Treatment of a Recurrent In-Stent Restenosis

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Presenter Disclosure Information

Presenter: Eun-Seok Shin, MD/PhD

Title: Treatment of a Recurrent In-Stent Restenosis

No relationships to disclose
No industry sponsorship

Case Review

Patient Demographics

Age: 62

Gender: M

Risk factors: None

PMH: CAG (2004-1-15 & 2004-3-10) for SA

Clinical Presentation

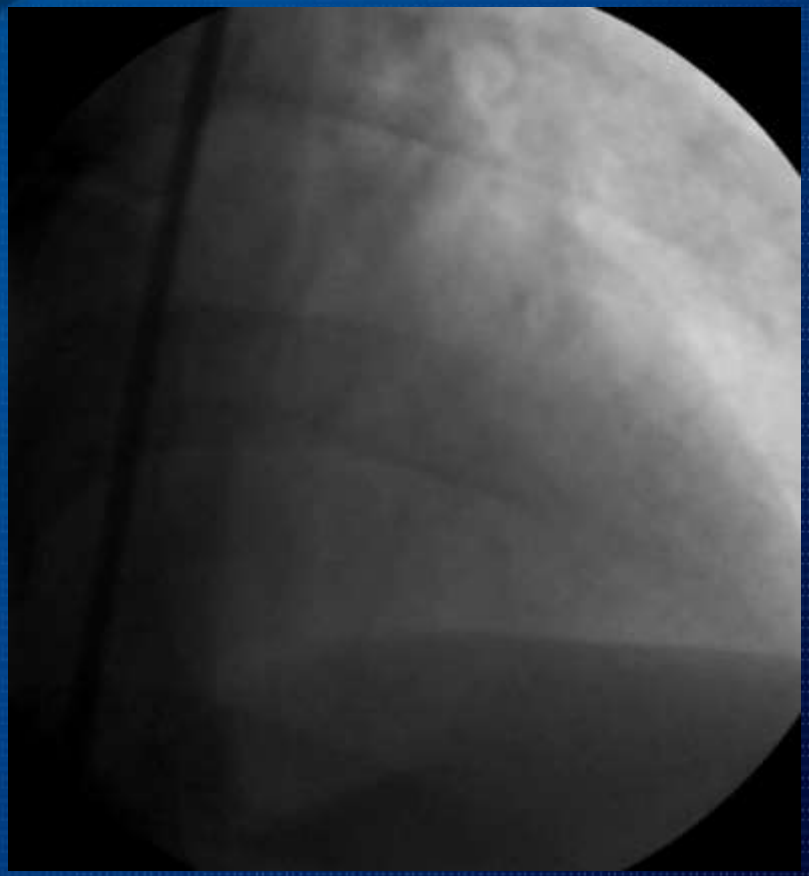
Intractable angina with optimal medication

(beta-blocker, calcium channel blocker, nitrate)

