



# CONTROVERSIES & UPDATES IN VASCULAR SURGERY

DIDACTICS

DEVELOPMENT

DISTRIBUTION



Nothing left behind concept:  
is it working?

Koen Deloose, MD

AZ Sint Blasius Dendermonde

Belgium



# Disclosure

Speaker name: Koen Deloose, MD

I have the following potential conflicts of interest to report:

Consulting: Medtronic, Spectranetics, Biotronik, Abbott, Bard  
iVascular, Bentley, Cook

- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest

Nothing left behind concept :  
is it working ?



**NO**



**Paclitaxel** left behind concept :  
is it working ?



**YES, quite often..**



**Paclitaxel** left behind concept :  
is it working ?



**The longer and more  
complex the lesions,  
the more scaffold you need**



Nothing left behind concept :  
is it working ?



**NO**

# Leaving nothing behind doesn't work...

- POB Angioplasty

*Catheter Cardiovasc Interv.* 2007 May 1;69(6):910-9.

Performance goals and endpoint assessments for clinical trials of femoropopliteal stents in patients with symptomatic peripheral arterial disease.

Rocha-Singh KJ<sup>1</sup>, Jaff MR, Crabtree TR, Bloch DA, Ansel CJ, et al.

⊕ Author information

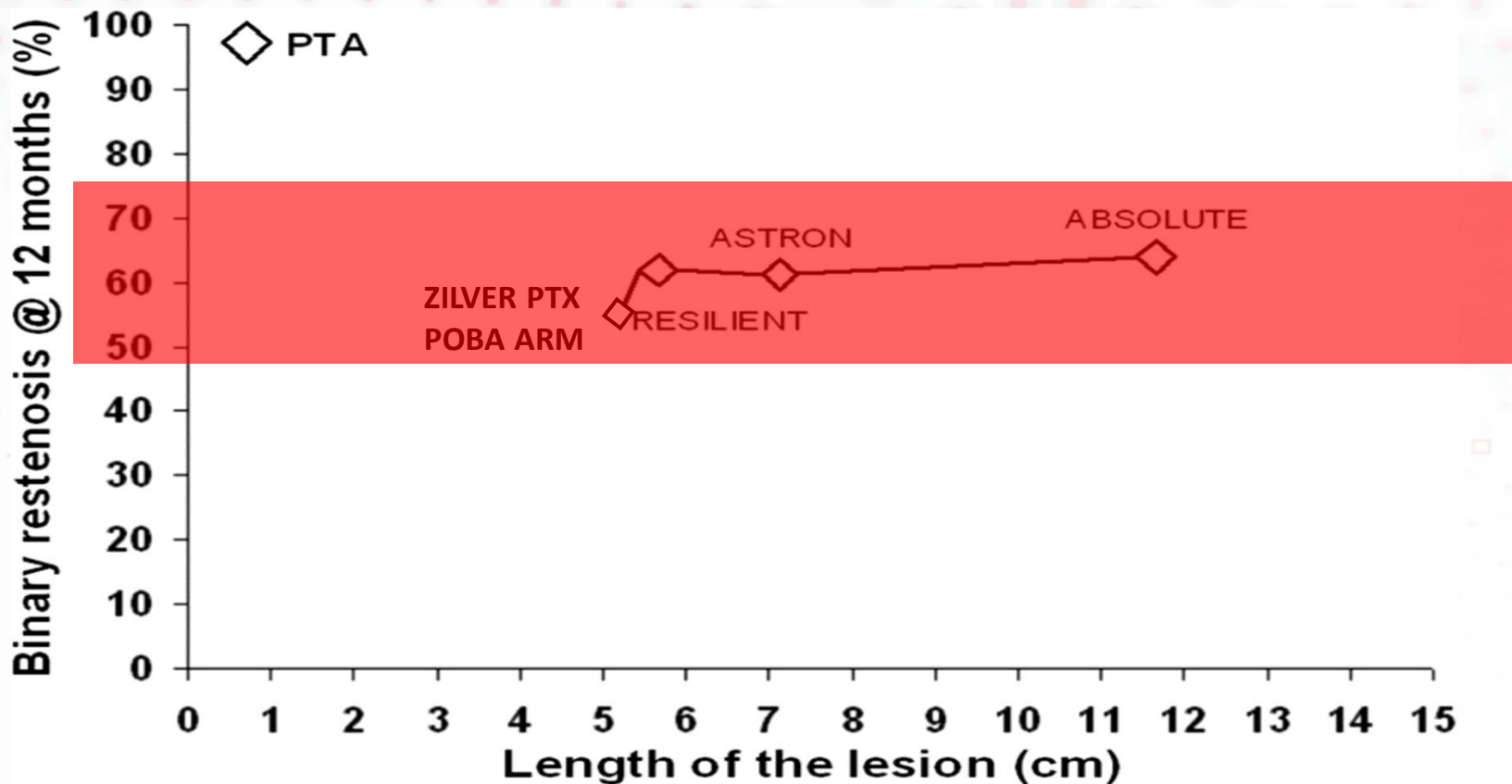
• 3 RCT (116 pts) – mll 8,7cm  
DUS 1 yr PPR 28%

• Literature surv 1990-2006 (191 pts) – mll 8,9cm  
DUS 1 yr PPR 38%

...industry clinical trial data and the medical literature, efficacy performance goal be set to equal twice this rate, the patency efficacy is provided on safety and other reporting standards and stent integrity evaluation for bare

# Leaving nothing behind doesn't work...

- POB Angioplasty

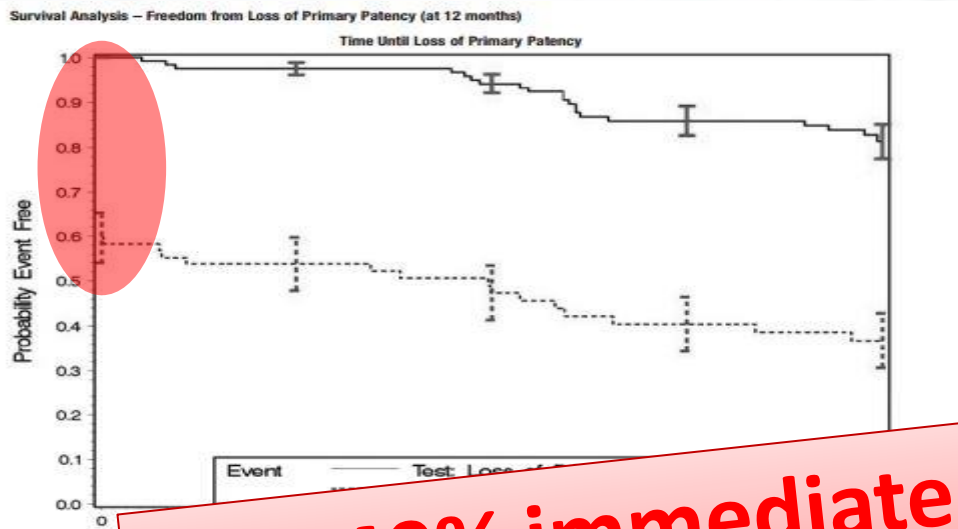




# Leaving nothing behind doesn't work...

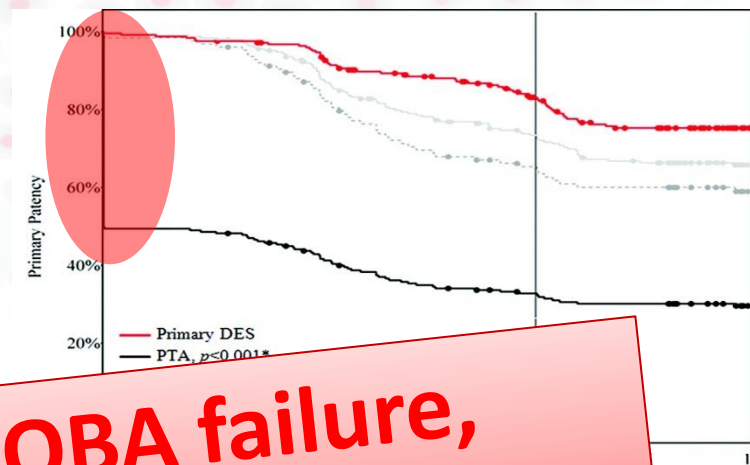
- POB Angioplasty

## RESILIENT 1 YR DATA



Loss of Primary	
Test (LifeStent® Stent)	
Control (balloon angioplasty)	
*p-value is from Log-Rank Test	

