FMRP
Flanders Medical Research Program

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ReFlow

How can we improve treatment of long femoropopliteal lesions with DCB?

Dr. Marc Bosiers
LINC 2018 , Leipzig

Conflict of interest

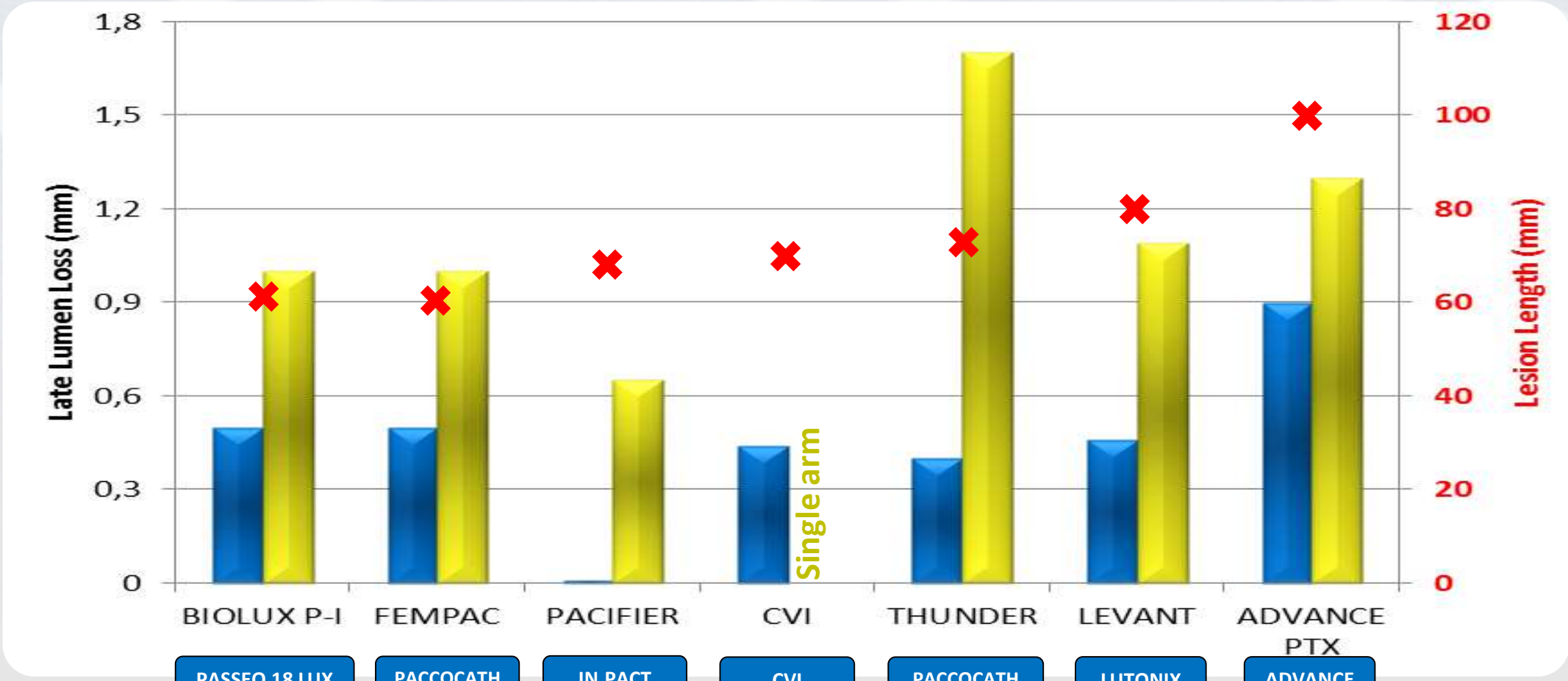
☐ have the following potential conflicts of interest to report:

- ☐ Consulting:
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☑ I do not have any potential conflict of interest

