Orsiro - Hybrid Drug Eluting Stent Clinical Update

A/Prof Michael Nguyen

JCR Meeting

Busan 2014

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Perth, Western Australia

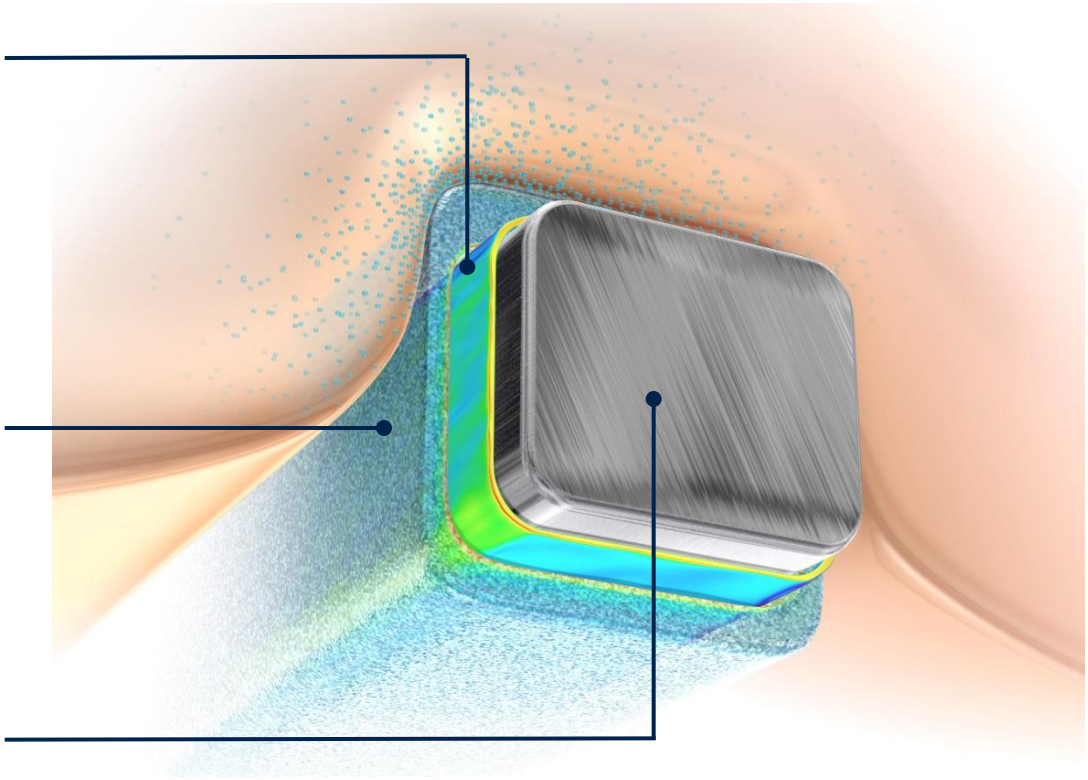
Fiona Stanley Hospital

Orsiro Hybrid DES with a bioabsorbable polymer

Combination of passive and active components

The hybrid structure:

- Passive PROBIO silicon carbide barrier encapsulates device, eliminating interaction between stent and the surroundings
- Active BIOlute contains bioabsorbable PLLA polymer combined with Limus drug (1.4 µg/mm^2)
- Underlying PRO-Kinetic Energy Stent



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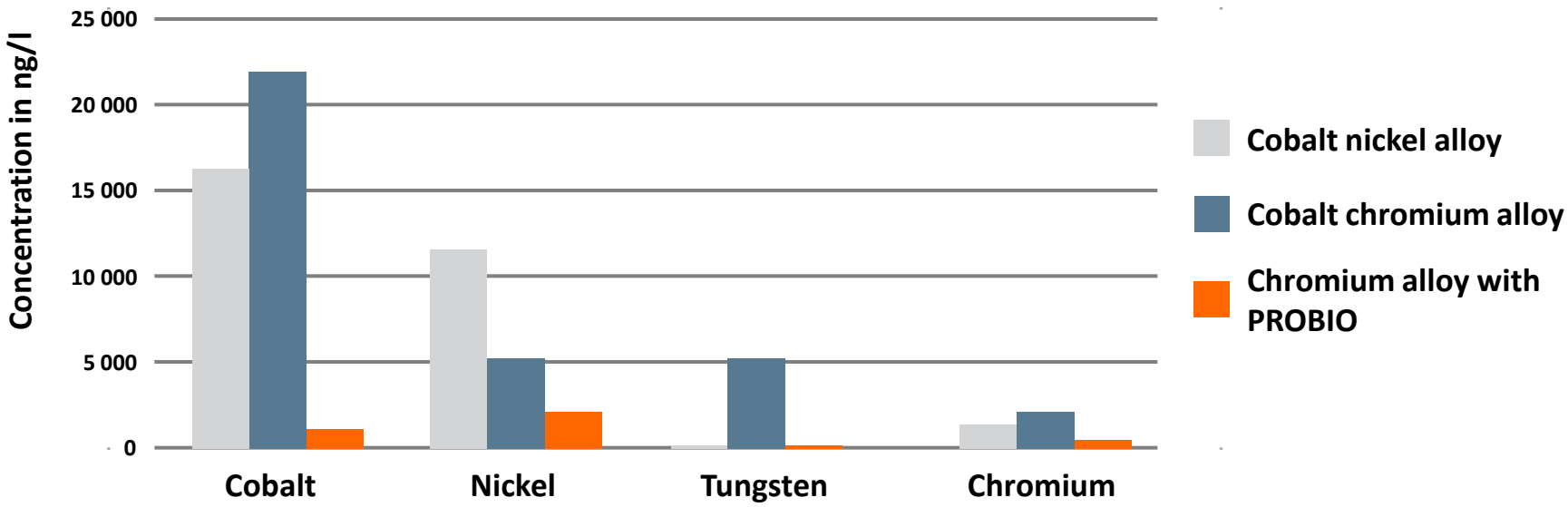
Passive Coating: PROBIO

Semi-Conductive Silicon Carbide Coating

- PROBIO reduces the interaction between tissue/blood with the metallic stent
- In vitro studies show up to a 96% reduction of metal ions

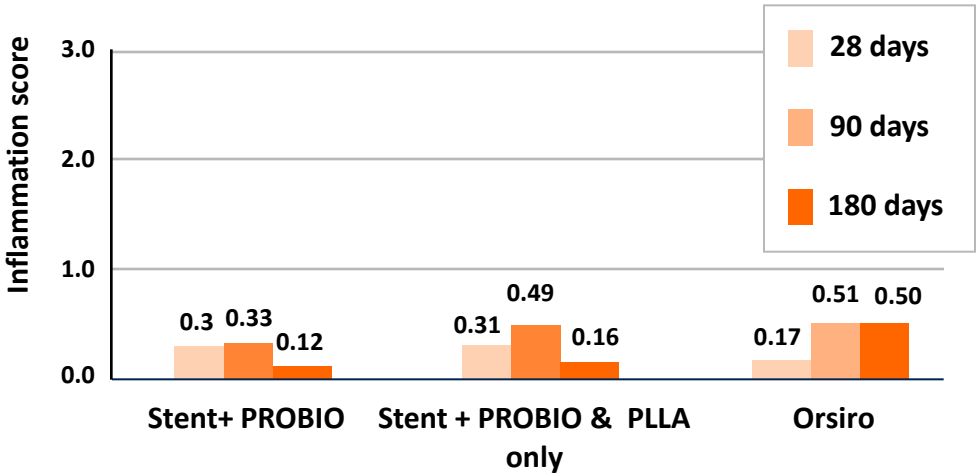


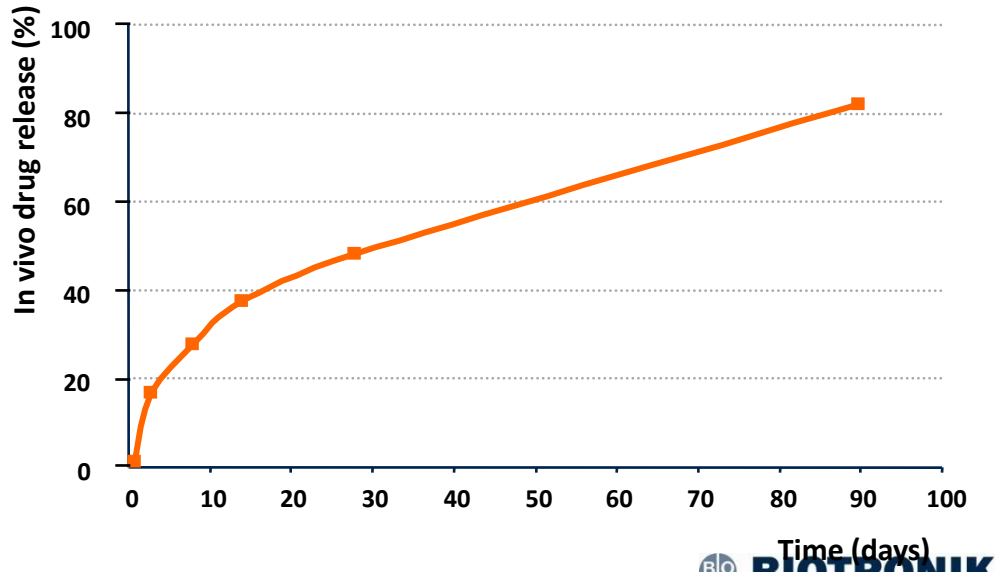
Source: Data on file, BIOTRONIK AG.

Active Coating: BIOlute

Bioabsorbable PLLA and Active Drug

- PLLA was chosen for its biocompatible and controlled drug release
- Metabolizes into CO_2 and H_2O
- Drug dose 1.4 µg/mm² with complete elution in about 100 days
- Elution curve is in-line with other Limus-based stents





Source: Koppara, T., et al. *Thrombosis and Haemostasis* 107. (2012): 1009–1194.

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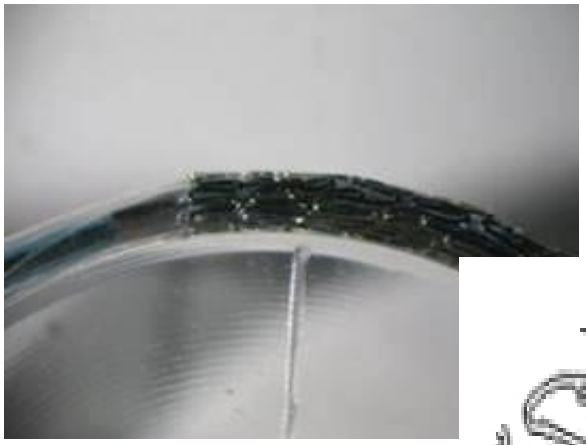
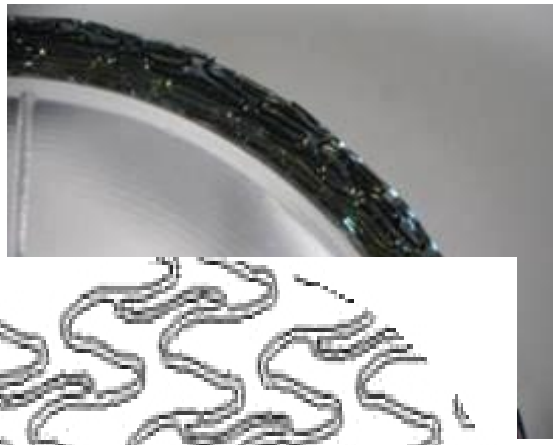
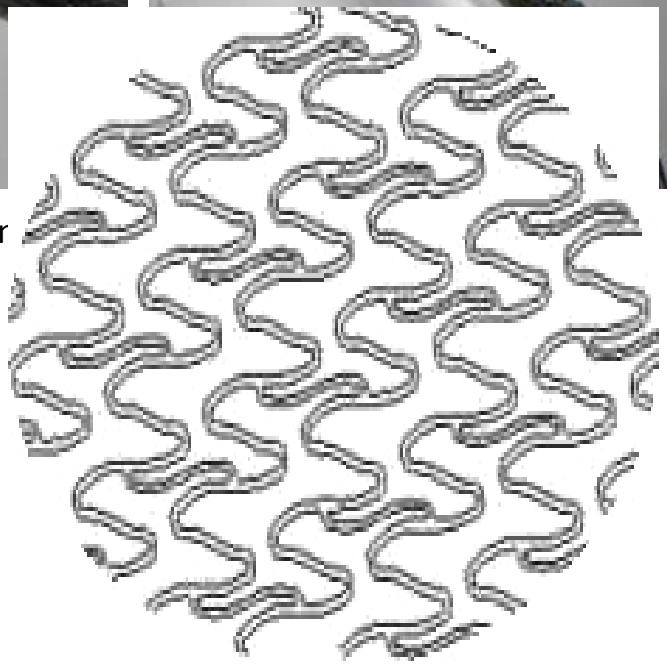
The Helical Stent Design

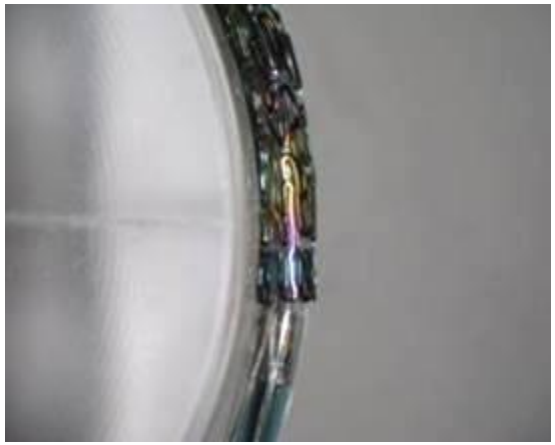
Yields a smooth outer contour during bending and a smooth transition throughout the stent