2004. 4. 28

Intractable angina

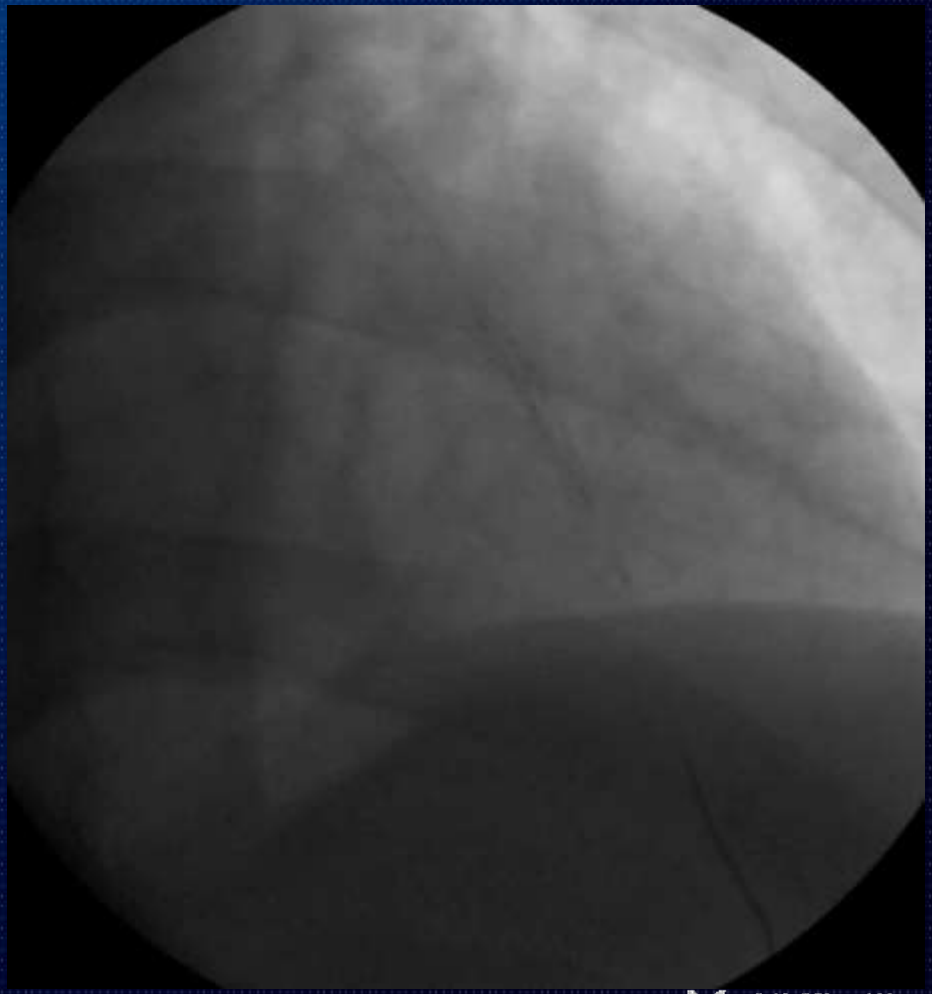
Cypher 3.0 x 23



After 6 months

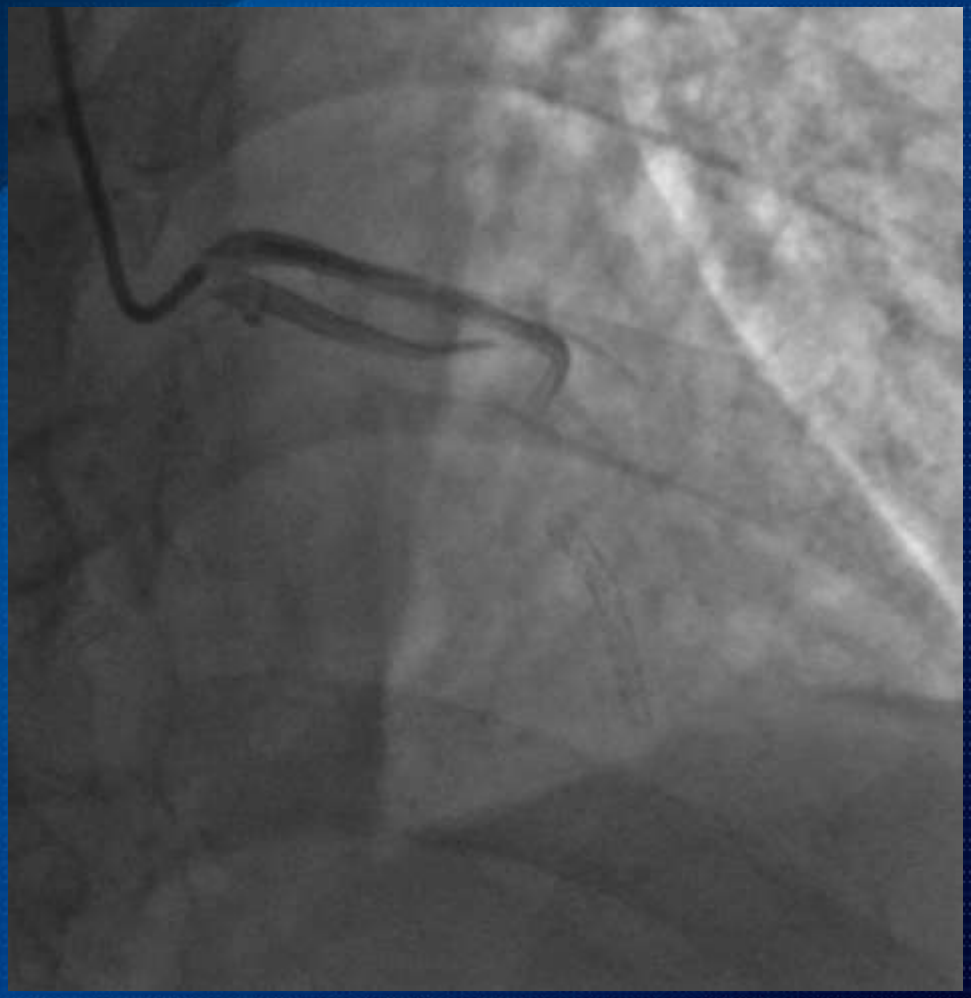
Focal ISR with angina

After POBA



After 10 months

2nd ISR with angina



