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Could a combination of DCB + stent be the answer in complex SFA lesions

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Disclosure

Speaker name: Sven Bräunlich

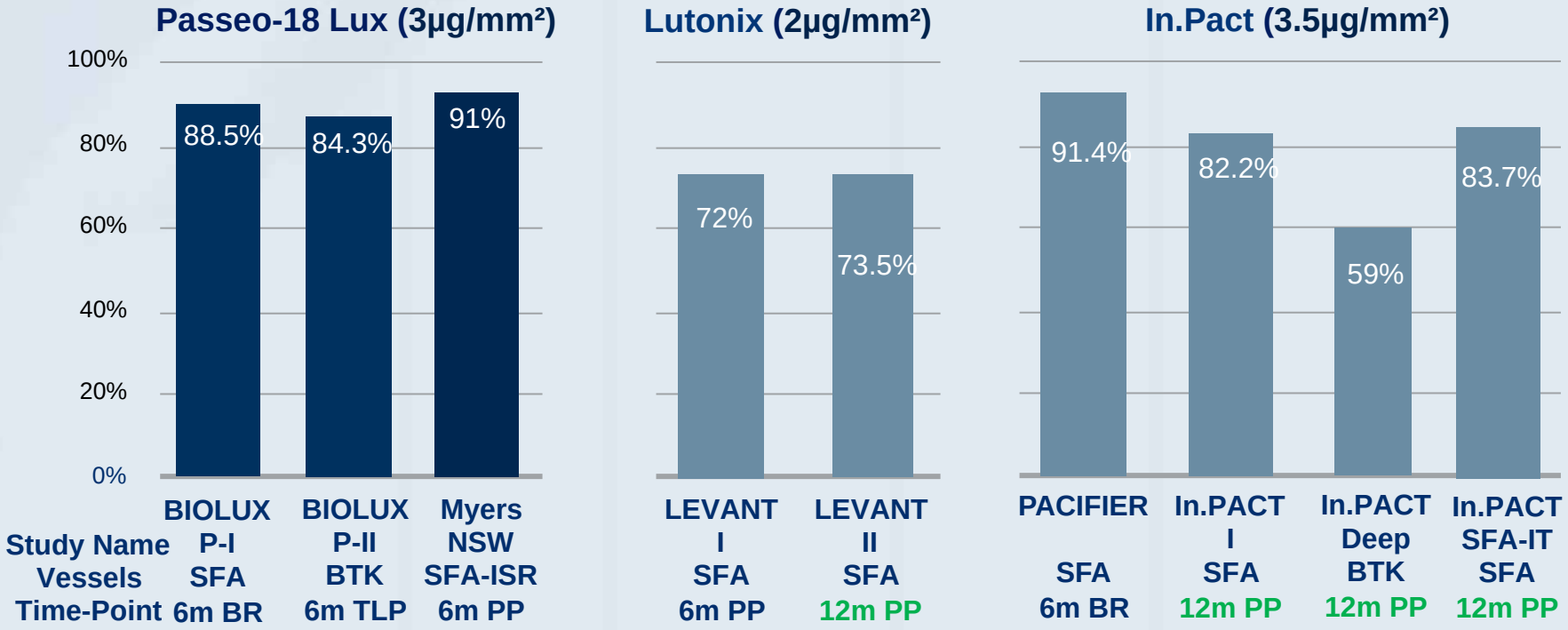
I have the following potential conflicts of interest to report:

Consulting: Abbott, Biotronik, Cook Medical, Cordis, Covidien, CR Bard, Medtronic, Straub Medical

