PCI with Polymer-free Stent

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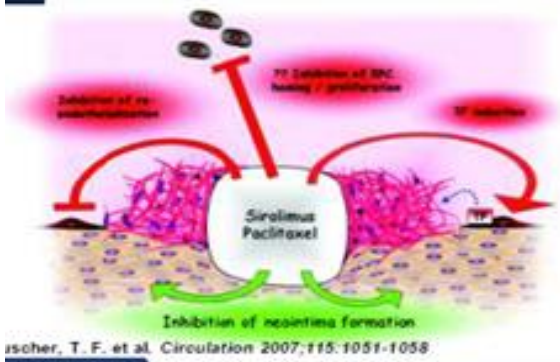
Berlin, Germany

2015 JR Joint meeting of Coronary Revascularization

Drug Eluting Stents: Present Coating Technology

Limitations of polymer use and metallic backbones in current DES



ischer, T. F. et al. *Circulation* 2007;115:1051-1058

- Stent thrombosis (late, very late) / Forced prolonged DAT duration / Bleeding / Resistance
- Delayed endothelialization
- Inflammation / Hypersensitivity
- Aneurysms
- Late catch-up
- Polymer disruption
- Remodeling (constrictive / expansive)
- Functional integrity

Solution Oriented Polymer-Free Angioplasty

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Development of DES Generations

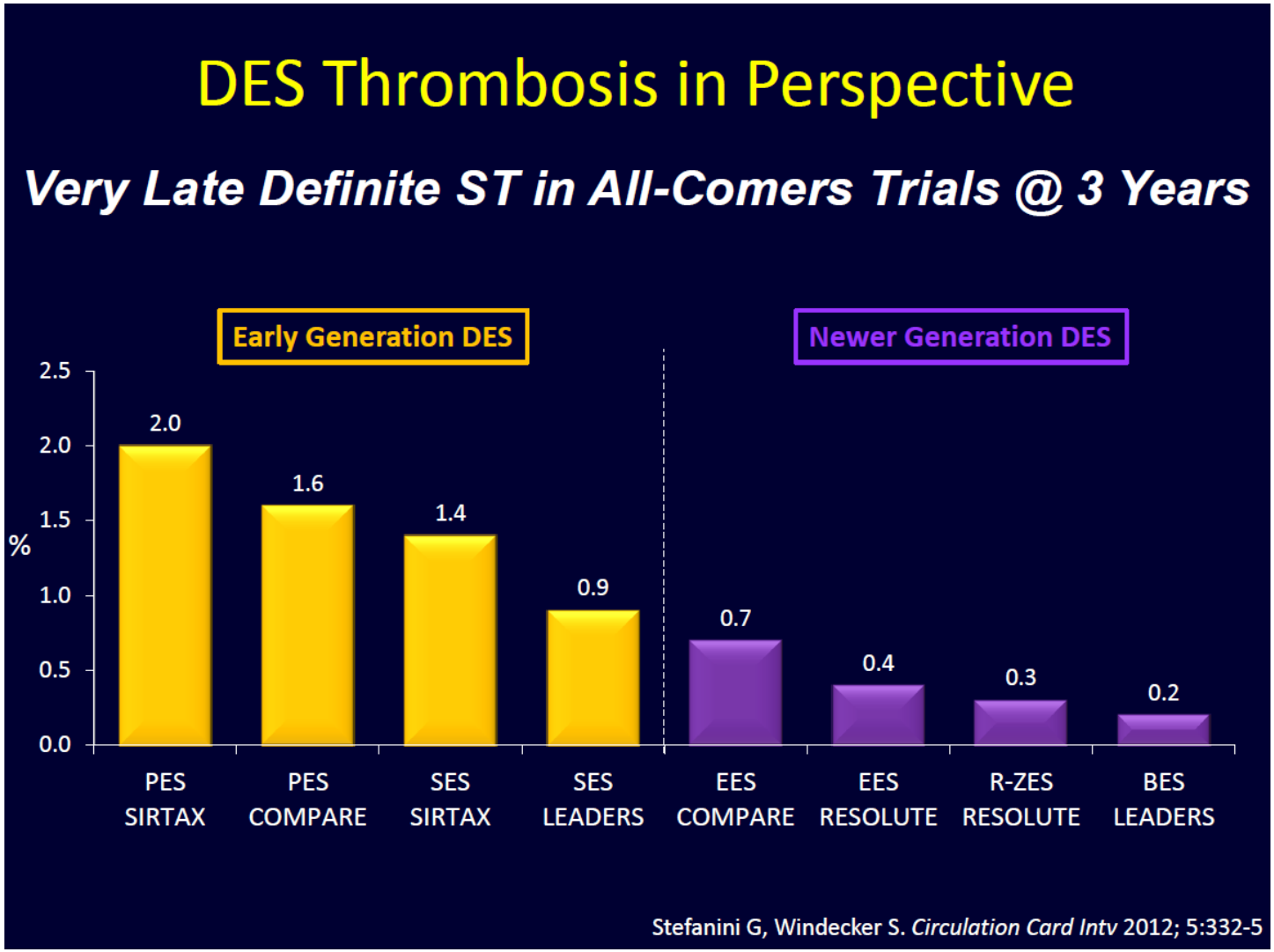
1st gen: permanent polymer

2nd gen: improved permanent polymer

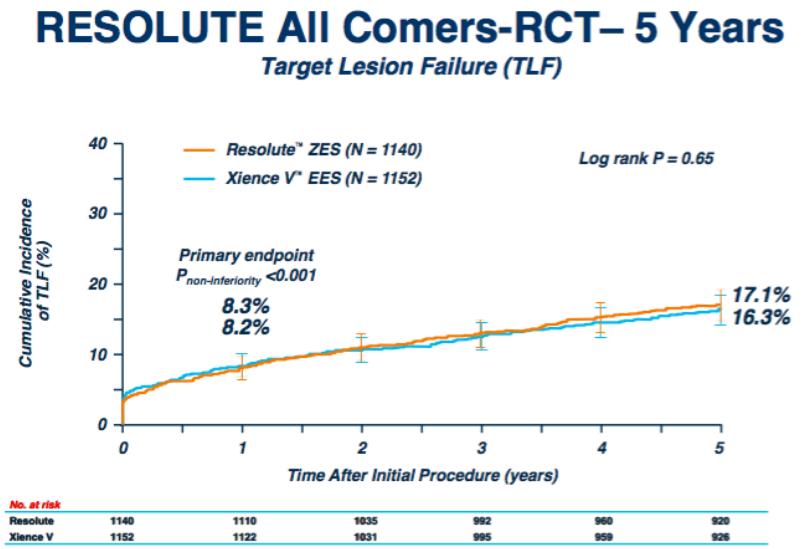
3rd gen: biodegradable polymer

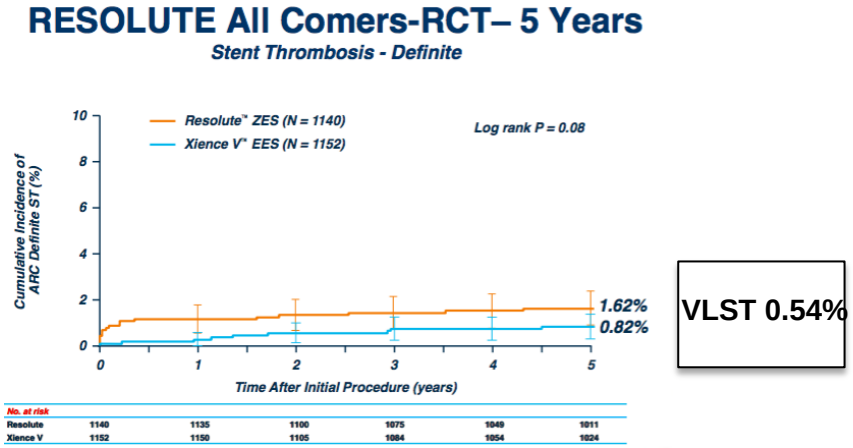
4th gen: polymer-free

Drug Eluting Stents:
Present Coating Technology

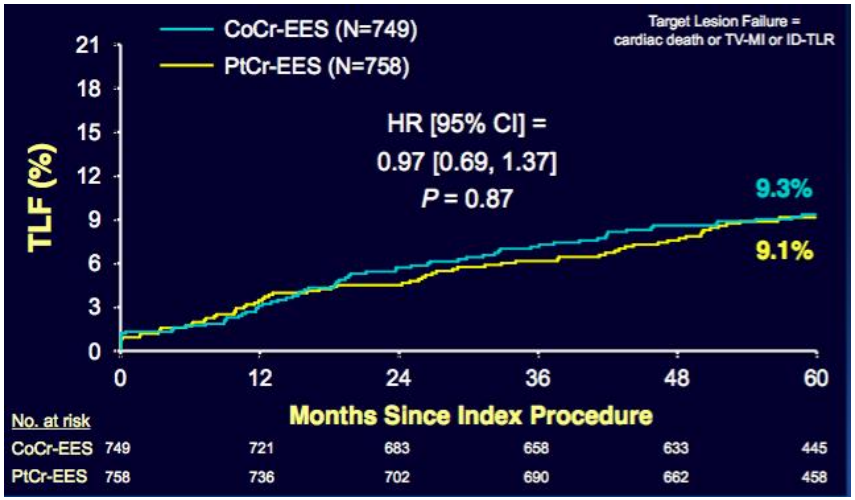


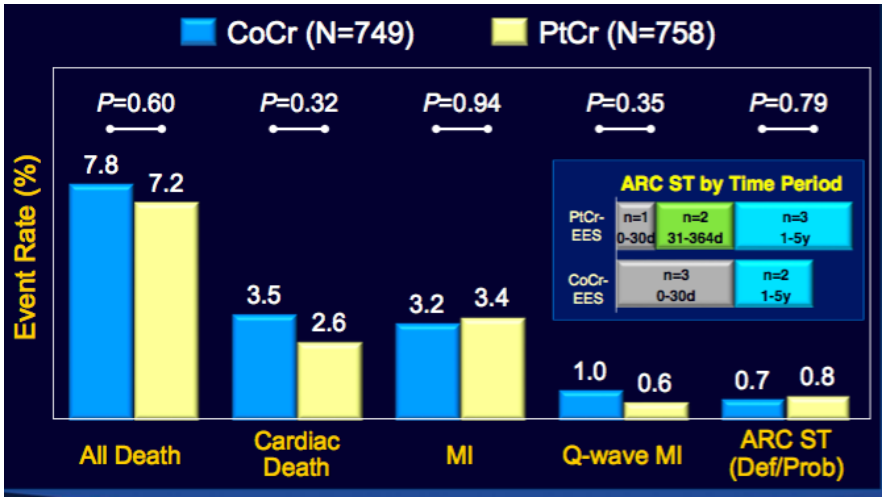
Target Lesion Failure (TLF) and Stentthrombosis DES with durables Polymer





VLST 0.54%

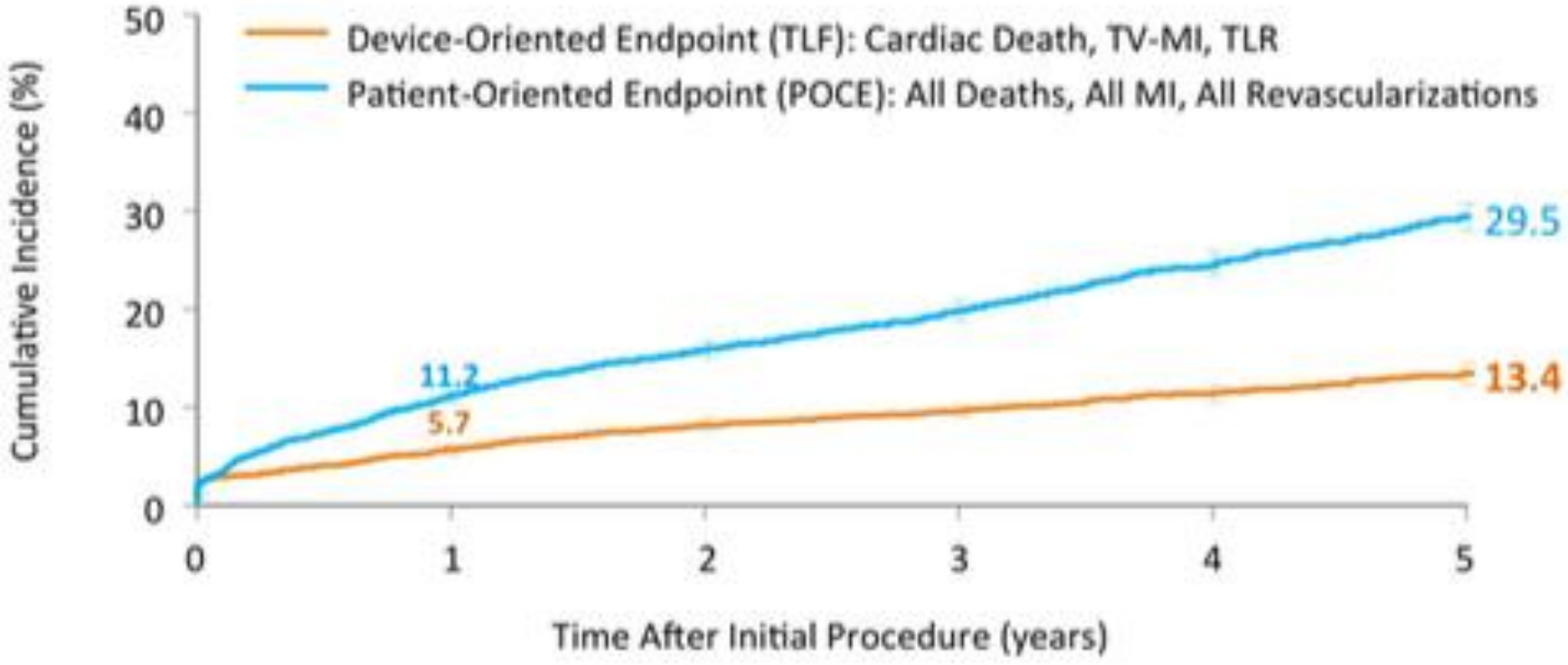




Silber S. TCT 2015, Stone GW et al. JACC 2015;65/ 10S 0.87 (Suppl A)

