

CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY

JANUARY 19-21 2017

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER

PARIS, FRANCE



Drug coated balloons are fine: but do they work for TASC C/D lesions?

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Disclosure

Peter A. Schneider

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I have the following potential conflicts of interest to report:

- Scientific Advisory Board (non-paid): Cardinal, Abbott, Medtronic
- Royalty (modest): Cook
- Co-founder and Chief Medical Officer: Intact, Cagent
- PI for IN.PACT SFA study (non-compensated)
- Enter patients into studies: Bard, Gore, Medtronic, BSI, Silk Road (no financial relationship).

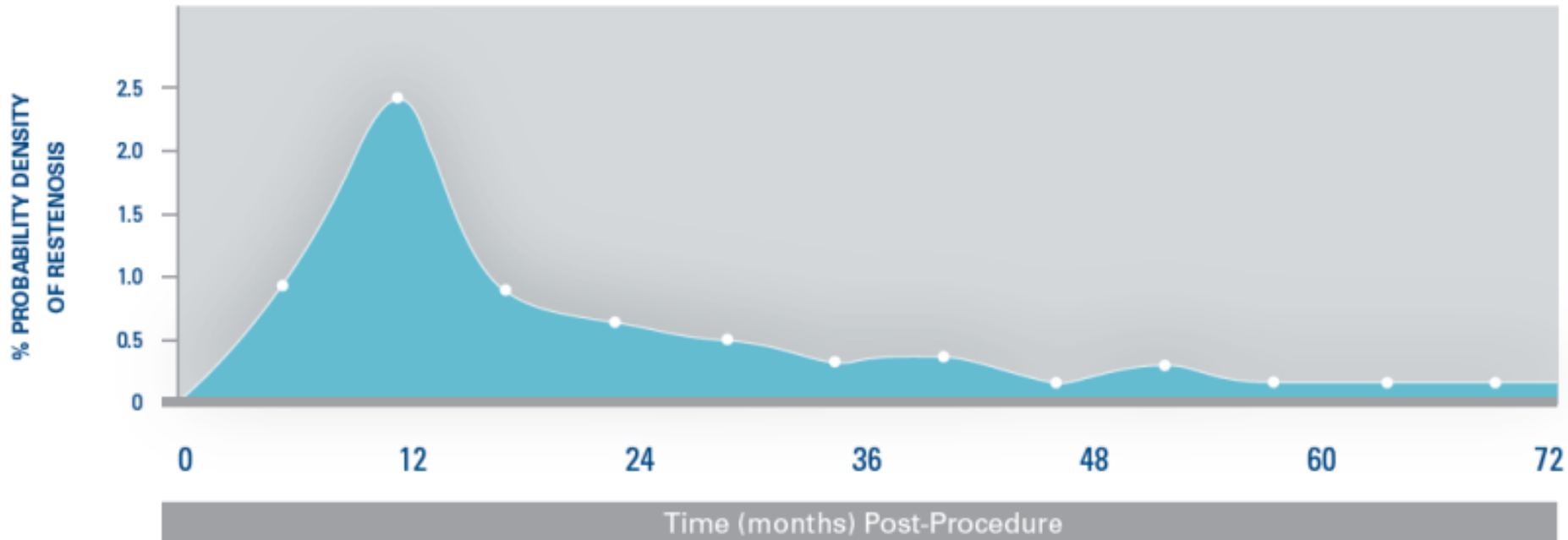
Probability of Restenosis

Restenosis after SFA intervention peaks at 12 months

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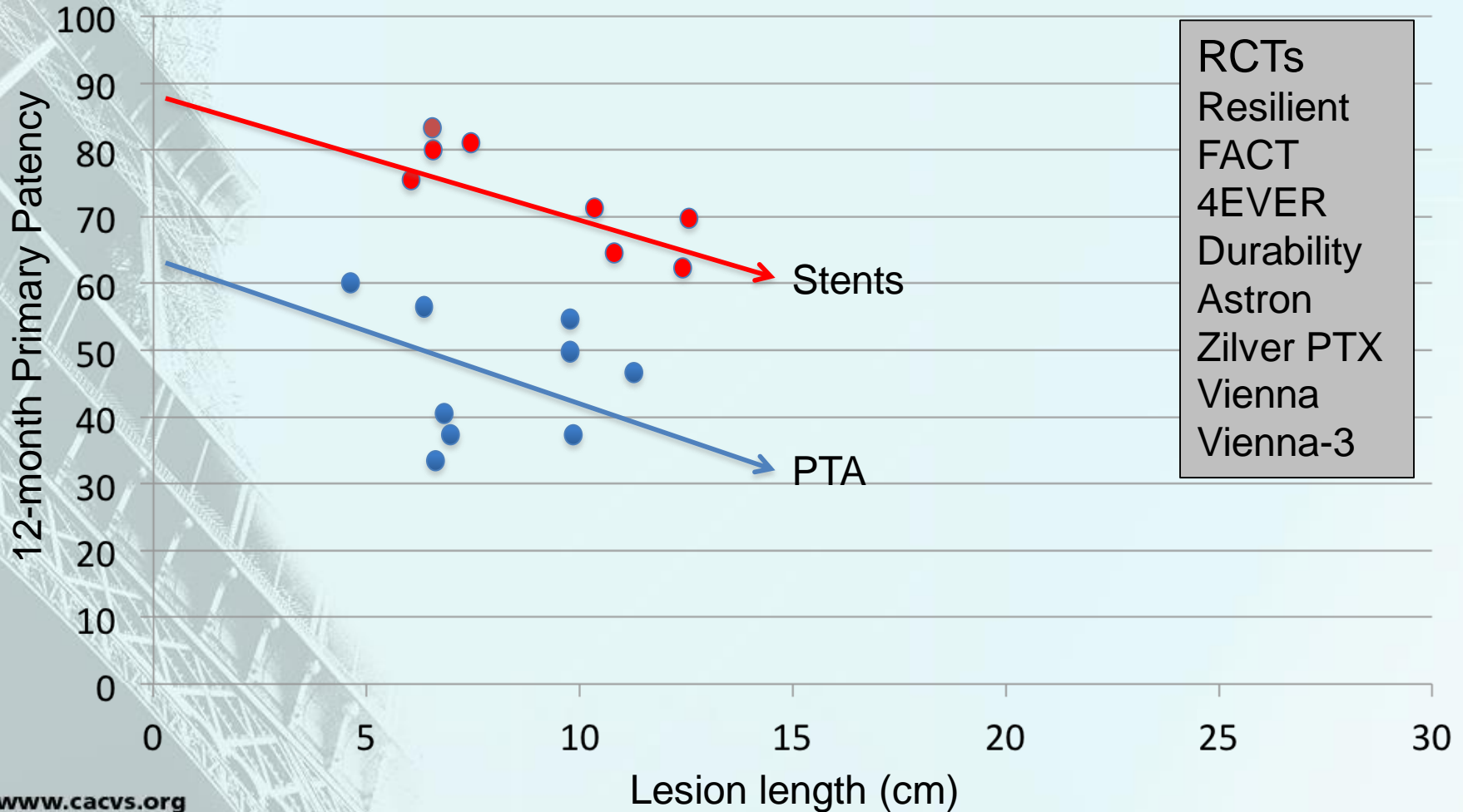
Key factors for restenosis in the SFA is lesion length.



