First 6-month results in 75 patients in the EVOLUTION study

Investigating the iVolution stent in femoropopliteal lesions

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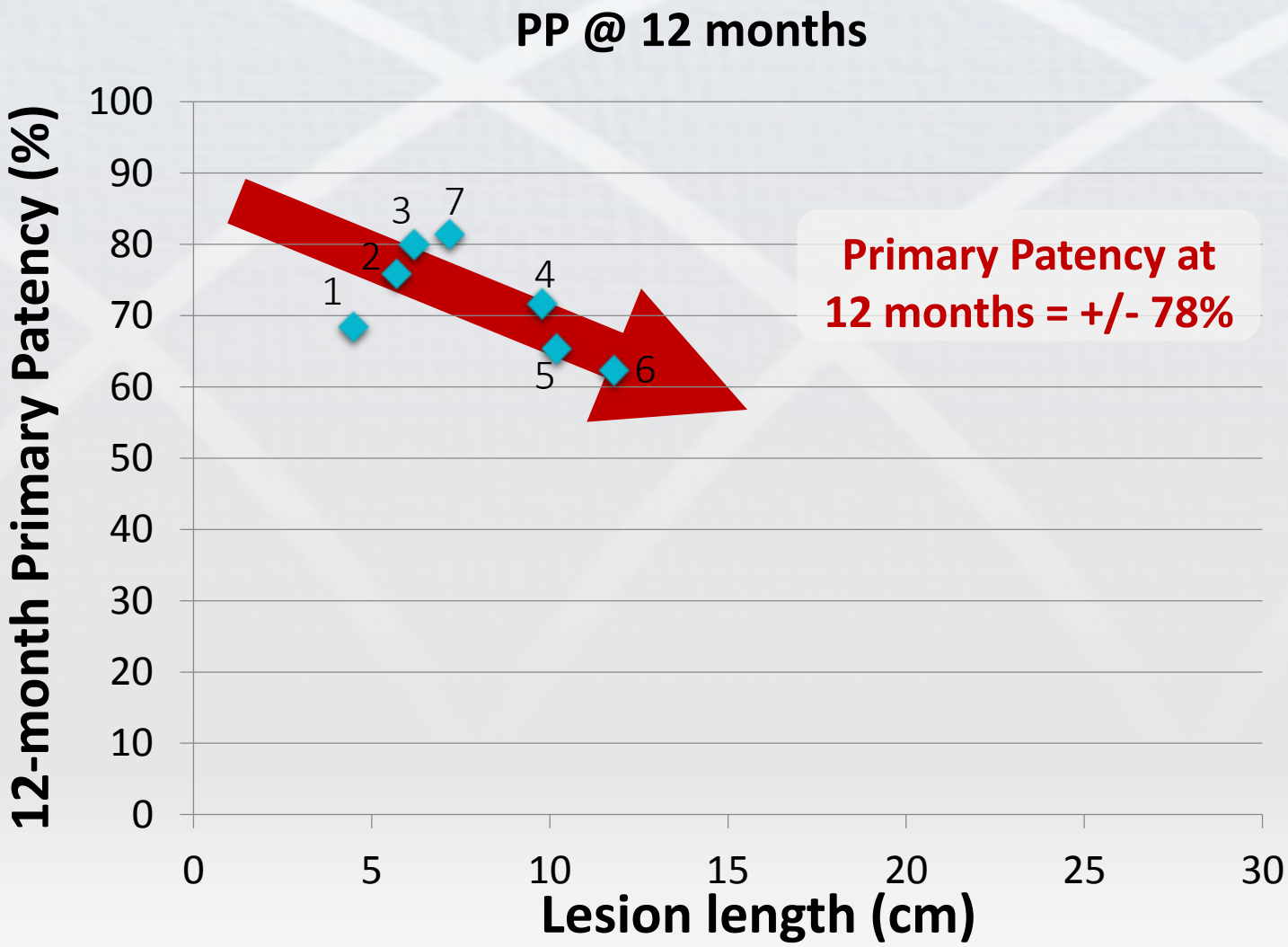
Conflict of interest