3.0/15, outer contour of ber
stent at proximal end

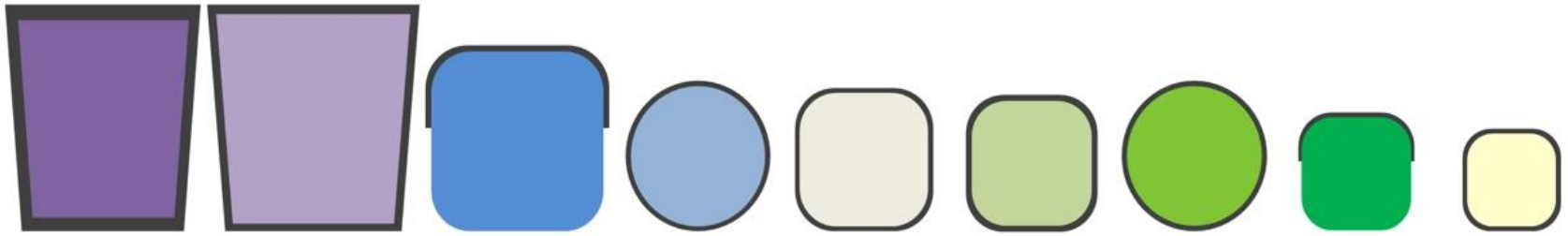






3.0/15, outer contour of bent
stent at distal end

Progression of strut evolution

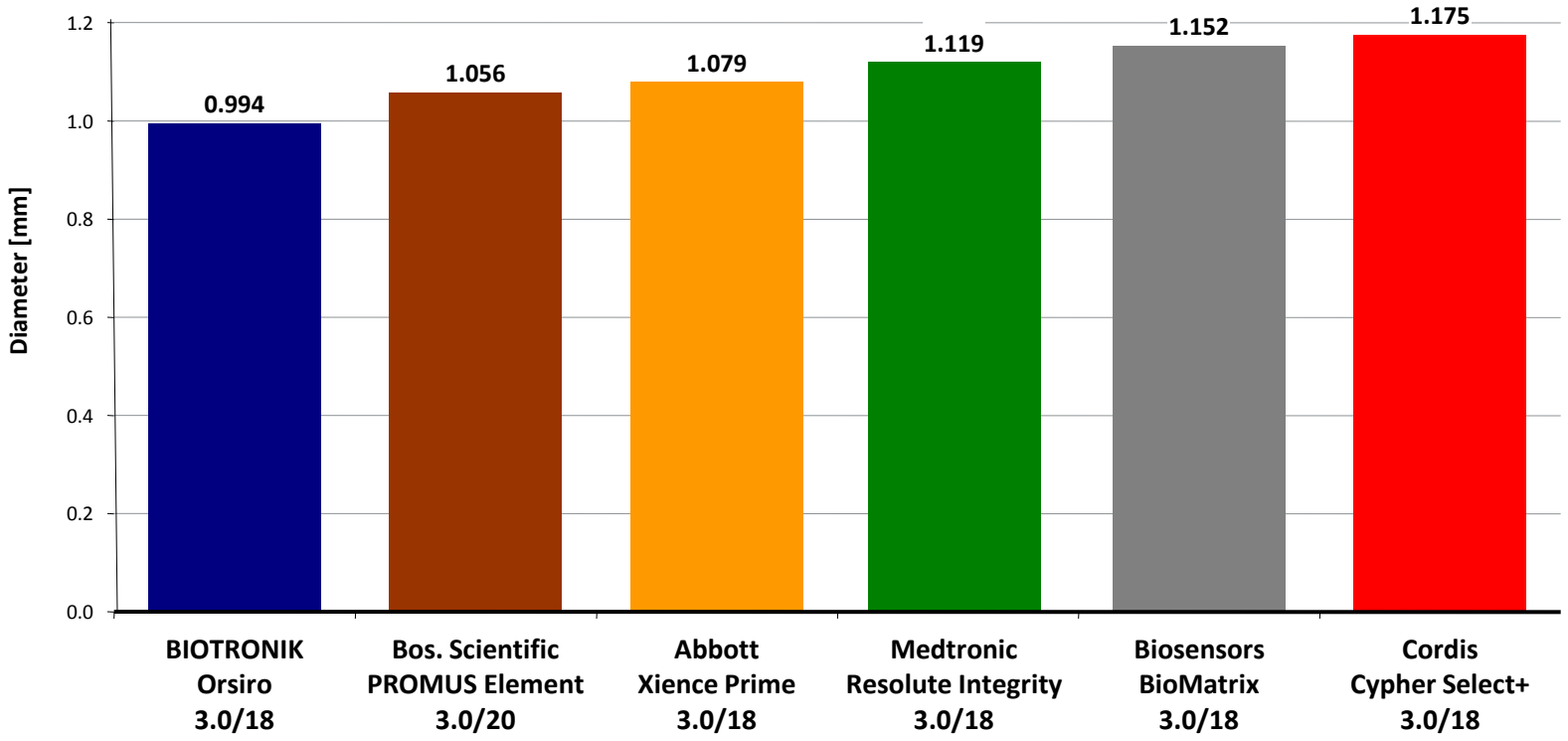


	Taxus	Cypher	BioMatrix Nobori	Endeavor	Yukon PC	Xience Promus	Resolute	Synergy	Orsiro
Platform material	SS	SS	SS	CoCr	SS	CoCr PtCr	CoCr	PtCr	CoCr
Strut thickness (µm)	132	140	120	91	87	81	91	74	60
Polymer type	Durable	Durable	Biodegradable	Durable	Biodegradable	Durable	Durable	Biodegradable	Biodegradable
Polymer material	SIBS	PEVA/PBMA	PDLLA	MPC/LMA/HPMA/ 3-MPMA	PDLLA	PBMA/PVDF-HFP	PBMA/PHMA/ PVP/PVA	PLGA	PLLA
Coating distribution	Circumferential	Circumferential	Abluminal	Circumferential	Circumferential	Circumferential	Circumferential	Abluminal	Circumferential
Polymer thickness (µm)	22	13	10	6	5	8	6	4	7
Additional coating	-	-	-	-	-	-	-	-	Silicon carbide
Drug released	Paclitaxel	Sirolimus	Biolimus	Zotarolimus	Sirolimus	Everolimus	Zotarolimus	Everolimus	Sirolimus

Source: Stefanini, Taniwaki, Windecker. *Heart* 2013, ahead of print

Benchtest Results: Crossing Profile

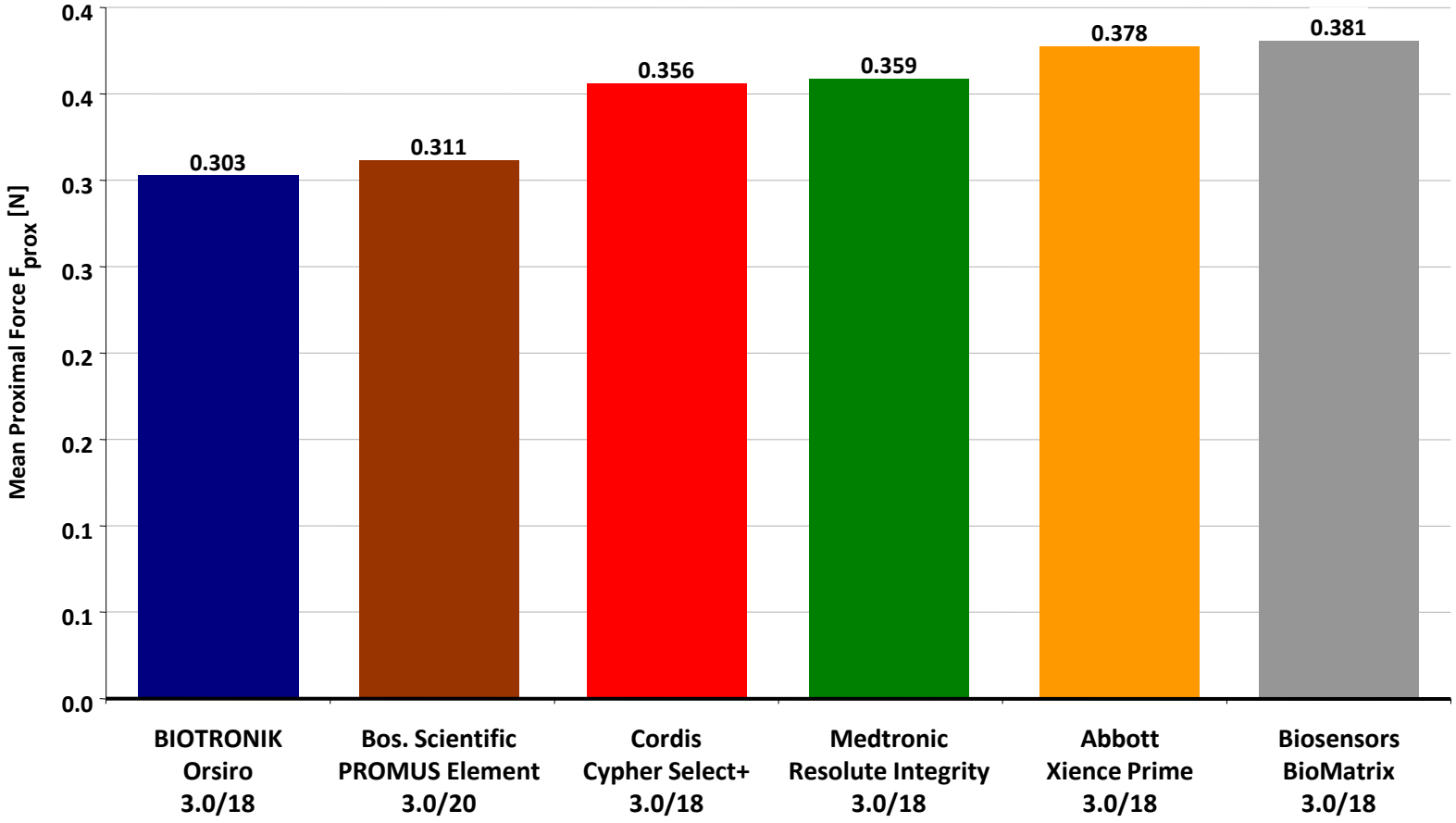
Stent profile of crimped stents as a mean value over the entire stent



Source: Comparative investigation of Coronary Stent Systems, Institute for Implant Technology and Biomaterials. Rostock, Germany 2011.

Benchtest Results: Crossability

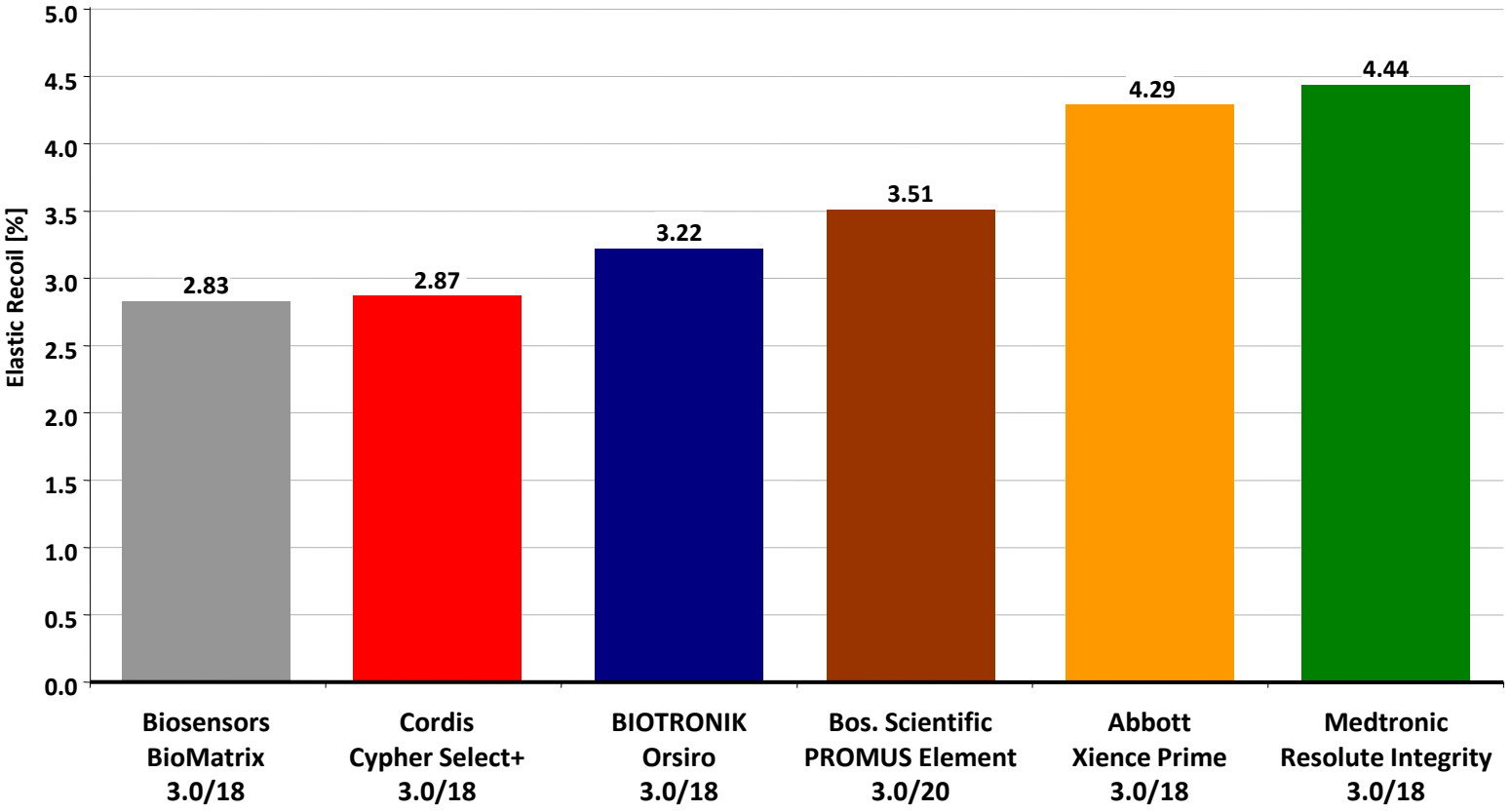
Mean proximal forces of crossability tests, stenosis model



Source: Comparative investigation of Coronary Stent Systems, Institute for Implant Technology and Biomaterials. Rostock, Germany 2011.

