
The Zilver PTX[®] Randomized Controlled Trial of Paclitaxel-Eluting Stents for Femoropopliteal Disease: **4-Year Results**

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On behalf of the Investigators

Faculty Disclosure

I have **no financial relationships** to disclose.

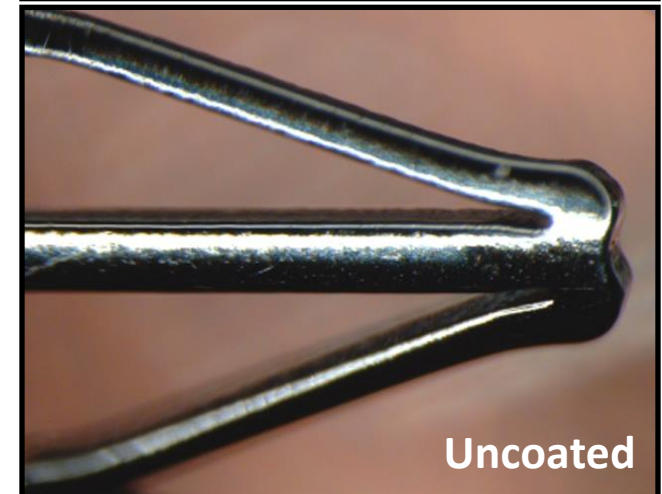
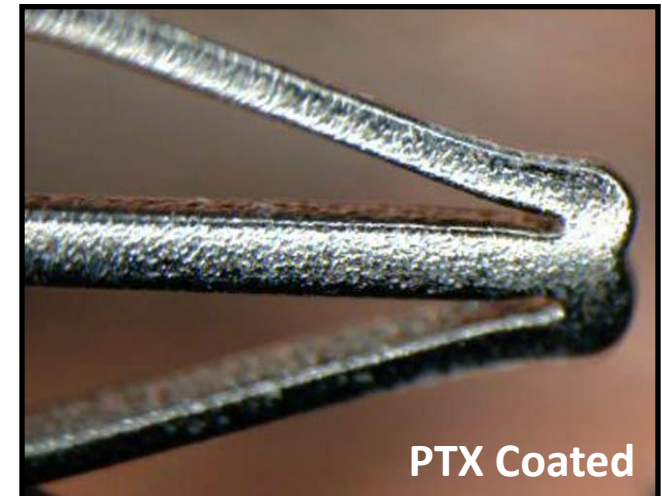
Je n'ai **aucune relation financière** à déclarer.