☐ 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

Results with stents in the SFA – TASC A & B



Stent

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

Stent design Affects Chronic Outward Force

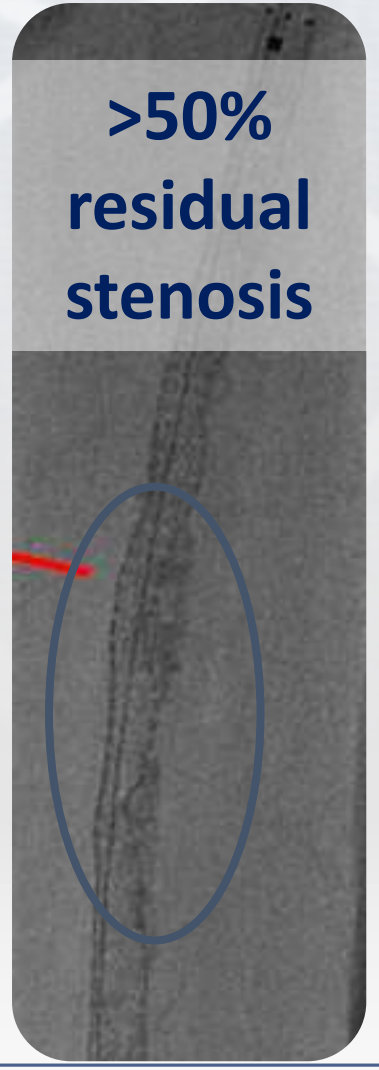
TOO LOW…

⇩

Impossible to open the lesion

⇩

Residual stenosis



Stent Design Affects Chronic Outward Force

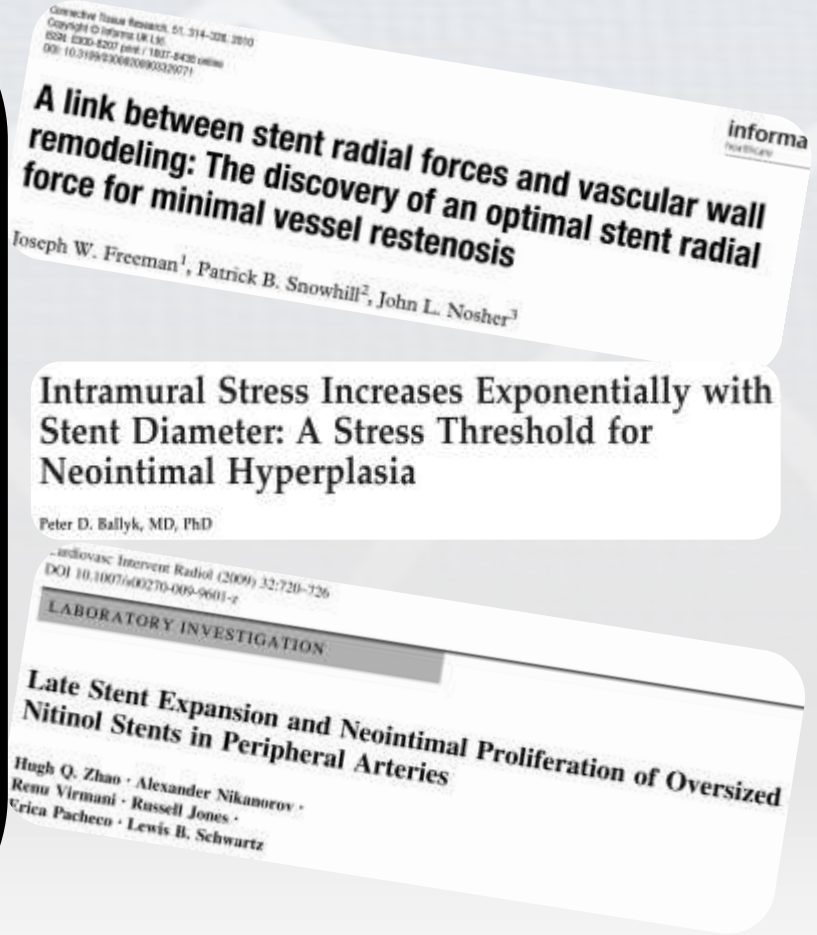
TOO HIGH…

⇩

Chronic stent-vessel irritation

⇩

Intimal Hyperplasia



A link between stent radial forces and vascular wall remodeling: The discovery of an optimal stent radial force for minimal vessel restenosis

Joseph W. Freeman[1], Patrick B. Snowhill[2], John L. Nosher[3]

Intramural Stress Increases Exponentially with Stent Diameter: A Stress Threshold for Neointimal Hyperplasia

Peter D. Ballyk, MD, PhD

LABORATORY INVESTIGATION

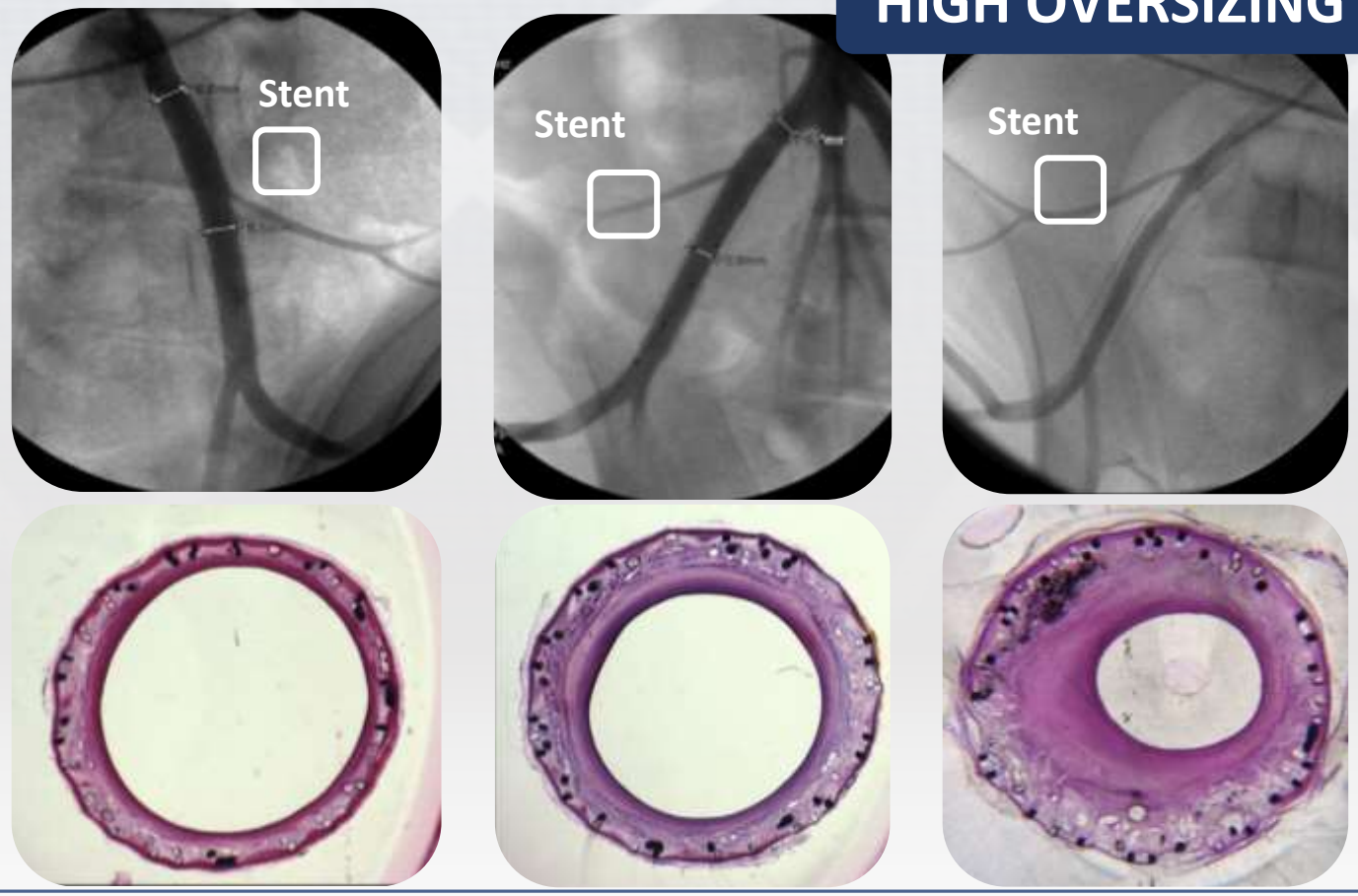
Late Stent Expansion and Neointimal Proliferation of Oversized Nitinol Stents in Peripheral Arteries

Hugh Q. Zhao · Alexander Nikanorov · Renu Virmani · Russell Jones · Erica Pacheco · Lewis B. Schwartz