RESOLUTE Program – 5 years

Device-Oriented (DOCE) vs. Patient-Oriented (POCE) Endpoint



F	7618	7532	7027	6280	4196	2257
DCE	7618	7530	6661	5801	3746	1926

Sigmund S. TCT 2015

Conclusion
DES with durables Polymer

- **Efficiacy (TLF) and safety (5 years)**

  Duarables Polymer (Fluopolymere)
- **Rate of Stenthrombosis ≈ 0.8-1.5%,**
- **Very late Stentthromboses (VLST) 50% of Stentthroboses**
- **50 % of MACE rate are Patient-oriented endpoint events (POCE)**

Solution Oriented Polymer-Free Angioplasty

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Development of DES Generations

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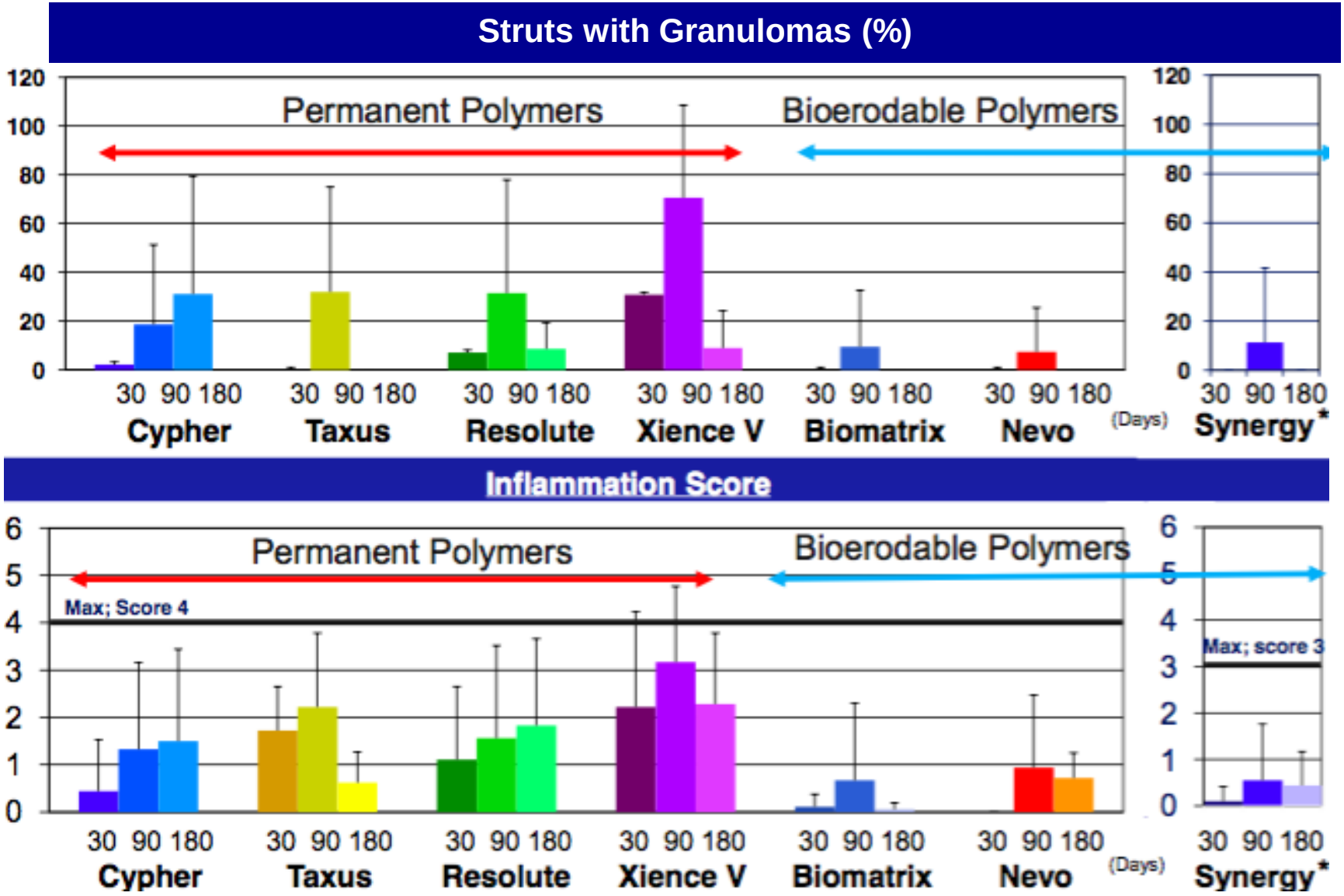
4th gen: polymer-free

Stent Technology
Inflammation (pig model)



EuroIntervention. 2012;8:250-7

DES with Biodegradable Abluminal Polymer

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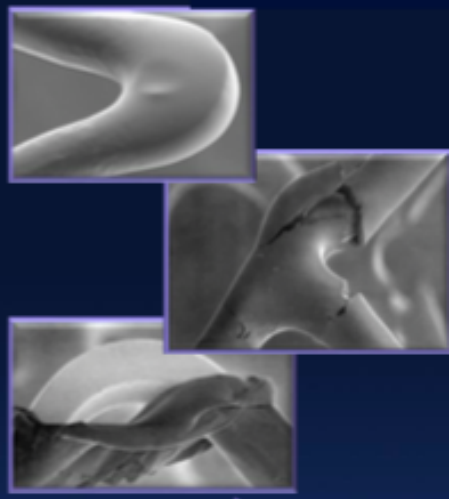
DES Polymer Considerations

Purpose of polymer:

- Provide mechanically stable reservoir for drug
- Modulate drug release - programmed drug delivery

Polymer has no function after drug release is complete

- All polymer coatings have potential to be damaged
- Damaged durable polymers are permanent



Safety

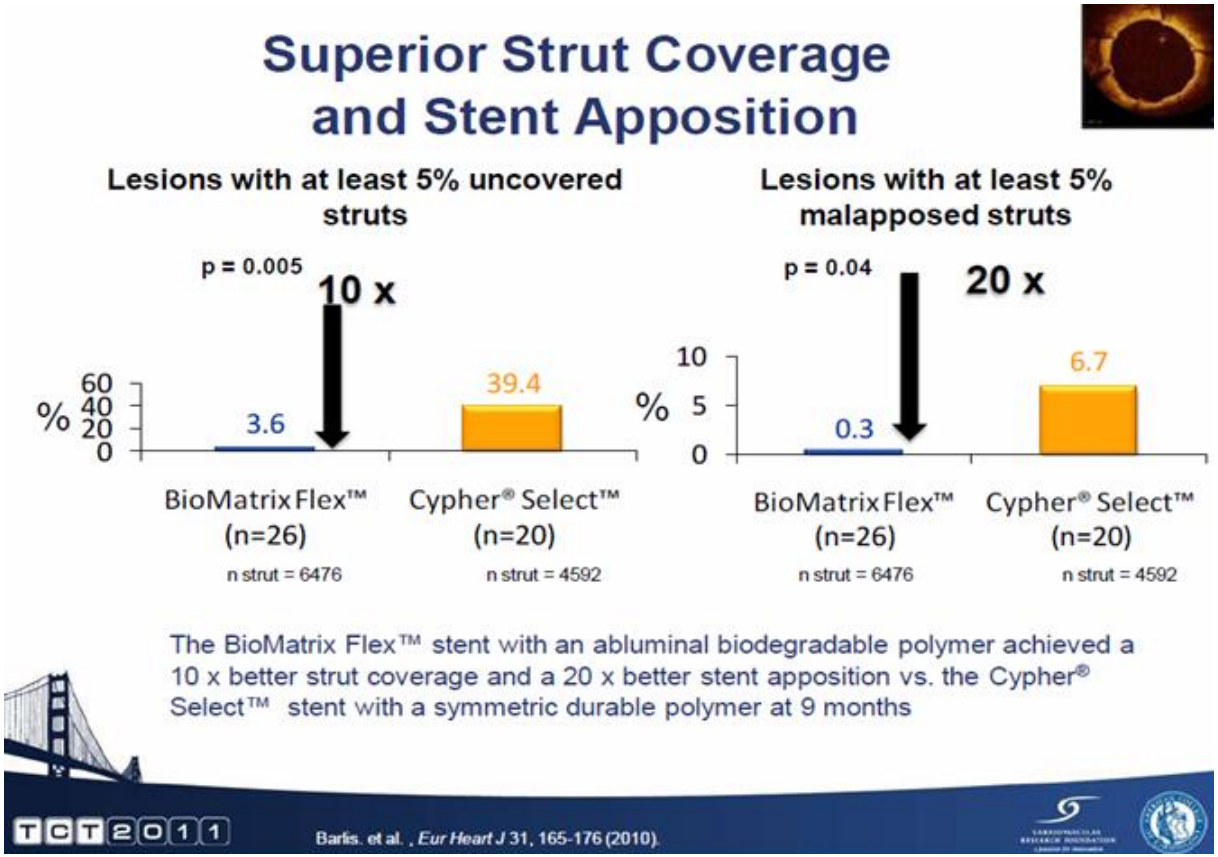
- Late / very late stent thrombosis
- Higher risk in certain patient populations
- Potentially require long-term DAPT

Efficacy

- Chronic inflammation with neoatherosclerosis
- Constant irritant may lead to late restenosis
- Hypersensitivity

Drug Eluting Stents: Biodegradable Coating Technology

Comparison of Biodegradable and Permanent Coatings



Biodegradable polymer show less uncovered struts and malapposition

Drug Eluting Stents: Biodegradable Coating Technology

Biodegradable Polymer DES versus Durable Polymer SES Through 4 Years

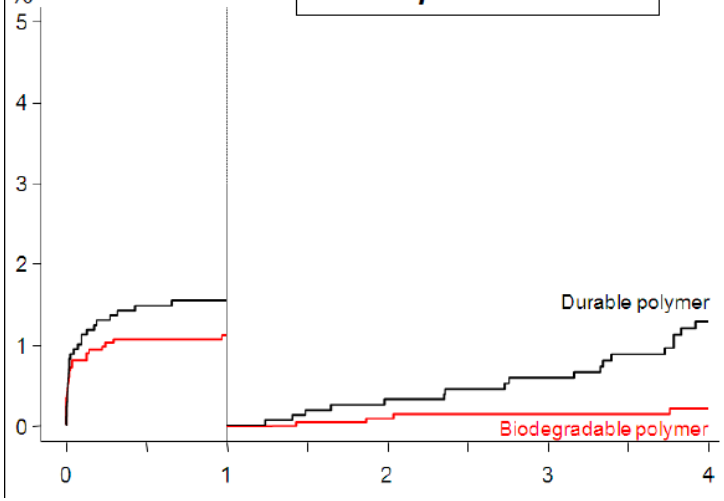
A Pooled Analysis of ISAR-TEST 3, ISAR-TEST 4, and LEADERS trial

Stefanini G et al. *Eur Heart J* 2012; 33:1214-22

Definite ST

0 to 1 year:
HR 0.80
(95% CI 0.47-1.38)
p=0.43

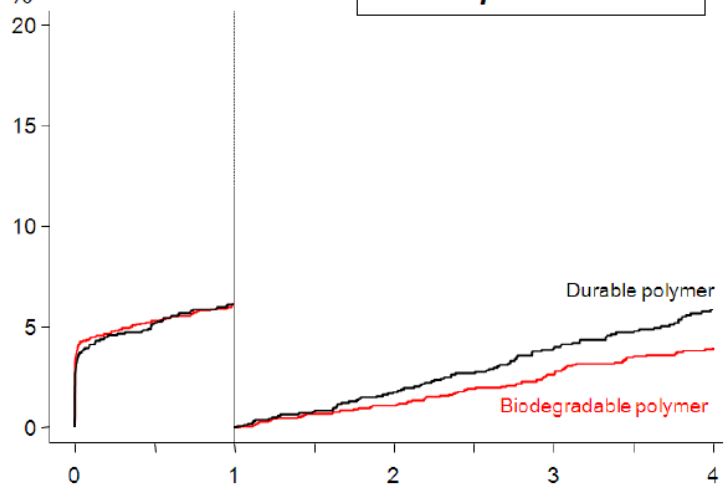
1 to 4 years:
HR 0.22
(95%CI 0.08 – 0.61)
p=0.004



