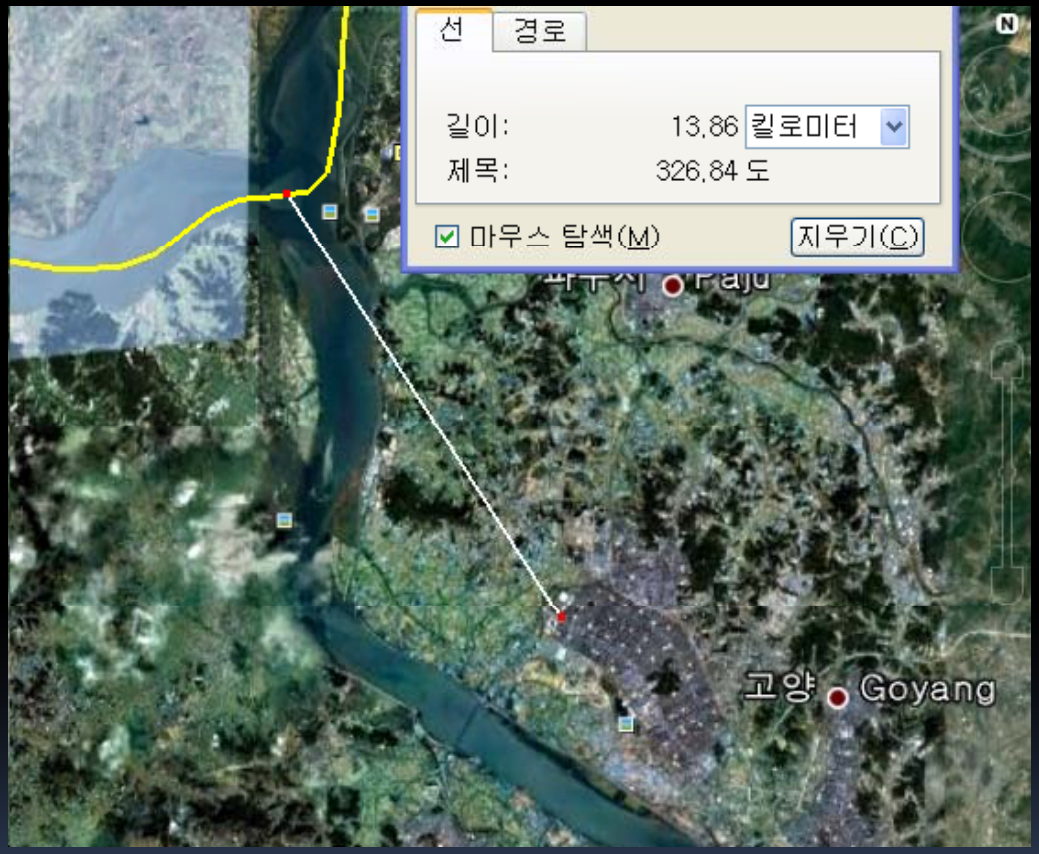
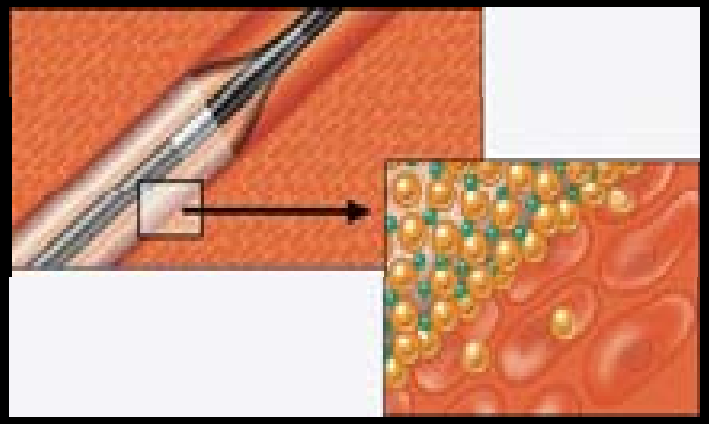
Drug Eluting Balloon in PCI





인제대학교 일산백병원
이성윤

- Rationale
- Technologies
- Paclitaxel DEB: Clinical Studies
  - DEB for ISR
  - DEB for de Novo Lesions
  - DEB for Bifurcation Lesions
- How to DEB
- Clinical Considerations and Unresolved Issues

Major PCI Devices

Balloon Angioplasty

- Overthe Wire System
- Evolutional device
- Limit
  - Elastic recoil
  - High TLR rate

Bare Metal Stent

- Overcome BA's Limit
- Limit
  - Stent Thrombosis
  - ISR by neointimal hyperplasia

Drug Eluting Stent

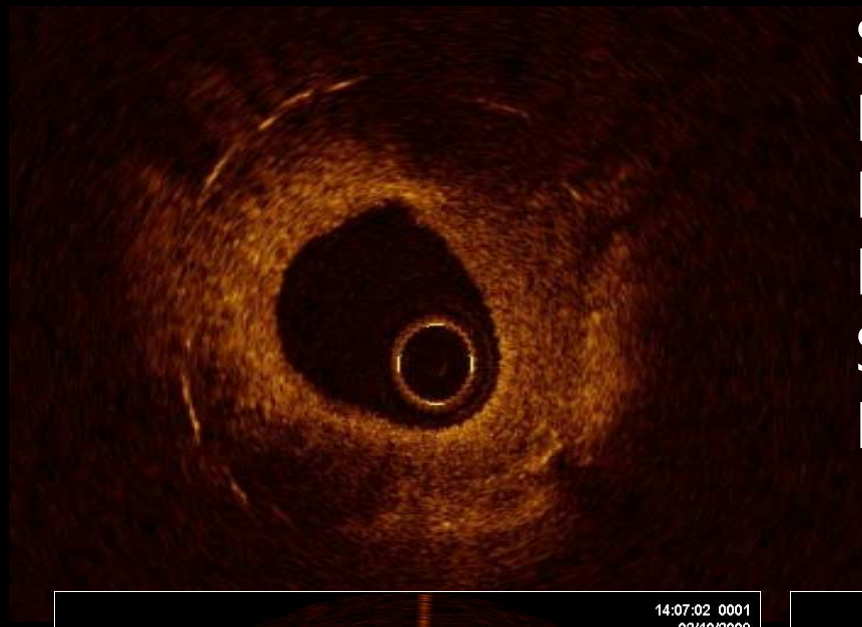
- Reduce TLR rate
- Limit
  - Late Stent Thrombosis, Stent Malapposiotion, Fracture
  - Triple Anti PLT Agent or Long Dual Anti PLT Agents
  - Still DES ISR by OCT

DES Efficacy –Safety Balance

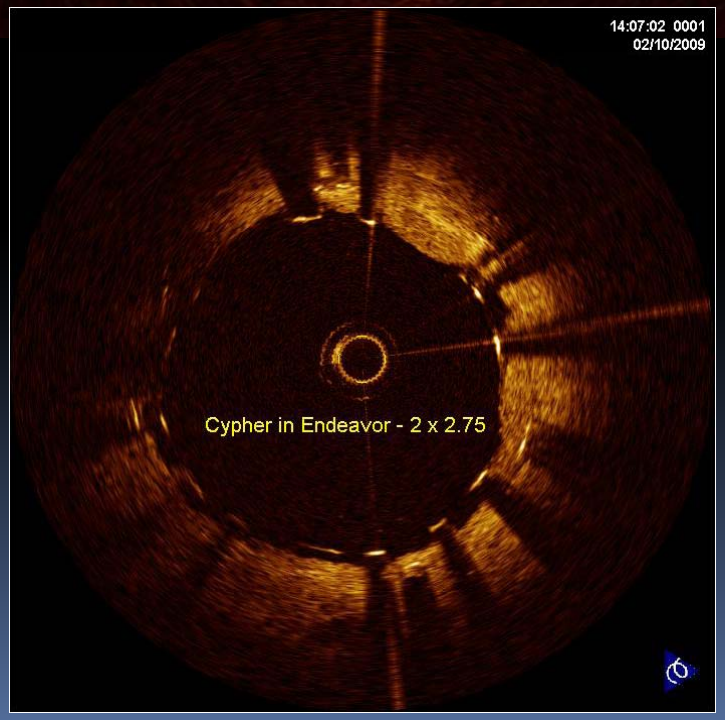
	Bare Metal Stents	CYPHER & TAXUS	ENDEAVOR DES	XIENCE DES
Safety	+++	++	+++	+++
Efficacy	++	++++	+++	++++
Deliverability	++++	++	++++	++++

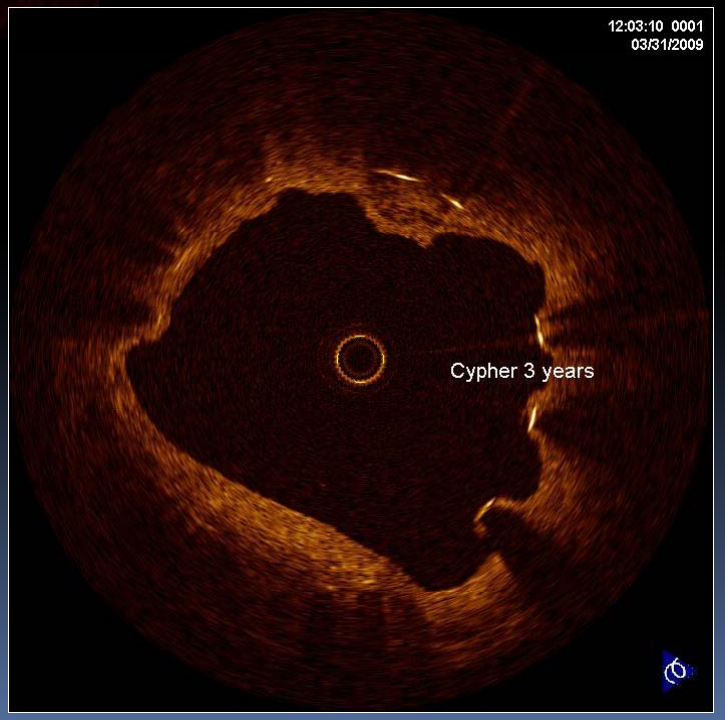
Improved efficacy, but diminished deliverability and safety

Improved deliverability (E,X), efficacy (X), safety (E)



Still DES –
Restenosis
Late stent malapposition
Late stent thrombosis
Stent Fracture
Long Dual antiplatelet agent





2010; Year of Brand New Stents

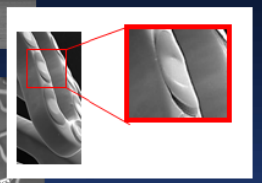
BIOMATRIX

Nobori

Drug Eluting Stent

- The NEVO™ stent provides:
  - **CoCr stent platform**
    Flexible, conformable, thin struts, maximized vessel coverage
  - **Reservoir technology**
    Reduced contact between vessel wall and polymer
  - **Biodegradable polymer**
    Rapid endothelialization
    Inflammation scores similar to BMS CYPHER-like release kinetics and tissue sirolimus levels
  - **Sirolimus**

Properties of the JACTAX Stent



JA®Coating

- *9.2 µg of Paclitaxel and 9.2 µg DLPLA (16 mm)*
- *2700 microdots (16 mm)*
- *Mass of polymer approx 3.4 ng per microdot*
- *> 1 micron thick, abluminal and lmw biodegradable polymer decreases persistence time*

Stent platform

- *Liberté ™pre-mounted stent (Boston Scientific)*

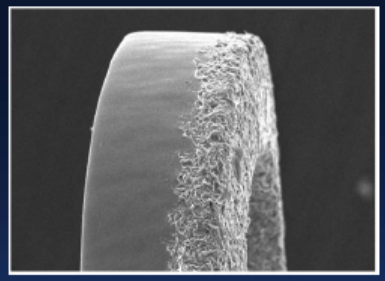
BioFreedom™

Hypothesis: Polymer-free drug release via porous-eluting stents may reduce late events caused by polymer stent coatings.

