T.I.N.T.I.N. trial : Final 12-month data with the combination of Luminor DCB + iVolution stent in TASC C and D lesions

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Koen Deloose, MD

Head Dept Vascular Surgery

AZ Sint Blasius

Dendermonde, Belgium

Disclosure slide

Speaker name: Koen Deloose, MD

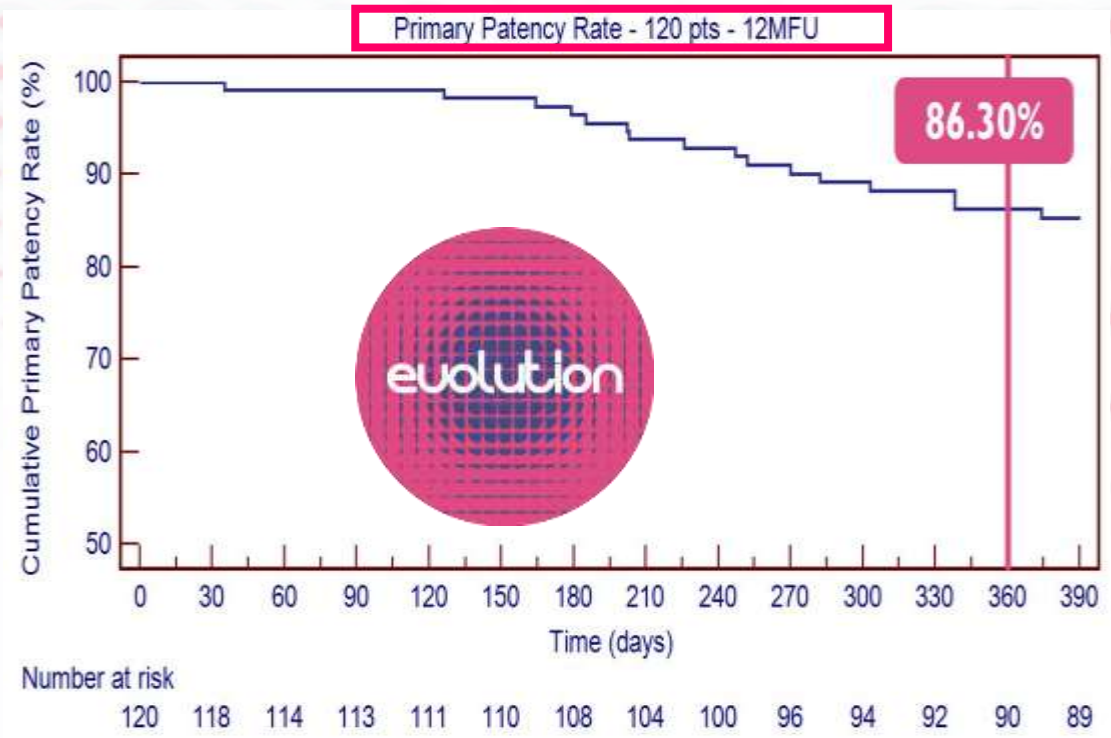
❑ I have the following potential conflicts of interest to report:

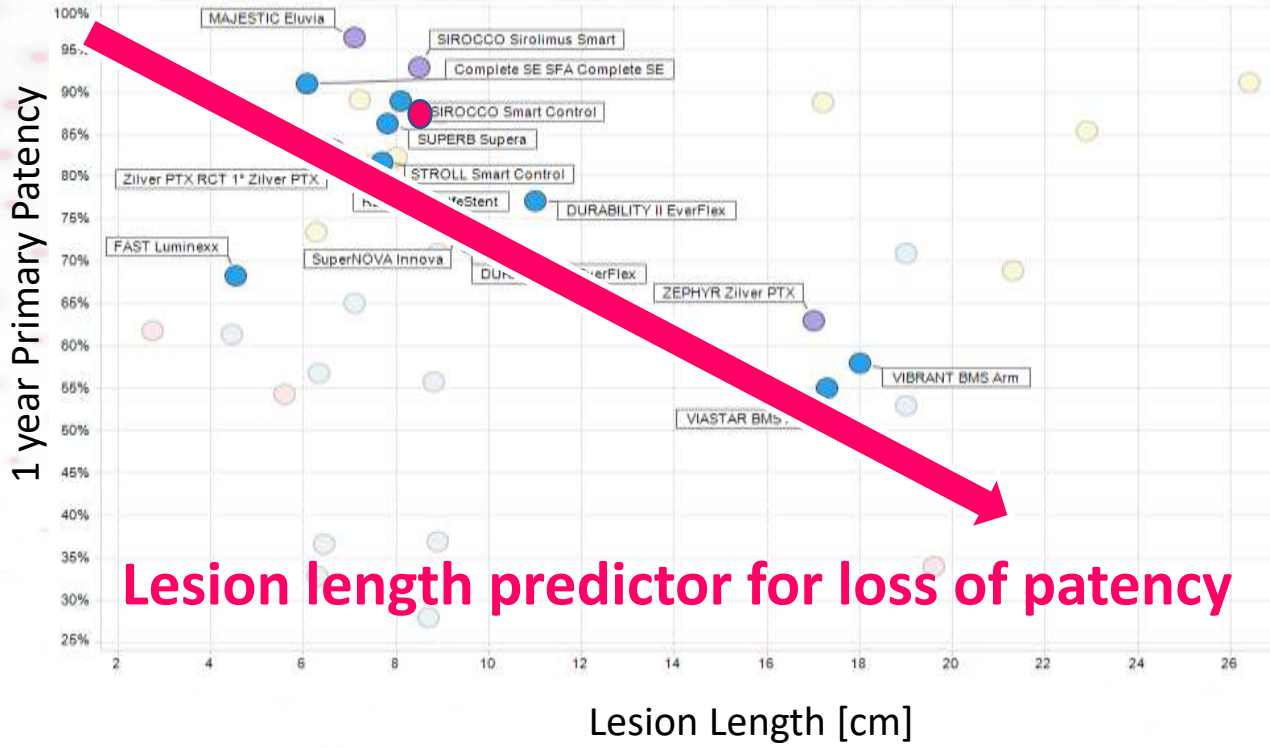
- ☒ Consulting: Abbott, BD, Biotronik, Boston Scientific, Cook, CTI vascular, iVascular, Medtronic, Philips, Terumo, CyndRX, Profusa
- ❑ Employment in industry
- ❑ Stockholder of a healthcare company
- ❑ Owner of a healthcare company
- ❑ Other(s)

