

Faculty Disclosure

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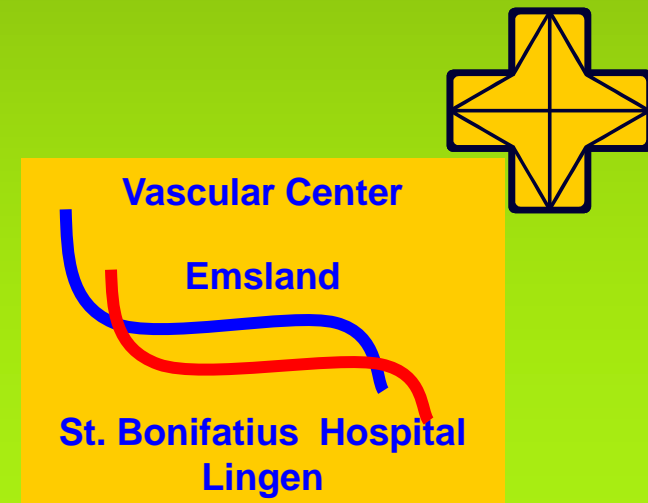
I disclose the following financial relationships:

Research grant from COOK Medical Inc.

Je déclare les informations suivantes :
représentant de la société COOK PI

Latest results of drug eluting stents in the SFA: The Zilver PTX[®] Randomized Trial: **3-Year Results**

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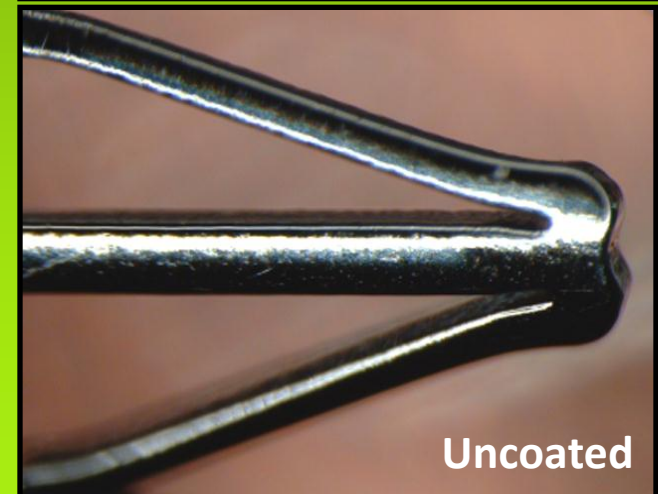
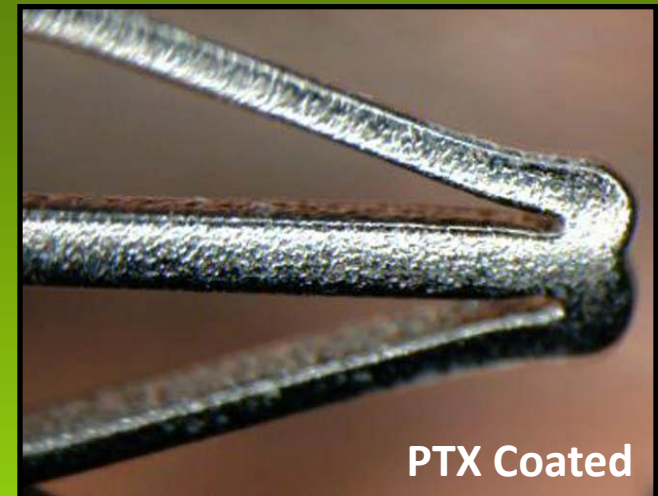


Drug eluting stents in the SFA for PAD and CLI

- Controversial discussion
 - SCIROCCO I/II
 - STRIDES
 - ZilverPTX

Zilver PTX Drug-Eluting Stent

- Designed for the SFA
- Available in 50 countries including EU and Japan
- Approval pending in US
- Dual therapy
 - **Mechanical scaffold:**
Zilver Flex[®] stent platform
 - **Drug therapy:** Paclitaxel only
 - No polymer or binder
 - 3 $\mu\text{g}/\text{mm}^2$ dose density
- Sponsor: Cook Medical



