

# DCB or DES in SFA treatment

## A difficult choice?

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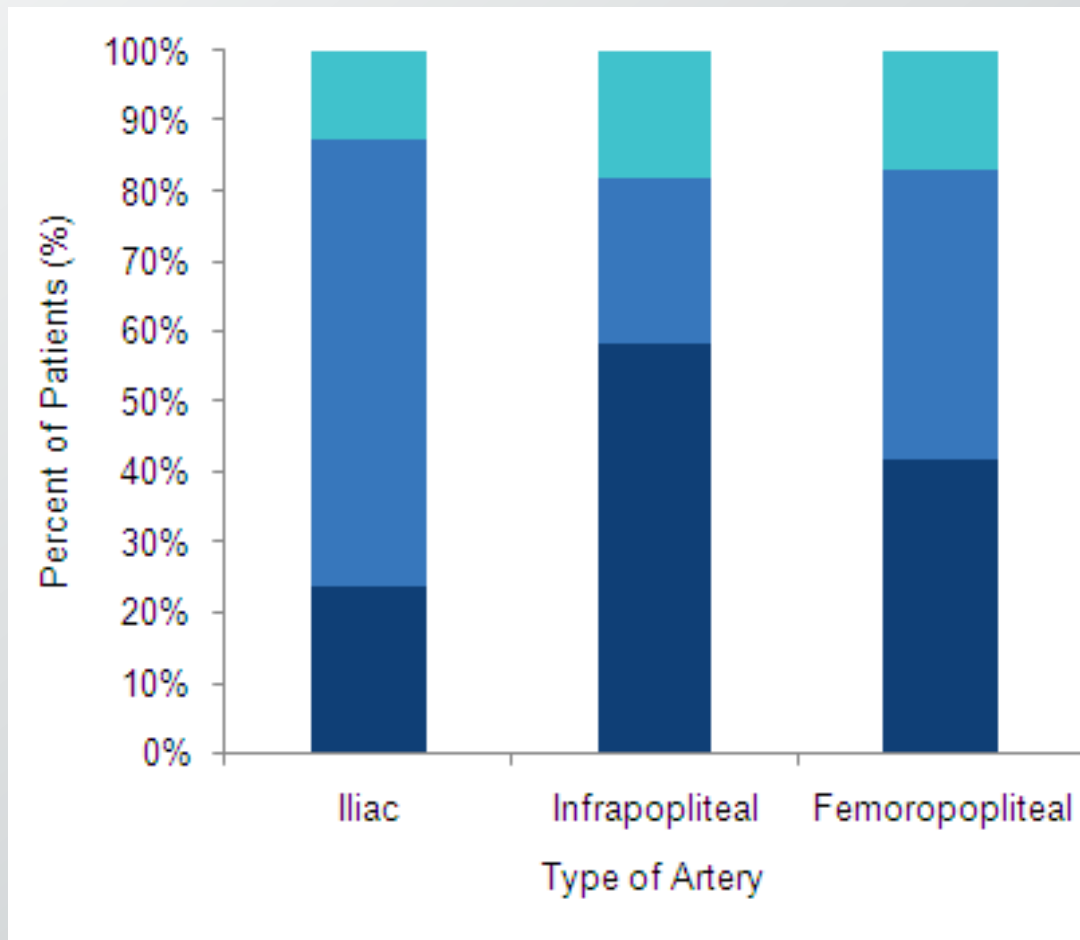


# Disclosure

- I have the following potential conflicts of interest to report:
  - Consulting
  - Employment in industry
  - Stockholder of a healthcare company
  - Owner of a healthcare company
  - Other(s)
- I do not have any potential conflict of interest

# PAD Treatment by Anatomy: Iliac, Femoropopliteal, Infrapopliteal

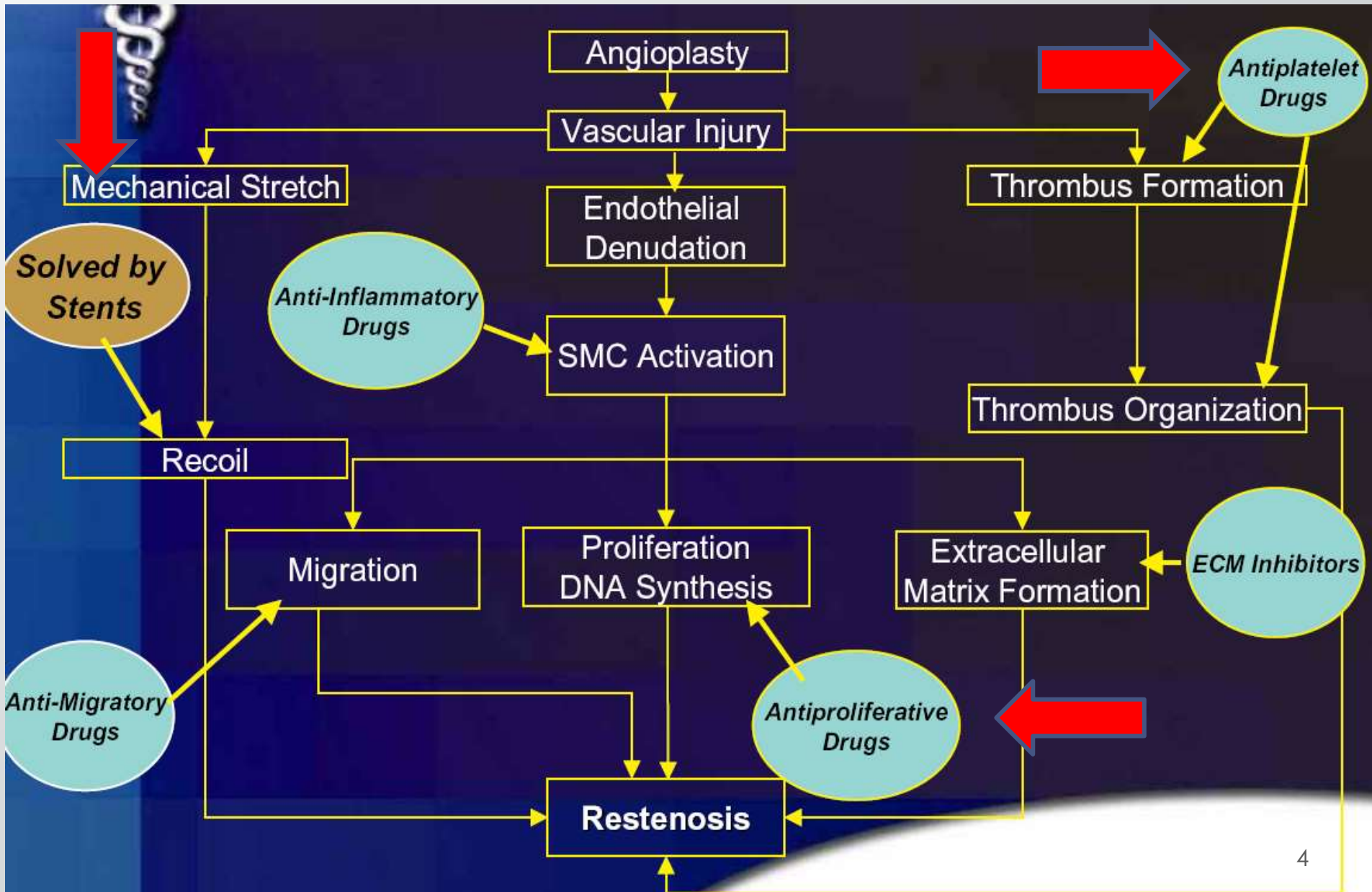
Percentage of patients with PAD who receive each therapy option only  
Global - 2012



■ Atherectomy  
■ Stenting  
■ Balloon Angioplasty

- Iliac: Stenting is typically the first treatment (>80%)
- Infrapopliteal: Balloon angioplasty most common
- Femoropopliteal: Stenting and angioplasty used equally