Stent Design Affects Chronic Outward Force

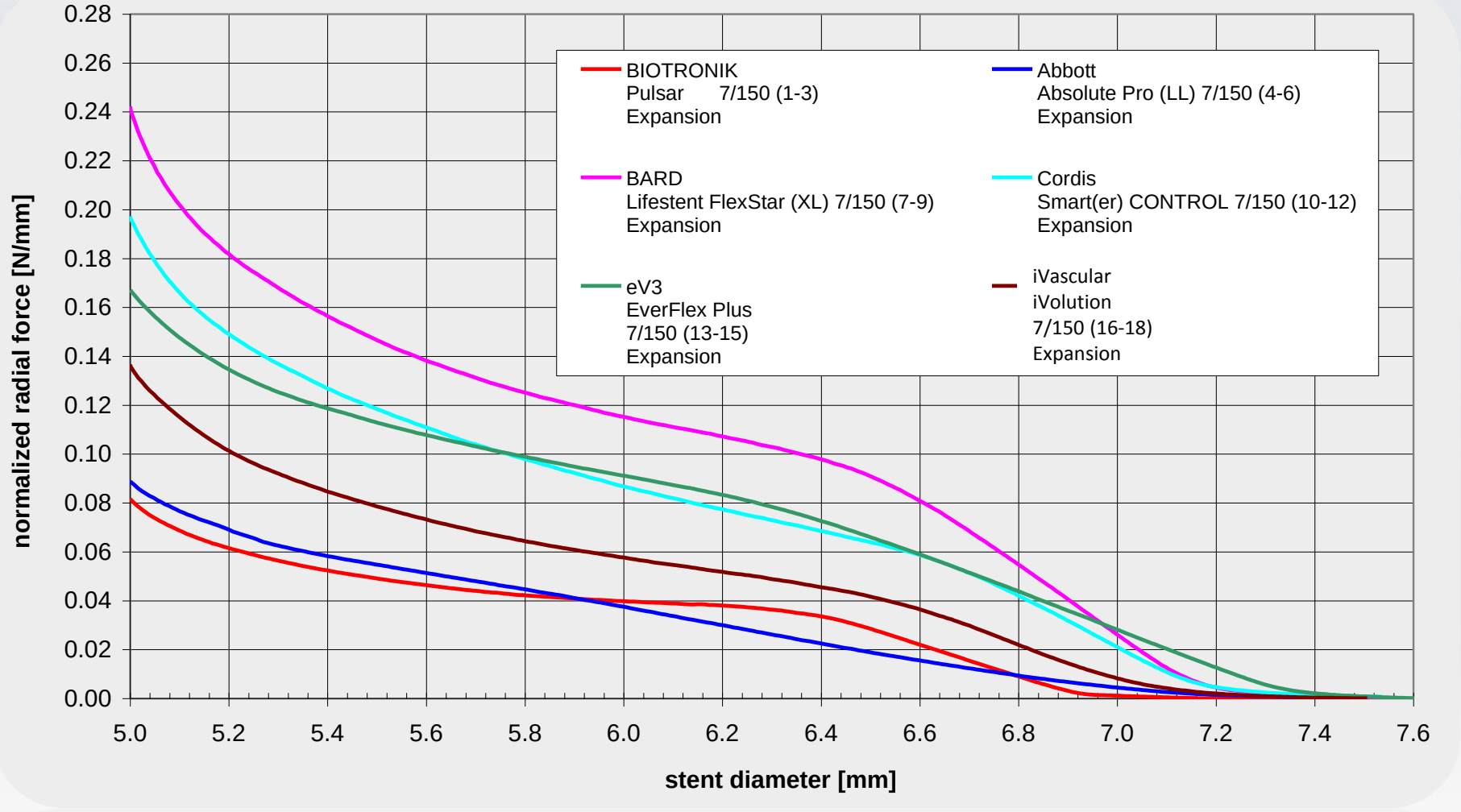
Example: 8 mm stent **7.3 – 6.2 mm** **6.2 – 5.0 mm** **5.0 – 4.2 mm**

HIGH OVERSIZING



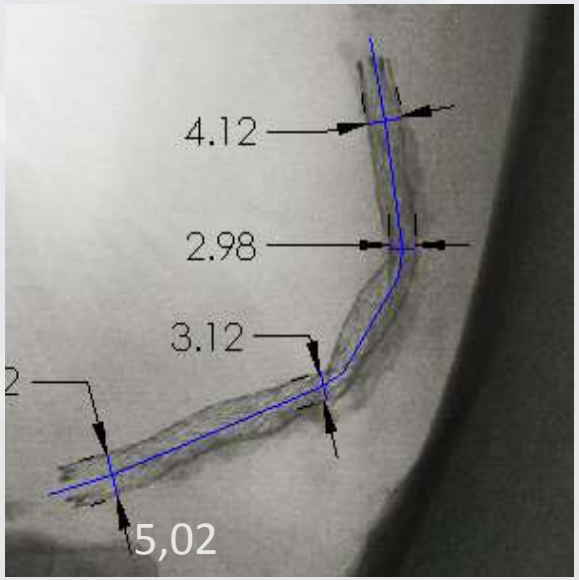
Stent Design Affects Chronic Outward Force

