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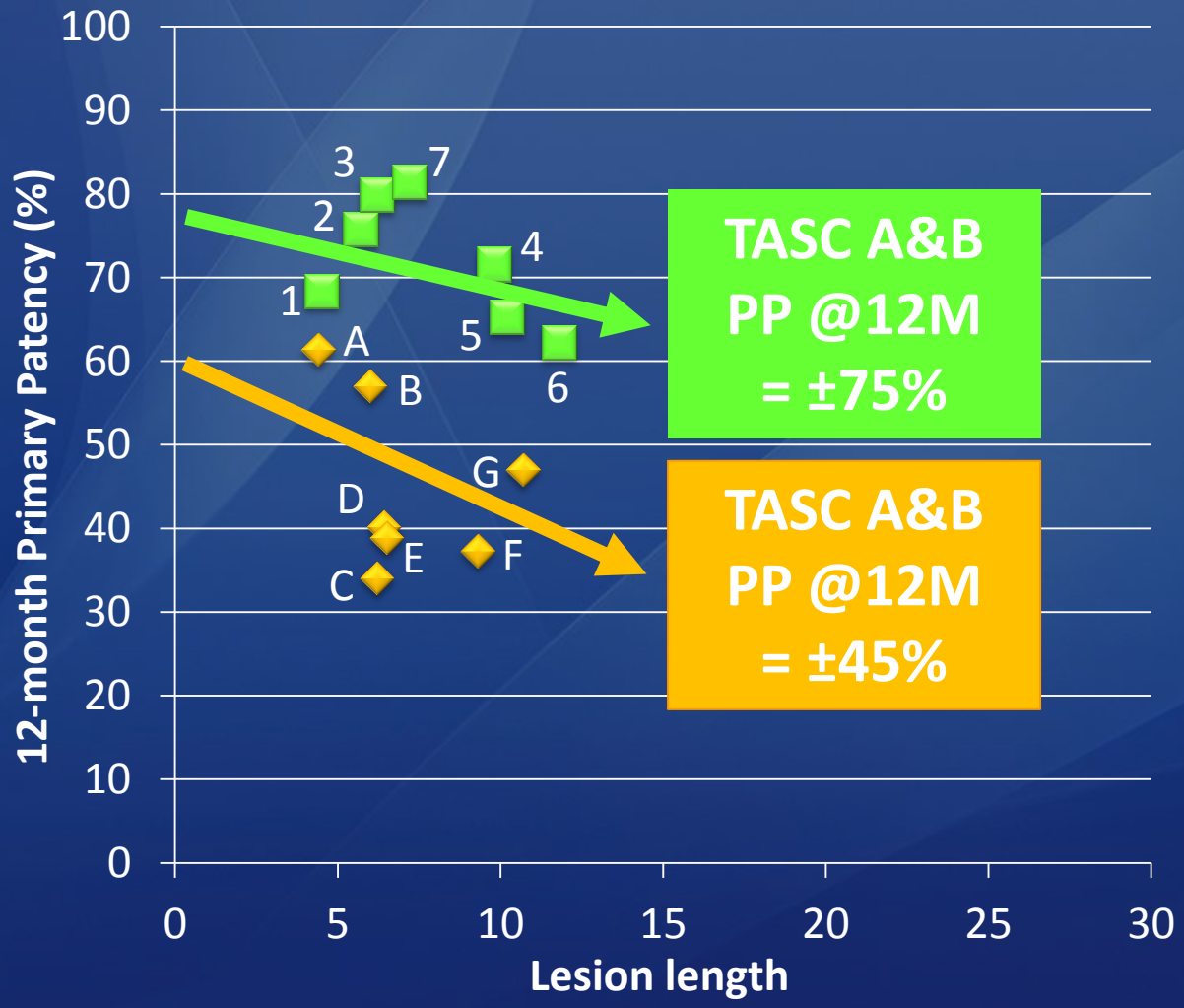
Does Zilver PTX DES yield better results than an open bypass?