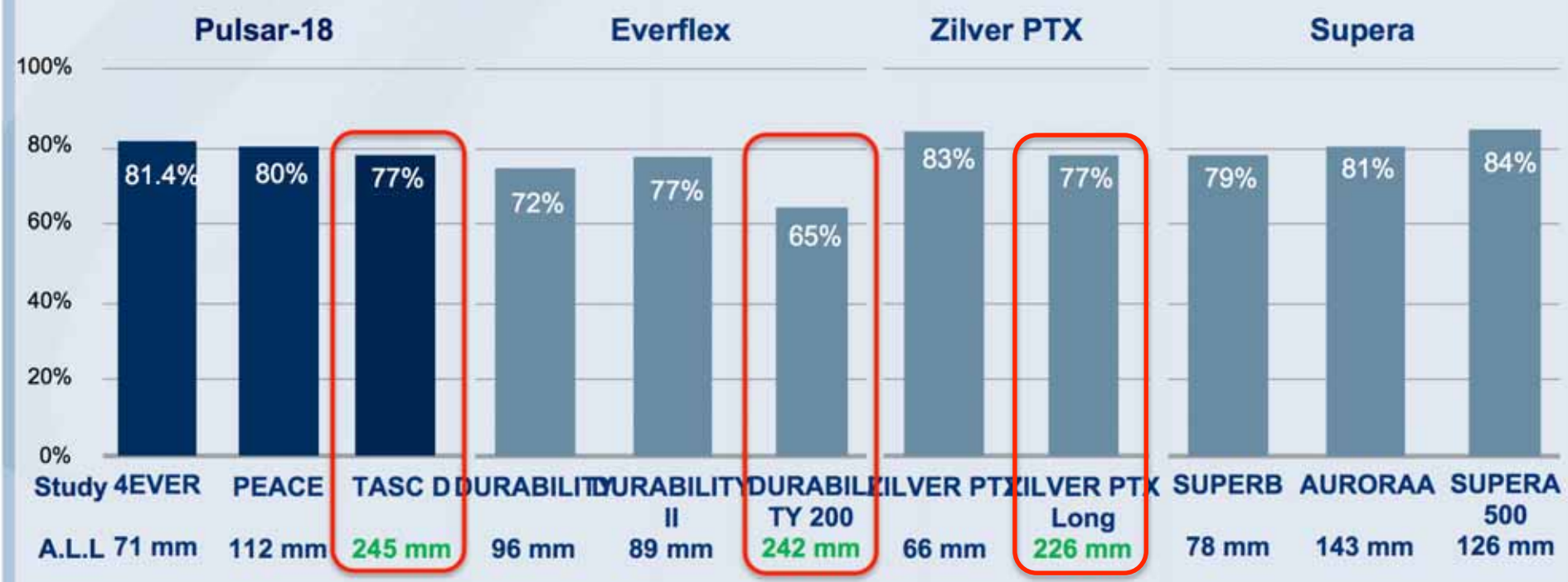
Statement

- **DCB represents a major step forward in the prevention of restenosis.**
- **DCB may have limitations in certain vessel morphologies and clinical situations.**
- **Adjunctive stenting as a primary treatment option may overcome some of these limitations and improve clinical outcomes.**

What we know: DCBs seem to work, though no class effect can be concluded



What we know: SE Stents appear to work, especially in short-mid length lesions

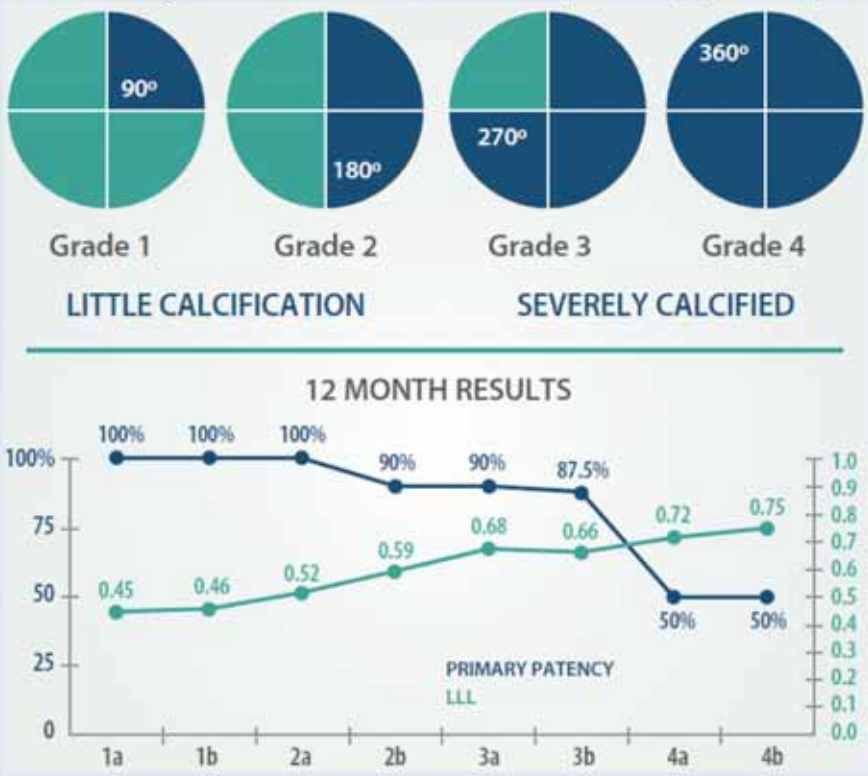


What we know: DCBs may have limitations

Limitations of DCB: Calcification

Calcification[1]

Relationship been clinical performance of DCB and degree of calcification and primary patency



Solution

- SE Stent?
- Prolonged PTA?
- Atherectomy?

