Follow the data:
Zilver PTX global data analysis

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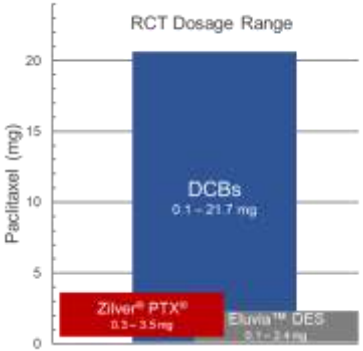
For the 12 months preceding this presentation, I disclose the following types of financial relationships:

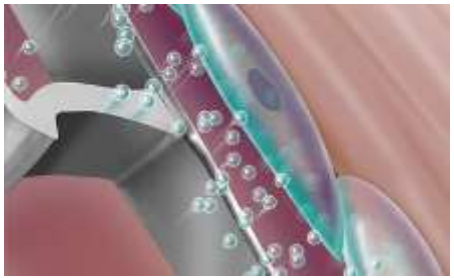
- **Honoraria received from:** Abbott Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Philips-Spectranetics, TriReme, Veryan, Shockwave, Biotronik, B. Braun
- **Consulted for:** Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Spectranetics, Veryan, Intact Vascular, Veryan
- **Common stock:** QT Medical

Zilver PTX Stent Overview



Coating

Low dose, amorphous coating with no polymer or excipient



Local Drug Delivery

Short-term drug delivery, no long-term paclitaxel exposure, only BMS remains

5
YEARS

Long-term data

Only peripheral DES with long-term safety data

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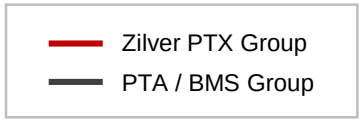
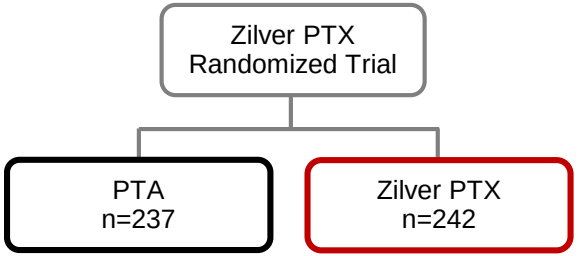
TRIAL DESIGN

