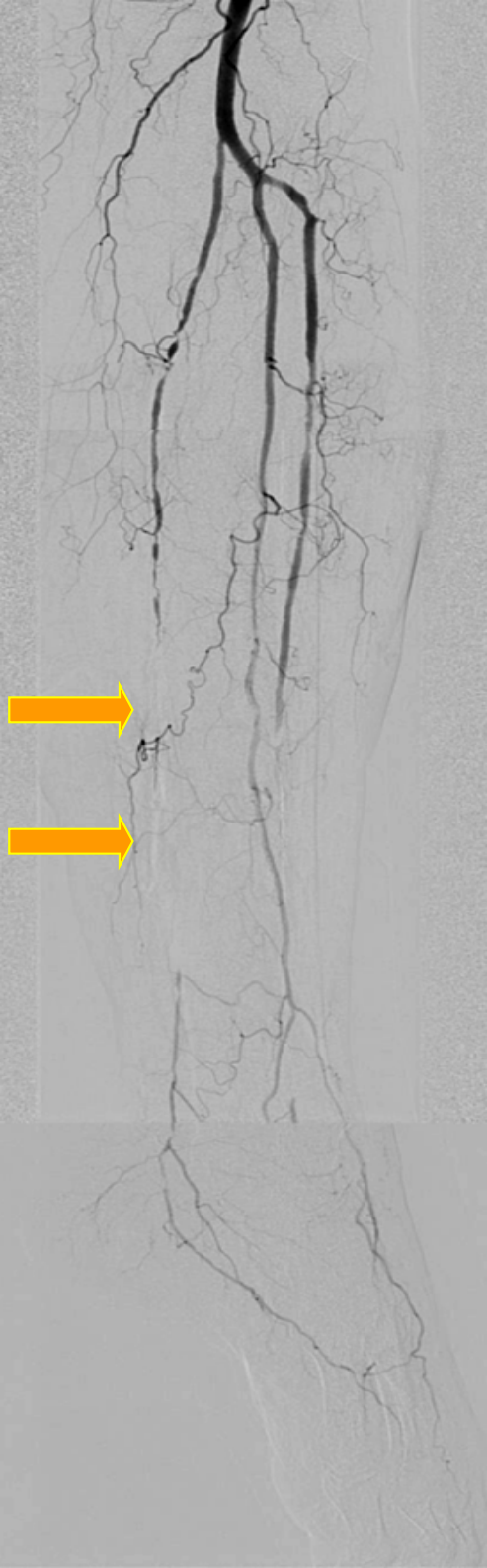
DOI 10.1007/s00270-010-9881-3

### CLINICAL INVESTIGATION

**PTA of Infrapopliteal Arteries: Long-term Clinical Follow-up and Analysis of Factors Influencing Clinical Outcome**

Jan H. Peregrin · Boris Kožnar · Josef Kováč ·  
Jarmila Laštovičková · Jiří Novotný ·  
Daniel Vedlich · Jelena Skibová

