Revolutioniert der medikamentenfreisetzende Ballon (DEB) die interventionelle Therapie der KHK?

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Universitätsklinikum des Saarlandes

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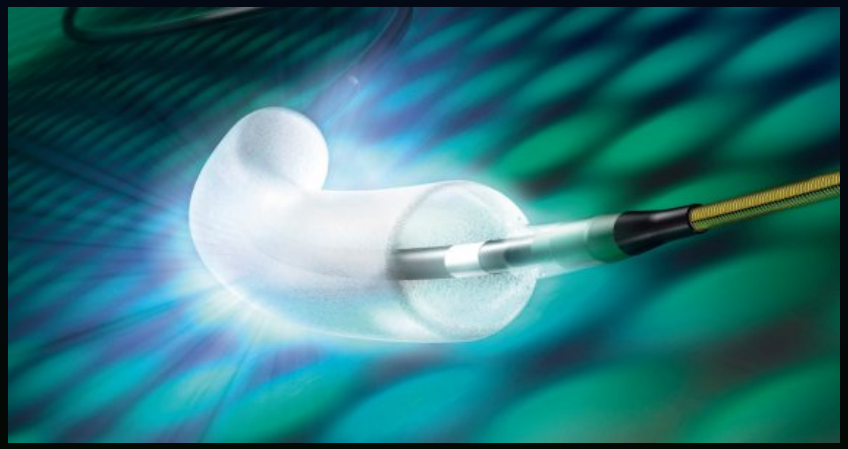
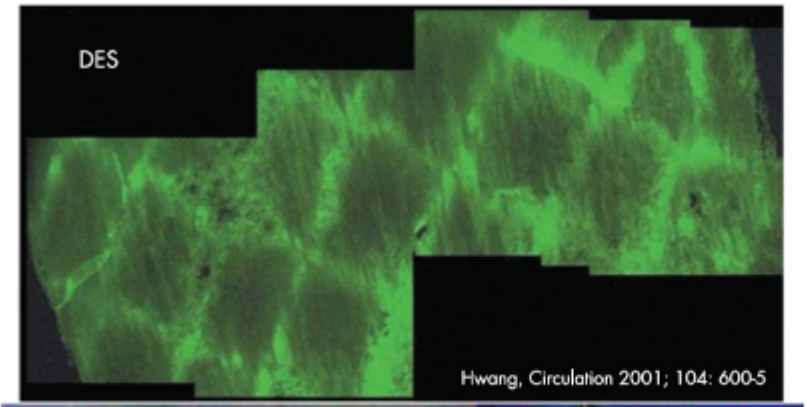
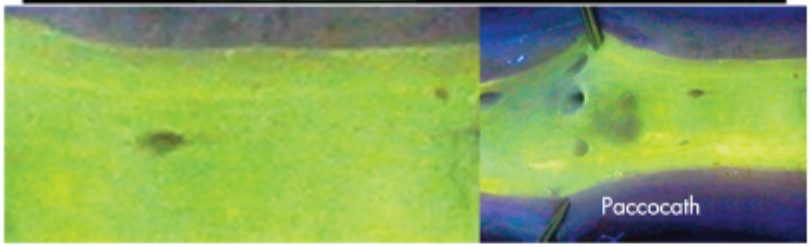
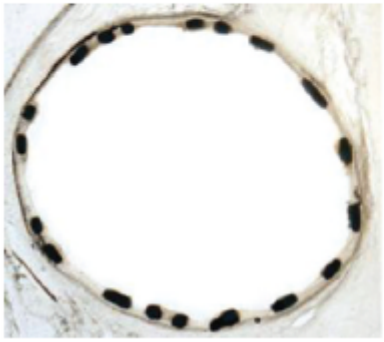
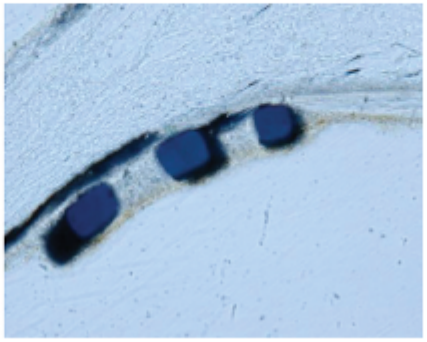


Local Drug Delivery: Paccocath-DEB vs. DES







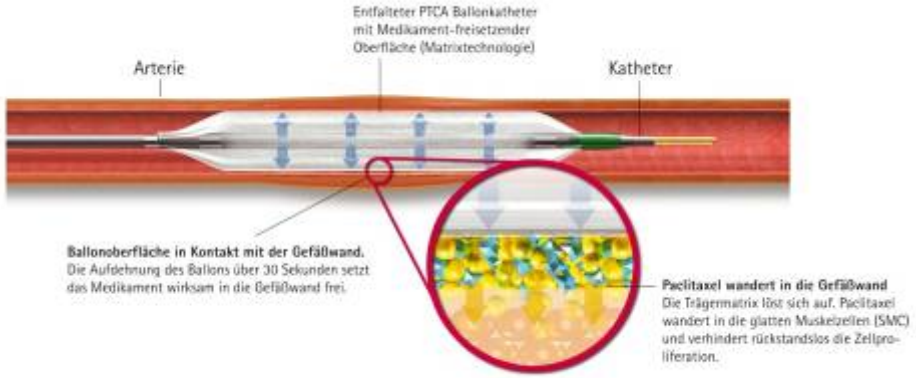


Drug Eluting Stent

- Slow release
- Persistent drug exposure
- ~ 100 - 200 µg dose
- Polymer
- Stent mandatory

Drug Eluting Balloon (PACCOCATH)

- Immediate release
- Short-lasting exposure
- ~ 300 - 600 µg dose
- No polymers
- Premounted stent optional



Scheller et al., Circulation 2004; 110: 810-4, Heart 2007, 93: 539-41

Interventional Rounds

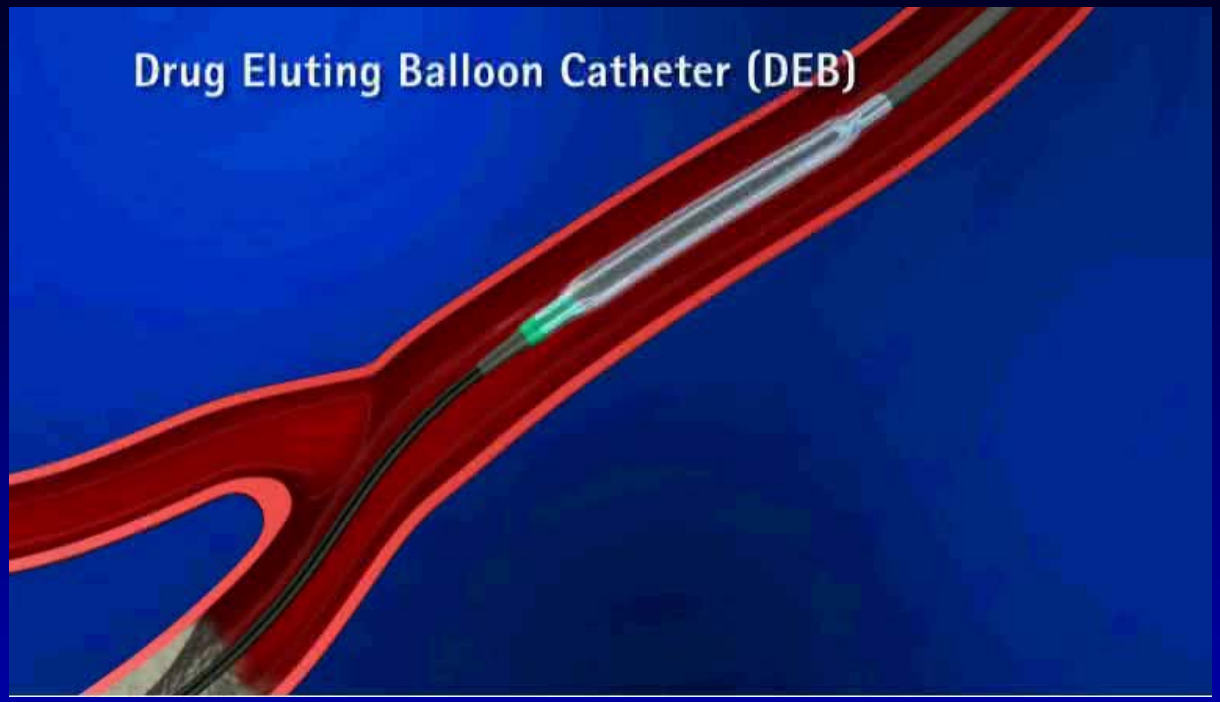
Paclitaxel-Eluting Balloon: From Bench to Bed

Axel De Labriolle, MD, Rajbabu Pakala, PhD, Laurent Bonello, MD, Gilles Lemesle, MD, Mickey Scheinowitz, PhD, and Ron Waksman* MD

"Non-stent-based local drug delivery and, particularly, a drug-eluting balloon could dramatically fulfill the goal of DES without duplicating the issues encountered with this technology. It could be of special interest for high-risk restenotic lesions such as small vessel-, bifurcation-, or in-stent restenotic lesions."

- Homogenous drug transfer to the vessel wall
- Drug concentrations highest at the time of injury (neointimal process most vigorous)
- Absence of drug could help to better re-endothelialize the stent (if used)
- Absence of polymer (decreased stimulus of chronic inflammation)
- Absence of stent (original anatomy / physiology of the arteries)
- Overdependence on antiplatelet therapy could be limited
- Local drug delivery possible in situations in which stents are not used or undesirable

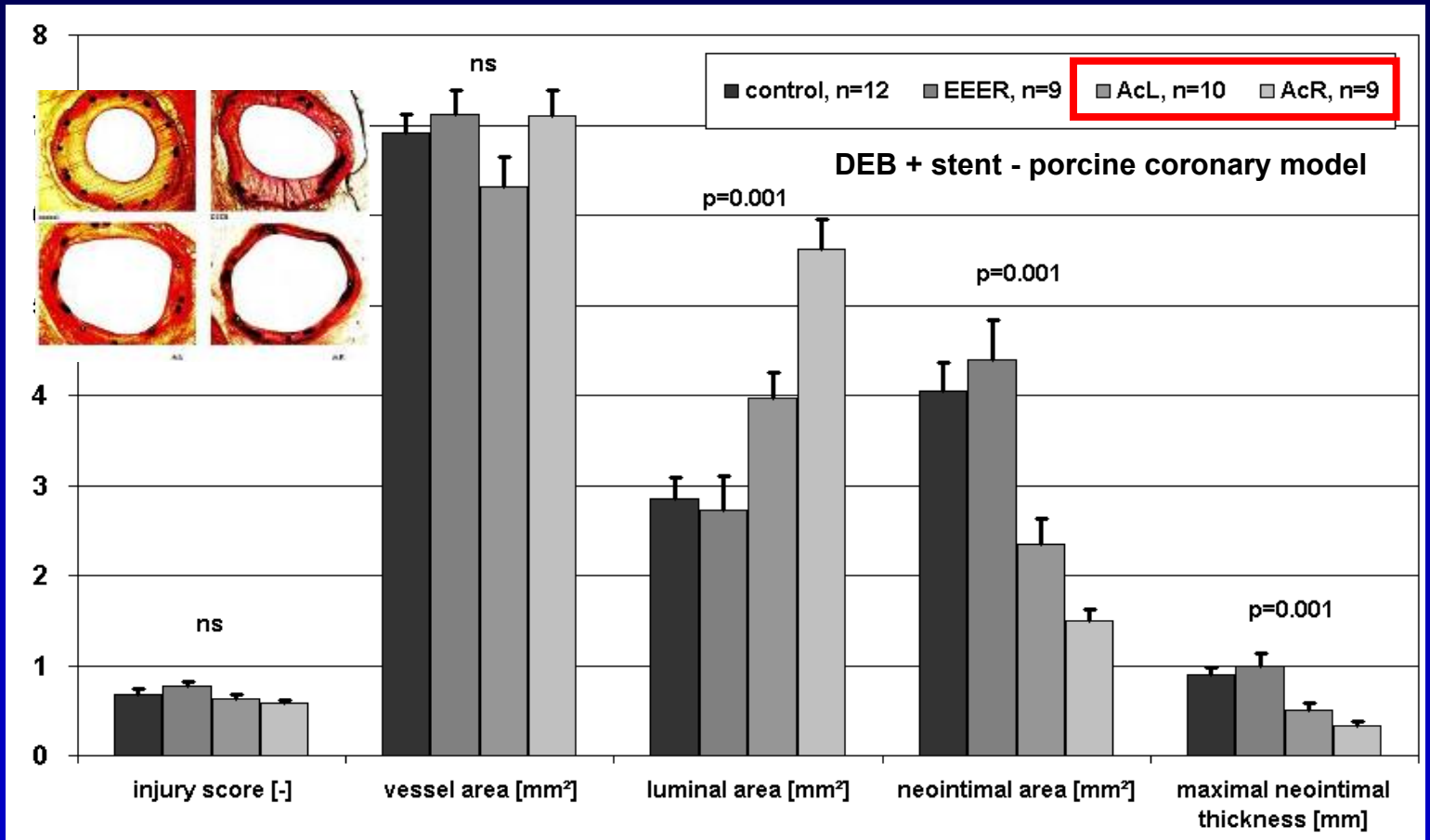
Local Drug Delivery: Possibilities of a Drug-Eluting Balloon (DEB)



- **Non-Stent based delivery of antiproliferative drugs with DEB**
- -> additional flexibilty and efficacy
- -> deliver drugs to vessel areas not directly covered by the stent (edges, small vessels, tortuous vessels)
- -> no sustained drug release from stent struts to allow for early healing and re-endothelialization
- -> no polymers or other sustained release technology inducing inflammation
- -> homogenous drug distribution to the arterial wall

Paclitaxel Balloon Coating, a Novel Method for Prevention and Therapy of Restenosis