Work in Progress

● PTA ● DES
● Stent

RCT Data: PTA vs Stent



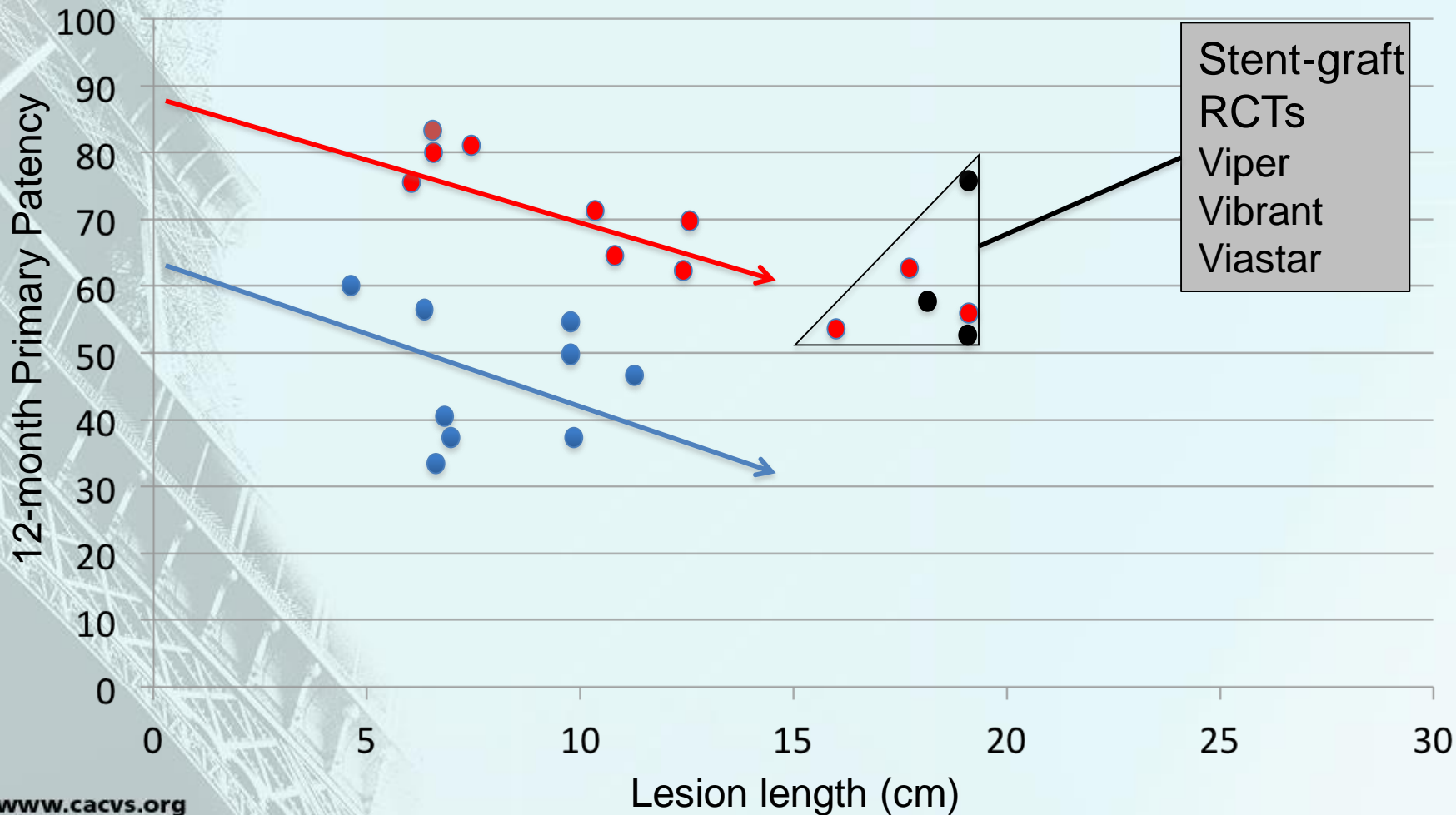


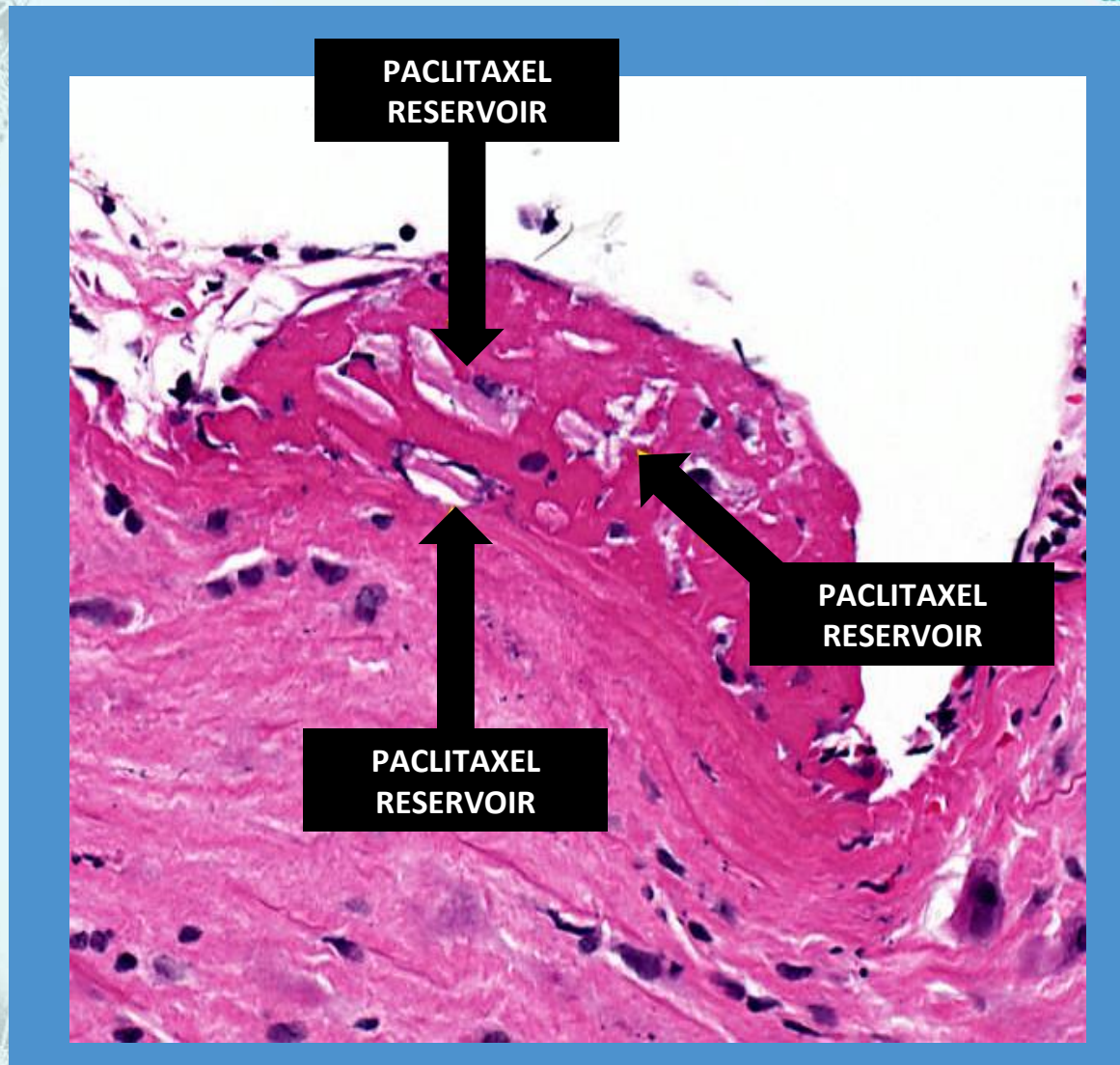
Drug Coated Balloons for TASC C/D

Work in Progress

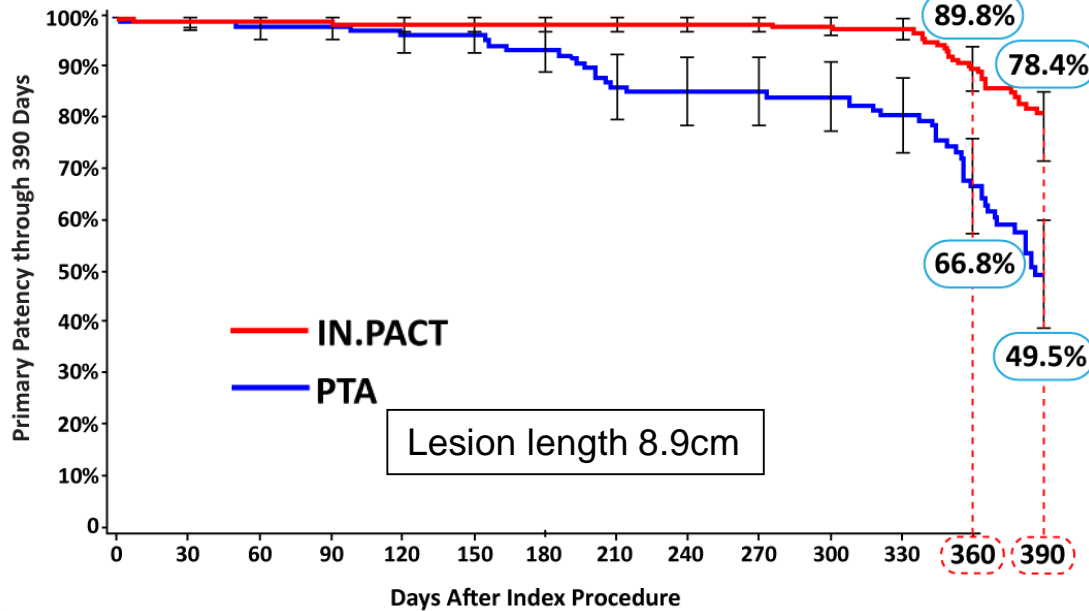
- PTA
- Stent
- Stent-graft
- DES

RCT Data: PTA, stent, DES, stent-graft



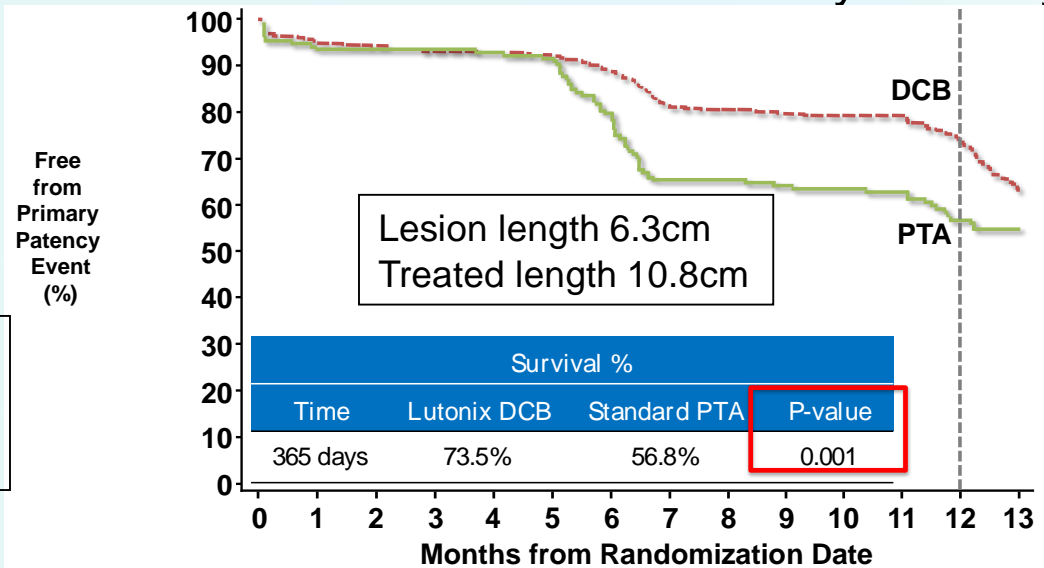


Solid phase paclitaxel is embedded in the vessel wall, creating “reservoirs” that provide sustained release of drug over time.



Levant Study 12-month Primary Patency

IN.PACT SFA 12-month Primary Patency



Randomized Control Trials DCB vs PTA

Proportions-based difference was 65.2% for DCB vs. 52.6% for standard PTA → 12.6% difference

