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FMRP
Flanders Medical Research Program

A.Z. Sint-Blasius, Dendermonde
Marc Bosiers
Koen Deloose
Joren Callaert

Imelda Hospital, Bonheiden
Patrick Peeters
Jürgen Verbist

OLV Hospital, Aalst
Lieven Maene
Roel Beelen

R.Z. Heilig Hart, Tienen
Koen Keirse

Covered stents provide better results

Marc Bosiers, MD

Faculty Disclosure

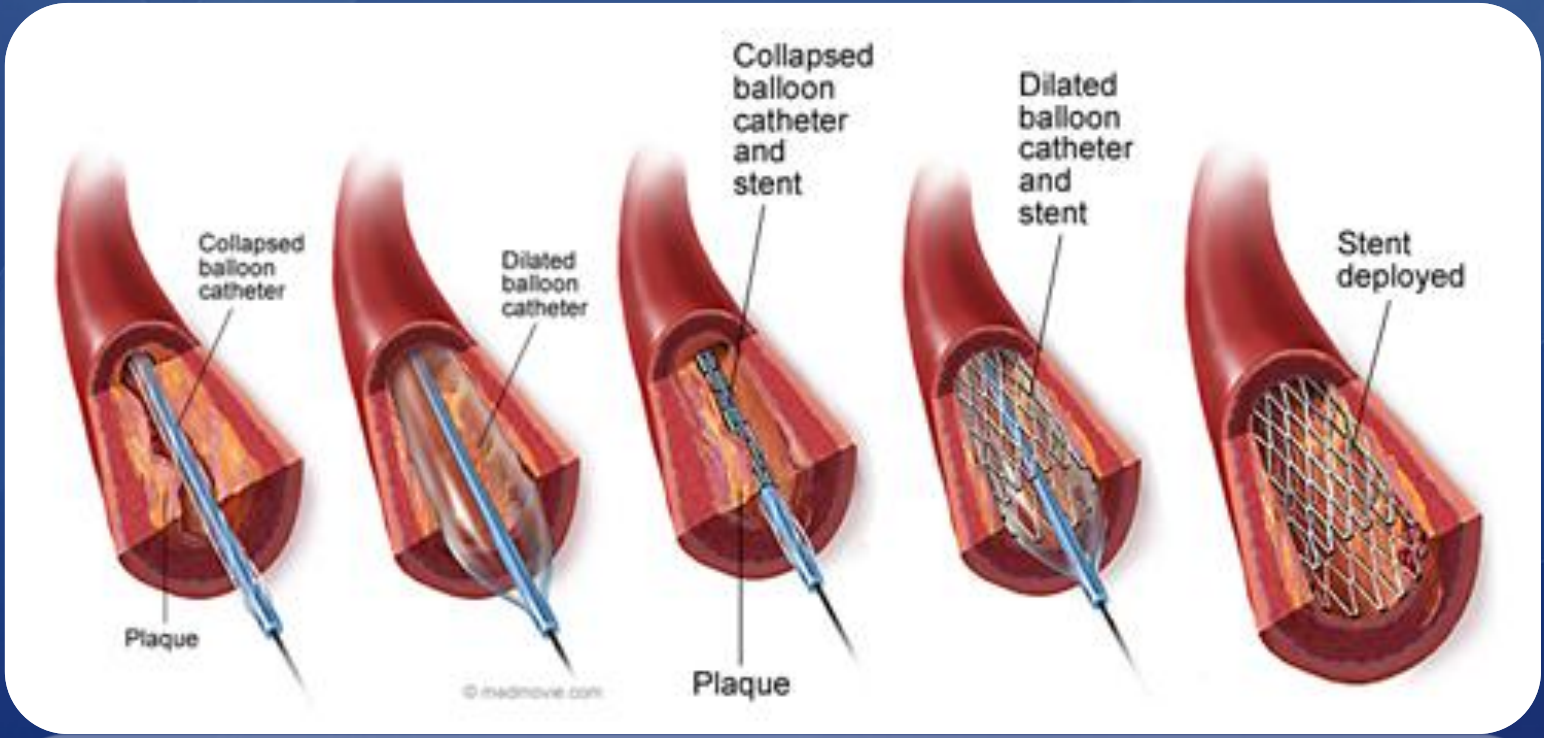
Marc Bosiers, MD

I disclose the following financial relationships:

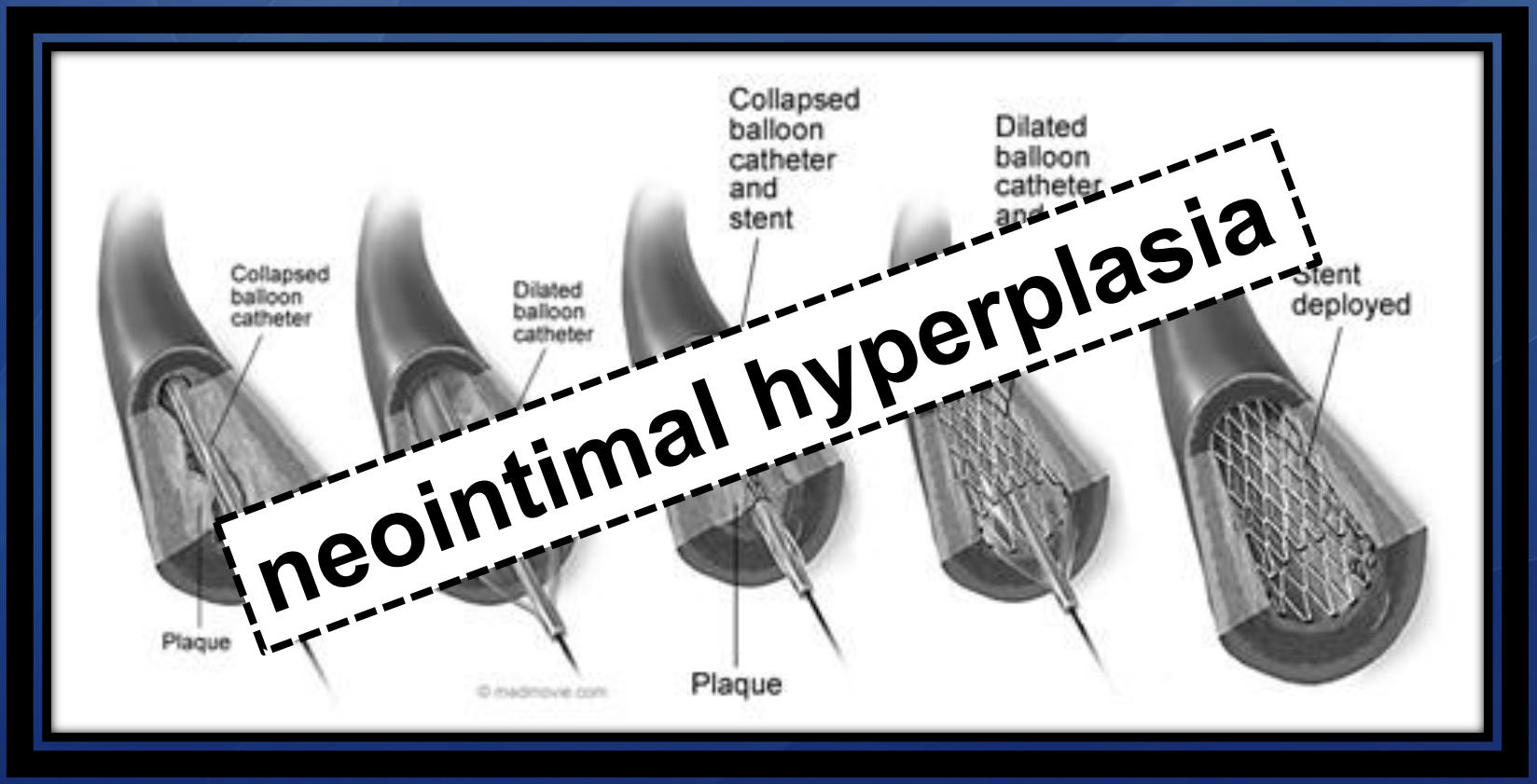
I have **no financial relationships** to disclose.