After cutting balloon

However…after 7 months…!

After 7 months

3rd ISR with angina

After stenting (Taxus 3.0x32)

sandwich technique

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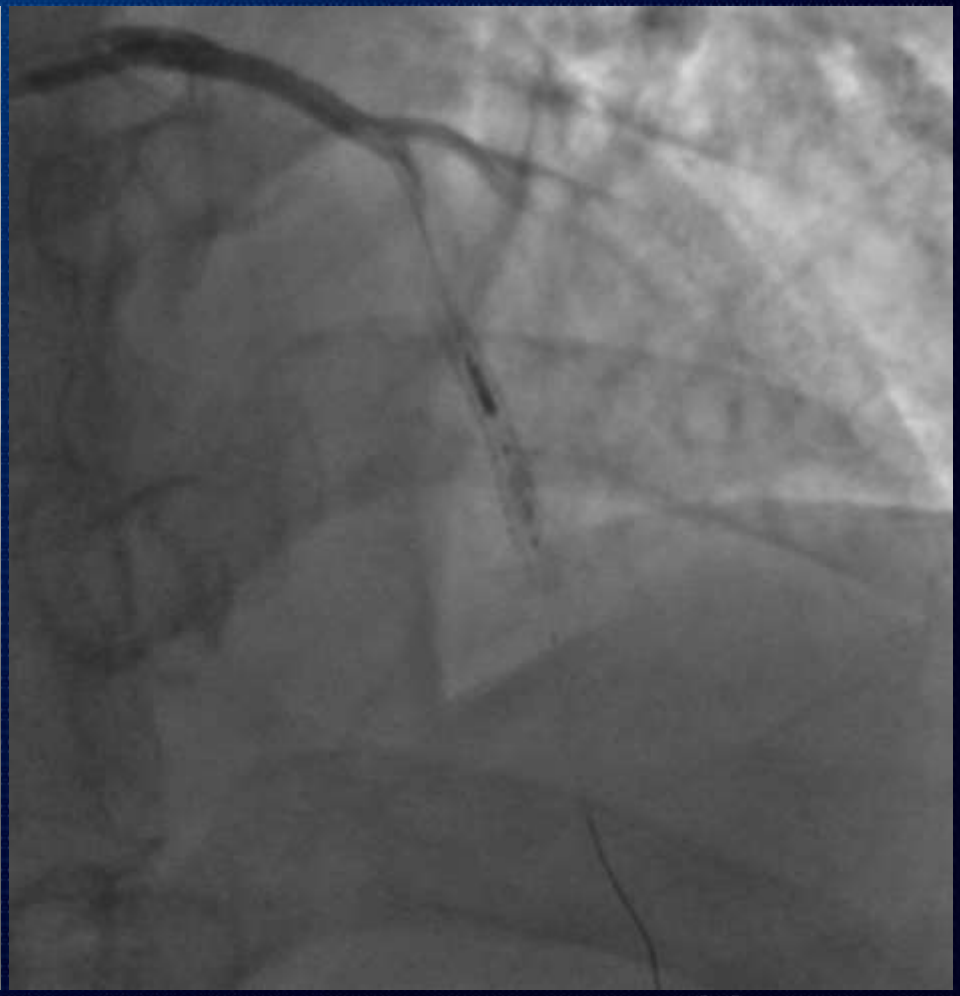
Please!