Even when oversizing low rates of COF, due to the flat expansion curve



Stent Design Affects Chronic Outward Force

Bent Leg: vessel diameter range: 5.02 - 2.98 mm : 6mm stent implant



Expansion force increases with decreasing diameter

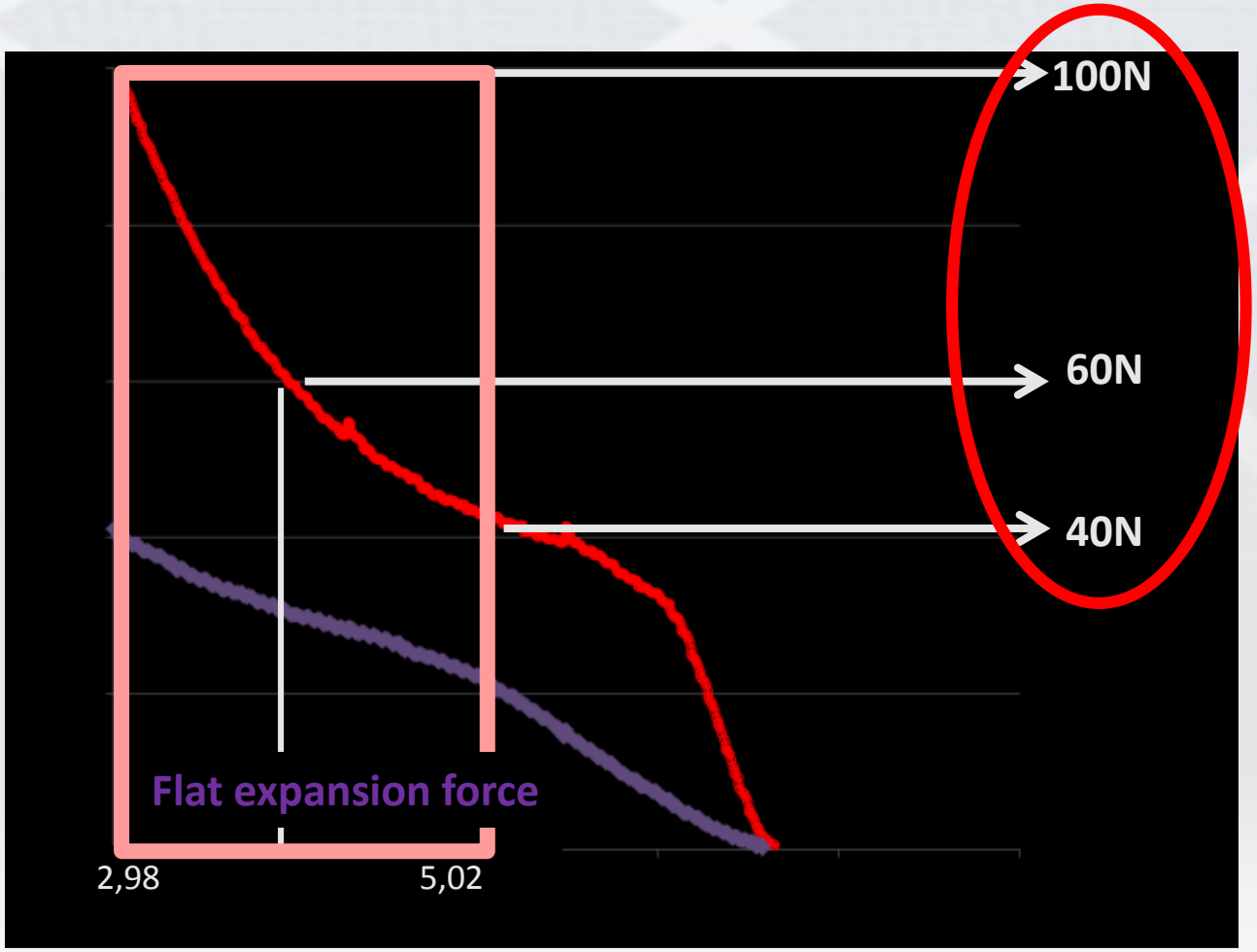


Illustration is artist's rendition

Stent Design Affects Chronic Outward Force

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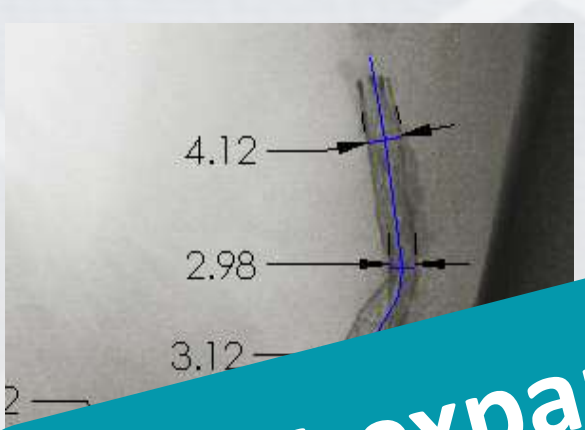
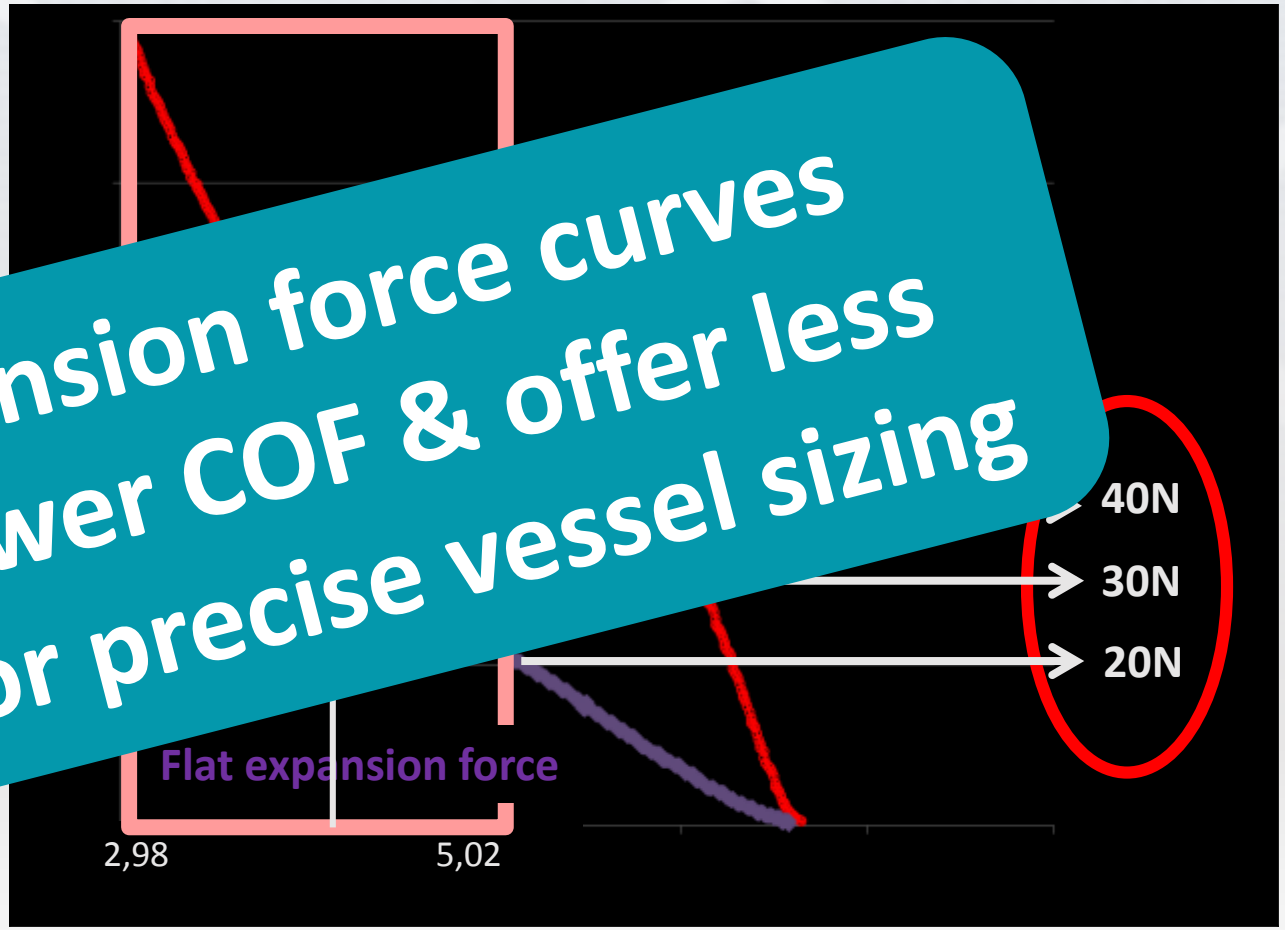




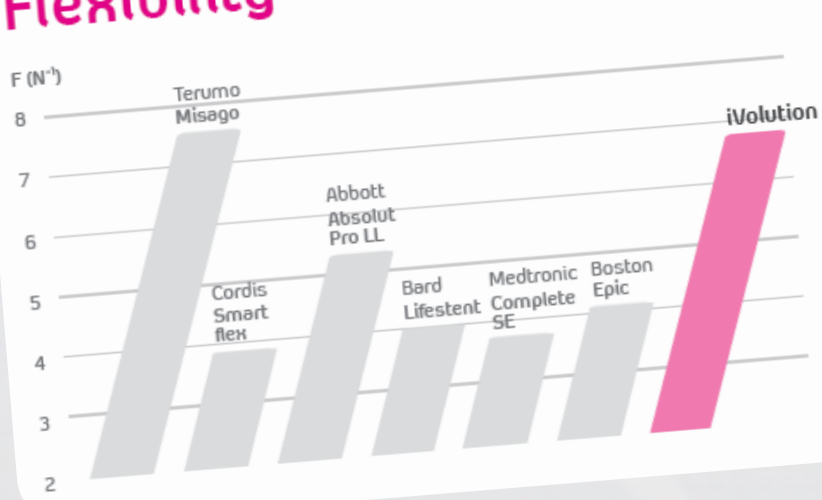
Flat expansion force curves induce lower COF & offer less concern for precise vessel sizing