Je déclare les informations suivantes :
je n'ai **aucune relation financière** à déclarer.

Bare metal stents provide scaffolding for the plaque that is pushed aside during PTA



But…


Collapsed balloon catheter
Plaque
Dilated balloon catheter
Collapsed balloon catheter and stent
Plaque
Dilated balloon catheter and
Stent deployed
neointimal hyperplasia

Can covered stents provide better results?

VIBRANT trial

Prospective, randomized, multicenter trial

Question : Does the use of GORE VIABAHN® Endoprosthesis result in greater mid- and long-term patency compared to bare nitinol stents in treating long SFA lesions (> 8 cm)

Number of enrolled subjects : 72 Viabahn/76 BNS (148)

VIBRANT trial

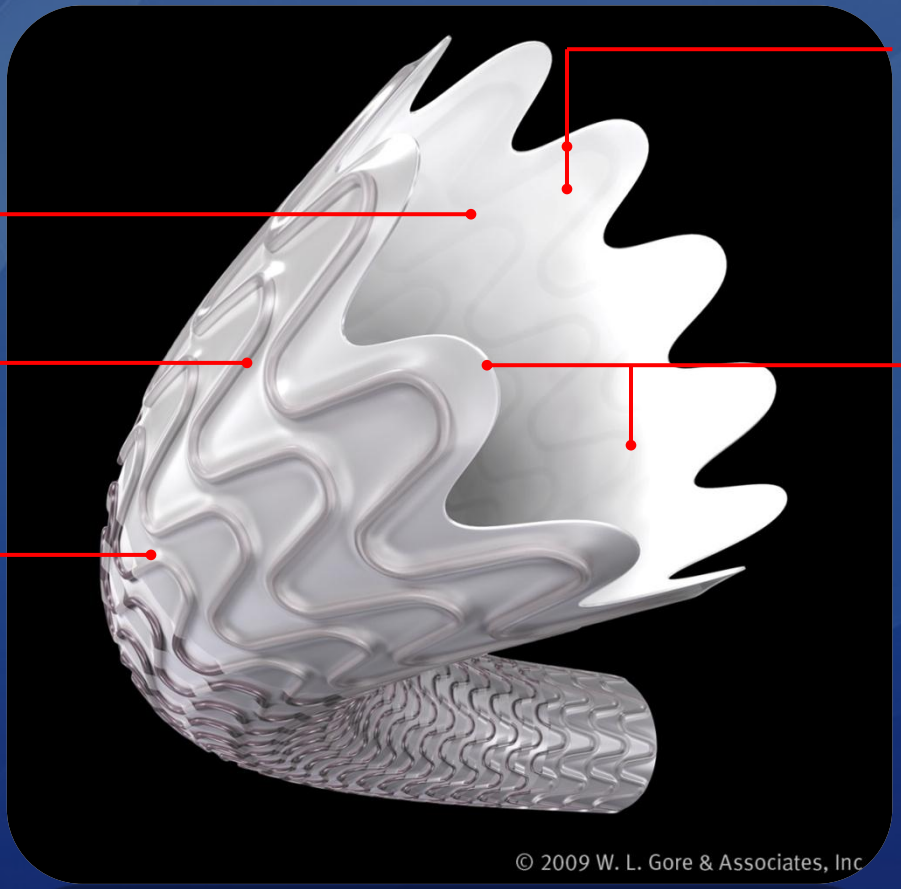
	Gore Viabahn Endoprosthesis	Bare nitinol stent	P-value
Number of randomized subjects	72	76	
Target lesion length *(standard deviation)*	19 cm (8)	18 cm (7)	0.87
Primary patency *(PSVR 2.5)*	**53%**	**58%**	**0.58**
Freedom from TLR	73%	69%	0.69

