DIDACTICS
DEVELOPMENT
DISTRIBUTION

DCB in SFA complex lesions : 1 + 1 = 3
TINTIN trial first outcomes

Koen Deloose, MD

Head Vascular Surgery, AZ Sint Blasius,

Dendermonde, Belgium

Disclosure slide

Speaker name: Koen Deloose, MD

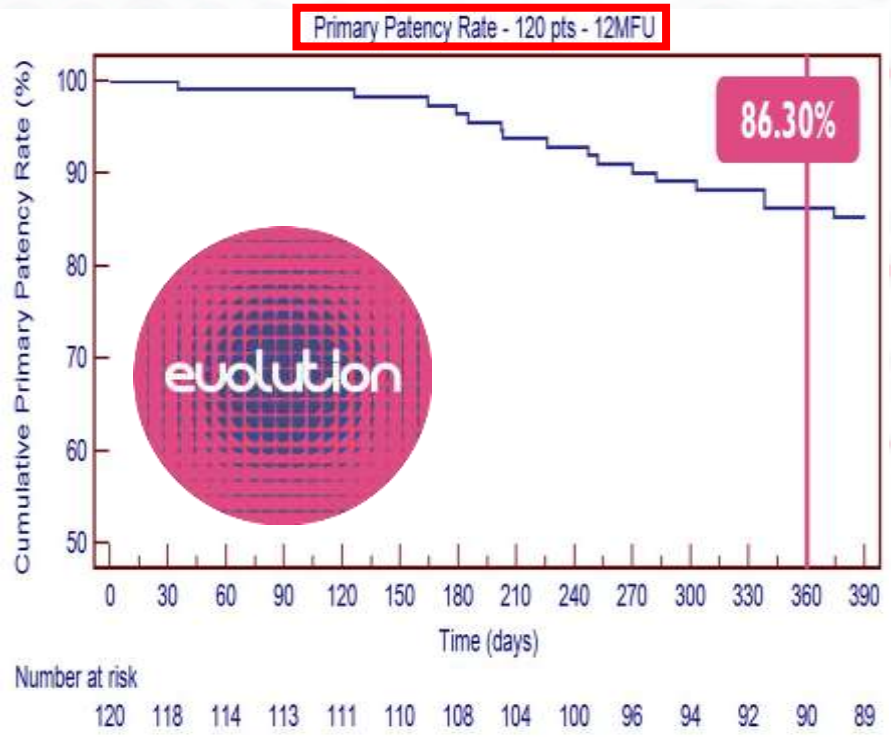
❑ I have the following potential conflicts of interest to report:

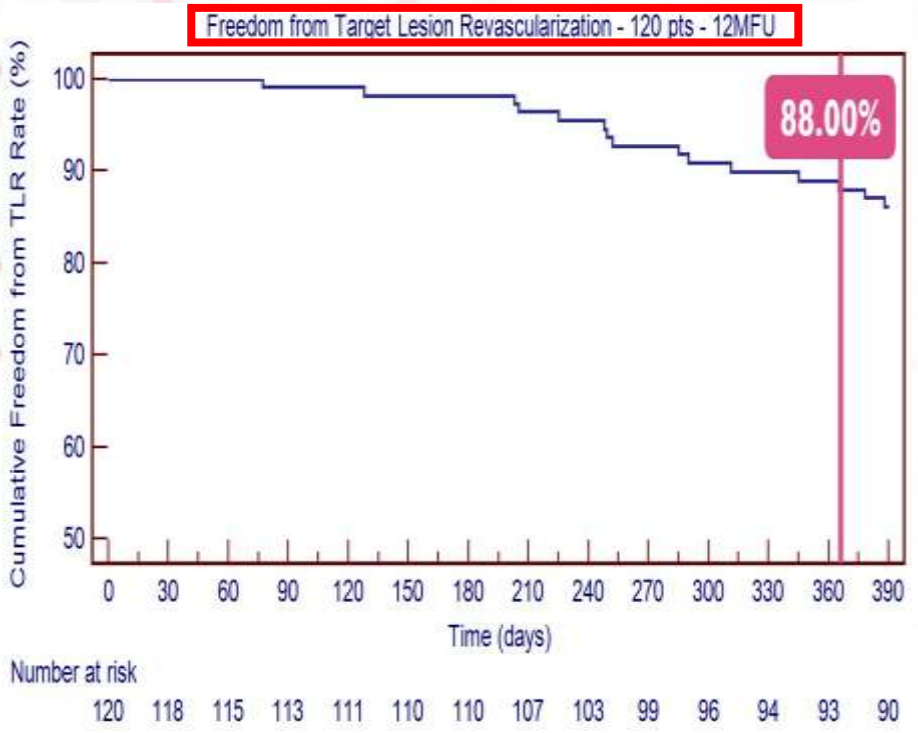
- ☒ Consulting: Medtronic, Spectranetics, Biotronik, Abbott, Bard iVascular, Bentley, Cook, GE Healthcare, Terumo, Boston Scientific, Contego Medical, B Braun
- ❑ Employment in industry
- ❑ Stockholder of a healthcare company
- ❑ Owner of a healthcare company
- ❑ Other(s)

