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# ***Yukon-BTK Study Results: Is a Polymer Required for DES in Tibial Lesions?***

# Potential Conflicts of Interest

Speaker's name: Thomas Zeller

## My Disclosures:

- Consulting Fees/Honoraria:  
Sanofi-Aventis, C.R. Bard, Cordis, ev3, Pathway Medical, Straub Medical, Invatec, Biotronik, Optimed, SquareOne
- Research Grants:  
Cook, Krauth Medical, Pathway Medical, Abbott Vascular, Invatec, Angioslide, Novostent, IDEV, Biotronik, Atheromed, ev3, C.R. Bard, Cordis



# Yukon-BTK Study Purpose

- **Prospective, double blind, randomized multi-centre (4 sites) study to report 12-month results after application of polymer free sirolimus-eluting stents compared to bare metal stents in infrapopliteal arteries for treatment of intermittent claudication and critical limb ischemia.**
- **The Yukon stent (Translumina, Hechingen, Germany) stent is not approved for peripheral use.**



# Study Design

- **Patient population:** 177 patients randomly assigned to either receive a 2% rapamycin coated stent or a placebo coated stent
  - Bad Krozingen (107 pts.)
  - Tübingen (Tepe, 30 pts.)
  - Hamburg (Krankenber, 12 pts.)
  - Hamburg (R. Zahorsky 15 pts.)
- Rutherford-Becker categories 3 to 5
- 1 single lesion
  - Lesion length up to 4.5mm,
  - angiographic diameter stenosis  $\geq 70\%$
- Stent sizes (maximum 2 stents=):
  - Diameter 2.0 to 3.5mm,
  - length 25mm
- No inflow procedure except iliac arteries



# Study Endpoints

- **Primary endpoint: 1-year Primary patency** (defined as freedom from restenosis of  $> 50\%$  detected either by ultrasound (PVR  $>2.4$  ) or by angiography).
- **Secondary endpoints:**
  - 6-month primary patency rate
  - 6 & 12-month secondary patency rate
  - 12-month TLR rate
  - Technical success rate (defined as a residual stenosis  $<30\%$  of reference vessel diameter)
  - Major and minor complication rates according to the Society of Interventional Radiology reporting standards
  - Clinical stage of disease according to the Rutherford-Becker classification after 6 and 12 months
  - Ankle-brachial index (ABI) after 6 and 12 months



# Patient Baseline Characteristics (n = 177)

	Group A (n=86)	Group B (n=91)	P value
Age (mean SD)	72.1 9.5 yrs	73.5 8.0 yrs	.28
Male Gender	65%	70%	.50
BMI (mean SD)	26.4 3.8	28.1 4.7	.009
Hypertension	87%	91%	.47
Diabetes	51%	58%	.36
Tobacco use	29%	17%	.065
Hypercholesterolemia	75%	78%	.72



# Lesion Baseline Characteristics (n = 177)

	Group A (n=86)	Group B (n=91)	P value
Anterior tibial artery [n]	24 (28%)	19 (21%)	NS
Posterior tibial artery [n]	11 (13%)	15 (16%)	NS
Peroneal artery [n]	22 (26%)	19 (21%)	NS
TPT [n]	29 (34%)	38 (42%)	NS
CTO	22%	22%	NS
Lesion length [mm]	31 ± 9	31 ± 10	NS
Reference vessel diameter [mm]	3.0 ± 0.4	3.0 ± 0.4	NS



# Medication

- 1. Preintervention: Aspirin 500mg/d & 600mg bolus of clopidogrel*
- 2. Intervention: Heparin Bolus 5000 IU*
- 3. Postintervention: Aspirin 100mg/d & clopidogrel 75mg/d for 6 months*