After 8 months (2007.2.1)

4th ISR with angina

IVUS could not passage



What should I do!

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.

I know, but ...

0.74 ± 0.86 mm	0.03 ± 0.48 mm

52 patients with in-stent restenosis

New Engl J Med 2006, 355: 2113-24

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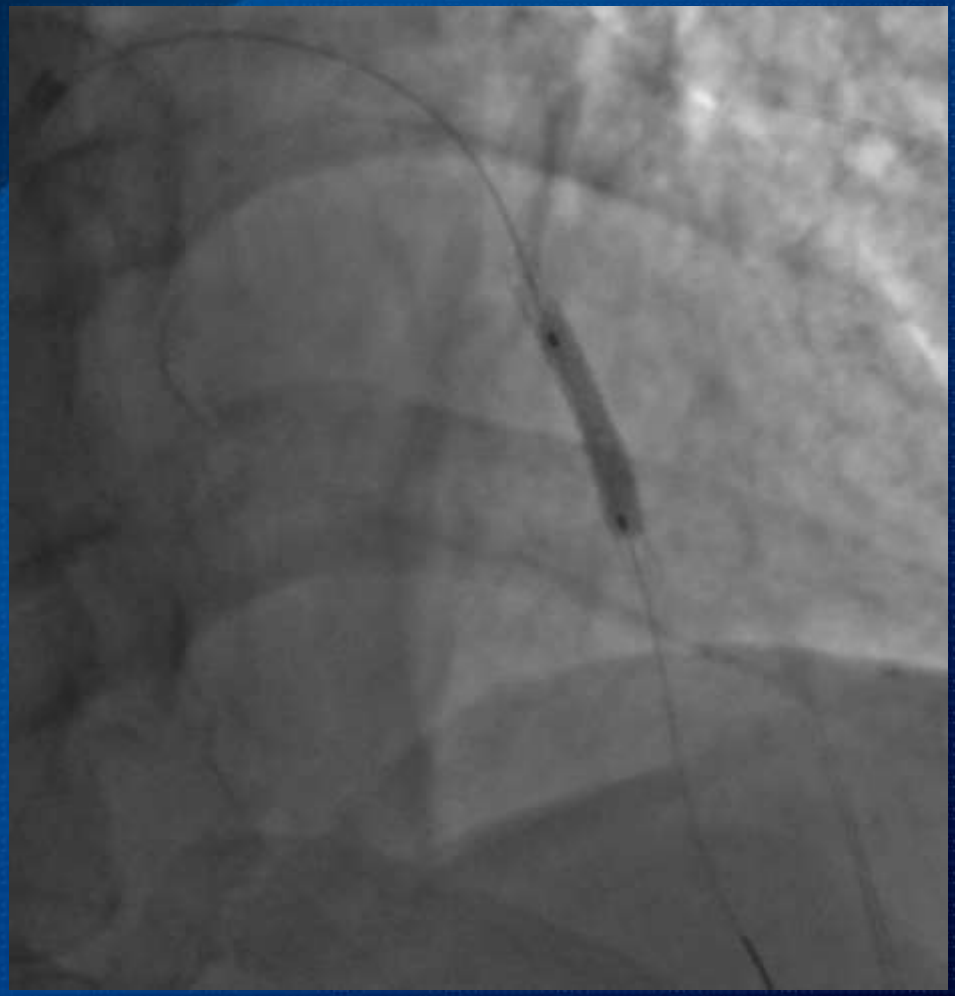
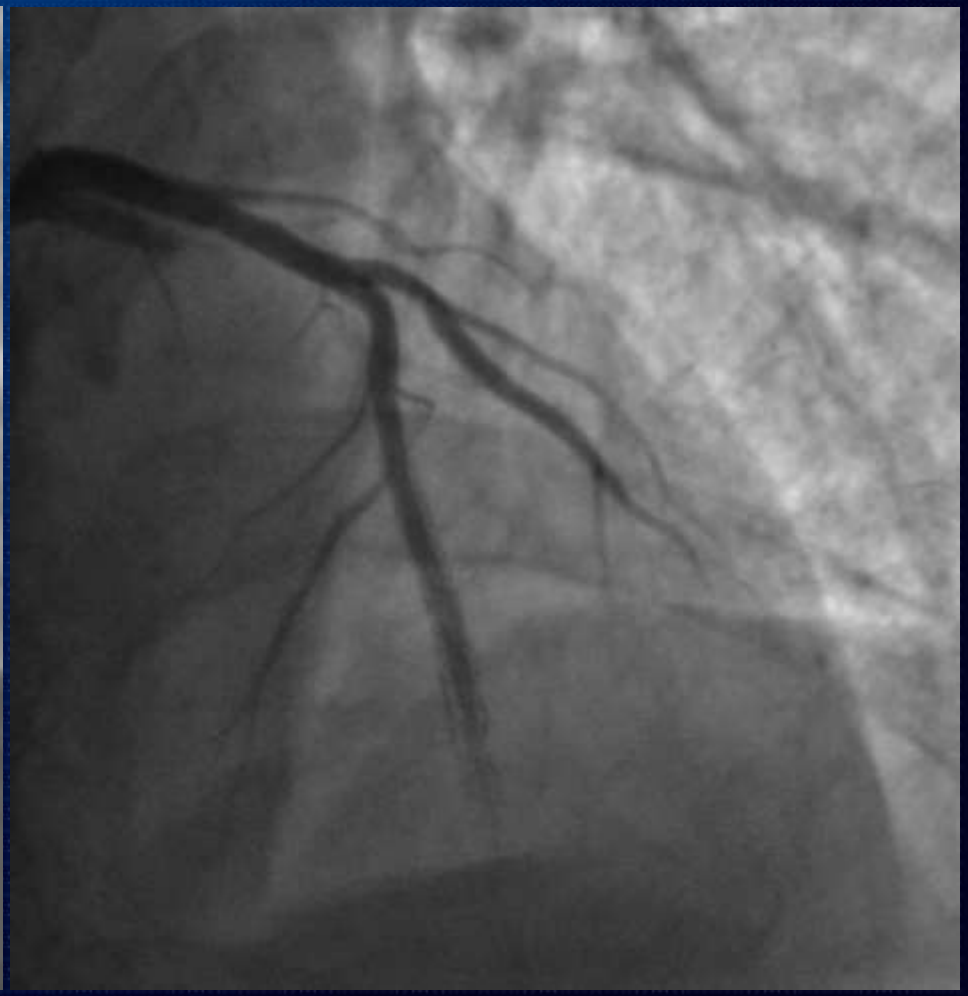
Handmade PCB in Cath Lab

