

DEB in SFA interventions Case and Focus Review

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TCTAP 2014
April 25 2014

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

Drug Eluting Balloon: Is it the future treatment?

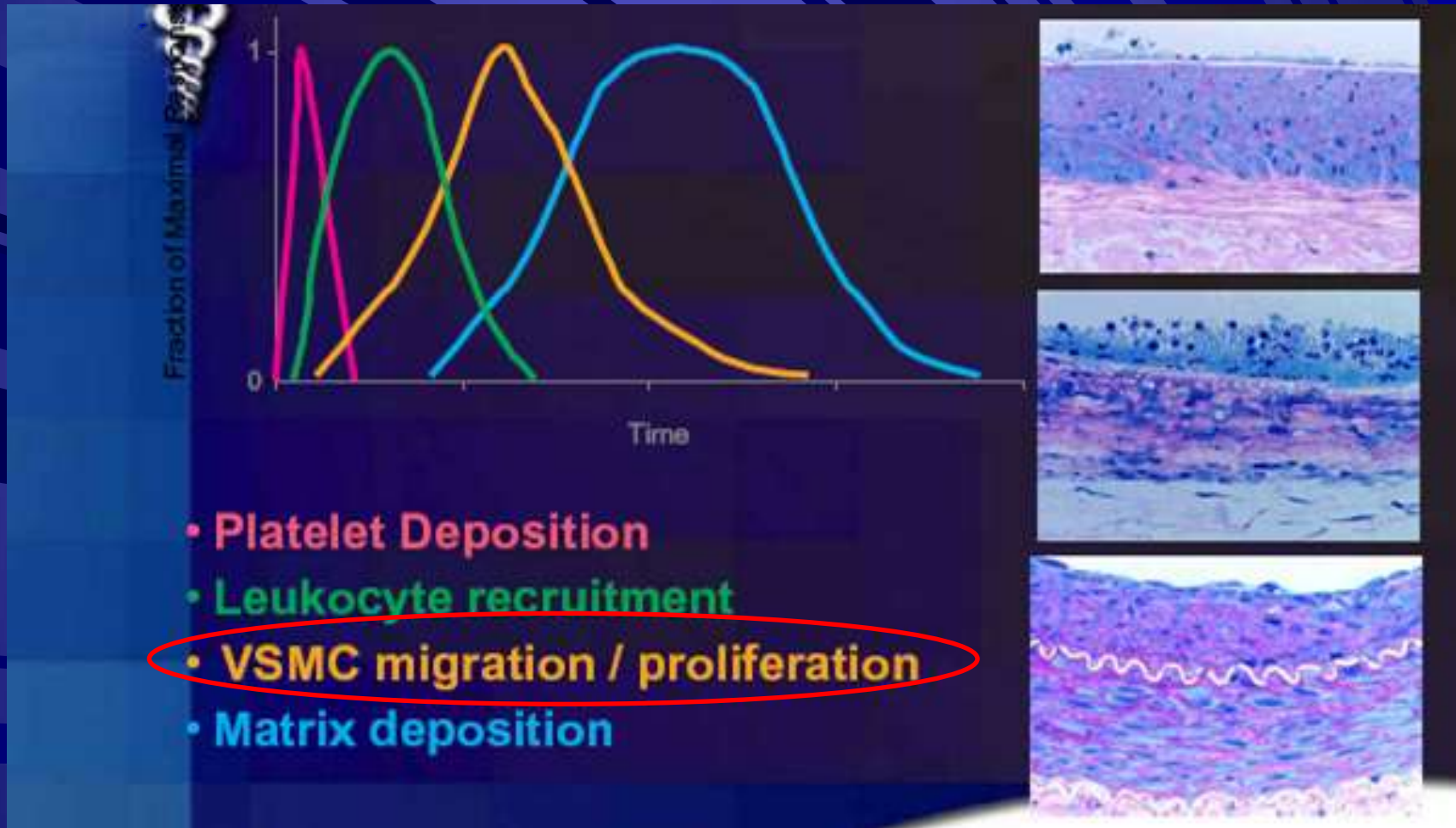


That one therapy is
suitable for all lesions.

