



Prediction model for freedom from TLR from a multi-study analysis of long-term results with the Zilver PTX DES

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Disclosure

Speaker name: Michael D. Dake, MD

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I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

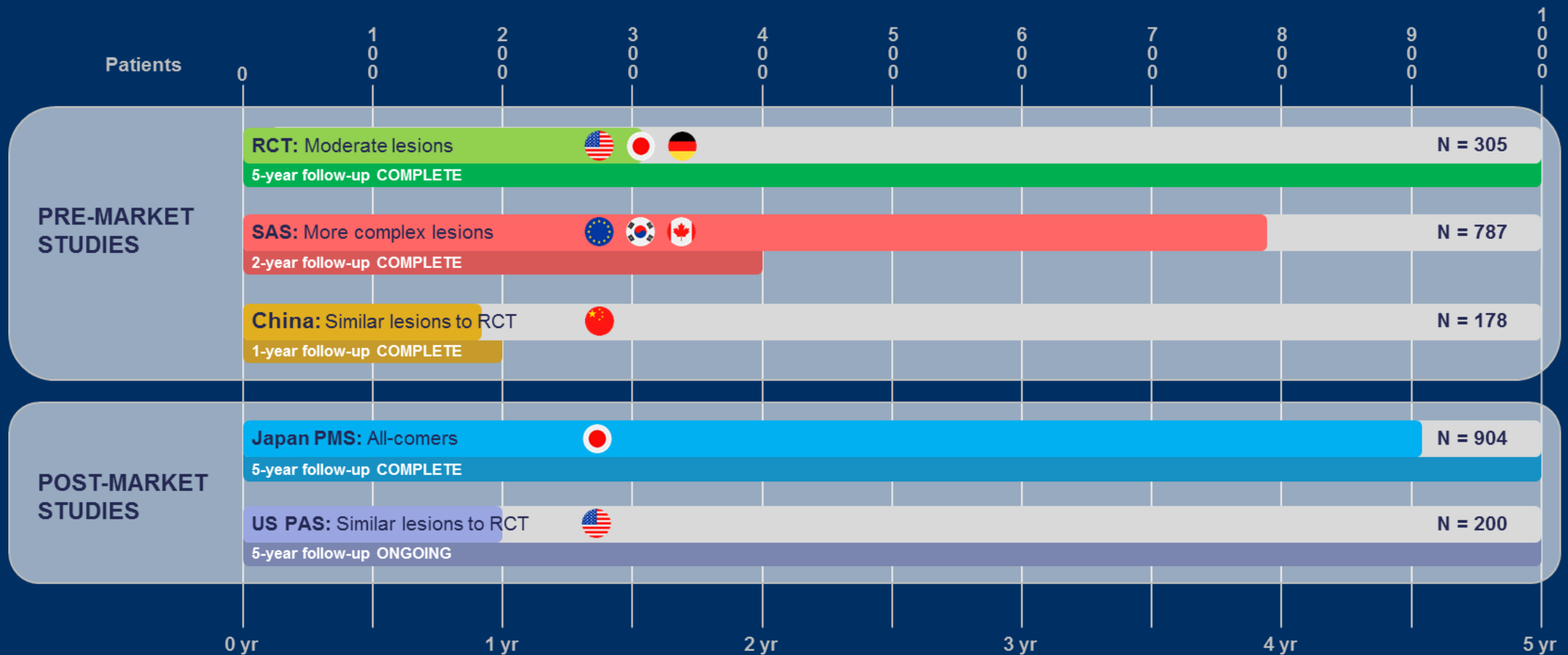
- I do not have any potential conflict of interest



Aim

- ▶ Develop a prediction model to determine the impact of patient and lesion factors on freedom from TLR through 5 years for patients who are candidates for Zilver PTX treatment

