24-month outcomes in the EVOLUTION study

Investigating the iVolution stent in fempop lesions

Dr. Marc Bosiers

LINC 2019 - Leipzig

FCRE

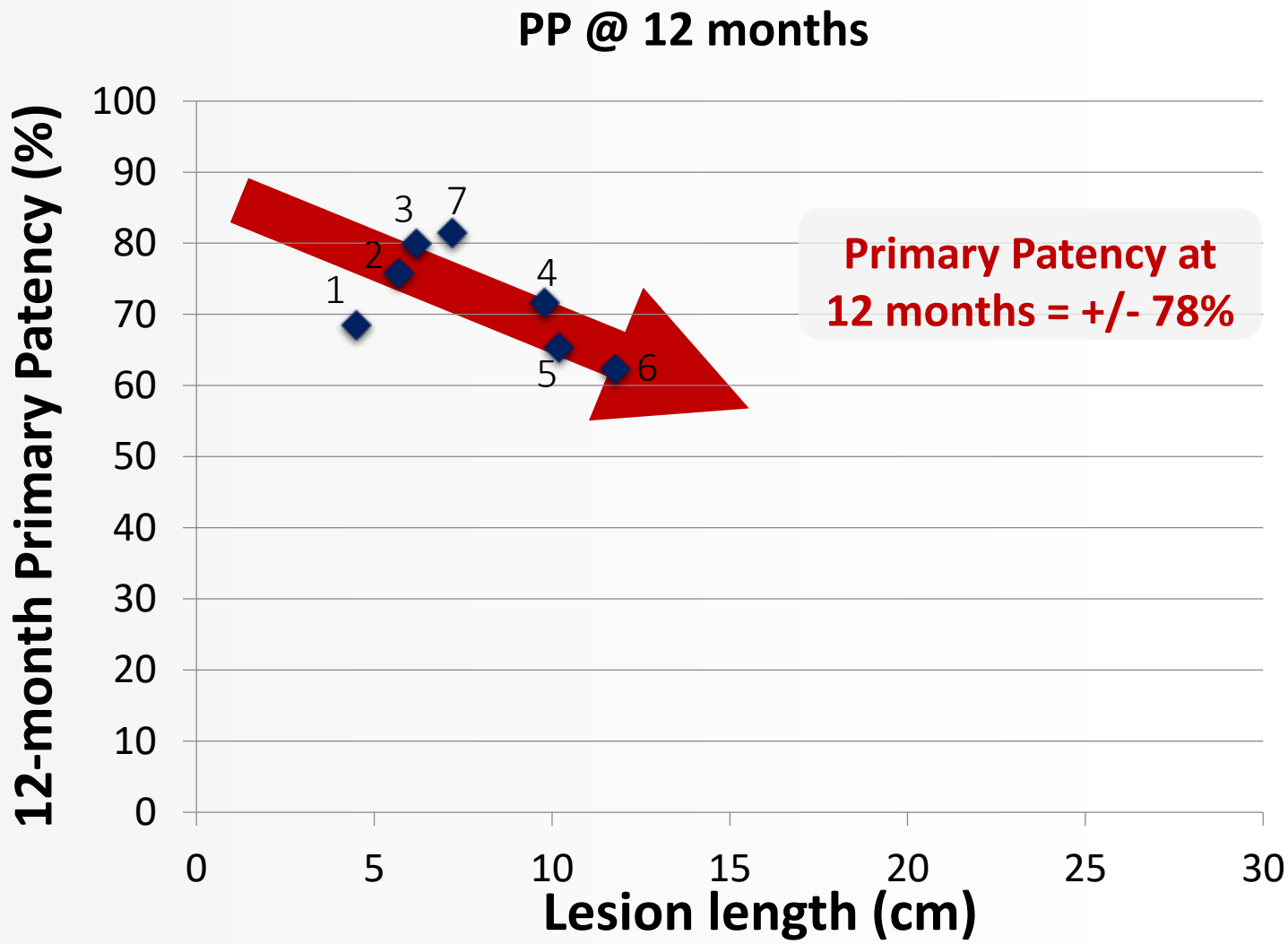
My disclosures

☒ I do not have any potential conflicts of interest to report

○ 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)