Case 1



**Operators need to be familiar with all the available techniques**

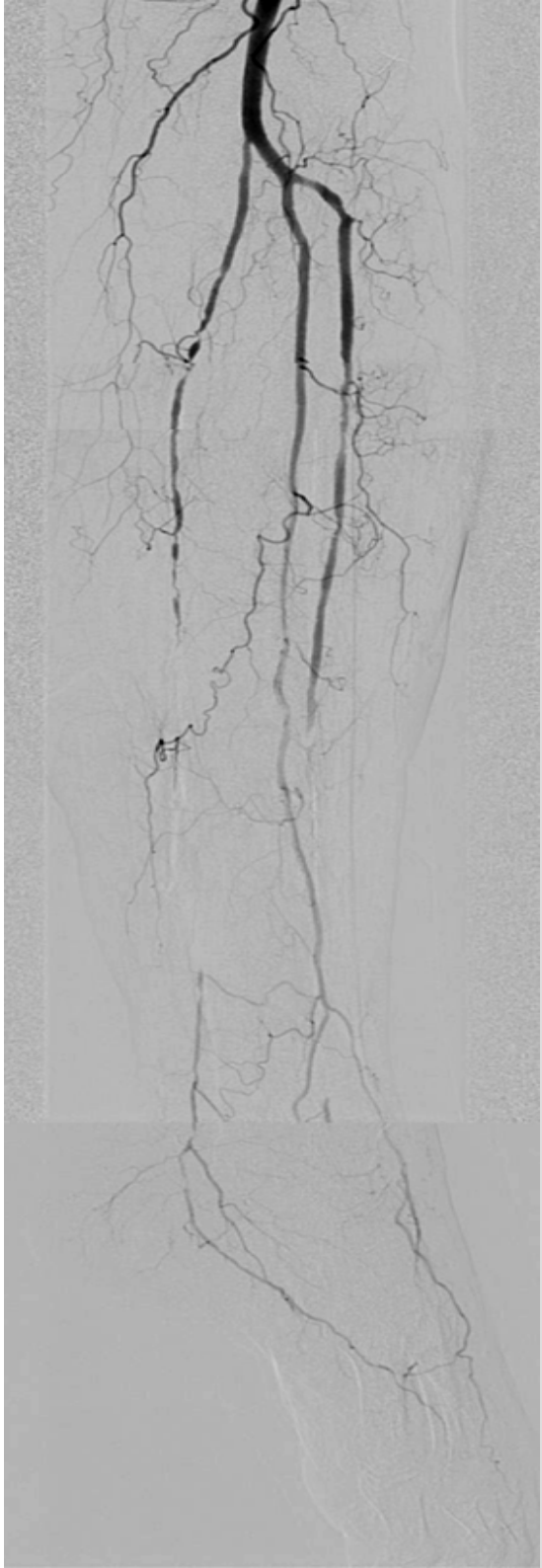
# Pedal-Plantar Loop Technique

Case 1





Case 1



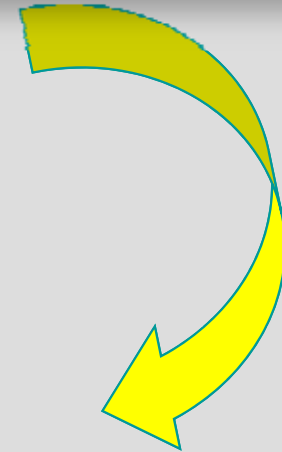
# Targets in BTK-CLI revascularization

1. Complete revascularization

**Failure!**

2. Wound related artery PTA

**Direct revascularization,  
bypass or PTA better than  
indirect revascularization**



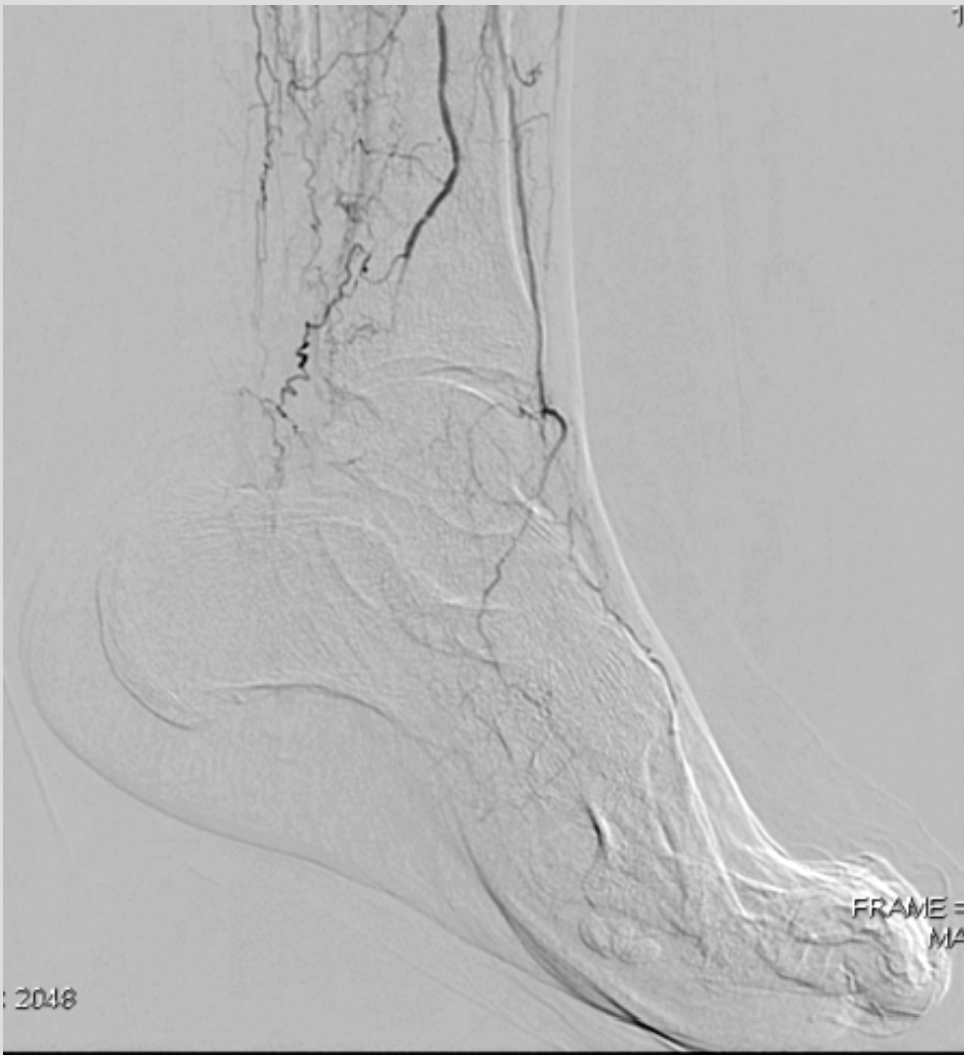
## Revascularization of a Specific Angiosome for Limb Salvage: Does the Target Artery Matte

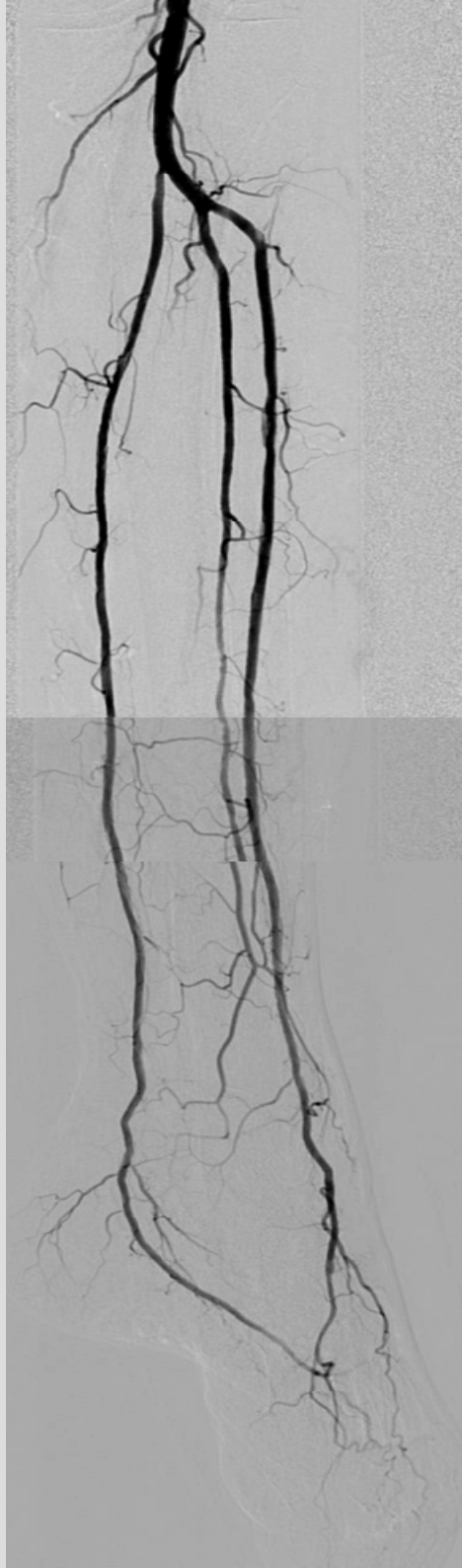
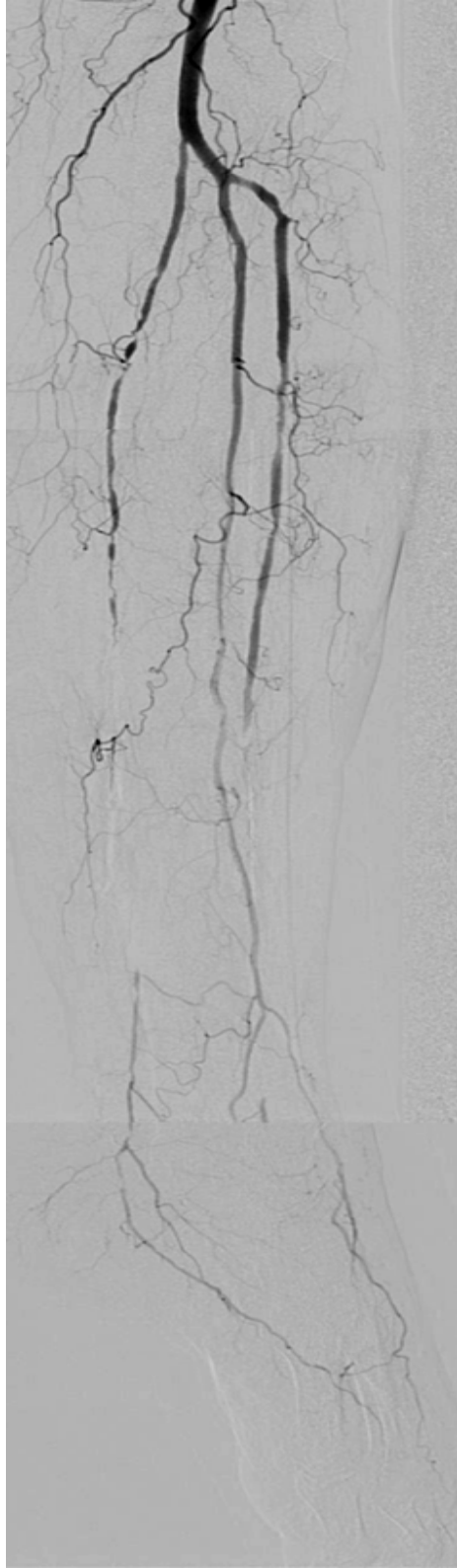
*Richard F. Neville,<sup>1</sup> Christopher E. Attinger,<sup>2</sup> Erwin J. Bulan,<sup>2</sup> Ivica Ducic,<sup>2</sup> Michael Thomassen,<sup>2</sup> and Anton N. Sidawy,<sup>3</sup> Washington, D.C.*

