

Can Legflow improve treatment
of long femoropopliteal lesions:
The REFLOW outcomes

*Dr. Marc Bosiers
LINC 2019 - Leipzig*

FCRE

My disclosures

~~o~~ I do not have any potential conflicts of interest to report

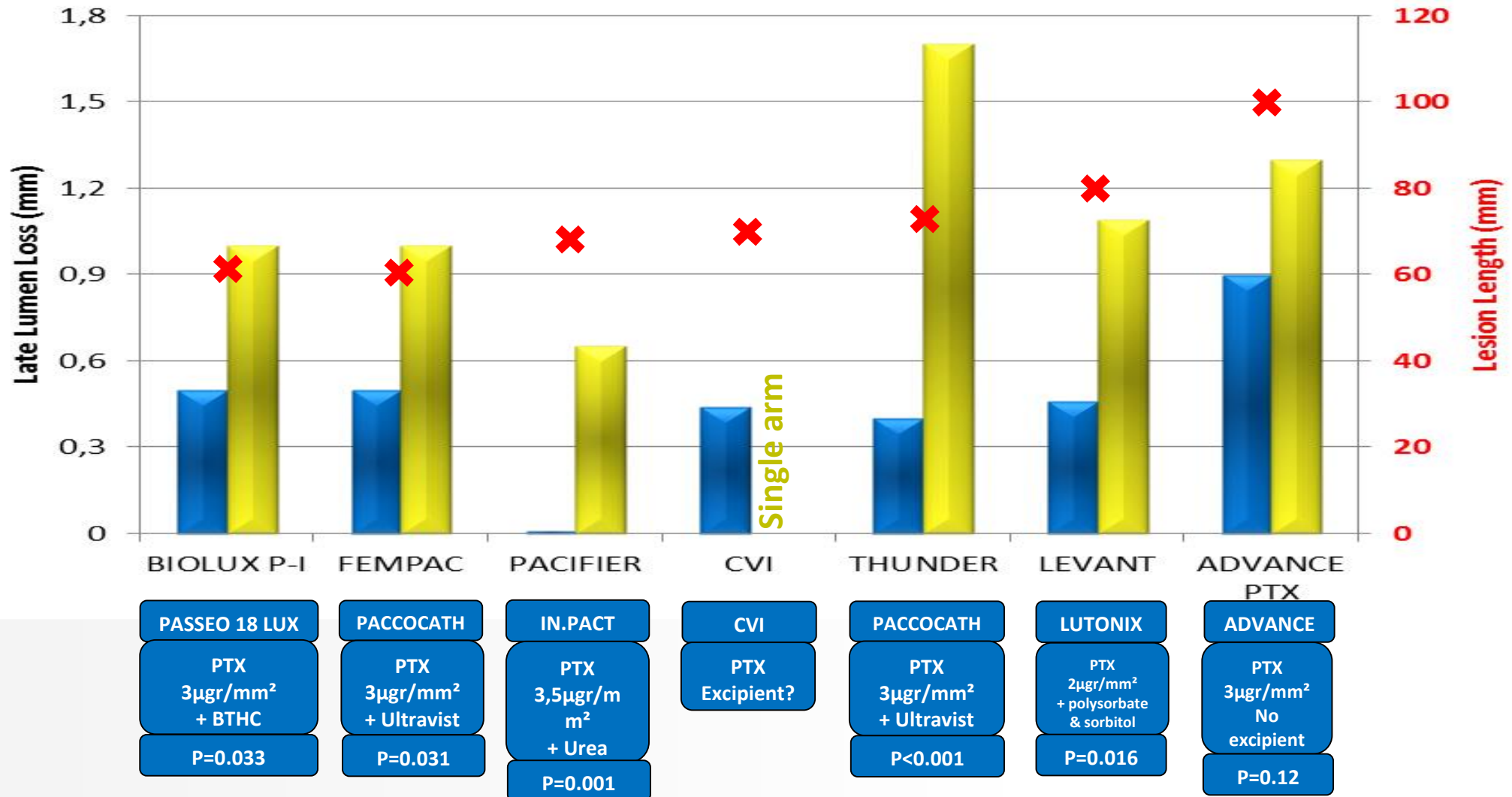
o I have the following potential conflicts of interest to report:

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

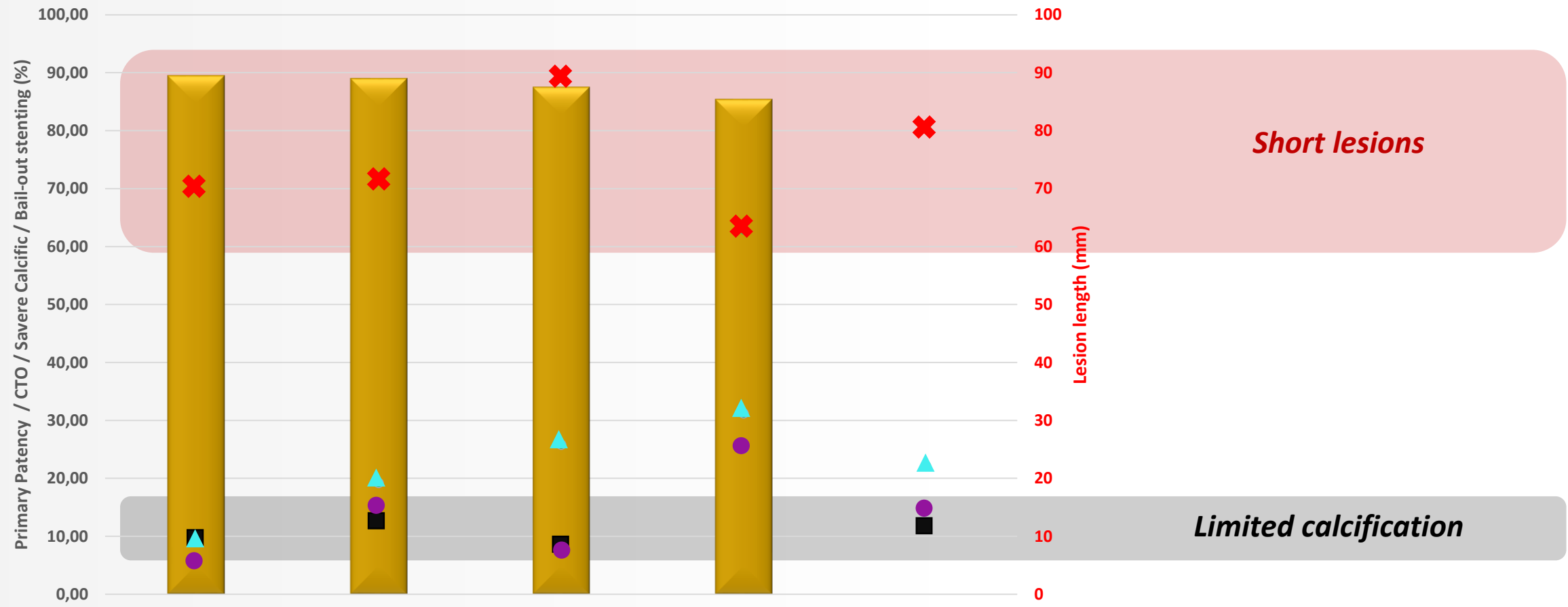
DCB-treatment works... Proof of concepts