Marc Bosiers, MD

Disclosure slide

- ☐ 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)
- ☑ I do not have any potential conflict of interest

Results with PTA and stents in the SFA



TASC A&B PP @12M = ±75%

TASC A&B PP @12M = ±45%

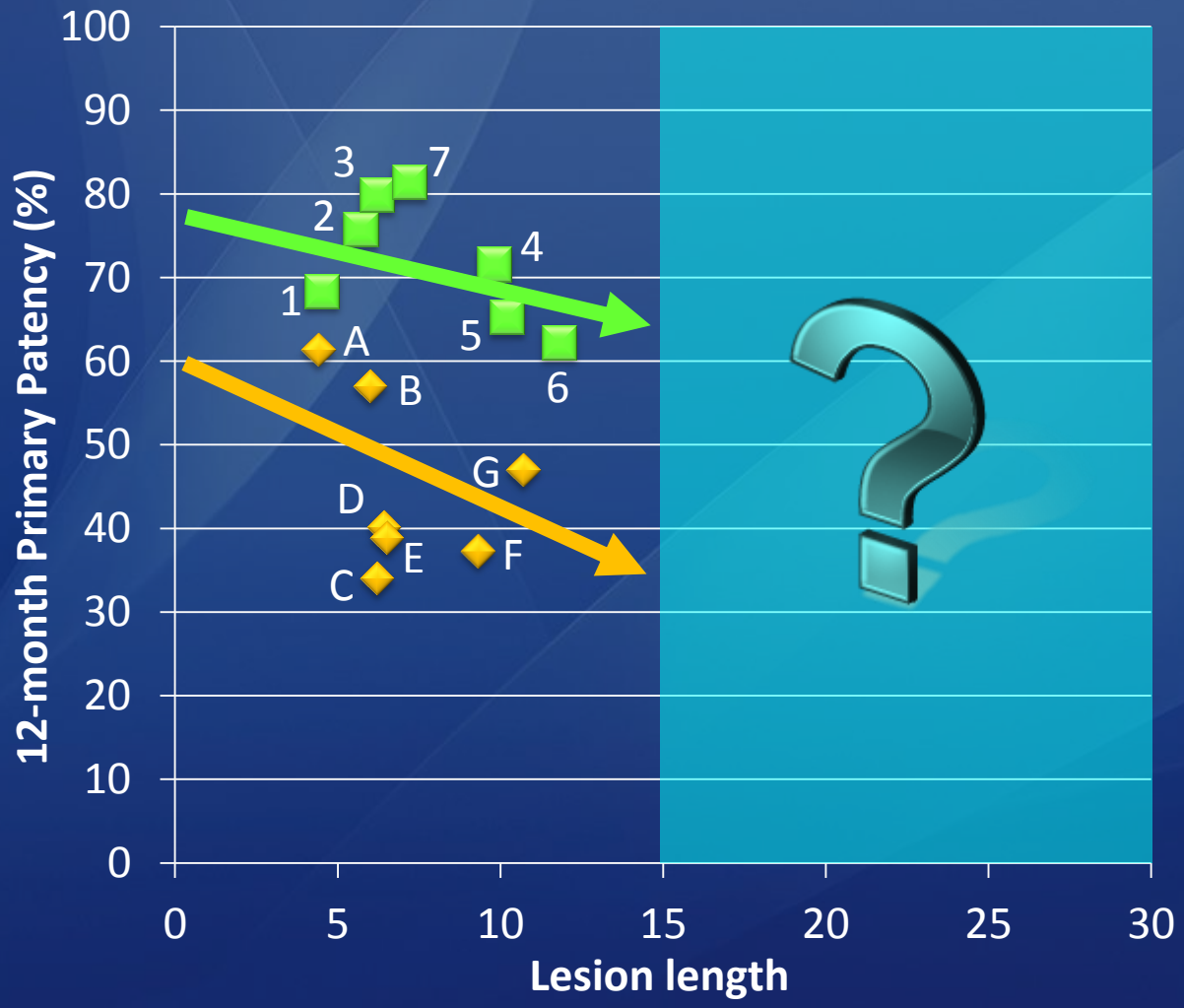
Stent

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

PTA

A. FAST
B. ZILVER PTX
C. RESILIENT
D. Saxon
E. ASTRON
F. VIENNA
G. VIENNA-3

What about long lesions?