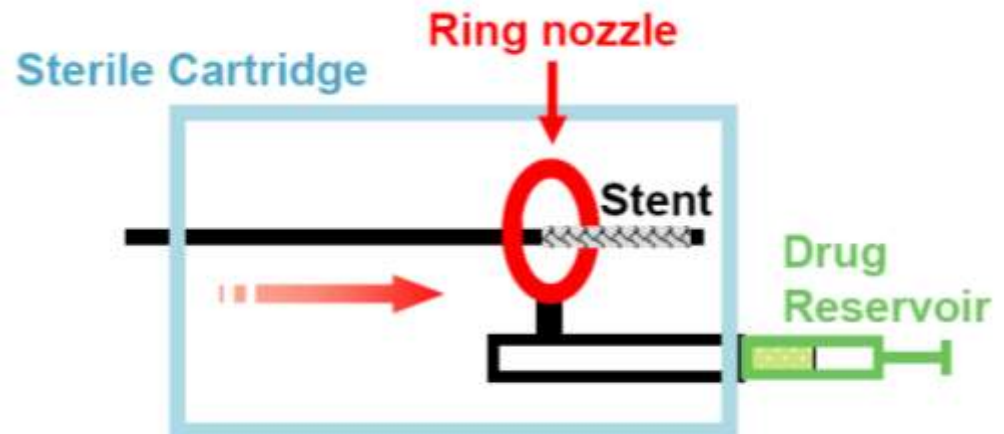


# Study Device: Yukon Stent System

## The Stent Coating Machines - inside



Current T-SCM2003