DCB

POBA

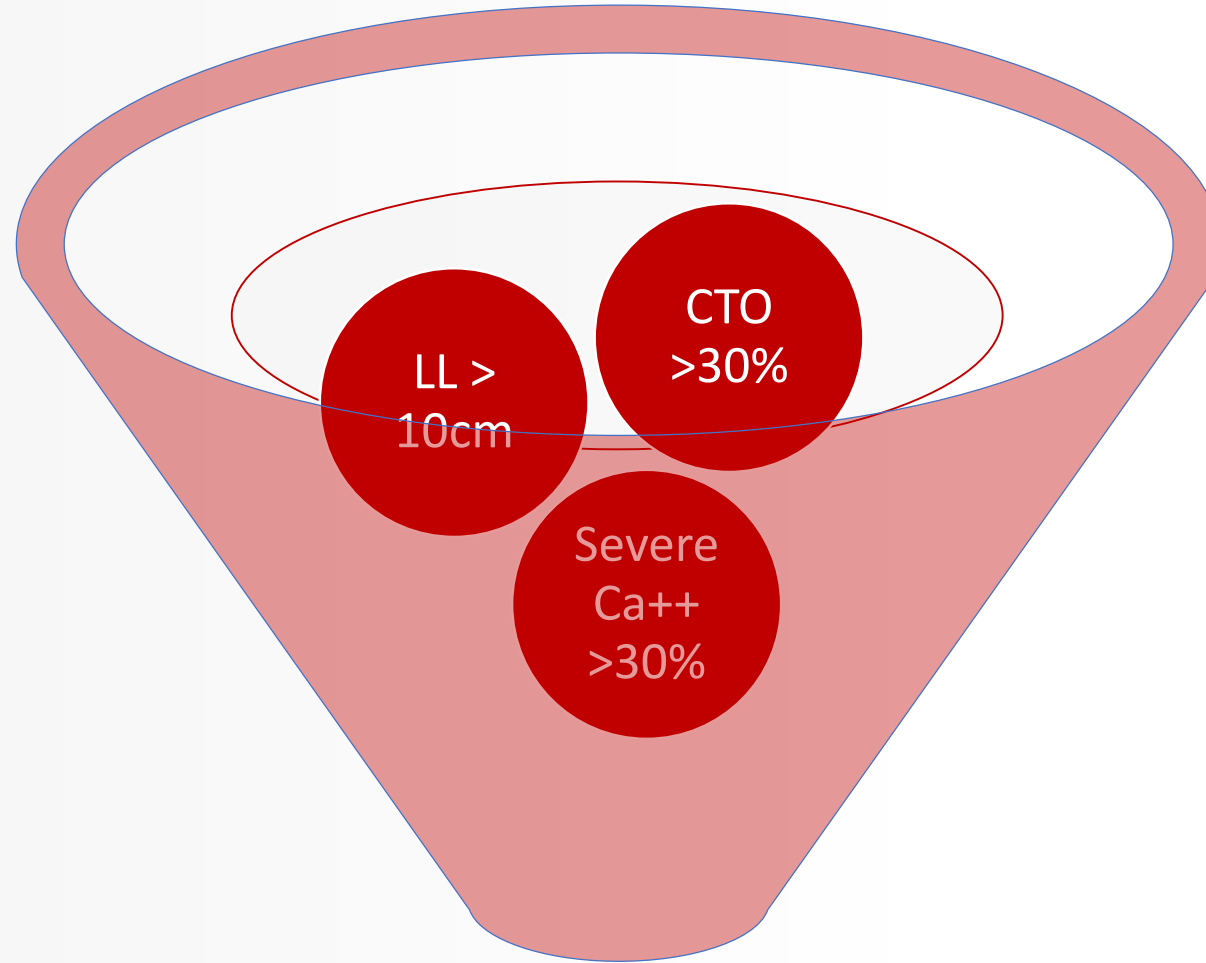


1-Year Patency Rates of DCB (in ideal circumstances)



	Illumenante FIH	Illumenante 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

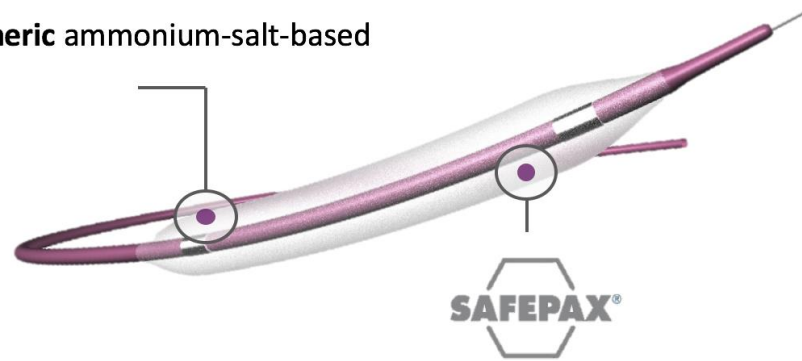


A study investigating the Efficacy of the LEGFLOW
Paclitaxel-Eluting for the treatment of long
femoropopliteal lesions(TASC C&D)