## Importance of the Angiosome Concept for Endovascular Therapy in Patients with Critical Limb Ischemia

*Osamu Iida,<sup>1</sup> MD, Shinsuke Nanto,<sup>2\*</sup> MD, PhD, Masaaki Uematsu,<sup>1</sup> MD, PhD, Kuniyasu Ikeoka,<sup>1</sup> MD, Shin Okamoto,<sup>1</sup> MD, Tomoharu Dohi,<sup>1</sup> MD, Masashi Fujita,<sup>1</sup> MD, PhD, Hiroto Terashi,<sup>3</sup> MD, PhD, and Seiki Nagata,<sup>1</sup> MD, PhD*

# Case 2





**... “complete” or  
WRA are the targets  
of BTK-CLI-  
revascularization**

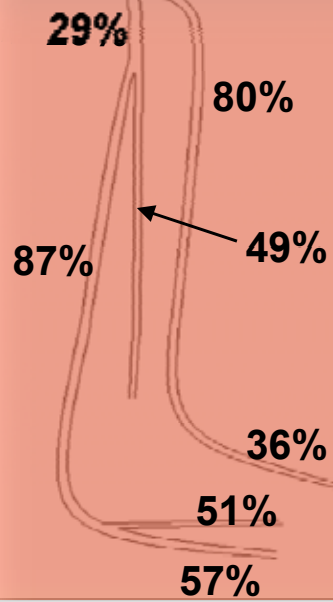
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# Mean length of treated lesions

Our last 1000 CLI patients

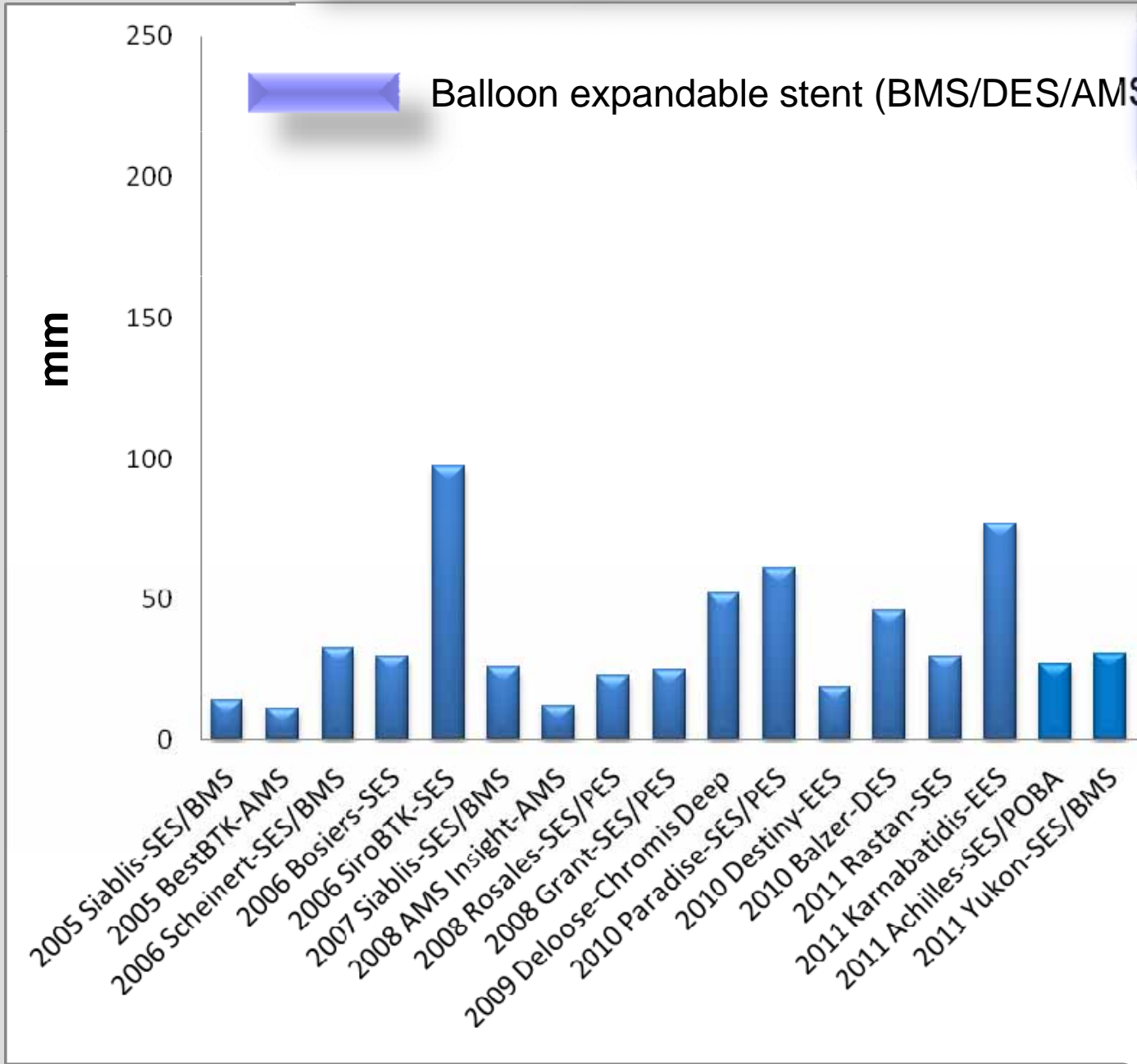
- 84% DM
- 17% ESRD-HD
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96% BTK