❑ I do not have any potential conflict of interest

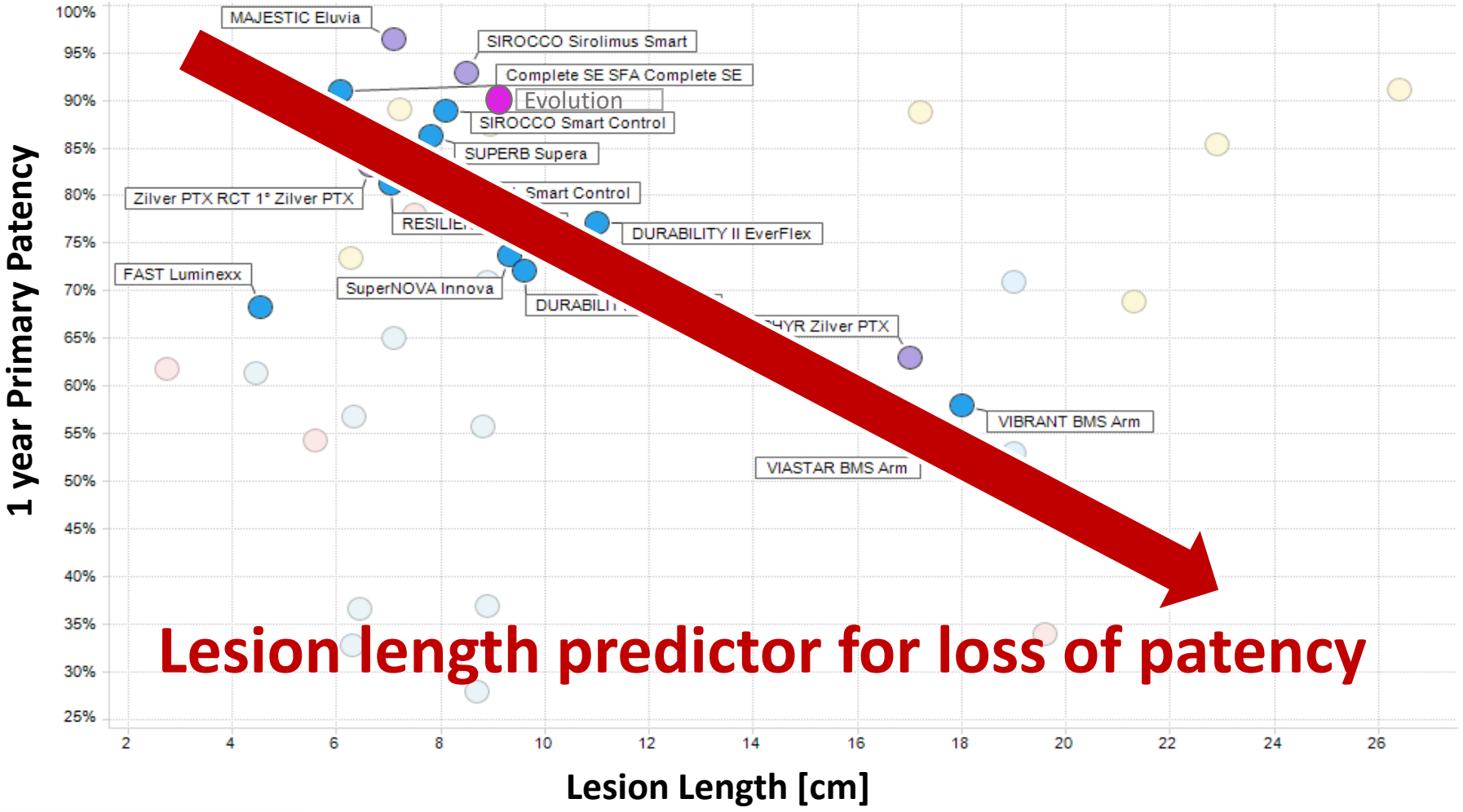
EVOLUTION trial

A Prospective, non-randomized, multi center study investigating the Efficacy of the Self-Expanding iVolution nitinol stent for treatment of femoropopliteal lesions ; **mll 8,9cm**





The reality of BMS anno 2019



EFFPAC trial

Multicenter Randomized Controlled Trial to Assess the

Effectiveness of Paclitaxel-coated Luminor® Balloon Catheter

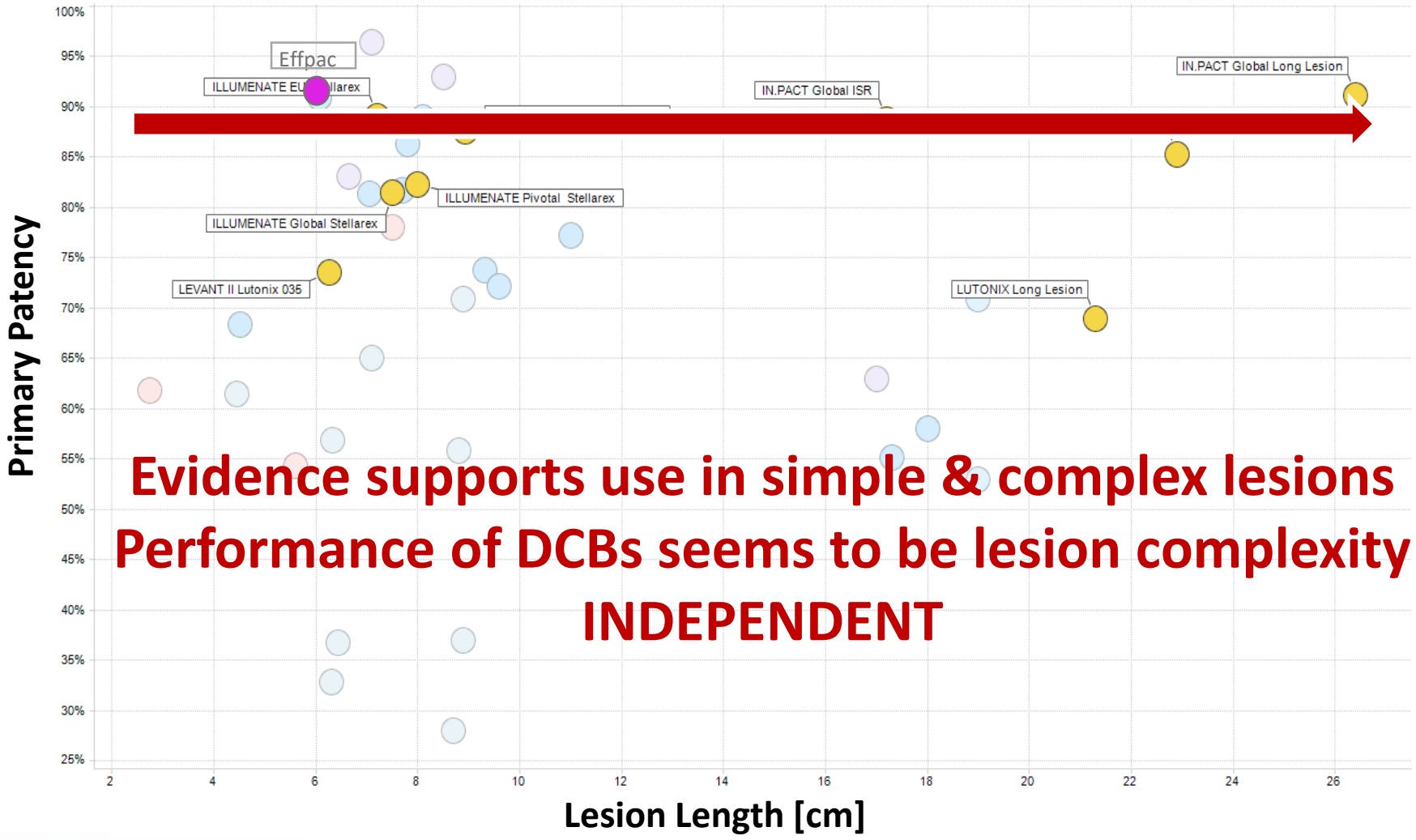
vs.