Legflow Drug Coated Balloon

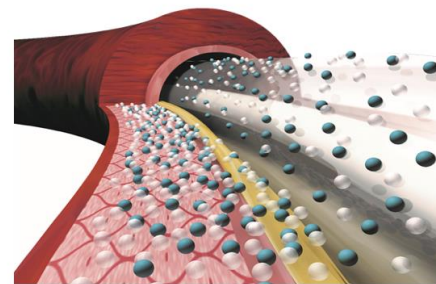
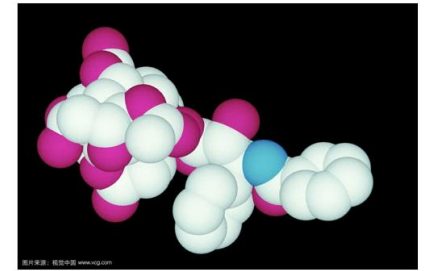
Excipient

-- **lipophilic** and **polymeric ammonium-salt-based**

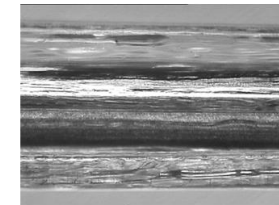


Paclitaxel

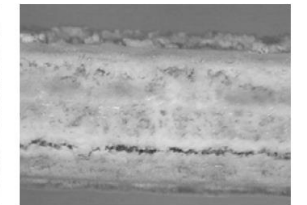
-- 3.0 $\mu\text{g}/\text{mm}^2$



Optical Imaging (100x)



LEGFLOW DCB
Homogeneous, smooth
amorphous coating



Hydrophilic Coating DCB
White powder of brittle
crystalline coating



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



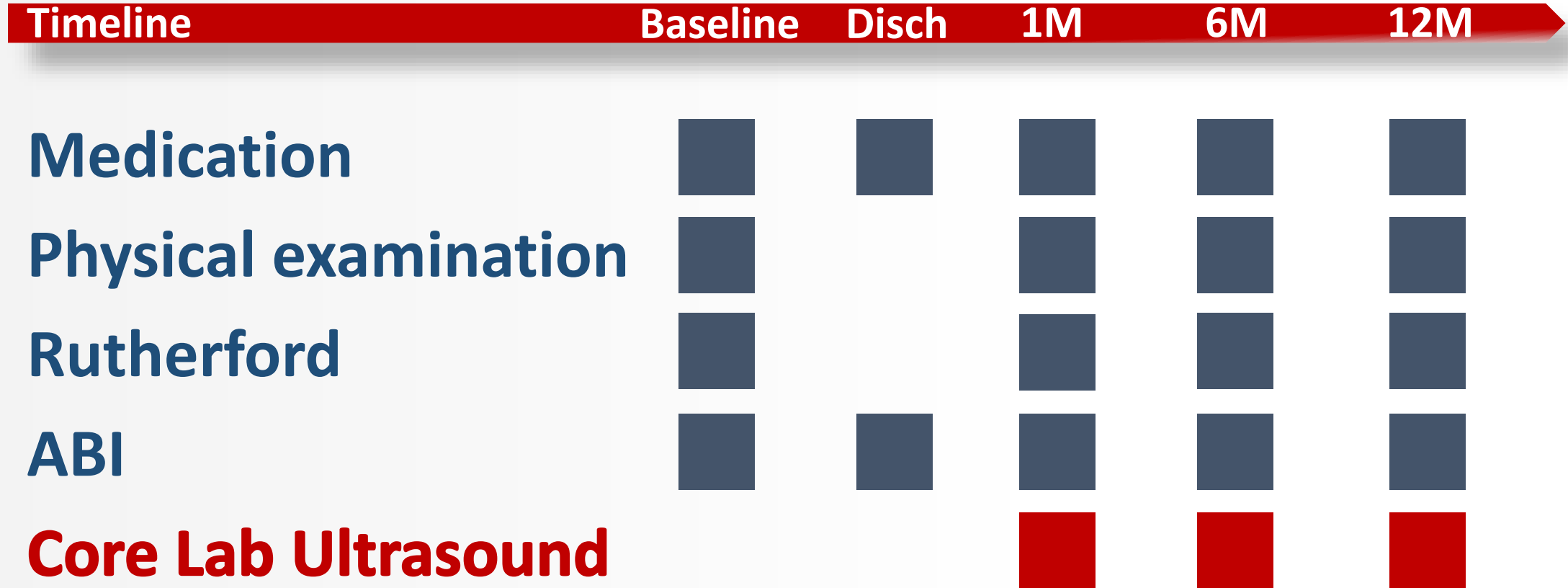
ReFlow

120 out of 120 patients enrolled (100%)

