Are drug-eluting stents keeping their promises in the long term?

Samedi, 24 Janvier, 2015 – Lower limbs solved and unsolved questions

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On behalf of the Investigators

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Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

- Research/Research Grants, Clinical Trial Support
  - W. L. Gore
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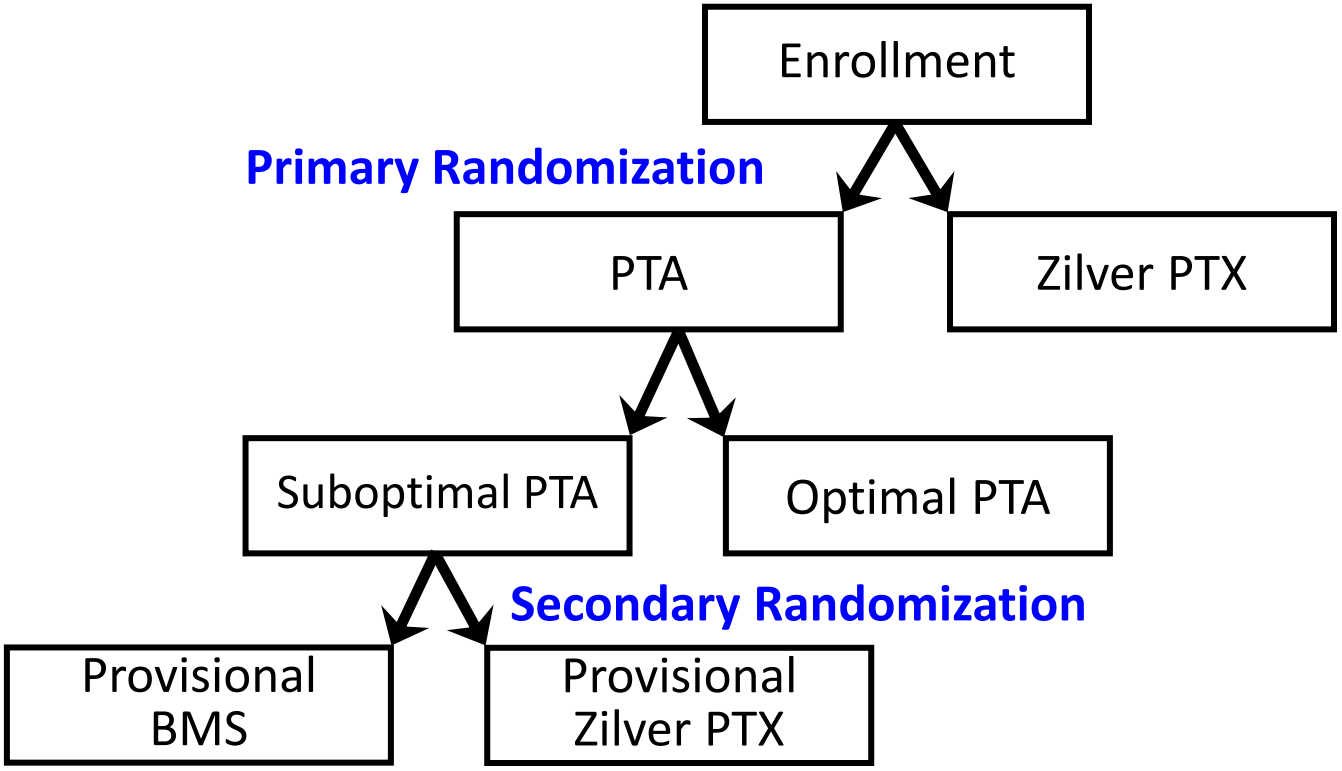
  - Microfabrica
  - 480 Medical
  - Arsenal
  - Intact Vascular
- Officer, Director, Board Member or other Fiduciary Role
  - VIVA Physicians Group
- Speaker's Bureau
  - None

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
***De novo* lesions**		94%	95%	0.68
Lesion calcification[1]	**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 Rate[1]
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 in challenging SFA environment