Uncoated Balloon Catheter

in the Superficial Femoral and Popliteal Arteries to Prevent Vessel Restenosis or Reocclusion

	Luminor	POBA	P value
Primary patency 1 yr %	90,3	65,3	< 0,001
Freedom TLR 1 yr %	98,7	82,3	< 0,001
Bail-out stent ratio %	15,3	18,8	0,684
Lesion length mm	59	56	0,731

The reality of DCB anno 2019

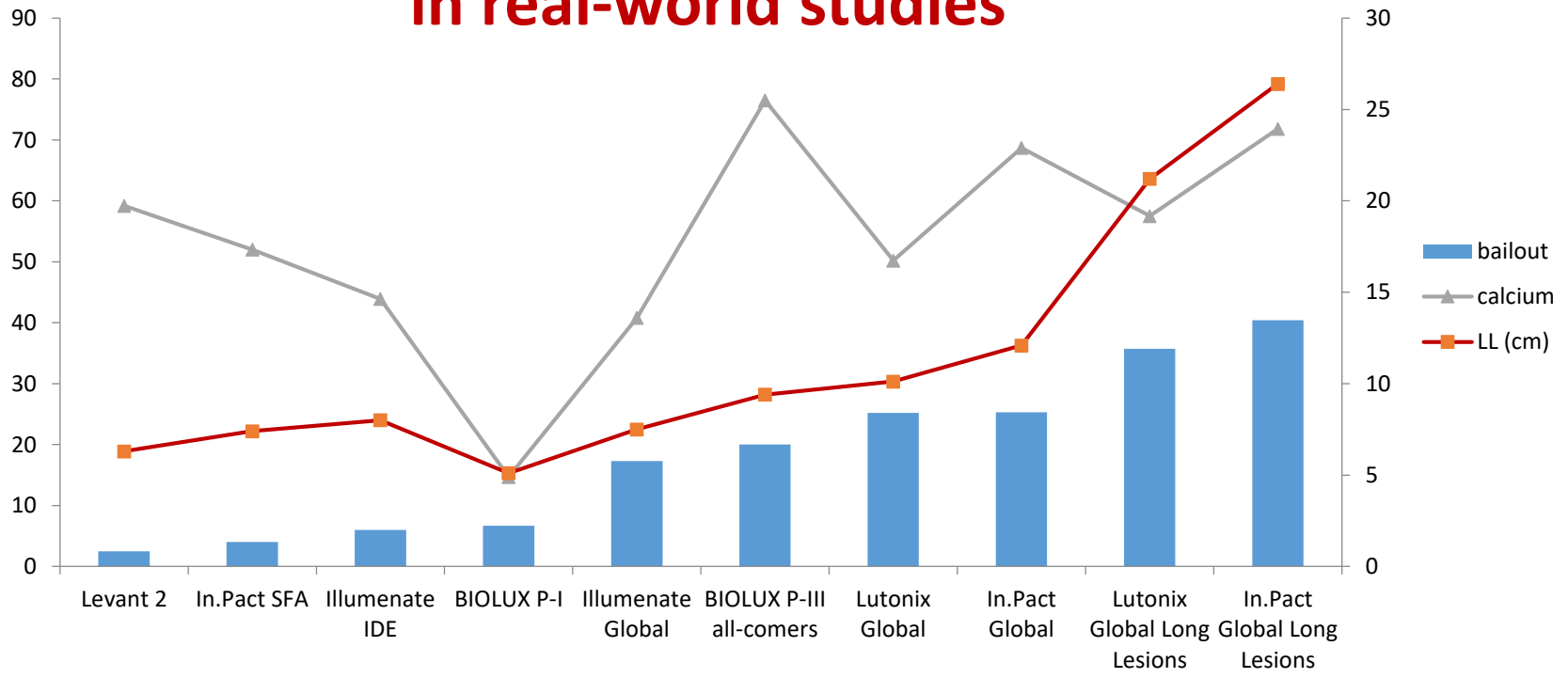


Evidence supports use in simple & complex lesions

Performance of DCBs seems to be lesion complexity INDEPENDENT

Can DCB alone fit it all?

Provisional stenting rate in DCB trial up to 40% in real-world studies



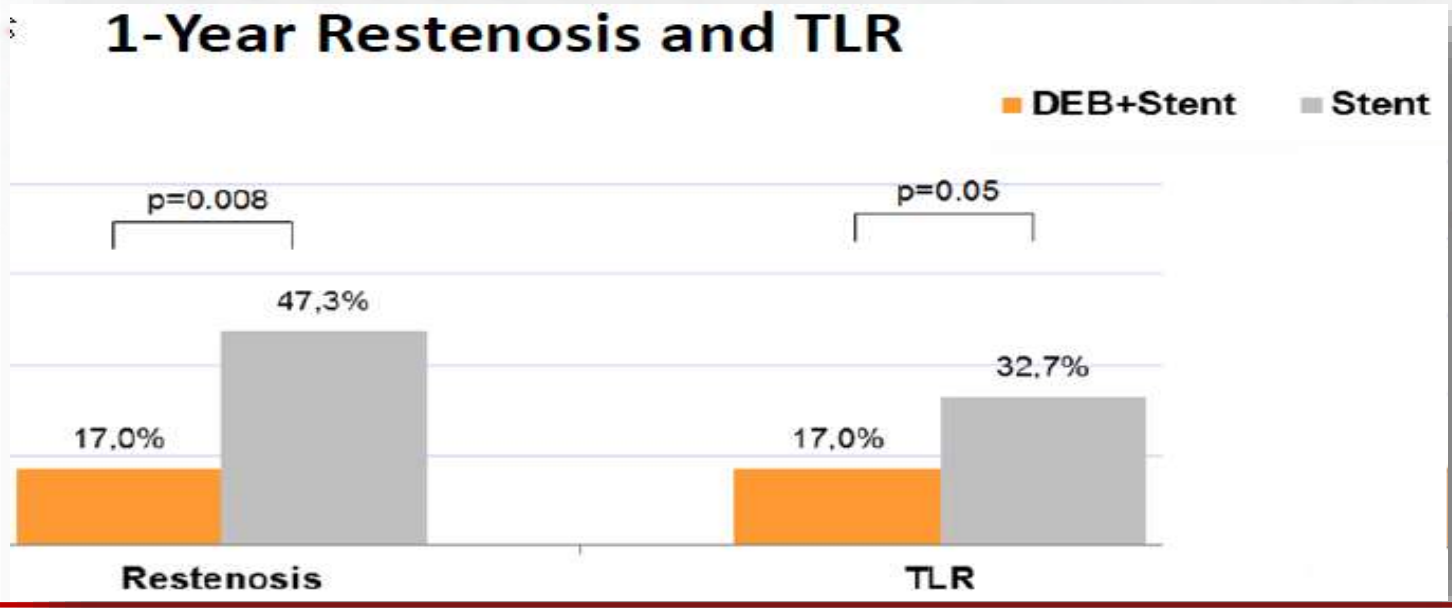
Illumenate Global : Schroë H. et al, Catheter Cardiovasc Interv 2017
BIOLUX P-III all comers: Tepe G, CIRSE 2017
Lutonix Global: Thieme M. et al, JACC: Cardiovascular Interventions 2017
Lutonix Global Long lesions[6]: Thieme M. et al, JACC: Cardiovascular Interventions 2017
In.Pact Global: Jaff MR, VIVA 2016
In.Pact Global Long Lesions: Ansel G. TCT 2015

Levant II : Rosenfield K. et al, N Engl J Med n. 2, 373, pp. 145–153 -
In.Pact SFA: [2], Tepe G. et al, Circulation n. 5, 131, pp. 495–502
Illumenate IDE : [3], Krishnan P. et al, Circulation. 2017;136:1102–1113
Biolux P-I: [4], Scheinert D. et al, J. Endovasc. Ther. 2015;22:14–21

What about this combination therapy for daily practice ?