Stent

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PTA

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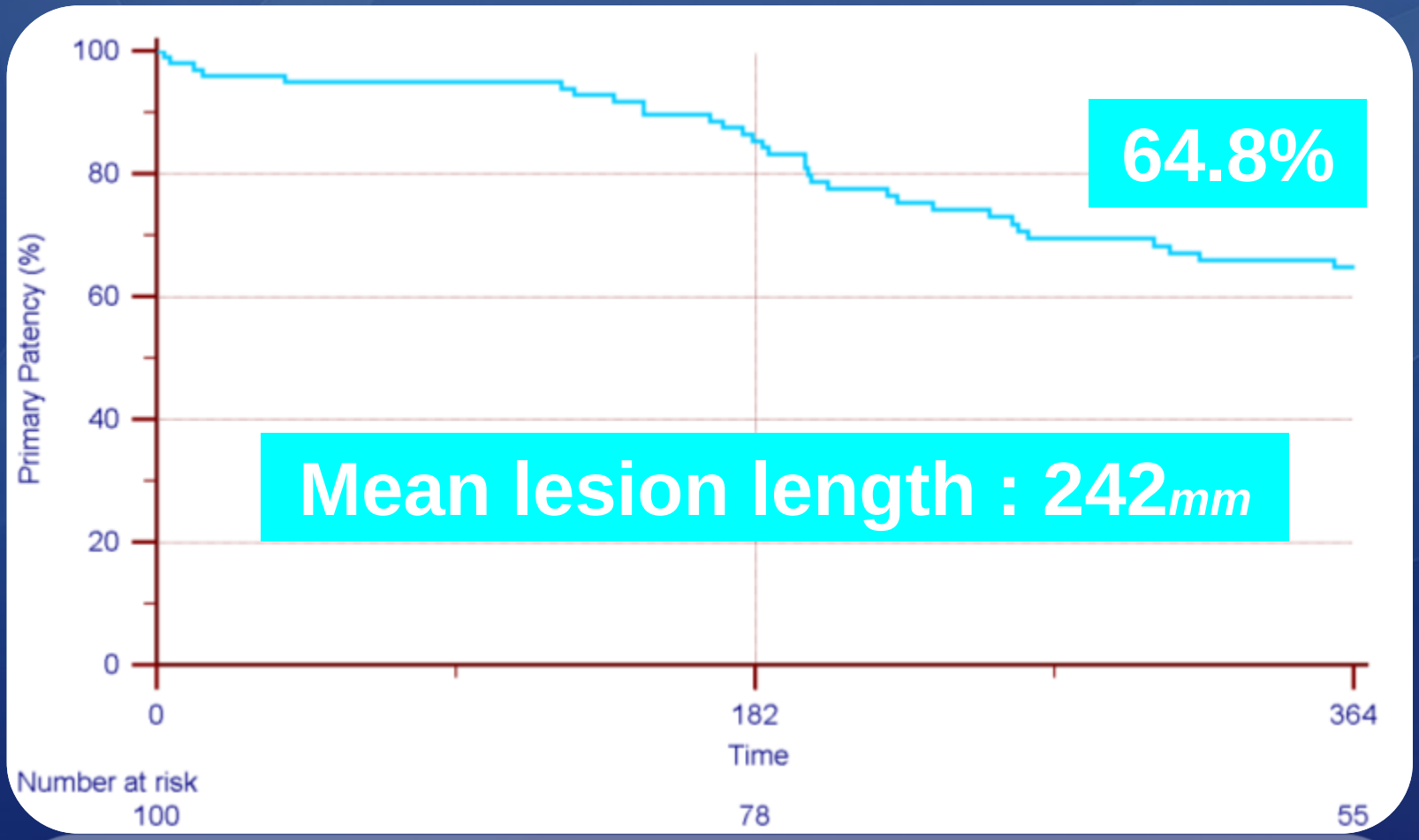
A] Nitinol stent

