Surgical Bypass vs. Zilver PTX stent for long SFA lesions : Interim results of the ZilverPass Trial

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Disclosure slide

Speaker name: Koen Deloose, MD

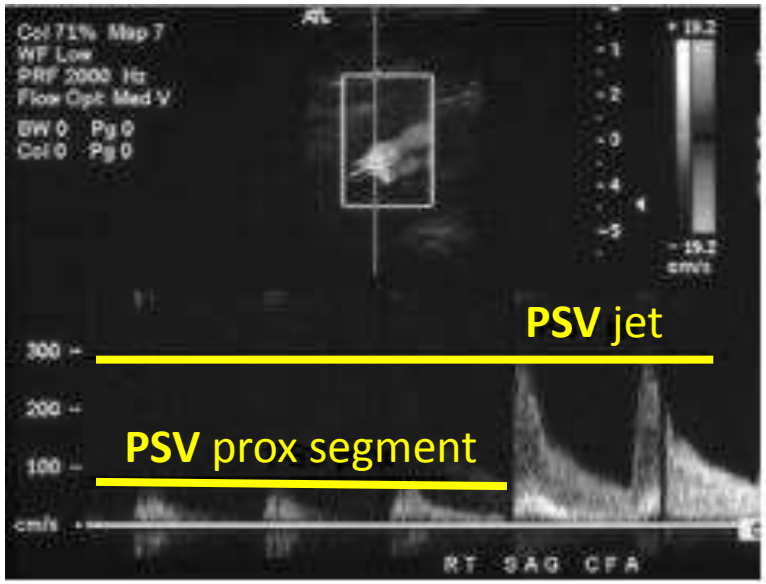
❑ I have the following potential conflicts of interest to report:

- ☒ Consulting: Medtronic, Spectranetics, Biotronik, Abbott, Bard iVascular, Bentley, Cook, GE Healthcare
- ❑ Employment in industry
- ❑ Stockholder of a healthcare company
- ❑ Owner of a healthcare company
- ❑ Other(s)

❑ I do not have any potential conflict of interest

Patencies Zilver PTX LONG LESIONS

PSVR (V r) = PSV (jet) / PSV (prox segment)



PSVR :
300/80 = 3,75

PSVR value (duplex US)
≤2,5
dovasc Ther 2011;18:613-23
≤2,5
diVasc Surg 2013;54:115-22
≤2,4
rdiol Intv 2016;9(3):271-77
≤2,0
INC 2014, Leipzig, Germany

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PSVR correlation to angiographically derived 50% DS:

TABLE III. Comparison of the Performance of PSVR for 50% Stenosis in Native and Stented Femoral Artery

Author (year)	Artery analyzed	Native/ stented	Denovo/ restenosis	Application of QVA	PSVR criteria for 50% stenosis	Sens. (%)	Spec. (%)	PPV (%)	NPV (%)	Accura. (%)
Polak et al. (1990)	Femoropopliteal	Native	Denovo	No	2	88	95	NR	NR	93
Legemate et al. (1991)	Femoropopliteal	Native	Denovo	No	2.5	65	97	69	96	94
Ranke et al. (1992)	Iliac to femoral	Native	Denovo	No	2.4	87	94	94	88	NR
Leng et al. (1993)	Femoropopliteal	Native	Denovo	No	3	70	96	95	74	NR
Aly et al. (1998)	Femoral	Native	Denovo	No	2	100	99	95	100	NR
Aly et al. (1998)	Femoropopliteal	Native	Denovo	No	2	95	99	94	99	NR
Schlager et al. (2007)	Femoropopliteal	Native (97%) and stented (3%)	Denovo and restenosis	No	2.4	81	93	84	91	NR
Baril et al. (2009)	Femoropopliteal	Stented	Restenosis	No	1.5	93	89	96	81	NR
Present study	Superficial femoral	Stented	Restenosis	Yes	2.85	88	84	85	88	86

Sens: sensitivity, Spec: specificity, PPV: positive predictive value, NPV: negative predictive value, Accura: accuracy, and NR: not reported.