Benchtest Results: Elastic Recoil

Measured recoil values

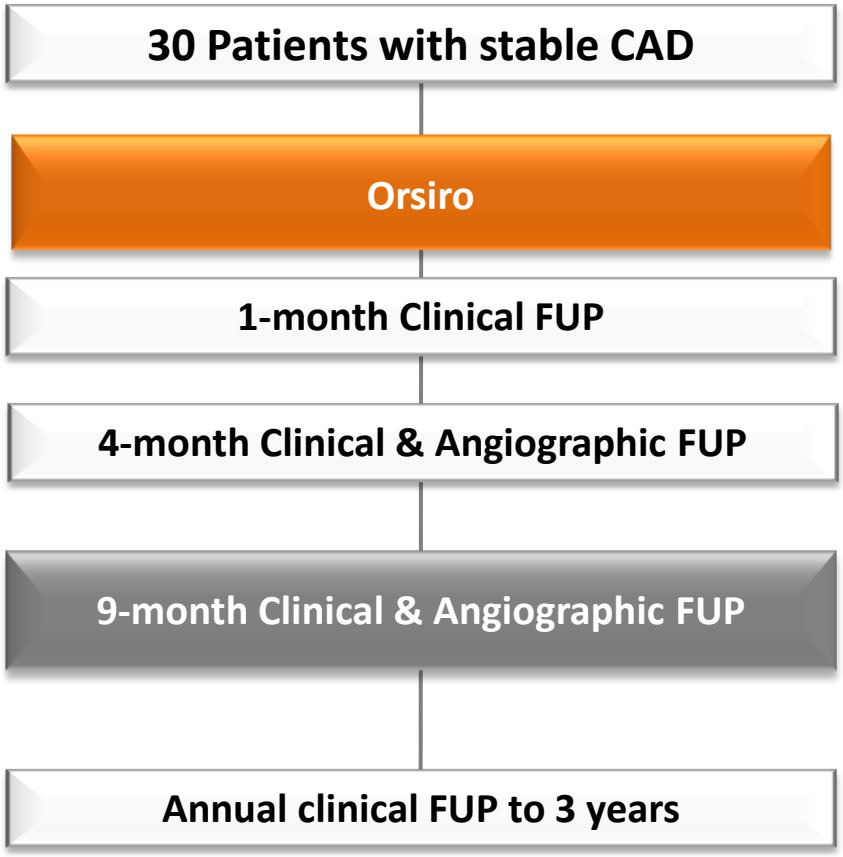


Source: Comparative investigation of Coronary Stent Systems, Institute for Implant Technology and Biomaterials. Rostock, Germany 2011.

BIOFLOW-I (FIM)

BIOFLOW-I

- DESIGN: Prospective, multicenter, non-randomized, first-in-man trial
- OBJECTIVE: To assess the safety and clinical performance of the Orsiro in coronary de-novo coronary artery lesions
- PRIMARY ENDPOINT: LLL at 9 months
- Clinical coordinate investigator:
  Prof. Martial Hamon,
  University Hospital of Caen, France
- PRINCIPAL INVESTIGATORS:
  Dr. Rodica Niculescu, MD, PhD, FESC, Dr. Dan Deleanu, MD, FESC



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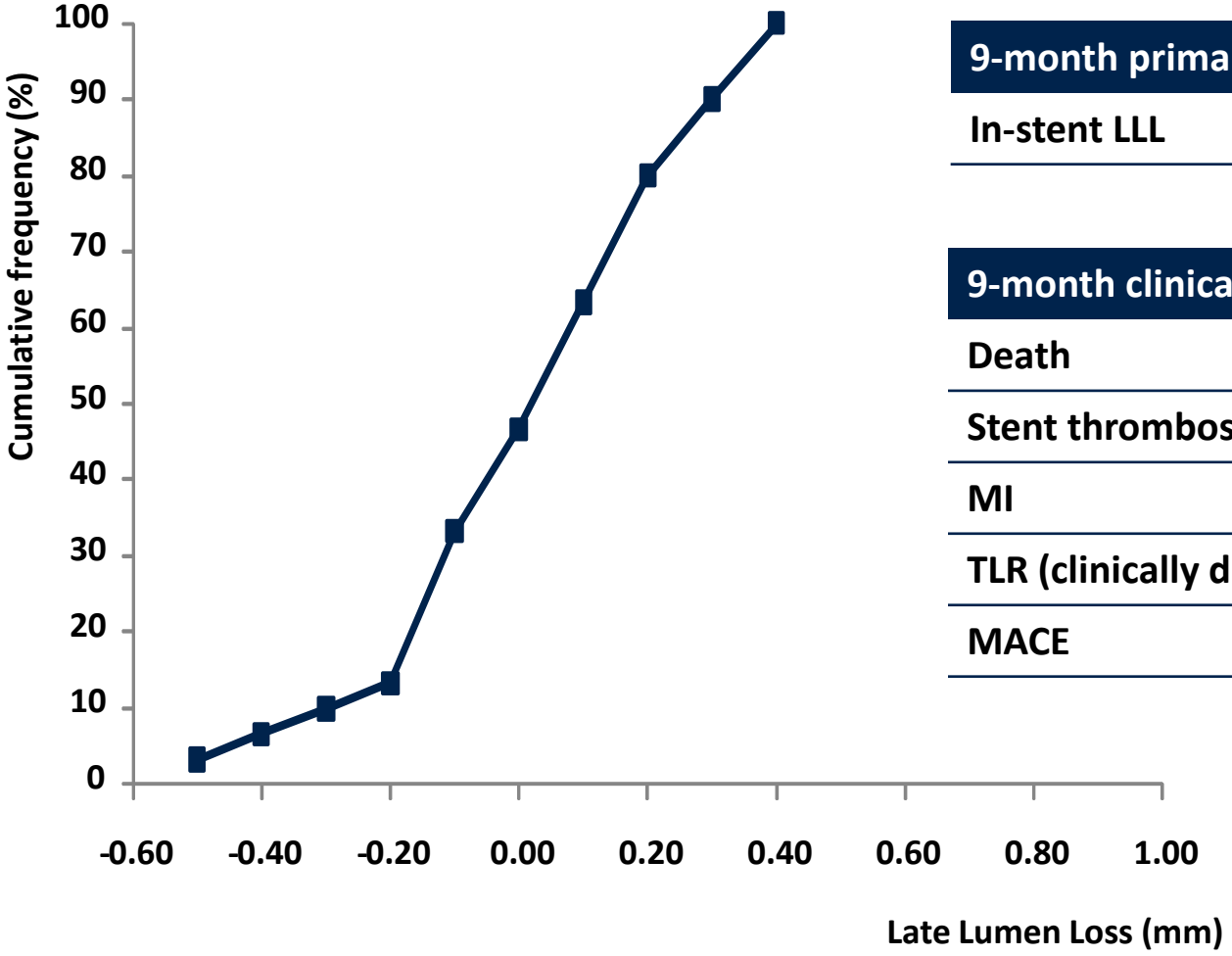
BIOFLOW-I Results

BIOFLOW-I



9-month primary endpoint	n=30
In-stent LLL	0.05 ± 0.22 mm

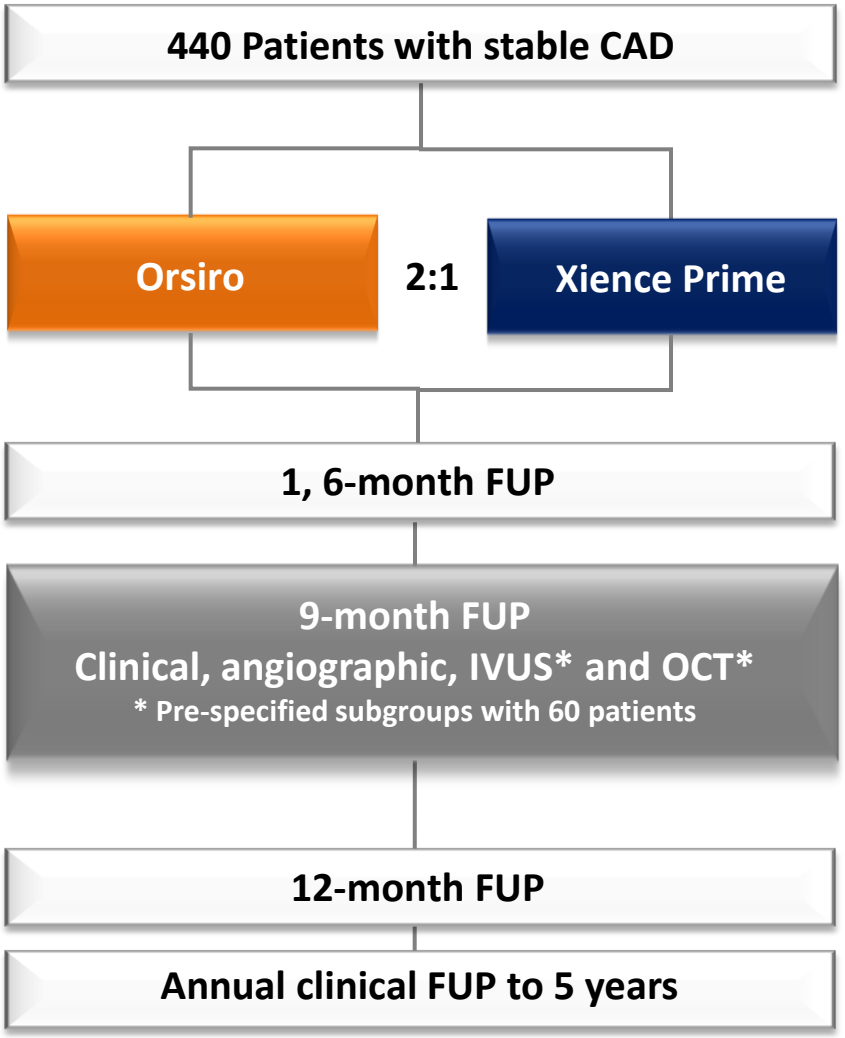
9-month clinical results	n	%
Death	0	0.0
Stent thrombosis	0	0.0
MI	0	0.0
TLR (clinically driven)	2	6.7
MACE	2	6.7

Source: Hamon M., et al. *EuroIntervention* 2013;8:1006-1011.

BIOFLOW-II Study Design

BIOFLOW-II

- DESIGN: A prospective, multicenter, international, non-inferiority, randomized controlled study
- OBJECTIVE: To compare the Orsiro to Xience Prime in de-novo coronary lesions
- PRIMARY ENDPOINT: In-stent late lumen loss at 9 months
- Co-PIs:
  Stephan Windecker
  University Hospital Bern, Switzerland
  Thierry Lefevre
  Hospital Jacques Cartier, Massy, France



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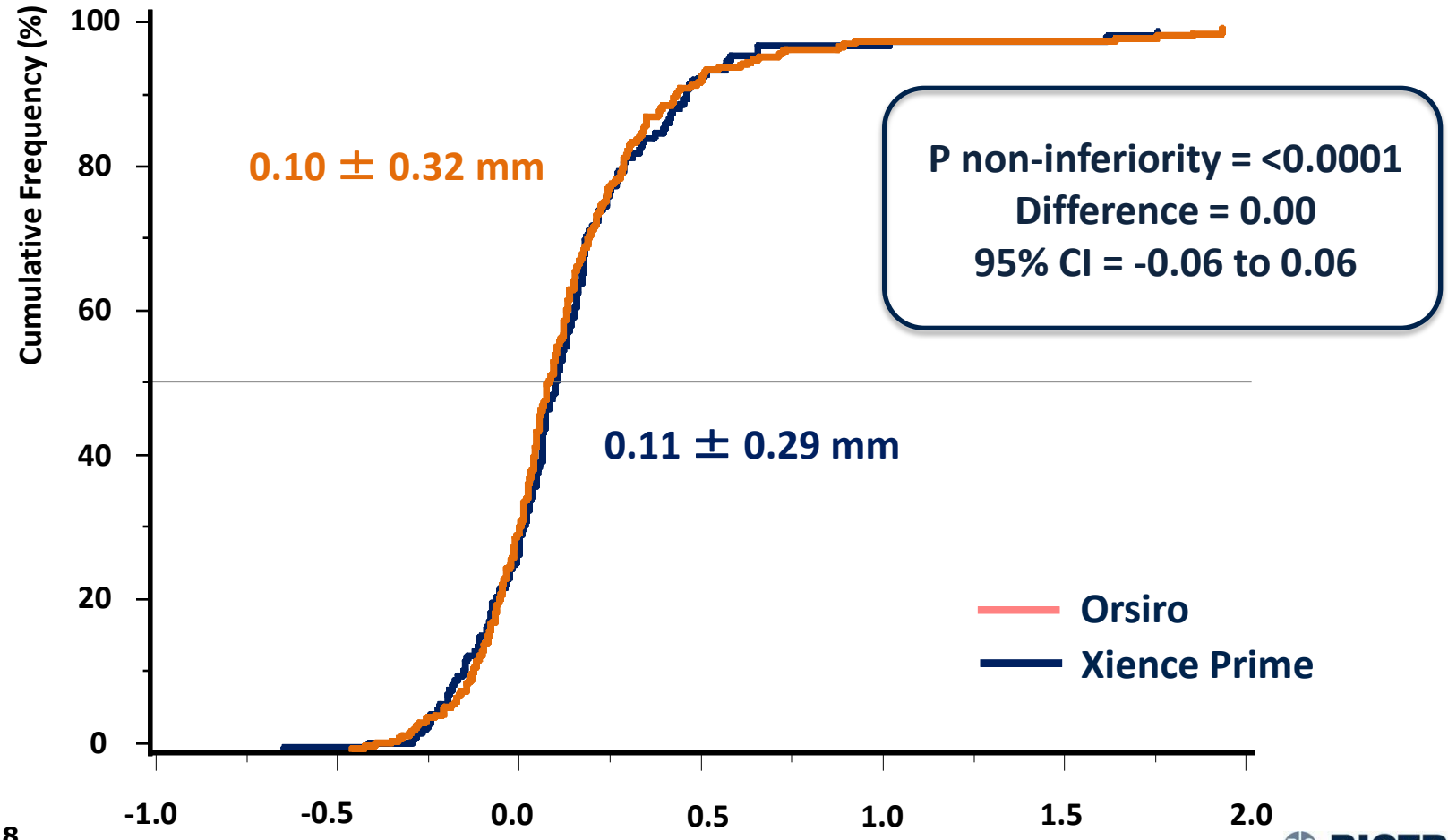
Primary Angiographic Endpoint

BIOFLOW-II

Cumulative frequency of in-stent late loss at 9 months (mm)



Source: Windecker S. EuroPCR, Paris, France. 21 May 2013. Oral presentation.