❑ 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**





Lesion length predictor for loss of patency

With the courtesy of M Bosiers, presented @LINC2019, Leipzig, Germany

EVOLUTION trial

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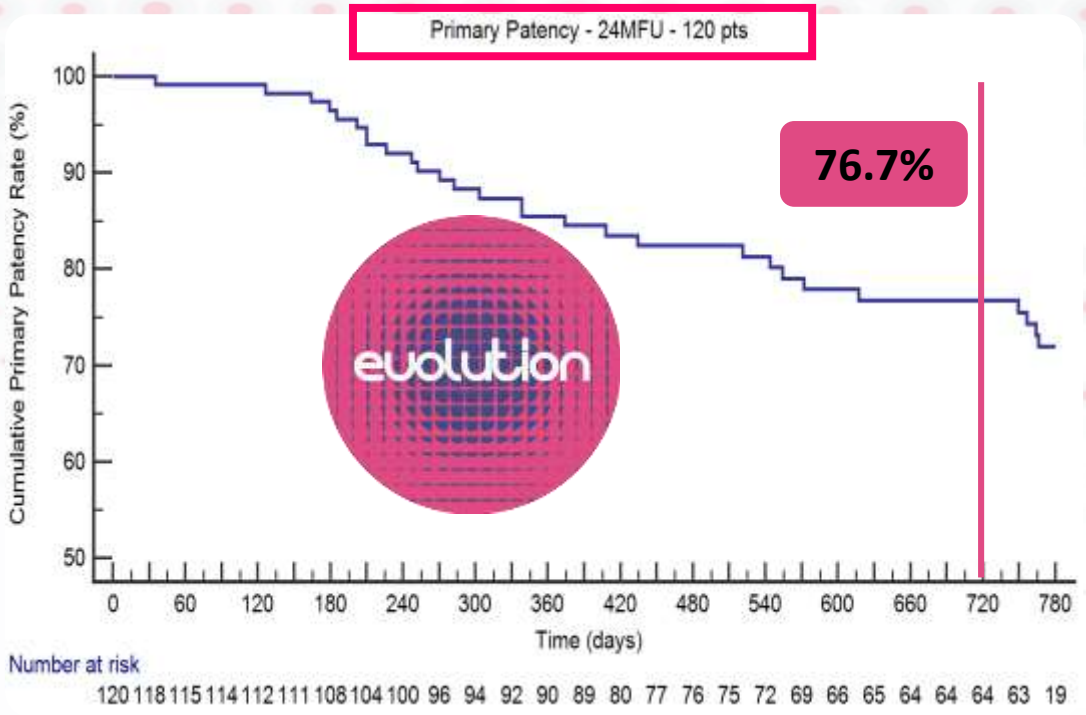
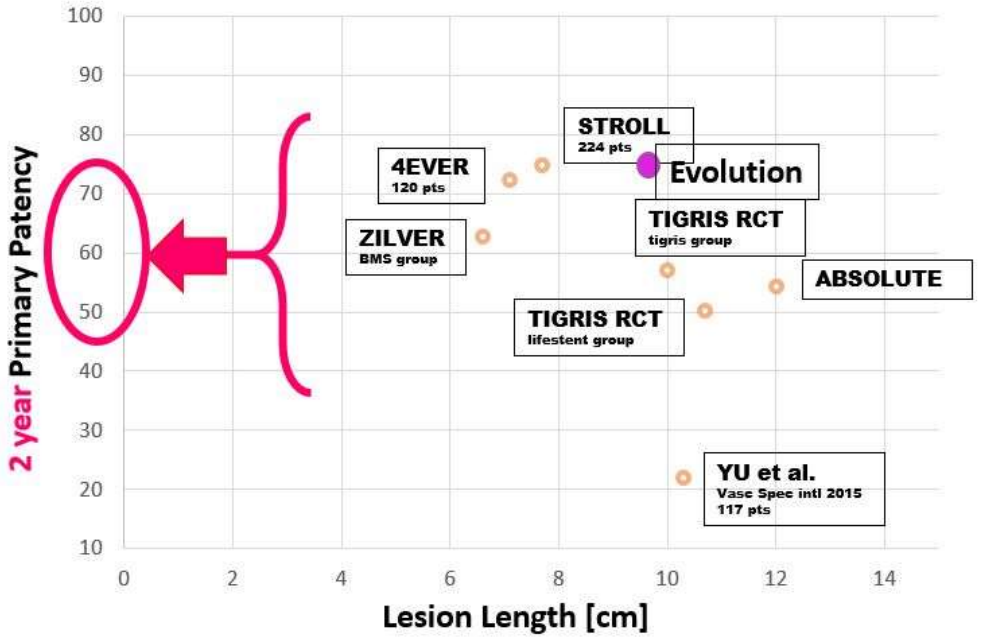