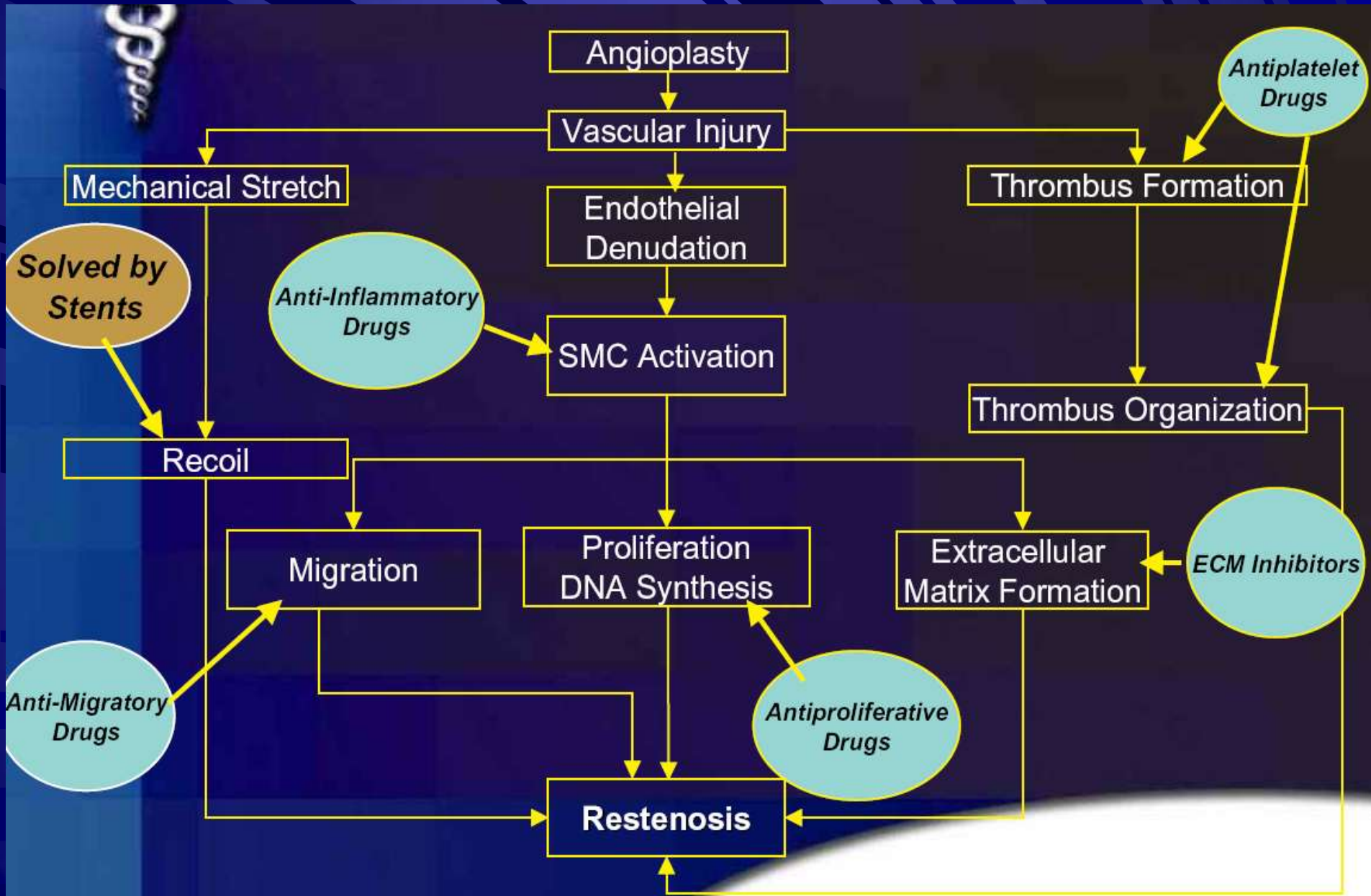
Overview

1. Cascade of healing
2. PTA , STENT and DES results
3. DEB mechanism and results
4. DEB in combination with (? selective) stenting
5. My daily practice
6. Conclusion