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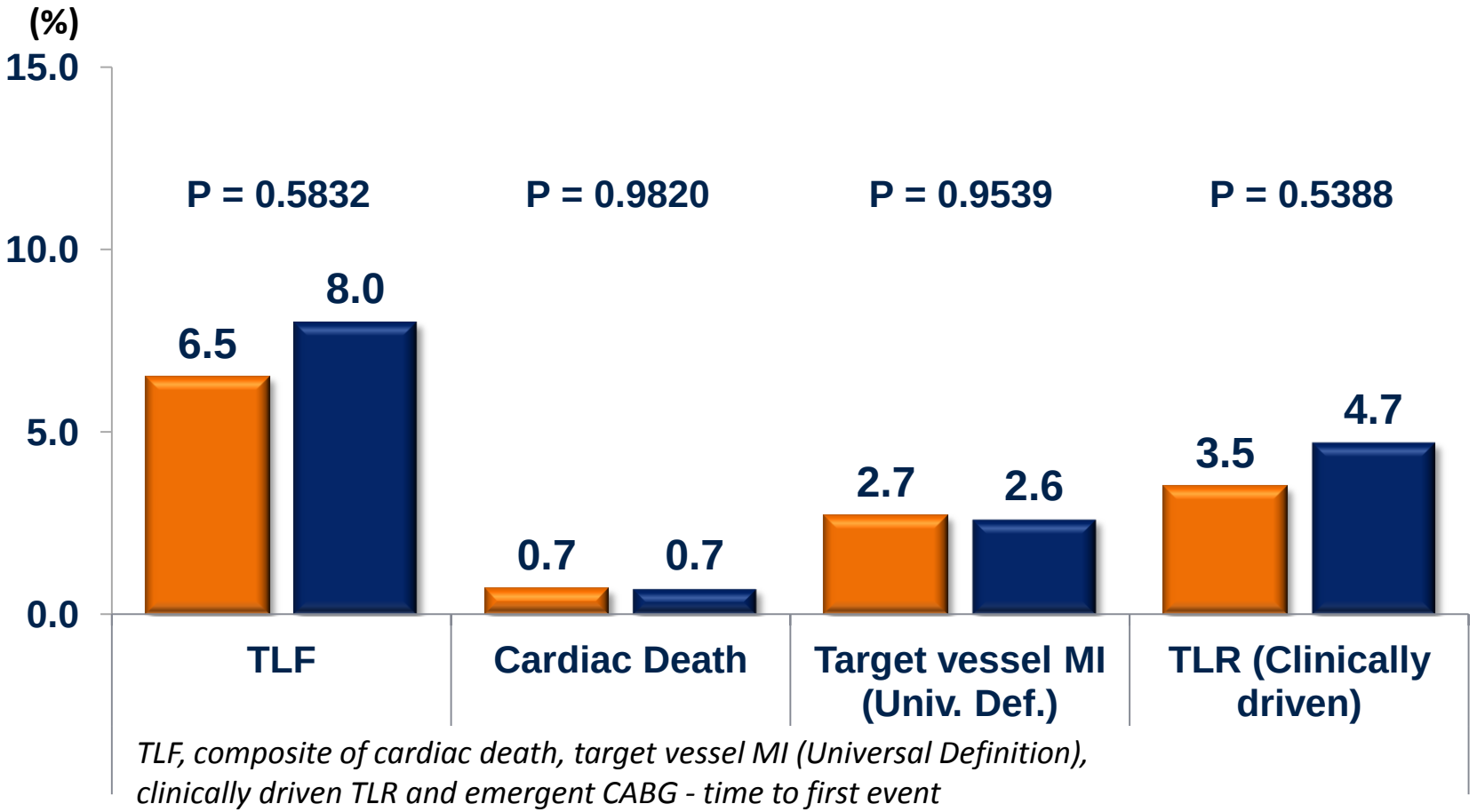
Target Lesion Failure Clinical Outcome at 12 Months

BIOFLOW-II



TLF, composite of cardiac death, target vessel MI (Universal Definition), clinically driven TLR and emergent CABG - time to first event

All events have been adjudicated by an independent clinical event committee

Source: Windecker S. TCT, San Francisco, USA, October 2013. Oral presentation.

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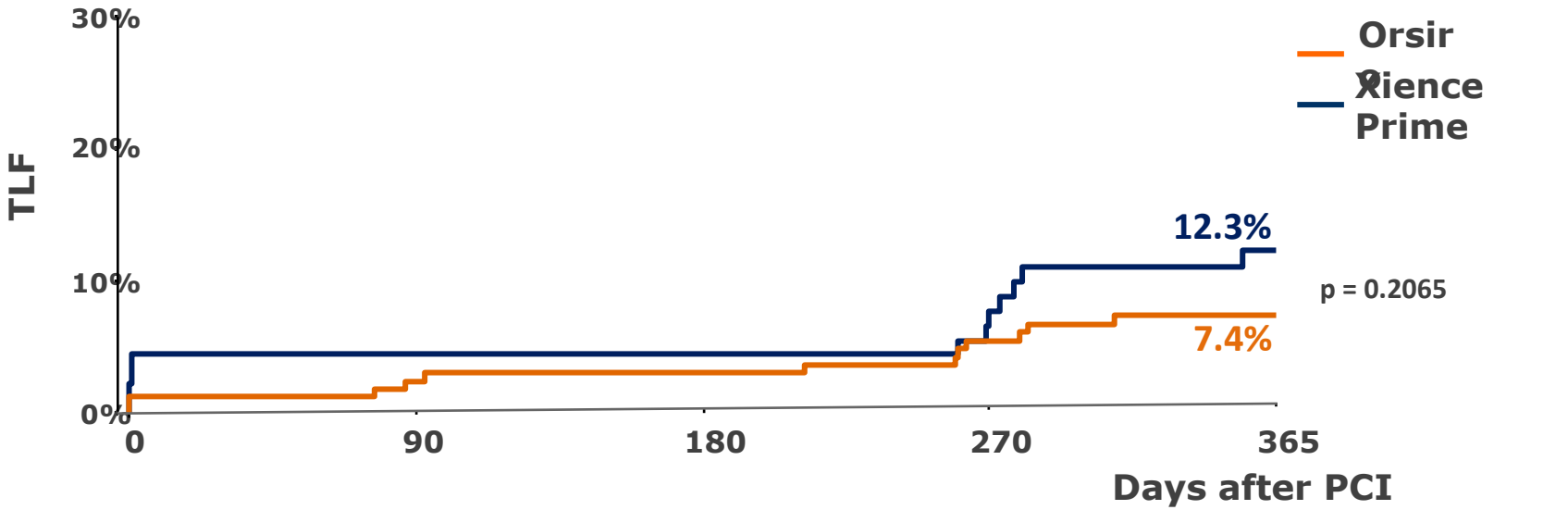
Small Vessel Subgroup (RVD ≤ 2.75 mm) Results

BIOFLOW-II



	Orsiro	Xience Prime	P value
In-stent LLL[1]	0.13 ± 0.33	0.15 ± 0.31	0.2025
Cardiac Death[2]	0.0	1.2	0.1752
Target vessel MI[2]	2.4	4.4	0.3749
TLR (Clinically driven)[2]	5.5	6.7	0.7447

[1] Nine-month follow-up
[2] Twelve-month follow-up

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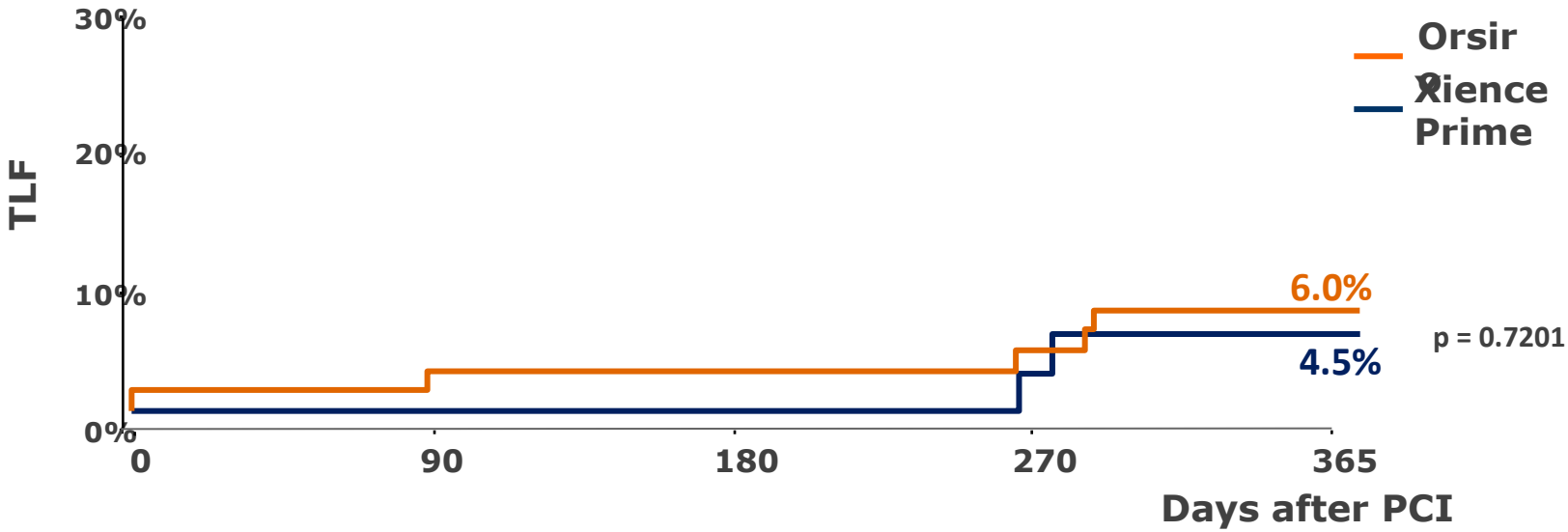
Diabetic Subgroup Results

BIOFLOW-II



	Orsiro	Xience Prime	P value
In-stent LLL[1]	0.10 ± 0.28	0.08 ± 0.32	0.5057
Cardiac Death[2]	0.0	0.0	1.0000
Target vessel MI[2]	1.2	0.0	0.4692
TLR (Clinically driven)[2]	4.9	4.5	0.9375

[1] Nine-month follow-up
[2] Twelve-month follow-up

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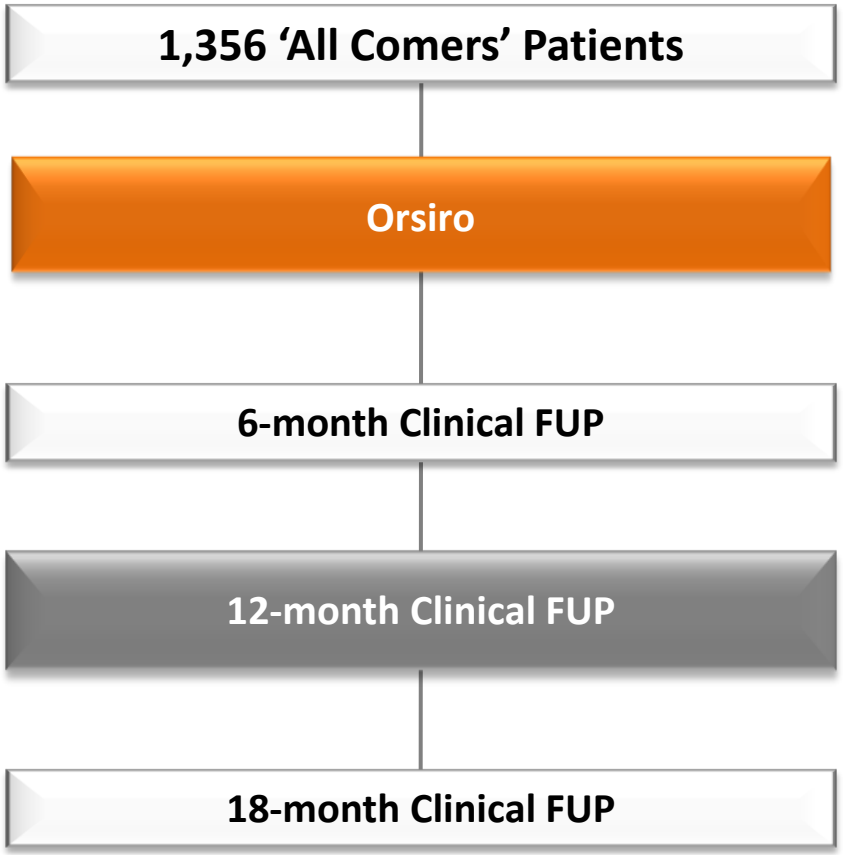
BIOFLOW-III Study Design

