

Strong Support for Lumen Patency: Clear Long-Term Efficacy of DES

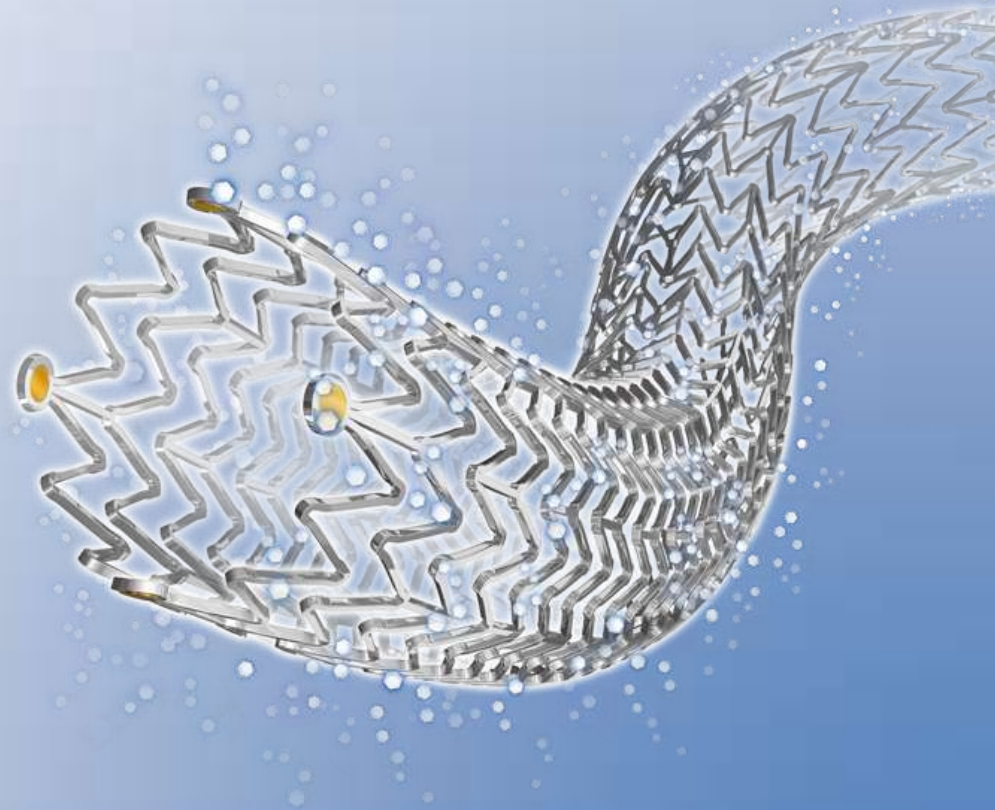
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This Is Not Hype...



Claudicant Enrolled 21 September 2007 Zilver PTX Trial

Recurrent symptoms

Angiogram 30 September 2013



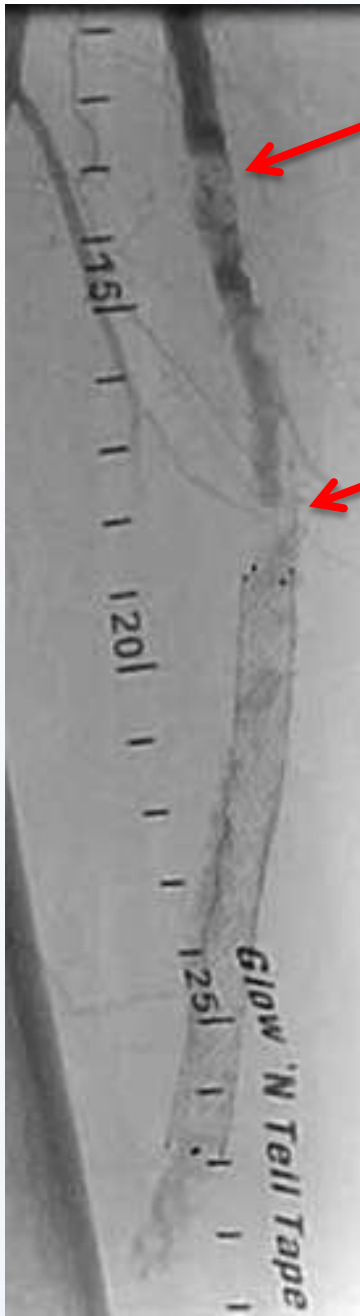
Antegrade Injection





Injection In Stent
(through end-hole catheter)