DEBATE TRIAL

- ✓ Single center, randomized trial
- ✓ 110 lesions : **55 DCB (IN.Pact Admiral) + BMS (Maris SX)** vs **55 POBA + BMS**
- ✓ Primary endpoint : 12 m binary restenosis
- ✓ A.L.L. : **94 ± 60 (DCB + BMS)** vs **96 ± 69 (POBA + BMS)**

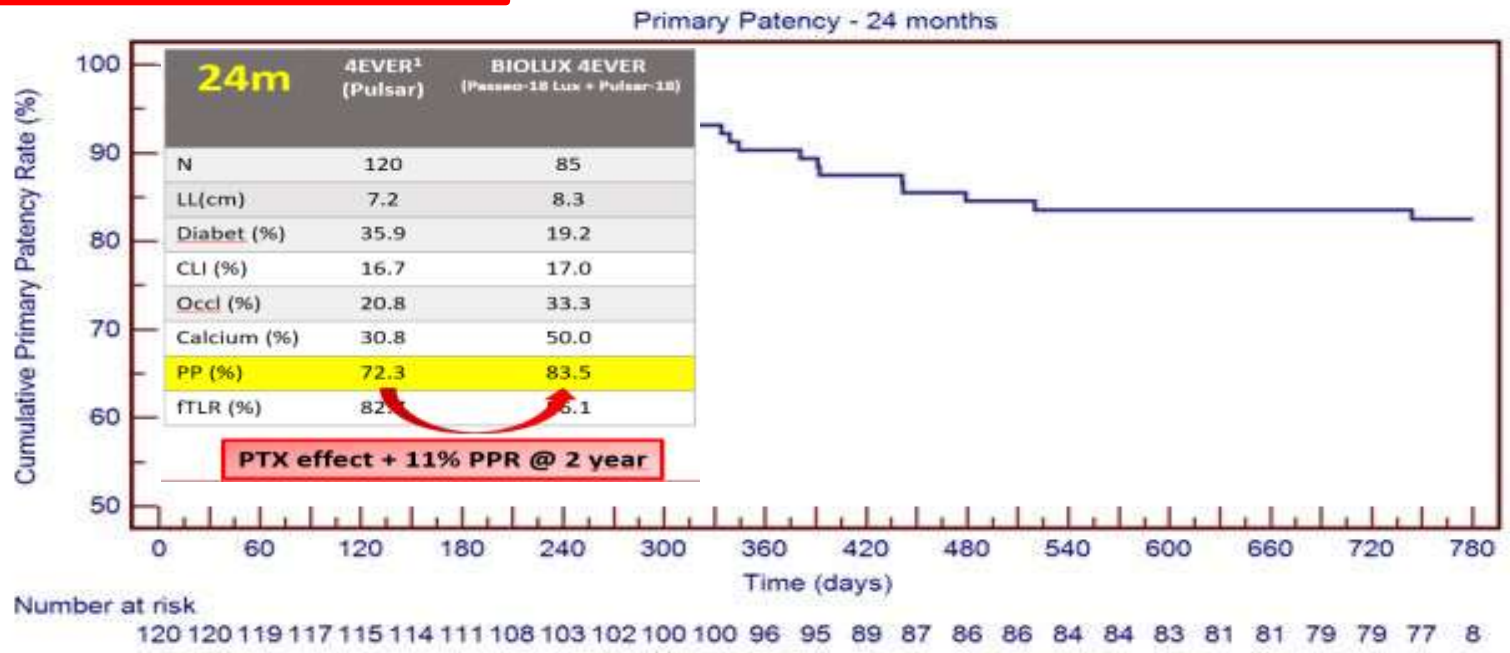


Liistro et al. *JACC* 2013;6(12):1295-1302

What about this combination therapy for daily practice ?

BIOLUX 4EVER

✓ **MLL : 8.33 cm (6.0 – 190 mm + 49.49)**

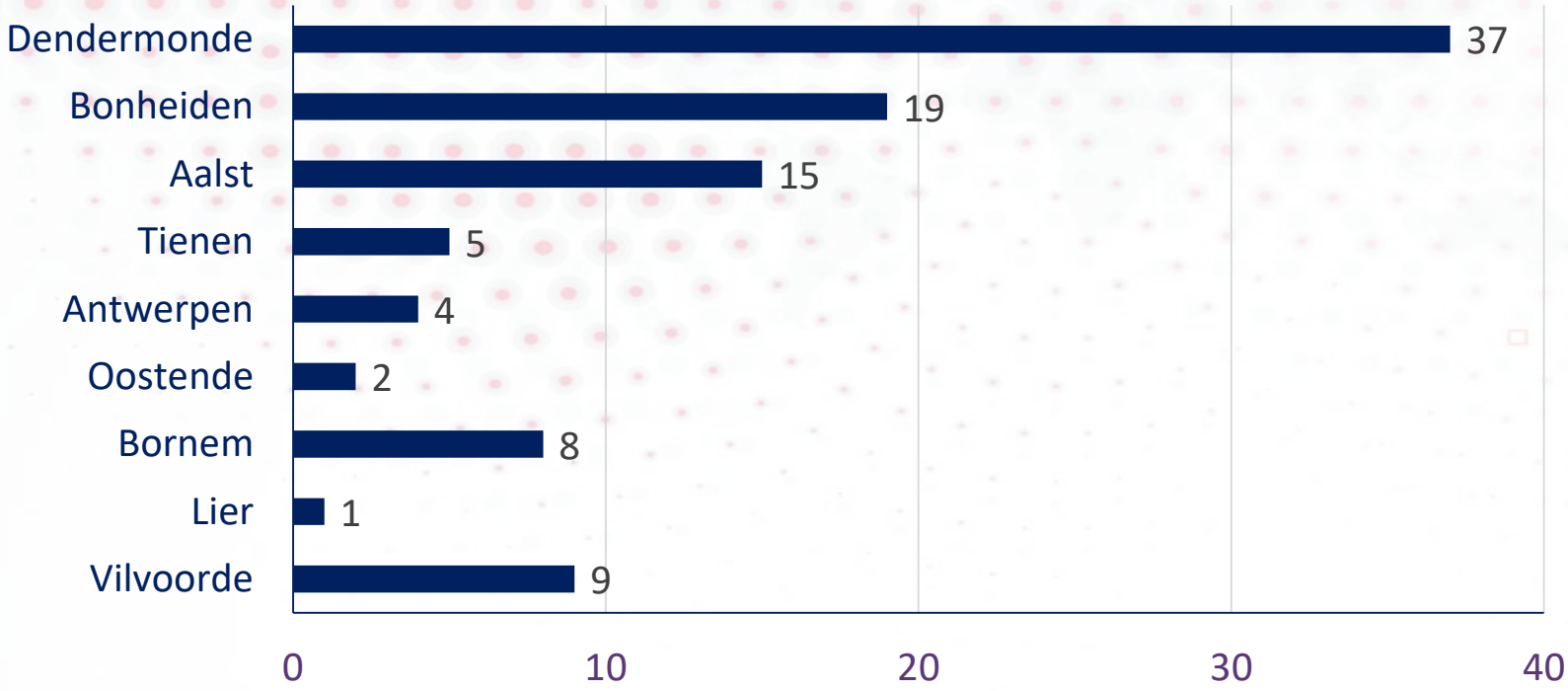


83.5 %

	Baseline	1M	6M	12M	24M – D730	24M – D760
% PP	100	100	94.90	90.30	83.50	82.50

T.I.N.T.I.N.