diameter

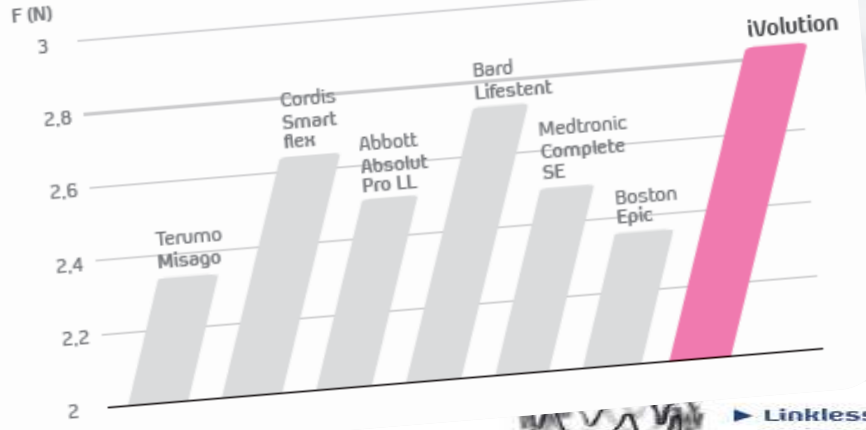
Illustration is artist's rendition

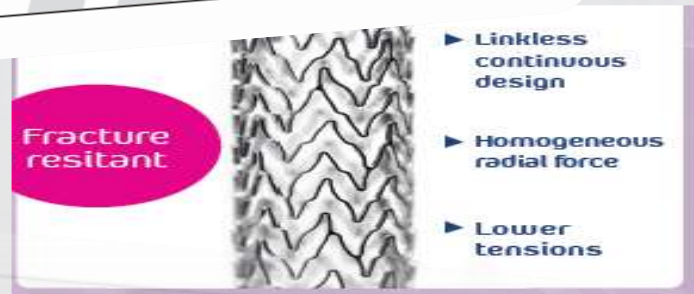
iVolution Stent Design

Flexibility



Radial force





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

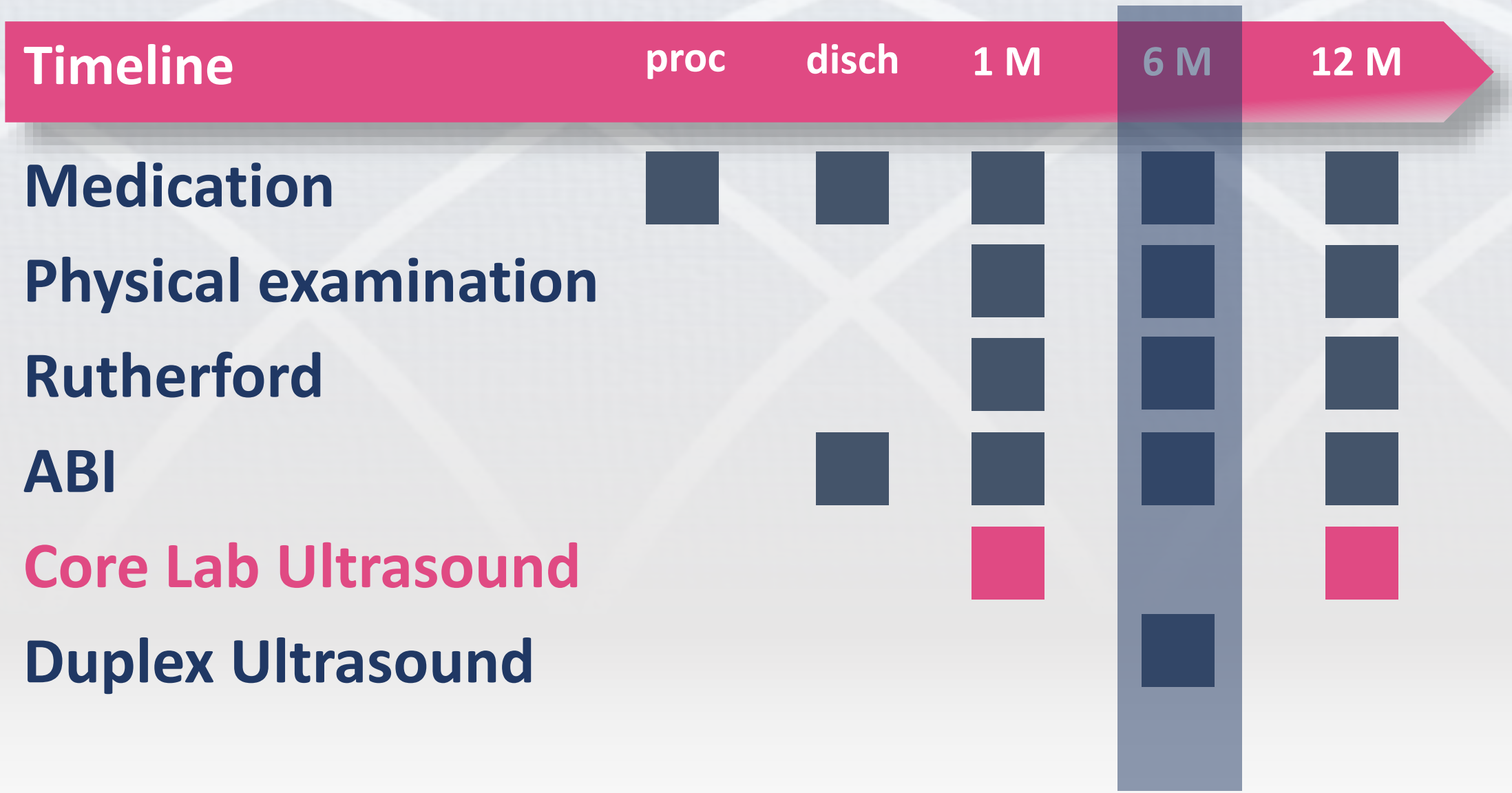
EVOLUTION

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**

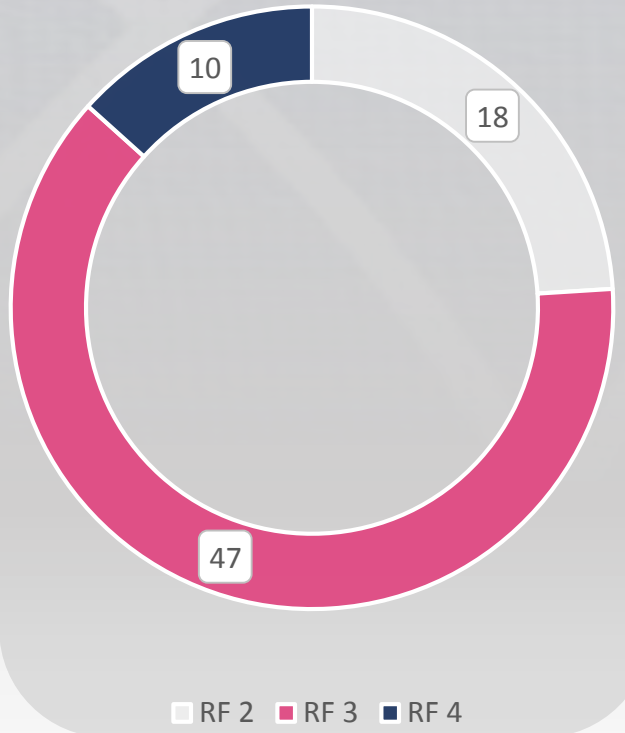
Study overview



Patient Demographics

	N = 75 out of 120
Male *(%)*	55 *(73.33%)*
Age *(min – max; ±SD)*	71.22 *(50.23 – 89.91 ; ±9.67)*
Nicotine abuse *(%)*	50 *(66.67%)*
Hypertension *(%)*	45 *(64.29%)*