Results with stents in the SFA – TASC A&B

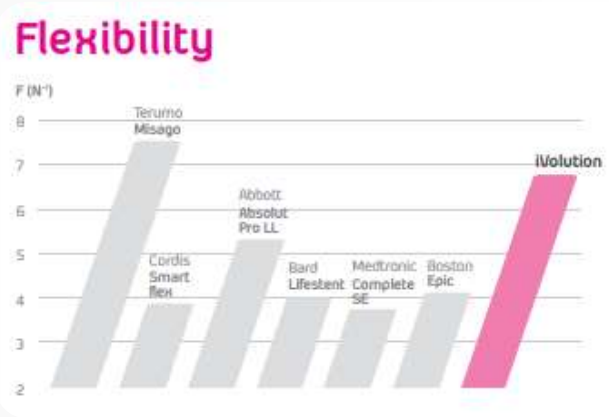


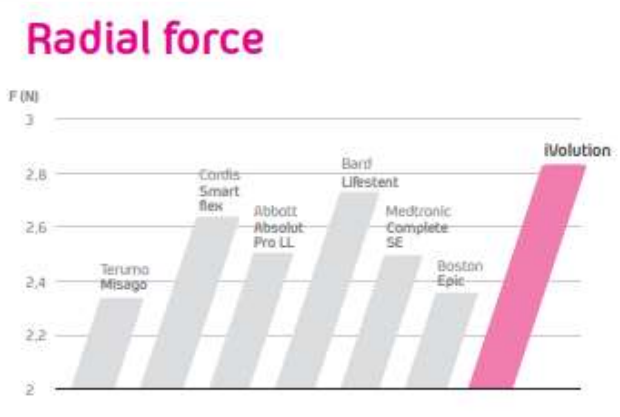
Stent

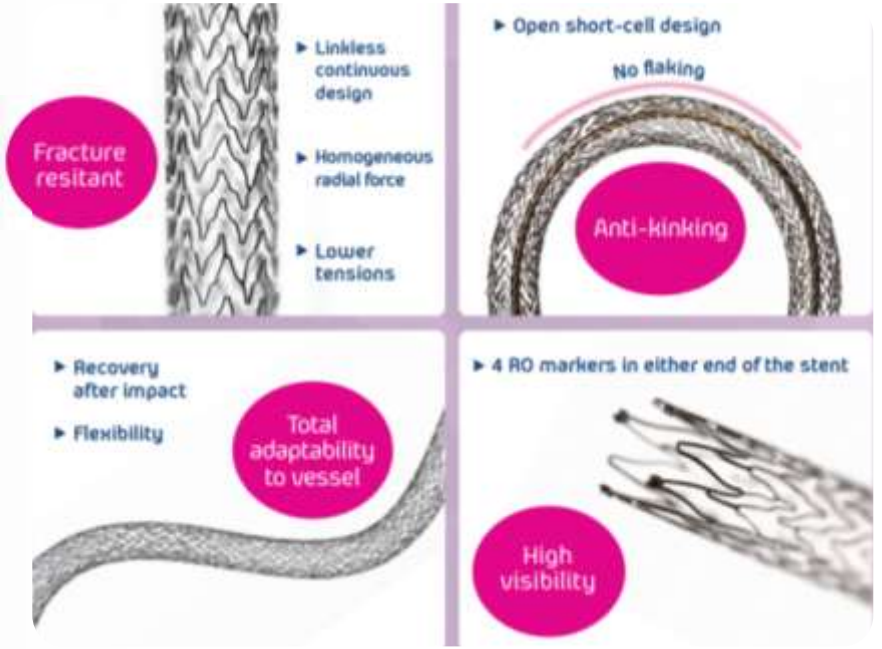
1. FAST
2. FACT
3. RESILIENT
4. DURABILITY
5. ASTRON
6. VIENNA
7. 4EVER

FCRE

iVolution Stent Design







FCRE

Evolution study

A Prospective, non-randomized, multi center study investigating the Efficacy of the Self-Expanding iVolution nitinol stent for treatment of femoropopliteal lesions

Study design

- **Study Objective:**
  To evaluate the **short-term** (up to 12 months) outcome of treatment by means of the self-expanding **iVolution nitinol stent** in symptomatic **(RF 2-4) femoropopliteal** stenotic or occlusive lesions

- **Primary Endpoint:**
  Primary Patency at 12Months, defined as freedom from >50% restenosis at 12months as indicated by an independently verified duplex ultrasound **PSVR <2.5** in the target vessel with no reintervention.

Participating centers

- **BELGIUM**
  - M. Bosiers, K. Deloose, J. Callaert - AZ Sint-Blasius, Dendermonde
  - P. Peeters, J. Verbist - Imelda Hospital, Bonheiden
  - L. Maene, R. Beelen - OLV, Aalst
  - K. Keirse - RZ Heilig Hart, Tienen