DEFINITIVE AR 12m results[2]

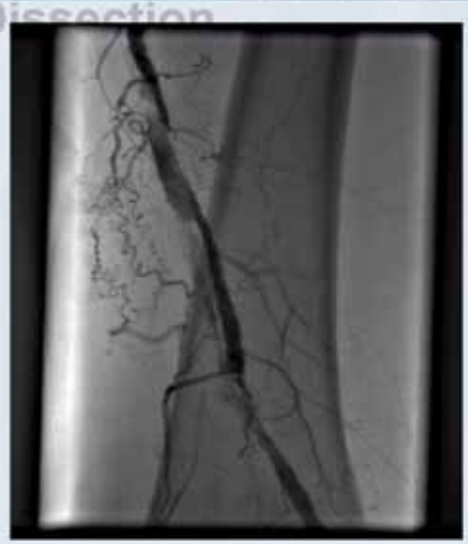
Atherectomy+DCB vs. DCB+PTA

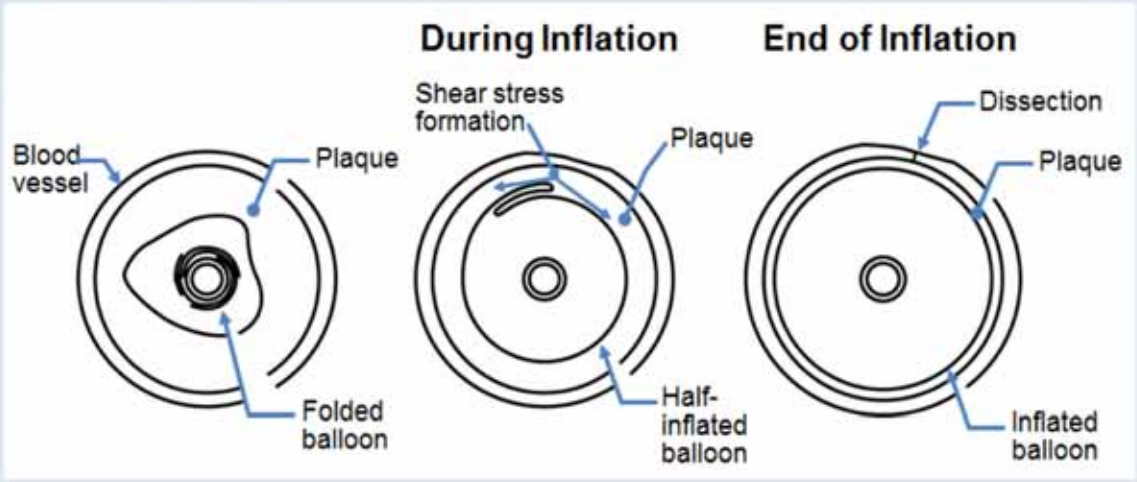
Presence of calcified lesions may impact DCB clinical outcomes .
New data suggest atherectomy holds promise.

Source: 1. Reproduced from EV Today Global Spring 2014 Supplement. Data from Fanelli calcified lesion experience. 2. DEFINITIVE AR 12m Zeller et al. Presented at VIVA 2014

What we know: DCBs may have limitations

Limitations of DCB: Vessel Recoil/ Dissection





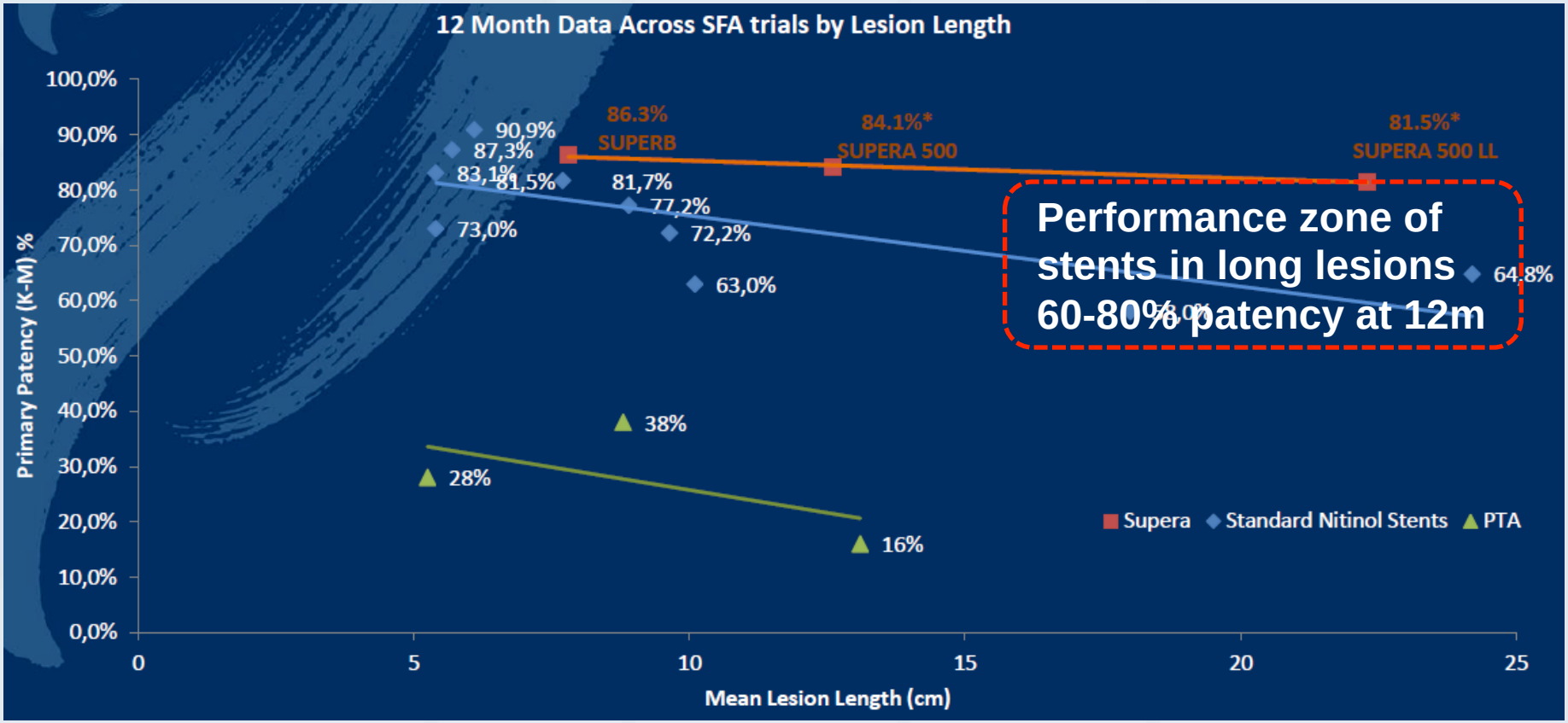
Solution?