The next generation
Gore VIABAHN Endoprosthesis

Ultra-thin wall ePTFE tube

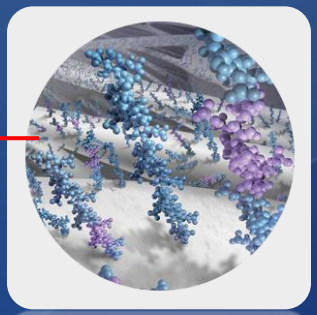
Unique, durable bonding film

Polished nitinol support



Contoured proximal edge

Propaten Bioactive Surface



Lengths:
2.5, 5, 10, 15, 25 cm

Diameters:
5 – 13 mm

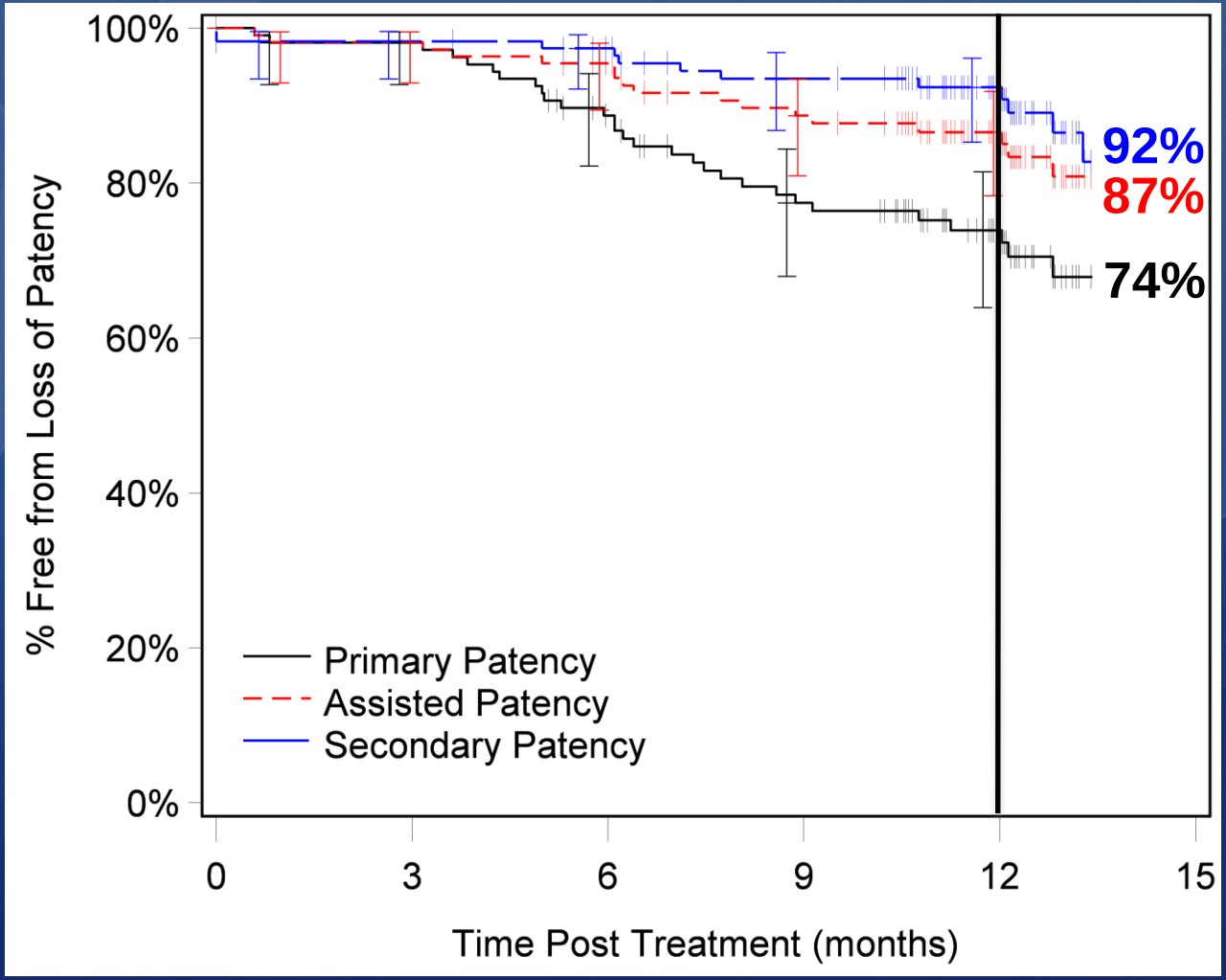
VIPER trial

Prospective, non-randomized, multicenter trial