Inclusion criteria

EVOLUTION

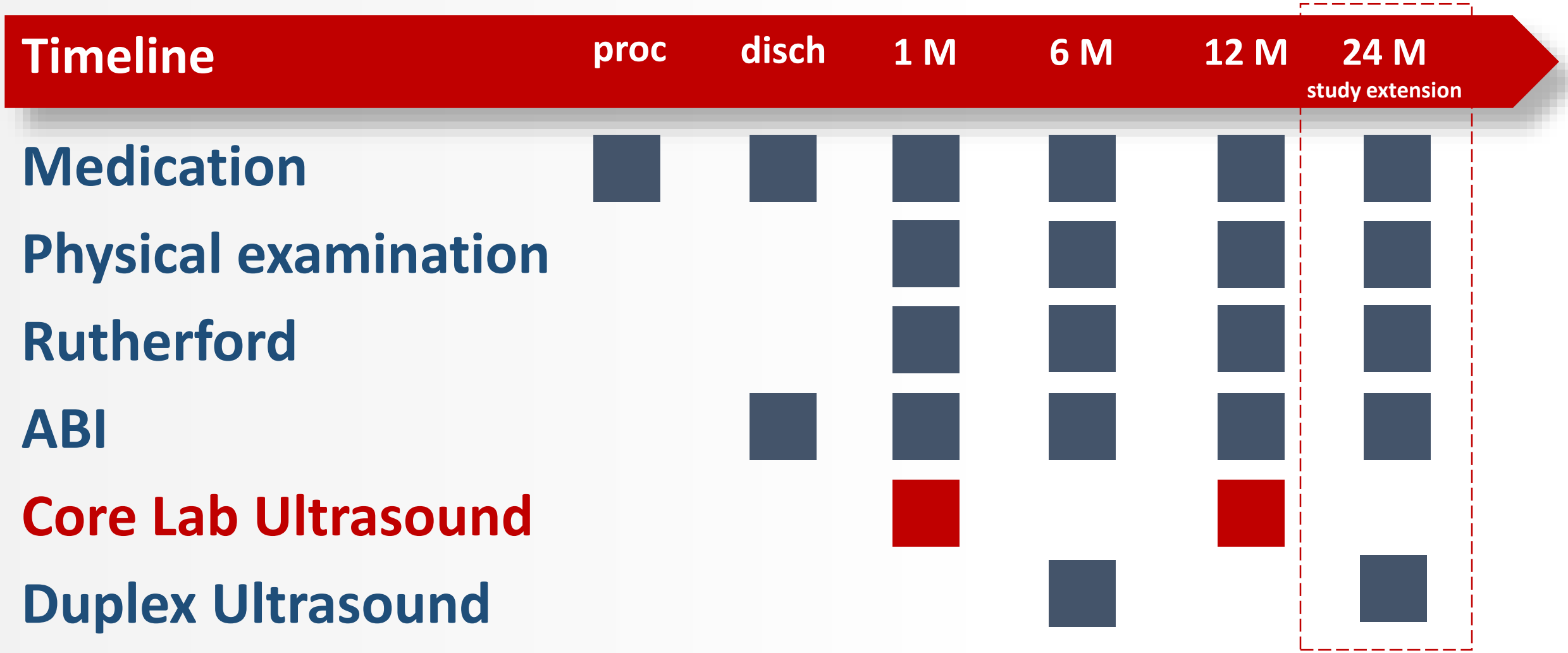
120 out of 120 patients enrolled (100%)

Main inclusion criteria

- **Rutherford classification from 2 to 4**
- **De novo lesion** in the femoropopliteal arteries, suitable for endovascular therapy
- Total target lesion length **≤ 150mm**

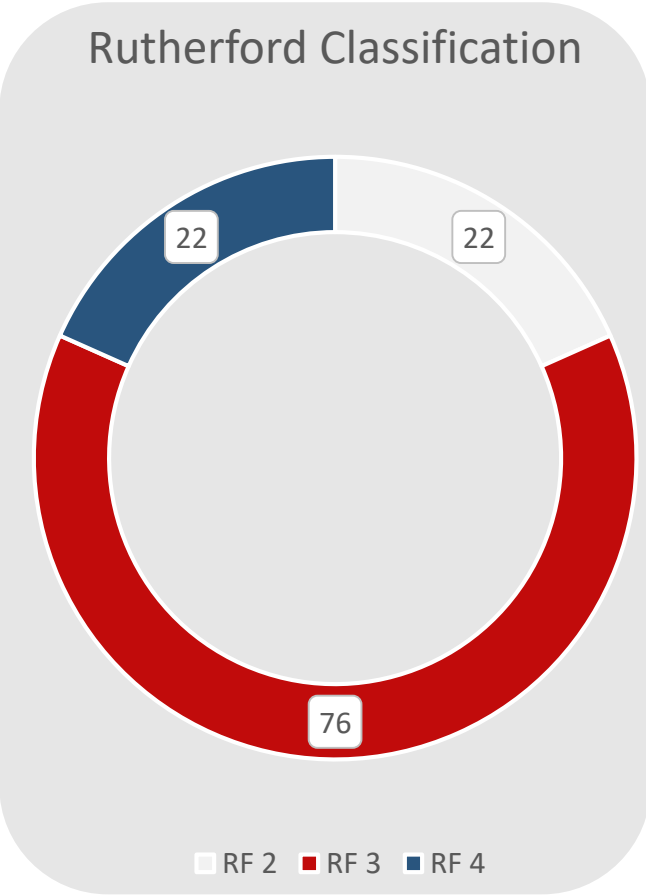
FCRE

Study overview



Patient demographics

	N = 120
Male	71.67% *(86/120)*
Age *(min – max; ±SD)*	71.07 *(42.74 – 94.88 ; ±10.68)*
Nicotine abuse	63.33% *(76/120)*
Hypertension	72.50% *(87/120)*
Diabetes mellitus	***21.67%*** *(26/120)*
Renal insufficiency	15.83% *(19/120)*
Hypercholesterolemia	55.00% *(66/120)*
Obesity	25.83% *(31/120)*