- Provisional SE Stent? Use of provisional stent rates in DCB trials varies from 4-57%
- Typical bail-out stent rates post-DCB treatment is approx. 25%

	THUNDER[1]		FEMPAC[2]		LEVANT I[3]		Italian Registry[4]	PACIFIER[5]		DEBELLUM[6]	
	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%

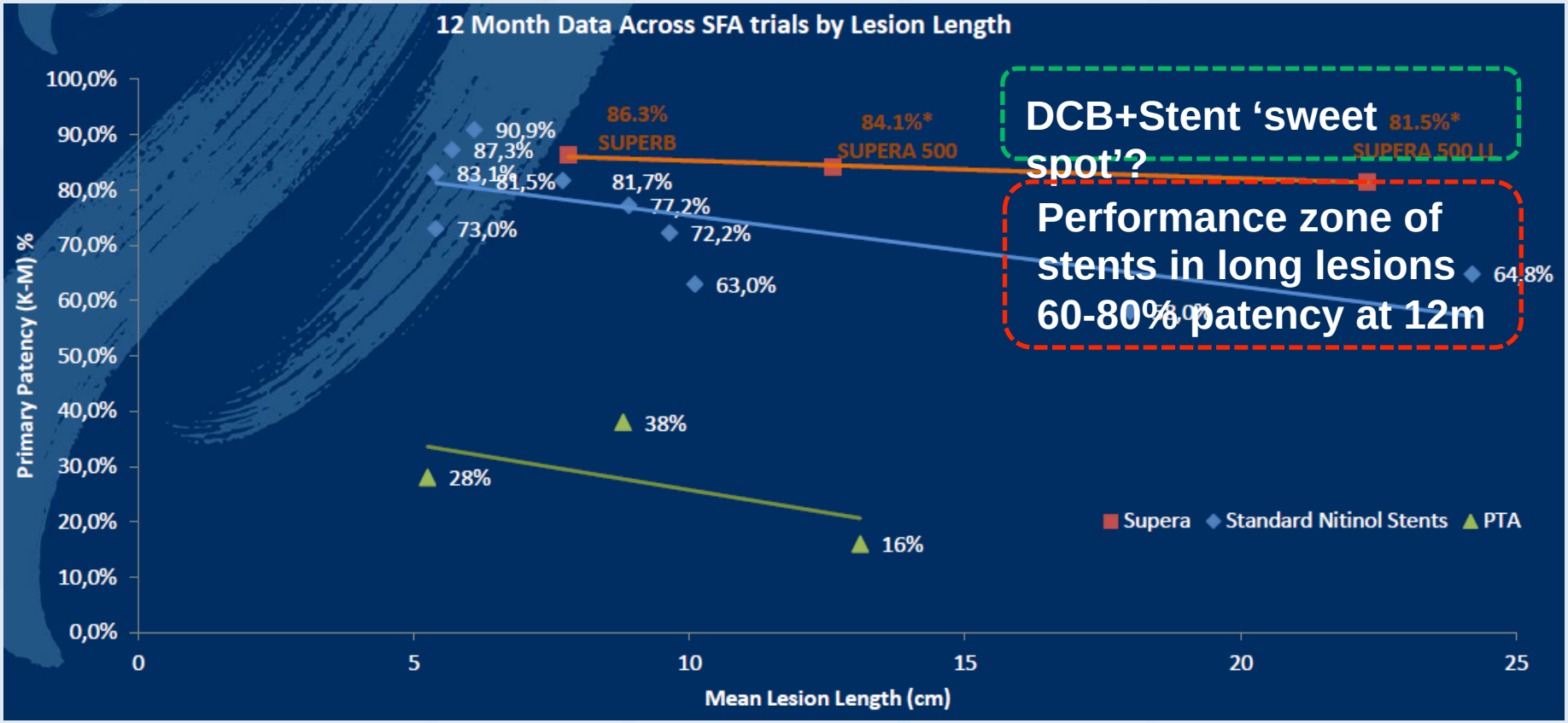
Source: Images reproduced from Bosiers M. FMRP. Presented at LINC 2015

What we know: Stents may have limitations, especially in long lesions



Source: Reproduced from Scheinert D. Presented at LINC 2014

What we know: Stents may have limitations, especially in long lesions. Can stents + DCB improve outcomes?