# Prevention of restenosis

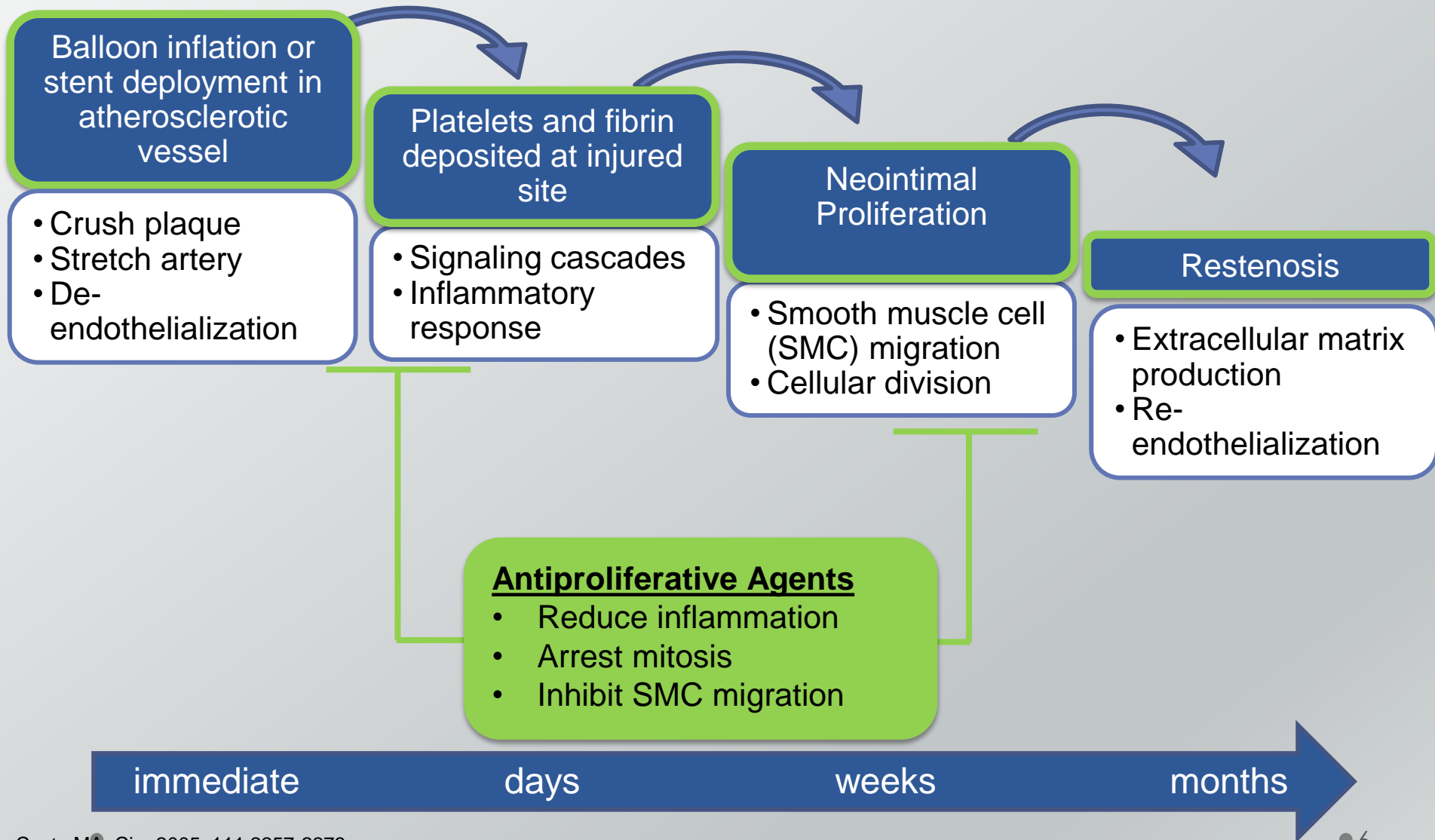


# What's the future treatment?



That one therapy is  
suitable for all lesions.

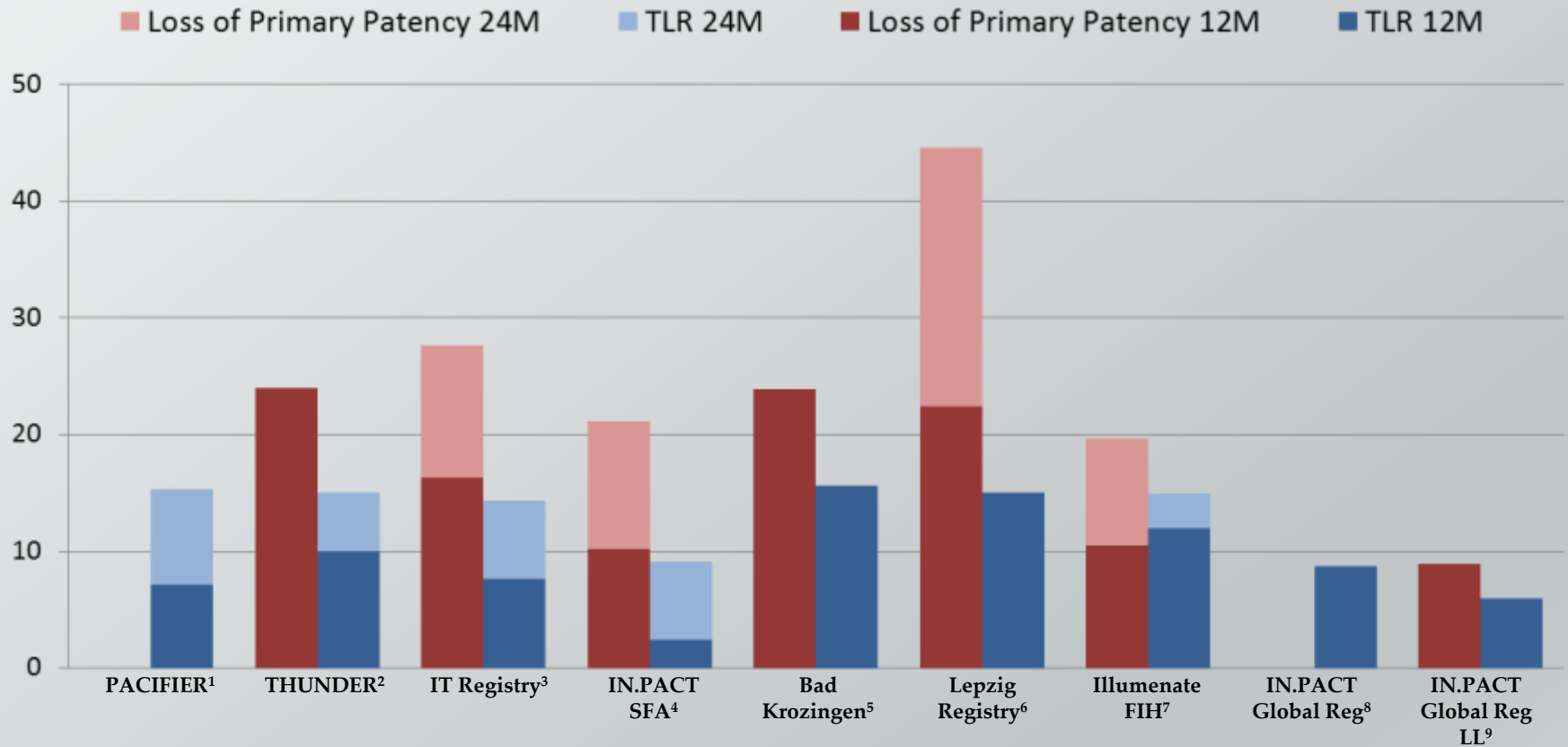
# Restenotic Cascade





# DCB Trial Outcomes

Between 12 and 24 months there is a marked loss in primary patency and rise in TLR



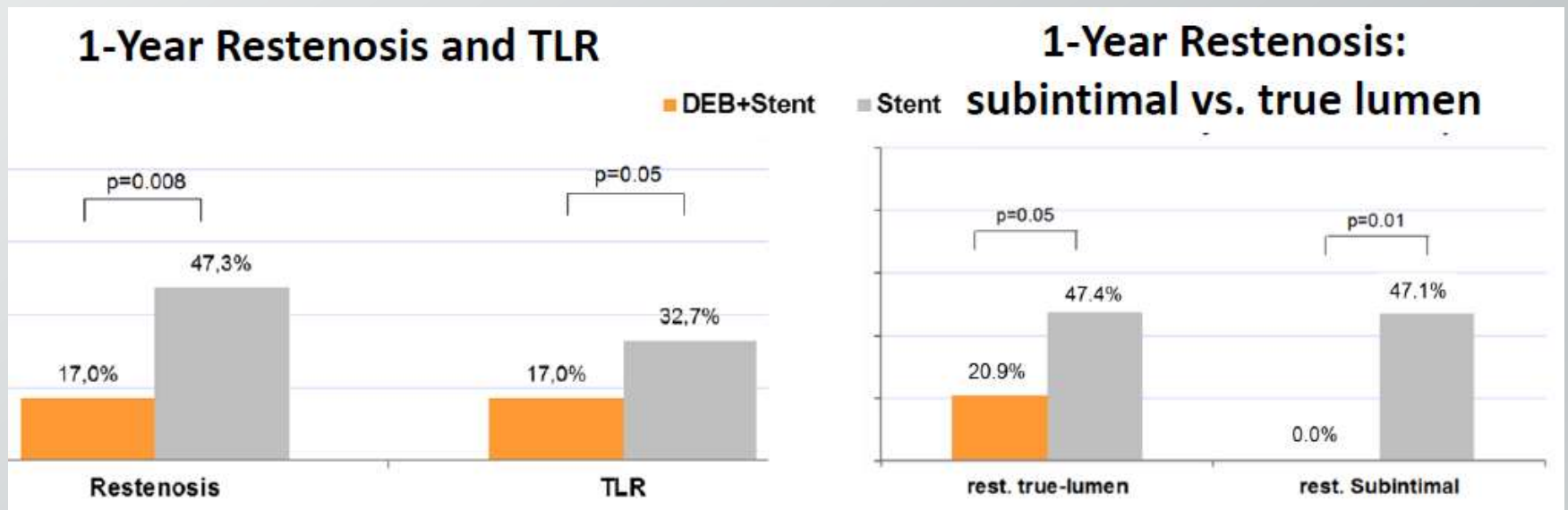
*Results from different trials are not directly comparable. Information provided for educational purposes.*

<sup>1</sup>Albrecht T et al. LINC 2013; <sup>2</sup>Tepe G et al. J of Am Coll of Cardiol Intv Jan 2015; <sup>3</sup>Micari A Et al. J Am Coll Cardiol Intv Jan 2013; <sup>4</sup>Laird J. TCT 2015; <sup>5</sup>Zeller T et al. J Endovasc Therapy 2014; <sup>6</sup>Schmidt A. TCT 2015; <sup>7</sup>Schroeder H et al. Catheter Cardiovasc Interv 2015; <sup>8</sup>Laird J. Endovascular Today Feb 2015; <sup>9</sup>Ansel G. TCT 2015.