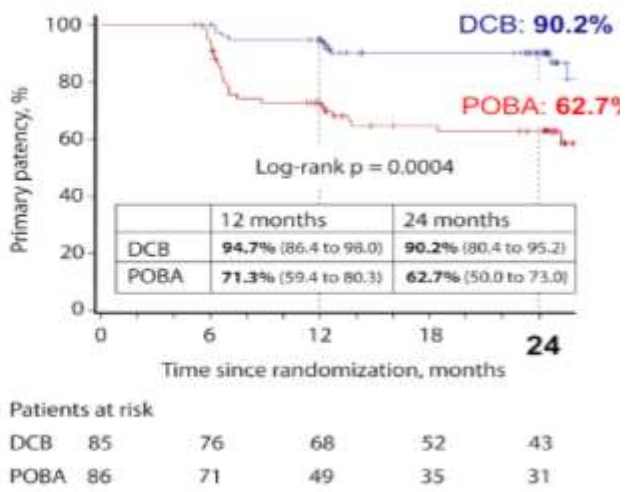
Durability seems to be an issue for BMS

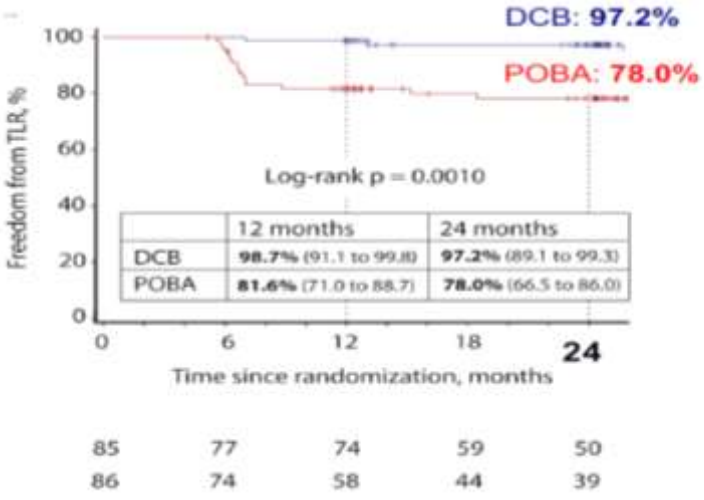
With the courtesy of M Bosiers, presented @LINC2019, Leipzig, Germany

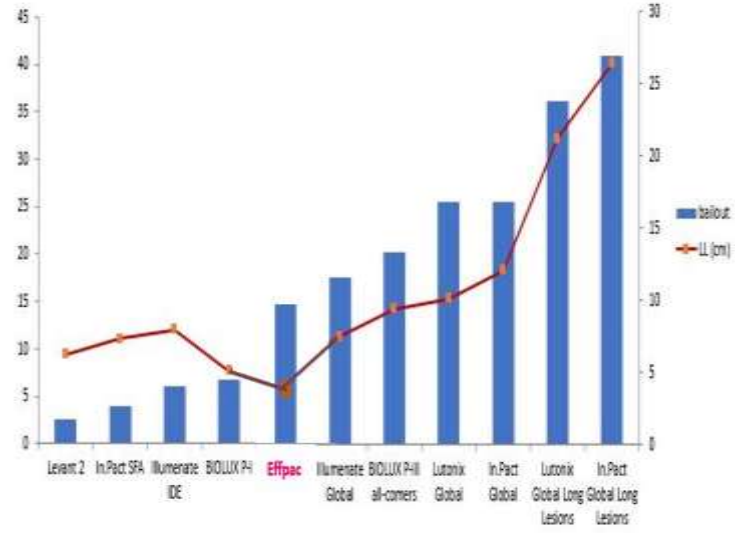
EFFPAC trial

Multicenter Randomized Controlled Trial to Assess the Effectiveness of Paclitaxel-coated Luminor® Balloon Catheter (85) versus Uncoated Balloon Catheter (86) in the Superficial Femoral and Popliteal Arteries to PreventVessel Restenosis or Reocclusion; mll 5,9cm

Primary patency:
Freedom from restenosis (determined by duplex ultrasound PSVR < 2.5) and freedom from TLR

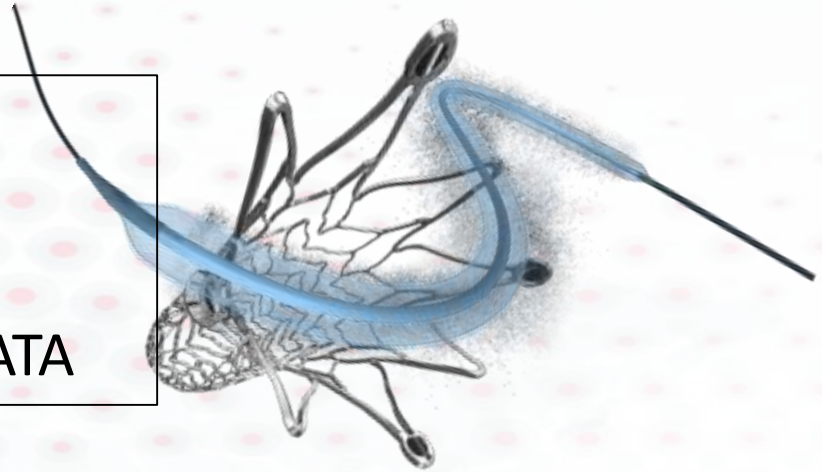






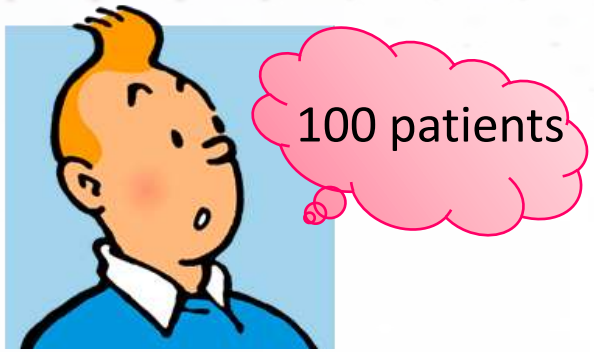
What about Luminor-iVolution combination…