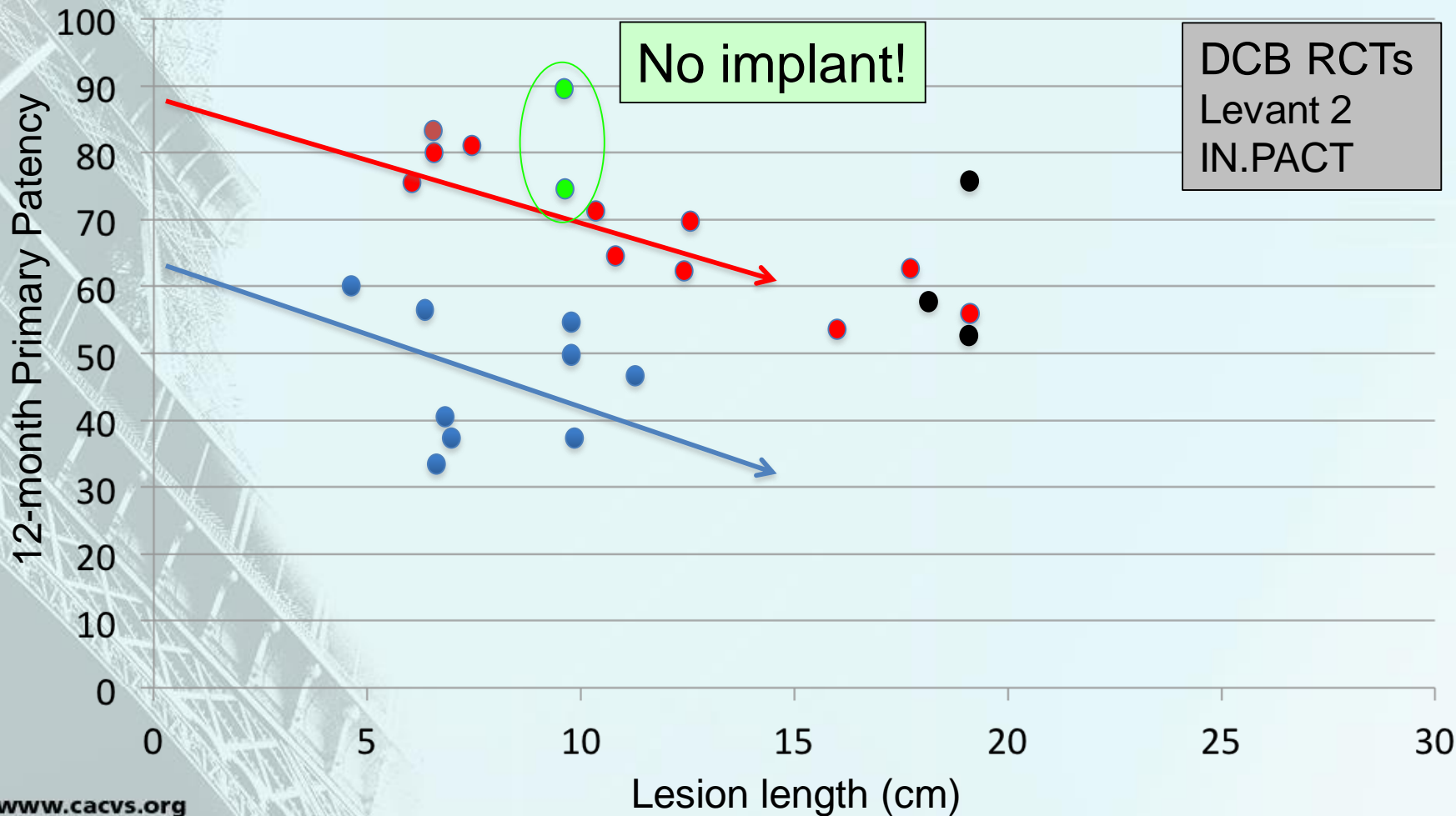
Drug Coated Balloons for TASC C/D

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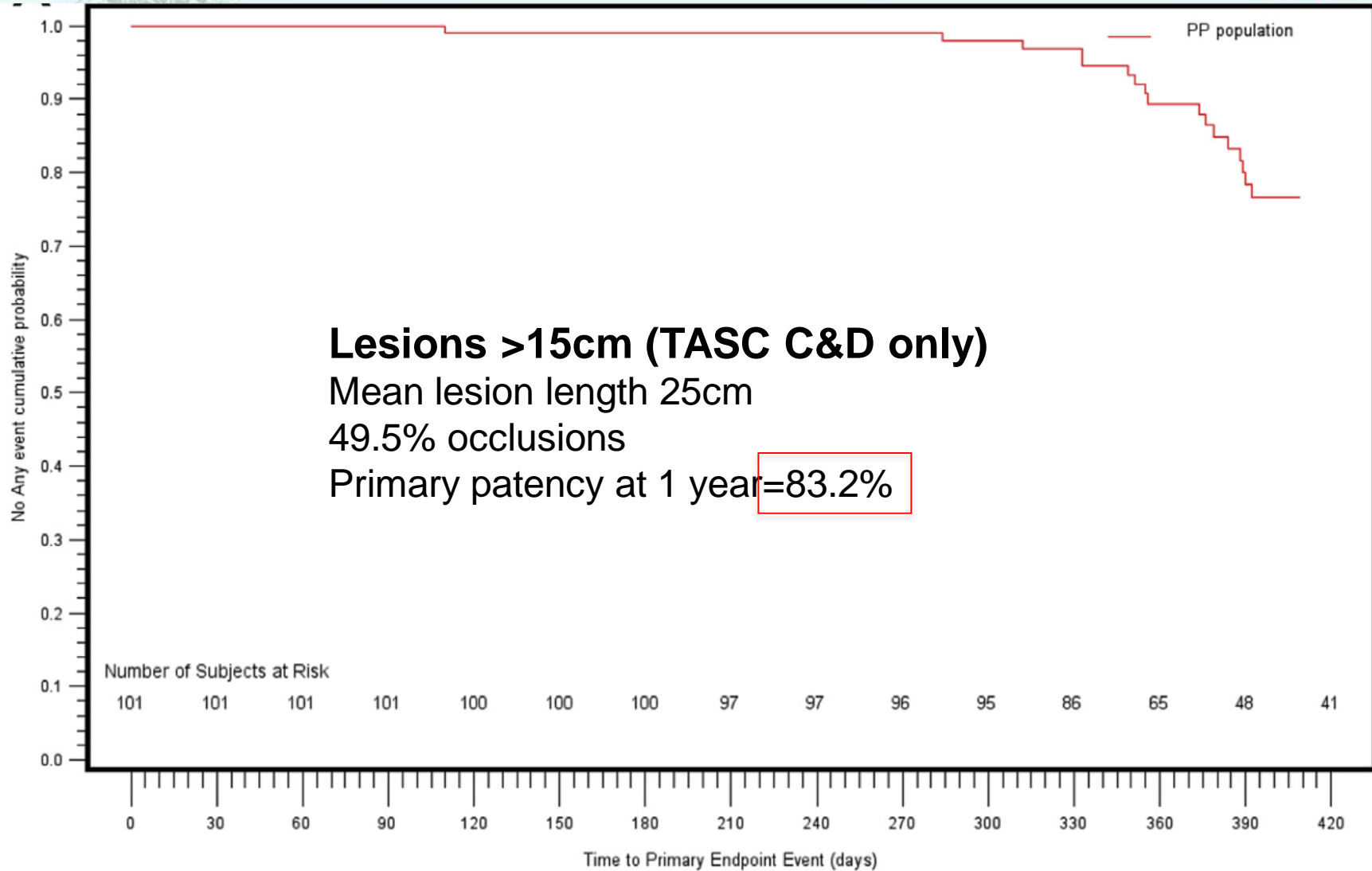
- PTA
- Stent
- Stent-graft
- DES
- DCB