# IN.PACT plus Systematic Stenting

Liistro et al. , JACCI 2013

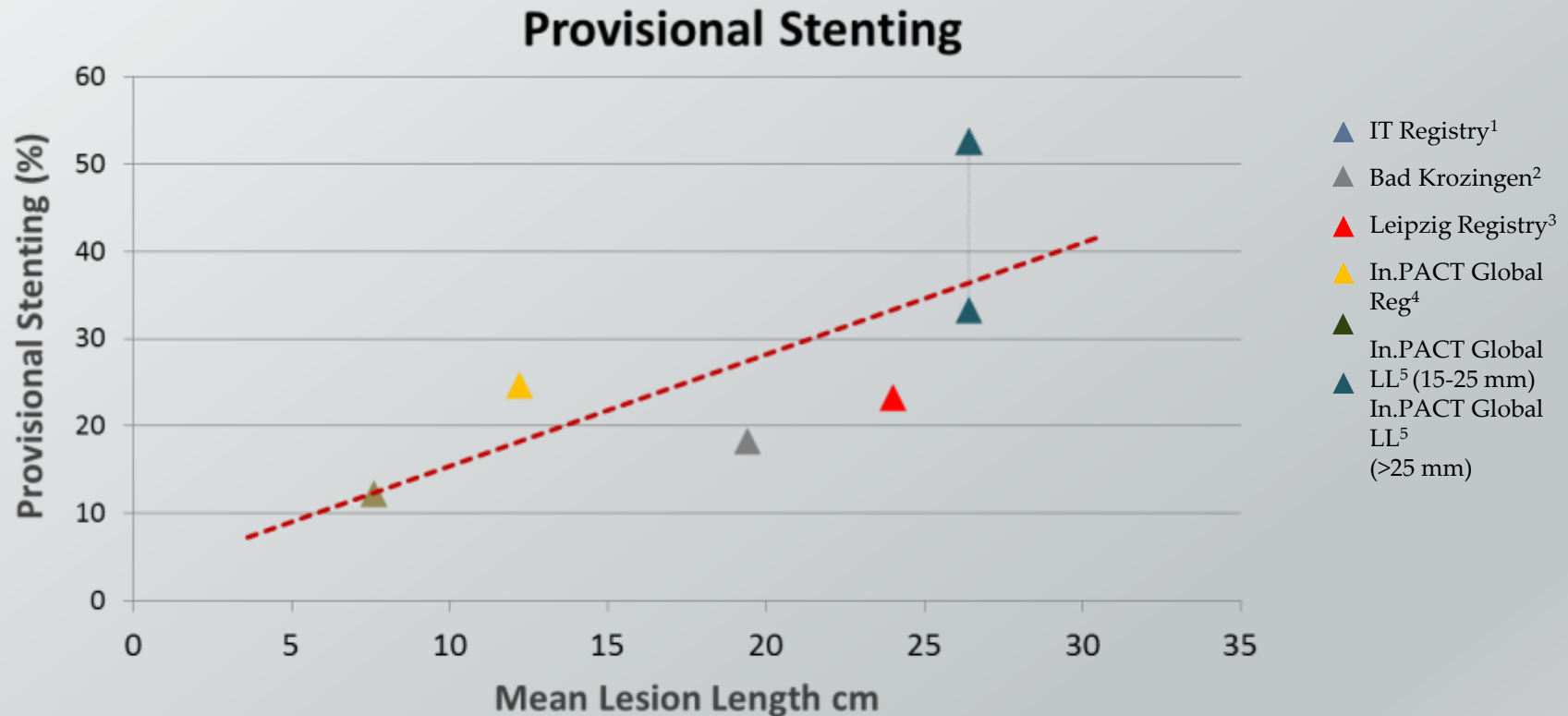
- 104 patients prospectively randomised
- IN.PACT + STENT vs PTA + STENT
- DCB improves stent results
- Less restenosis irrespective of lesion length or recanalisation technique





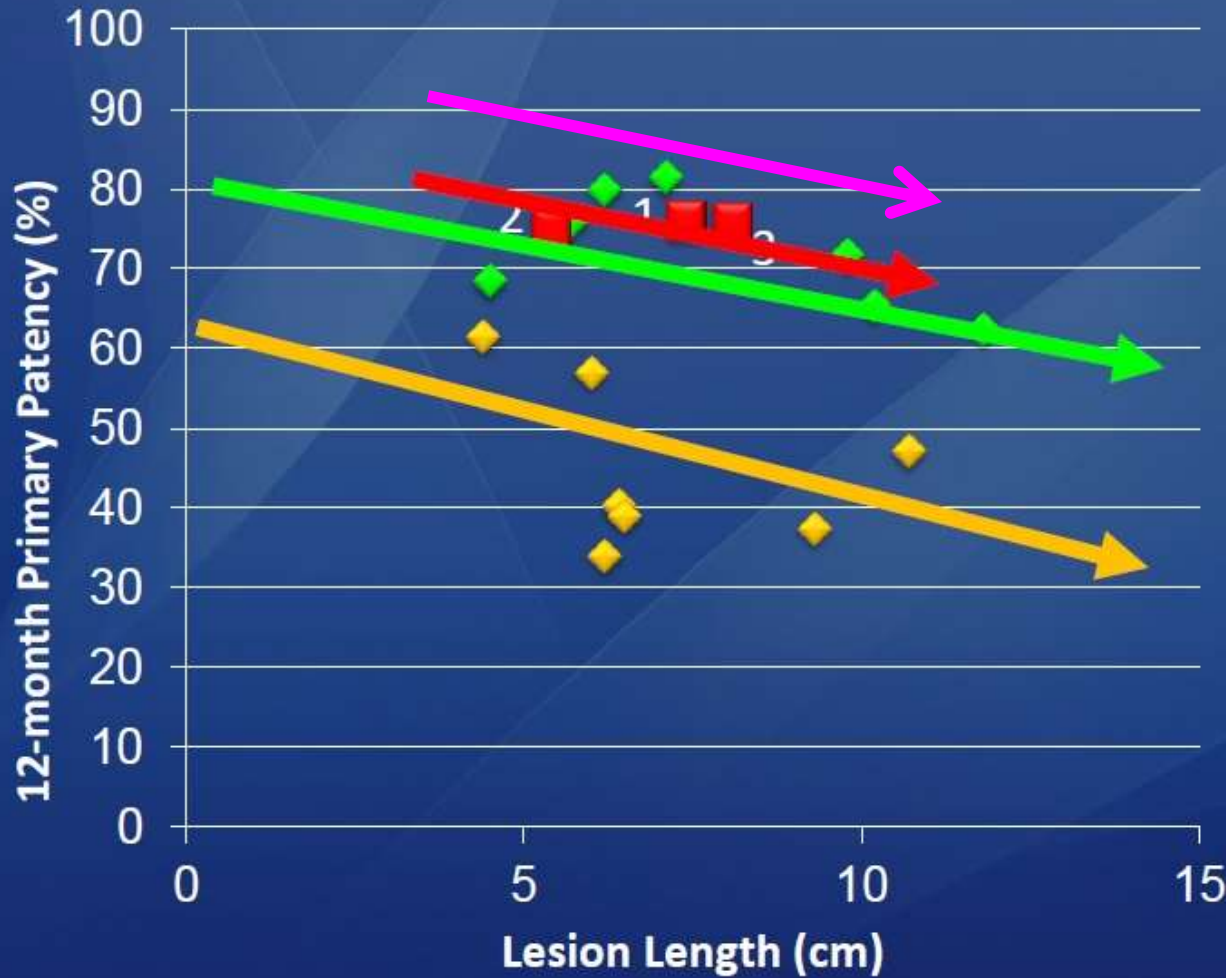
# Stents used in Real World DCB studies

- Real world DCB studies show higher rates of provisional stenting than RCT
- Longer mean lesion length is correlated with higher provisional stenting rate



*Results from different trials are not directly comparable.  
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# Today's practice ?