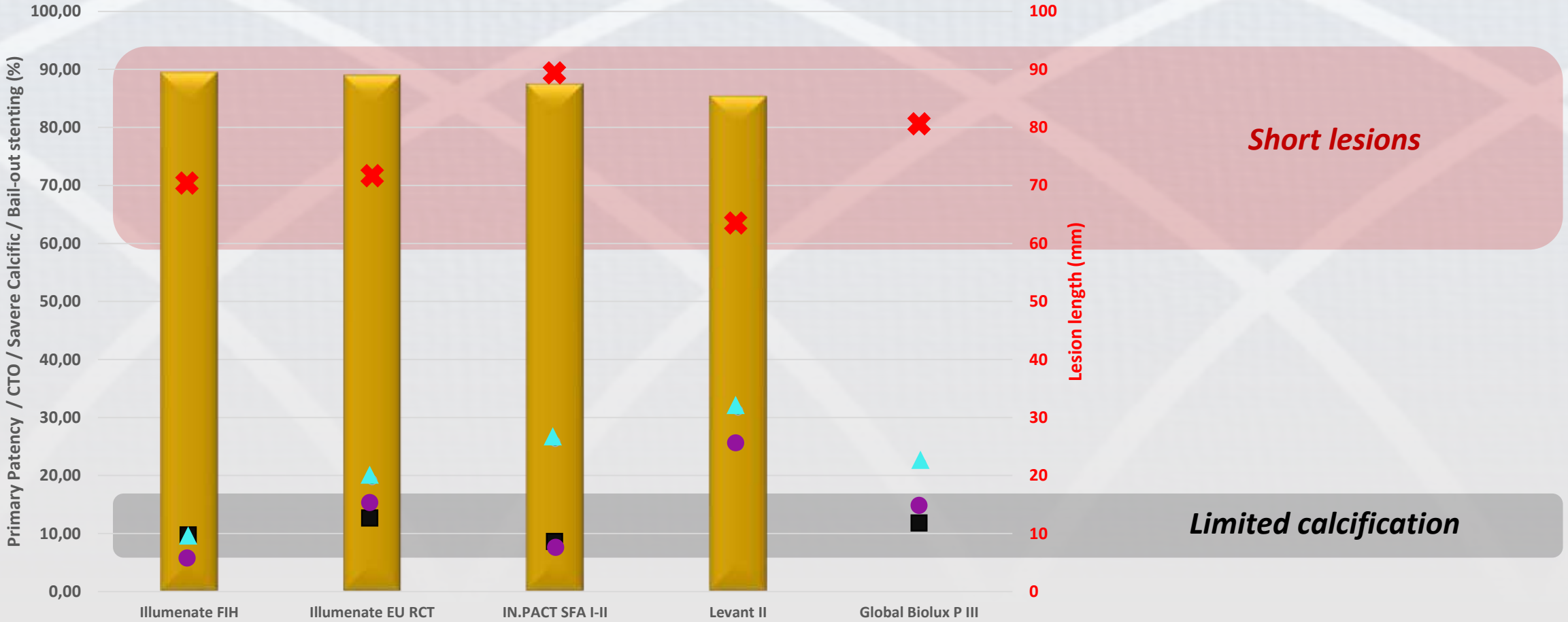
DCB-treatment works… Proof of concepts

DCB POBA



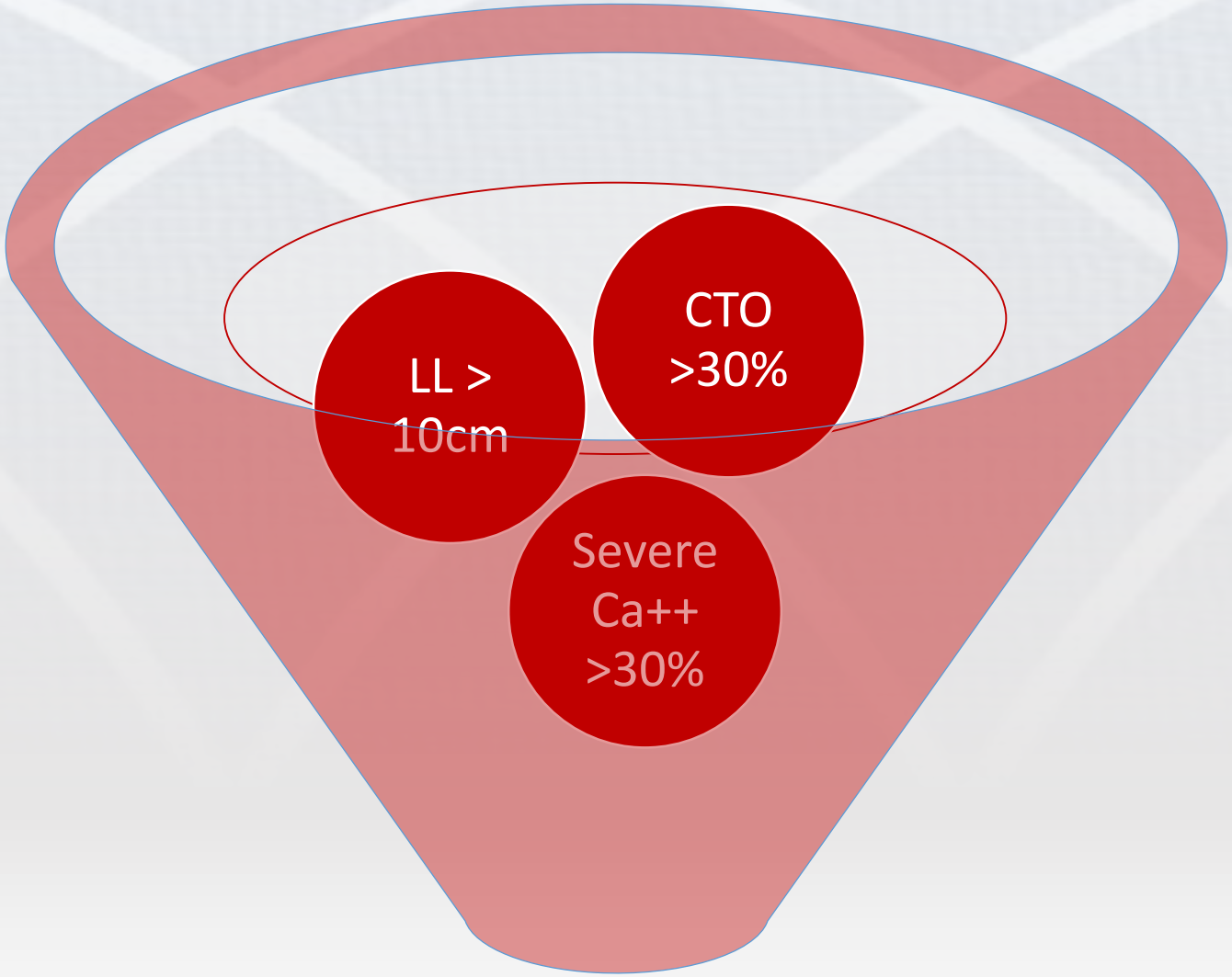
PASSEO 18 LUX	PACCOCATH	IN.PACT	CVI	PACCOCATH	LUTONIX	ADVANCE
PTX 3µgr/mm² + BTHC	PTX 3µgr/mm² + Ultravist	PTX 3,5µgr/mm² + Urea	PTX Excipient?	PTX 3µgr/mm² + Ultravist	PTX 2µgr/mm² + polysorbate & sorbitol	PTX 3µgr/mm² No excipient
P=0.033	P=0.031	P=0.001		P<0.001	P=0.016	P=0.12

1-Year Patency Rates of DCB (in ideal circumstances)



	Illumenate FIH	Illumenate EU RCT	IN.PACT SFA I-II	Levant II	Global Biolux P III
Primary Patency (%)	89.50	89.00	87.50	85.40	N.A.
Lesion Length (mm)	70	72	89.4	62.9	80.4
% Bail-out stenting	6	15.4	7.3	25.2	14.5
% CTO	9.4	19.2	25.8	31.2	22.1
% Severe Ca++	9.4	12.7	8.1	N.A.	11.7

However in “Real Life”



REFLOW study

A study investigating the Efficacy of the LEGFLOW Paclitaxel-Eluting for the treatment of long femoropopliteal lesions(TASC C&D)

Legflow Drug Coated Balloon

Study design

- **Study Objective:**
  To evaluate the performance of the **LEGFLOW Paclitaxel-Eluting** Peripheral balloon catheter for the treatment of **long femoropopliteal lesions (TASC C&D)**.