1 .Cascade of events leading to wound healing also leads to restenosis



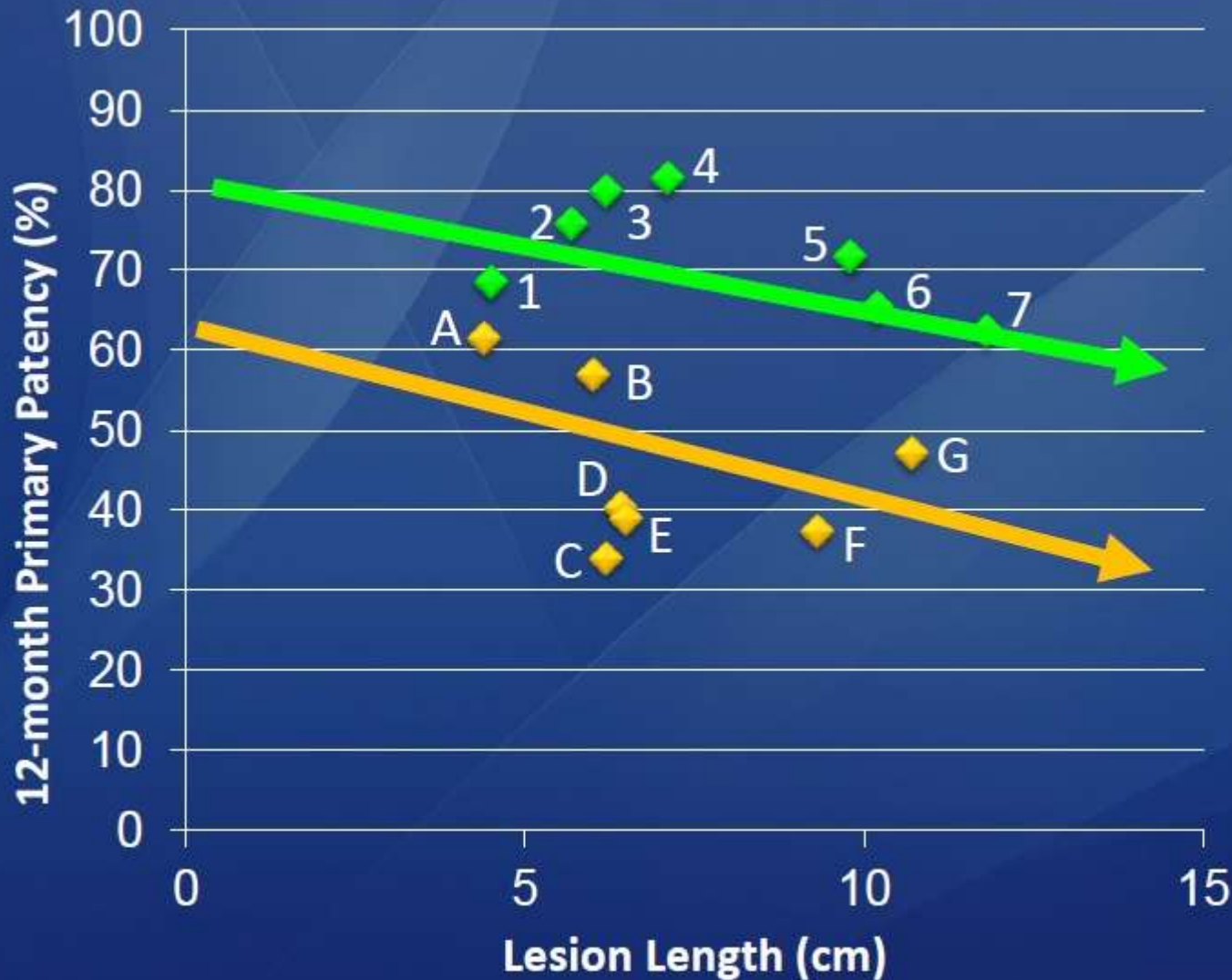
Prevention of restenosis



2. PTA VS STENT in treating SFA lesions

primary patency vs lesion length

FRMP Linc 2014



Stent

1. FAST
2. FACT
3. RESILIENT
4. 4EVER
5. DURABILITY
6. ASTRON
7. VIENNA

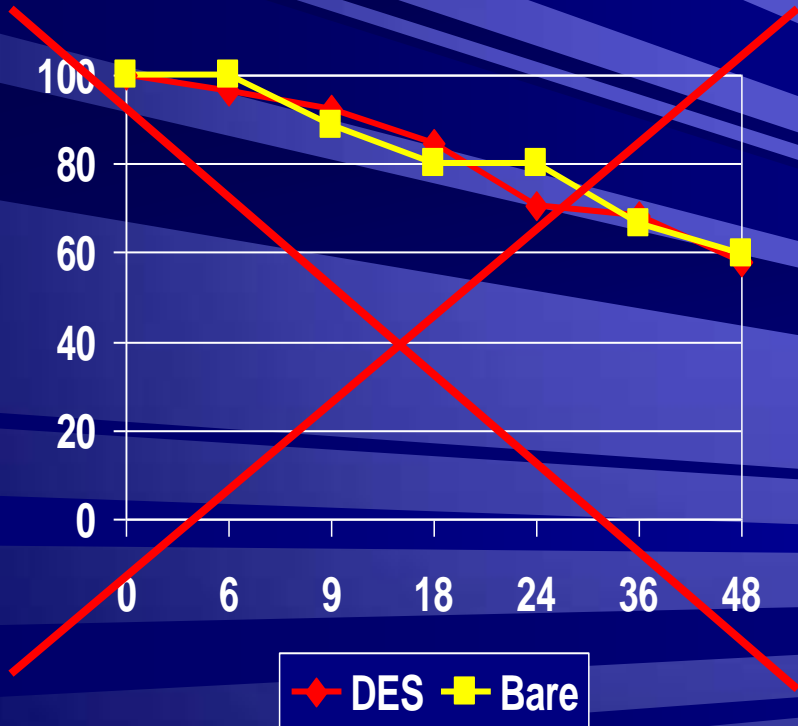
PTA

- A. FAST
- B. ZILVER PTX
- C. RESILIENT
- D. SAXON
- E. ASTRON
- F. VIENNA
- G. VIENNA-3

Drug-eluting stents in SFA

Sirocco

Binary restenosis rate



Strides

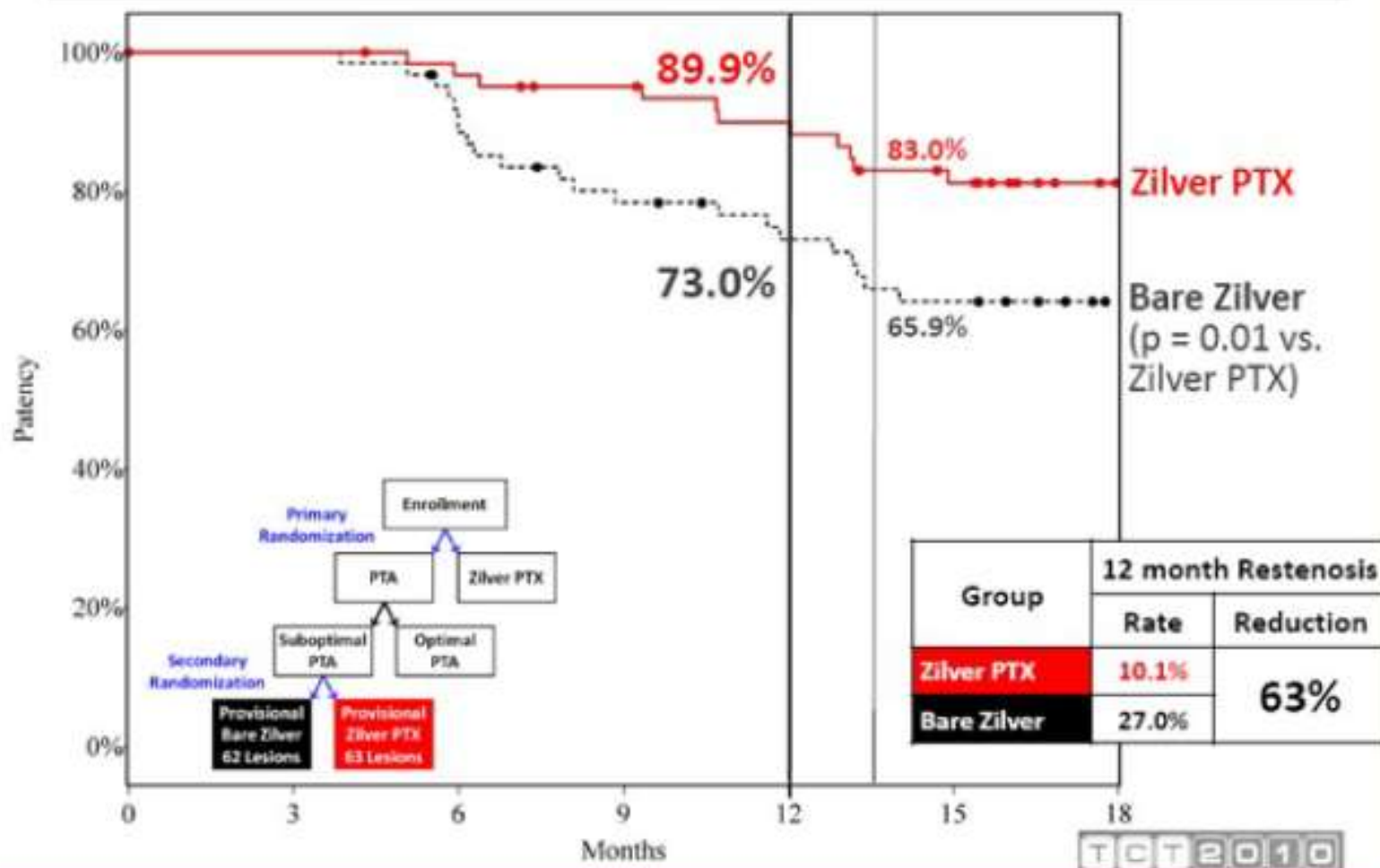
- 100 patients
- Everolimus-eluting Dynalink

Zilver

Registry Study	%	from TLR
TASC A and B	95%	(of 57 lesions)
TASC C and D		(of 34 lesions)
De novo		(of 57 lesions)
Restenotic		(of 34 lesions)
in-stent Restenosis	92%	(of 24 lesions)
≤ 7cm lesions		(of 43 lesions)
> 7 cm lesions		(of 48 lesions)
Overall		(of 91 lesions)