Physician-initiated trial investigating the safety and efficacy of the Treatment with the LumINor DCB and The IvolutioN stent of iVascular in TASC C and D femoropopliteal lesions



T.I.N.T.I.N.: Endpoints

Primary Endpoint

- *Efficacy endpoint*: Freedom from CD-TLR @ 12 months

Secondary Endpoints

- *Primary patency* @ 6 and 12 months (DUS PSVR < 2,5)
- *Technical success* (angiographical RS < 30%)
- *Freedom from CD-TLR* @ 6 months
- *Clinical success*: defined as improvement of RB classification
- *Serious adverse events* up to 30 days post-index procedure

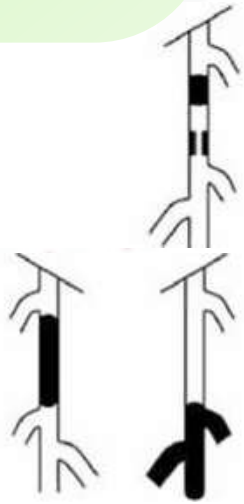
T.I.N.T.I.N.: In/Exclusion criteria

- Rutherford 2 – 5
- Native, de novo and post PTA fempop lesions
- TASC II C or D
- TLL ≥ 150mm
- >50% stenosis
- 4mm < Ø < 6,5mm
- Patent run-off

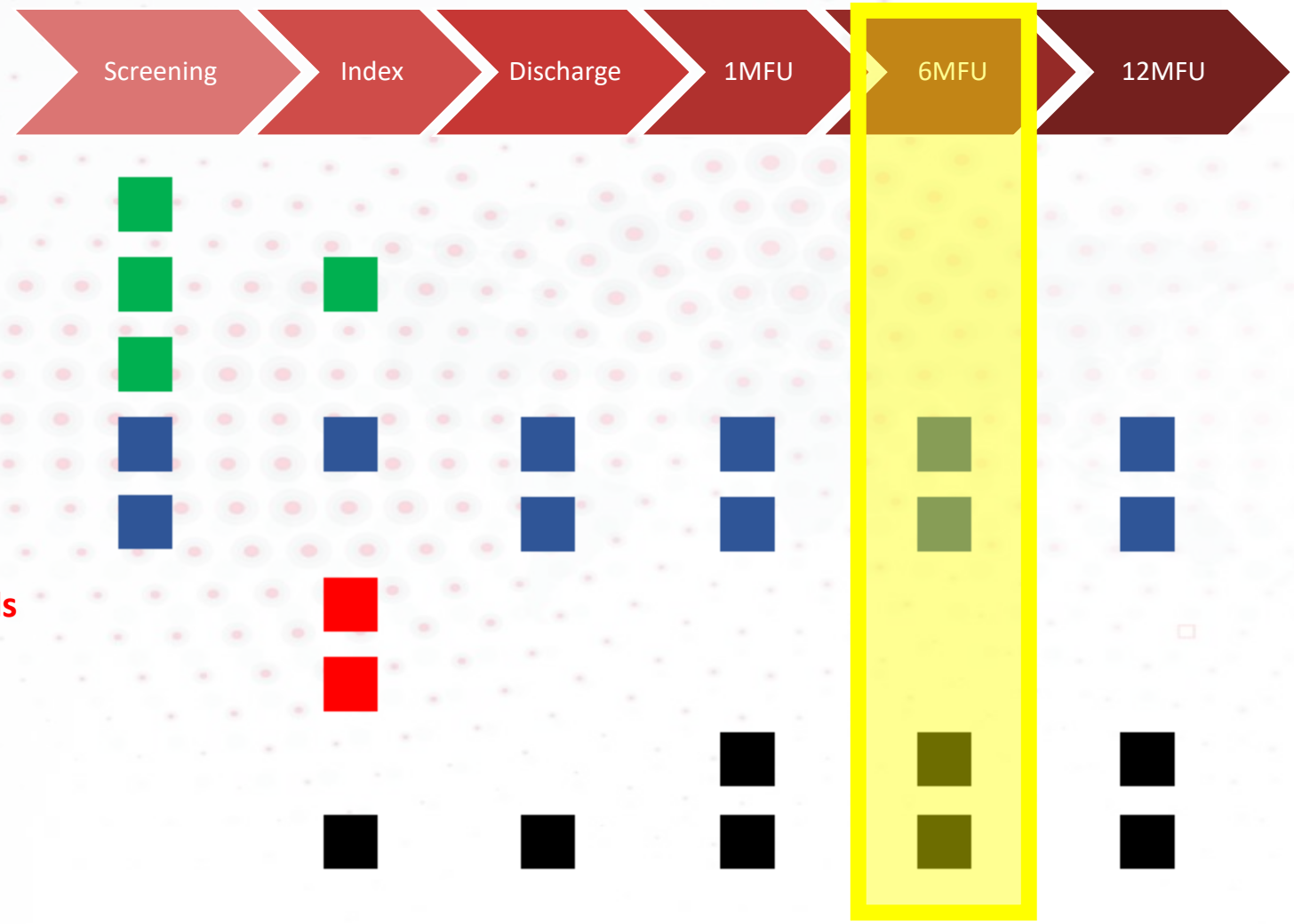
- Presence of a stent in TL
- Non-treatable inflow lesion
- Any previous surgery in TV
- Aneurysm in SFA or PA
- Major amputation
- Debulking technologies

Type C Lesions
- Multiple Stenoses or Occlusions Totaling >15 cm With or Without Heavy Calcification
- Recurrent Stenoses or Occlusions That Need Treatment After 2 Endovascular Interventions

Type D Lesions
- Chronic Total Occlusions of CFA or SFA (>20 cm, Involving the Popliteal Artery)
- Chronic Total Occlusion of Popliteal Artery and Proximal Trifurcation Vessels