BIOFLOW-III

- DESIGN
  International, prospective, non-randomized, multicenter, open-label clinical evaluation
- OBJECTIVE
  To assess the clinical performance of the ORSIRO in coronary arteries in an “all comers” population
- PRIMARY ENDPOINT
  TLF at 12 months
- COORDINATING INVESTIGATOR:
  Johannes Waltenberger
  University Hospital Muenster, Germany



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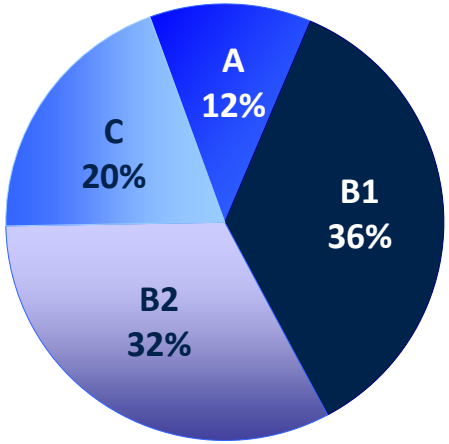
Patient Characteristics

BIOFLOW-III

Patients	N = 1,356
Age (mean ± SD)	66 ± 11 yrs
Male % (N)	72% (971)
Age ≥ 75 yrs	25% (335)
Hypertension	76% (1,029)
Hypercholesteremia	60% (815)
Smoking	55% (741)
Diabetes mellitus	30% (403)
Insulin dependent	34% (138)
Non-Insulin dependent	66% (256)
History of MI	28% (376)
Acute MI	33% (442)
Lesion	**N = 1,738**
Small vessels (≤2.75mm)	48% (828)*
Chronic Total Occlusion	4% (65)

*Related to 1,724 lesions

ACC/AHA Lesion Classification



Lesion length (mm ± SD)	15.8 ± 9.1
Ref. vess. diameter (mm ± SD)	3.0 ± 0.4
Diameter stenosis (% ± SD)	85.6 ± 13.4
Moderate calcification	24%
Severe calcification	7%
Bifurcation	16%

Source: Waltenberger J. TCT, San Francisco, USA. October 2013. Poster.

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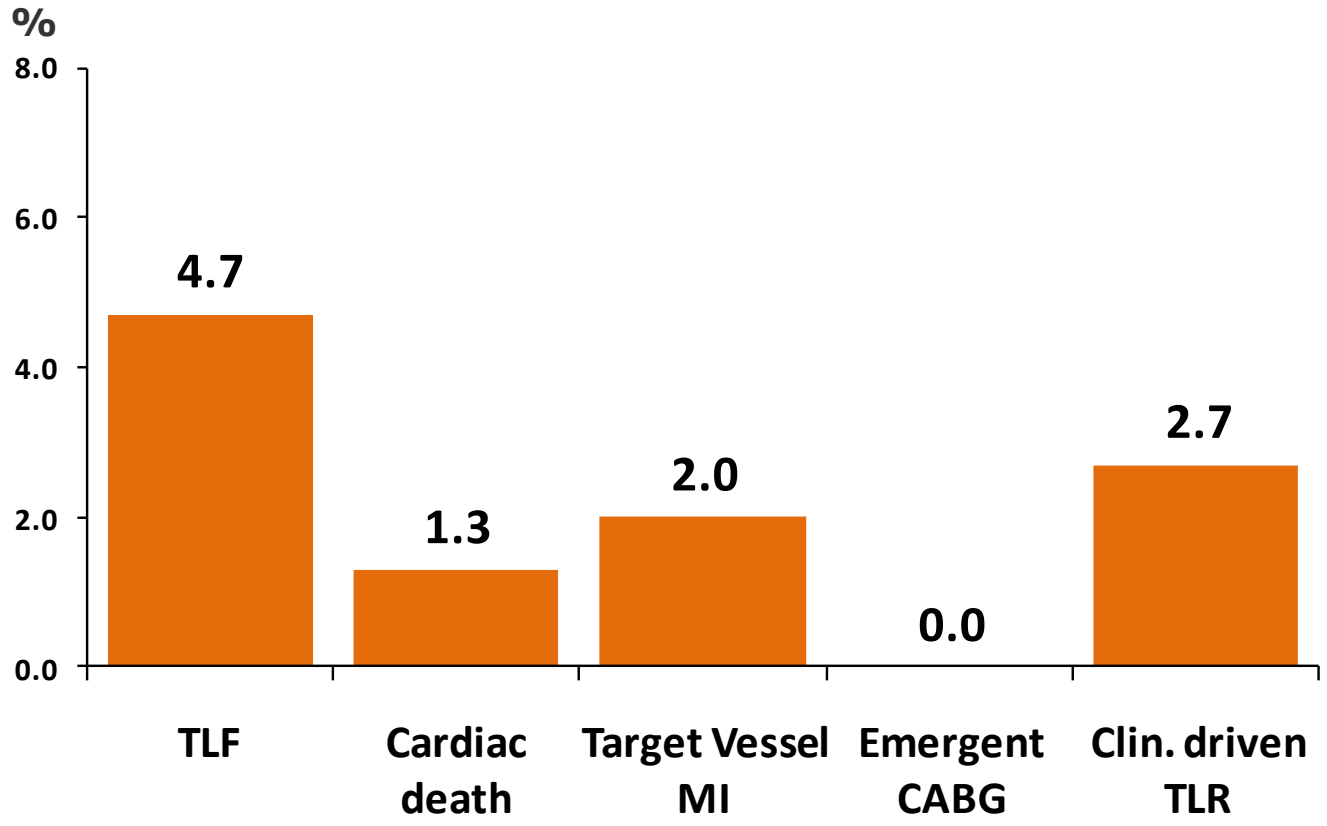
Primary Endpoint Target Lesion Failure (TLF) up to 12 months

BIOFLOW-III



Source: Waltenberger J. TCT, San Francisco, USA. October 2013. Poster.

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Secondary endpoints

BIOFLOW-III

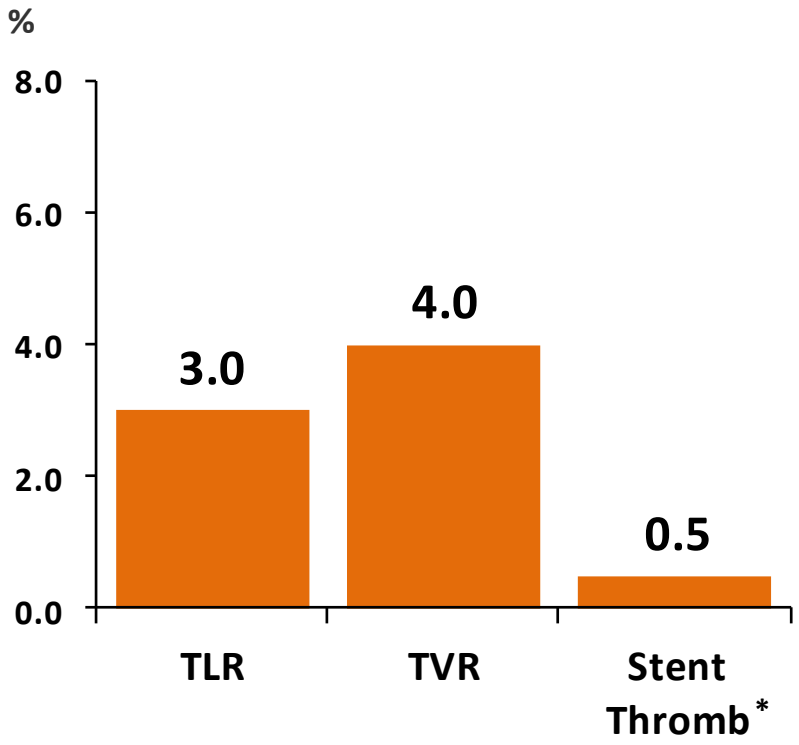
Device and procedure success

Devices	N = 1,738
Device success	**98.7%**
Procedures	N = 1,356
Procedure success	**98.2%**

Device Success: Successful delivery/deployment, withdrawal of the delivery system with attainment of a final residual stenosis of less than 50% by visual estimation.

Procedure Success: Device Success without the occurrence of ID-MACE during hospital stay to 7 days post index procedure.

12 months



*According to ARC definition: Includes definite and probable stent thrombosis

Source: Waltenberger J. TCT, San Francisco, USA. October 2013. Poster.

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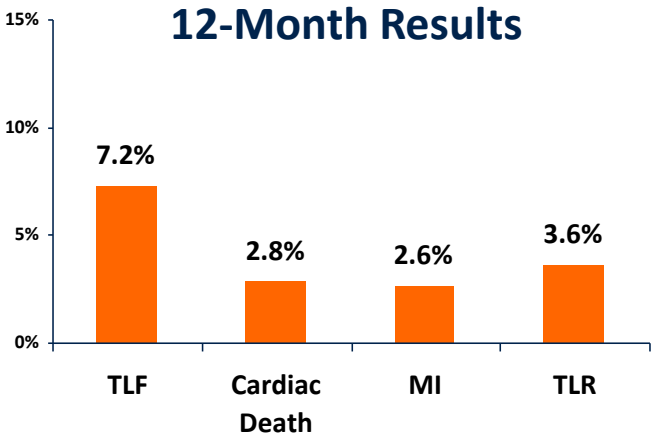
Diabetic subgroup analysis

BIOFLOW-III

Patients N = 1,355*	Diabetics N = 403	Non-diabetics N = 952	P-value
Age (mean yrs ± SD yrs)	68.6 ± 10	65.1 ± 11	< 0.0001
Hypertension	87% (352)	71% (677)	< 0.0001
Hypercholesteremia	64% (256)	59% (559)	0.0986
Insulin dependent	34% (138)	0% (0)	n/a
Non-Insulin dependent	66% (265)	0% (0)	n/a



Lesions N = 1,738	Diabetics N = 519	Non-diabetics N = 1,218	P-value
B2/C type lesions	49% (255)	53% (649)	0.1129
Stents N = 1,842	**N = 597**	**N = 1,375**	
Mean stent length (mm)	18.1 ± 5.7	18.2 ± 5.8	0.9777
Mean stent diameter (mm)	3.0 ± 0.4	3.0 ± 0.4	0.4503

	Diabetics	Non-diabetics
Device success	99.0%	98.6%
Procedure success	98.0%	98.2%

* Unknown diabetic status N=1

Source: Waltenberger J. TCT, San Francisco, USA. October 2013. Poster.

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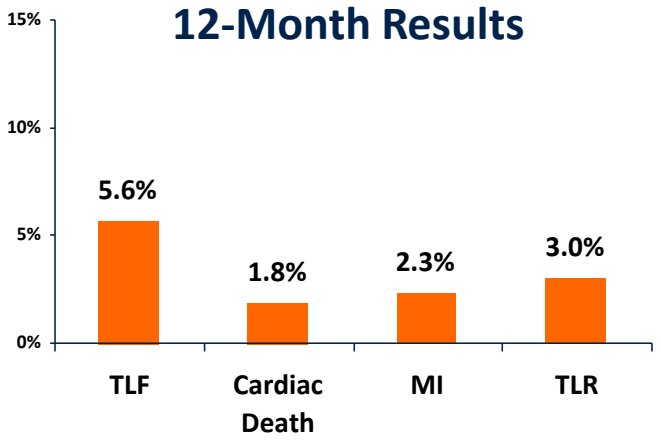
Small vessel subgroup analysis

BIOFLOW-III

Patients N= 1,341*	≤ 2.75mm** N = 575	>2.75mm N = 766	P-value
Age (mean yrs ± SD yrs)	67.2 ± 11	65.3 ± 11	0.0012
Hypertension	79% (454)	74% (567)	0.0359
Hypercholesteremia	61% (351)	59% (454)	0.5115
Diabetes	33% (188)	28% (211)	0.0412
Non-Insulin dependent	60% (113)	71% (149)	0.0273
Insulin dependent	40% (75)	30% (62)	



Lesions N = 1,724	≤ 2.75mm N = 828	>2.75mm N = 896	P-value
B2/C type lesions	50% (413)	55% (490)	0.0458
Stents N = 1,957	**N = 931**	**N = 1,026**	
Mean stent length (mm SD)	17.7 ± 5.7	18.5 ± 5.9	0.0011
Mean stent diameter (mm)	2.7 ± 0.3	3.2 ± 0.4	< 0.0001

	Small Vessels	Non-small Vessels
Device success	99.3%	98.2%
Procedure success	98.3%	98.0%

*Unknown Vessel diameter N=15
**Reference vessel diameter (RVD) ≤2.75mm

Source: Waltenberger J. TCT, San Francisco, USA. October 2013. Poster.