Patient Demographics and Comorbidities

	PTA	Zilver PTX [®]	<i>p</i> -value
Patients	238	236	
Age (years)	68 ± 11	68 ± 10	0.88
Male	64%	66%	0.70
Height (in)	66 ± 4	67 ± 4	0.55
Weight (lbs)	179 ± 44	180 ± 40	0.62
Diabetes	42%	50%	0.11
High cholesterol	70%	76%	0.12
Hypertension	82%	89%	0.02*
Past/current smoker	84%	86%	0.70

* Statistically significant

Baseline Lesion Characteristics

		PTA	Zilver PTX®	p-value
Lesions		251	247	
Normal-to-normal lesion length (mm)		63 ± 41	66 ± 39	0.36
Stenosed lesion length (mm)^{1,2}		53 ± 40	55 ± 41	0.71
Diameter stenosis (%)¹		78 ± 17	80 ± 17	0.38
Total occlusions		27%	33%	0.20
De novo lesions		94%	95%	0.69
Lesion calcification¹	None	5%	2%	< 0.01*
	Little	38%	26%	
	Moderate	22%	35%	
	Severe	35%	37%	

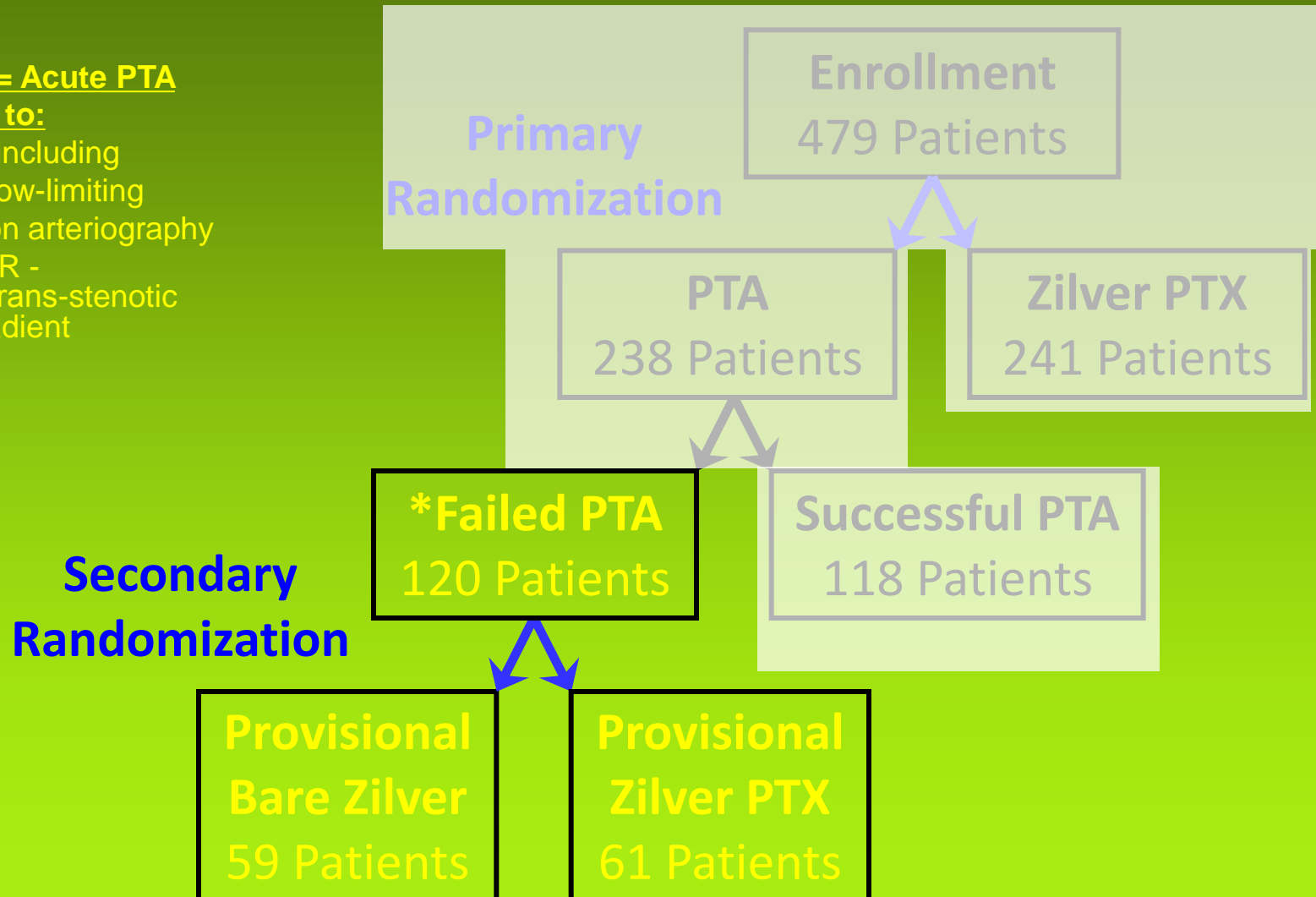
¹ Angiographic core lab assessment

Clinical Trial Design

* Failed PTA = Acute PTA

Failure Due to:

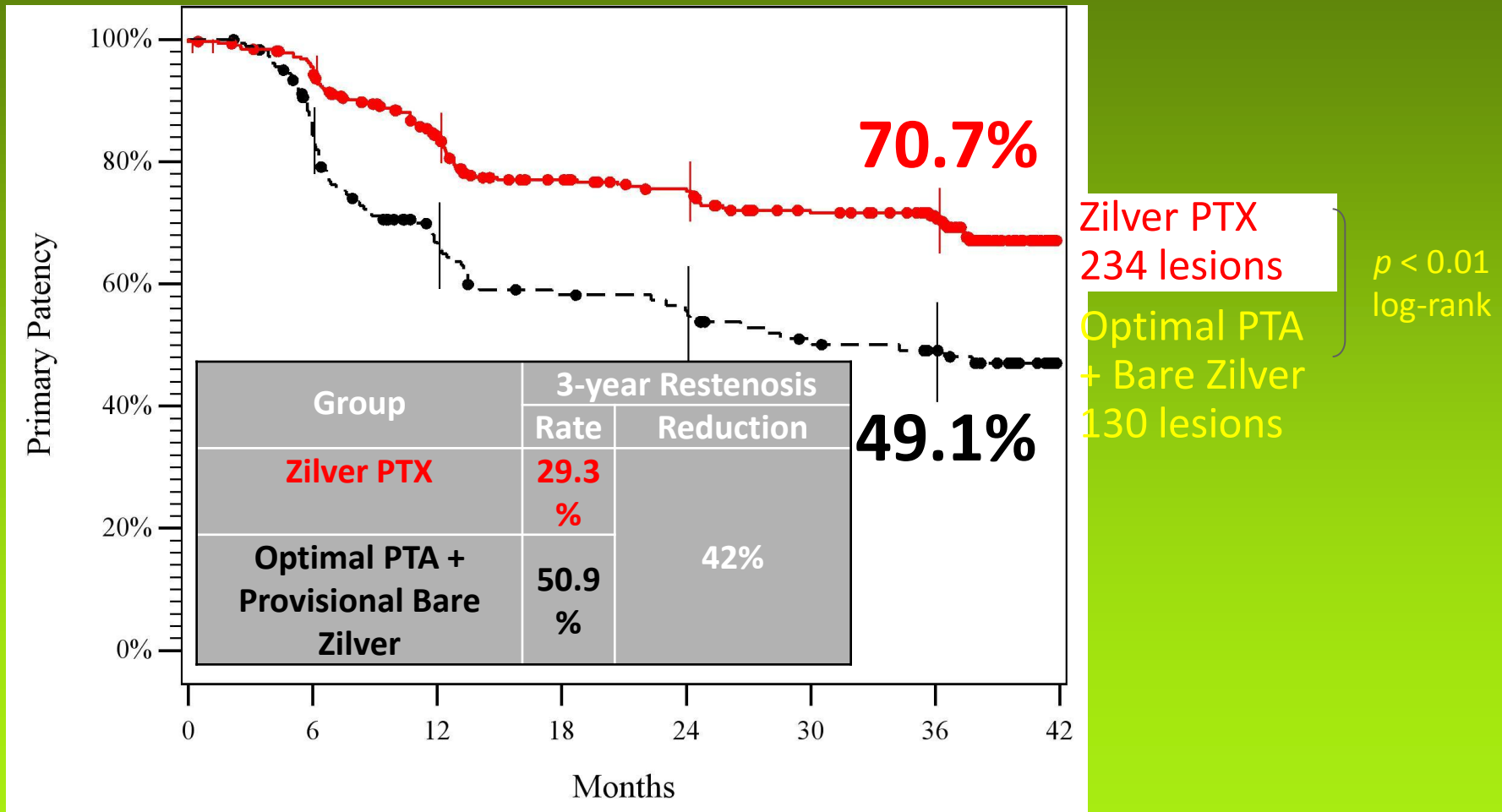
- ≥ 30 %DS (including persistent, flow-limiting dissection) on arteriography
- OR -
- ≥ 5 mmHg trans-stenotic pressure gradient