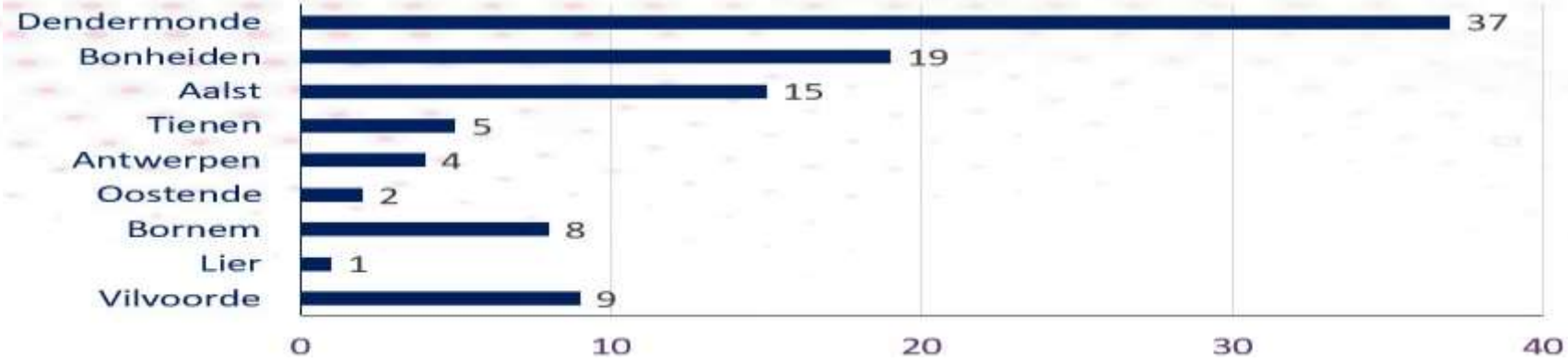
*OUTSTANDING DCB
*PROVEN SCAFFOLD
*NEED FOR REAL LIFE LESIONS
*IMPROVEMENT LONGER TERM DATA



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

Physician-initiated trial investigating the safety and efficacy of the Treatment with the LumINor DCB (0,018/0,035) & The IvolutioN stent of iVascular in TASC C and D femoropopliteal lesions





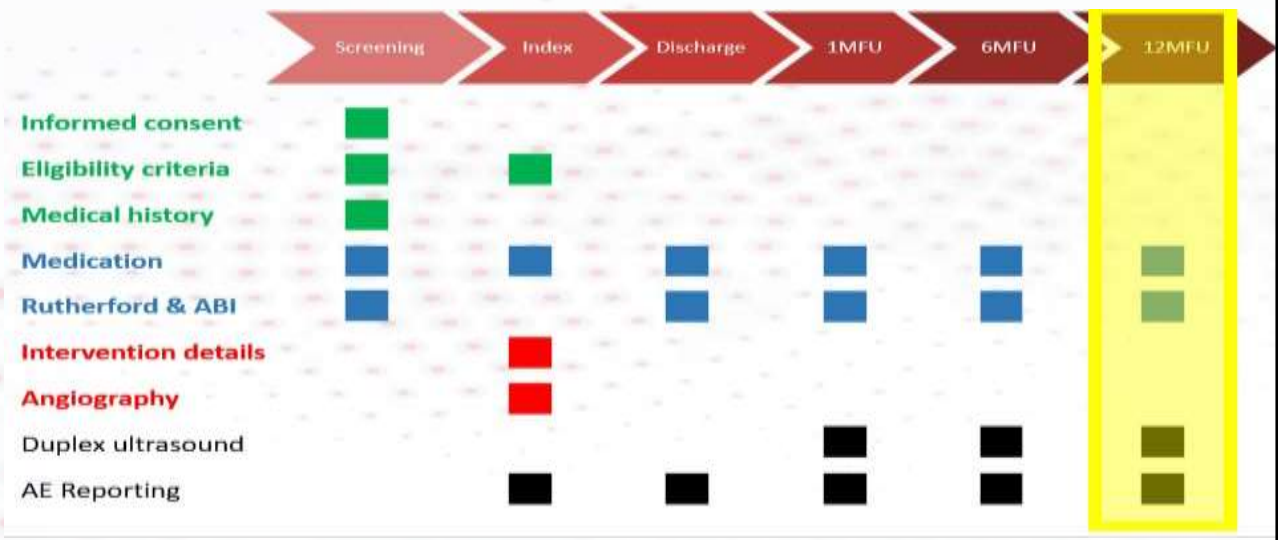
T.I.N.T.I.N.

