

# Latest information on long-term efficacy and safety on the Zilver PTX programme

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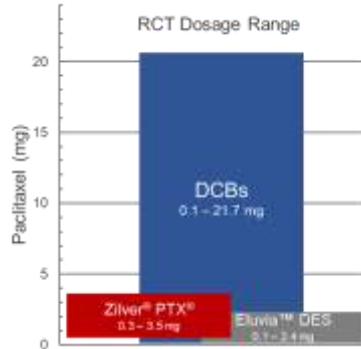


# Thomas Zeller, MD

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

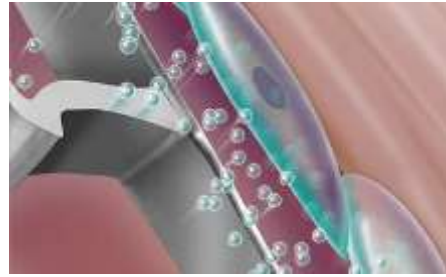
- **Honoraria received from:** Abbott Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Philips-Spectranetics, TriReme, Veryan, Shockwave, Biotronik, B. Braun
- **Consulted for:** Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Spectranetics,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

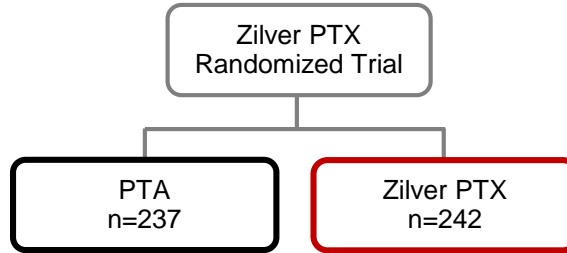
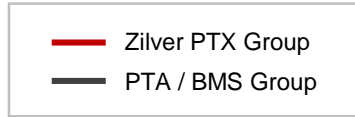
Short-term drug delivery, no long-term paclitaxel exposure, only BMS remains