Source: Reproduced from Scheinert D. Presented at LINC 2014

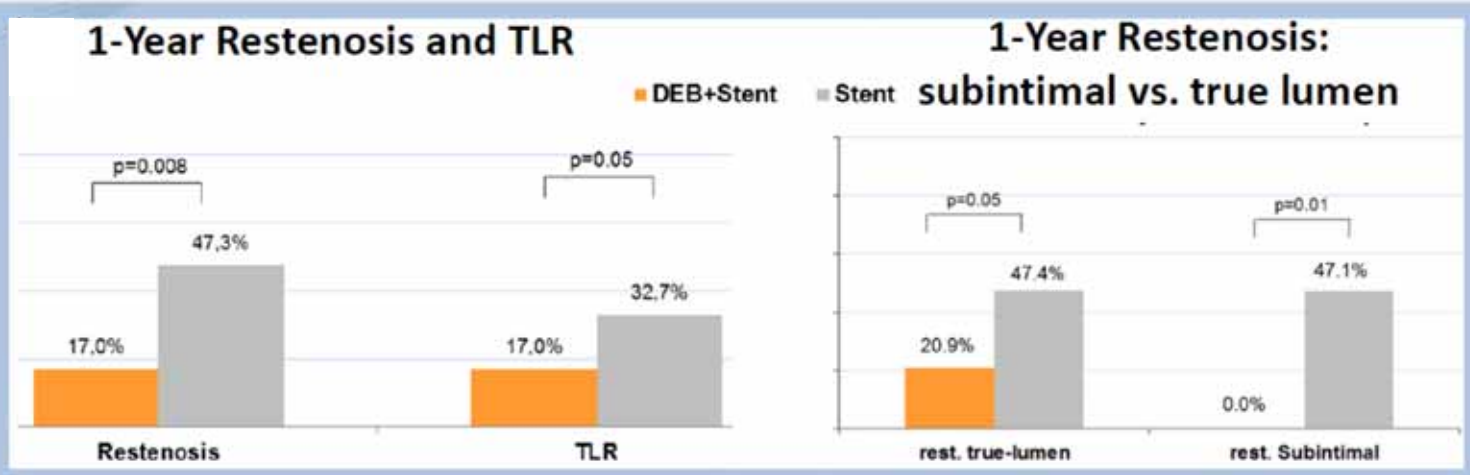
What data exists to support stents + DCB?

DEBATE-SFA

DESIGN: RCT comparing DEB +BMS vs. PTA+BMS in femoropopliteal vessels

Device	In.PACT Admiral (Medtronic)
PI	Dr. F Liistro (Arezzo, IT)
1º EP	BR @ 12m
2º EP	FTLR and Major AMP
Pat No	104
Les No	110 (DEB 55 vs. PTA 55)

RESULTS	DEB+BMS 12m	PTA+BMS 12m
LLL (mm)	1.29	2.74
BR (%)	**17**	**47.3**
TLR (%)	17	32.7
MAE (%)	24.5	35.3



Conclusion: Use of DCB resulted in a significant reduction in restenosis, irrespective of recanalisation technique