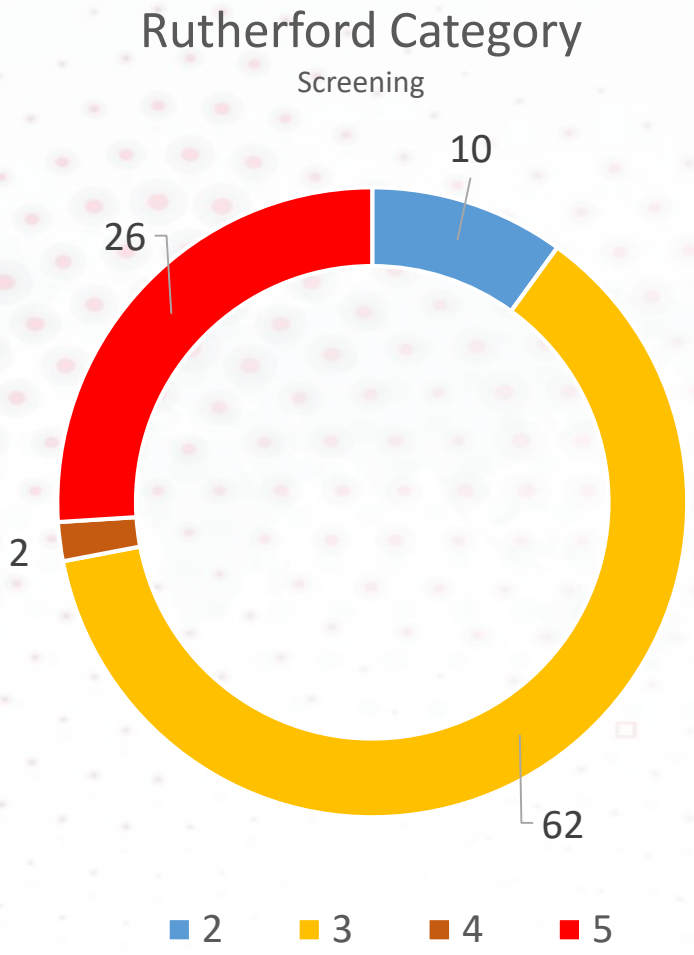


T.I.N.T.I.N.: Timeline



T.I.N.T.I.N.: Demographics

	N = 100 out of 100
Male (%)	67 (67%)
Age (min-max ± SD)	73,47 (53 - 92 ± 9,37)
Nicotine (%)	48 (48%)
Hypertension (%)	73 (73%)
Diabetes (%)	37 (37%)
Renal insufficiency (%)	13 (13%)
Hypercholesterolemia (%)	63 (63%)
Obesity (%)	32 (32%)
Previous PAD (%)	40 (40%)
Claudicant (%)	72 (72%)
CLI patient (%)	28 (28%)



T.I.N.T.I.N.: Lesion characteristics

	N = 100 out of 100
Lesion length (min-max ± SD)	242,65mm (150mm – 450mm ± 73.72mm)
Reference vessel diameter (min-max ± SD)	5,50mm (5mm – 6mm ± 0.48mm)
Degree of stenosis (min-max ± SD)	93.93% (70% – 100% ± 8.83%)
Occlusion (%)	60% (60%)
Calcified lesion (moderate – severe) (%)	73% (73%)
TASC II C lesion (%)	62% (62%)
TASC II D lesion (%)	38% (38%)

T.I.N.T.I.N.: Procedure characteristics

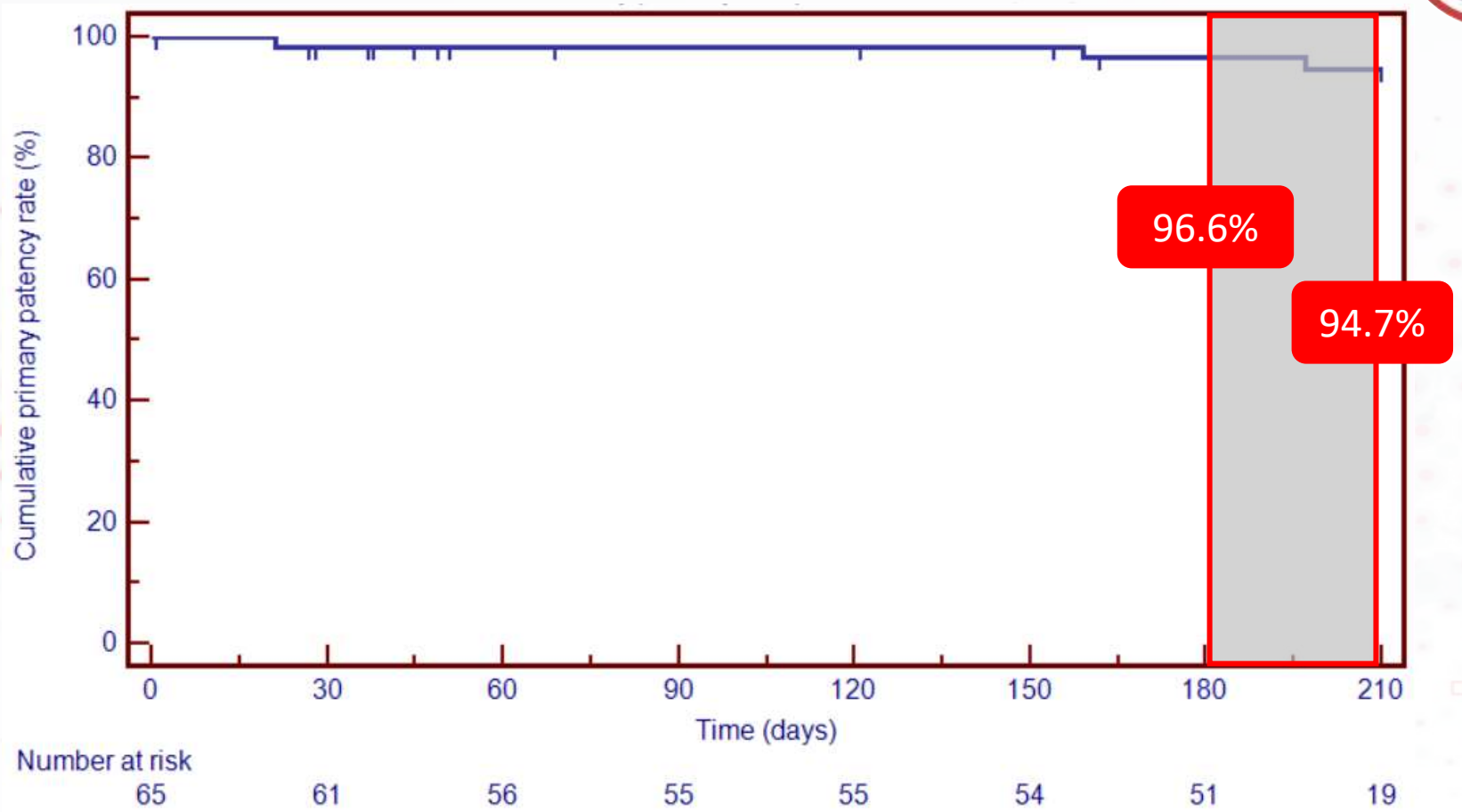
	N = 100 out of 100
Procedure time (min-max ± SD)	69.3min (25min – 170min ± 27.4min)
Scopy time (min-max ± SD)	17.5min (5min – 51min ± 11.1min)
Contrast (min-max ± SD)	92,6ml (20ml – 200ml ± 36.2%)
Femoral access (%)	100% (100%)
Cross-over performed (%)	77% (77%)
Inflow lesion (%)	14% (14%)
Outflow lesion (%)	21% (21%)
Predilatation performed (%)	88 (88%)
Diameter predilatation balloon (min-max ± SD)	4.62mm (3mm – 6mm ± 0.68mm)
Length predillatation balloon (min-max ± SD)	156.53mm (40mm – 220mm ± 42.95mm)