## ZILVER PTX 1 YR DATA



**>40% immediate POBA failure, requiring bail-out stenting**

	Primary DES	PTA	Primary DES	PTA	Primary DES	PTA	Primary DES	PTA
0	42.5 ± 3.1%	94.7 ± 1.4%	127	2	0	0	125	246
12	32.8 ± 3.0%	83.1 ± 2.4%	144	13	5	3	102	231
			167	40	10	26	74	181

# Leaving nothing behind doesn't work...

- POB Angioplasty =

Increasing pressure till plaque/lesion breaks

Once plaque fractures -> all pressure to arterial wall  
**IN AN UNCONTROLLED WAY**



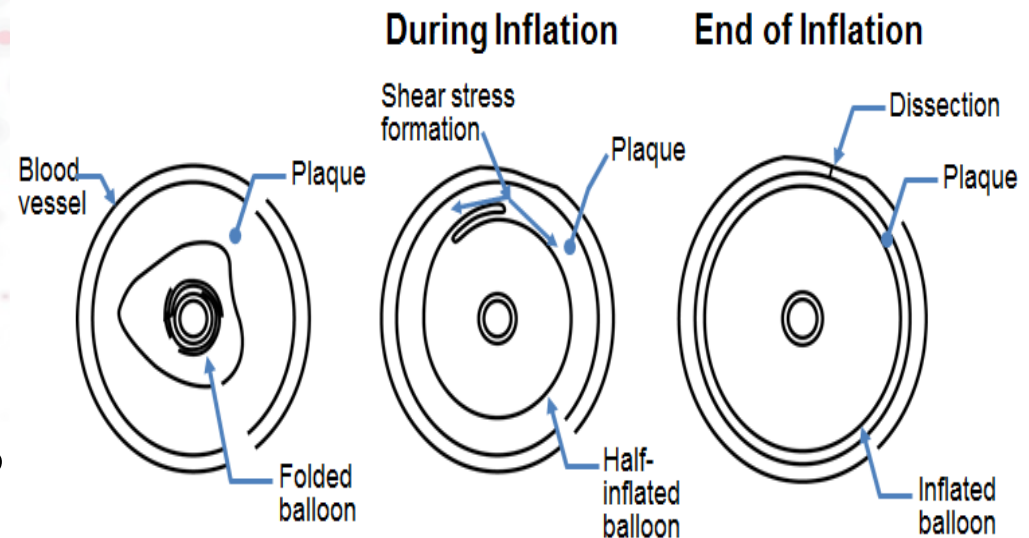
**UNCONTROLLED INJURY**



**DISSECTION - RECOIL**



**OBLIGATORY RESTENOSIS**



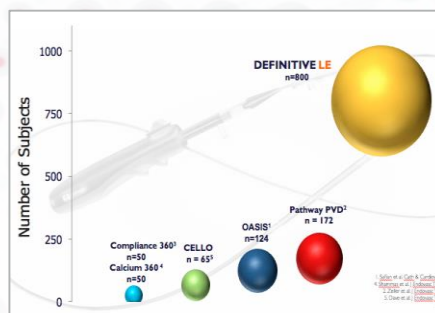
# Leaving nothing behind doesn't work...

- Atherectomy : **DEFINITIVE LE TRIAL**



### Goal:

Measure effectiveness of stand-alone directional atherectomy



Largest Core Lab Adjudicated atherectomy trial EVER



- 800 Patients
- 47 Centers
- Pre-specified comparison of Patients with/without diabetes





Leaving nothing behind doesn't work...

- Atherectomy : **DEFINITIVE LE TRIAL**

Characteristics	Claudication (RCC 1-3)	CLI (RCC 4-6)	All Subjects (RCC 1-6)
Number of Patients	598	201	799
Number of Lesions	743	279	1022
<b>Mean Length (cm)</b>	<b>7.5</b>	<b>7.2</b>	<b>7.4</b>
Baseline Stenosis (%)	73	76	74
Occlusions (%)	17	30	21
<b>1 yr Primary Patency (%) (DUS PSVR &lt; 2,4)</b>	<b>78</b>	<b>71</b>	<b>na</b>

# Leaving nothing behind doesn't work...

- Atherectomy =

Removing plaque/lesion  
IN AN UNCONTROLLED WAY



Adventitia/media INJURY



INFLAMMATION



OBLIGATORY RESTENOSIS

Histopathological Evidence of Adventitial or Medial Injury Is a Strong Predictor of Restenosis During Directional Atherectomy for Peripheral Artery Disease.

(PMID:26208657)

[Tarricone A](#), [Ali Z](#), [Rajamanickam A](#), [Gujja K](#), [Kapur V](#), [Purushothaman KR](#), [Purushothaman M](#), [Vasquez M](#), [Zalewski A](#), [Parides M](#), [Overbey J](#), [Wiley J](#), [Krishnan P](#)

Mount Sinai Heart, Mount Sinai Medical Center, New York, NY, USA.

[Journal of Endovascular Therapy : an Official Journal of the International Society of Endovascular Specialists](#) [2015, 22(5):712-715]

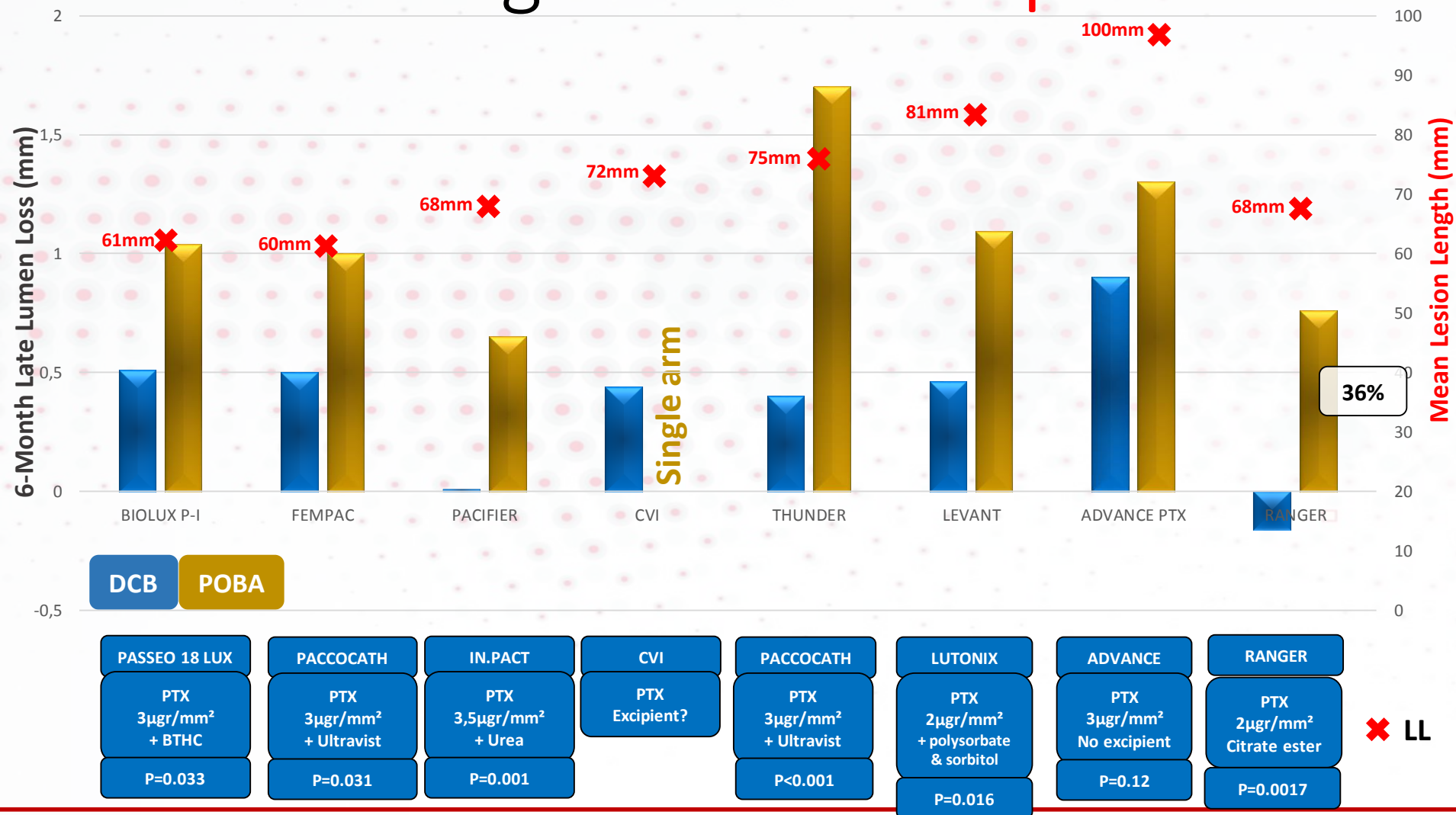
**Paclitaxel** left behind concept :  
is it working ?