Low Stent Fracture Rate

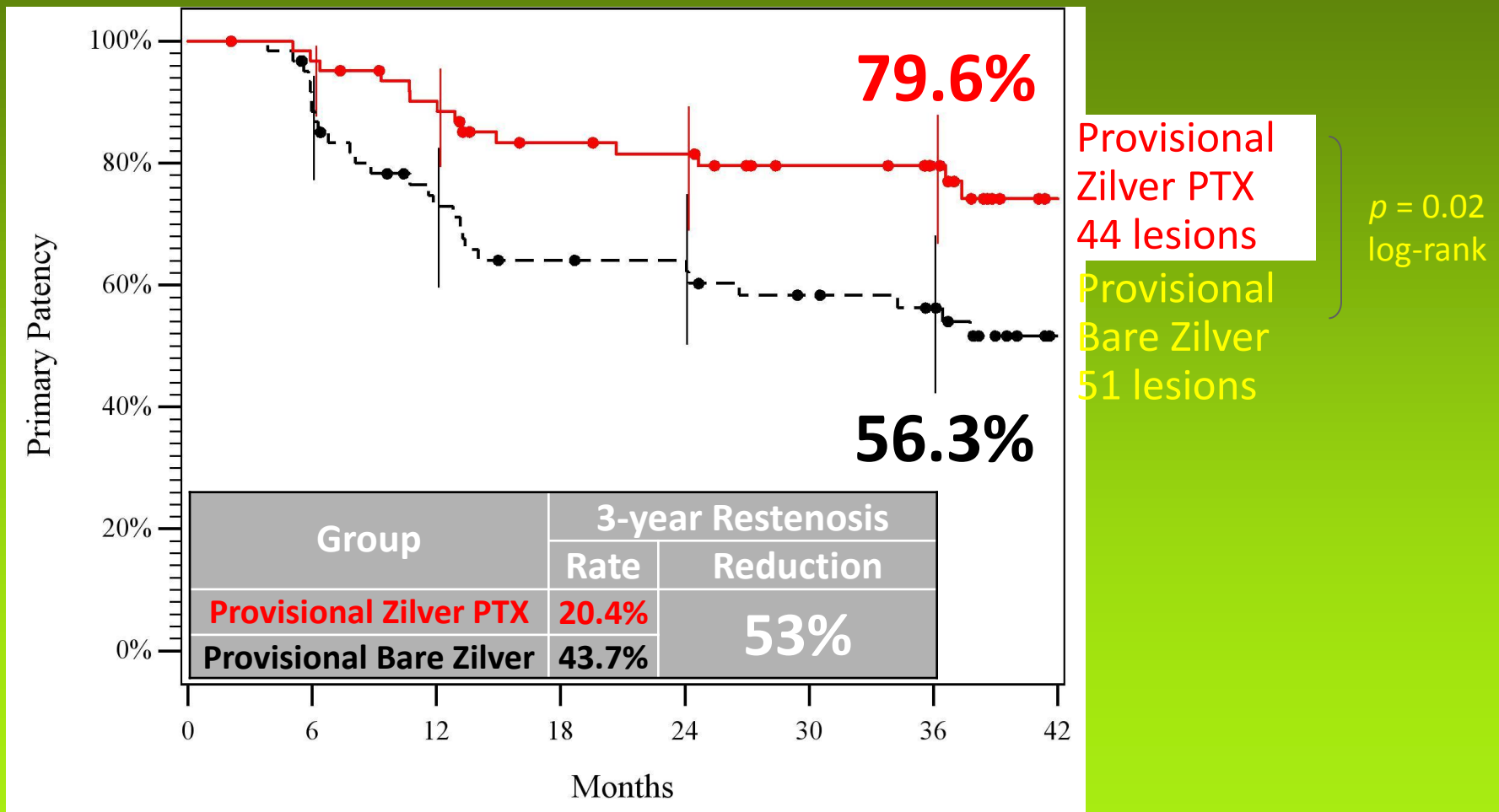
- 546 stents implanted
 - 453 Zilver PTX (average of 1.5 stents per patient)
 - 93 Zilver BMS
- X-ray core laboratory analysis of 457 stents at 1 year
 - Four stent fractures
 - 0.9% fracture rate by Kaplan-Meier
- X-ray core laboratory analysis of 250 stents at 3 years
 - Three additional stent fractures
 - 2.1% fracture rate by Kaplan-Meier