- **Primary Endpoint:**
  Primary Patency at 12 months, defined as absence of a hemodynamically significant stenosis on duplex ultrasound (systolic velocity ratio ≤2.4) at the target lesion and without reintervention.

Participating centers

- **BELGIUM**
  - M. Bosiers, K. Deloose, J. Callaert - AZ Sint-Blasius, Dendermonde
  - P. Peeters, J. Verbist, W. Van den Eynde - Imelda Hospital, Bonheiden
  - L. Maene, R. Beelen - OLV, Aalst
  - K. Keirse - RZ Heilig Hart, Tienen
  - J. Hendriks, P. Lauwers – University Hospital Antwerp, Edegem

- **GERMANY**
  - G. Torsello – St. Franziskus-Hospital Münster
  - D. Scheinert – Universitätsklinikum Leipzig

Inclusion criteria

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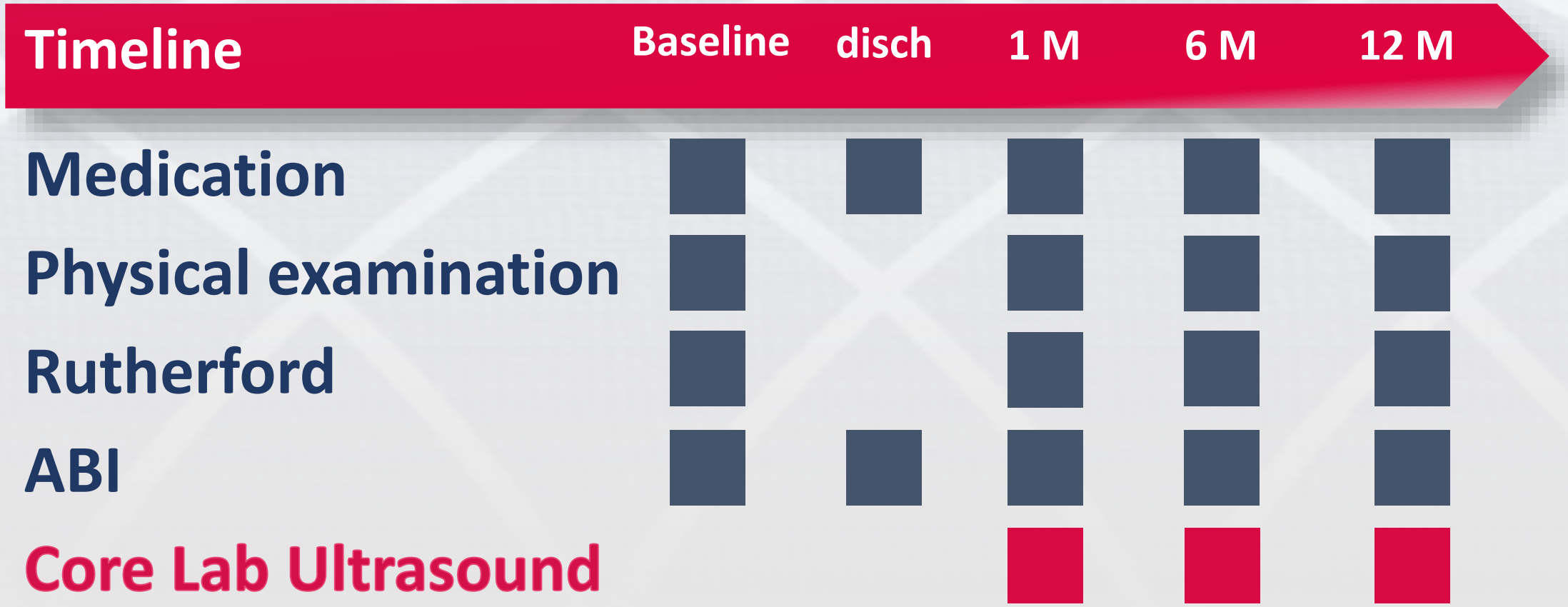
101 out of 120 patients enrolled (84%)