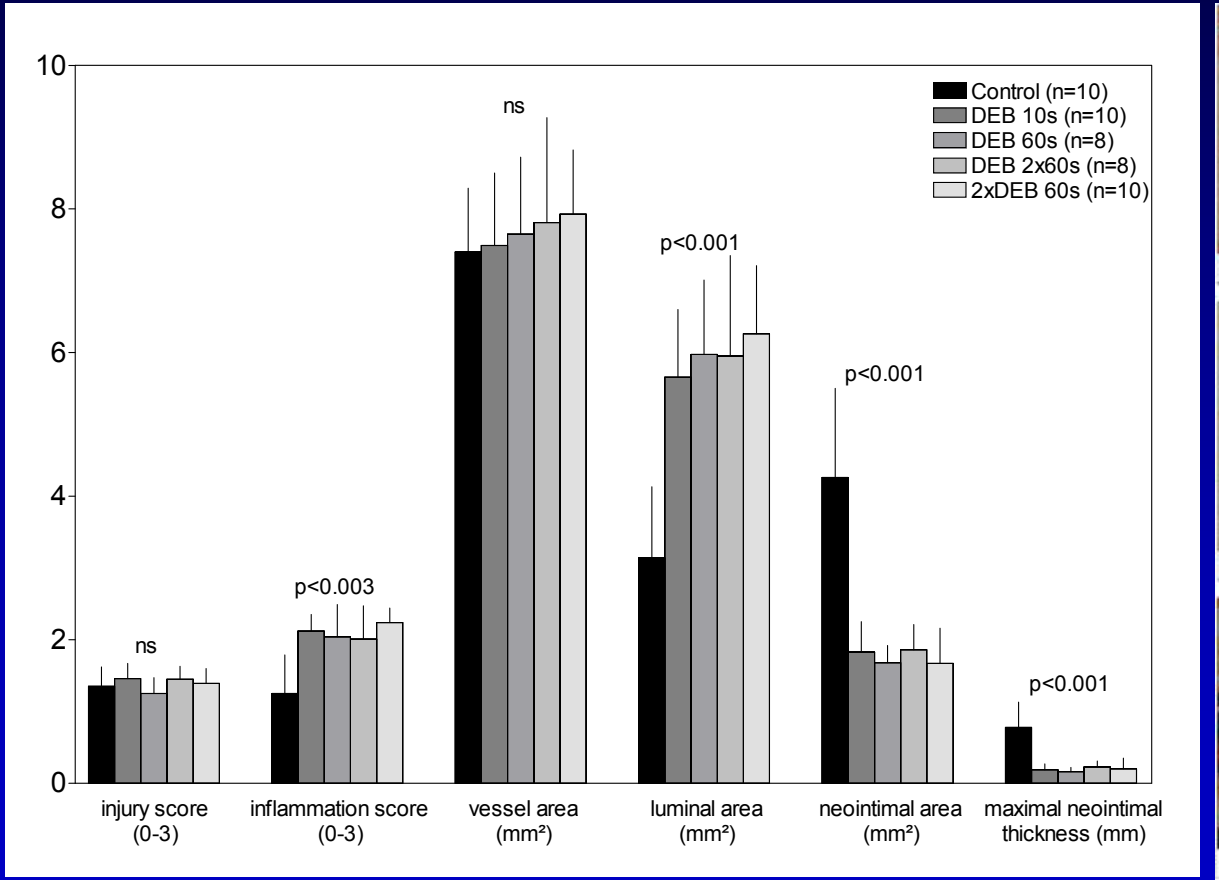
Bruno Scheller, MD; Ulrich Speck, PhD; Claudia Abramjuk, DVM; Ulrich Bernhardt, PhD; Michael Böhm, MD; Georg Nickenig MD

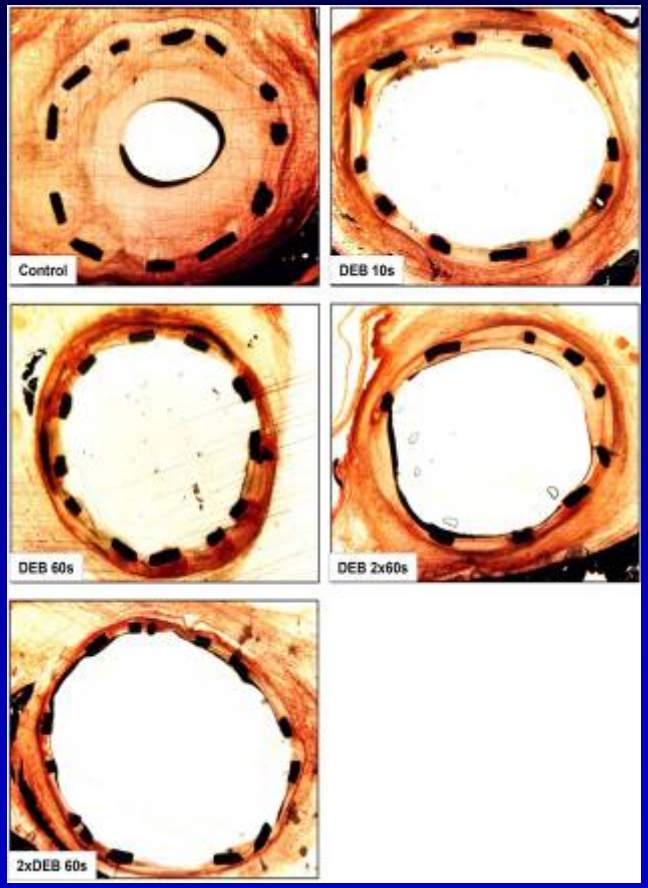


Scheller et al., Circulation 2004; 110: 810-4

Overdosing and Balloon Inflation Time

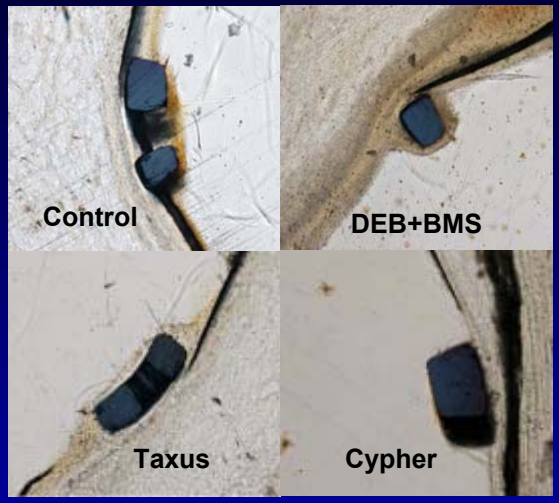
Paclitaxel 5 µg/mm², 28 days follow-up, n=56



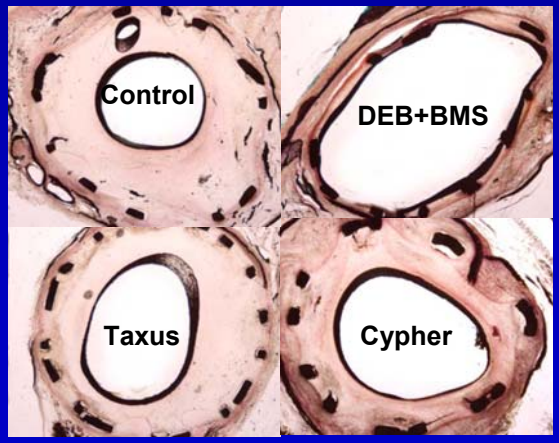


Endothelialization and long-term efficacy

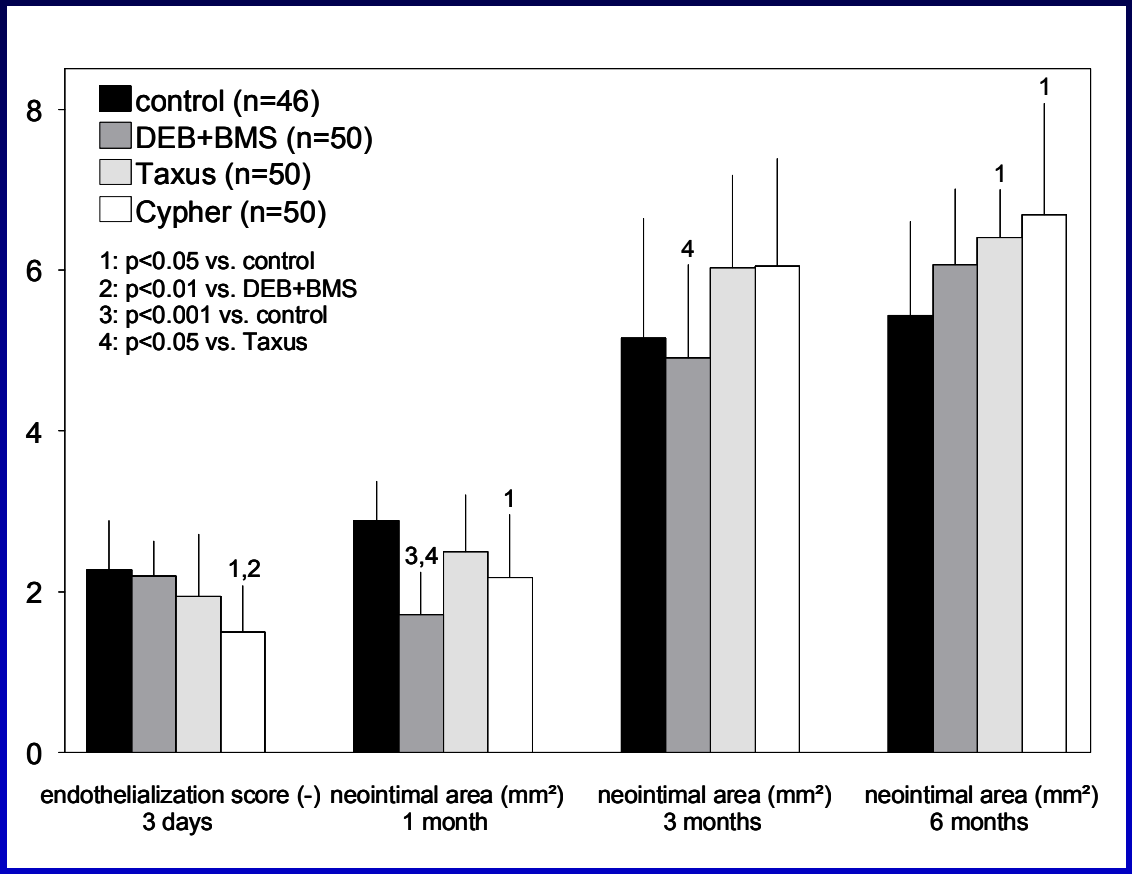
DEB+BMS vs. DES, porcine coronary model, n=196



Endothelialization 3 days follow-up
von Willebrand antibody staining



28 days follow-up, HE staining

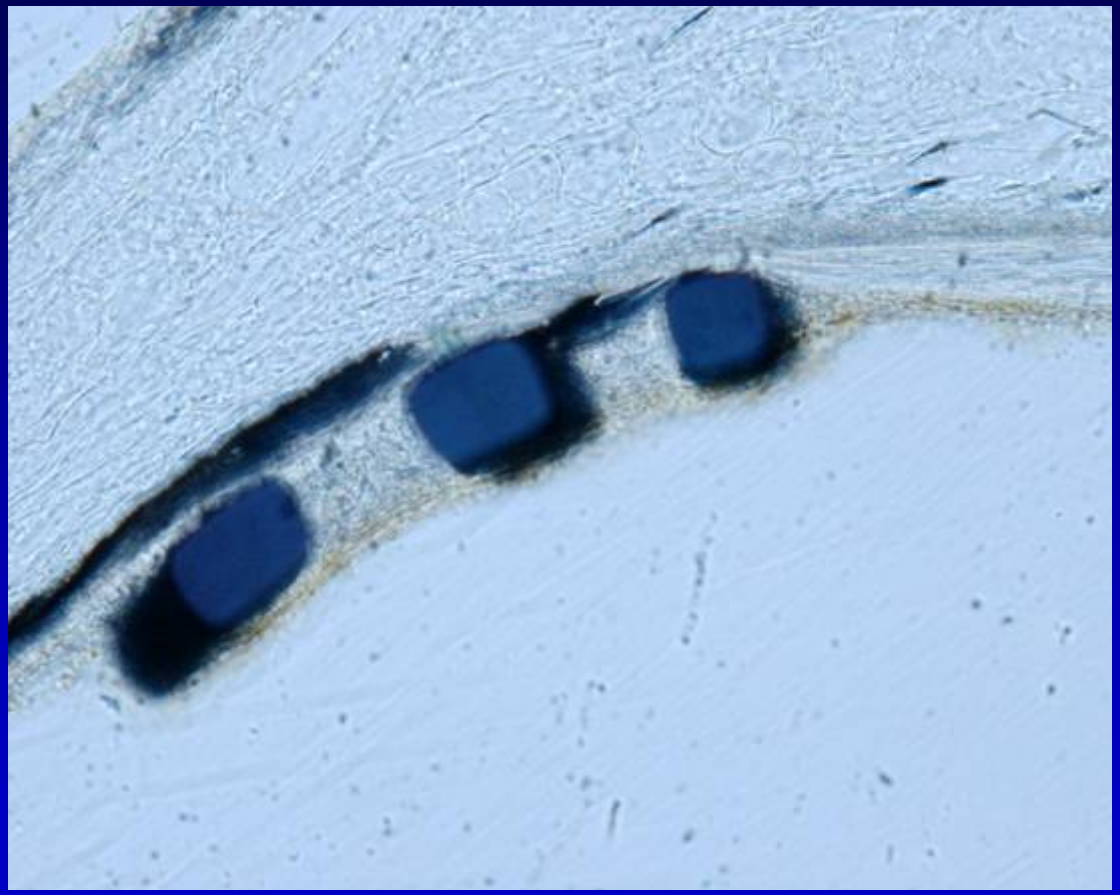


Cremers et al., Eur Heart J 2008; 29 (Suppl): 335

Early Endothelialization: Paccocath-DEB + Stent

Histology

Porcine coronary overstretch model, 5 days vWF staining



Clinical Results

Drug-Eluting Balloon

in-Stent Restenosis

FIM Treatment of Coronary In-Stent Restenosis with DEB

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Treatment of Coronary In-Stent Restenosis with a Paclitaxel-Coated Balloon Catheter

Bruno Scheller, M.D., Christoph Hehrlein, M.D., Wolfgang Bocksch, M.D., Wolfgang Rutsch, M.D., Dariush Haghi, M.D., Ulrich Dietz, M.D., Michael Böhm, M.D., and Ulrich Speck, Ph.D.