**YES, quite often..**



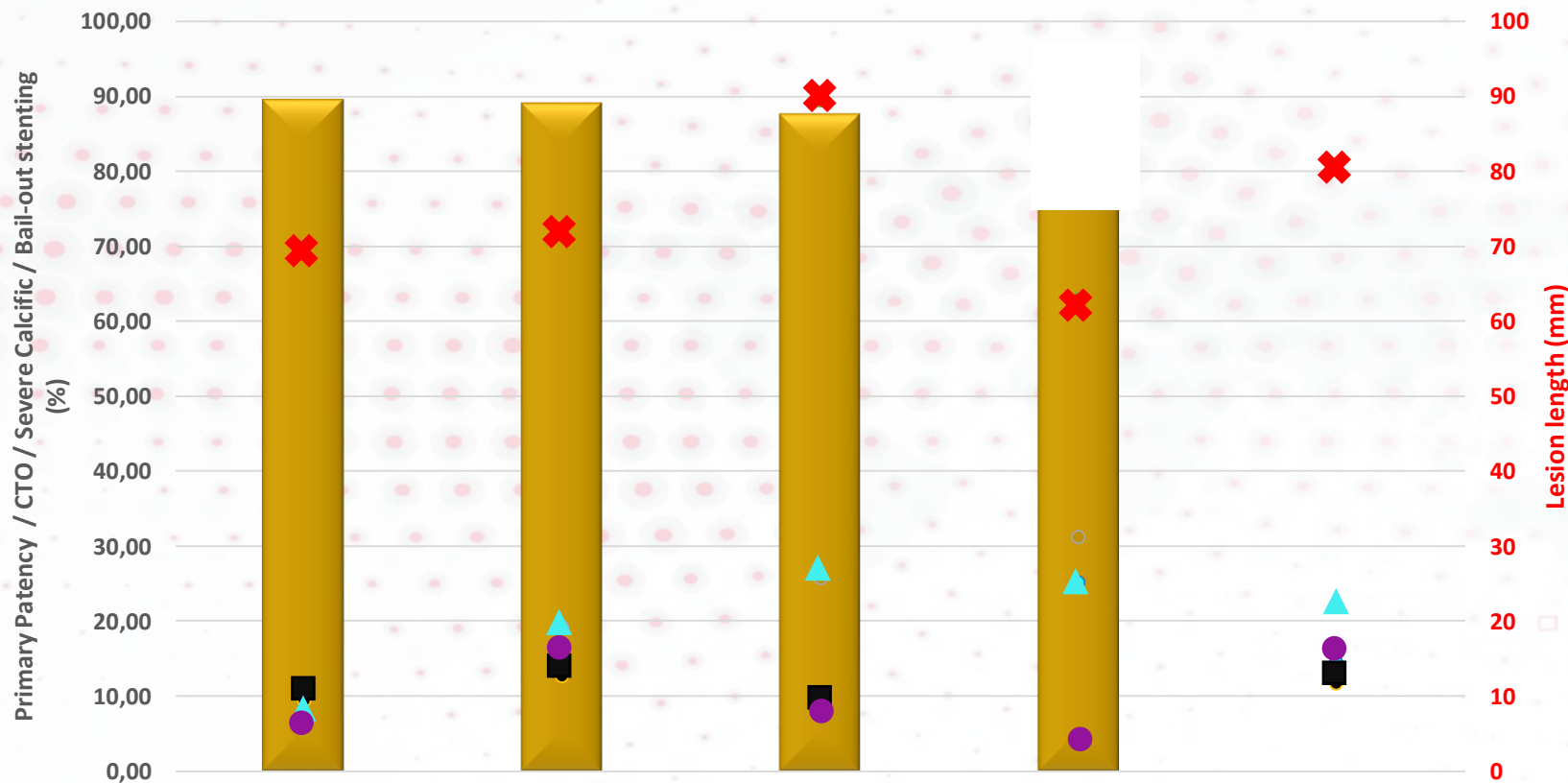
# Paclitaxel left behind concept : is it working? Proof of concepts