T.I.N.T.I.N.: Procedure characteristics

	N = 100 out of 100
Mean # Luminors used per procedure	1.82 (1 – 4 ± 0.73)
Luminor 18 - 35	<table><tr><th></th><th>Total</th></tr><tr><td>Luminor-18</td><td>106 (58%)</td></tr><tr><td>Luminor-35</td><td>76 (42%)</td></tr></table>
Diameter Luminor (min-max ± SD)	5.29mm 4mm – 6mm ± 0.46mm)
Mean # iVolutions used per procedure	1.84 (1 – 4 ± 0.69)
Diameter iVolution (min-max ± SD)	5.74mm 5mm – 7mm ± 0.45mm)
Post-dilatation done	85

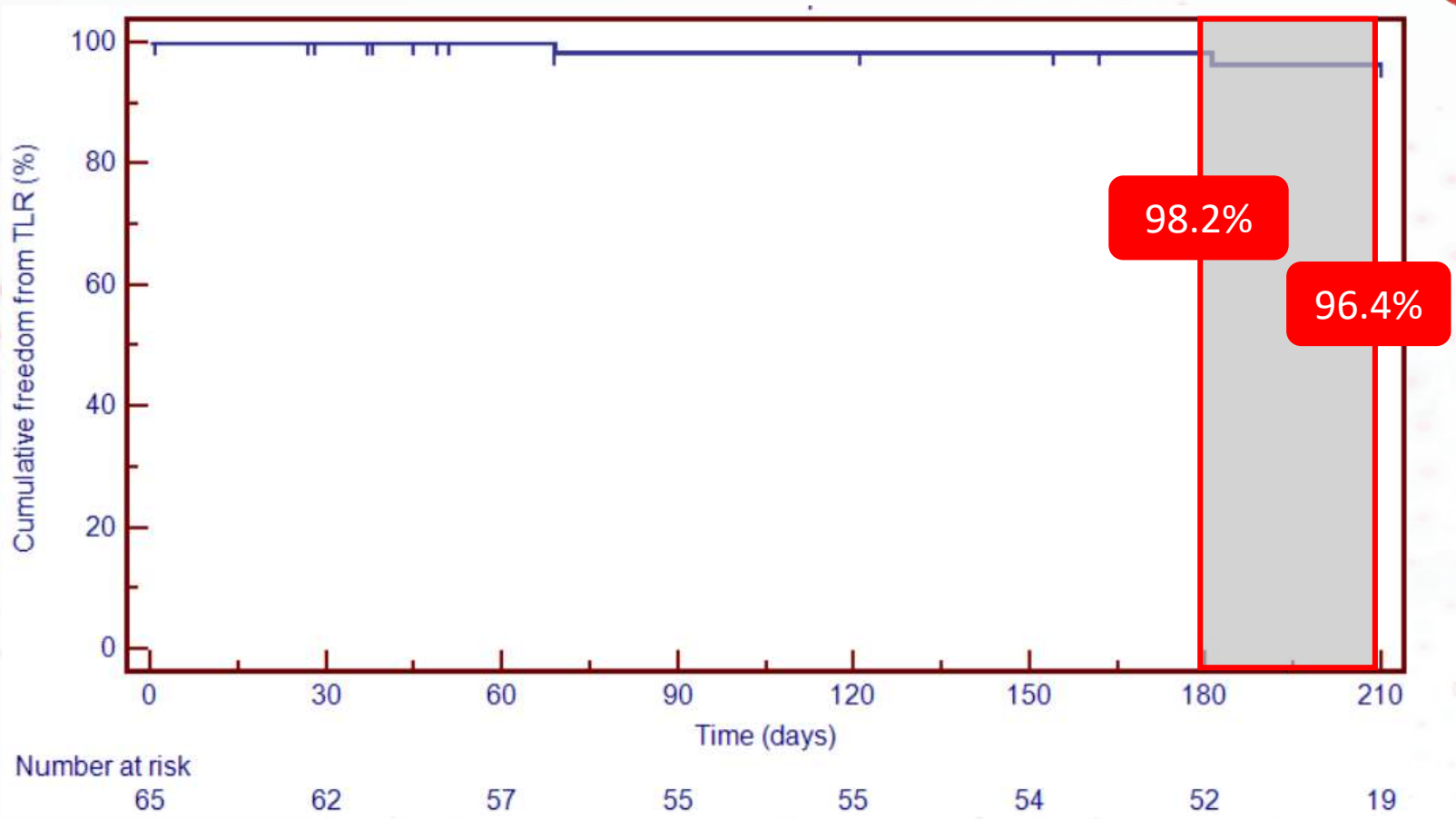
5,50mm

T.I.N.T.I.N.: Primary Patency 6m (65 pts)



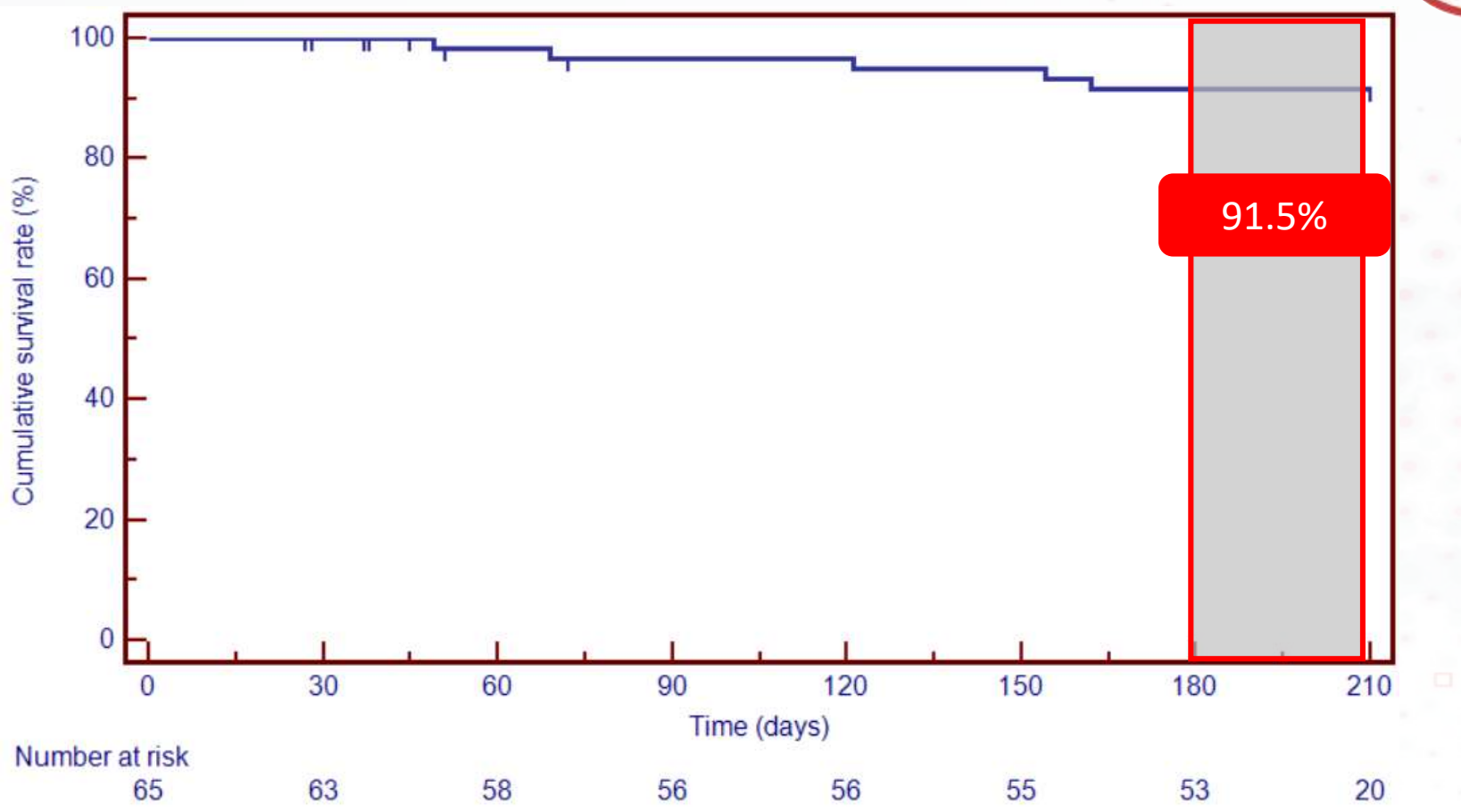
time	baseline	1MFU (30 days)		6MFU (180 days)	6MFU (210 days)
at risk	65	61		51	19
%	100	98.4		96.6	94.7