Primary endpoint (late lumen loss in-segment)

Uncoated balloon	PACCOCATH
0.74 ± 0.86 mm	0.03 ± 0.48 mm

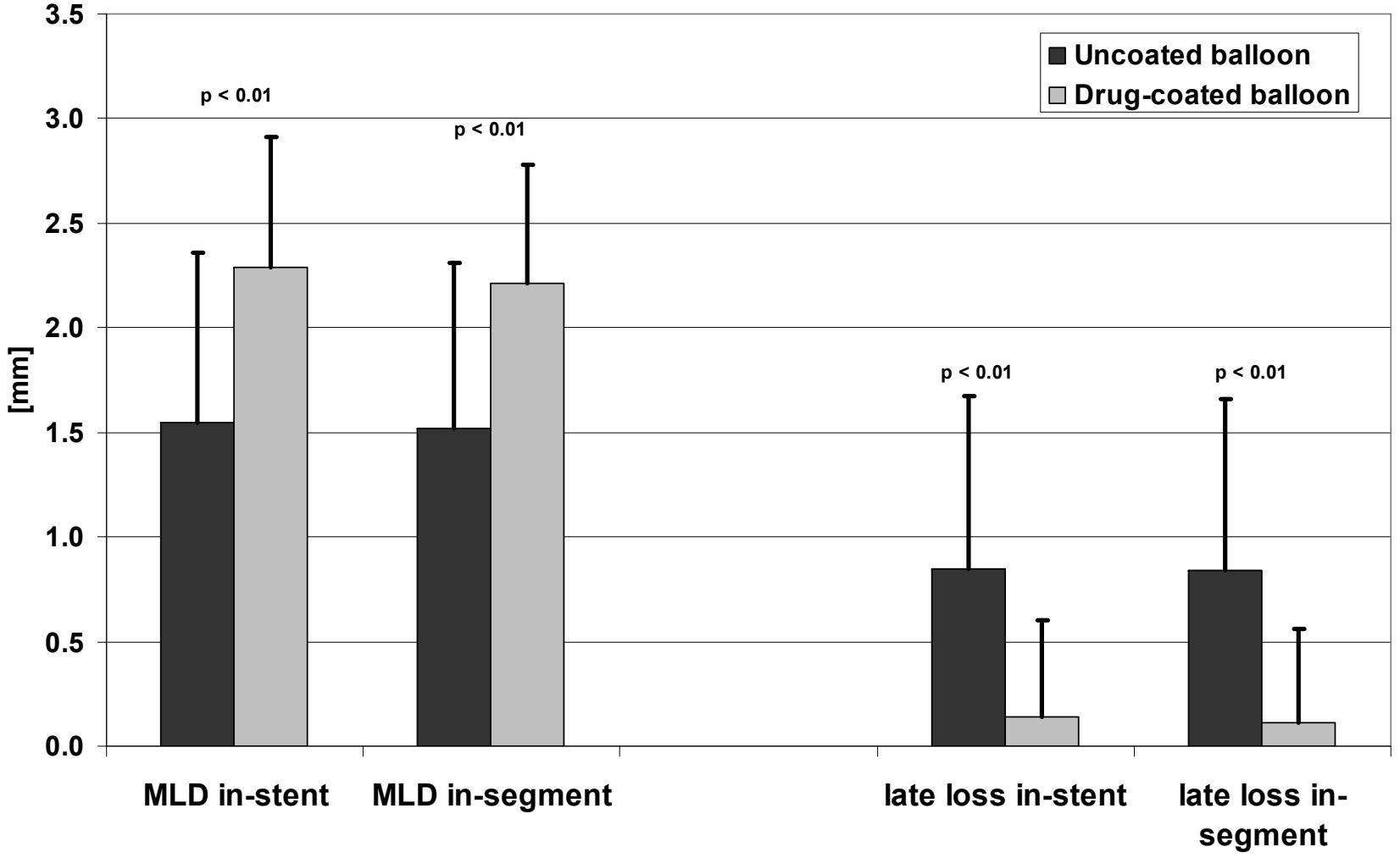
Table 2. Procedural Data and Angiographic Findings during Intervention and at 6 Months (Intention-to-Treat Analysis).*

Variable	Uncoated Balloon (N=26)	Paclitaxel-Coated Balloon (N=26)	Absolute Difference (95% CI)	P Value
Angiographic findings at 6 mo				
No. of patients	23	22		
Minimal luminal diameter — mm				
In-stent	1.60±0.89	2.31±0.66	−0.71 (−1.18 to 0.24)	0.004
In-segment	1.57±0.86	2.22±0.57	−0.65 (−1.09 to 0.21)	0.005
Late luminal loss — mm				
In-stent	0.76±0.86	0.09±0.49	0.67 (0.24 to 1.09)	0.003
In-segment	0.74±0.86	0.03±0.48	0.70 (0.28 to 1.12)	0.002
Restenosis — no. (%)				
In-stent	10 (43)	1 (5)	0.39 (0.15 to 0.63)	0.002
In-segment	10 (43)	1 (5)	0.39 (0.15 to 0.63)	0.002

Scheller et al., N Engl J Med 2006;355: 2113

PACCOCATH ISR I/II

QCA Control Angiography (n=96/108, 89 %)

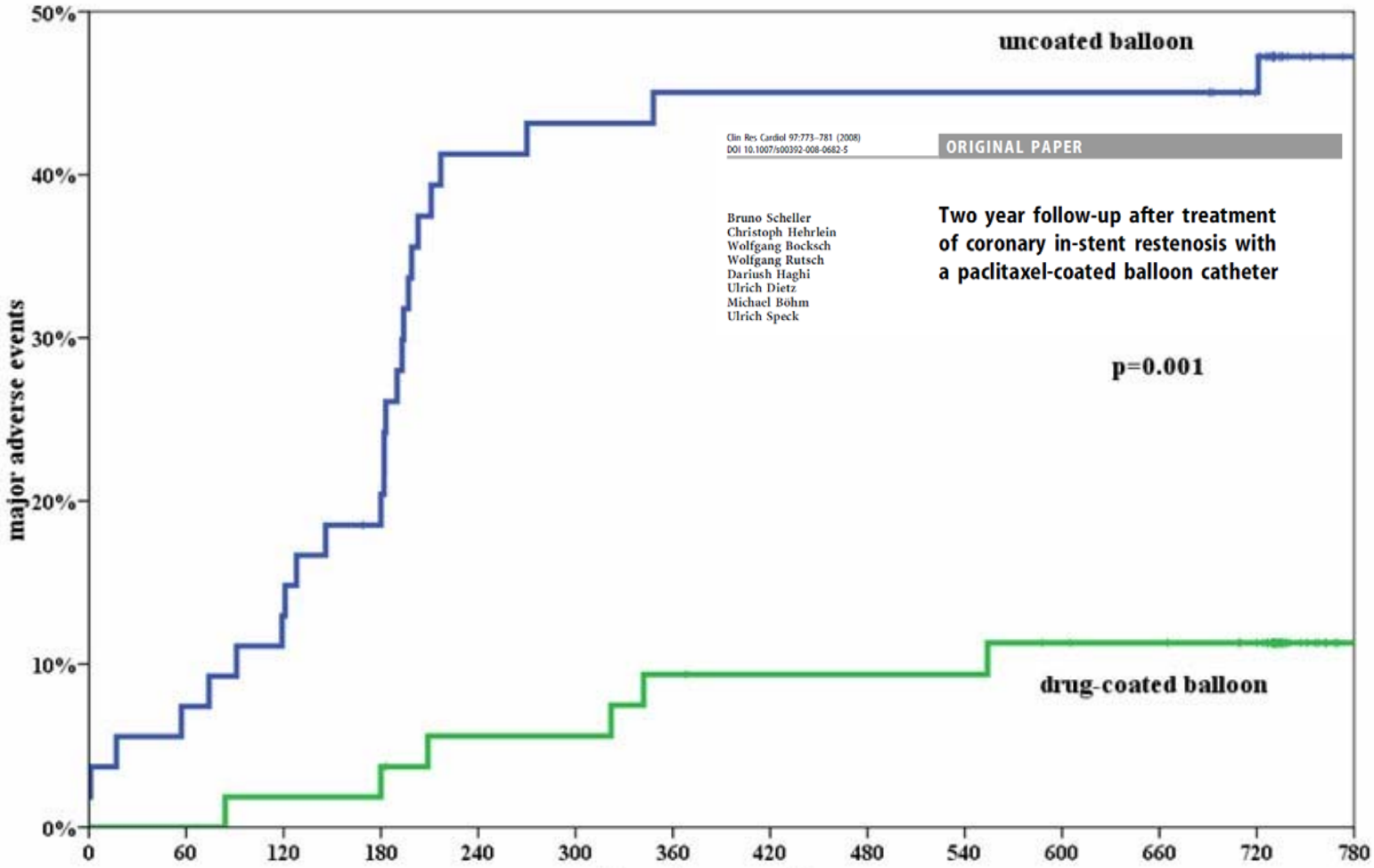


p-values adjusted according to Fisher's method of combining independent tests

PACCOCATH ISR I/II

MACE (Major Adverse Cardiac Events), 24 month follow-up

TLR, MI, acute/subacute closure, stroke, or death



Clin Res Cardiol 97:773–781 (2008)
DOI 10.1007/s00392-008-0682-5

ORIGINAL PAPER

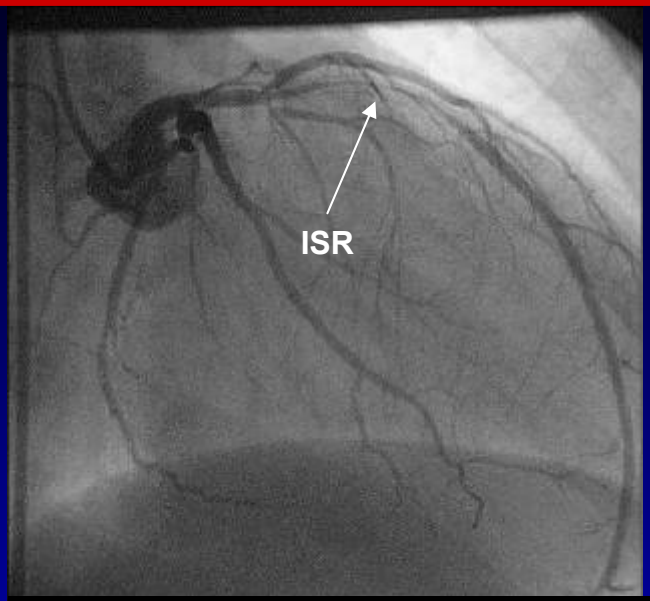
Bruno Scheller
Christoph Hehrlein
Wolfgang Bocksch
Wolfgang Rutsch
Dariush Haghi
Ulrich Dietz
Michael Böhm
Ulrich Speck

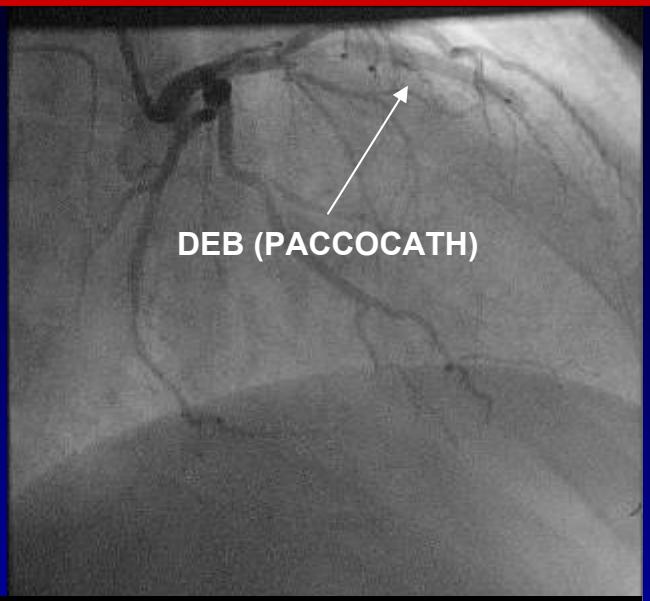
Two year follow-up after treatment of coronary in-stent restenosis with a paclitaxel-coated balloon catheter

No. at risk							
Drug-coated balloon	54	53	51	49	49	48	48
Uncoated balloon	54	47	32	30	30	30	29

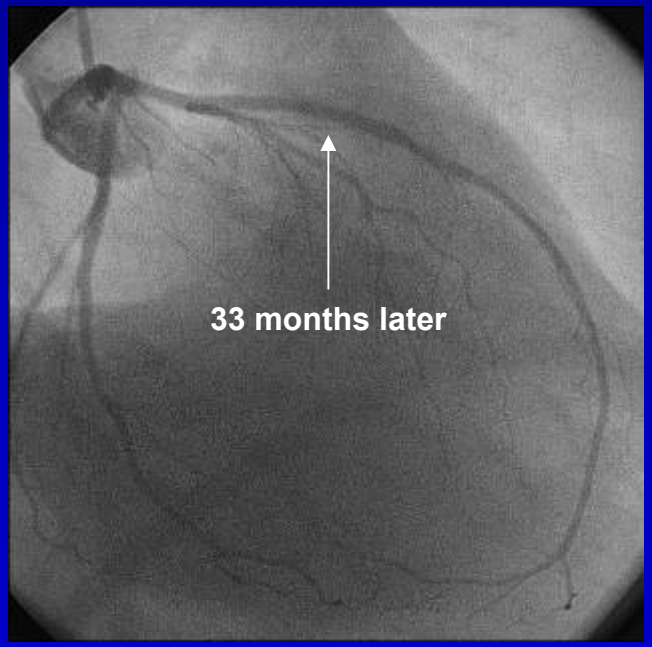
Mantel-Cox log-rank test; p-values adjusted according to Fisher's method of combining independent tests