Diabetes mellitus *(%)*	***15*** *(21.43%)*
Renal insufficiency *(%)*	9 *(12.00%)*
Hypercholesterolemia *(%)*	37 *(49.33%)*
Obesity *(%)*	17 *(22.67%)*

Rutherford Classification



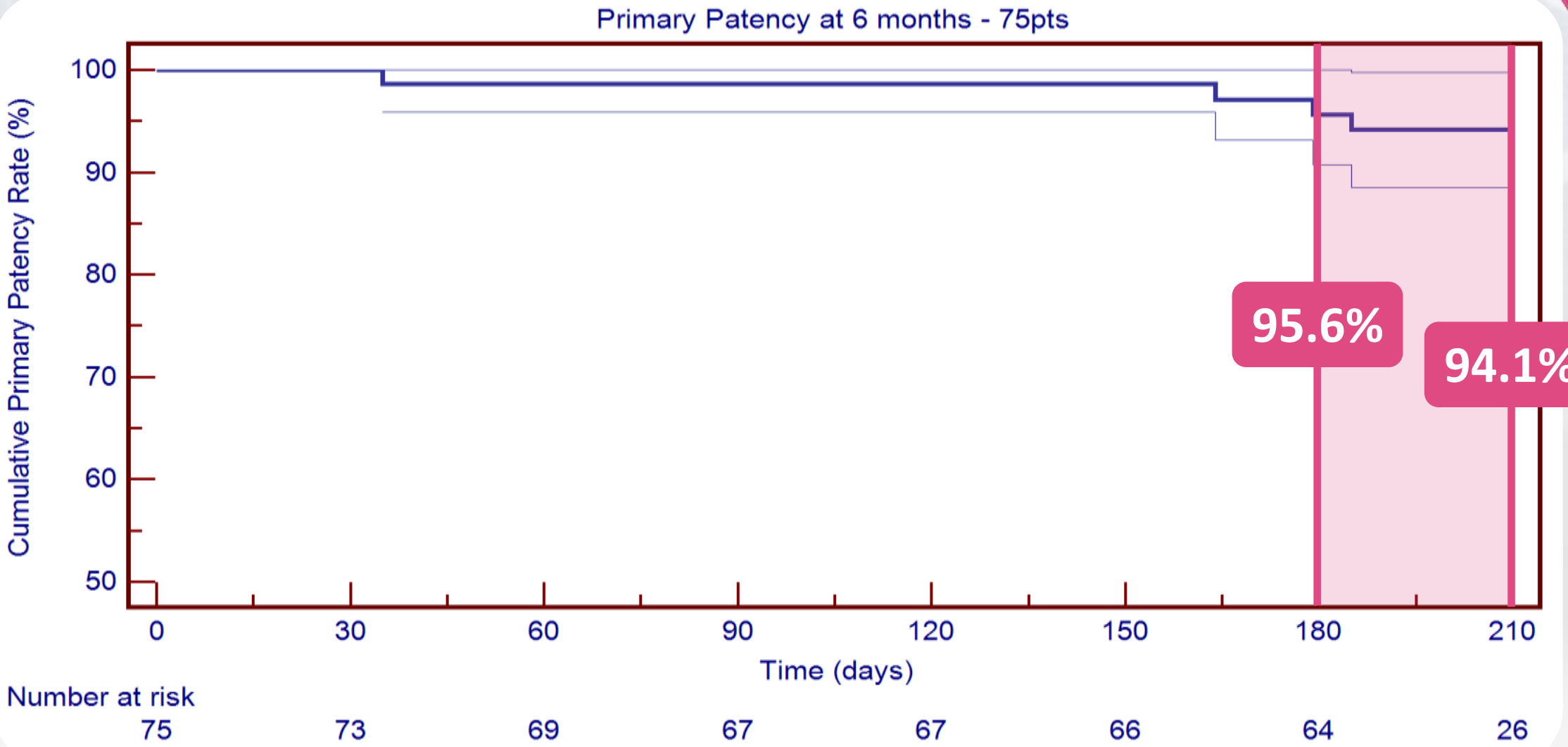
Procedural characteristics

	N = 75 out of 120
Procedure time *(min-max ; ±SD)*	**41.49 min** *(16.0 – 109.0; ±41.49)*
Scopy time *(min – max; ±SD)*	10.02 min *(3.40 – 70.00 ; ±8.47)*
Contrast *(min – max; ±SD)*	78.67 mL *(15.00 – 200.00 ; ±35.81)*
Cross-over performed *(%)*	67 *(89.33%)*
Inflow Lesion *(%)*	14 *(18.67%)*
Outflow lesion *(%)*	7 *(9.33%)*