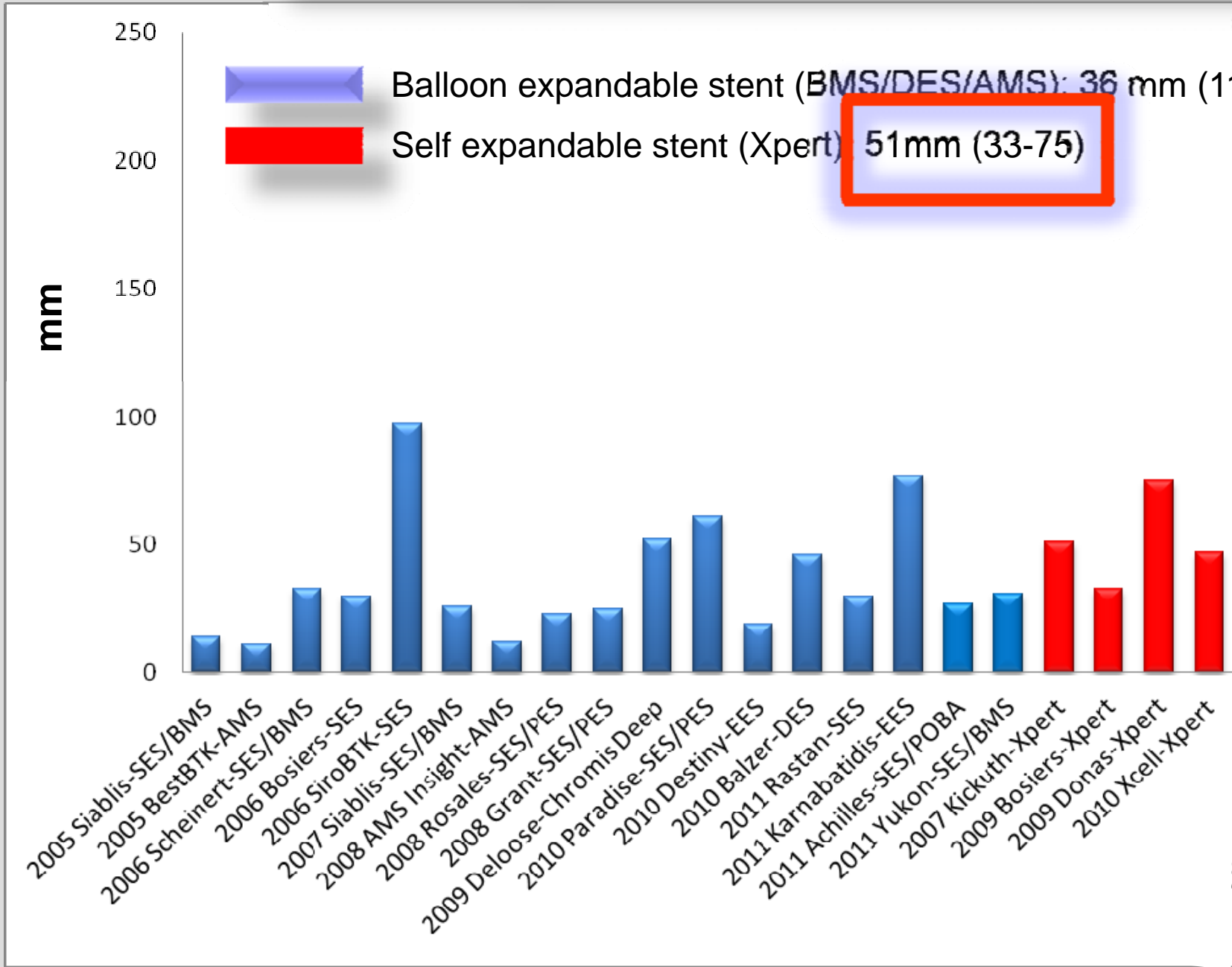
185 ± 121 mm

# Length of BTK treated lesion



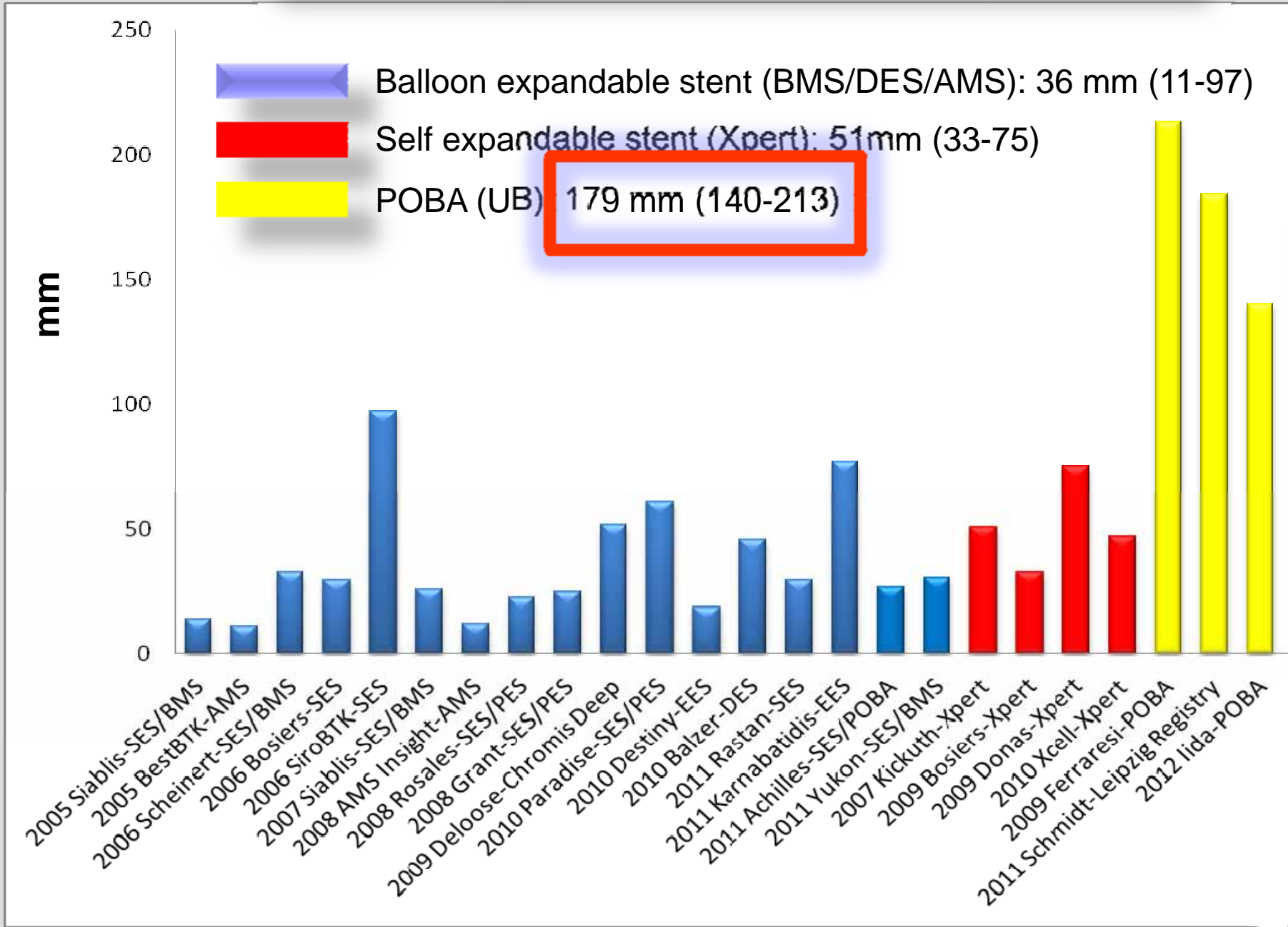
36 mm (11-97)