RCT Data: DCB

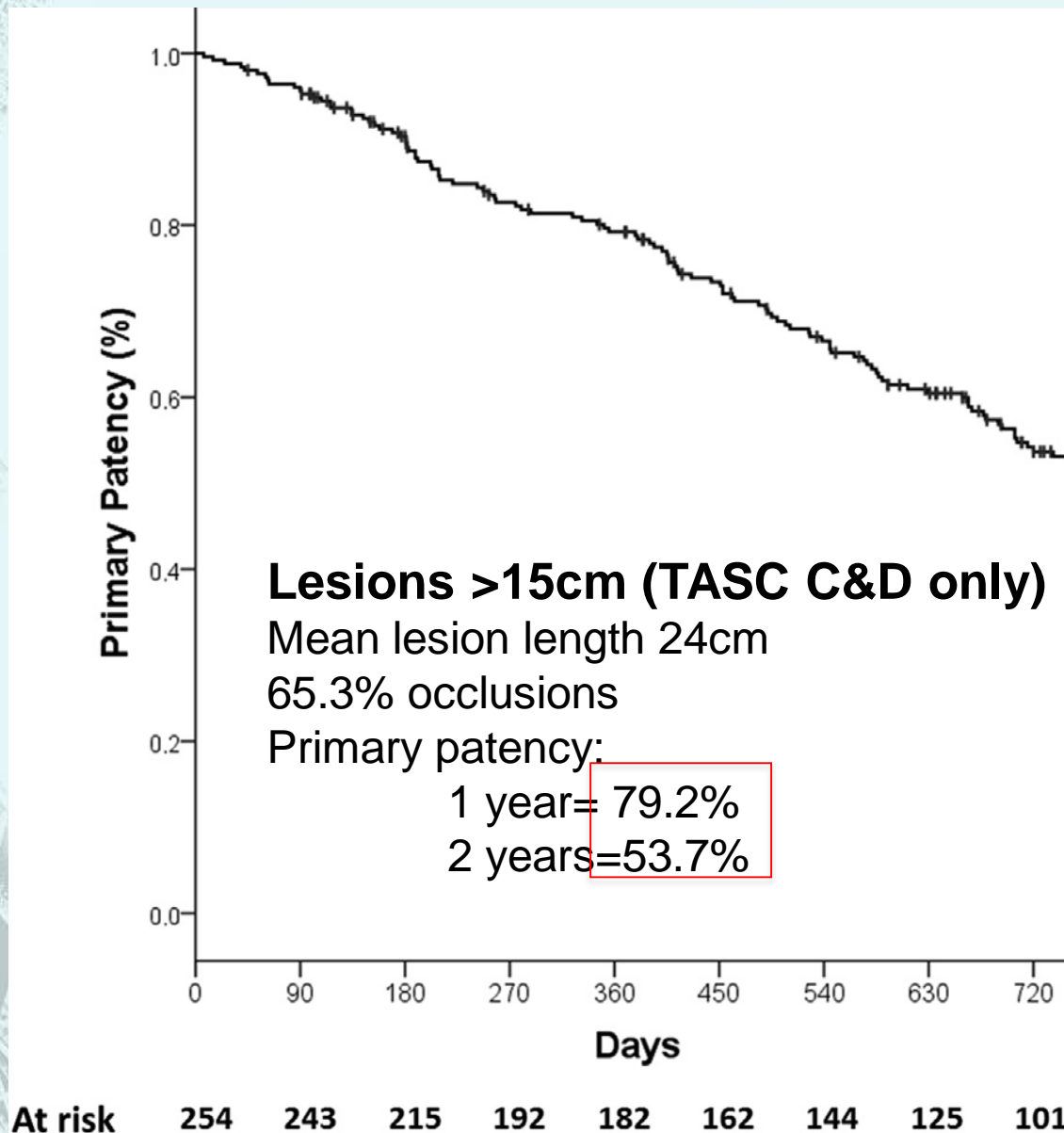




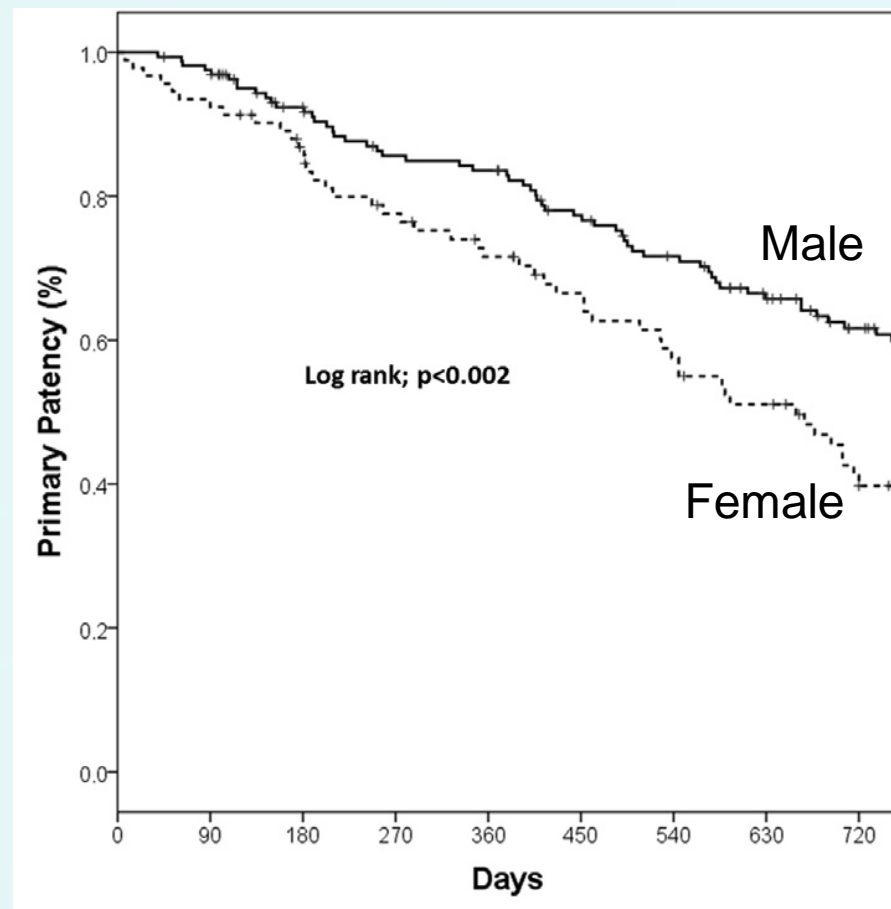
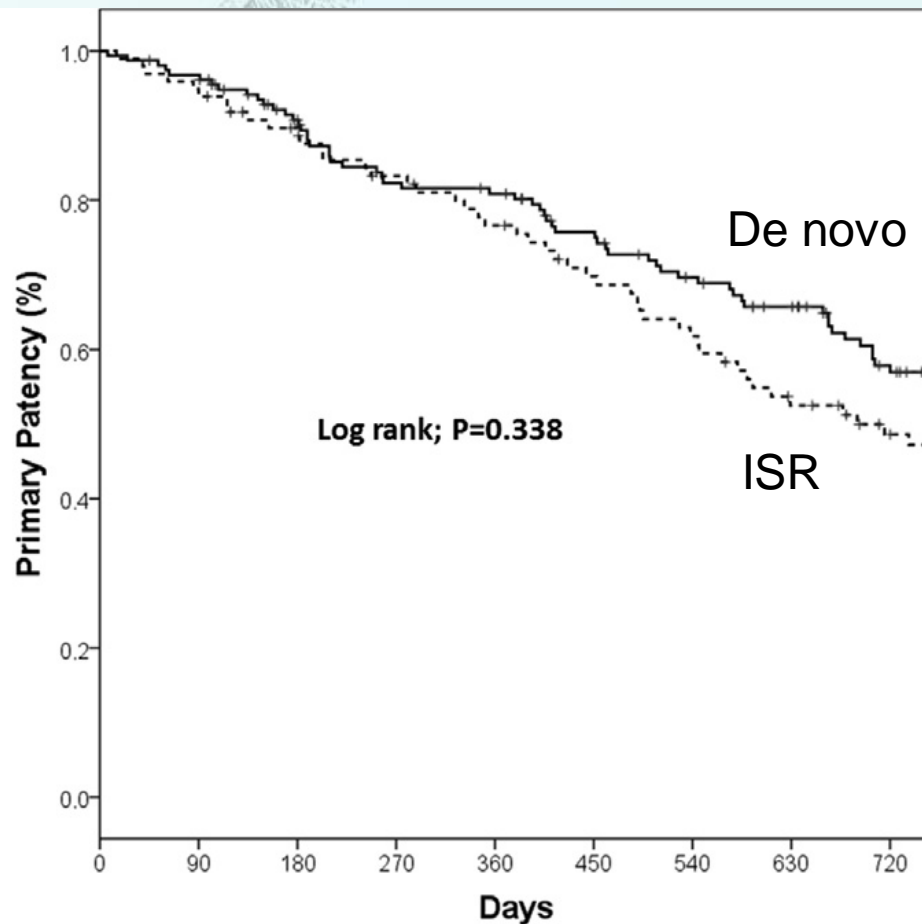
Primary Patency-DCB Long Lesions