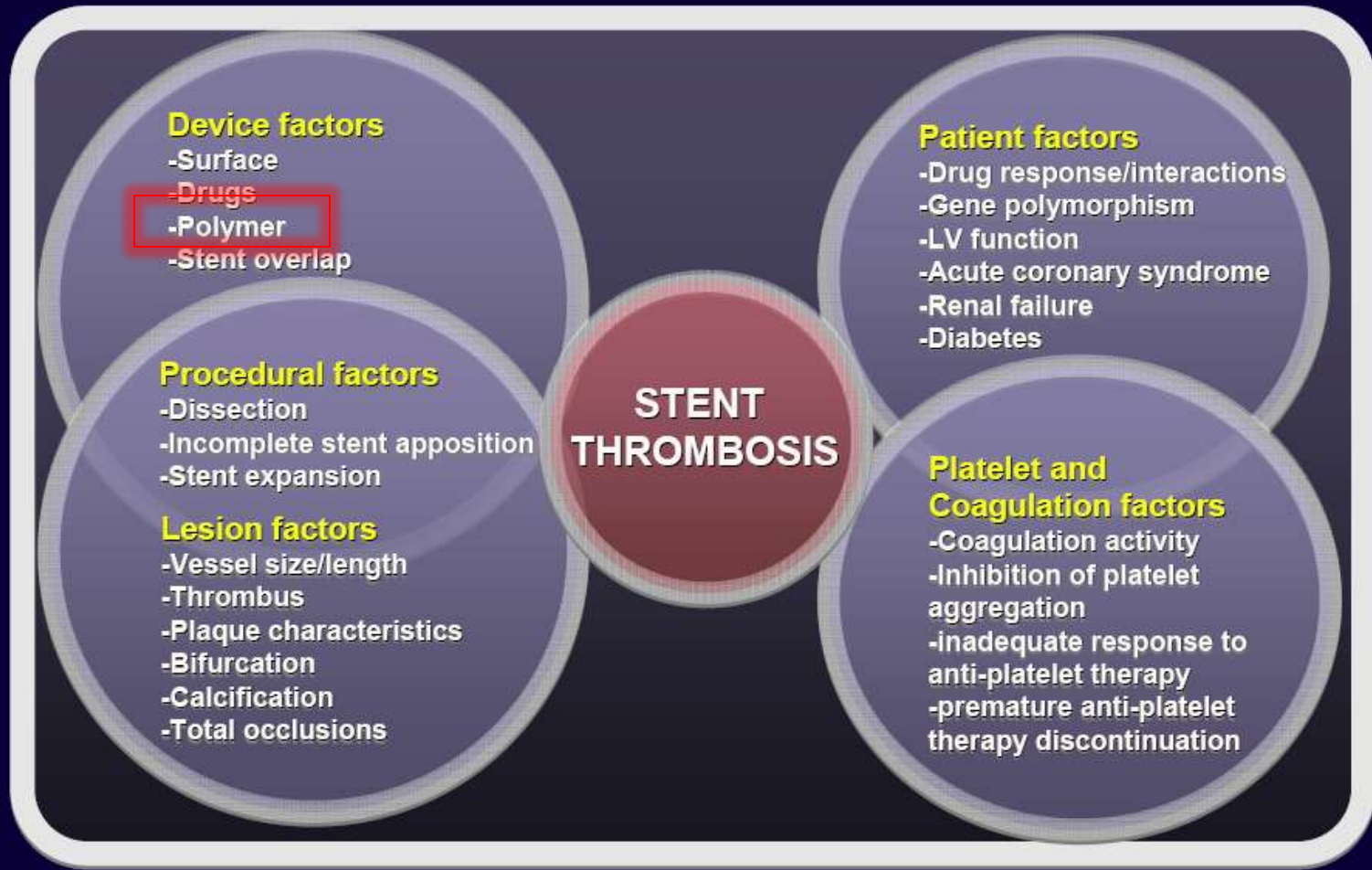


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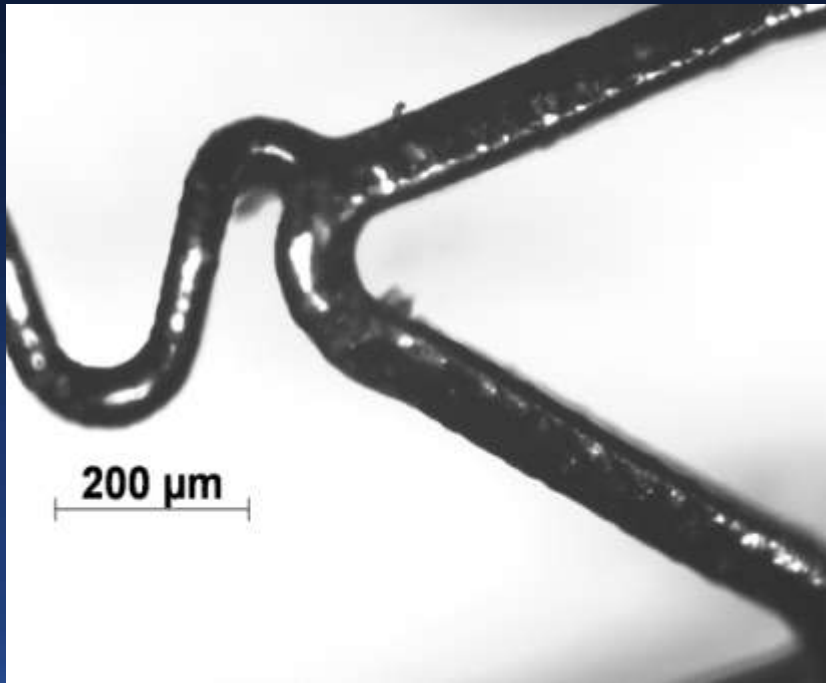
# Multifactorial Nature of Stent Thrombosis