## DCB

1. THUNDER
2. FEMPAC
3. LEVANT I

## STENT

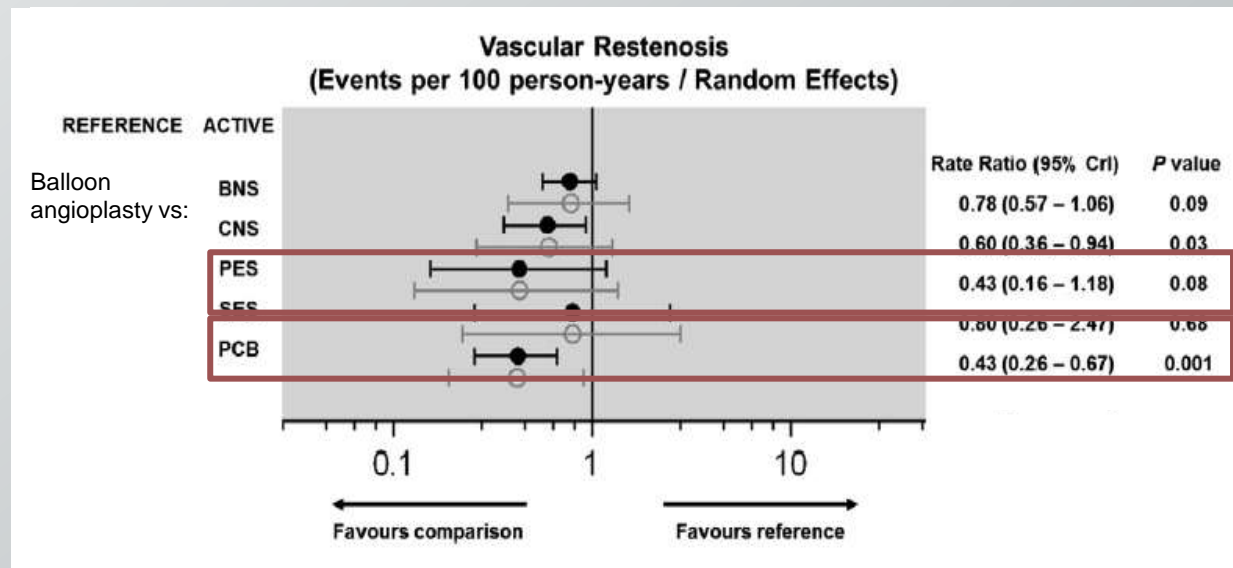
## PTA

DCB + stent  
or  
DES

# Comparing Outcomes of Treatments for Femoropopliteal Arterial Disease

## Femoropopliteal Arterial Disease

- Katsanos et al : network meta-analysis of RCTs SFA
- Compared POBA, DCB, DES, bare nitinol stents, and covered nitinol stents
  - Vascular restenosis lowest with DES and DCB
  - TLR lowest with DES and DCB



# DCB

# Which ?

Not all DCB's are created equal but in general ...

- ✓ Better results compared to POBA
- ✓ Safe
  - Endothelial loss → thrombosis
  - Necrosis → aneurysmal dilatation
  - Downstream effects
    - Ischemic changes
    - Emboli
    - Changes in skeletal muscle
    - Systemic toxicity

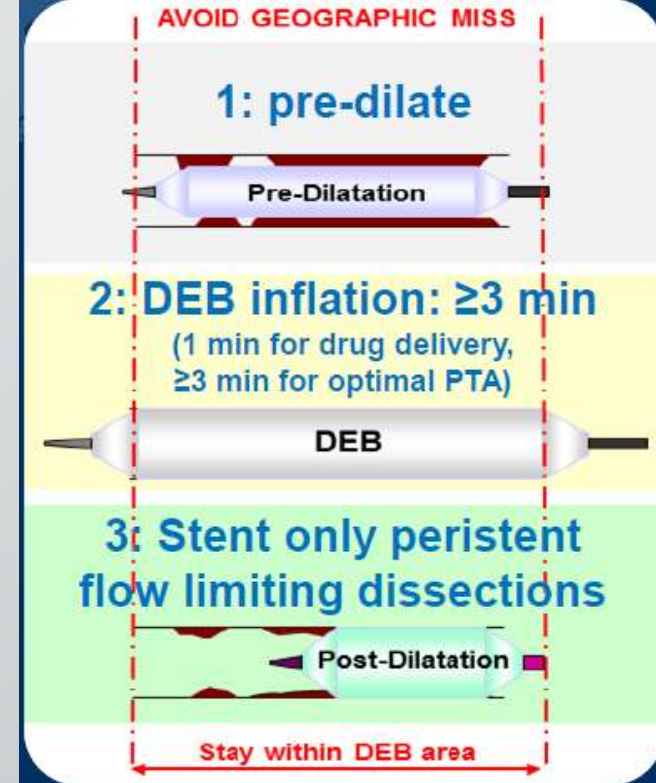
# Technique

## DCB

- ✓ Importance of geographic miss
- ✓ Influence of prolonged PTA
- ✓ Importance of predilatation?

- Vessel preparation
- Long balloon
- Gradual dilatation
- More accurate sizing
- DES instead of DCB in case of bad result after predilatation
- DCB cannot be used with DES in the same lesion :  
DRUGLOAD