Drug Elution Now in the Periphery

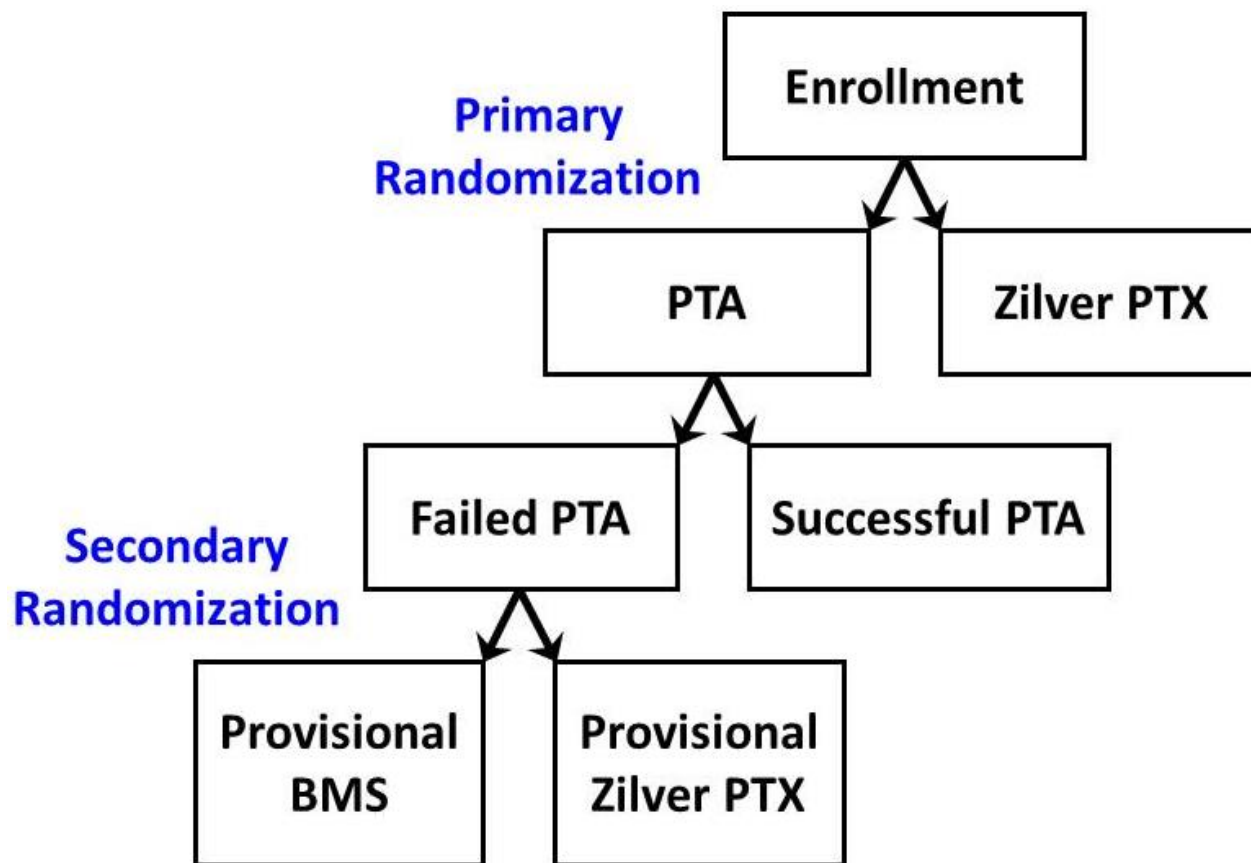
- Multiple drug-eluting stent and drug-eluting balloon trials underway
- Cook Medical is the only company to offer drug-eluting stents for the SFA

Zilver PTX Drug-Eluting Peripheral Stent

- New generation SFA Stent
- Approved in EU, Japan, and US
- Scaffold plus drug
 - **Mechanical scaffold:**
Zilver Flex® Stent Platform
 - **Drug therapy:** Paclitaxel only
 - No polymer or binder
 - 3 $\mu\text{g}/\text{mm}^2$ dose density



Zilver PTX Study Design (Dake M et al. Circ cardiovasc Interv 2011;4:495-504.)