# Paclitaxel left behind concept : is it working? Ideal circumstances

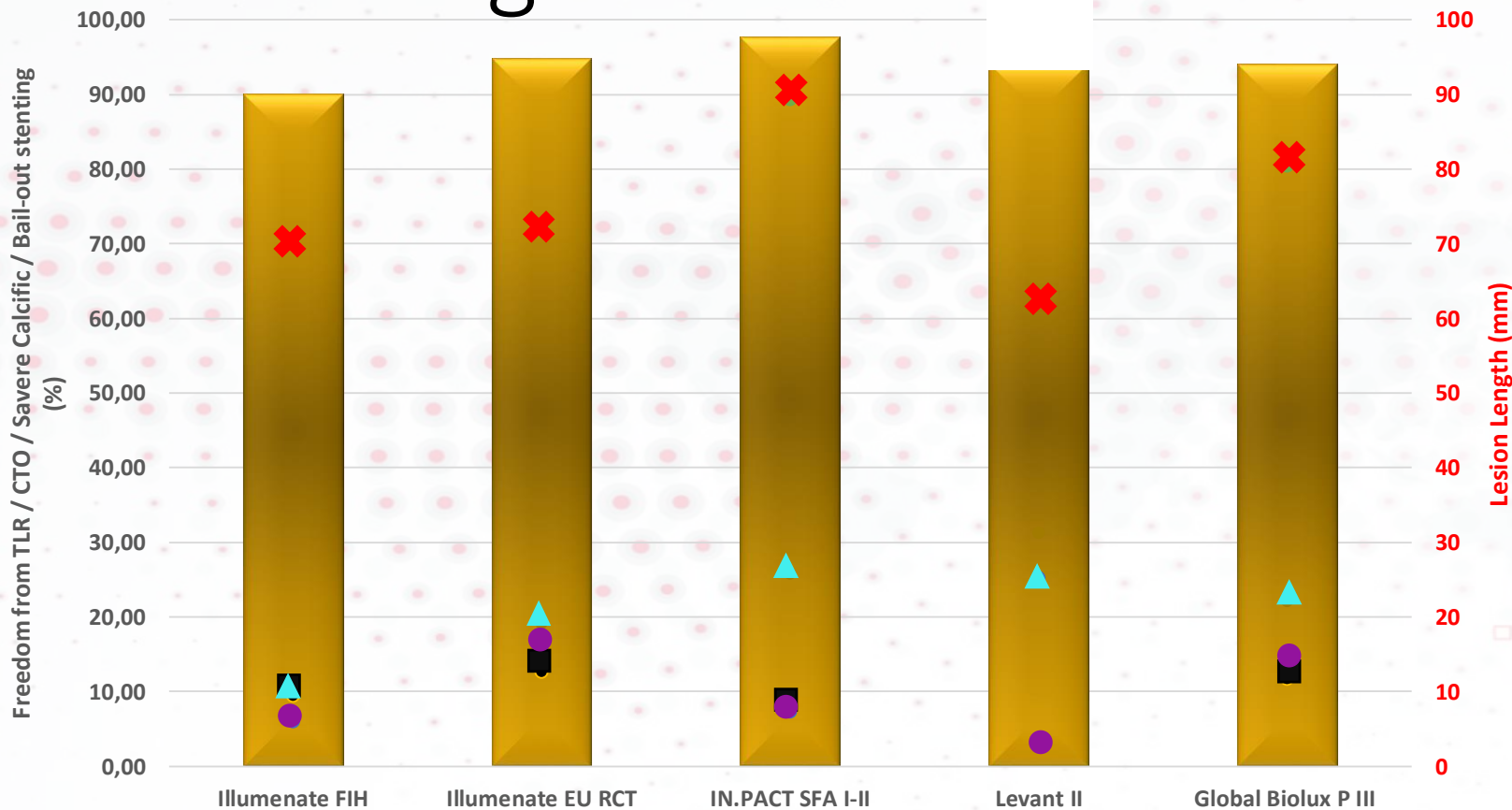
1 yr primary patency



	Illuminate FIH	Illuminate EU RCT	IN.PACT SFA I-II	Levant II	Global Biolux P III
Primary Patency (%)	89.50	89.00	87.50	73.50	N.A.
Lesion Length (mm)	70	72	89.4	62.9	80.4
% Bail-out stenting	6	15.4	7.3	2.52	14.5
% CTO	9.4	19.2	25.8	21.0	22.1
% Severe Ca++	9.4	12.7	8.1	N.A.	11.7

# Paclitaxel left behind concept : is it working? Ideal circumstances

## 1 yr freedom TLR

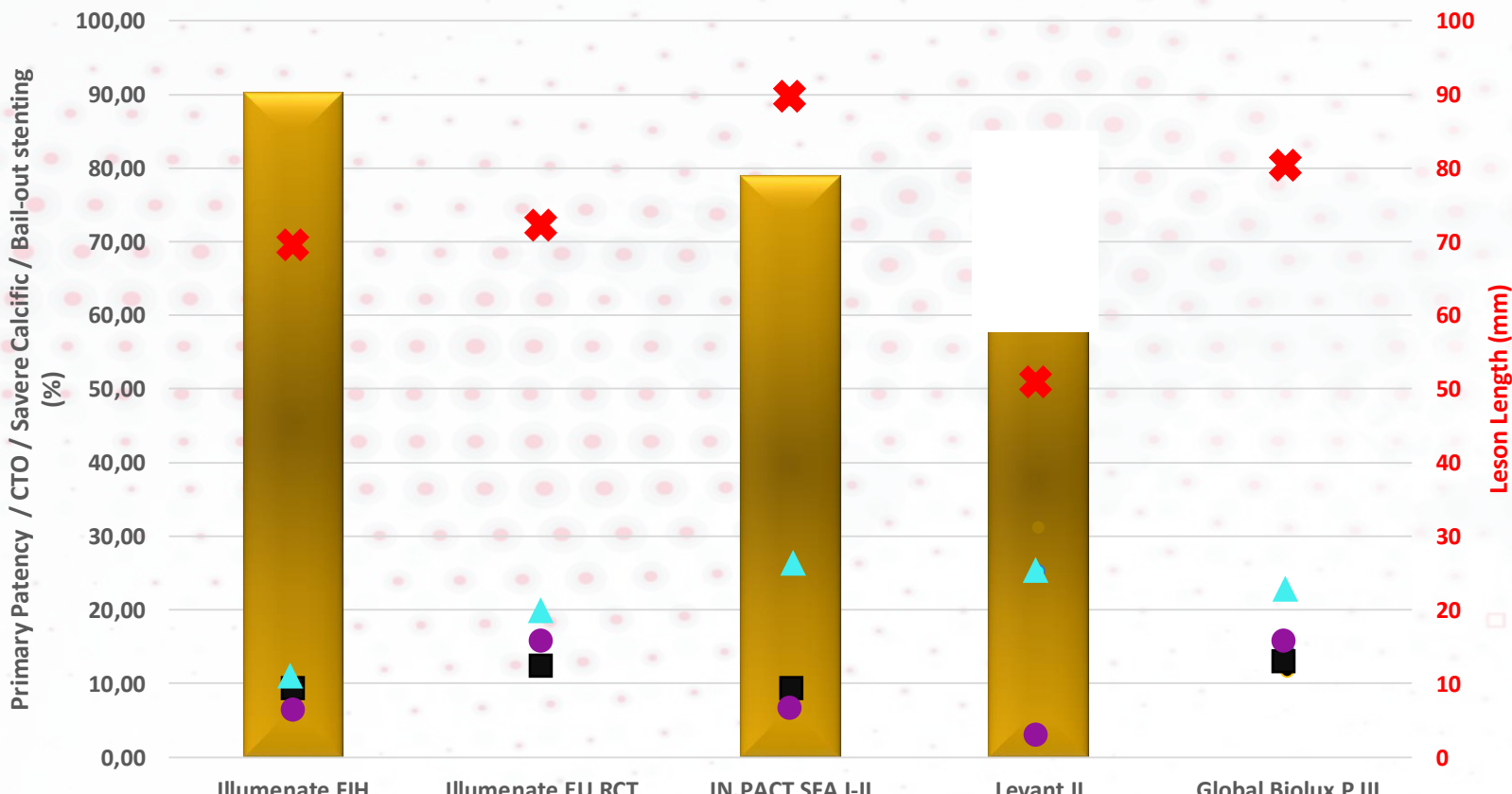


Freedom from TLR (%)	90.0	94.80	97.60	87.7	94.00
Lesion Length (mm)	70	72	89.4	62.9	80.4
% Bail-out stenting	6	15.4	7.3	2.52	14.5
% CTO	9.4	19.2	25.8	21.0	22.1
% Severe Ca++	9.4	12.7	8.1	N.A.	11.7