## Long-term data

Only peripheral DES with long-term safety data

# Primary Randomization



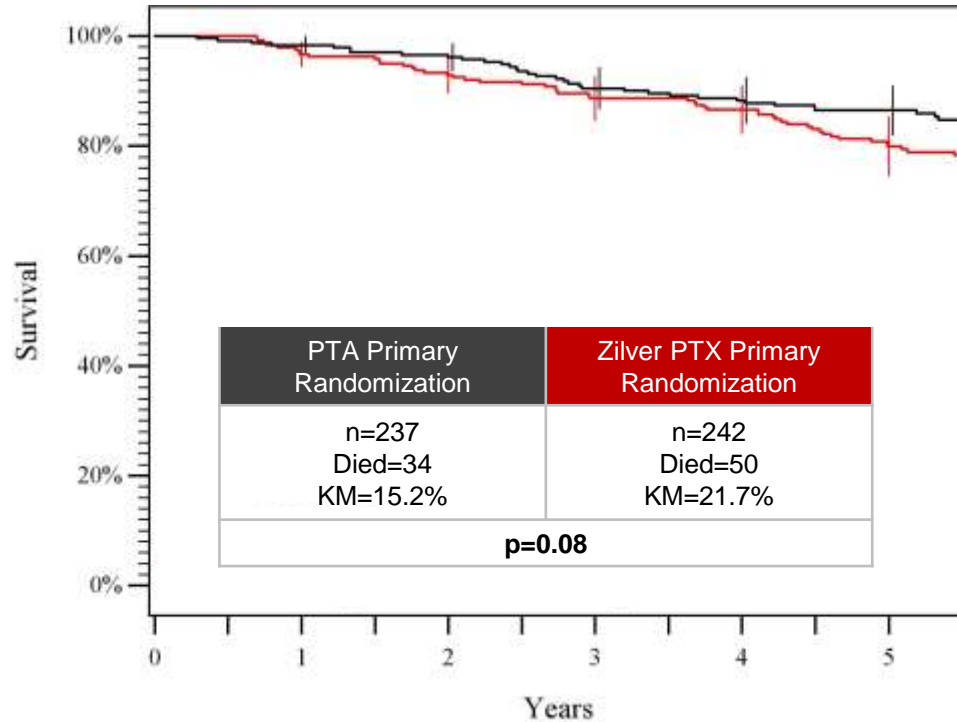
# Randomization

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- RCTs are not designed to ensure balance across numerous baseline risk factors
- Randomization was stratified only by lesion length
  - Stratification by lesion length does not ensure balance across multiple patient comorbidities and demographics

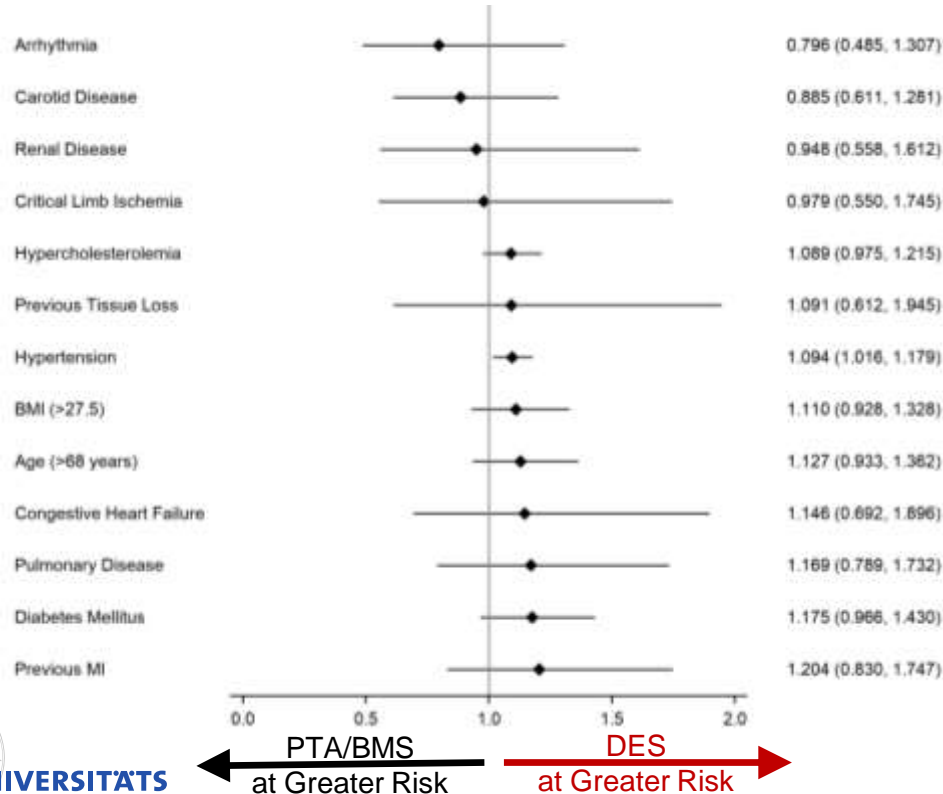
## INTENT-TO-TREAT

# Mortality Analysis



- ▶ 5-year vital status for 94% of patients
- ▶ DES patients included in PTA group
- ▶ Not significant
- ▶ Difference may be due to imbalance of risk factors

# Baseline Mortality Risk Factors

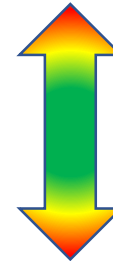


- ▶ Risk factors common in PAD patients may collectively contribute to overall patient prognosis
- ▶ Imbalance of risk factors, despite randomization

# Baseline Patient Risk Factors for Mortality

- Combinations of risk factors more prevalent in Zilver PTX primary randomization group ( $p < 0.01$ )