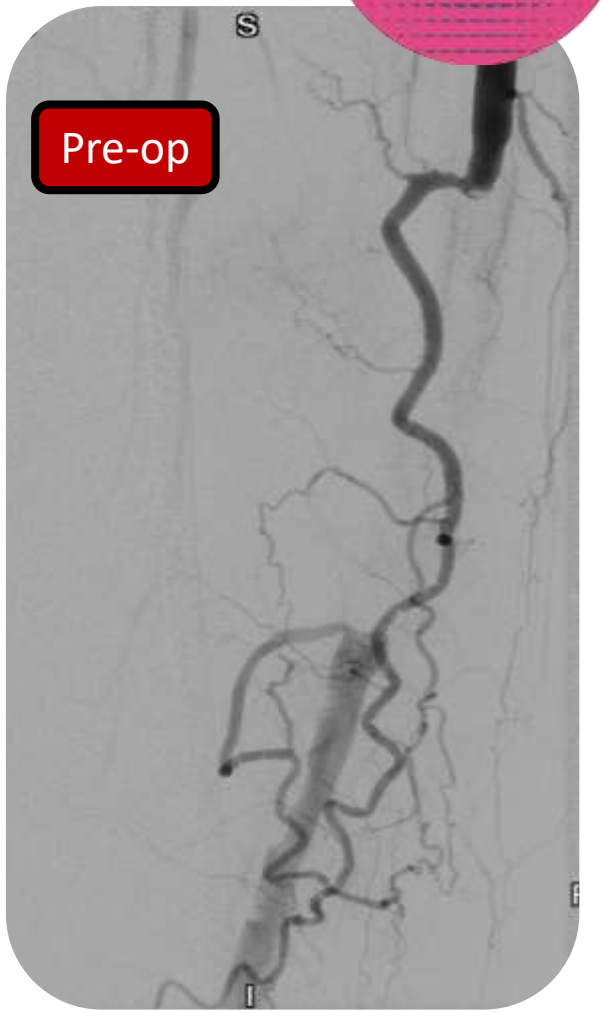


Procedural characteristics

	N = 120
Procedure time *(min-max ; ±SD)*	**41.93 min** *(13.0 – 109.0; ±15.74)*
Scopy time *(min – max; ±SD)*	10.39 min *(3.40 – 70.00 ; ±8.11)*
Contrast *(min – max; ±SD)*	76.88 mL *(15.00 – 200.00 ; ±34.08)*
Cross-over performed	87.50% *(105/120)*
Inflow Lesion	15 *(18/120)*
Outflow lesion	18.33% *(22/120)*