Goal : Evaluate the performance of GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface in treating long-segment SFA disease (> 5 cm in length)

Number of enrolled subjects : 120 SFA lesions

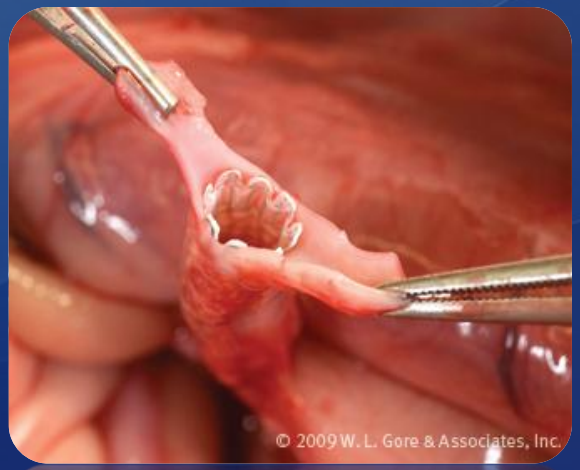
VIPER trial


100%
80%
60%
40%
20%
0%
% Free from Loss of Patency
0
3
6
9
12
15
Time Post Treatment (months)
Primary Patency
Assisted Patency
Secondary Patency
92%
87%
74%