Main inclusion criteria

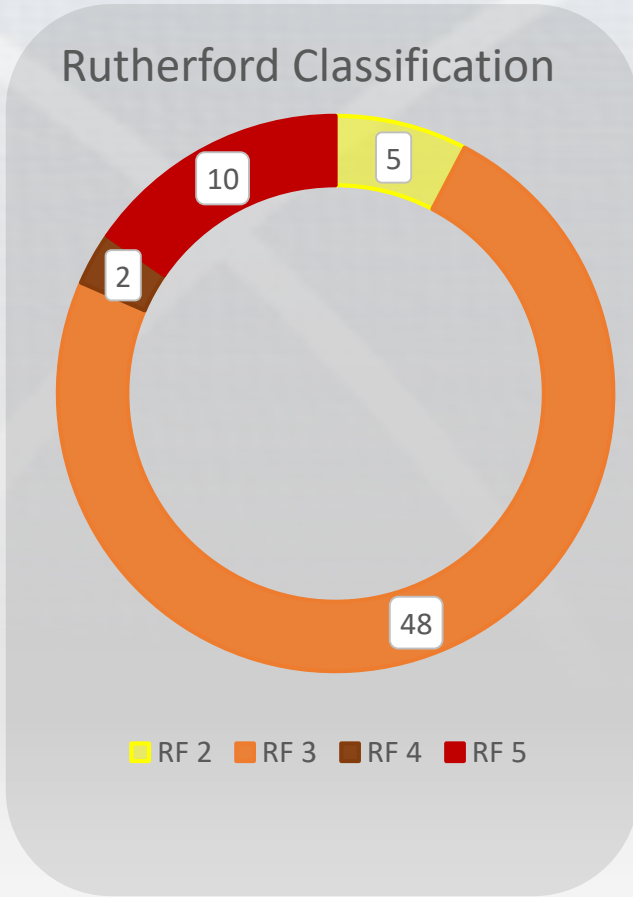
- **Rutherford classification from 2 to 5**
- **De novo lesion** in the femoropopliteal arteries, suitable for endovascular therapy
- Total target lesion length **> 150mm**

Study overview



Patient Demographics

	N = 65 out of 120
Male *(%)*	43 *(66.15%)*
Age *(min – max)*	70.01 *(35.05 – 89.27) years*
Nicotine abuse *(%)*	39 *(60.00%)*
Hypertension *(%)*	49 *(75.38%)*
Diabetes mellitus *(%)*	**20** *(30.77%)*
Renal insufficiency *(%)*	9 *(13.85%)*
Hypercholesterolemia *(%)*	36 *(55.38%)*
Obesity *(%)*	13 *(20.00%)*