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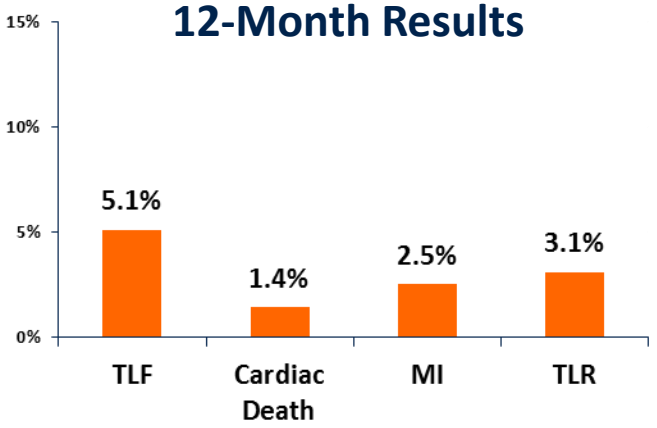
Complex lesion subgroup analysis

BIOFLOW-III

Patients N= 1,356*	B2/C N = 743	A/B1 N = 611	P-value
Age (mean yrs ± SD yrs)	66.3 ± 10.8	66.0 ± 10.7	0.6256
Hypertension	76% (561)	76% (466)	0.7769
Hypercholesteremia	61% (454)	59% (359)	0.3477
Diabetes	28% (207)	32% (195)	0.1076
Insulin dependent	35% (72)	33% (65)	0.7593
Non-Insulin dependent	65% (135)	67% (130)	

Lesions N = 1,289	B2/C N = 705	A/B1 N = 584	P-value
Lesion Length (mm)	17.6 ± 10.4	13.1 ± 5.8	<0.0001
RVD (mm)	3.0 ± 0.4	3.0 ± 0.4	0.0070
Diameter stenosis (%)	87.6 ± 11.3	84.4 ± 10.6	<0.0001
Calcification - Moderate	26.0	20.7	0.0102
Calcification – Severe (%)	10.7	2.0	<0.0001
Bifurcation (%)	19.8	11.1	<0.0001
CTO (%)	6.0	1.2	<0.0001
Tortuosity – Excessive (%)	4.1	0.8	<0.0001

12-Month Results



	B2/C	A/B1
Device success	99.3	99.7
Procedure success	98.2	99.2

* Two subjects with unknown lesion type not included in analysis

Source: Vander Hayden J. EuroPCR, Paris, France. May 2014 2013. Oral presentation.

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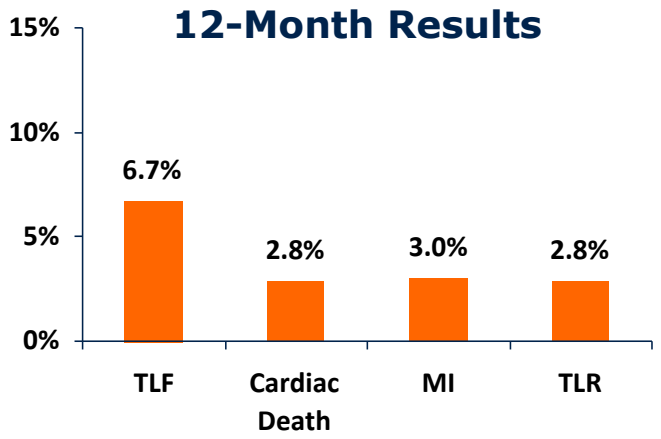
Acute MI subgroup analysis

BIOFLOW-III

Patients N = 1,356	Acute MI N = 442	Others N = 914	P-value
Age (mean yrs ± SD yrs)	64.9 ± 12	66.7 ± 10	0.0033
Hypertension	66% (293)	81% (736)	< 0.0001
Hypercholesteremia	50% (222)	65% (593)	< 0.0001
Diabetes	26% (115)	32% (288)	0.0381
Non-Insulin dependent	61% (70)	68% (195)	0.1914
Insulin dependent	39% (45)	32% (93)	



Lesions N = 1,738	Acute MI N = 519	Others N = 1,218	P-value
B2/C type lesions	58% (318)	50% (587)	0.0013
Stents N = 1,973	N = 614	N = 1,359	
Mean stent length (mm)	18.0 ± 5.7	18.2 ± 5.8	0.5785
Mean stent diameter (mm)	3.0 ± 0.4	2.9 ± 0.4	0.0014

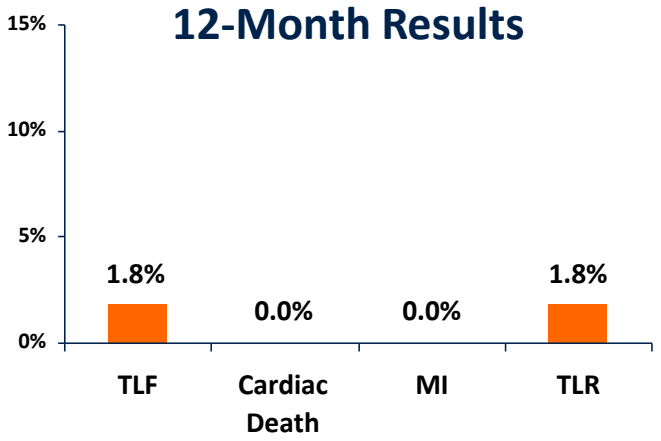
	Acute MI	Others
Device success	98.2%	99.0%
Procedure success	97.1%	98.7%

Source: Waltenberger J. EuroPCR, Paris, France. 21 May 2013. Oral presentation.

CTO subgroup analysis

BIOFLOW-III

Patients N= 1,265*	CTO N = 58	Non-CTO N = 1,207	P-value
Age (mean yrs ± SD yrs)	64.7 ± 10	66.1 ± 11	0.3212
Hypertension	81% (47)	76% (919)	0.3914
Hypercholesteremia	60% (35)	60% (722)	0.9362
Diabetes	28% (16)	29% (346)	0.8589
Non-Insulin dependent	63% (10)	67% (230)	0.7423
Insulin dependent	38% (6)	34% (116)	



Lesions N = 1,613	CTO N = 83	Non-CTO N = 1,530	P-value
B2/C type lesions	81% (67)	51% (785)	< 0.0001
Stents N = 1,842	**N = 120**	**N = 1,722**	
Mean stent length (mm)	20.4 ± 6.6	18.0 ± 5.7	< 0.0001
Mean stent diameter (mm)	2.9 ± 0.4	3.0 ± 0.4	0.0043

	CTO	Non-CTO
Device success	100.0%	98.6%
Procedure success	100.0%	97.9%

*Unknown CTO status N=91

Source: Waltenberger J. TCT, San Francisco, USA. October 2013. Poster.

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BIOSCIENCE Trial

Randomised comparison of a novel, ultrathin strut biodegradable polymer sirolimus-eluting stent with a durable polymer everolimus-eluting stent for percutaneous coronary revascularization

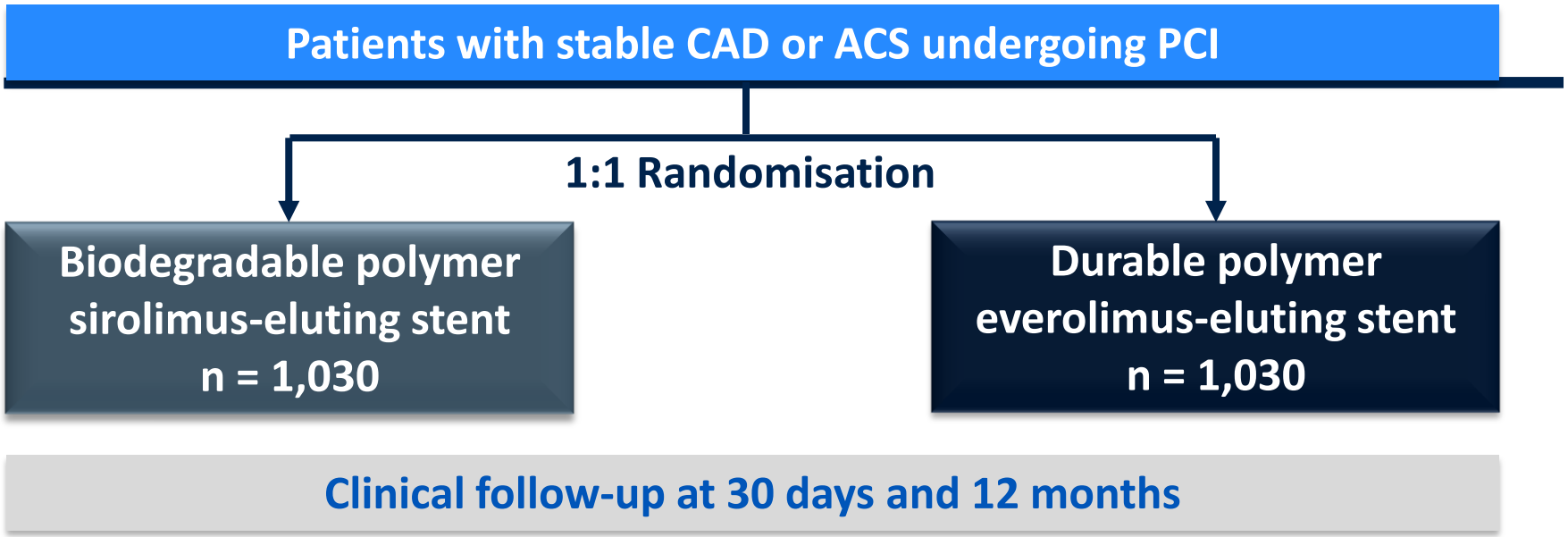
NCT01443104

- **Thomas Pilgrim, MD; Dik Heg, PhD; Marco Roffi, MD; David Tüller, MD;**
- **Olivier Muller, MD; André Vuilliomenet, MD; Stéphane Cook, MD;**
- **Daniel Weilenmann, MD; Christoph Kaiser, MD; Peiman Jamshidi, MD;**
- **Bernhard Meier, MD; Peter Jüni, MD; Stephan Windecker, MD**
-
- Department of Cardiology, Swiss Cardiovascular Center, University Hospital, Bern; Institute of Social and Preventive Medicine and Clinical Trials Unit
- Bern University Hospital, Switzerland1

OBJECTIVE

- To compare the safety and efficacy of a novel, ultrathin strut, biodegradable polymer based sirolimus-eluting stent with a thin strut, durable polymer everolimus-eluting stent for percutaneous coronary revascularization.

TRIAL DESIGN



PRIMARY ENDPOINT

Composite of cardiac death, target vessel myocardial infarction, and clinically-indicated target lesion revascularization at 12 months

SECONDARY ENDPOINTS

Death, cardiac death, myocardial infarction, TLR, TVR, definite ST, definite and probable ST, target vessel failure

ELIGIBILITY FOR PATIENT ENROLLMENT

Inclusion criteria

- Age ≥ 18 years
- Coronary artery disease
  - stable CAD, silent ischemia
  - acute coronary syndromes: UA, NSTEMI, and STEMI
- At least one lesion with diameter stenosis >50% in a native coronary artery or a bypass graft
  - no. of vessels: no limitation
  - no. of lesions: no limitation
  - lesion length: no limitation

Exclusion criteria

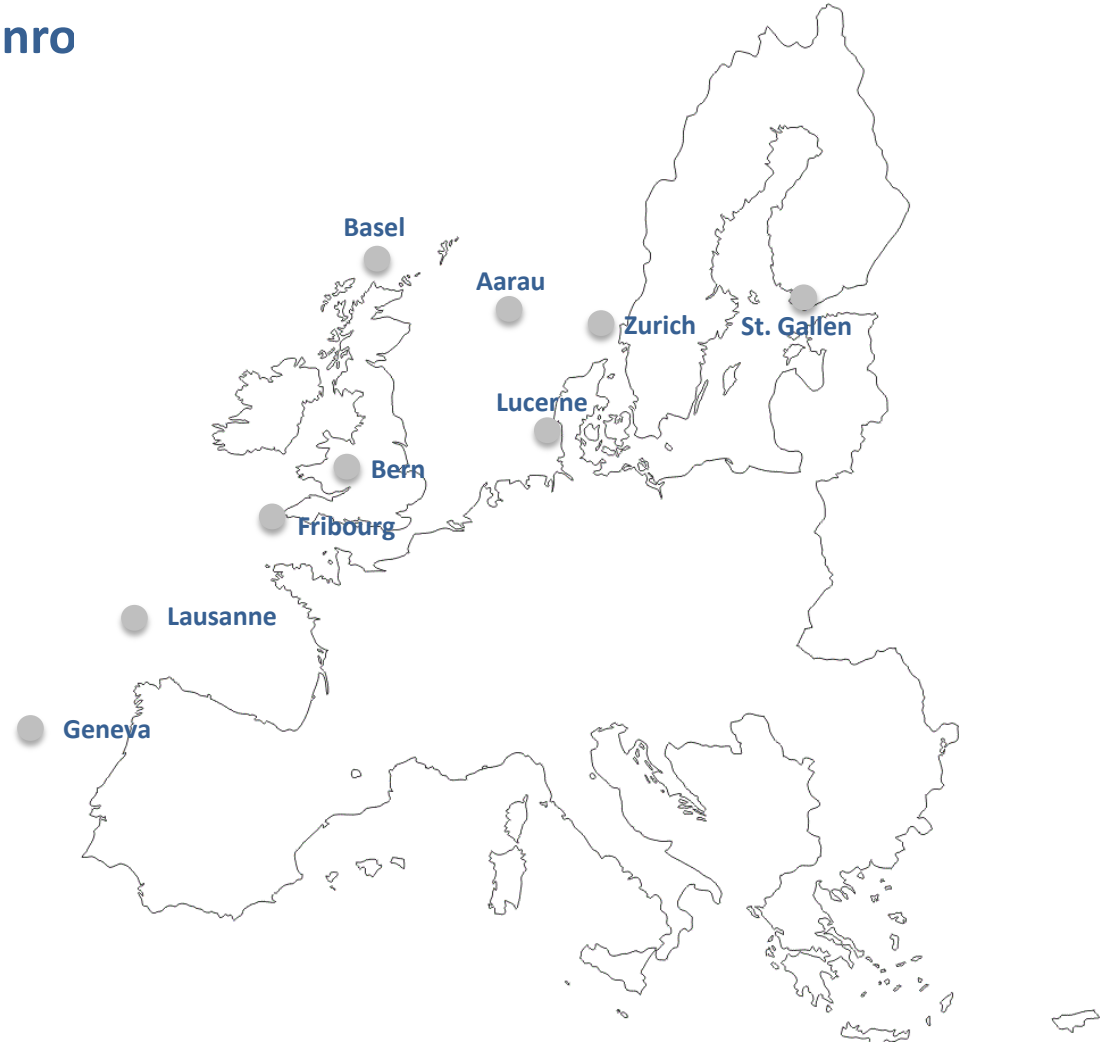
- Pregnancy
- Planned surgery within 6 months of PCI
- Intolerance to aspirin, clopidogrel, heparin, sirolimus, everolimus, contrast material
- Inability to provide informed consent
- Participation in another trial