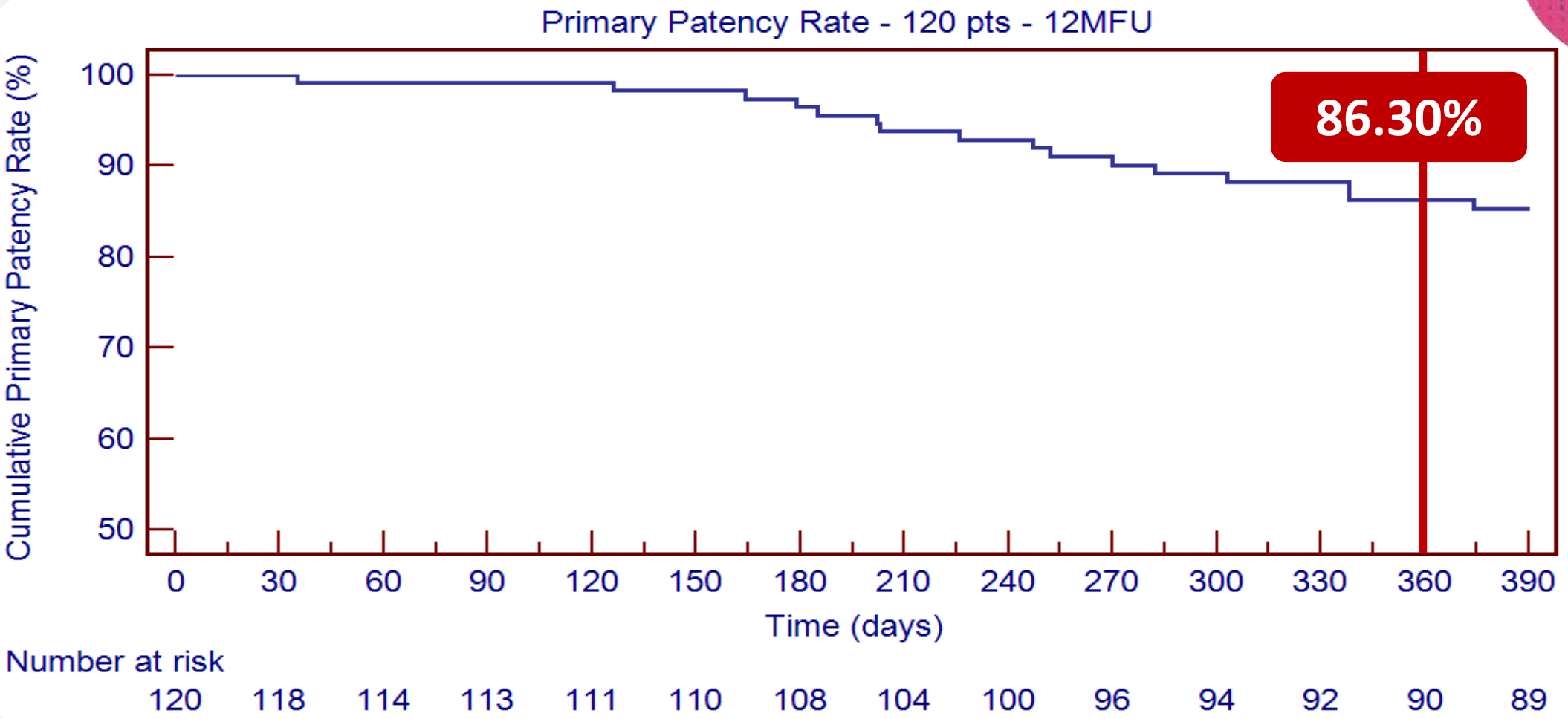
Lesion Characteristics

	N = 120
Lesion length ***(min – max; ±SD)***	**89.63 mm** ***(9.0 – 150.0; ±44.68)***
Ref Vessel Diameter (*min – max; ±SD)*	5.63 mm *(4.00 – 7.00 ; ±0.58)*
1 study stent implanted	93.33% *(112/120)*
2 study stents implanted	6.67% *(8/120)*
Occlusion	**40.00% (48/120)**
Calcified lesion	**71.67% (86/120)**