Primary Patency-DCB Long Lesions



Primary Patency-DCB Long Lesions





DCB for Long Femoropopliteal Lesions

Provisional Stent: 23%

Full lesion stenting: 6%

Focal stenting: 17%

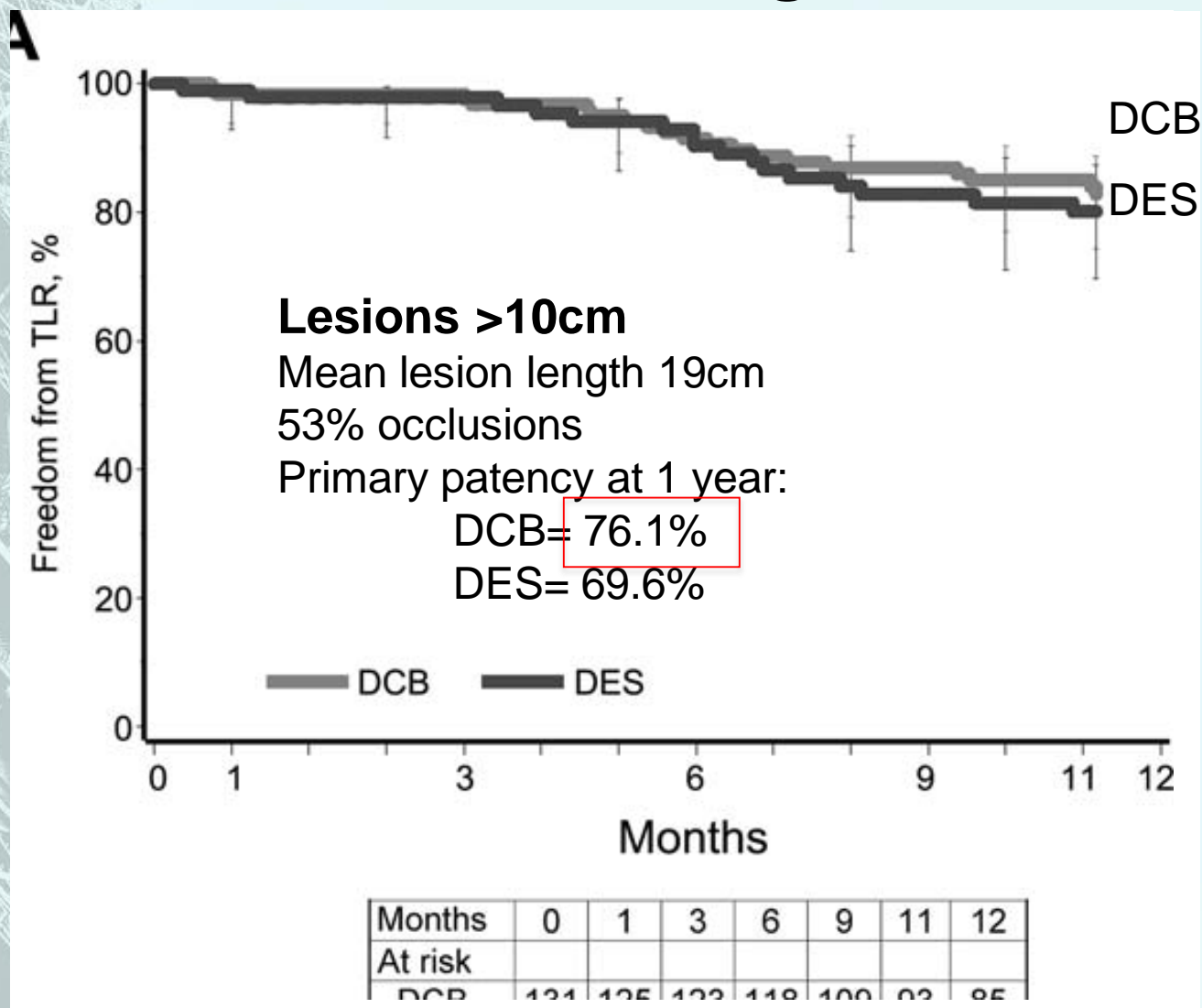
Stent-length compared to DCB-length (mean)

Lesion length 291 mm

Stented length 112 mm

Primary Patency

DCB vs DES for Long Lesions

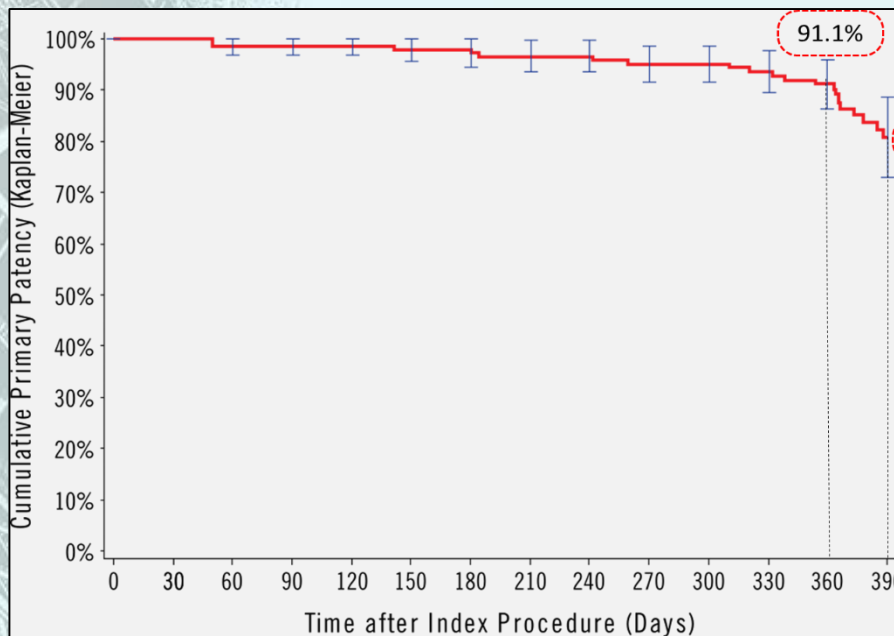


IN.PACT Global (>1500 patients)