PATIENT RECRUITMENT

February 2012 to May 2013

2,119 patients were enro

Investigator	City	Patients
Thomas Pilgrim, MD	Bern	1,216
Marco Roffi, MD	Geneva	209
David Tüller, MD	Zurich	179
André Vuilliomenet, MD	Aarau	102
Olivier Muller, MD	Lausanne	101
Stéphane Cook, MD	Fribourg	100
Daniel Weilenmann, MD	St. Gallen	99
Christoph Kaiser, MD	Basel	60
Peiman Jamshidi, MD	Lucerne	53



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BASELINE CHARACTERISTICS

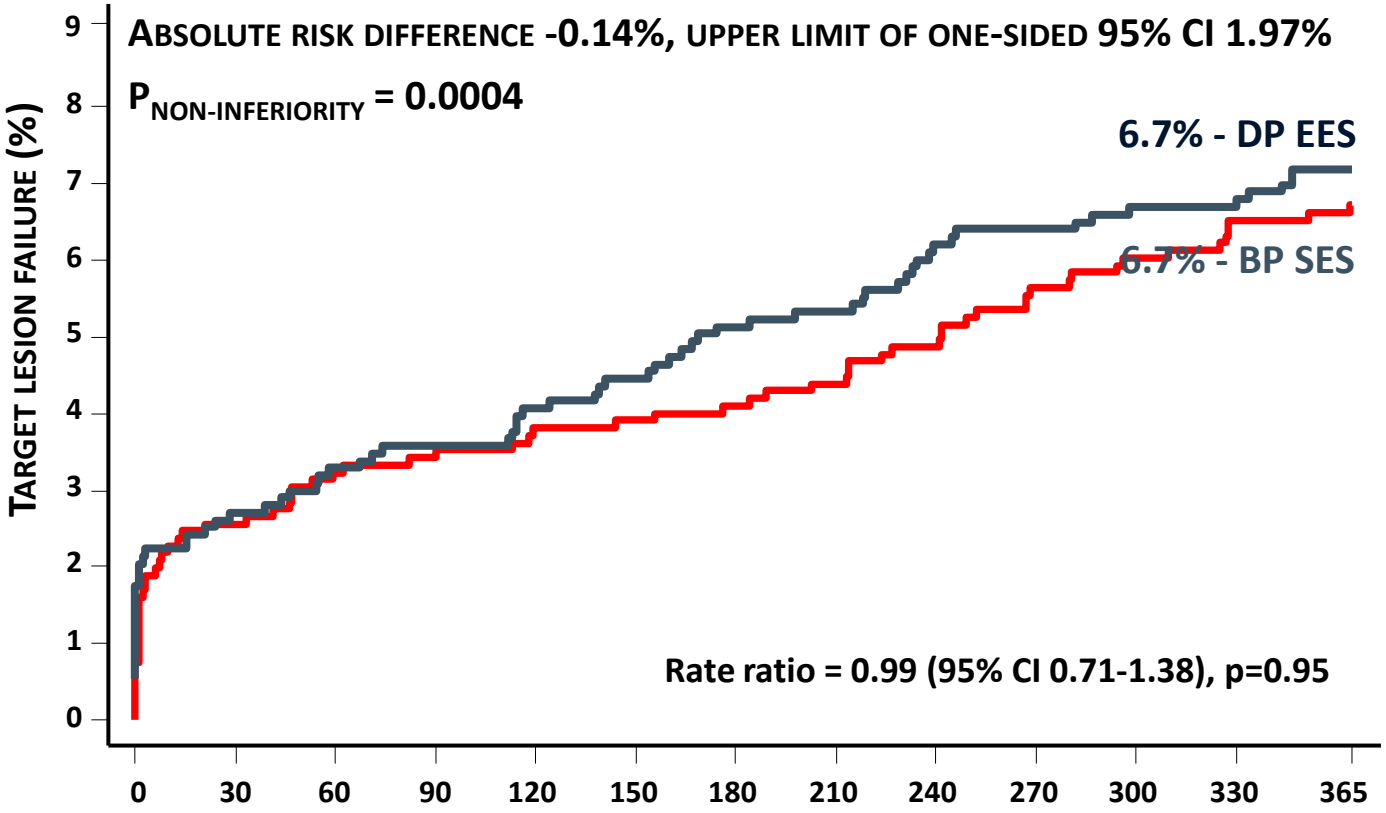
	BP SES (n=1,063)	DP EES (n=1,056)
Age (years) — mean ± SD	66.1 ± 11.6	65.9 ± 11.4
Male gender — n (%)	818 (77%)	816 (77%)
Diabetes mellitus — n (%)	257 (24%)	229 (22%)
Hypertension — n (%)	728 (69%)	706 (67%)
Hypercholesterolemia — n (%)	712 (67%)	716 (68%)
Previous PCI — n (%)	325 (31%)	292 (28%)
Previous CABG — n (%)	113 (11%)	98 (9%)
Renal Failure (GFR<60 ml/min) — n (%)	151 (15%)	130 (13%)
Left ventricular ejection fraction (%) — mean ± SD	55.7 ± 12.1	55.9 ± 12.6
Indication — n (%)		
Unstable angina	78 (7%)	74 (7%)
Non ST-segment elevation MI	288 (27%)	284 (27%)
ST-segment elevation MI	211 (20%)	196 (19%)
Stable angina	325 (31%)	332 (31%)
Silent ischemia	161 (15%)	171 (16%)

ANGIOGRAPHIC CHARACTERISTICS

	BP SES (n=1,594)	DP EES (n=1,545)
Target-vessel location per lesion — n (%)		
Left main artery	29 (2%)	27 (2%)
Left anterior descending artery	649 (41%)	679 (44%)
Left circumflex artery	370 (23%)	341 (22%)
Right coronary artery	505 (32%)	452 (29%)
Saphenous vein graft	38 (2%)	40 (3%)
Arterial graft	3 (0.2%)	6 (0.4%)
Number of treated lesions per patient — mean ± SD	1.50 ± 0.79	1.46 ± 0.73
Number of stents per lesion — mean ± SD	1.31 ± 0.61	1.34 ± 0.64
Total stent length per lesion (mm) — mean ± SD	25.91 ± 15.40	27.45 ± 16.77
Maximum stent diameter per lesion (mm) — mean ± SD	3.05 ± 0.49	3.03 ± 0.49
Off-label stent use per lesion — n (%)	690 (46%)	735 (50%)
Long lesion per lesion (>20 mm) — n (%)	826 (54%)	839 (57%)
Small-vessel per lesion (<2.75 mm) — n (%)	439 (29%)	468 (32%)

PRIMARY ENDPOINT

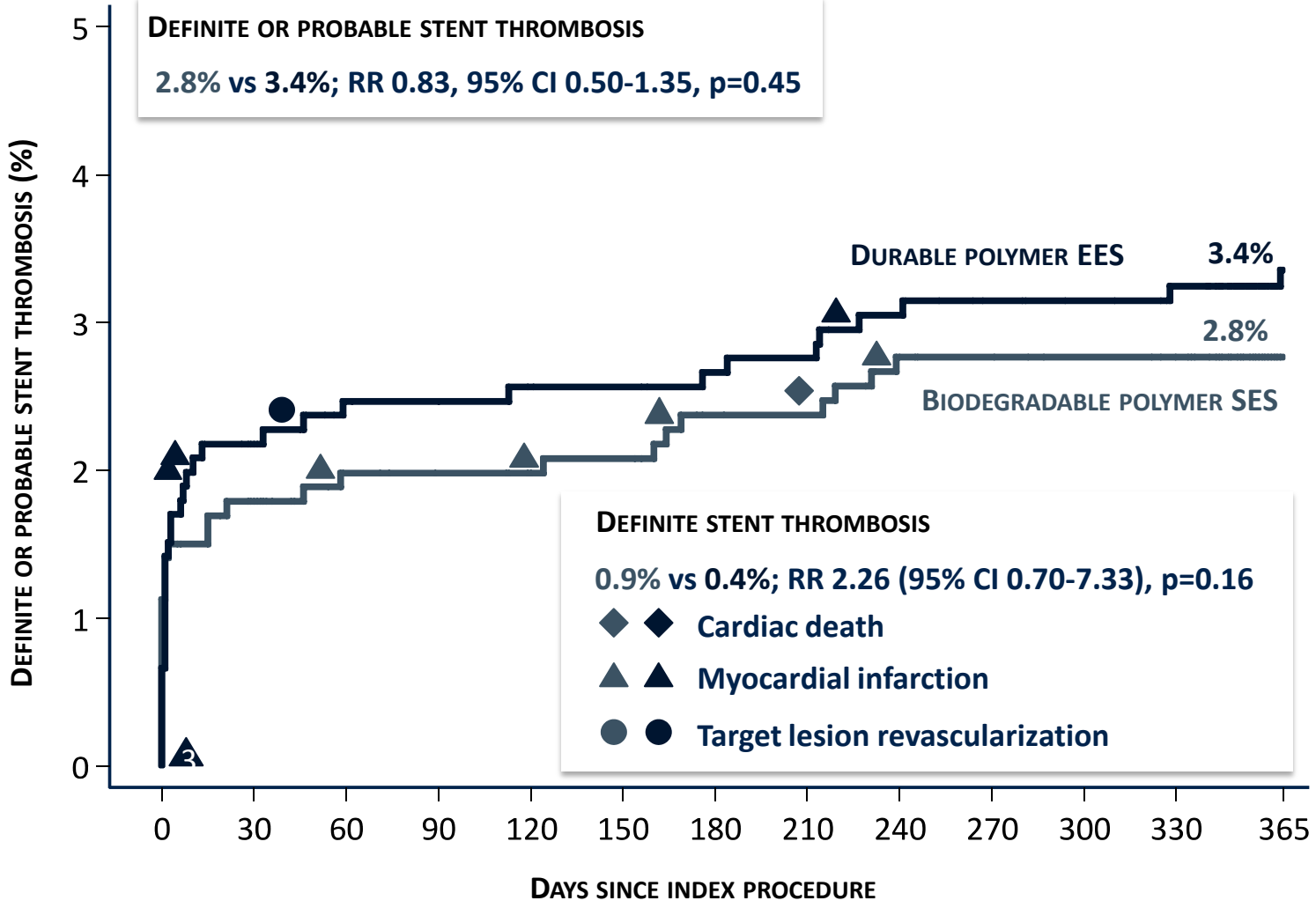
TARGET LESION FAILURE



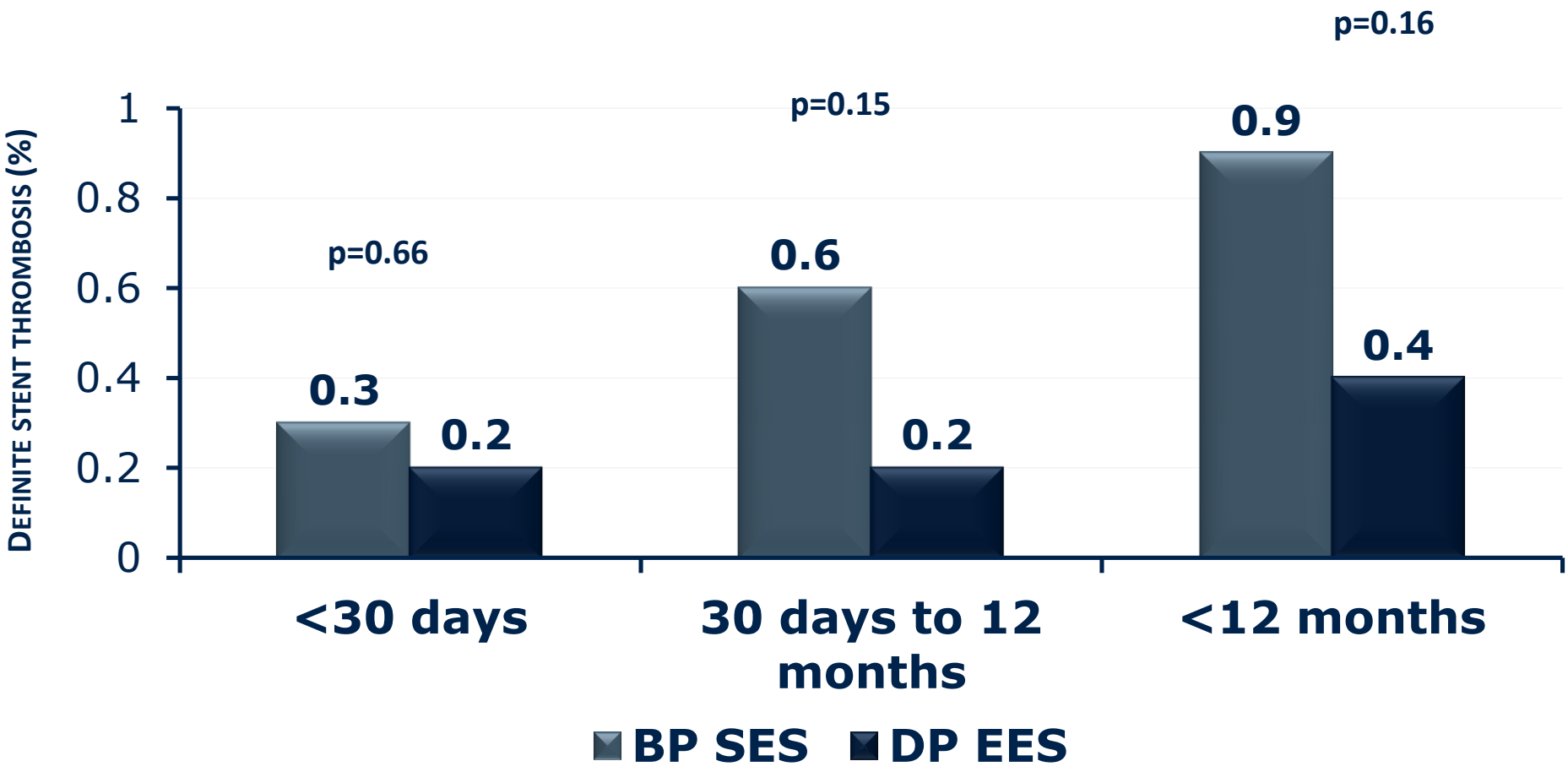
NUMBER AT RISK

DP EES	1056	1021	1004	1002	998	996	994	991	985	975	971	966	945
BP SES	1063	1025	1004	1000	993	988	980	977	967	964	960	958	941