VIPER trial

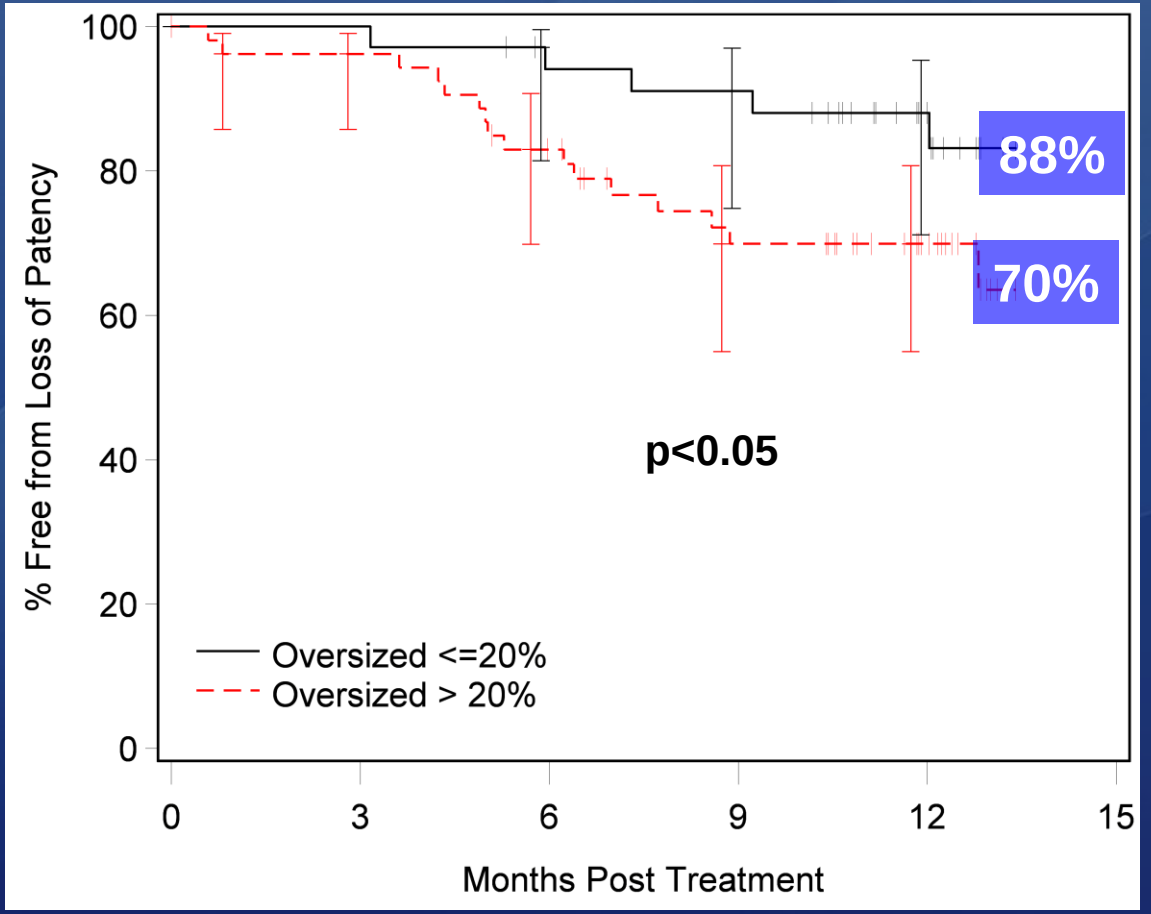
The GORE® VIABAHN® Endoprosthesis Device with Heparin Bioactive Surface exhibits good Patency in Long SFA Lesions that is:

- **Independent of lesion lengths**
  - **<20cm** lesions (n=68): Primary patency = **75%**
  - **>20cm** lesions (n=51): Primary patency = **70%**
- Independent of device diameter used
  - 5mm (n=23): Primary patency = 79%
  - 6mm (n=85): Primary patency = 69%
  - 7mm (n=8): Primary patency = 100%



VIPER trial

- **Sizing is Critical**
  - Primary patency is significantly better when IFU sizing is not exceeded at the proximal edge



No comparison…

VIASTAR trial

Prospective, **randomized**, multicenter trial

Goal : Evaluate the new generation GORE® VIABAHN® Endoprosthesis versus Bare Nitinol Stent in the treatment of SFA **TASC B, C and D lesions**

Number of enrolled subjects : 51 Viabahn/47 BNS (98)

VIASTAR trial

final 12 months results
as presented at CIRSE 2012

	Viabahn	BMS	p value
Primary patency	78%	53%	0.01
Freedom from TLR	85%	77%	0.37
Secondary patency	95%	98%	0.35

VIABAHN has a significantly higher
1 year primary patency rate

We have a winner!

What is the biggest challenge in SFA?

Look close!