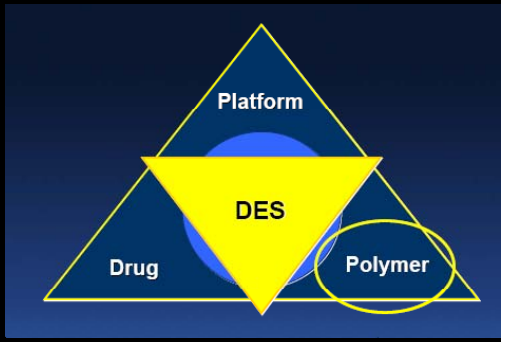
Potential advantage

- Avoid long term late adverse effects that might be attributable to the polymer

Selectively micro-structured surface holds drug in abluminal surface structures



Rationale



1. Limitations of DES

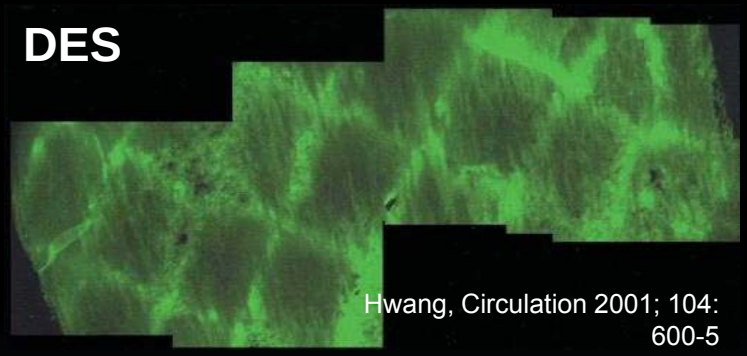
- Nonstent-based local drug delivery
  - Without the limitations of DES
  - Maintains the antiproliferative properties of DES
  - No chronic polymer effects +Reduced drug exposure = Optimal Biocompatibility

2. **Lesions where DES cannot be delivered or where DES do not perform well**
  - Distal, tortuous, calcified etc.
  - Instent Restenosis
  - Bifurcations (esp. ostium sidebranch)
  - Diabetics
  - Small vessels
  - Diffuse disease

3.비 심장 동맥 병변 –
  - 말초혈관 병변 (both SFA and infra-popliteal)
  - 뇌혈관 병변

Potential Advantages of Drug Eluting Balloon

- Local drug delivery over Very short period of time
- Polymer Free - Avoid chronic inflammation
- 100% lesion coverage (DES 15% lesion coverage by strut)



- Reduced dual anti-platelet therapy
- No double / triple metal layers in case of ISR or BIF
- Easy lesion crossing / deliverability by balloon only

DES Versus DEB

	DES	DEB
Platform of drug delivery	Stent scaffolding	Balloon
Retention	Polymer based	Embedded imprinted
Drug dose	Low: 100 to 200 μg	High: 300 to 600 μg
Release kinetics	Slow and controlled	Fast release
Distribution	Strut-based vascular penetration	Balloon surface homogenous distribution
Advantages	Mechanical support Abluminal trapping Less drug spillage into the circulation Proven efficacy in many indications No acute recoil tackled dissection	Leave no implant Larger surface area Less drug localization in the vessel wall Accessible to complex lesions and long segments May not require prolonged DAPT

Technologies

Local drug delivery system

using the balloon as a passive drug transfer conduit

- **Variables ?**
  - Which drug
    - Drug lipophilicity
    - 2ndary release from cytoskeletion
  - Transfer efficiency (carrier agents)
  - Drug dose
  - Balloon inflation times, and # inflations
- Methodologies to load the drug to the balloon

  spraying, dipping, nanoparticles, and imprinting the drug on the rough surface of the balloon
- **Issues**
  - Predictable drug transfer
  - Consistent tissue pharmacodynamics;

Drug-Eluting or Delivery Balloon Systems

Name	Manufacturer	Principle
Paccocath	Bayer (Bavaria Medizin Technologie, Oberpfaffenhofen, Germany)	Paccocath technology (paclitaxel embedded in hydrophilic iopromide coating)
SeQuent Please	B. Braun Melsungen AG (Melsungen, Germany)	Improved Paccocath technology
Coroflex DEBlue	B. Braun Melsungen AG	Drug-eluting balloon with a thin strut CoCr stent
DIOR	Eurocor (Bonn, Germany)	Paclitaxel coated onto microporous balloon surface and folded
MAGICAL	Eurocor	Folded balloon in combination with stent
Elutex	Aachen Resonance (Aachen,Germany)	Folded balloon
GENIE	Acrostak Corporation (Winterthur, Switzerland)	Liquid drug delivery catheter
IN.PACT Amphirion	INVAtec (Italy)	FreePac, a proprietary coating that balances hydrophilic and lipophilic properties
IN.PACT Falcon	INVAtec	FreePac
Advance PTX	Cook Medical (Bloomington, Ind)	DEB

Methods & Technologies

Several techniques and methods…

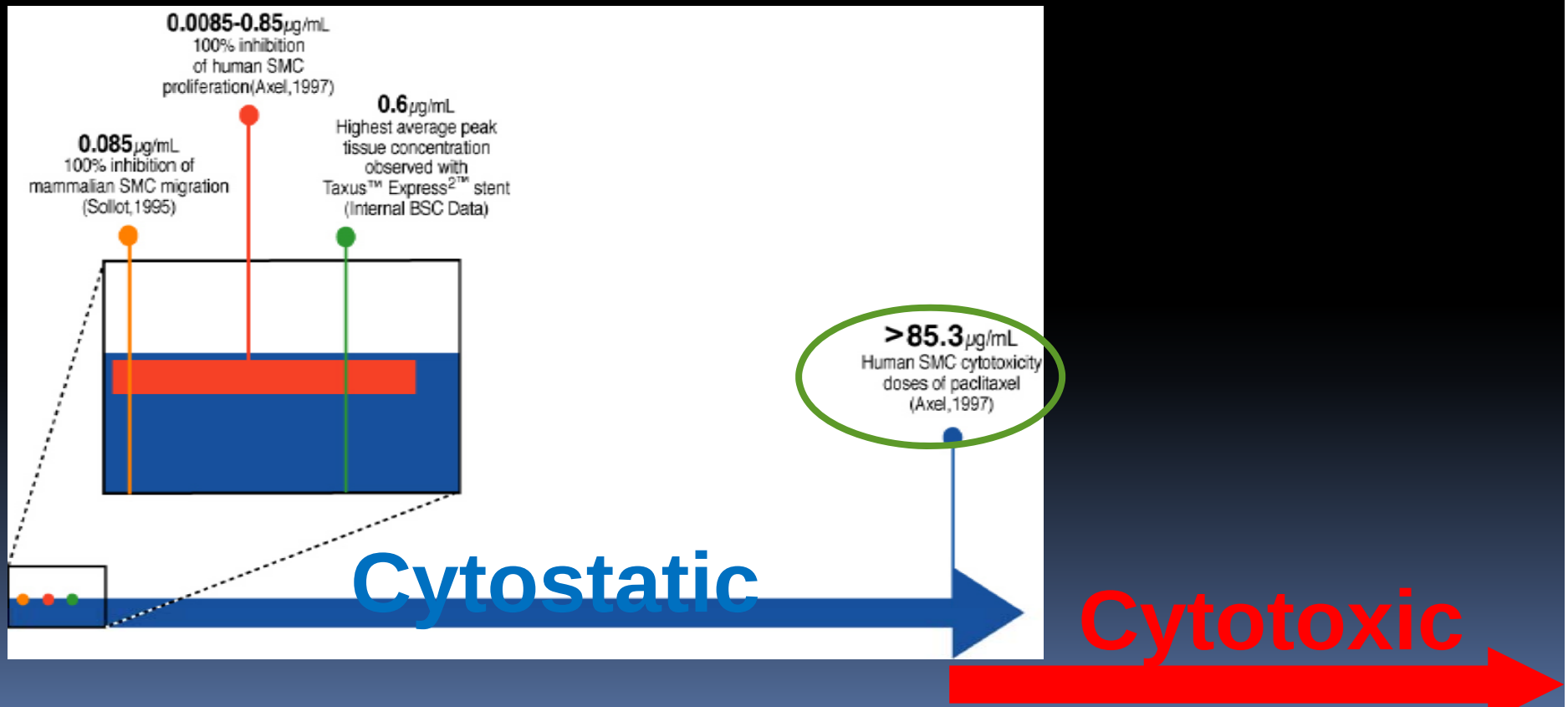
However **Properties in common**:

- **Lipophylic-drug** (rapid absorption) for short inflation times
- **Currently, paclitaxel preferred drug**

  due to increased tissue residence times
- **2~3 µg paclitacel /** ㎟ balloon surface
- Sustained retention into tissue (microtubuli/ cytoskeleton)
- Prevention of drug release before landing at ‘ target ‘
- Increased profile compared to non-coated balloon

Why Paclitaxel?*

1. The ideal drug needs to inhibit cell proliferation without killing the cells.
2. Paclitaxel has a dose dependant effect associated with a large therapeutic window.