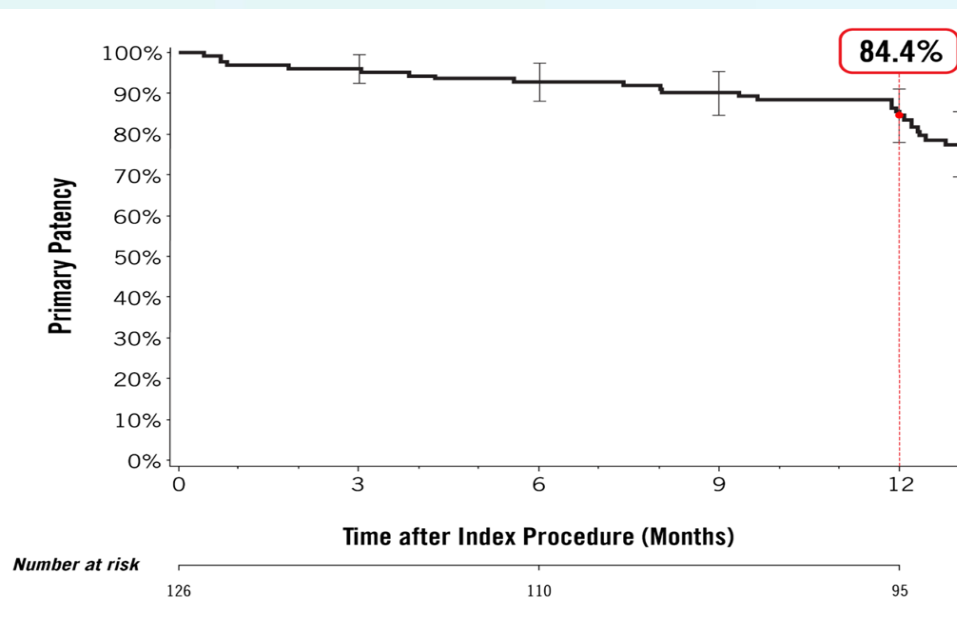
Long Lesions

Occlusions



N=157

Mean length 26.4cm



N=126

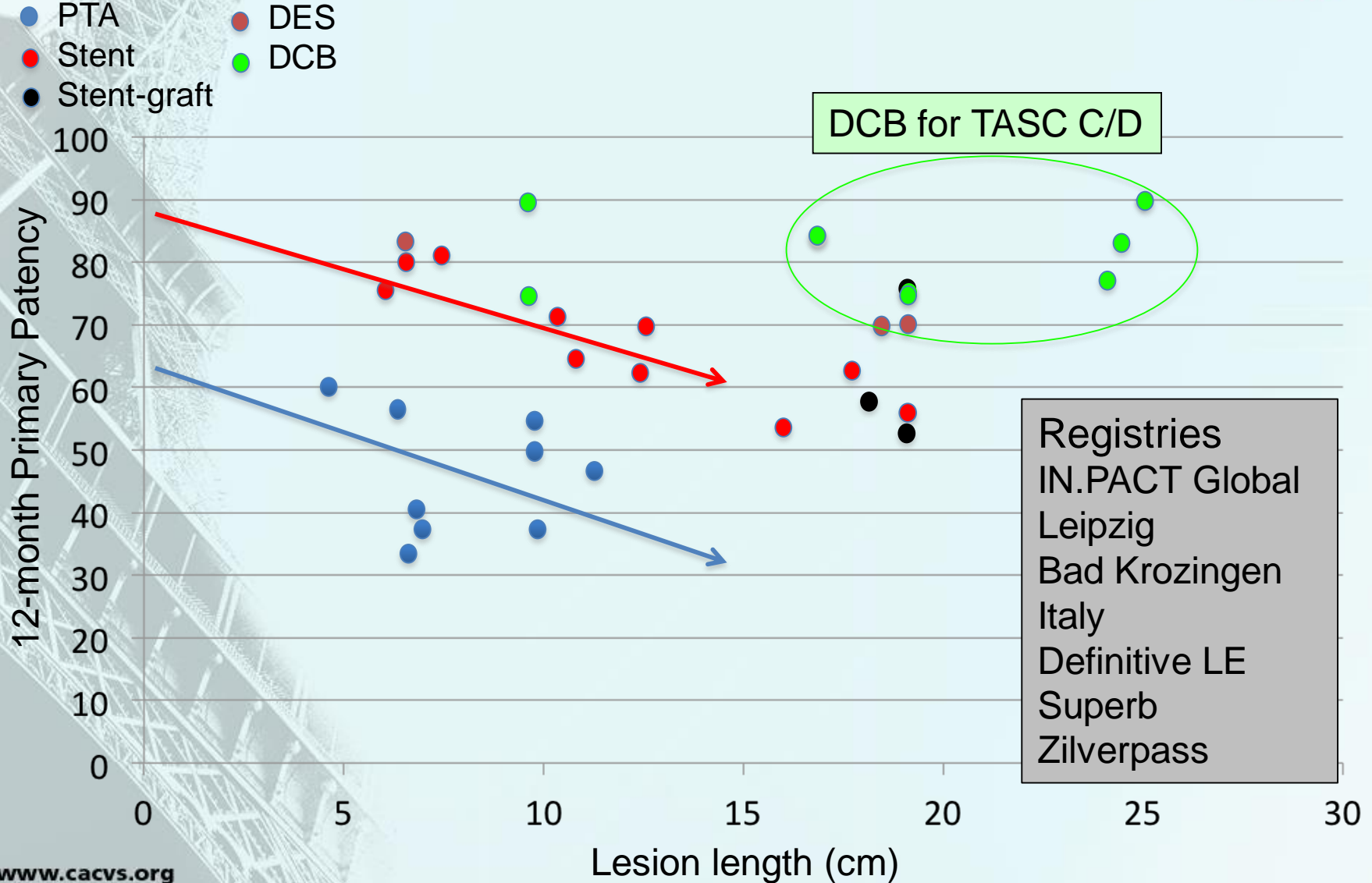
Mean occlusion length 22.9cm

Provisional Stent	40.4% (63/156)
LL 15-25 cm:	33.3% (33/99)
LL > 25 cm:	52.6% (30/57)