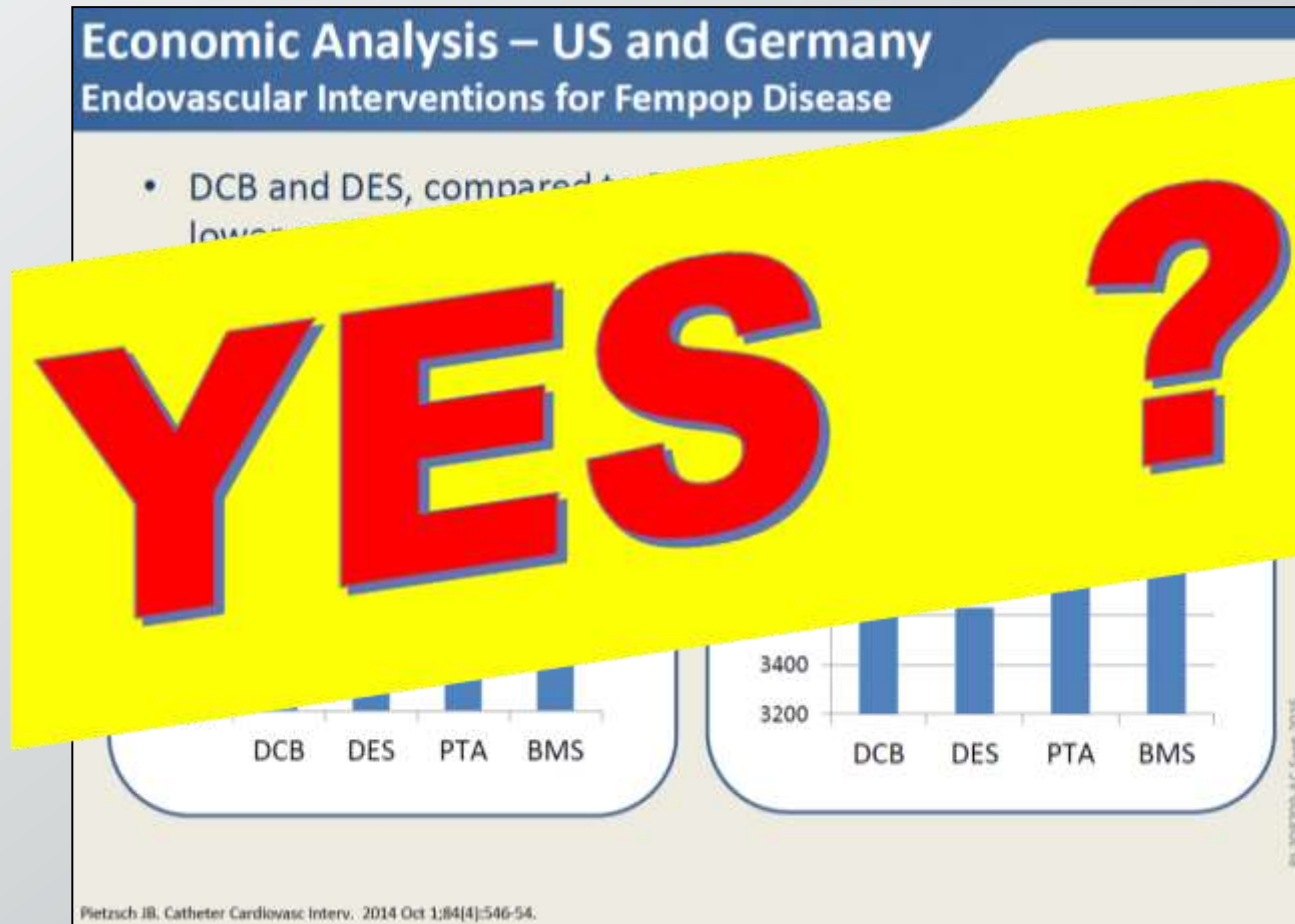
Evidence? -> ILLUMENATE FIH



# 1. Always instead of POBA

## DCB

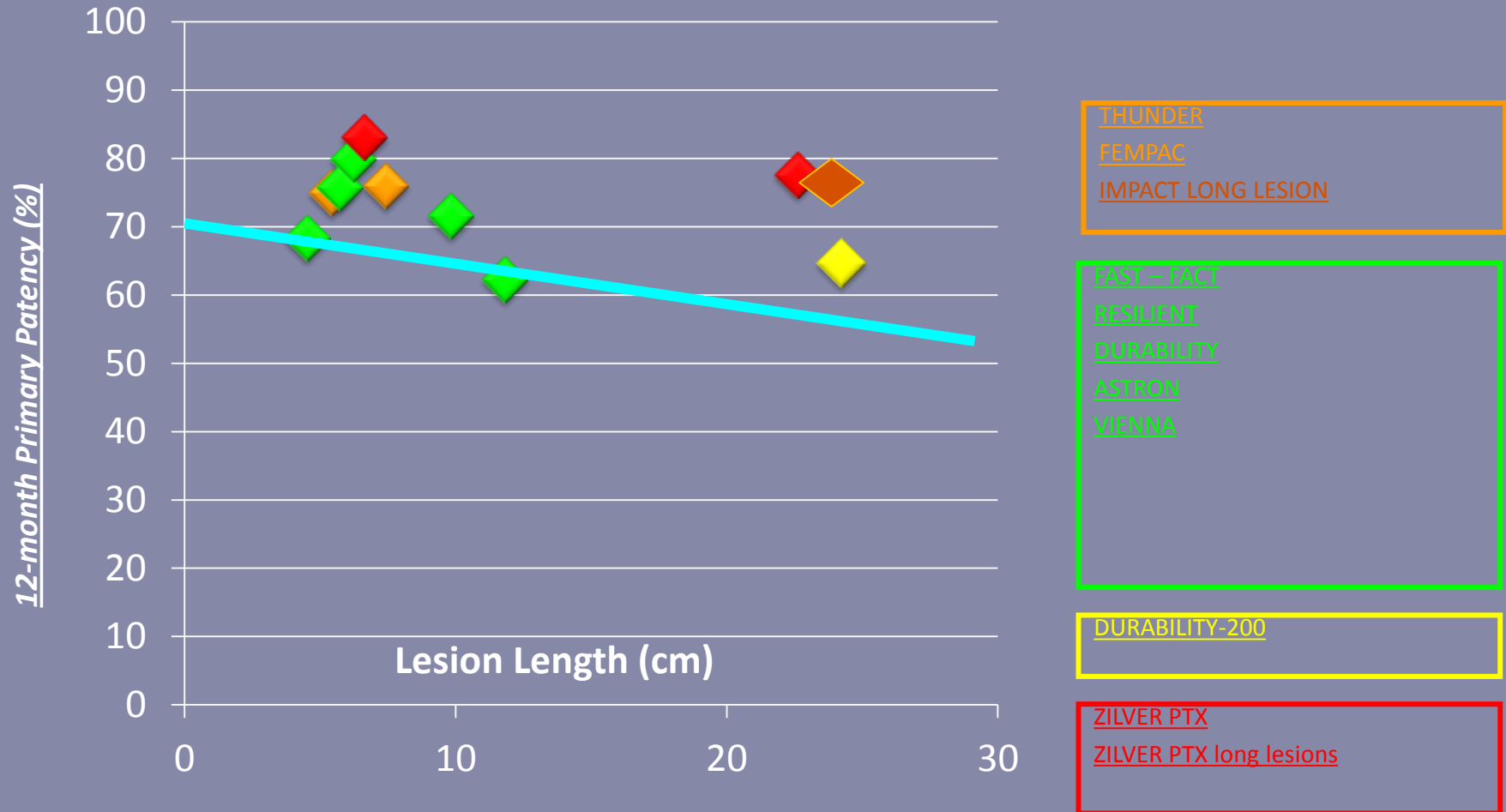
- Results better then POBA
- Combination with stent possible
- BUT : Economic impact ?





