Preliminary 12 Months results of the RAPID trial

Multi-center Randomised trial of Legflow® DEB supported stenting vs. stenting alone in intermediate and long SFA lesions

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On behalf of the RAPID trial investigators

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Disclosure

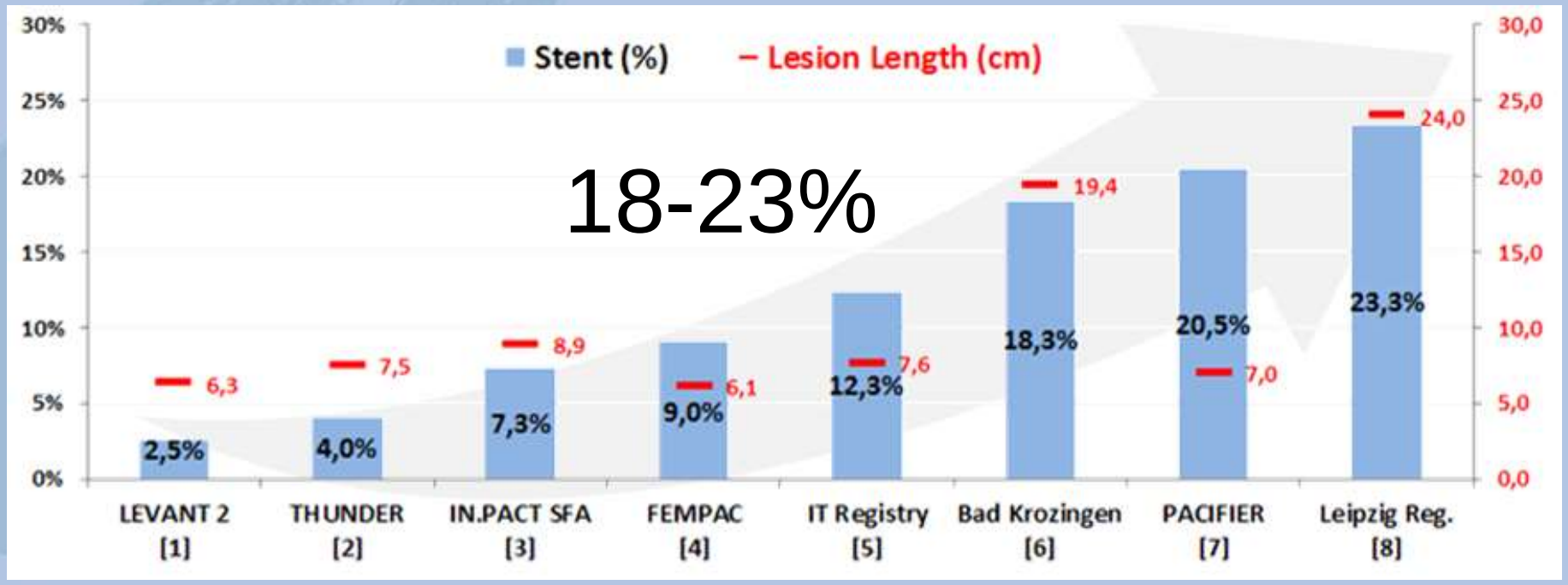
I have the following potential conflicts of interest to report:

Other(s): Unrestricted Grant by Cardionovum

Rationale of the RAPID Trial

- Design of study in 2012
- We are faced with more and more challenging, long, heavily calcified lesions of the SFA
- DCB were not the first choice for these lesions
- Today they are, but bail out stenting remains high

Stenting Rates in DCB trials



Scaffolds still needed, likely at rates proportional to lesion complexity

Rationale of the RAPID Trial

The RAPID trial was designed to investigate what the patencies would be if:

A challenging long SFA lesion is primary stented with a high performance stent and supported with an effective DCB

Best of Both Worlds?