RELINE trial

* After Protocol Deviations were excluded

RELINE trial

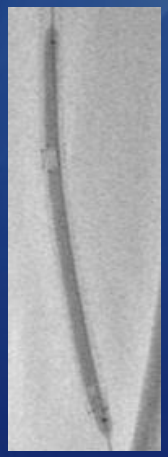
Primary endpoints

- **Primary patency at 12 months**
  - = no evidence of restenosis or occlusion within the originally treated lesion based on color-flow duplex ultrasound (CFDU) measuring a peak systolic velocity ratio ≤2.5 and without target lesion revascularization (TLR) within 12 months

- Proportion of subjects who experience **serious device-related adverse events within 30 days post-procedure**

RELINE trial

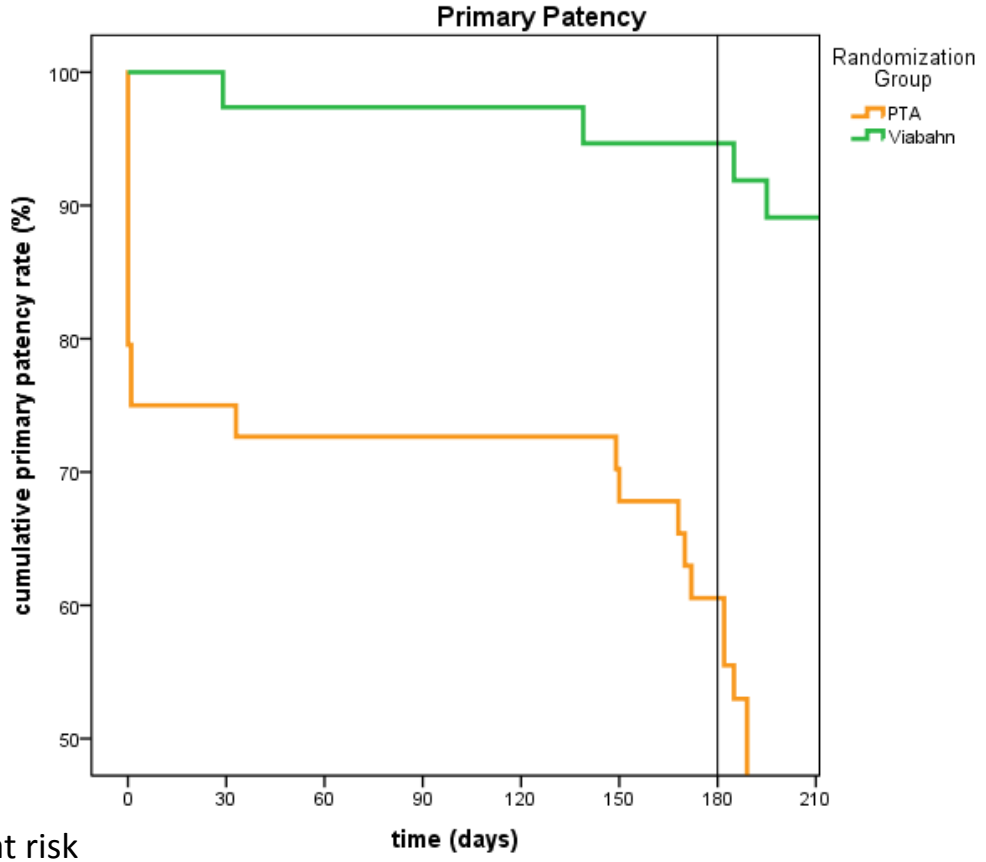
	PTA (N=44)	Viabahn (N=39)
Avg lesion length	190 (30-270)*	173 (30-330)
stenosis (pre)	75.0 %	76.9 %
chronic occlusion	25.0 %	20.5 %
acute occlusion	0.0 %	2.6 %
Calcified lesion	25.0 %**	33.3%



8 bail-out procedures after failed PTA

* Missing data of 3 patients
** Missing data of 1 patient

RELINE trial – 6M Primary Patency
VIABAHN vs. PTA



number at risk

PTA	44	33		24
VIABAHN	39	37		35

94.7 %

60.5 %

p<0.001

Conclusion

1) De novo lesions:

   The VIABAHN endoprosthesis shows higher primary patency rates when compared with Bare Metal Stents.

2) In-Stent Restenosis:

   The VIABAHN endoprosthesis is a promising tool.

Over & out