Primary Endpoint

- *Freedom from CD-TLR @ 12 months*

Secondary Endpoints

- *Primary patency* @6-12 months(DUS PSVR<2,5)
- *Technical success* (angiographical RS<30%)
- *Freedom from CD-TLR* @6-12 months
- *Clinical success*: improvement of RB classification
- *Serious adverse events* @30 days
- *Survival @ 6 & 12 months*



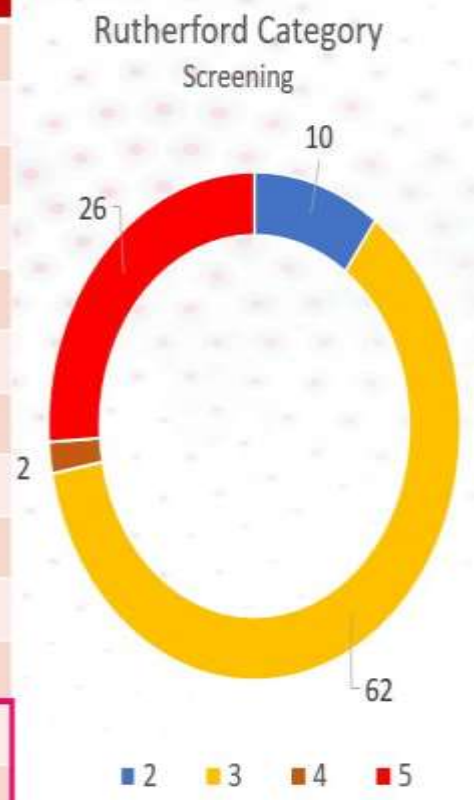
- Rutherford 2 – 5
- De novo,post PTA
- TASC II C or D
- TLL ≥ 150mm
- >50% stenosis
- 4mm < Ø < 6,5mm
- 1 vessel Patent run-off

- Stent Presence in TL
- Untreatable inflow lesion
- Previous surgery in TV
- Aneurysm in SFA or PA
- Major amputation
- Debulking technologies

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

PATIENT 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%)



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%)

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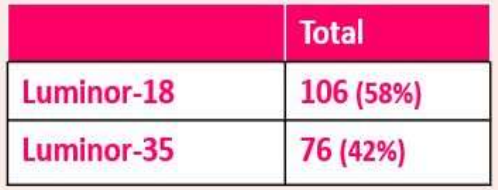
PROCEDURAL CHARACTERISTICS

	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 predilatation balloon (min-max ± SD)	156.53mm (40mm – 220mm ± 42.95mm)

	N = 100 out of 100
Mean # Luminors used per procedure	1.82 (1 – 4 ± 0.73)
Luminor 18 - 35	
Diameter Luminor (min-max ± SD)	5.29mm (4mm – 6mm ± 0.46mm)
VD 5.50mm	
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

	Total
Luminor-18	106 (58%)
Luminor-35	76 (42%)

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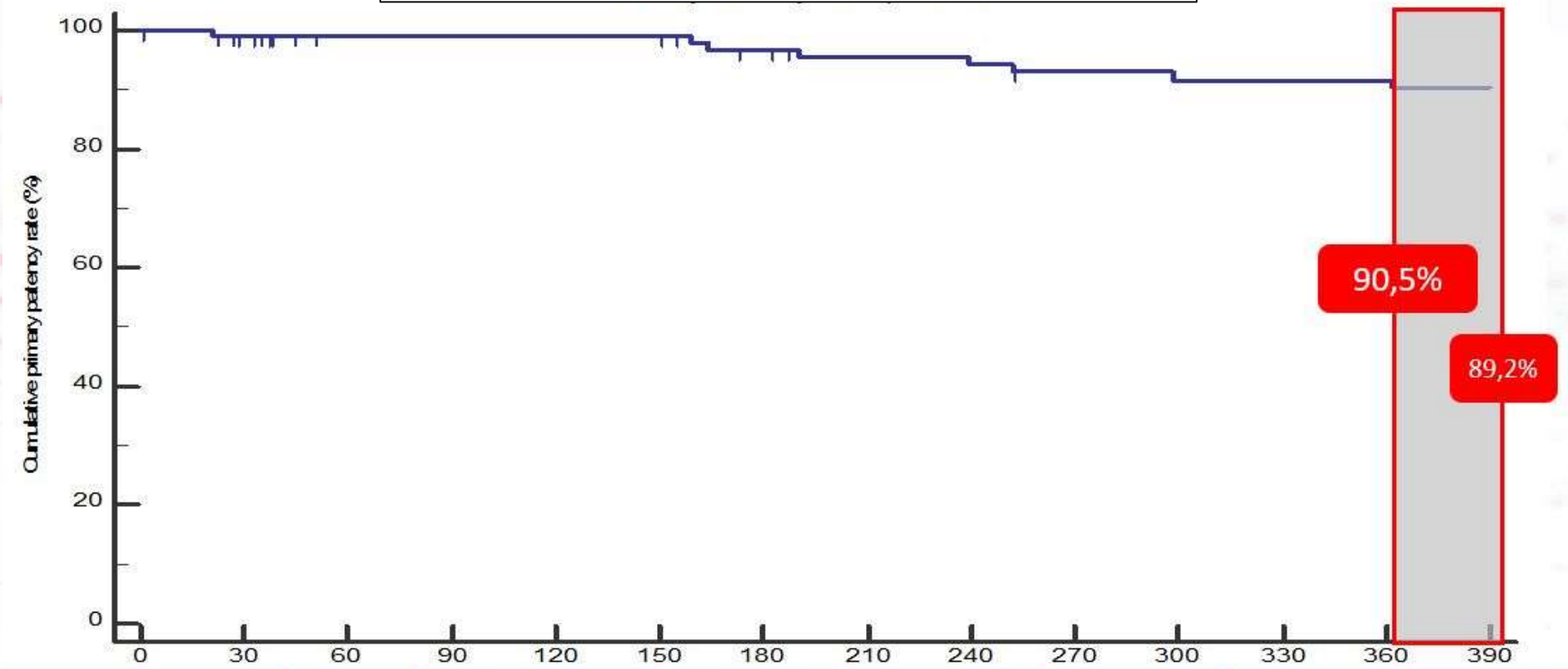
PRIMARY PATENCY @12M – 100 PT



time	baseline	1MFU (30 days)		6MFU (180 days)	6MFU (210 days)		12MFU (365 days)	12MFU (395 days)
at risk	100	93		81	78		73	4
%	100	99		96,5%	95,0%		90,5%	89,2%