# Length of BTK treated lesion





# Length of BTK treated lesion



# BTK Intervention: Drug-Eluting Balloon

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# Restenosis in extensive BTK PTA with UB

## Angiographic Patency and Clinical Outcome After Balloon-Angioplasty for Extensive Infrapopliteal Arterial Disease

Andrej Schmidt,<sup>1,2\*</sup> MD, Matthias Ulrich,<sup>1</sup> MD, Bert Winkler,<sup>1</sup> Christina Klaeffling,<sup>3</sup> MD, Yvonne Bausback,<sup>1</sup> MD, Sven Bräunlich,<sup>1</sup> MD, Spiridon Botsios,<sup>4</sup> MD, Hans-Joachim Kruse,<sup>5</sup> MD, Ramon L. Varcoe,<sup>6</sup> FRACS (Vasc), MD, Steven Kum,<sup>1</sup> MD, and Dierk Scheinert,<sup>1,2</sup> MD

European Journal of Vascular and Endovascular Surgery 44 (2012) 425–431



Contents lists available at SciVerse ScienceDirect

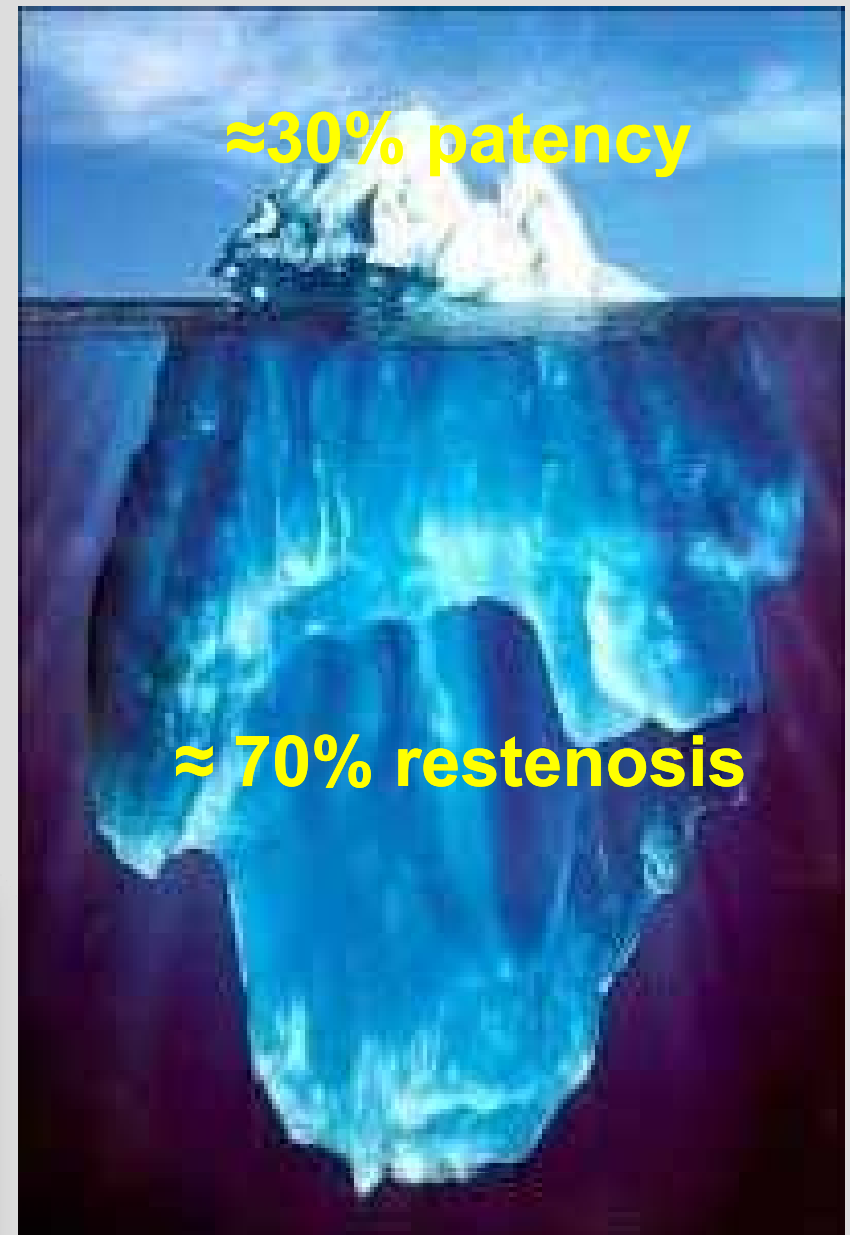
European Journal of Vascular and Endovascular Surgery

journal homepage: [www.ejves.com](http://www.ejves.com)