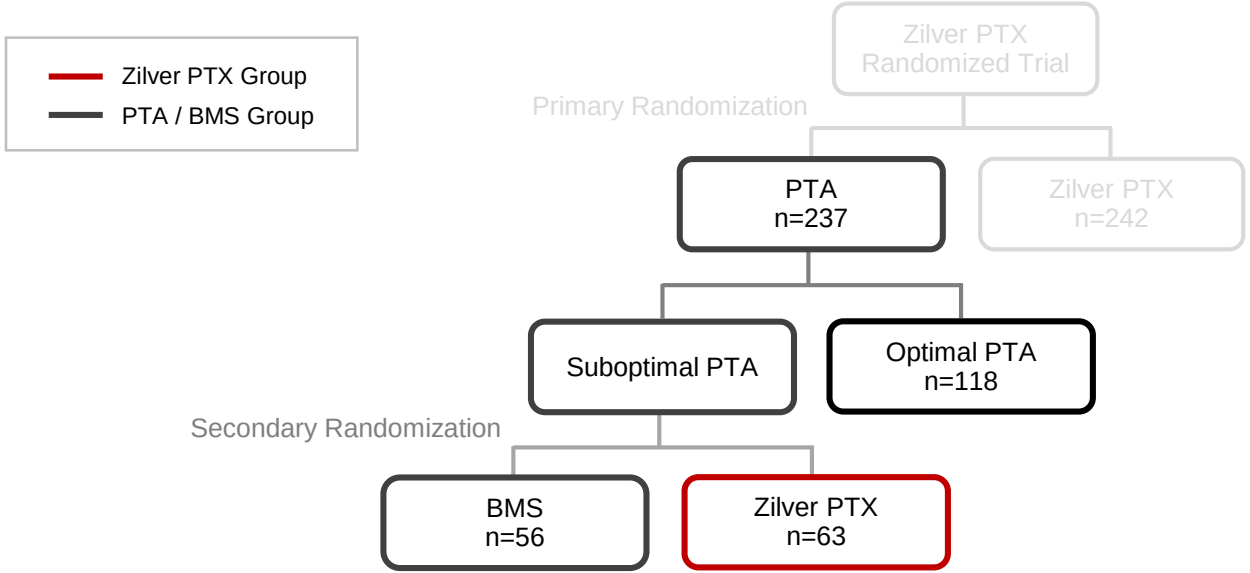
Primary Randomization





TRIAL DESIGN

Secondary Randomization



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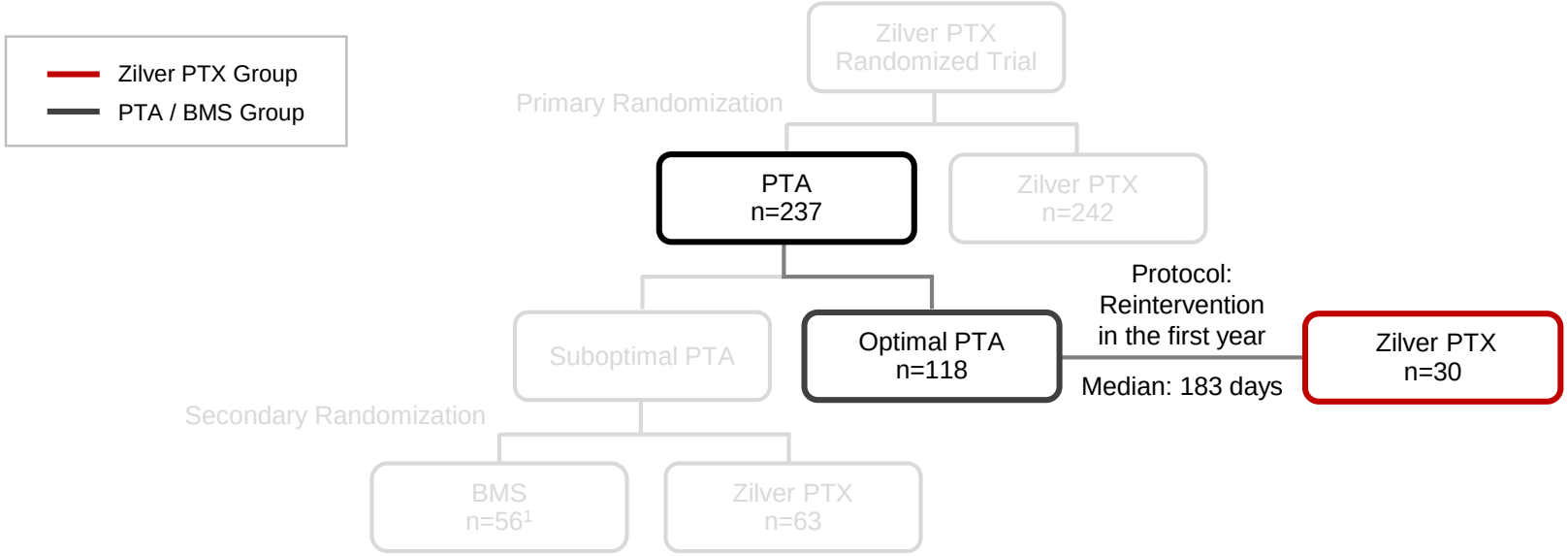
TRIAL DESIGN

Early Crossover

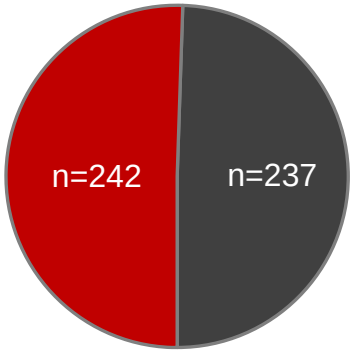


[1] One BMS patient received Zilver PTX during reintervention within the first year.

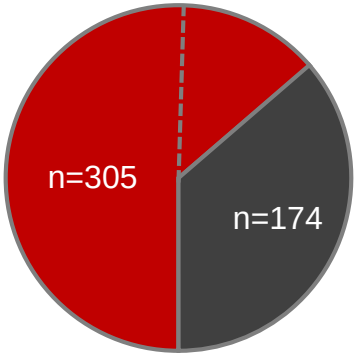
Treatment Results

- Zilver PTX
- PTA / BMS

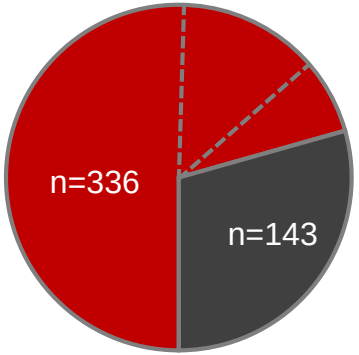
Primary Randomization



Primary + Secondary Randomization



Actual Treatment = Primary + Secondary + Crossover



40% of patients initially randomized to PTA were actually treated with Zilver PTX