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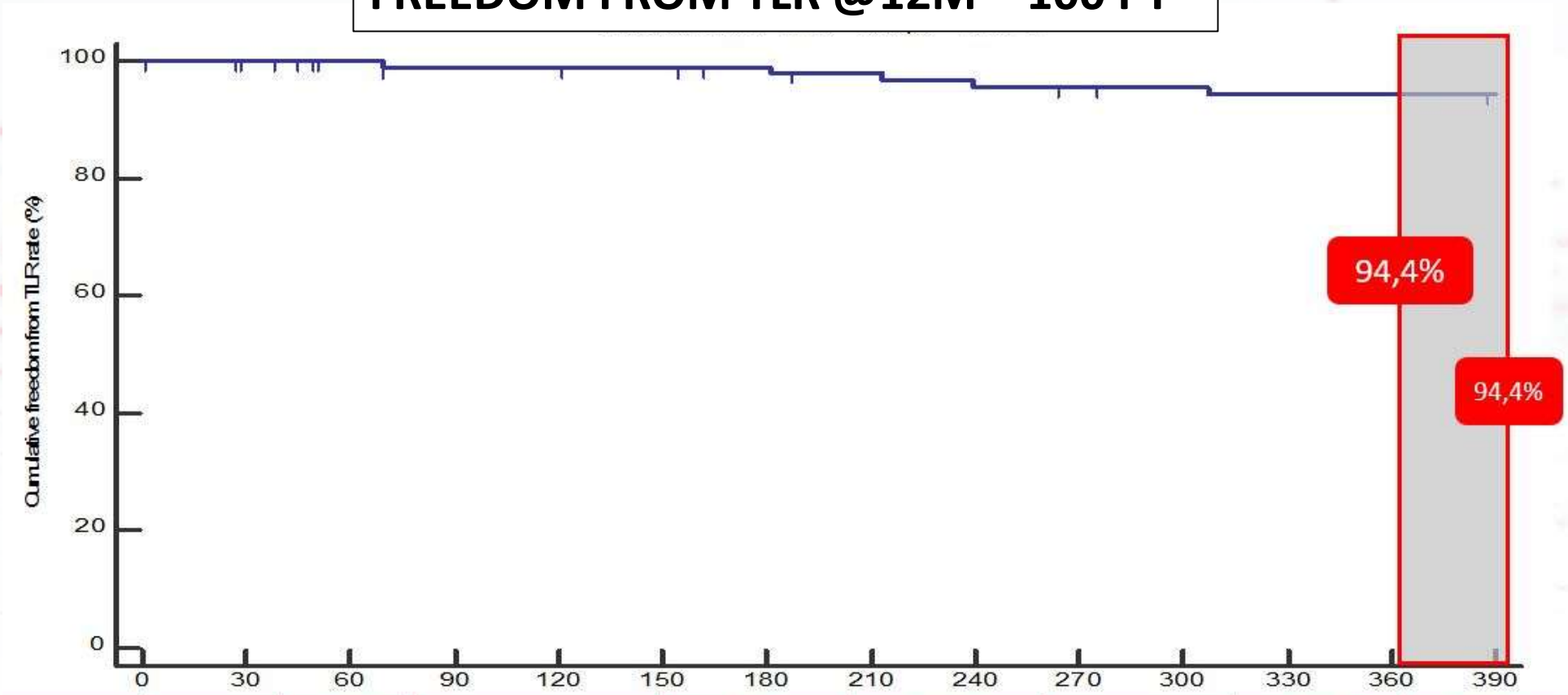
FREEDOM FROM TLR @12M – 100 PT



time	baseline	1MFU (30 days)		6MFU (180 days)	6MFU (210 days)		12MFU (365 days)	12MFU (395 days)
at risk	100	93		81	78		81	10
%	100	100%		98,9%	97,7%		94,4%	94,4%

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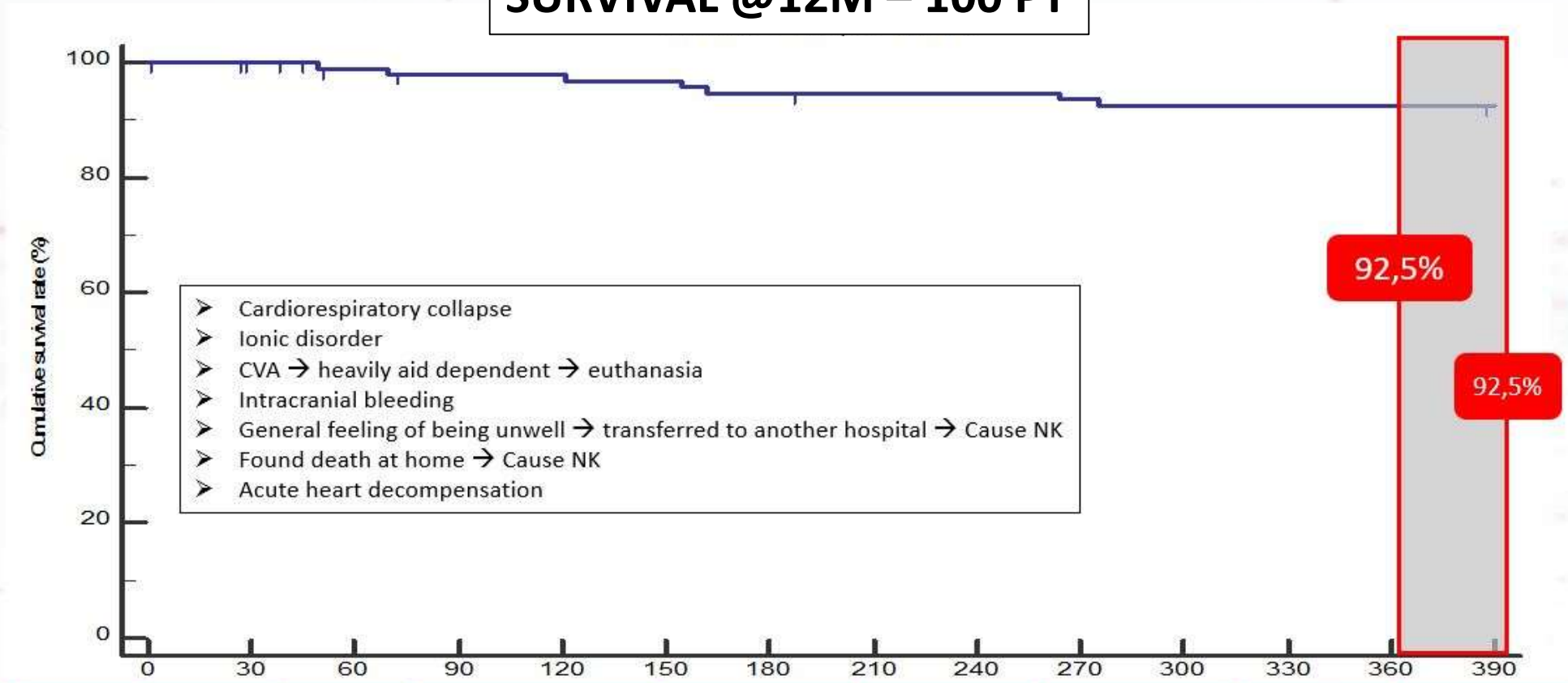
SURVIVAL @12M – 100 PT