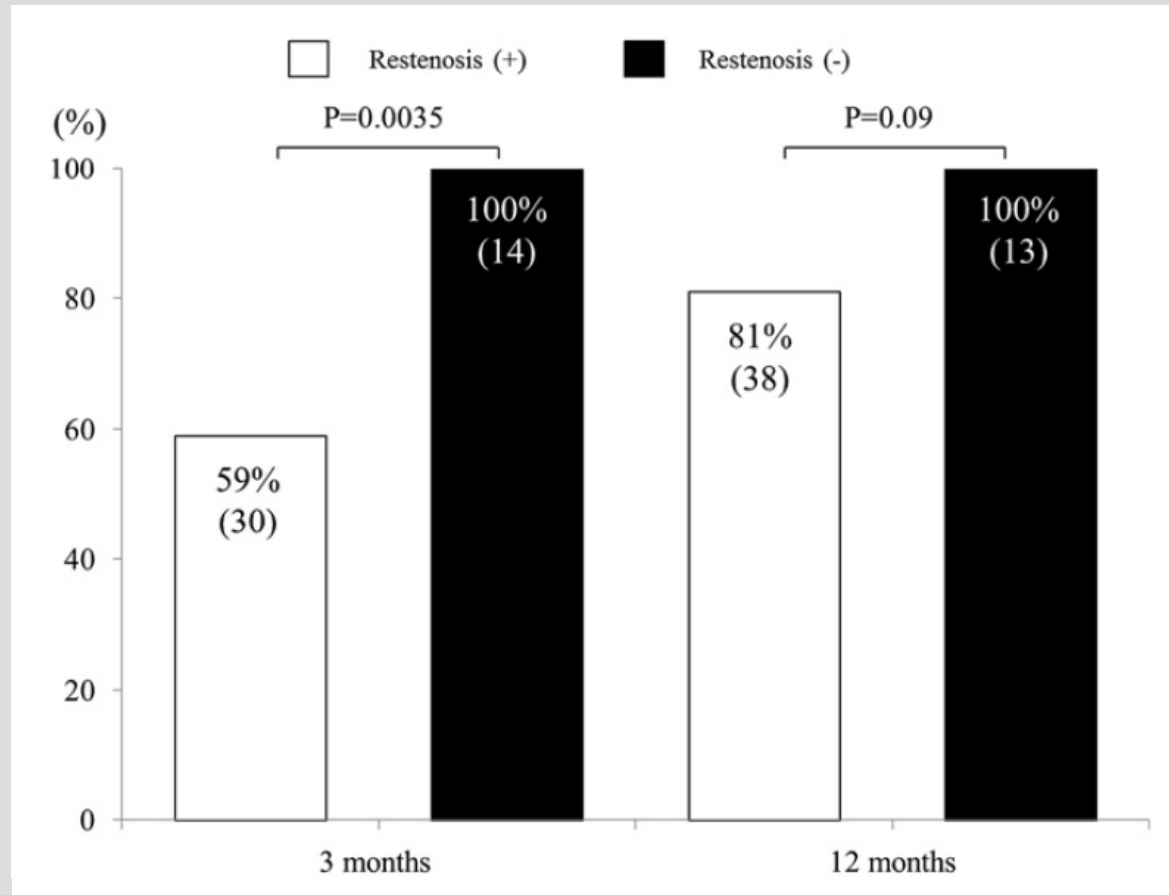
### Angiographic Restenosis and Its Clinical Impact after Infrapopliteal Angioplasty

O. Iida<sup>a,\*</sup>, Y. Soga<sup>b</sup>, D. Kawasaki<sup>c</sup>, K. Hirano<sup>d</sup>, T. Yamaoka<sup>e</sup>, K. Suzuki<sup>f</sup>, Y. Miyashita<sup>g</sup>, H. Yokoi<sup>b</sup>, M. Takahara<sup>h</sup>, M. Uematsu<sup>a</sup>

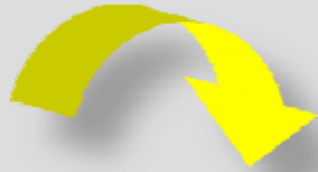


Restenosis in extensive BTK-FOOT-PTA is precocious and aggressive: 70% at 3 months

# Restenosis delays healing of tissue lesions!



**Figure 5.** Comparison of frequency of complete ulcer healing or lack of rest pain with and without restenosis after 3 and 12 months.



**3 months!**

**Restenosis in extensive BTK-FOOT-CLI-PTA with UB is precocious and aggressive and delays healing of tissue lesions: in 3 months 70% of our work has gone away**

# DEB in BTK-CLI

## DEB BTK Registry

104 patients (CLI = 82.6%; Diabetics = 73%)  
treated with IN.PACT Amphirion for long BTK  
stenosis and occlusions (avg length  $173 \pm 87$  mm)  
Primary EP: 3m Angiographic Rest. Rate

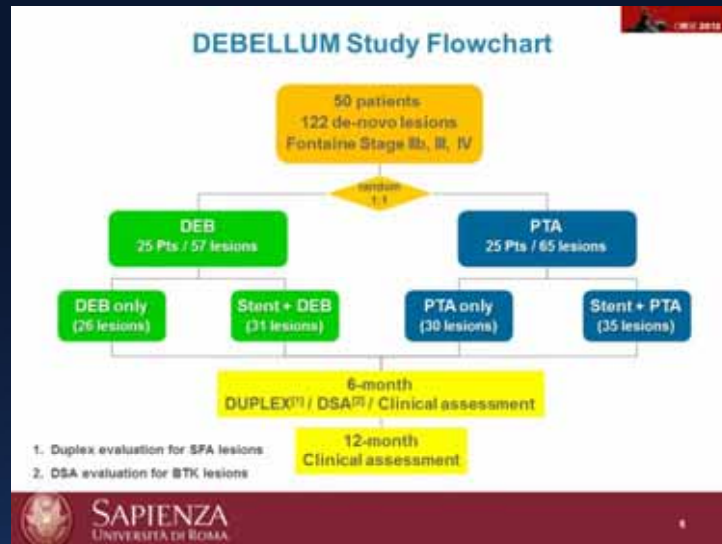
**Remarkably low Restenosis rate at 3m  
vs. historical PTA cohort**

	DEB	PTA*
<b>Angiographic FU</b>	<b>3-month</b>	<b>3-month</b>
Restenosis (>50%)	27.4%	69%
Full-segment Resten.	10%	56%
Restenosis Length	64 mm	155 mm
<b>Clinical FU</b>	<b>12-month</b>	<b>15-month</b>
Deaths	16.3%	10.5%
Limb Salvage	95.6%	100%
Clinic. Improvem.	91.2%	76.5%
Compl. wound healing	74.2%	78.6%
TLR	17.3%	50%

\* PTA historical cohort (A. Schmidt et al. CCI 2010)

# DEB in BTK-CLI: randomized studies

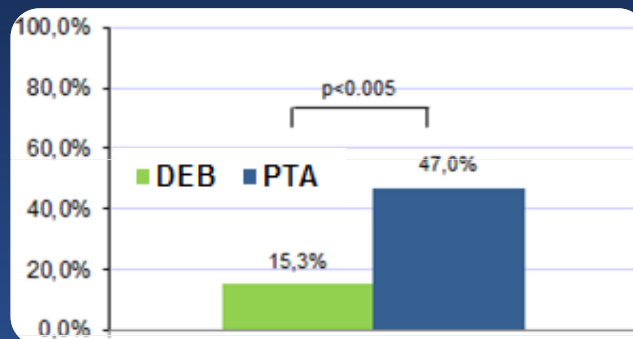
**Significant reduction in LLL and Restenosis at 6-m and TLR reduction at 12-m vs. PTA**