Reference: DEBATE-SFA. Liistro et al. *JACC Intv*. 2013;6(12):1295-1302

DCB + stent: Unanswered questions remain

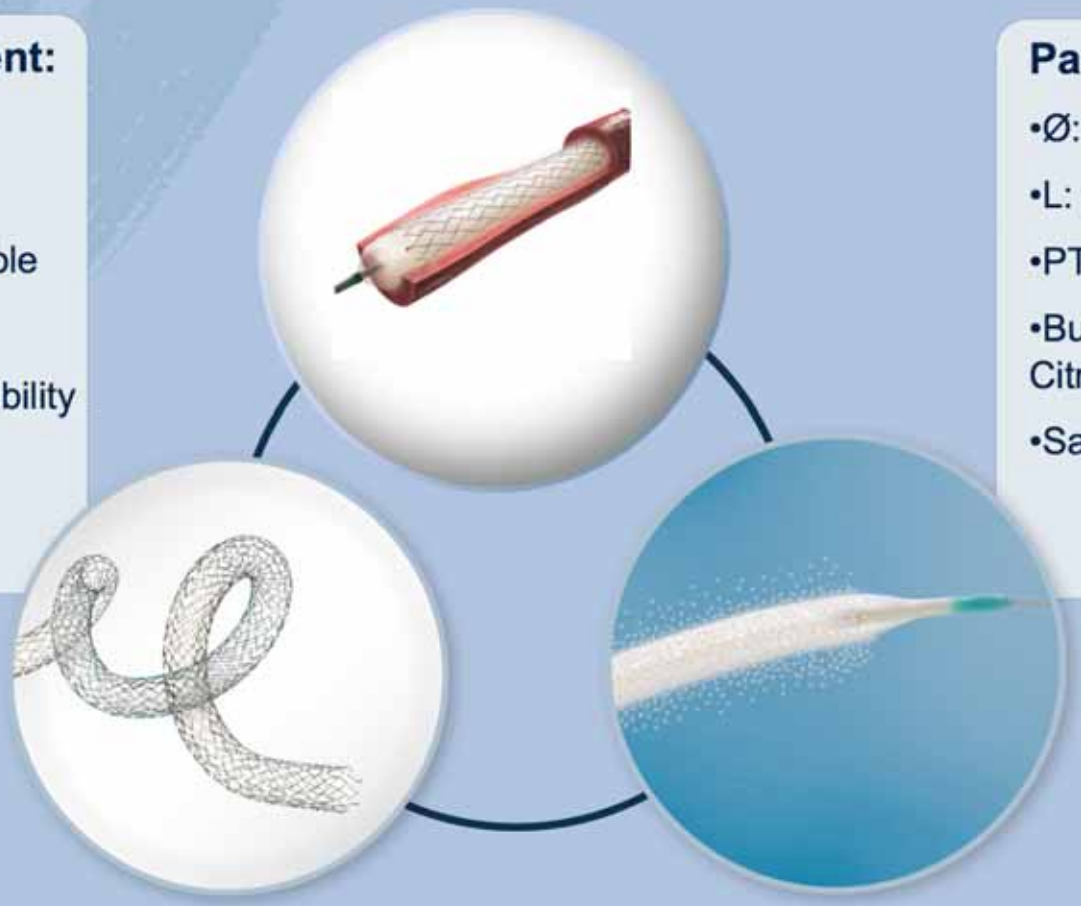
- Should I use DCB **before or after** stent implantation?
- Should I spot stent or use 'Full Metal Jacket' (FMJ) after DCB
- If 'FMJ' should the DCB segment exceed the length of the stent
- Should I only use a stent as a last resort and even approved?

Ongoing studies such as BIOLUX 4EVER and DEBAS-I may generate the answers!

BIOLUX 4EVER + DEBAS-I study devices

Pulsar-18 SE stent:

- Ø: 4-7mm
- L: 20-200mm
- 4F sheath compatible
- Thin strut design
- High multiaxial flexibility
- Optimised chronic outward force

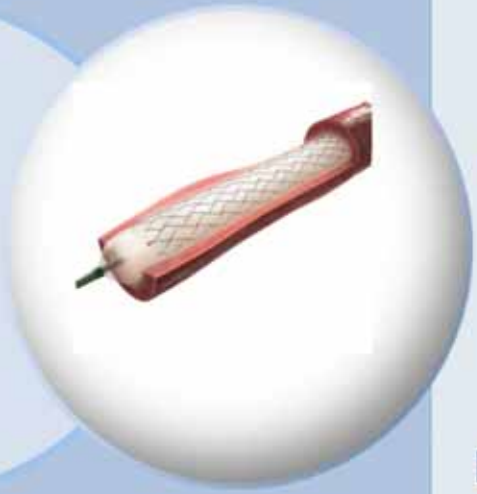


Passeo-18 Lux DCB:

- Ø: 3-7mm
- L: 40-120mm
- PTX Drug 3µg/mm²
- Butyryl-Tri Hexcyl Citrate (BTHC) excipient
- SafeGuard Insertion Aid

Can the combination of SE stent first, then DCB increase clinical efficacy?

DEBAS-I



Treatment approach:

Predilate lesion

↓

Implant SE Stent in diseased segment

↓

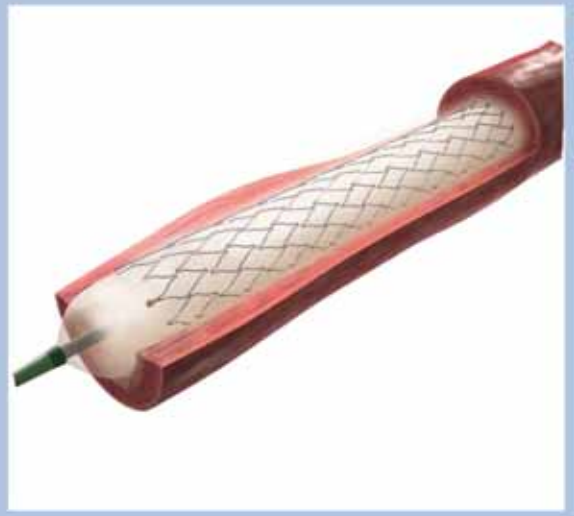
Deliver DCB to entire stented segment

Rationale

DEBAS-I

Treatment Rationale

- In complex TASC C and D lesions, PTA will damage intima, often requiring stent implantation.
- Stent placement in long lesions is associated with higher rates of restenosis
- Inflating DCB within stent will ensure barotrauma is evenly spread across stented length without significantly impeding drug transfer
- Adjunctive DCB may reduce risk of restenosis in stented segment