time	baseline	1MFU (30 days)		6MFU (180 days)	6MFU (210 days)		12MFU (365 days)	12MFU (395 days)
at risk	100	97		88	87		85	10
%	100	100%		94,6%	94,6%		92,5%	92,5%

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SAFETY PROFILE – 100 PT

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	180 days	210 days	365 days	395 days
Death (N)	5	5	7	7
CD-TLR (N)	1	2	5	5
Target limb major amputation (N)	0	0	0	0
Thrombosis (N)	1	1	1	1

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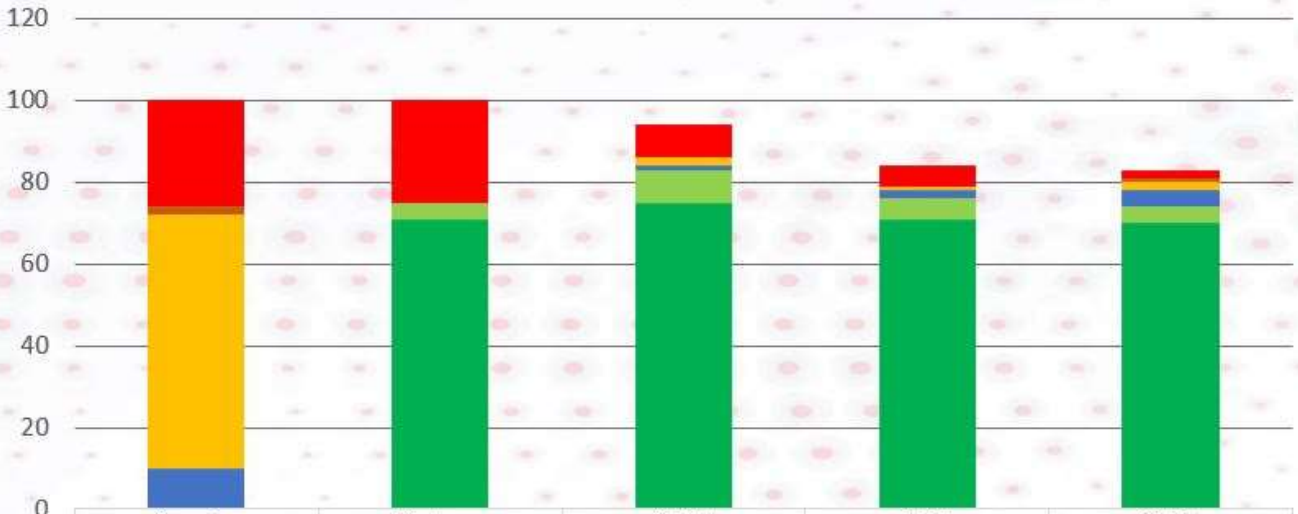
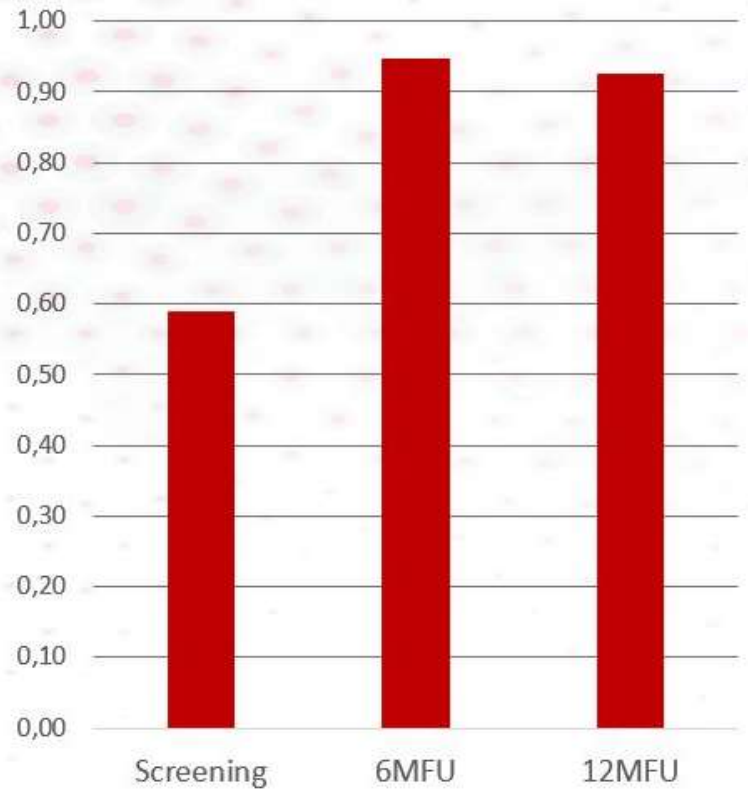
CLINICAL OUTCOMES @12 M – 100 PT