Durability-200: 12M primary patency



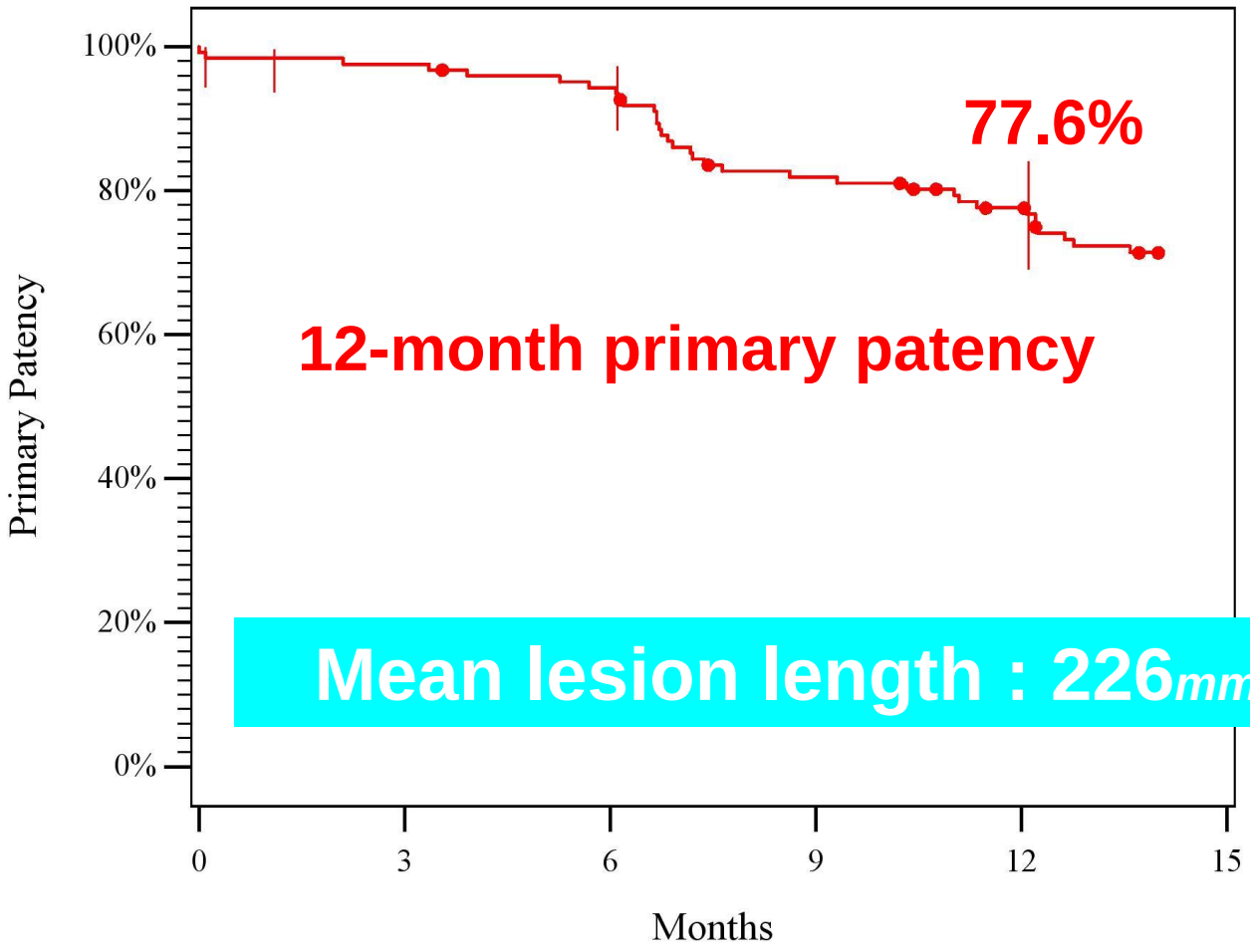
B] Stent graft
Viastar study: 12M results

	Viabahn	BMS	p value
% Chronic occlusions	76.9%	71.4%	0.55
Lesion length (mm)	**194**	**174**	**0.08**
Stented length (mm)	236	206	0.02
Target vessel reference diameter	6.2	5.3	0.31