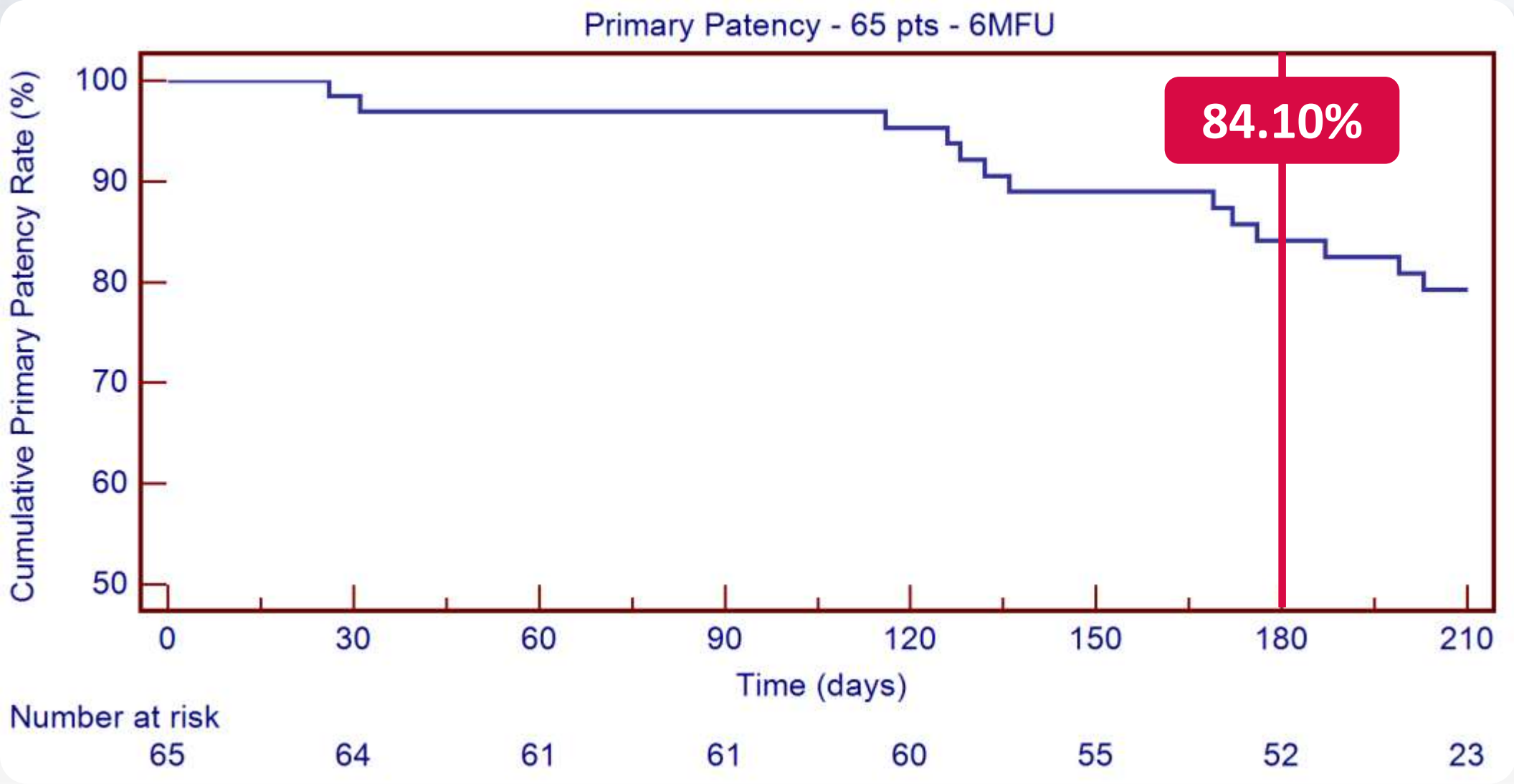
Procedural characteristics

	N = 65 out of 100
Procedure time ***(min-max)***	***49.06*** ***(20-115) minutes***
Scopy time *(min – max)*	11.70 *(3 – 38.50) minutes* **missing information for 1 patient*
Contrast *(min – max)*	96.89 *(25 – 195) mL*
Cross-over performed *(%)*	*37 (56.92%)*
Inflow Lesion *(%)*	*5 (7.69%)*
Outflow lesion *(%)*	*14 (21.54%)*