# ✓ 2 . Long lesions ?

# DCB

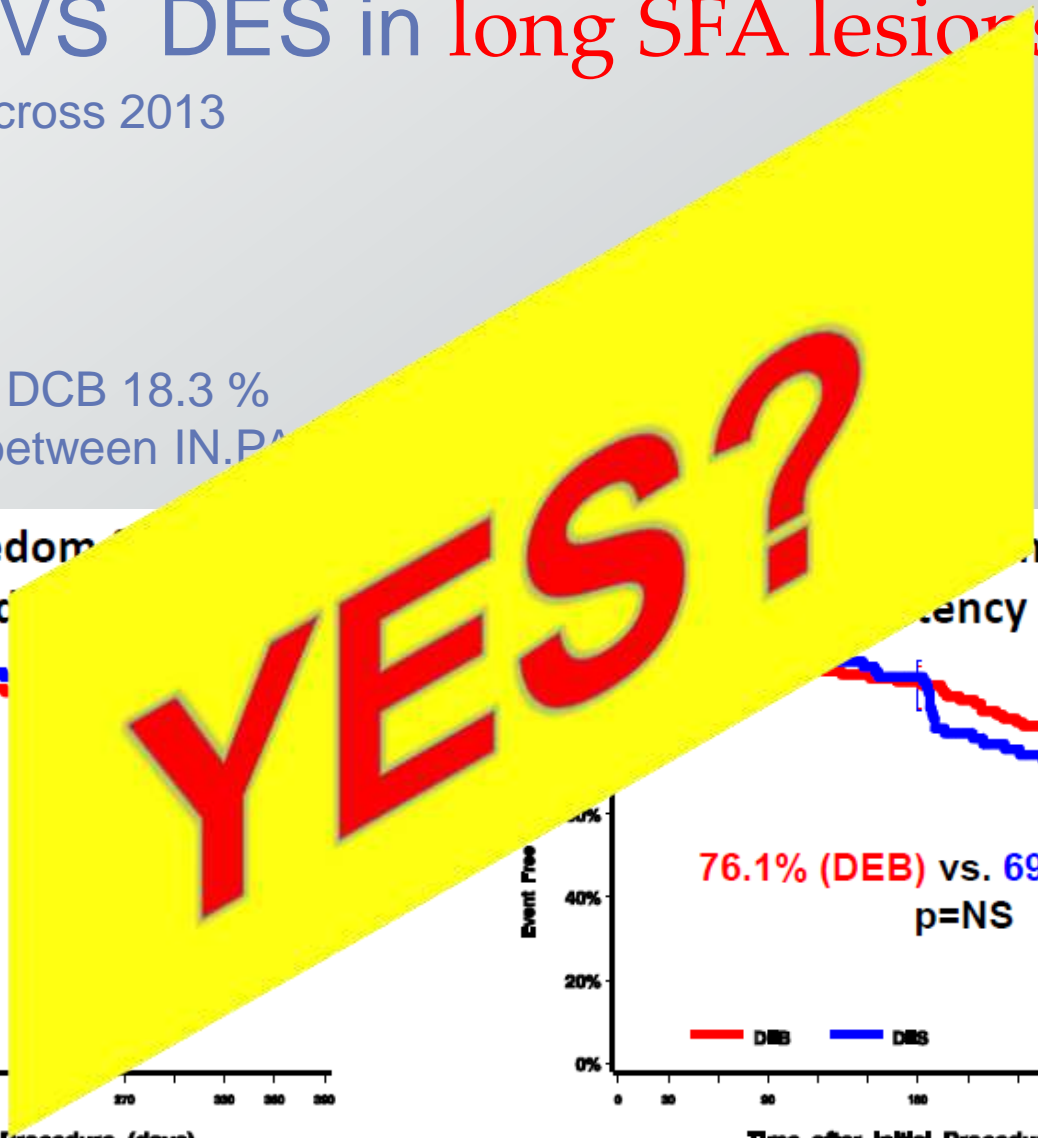




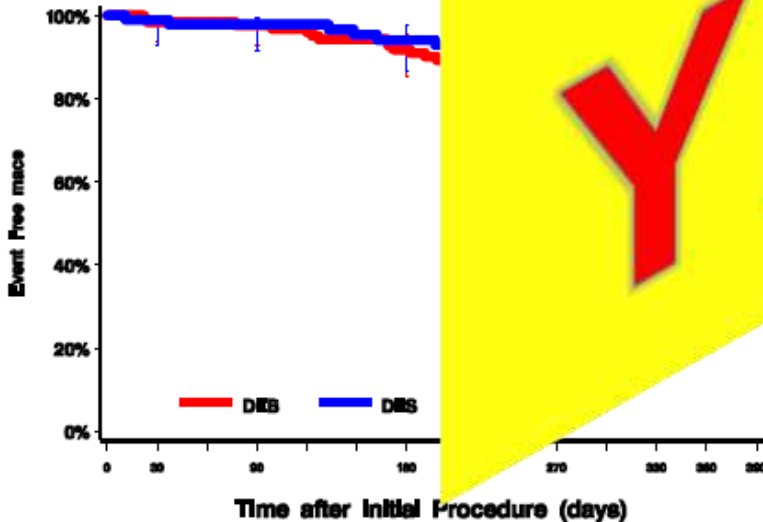
# IN.PACT VS DES in long SFA lesions

Zeller T Charing cross 2013

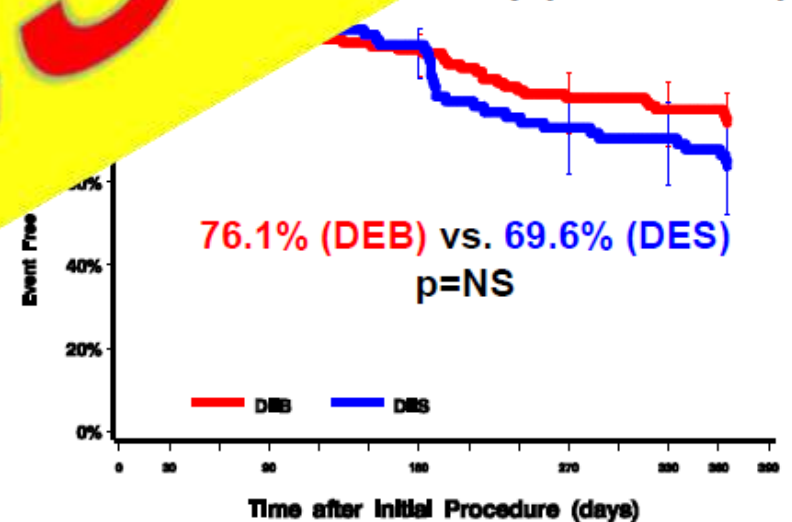
- Retrospective
- 228 patients
- Lesions 19 cm
- Stent rate post DCB 18.3 %
- No difference between IN.PACT



12-month freedom from death and



freedom from stenosis (PSVR < 2.4)



# ✓ 3 . Instent restenosis ?

## DCB

FAIR trial

POBA versus DCB (Instant restenosis)  
Freedom from TLR

DCB

**YES**

DEBELLU

La

		DCB	
P		0,5	p < 0,01
IS	1,7	0,5	P < 0,01

# DCB

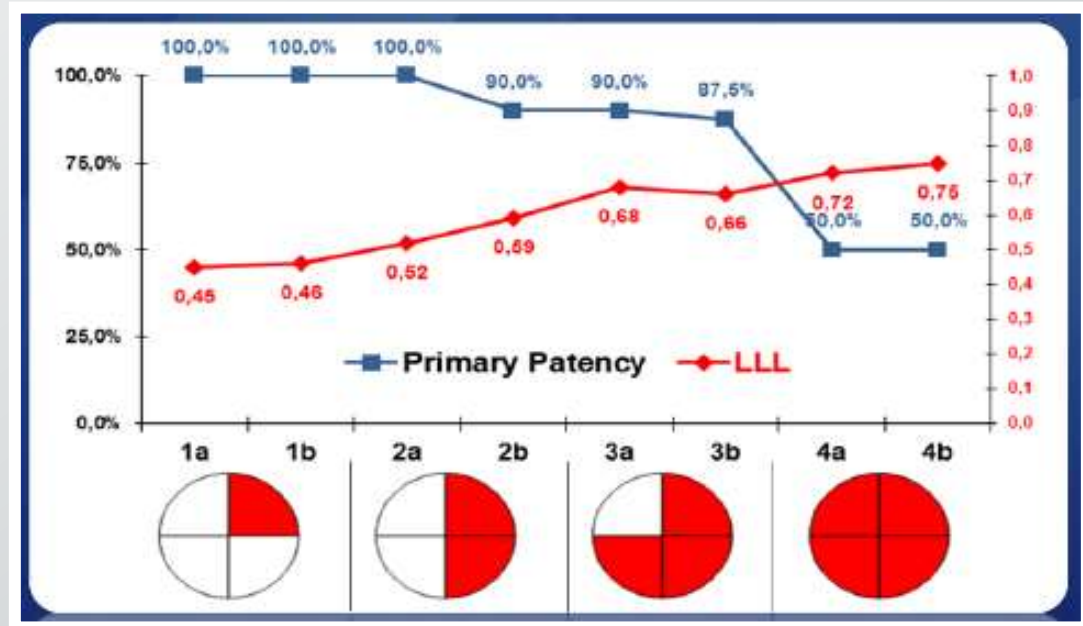
## ✓ 4. Occlusions ?

Higher rate of baseline occlusive lesions corresponded with higher TLR rates at 1 year



# ✓5 . Calcified lesions?

## DCB



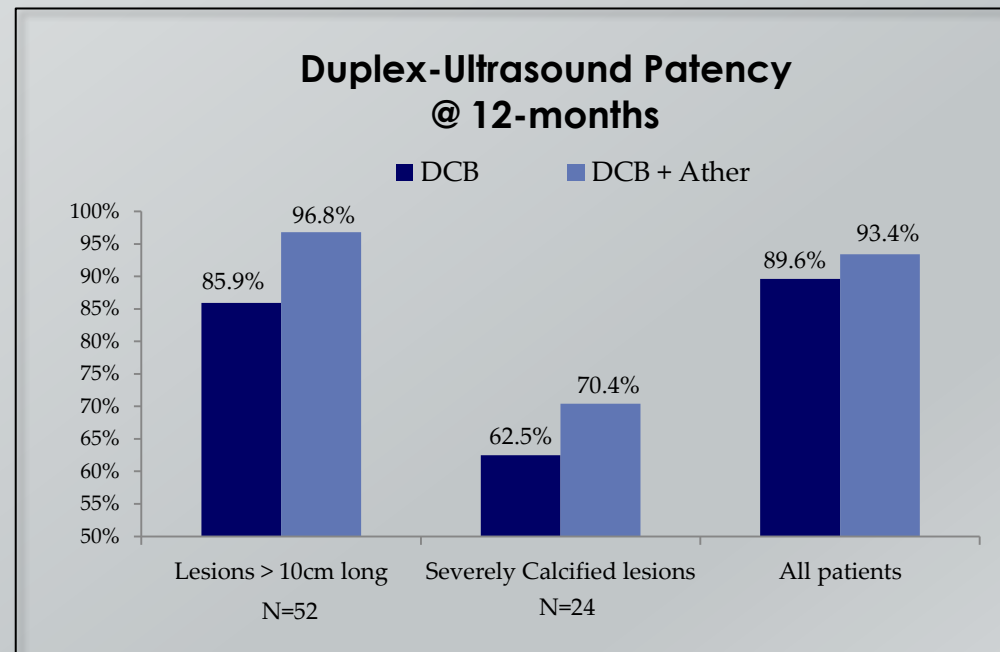
- 60 patients with SFA stenosis or occlusion treated with DCB
- CTA, DSA, and IVUS used to quantify the calcium burden
- At 1 year, greater calcification was associated with:
  - Lower patency (50% for 270° - 360° vs 100% for 0° - 90°)
  - Lower ABI
  - Greater late lumen loss and TLR rate

# Calcium associated with lower DCB efficacy

- **DEFINITIVE AR:** directional atherectomy + DCB vs DCB alone
- Removing calcium via adjunctive atherectomy may improve procedural and clinical outcomes following DCB treatment of the SFA and/or popliteal artery, particularly for longer or severely calcified lesions