PACCOCATH ISR I/II: *Case Report I, Follow-up 3 years*

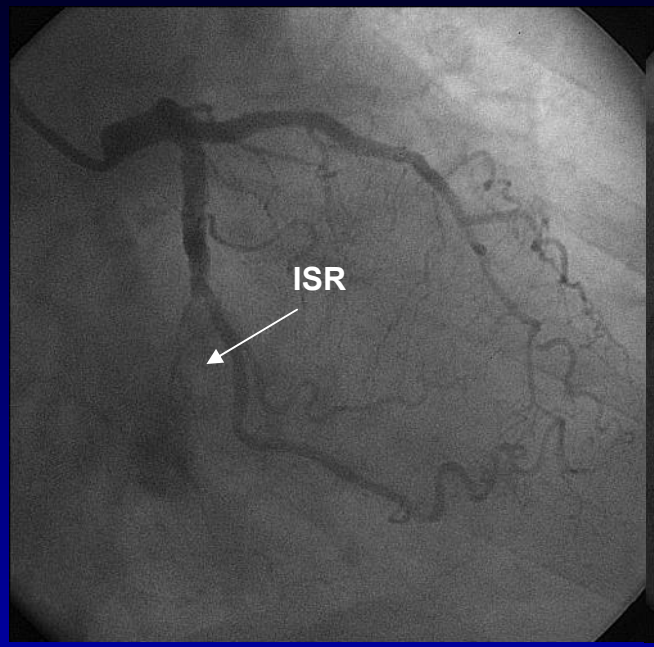


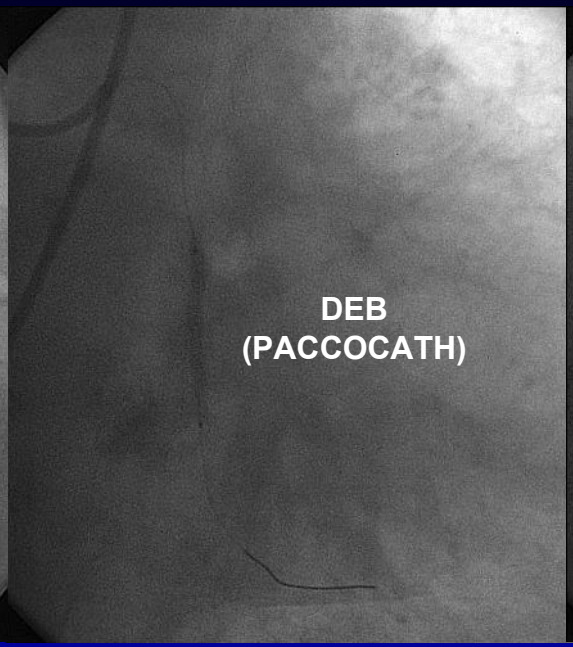


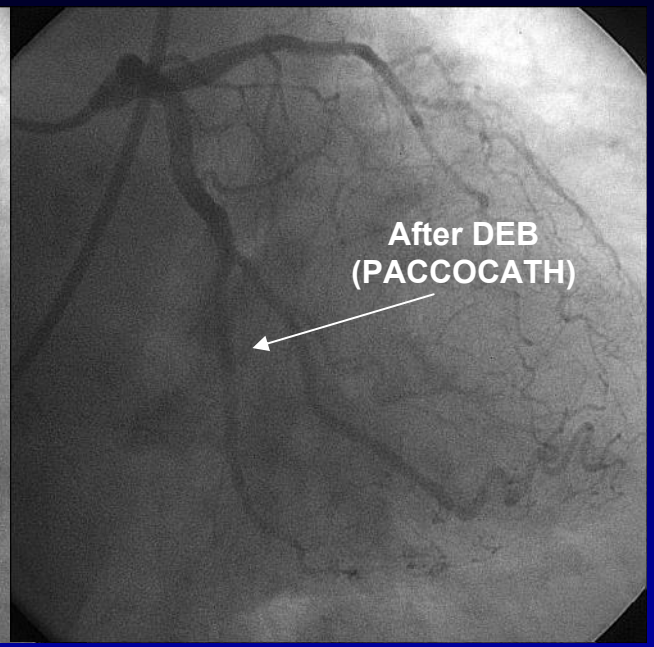
Treatment of coronary ISR with Paclitaxel-coated PACCOCATH Balloon Catheter



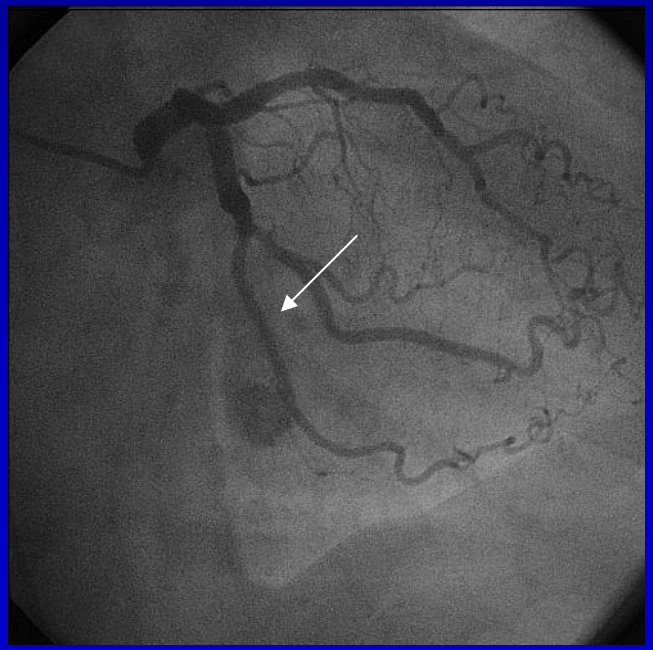
PACCOCATH ISR I/II: *Case Report III, Follow-up 4 years*

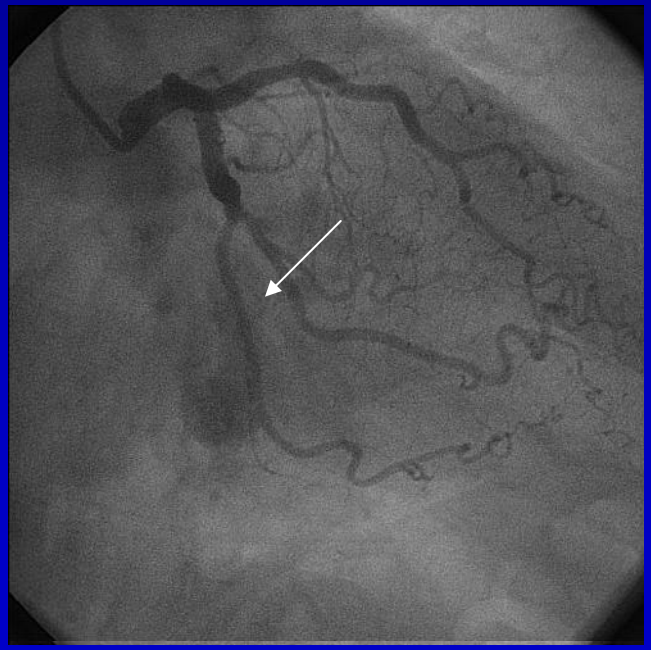






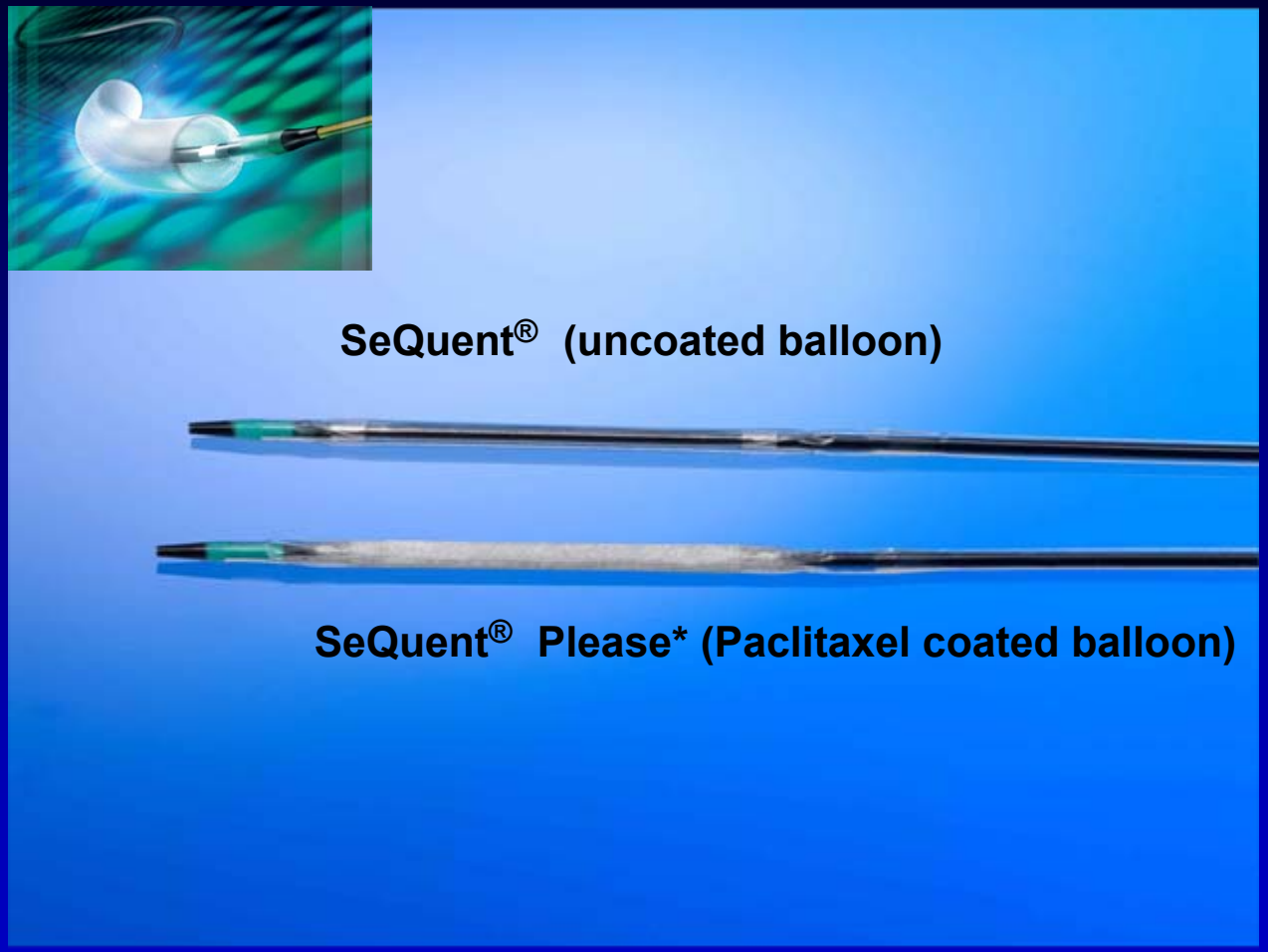
2 years later





4 years later

SeQuent® Please: Next Generation DEB



*SeQuent® Please is manufactured based on the PACCOCATH technology with 3 µg paclitaxel / mm²; CE mark since 11.03.2009

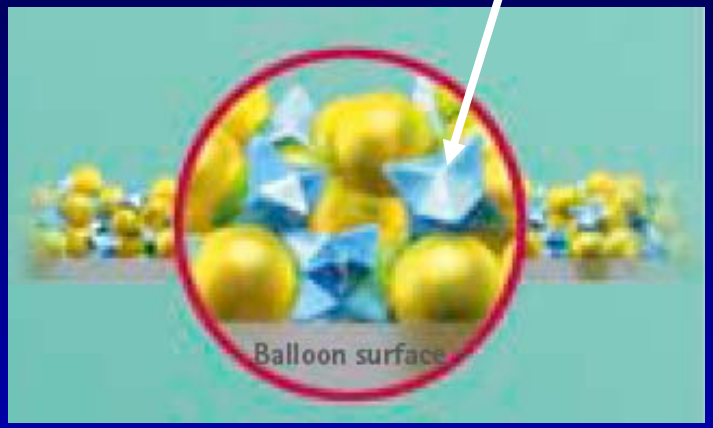
The Matrix Coating (SeQuent® Please)

PACCOCATH technology creates a unique matrix coating

pure paclitaxel

matrix coating:

paclitaxel + hydrophilic spacer (iopromide)



the hydrophilic spacer leads to:

- porous coating with a high contact surface between the lipophilic drug molecules and the vessel wall
- uniform and complete release of the target drug dose after first balloon expansion

that guarantees:

- a high bioavailability of paclitaxel on the target side for rapid drug absorption by the vessel wall

PEPCAD II ISR: FIM Comparison to DES

"The Paclitaxel-Eluting PTCA-Balloon Catheter in Coronary Artery Disease to Treat In-Stent Restenoses: A Comparison to the Paclitaxel-Eluting Taxus™ Stent"

prospective, randomized, multi-center, two-armed phase-II study
Taxus vs. SeQuent Please in coronary ISR

Primary Variable

- 6-month late lumen loss

Secondary Variables

- Procedural success (≤30%)
- 6-month binary restenosis rate
- 6-month MACE
- MACE at 1 and 3 years

Inclusion Criteria

- Stable or unstable angina (no MI)
- ISR in native coronary arteries

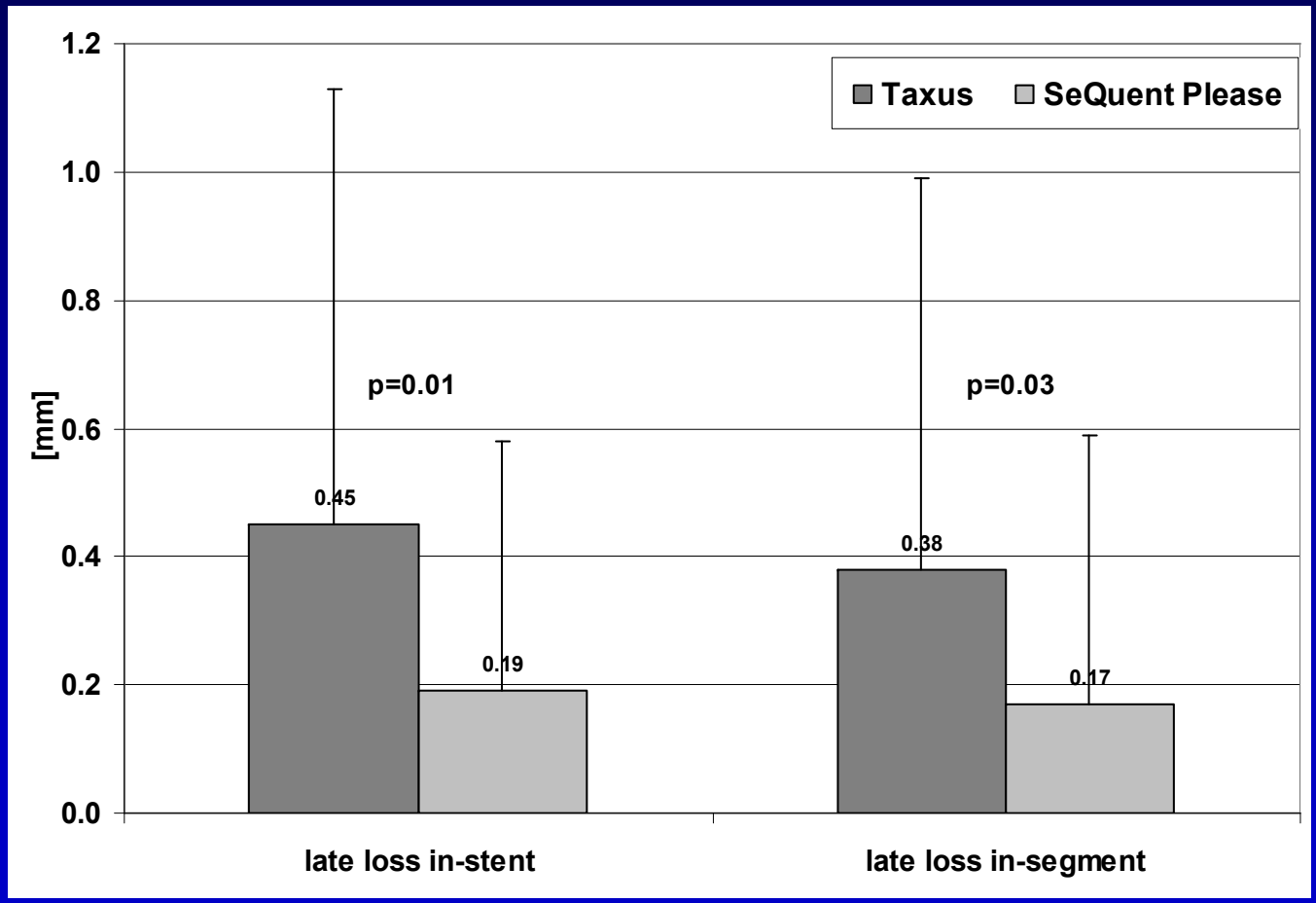
Medication

- ASS ≥ 100 mg daily
- Clopidogrel 75 mg daily
  - –3 months DEB
  - –6 months DES