Cardiac Death or MI

0 to 1 year:
HR 1.02
(95% CI 0.78-1.31)
p=0.91

1 to 4 years:
HR 0.73
(95% CI 0.53 – 1.00)
p=0.05



Durable biocompatible circumferential vs biodegradable abluminal Stentcoating

- **No significant diferences (non-inferiority) for...**
  - **Efficiacy (TLF)**
  - **Safety (Stentthrombosis)**
- **No differences in VLST**
  - **(Very Late Stent Thrombosis, VLST)**
- **Theoretical superiority of a biodegradable (abluminal) Stentdesign especially for Stentthrombosis**

  Data for this hypothesis in RCT not evident

Solution Oriented Polymer-Free Angioplasty

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Development of DES Generations

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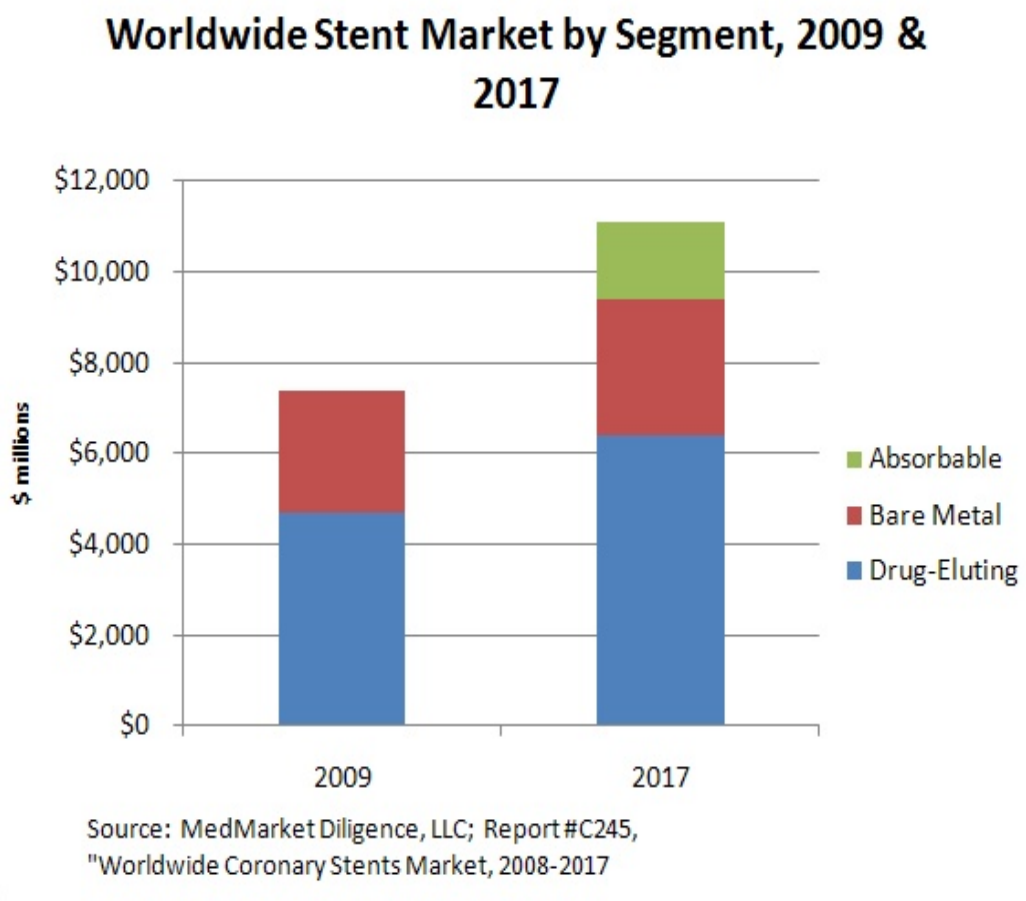
PCI Market Development



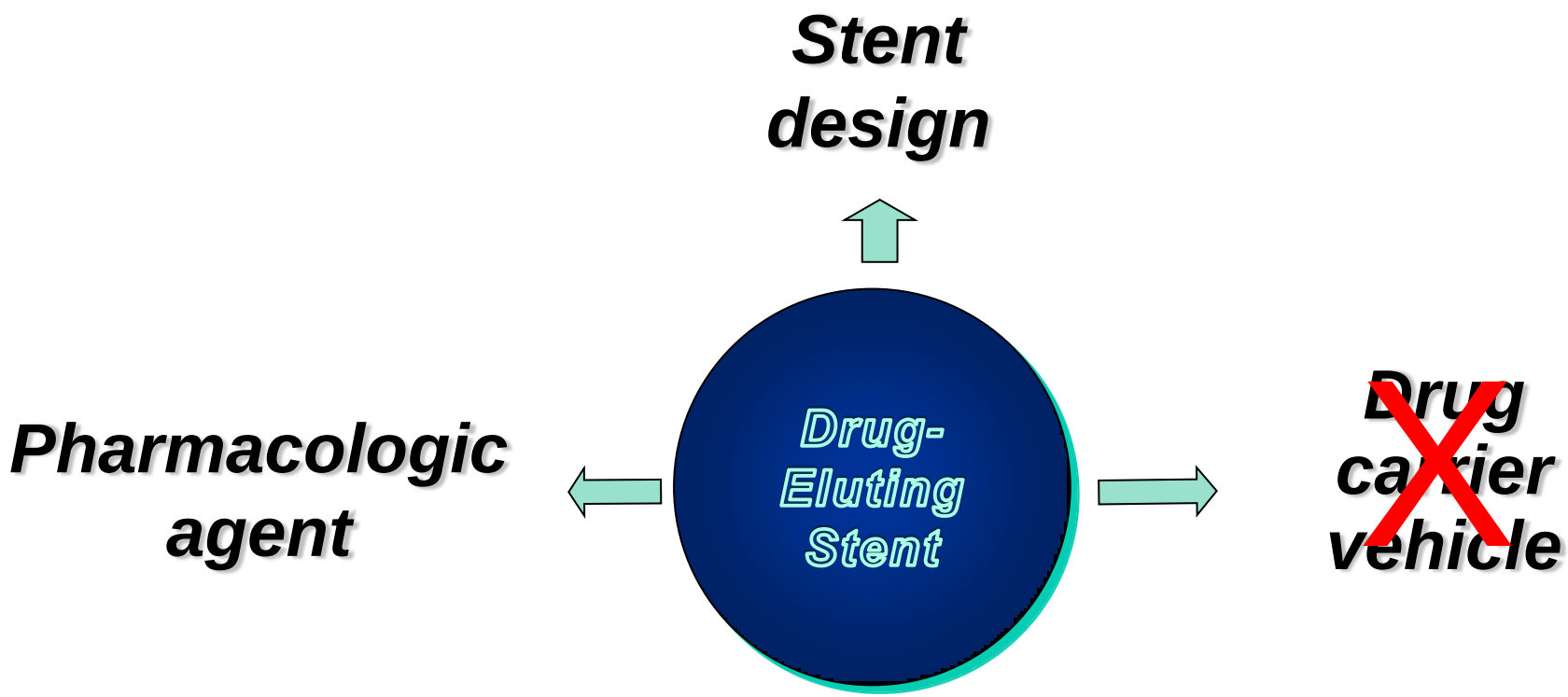
Growth Driver: Local Drug Delivery

- Europe 1.7 Mio DES in 2014
- PCI DES (Drug-Eluting)
- BMS stagnating (price/unit erosion)
- BVS Market Share approx. 10%, if RCT would show efficacy

Drug Coated Stents: Biodegradable Coating Technology

Better than any polymer is …

… no polymer



Drug Eluting Stents: Development in Coating Technology

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Future DES Requirements

1. Reduction of the duration of DAPT

2. Lower late stent thrombosis

3. Improved deliverability

4. Better efficacy

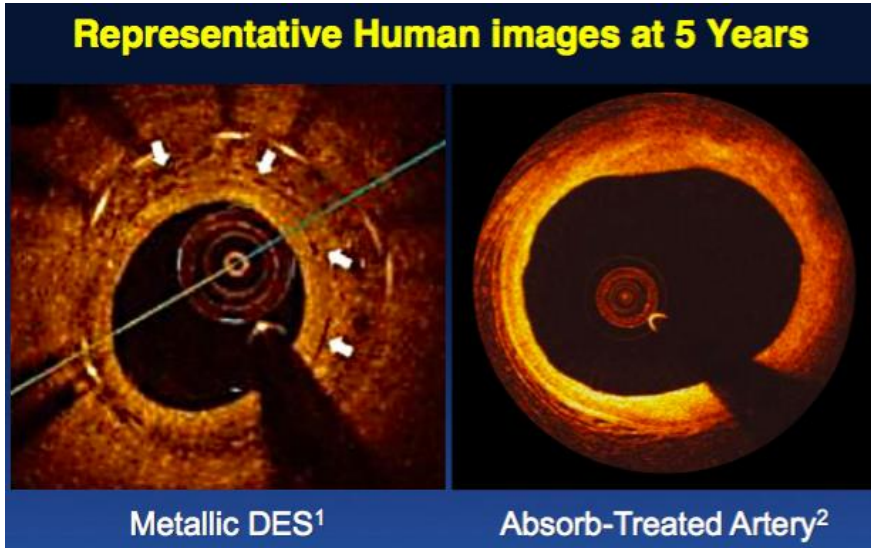
5. Natural vessel restoration

Solution Oriented Polymer-Free Angioplasty

4th gen: polymer-free Angioplasty

Drug coated Balloons	To avoid unnecessary stenting „The best stent is No Stent“ in defined indications
Scaffolds	Natural vessel restoration
Drug coated Stents	Indications ?
BioFreedom	workhorse ?
CoroFlex ISAR	

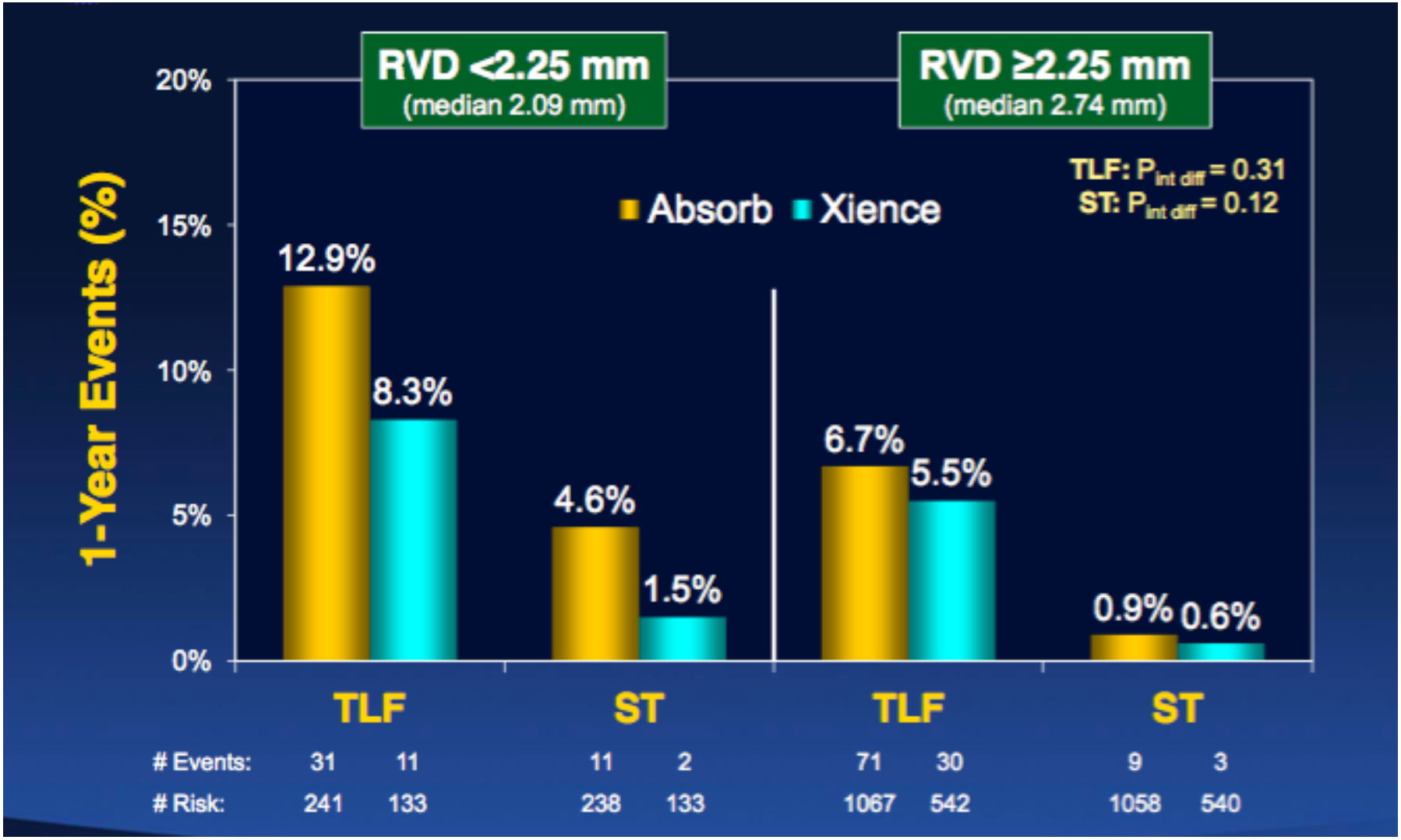
Bioresorbable Scaffolds (BVS)