4th ISR treated by PCB (2007.2.1)

Handmade PCB apply



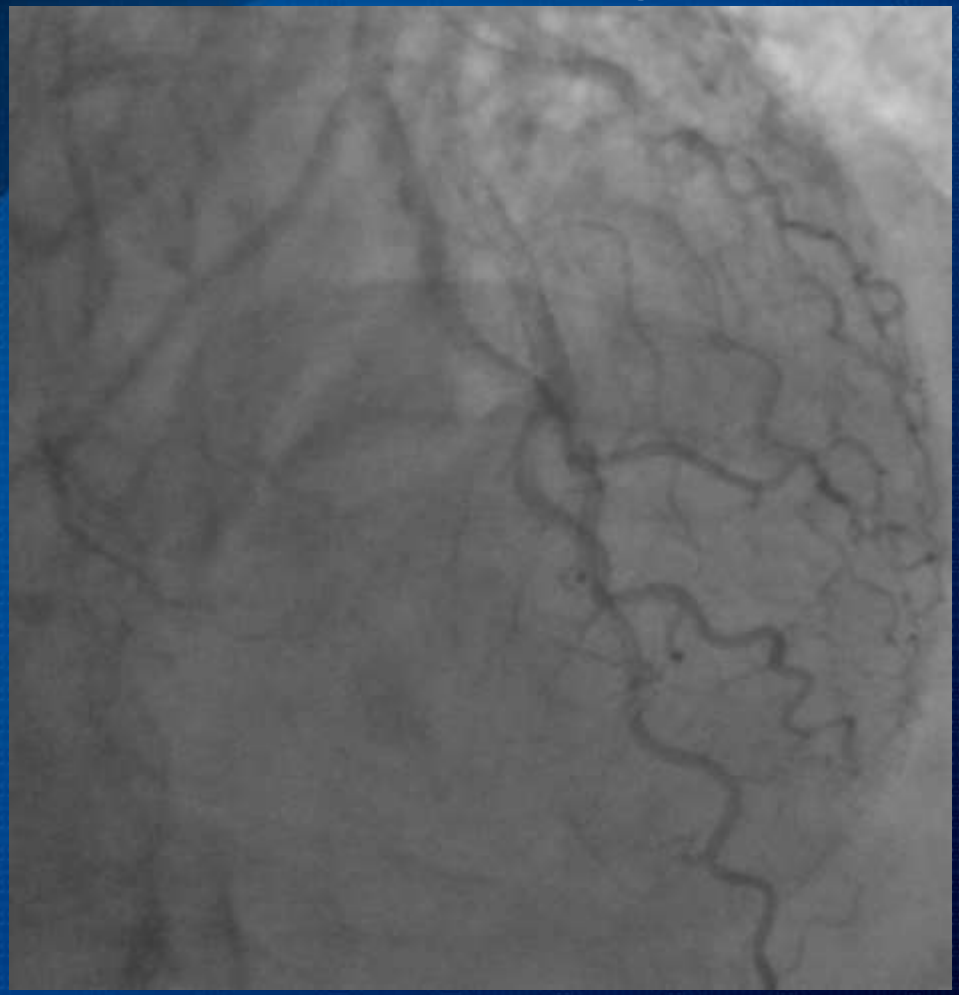
Final CAG



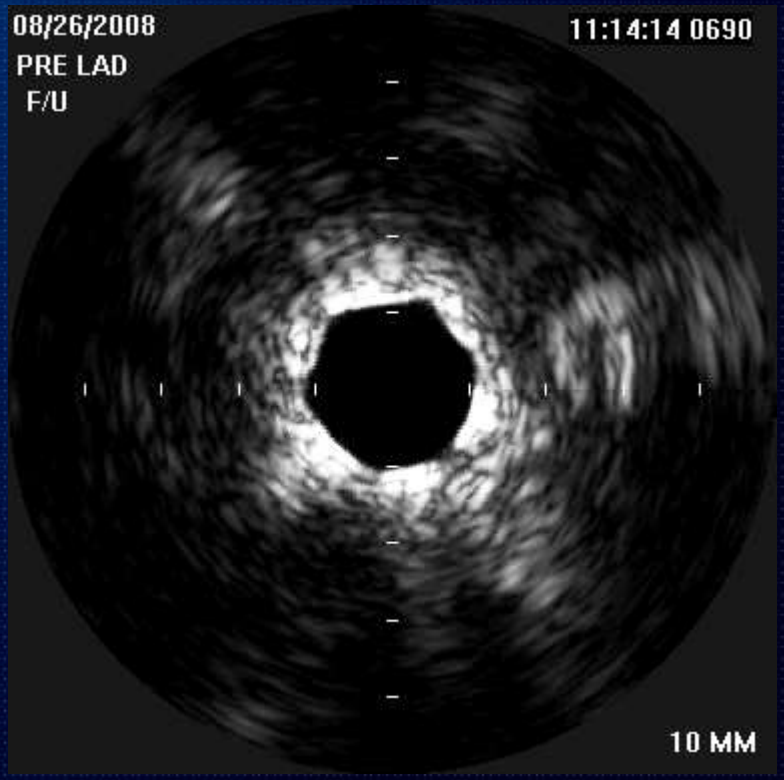
has been well since then

After 18 months

FU CAG (No angina)