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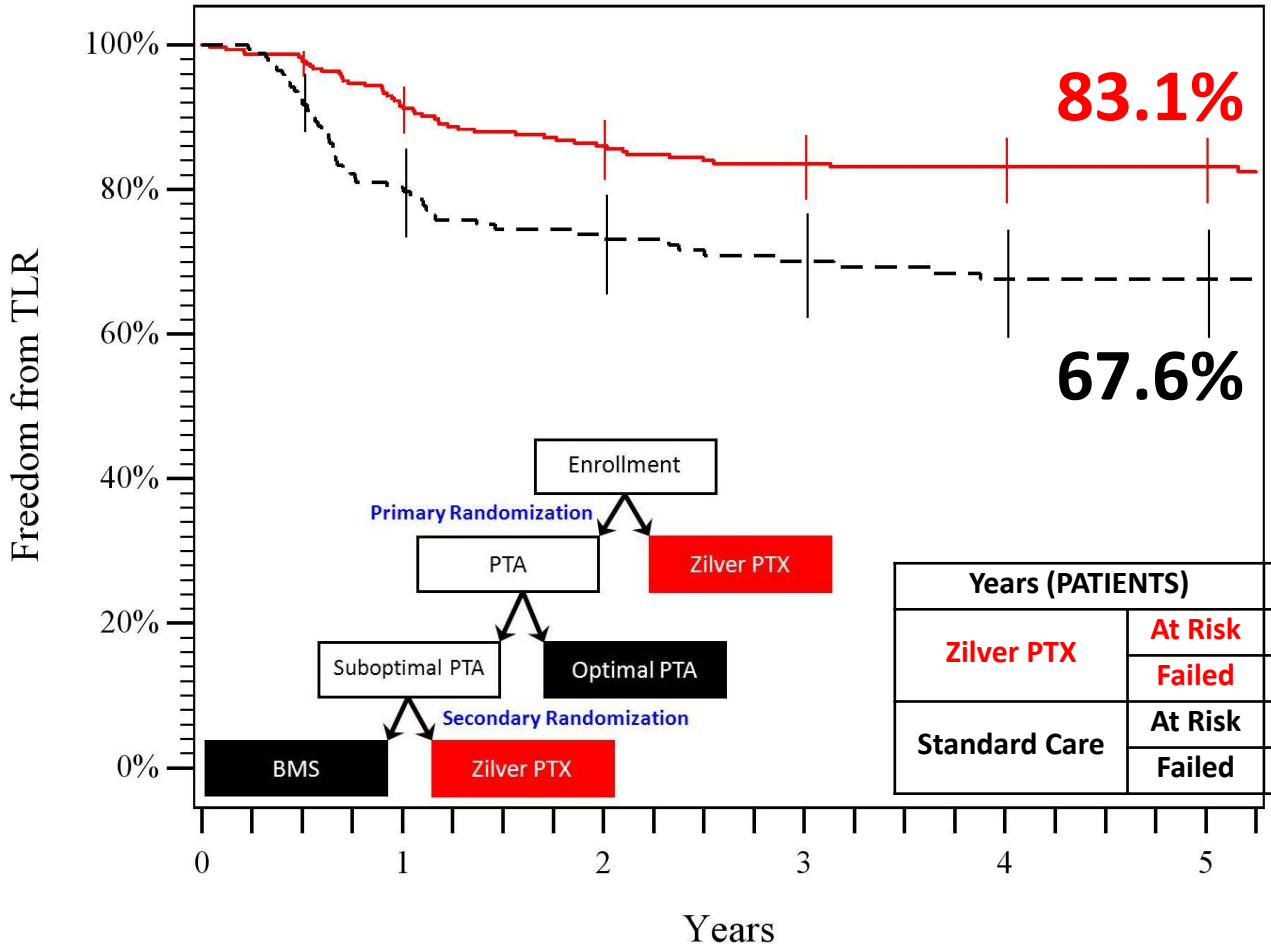
5-year Freedom from TLR