Study Design

- Physician initiated prospective, multi-center randomized trial
- 160 patients
- Intermediate (5 Primary stenting cm) SFA
- 1:1 randomization: with either a Legflow® DCB + Supera (n=80) or standard PTA + Supera (n=80)
- Powered on event rates from SNS studies

Study Design

DCB Legflow® balloon

- Excellent manoeuvrability
- Highly stable coating matrix
- Homogeneous drug transfer
- High inflation pressures and homogeneous inflation

Market-leading stent: Supera VMI

Endpoints

Primary Endpoint

Primary patency at 24mo (absence of binary restenosis on DUS with a PSVR ≥2.4)

Secondary Endpoints

freedom from CD-TLR, secondary patency, amputation rate, sustained Rutherford class improvement, and sustained ABI and toe pressure improvement

Safety Endpoints

Combined freedom from death and freedom from MALE at 30 days and freedom from all-cause death at 1 year.

Key Inclusion and Exclusion Criteria

Inclusion

- Rutherford Baker Classification 2-6
- De novo lesions of the SFA
- Lesion length 5-15 cm; >15 cm

Exclusion

- Contra indication for anticoagulation
- Severe renal failure (e-GFR <30 mL/min/1.73 m2)
- Acute or acute on chronic limb ischemia

Baseline patient characteristics

	PEB + Stent (n=80)	BA + Stent (n=80)	p
Age, y	67.6±7.5	67.0±8.0	0.626
Men	52 (65.0)	50 (62.5)	0.869
Rutherford category			0.836
2	37 (46.2)	39 (48.8)	
3	29 (36.2)	28 (35.0)	
4	7 (8.8)	5 (6.3)	
5	6 (7.6)	5 (6.3)	
6	1 (1.3)	3 (3.8)	
ABI			
Rest	0.59±0.20	0.61±0.19	0.480
After exercise	0.34±0.18	0.38±0.19	0.225
Toe pressure, mm Hg			
Digit 1	59±28.9	64±40.0	0.513
Digit 2	61±48.3	96±71.8	0.245
SVS risk score (0–24)	5.8±3.2	5.5±3.0	0.547
Creatinine, μmol/L	80.9±21.8	82.7±27.5	0.649
Risk factors			
Diabetes	23 (28.8)	24 (30.0)	0.863
Smoking, current or recent	40 (50.0)	39 (48.8)	1.000
BMI, kg/m^2	26.4±4.9	27.1±4.3	0.375

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17% CLI

Baseline lesion characteristics

	PEB + Stent (n=80)	BA + Stent (n=80)	p
TASC II class			0.747
A	8 (10.0)	10 (12.5)	
B	40 (50.0)	35 (43.8)	
C	15 (18.8)	20 (25.0)	
D	17 (21.3)	15 (18.8)	
Side (right)	44 (55.0)	45 (56.3)	0.873
Occlusion	61 (76.3)	56 (70.0)	0.476
Length on angiogram, cm	15.8±7.4	15.8±7.6	0.996
Long lesions (≥15 cm)	40 (50.0)	44 (55.0)	0.526
Reference diameter, mm	5.1±0.7	5.2±0.8	0.624

42% C&D

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Preliminary 12 Months Results