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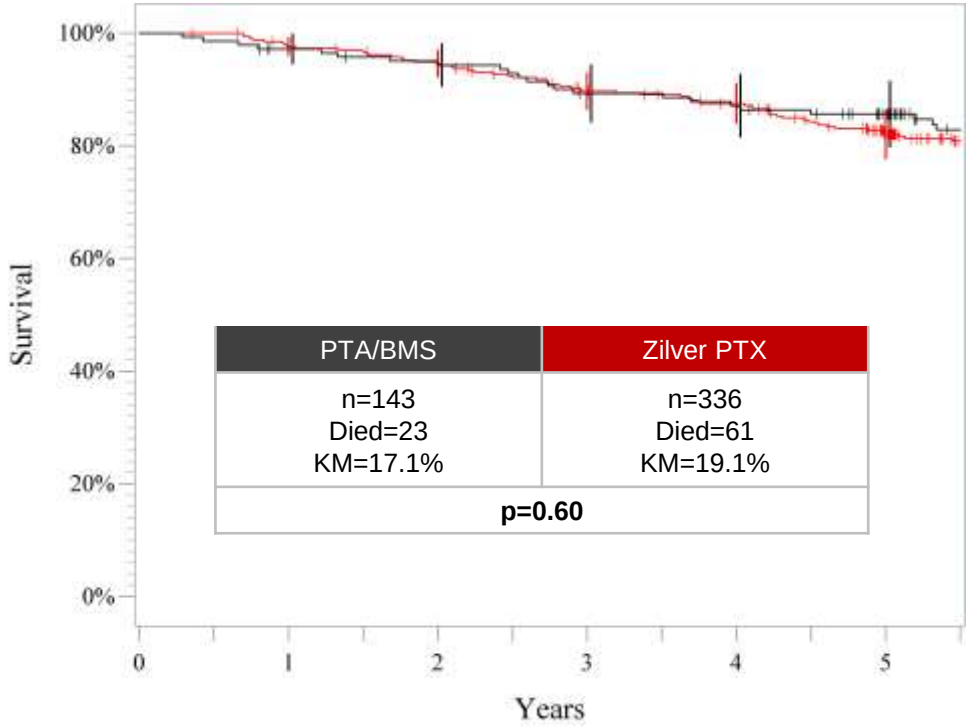
ACTUAL TREATMENT

Mortality Analysis



- 5-year vital status for 94% of patients
- All patients analyzed by actual treatment
- No mortality signal

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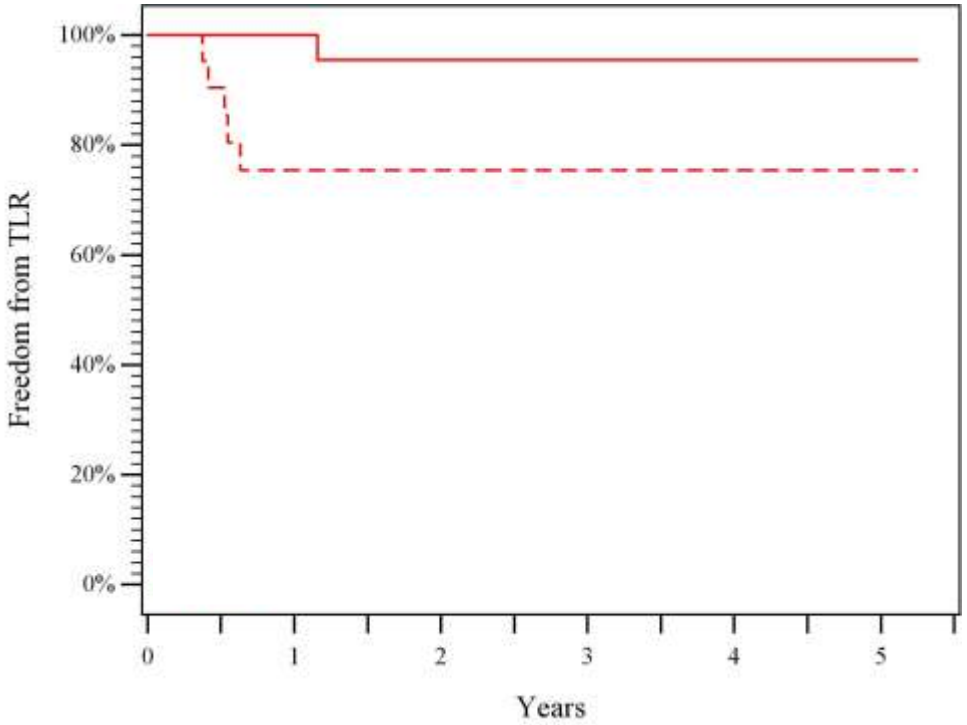
Preliminary TLR Risk Factor Model