T.I.N.T.I.N.: freedom TLR 6m (65 pts)



time	baseline	1MFU (30 days)		6MFU (180 days)	6MFU (210 days)
at risk	65	62		52	19
%	100	100		98.2	96.4

T.I.N.T.I.N.: Survival 6m (65 pts)



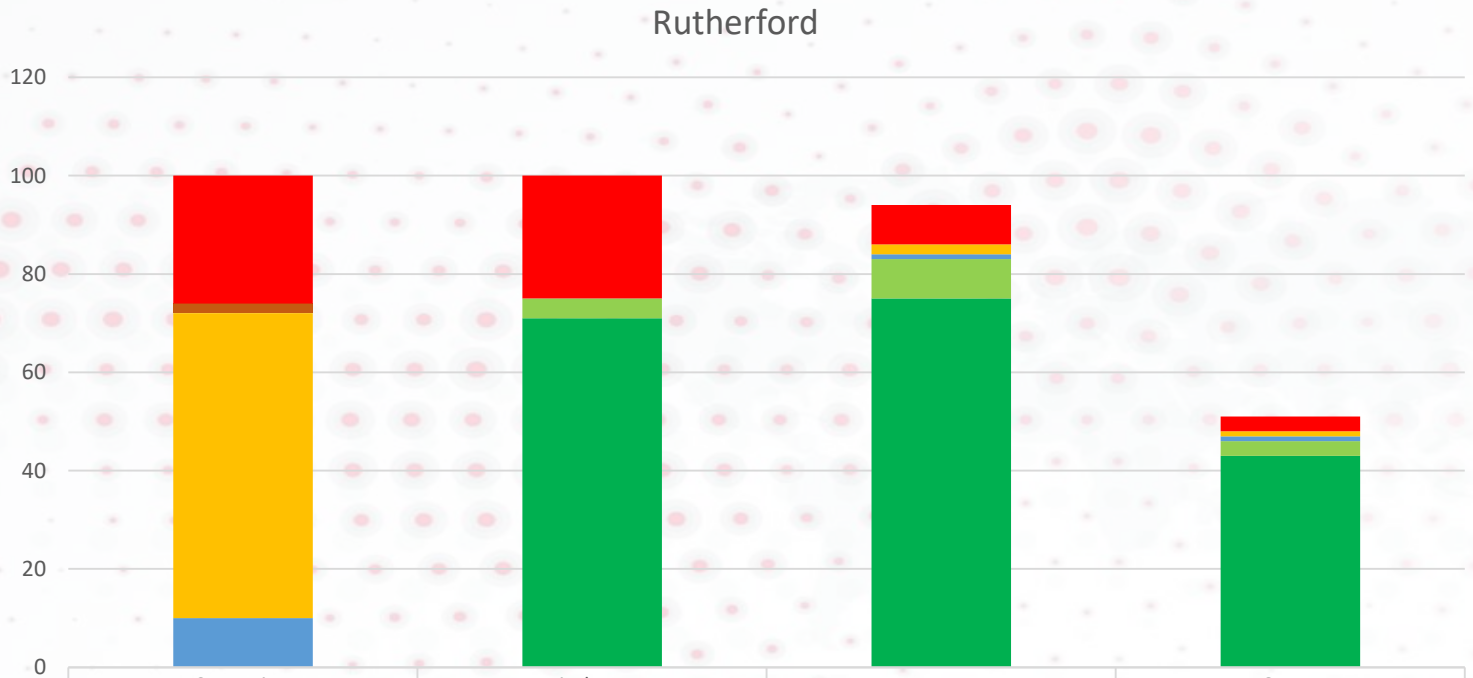
time	baseline	1MFU (30 days)		6MFU (180 days)	6MFU (210 days)
at risk	65	63		53	20
%	100	100		91.5	91.5

T.I.N.T.I.N.: Safety outcomes

Primary safety endpoint (100 patients)	30 days
Device or procedure related death (N)	0
CD-TLR (N)	0
Target limb major amputation (N)	0

MAEs (65 patients)	180 days	210 days
Death (N)	5	5
CD-TLR (N)	1	2
Target limb major amputation (N)	0	0
Thrombosis (N)	1	1

T.I.N.T.I.N.: Clinical outcomes



	Screening	Discharge	1MFU	6MFU
6	0	0	0	0
5	26	25	8	3
4	2	0	0	0
3	62	0	2	1
2	10	0	1	1
1	0	4	8	3
0	0	71	75	43

Summary

- iVolution BMS (iVascular) shows 86.3% primary patency rate and 88% freedom from TLR @1 year (Evolution trial) in TASC A/B lesions
- Luminor DCB (iVascular) shows 90.3% primary patency rate and 98.7% freedom from TLR @1year (Effpac trial) in TASC A/B lesions
- It is clear out of the literature that neither BMS nor DCB alone are winners in long, complex lesions and on the longer run
- The combination of both is the key to success in these situations
- An early confirming trend for this statement is noticed in the combination of the Luminor and the iVolution : Belgian T.I.N.T.I.N. trial shows impressive preliminary 6 months results in lesions of 24 cm : primary patency of 96,6% and freedom from TLR of 98,2% ; 12 and 24 month results are on the run

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