Zilver PTX Patent



The Strength of the ZILVER PTX Study

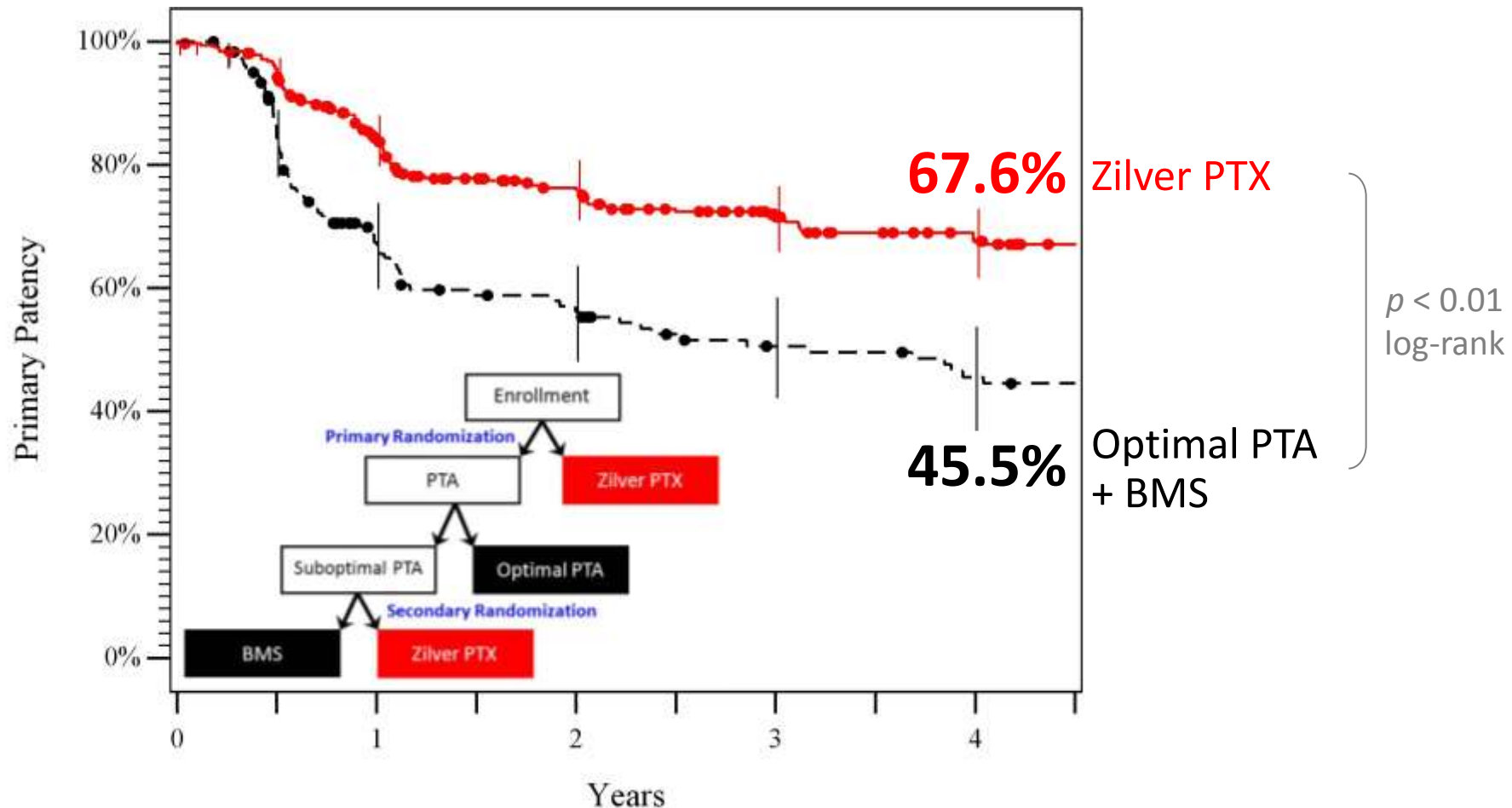
- Size: 474 patients
- Randomized design
- Data Safety Monitoring Board
- Clinical Events Committee
- Core labs
- True-to-life randomization scheme