PTA FIRST BECAUSE NO FDA- APPROVED BMS FOR FEMOROPOLITEAL ARTERY
479 patients

Baseline Lesion Characteristics

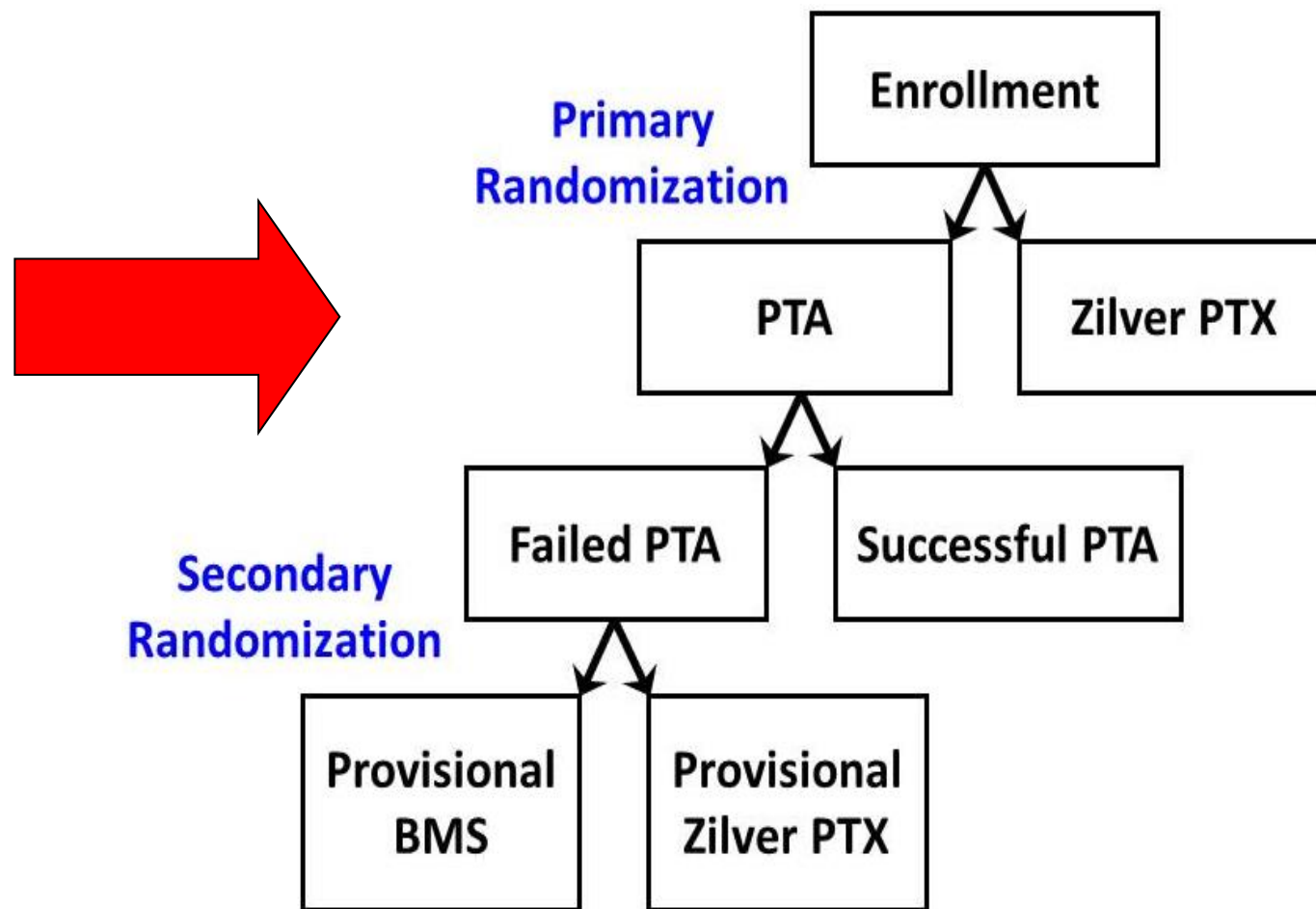
	PTA	Zilver PTX®	p-value
Lesions	251	247	
CLAUDICANT	91%	90%	
DIABETES	42%	50%	0.36
Stenosed lesion length (mm)^{1,2}	53 ± 40	55 ± 41	0.71
Total occlusions	27%	33%	0.20