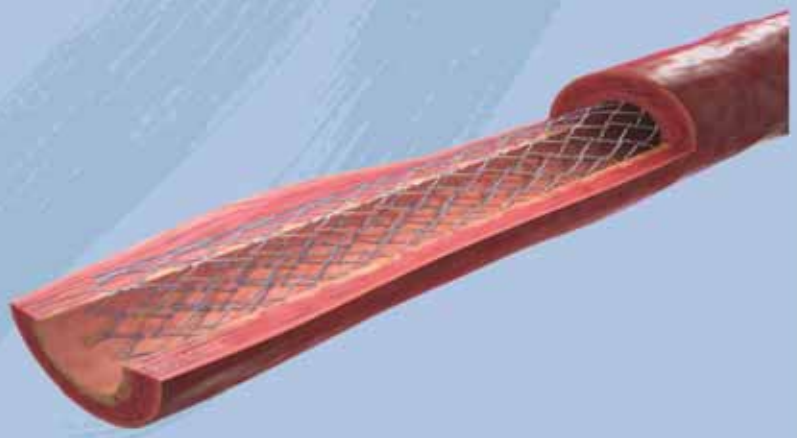
Device Rationale

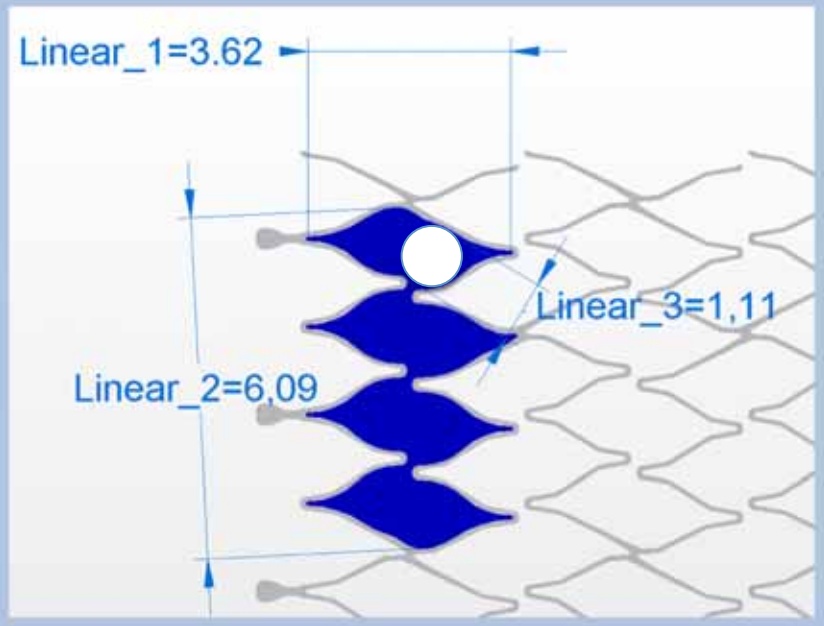
- Thinner struts decrease distance between DCB coating and vessel wall
- Low metal to artery ratio
- Thin struts may have a 'scoring effect' on vessel wall when DCB is inflated within stent- potentially reducing barotrauma.

Comparison of Strut Thickness

Pulsar-18 **Typical SE stent**

How much artery wall is covered by stent struts?





Pulsar-18 SE Stent: Stent-Artery Ratio (6/40mm)

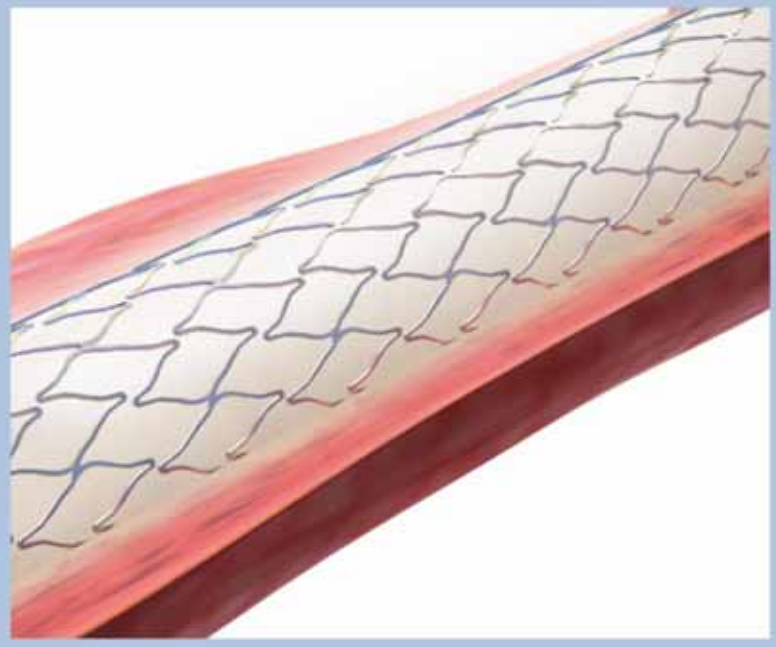
Metal-Artery Ratio		Implant-free vessel surface area	
In 4mm vessel	In 5mm vessel	In 4mm vessel	In 5mm vessel
16.8%	13.5%	83.2%	86.5%

How could the application of DCB after stent implantation affect drug delivery?