The Zilver PTX[®] Randomized Controlled Trial

4-Year Results

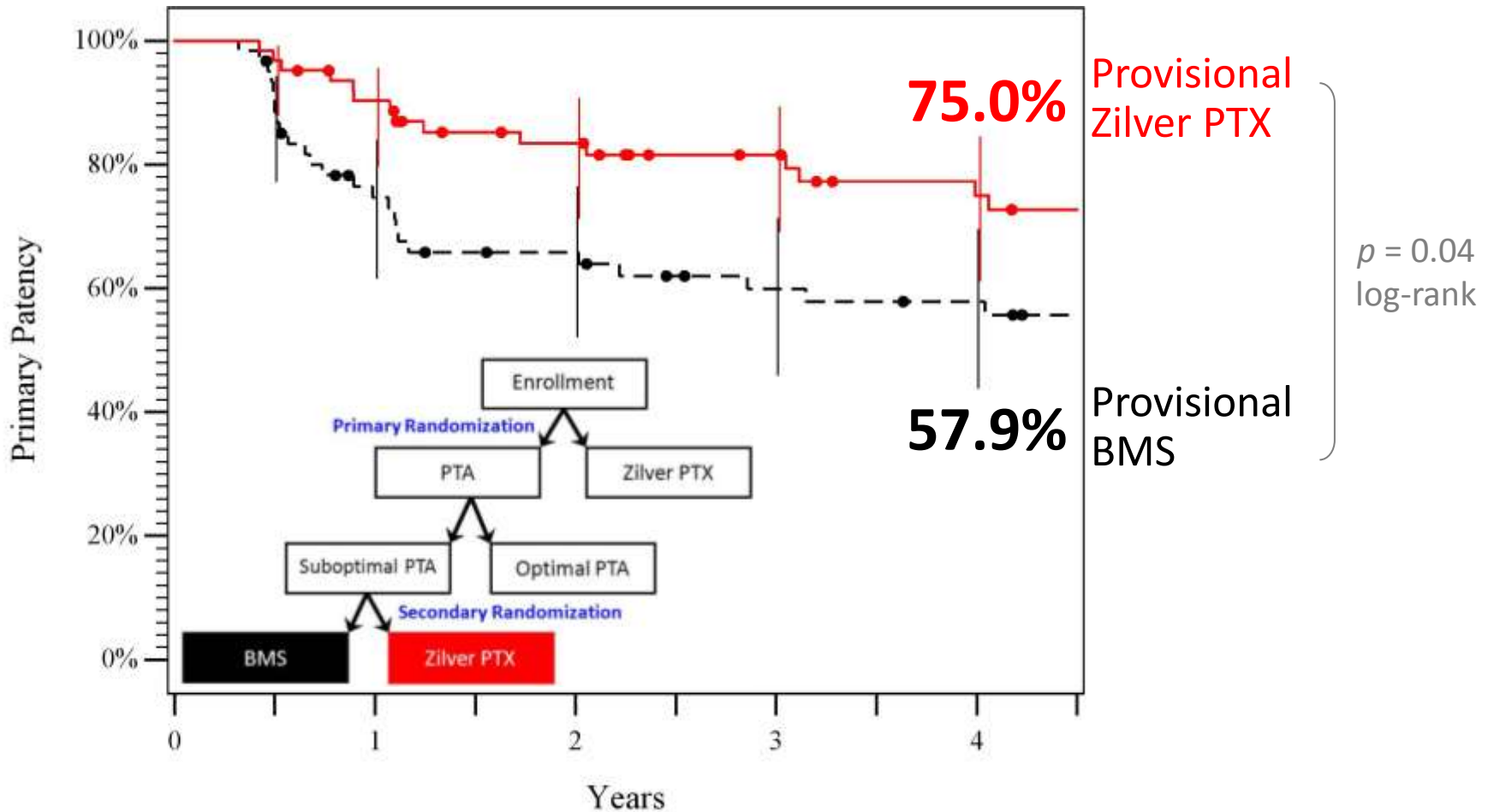
4-Year Primary Patency (PSVR < 2.0)