PEPCAD II ISR – Angiographic follow-up

Paclitaxel-Coated Balloon Catheter Versus Paclitaxel-Coated Stent for the Treatment of Coronary In-Stent Restenosis

Martin Unverdorben, MD; Christian Vallbracht, MD; Bodo Cremers, MD; Hubertus Heuer, MD; Christian Hengstenberg, MD; Christian Maikowski, MD; Gerald S. Werner, MD; Diethmar Antoni, MD; Franz X. Kleber, MD; Wolfgang Bocksch, MD; Matthias Leschke, MD; Hanns Ackermann, PhD; Michael Boxberger, PhD; Ulrich Speck, PhD; Ralf Degenhardt, PhD; Bruno Scheller, MD



PEPCAD II ISR – Angiographic follow-up

Paclitaxel-Coated Balloon Catheter Versus Paclitaxel-Coated Stent for the Treatment of Coronary In-Stent Restenosis

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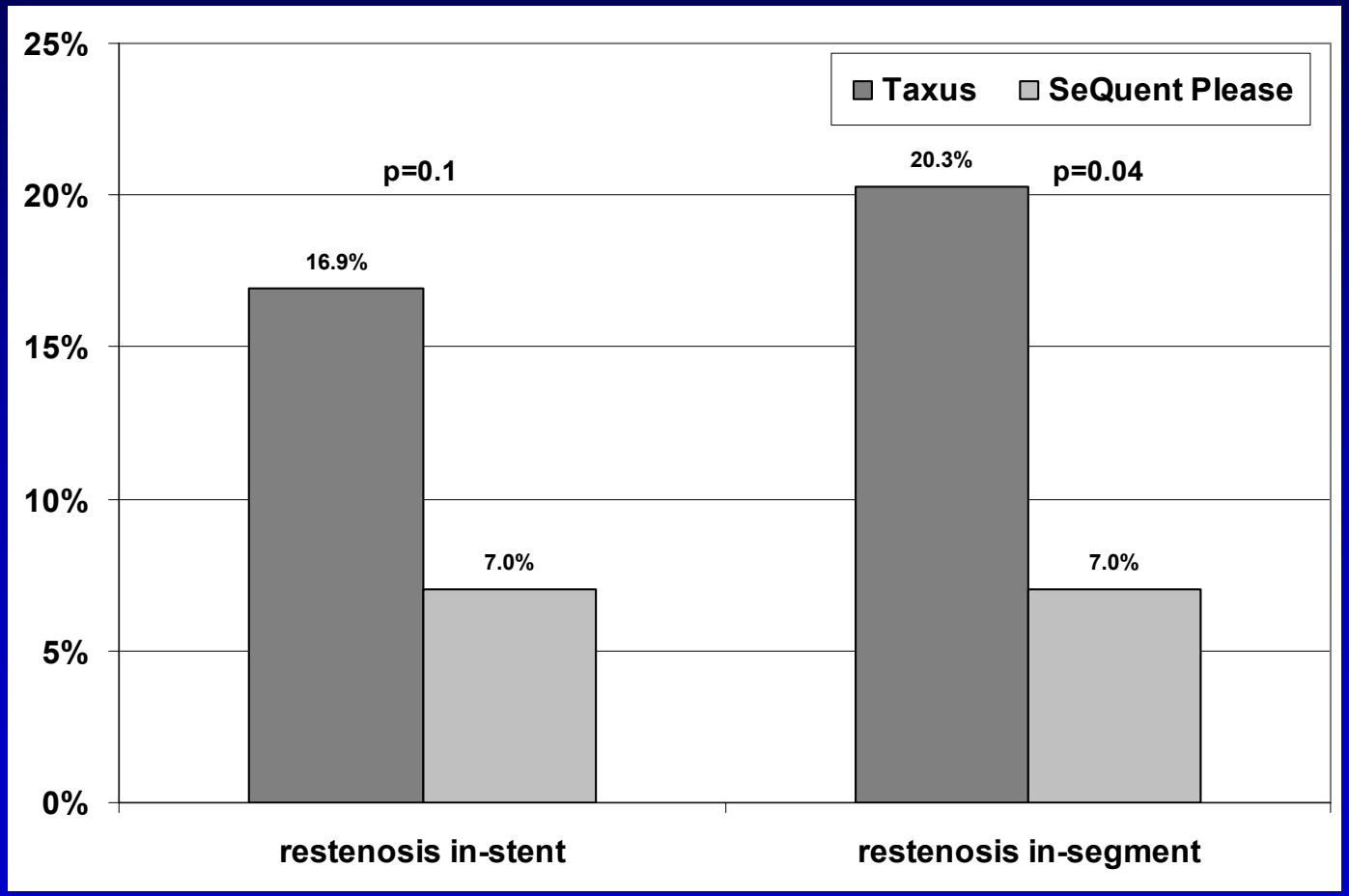
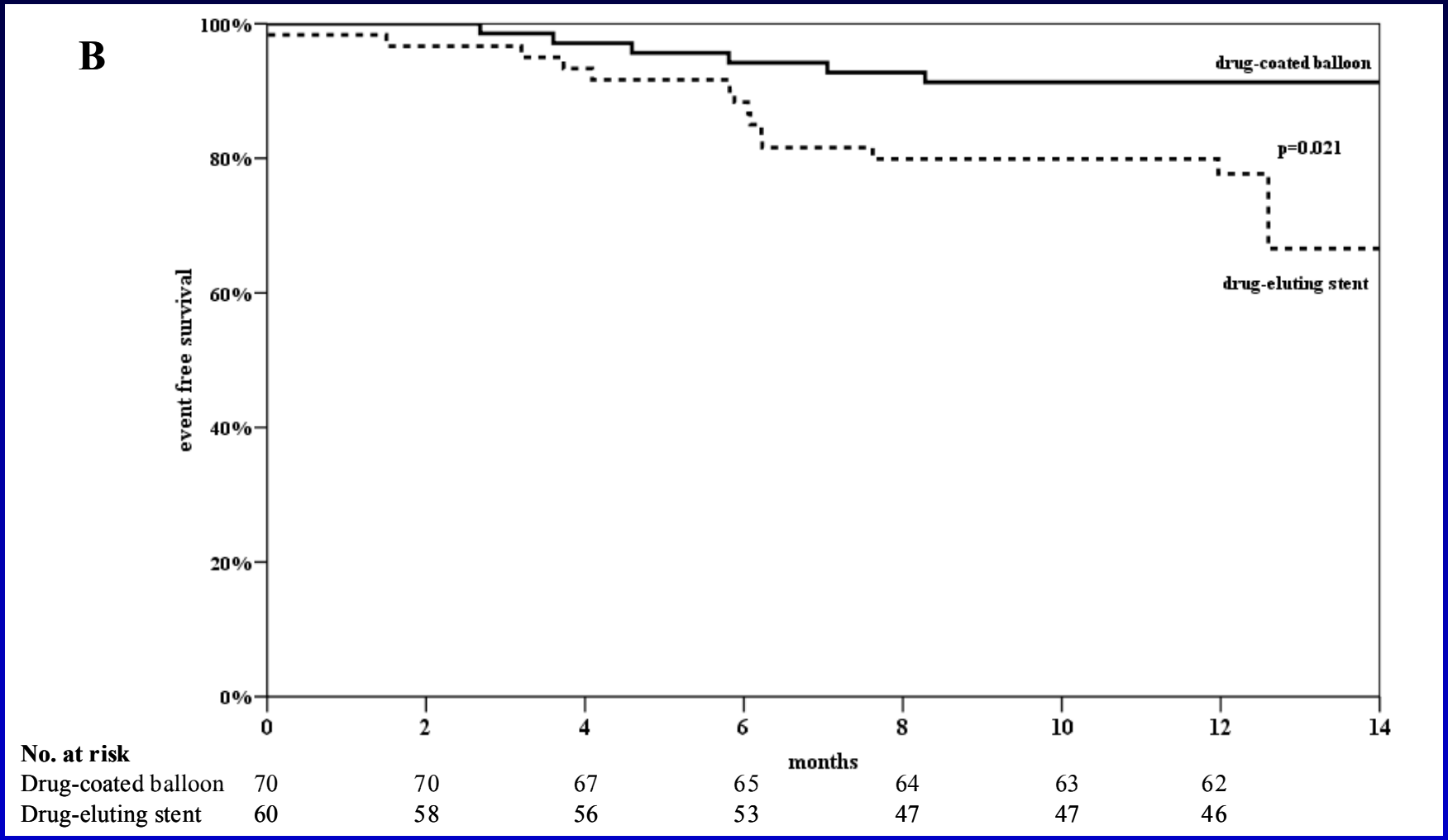


Circulation 2009; 119: 2986-2994

PEPCAD II ISR - Outcome

Freedom from stent thrombosis, target lesion revascularization, myocardial infarction, and death



No. at risk							
Drug-coated balloon	70	70	67	65	64	63	62
Drug-eluting stent	60	58	56	53	47	47	46

PEPCAD II ISR: Conclusion

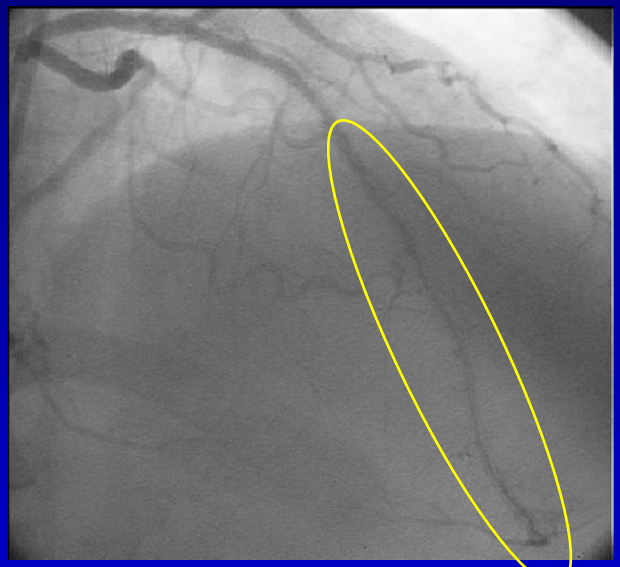
"The Paclitaxel-Eluting PTCA-Balloon Catheter in Coronary Artery Disease to Treat In-Stent Restenoses: A Comparison to the Paclitaxel-Eluting Taxus™ Stent"

SeQuent® Please for the treatment of coronary in-stent restenosis

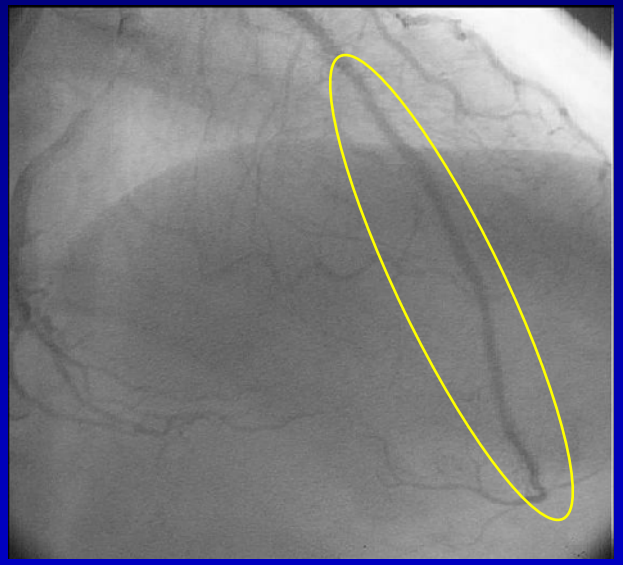
- **Safe, high procedural success rate**
- **DEB (SeQuent® Please) avoids the stent-in-stent approach with a second layer of metal in a native coronary artery**
- **Confirms the findings of PACCOCATH ISR I and II trials**
- **Sequent® Please superior to Taxus® in the treatment of ISR**
- **DEB reduces anti-platelet therapy compared to DES**

