Insights from the REAL PTX-RCT on DES vs. DCB in complex femoropopliteal lesions – 3-year data

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Disclosure

Dierk Scheinert, MD

Advisory Board /Consultant:

Abbott, Bayer, Boston Scientific, Cook Medical, Cardionovum, CR Bard, Gardia Medical/Allium, Medtronic, Philips, Upstream Peripheral Technologies

Study Design

- Prospective, multicenter (5 centers in Europe), randomized, controlled trial
- Zilver PTX drug eluting stent vs drug coated ballon (1:1) in native femoropopliteal disease
- Investigator initiated: PI Prof. D. Scheinert, Germany
- N= 150 patients, 75 in each group
- Stratification for lesion length for both groups (1:1:1)

  short: ≤ 10 cm

  middle: > 10 and ≤ 20 cm

  long: > 20 and ≤ 30 cm
- Mean lesion length: 152.6 ± 88.2 mm
- Independend core-lab assessment for angio and duplex

Study Design

Follow up: 3 Years

Endpoints

- Primary: Primary Patency @ 12 Month (Duplex)
- Secondary: Procedural sucess

  Mayor Adverse Event (Mayor Amputation; Death or TLR within 30 days)

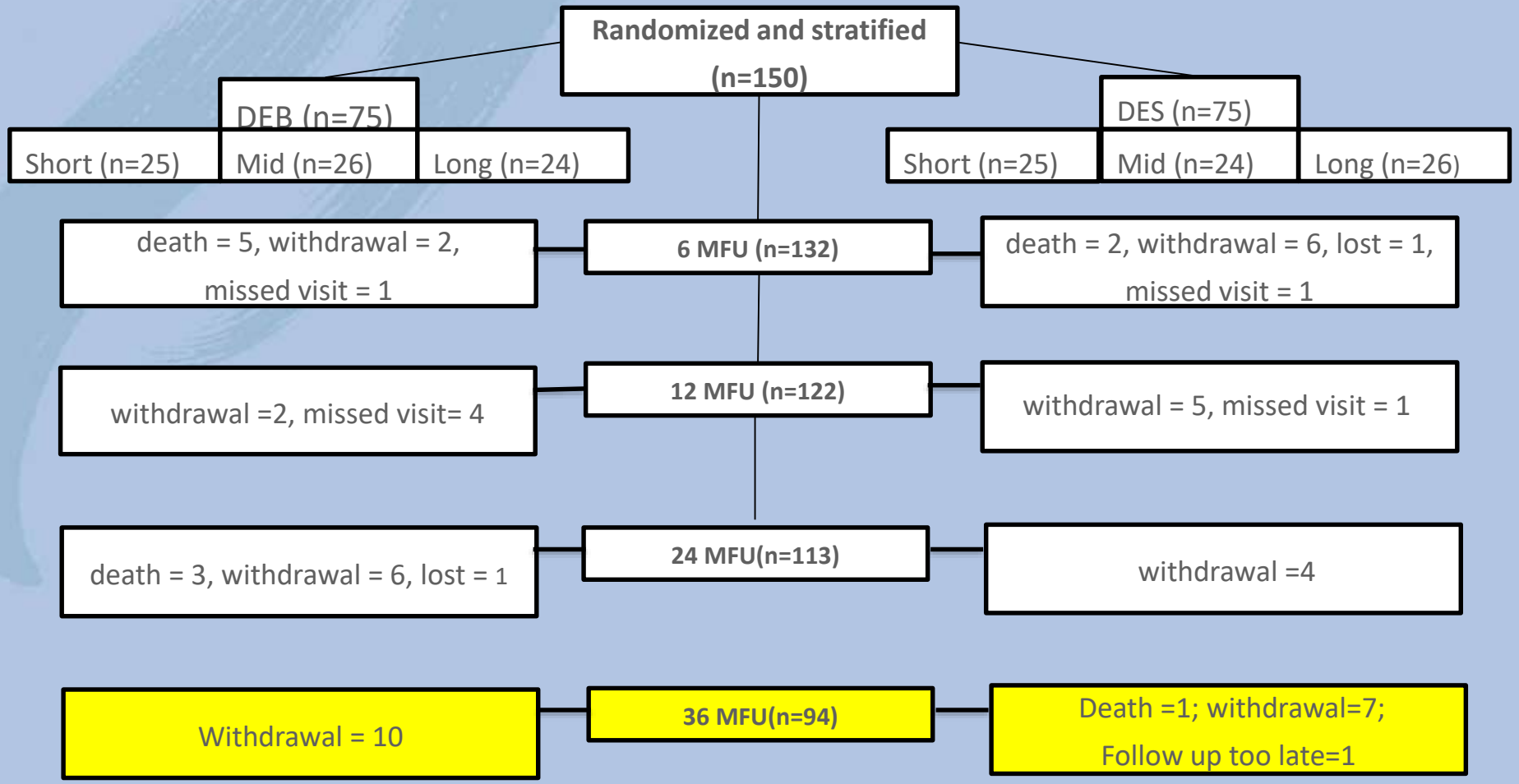
  Primary Patency @ 24, 36 Month

  Clinically driven target lesion revascularisation (TLR)

  ABI, Improvement in Rutherford Categories, Assessment of walking capacity (WIQ)

  Mortality

Patient Flow Chart



Patient Characteristics

	DCB (n=75)	ZilverPTX (n=75)	p-value
Age in years (± SD)	68.2 ± 9.6	69.5 ± 9.5	0.4
Gender (male %)	60.0	76.0	0.05
BMI, mean (± SD)	26.5 ± 4.3	27.5 ± 3.9	0.1
Myocardial Infarction, n (%)	11 (14.7)	9 (12)	0.6
Heart Failure, n (%)	6 (8.0)	1 (1.3)	0.1
Cerebral Vascular Disease, n (%)	12 (16.0)	9 (12.0)	0.6
Hyperlipidemia, n (%)	51 (68.0)	56 (74.7)	0.3
Hypertension, n (%)	59 (78.7)	61 (81.3)	0.9
Renal Insufficiency, n (%)	16 (21.3)	14 (18.6)	0.8
Smoking, n (%)			0.5
Current, n (%)	32 (42.7)	29 (38.7)	
Previous, n (%)	22 (29.3)	29 (38.7)	
Diabetes, n (%)	25 (34.7)	23 (30.7)	0.7
Type 1, n (%)	1 (1.3)	1 (1.3)	
Type 2, n (%)	24 (32.0)	22 (29.3)	
Claudication (RC 2-3), n (%)	67 (89.3)	63 (84.0)	0.5
Critical limb ischemia (RC 4-5), n (%)	8 (10.7)	12 (16.0)	

Data are given as mean±std or number (%).