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

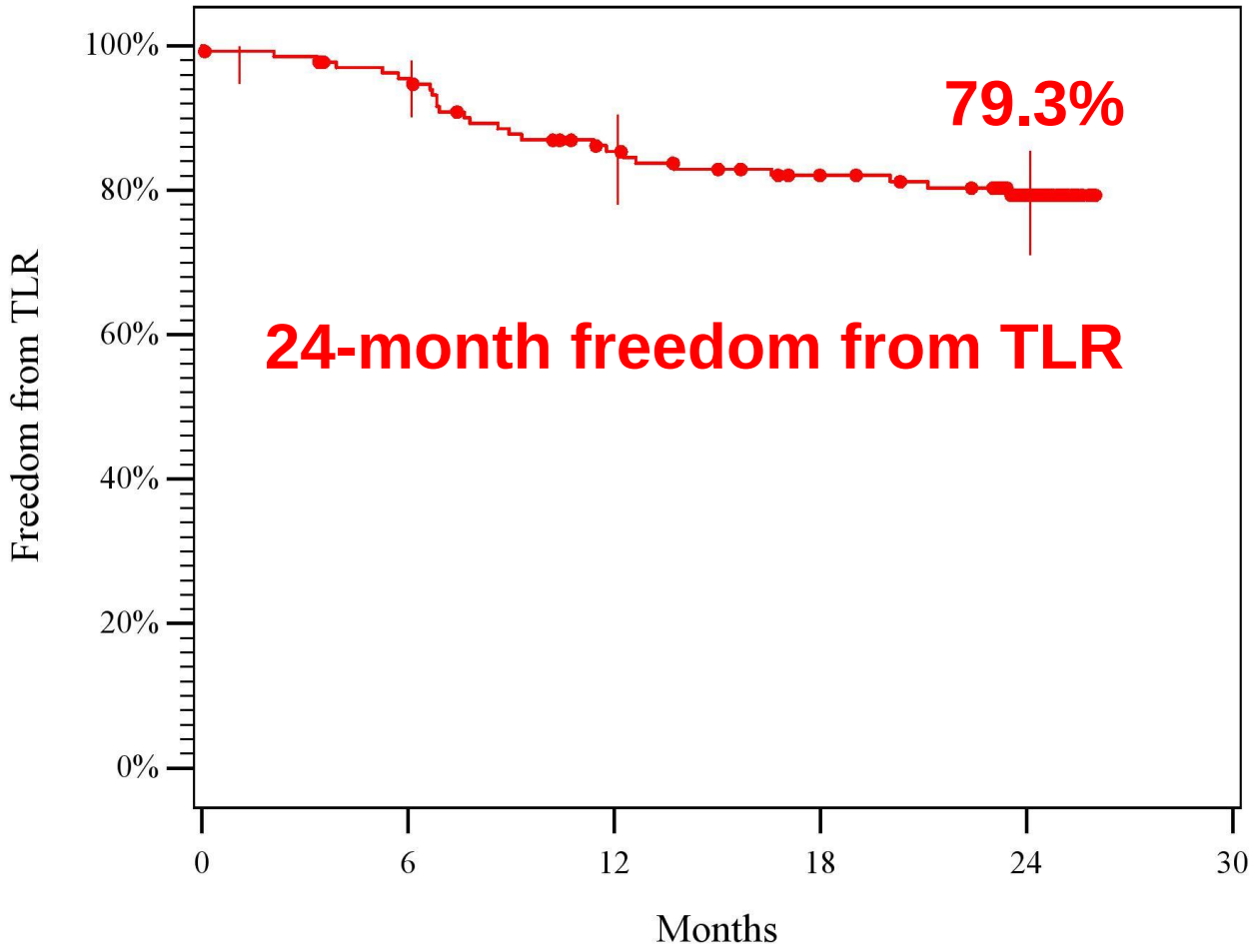
C] Drug-eluting stent

Zilver PTX (long lesions): 12M primary patency

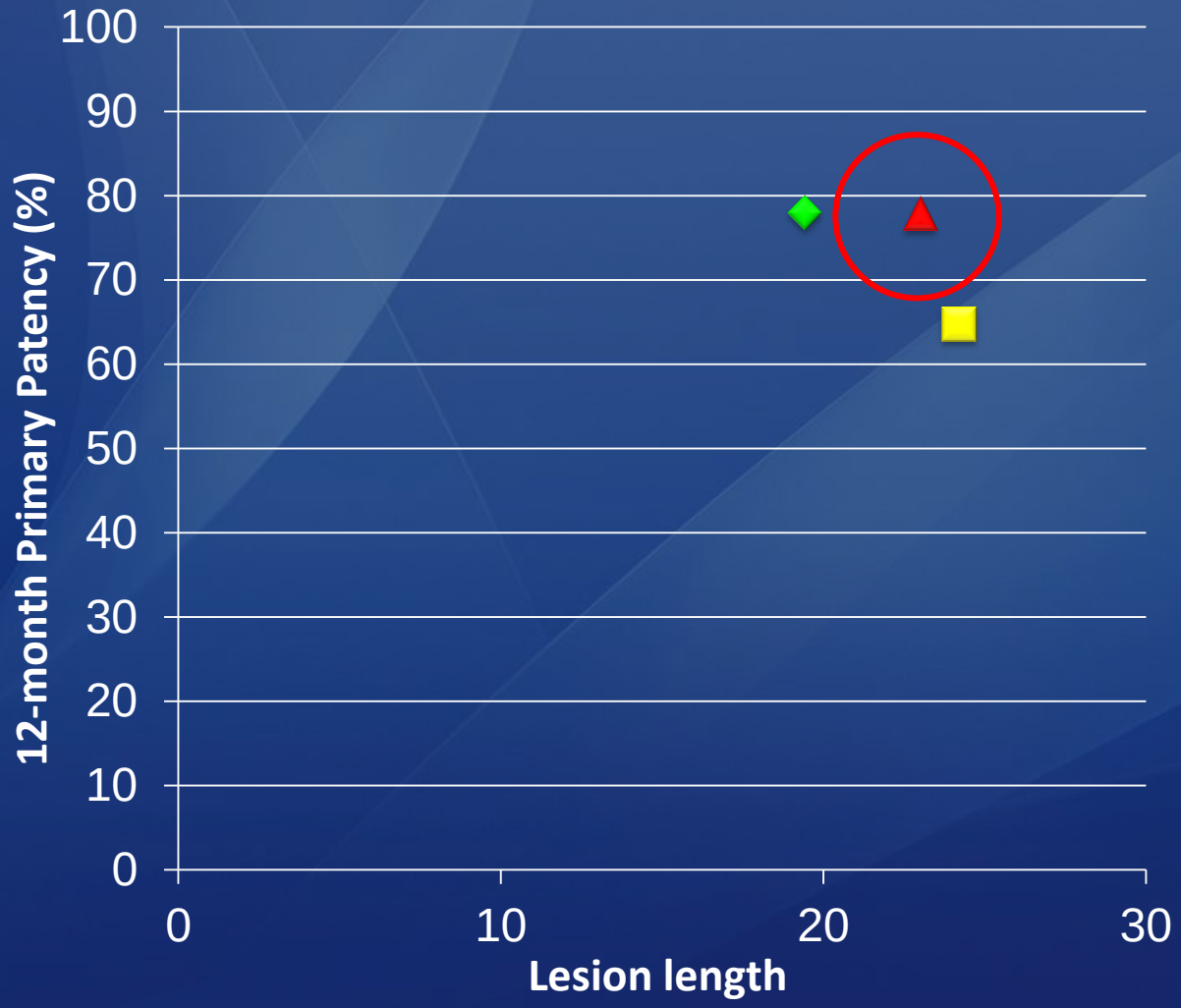


Mean lesion length : 226*mm* ± 44

Zilver PTX (long lesions): 24M freedom from TLR