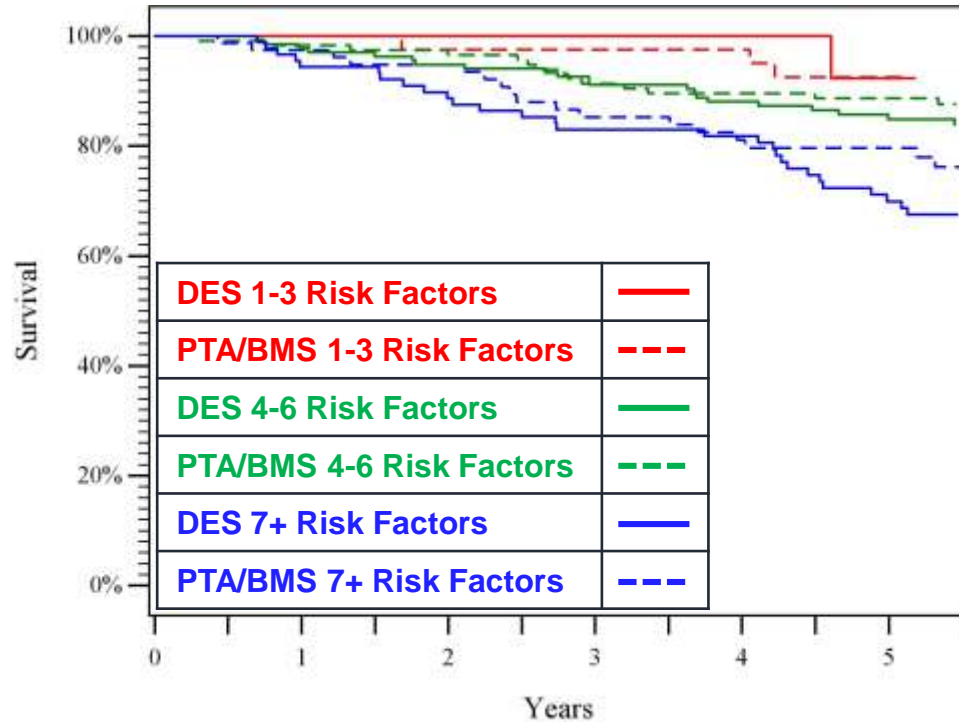
Risk Factors	PTA Primary Randomization	Zilver PTX Primary Randomization
1-3	18%	7%
4-6	50%	56%
7+	33%	37%