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Patencies prosthetic bypass ATK

recurrent arterial or graft stenosis. Primary and secondary patency rates and graft failure rates were defined with the criteria previously described by Ahn[15] and Rutherford.[16]

Criteria for patency

Articles in scientific journals should only accept patency rates that are based on objective findings. A bypass graft or otherwise reconstructed arterial segment may be considered patent when one of the following five criteria is met. Beyond the last date of such proof of patency, they must be considered lost to follow-up.

1. Demonstrably patent graft by an accepted vascular imaging technique, such as arteriography, Duplex ultrasound color-flow scan, or magnetic resonance imaging.
2. The presence of a palpable pulse, or the recording of a biphasic or triphasic Doppler wave form at *two* points directly over a *superficially* placed graft.
3. Maintenance of the achieved improvement in the *appropriate* segmental limb pressure index, that is, not more than 0.10 below the highest postoperative index. Although a greater reduction in pressure index may occur and the graft or reopened segment may still be patent, *imaging proof is required in these instances or any other doubtful or marginal circumstances covered under criteria 2, 3, or 4.* To avoid the confusing effects of distal runoff disease, the most appropriate pressure index for this purpose is at the next level beyond the revascularized segment or distal anastomosis (see comment below).
4. Maintenance of a plethysmographic tracing distal to the reconstruction that is at least 50% or 5 mm greater in magnitude than the preoperative value and close to the postoperative value. (This is the weakest criterion and acceptable *only* when accurate pressures cannot be measured, as with calcific arteritis in a diabetic patient. However, even in such cases, stronger evidence of patency, in the form of imaging, is clearly preferred.)
5. Direct observation of patency at operation or postmortem examination.

1 yr Primary Patency
Stentgraft : 72% Bypass : 77%
Stentgraft : 73,5% Bypass 74,2%
Dacron : 78% PTFE : 72%
Claudicants : 85,3% CLI : 76,3%

Rutherford R et al. JVS 1997 (Sept);26(3):517-38

Difference in Primary Patency definition

- **Surgical**

→Assessing flow through the bypass: open or closed?

- **Endovascular**

→Absence of binary restenosis (PSV≥2.0 ; 2,4 ; 2,5)

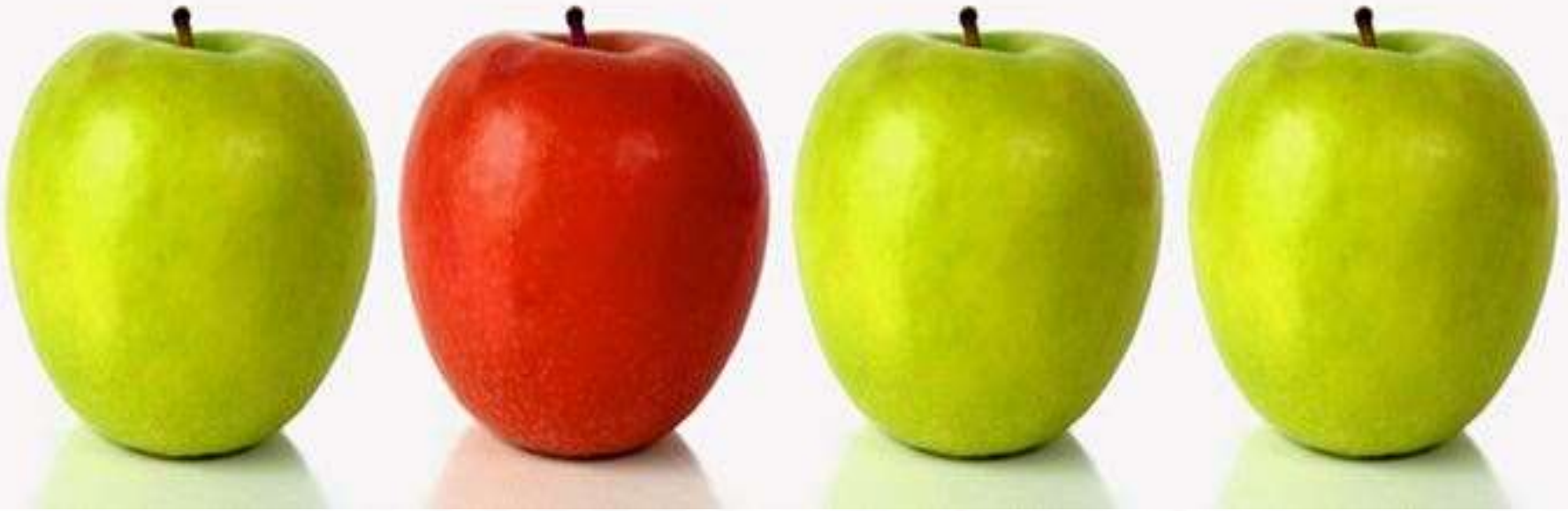
Analysis of PSVR in 100 surgical, primary patent bypasses