Evolution of endovascular tools and results



DES

ZILVER PTX

VIABAHN

VIASTAR: Viabahn

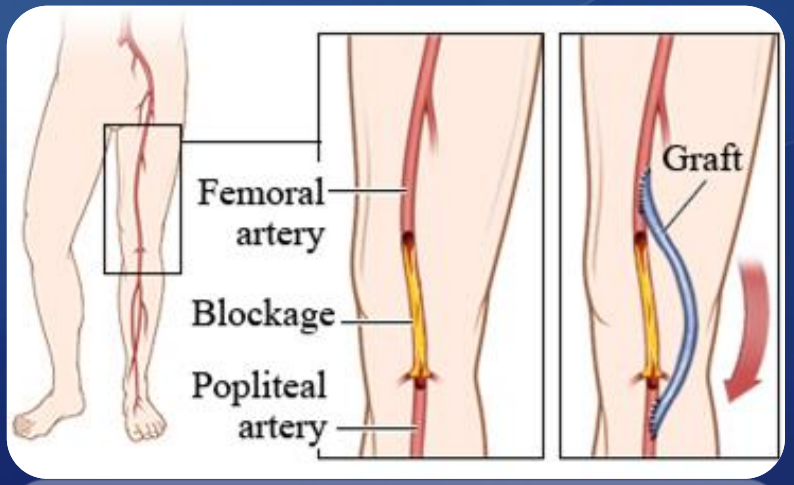
NITINOL STENT

DURABILITY-200

Drug-eluting stent is the superior endovascular therapy for long lesions

And compared to bypass?