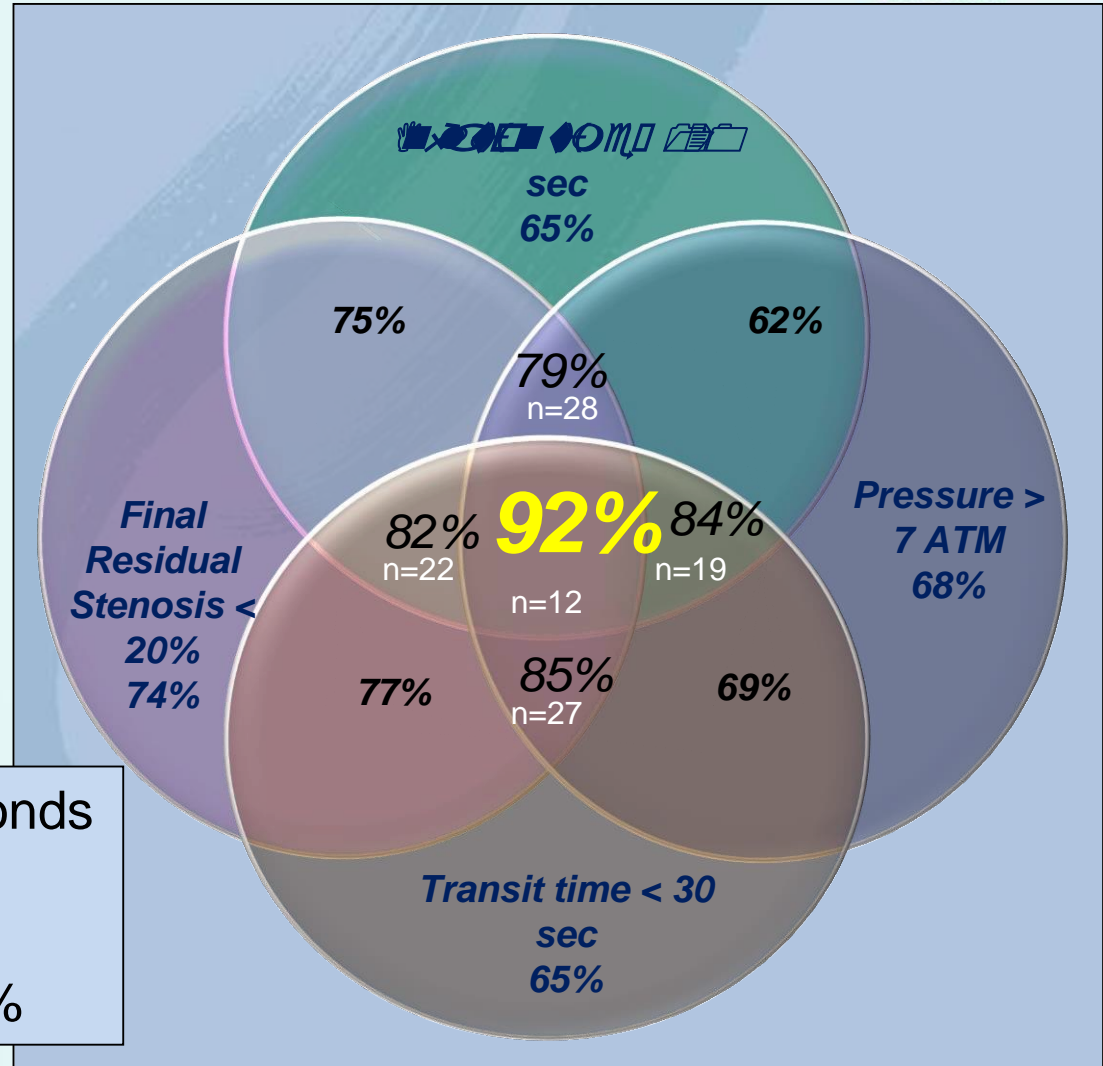
Provisional Stent	46.8% (59/126)
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Drug Coated Balloons for TASC C/D

Work in Progress



Challenges with Long Lesions Managing Technical Issues



Balloon transit time <30 seconds
Inflation pressure >7atm
Inflation time >2 min
Final diameter stenosis <20%

Key Variables in with Lutonix SFA DCB



Challenges with Long Lesions Paclitaxel Dose?

- Mechanism: slowly dissolving transferred to wall during balloon
- Cytostatic agent-acts on micro
- Intravascular dose for tumor is

DCB	Dose (µg/mm ²)	Excipient
IN.PACT	3.5	Urea
LUTONIX	2.0	Polysorbate and Sorbitol
STELLAREX	2.0	Polyethylene Glycol
PASSEO 18 LUX	3.0	Butyryl-tri-hexyl Citrate

- Si
- M

Where Does the Drug Go?

Range

Wash off during transit

5-30%

Lost in runoff during balloon inflation

40-70%

Transferred to artery wall

5-20%

Drug on used balloon

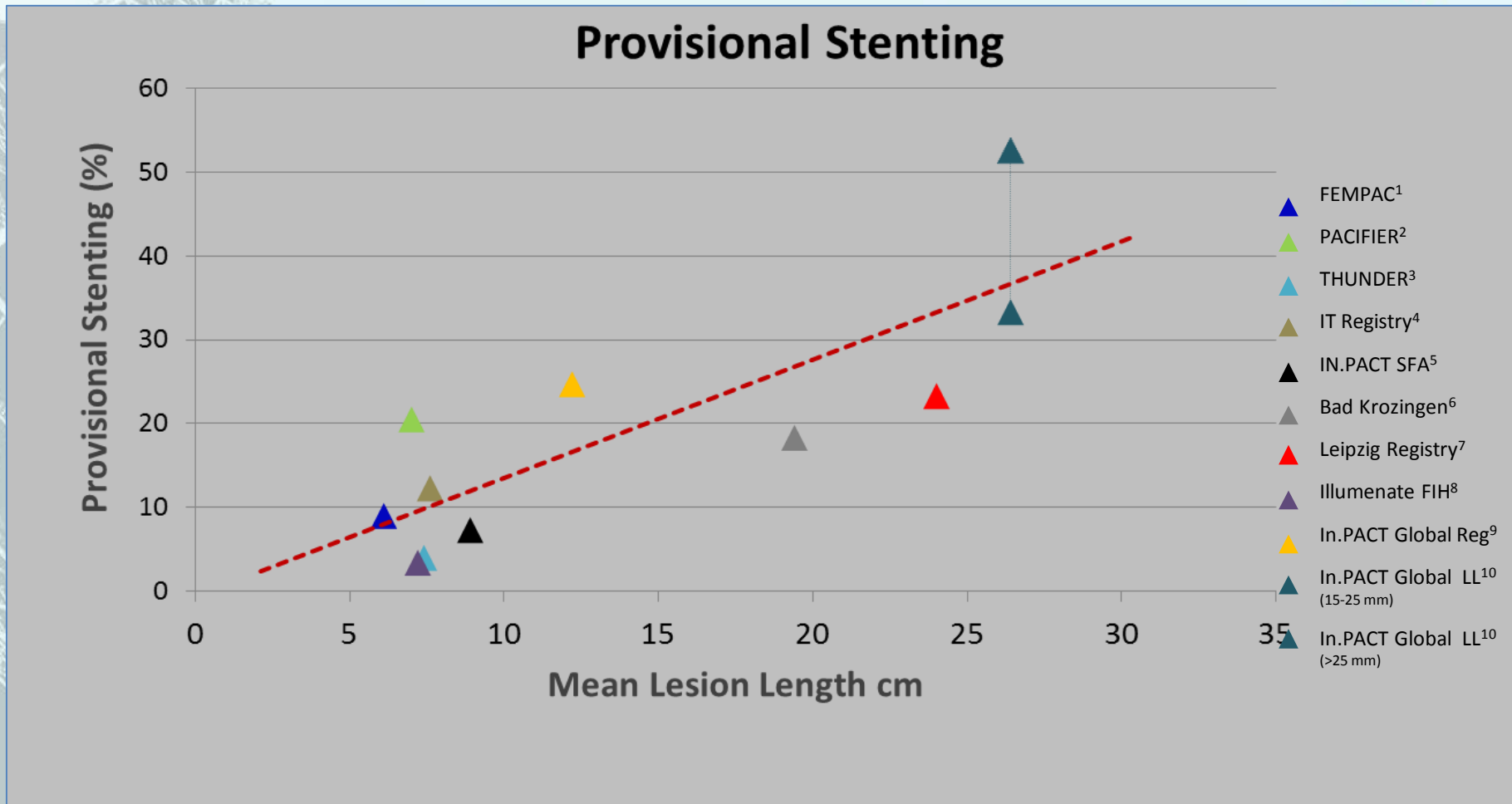
0-30%

Biopath

3.0

Shellac

Challenges with Long Lesions Need for Dissection Repair



Provisional Stenting in Randomized Controlled Trials may not be representative of actual stenting in studies due to study design



Conclusion

Drug-Coated Balloons for TASC C/D

- One-year patency: 76-91%
 - More challenging lesions being evaluated.
 - Multiple studies are looking beyond 1 year.
 - No randomized trials.
- DCB will likely play a major role in TASC C/D lesions but technical challenges will increase.