A Series of Randomized Trials Designed to:

- Demonstrate similar (non-inferior) results with ABSORB BVS compared to Xience CoCr-EES at 1 year
- Demonstrate superior results with ABSORB BVS compared to Xience CoCr-EES between 1 and 5 years

Bioresorbable Scaffolds (BVS)
ABSORB III Results due to lumen diameter



Bioresorbable Scaffolds (BVS)

One year Meta-Analysis: ABSORB II, ABSORB III, ABSORB Japan, ABSORB China

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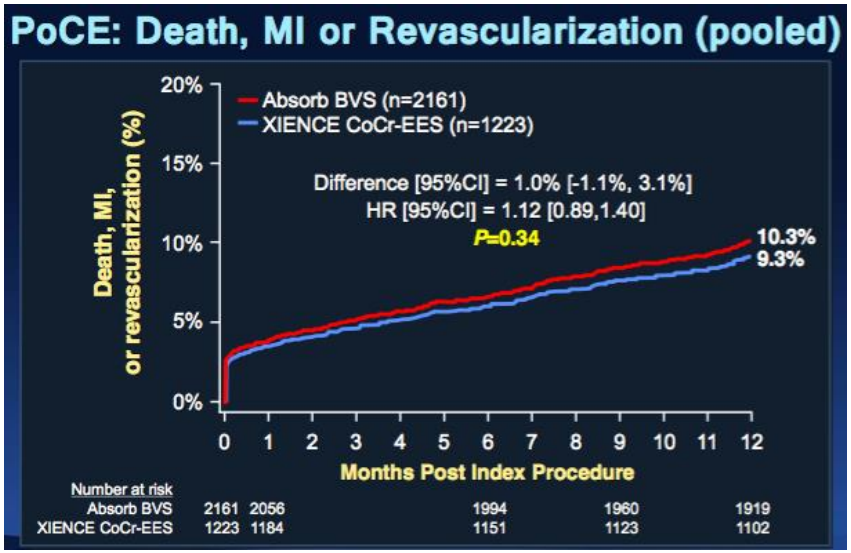

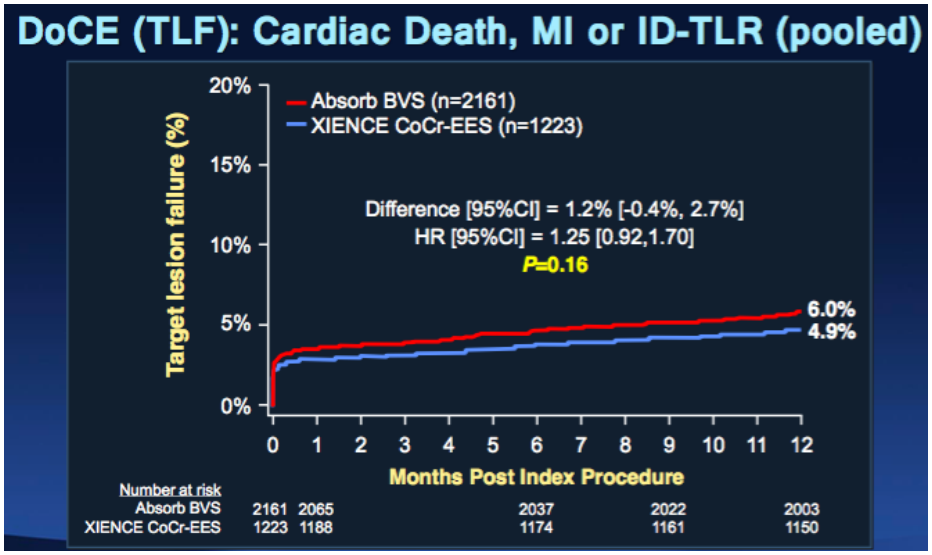

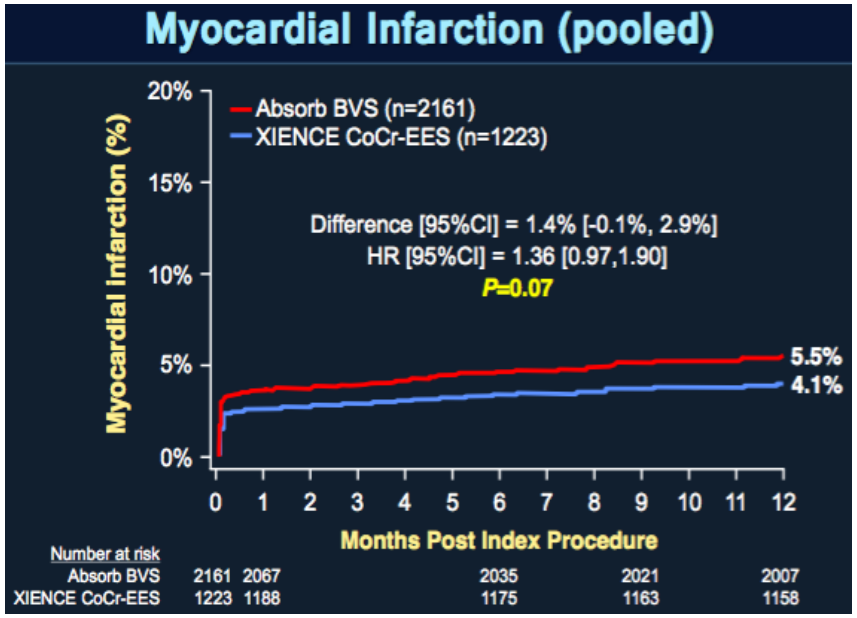

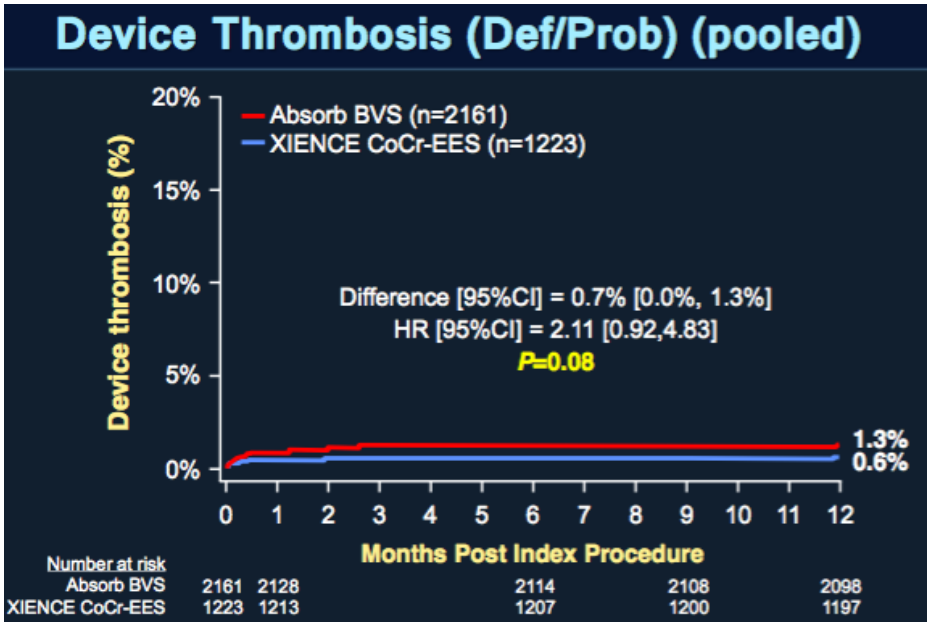

Stentthrombosis after 1 year BVS vs Xience

Meta-Analysis ABOSRBII, ABSORB III, ABSORP Japan & China

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	BVS (N=2164)	CoCr-EES (N=1225)	RR [95% CI] Fixed effect	P Value	I^2	P het
Device thrombosis (def/prob)	1.3%	0.6%	2.09 [0.92, 4.75]	0.08	0%	0.40
- Definite	1.1%	0.5%	2.06 [0.85, 5.03]	0.11	0%	0.84
- Probable	0.2%	0.1%	2.28 [0.28, 18.51]	0.44	NA	NA
- Early (0-30 days)	0.9%	0.5%	1.76 [0.72, 4.34]	0.22	0%	0.70
- Late (30 days - 1 year)	0.4%	0.1%	4.10 [0.52, 32.56]	0.18	NA	NA

Non significant higher rate of stent thrombosis
For scaffolds independent of DAPT Duration

Stone G et al TCT 2015

Bioabresobable Scaffolds (BVS)

One-Year Meta-Analyse: ABSORB II, ABSORB III, ABSORB Japan, ABSORB China

- **Non-complex and moderat complex lesions and ACS coparable results of BVS compared to a second generation DES**
- **One-Year: POCE und DOCE no difference**
- **Safety: Non-significant differences**
- **Higher MACE Rate in small vessels**

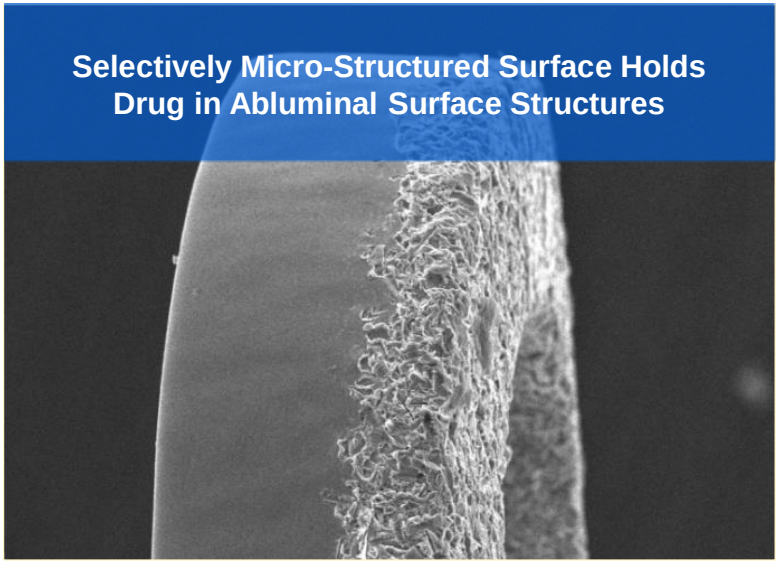
LEADERS FREE

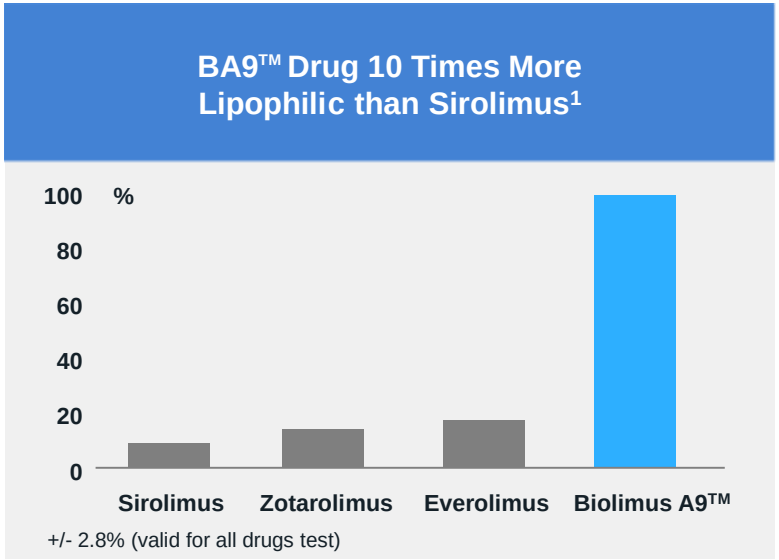
Biolimus-Coated vs. Bare-Metal Coronary Stents in High Bleeding Risk Patients

Philip Urban, Alexandre Abizaid, Ian T. Meredith,
Stuart J. Pocock, Didier Carrié, Christoph Naber,
John Gregson, Samantha Greene, Hans Peter Stoll
and Marie-Claude Morice for the LEADERS FREE Investigators

Drug Coated Stent - Biofreedom

BioFreedom™ Drug Coated Stent (C S)



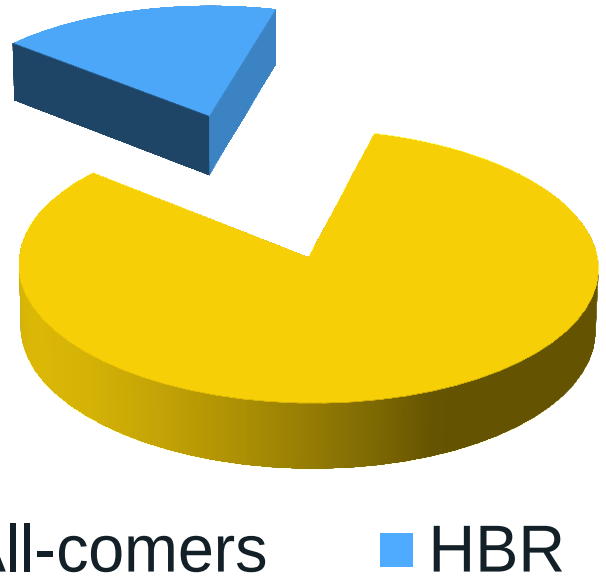


Potential Advantages:

- ✓ Avoid any possible polymer-related adverse effects
- ✓ Rapid drug transfer to vessel wall (98% within one month[2])
- ✓ Safe to shorten DAPT?