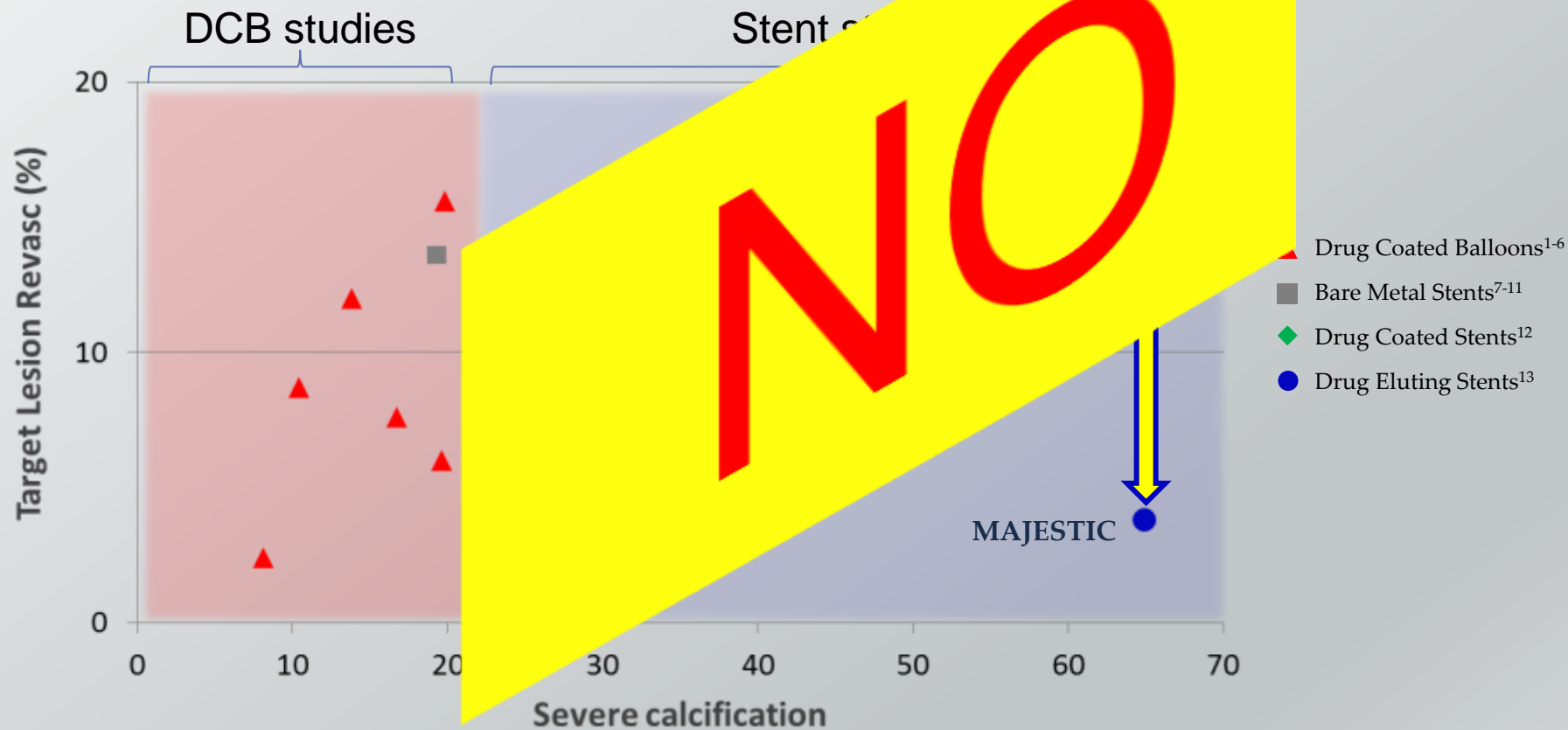
## Procedural Results

	DCB	Ath + DCB
<b>Technical Success*</b>	64.2%	89.6%
<b>Bail-out Stent</b>	3.7%	0%
<b>Flow-limiting Dissection</b>	19%	2%



# Severe calcification : DCB and Stent studies

- Severe calcification was more prevalent in stenting studies
- Severe calcification did not have a negative effect on the rate in the MAJESTIC study



Results from different trials are not directly comparable. Information provided for educational purposes.

<sup>1</sup>Micari A Et al. J Am Coll Cardiol Interv 2012; <sup>2</sup>Tepe G et al. Circulation 2015; <sup>3</sup>Zeller T et al. J Endovasc Therapy 2014; <sup>4</sup>Schroeder H et al. Catheter Cardiovasc Interv 2015; <sup>5</sup>Laird J. Endovascular Today Feb 2015; <sup>6</sup>Ansel G. TCT 2015; <sup>7</sup>Matsumura et al. J of Vasc Surg. Jul 2013; <sup>8-9</sup>www.accessdata.fda.gov; <sup>10</sup>www.endovascularmagazine.eu 2013; <sup>11</sup>Powell, R. Charing Cross 2015; <sup>12</sup>Dake MD et al. Circ Cardiovasc Interv 2011; <sup>13</sup>Müller-Hülsbeck, S. VIVA 2015.



## 6 . Popliteal lesions ?

# DCB



**YES**

After DCB

OPTIMAL ?



## 7. Flow limiting dissection

# DCB

- Predilatation with flowlimiting dissection or PTA DCB

**Reconsider  
therapy**

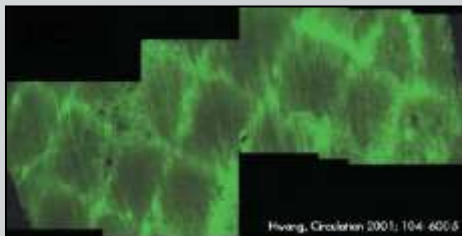
(miss )  
of the margins of DCB

# DES vs DCB

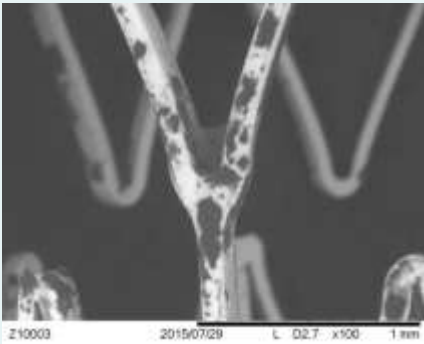
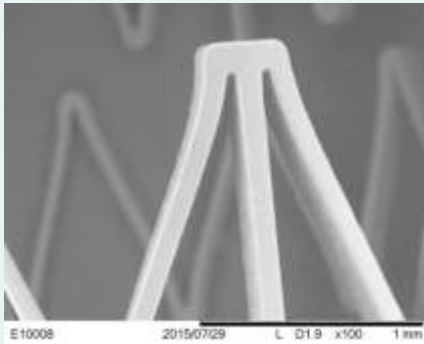
## Consideration

### HOW IS DCB DIFFERENT FROM DES

Parameters that distinguish DCB from DES	DES	DCB
Drug concentration on the device	Low 5-10 $\mu\text{g}/\text{mm}$	Very High 2-3 $\mu\text{g}/\text{mm}^2$ ( $\approx$ 20-30 $\mu\text{g}/\text{mm}$ )
Drug transfer at the time of deployment	Slow	Rapid, all at once
Reservoir of drug	Polymer	No (excipient important)
Drug retention in tissues	Short term	Need a drug which binds to cell membranes and is easily transferable to adjacent cells
Diffusion	Good	Excellent
Lipophilic	yes	Even better
Active ingredient	Not necessary	Should be active immediately

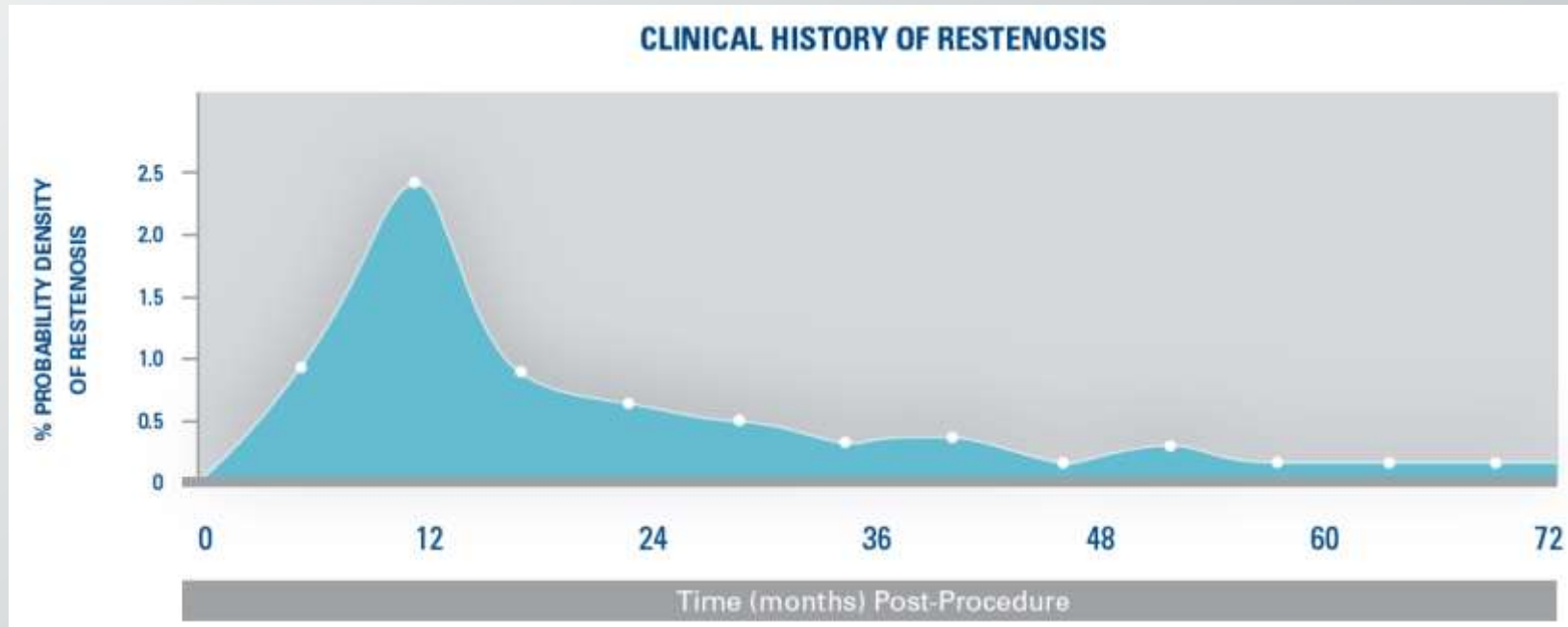


# DES Coating Design Specifications

	Zilver PTX	Eluvia
Drug	Paclitaxel	Paclitaxel
Coating Design	No carrier	PROMUS Polymer
Drug/Total Dose	$3\mu\text{g}/\text{mm}^2$ $8 \times 120\text{mm} = 1112 \mu\text{g}$	$0.167\mu\text{g}/\text{mm}^2$ $7 \times 150\text{mm} = 517 \mu\text{g}$
Size Matrix	6-8mm 40-120mm	6 & 7mm 40-150 mm
SEM Image 100x		