Global Clinical Program



2374 patients treated with the Zilver PTX DES

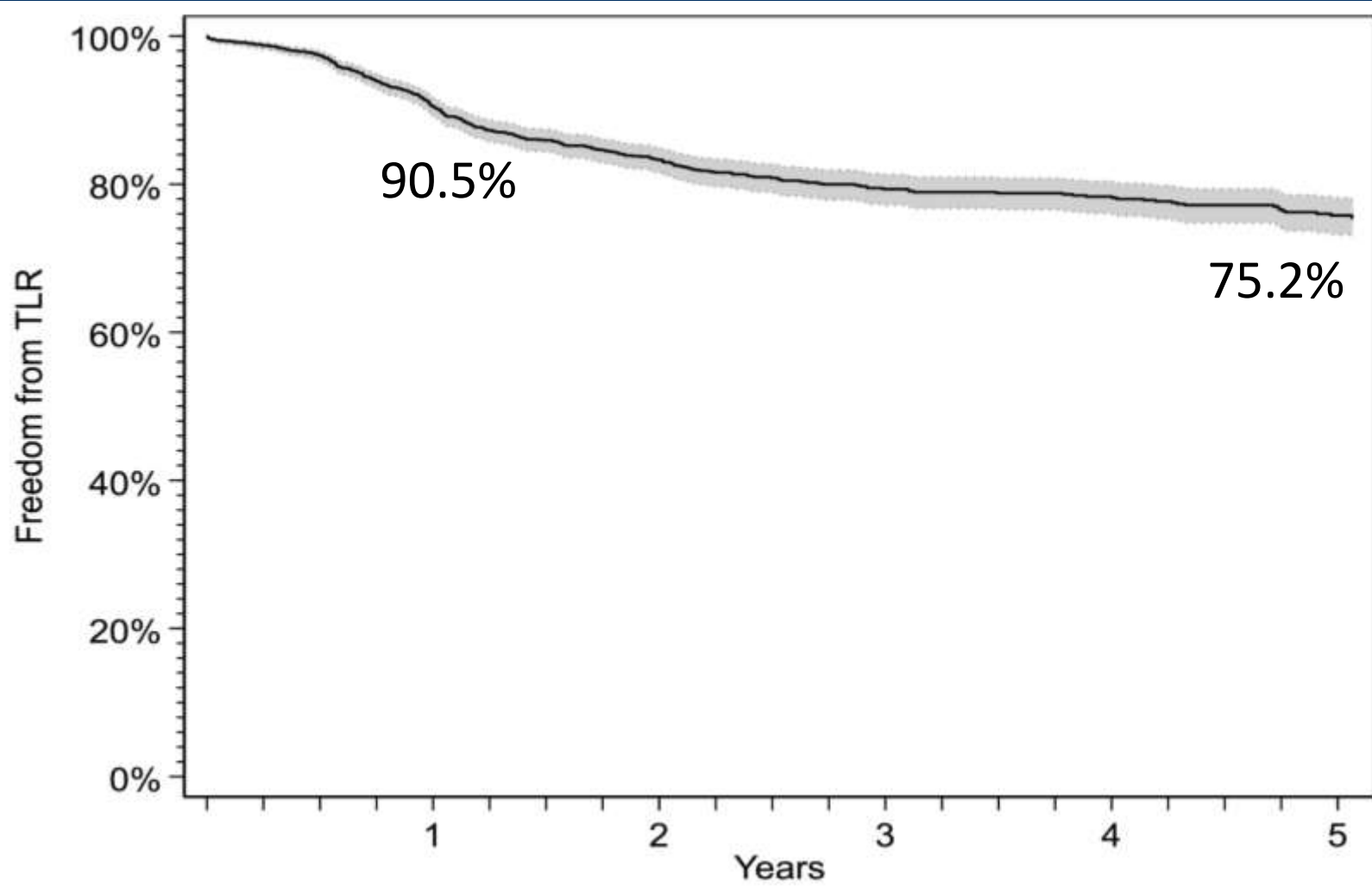
Study Characteristics

	RCT	SAS	China	US PAS	Japan PMS
Study design	Prospective, multicenter, RCT	Prospective, multicenter, single-arm study	Prospective, multicenter, single-arm study	Prospective, multicenter, single-arm study	Prospective, multicenter, single-arm study
Number of DES patients	305	787	178	200	904
Prior stent in SFA	No	Yes (ISR)	No	No	No exclusion criteria All patients treated with the DES enrolled (up to enrollment limit)
Lesion length	≤ 140 mm	No exclusion	≤ 140 mm	≤ 140 mm	
Renal exclusion	Serum creatinine > 2.0, renal failure, or dialysis	No exclusion	Chronic renal failure ^a or dialysis	No exclusion	
Core laboratory	Angiography Duplex Ultrasound X-Ray	X-Ray ^b	Angiography Duplex Ultrasound	Angiography Duplex Ultrasound X-Ray	X-Ray ^b

^a eGFR < 30 mLs/ min/1.73m²

^b In the event a stent fracture was reported by an investigative site, an independent core laboratory reviewed the imaging, confirmed the fracture, and classified the fracture by type (I-IV).