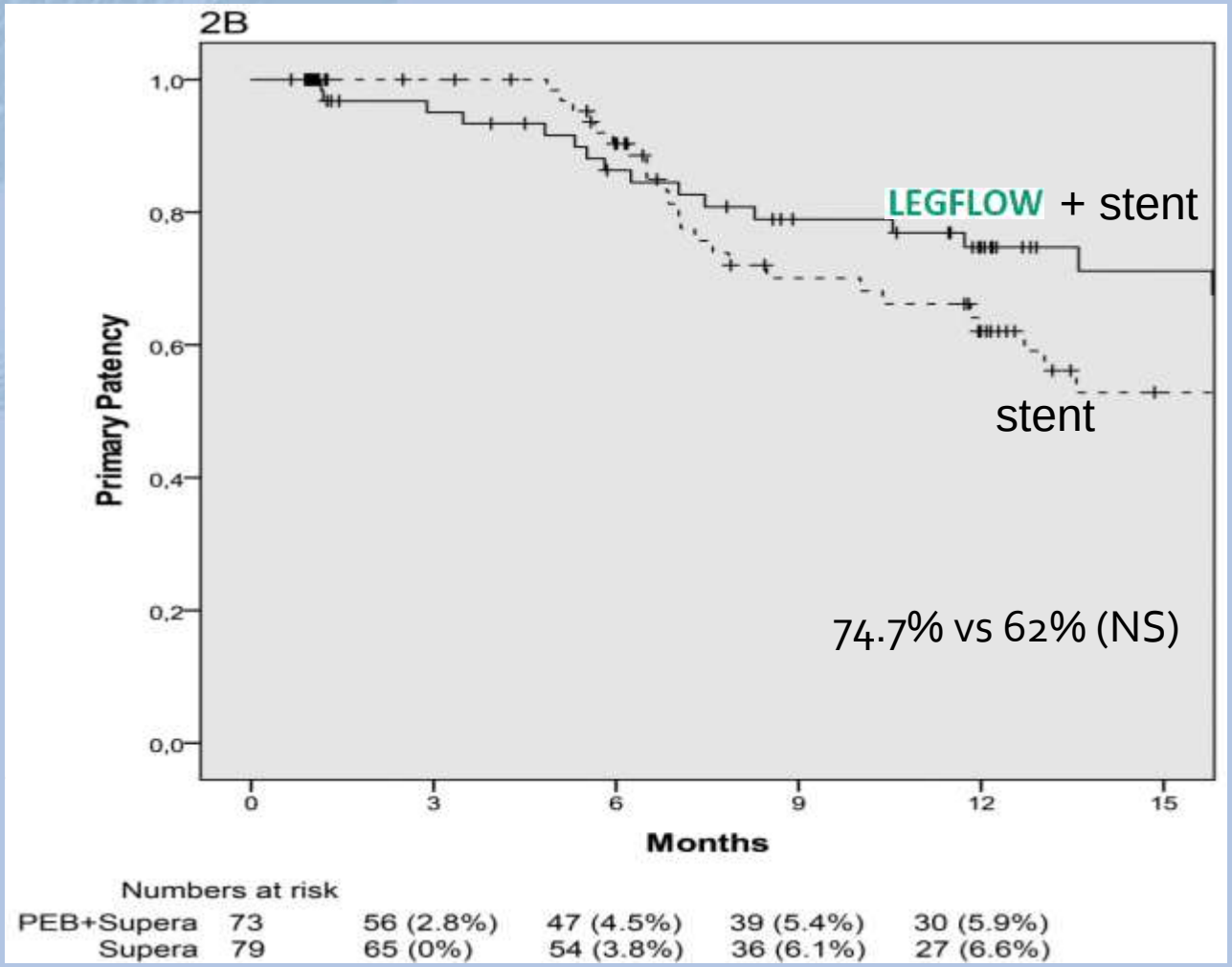
Safety analysis

1 major adverse limb event (MALE) within 30 days in the DEB+stent group (acute thrombosis)