Lesion Characteristics

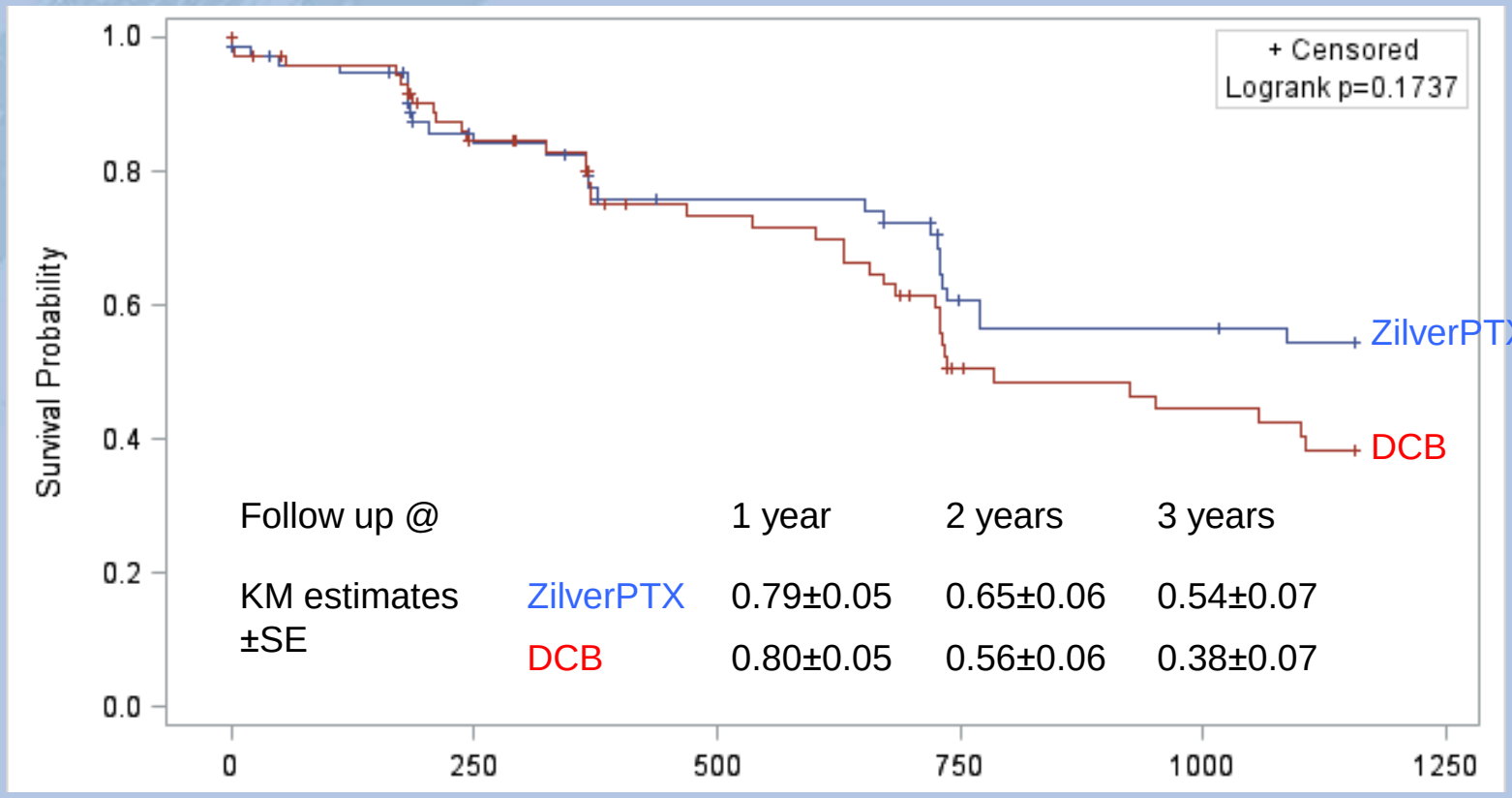
	DEB (n=75)	ZilverPTX (n=75)	p-value
Target lesion length, mm	144.8 ± 92.1	159.6 ± 97.3	0.3
Diameter stenosis	87.4 ± 16.8	86.9 ± 15.2	0.8
Chronic total occlusions	40 (53.3)	39 (52.0)	0.9
Popliteal involvement	15 (20.0)	12 (16.0)	0.5
Lesion calcification			0.5
None/mild	41 (54.7)	28 (37.3)	
Moderate/Mod. Severe/Severe	34 (45.3)	47 (62.7)	

Procedural Outcome

	DEB (n=75)	ZilverPTX (n=75)	p-value
Bailout Stenting CoreLab	19 (25.3)	NA	
Dissection	54 (72.0)	29 (38.7)	< 0.001
Type A/B	19 (25.3)	11 (14.7)	
Type C-F	35 (46.7)	18 (24.0)	
Complication			
Embolic event	4 (5.3)	1 (1.3)	
AV-Fistel (local)	6 (8.0)	2 (2.7)	
Target Vessel Perforation	1 (1.3)	0	

Data are given as mean±std or number (%).