Results of Combined Studies



- ▶ 2227 cases (94%) with complete data used to generate the model
- ▶ 2 years median follow-up time
- ▶ Freedom from TLR
 - 90.5% at 1 year
 - 75.2% at 5 years

Factors Included in Prediction Model

Patient Demographics	Lesion Characteristics
Sex	Lesion length
Age	RVD
Diabetes	Popliteal involvement
Hypertension	Total occlusion
Hypercholesterolemia	Calcification
Renal disease	Prior interventions
Smoking status	Number of patent runoff vessels
Rutherford classification	

Baseline Patient Demographics

Characteristic		RCT (n=301)	SAS (n=707)	China (n=175)	US PAS (n=200)	Japan PMS (n=844)	Overall (n=2227)
Sex	Male	67%	74%	79%	63%	70%	71%
Age	<65	39%	39%	41%	37%	16%	30%
	65-74	34%	40%	35%	39%	37%	38%
	75-84	25%	20%	21%	21%	39%	28%
	>85	2%	1%	3%	4%	8%	4%
Diabetes		48%	36%	55%	46%	60%	49%
Hypertension		88%	79%	77%	94%	85%	84%
Hypercholesterolemia		76%	58%	19%	87%	61%	61%
Renal disease		9%	11%	6%	13%	43%	23%
Smoking status	Never	14%	17%	42%	16%	36%	26%
	Past	56%	49%	25%	43%	45%	46%
	Current	30%	34%	33%	42%	18%	28%
Rutherford	Claudicant	92%	90%	92%	86%	78%	85%
	CLI	8%	11%	8%	14%	22%	15%

Baseline Lesion Characteristics

Characteristic		RCT (n=301)	SAS (n=707)	China (n=175)	US PAS (n=200)	Japan PMS (n=844)	Overall (n=2227)
Lesion length (mm)	<50	46%	28%	35%	28%	15%	26%
	50-99	34%	28%	36%	50%	17%	27%
	100-149	18%	16%	18%	17%	20%	18%
	150-199	2%	9%	9%	4%	9%	8%
	200-249	0.3%	9%	1%	1%	18%	10%
	250-299	0%	9%	0%	1%	10%	7%
	>300	0%	2%	0%	0%	11%	5%
RVD (mm)	<5	42%	20%	69%	41%	19%	28%
	≥5	58%	80%	31%	60%	81%	72%
Popliteal involvement		6%	10%	2%	8%	8%	8%
Total occlusion		33%	43%	50%	37%	44%	42%
Calcification	None	25%	19%	25%	14%	28%	23%
	Mild/moderate	61%	60%	66%	70%	54%	59%
	Severe	15%	21%	10%	17%	18%	18%
Prior interventions		5%	25%	1%	13%	29%	21%
Number of runoff vessels	0-1	23%	18%	38%	23%	39%	29%
	>2	77%	82%	62%	78%	61%	71%

Multivariate Model Results

Characteristic		Hazard Ratio	p-value
Male		0.760	0.022*
Age	65-74	0.734	0.002*
	75-84	0.637	
	>85	0.398	
Diabetes		1.033	0.766
Hypertension		0.927	0.596
Hypercholesterolemia		1.126	0.296
Renal disease		1.072	0.578
Smoking status	Past	0.825	0.187
	Current	1.020	
Rutherford	CLI	1.429	0.010*
Lesion length (mm)	50-99	1.443	<0.001*
	100-149	2.066	
	150-199	2.205	
	200-249	2.847	
	250-299	2.899	
	>300	3.454	
RVD (mm)	≥5	0.727	0.006*
Popliteal involvement		1.042	0.815
Total occlusion		1.406	0.004*
Calcification	Mild/moderate	0.994	0.845
	Severe	1.078	
Prior interventions		1.815	<0.001*
Number of runoff vessels	≥2	0.958	0.719