Zilver PTX vs. Standard Care – Drug Effect



Proven Drug Effect at 4 Years

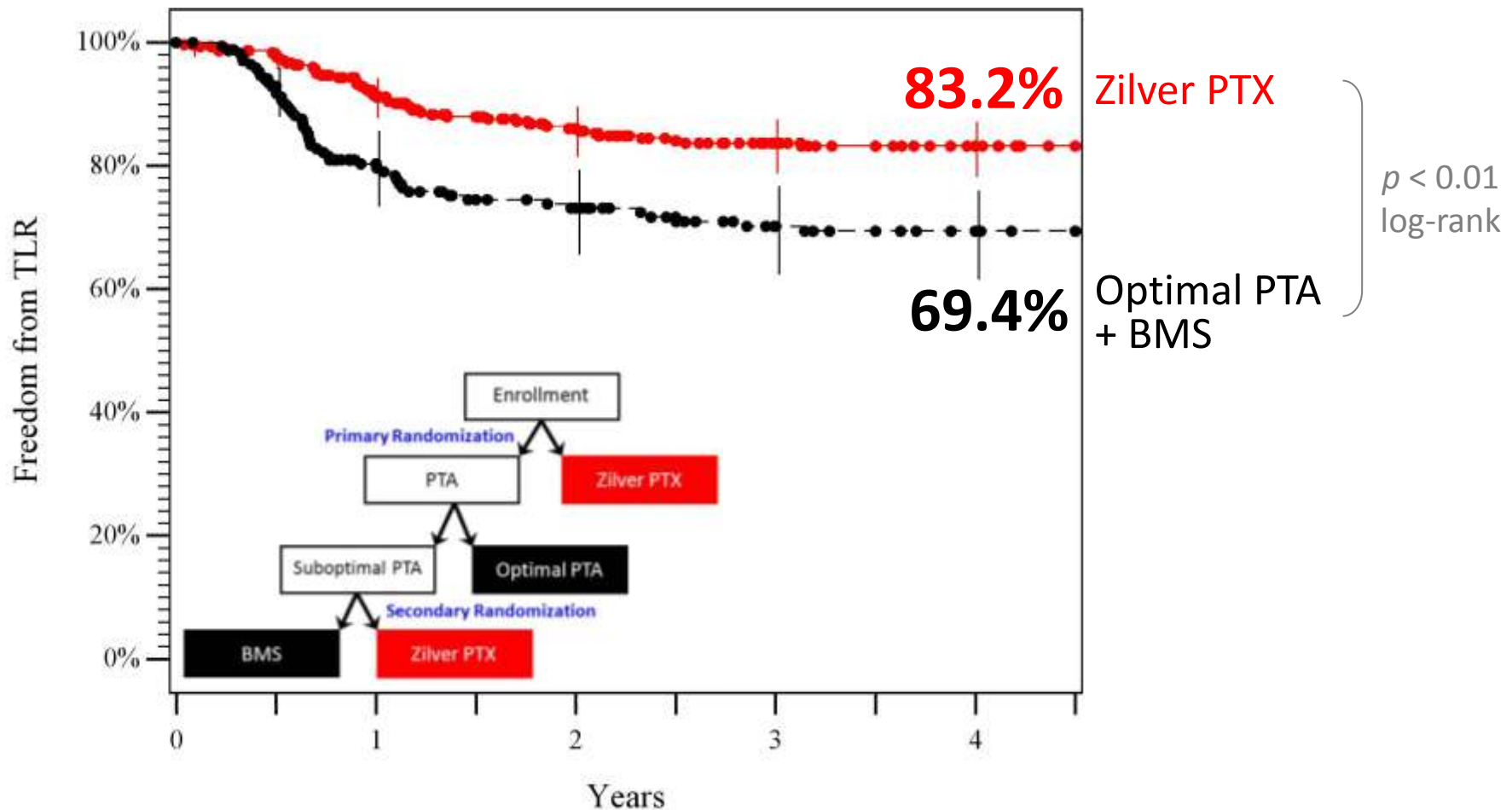
Patency (PSVR < 2.0): Provisional Zilver PTX vs. BMS