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**

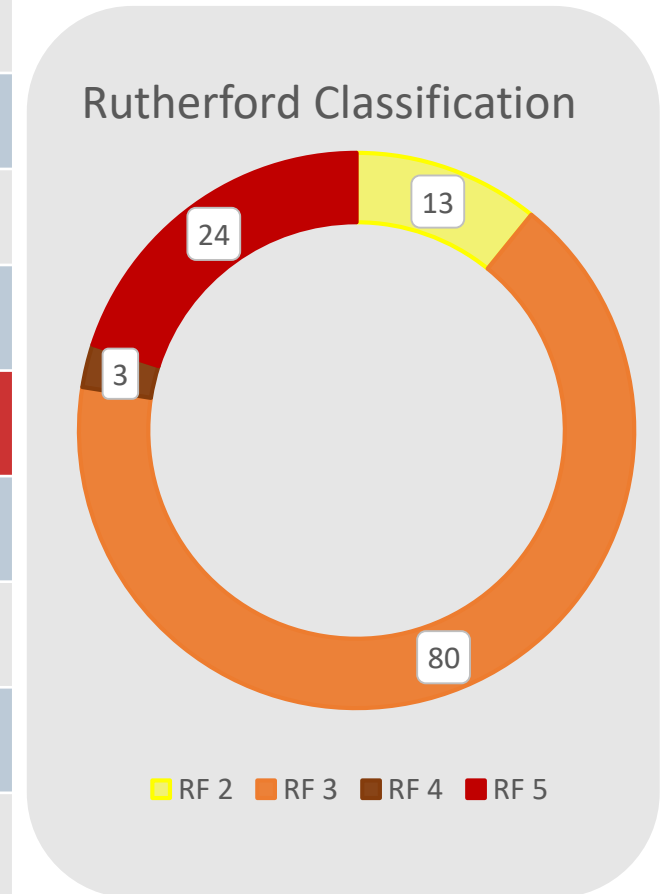
Study overview





Patient Demographics

	N = 120
Male (%)	65.80% (79/120)
Age (min – max)	71.06 (35.05 – 93.16) years
Nicotine abuse (%)	56.67% (68/120)
Hypertension (%)	77.50% (93/120)
Diabetes mellitus (%)	30.00% (36/120)
Renal insufficiency (%)	15.00% (18/120)
Hypercholesterolemia (%)	53.30% (64/120)
Obesity (%)	19.20% (23/120)





Procedural characteristics

	N = 120
Procedure time (min-max)	52.17 (19-165) minutes
Scopy time (min – max)	7.32 (1.7 – 39.24) minutes <i>*missing information for 2 patients</i>
Contrast (min – max)	88.09 (9 – 195) mL
Cross-over performed (%)	83.33% (100/120)
Inflow Lesion (%)	10.83% (13/120)
Outflow lesion (%)	21.67% (26/120)

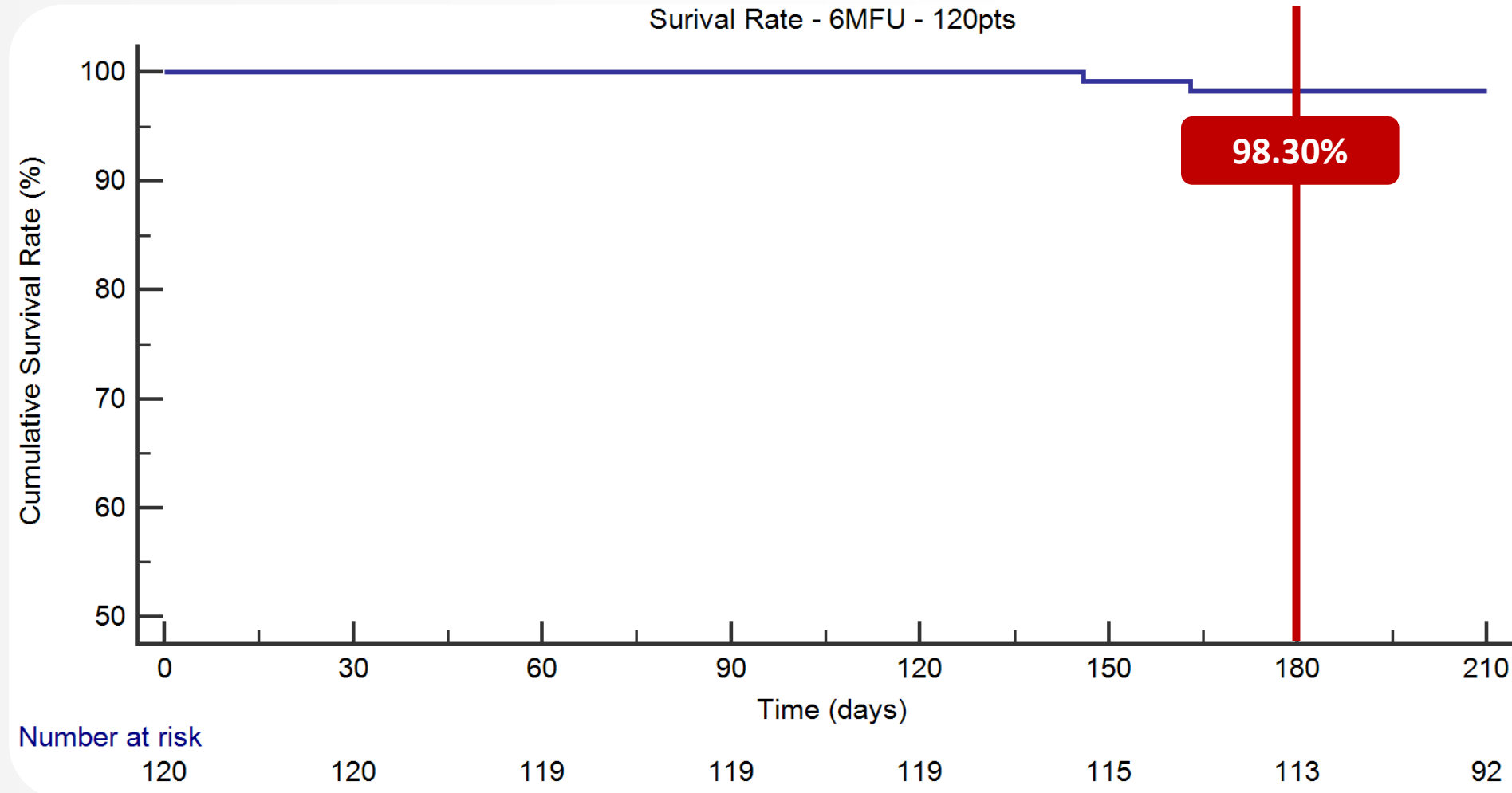


Lesion Characteristics

	N = 120
Lesion length (<i>min – max</i>)	216.08 (150 – 390) mm
Ref Vessel Diameter (<i>min – max</i>)	5.40 (4.05 – 6.00) mm
Pre-dilatation	64.20% (77/120)
1 DCB (%)	25.83% (31/120)
2 DCB's (%)	57.50% (69/120)
3 DCB's (%)	16.67% (20/120)
Post-dilatation (%)	22.50% (27/120)
Bail-out stenting (%)	35.00% (42/120)
Occlusion (%)	45.00% (54/120)
Calcified lesion (%)	67.50% (81/120)