3-Year Primary Patency (PSVR < 2.0) Zilver PTX vs. Standard Care

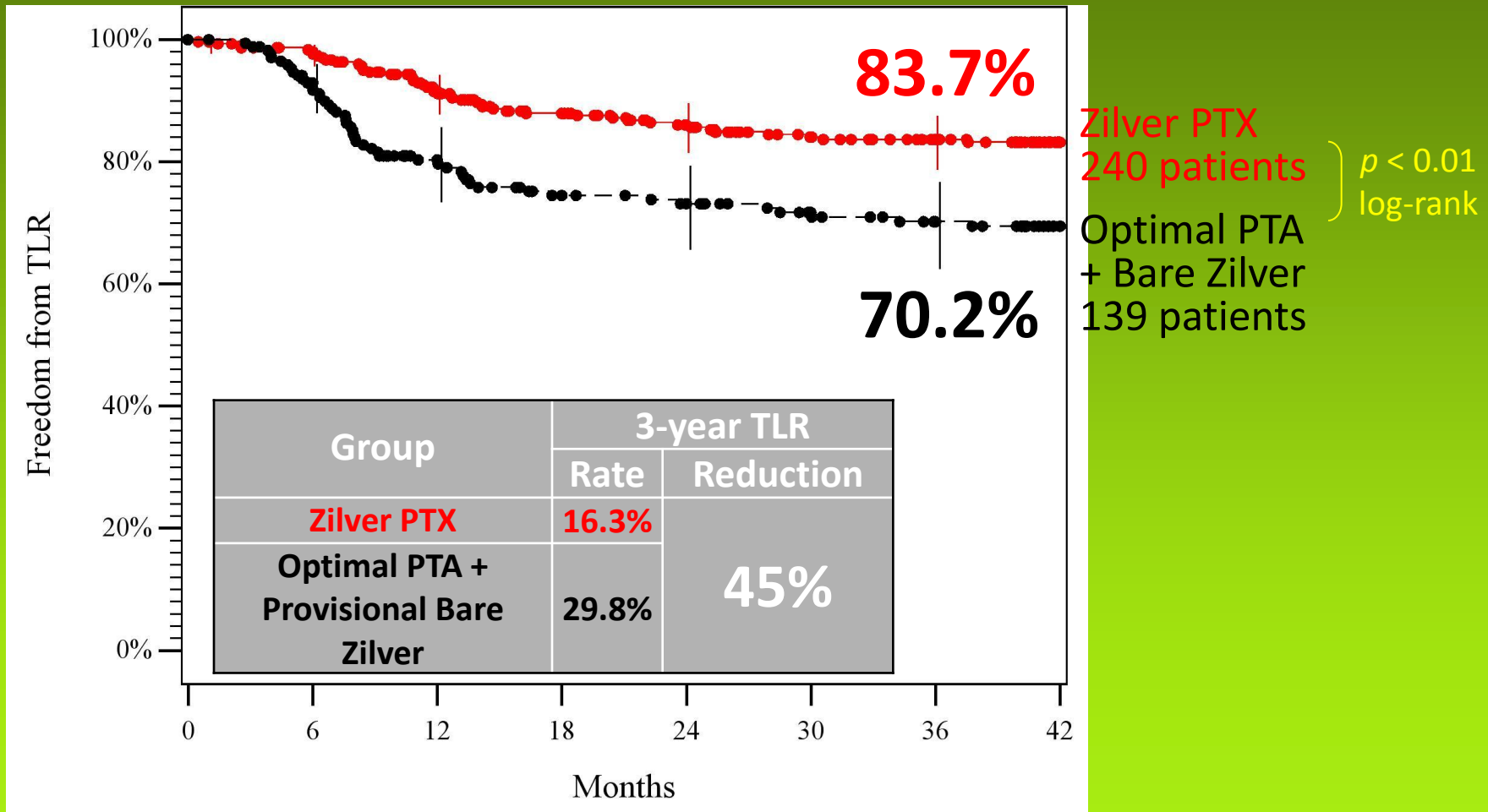


3-Year Paclitaxel Effect