High Bleeding Risk Patients (HBR)

- Mostly excluded from device and APT trials
- Never specifically studied
- Current guideline recommendations:
  - BMS + one month DAPT
  - DES + “shortened” DAPT



Drug Coated Stent - Biofreedom

LEADERS FREE Trial Design

Prospective, double-blind randomized (1:1) trial
2466 High bleeding risk (HBR) PCI patients

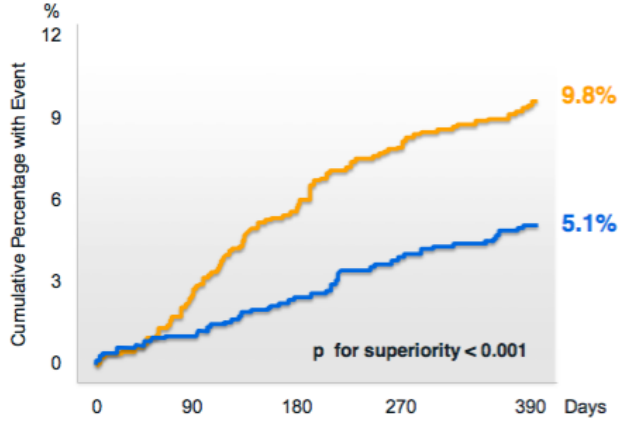
BioFreedom™ DCS **vs.** **Gazelle™ BMS**

DAPT mandated for 1 month only, followed by long-term SAPT

- **Primary safety endpoint:**
  Composite of cardiac death, MI, definite / probable stent thrombosis at 1 year (non-inferiority then superiority)
- **Primary efficacy endpoint:**
  Clinically-driven TLR at 1 year (superiority)

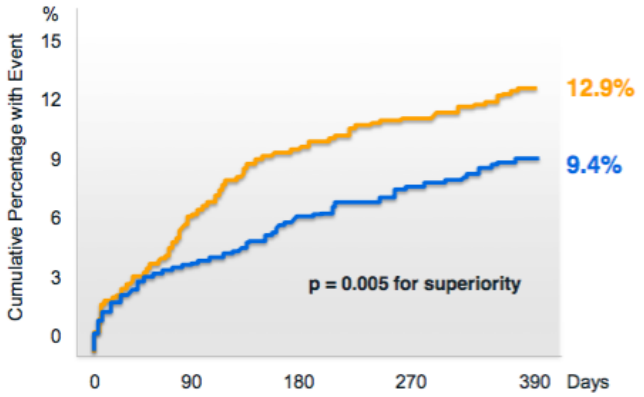
Drug Coated Stent - Biofreedom

Primary Efficacy Endpoint (Clinically-Driven TLR)



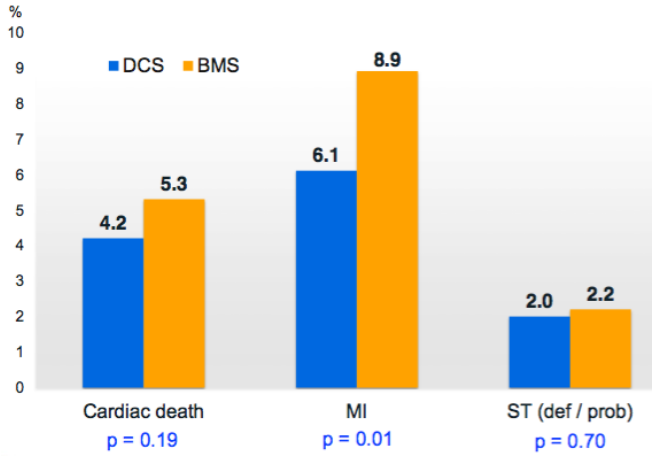
Number at Risk					
DCS	1221	1167	1130	1098	1053
BMS	1211	1131	1072	1034	984

Primary Safety Endpoint (Cardiac Death, MI, ST)

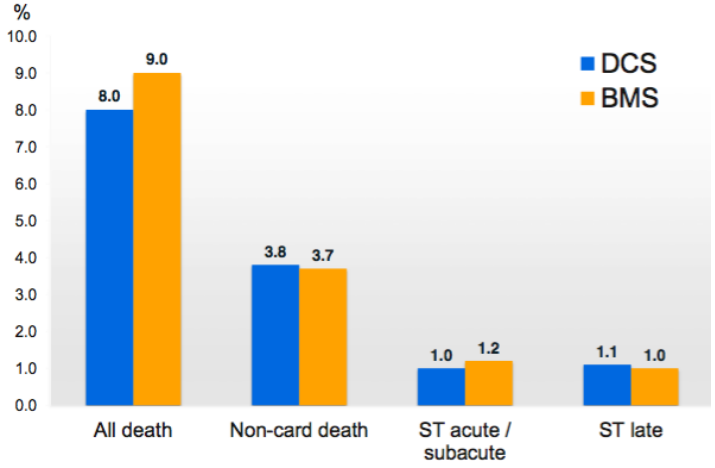


Number at Risk					
DCS	1221	1146	1105	1081	1045
BMS	1211	1115	1066	1037	1000

Components of Safety Endpoint



Selected Secondary Safety Endpoints



Drug Coated Stent - Biofreedom

- **First study patients with high bleeding risk**
- **Excluded in most RCT**
- **The Biolimus-Drug-Coated-Stent-Design is more effective and safe compared to BMS**

The NEW ENGLAND JOURNAL of MEDICINE

LEADERS FREE

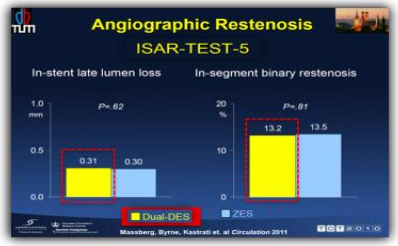
published online October 14, 2015

Drug coated Stent - Coroflex ISAR

Matrix

100% Polymer-Free Sirolimus Drug Delivery

- Probucol as Matrix-Builder, to retard the release of Sirolimus over time
- Abluminal coating for effective drug release
- Release kinetics equal to Cypher-stent



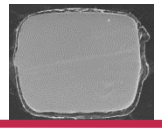
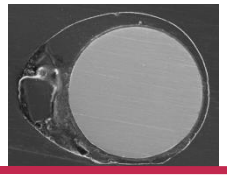
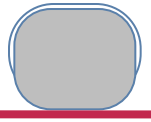
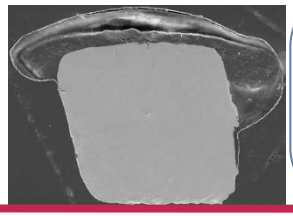
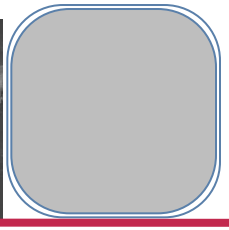
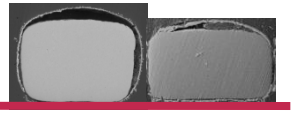
Clinical Evidence

- Sirolimus, one of the best approved drugs ever
- Clinical endpoint trial - **ISAR Test 5 (incl. long-term results)**
- Safe reduction of unwanted cell proliferation
- Efficacy and Safety Profile like the latest generation Resolute Integrity

Stent Performance

- **High Flexibility** due to Coroflex Blue Neo & Ultra stent platform
- Lowest Crossing Profile (0.79 - 0.93 mm)
- Lowest stent strut thickness (50/60 µm)
- Complete Portfolio (incl. 2.0, 2.25 mm up to 32mm length)

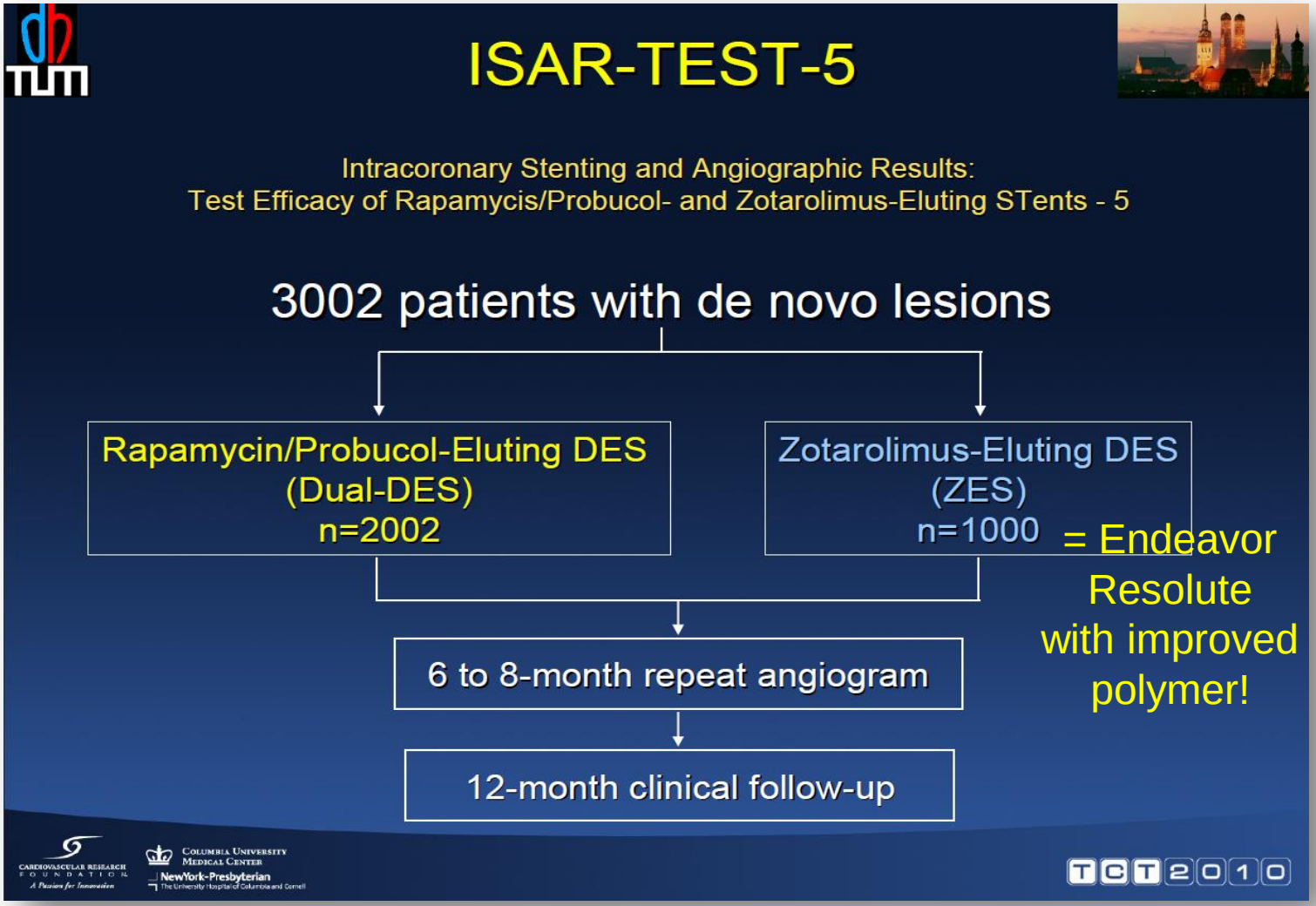
Do newer generation stents have lower strut thickness?