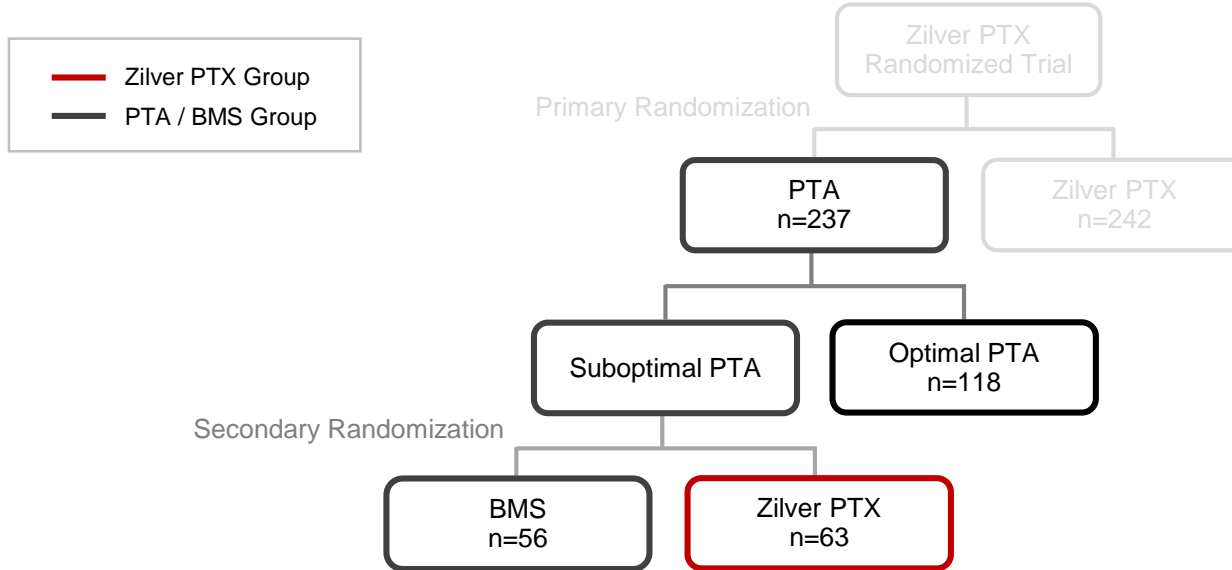
INTENT-TO-TREAT

# Risk Factor Mortality Analysis

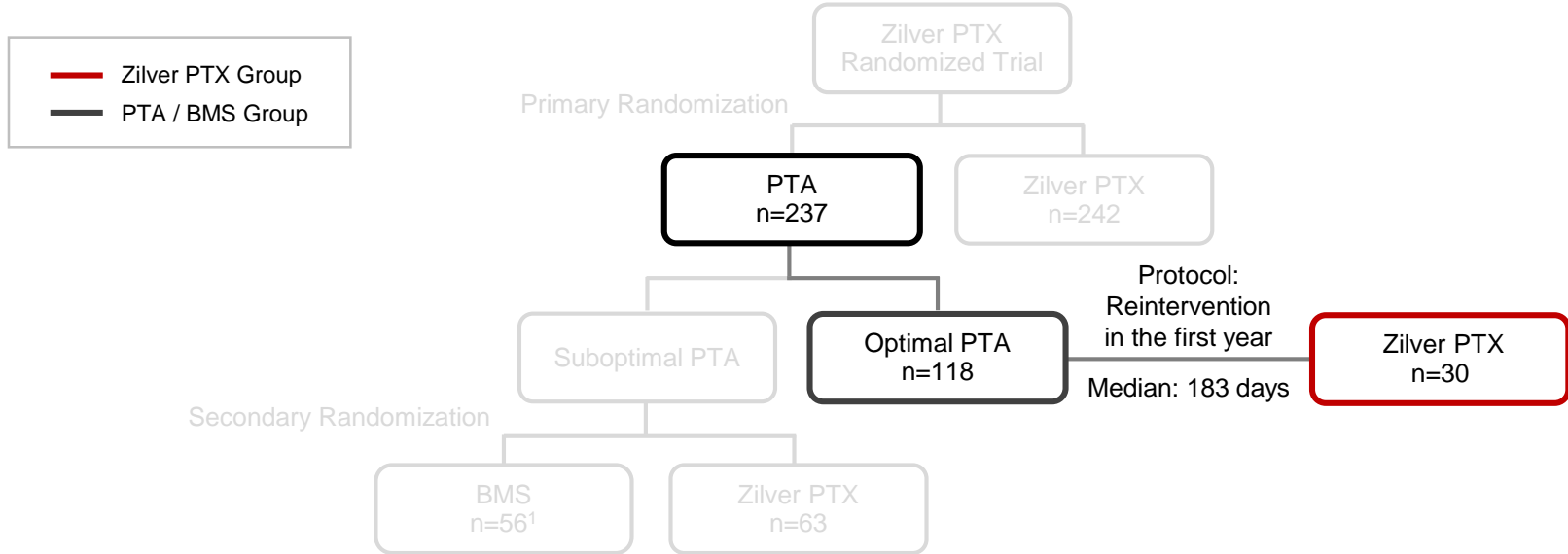


- ▶ Mortality rate decreases with fewer risk factors

# Secondary Randomization



# Early Crossover

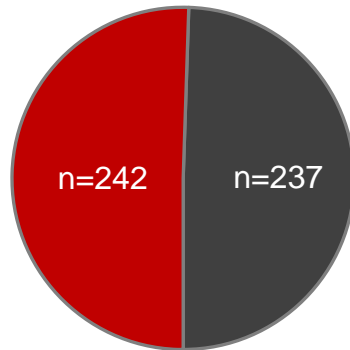


<sup>1</sup> One BMS patient received Zilver PTX during reintervention within the first year.