VS



Results of bypass studies

First Author/Yr	Type of Study	Study Population	Primary patency
Hines/2010	Retrospective	27 patients with TASC D lesions above- and below-knee venous FP bypass bypass	12 months: 73.2%
McQuade/2009	Prospective, randomized ePTFE/nitinol stent graft vs AK-popliteal bypass with synthetic material	86 patients/100 limbs 50 limbs: stent graft 50 limbs: by	12-month: Stent-graft: 72% Bypass: 77%
Kedora/2007	Prosepctive,R Viabahn stent prosthetic fem knee) popliteal		12-month: Stent: 73.5% Bypass: 74.2%
Jensen/2007	Prospective, Ran PTFE and Dacron the knee femoropopliteal bypass	ients with chronic lower limb ischemia with bypass for supragenicular bypass: 205 with PTFE and 208 with Dacron	12-month: Dacron: ~78% PTFE: ~70%
Berglund/2005	Retrospective comparison: autologous saphenous vein grafts to PTFE grafts	499 patients undergoing bypassfor CLI or claudication: -139 with vein graft -360 with ePTFE	Vein, claudication: ~87% ePTFE, claudication: ~75%

Bypass PP @12M = +/-78%

Difference in Primary Patency definition

- **Surgical**

  →Assessing flow through the bypass: open or closed?

- **Endovascular**

  →Absence of binary restenosis (PSV≥2.4)

Analysis of PSV in 100 surgical, primary patent bypasses

	Total (N=100)	Binary restenosis (N=11)
F-P1	37	3
F-P2	0	0
F-P3	47	6
F-tibial	16	2

100% surgical primary patent = 89% endo primary patent

Bypass PP @12M = +/-78%

Bypass PP @12M = +/-70%

ZILVERPASS study

The Cook Zilver PTX drug-eluting stent

versus

bypass surgery

for the treatment of

femoropopliteal TASC C&D lesions.

ZILVERPASS study

- Prospective, randomized, multicenter trial

- Objective:

  To evaluate the performance of the Cook Zilver PTX paclitaxel-eluting stent compared to bypass surgery for the treatment of TASC C & D lesions

Study design

Participating Centers

Country	Center
Belgium	AZ Sint-Blasius **Dendermonde** Imelda Ziekenhuis **Bonheiden** OLV Ziekenhuis **Aalst** RZ Heilig Hart **Tienen** Universitair Ziekenhuis Antwerpen - **Edegem**
Germany	Herzzentrum / Park-Krankenhaus **Leipzig** St. Fransiskus Hospital **Münster** Klinikum Rechts der Isar **München** Universitätsklinikum Hamburg-Eppendorf **Hamburg** St. Bonifatius Hospital **Lingen**
Italy	Universitaria di **Siena** Ospedale San Donato di **Arezzo** Ospedale di **Udine** Azienda Ospedaliero – Universitaria di **Modena** Ospedale San Raffaele di **Milano** Universitaria di **Catania**

ZILVERPASS study
Primary endpoints

- **Primary patency at 12 months**
  - Zilver PTX stent:

    absence of evidence of binary restenosis or occlusion based on color-flow duplex ultrasound (CFDU)
  - Bypass arm:

    absence of evidence of binary restenosis or occlusion at the proximal and distal anastomoses