Zilver PTX vs. Standard Care

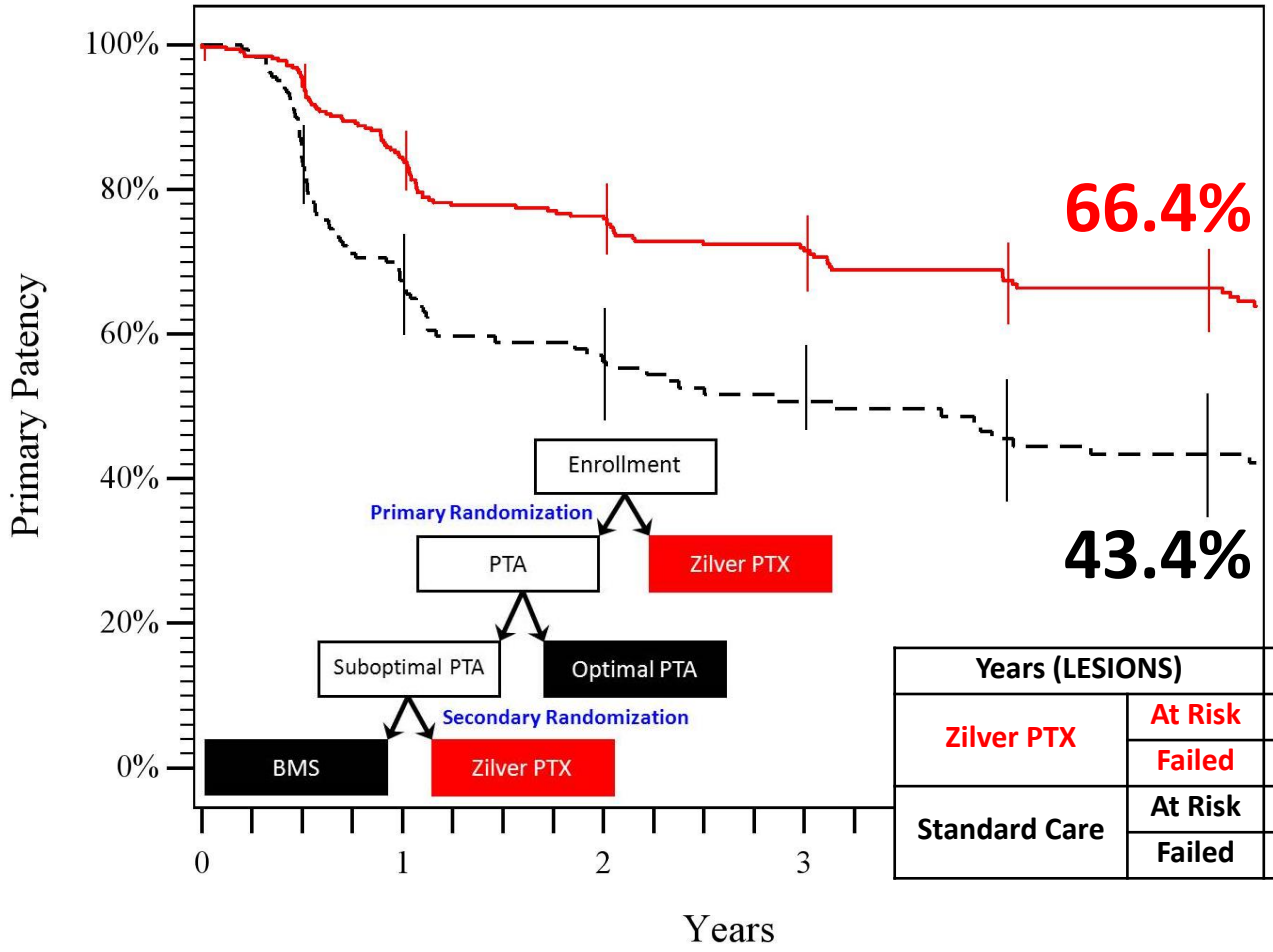


Years (PATIENTS)		0	1	2	3	4	5
Zilver PTX	At Risk	305	260	220	187	164	133
	Failed	0	25	40	46	47	47
Standard Care	At Risk	172	125	106	88	78	69
	Failed	0	33	44	48	51	51

At 5 years, Zilver PTX demonstrates a 48% reduction in reintervention compared to standard care

5-year Primary Patency (PSVR < 2.0)