- FDA recommends physicians consider if the benefits of using a paclitaxel-coated device outweigh the risk of late mortality
  - Especially for patients determined to be at particularly high risk for restenosis and reintervention

- Potential risk factors for TLR were selected for this initial analysis
  - All factors weighted equally

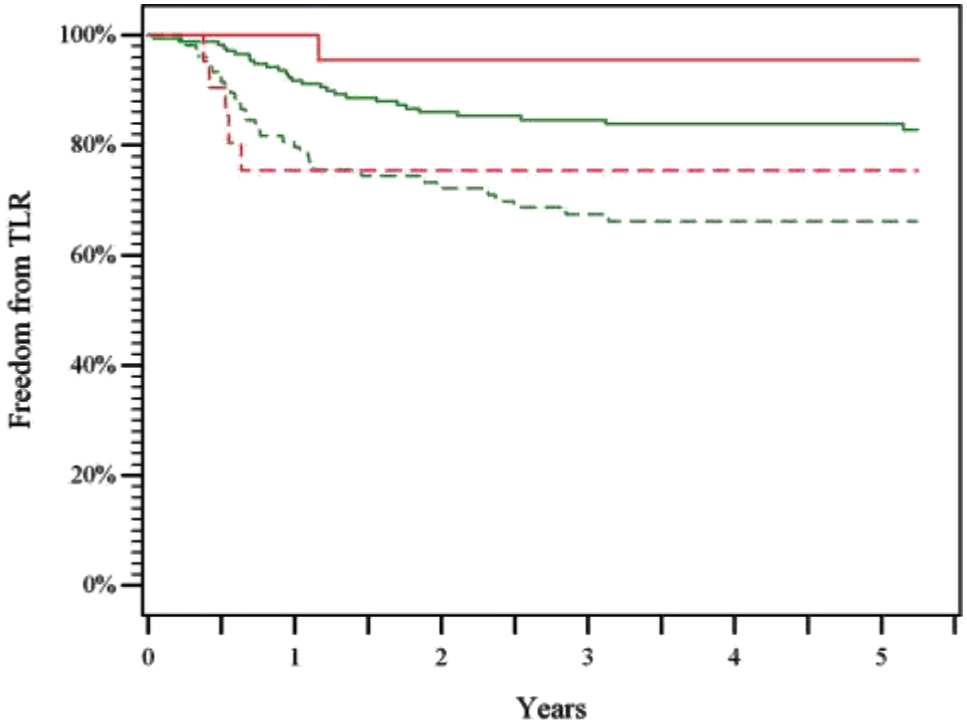
Potential Risk Factors
Occlusion
Calcification
CLI
Tissue loss
Diabetes
Renal disease
Hypercholesterolemia
Smoking