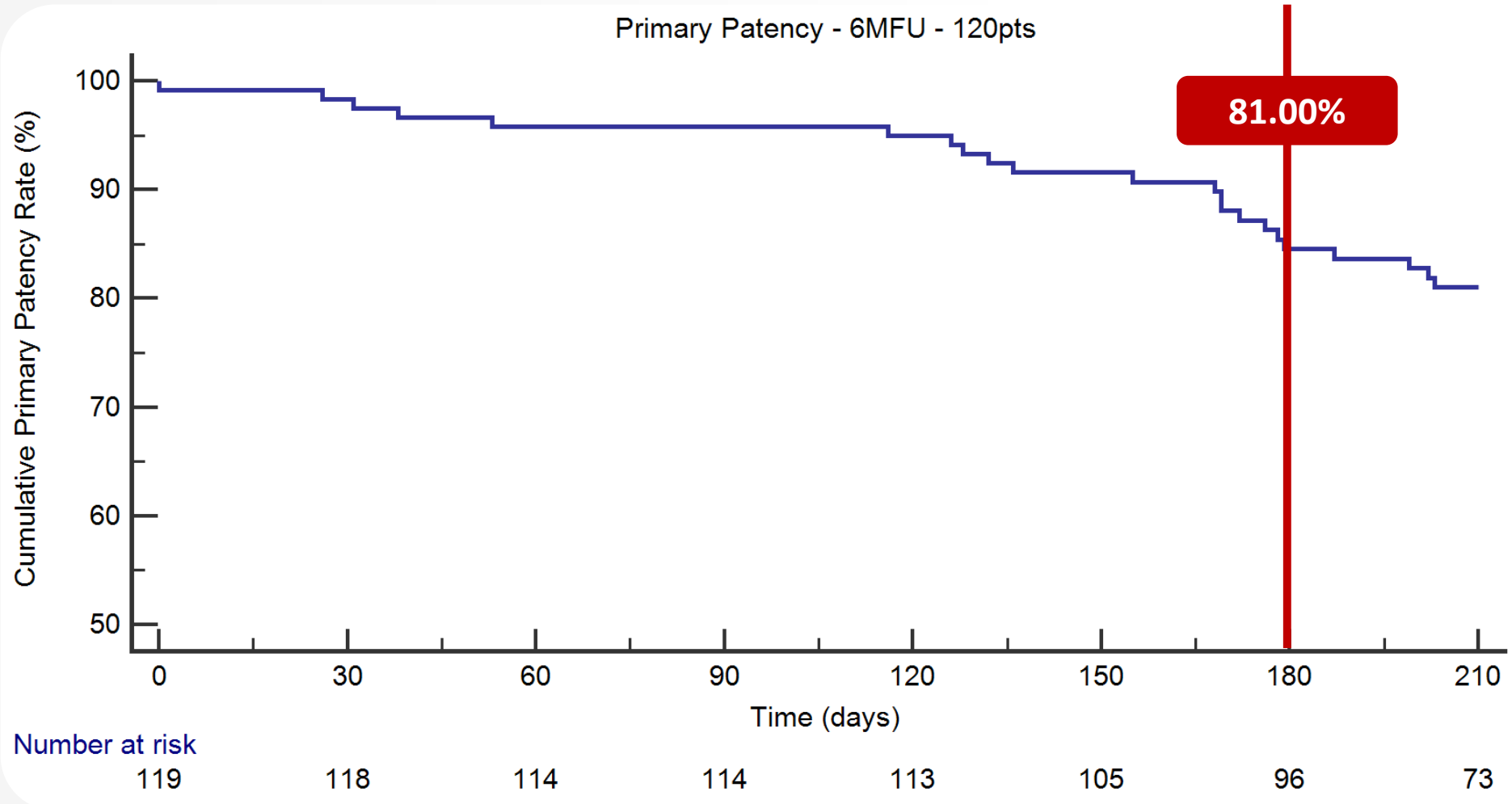


6-month Survival Rate in 120pts



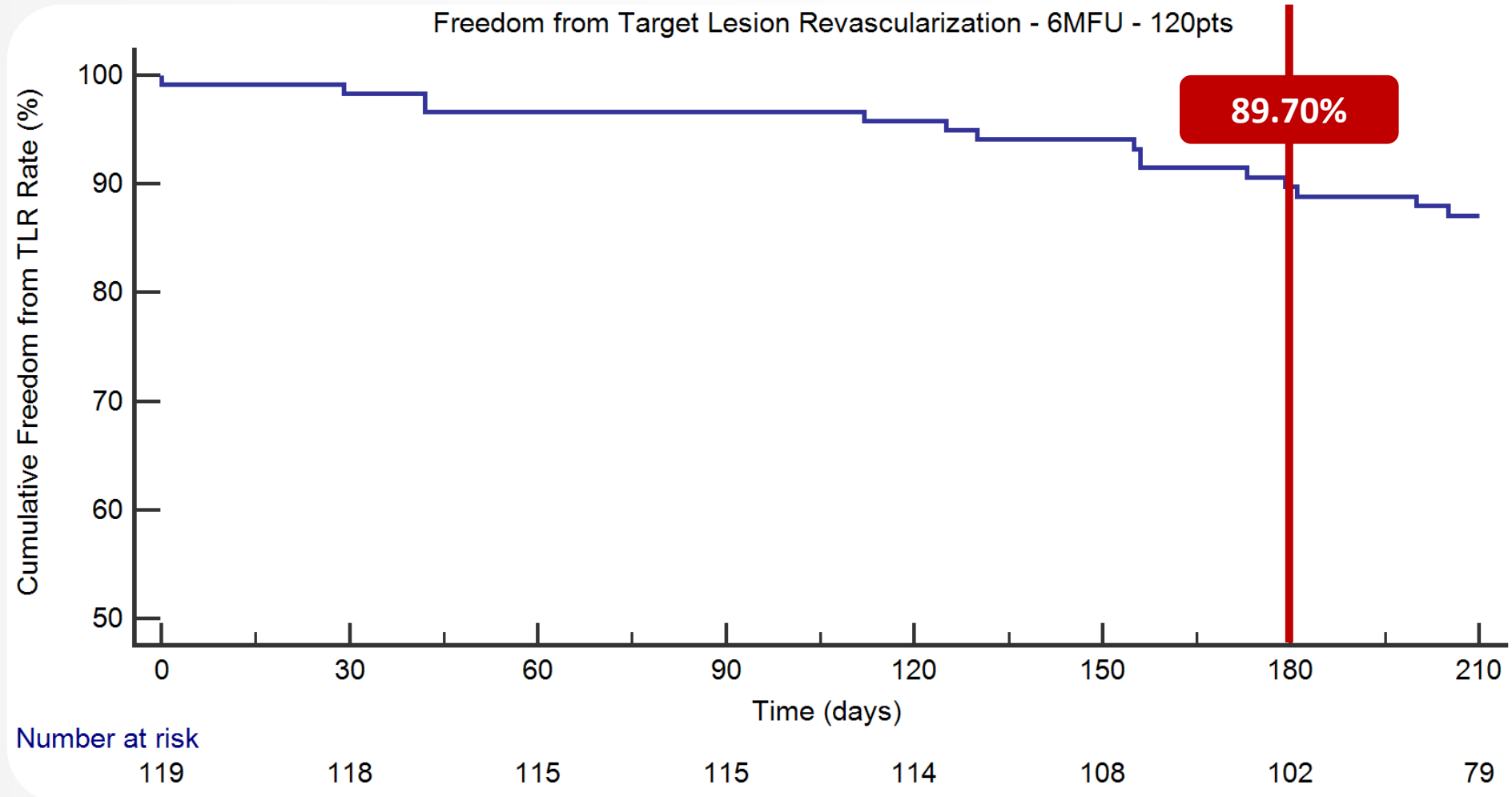


6-month Primary Patency in 120 pts