Windecker S, Meier B. *Circulation* 2007;116:1952-65

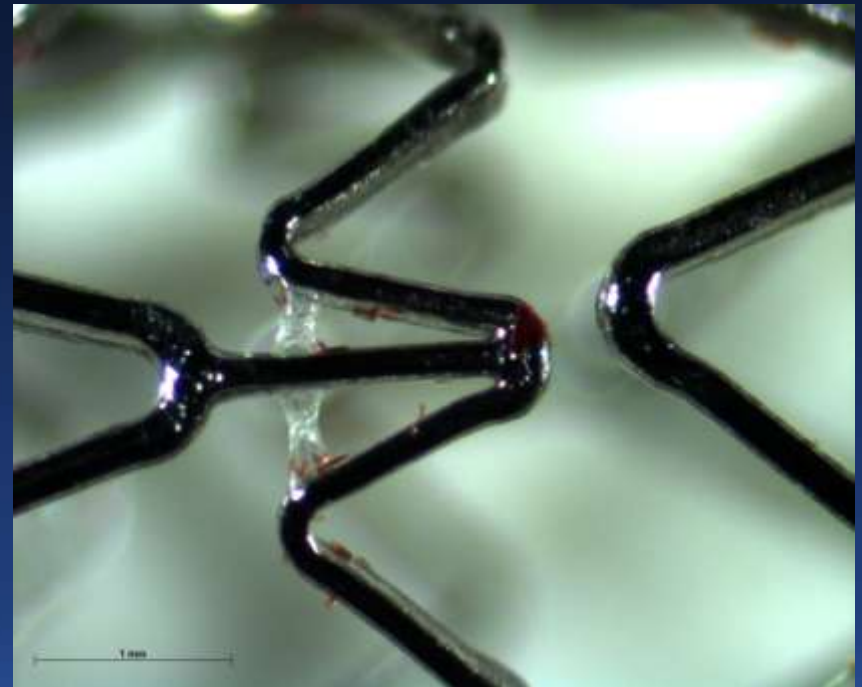


# Draw backs of Polymers

*The non-absorbable coatings have defects before and even more after dilatation*



*Cypher*



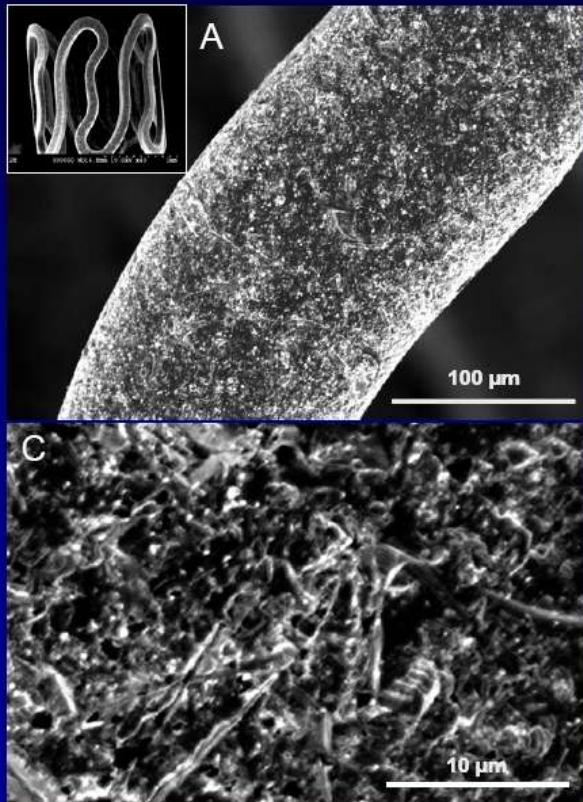
*Taxus*



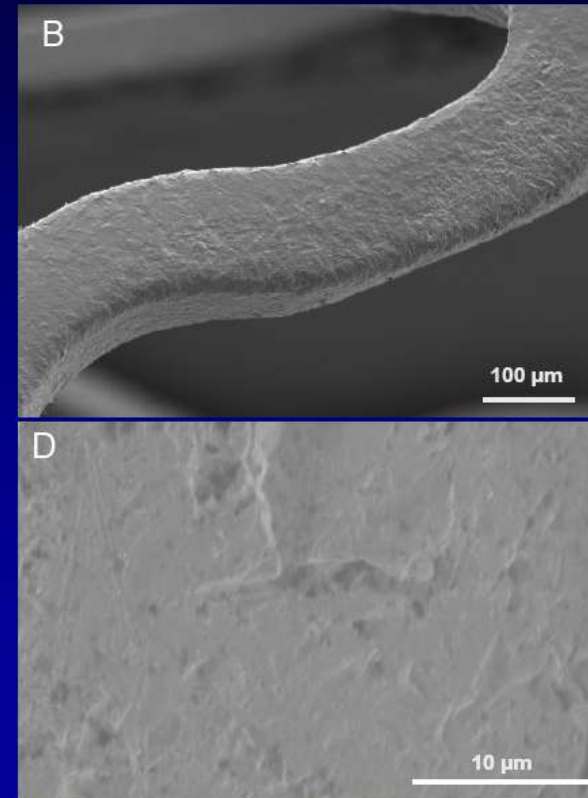
# Yukon Stent System

## Unique Microporous Stent Surface

before coating



after coating



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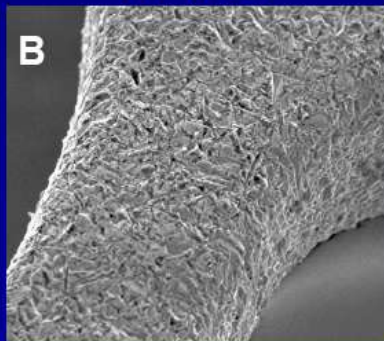
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# Does the Rough Microporous Stent Surface Influence Restenosis Development?