TLR Risk Factor Model



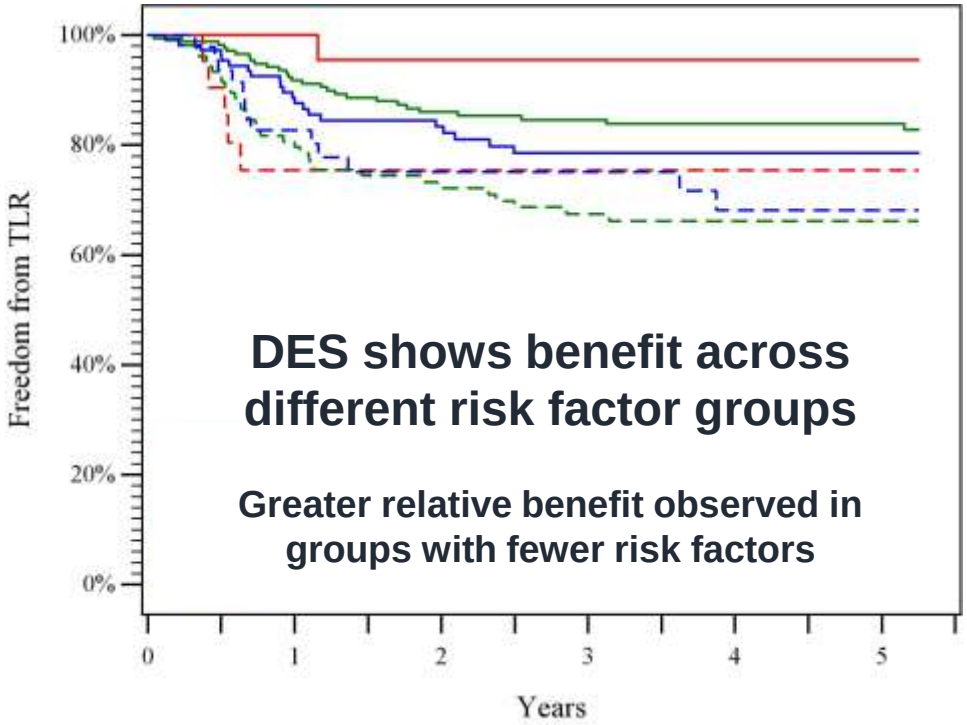
Group		N	2-year	5-year
DES 0-1	———	24	95.5%	95.5%
PTA/BMS 0-1	- - -	21	75.4%	75.4%

TLR Risk Factor Model



Group		N	2-year	5-year
DES 0-1	———	24	95.5%	95.5%
PTA/BMS 0-1	- - -	21	75.4%	75.4%
DES 2-3	———	173	86.0%	83.8%
PTA/BMS 2-3	- - -	105	72.2%	66.2%

TLR Risk Factor Model



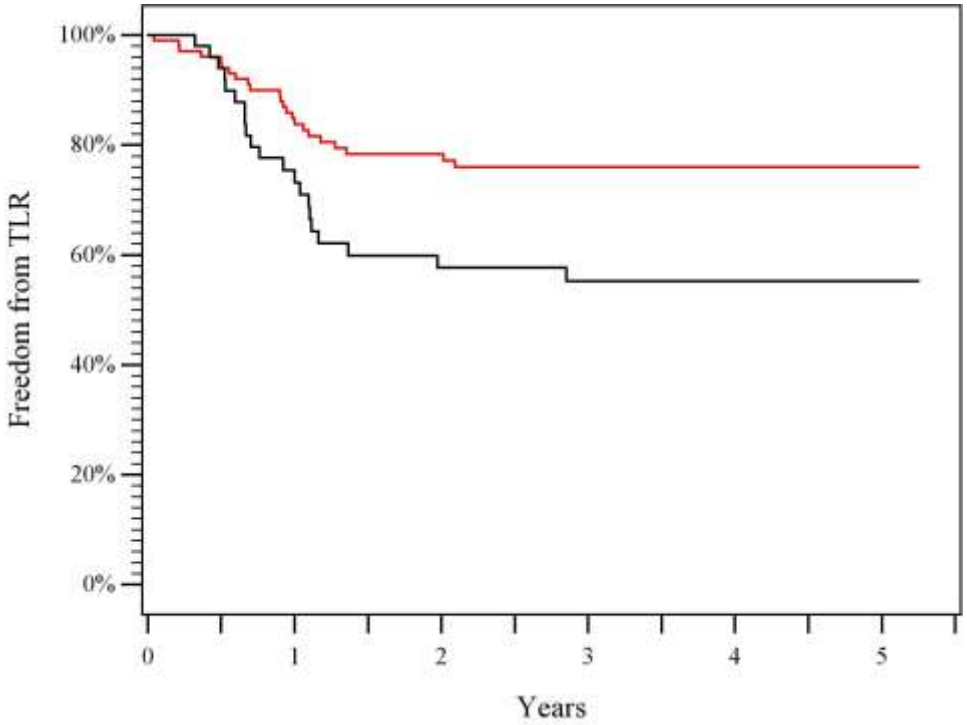
Group		N	2-year	5-year
DES 0-1	———	24	95.5%	95.5%
PTA/BMS 0-1	- - -	21	75.4%	75.4%
DES 2-3	———	173	86.0%	83.8%
PTA/BMS 2-3	- - -	105	72.2%	66.2%
DES 4+	———	108	83.4%	78.5%
PTA/BMS 4+	- - -	48	75.1%	68.1%