Rutherford

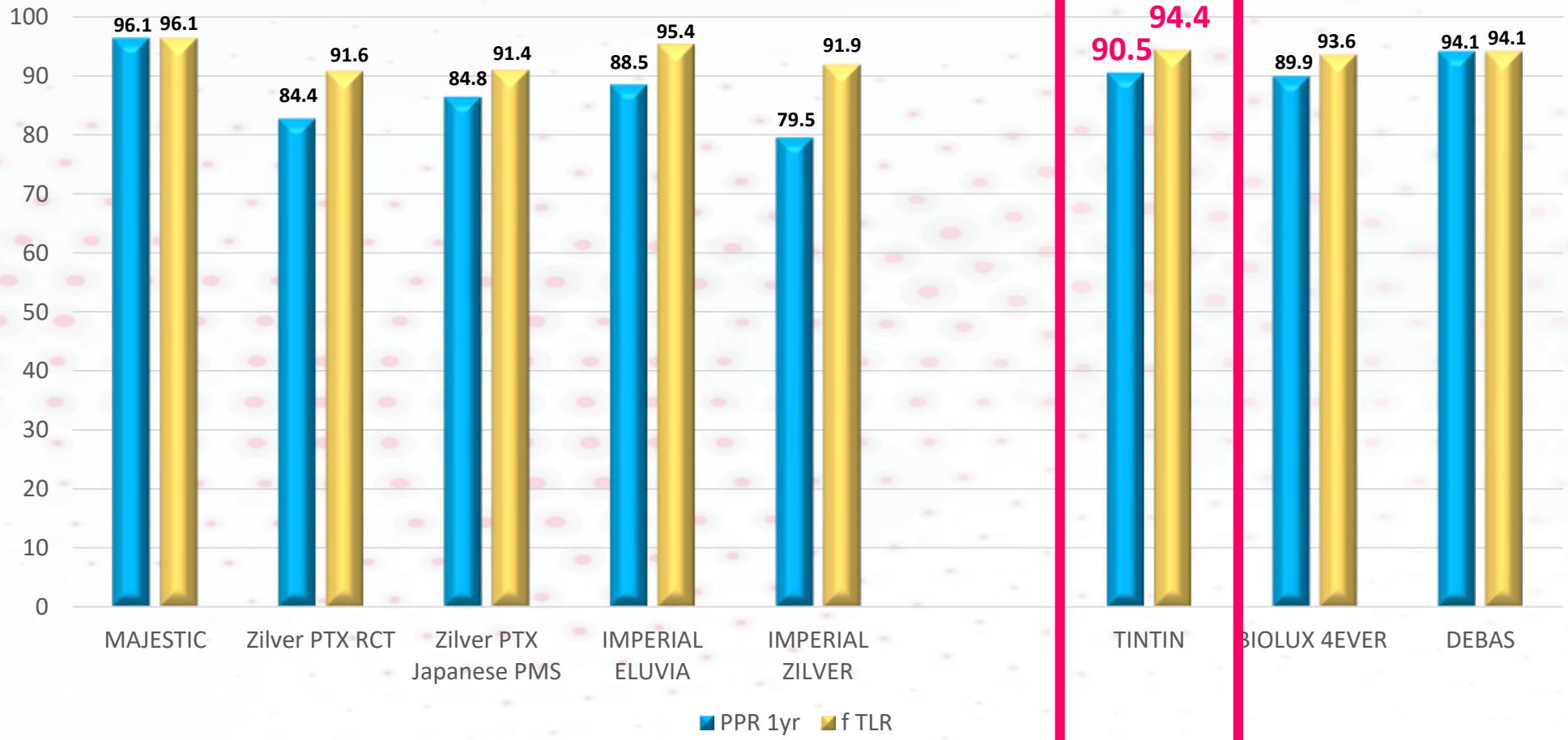


	Screening	Discharge	1MFU	6MFU	12MFU
6	0	0	0	0	0
5	26	25	8	5	2
4	2	0	0	0	1
3	62	0	2	1	2
2	10	0	1	2	4
1	0	4	8	5	4
0	0	71	75	71	70

Mean ABI



Benchmarking with others….



LL (cm)	7,0	5,5	14,7	8,6	8,2	24,3	8,3	18,7
PSVR (≤)	2,5	2,0	2,4	2,4	2,4	2,5	2,5	2,5

Summary

- iVolution BMS (iVascular) shows 76,7% primary patency rate and 77,2% freedom from TLR @2 year (Evolution trial) in TASC A/B lesions
- Luminor DCB (iVascular) shows 90,2% primary patency rate and 97,2% freedom from TLR @2year (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 & on the longer run
- The combination of both is one of the keys to success in real life lesion treatment
- Belgian T.I.N.T.I.N. trial shows impressive 12 months results in lesions of 24 cm and 30% CLI patients : primary patency of 90,5% and freedom from TLR of 94,4%. The safety profile up to 1 year is excellent
- Benchmarking of this combination with DES shows equivalent results, but in much longer lesions

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