41% reduction in restenosis due to the drug

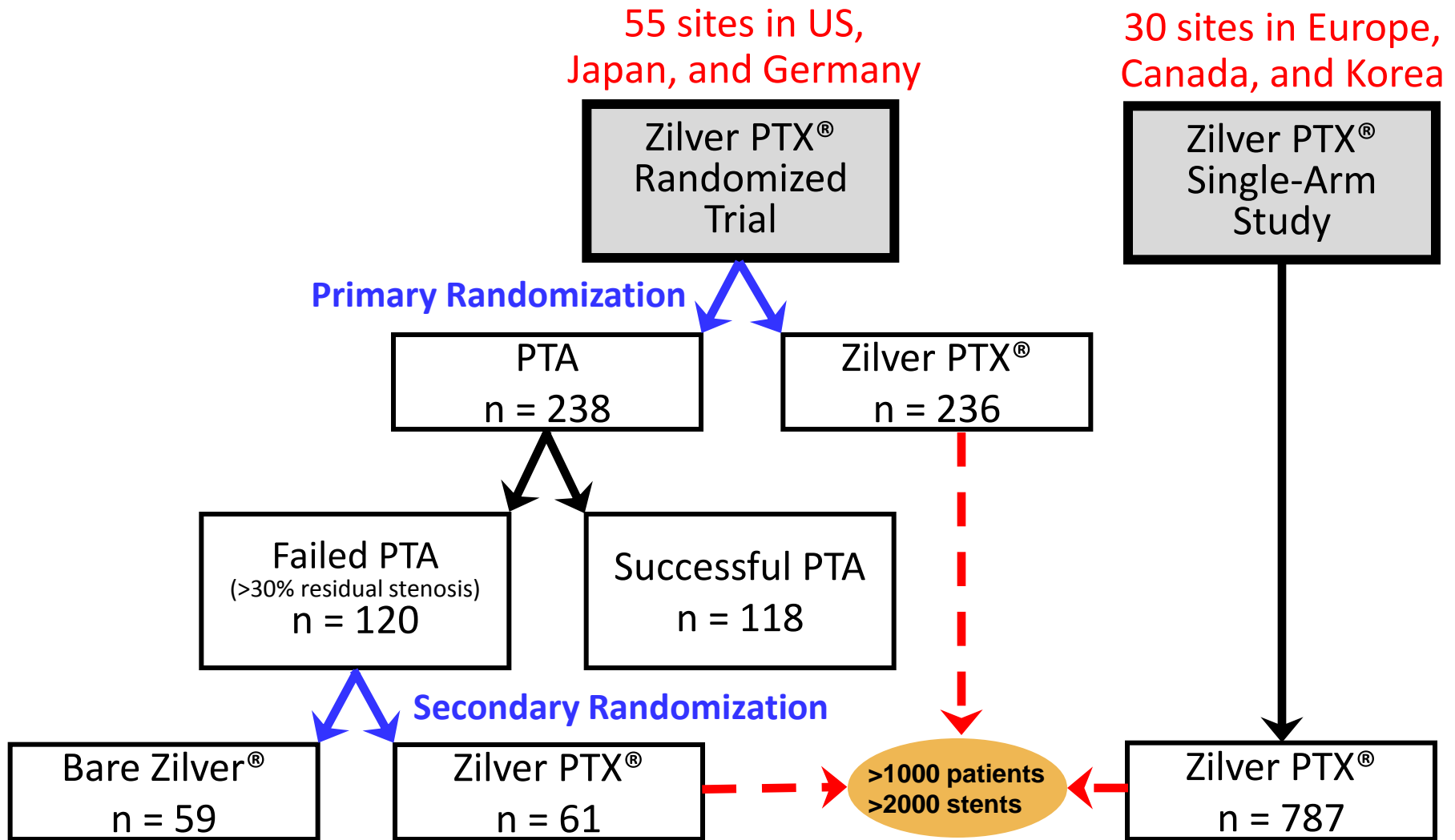
4-Year Freedom from TLR

Zilver PTX vs. Standard Care – Drug Effect



45% reduction in reintervention rate due to the drug

Complementary Zilver PTX[®] Clinical Studies



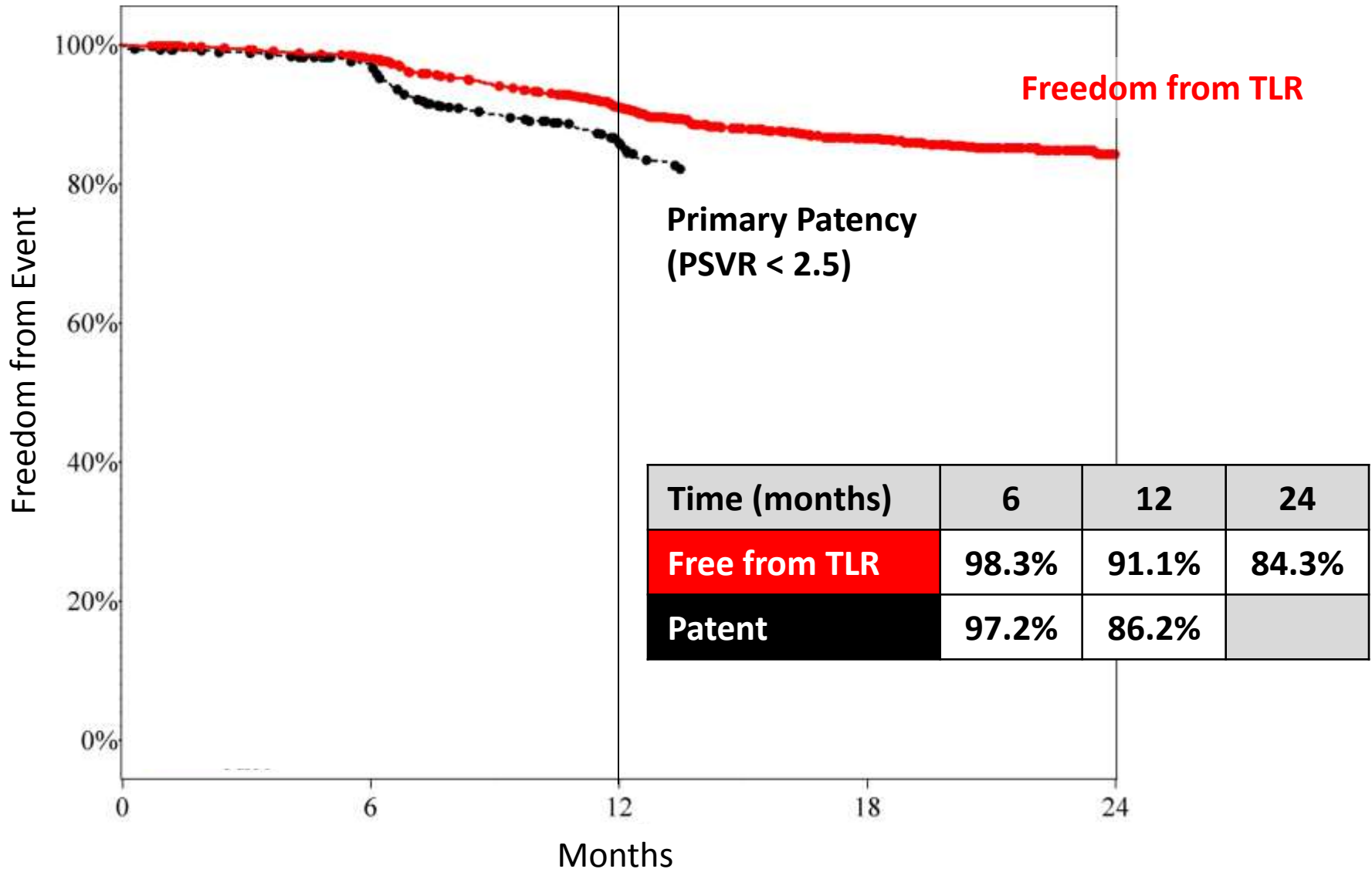
Zilver[®] PTX[®] Single-Arm Study

- **Largest study to date** for endovascular treatment of SFA disease (787 patients, 900 lesions)
- **Up to 4 Zilver[®] PTX[®] stents** per patient
- **Broad inclusion criteria** to study Zilver[®] PTX[®] stenting in a real-world patient population