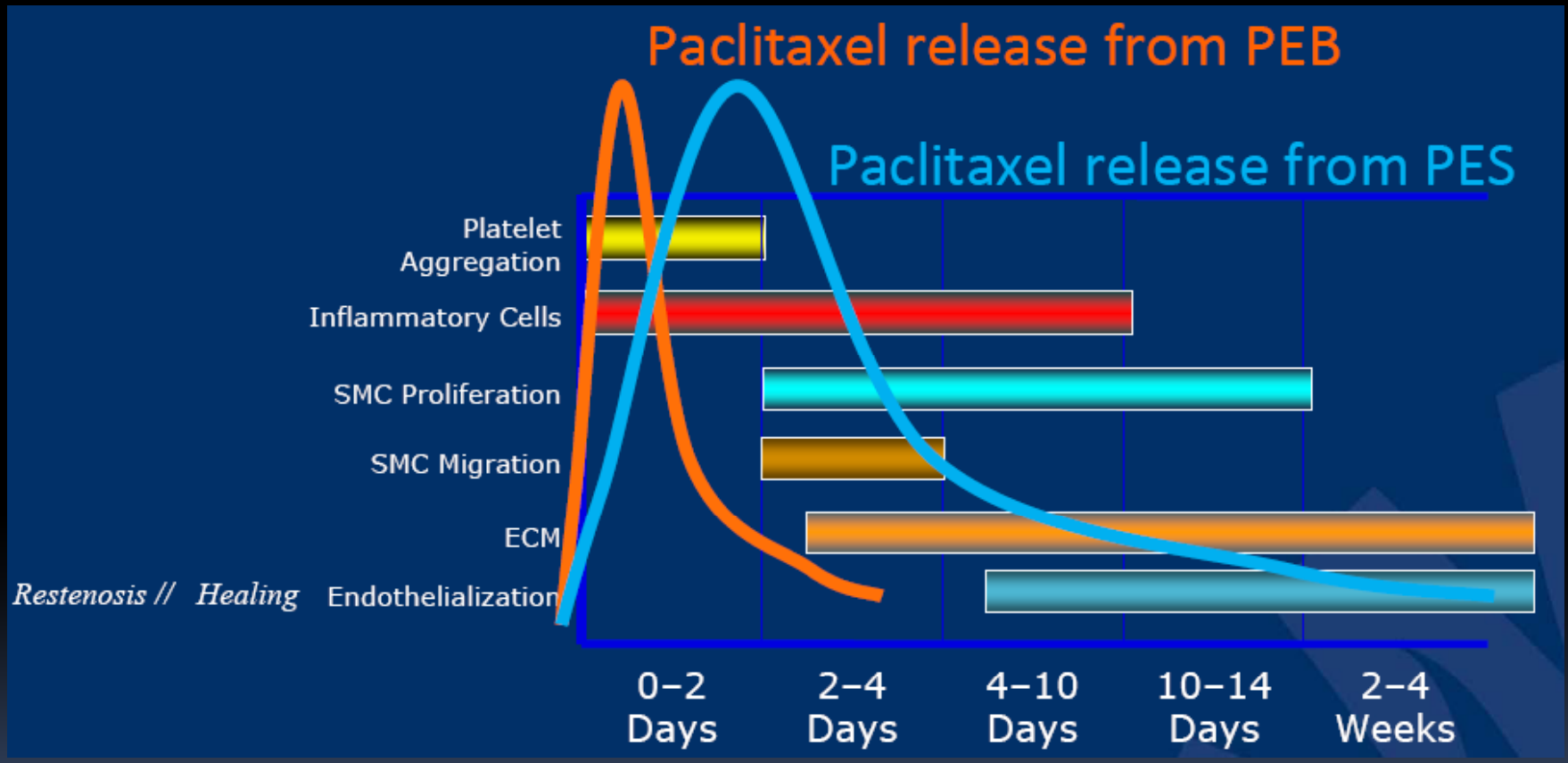


* Axel et al: Circulation. 1997; 96:636-645; Sollotet al; J. Clin.Invest.1995; 95: 1869-1876;

How does it work?

Restenosis is a complex mechanism

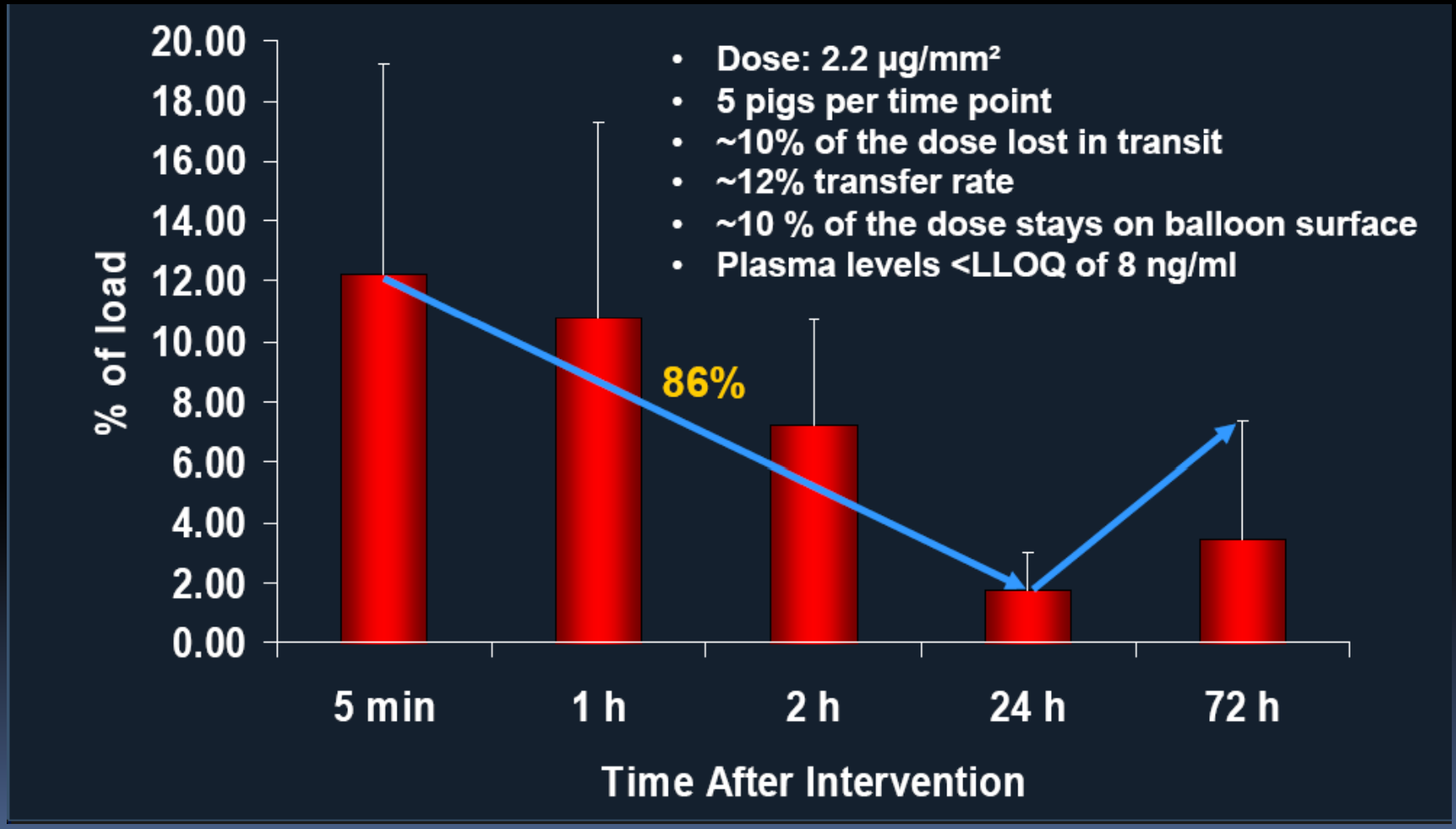
involving many factors



Restenotic cascade*

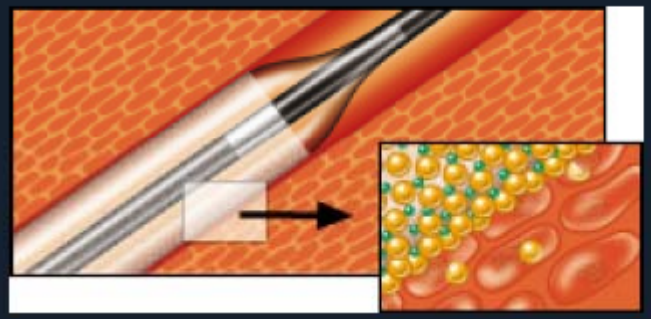
* Table adapted from Fernset al: International Journal of Experimental Pathology, 2000; 81:63-88

Paclitaxel Levels in Vessel Wall
Short Term PK Findings



SeQuent® Please
Paccocath® Technology – B. Braun

In.Pact
Invatec



DIOR® - EuroCor

Elutax® - Aachen Resonance

Cricket™
Mercator

Genie™
Acrostak

ClearWay™
Atrium

Methods & Technologies

Paclitaxel without Matrix

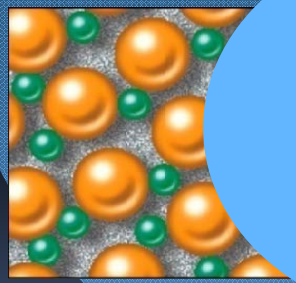
Genie™
(Acrostak)

Dior™
(Eurocor)

Elutax™
(Aachen Resonance)