Patency (PSVR < 2.0): Provisional Zilver PTX vs. BMS

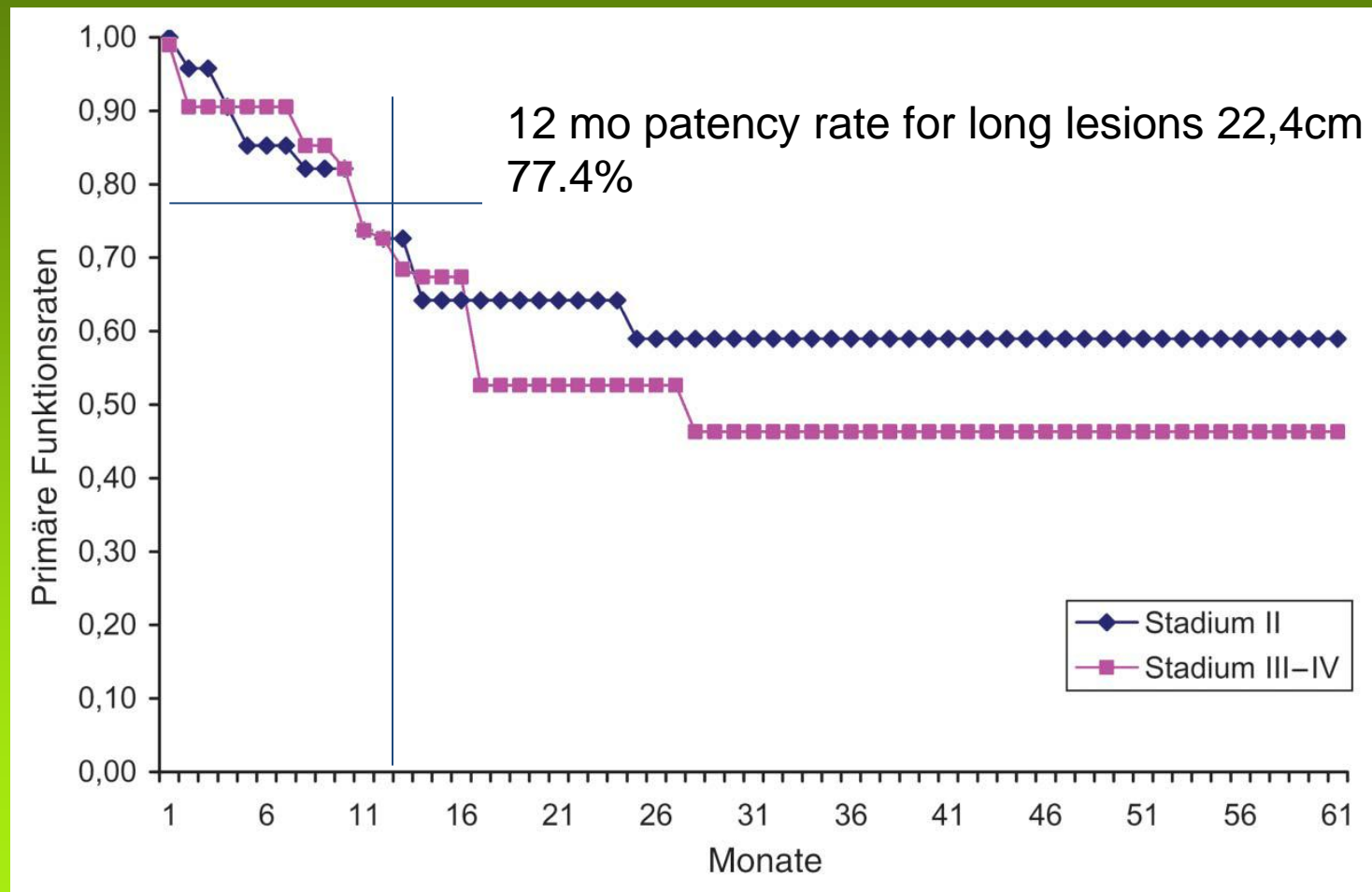


3-Year Freedom from TLR Zilver PTX vs. Standard Care