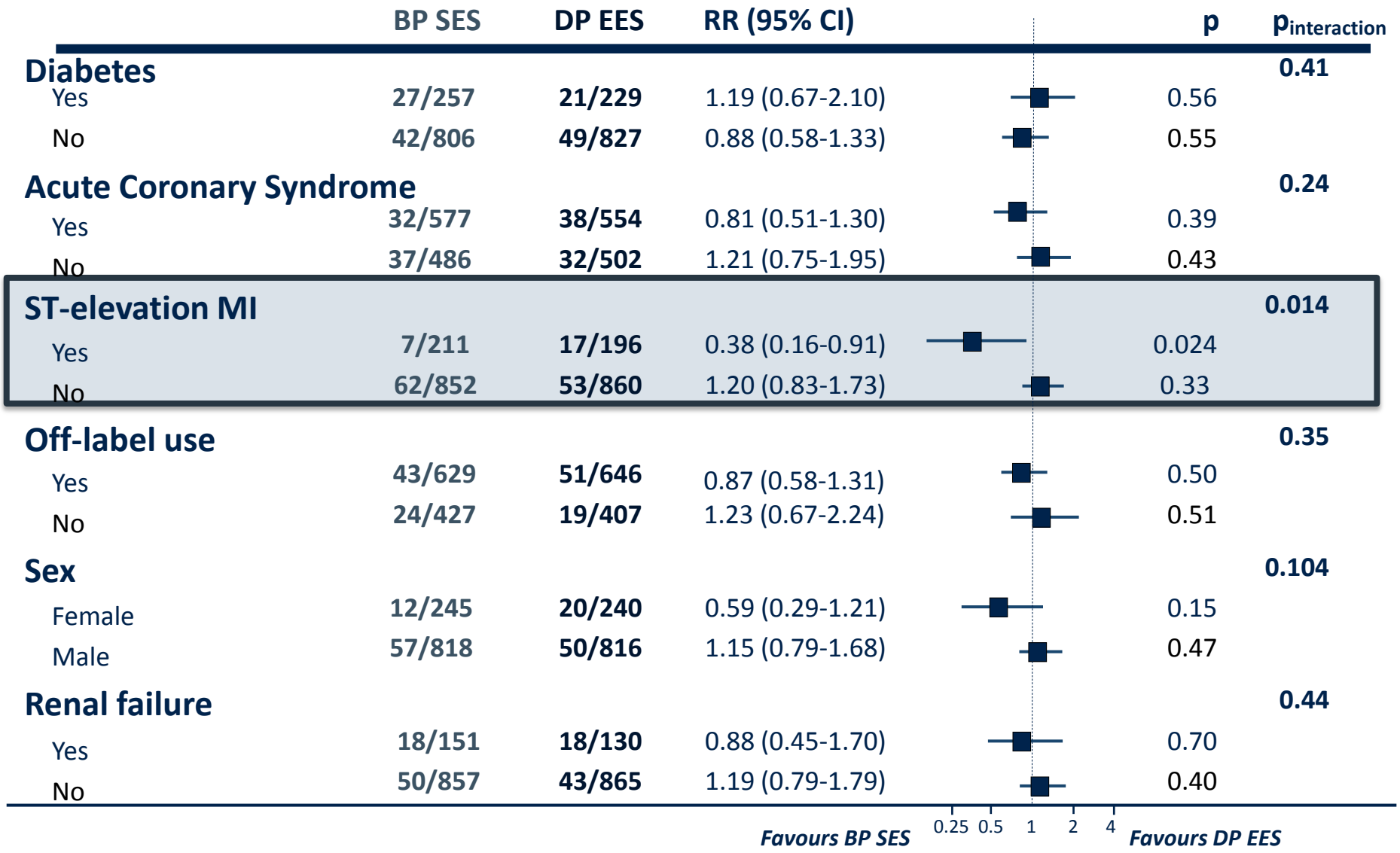
STENT THROMBOSIS



DEFINITE STENT THROMBOSIS



STRATIFIED ANALYSIS OF PRIMARY ENDPOINT



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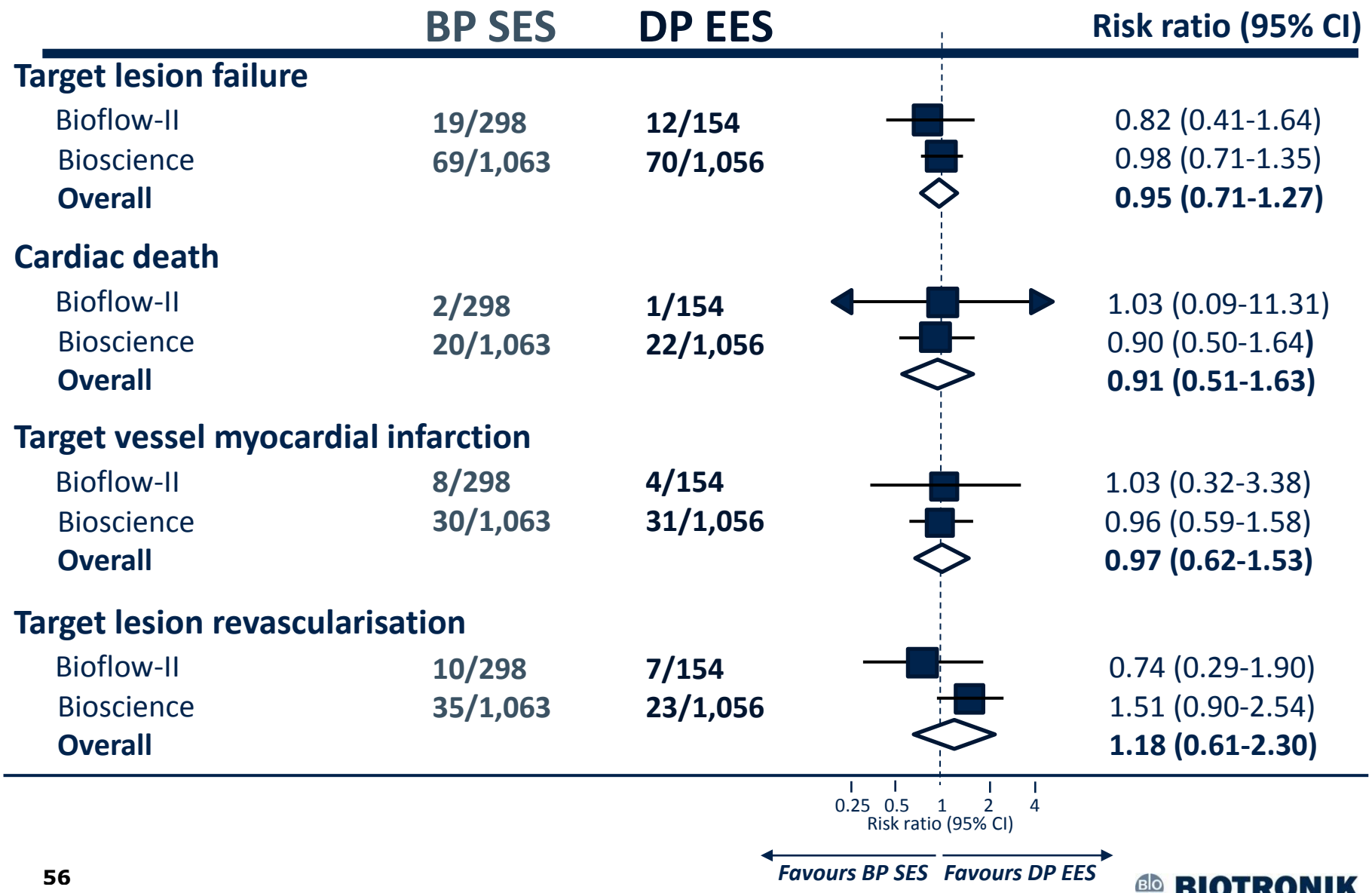
LIMITATIONS

- Missing information on patients assessed for eligibility, but not included into the trial.
- The trial was powered for the primary composite outcome but not individual components.
- The primary endpoint results were determined at 12 months precluding conclusions regarding the long-term safety and efficacy.
- One third of patients had undergone previous PCI and some adverse events may have been related to previously implanted devices.

META-ANALYSIS OF BIOSCIENCE AND BIOFLOW II



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CONCLUSIONS

- Ultrathin strut biodegradable polymer sirolimus-eluting stents were non-inferior to durable polymer everolimus-eluting stents for the primary endpoint target lesion failure at 1 year in a population with minimal exclusion criteria.
- The observed benefit in the subgroup of patients with ST-segment elevation myocardial infarction warrants confirmation in appropriately designed studies.

Ultrathin strut biodegradable polymer sirolimus-eluting stent versus durable polymer everolimus-eluting stent for percutaneous coronary revascularisation (BIOSCIENCE): a randomised, single-blind, non-inferiority trial

Thomas Pilgrim, Dik Heg*, Marco Roffi, David Tüller, Olivier Muller, André Vuilliomenet, Stéphane Cook, Daniel Weilenmann, Christoph Kaiser, Peiman Jamshidi, Therese Fahrni, Aris Moschovitis, Stéphane Noble, Franz R Eberli, Peter Wenaweser, Peter Jüni, Stephan Windecker*

Summary

Background Refinements in stent design affecting strut thickness, surface polymer, and drug release have improved clinical outcomes of drug-eluting stents. We aimed to compare the safety and efficacy of a novel, ultrathin strut cobalt-chromium stent releasing sirolimus from a biodegradable polymer with a thin strut durable polymer everolimus-eluting stent.

Methods We did a randomised, single-blind, non-inferiority trial with minimum exclusion criteria at nine hospitals in Switzerland. We randomly assigned (1:1) patients aged 18 years or older with chronic stable coronary artery disease or acute coronary syndromes undergoing percutaneous coronary intervention to treatment with biodegradable polymer sirolimus-eluting stents or durable polymer everolimus-eluting stents. Randomisation was via a central web-based system and stratified by centre and presence of ST segment elevation myocardial infarction. Patients and outcome assessors were masked to treatment allocation, but treating physicians were not. The primary endpoint, target lesion failure, was a composite of cardiac death, target vessel myocardial infarction, and clinically-indicated target lesion revascularisation at 12 months. A margin of 3·5% was defined for non-inferiority of the biodegradable polymer sirolimus-eluting stent compared with the durable polymer everolimus-eluting stent. Analysis was by intention to treat. The trial is registered with ClinicalTrials.gov, number NCT01443104.

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*TP and DH contributed equally

Department of Cardiology, Swiss Cardiovascular Center, University Hospital, Bern, Switzerland (T Pilgrim MD, T Fahrni RN, A Moschovitis MD, Prof P Wenaweser MD, Prof S Windecker MD); Department of Cardiology, University Hospital, Geneva, Switzerland (Prof M Roffi MD, ent of

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Orsiro clinical program

	Study	Study design	N	Primary endpoint	Status
BIOTRONIK initiated	BIOFLOW-I	FIM	30	9-mo LLL	Study completed
	BIOFLOW-INDIA	Indian single-armed trial	120	9-mo LLL	Study completed
	BIOFLOW-III	International registry	1000	12-mo TLF	Study completed
	BIOFLOW-II	International, RCT vs. Xience Prime	440	9-mo LLL	Primary endpoint reached
	BIOFLOW-III	Satellite registries	>3,000	12-mo TLF	Enrolling
	BIOFLOW-IV	Japanese approval study, international RCT	555	12-mo TLF	Enrolling
	BIOLUX RCT	RCT vs. Pantera Lux in ISR	210	6-mo LLL	Enrolling
Investigator initiated	HAT-TRICK-OCT	RCT vs. Integrity	40	3-mo strut coverage	Study completed
	ORSIRO OCT	RCT vs. Xience Prime	60	6- & 24-mo strut coverage	Enrollment completed
	BIOSCIENCE	RCT vs. Xience Prime	2,100	12-mo TLF	Enrollment completed
	SORT OUT VII	RCT vs. Nobori	2,314	12-mo TLF	Enrollment completed
	PRISON-IV	International, RCT vs. Xience Prime	330	9-mo LLL	Enrolling
	BIO-RESORT	RCT vs. Synergy & Integrity	3,530	12-mo TVF	Enrolling
	ORIENT	RCT vs. Integrity	345	9-mo LLL	Enrolling

Personal Experience

- Currently commercially available in Australia. Long lengths available up to 40mm.
- Rapidly becoming DES of choice due to deliverability, ease of use and emerging efficacy and safety data
- My first experience – Live case in Vietnam. Diffuse, tortuous and calcified LAD. 3.0 x 26mm stent had no difficulty delivering to mid LAD.
- Recruited first patient for Bioflow IV trial this week.