200 patients with significant stenosis  
in native coronary artery

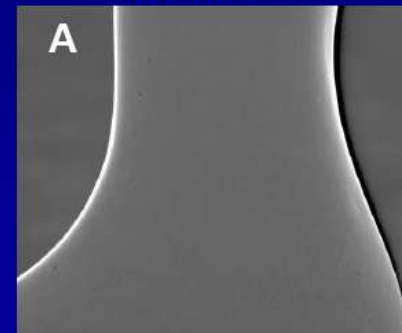
**Rough Surface**

n=100



**Polished Surface**

n=100



Dibra et al, *Cath Cardiovasc Interv* 2005



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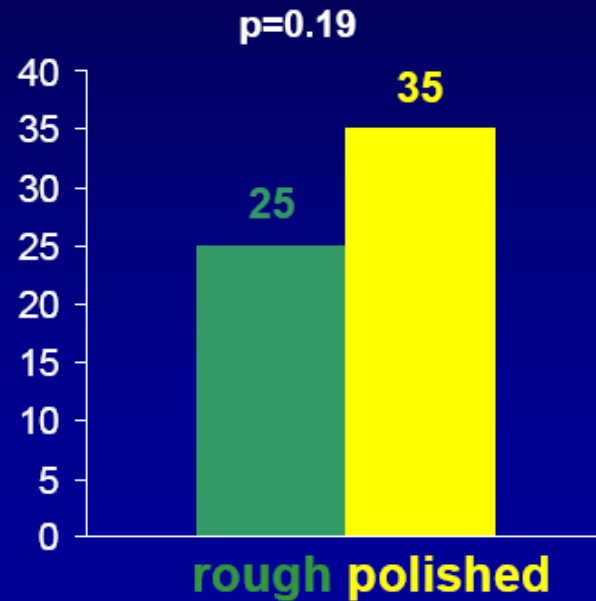
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# Does the Rough Microporous Stent Surface Influence Restenosis Development?

no thrombotic stent occlusion in both groups

angiographic  
restenosis  
rate (%)