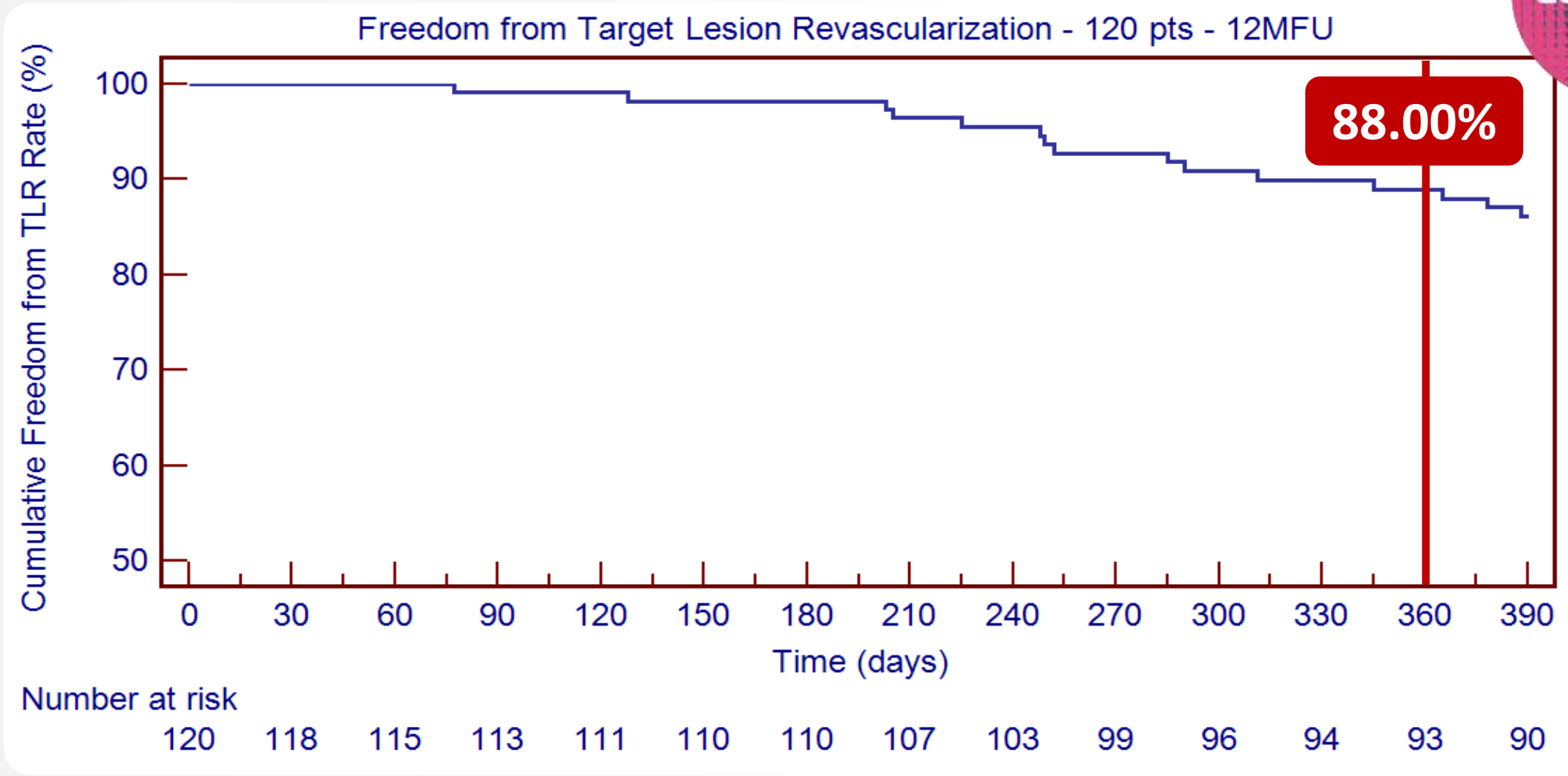


FCRE

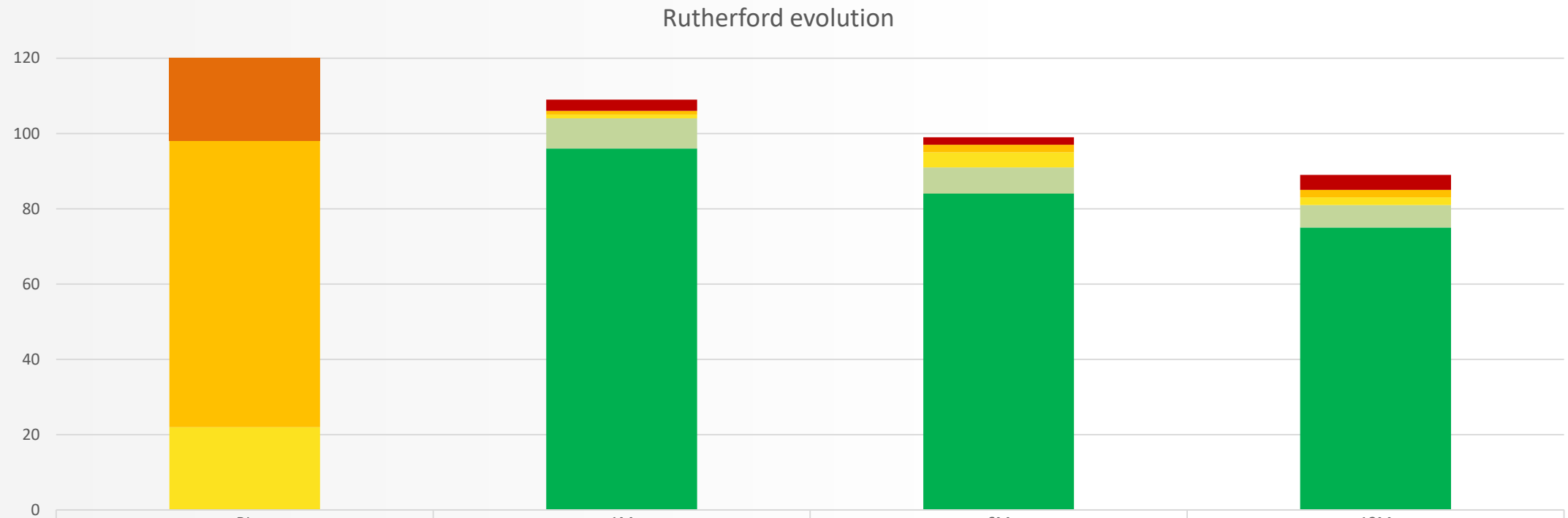
12-month Primary Patency



12-month Freedom from TLR



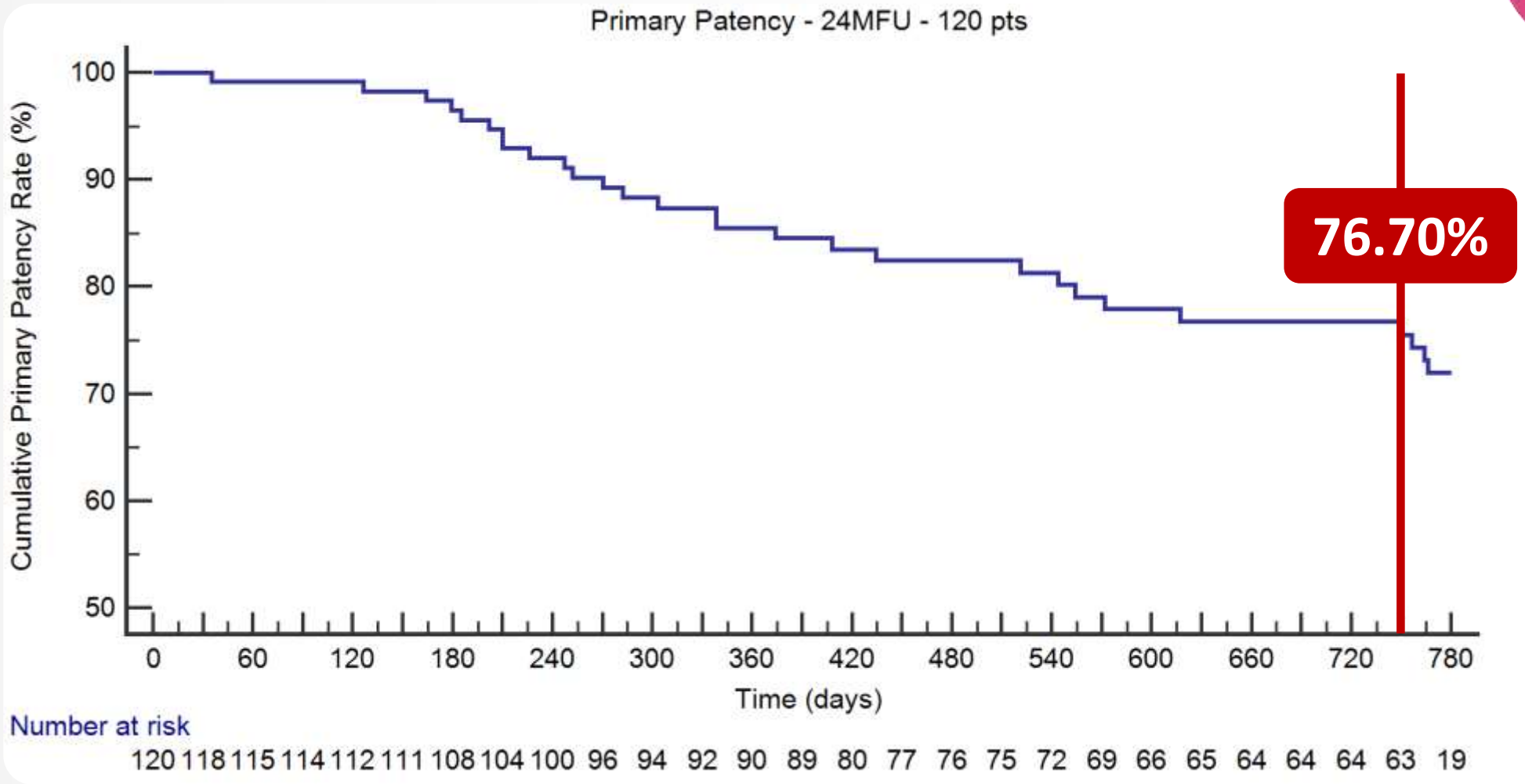
12-month evolution in Rutherford Classification