**6-month LLL**



**12-month TLR**

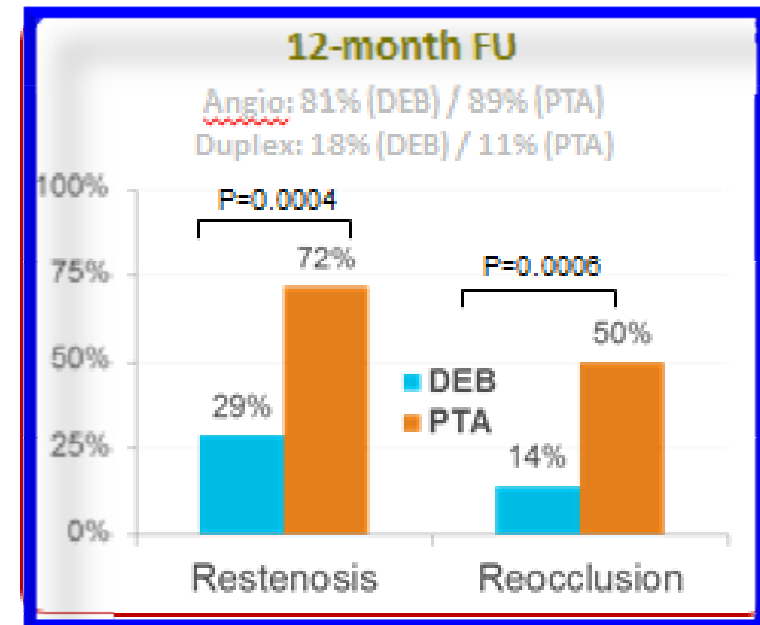


## DEBATE BTK RCT

120 patients with CLI and Diabetes randomized to IN.PACT Amphirion vs. PTA

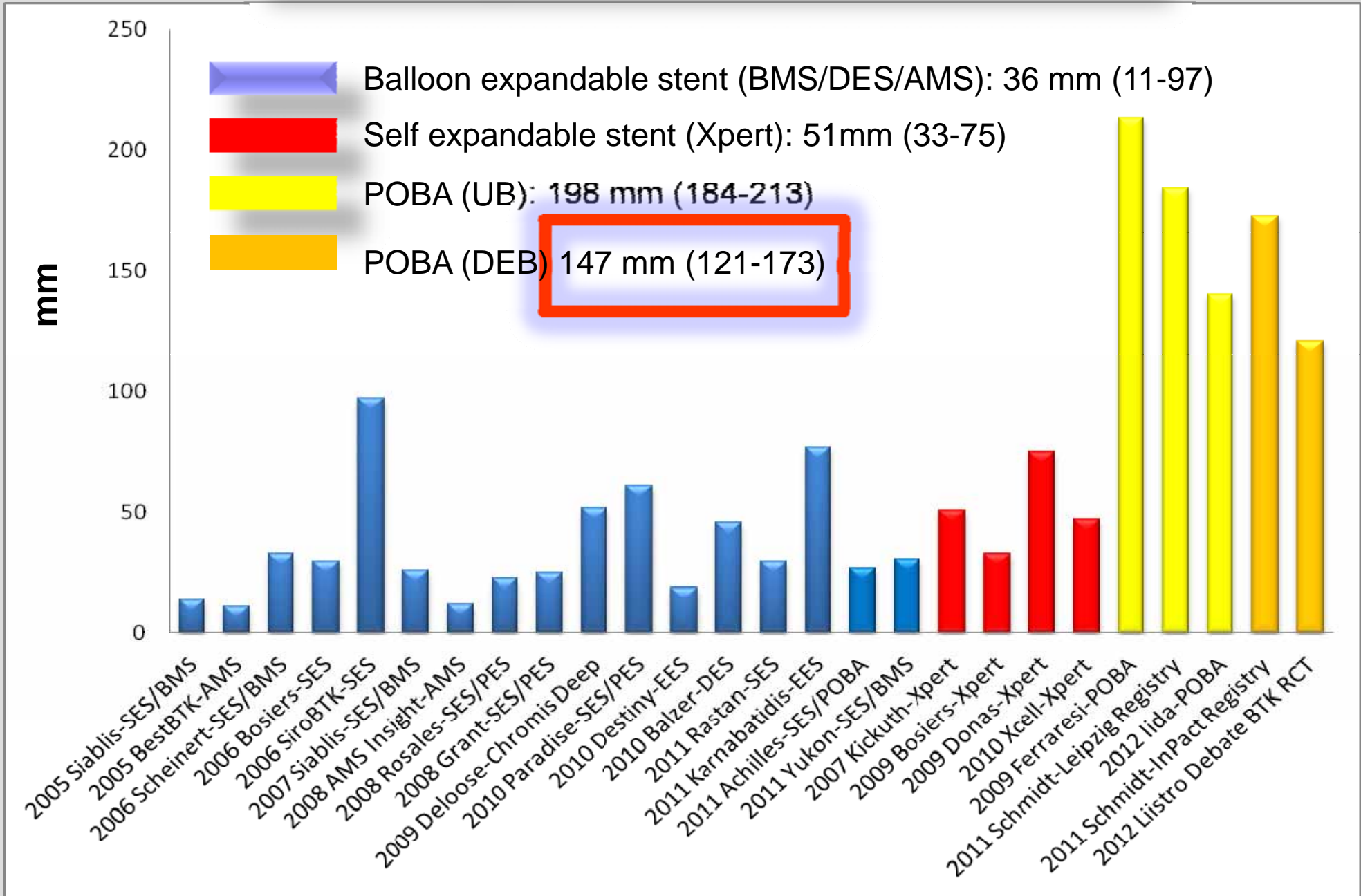
Primary EP: 12m Angiographic Rest. Rate

**Significant reduction of 12m Rest. Rate vs. PTA in BTK / CLI / Diabetics**

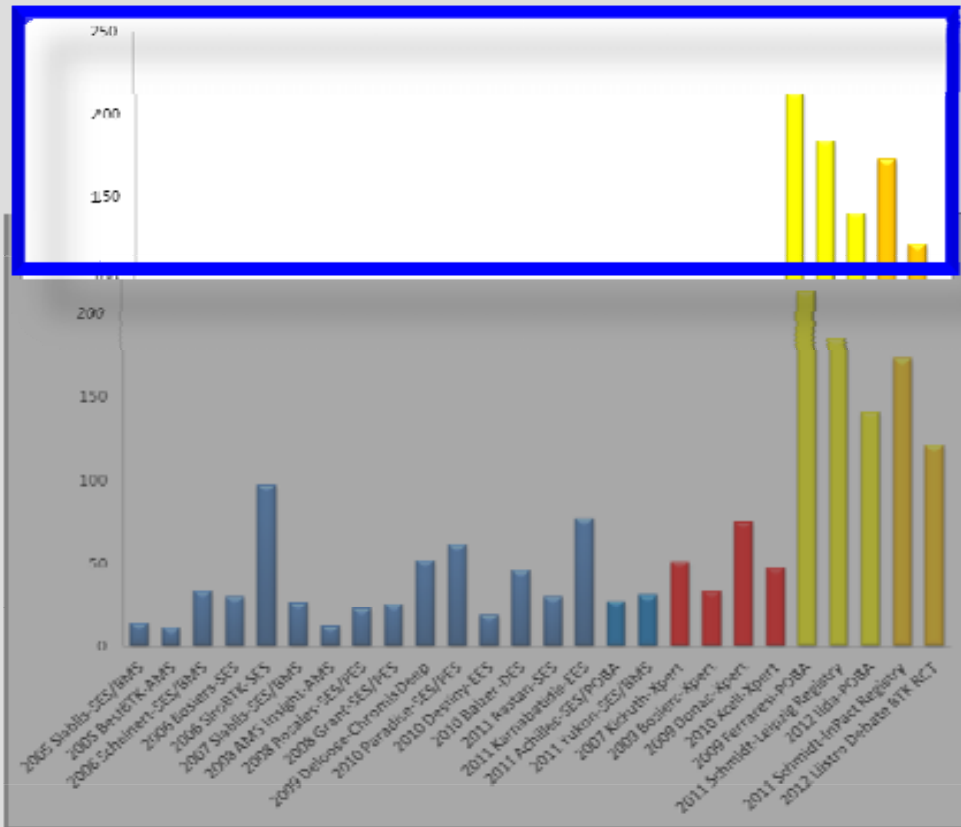


(F.Liistro LINC 2012)

# Length of BTK treated lesion



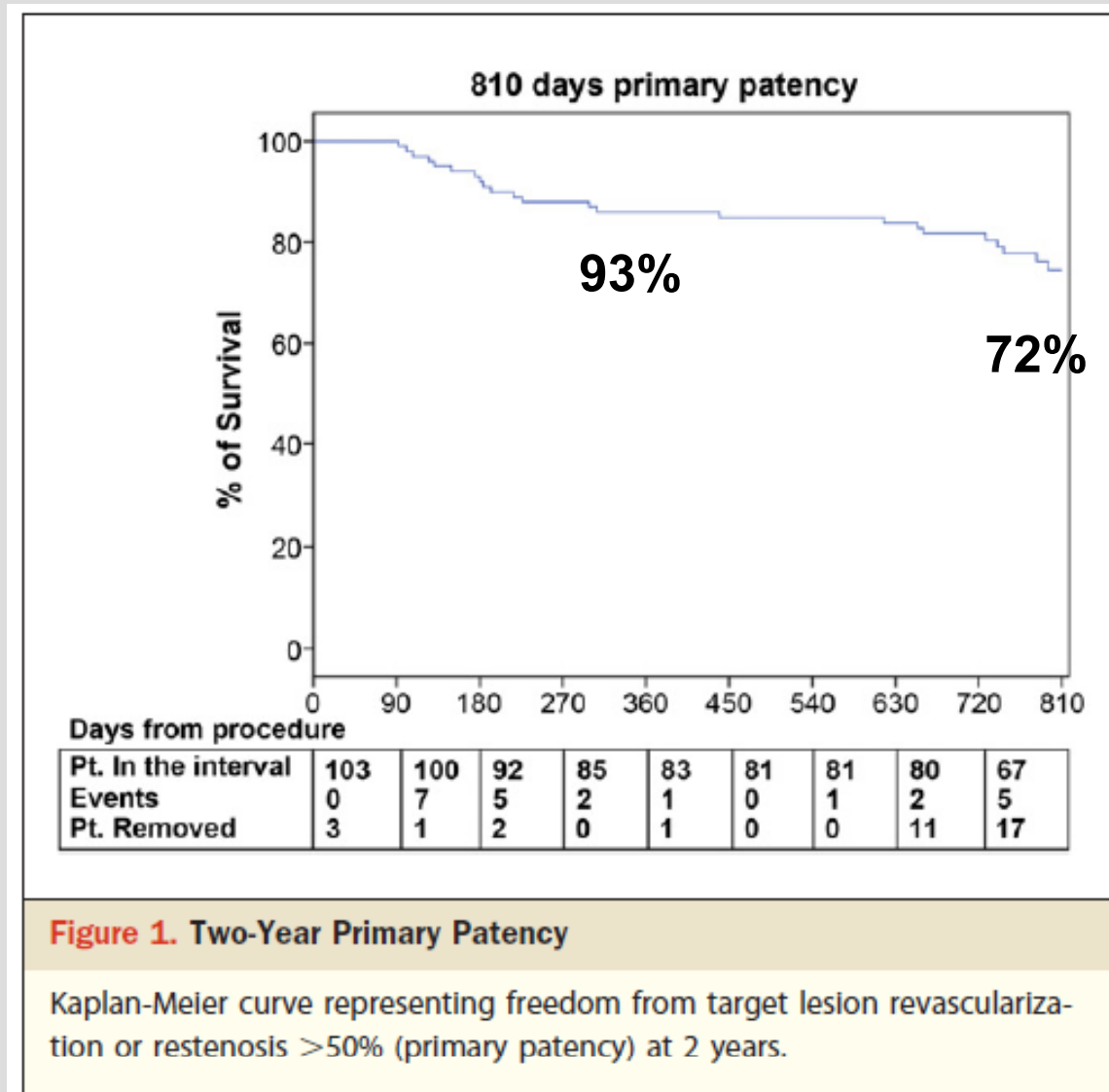




**Only POBA (UB & DEB) can treat the long lesions typical of BTK&FOOT vessel disease**

# 2-Year Results of Paclitaxel-Eluting Balloons for Femoropopliteal Artery Disease

Evidence From a Multicenter Registry



# DEB Technology Overview

Manufacturer	DEB	Drug	Dose ( $\mu\text{gr}/\text{mm}^2$ )	Excipient
MEDRAD	PACCOATH	Paclitaxel	3	Ultravist
MEDTRONIC	IN.PACT	Paclitaxel	3	Urea
BARD	Lutonix	Paclitaxel	2	Polysorbate & Sorbitol
EUROCOR	Freeway	Paclitaxel	3	Shellac
BIOTRONIK	Passeo 18 Lux	Paclitaxel	3	BTHC
COOK	Advance PTX	Paclitaxel	3	<i>none</i>
COVIDIEN	CVI	Paclitaxel	?	?

# CONCLUSIONS

## DEB are the Present for BTK Lesions

**DEBs are the only devices able to guarantee:**

- 1. Extensive BTK&FOOT vessel treatment**
- 2. Long term vessel patency**
- 3. Reduced TLR**
- 4. And *probably* reduced healing time**