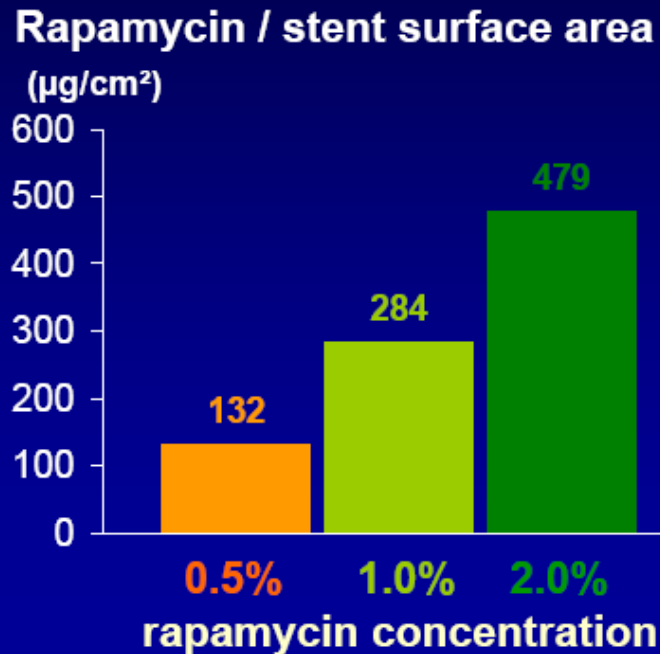


Dibra et al, *Cath Cardiovasc Interv* 2005

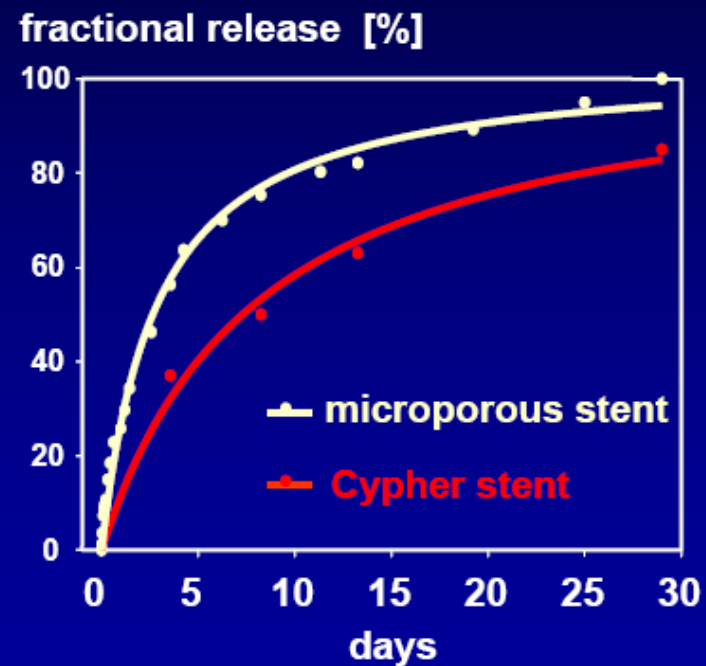


# Rapamycin Coating Capacity & Release Kinetics of the Microporous Stent

## Coating Capacity



## Release Kinetics



# Yukon Stent System

## Advantages of the Coating Technology

- No Polymer - recent studies have shown that permanent polymers being part of DES coating can lead to severe inflammatory reactions and late stent thrombosis !
- Perfect endothelialization – OCT trial showed 99,9% stent strut coverage after only 3 months, stents allows natural healing !
- 2- Year angiographic follow-up data available, no late catch-up !
- Yukon Choice 4<sup>DES</sup> – high cost advantage due to strong reduction in antiplatelet-therapy, e.g. Germany 900 Euro/year



# Yukon Stent System

## Advantages of the Coating Technology

1. Late catch-up of the 2 polymer-based DES, indicating pro-inflammatory processes still ongoing after 2 years.
2. The polymer-free Yukon DES with stable and low late-loss and less delayed restenosis after 2 years.
3. Commentary article of Virmani-group shows that polymer-based DES have late catch-up in the pig trials and late TLR up to 5 years.