- ▶ Risk factors common in PAD patients may collectively contribute to overall patient prognosis
- ▶ As expected, CLI, lesion length, and total occlusion have a significant impact on TLR
 - Other factors such as diabetes and calcification did not have a significant impact on TLR



Prediction for Example Patient Profile #1

Factor	Patient Profile #1
Sex	Male
Age	65-74
Diabetes	Yes
Hypertension	Yes
Hypercholesterolemia	Yes
Renal disease	No
Smoking status	Past smoker
Rutherford classification	Claudicant
Lesion length	<50 mm
RVD	≥5 mm
Popliteal involvement	No
Occlusion	No
Calcification severity	Mild/moderate
Prior interventions	No
Number of runoff vessels	2+

Patient Demographics

Sex: Male Female

Age (yrs): <65 65-74 75-84 85+

Diabetes: No Yes

Hypertension: No Yes

Hypercholesterolemia: No Yes

Renal Insufficiency: No Yes

Smoking: Never Current Past

Limb Status: Claudicant CLI

Lesion Characteristics

Lesion Length (mm): <50 50-99 100-149 150-199 200-249 250-299 300+

Reference Vessel Diameter (mm): <5 ≥5

Popliteal Involvement: No Yes

Chronic Total Occlusion: No Yes

Lesion Calcification: None Mild/Mod Severe