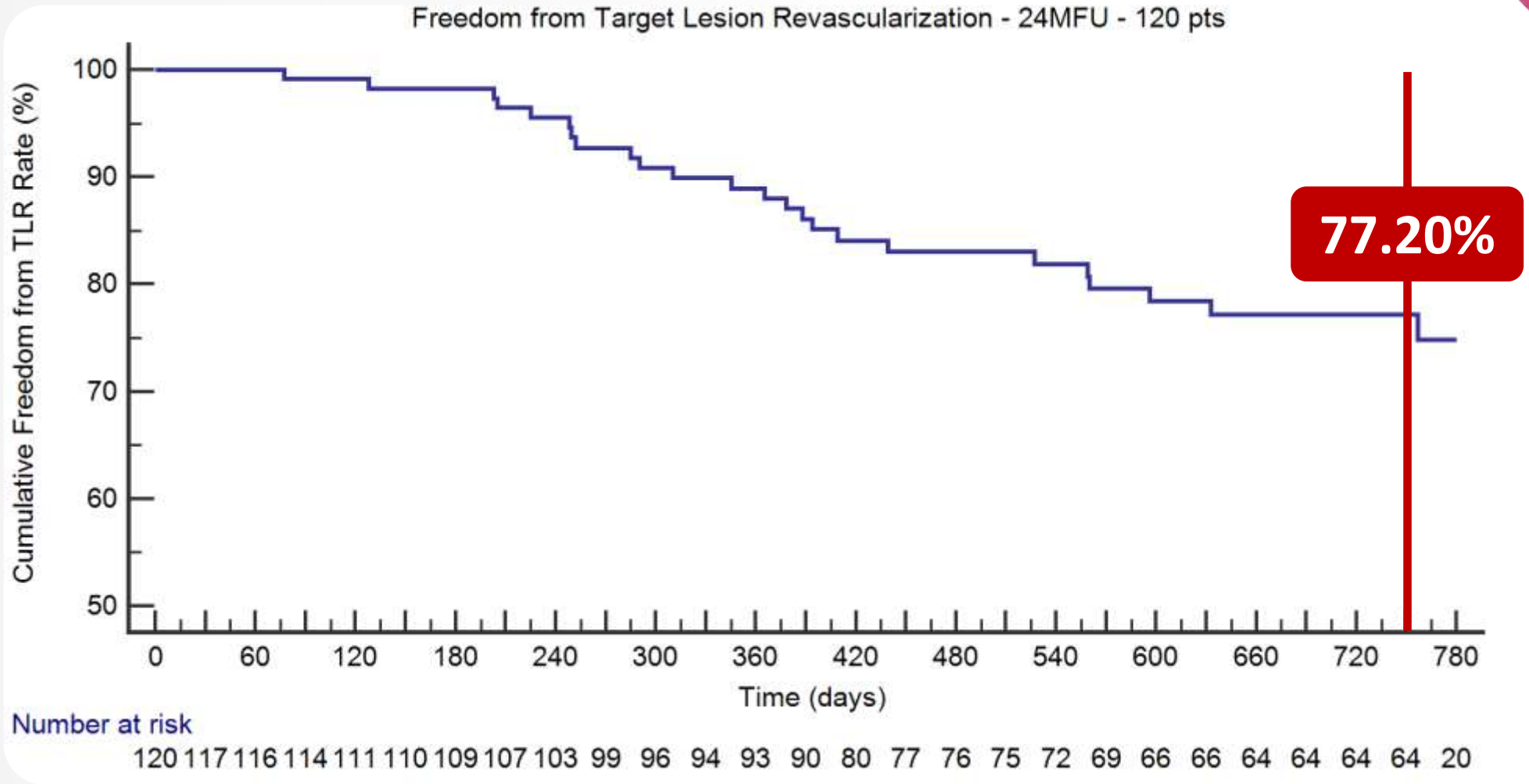
	BL	1M	6M	12M
RF5	0	3	2	4
RF4	22	0	0	0
RF3	76	1	2	2
RF2	22	1	4	2
RF1	0	8	7	6
RF0	0	96	84	75