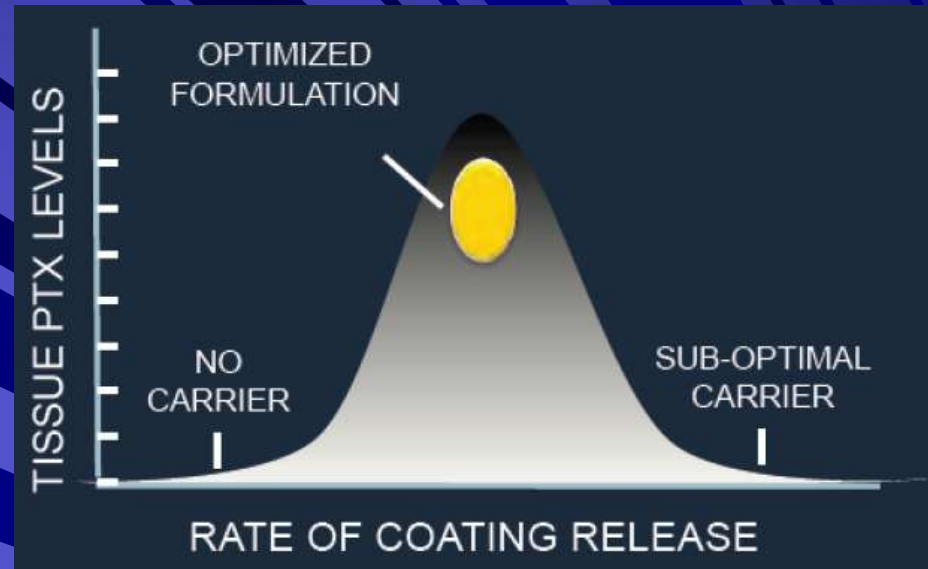
Patency (PSVR < 2.0) for Zilver PTX vs. BMS

Is the drug effect significant?



3. Drug Eluting Balloon

Ideal



- Fully maintain antiproliferative drug on balloon
- Until positioned at the lesion
- Have the intended dose leave the balloon
- Dose resides completely in the intended tissue
- No systemic loss

Sample of testing required for DEB 's

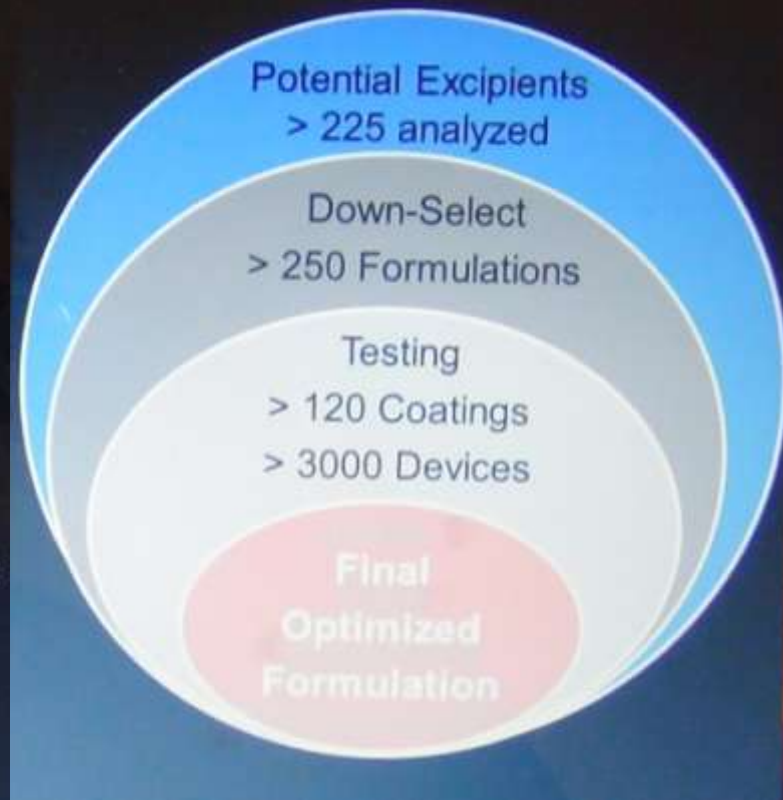
In Vitro Studies

- Coating performance
- Formulation stability
- Manufacturability

In Vivo Studies

- Peak drug levels in tissue
- Drug half-life in tissue
- Transit/Inflation time: dose impact
- Particulate analysis
- Serum, myocardial and organ drug levels
- Histopathology