# Paclitaxel left behind concept : is it working? Ideal circumstances

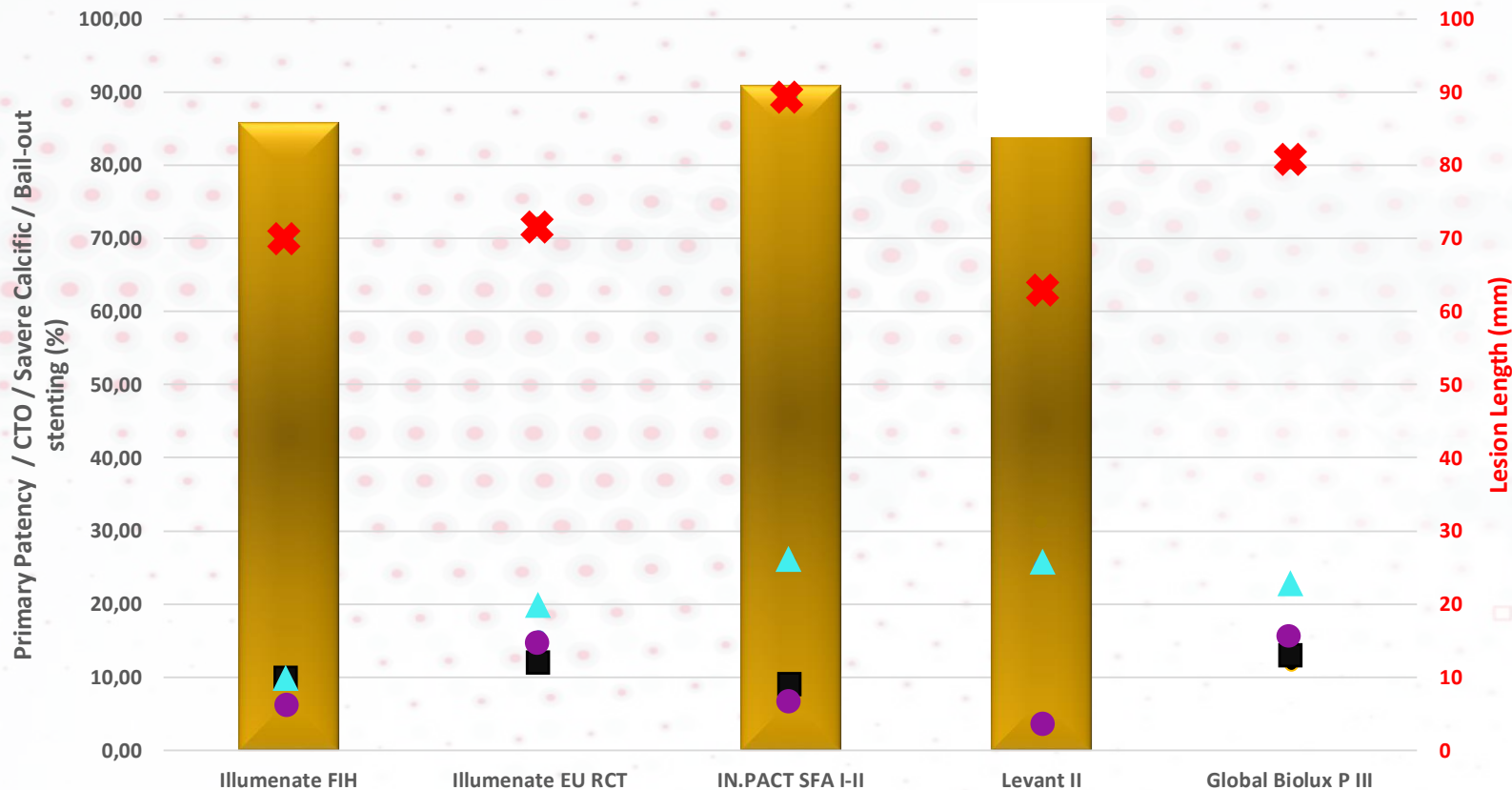
2 yr primary patency



	Illuminate FIH	Illuminate EU RCT	IN.PACT SFA I-II	Levant II	Global Biolux P III
Primary Patency (%)	90.3	N.A.	78.90	58.60	
Lesion Length (mm)	70	72	89.4	62.9	80.4
% Bail-out stenting	6	15.4	7.3	2.52	14.5
% CTO	9.4	19.2	25.8	21.0	22.1
% Severe Ca++	9.4	12.7	8.1	N.A.	11.7

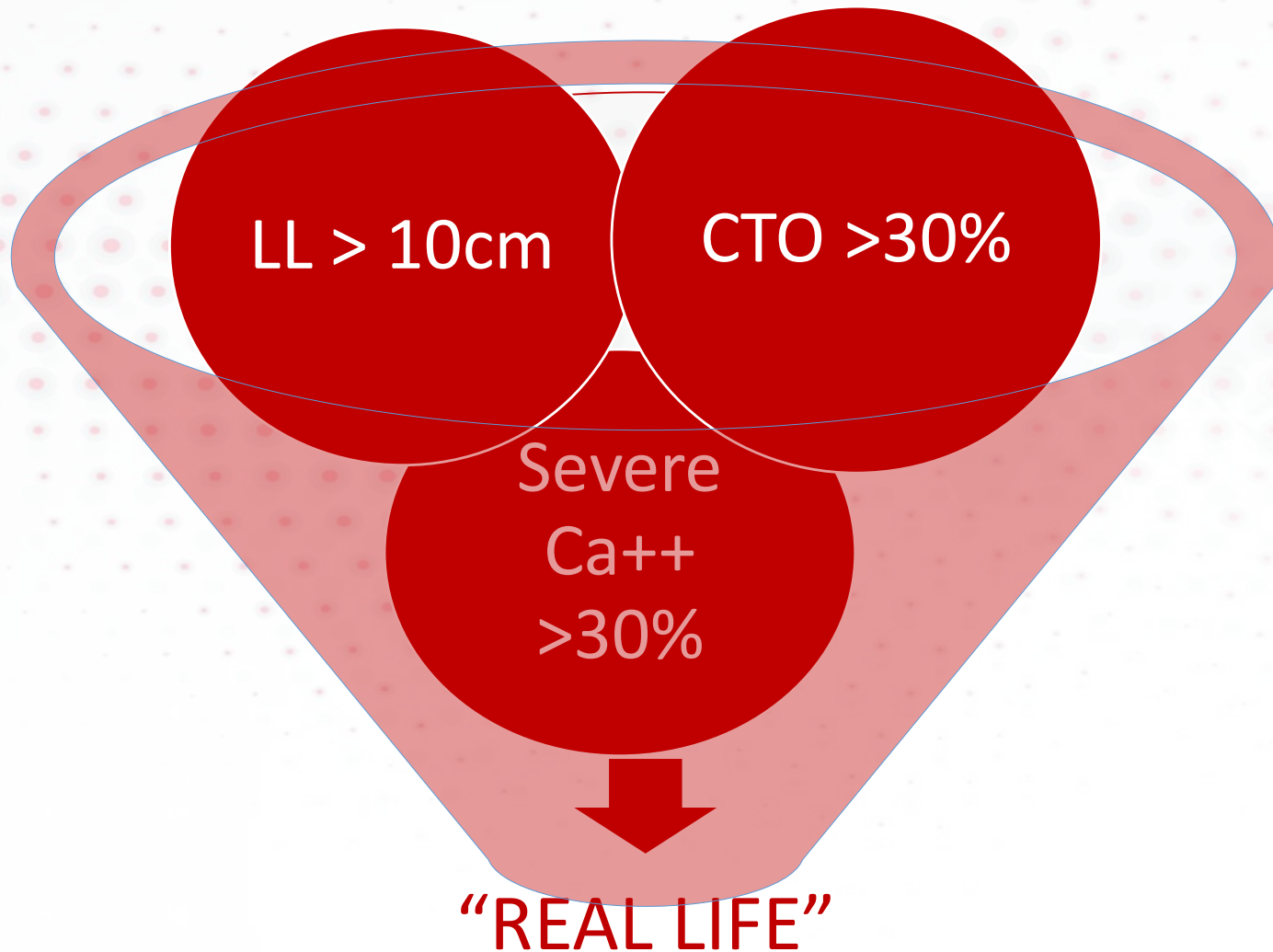
# Paclitaxel left behind concept : is it working? Ideal circumstances

2 yr freedom TLR



Freedom from TLR (%)	85.80	N.A.	90.90	82.00	N.A.
Lesion Length (mm)	70	72	89.4	62.9	80.4
% Bail-out stenting	6	15.4	7.3	2.52	14.5
% CTO	9.4	19.2	25.8	21.0	22.1
% Severe Ca++	9.4	12.7	8.1	N.A.	11.7