	Total (N=100)	Binary restenosis (N= 11)(PSVR >2,4)
F-P1	37	3
F-P2	0	0
F-P3	47	6
F-tibial	16	2

100% "open" bypasses

89% "open" bypasses

Compare *Apples to Apples* . . .
Anytime, Anywhere.



Let us randomize with the same assessment methods!

ZILVERPASS STUDY :

The Zilver PTX (Cook°) versus bypass surgery for the treatment of femoropopliteal TASC C&D lesions

Let us randomize with the same assessment methods!

prospective, multicenter, randomized

1:1 randomization

220 patients

Tasc C & D lesions

Belgium, Germany, Italy, Brazil

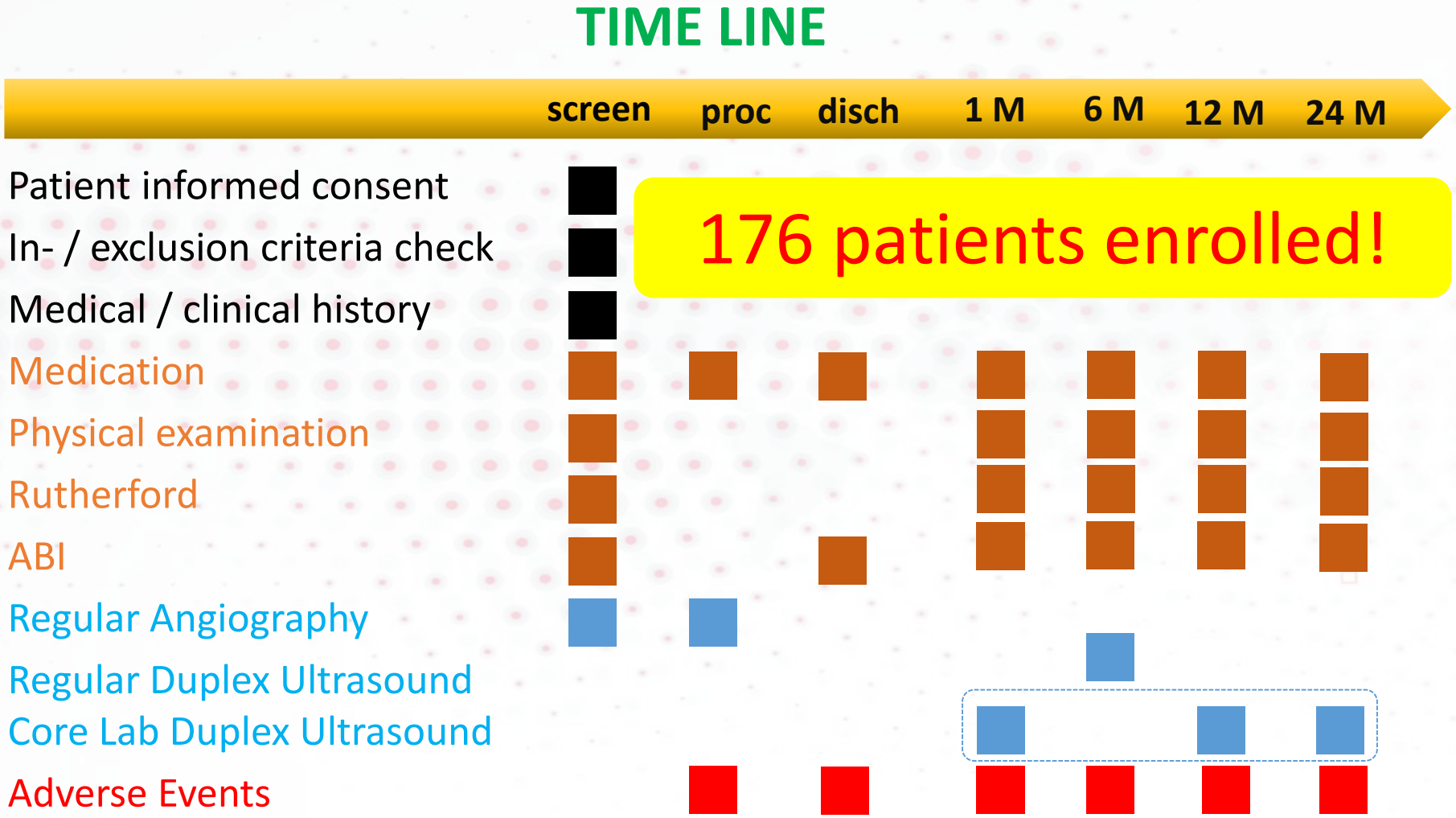
Zilver PTX

Surgical bypass

PRIMARY ENDPOINT

Absence of binary restenosis/ occlusion within treated lesion (CFDU PSVR < 2,4)	Absence of binary restenosis/ occlusion @ proximal/distal anastomoses/over the entire length of bypass graft (CFDU PSVR < 2,4)
Without TLR within 12 months	Without clinically driven reintervention to restore flow in bypass.

Let us randomize with the same assessment methods!



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Patient demographics

Preliminary
115 patients

		Total	ZILVER PTX	BYPASS	Signific
Gender	Female	35 (30.4%)	17 (30.36%)	18 (30.51%)	
	Male	80 (69.5%)	39 (69.64%)	41 (69.49%)	
Rutherford Baseline	2	11 (9.57%)	8 (14.29%)	3 (5.08%)	
	3	65 (56.52%)	33 (58.93%)	32 (54.24%)	
	4	16 (13.91%)	4 (7.14%)	12 (20.34%)	
	5	23 (20.00%)	11 (19.64%)	12 (20.34%)	
	Missing	0	0	0	
Age	(years)	69.08 ± 9.52	70.18 ± 10.26	68.04 ± 8.72	P = 0.229

Let us randomize with the same assessment methods!