¹ Angiographic core lab assessment

² Region with > 20% diameter stenosis

*Statistically significant

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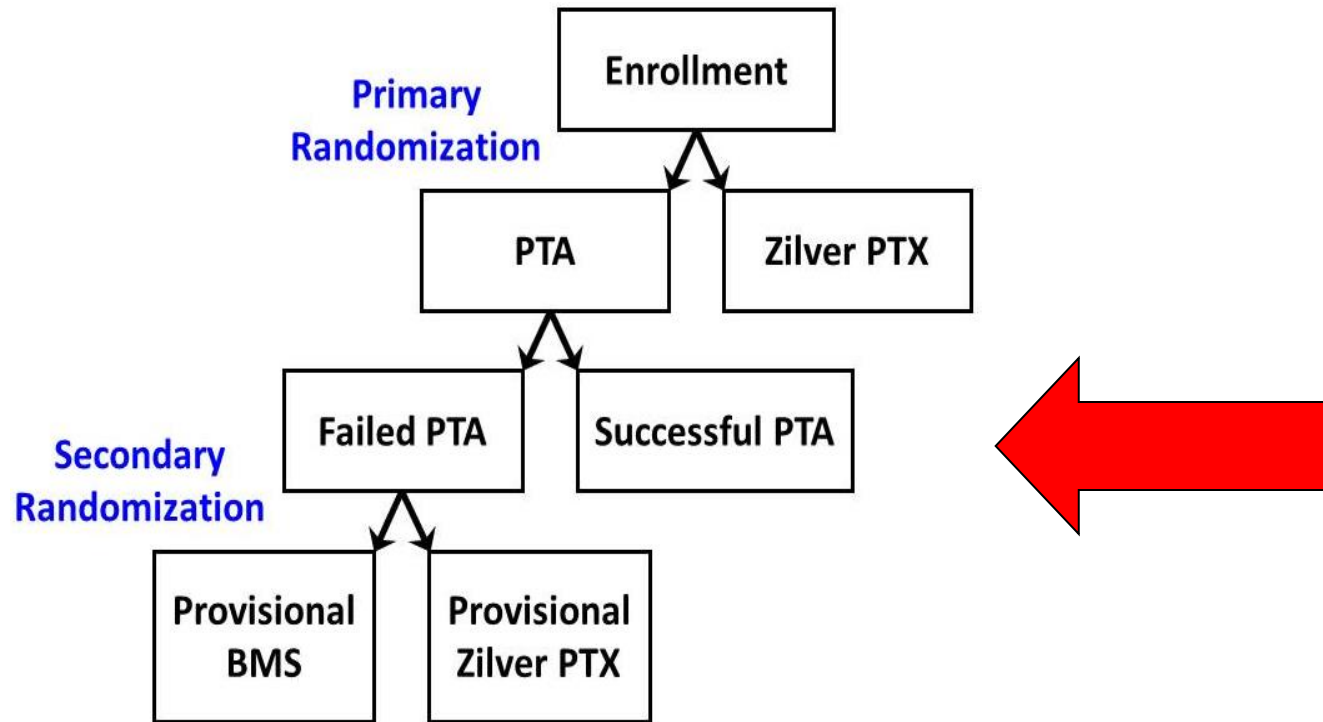
PRIMARY STENTING

IS IT BETTER TO HAVE AN OPTIMAL PTA OR A PRIMARY STENTING ?