In non-atherosclerotic porcine models: **≈10% to 15%** of the total balloon coating dose is immediately transferred onto the peripheral vessel wall[1]

Assuming a **6mm** SE stent in a **5mm** vessel
(1mm oversize):
Metal-artery ratio= **13.5%**

Potential reduction of drug transferred to vessel:
Assuming 15% drug delivery-reduction to **13% of total balloon coating dose**
Assuming 10% drug delivery-reduction to **8.7% of total drug balloon coating dose**



1. Gray WA and Granada JF. Drug-Coated Balloons for the Prevention of Vascular Restenosis. Circulation 12124):2672-2680, 2010

DEBAS-I

DEBAS-I

Principal Investigator: Prof. Patrice Mwipatayi, Perth Australia

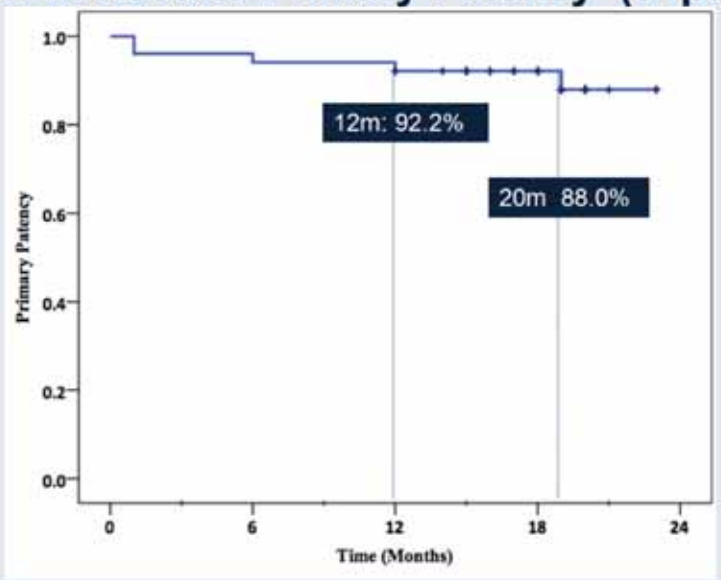
Study Design: Prospective, multicentre feasibility study investigating safety and efficacy of BMS + DCB in TASC C/D lesions. N=65 enrolled (51pts reached 18m f/u)

Study Devices: Pulsar-18 SE stent (full segment coverage), followed immediately by Passeo-18 Lux DCB (full segment coverage)

Primary Endpoint: Primary patency at 12 and 24 months, defined as a PSVR at DU < 2.0 at the stented target lesion

PARAMETER	N (%)	RANGE
Total Lesion Length (mm)	**187.55**	**80-300**
Calcification		
Minimal	31.4	--
Moderate	43.1	--
Severe	23.5	--
No. of Stents	1.57	1-3
No. of DEBs	2.45	**1-5**

12m Results Primary Patency (51pts)



Source: Mwipatayi P. Presented at LINC 2015

BIOLUX 4EVER study will investigate Passeo-18 Lux DCB combined with Pulsar SE stent

DESIGN:
Multicentre, international registry of 120 patients to evaluate the short- and long-term (up to 24 months) outcome of treatment with **Passeo-18 Lux** drug releasing balloon and Pulsar-18 stent implantation in symptomatic (RC 2-4) fem-pop arterial lesions.

PRINCIPAL INVESTIGATOR:
Dr M. Bosiers, Dendermonde, Belgium

PRIMARY ENDPOINT:
Primary patency at 12 months, (freedom from >50% restenosis as indicated by an independently verified PSVR <2.5 in the target vessel with no re-intervention)

SECONDARY ENDPOINTS: (selected)
Primary patency rate at 6- & 24-month follow-up,
Freedom from TLR at 1-, 6-, 12- & 24-month follow-up
Technical Success
Puncture Site Complications
Clinical success at follow-up (improvement of RC)

120 patients in c.6 clinical sites in Europe
37% enrolled

Passeo-18 Lux + Pulsar

6 months: PP, FTLR, change in ABI, RC

12 months: PP, FTLR, change in ABI, RC

24 months: PP, FTLR, change in ABI, RC

Conclusion

- Drug elution and scaffolding are the key factors for long-term success
- DES, DCB and BMS provide different opportunities but each with their own “dark side”
- There is some evidence that the combination of DCB with scaffolding BMS creates a win-win situation
- However, many unanswered questios remain: DCB +BMS? BMS+DCB? Spot stenting or full lesion coverage? …
- DEBAS1 and BIOLUX 4EVER studies will help to clarify this topic

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