# Paclitaxel left behind concept : is it working? **REAL LIFE**

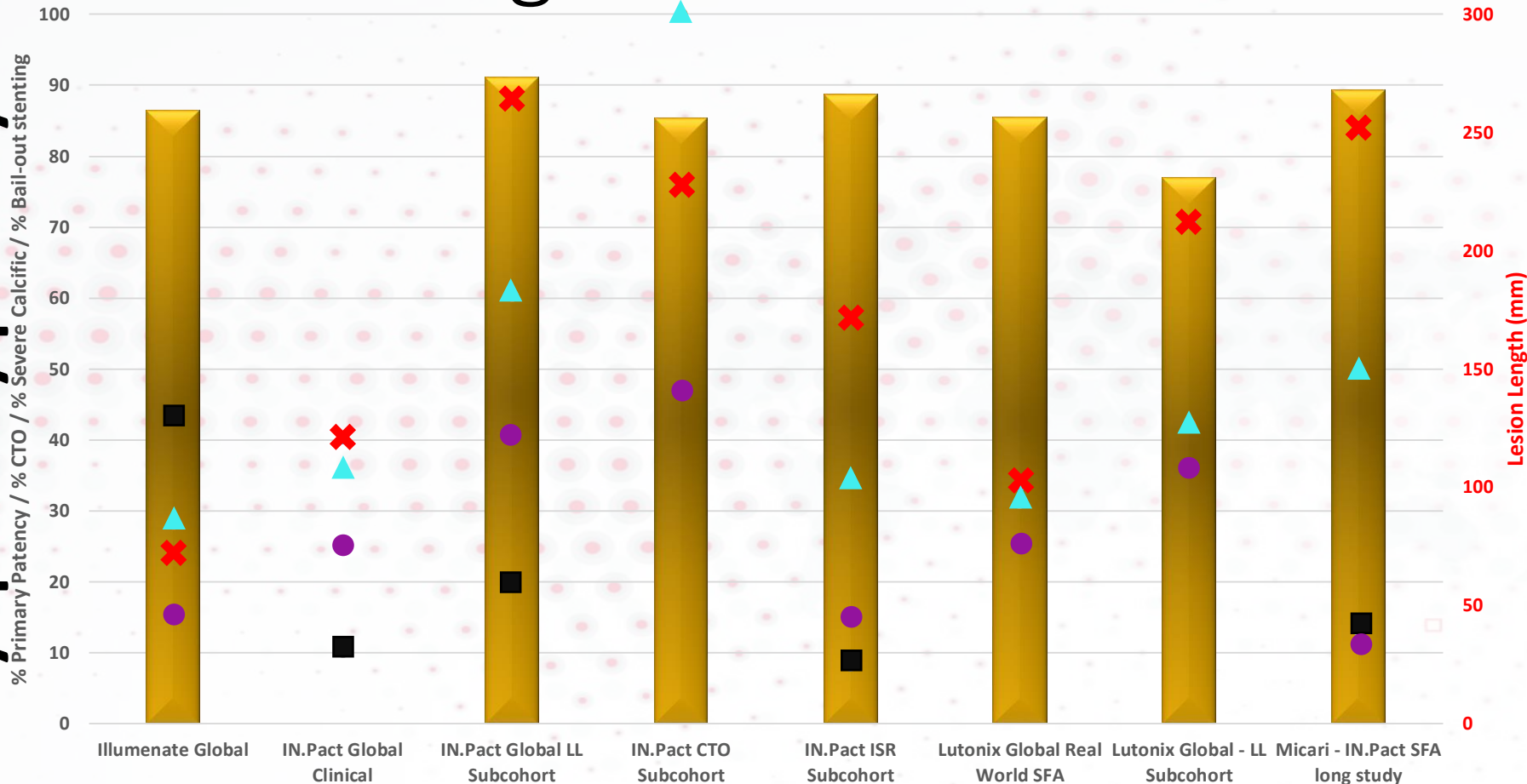




# Paclitaxel left behind concept : is it working? REAL LIFE



1 yr primary patency

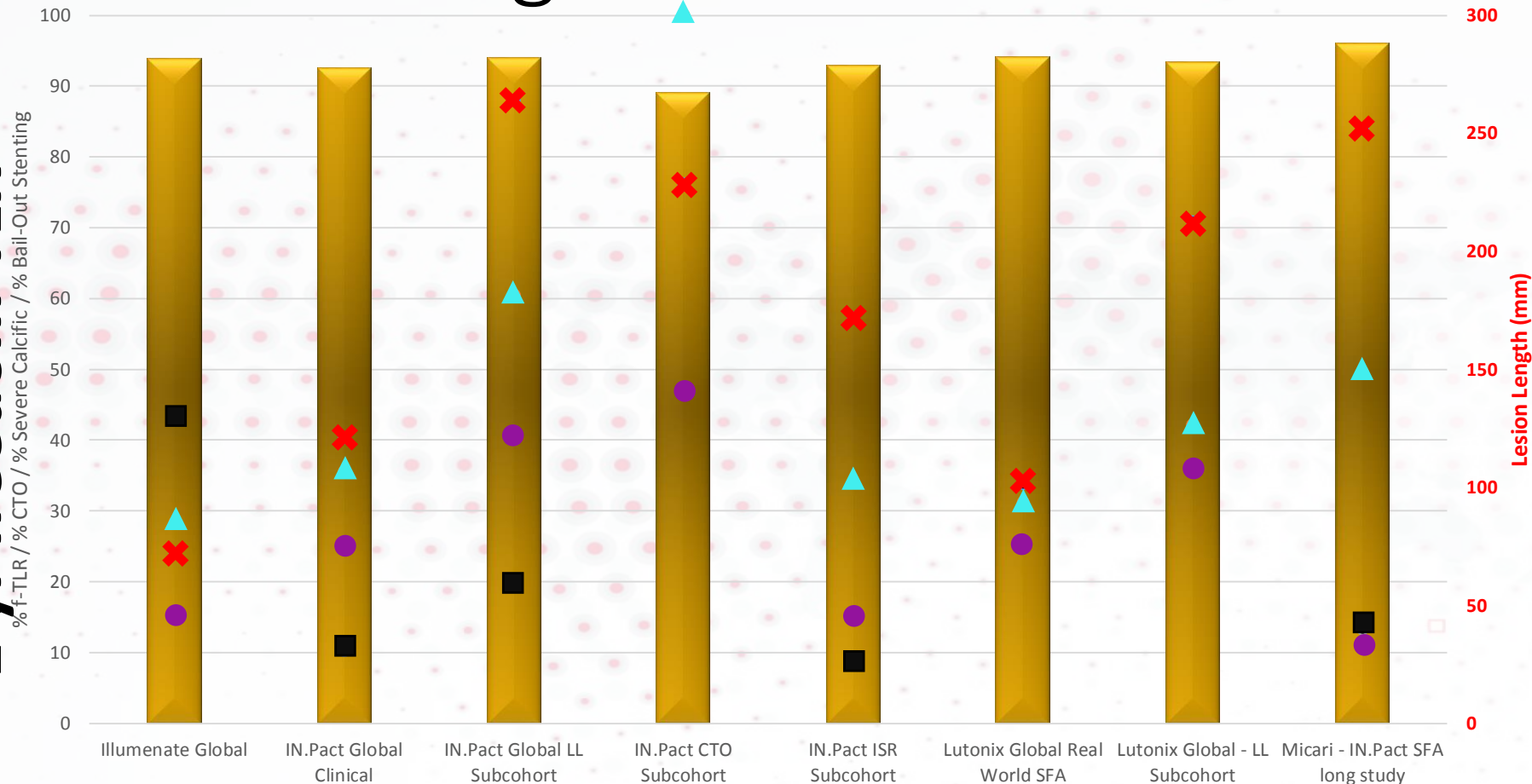


	Illuminate Global	IN.Pact Global Clinical	IN.Pact Global LL Subcohort	IN.Pact CTO Subcohort	IN.Pact ISR Subcohort	Lutonix Global Real World SFA	Lutonix Global - LL Subcohort	Micari - IN.Pact SFA long study
PP (%)	86.5	N.A.	91.1	85.3	88.7	85.4	76.9	89.3
MLL (mm)	72	120.9	264	228.3	171.7	101.2	212.3	251.7
% B-O stent	15	25.3	40.4	46.8	14.5	25.2	35.7	10.9
% CTO	28.3	35.5	60.4	100	34	31.2	42.1	49.5
% Sev Ca++	43.4	10.2	19.6	N.A.	8.3	N.A.	N.A.	13.3