Prior Intervention: No Yes

Tibial Runoff Vessels: 2+ 0/1

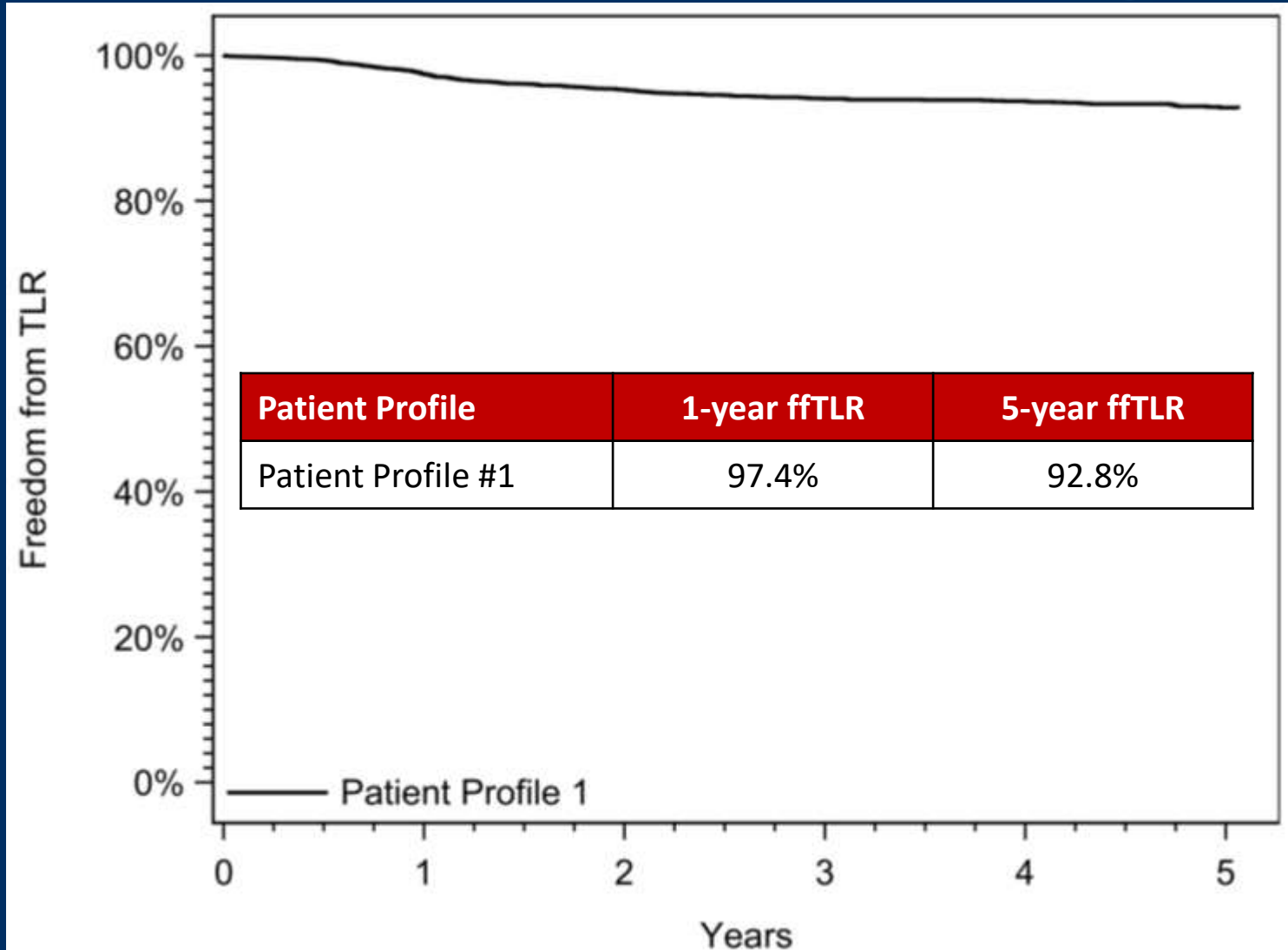
Results

	12 Months	24 Months	36 Months	48 Months	60 Months
Freedom from TLR	97.4%	95.3%	94.0%	93.7%	92.8%
Standard Error	0.5%	0.9%	1.2%	1.2%	1.4%
Lower 95% CI	96.4%	93.4%	91.8%	91.3%	90.1%
Upper 95% CI	98.5%	97.1%	96.4%	96.2%	95.6%



Prediction for Example Patient Profile #1

Factor	Patient Profile #1
Sex	Male
Age	65-74
Diabetes	Yes
Hypertension	Yes
Hypercholesterolemia	Yes
Renal disease	No
Smoking status	Past smoker
Rutherford classification	Claudicant
Lesion length	<50 mm
RVD	≥5 mm
Popliteal involvement	No
Occlusion	No
Calcification severity	Mild/moderate
Prior interventions	No
Number of runoff vessels	2+





Prediction for Example Patient Profile #2

Factor	Patient Profile #2
Sex	Female
Age	65-74
Diabetes	Yes
Hypertension	Yes
Hypercholesterolemia	Yes
Renal disease	No
Smoking status	Past smoker
Rutherford classification	Claudicant
Lesion length	100-149 mm
RVD	≥5 mm
Popliteal involvement	No
Occlusion	No
Calcification severity	Severe
Prior interventions	No
Number of runoff vessels	0 or 1