**Sure, the search after ideal polymers should continue,  
but...**

**The best polymer...  
is no polymer at all!**

*Leon, TCT 2004*



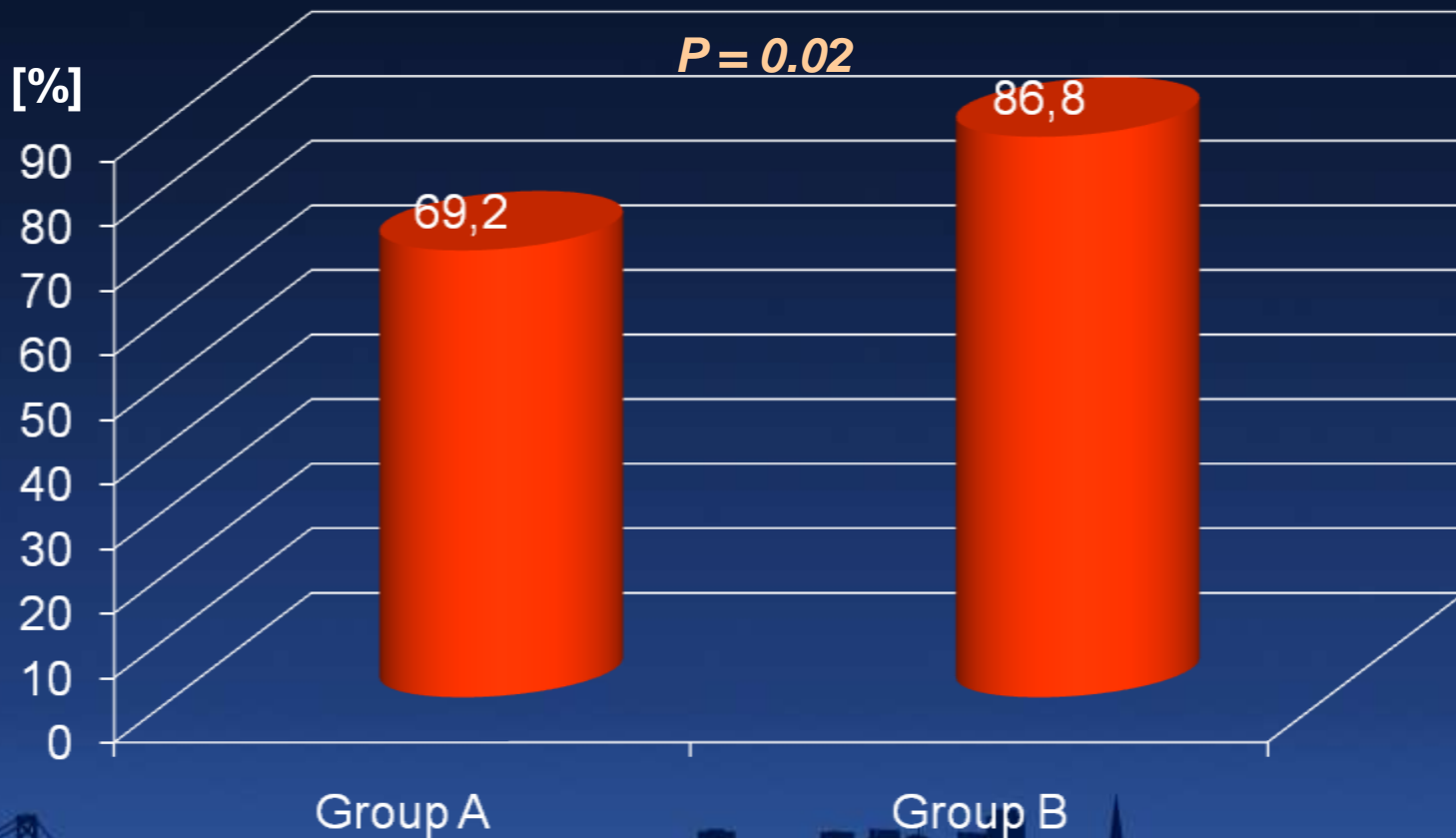
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# Interim Results – Secondary Endpoint 6-month Primary Patency