12-MONTH PRIMARY PATENCY :

- **PRIMARY STENTING WITH Zilver PTX: 83%**
- **OPTIMAL PTA: 65%**

QS 2 : WHAT IS THE POURCENTAGE ON NON OPTIMAL PTA ?



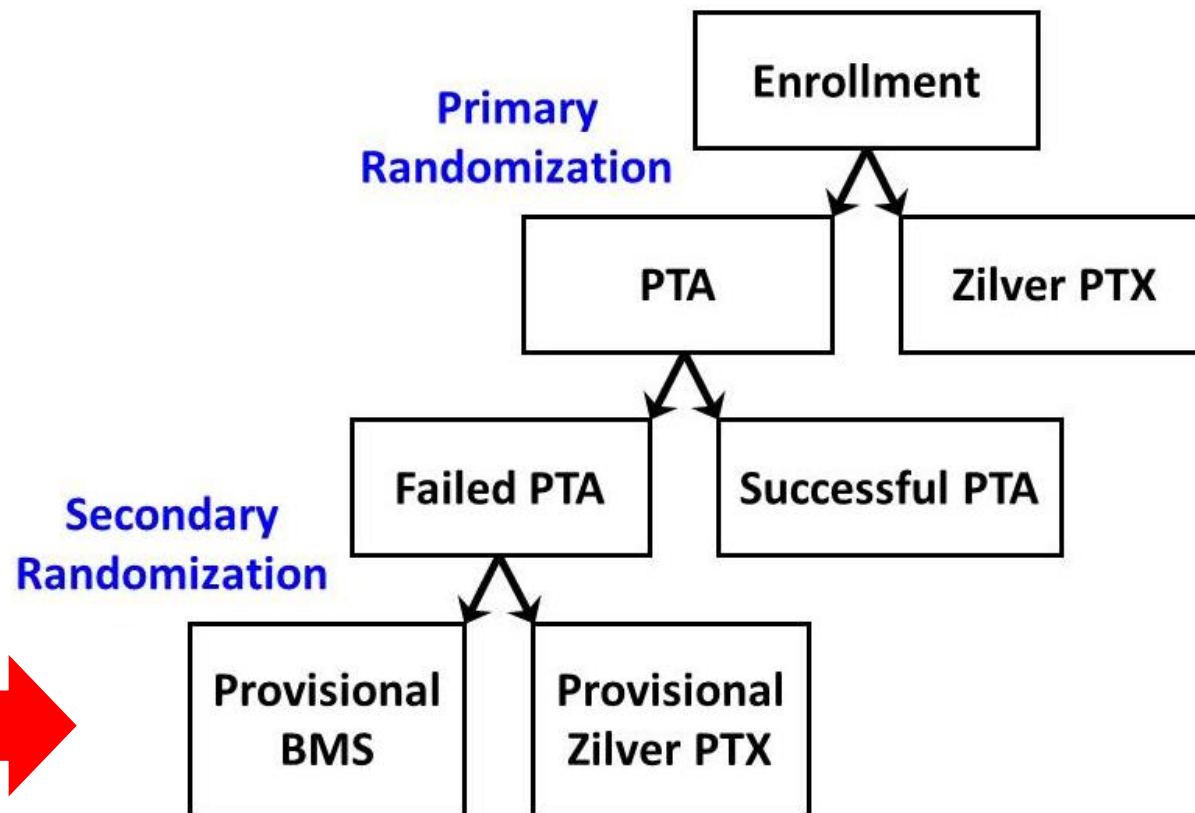
QS 2 : WHAT IS THE POURCENTAGE ON NON OPTIMAL PTA ?