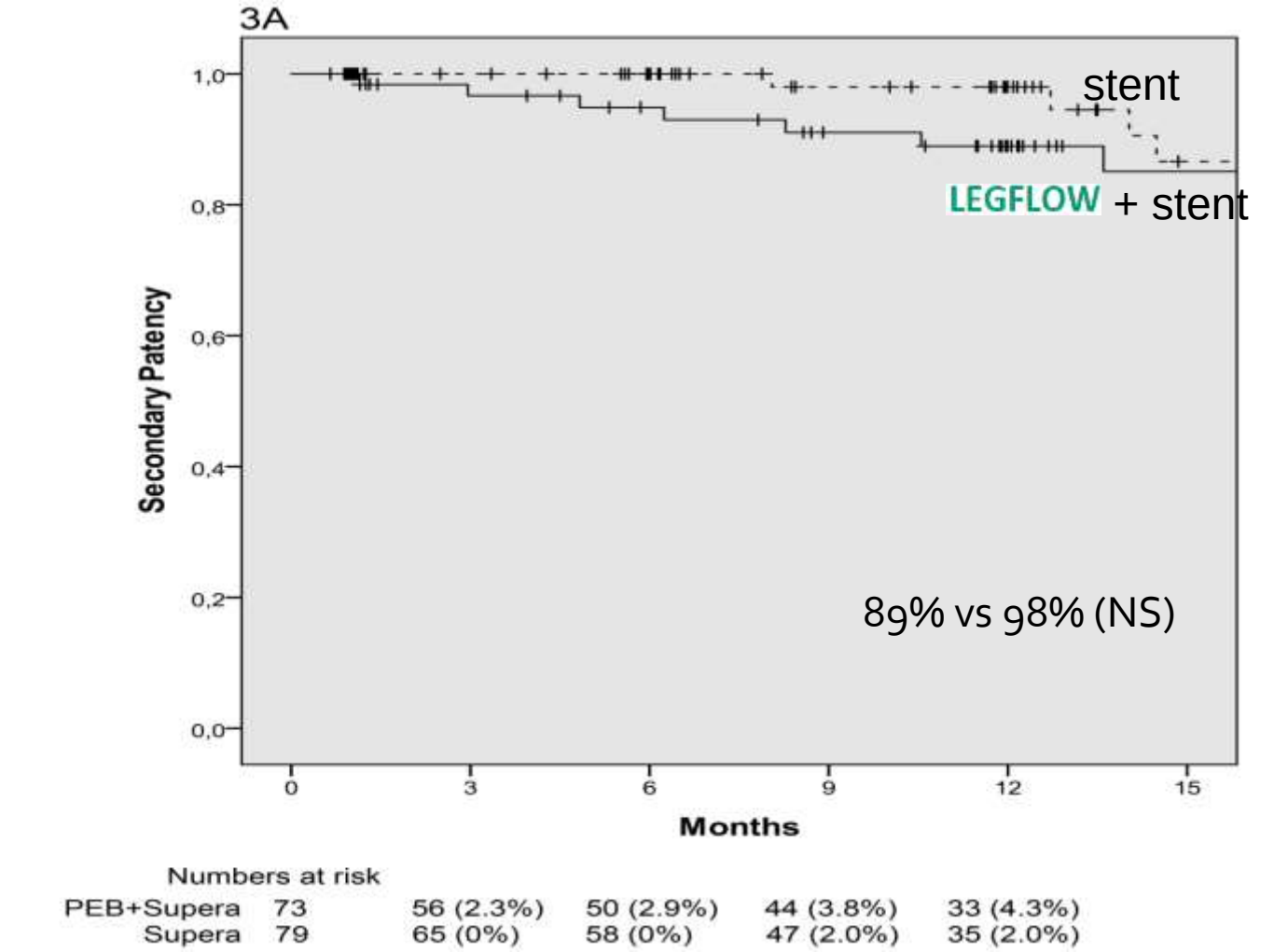
No difference between groups at 12 months in freedom from MALE or all-cause mortality (P=0.295)