41	Pre-Clinical Studies
10	GLP Studies
634	Animals



Courtesy of Lutonix LTD



NOT ALL DEB's are equal

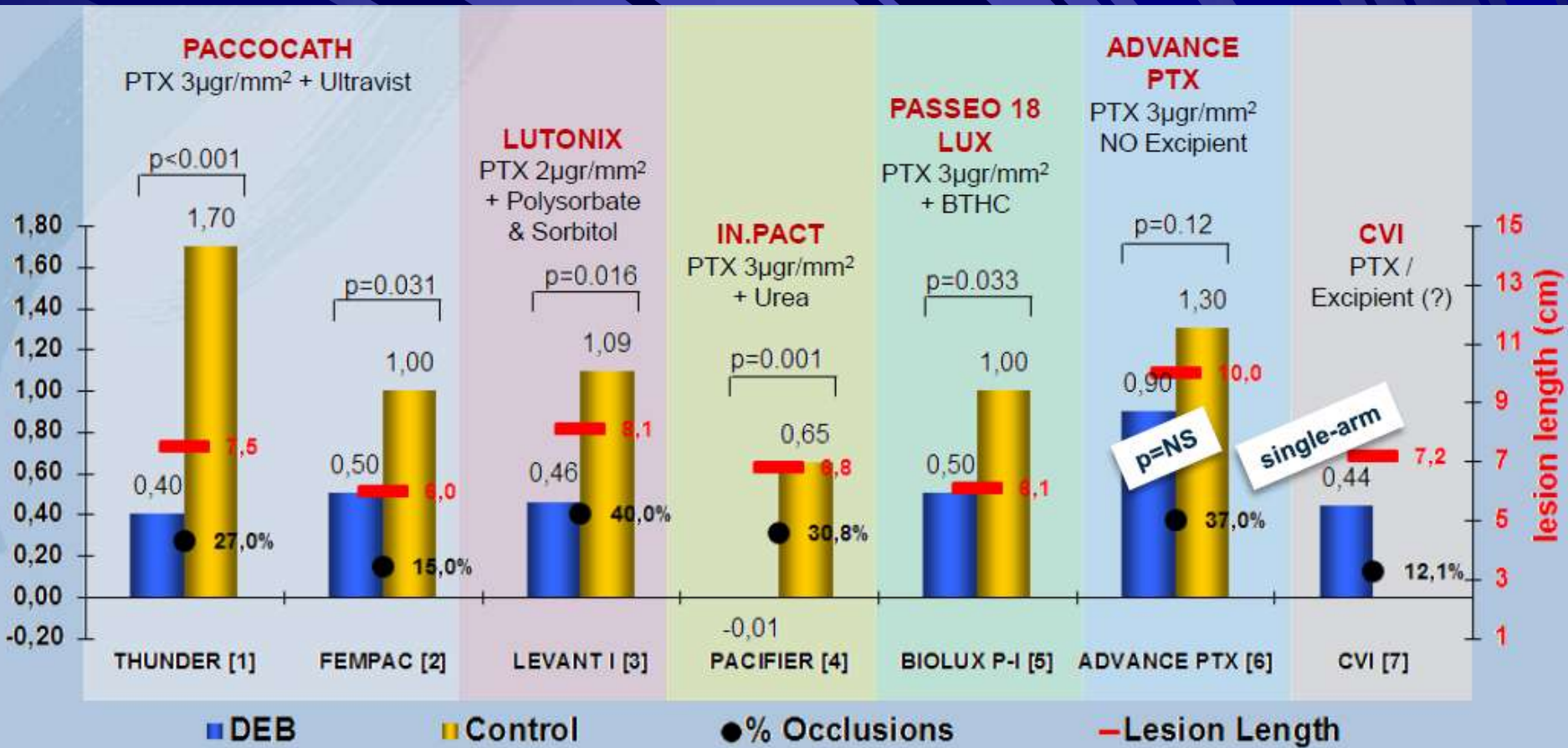
- Excipient determines coating characteristics
- DEB may differ in the uniformity of the drug coating
- Difference in manufacturing and formulations can give uneven coating and less uniform dose delivery
- We are only at the beginning of a new therapy

Antiproliferative agent for DEB PACLITAXEL ?? LIMUS

IDEAL

- High lipofylicity = high absorbtion
- Long term antiproliferative effects
- No local or systemic toxicity
- Easily to apply to balloon surface
 1. uniform distribution
 2. minimal loss pre usage
 3. minimal loss on transition through the body and early inflation

DEB vs POBA : LLL after 6 months



[1] G.Tepe et al. - NEJM 2008; [2] M.Werk et al. - Circulation 2008; [3] D.Scheinert - TCT 2012 oral presentation; [4] M.Werk et al. - Circulation CI 2012; [5] D.Scheinert - EuroPCR 2012 oral presentation; [6] D.Scheinert - LINC 2013 oral presentation; [7] S.Duda - EuroPCR 2013 oral presentation

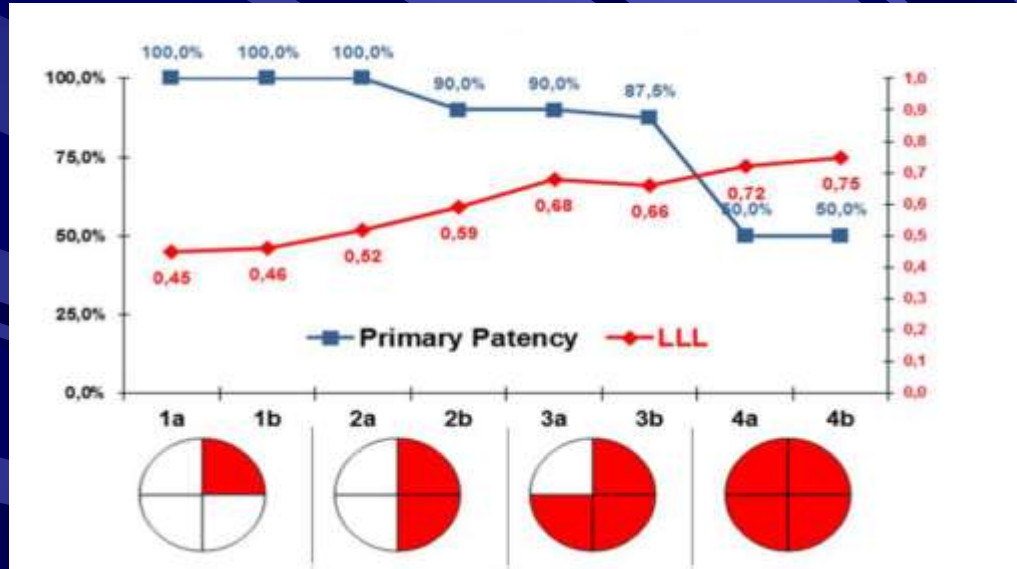
REMARKS

1. Higher stent rate in POBA
2. Only short lesions : mean length 6.1 to 8.1 cm

TASC II A lesions

	THUNDER		FEMPAC		LEVANT		Italian Registry	PACIFIER		DEBELLUM	
	DCB	POBA	DCB	POBA	DCB	POBA	DCB	DCB	POBA	DCB	POBA
N	48	54	45	42	49	52	105	44	47	25	25
Length (cm)	7.5	7.4	6.1	5.7	8.1	8.0	7.63	7	6.6	7.6	7.8
Stent Rate	4%	22%	9%	14%	24%	33%	12%	21%	34%	57%	56%

Calcium is a barrier to optimal drug absorption



Fanelli , LINC 2014

- Circumferential calcium seems to be the most influencing factor (as the media is the target for drug deposition in DEB)
- Total occlusion does not seem to influence outcomes
- In highly calcified arteries combined therapy should be considered



Result : OPTIMAL ?