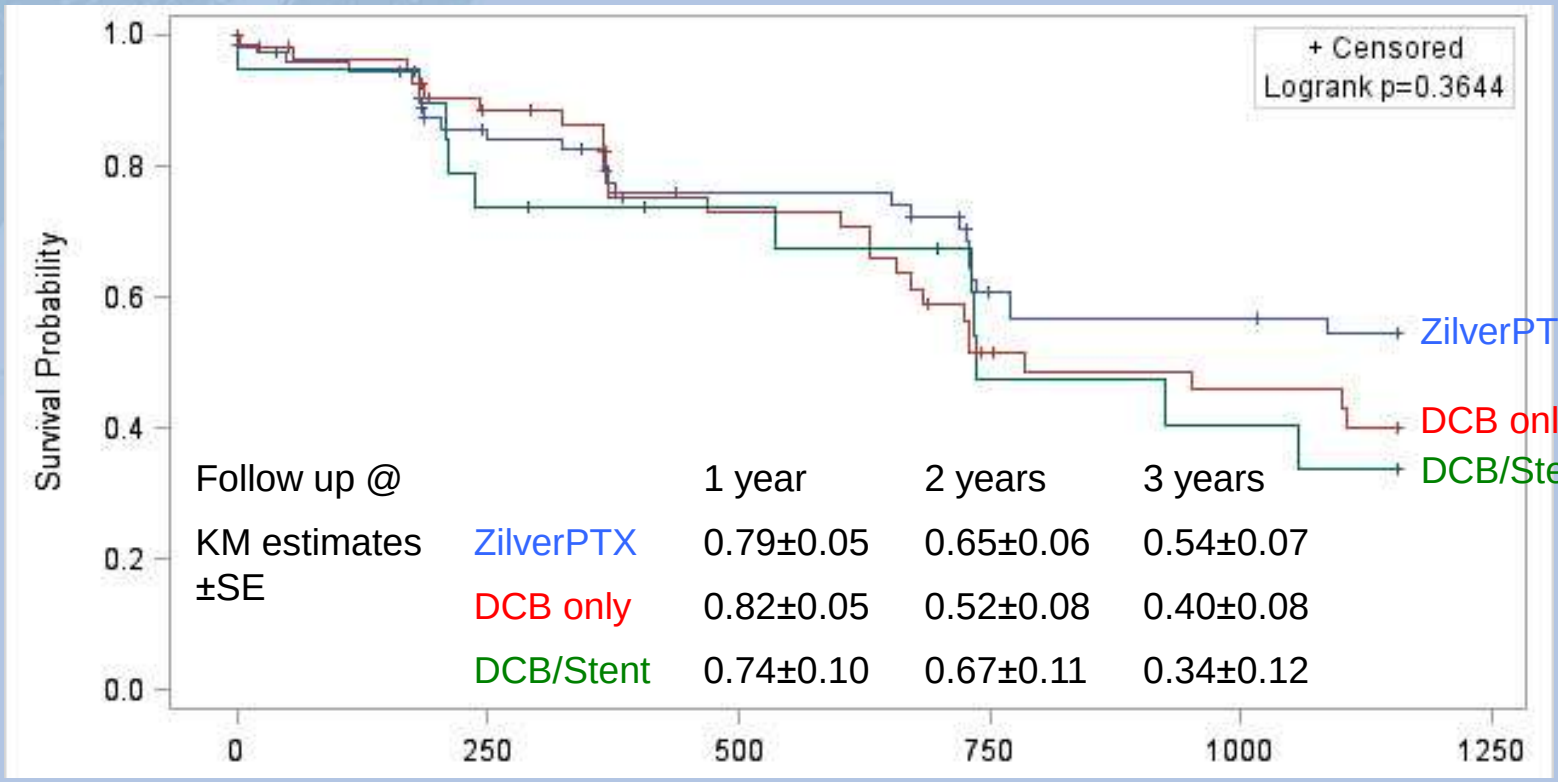
Primary Patency @ 36 months months – ITT



Follow up @		1 year	2 years	3 years
KM estimates ±SE	ZilverPTX	0.79±0.05	0.65±0.06	0.54±0.07
	DCB	0.80±0.05	0.56±0.06	0.38±0.07