# Paclitaxel left behind concept : is it working? REAL LIFE



1 yr freedom TLR

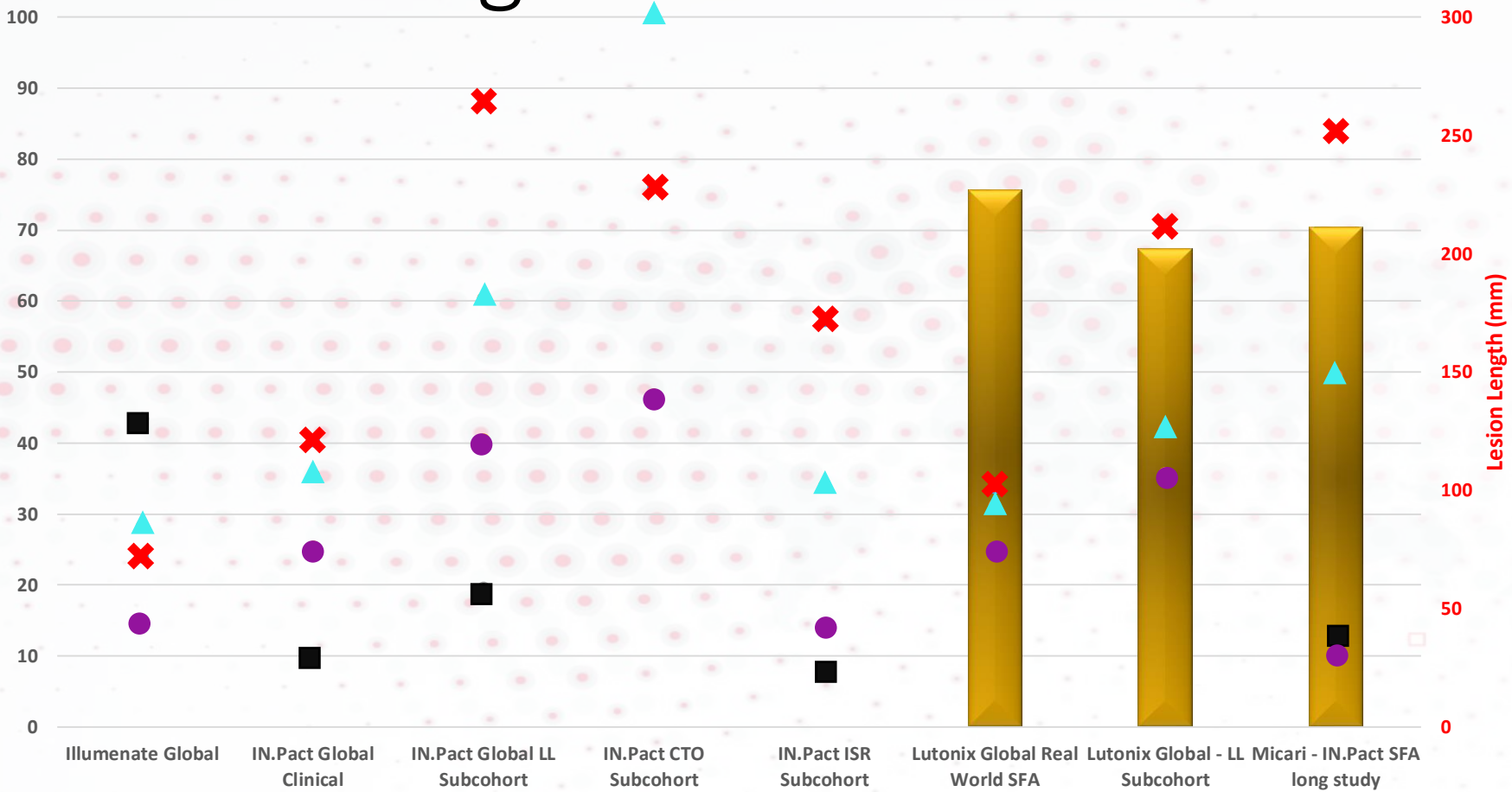


	Illuminate Global	IN.Pact Global Clinical	IN.Pact Global LL Subcohort	IN.Pact CTO Subcohort	IN.Pact ISR Subcohort	Lutonix Global Real World SFA	Lutonix Global - LL Subcohort	Micari - IN.Pact SFA long study
<b>F-TLR (%)</b>	93.9	92.6	94.0	89.1	92.9	94.1	93.4	96.0
<b>MLL (mm)</b>	72	120.9	264	228.3	171.7	101.2	212.3	251.7
<b>% B-O stent</b>	15	25.3	40.4	46.8	14.5	25.2	35.7	10.9
<b>% CTO</b>	28.3	35.5	60.4	100	34	31.2	42.1	49.5
<b>% Sev Ca++</b>	43.4	10.2	19.6	N.A.	8.3	N.A.	N.A.	13.3

# Paclitaxel left behind concept : is it working? REAL LIFE



2 yr primary patency



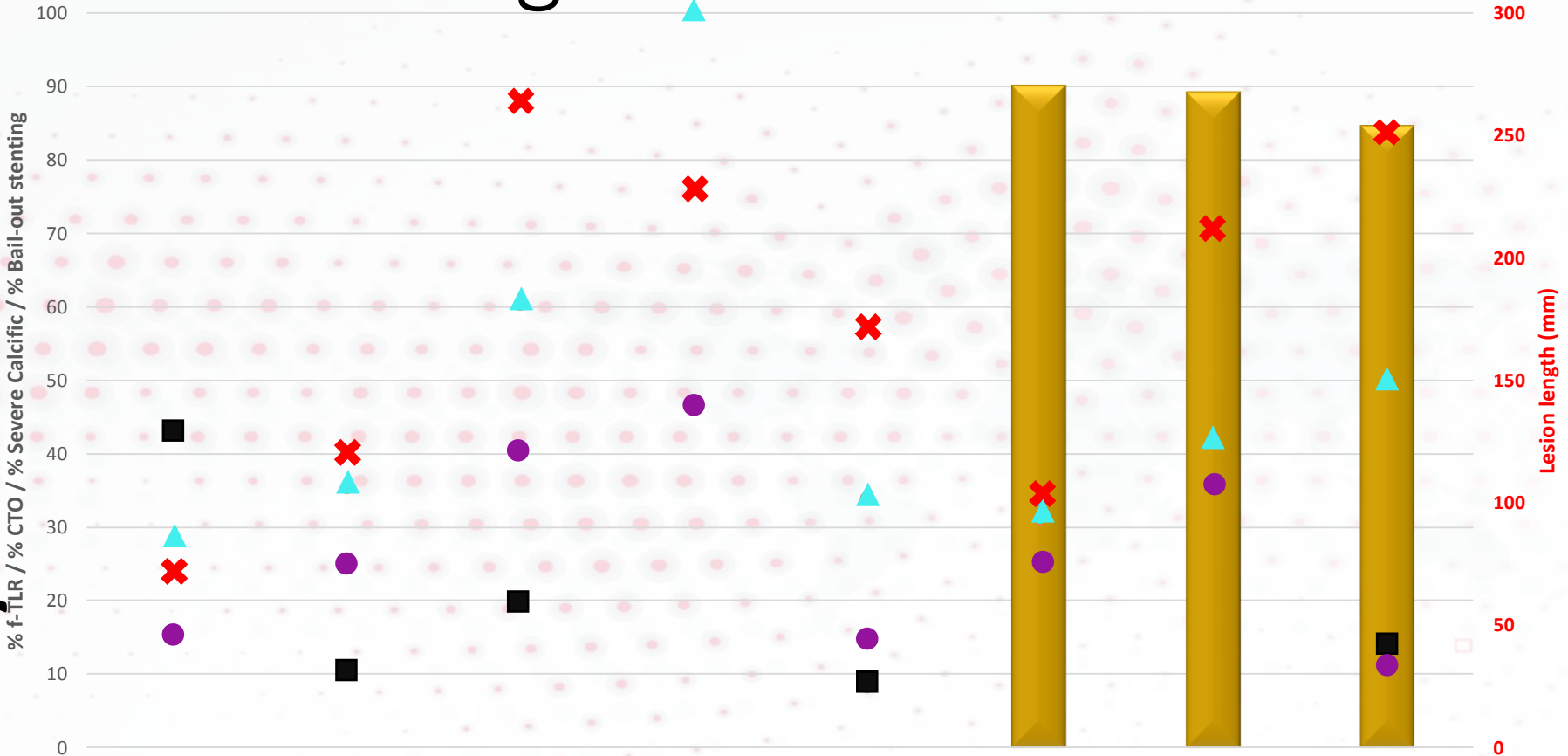
	PP (%)	N.A.	N.A.	N.A.	N.A.	N.A.	75.6	67.3	70.4
✗ MLL (mm)		72	120.9	264	228.3	171.7	101.2	212.3	251.7
● % B-O stent		15	25.3	40.4	46.8	14.5	25.2	35.7	10.9
▲ % CTO		28.3	35.5	60.4	100	34	31.2	42.1	49.5
■ % Sev Ca++		43.4	10.2	19.6	N.A.	8.3	N.A.	N.A.	13.3



# Paclitaxel left behind concept : is it working? REAL LIFE



2 yr freedom TLR



300

250

200

150

100

50

0

Lesion length (mm)