Paclitaxel with Matrix

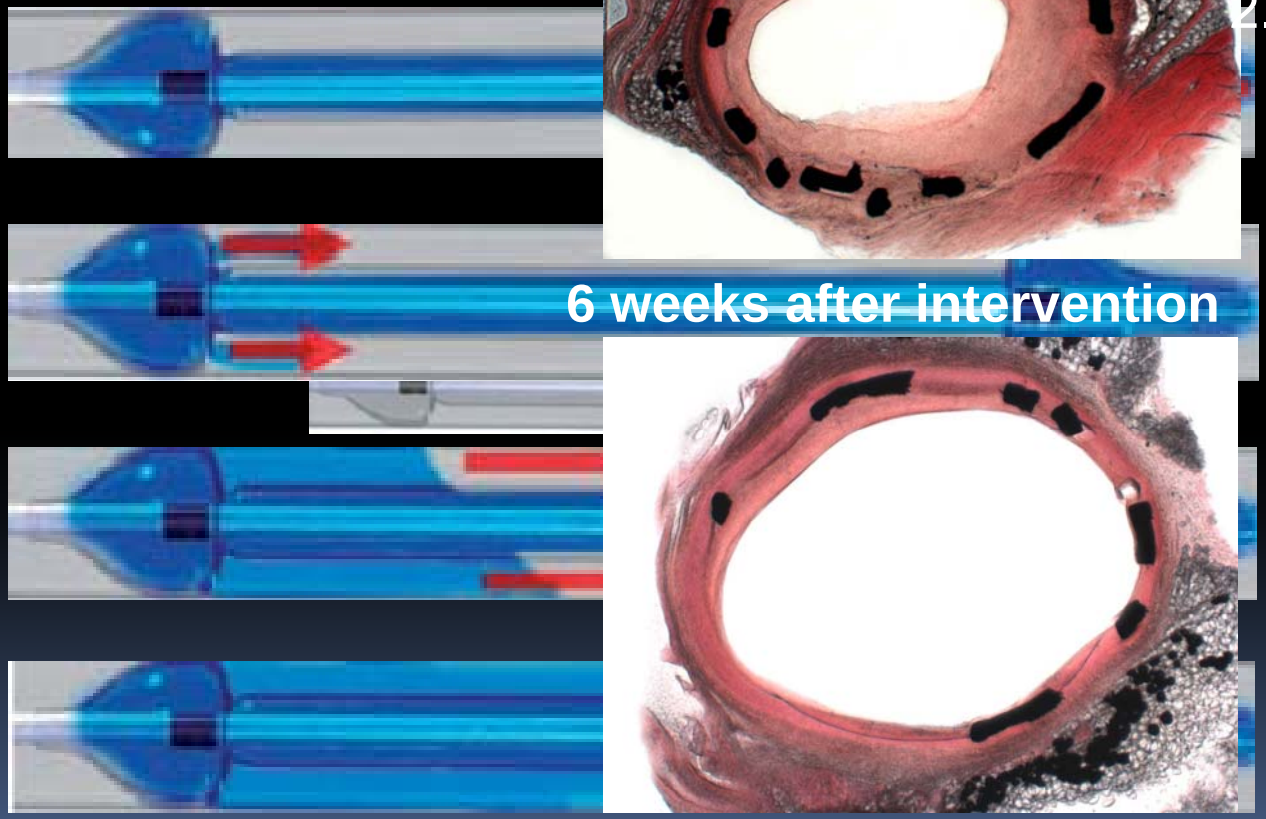
SeQuent Please™
(B. Braun)



IN.PACT Falcon™
(Invatec)

Genie™

- Liquid Drug Delivery
- Easy use of other drugs
- Additional device/step
- Technology complex
- Handling needs training



Neointimal area

2.37±0.23mm²

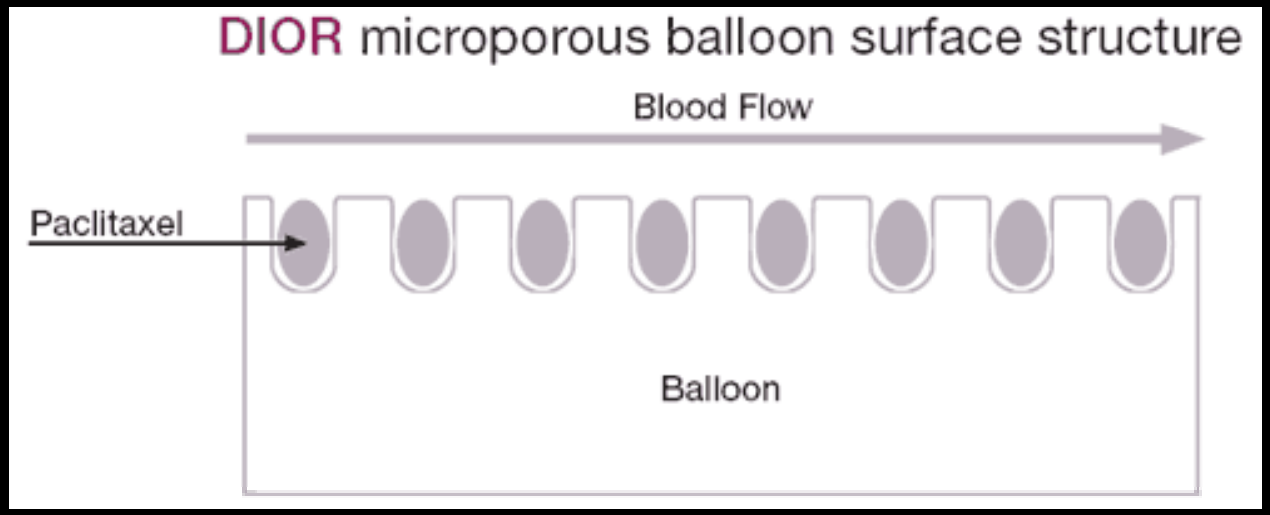
6 weeks after intervention

P<0.001

1.04±0.1mm²

Herdeg, C EuroInterv 2007;3:286-8

Dior™



- Handling like a typical PTCA catheter
- Inflation up to 60 seconds for full drug release
- 1st inflation of 20s releases ≈35-79% of the drug
- 2nd inflation of 20s releases another ≈35-79% of the drug
- Concern: reproducibility of drug delivery

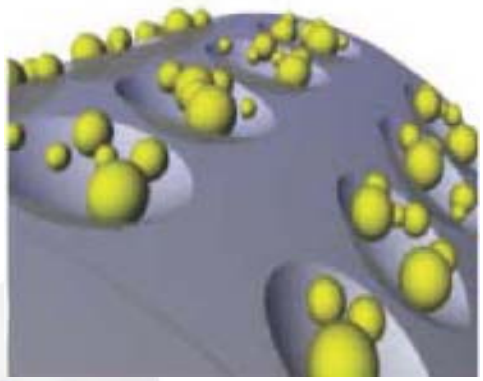
ELUTAX™

AACHEN RESONANCE GMBH

ELUTAX

Paclitaxel - Eluting Balloon

DRUG LOADING

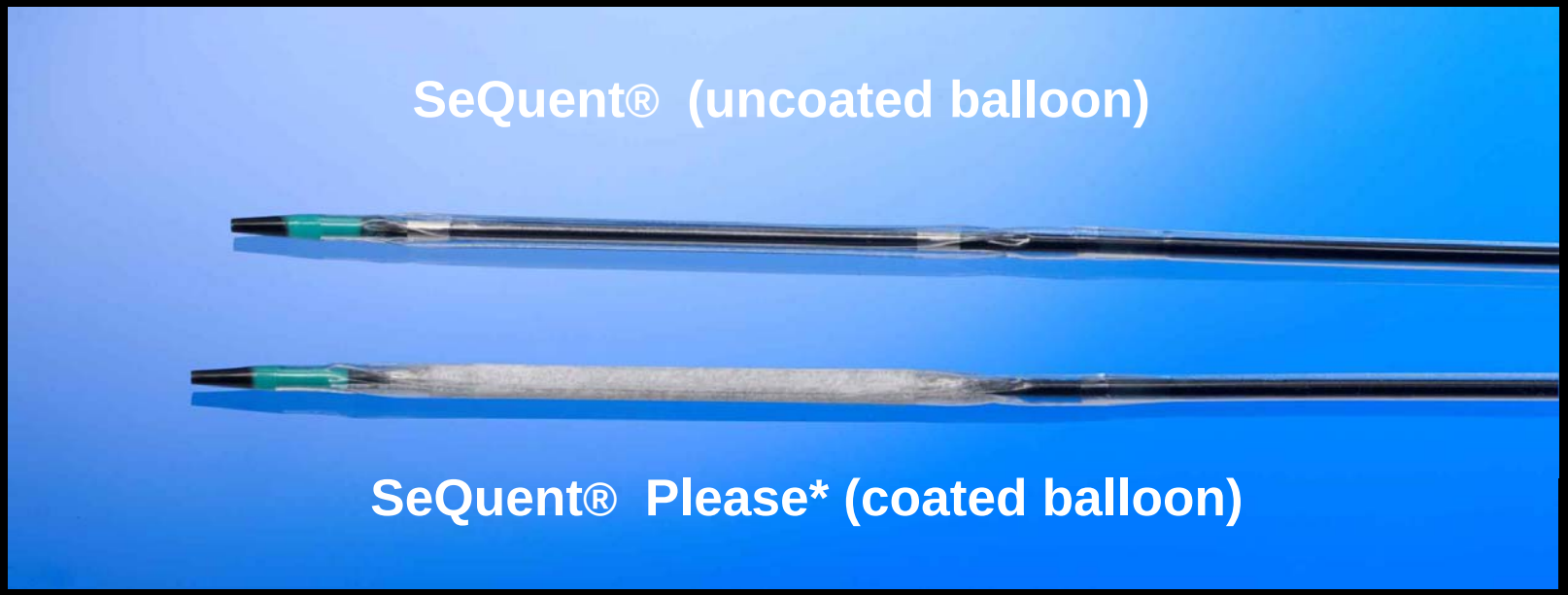


- 2 µg paclitaxel per square millimeter balloon surface

- No polymer or solvent use when releasing the drug

- Drug wash-off protection through:
  - encasing the drug in the balloon's microporous surface
  - "hiding" the drug between the folds
  - paclitaxel is hydrophobic and releases after contact with the arterial wall

SeQuent Please™



*SeQuent® Please (**B.Braun** Vascular Systems, Berlin, Germany)
is manufactured based on the **PACCOCATH technology** with
3µg paclitaxel/mm²;
CE marked in the EU,
approved in other countries

SeQuent Please™

The Matrix Coating

PACCOCATH technology creates a unique matrix coating

pure paclitaxel

paclitaxel + iopromide

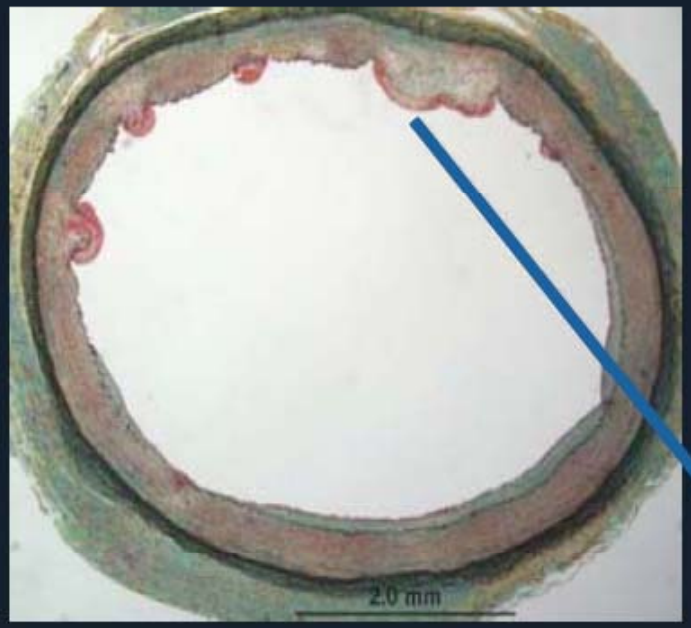
(hydrophilic spacer)