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50%

QS 3 : IN CASE OF PROVISIONAL STENTING , IS IT BETTER TO USE A BMS OR A DES?

- PRESPECIFIED COMPARISON



QS 3 : IN CASE OF PROVISIONAL STENTING , IS IT BETTER TO USE A BMS OR A DES?

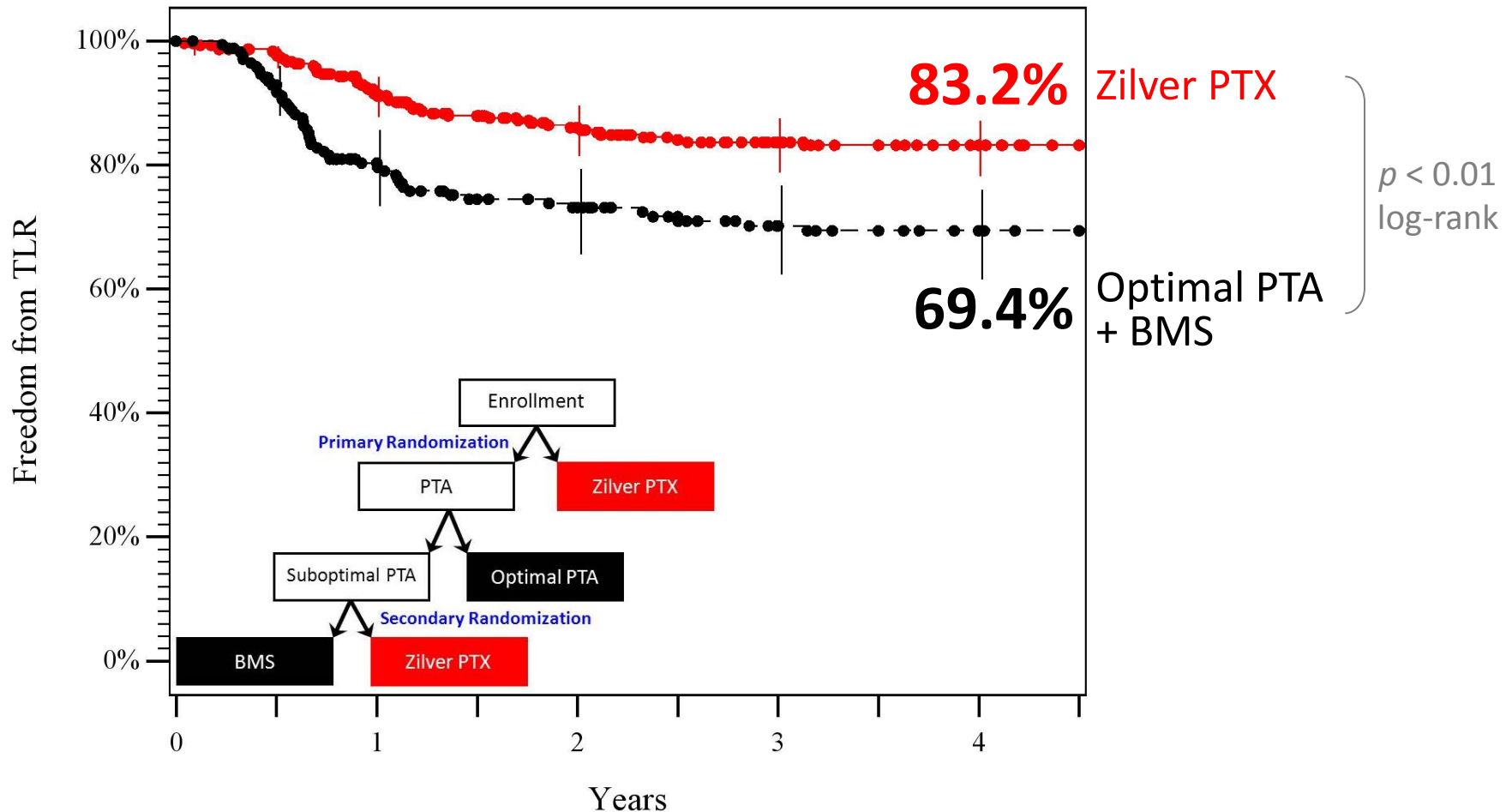
DES

QS 3 : IN CASE OF PROVISIONAL STENTING , IS IT BETTER TO USE A BMS OR A DES?

- 12-MONTH PRIMARY PATENCY :
90% (DES) VS **73%** (BMS)
- 4 YEARS PRIMARY PATENCY :
75% (DES) VS **58%** (BMS)