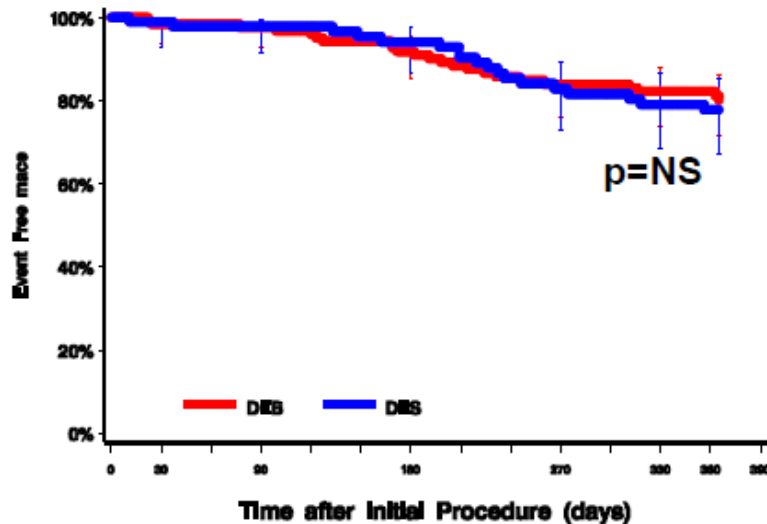
Duplex scan on discharge : no stenosis

IN.PACT VS DES in long SFA lesions

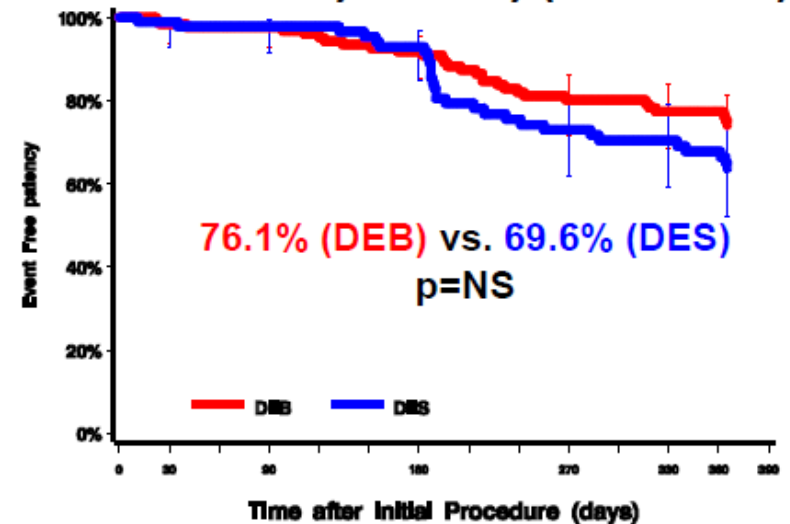
Zeller T Charing cross 2013

- Retrospective
- 228 patients
- Lesions 19 cm
- Stent rate post DEB 18.3 %
- No difference between IN.PACT and SILVER PTX in SFA

12-month freedom from death and TLR



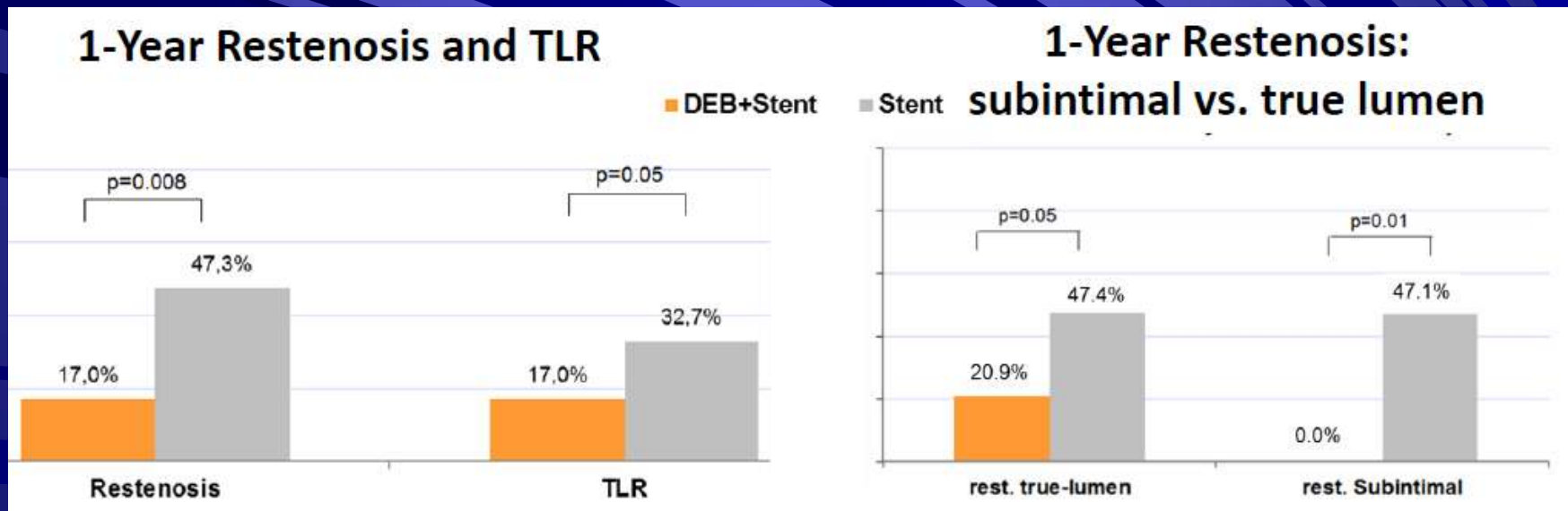
12-month freedom from loss of Primary Patency (PSVR < 2.4)