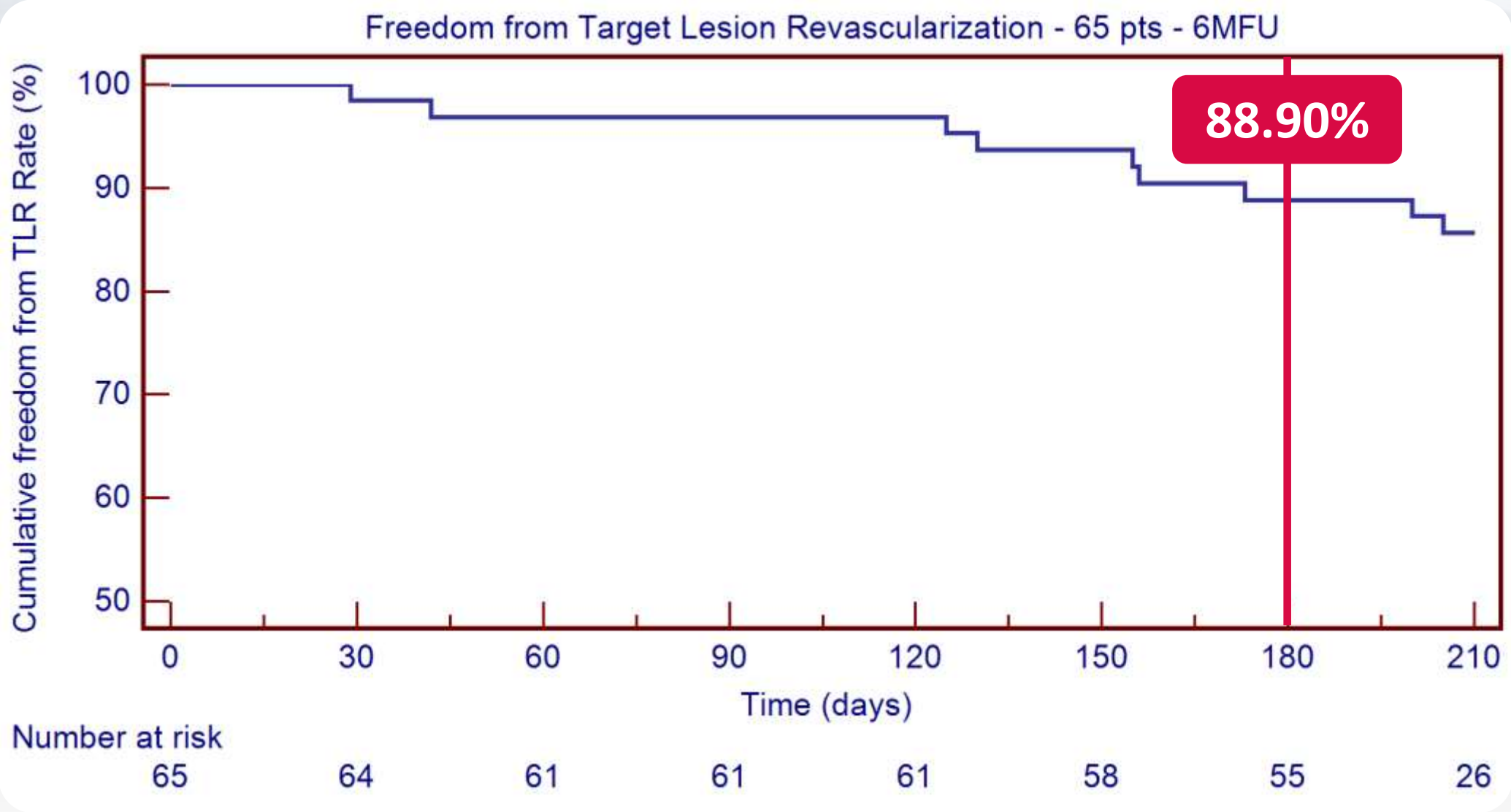
Lesion Characteristics

	N = 65 out of 100
Lesion length ***(min – max)***	**218** ***(150 – 390) mm***
Ref Vessel Diameter *(min – max)*	5.37 *(4.5 – 6.0) mm*
Pre-dilatation (%)	41 (63.08%)
1 DCB (%) 2 DCB's (%) 3 DCB's (%)	16 (24.62%) 37 (56.92%) 12 (18.46%)
Post-dilatation (%)	14 (21.54%)
Bail-out stenting ***(%)***	**13** ***(20.00%)***
Occlusion *(%)*	25 *(31.25%)*
Calcified lesion (%)	**43** ***(53.75%)***