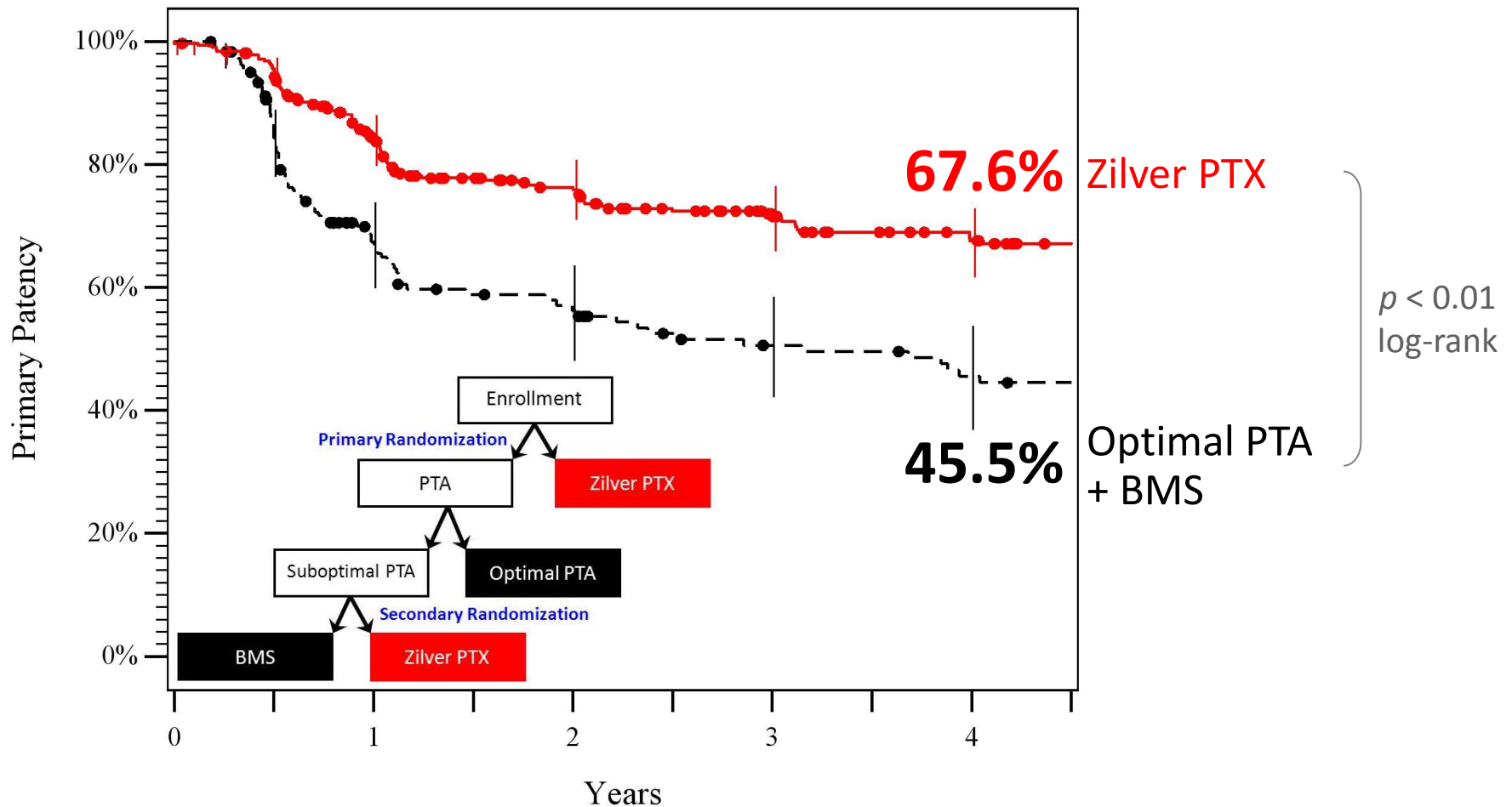
4-Year Freedom from TLR

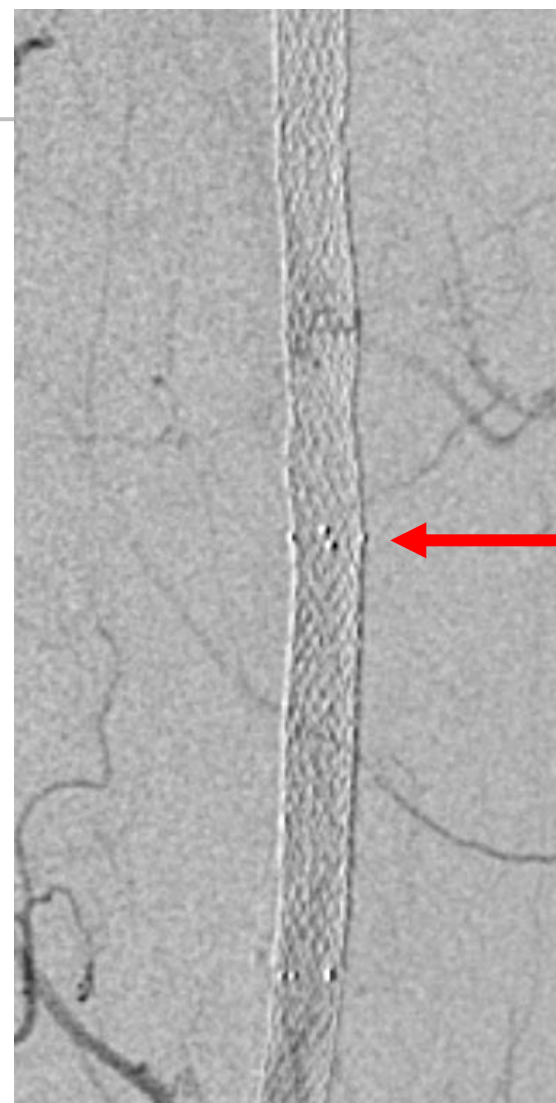
Zilver PTX vs. Standard Care – Drug Effect



45% reduction in reintervention rate due to the drug

4-Year Primary **PATENCY** (PSVR < 2.0) Zilver PTX vs. Standard Care – Drug Effect





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