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

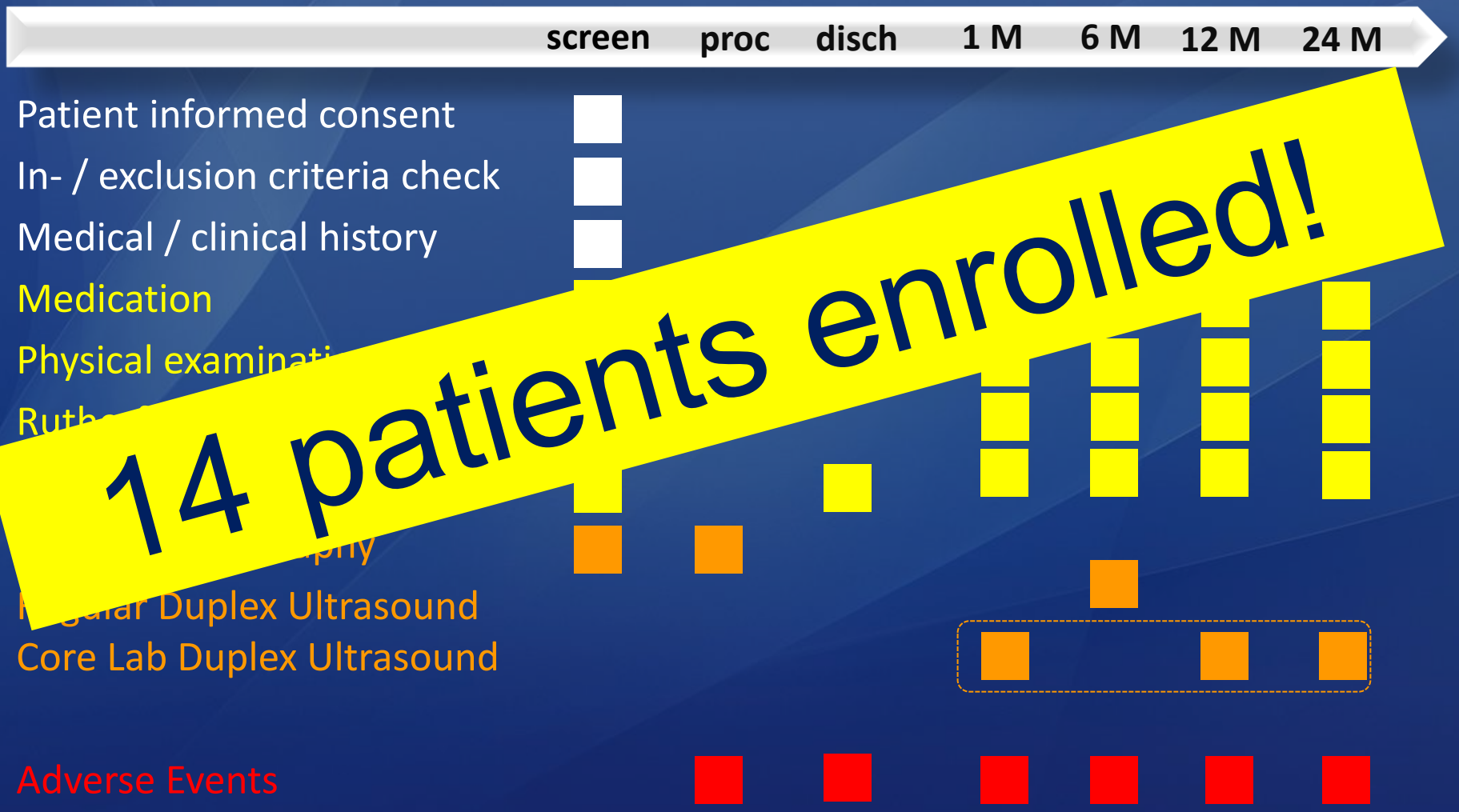
ZILVERPASS study
Secondary endpoints

- **Technical success:**
  - Zilver PTX stent: defined as the ability to cross and stent the lesion to achieve residual angiographic stenosis no greater than 30% and residual stenosis less than 50% by duplex imaging
  - Bypass arm: defined as no graft lesion and a low resistance blood flow pattern in the distal graft and outflow artery, as evidenced by duplex
- **Infection rate / hematoma** at puncture site or at incision sites requiring intervention
- **Hemodynamic primary patency rate** at 1, 6, 12 and 24-month follow-up.
- **Primary assisted patency rate** at 1, 6, 12 and 24-month follow-up.

ZILVERPASS study
Secondary endpoints

- **Secondary patency rate** at 1, 6, 12 and 24-month follow-up
- **Target lesion revascularization** (TLR) at 1, 6, 12 and 24-month follow-up
- **Clinical success** at follow-up is defined as an improvment of Rutherford classification at 1 day and 1, 6, 12 and 24-month follow-up of one or more as compared to the pre-procedure Rutherford classification
- **Serious Adverse Events** (SAEs) as defined within ISO 14155:2011

Timeline | screening & hospitalization



14 patients enrolled!

Let’s see what happens…