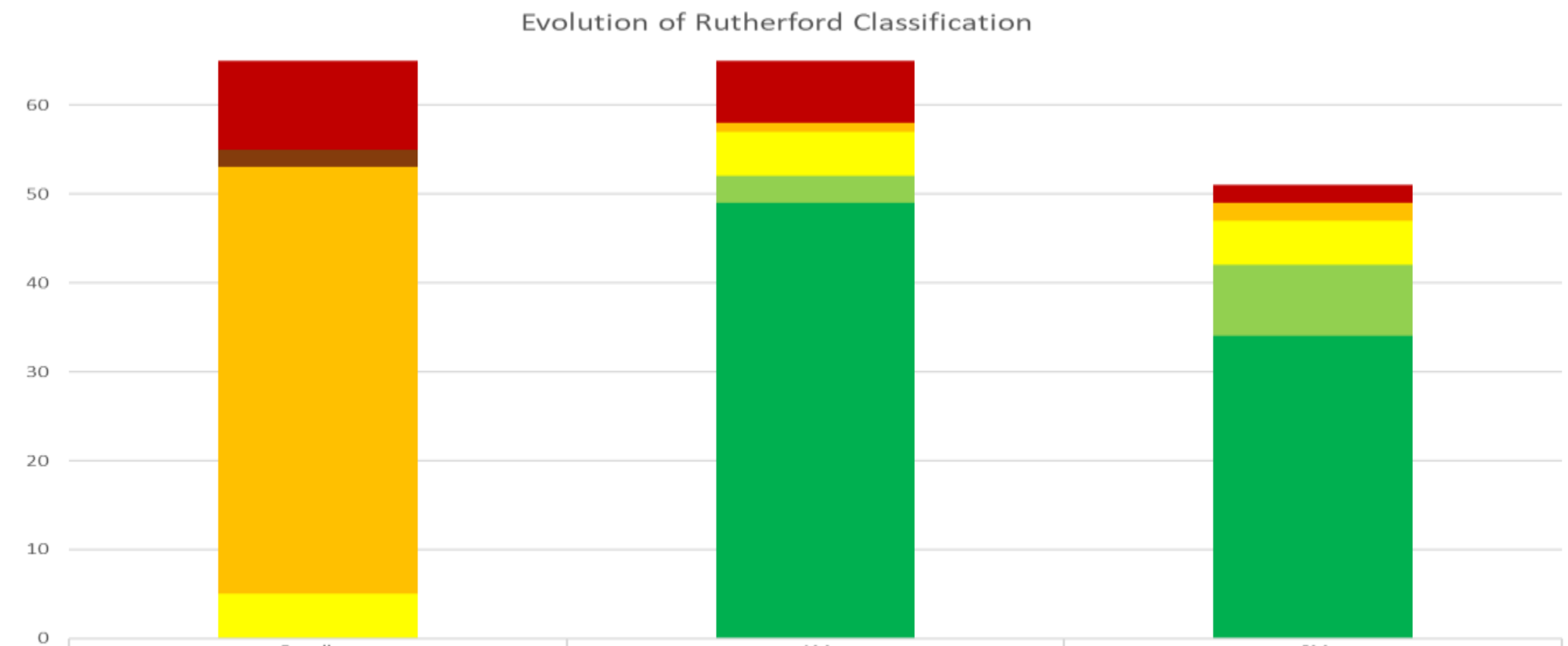
6-month Primary Patency – 65 pts



6-month Freedom from TLR – 65 pts



6-month Rutherford evolution – 65 pts



	Baseline	1M	6M
RF5	10	7	2
RF4	2	0	0
RF3	48	1	2
RF2	5	5	5
RF1	0	3	8
RF0	0	49	34

Conclusion

- Preliminary results suggest that the LEGFLOW DCB is a valid and **effective** alternative to treat **“real-life”** long, complex and calcified femoropopliteal lesions

- Awaiting for the final 12-month results

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