Zilver PTX vs. Standard Care



66.4% Zilver PTX

43.4% Optimal PTA + BMS

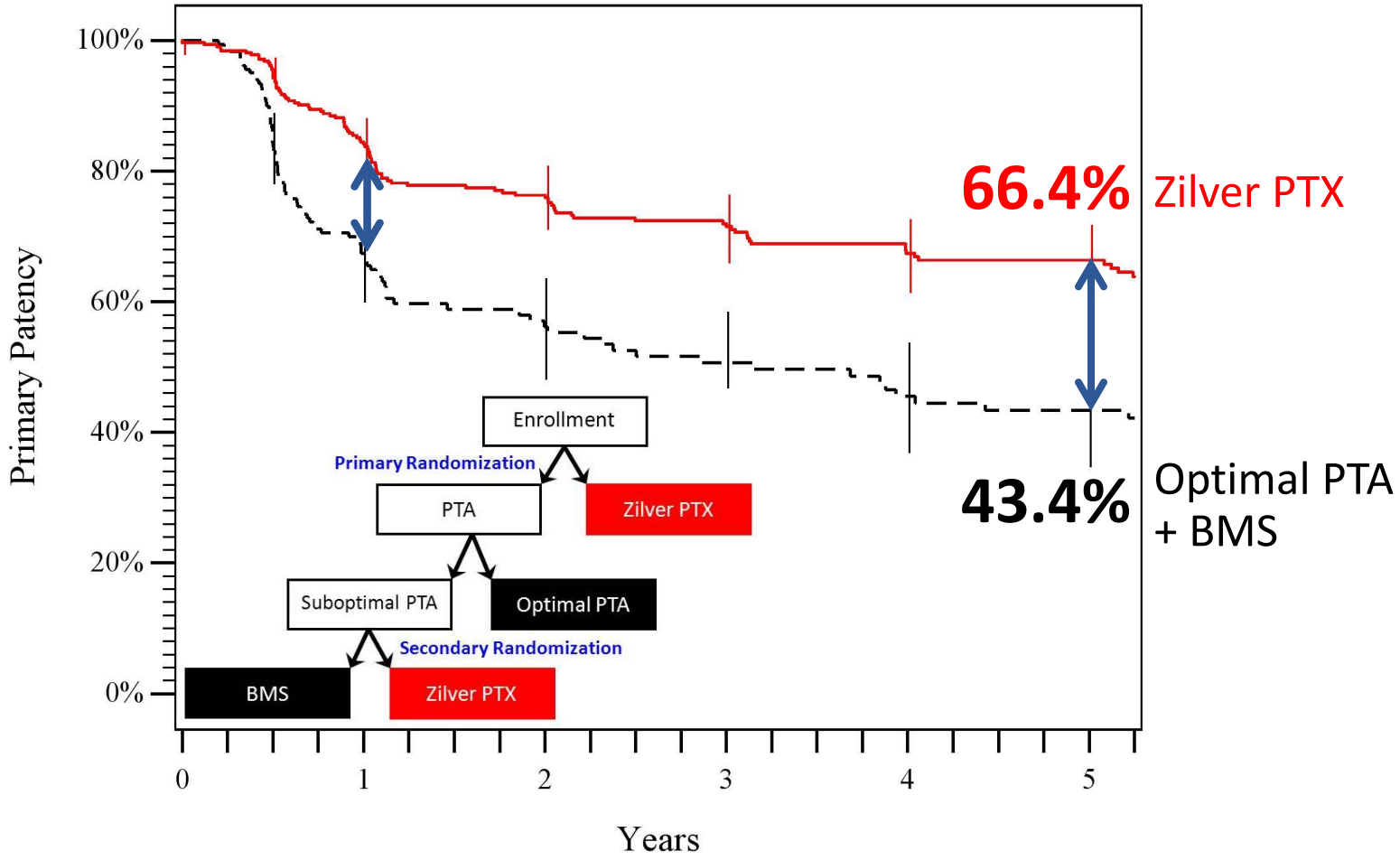
$p < 0.01$ log-rank

Years (LESIONS)		0	1	2	3	4	5
Zilver PTX	At Risk	318	246	199	163	137	109
	Failed	1	48	71	83	92	94
Standard Care	At Risk	183	108	64	52	44	38
	Failed	0	57	73	79	84	86

At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to standard care

5-year Primary Patency (PSVR < 2.0)