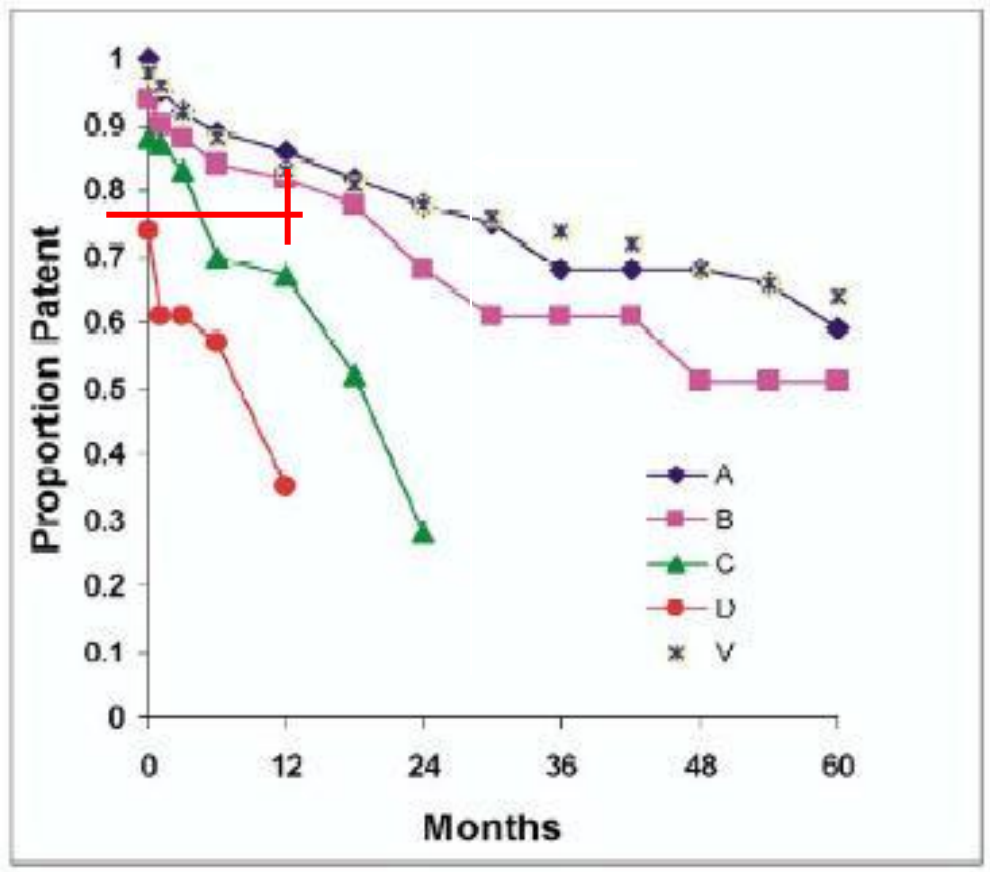
Treatment of femoral artery occlusions: indications, technique and results from the surgeons standpoint