IVUS could passage



MLA: 2.4 mm^2

Paclitaxel-Coated Balloon

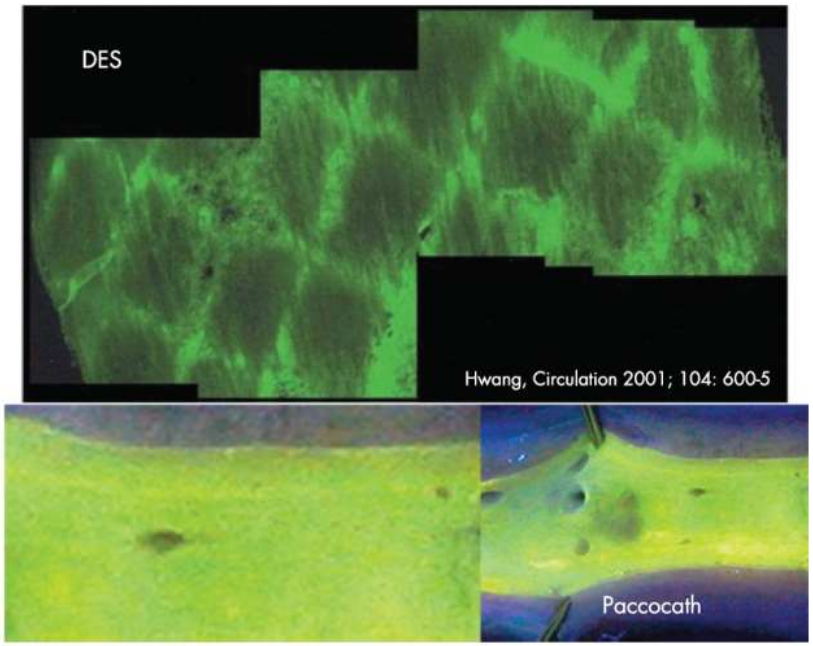


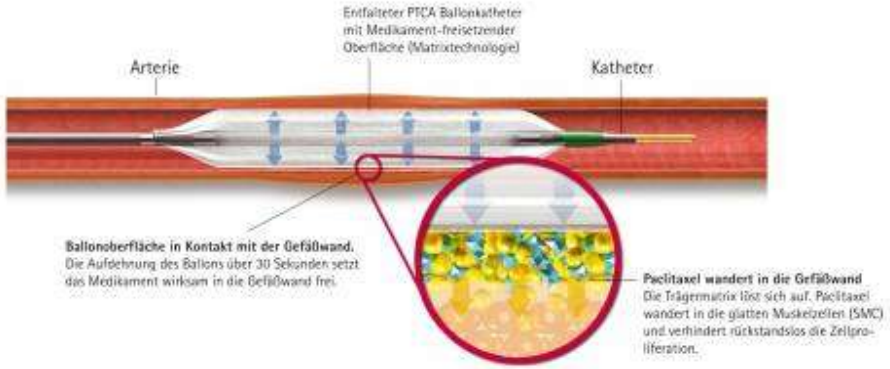
Figure 1 Inhomogeneous drug distribution from luminal surface after implantation of a drug-eluting stent (DES) (reprinted with permission from Hwang CW, Wu D, Edelman ER. Physiological transport forces govern drug distribution for stent-based delivery. *Circulation* 2001;104:600–5).[11] Homogeneous drug distribution from luminal surface after an inflation of 60 s with a drug-coated balloon (porcine coronary artery, experiments done by Nicola Kaufels, Berlin, Germany).