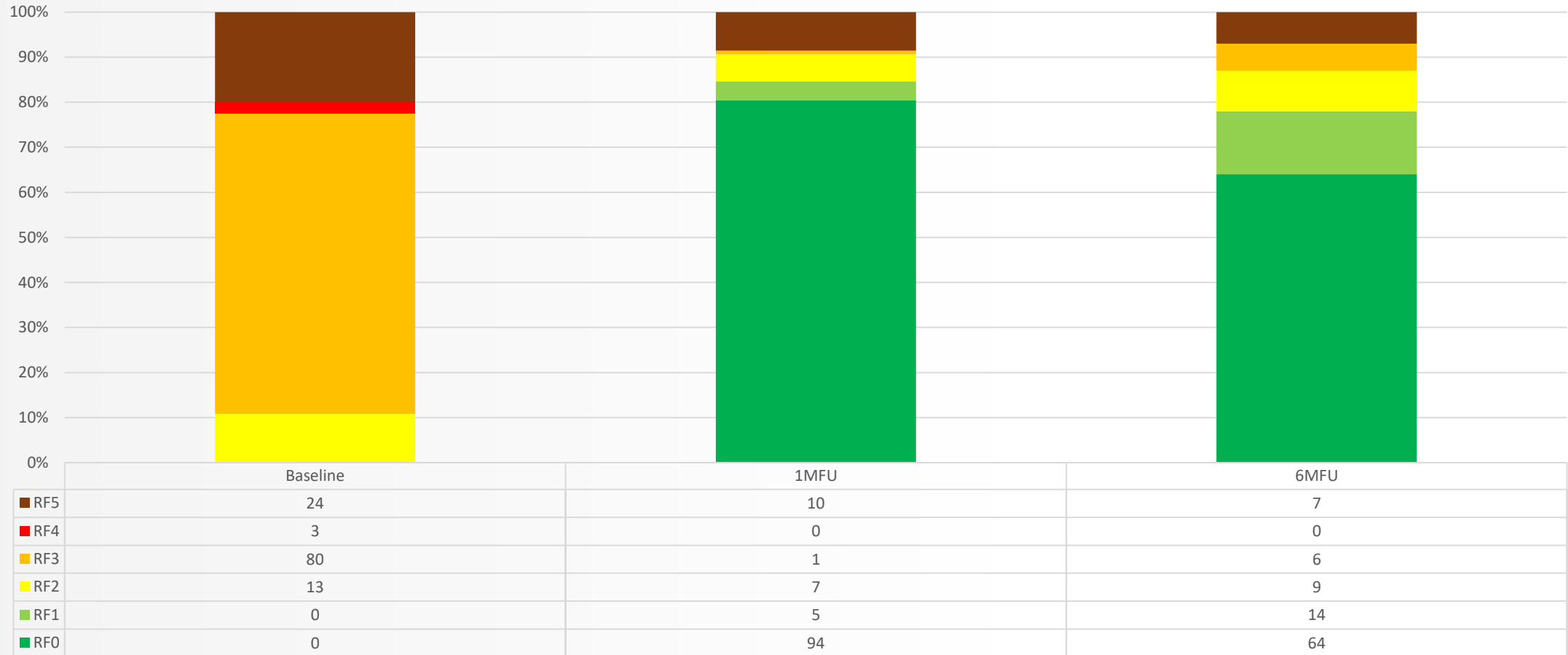
6-month Freedom from TLR in 120 pts



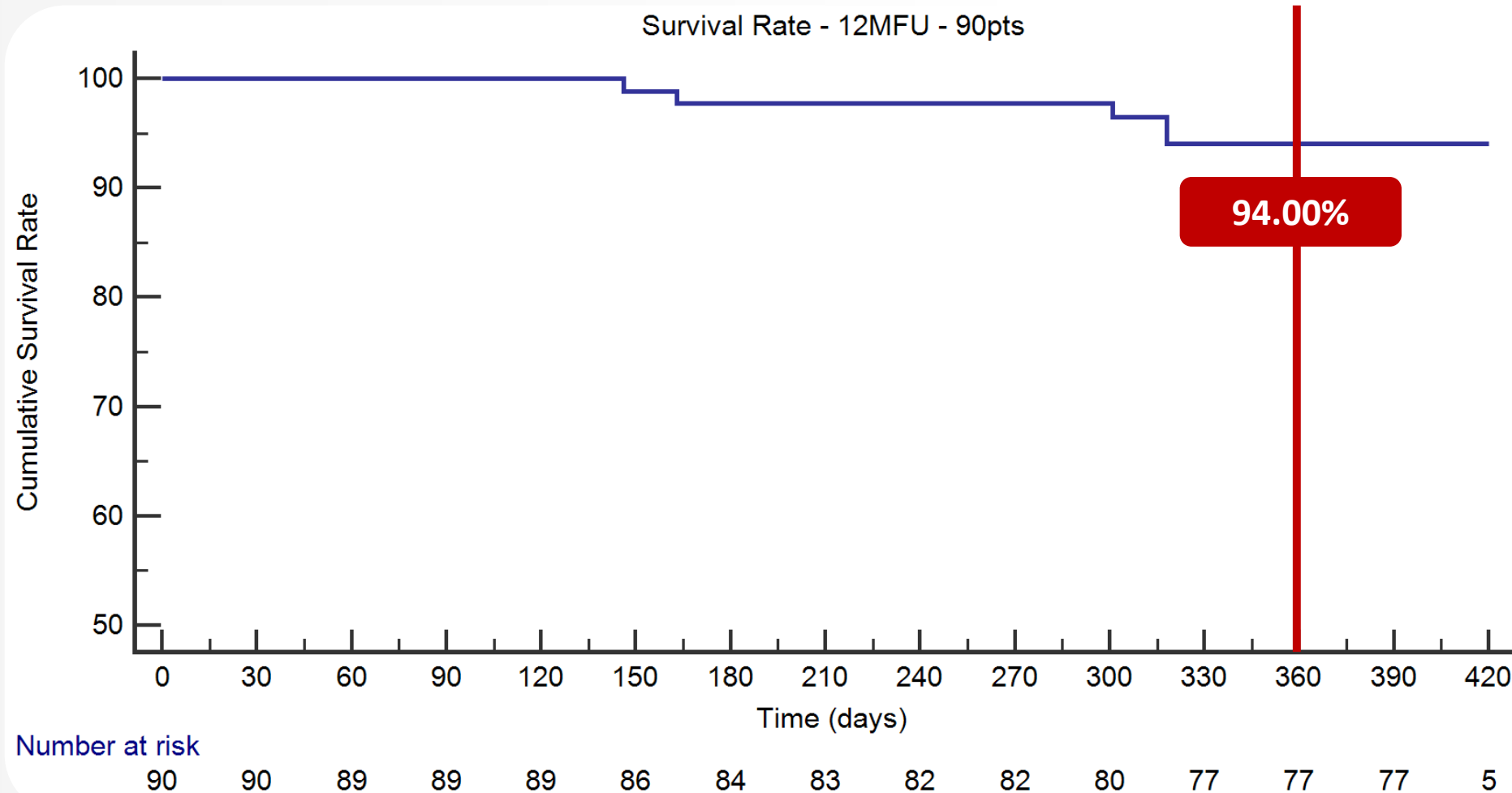
6-month Rutherford evolution – 120 pts