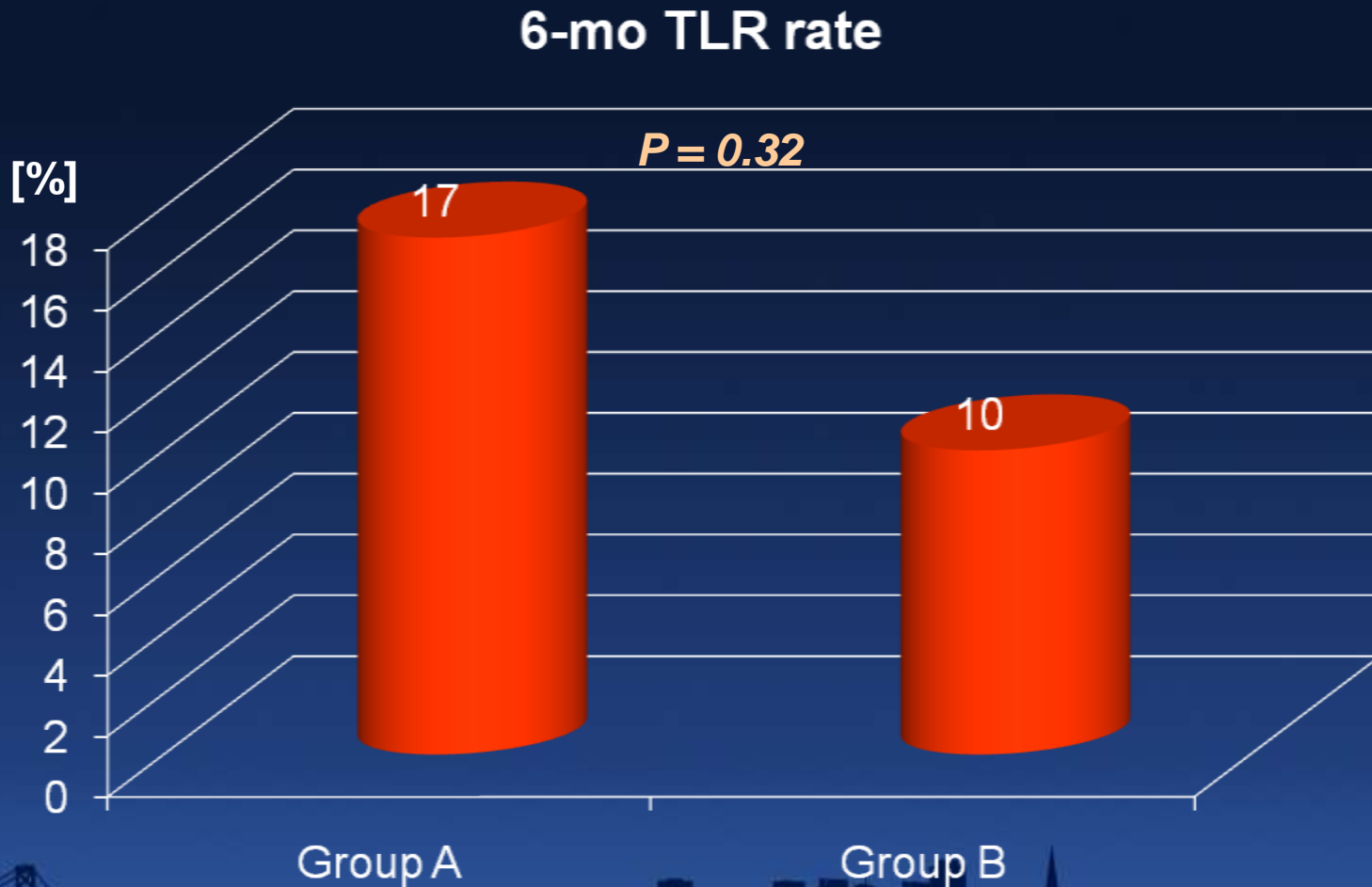
6-mo primary patency



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# Interim Results – Secondary Endpoint 6-month TLR Rates



# Clinical Outcome at 6 Months

	Group A	Group B	<i>P value</i>
ABI baseline (mean SD)	0.56 0.15	0.52 0.18	NS
ABI 6 months (mean SD)	0.78 0.24	0.73 0.25	NS
<i>P value</i>	< 0.0001	< 0.0001	
Rutherford baseline (mean SD)	3.7 1.1	3.7 1.1	NS
Rutherford 6 months (mean SD)	2.2 1.6	2.1 1.8	NS
<i>P value</i>	< 0.0001	< 0.0001	



# Summary

- Short term analysis shows promising technical and clinical results for a custom made polymer free rapamycin eluting stent compared to the uncoated bare metal stent platform in short tibial lesions.
- The 1-year results must be waited for before drawing final conclusions.
- These data are expected for I/2010