Impact of Individual Lesion Characteristics on TLR

- Higher rates of freedom from TLR for Zilver PTX vs. PTA/BMS for
  - Occluded lesions
  - Severely calcified lesions
  - Lesions >10cm
  - Vessels <4.5mm

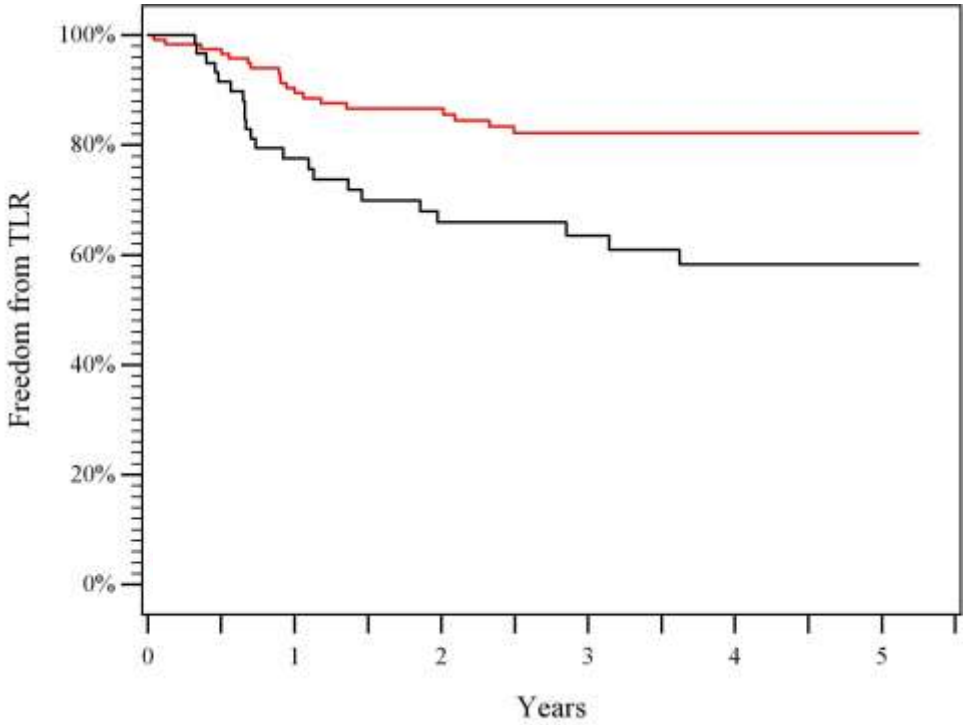
Including ~13% CLI patients

Impact of Occlusion on TLR



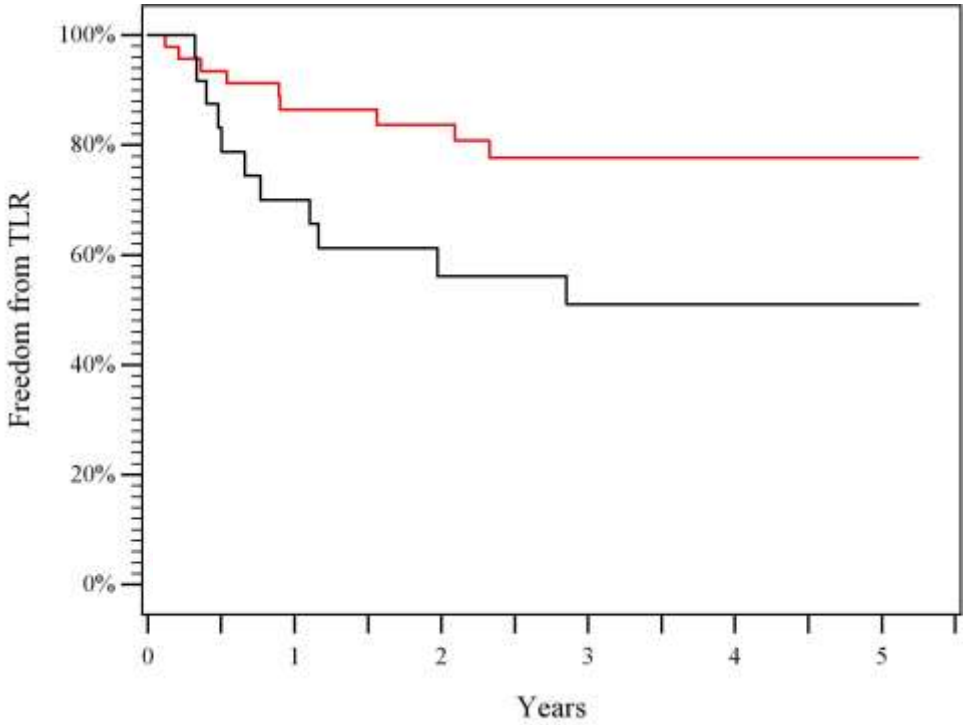
Group	N	2-year	5-year	p-value
DES	101	78.3%	76.0%	0.01
PTA/BMS	50	55.7%	53.3%	