Preliminary
115 patients

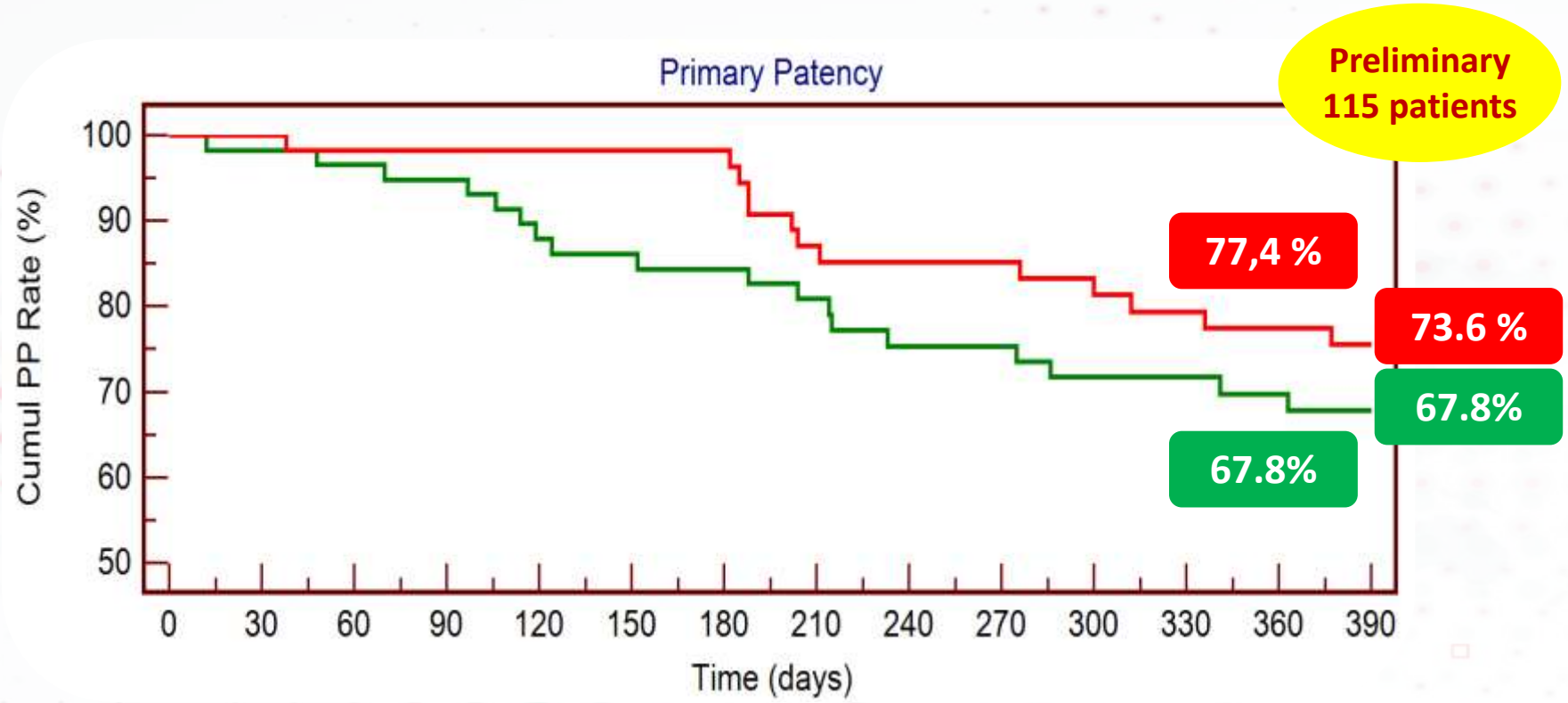
Lesion characteristics

	Total	ZILVER PTX	BYPASS	Signific
Stenosis % ; ± SD	98.95 ± 3.89 (N=115)	98.84 ± 4.16 (N=56)	99.07 ± 3.65 (N=59)	P = 0.553
Lesion Length Mm ; ± SD	253.45 ± 71.22 (N=115)	239.71 ± 64.11 (N=56)	266.49 ± 75.61 (N=59)	P = 0.114
ABI Baseline ± SD	0.594 ± 0.15 (N=115)	0.619 ± 0.14 (N=52)	0.570 ± 0.17 (N=53)	P = 0.468