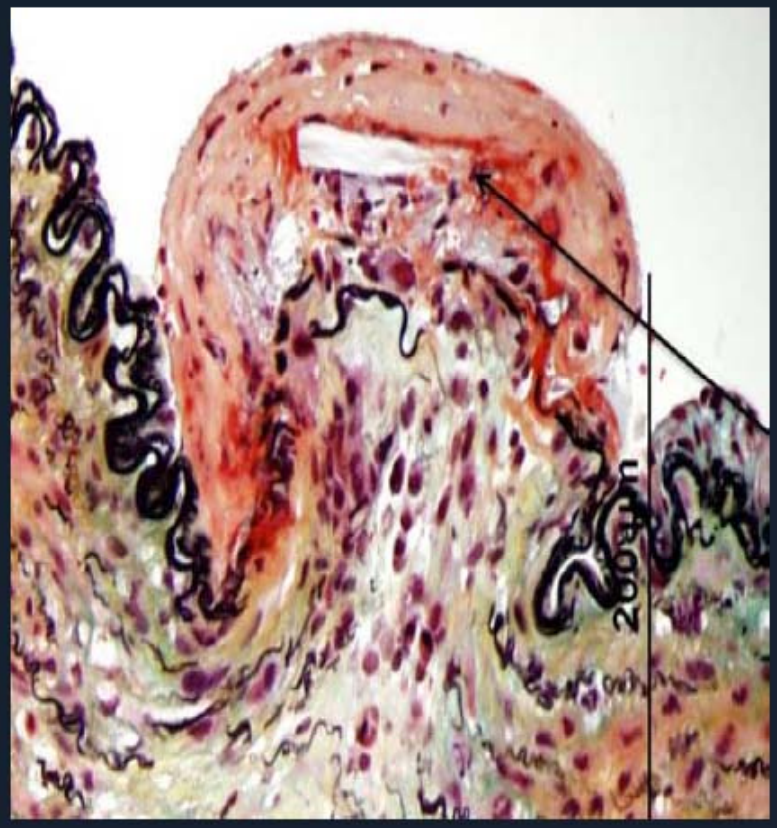
without

with **PACCOCATH technology**

- huge contact surface between lipophilic drug and the vessel wall
- high bioavailability of paclitaxel at the target site for rapid drug absorption by the vessel wall
- Paccocath coating 은 ethylene oxide sterilization을 해도 안정적이며 풍선의 유효기간은 약 1년 정도

PACCOCATH Technology
Proposed Mechanism of Action





Localized vascular retention of paclitaxel acting as micro "depots" producing secondary local drug delivery.

Efficacy of BMS Crimped on Paclitaxel Eluting Angioplasty Balloons in the Porcine Coronary Restenosis Model

Neointimal Area:

HD-DEB= 0.86 ± 0.29 mm^2

PP-DEB= 0.99 ± 0.40 mm^2

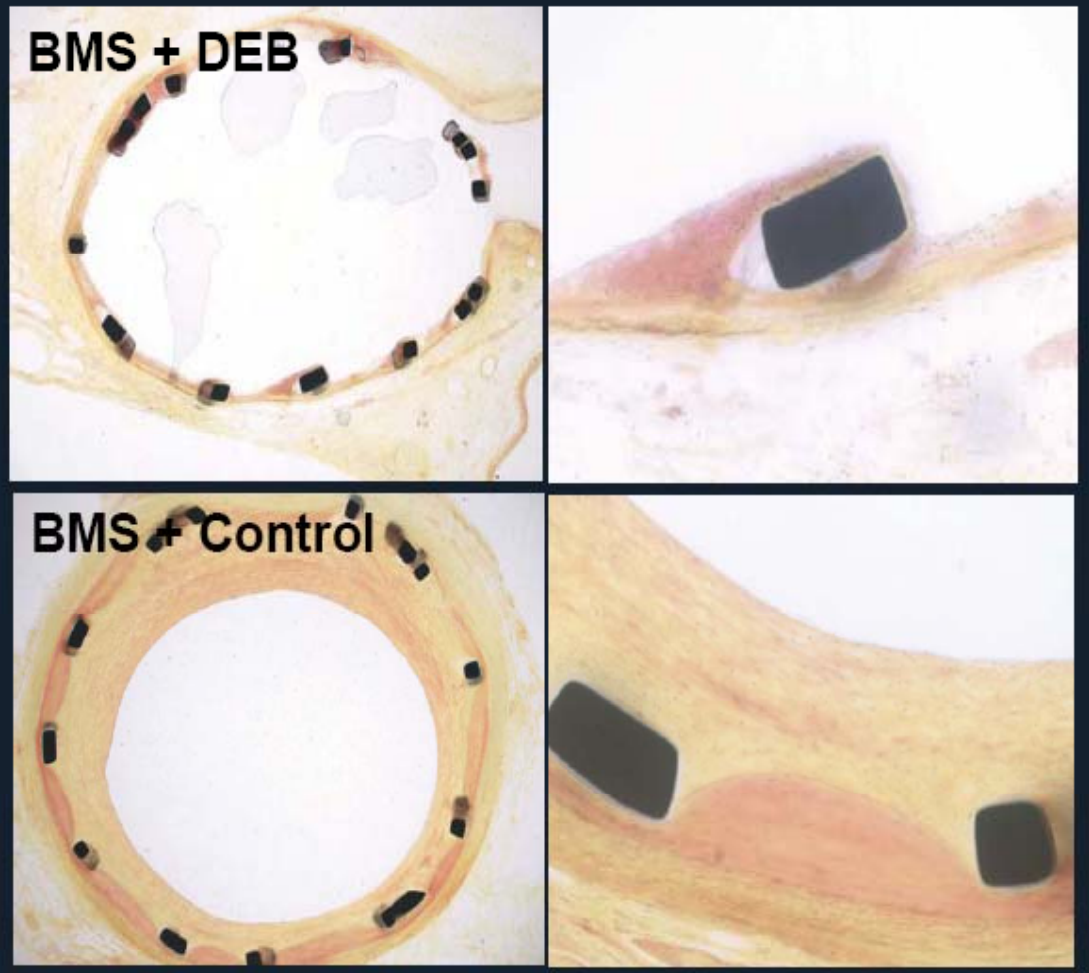
Control= 2.11 ± 1.03 mm^2

Late Lumen Loss:

HD-DEB= 0.20 ± 0.18 mm

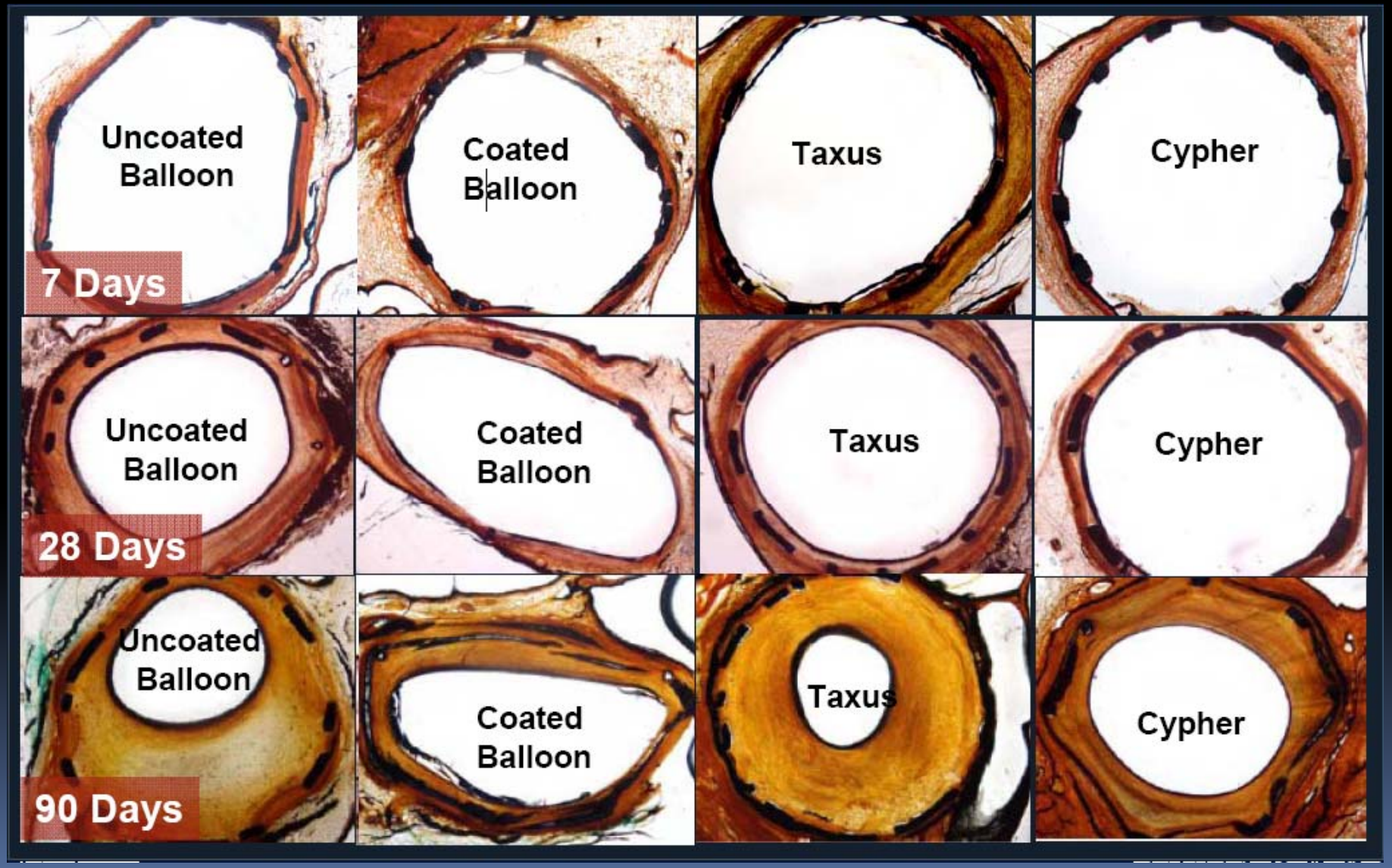
PP-DEB= 0.39 ± 0.21 mm

Control= 0.92 ± 0.72 mm



Troels T. Submitted to Circulation.