Similar safety profiles

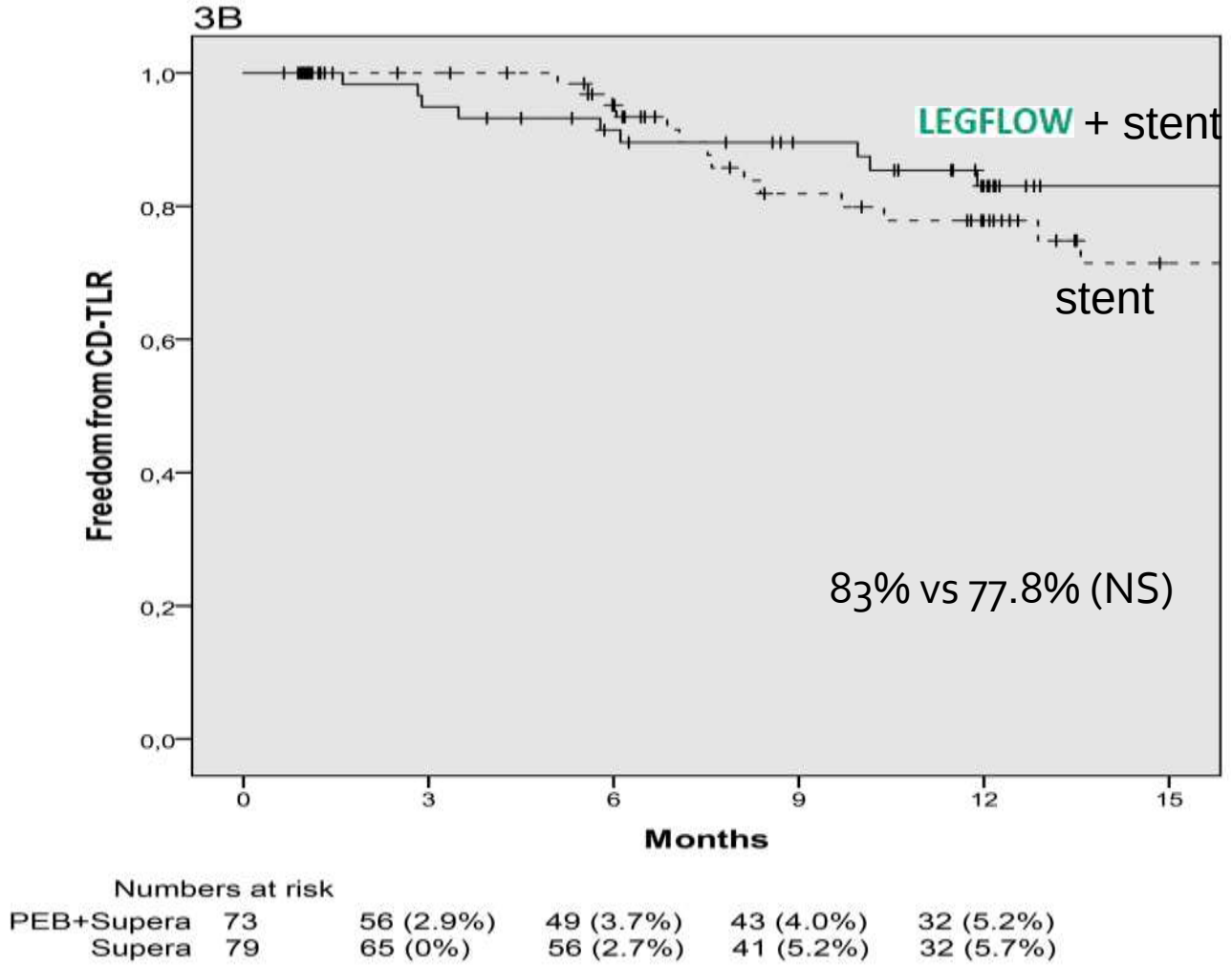
Preliminary 12 months Primary Patency



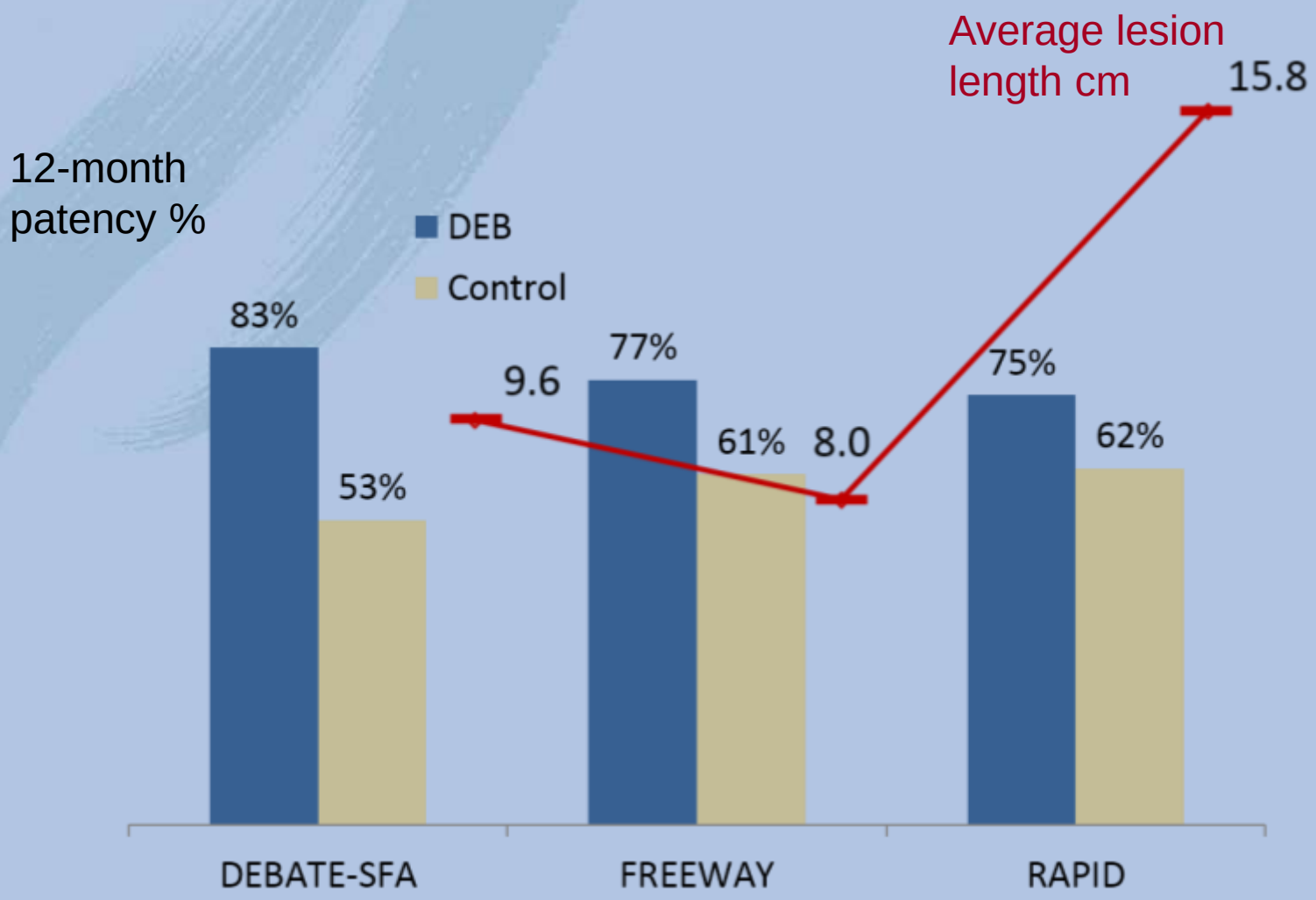
Preliminary 12 months secondary Patency



Preliminary 12 months freedom from CD-TLR



Trials with DCB + stent in SFA



Tacke, presentation at CIRSE 2017
de Boer et al, J Endovasc Ther 2017
Liistro F. JACC: Cardiovascular Interventions. 2013;6(12):1295-1302.

Conclusions from RAPID

- Average lesions in RAPID were the longest of any DCB+stent SFA trial
- Legflow DEB plus Supera stenting is as safe as POBA plus Supera stenting
- Legflow provides an additional 21% reduction in restenosis rates in patients treated with a Supera stent for complex femoral popliteal disease
- The interim 12-month RAPID results included ~40% of the full trial population which reduced the power of the analysis
- Data from the full population and 2 years follow-up are in the process of being analysed

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