SeQuent® Please: *Case Report, ISR*

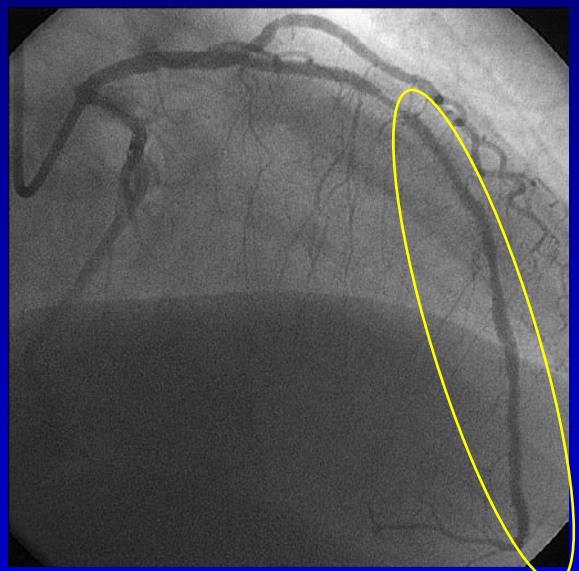
- 70 years female, insulin dependent diabetes mellitus
- 04/06 STEMI, BMS LAD, stent thrombosis (dissection), 2 additional BMS (different cathlab)
- 05/07 reocclusion (ISR), recanalization 3 x Xience V
- 02/08 reocclusion (ISR), recanalization PTCA + 4 BMS (dissection)
- 06/08 reocclusion (ISR), recanalization PTCA
- 07/08 early ISR => 6 x SeQuent Please (2.5/3.0 20 mm each) + PTCA prox. DES



Pre intervention



Final result



3 months

Drug-Eluting Balloon

small coronary vessels

PEPCAD I SVD

"The Paclitaxel-Eluting PTCA-Balloon Catheter to Treat Small Vessel Coronary Artery Disease. A Pilot Study"

prospective, non-randomized, multi-center, one-arm phase-II pilot study
De-novo lesions, reference diameter 2.25 - 2.8 mm; SeQuent Please

Primary Variable

- 6-month late lumen loss

Secondary Variables

- Procedural success (≤30% stenosis)
- 6-month binary restenosis rate
- 6-month MACE
- MACE at 1 and 3 years

Inclusion Criteria

- Stable or unstable angina (no MI)
- De-novo lesion in native coronary arteries

Medication

- ASS ≥ 100 mg daily
- Clopidogrel 75 mg daily
  - –1 month DEB only
  - –3 months DEB with additional non-DES stent

PEPCAD I SVD – QCA, 6 months FU

ITT, n=120

Diabetic patients	41 / 120 (34.2 %)
Reference diameter	2.36 ± 0.19 mm
Lesion length	11.46 ± 4.72 mm
MLD pre PCI MLD post PCI	0.71 ± 0.25 mm 1.89 ± 0.30 mm
Follow-up	6.4 ± 1.3 months
Control angiography	104 / 120 (86.7 %)
Late lumen loss	0.32 ± 0.56 mm
Binary restenosis in-segment	18 / 104 (17.3 %)
Binary restenosis in-lesion	17 / 104 (16.3 %)
TLR	14 / 120 (11.7 %)
Total MACE	18 / 120 (15.0 %)

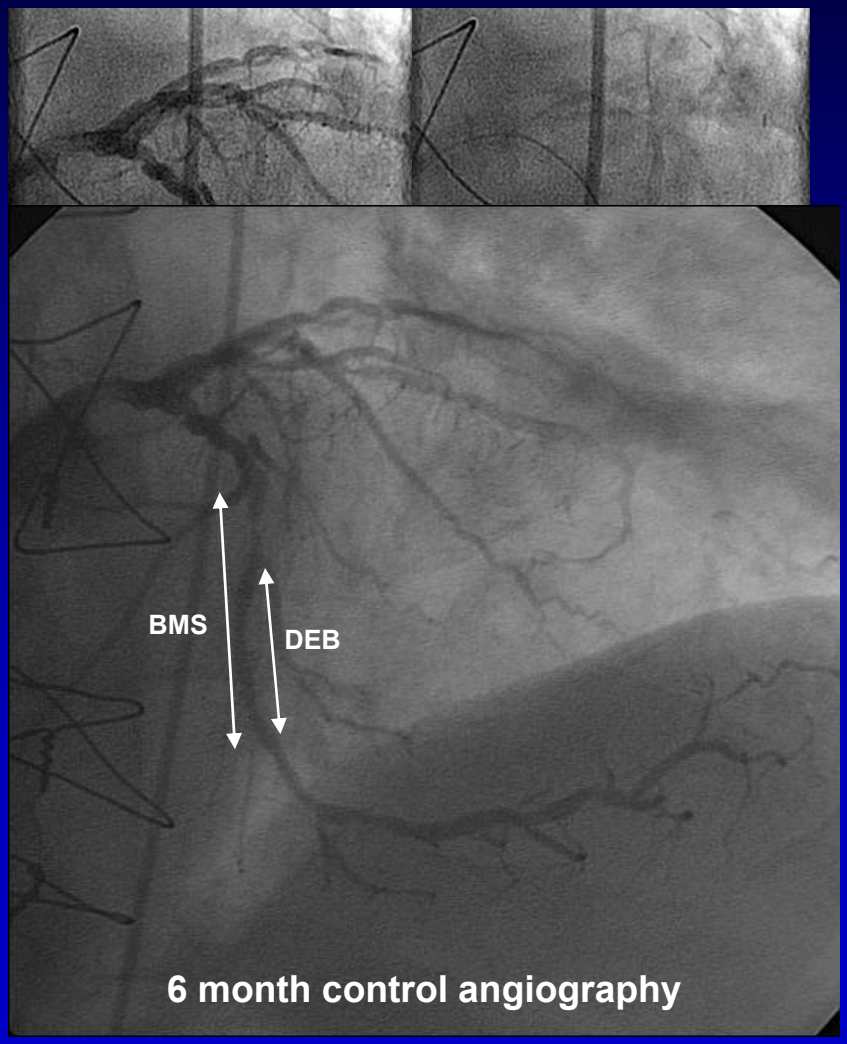
PEPCAD I SVD – Outcome, 6 months FU

	DEB only	DEB & BMS	p
n	82	32	
Follow-up	6.4 ± 1.2 months	6.5 ± 1.5 months	0.9
Control angiography	73 (89 %)	29 (91 %)	1
Late lumen loss	0.18 ± 0.38 mm	0.73 ± 0.74 mm	0.0006
Binary restenosis in-segment Binary restenosis in-lesion	4 / 73 (5.5 %) 4 / 73 (5.5 %)	13 / 29 (44.8 %) 12 / 29 (41.3 %)	<0.0001 <0.0001
TLR	4 (4.9 %)	9 (28.1 %)	0.001
Stent thromboses and TLR	N/A	2 (6.3%)	
Myocardial infarction	1 (1.2 %)	1 (3.3 %)	1
Death	0 (0 %)	0 (0 %)	1
Total MACE	5 (6.1 %)	12 (37.5 %)	<0.0001

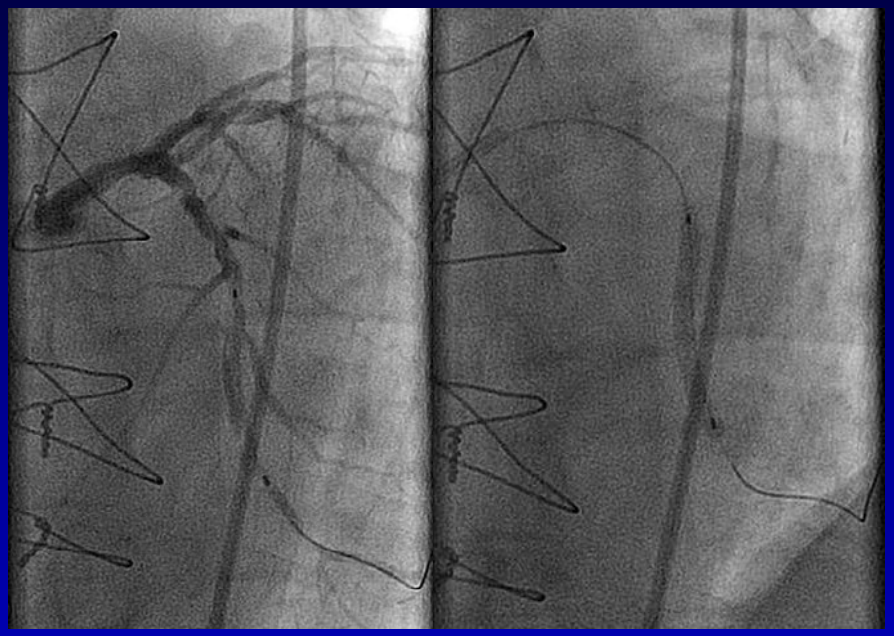
PEPCAD I SVD – DEB + BMS

Geographic Mismatch

DEB 2.5 17 mm



BMS 2.5 25 mm



	Restenosis (N=13)	No restenosis (N=16)	p
Geographic mismatch	10 / 13 (77 %)	3 / 16 (19 %)	0.029
Total stent length	19.4 ± 8.4 mm	14.4 ± 10.2 mm	0.035
Balloon length – stent length	-2.31 ± 10.72 mm	2.75 ± 7.71 mm	0.096

PEPCAD I – 6 month FU

			* Stone,G JAMA 2005;294:1215-23	
PEPCAD I	DEB ITT N=120	DEB Only N=82	Taxus*	BMS*
Follow-up [mo]	6.7±2.1	6.7±1.9	9	9
Late loss [mm]	0.3±0.55	0.18±0.38	0.49±0.61	0.90±0.63
Restenosis (segment)	15.5%	5.5%	31.2%	49.4%
TLR	12%	4.9%	10.4%	21.5%
Myocardial infarction	0.8%	1.2%	5.7%	2.2%
Cardiac death	0%	0%	1.9%	1.1%
Total MACE	13.7%	6.1%	18.9%	26.9%

PEPCAD I SVD: Conclusion

"The Paclitaxel-Eluting PTCA-Balloon Catheter to Treat Small Vessel Coronary Artery Disease"

SeQuent® Please for the treatment of small coronary vessels

- **Safe, high procedural success rate**
- **DEB only**
  - **5.5 % restenosis rate**
- **DEB + BMS**
  - **additional stenting in 28 % of patients**
  - **no geographical mismatch: 19 % restenosis**
  - **geographical mismatch**
    - **high recurrence rates**
    - **DEB must overlap the stented area!**

‘GEOGRAPHIC MISS’ IN DEB

‘Textbook’ DEB + BMS technique

‘Real-world’ DEB + BMS technique

Stent edge restenosis (‘geographic miss’)
due to stent covering area not ‘touched’ by DEB

Drug-Eluting Balloon

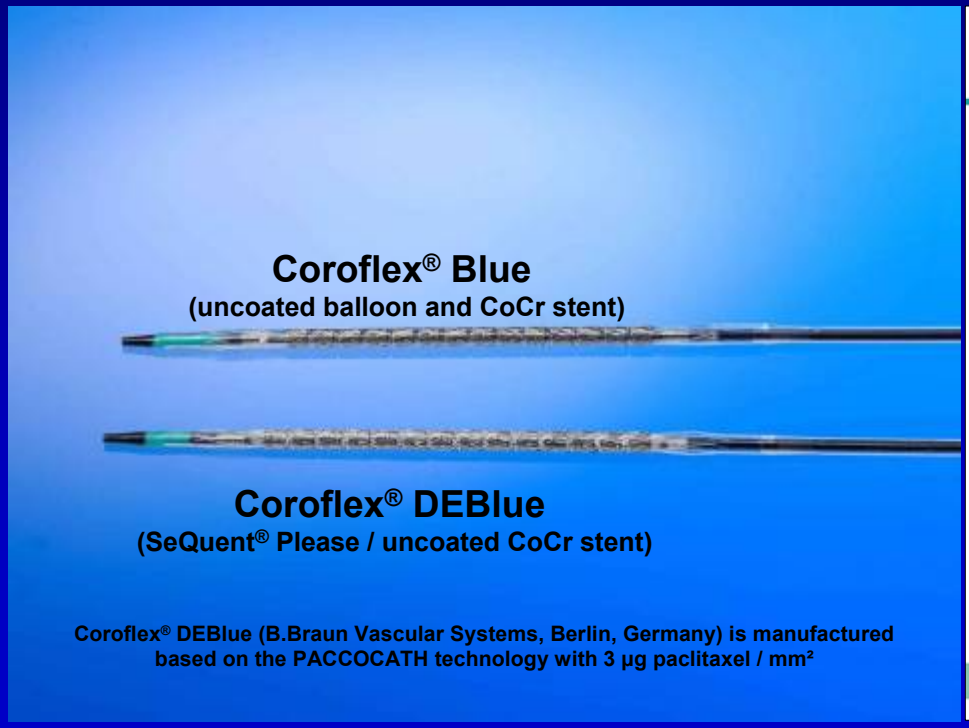
DEB+BMS in coronary de-novo lesions

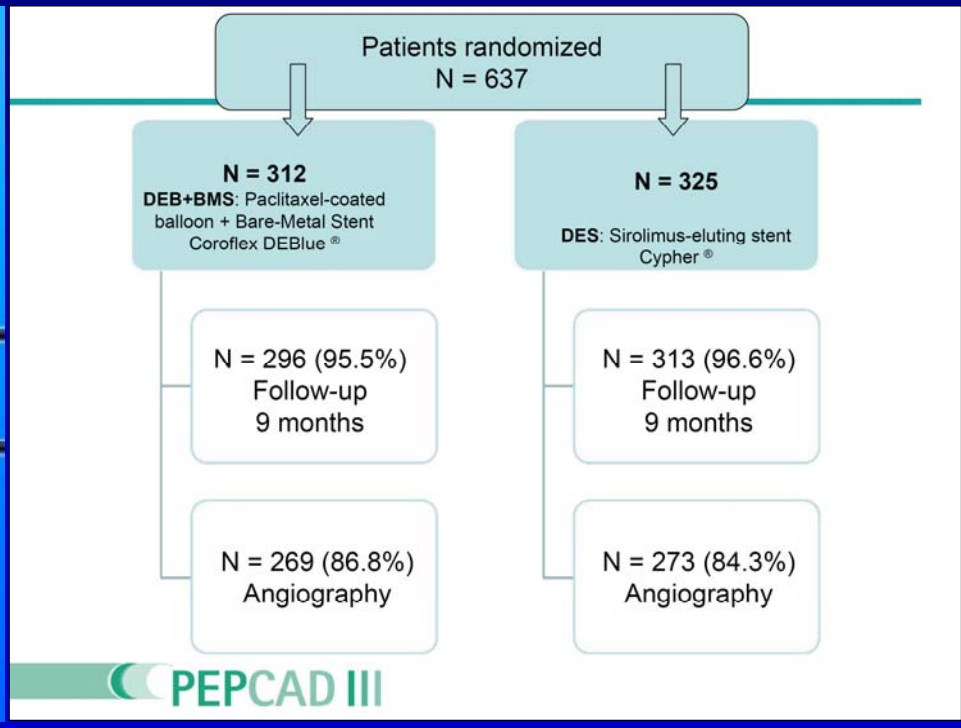
DEB / BMS PEPCAD III

"Paclitaxel-Eluting PTCA-Balloon in Combination with the Coroflex Blue Stent vs. the Sirolimus Coated Cypher Stent in the Treatment of Advanced Coronary Artery Disease"

n = 637 patients, European multicenter trial, *complex de-novo lesions*

Christian Hamm, Bad Nauheim / Bruno Scheller, Homburg / Saar
IKKF, München; B.Braun Vascular Systems, Berlin