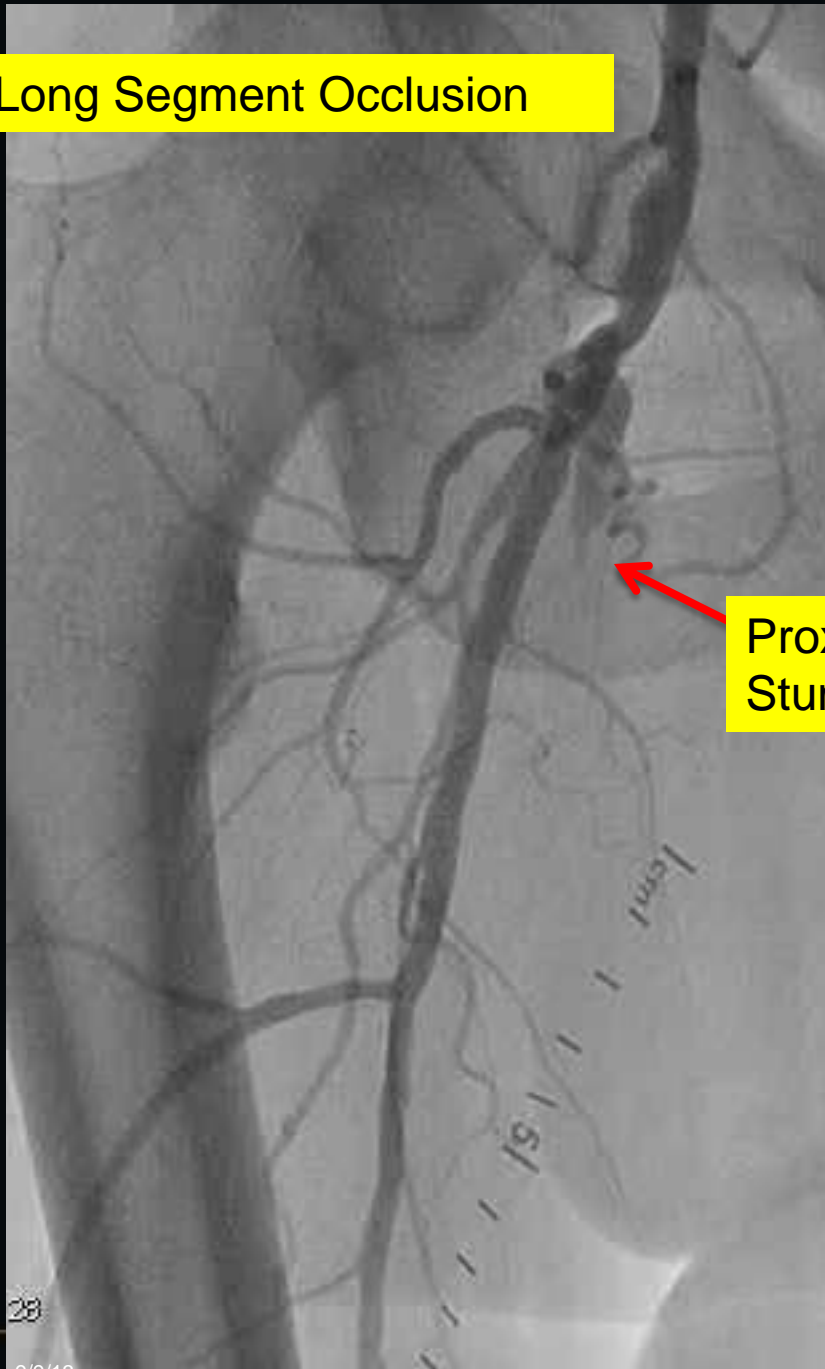
Baseline Lesion Characteristics

Lesions		900
Lesion length (mm)		100 ± 82
Diameter stenosis		85 ± 16%
TASC 2000 class	A	26%
	B	29%
	C	25%
	D	14%
Lesions > 7 cm		48%
Lesions > 15 cm		22%
Total occlusions		38%
Restenosis (all)		24%
In-stent restenosis (ISR)		14%

Long-term Effectiveness



Long Segment Occlusion



Proximal Stump



Distal Reconstitution

After Subintimal Angioplasty and Zilver PTX Stents



MD

2014 Status

- Available in over 50 countries
- Approved in Korea, EU, Japan, and US

Zilver[®] PTX[®]

DRUG-ELUTING PERIPHERAL STENT

Order Number	Reference Part Number	Accepts Wire Guide Diameter inch	Stent Diameter mm	Stent Length mm	Minimum Sheath Fr
125 cm Over-the-Wire Delivery System					
G24888	ZIV6-35-125-6-40-PTX	.035	6	40	6.0
G24889	ZIV6-35-125-6-60-PTX	.035	6	60	6.0
G24890	ZIV6-35-125-6-80-PTX	.035	6	80	6.0
G24935	ZIV6-35-125-6-100-PTX	.035	6	100	6.0
G24891	ZIV6-35-125-7-40-PTX	.035	7	40	6.0
G24894	ZIV6-35-125-7-60-PTX	.035	7	60	6.0
G24895	ZIV6-35-125-7-80-PTX	.035	7	80	6.0
G24937	ZIV6-35-125-7-100-PTX	.035	7	100	6.0

ZILVER PTX: Summary

- Long-term data in over 1000 patients
- Anecdotal experience to 8 years
- 4-year randomized data
- Superior to conventional therapy
- The only SFA drug-eluting stent option

High Stent Integrity

- 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

Conclusions

- **4-year results** support sustained safety and effectiveness of Zilver PTX (no evidence of late “catch-up”)
 - Significantly lower TLR rate than standard care
 - Significantly higher patency rate than standard care
 - Significantly higher patency rate than BMS
 - Greater than 40% reduction in restenosis due to the drug effect

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
<i>De novo</i> 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

² Region with > 20% diameter stenosis

*Statistically significant