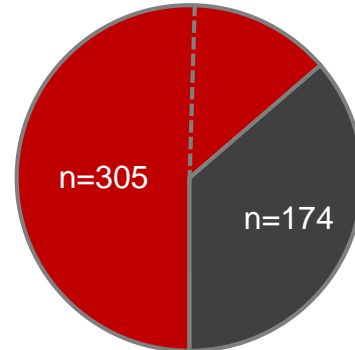
# Treatment Results

- Zilver PTX
- PTA / BMS

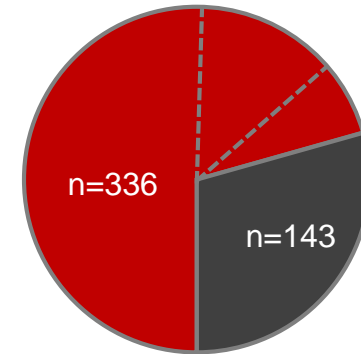
Primary  
Randomization



Primary + Secondary  
Randomization



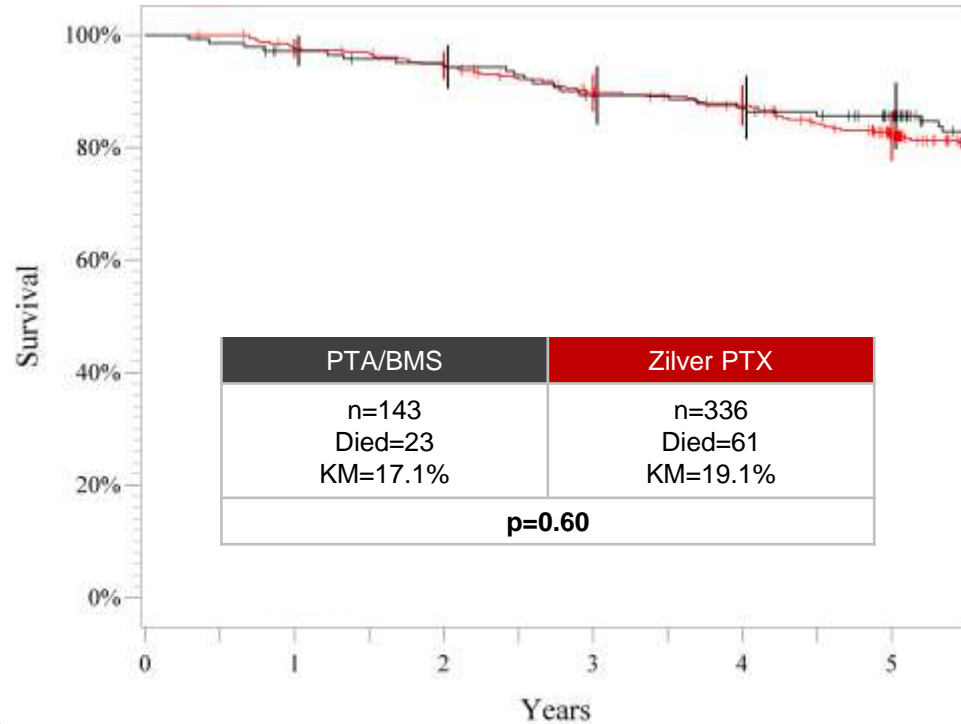
Actual Treatment =  
Primary + Secondary + Crossover