Patient Demographics

Sex Male Female

Age (yrs) <65 65-74 75-84 85+

Diabetes No Yes

Hypertension No Yes

Hypercholesterolemia No Yes

Renal Insufficiency No Yes

Smoking Never Current Past

Limb Status Claudicant CLI

Lesion Characteristics

Lesion Length (mm) <50 50-99 100-149 150-199 200-249 250-299 300+

Reference Vessel Diameter (mm) <5 ≥5

Popliteal Involvement No Yes

Chronic Total Occlusion No Yes

Lesion Calcification None Mild/Mod Severe

Prior Intervention No Yes

Tibial Runoff Vessels 2+ 0/1

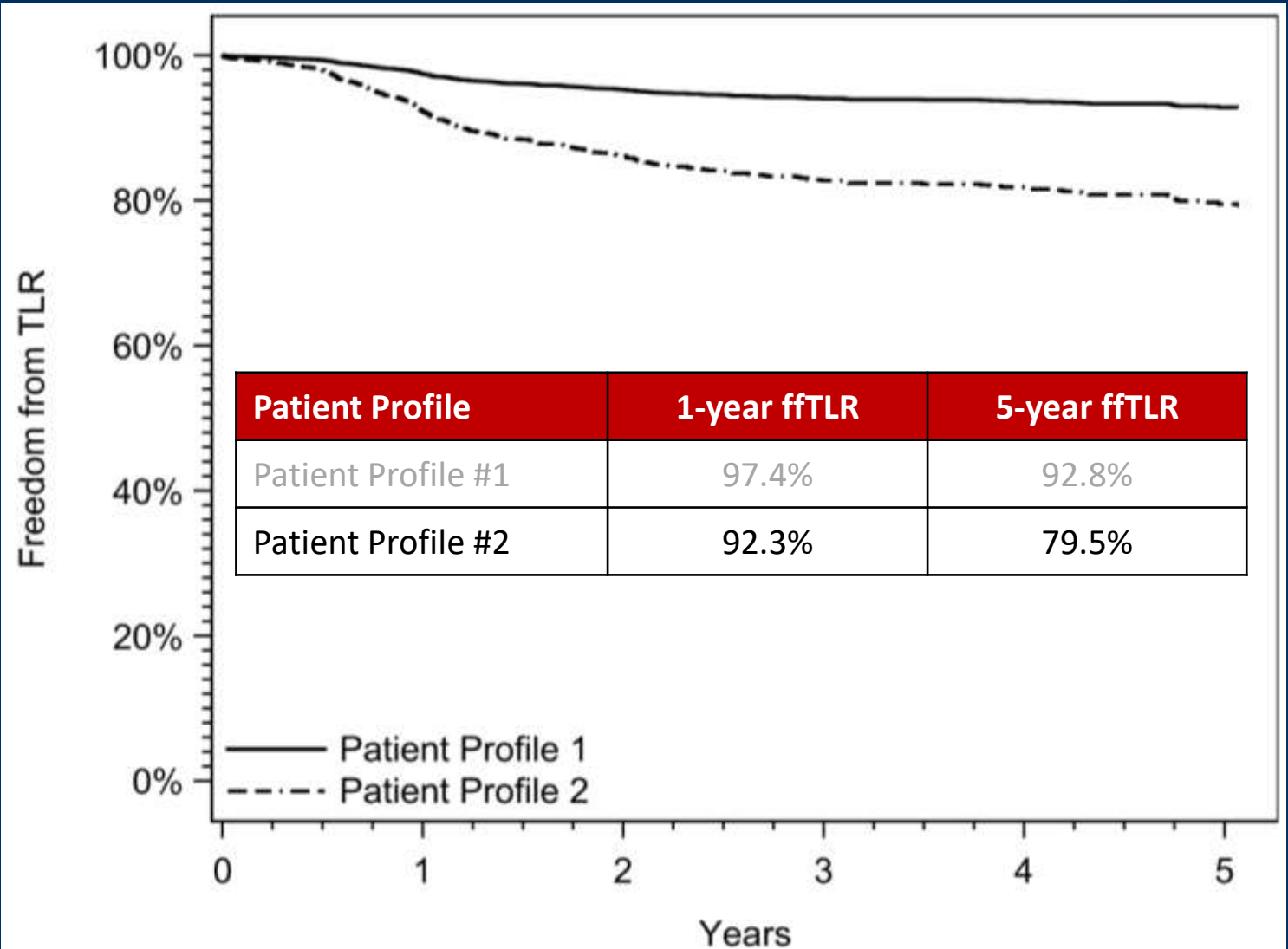
Results

	12 Months	24 Months	36 Months	48 Months	60 Months
Freedom from TLR	92.3%	86.1%	82.7%	81.8%	79.5%
Standard Error	1.9%	3.3%	4.0%	4.2%	4.7%
Lower 95% CI	88.6%	79.9%	75.2%	74.0%	70.8%
Upper 95% CI	96.2%	92.8%	91.0%	90.5%	89.2%



Prediction for Example Patient Profile #2

Factor	Patient Profile #2
Sex	Female
Age	65-74
Diabetes	Yes
Hypertension	Yes
Hypercholesterolemia	Yes
Renal disease	No
Smoking status	Past smoker
Rutherford classification	Claudicant
Lesion length	100-149 mm
RVD	≥5 mm
Popliteal involvement	No
Occlusion	No
Calcification severity	Severe
Prior interventions	No
Number of runoff vessels	0 or 1