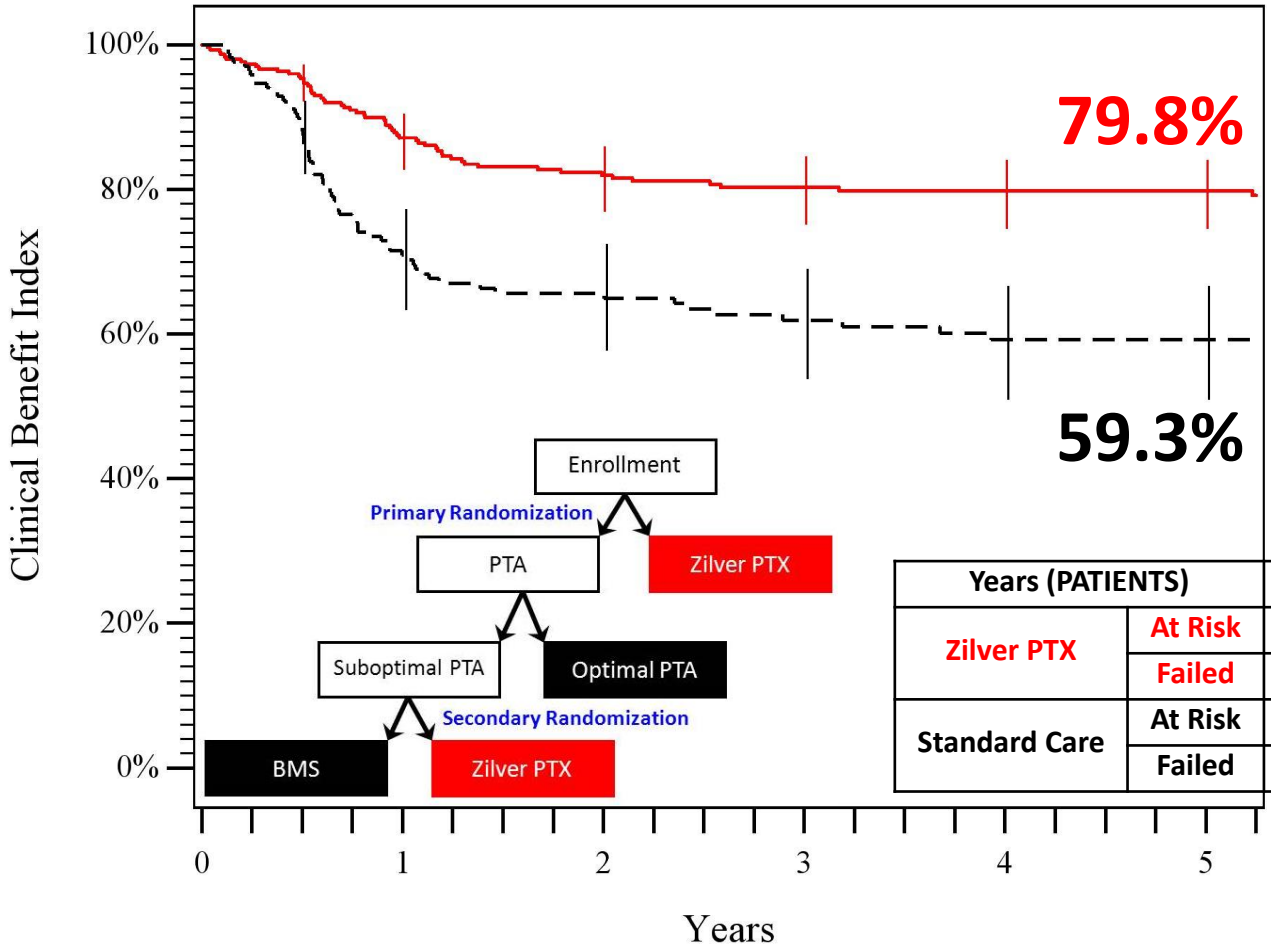
Zilver PTX vs. Standard Care



From 1-5 years, the relative separation increases by 35%

5-year Clinical Benefit Index

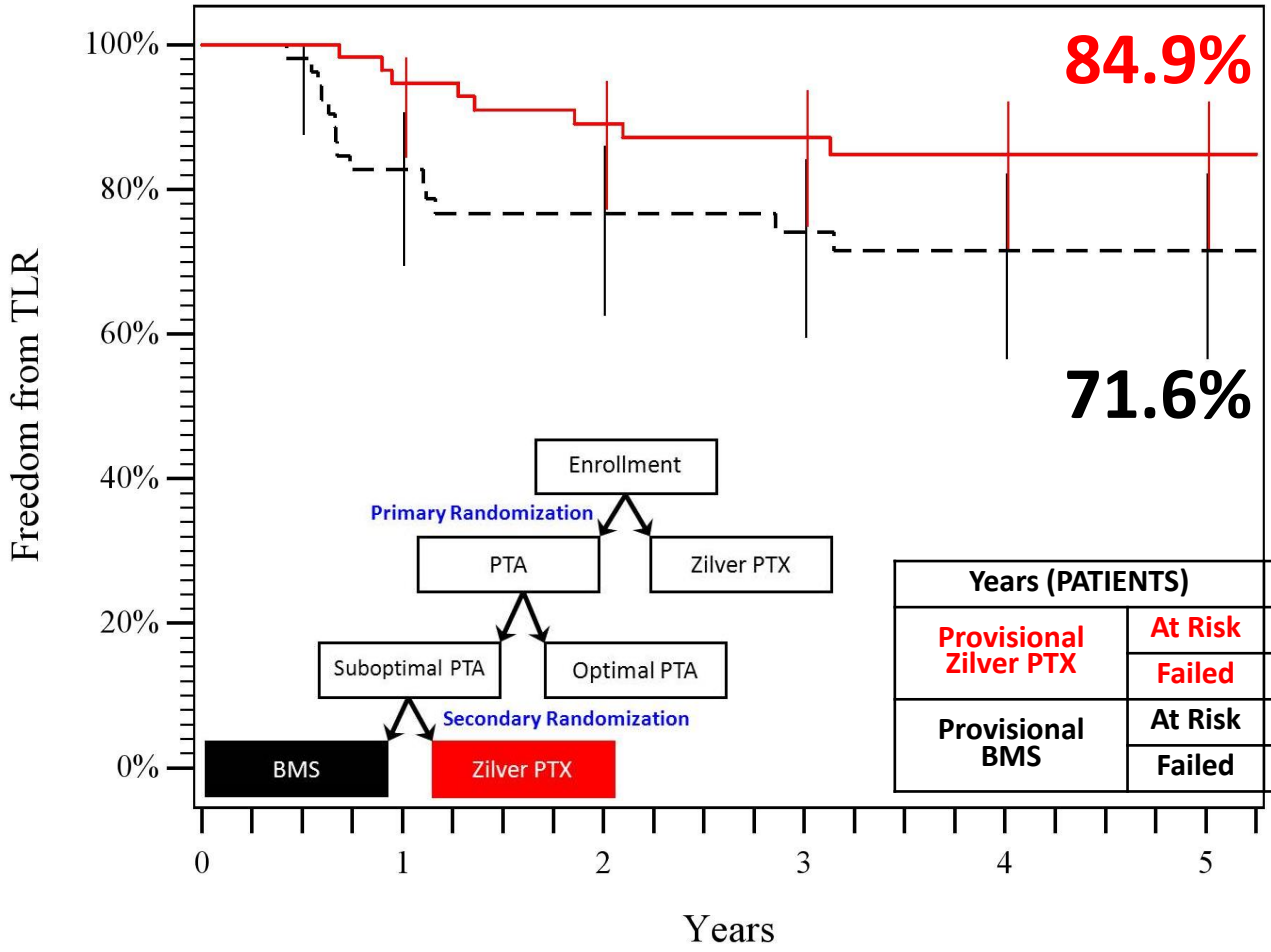
Zilver PTX vs. Standard Care



Years (PATIENTS)		0	1	2	3	4	5
Zilver PTX	At Risk	301	247	206	179	158	129
	Failed	0	38	52	56	57	57
Standard Care	At Risk	170	109	94	76	67	60
	Failed	0	48	56	61	64	64

