



BAD KROZINGEN

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Zilver-PTX 5-Year Data

Faculty Disclosure

Thomas Zeller, MD

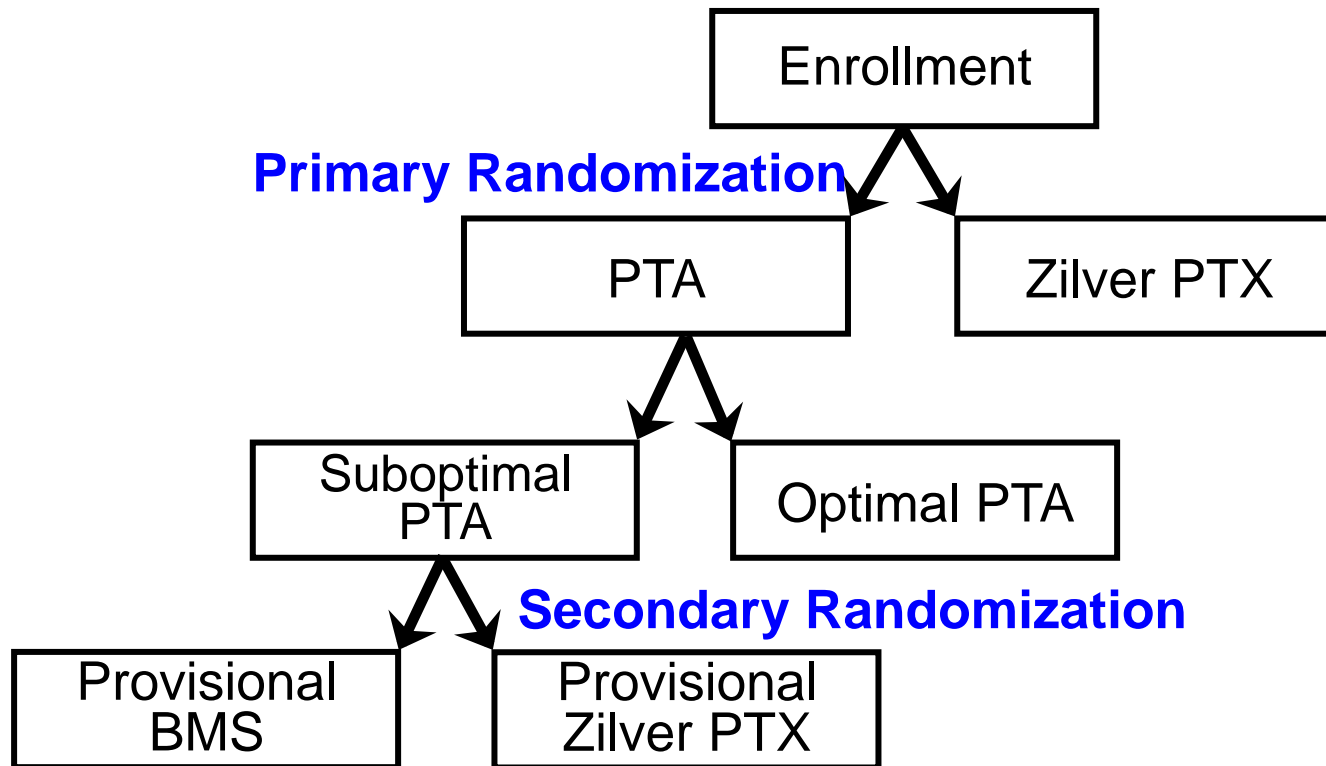
For the 12 months preceding this presentation, I disclose the following types of financial relationships:

- **Honoraria received from:** Abbott Vascular, Angioslide, Bard Peripheral Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Cordis Corp., Covidien, Gore & Associates, Medtronic, Spectranetics, Straub Medical, TriReme, VIVA Physicians
- **Consulted for:** Abbott Vascular, Bard Peripheral Vascular, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Spectranetics, ReCor
- **Research, clinical trial, or drug study funds received from:** 480 biomedical, Bard Peripheral Vascular, Veryan, Biotronik, Cook Medical, Cordis Corp., Covidien, Gore & Associates, Abbott Vascular -DEV Technologies, Inc., Medtronic, Spectranetics, Terumo, TriReme, Volcano

Outline

- Study design and baseline characteristics
- Safety results through 5 years
 - Stent integrity
- Effectiveness results through 5 years
 - Zilver PTX vs. standard care
 - Provisional Zilver PTX vs. Provisional BMS
- Conclusions