Prediction for Example Patient Profile #3

Factor	Patient Profile #3
Sex	Male
Age	75-84
Diabetes	No
Hypertension	Yes
Hypercholesterolemia	No
Renal disease	Yes
Smoking status	Past smoker
Rutherford classification	Claudicant
Lesion length	200-249 mm
RVD	≥5 mm
Popliteal involvement	No
Occlusion	Yes
Calcification severity	Mild/moderate
Prior interventions	Yes
Number of runoff vessels	2+

Patient Demographics

Sex: Male Female

Age (yr): <65 65-74 75-84 85+

Diabetes: No Yes

Hypertension: No Yes

Hypercholesterolemia: No Yes

Renal Insufficiency: No Yes

Smoking: Never Current Past

Limb Status: Claudicant GIJ

Lesion Characteristics

Lesion Length (mm): <60 60-99 100-149 150-199 200-249 250-299 300+

Reference Vessel Diameter (mm): <6 ≥6

Popliteal Involvement: No Yes

Chronic Total Occlusion: No Yes

Lesion Calcification: None Mid/Med Severe

Prior Intervention: No Yes

Total Runoff Vessels: 2+ 0/1

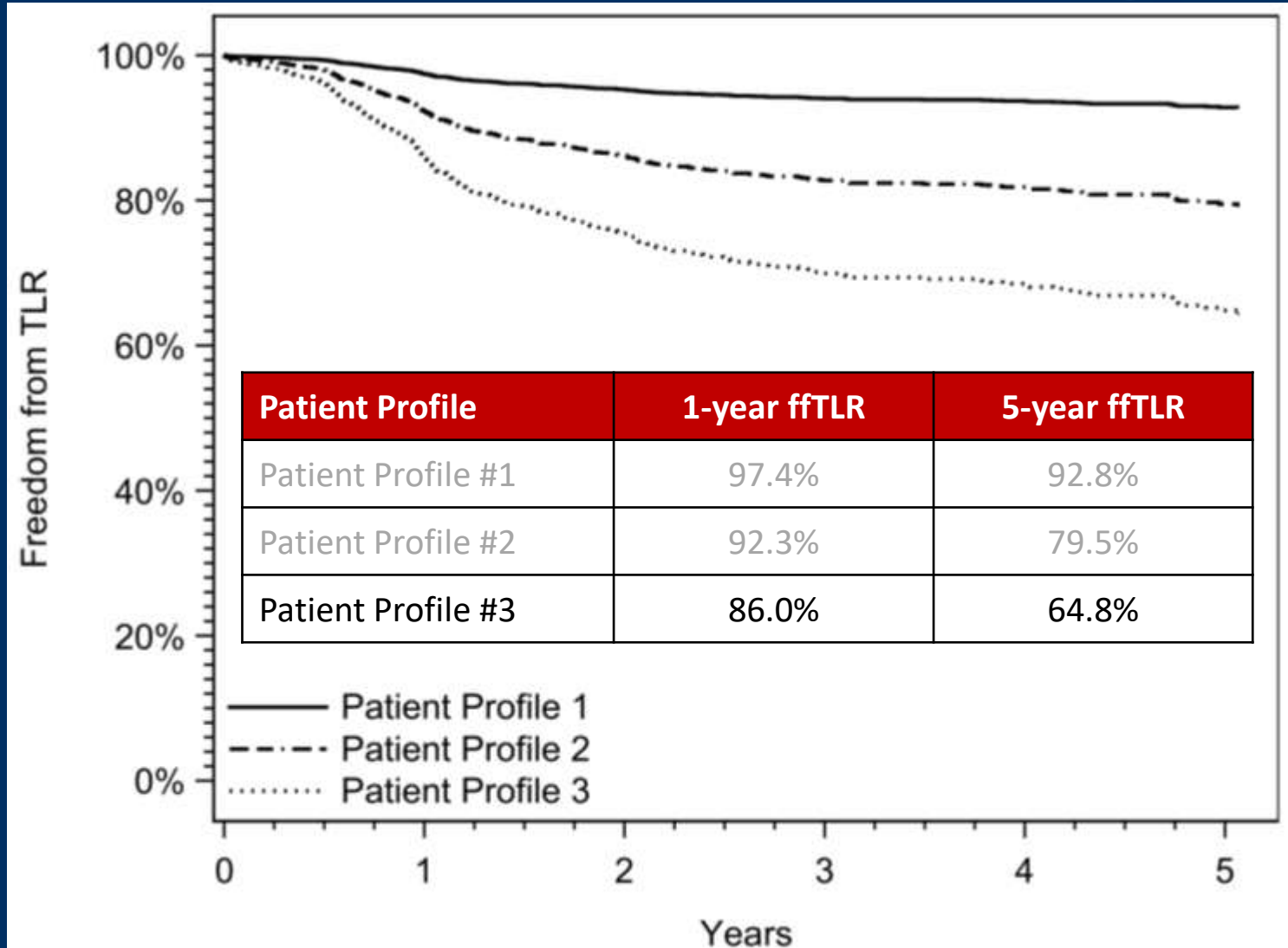
Results

	12 Months	24 Months	36 Months	48 Months	60 Months
Freedom from TLR	86.0%	75.4%	69.9%	66.5%	64.8%
Standard Error	3.2%	5.2%	6.1%	6.3%	6.0%
Lower 95% CI	79.9%	65.9%	59.0%	57.2%	52.7%
Upper 95% CI	92.1%	86.3%	82.9%	82.0%	79.7%



Prediction for Example Patient Profile #3

Factor	Patient Profile #3
Sex	Male
Age	75-84
Diabetes	No
Hypertension	Yes
Hypercholesterolemia	No
Renal disease	Yes
Smoking status	Past smoker
Rutherford classification	Claudicant
Lesion length	200-249 mm
RVD	≥5 mm
Popliteal involvement	No
Occlusion	Yes
Calcification severity	Mild/moderate
Prior interventions	Yes
Number of runoff vessels	2+



Conclusion

- ▶ Patient and lesion factors from 5 global clinical studies used to develop a prediction model for freedom from TLR
 - Data from over 2200 patients used to create the model
- ▶ First prediction model to estimate the impact of patient and lesion characteristics on freedom from TLR through 5 years for patients with PAD
 - Based on unique patient profile, model provides expected patient outcomes following treatment with the Zilver PTX DES