FCRE

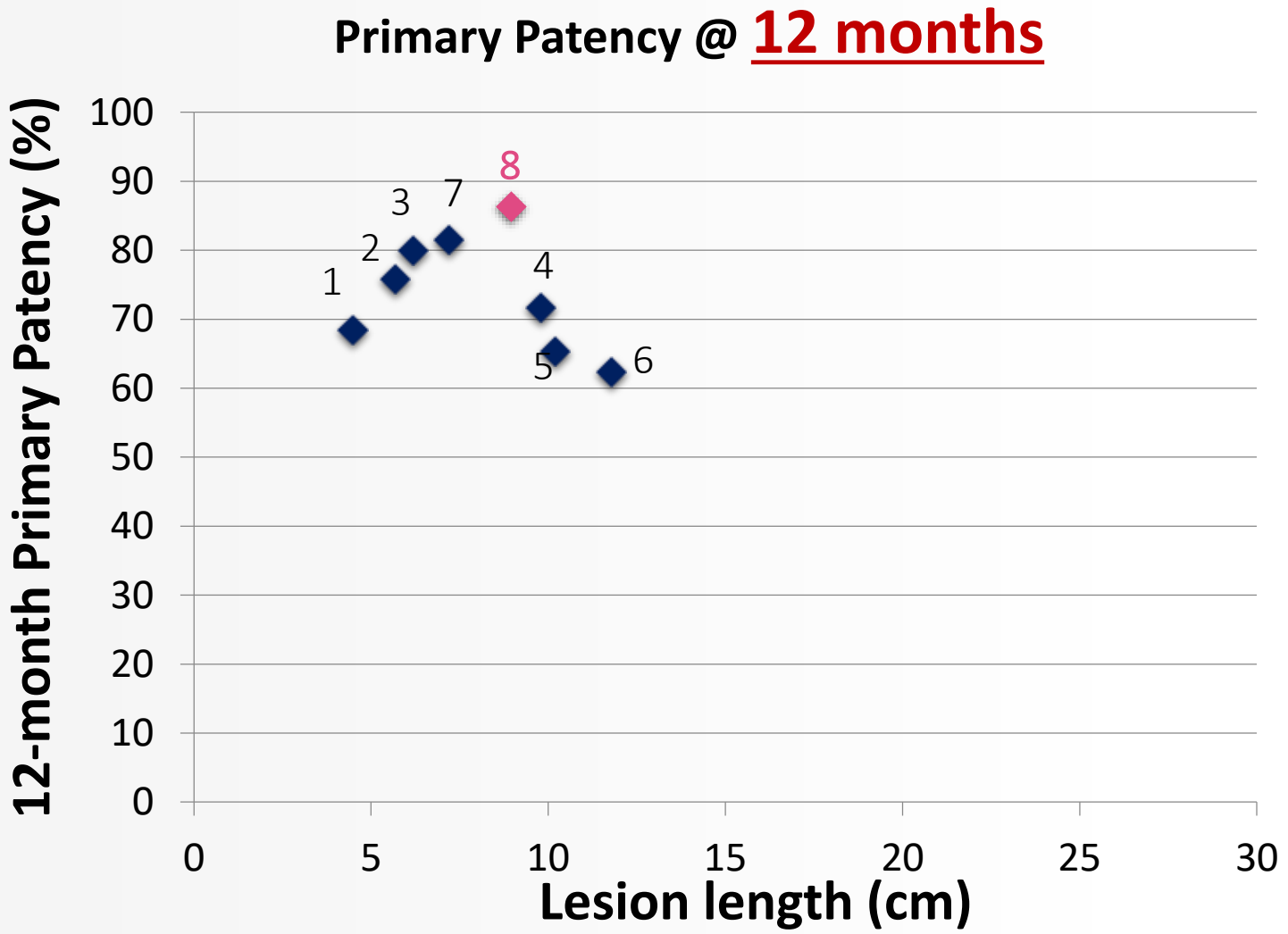
24-month Primary Patency



24-month Freedom from TLR



Results with stents in the SFA – TASC A&B



Stent

1. FAST
2. FACT
3. RESILIENT
4. DURABILITY
5. ASTRON
6. VIENNA
7. 4EVER

8. Evolution

FCRE

Results in perspective…

	ALL (mm)	Occlusions (%)	2-Year PP (%)
EVOLUTION	**89.63**	**40.00**	**76.70**
DURABILITY II	89	48.00	66.00
SUPERA	90	31.00	76.10
STROLL	77	23.60	74.90
ZILVER PTX	66	30.00	74.80
4EVER	71	20.80	72.30

Conclusion

- Final results show that the iVolution stent is a very effective treatment for femoropopliteal TASC A&B lesions

- Even on the longer term…

FCRE