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

5-year Freedom from TLR
Provisional Zilver PTX vs. BMS

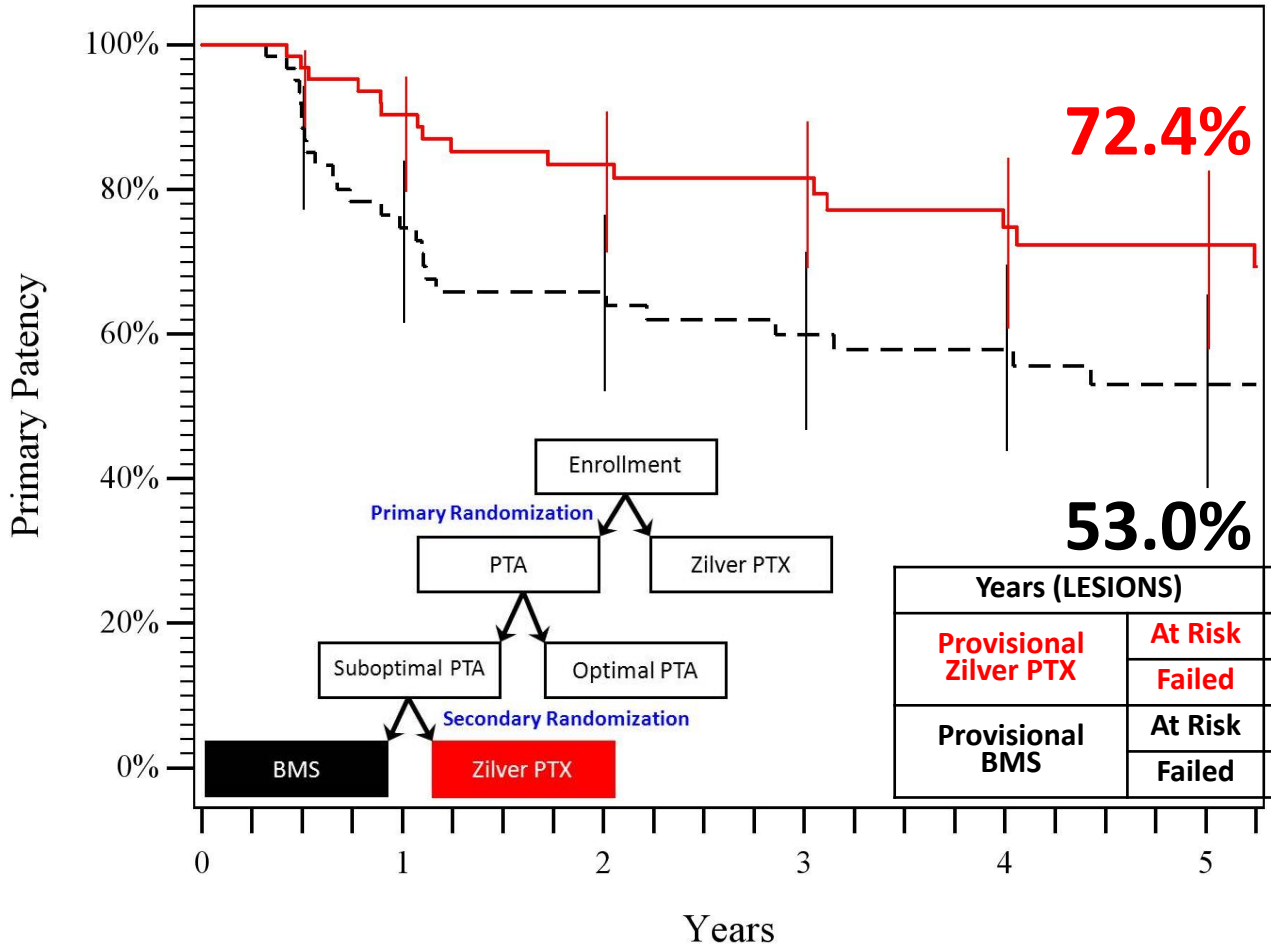


Years (PATIENTS)		0	1	2	3	4	5
Provisional Zilver PTX	At Risk	60	53	47	39	34	31
	Failed	0	3	6	7	8	8
Provisional BMS	At Risk	54	41	36	29	27	23
	Failed	0	9	12	13	14	14

At 5 years, Zilver PTX demonstrates a 47% reduction in reintervention compared to BMS

5-year Primary Patency (PSVR < 2.0)