Illuminate Global    IN.Pact Global Clinical    IN.Pact Global LL Subcohort    IN.Pact CTO Subcohort    IN.Pact ISR Subcohort    Lutonix Global Real World SFA    Lutonix Global - LL Subcohort    Micari - IN.Pact SFA long study

	F-TLR (%)	N.A.	N.A.	N.A.	N.A.	N.A.	90.3	89.4	84.7
<span style="color: red;">✘</span> MLL (mm)		72	120.9	264	228.3	171.7	101.2	212.3	251.7
<span style="color: purple;">●</span> % B-O stent		15	25.3	40.4	46.8	14.5	25.2	35.7	10.9
<span style="color: cyan;">▲</span> % CTO		28.3	35.5	60.4	100	34	31.2	42.1	49.5
<span style="color: black;">■</span> % Sev Ca++		43.4	10.2	19.6	N.A.	8.3	N.A.	N.A.	13.3

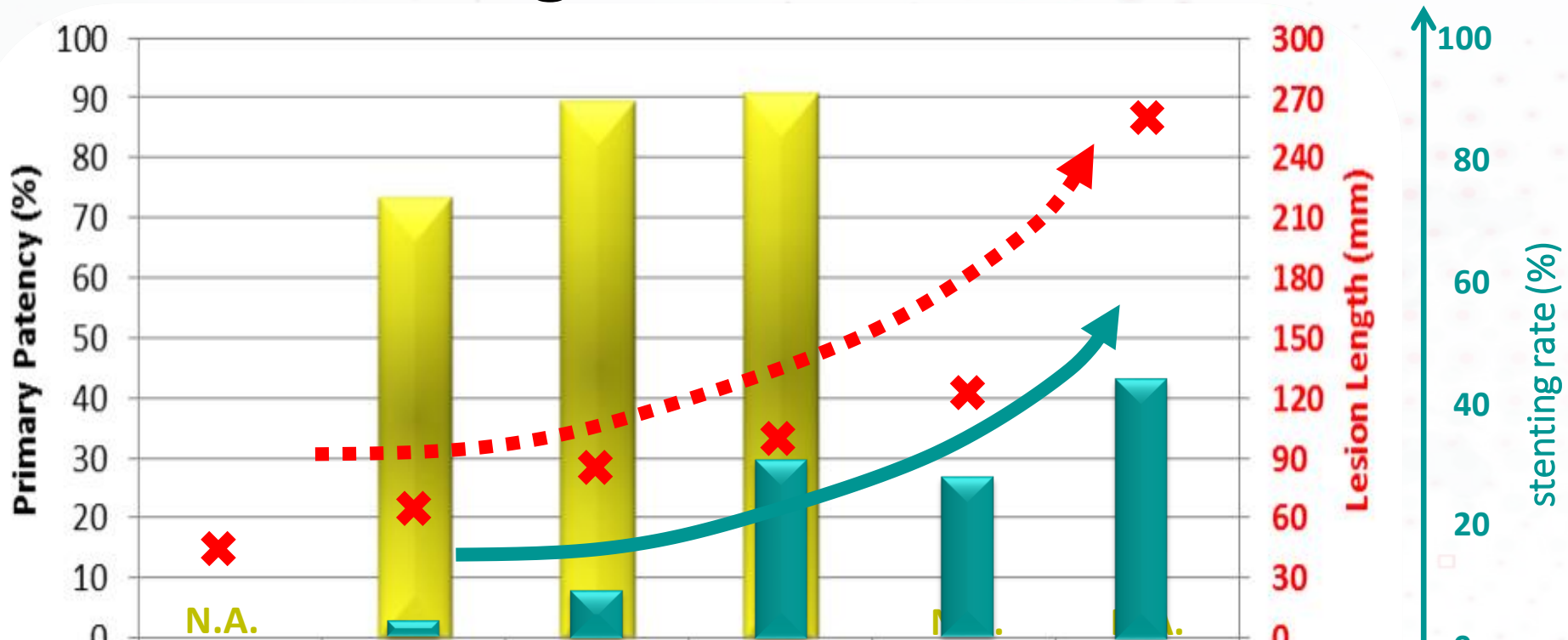
**Paclitaxel** left behind concept :  
is it working ?



**The longer and more  
complex the lesions,  
the more scaffold you need**



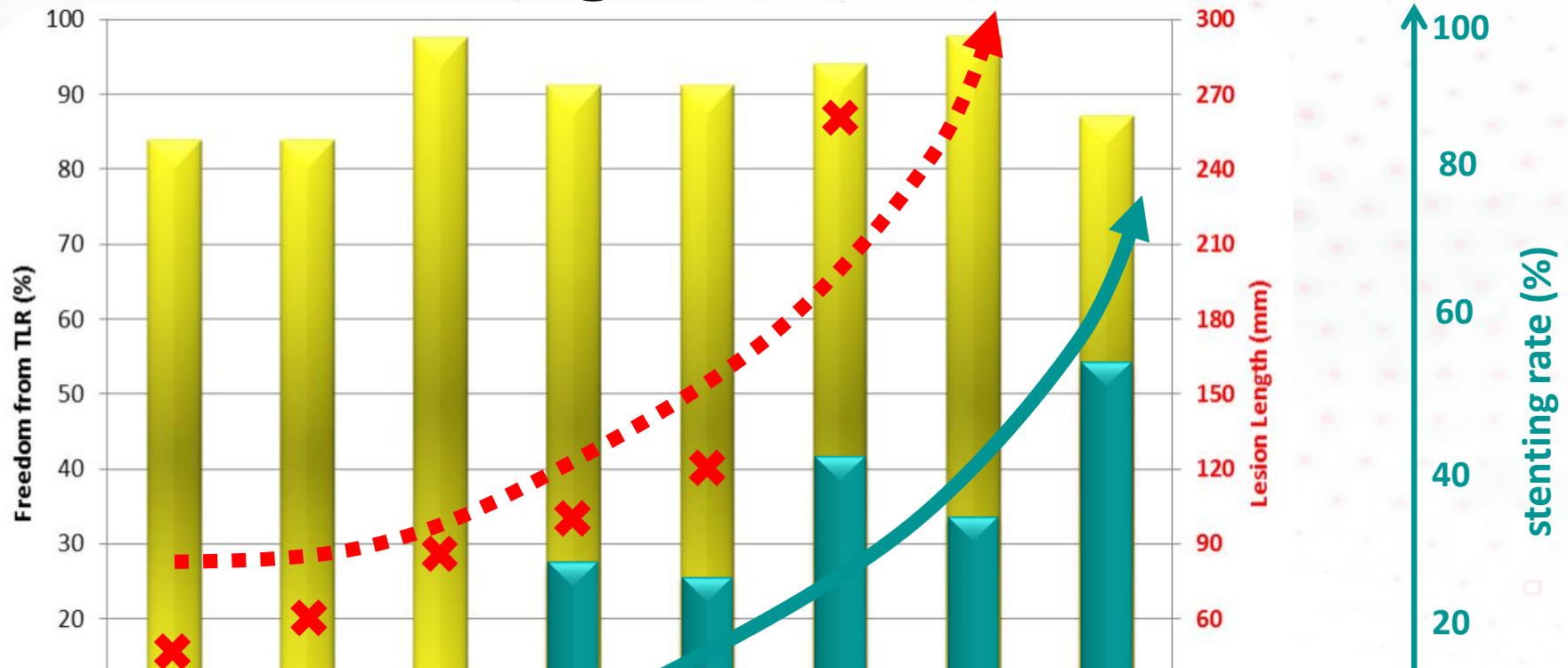
# Paclitaxel left behind concept : is it working ?



**The longer and more complex the lesions, the more scaffold you need**



# Paclitaxel left behind concept : is it working ?



**The longer and more complex the lesions, the more scaffold you need**

# Conclusion

- **Nothing left behind concept doesn't work : POBA results are unacceptable in 2017, atherectomy not as a stand alone therapy.**
- **Paclitaxel left behind concept clearly works : some of the recent DCB results are very successful.**
- **The longer and more complex the lesions, the more scaffold you need : bail-out (spot) stenting? DES?**