Procedural characteristics

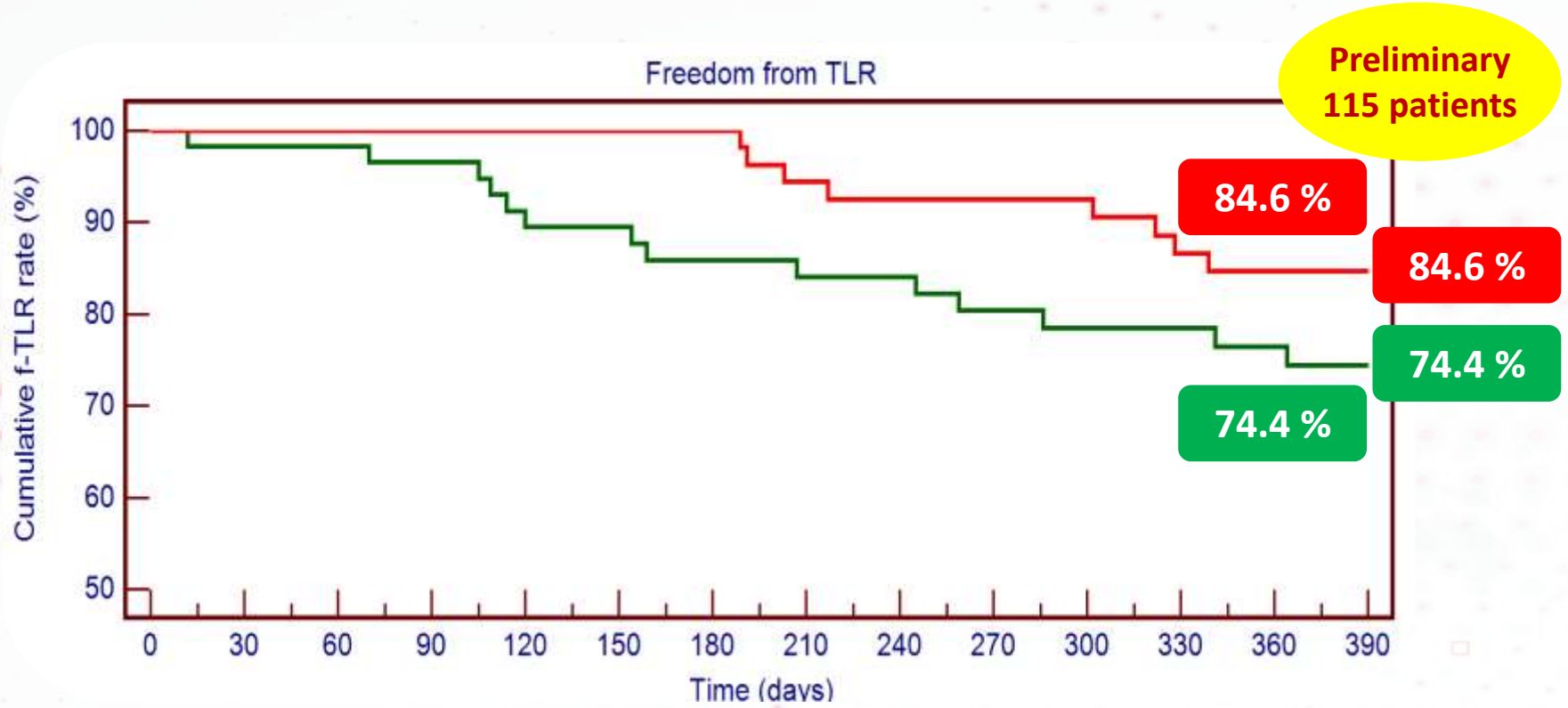
	Total	ZILVER PTX	BYPASS	Signific
Duration Procedure Minutes ; ± SD	82.00 ± 40.86 (N=112)	56.37 ± 20.80 (N=54)	105.86 ± 40.59 (N= 58)	P < 0.001

Let us randomize with the same assessment methods!



		Baseline	30 days	6MFU	12MFU – D365	12MFU D-395	
ZILVER PTX	Tar	56	55	53	40	40	P = 0.6005
	%	100	100	87.1	77.4	73.6	
BYPASS	Tar	59	57	48	36	36	
	%	100	98.3	80.9	67.8	67.8	

Let us randomize with the same assessment methods!



		Baseline	30 days	6MFU	12MFU – D365	12MFU D-395	
ZILVER PTX	Tar	56	55	54	43	43	P = 0.2809
	%	100	100	94.4	84.6	84.6	
BYPASS	Tar	59	57	48	38	38	
	%	100	98.3	84.1	74.4	74.4	

Conclusions

- Zilver PTX is obtaining outstanding primary patencies, also in long & more complex SFA lesions
- Patency analysis in these study cohorts are based on (relatively) objective CFDU PSVR assessments
- Maybe Prosthetic Bypass results are not that great in terms of patency, as we, vascular surgeons, always considered, especially when you use an “endovascular CFDU PSVR” based patency assessment
- Randomized controled trials, like the ZILVERPASS, with the same assessments and methodologies in both arms need to clarify the situation.
- Preliminary results in 115 patients show at least a non-inferiority of Zilver PTX versus prosthetic bypass surgery ATK.

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