Days		150	320	670	1035
No@Risk	ZilverPTX	69	53	42	27
	DCB	69	55	38	22

Primary Patency @ 36 months
ZilverPTX vs DCB only vs DCB plus Stent

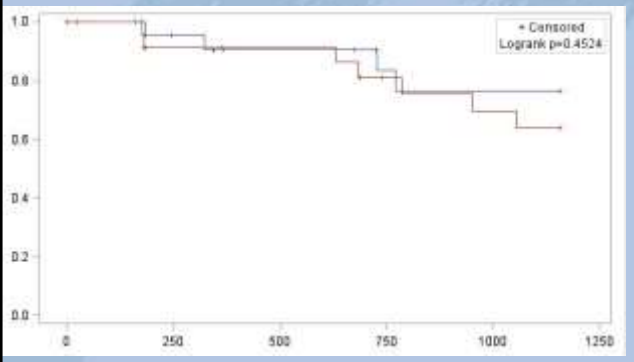


Follow up @		1 year	2 years	3 years
KM estimates ±SE	ZilverPTX	0.79±0.05	0.65±0.06	0.54±0.07
	DCB only	0.82±0.05	0.52±0.08	0.40±0.08
	DCB/Stent	0.74±0.10	0.67±0.11	0.34±0.12

Days		150	320	670	1035
No@Risk	ZilverPTX	69	53	42	27
	DCB only	51	42	27	16
	DCB/Stent	18	13	11	6

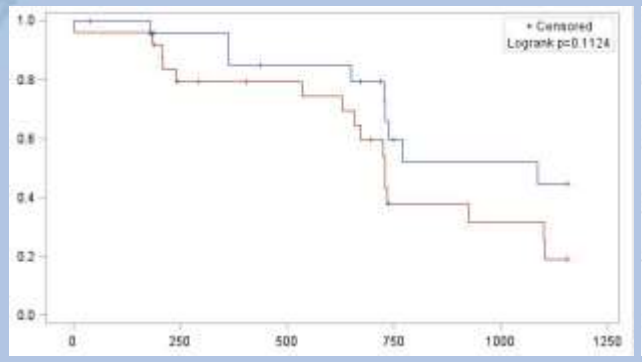
Primary Patency @ 36 months
Stratification for lesion length - ITT

Short lesions



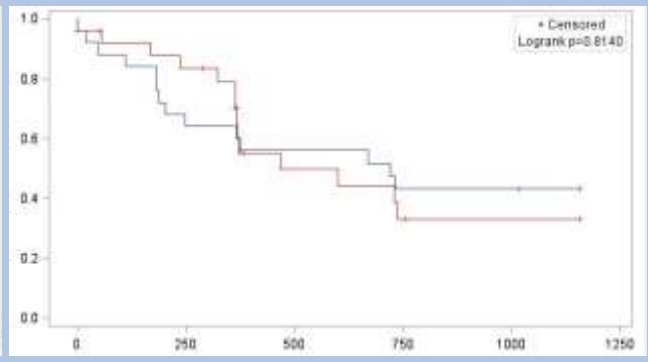
Follow up @		1 years
KM estimates ±SE	ZilverPTX	0.90±0.07
	DCB	0.91±0.06
Follow up @		2 years
KM estimates ±SE	ZilverPTX	0.84±0.09
	DCB	0.81±0.09
Follow up @		3 years
KM estimates ±SE	ZilverPTX	0.77±0.09
	DCB	0.64±0.11