Paclitaxel Delivery Directly into the Vessel Wall Using a DEB: PACCOCATH



1. PEB for Instent Restenosis

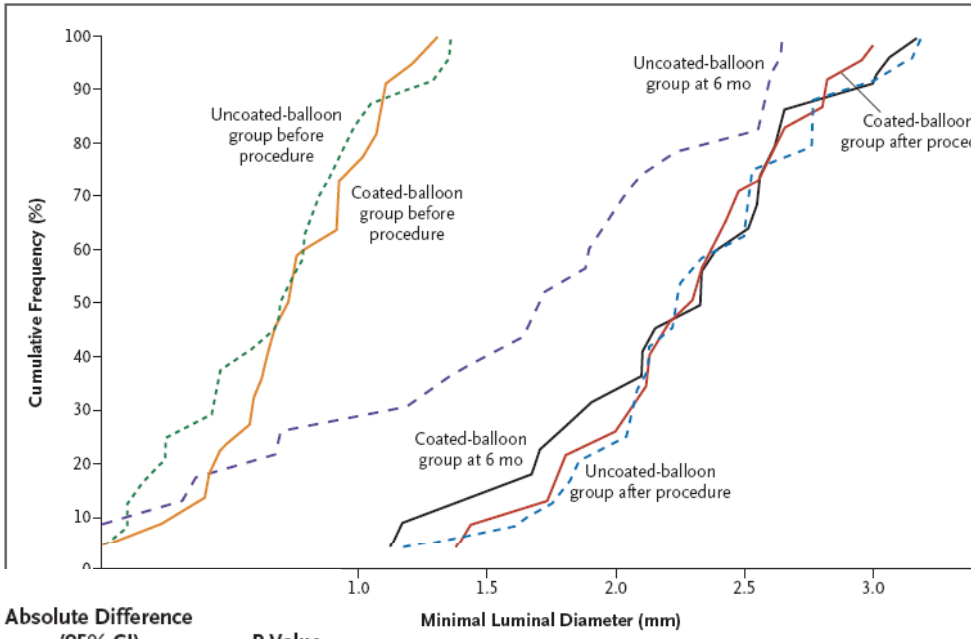
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

◄ Previous Volume 355:2113-2124 November 16, 2006 Number 20 Next ►

Treatment of Coronary In-Stent Restenosis with a Paclitaxel-Coate Catheter

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



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

ibution of In-Segment Minimal Luminal Diameter on Quantitative Corona sis).

oon group and the coated-balloon group before the procedure, after the

PEB vs. Uncoated Balloon for ISR Lesions

Trial	Group, No.of Pts	6-mo Late Loss In-Stent, mm	6-mo Restenosis InSegment, n(%)	6-mo TLR, n(%)	TLR (% at mo)	MACE (% at mo)
Paccocath ISR I	PEB (n=26)	0.09±0.49	1 (5)	0	0 (0% at 24)	1 (4% at 24)
	UB (n=26)	0.76±0.86	10 (43)	6 (23)	6 (23% at 24)	9 (35% at 24)
Paccocath ISR II	PEB (n=28)	0.19±0.43	2 (8)	2 (8)	3 (11% at 24)	5 (18% at 24)
	UB (n=28)	0.74±0.86	15 (58)	14 (50)	14 (50% at 24)	16 (57% at 24)

2 Years F/U of PACOCATH ISR I + II pooled data of 108 pts.
PEB vs Uncoated balloon
Binary restenosis rate : 3/47 vs 25/49, $p<0.001$)
12 months TLR : 2/49 vs 20/47($p<0.001$).

Clin Res Cardiol. 2008;97:773–781

.

PEPCAD II-ISR

	Sequent Please (N=66)	Taxus stent (N=60)	P=
Follow-up: clinical [months]	6.2 ± 0.8	6.2 ± 0.8	0.7
Follow-up: clinical [N]	64 (97.0%)	60 (100%)	0.4
Follow-up: angiographic [N]	58 (87.9%)	54 (90.0%)	0.8
Late lumen loss [mm]	0.19 ± 0.38	0.47 ± 0.71	0.03
Binary restenosis in segment	2/58 (3.4%)	11/54 (20.4%)	0.007
TLR	2/64 (3.1%)	10/60 (16.7%)	0.02
Myocardial infarction	0/64 (0.0%)	[f]1/60 (1.7%)	1
Death	*2/64 (3.1%)	**1/60 (1.7%)	1
Total MACE (w/o noncardiac death)	3/64 (4.7%)	11/60 (18.3%)	0.02

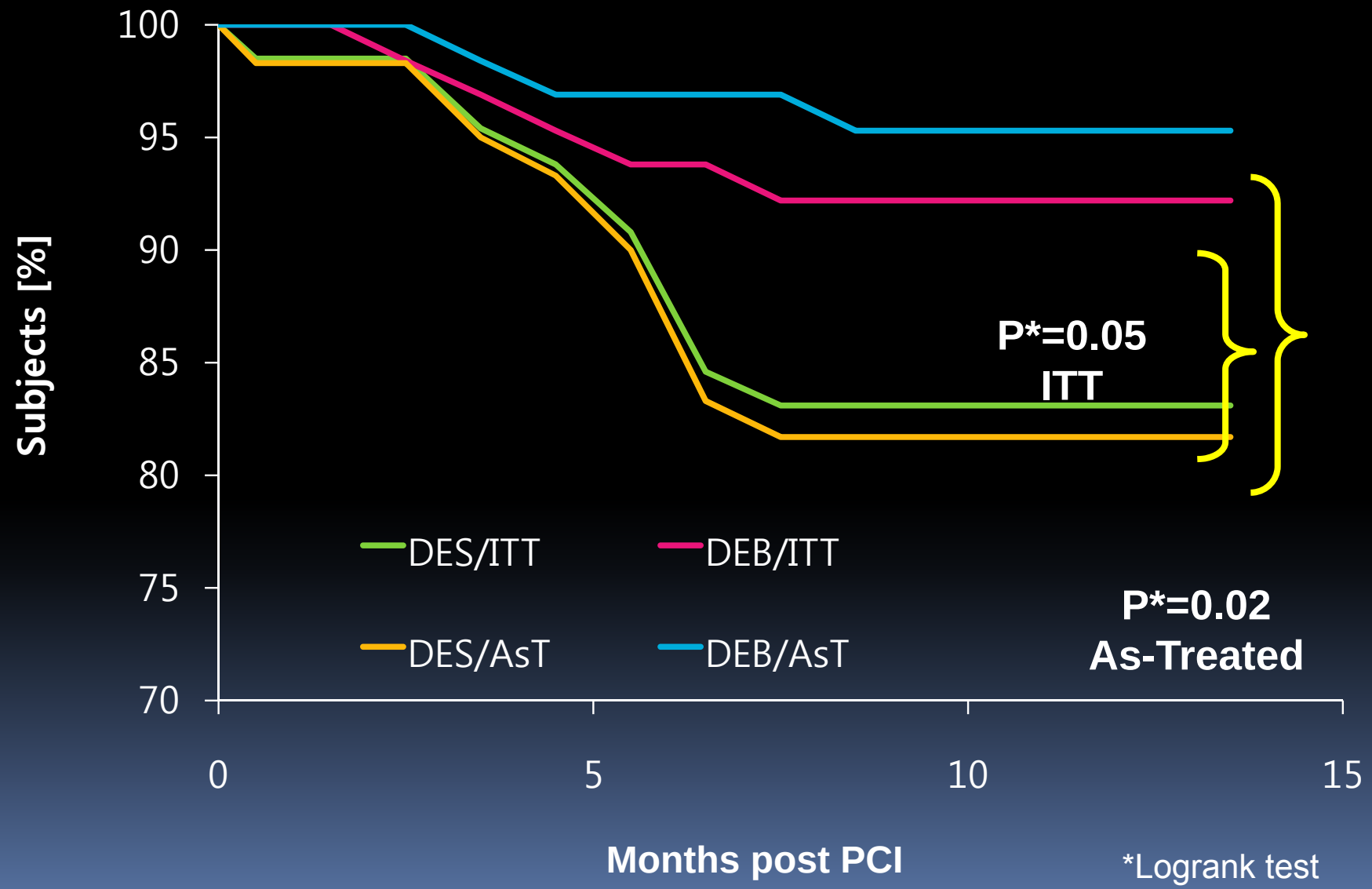
*1 cardiac, not lesion related 2 non cardiac

** non-cardiac death

[f]NSTEMI due to side branch occlusion

Circulation 2009;119:2986-94

12-Month Event Free Survival



*Logrank test

Circulation 2009;119:2986-94

Angiographic and Clinical Results From PEB for ISR Lesions

Trial	Group, No.of Pts	6-mo Late Loss In-Stent, mm	6-mo Restenosis InSegment, N (%)	6-mo TLR, N (%)	TLR (% at mo)	MACE (% at mo)
Paccocath ISR I	PEB (n=26)	0.09±0.49	1 (5)	0	0 (0% at 24)	1 (4% at 24)
	PB (n=26)	0.76±0.86	10 (43)	6 (23)	6 (23% at 24)	9 (35% at 24)
Paccocath ISR II	PEB (n=28)	0.19±0.43	2 (8)	2 (8)	3 (11% at 24)	5 (18% at 24)
	PB (n=28)	0.74±0.86	15 (58)	14 (50)	14 (50% at 24)	16 (57% at 24)
PEPCAD II	PEB (n=66)	0.19±0.38	4/57 (7)	2/64(3.1)	4 (6% at 12)	6 (9% at 12)
	Taxus(n=65)	0.47±0.71	12/59 (20)	10/60(16.7)	10 (15% at 12)	15 (22% at 12)

RELEASE PRESS RELEASE PRESS RELEASE

EUROCOR • Enrollment finished for Valentines Trial

Eurocor, Bonn Germany • The Valentines Trial

The Valentines Trial is the **first global registry** to include ISR cases treated with the drug eluting balloon DIOR®, as it was connected to CRT 2010, it has been the fist congress dedicated clinical trial ever. As planned, the enrollment started on Valentines day 2010 and proceeded through February 23, 2010 – the closing day of the CRT congress in Washington DC. The organizers: Prof. Sigmund Silber *(Munich)*, Dr. Pieter Stella *(Utrecht)*, Dr. Giuseppe Sangiorgi *(Modena)*, Dr. Ron Waksman *(Washington DC)* and Dr. Rembert Pogge von Strandmann *(Bonn)* are delighted to announce that more than **230 patients** have been treated according the protocol in the stipulated timeframe.