Zilver PTX Study Design



Patient Demographics and Comorbidities

	PTA	Zilver PTX	p-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
<i>De novo</i> lesions		94%	95%	0.68
Lesion calcification¹	None	5%	2%	< 0.01*
	Little	38%	26%	
	Moderate	22%	35%	
	Severe	35%	37%	

¹ Angiographic core lab assessment

² Region with > 20% diameter stenosis

* Statistically significant

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5-year Stent Integrity

Study Period	Number of New Events	Fracture Rate¹
Enrollment	0	0.0%
1-year	4	0.9%
3-year	3	1.9%
5-year	0	1.9%

¹ Kaplan-Meier estimates

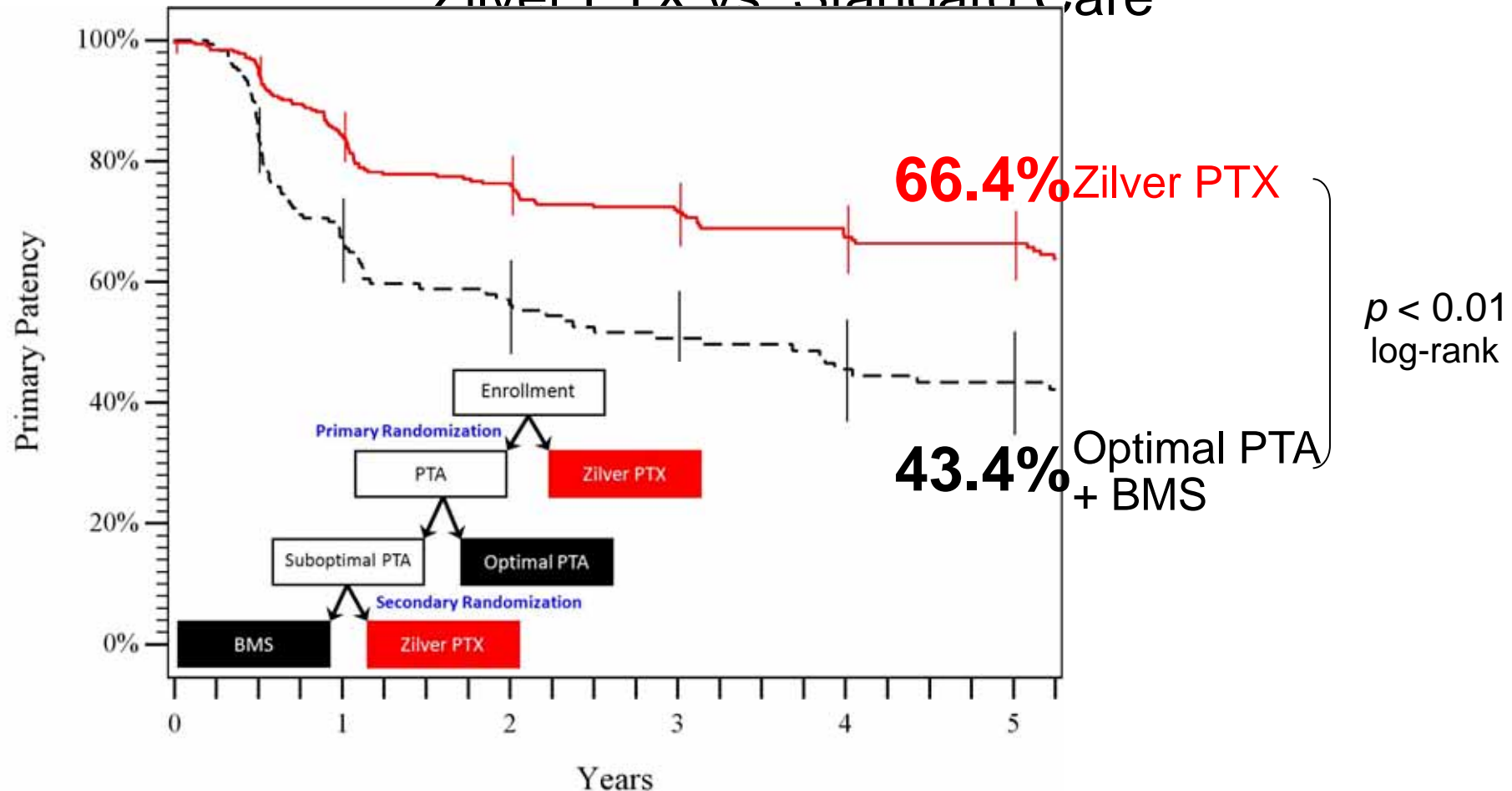
Zilver PTX has excellent durability

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5-year Primary Patency (PSVR < 2.0)