Impact of Severe Calcification on TLR



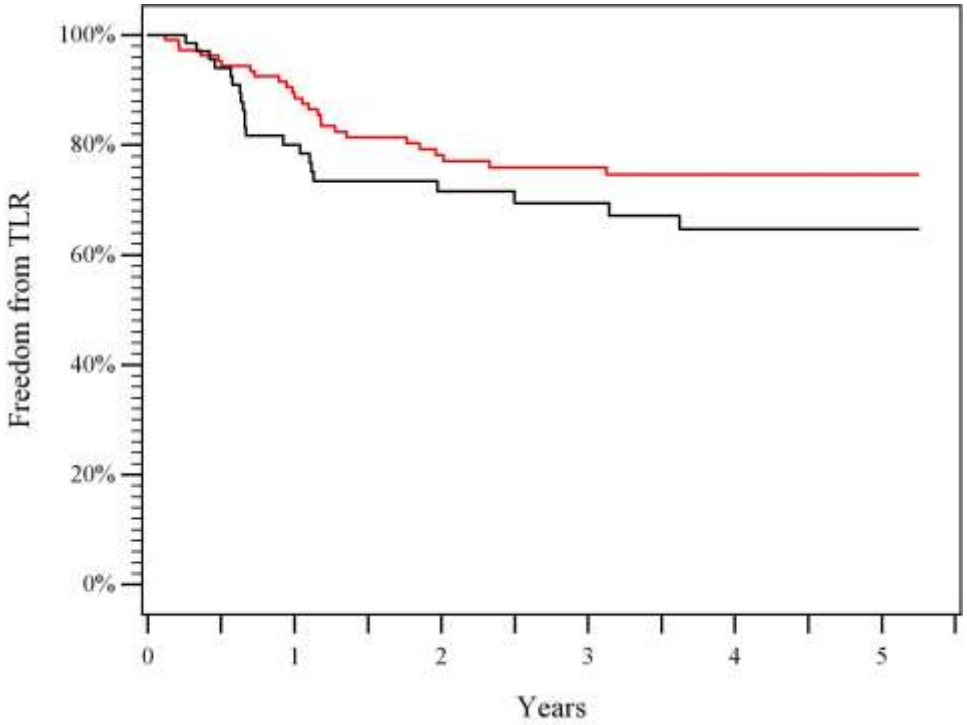
Group	N	2-year	5-year	p-value
DES	117	86.6%	82.2%	<0.01
PTA/BMS	59	65.9%	58.3%	

Impact of Lesion Length (>10cm) on TLR



Group	N	2-year	5-year	p-value
DES	46	83.7%	77.7%	0.02
PTA/BMS	24	56.1%	51.0%	

Impact of Vessel Diameter (<4.5mm) on TLR



Group	N	2-year	5-year	p-value
DES	107	78.2%	74.6%	0.16
PTA/BMS	68	71.5%	64.7%	

Conclusions and Next Steps

- 40% of patients in PTA primary randomization group treated with Zilver PTX
  - No mortality signal
- Zilver PTX shows TLR benefit across different risk factor groups
  - Greater relative benefit observed in groups with fewer risk factors
- Higher rates of freedom from TLR for Zilver PTX vs. PTA/BMS for occluded lesions, severely calcified lesions, lesions >10cm, and vessels <4.5mm
- Risk factors need to be further analyzed to determine relative impact on mortality and restenosis and reintervention
- Benefit-risk ratio must be considered for individual patients?

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