The Valentines Trial Website

The Valentines Trial

2. DEB for de Novo Lesions

- Small vessel disease
- Complex Lesion

Trial	Device Used	Treated Lesion	No of Pts	Trial Results
PEPCAD I SVD	SeQuent Please De novo	Small vessels	120	Binary restenosis at 6 mo
PEPCAD III	Coroflex DEBlue vs Cypher	Complex, de novo lesions	600	Failed to show non-inferiority
PEPCAD IV DM	SeQuent PleaseCorflex Blue vs Taxus	De novo lesions in diabetics	128	Ongoing
PEPCAD V	SeQuent Please+ Coreflex	Bifurcation	25	**9 mo late loss 0.12~0.20 mm in only DEB 0.38~0.73 mm with Coroflex**
PEPCAD VI	SeQuent Please+ Corflex Blue	CTO	48	Ongoing
DEBIUT	Dior	Bifurcation	20	No events at 4 mo

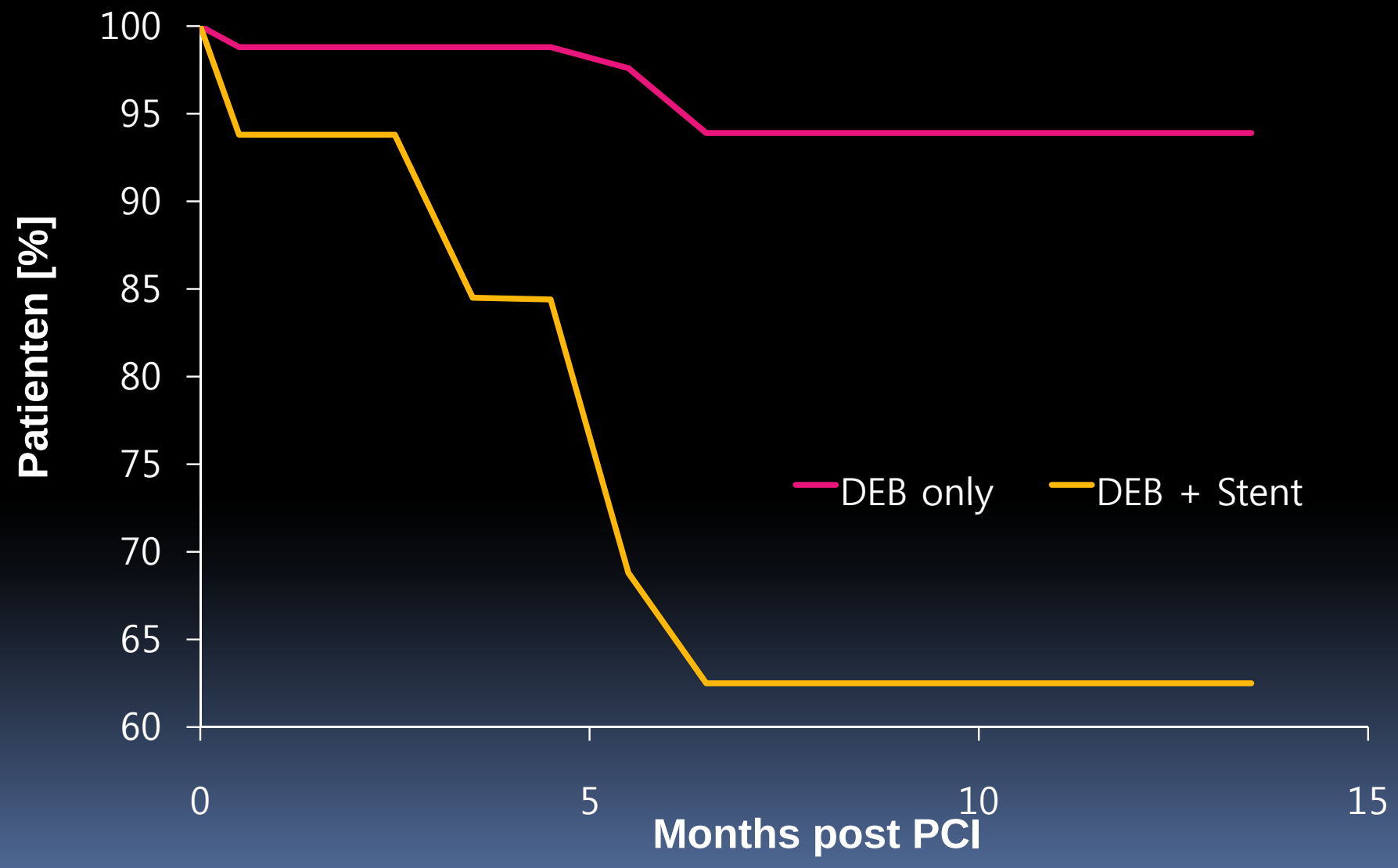
PEPCAD I -Small Vessel Disease

- 120 pts with diameter < 2.8 mm
- Prospective, nonrandomized, multicenter
- 1-arm phase II pilot study
- Primary end point
  - late loss at 6 months
- secondary end points
  - binary restenosis
  - MACE at 6 months, and MACE at 1 and 3 years.
- Of the 114 patients treated with DEB, 32 required stenting postprocedure.

Outcome (N=114)

	DEB Only (N=82)	DEB & BMS (N=32)
Follow-up: clinical [months]	6.4 ± 1.2	6.5 ± 1.5
Follow-up: clinical [N]	82 (100%)	32 (100%)
Follow-up: angiographic	73 (89%)	29 (90.6%)
Late lumen loss [mm]	0.18 ± 0.38	0.73 ± 0.74
Binary restenosis in segment	4/73 (5.5%)	13/29 (44.8%)
Binary restenosis in lesion	4/73 (5.5%)	12/29 (41.3%)
TLR	4/82 (4.9%)	9/32 (28.1%)
Stent thromboses with PCI	N/A	2/120 (1.7%)
Myocardial infarction	1/82 (1.2%)	1/32 (3.3%)
Death	0/82 (0 %)	0/30 (0 %)
Total MACE	5/82 (6.1%)	12/32 (37.5%)

1-Year Event Free Survival



PEPCAD III

600 pts with significant stenosis in native coronary arteries with nominal diameters 2.5 mm ~ 3.5 mm
< 24 mm in length

Comparison

- ✓ Paclitaxel-Coated Balloon + Bare-Metal Stent
  (DEB+BMS, 'Coroflex® DEBlue')
  vs.
- ✓ Sirolimus-Eluting Cypher® (DES) stent

Prospective, randomized, multi-center, two-armed phase-II
pilot study conducted in Europe.

	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**

9 Months

	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

This first Drug-Eluting Balloon / Stent system did not meet the non-inferiority criteria versus Cypher®

3. Bifurcation Lesions

DEBIUT Trial (Netherlands / Belgium)

Wiring of both branches with a 0.014 coronary guide wire

Pre-dilation with adequately sized compliant balloon of both main branch and side branch at low pressures (12 atmospheres)

Dilatation with DIOR balloon: first main branch, then side branch

Stent deployment in main vessel

In case of suboptimal result or dissection tion in the side branch: stent in side branch

“Kissing ” post-dilatation with normal balloons

DEBIUT

Dior™

Catheterization and Cardiovascular Interventions 71:629–635 (2008)

Safety and Efficacy of Drug-Eluting Balloons in Percutaneous Treatment of Bifurcation Lesions: The DEBIUT (*D*rug-*E*luting *B*alloon in *BI*furcaton *UT*recht) Registry

James C. Fanggiday, MD, Pieter R. Stella,* MD, Siyrous Hoseyni Guyomi, MD, and Pieter A. Doevendans, MD, PhD

The use of paclitaxel-coated balloon catheters is effective and safe in PCI for coronary artery bifurcation lesions, without clinical signs of restenosis at 4 months follow up. Although all patients stopped Clopidogrel at 3 months after the index procedure so far no late thrombosis was reported.

DEBIUT Trial (Netherlands / Belgium)

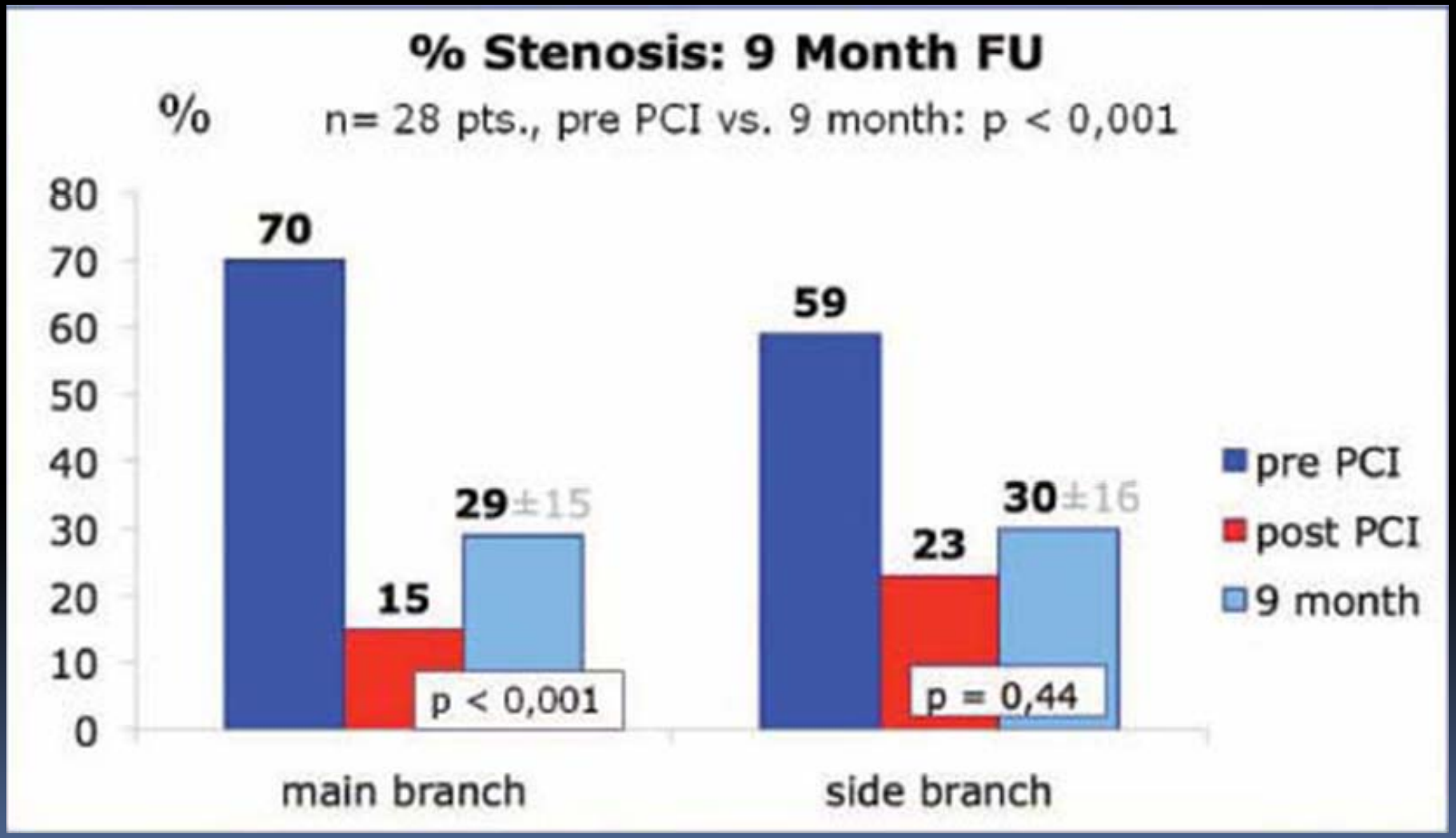
CONCLUSIONS :

This registry provides encouraging results with respect to the safety and efficacy of the drug-eluting balloon.