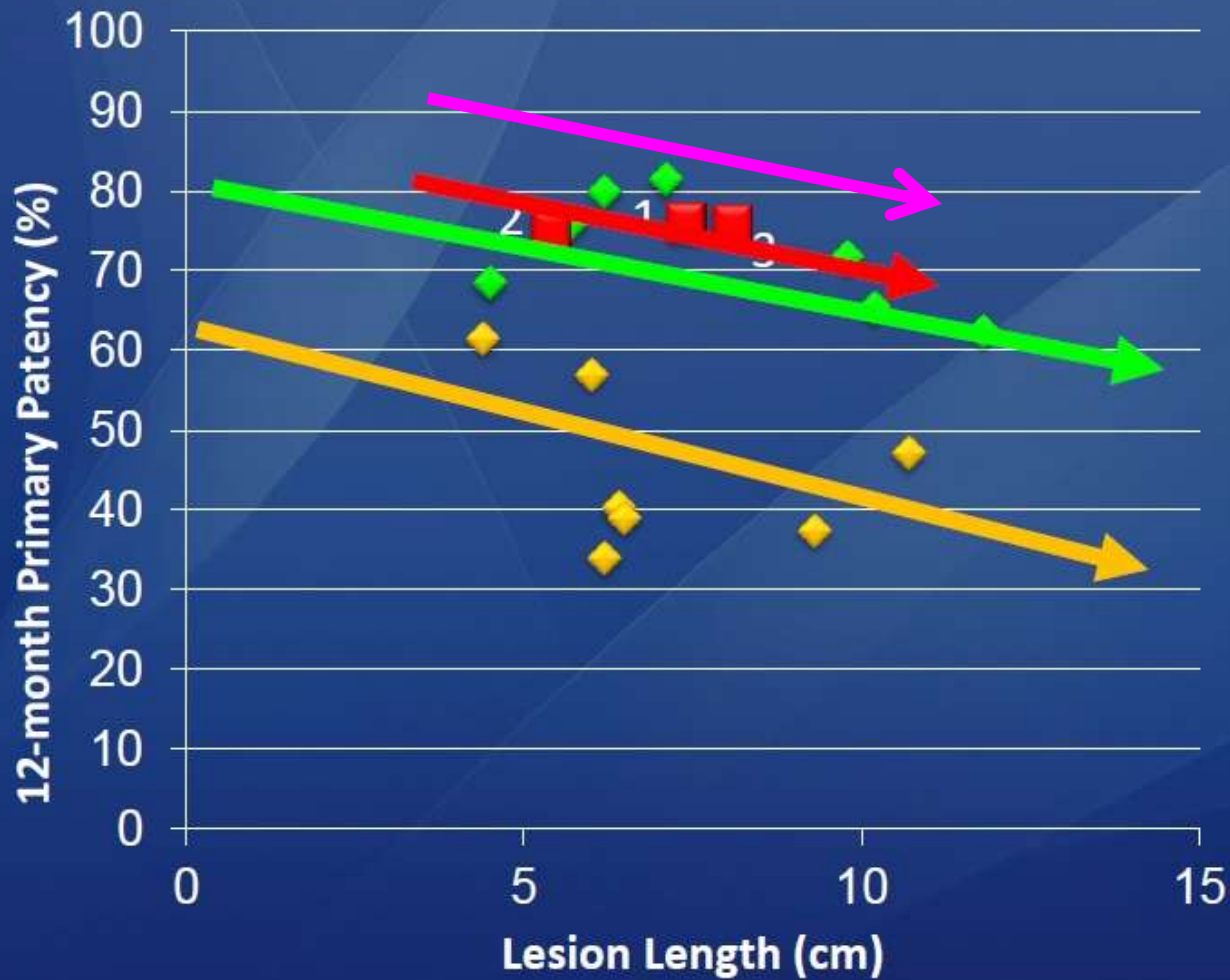


4. IN.PACT plus Systematic Stenting

Liistro et al. , JACCI 2013

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





- DCB**
1. THUNDER
 2. FEMPAC
 3. LEVANT I

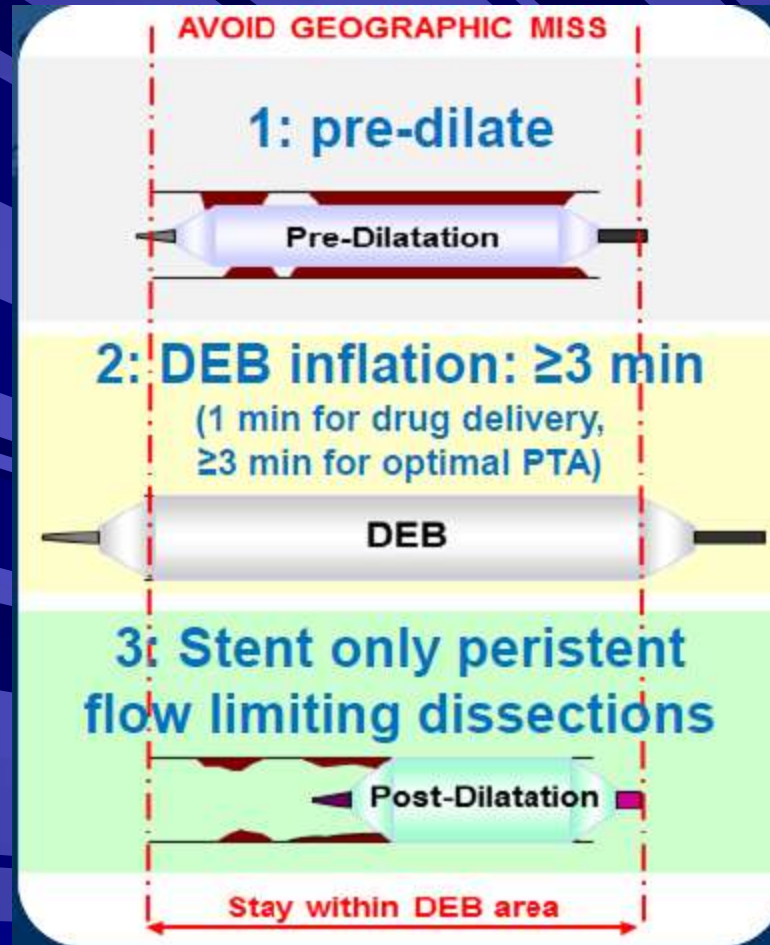
STENT

PTA

DEB + stent

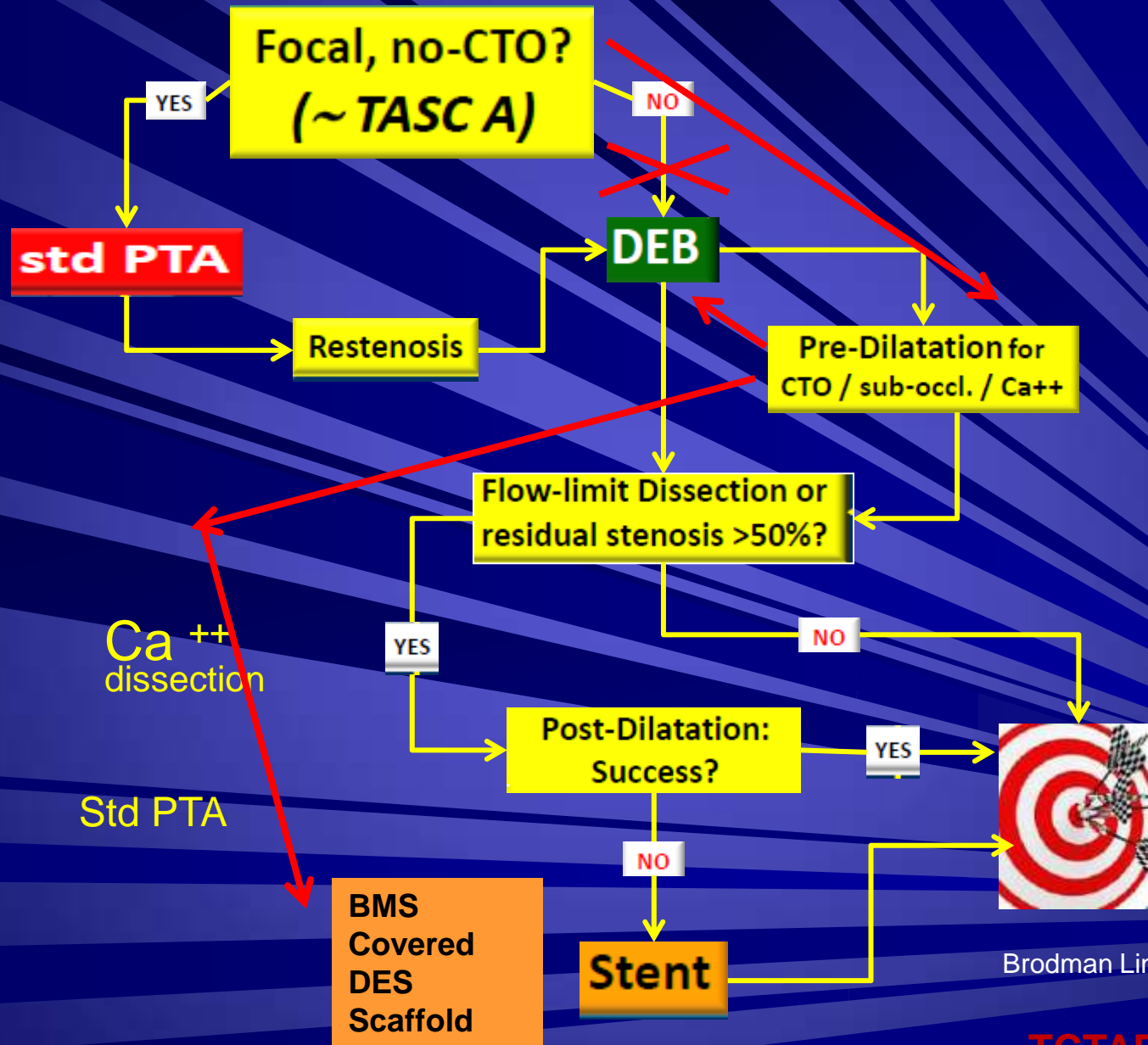
5. My daily practice

OPTIMAL PTA is essential in DEB

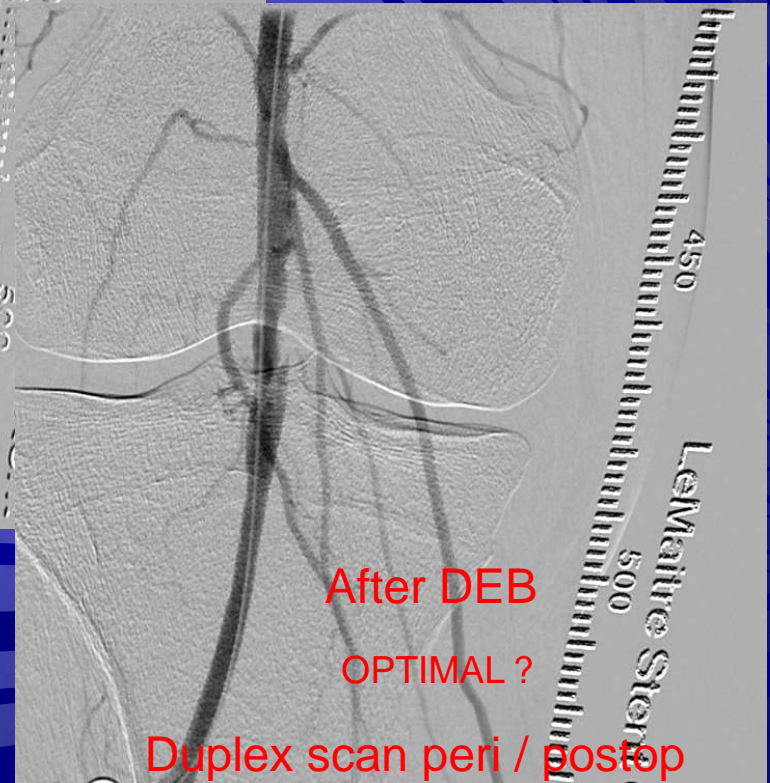


Zorger et al. , JVIR 2002

DEB in daily practice



Brodman Linc 2014



After DEB

OPTIMAL ?

Duplex scan peri / postop

6. Conclusion

- DEB is an important tool with proven evidence in low calcified TASC A and B lesions in instent restenosis even improving stent results
- DEB result is limited in calcified lesions flow limiting dissections **so extra therapy is needed**
- More evidence is needed in RCT's
 - o DEB with stent vs DES
 - o comparision of different DEB's
 - o ideal treatment for long lesions ? bailout stenting
 - o economic consequences

GIVE A GIRL
THE RIGHT
SHOES,
AND SHE CAN
CONQUER
THE WORLD.

-MARILYN MONROE-



Give an interventionalist the right tools
and he can conquer all lesions