Quantitative Coronary Angiography

9 month FU	DEB+BMS Coroflex DEBlue®	DES Cypher®	P-value
Reference diameter	2.87 ± 0.38	2.87 ± 0.37	0.68
MLD before	0.67 ± 0.37	0.67 ± 0.38	0.97
MLD final In-stent In-segment	 2.59 ± 0.40 2.16 ± 0.48	 2.62 ± 0.36 2.16 ± 0.43	 0.41 0.98
MLD 9 months In-stent In-segment	 2.17 ± 0.63 1.95 ± 0.62	 2.46 ± 0.49 2.05 ± 0.50	 < 0.0001 0.07
Late Lumen Loss In-stent In-segment	 **0.41 ± 0.51 mm** **0.20 ± 0.52 mm**	 **0.16 ± 0.39 mm** **0.11 ± 0.40 mm**	 **<0.001** **0.06**

PEPCAD III

Per protocol analysis

Hamm, AHA 2009

Angiographic 2nd Endpoints

9 month FU	DEB+BMS Coroflex DEBlue®	DES Cypher®	P - value
Binary Restenosis			
In-stent*	10.0 %	2.9 %	<0.01
In-segment*	13.8 %	4.9 %	<0.001
TVR**	13.8 %	6.9 %	<0.01
TLR**	10.5 %	4.7 %	<0.01

PEPCAD III

*Per protocol analysis
**Intention-to-treat analysis

Hamm, AHA 2009

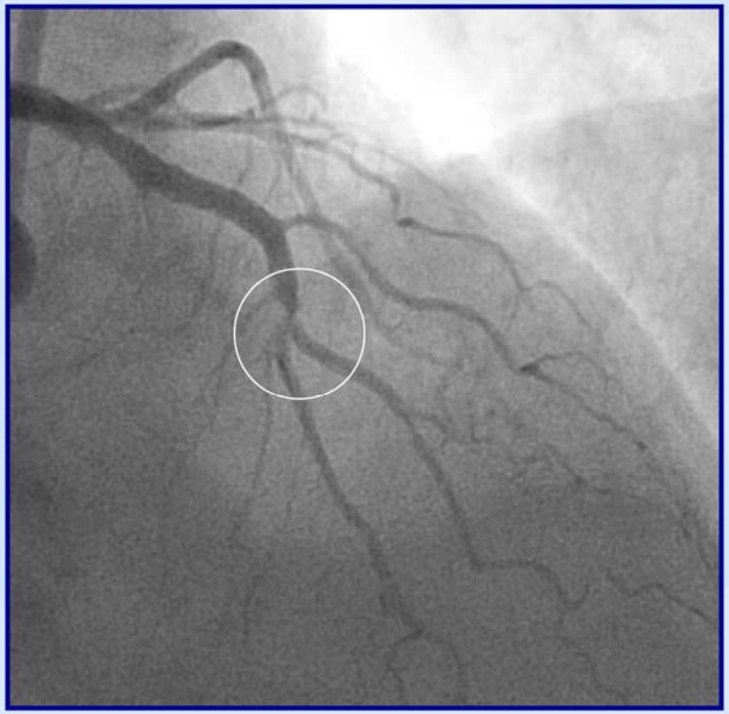
Drug-Eluting Balloon

Bifurcations

DEB Procedure in Bifurcation Lesions

Center for Cardiology and Vascular Intervention Hamburg, Germany

Bifurcation stenosis LAD/D2



07-02-2195_1

TCT2009 TRANSCATHETER CARDIOVASCULAR THERAPEUTICS

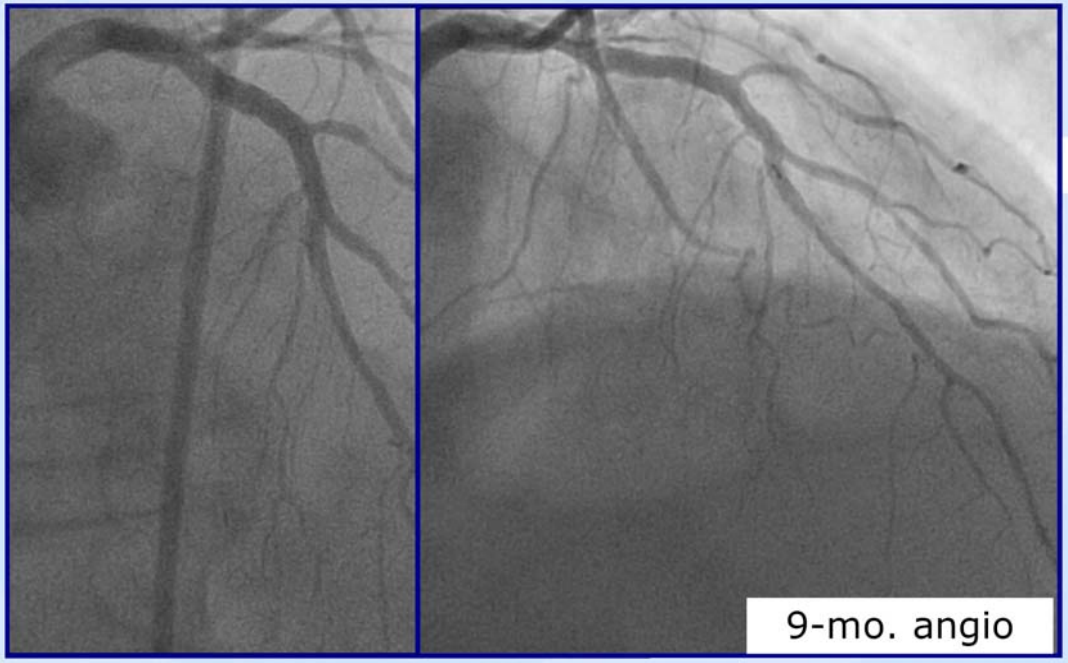
Mathey, TCT 2009

DEB Procedure in Bifurcation Lesions

Center for Cardiology and Vascular Intervention Hamburg, Germany

Acute Result

After 9 month



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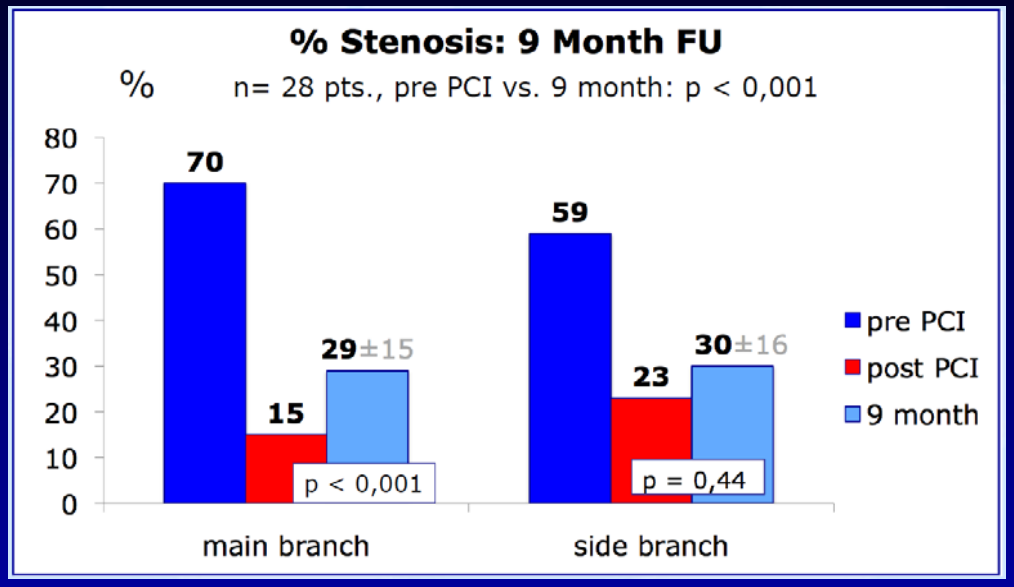
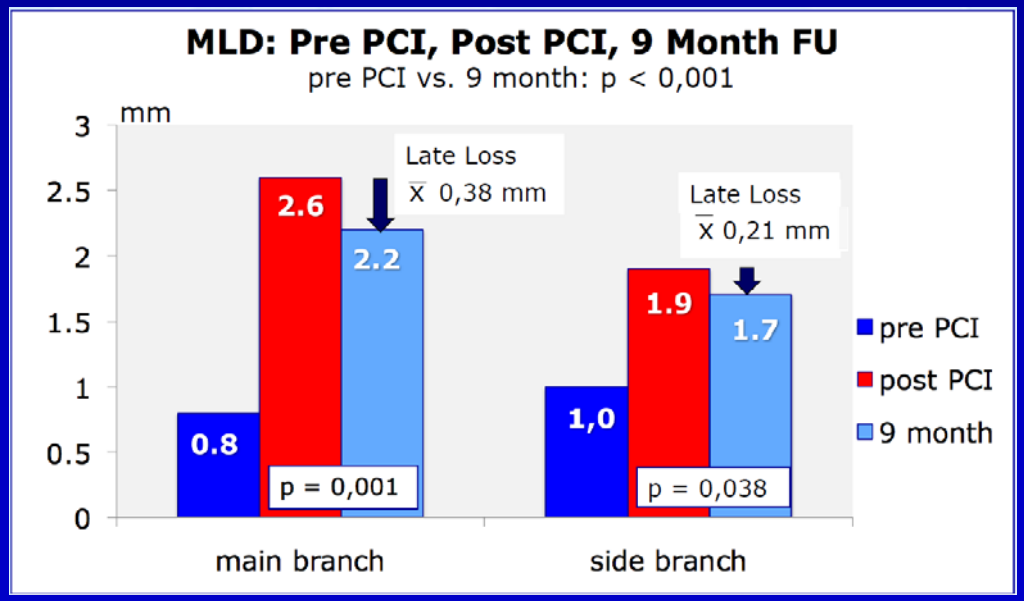
TCT2009 TRANSCATHETER CARDIOVASCULAR THERAPEUTICS

DEB in Bifurcations – PEPCAD V





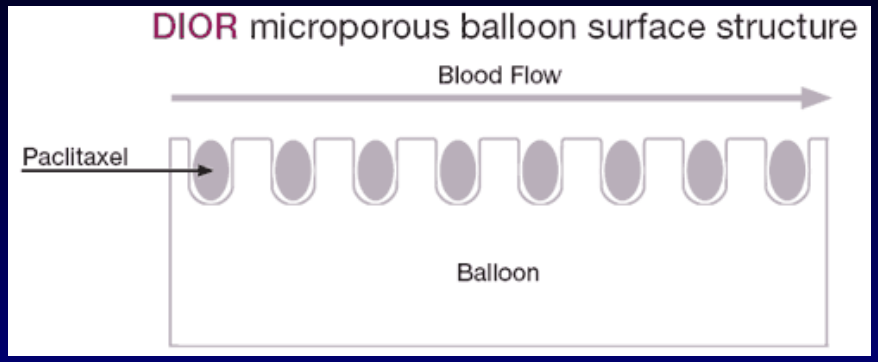
PEPCAD Clinical Program

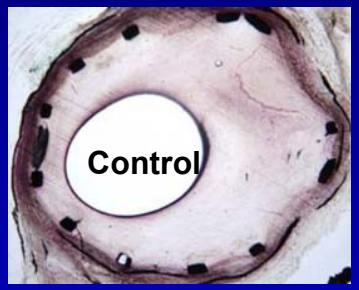
Trial	Countries	PI	Devices used	Lesions	Number of Patients	Follow-up (FU)
Trial status: Completed						
PEPCAD I SVD	Germany	M. Unverdorben	SeQuent® Please	*De novo* lesions in small coronary vessels	120	6-month angiographic FU 12-month clinical FU
PEPCAD II ISR	Germany	M. Unverdorben	SeQuent® Please vs. Taxus™	Coronary in-stent restenosis	131	6-month angiographic FU 12-month clinical FU
PEPCAD III	Europe	C. Hamm B. Scheller	Coroflex® DEB blue vs. Cypher™	Native coronary stenosis	637	9-month angiographic FU 9-month clinical FU
PEPCAD V	Germany	D. Mathey F.X. Kleber	SeQuent® Please + Coroflex®	*De novo* lesions in coronary bifurcations	28	9-month angiographic FU 30-day (MACE) and 9-month (death) clinical FU
Trial Status: Ongoing, but not recruiting participants						
PEPCAD IV	Malaysia, Thailand	M.A. Rosli	SeQuent® Please + Coroflex® Blue vs. Taxus™	*De novo* coronary stenosis in diabetic patients	84	9-month angiographic FU 9-month clinical FU
PEPCAD-CTO	Germany	J. Woehrle G. Werner	SeQuent® Please + Coroflex® Blue	Chronic total occlusion in native coronary arteries	48	6-month angiographic FU 30-day, 6-, 12- and 24-month clinical FU
INDICOR	India	U. Kaul	SeQuent® Please + Coroflex® Blue	*De novo* and restenotic lesions in native coronary arteries (Real world)	125	6-month angiographic FU
DEB-AMI	Singapore	V. Lim	SeQuent® Please + Coroflex® Blue	STEMI	30	
Trial status: Recruiting participants						
ISAR-DESIRE-III	Germany	J. Mehilli	SeQuent® Please vs. Taxus™ vs. conventional balloon	Coronary restenosis in "Limus"-eluting stents	375 (estimated)	6-8 month angiographic FU 1- and 2-year clinical FU
PEPCAD-DES	Germany	H. Rittger	SeQuent® Please vs. uncoated SeQuent®	Coronary in-stent restenosis in native arteries initially deployed with a Cypher™ or Taxus™ stent	120 (estimated)	6-month angiographic FU 6-month, 1- and 3-year clinical FU