 - May assist in defining treatment algorithms for patients as the value of population management is increasingly recognized

Zilver® PTX® Predictability Model

Disclaimer

The Dataset includes data collected from Cook-sponsored studies, including pre-market data, post-approval data, and real-world data collected as a requirement of approval. The model generates predictions for freedom from target lesion revascularization based on the Dataset. The model outcomes resulting from the Dataset are provided for transparency and as part of ongoing scientific exchange regarding clinical evidence associated with the Zilver® PTX® stent.

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Patient Demographics

Sex Male Female

Age (yrs) <65 65-74 75-84 85+

Diabetes No Yes

Hypertension No Yes

Hypercholesterolemia No Yes

Renal Insufficiency No Yes

Smoking Never Current Past

Limb Status Claudicant CLI

Patient Demographics

Sex Male Female

Age (yrs) <65 65-74 75-84 85+

Diabetes No Yes

Hypertension No Yes

Hypercholesterolemia No Yes

Renal Insufficiency No Yes

Smoking Never Current Past

Limb Status Claudicant CLI

Lesion Characteristics

Lesion Length (mm) <50 50-99 100-149 150-199 200-249 250-299 300+

Reference Vessel Diameter (mm) <5 >=5

Popliteal Involvement No Yes

Chronic Total Occlusion No Yes

Lesion Calcification None Mild/Mod Severe

Prior Intervention No Yes

Tibial Runoff Vessels 2+ 0/1

Results

	12 Months	24 Months	36 Months	48 Months	60 Months
Freedom from TLR	97.4%	95.3%	94.0%	93.7%	92.8%
Standard Error	0.5%	0.9%	1.2%	1.2%	1.4%
Lower 95% CI	96.4%	93.4%	91.8%	91.3%	90.1%
Upper 95% CI	98.5%	97.1%	96.4%	96.2%	95.6%

Visit the interactive web-based tool to see how Zilver PTX might help your patients

<https://cooksfa.z13.web.core.windows.net>



Prediction Model for Freedom from TLR from a Multi-study Analysis of Long-Term Results with the Zilver PTX Drug-Eluting Peripheral Stent

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