Z GEFÄSSMED 2005; 2 (3), 4-11



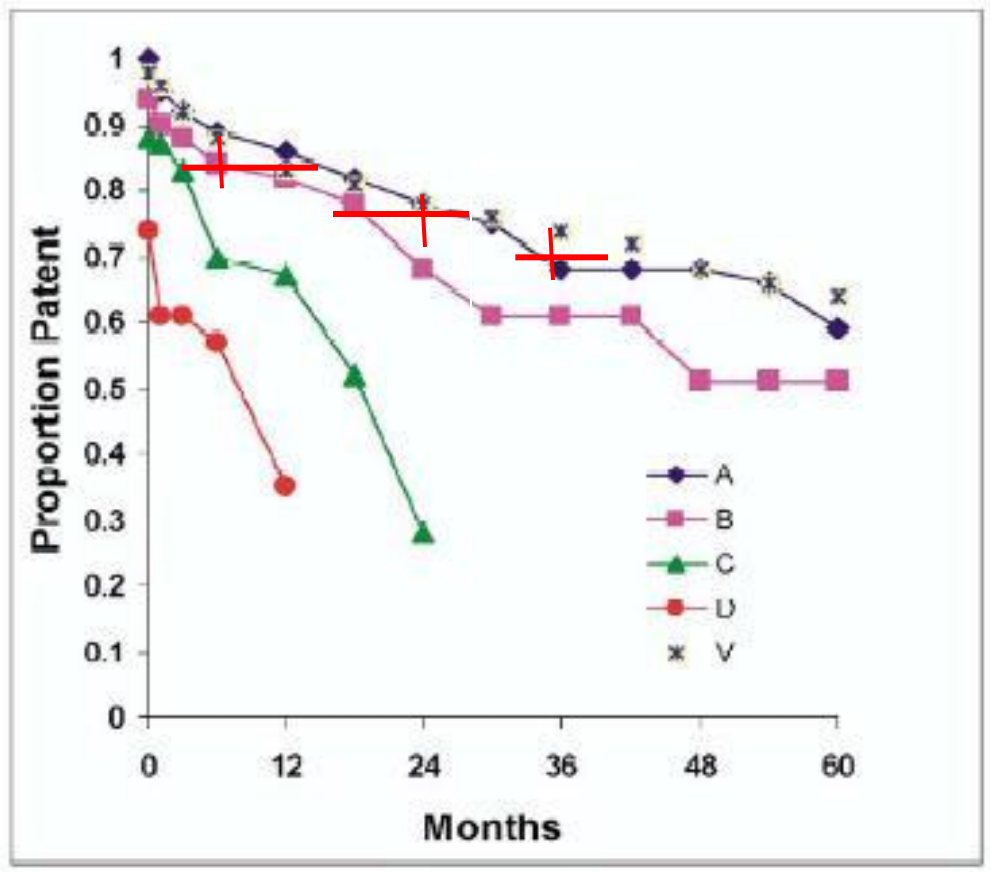
Results of bypass surgery AKH Wien

Primary patency of SFA PTA/S broken down by TASC lesion type compared with femoropopliteal bypass with vein (*)



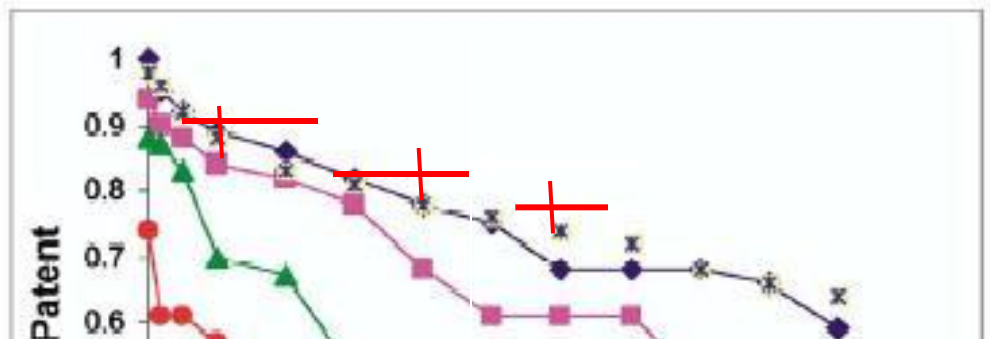
PTX long lesions (C/D) subgroup analysis
22 cm +/- 4,1cm
12 mo pp : 77,4%

Primary patency of SFA PTA/S broken down by TASC lesion type compared with femoropopliteal bypass with vein (*)



Zilver PTX
pp 12/24/36 months
90.4%
83.6%
70.7%.

Primary patency of SFA PTA/S broken down by TASC lesion type compared with femoropopliteal bypass with vein (*)



Provisional Zilver PTX

months

perioperative mortality for femoropopliteal bypass ranges from 0,4 % to 9.7% ; Feinglas et al. JVS, August 2001; 283-90; The 30-day mortality of the trial was 0



Conclusions

- **3-year results** support sustained safety and effectiveness of Zilver PTX (no evidence of late “catch-up”)
 - Significantly lower TLR rate than standard care ($p < 0.01$)
 - Significantly higher patency rate than standard care ($p < 0.01$) and BMS ($p=0.02$)
 - PTX coating reduces provisional stent restenosis rate by 53%
 - perioperative mortality for femoropopliteal bypass ranges from 0,4 % to 9.7%



Thank You for your attention!

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