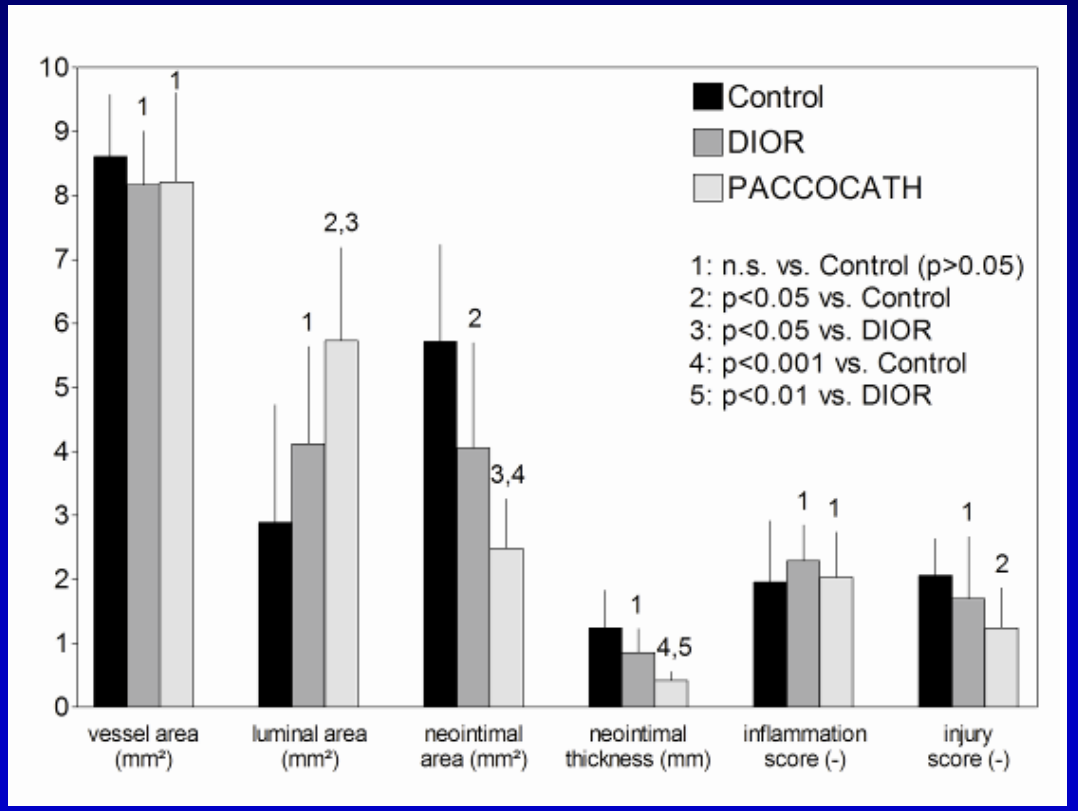
Drug-Eluting Balloon

Are they all equal?

Drug-Eluting Balloons: *Are they all equal?*







Cremers et al., Clin Res Cardiol 2009; 98: 325-330

Paclitaxel-eluting balloon versus paclitaxel-eluting stent in small coronary vessel disease.

The Piccoleto Trial

B. Cortese, MD, FESC,
A. Micheli, MD, A. Picchi, MD, A. Coppolaro,
S. Severi, MD, U. Limbruno, MD, FESC
U.O. Emodinamica, Cardiologic Dpt.
Ospedale Misericordia Grosseto

RESULTS

AD INTERIM ANALYSIS:
SUPERIORITY OF A STUDY GROUP

ENROLMENT STOPPED

Piccoleto trial
Dior vs. Taxus in SVD

ANGIOGRAPHIC FOLLOW UP (6 mo.)

	PEB	*PES*	*p*
Reference vessel diameter, mm ± SD	2.54 ± 0.47	2.58 ± 0.24	*0.73*
Minimal lumen diameter, mm ± SD	1.11 ± 0.65	1.94 ± 0.72	*0.0002*
Angiographic binary restenosis, n (%)	9 (32.1)	3 (10.3)	*0.043*

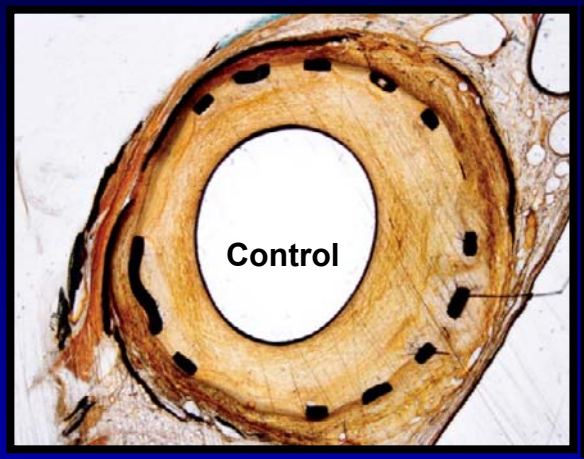
CLINICAL FOLLOW UP (9 mo.)

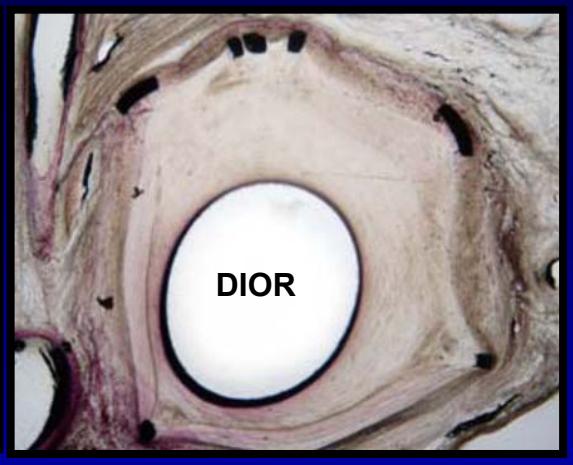
	PEB	*PES*	*p*
Death, n (%)	1 (3.6)	1 (3.5)	*0.98*
Cardiac death, n (%)	0 (0)	0 (0)	*0.97*
Myocardial infarction, n (%)	1 (3.6)	0 (0)	*0.30*
Target lesion revascularization, n (%)	9 (32.1)	3 (10.3)	*0.15*
Stent thrombosis/abrupt vessel closure (def/prob, ARC), n (%)	0 (0)	0 (0)	*0.97*
MACE, n (%)	10 (35.7)	4 (13.8)	*0.054*

Drug Coated Balloon

Different approaches in the porcine model

Bare Metal Stent
No drug

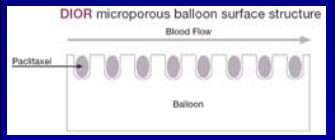




Roughened Balloon Surface

Dior® (Eurocor)
Elutax® (Aachen Resonance)

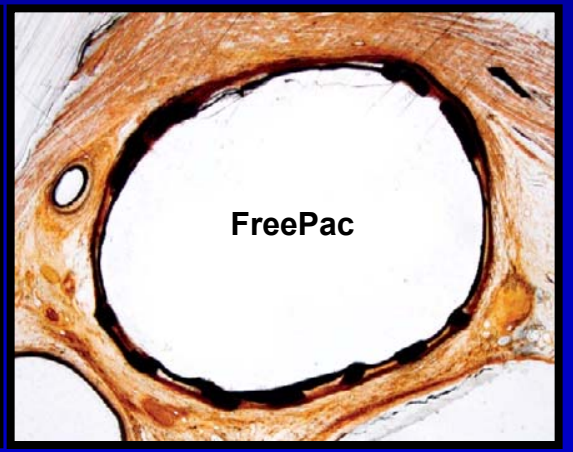
Paclitaxel 3 µg / mm²



PACCOCATH
Matrix Coating

SeQuent® Please (B.Braun)
Cotavance® (Bayer / Medrad)

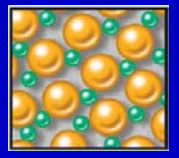
Paclitaxel 3 µg / mm²



Proprietary hydrophilic coating formulation

FreePac® (Invatec)

Paclitaxel 3 µg / mm²



Data from: Cremers, Clin Res Cardiol Epub 2009 Mar 12. Eurocor commercial information 2008, Invatec commercial information 2009

DEB: Currently on the market or in development

Company/Sponsor	Product	Drug formulation	Stage of development / Launch status / Trial activity	Data (published)
B. Braun Melsungen AG (Germany)	SeQuent® Please	Modified Paccocath® (Paclitaxel with iopromide (Ultravist®) formulation) 3 µg paclitaxel/mm² of balloon surface	CE (since 2009)	[1,2,3,4,5,6,7,8,9,10]
Eurocor GmbH (Germany)	DIOR® I	Paclitaxel admixed to DMSO delivered from the rough (i.e., microporous) balloon surface 3 µg/mm²	CE (since 2007, but now withdrawn)	[3,11,12,13,14]
	DIOR® II (2nd generation)	Coating method: 1:1 mixture of paclitaxel with shellac (natural resin composed of shellolic and alleuritic acid) 3 µg/mm²	CE for the coating technique Clinical trials: • DEBIUT (ongoing) • Valentines (ongoing) • DEB-AMI (recruiting)	
Lutonix, Inc. (USA)	MOXY™	Paclitaxel, matrix not disclosed 2 µg/mm²	? Clinical trials: • De Novo Pilot (ongoing) • PERVIDEO I Registry (ongoing)	-
Medtronic Invatec (Italy)	IN.PACT™ Falcon	Paclitaxel, matrix: hydrophilic FreePac™ 3 µg/mm²	CE (since 2009) Clinical trials: • Bello (not yet open) • IN-PACT CORO (recruiting)	Bioequivalence to Paccocath®
Aachen Resonance GmbH (Germany)	Elutax© I	Paclitaxel coated on structured balloon surface	CE (since 2008, but now withdrawn)	-
	Elutax© II	Coating: two layers of paclitaxel (elastic and drug depot) 2 µg/mm²	? Clinical trial: • EREMUS study (not yet open)	-
Biotronik AG (Germany)	Pantera® Lux	Paclitaxel, matrix: Butyryl-tri-hexyl citrate (BTHC) 3 µg/mm²	? Clinical trials: • PEPPER (ongoing) • Drug eluting Pantera® Lux Catheter Registry (recruiting)	[15]

Drug-Eluting Balloon - 2010

Alternative

- Treatment of coronary ISR (avoids a second stent)
  - BMS: clopidogrel 4 weeks
  - DES: clopidogrel 6 months
- De-novo lesions in small coronary vessels
- De-novo and restenotic lesions in PAVD

Possible alternative

- Bifurcations
- CTO
- Long lesions (avoids full-metal jacket)
- Pediatric interventions
- Peripheral applications: renal, cerebral, etc.

-> DEB are not a replacement for DES.

-> It may become the fourth platform in interventional cardiology and angiology (PTCA/PTA, BMS, and DES)

DEB: Guidelines

European Heart Journal
doi:10.1093/eurheartj/ehq277

ESC/EACTS GUIDELINES

Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Developed with the special contribution of the European Association

Table 33 Recommendations for specific percutaneous coronary intervention devices and pharmacotherapy

	Class[a]	Level[b]	Ref.[c]
FFR-guided PCI is recommended for detection of ischaemia-related lesion(s) when objective evidence of vessel-related ischaemia is not available.	I	A	15, 28
DES[d] are recommended for reduction of restenosis/re-occlusion, if no contraindication to extended DAPT.	I	A	45, 46, 55, 215
Distal embolic protection is recommended during PCI of SVG disease to avoid distal embolization of debris and prevent MI.	I	B	171, 213
Rotablation is recommended for preparation of heavily calcified or severely fibrotic lesions that cannot be crossed by a balloon or adequately dilated before planned stenting.	I	C	—
Manual catheter thrombus aspiration should be considered during PCI of the culprit lesion in STEMI.	IIa	A	204–208
For PCI of unstable lesions, i.v. abciximab should be considered for pharmacological treatment of no-reflow.	IIa	B	55, 209, 212
Drug-eluting balloons[d] should be considered for the treatment of in-stent restenosis after prior BMS.	IIa	B	174, 175
Proximal embolic protection may be considered during PCI of SVG disease.	IIb	B	214
For PCI of unstable lesions, intracoronary or i.v. adenosine may be considered for pharmacological treatment of no-reflow.	IIb	B	209
Tornus catheter may be used for preparation of heavily calcified or severely fibrotic lesions that cannot be crossed by a balloon or adequately dilated before planned stenting.	IIb	C	—
Cutting or scoring balloons may be considered for dilatation of in-stent restenosis, to avoid slipping-induced vessel trauma of adjacent segments.	IIb	C	—
IVUS-guided stent implantation may be considered for unprotected left main PCI.	IIb	C	—
Mesh-based protection may be considered for PCI of highly thrombotic or SVG lesions.	IIb	C	—
For PCI of unstable lesions, intracoronary nitroprusside or other vasodilators may be considered for pharmacological treatment of no-reflow.	IIb	C	—

[a]Class of recommendation.
[b]Level of evidence.
[c]References.
[d]Recommendation is only valid for specific devices with proven efficacy/safety profile, according to the respective lesion characteristics of the studies.
DAPT = dual antiplatelet therapy; DES = drug-eluting stent; FFR = fractional flow reserve; IVUS = intravascular ultrasound; MI = myocardial infarction; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction; SVG = saphenous vein graft.

Vielen Dank !

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J. Becker, P. Günther

Institut für Medizintechnologie GmbH
(Magdeburg), Dr. Dirk Mahnkopf

Anakat GmbH (Berlin)
InnoRa GmbH (Berlin)

Clinical trials
CRO: Parexel (Berlin), Gimbel (Saarlouis), IKKF (München), CRI (Rotenburg)
Core Lab: Dietz (Wiesbaden), Degenhardt (Rotenburg), Beregi (Lille, FR)
Peripheral: Tepe (Tübingen), Zeller (Bad Krozingen), Ricke (Berlin), Albrecht (Berlin), Hosten (Greifswald)
Coronary: Antoni (München), Bocksch (Berlin), Buerke (Halle), Figulla (Jena), Haghi (Mannheim), Hamm (Bad Nauheim), Hehrlein (Freiburg), Hengstenberg (Regensburg), Heuer (Dortmund), Kleber (Berlin), Kücherer (Heidelberg), Leschke (Esslingen), Mathey (Hamburg), Nienaber (Rostock), Rutsch (Berlin), Schieffer (Hannover), Vallbracht (Rotenburg), Werner (Darmstadt), Zeymer (Ludwigshafen)
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