Provisional Zilver PTX vs. BMS

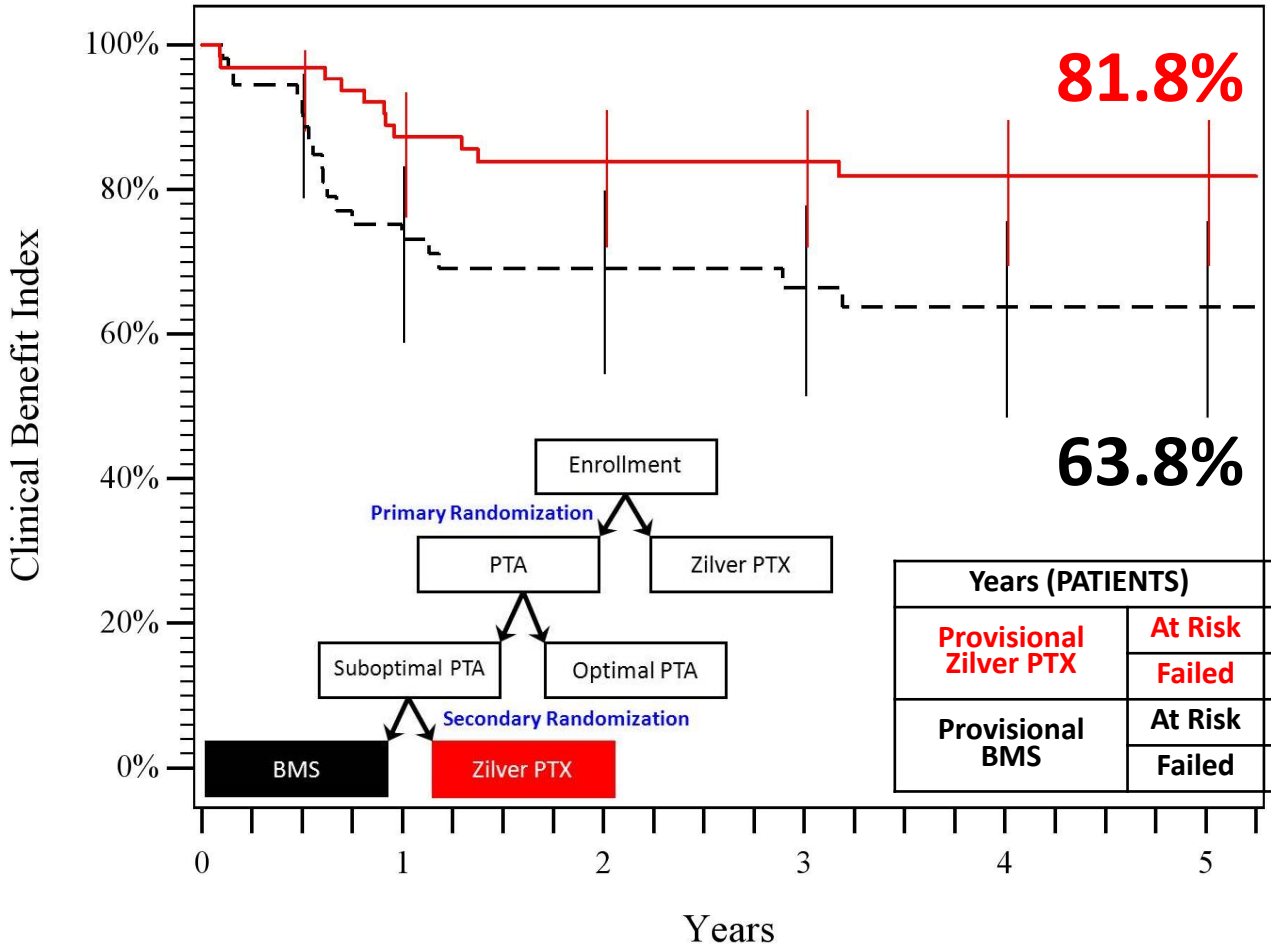


Years (LESIONS)		0	1	2	3	4	5
Provisional Zilver PTX	At Risk	63	55	46	38	31	25
	Failed	0	6	10	11	14	15
Provisional BMS	At Risk	62	42	35	29	26	19
	Failed	0	15	20	23	24	26

At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to BMS

5-year Clinical Benefit Index

Provisional Zilver PTX vs. BMS



Years (PATIENTS)		0	1	2	3	4	5
Provisional Zilver PTX	At Risk	64	54	48	42	38	34
	Failed	0	8	10	10	11	11
Provisional BMS	At Risk	54	36	32	25	23	20
	Failed	0	14	16	17	18	18

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

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