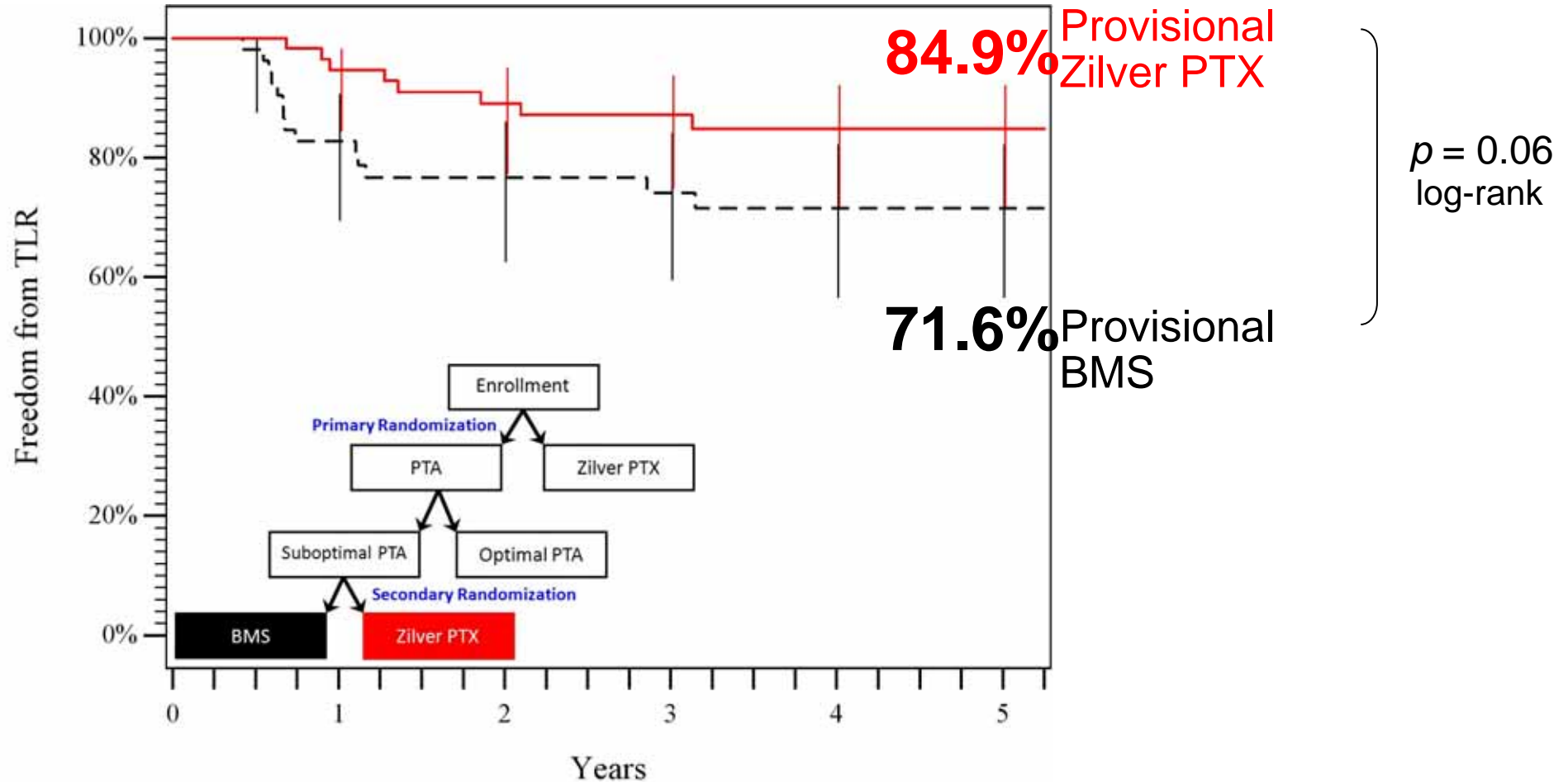
Zilver PTX vs. Standard Care



At 5 years, Zilver PTX demonstrates a 41% reduction

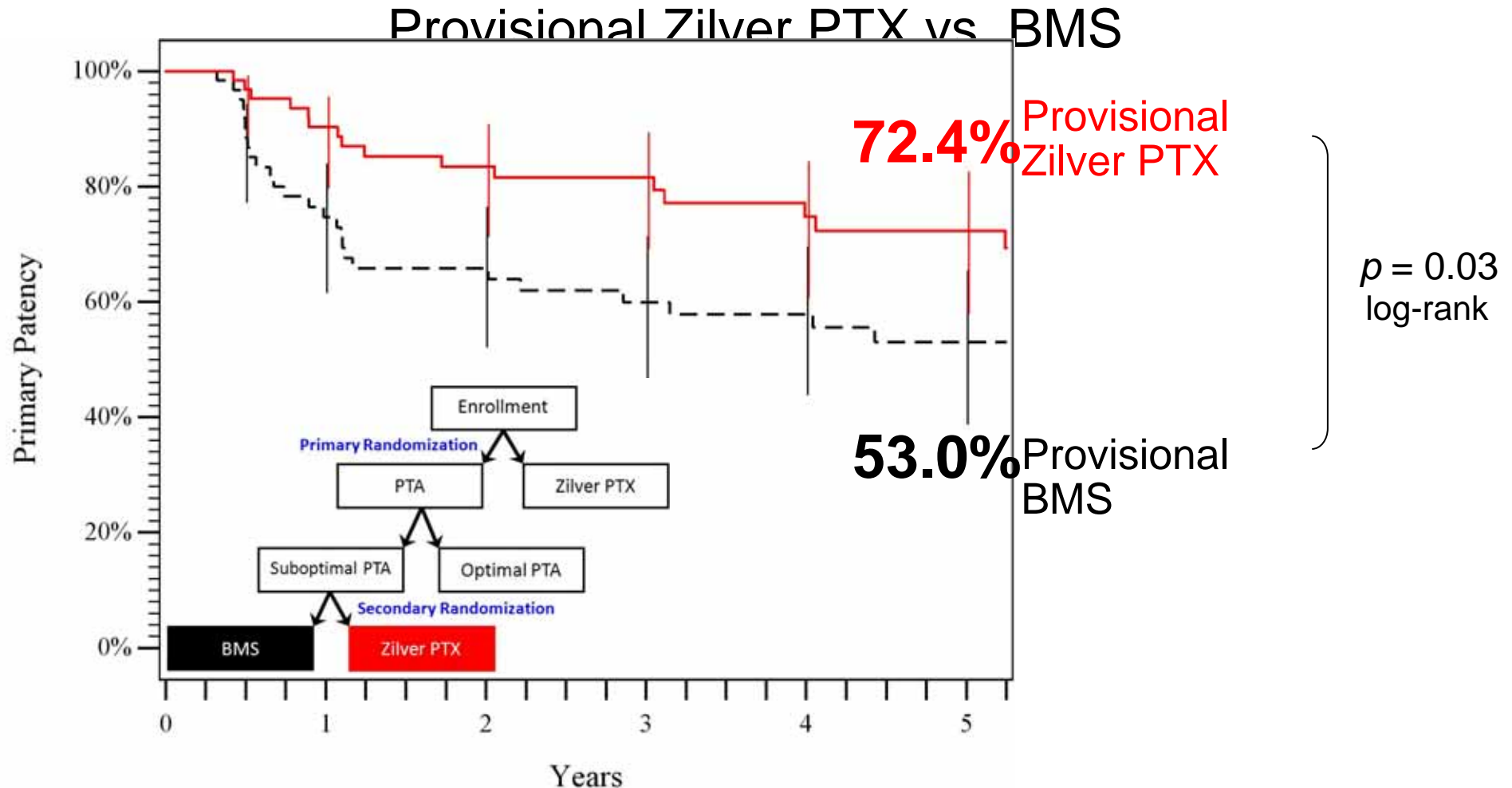
5-year Freedom from TLR

Provisional Zilver PTX vs. BMS



At 5 years, Zilver PTX demonstrates a 47% reduction

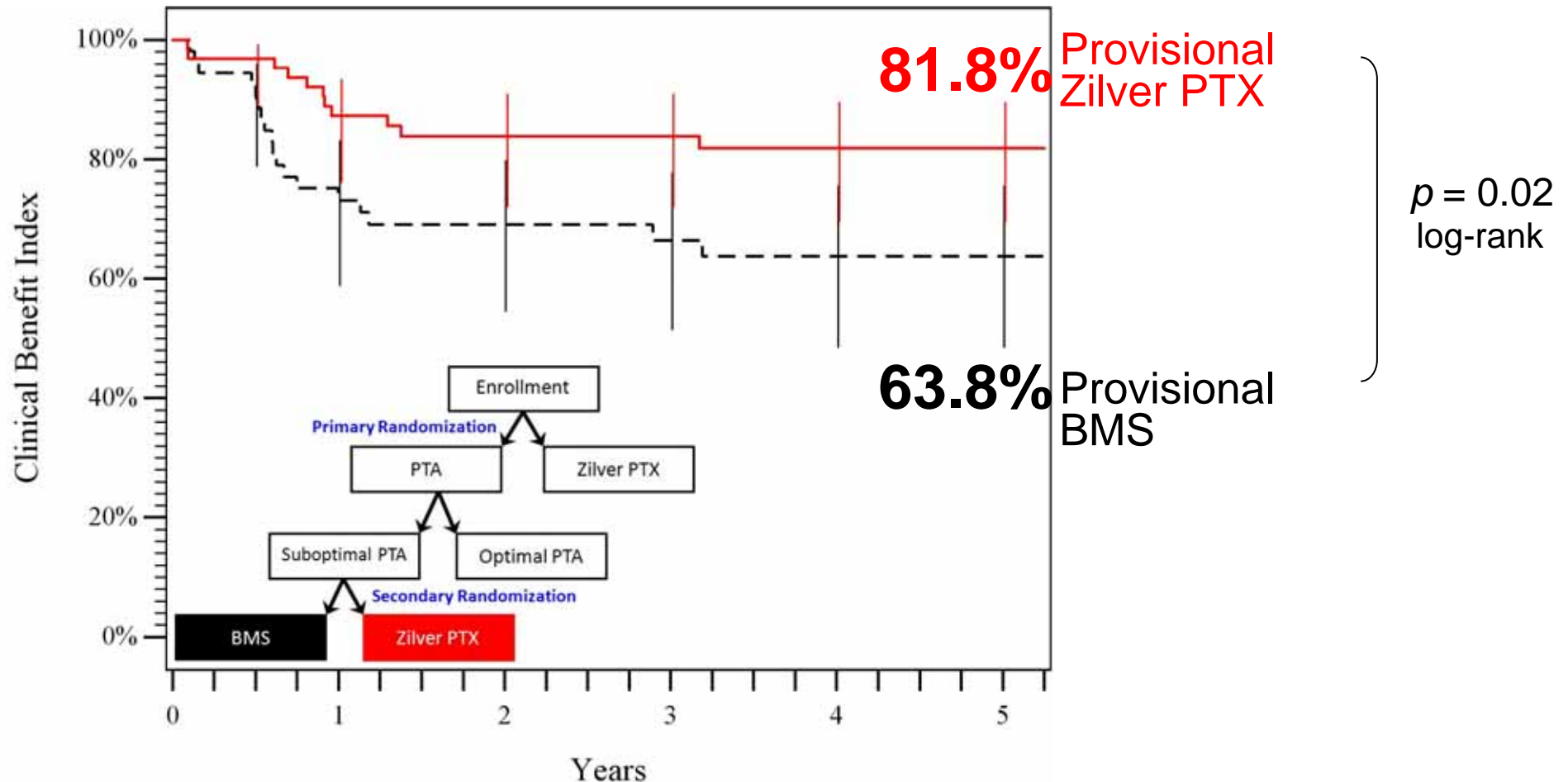
5-year Primary Patency (PSVR < 2.0)



At 5 years, Zilver PTX demonstrates a 41% reduction

5-year Clinical Benefit Index

Provisional Zilver PTX vs. BMS



At 5 years, Zilver PTX has a superior rate of freedom from persistent or worsening claudication, rest pain, ulcer, or

Conclusions for 5-year Zilver PTX RCT

- As the first randomized controlled SFA device trial with 5-year follow-up, these results with the Zilver PTX stent provide important insights regarding long-term outcomes for endovascular treatment
- 5-year data for Zilver PTX versus standard care
 - Greater than 40% reduction in reintervention and restenosis
 - Superior clinical benefit
 - These benefits increase with time – results with Zilver PTX continue to diverge from standard care over 5 years with no late catch-up
- 5-year results confirm long-term superiority of Zilver PTX versus bare metal stents



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