Durable Polymer Coated Stents			Bioabsorbable Polymer Coated Stents			Bio-absorbable Scaffold	Polymer-Free Coated Stent
Xience Prime™	PROMUS Element™	Resolute Integrity™	Orsiro™	SYNERGY™	BioMatrix Flex™	Absorb BVS	Coroflex® ISAR
							
Strut Thickness (nominal and measured)							
81 µm (0.0032”)	81 µm (0.0032”)	89 µm (0.0035”) 100 µm	60 µm (0.0024”) 67 µm	74 µm (0.0029”)	120 µm (0.0047”) 117 µm	150 µm (0.0059”) -	50/60 µm (0.0020”/ 0.0024”)
Coating Thickness (nominal and measured)							
Conformal 8µm / side 4 - 10 µm	Conformal 8µm	Conformal 6µm / side 5 - 38 µm	Asymetr. 7µm 7 - 9 µm	Abluminal 4µm	Abluminal 10µm 10 - 25µm	Conformal 3µm	Abluminal 4 µm
Content (nominal)							
Everolimus 100 µg/cm²	Everolimus 100 µg/cm²	Zotarolimus 160 µg/cm²	Sirolimus 140 µg/cm²	Everolimus 16 µg/mm²	Biolimus A9 15.6 µg/mm²	Everolimus 98 µg/cm²	Sirolimus 120 µg/cm²

Source: R&D, internal tests

Drug coated Stent - Coroflex ISAR

Clinical Trial ISAR Test 5



Drug coated Stent - Coroflex ISAR

ISARSTENT: Clinical Evaluation ISAR Test 5

Final Five-Year Follow-Up of Polymer-Free Sirolimus- and Probucol-Eluting Stents vs. New Generation Zotarolimus-Eluting Stents in Patients with Coronary Artery Disease

Technische Universität München

The Intracoronary Stenting and Angiographic Results: Test Efficacy of Sirolimus- and Probucol- and Zotarolimus- Eluting Stents **(ISAR-TEST 5)** Trial

R.A. Byrne, S. Kufner, J. Sorges, J. Repp, S. Cassese, T. Ibrahim, K.-L. Laugwitz, A. Kastrati

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Background

ISAR-TEST 5 was a large-scale randomized trial which demonstrated the non-inferiority of a polymer-free dual-drug sirolimus- and probucol-eluting stent (Dual-DES) compared to a new generation durable polymer zotarolimus-eluting stent (ZES) in 3002 randomized patients at 1-year follow-up. Long-term follow-up is required to determine durability of efficacy and to investigate the hypothesized late performance advantage of polymer-free DES.

The aim of the present analysis was to evaluate clinical outcomes at 5 years.

Methods

A total of 3002 patients undergoing percutaneous coronary intervention were randomly assigned to treatment with a polymer-free sirolimus- and probucol-eluting stent (backbone Translumina, Hechingen, GERMANY; n=2002) versus a ZES stent (Endeavor Resolute, Medtronic Vascular, Santa Rosa, Ca., USA; n=1000). There were minimal exclusion criteria. Clinical follow-up was performed to 5 years post enrolment.

The primary endpoint was the combined incidence of cardiac death, target-vessel-related myocardial infarction (MI) or target lesion revascularization. Secondary endpoints comprised the composite of death or any MI, target lesion revascularization and definite or probable stent thrombosis. The primary endpoint will also be evaluated in pre-defined sub-groups according to sex, age, reference vessel diameter and diabetes.

NOTE: The probucol- and sirolimus-eluting Dual-DES is commercially-available as the Coroflex-ISAR DES (B. Braun Melsungen AG, Melsungen, GERMANY).

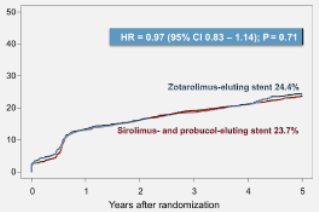
DISCLOSURES: RAB reports lecture fees from B. Braun Melsungen AG and Biotronik. AK reports speakers fees for MSD and patent applications in respect of drug-eluting stent coatings

Results

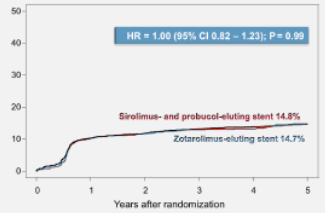
Baseline characteristics

	Dual-DES	Resolute ZES	P-value
Age (years)	67.7±11.2	68.1±10.8	0.30
Female	470 (23.5)	237 (23.7)	0.89
Diabetes mellitus	575 (28.7)	295 (29.5)	0.66
Insulin-dependent	197 (9.8)	109 (10.9)	0.37
Hypertension	1336 (66.7)	666 (66.6)	0.94
Hyperlipidemia	1257 (62.8)	650 (65.0)	0.24
Current smoker	357 (17.8)	166 (16.6)	0.40
Prior myocardial infarction	586 (29.3)	299 (29.9)	0.72
Prior bypass surgery	188 (9.4)	96 (9.6)	0.85
Multivessel disease	1658 (82.3)	855 (85.5)	0.06
Clinical presentation			0.60
acute myocardial infarction	215 (10.7)	96 (9.6)	
unstable angina	596 (29.8)	325 (32.5)	
stable angina	1191 (59.5)	579 (57.9)	
Multilesion intervention	715 (35.7)	378 (37.8)	0.26
Ejection fraction (%)*	52.6±11.9	52.4±11.4	0.74
Target vessel			0.55
left anterior descending	1315 (45.2)	666 (45.0)	
left circumflex	711 (24.4)	386 (26.1)	
right coronary artery	886 (30.4)	427 (28.9)	
Chronic total occlusion	174 (6.0)	76 (5.1)	0.28
Bifurcation	798 (27.4)	427 (28.9)	0.39
Ostial	583 (20.0)	305 (20.6)	0.66
Complex lesion (B2/C)	2164 (74.3)	1088 (73.6)	0.63
Lesion length (mm)	16.4±9.6	16.9±10.0	0.09
Vessel size (mm)	2.78±0.50	2.80±0.50	0.23

Cardiac death, target-vessel MI, target lesion revascularization, %

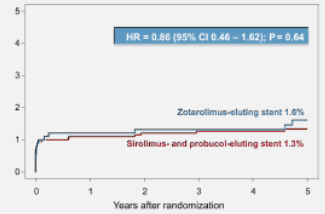


Target lesion revascularization, %



Cardiac death or target-vessel myocardial infarction, %

Definite or probable stent thrombosis, %



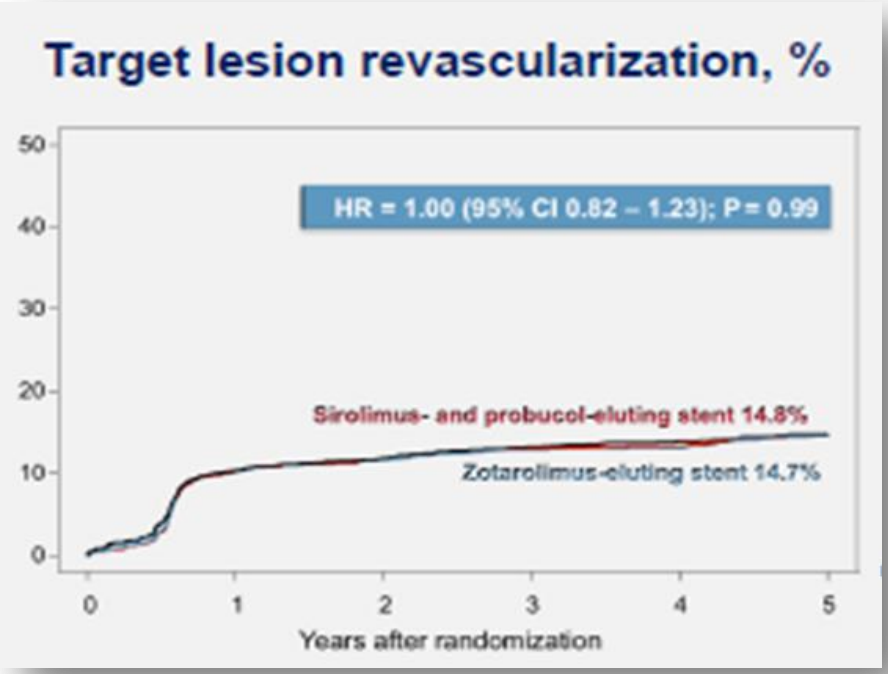
Results for the primary endpoint were consistent across pre-specified subgroups of age, sex, presence or absence of diabetes mellitus and vessel size.

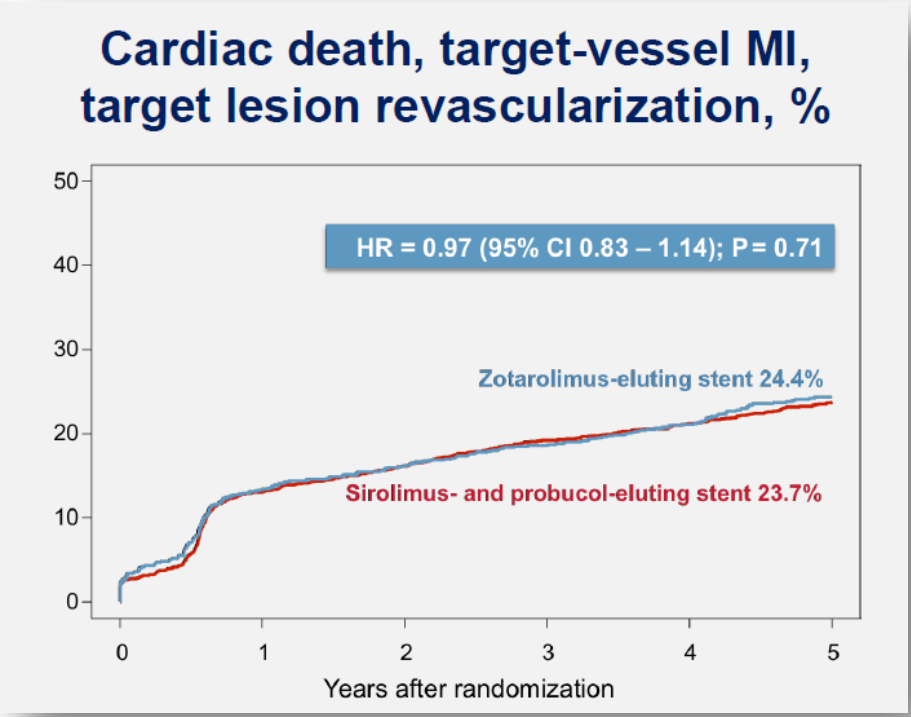
Conclusion

In the setting of a large-scale clinical trial with broad inclusion criteria both the polymer-free sirolimus- and probucol-eluting stent and the new generation durable polymer zotarolimus-eluting stent showed durable efficacy and high safety out to 5 years. In terms of stent thrombosis rates were low and comparable in both groups with few events beyond 1 year.

Drug coated Stent - Coroflex ISAR

Clinical Trial ISAR Test 5





Durable efficiacy and high safety out to 5 years
Low stent thrombosis rates and comparable data to second generation DES

MATRIX COATING TECHNOLOGY

Polymer-Free Matrix Coating Technology

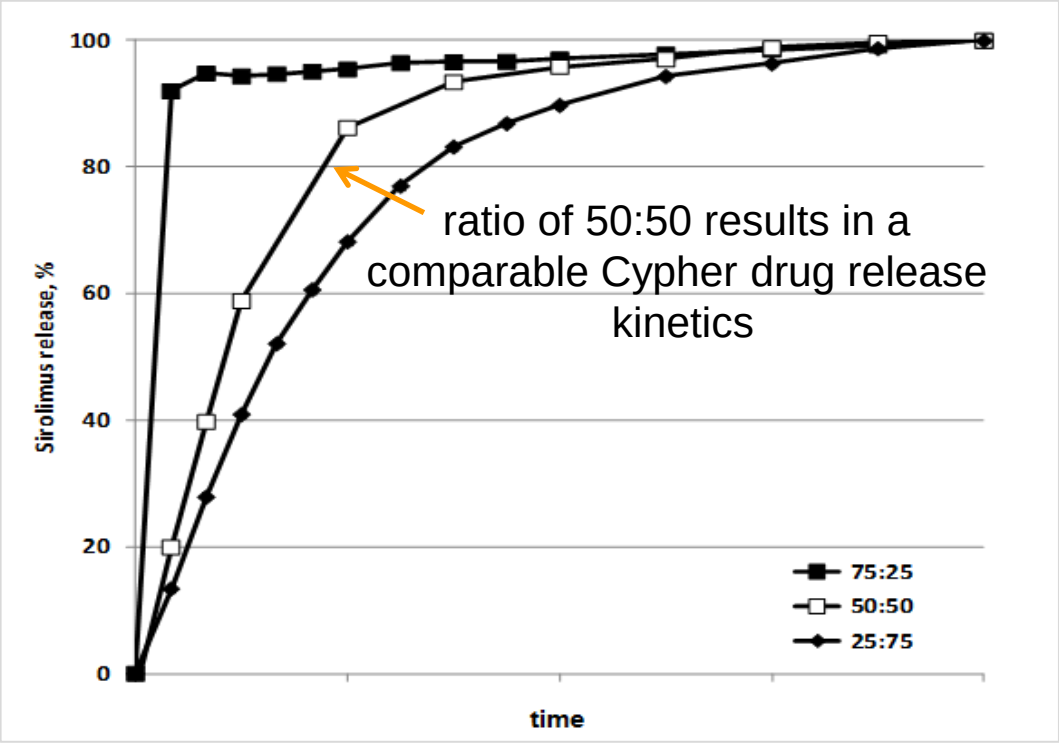
- The Coroflex ISAR stent is covered with a Sirolimus containing matrix, which consists in equal shares (1:1) of the drug Sirolimus (active agent) and Probucol (excipient - matrix builder)
- Probucol is used as an hydrophobic, antioxidantic excipient. The release of Sirolimus is controlled by the Probucol. Probucol is needed to bind the drug on the stent and to facilitate a controlled & continuous drug release.
- Probucol mimics the function of a polymer by retarding the release of Sirolimus over a time period of several weeks
- The drug load is 1.2µg/mm² Sirolimus
- The Matrix Coating is applied only on the abluminal Coroflex ISAR stent surface for improved endothelial healing