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

ACTUAL TREATMENT

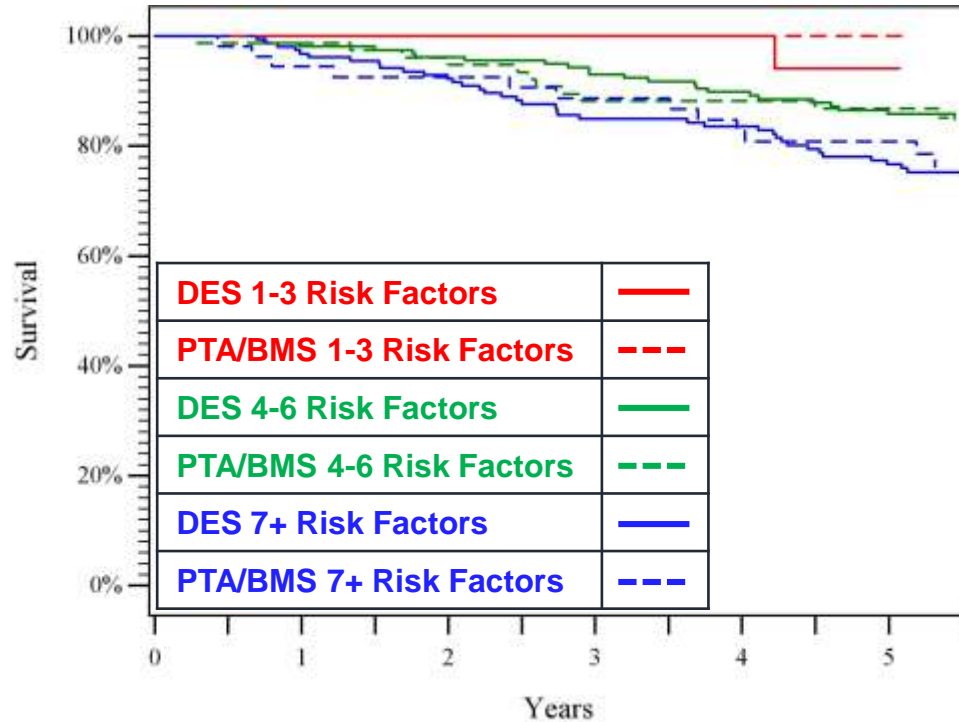
# Mortality Analysis



- ▶ All patients analyzed by actual treatment
- ▶ No mortality signal

ACTUAL TREATMENT

# Risk Factor Mortality Analysis



- ▶ Mortality rate decreases with fewer risk factors
- ▶ No mortality signal for actual treatment

# Conclusions and Next Steps

- Vital status through 5 years for 94% of patients
- Intent-to-treat:
  - No significant difference in mortality;
  - Imbalance in risk factors ( $p < 0.01$ ), despite randomization
- Actual treatment:
  - 40% of patients in PTA primary randomization group treated with Zilver PTX
- No mortality signal

# Paclitaxel-Coated Zilver PTX Drug-Eluting Stent Treatment Does Not Result in Increased Long-Term All-Cause Mortality Compared to Uncoated Devices

Michael D. Dake<sup>1</sup> · Gary M. Ansel<sup>2</sup> · Marc Bosiers<sup>3</sup> · Andrew Holden<sup>4</sup> · Osamu Iida<sup>5</sup> · Michael R. Jaff<sup>6</sup> · Aaron E. Lottes<sup>7</sup> · Erin E. O’Leary<sup>7</sup> · Alan T. Saunders<sup>7</sup> · Marc Schermerhorn<sup>8</sup> · Hiroyoshi Yokoi<sup>9</sup> · Thomas Zeller<sup>10</sup>

The patient-level data used for the analyses presented here is available on the following website:

<https://www.cookmedical.com/peripheral-intervention/paclitaxel/>





# TLR teaser slide

- Introduce TLR to be discussed in lunch symposium

Paclitaxel and your practice: Global perspectives

12:30-13:25

Room 1, Main Arena 1

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