Stenting of the side branch does not lower the rate of restenosis, while the placement of two stents in BiF makes the procedure more difficult to perform.
The drug-eluting-balloon makes the procedure easier and may even lower long-term restenosis rates in the side branch.

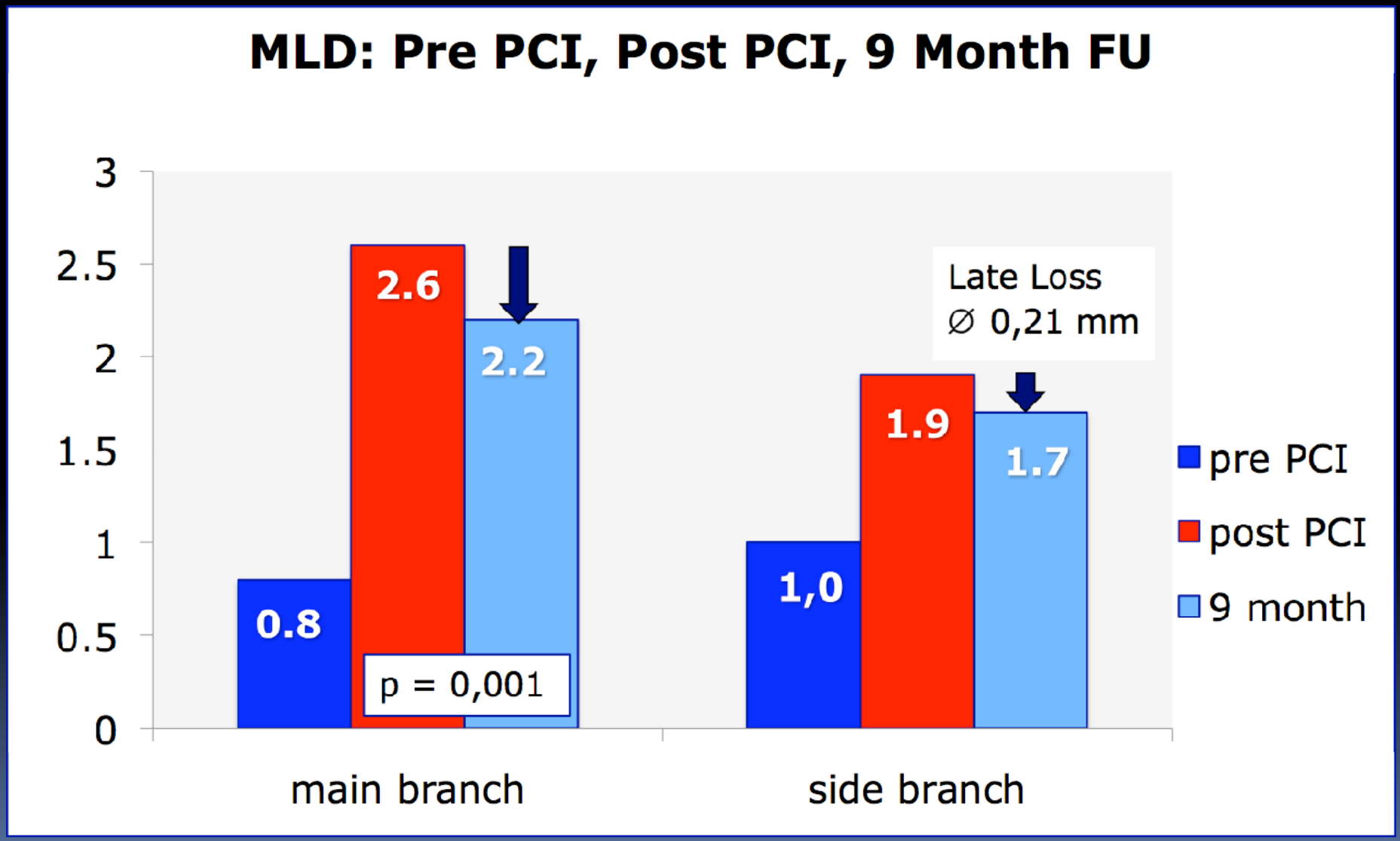
Future randomized studies need to compare the use of the drug-eluting-balloons and drug-eluting-stents in Bifurcation lesions
and assess the long-term efficacy and safety of the drug-eluting balloon.

PEPCAD V BIF 9M F/U
28 pts.



PEPCAD V BIF 9M F/U

SeQuent Please™



PEPCAD V BIF 9M F/U

	(N = 28)
Technical Success rate	28 (100%)
30 –day MACE	0 (0%)
9 Month Angiographic Follow up	
Late Loss (only DEB in the MB & SB)	0.12~0.20 mm
Late Loss (with additional BMS)	0.38~0.73 mm
TLR	1 (3.6%)
*Stent Thrombosis	2 (7.1%)
Death	0 (0%)
MACE	3 (10.7%)

* Stent Thrombosis – definite thrombosis with incomplete wall apposition, Plavix non-resp

PEPCAD V BIF Conclusions

- In the PEPCAD V pilot trial, the DEB *(SeQuent® Please, B.Braun)* in combina-tion with a BMS *(Coroflex®, B.Braun)* shows excellent procedural results in bifurcational lesions, with no MACE up to 30 days.

- The method may help to improve and simplify the treatment of bifurcation lesions.

D.Mathey, PI PEPCAD V, TCT 2009

The PEPCAD Program

Paclitaxel-Eluting PTCA-Catheter in Coronary Artery Disease

Title	Design	Status
PEPCAD I SVD	Sequent in ≤2.8mm, 120px, multi-center, Germany	3yr FU in 2010
PEPCAD II ISR	Sequent vs Taxus in ISR, 131px, multi-center, Germany	3yr FU in 2010
PEPCAD III	Sequent + pre-loaded Coroflex Blue vs Cypher, 637x, Europe	9mo FU at AHA 2009
PEPCAD IV DM	Sequent vs Taxus in DM, 160px, multi-center, Thailand, Malaysia	9mo FU in 2010
PEPCAD V BIF	Sequent, 28px, dual-center, GER	3yr FU in 2011
PEPCAD CTO	Sequent, 50px, single-center, Germany	9mo FU in 2010
INDICOR	Coroflex Blue + Sequent, Real World, 125px, India	6mo FU in 2011
PEPCAD WW	Studies worldwide in preparation (RCTs for additional indications, real world, registires)	

How to PEB

- **Do Like Stent**
  - Pre PEB plaque modification with conventional balloon before using the study device
  - The diameter of the conventional balloon ; 0.5 mm smaller than that of the drug-coated study balloon or stent
  - The recommended inflation time for the drug-coated balloon was 30 sec
  - 1st inflation release 90% of drug

	Bar	Balloon Diameter mm						
		2.00	2.25	2.50	2.75	3.00	3.50	4.00
	2	1.71	1.96	2.21	2.46	2.71	3.21	3.71
	4	1.81	2.06	2.31	2.56	2.81	3.31	3.81
	6	1.91	2.16	2.41	2.66	2.91	3.14	3.91
Nominal Pressure	8	2.00	2.25	2.50	2.75	3.00	3.50	4.00
	10	2.06	2.31	2.56	2.81	3.06	3.56	4.08
	12	2.12	2.37	2.62	2.87	3.12	3.62	4.16
	14	2.18	2.43	2.68	2.93	3.18	3.68	4.24
Rated burst pressure	16	2.24	2.49	2.74	2.99	3.24	3.74	4.30
	18	2.27	2.57	2.78	3.03	3.29	3.80	4.36

Summary

- Late Lumen Loss
  - Standard-alone DEB procedures; < 0.2 mm with low MACE
  - DEB + add BMS for dissection or elastic recoils; 0.38 ~ 0.73 mm with high MACE
- No thrombosis in standard-alone DEB have reported up to 2.5 yrs
- Relative short term anti PLT Tx. Periods of 1 ~ 3 months in PEPCAD I, II & V

SeQuent Please vs Dior

- Paccocath prototype & SeQuent Please;
  positive clinical trial results for the treatment of
  - ISR [Paccocath ISR I, Paccocath ISR II, PEPCAD II]
  - de-novo lesions in small coronary vessels [PEPCAD I]
  - de-novo and restenotic lesions in the SFA
    [Thunder, FemPac])

- Roughened balloon surface (Dior; negative Piccoletto trial)
  noninferiority study
  - stable or unstable angina
  - small coronary vessels (≤ 2.75 mm) to PCI with the Dior (Eurocor, Bonn, Germany) paclitaxel-eluting balloon or Taxus Libertè paclitaxel-eluting stents (Boston Scientific, Natick, MA)

Clinical Considerations and Unresolved Issues

- Acute recoil seen postballoon angioplasty.
- It is not clear whether DEB can eliminate the late negative remodeling seen with noncoated balloons.
- The efficacy and safety parameters when using DEB as adjunct therapy to bare metal stents (BMS) must also be determined.
- Systemic effect of washed-out drug ?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공부의 신
나를 선생이라 부르지마라!
대한민국 최고의 입시 트레이너일 뿐이다.
2010.1.4. 첫방송
KBS2TV 월화 PM 9:55
연합뉴스
YONHAPNEWS

Take Home Message
冠狀動脈 施術의 神

Drug-eluting balloons –

interesting and potentially

very useful *complementary technology*

esp. in ISR, Small vessel disease, Side Branch Ostium

to "fill gaps" and enhance overall PCI safety/efficacy

Early results with paclitaxel systems promising, BUT need

(1) More consistent drug elution profiles and tissue pharmacodynamics,

(2) Better solutions when combined with either BMS or DES

(3) More carefully conducted clinical trials (larger RCTs with optimal endpoints and FU)

(4) Operational systems with sirolimus analogues

경청하여 주셔서 감사합니다.