Middle lesions



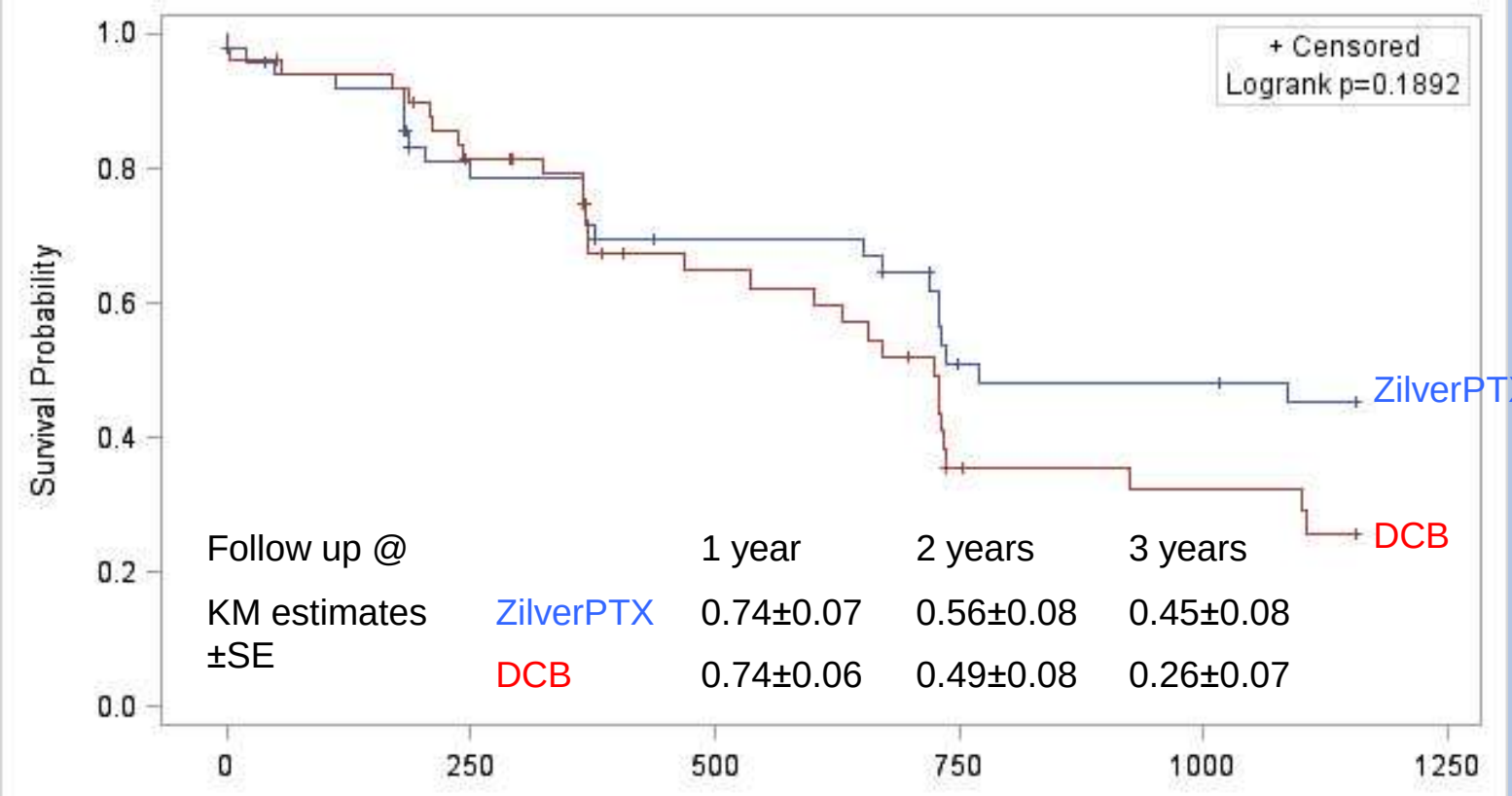
		1 years
	ZilverPTX	0.85±0.08
	DCB	0.80±0.08
		2 years
	ZilverPTX	0.66±0.12
	DCB	0.49±0.11
		3 years
	ZilverPTX	0.45±0.13
	DCB	0.19±0.10

Long lesions



		1 years
	ZilverPTX	0.64±0.10
	DCB	0.79±0.08
		2 years
	ZilverPTX	0.48±0.10
	DCB	0.70±0.10
		3 years
	ZilverPTX	0.43±0.10
	DCB	0.33±0.11