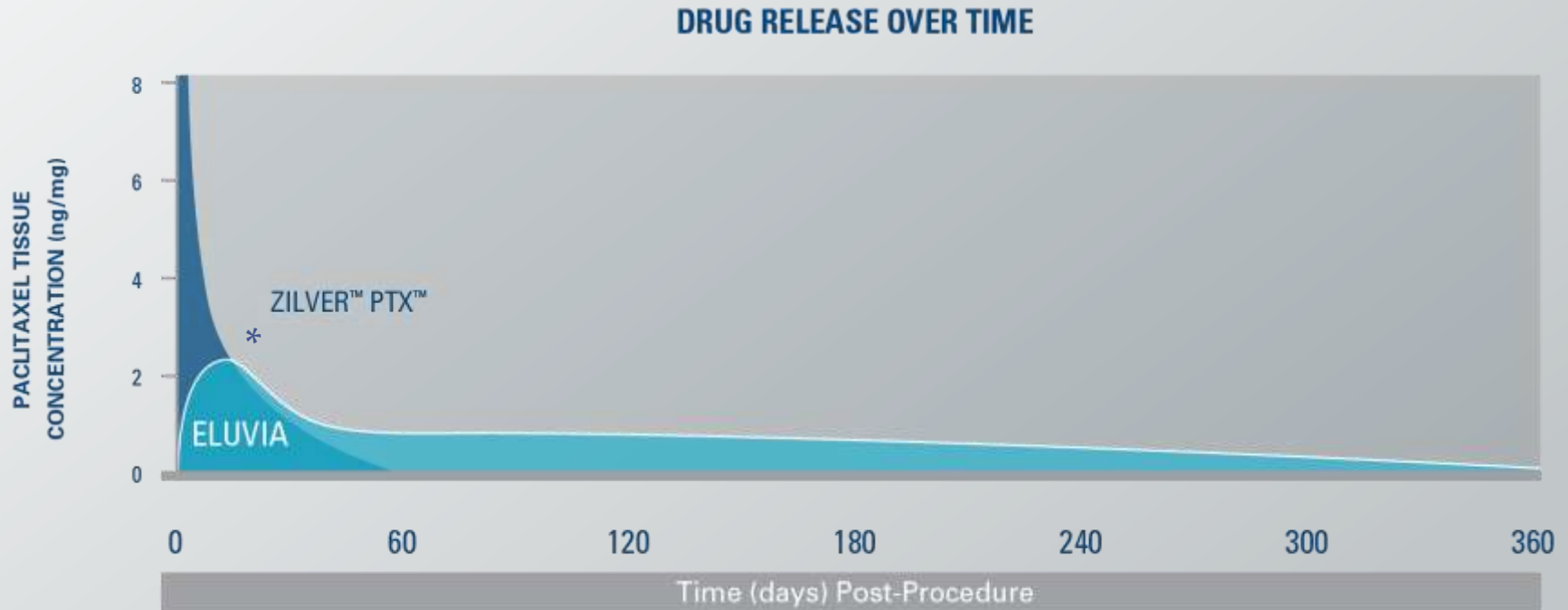
# Clinical Probability of Restenosis Following SFA Stenting

Restenosis following nitinol stenting in the SFA peaks at around 12 months



- Timing of SFA restenosis is longer compared to coronary stenting, which predominantly occurs within 6 months after stenting
- Factors for restenosis in the SFA include the number of runoff vessels, severity of lower limb ischemia, and length of diseased segments

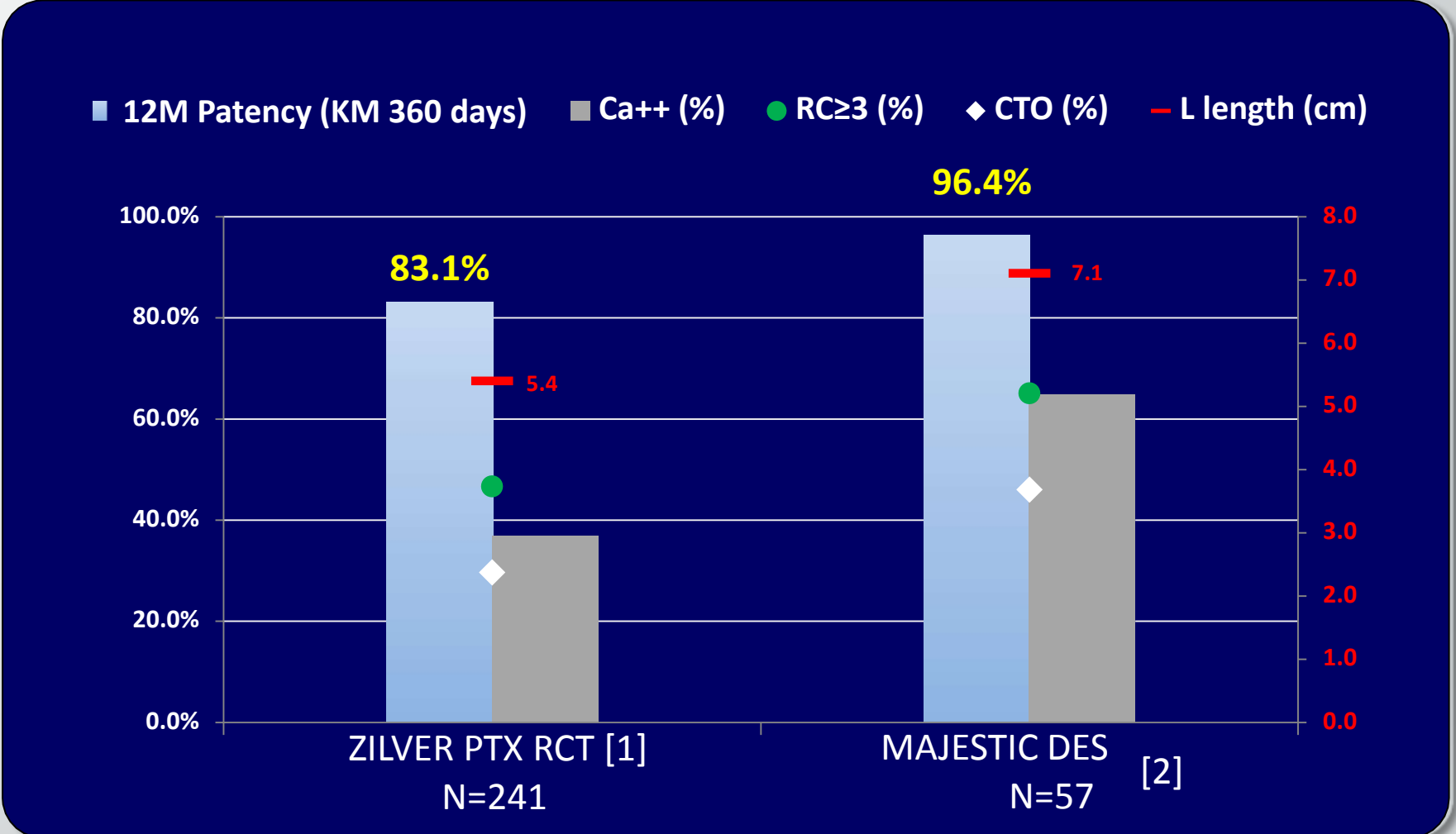
# DES Sustained Drug Release



Drug release from the Eluvia system is sustained over time

- >90% of drug is released at 1 year
- Drug release coincides with the restenotic cascade

# Results Zilver PTX - Eluvia



Imperial trial including / 485 patients 2:1 Eluvia vs Zilver PTX

[1] Dake MD et al. Circ Cardiovasc Interv. 2011. [2] Müller-Hülsbeck, S. CIRSE 2015.

# Leave nothing behind

## Shift in strategy?

- The strategy of leaving nothing behind is based on the assumption that a future intervention is inevitable...
- What is the threshold to this shift in strategy ?
  - How low should reintervention rates be?
  - How high should patency rates be?
  - Threshold for stent fracture rate?
  - In certain lesions, should primary DES be considered?



# DCB vs DES in PAD

## Severe calcium

initial adjunctive atherectomy and/or DES

## Predilate to assess vessel response

uncoated balloon angioplasty



# DCB vs DES

The “leaving nothing behind” concept



POBA + DES

?

DCB + BMS

?

POBA +  
bio-absorbable DE scaffold

?

# Conclusion

Drug-eluting technologies play an expanding role in endovascular treatment of PAD

**DE clinical data is driving real world adoption**

**Adjunctive atherectomy + DCB a : growing trend / DES**

- **DCB is an important tool with proven evidence**

- o . in low calcified TASC A and B lesions
- o . in instent restenosis
- o . improving stent results
- o . In popliteal lesions

- **DES proves to be better in**

- o . calcified lesions
- o . flow limiting dissections or reststenosis

- **More evidence is needed in RCT's**

- o . DCB with BMS vs DES
- o . ideal treatment for long lesions ? bailout stenting
- o . economic consequences