Evolution in Rutherford Classification

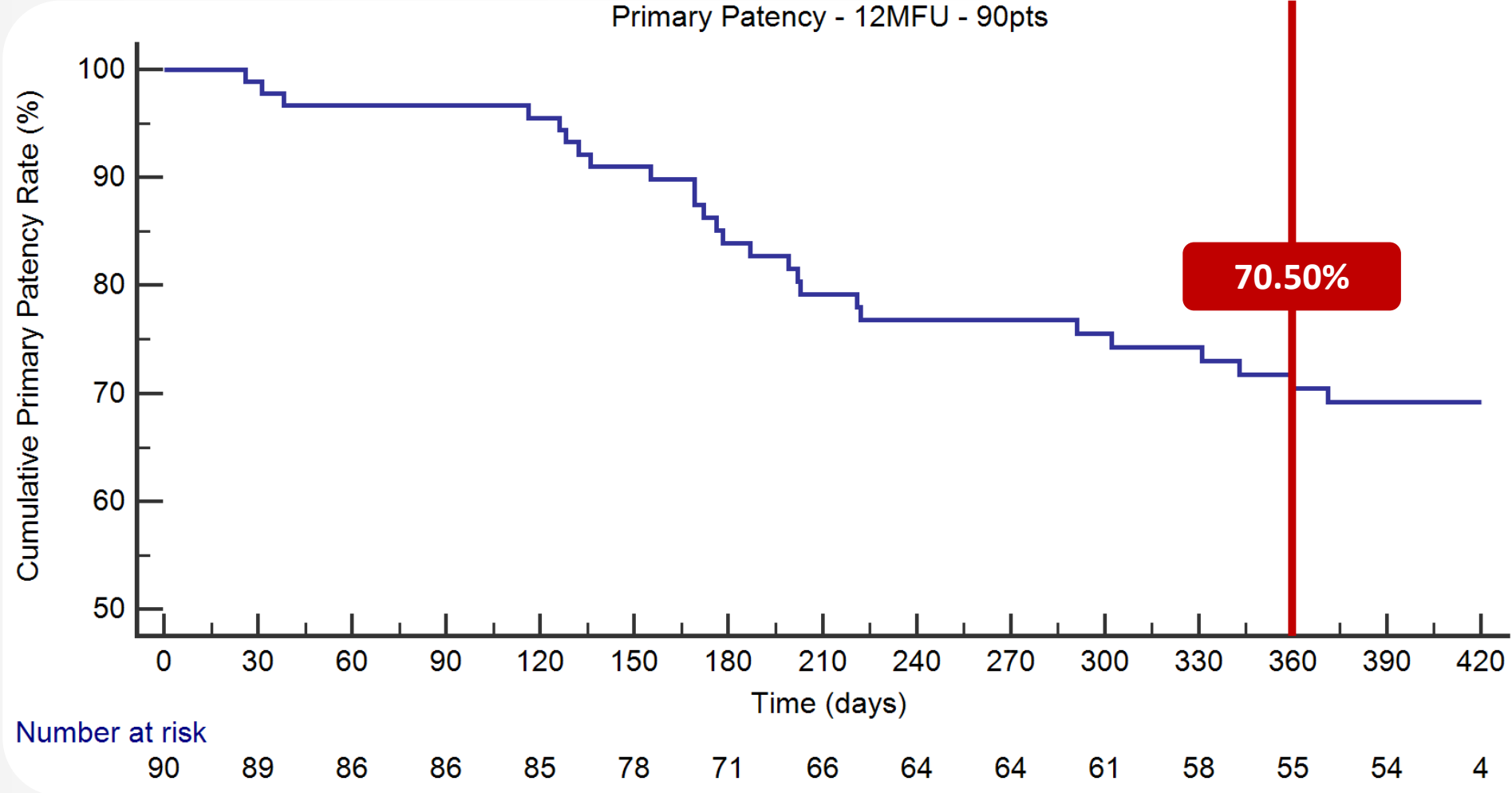


12-month Survival Rate in 90pts (preliminary)

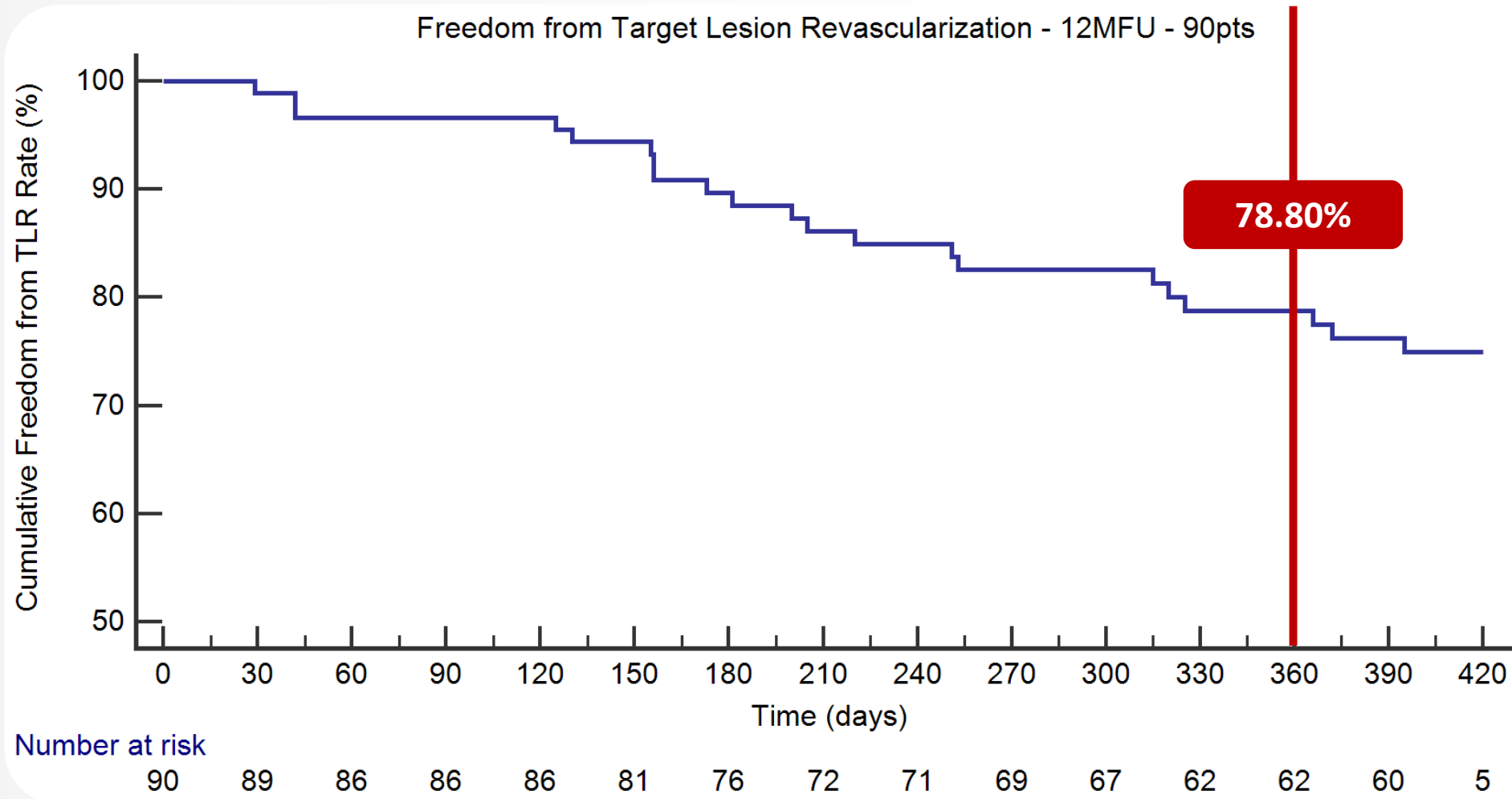




12-month Primary Patency in 90pts (preliminary)



12-month Freedom from TLR in 90pts (preliminary)



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