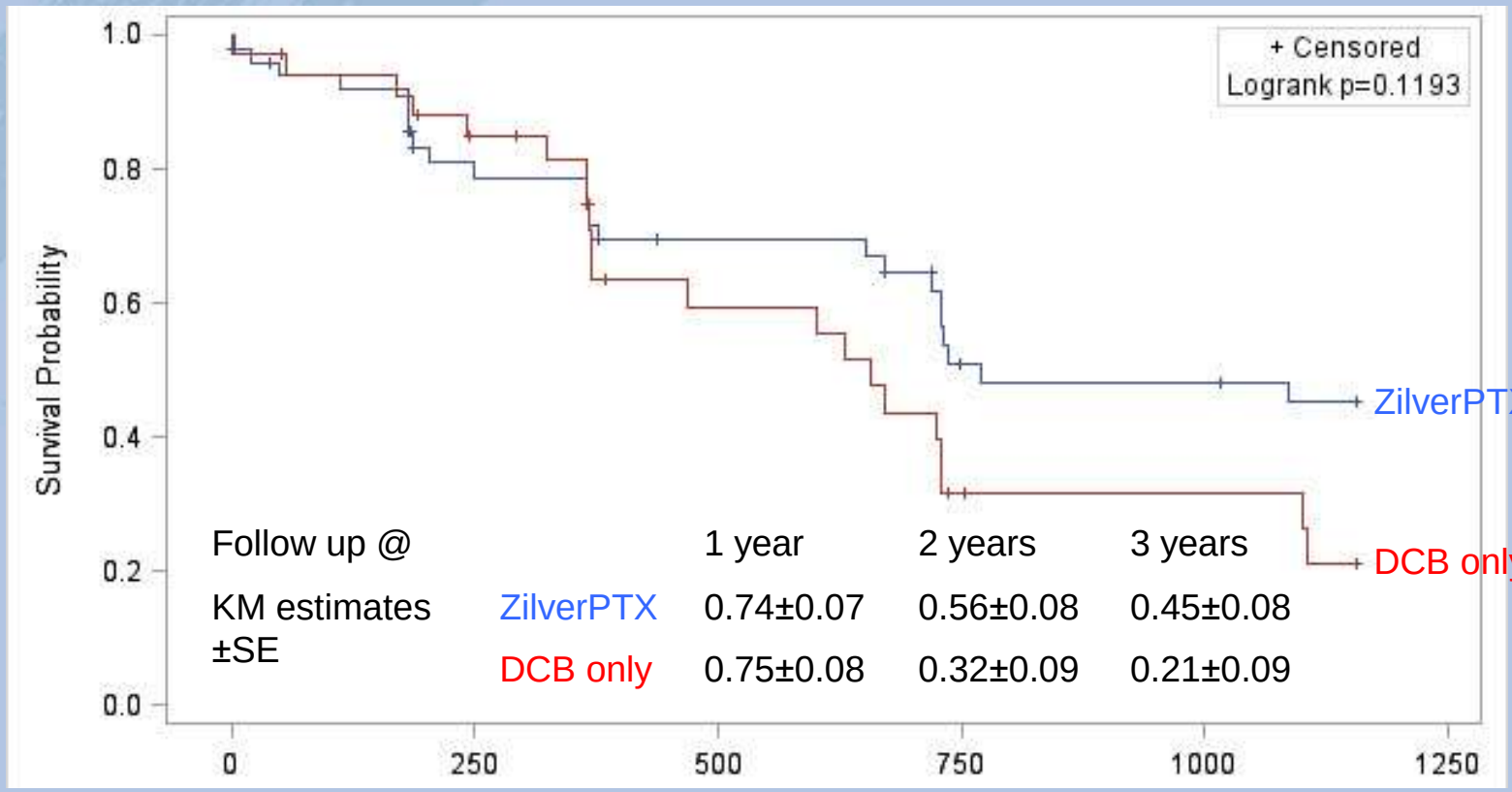
Primary Patency @ 36 months - ITT in middle and long lesions >10cm



Follow up @		1 year	2 years	3 years
KM estimates ±SE	ZilverPTX	0.74±0.07	0.56±0.08	0.45±0.08
	DCB	0.74±0.06	0.49±0.08	0.26±0.07

Days		150	320	670	1035
No@Risk	ZilverPTX	44	34	27	16
	DCB	46	36	21	10

Primary Patency @ 36 months – PP
ZilverPTX vs DCB only
in middle and long lesions >10cm



Follow up @		1 year	2 years	3 years
KM estimates ±SE	ZilverPTX	0.74±0.07	0.56±0.08	0.45±0.08
	DCB only	0.75±0.08	0.32±0.09	0.21±0.09

Days		150	320	670	1035
No@Risk	ZilverPTX	44	34	27	16
	DCB only	31	25	12	6

Conclusion

- No significant difference between DCB and DES in Primary Patency @ 1 year
- Long-term trend showing better durability of DES treatment at 2 and 3 years
- Equal performance of DCB and DES in short lesions up to 10 cm
- Increased benefit of DES in lesions >10cm in comparison to DCB treatment
- Vessel preparation is mandatory for both DCB and DES – particularly in complex lesions!
- Pilot trial – not powered to show statistical significance

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