Coroflex® ISAR
Abluminal, Polymer-Free Drug Delivery

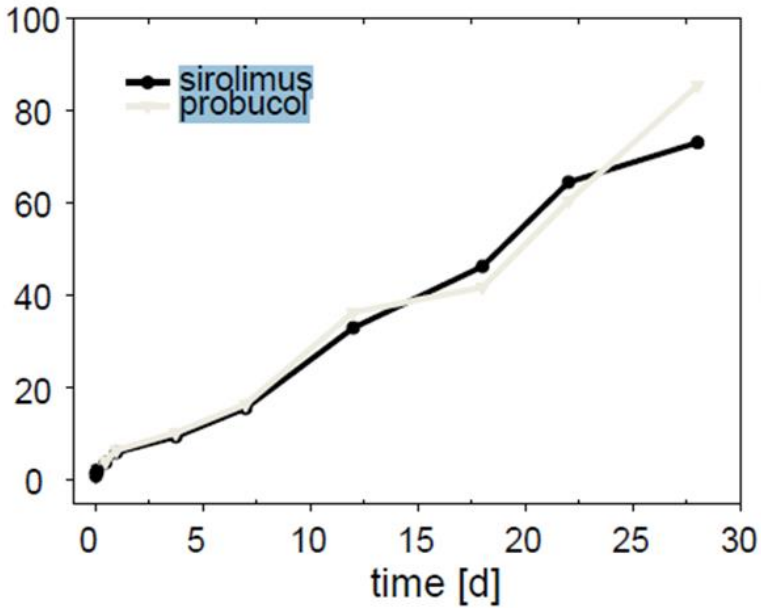
MATRIX COATING TECHNOLOGY

Coroflex ISAR Drug Release Kinetics

Sirolimus release as function of the Sirolimus: Probucol ratio in the coating of Coroflex ISAR



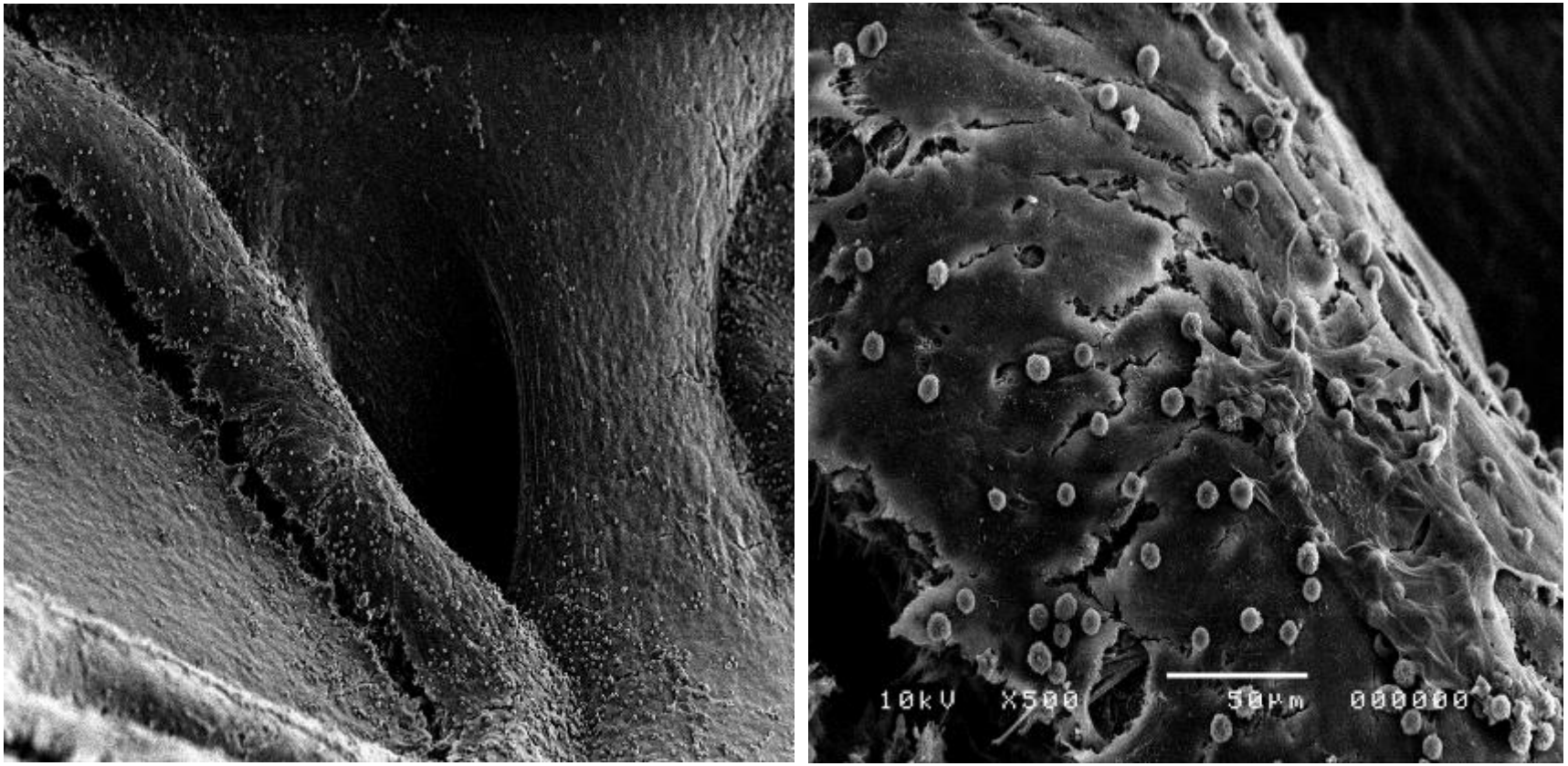
The 50:50 ratio corresponds to the drug release of the Cypher stent without using a non-degradable polymer!



Coroflex ISAR Drug Matrix is >80% released and bioabsorbed after **30 days**

Endothelialization of the luminal Stentsurface

Improved endothelial healing due to
the absence of a polymer-carrier



EM of a Genous stent at 48 hours following stenting shows complete coverage of the stents by endothelium (left). The detail (right) shows leucocyte adherence and incomplete cell-cell contact.

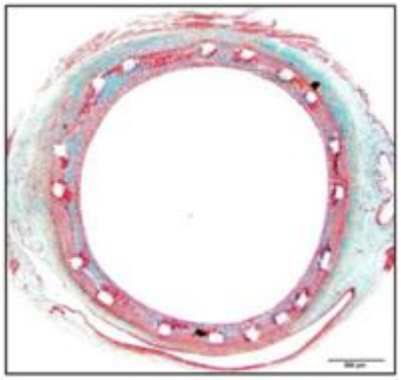
Abizaid et al. 2009

Drug coated Stent - Coroflex ISAR

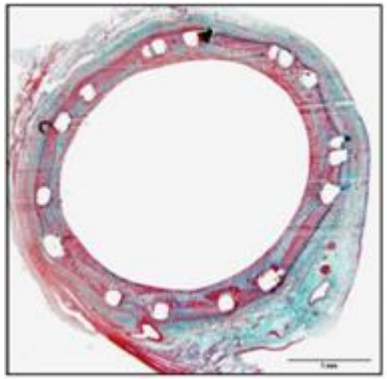
Pre-clinical results at 28 days:

28 days	Neointimal thickness (mm)	Inflammation score (0-3)	Injury score (0-3)	Endotheliali-zation (%)
Coroflex® ISAR	0.17 ±0.09	0.0 ±0.0	0.4 ±0.3	98.8 ±1.7
Cypher	0.19 ±0.07	0.1 ±0.2	0.6 ±0.3	87.2 ±32.8
Coroflex ISAR (without drug)	0.21 ±0.13	0.3 ±0.7	0.3 ±0.2	99.6 ±0.5