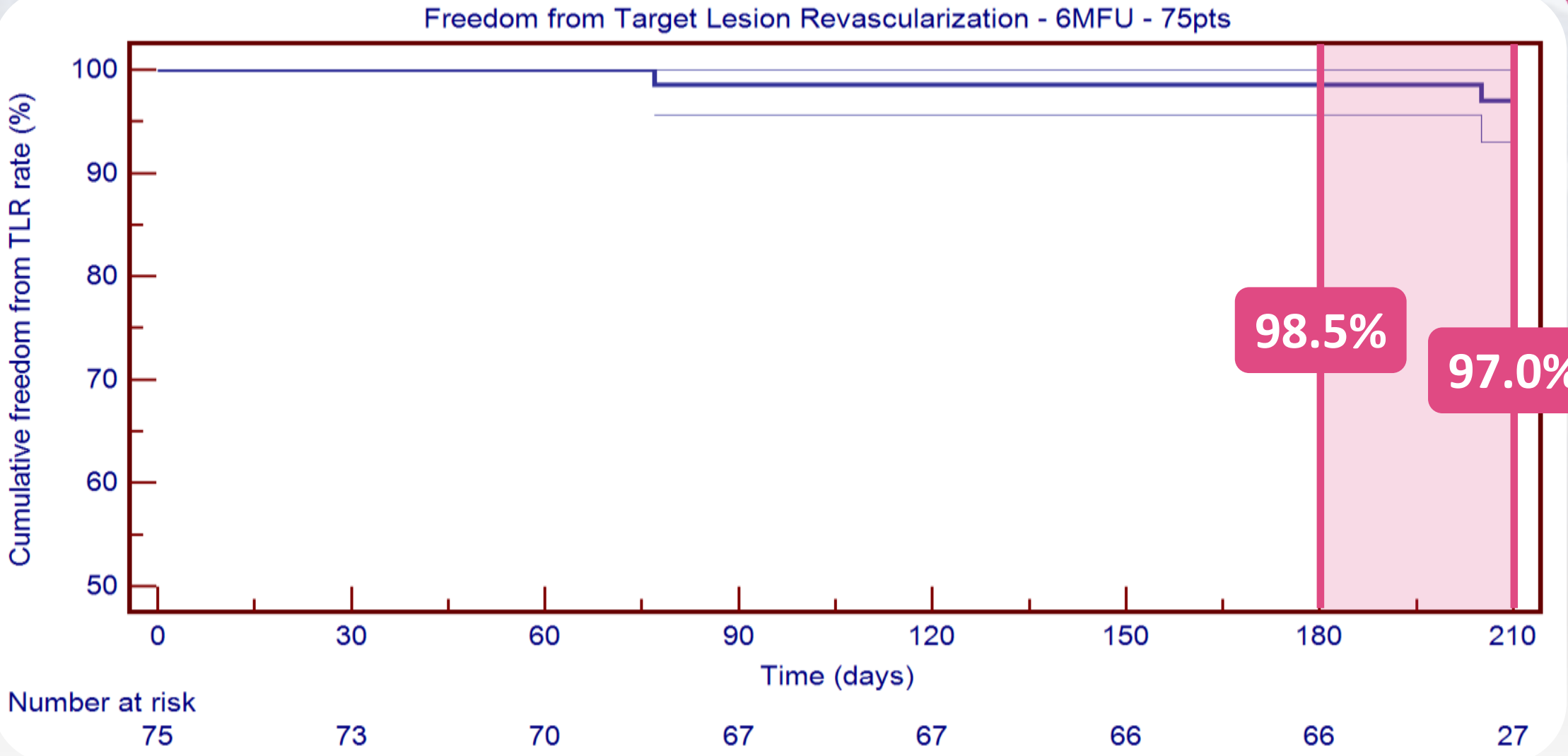
Lesion Characteristics

	N = 75 out of 120
Lesion length *(min – max; ±SD)*	**86.64 mm** *(9.0 – 150.0; ±45.24)*
Ref Vessel Diameter (*min – max; ±SD)*	5.57 mm *(4.00 – 7.00 ; ±0.591)*
1 stent received (%)	67 *(89.33%)*
2 stents received *(%)*	8 *(10.67%)*
Occlusion *(%)*	31 *(41.33%)*
Calcified lesion *(%)*	48 *(64.00%)*

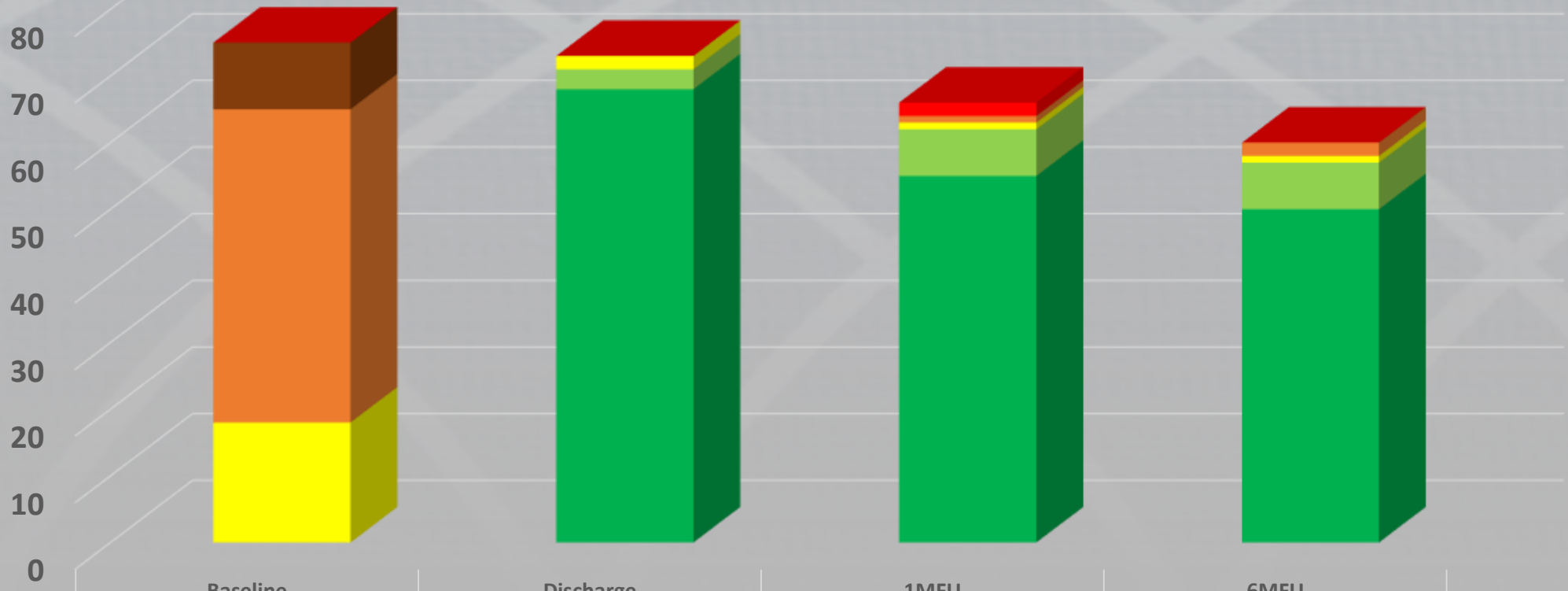
6-month Primary Patency



6-month Freedom from TLR

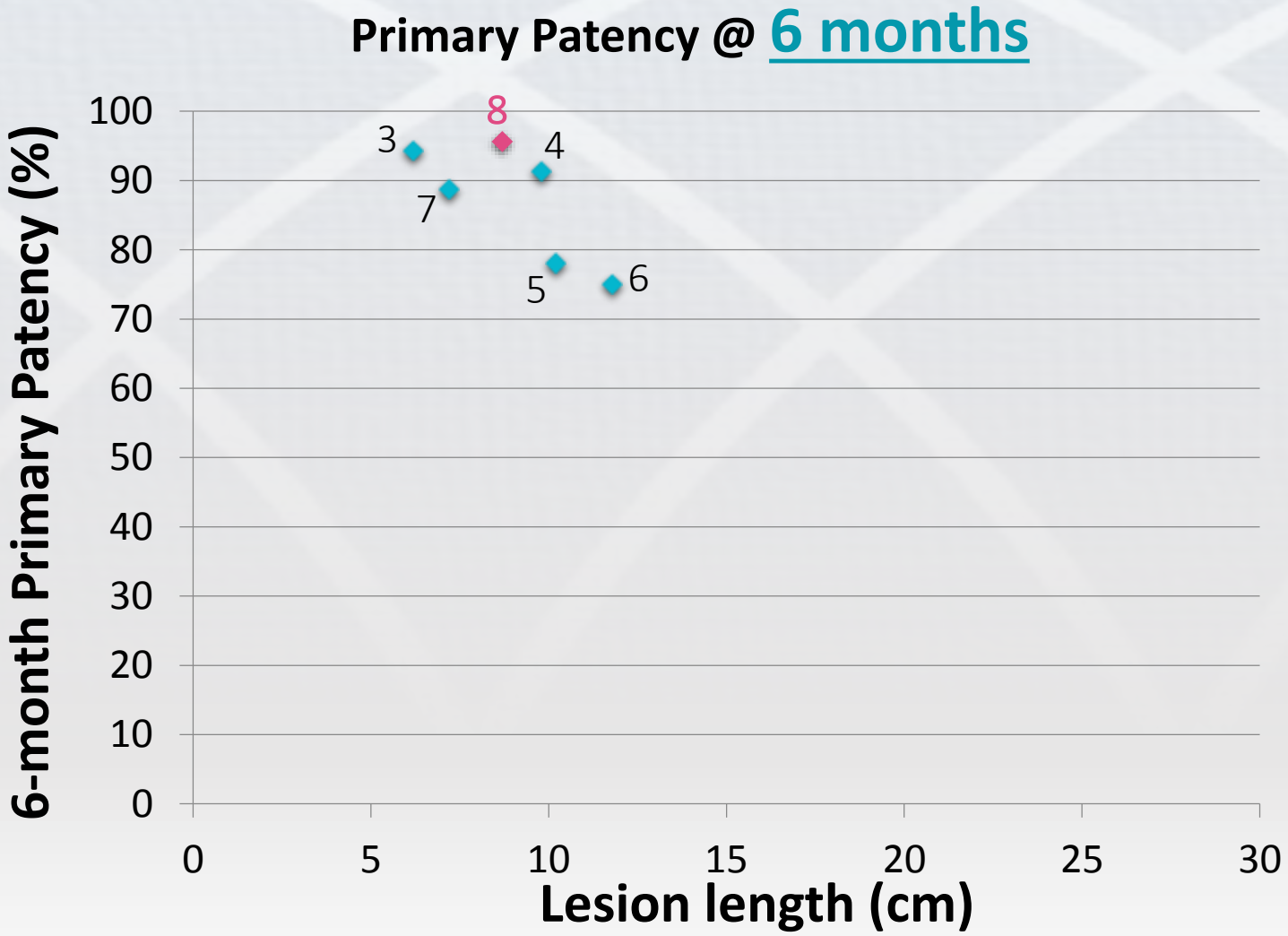


6-month Rutherford evolution



	Baseline	Discharge	1MFU	6MFU
RF5	0	0	2	0
RF4	10	0	0	0
RF3	47	0	1	2
RF2	18	2	1	1
RF1	0	3	7	7
RF0	0	68	55	50

Results with stents in the SFA – TASC A & B



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8. Evolution

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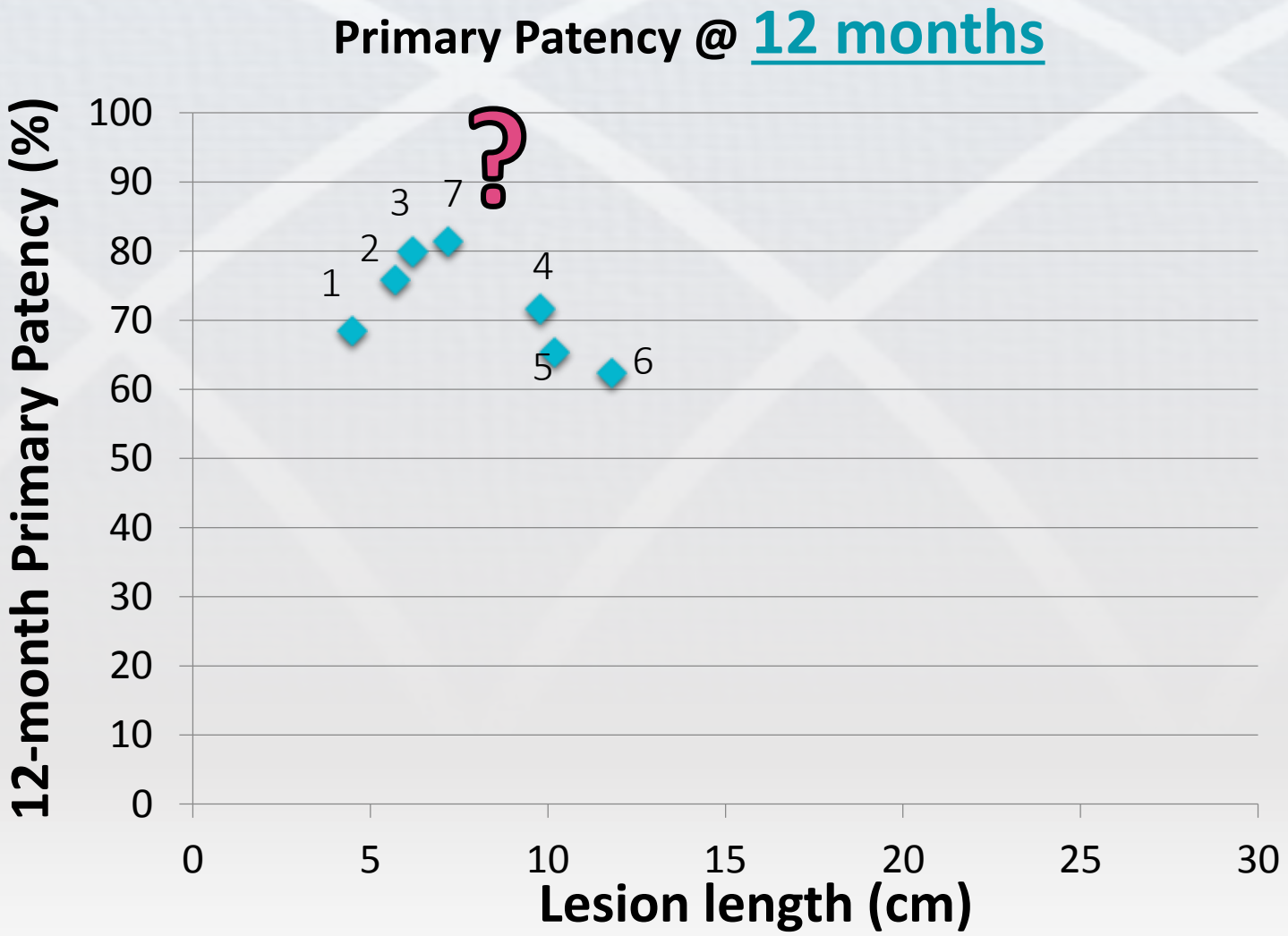

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Conclusion

- Preliminary results suggest that the iVolution stent is a valid en effective alternative to treat femoropopliteal TASC A&B lesions

- Awaiting for the final 12-month results

First 6-month results in 75 patients in the EVOLUTION study

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