Coroflex® ISAR

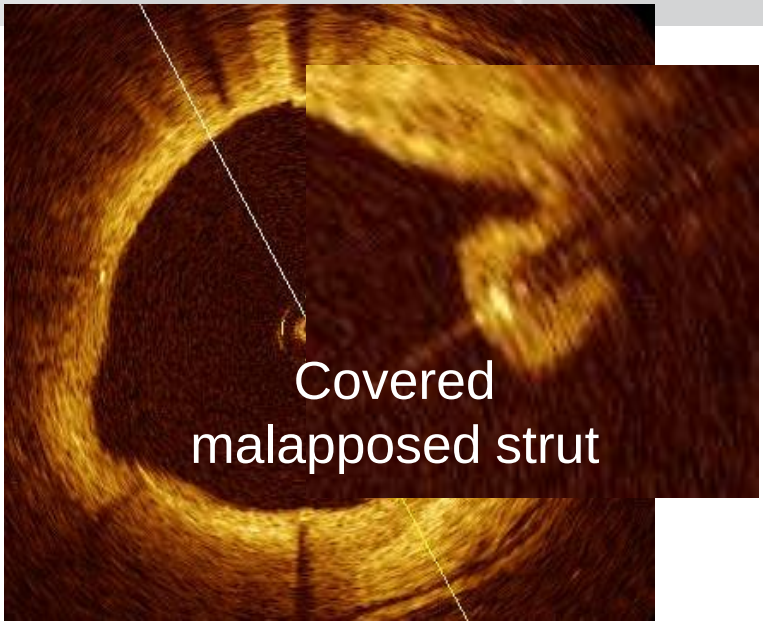


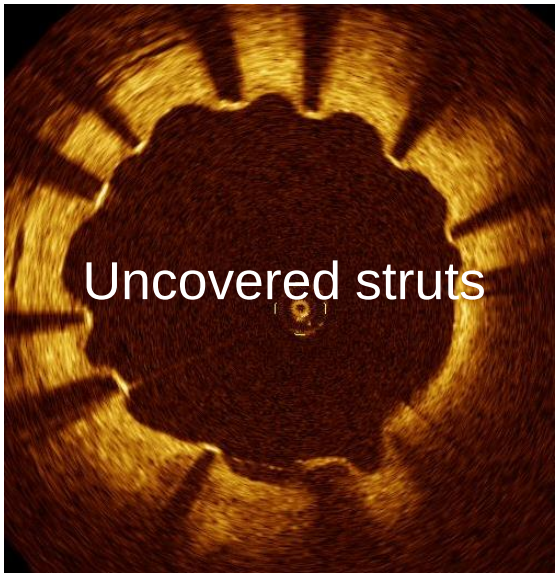
Cypher

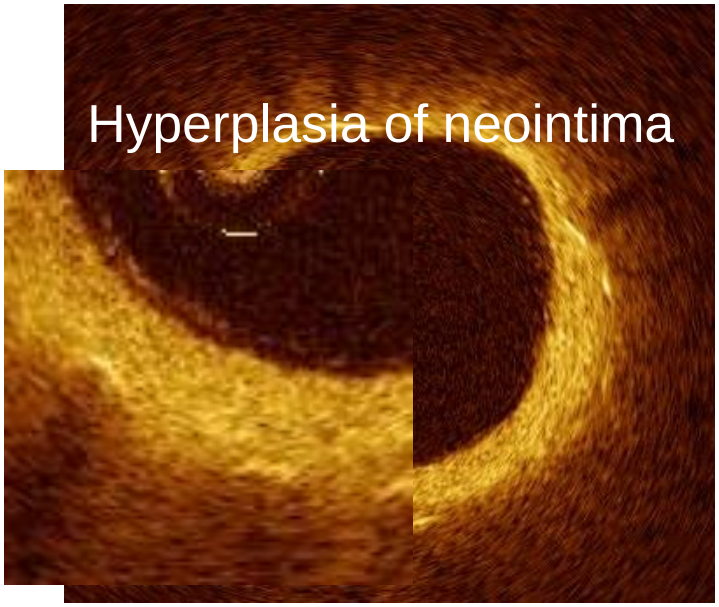


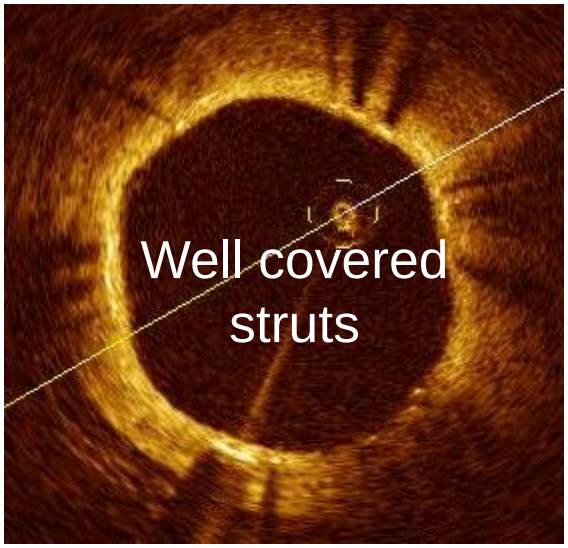
Proven Inhibition of neointimal growth

Intravascular Imaging - OCT





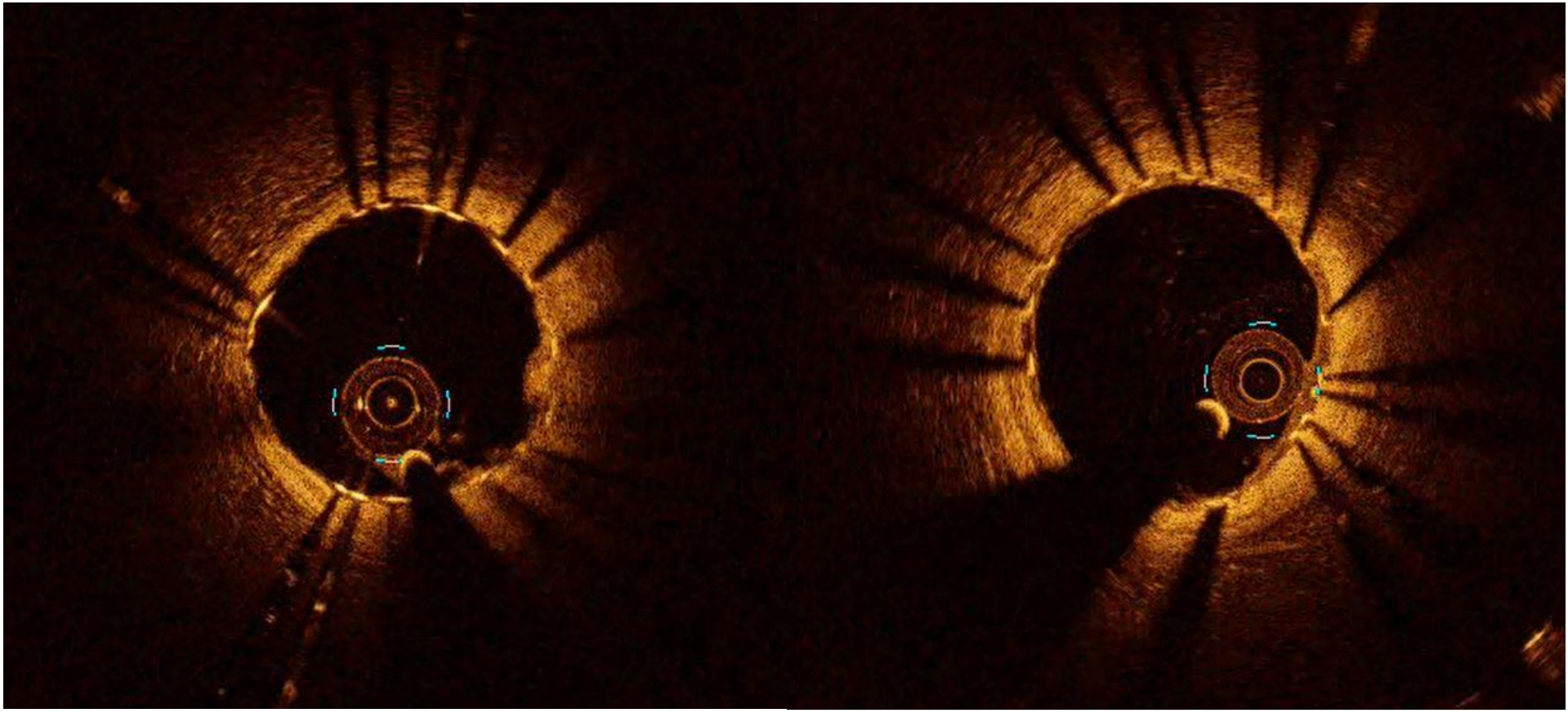




Coroflex® ISAR OCT

OCT post-PCI

OCT 6 weeks later



Coroflex ISAR 2.75 , LAD-7

75 years old patient

ISAR-DAPT STUDY – KOREA

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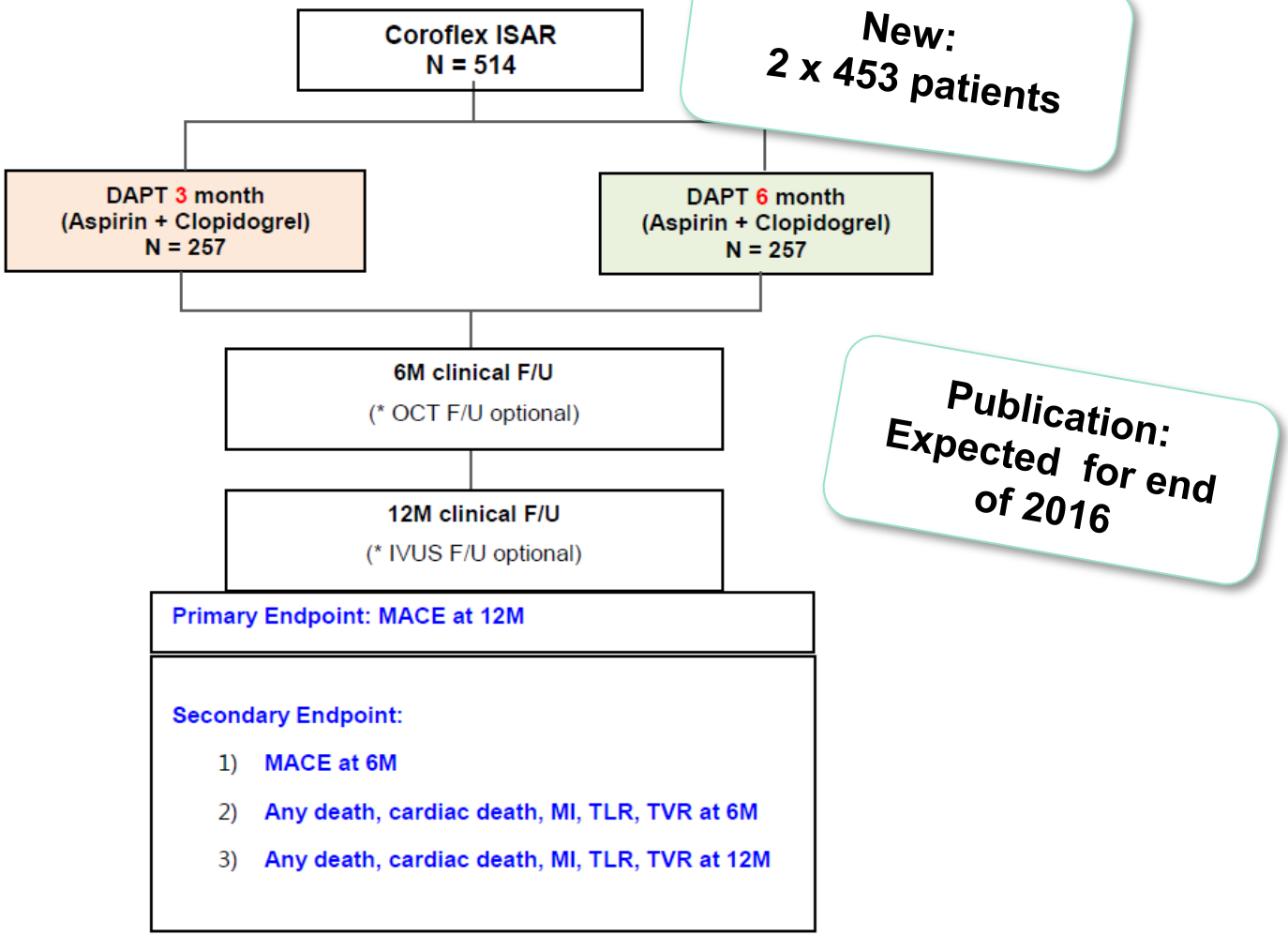
A Comparative Evaluation of Efficacy and Safety in the 3-Months DAPT Group vs. the 6-Months DAPT Group of Patients Treated with the Coroflex ISAR Stent; A Prospective, Multicenter, Randomized, Open-Label Clinical Trial

Research Title	**(Korean) ISAR-DAPT**: Coroflex ISAR 스텐트를 시술 받은 환자를 대상으로 이중항혈소판제 복용 기간에 따른 효과와 안전성을 비교 평가하기 위한 다기관, 전향적, 무작위 배정 임상시험
	(English) ISAR-DAPT: A Comparative Evaluation of Efficacy and Safety in the 3-Months DAPT Group vs. the 6-Months DAPT Group of Patients Treated with the Coroflex ISAR Stent; A Prospective, Multicenter, Randomized, Open-Label Clinical Trial
Objective	This clinical trial studies patients treated with the Coroflex ISAR Stent for coronary artery disease in order for the objective of verifying the non-inferiority of results that among patients who were administered DAPT for 3 months compared to patients who were administered DAPT for 6 months, in terms of the efficacy and safety of DAPT.
Principal Investigator	Ajou University Hospital Department of Cardiology Professor Myeong-Ho Yoon
Clinical Trial Design	Multicenter, prospective, randomized clinical trial

Research Institution	Ajou University Hospital
Principal Investigator	Department of Cardiology Professor Myeong-Ho Yoon

ISAR-DAPT STUDY – KOREA



New:
2 x 453 patients

Publication:
Expected for end of 2016

Coroflex® ISAR Registry Update November 2015

Objective	The aim of the study is to assess the safety and efficacy of elective deployment of the Sirolimus-eluting Coroflex ISAR Stent™ in the treatment of "real world" de-novo and restenotic lesions after stand-alone angioplasty in coronary arteries between ≥ 2.0 mm and ≤ 4.0 mm in diameter of less or equal than 30 mm in length for procedural success and preservation of vessel patency.
Study Design	The Coroflex ISAR Registry is an international, multi-center 'all comer'/ 'real world' registry
Number of patients	Minimum of 20 patients per center.
Target patient recruitment	>2000 pts.
Selection criteria	No patient exclusion criteria except patients with contraindications for dual anti-platelet therapy
Primary endpoint	Clinically driven target lesion revascularization rate (TLR) at 9 months
Secondary endpoints	Success of stent deployment Acute MACE rate Cumulative MACE (TLR, cardiac death, MI) rate at 9 months
Scheduled follow-up	Clinical follow-up scheduled at 9 months for all patients

Coroflex® ISAR Registry

Variable	all patients	non 32 mm stents	32 mm only	p-value
Number of patients	2250	2000	250	-
Number of lesions	2871	2551	320	
Age (years)	64.0 ± 11.7	64.4 ± 11.7	61.2 ± 10.7	<0.001
Male gender	1695 (75.3%)	1495 (74.8%)	200 (80.0%)	0.069
Diabetes	863 (38.4%)	745 (37.2%)	118 (47.2%)	0.002
Hypertension	1559 (69.3%)	1383 (69.2%)	176 (70.4%)	0.686
End stage renal disease	99 (4.4%)	93 (4.6%)	6 (2.4%)	0.102
STEMI	412 (18.3%)	359 (18.0%)	53 (21.2%)	0.396
NSTEMI	502 (22.3%)	445 (22.2%)	57 (22.8%)	
no MI	1336 (59.4%)	1196 (59.8%)	140 (56.0%)	

Coroflex® ISAR Registry

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Variable	all patients	non 32 mm stents	32 mm only	p-value
Number of patients	322	274	48	
accumulated 9-month MI	5 (1.6%)	4 (1.5%)	1 (2.1%)	0.747
accumulated 9-month TLR	4 (1.2%)	4 (1.5%)	0 (0.0%)	0.400
accumulated 9-month cardiac death	6 (1.9%)	5 (1.8%)	1 (2.1%)	0.901
accumulated 9-month MACE	11 (3.4%)	10 (3.6%)	1 (2.1%)	0.532

The registry is still ongoing, the number of available 9-month follow-up is limited.

Accumulated 9-MACE rate of 2.1%.

Most importantly, there was no difference in terms of accumulated MACE at 9 months between the two patient groups who have received either the 32 mm stents or the shorter versions (p=0.532).

This is a important finding based on the fact the lesions treated with the longer lesions were more complex and the patients had more pronounced cardiovascular risk factors

Conclusion

Solution Oriented Polymer-Free Angioplasty

DES:	„The workhorse“
DCB:	To avoid unnecessary stenting „The best stent is No Stent“ in-Stent-Restenosis small vessel disease side branch treatment
Scaffold:	natural vessel restoration Younger patients Diabetic patients long stent distance ACS
DCS	shorter DAPT duration older patients patients with higher bleeding risk Patient with indication for non cardiac surgery

Coroflex-ISAR DCS

Polymer-Free Angioplasty

Thank you very much for your attention.