Drug Eluting Stent

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

Drug Coated Balloon

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



Circulation 2004; 110: 810-4
Heart 2007, 93: 539-41

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PCB – Clinical Applications

1. Endovascular

2. Coronary Artery

PCB for Coronary Artery

1. In-Stent Restenosis

2. De-novo lesions

Drug Coated Balloons for Coronary Artery

1. In-Stent Restenosis

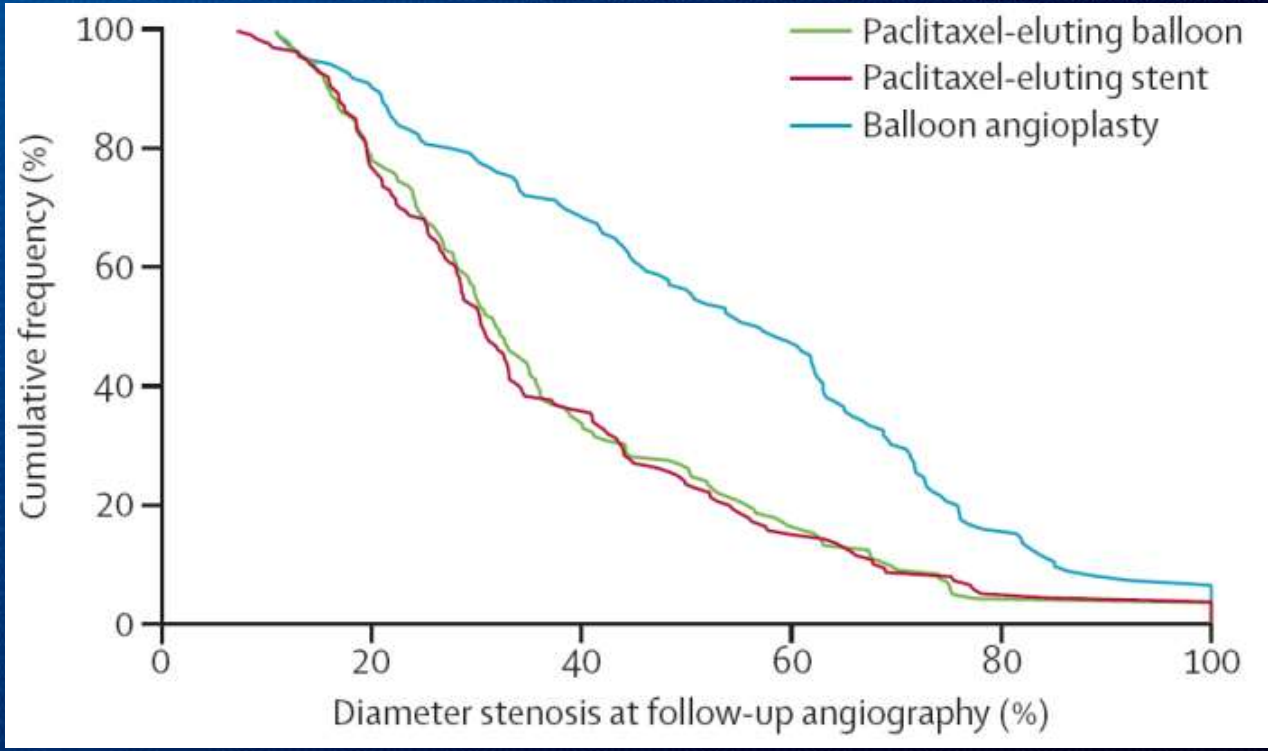
2. De-novo lesions

9 Randomized Controlled Trials

ISR	Intervention	N	End point	Study
BMS	PCB-POBA	108	LLL	PACCPCATH ISR
	PCB-PES	131	LLL	PEPCAD 2 ISR
	PCB-EES	189	MLD	RIBS V
DES	PCB-POBA	110	LLL	PEPCAD-DES
	PCB-POBA	208	LLL	Habara et al
	PCB-POBA	50 (SES)	LLL	Habara et al
	PCB-PES	402	DS	ISAR-DESIRE 3
	PCB-PES	215	LLL	PEPCAD-ISR-China
	PCB-EES	309	MLD	RIBS IV

Paclitaxel-eluting balloons, paclitaxel-eluting stents, and balloon angioplasty in patients with restenosis after implantation of a drug-eluting stent (ISAR-DESIRE 3): a randomised, open-label trial

Robert A Byrne, Franz-Josef Neumann, Julinda Mehilli, Susanne Pinieck, Britta Wolff, Klaus Tiroch, Stefanie Schulz, Massimiliano Fusaro, Ilka Ott, Tareq Ibrahim, Jörg Hausleiter, Christian Valina, Jürgen Pache, Karl-Ludwig Laugwitz, Steffen Massberg, Adnan Kastrati, for the ISAR-DESIRE 3 investigators

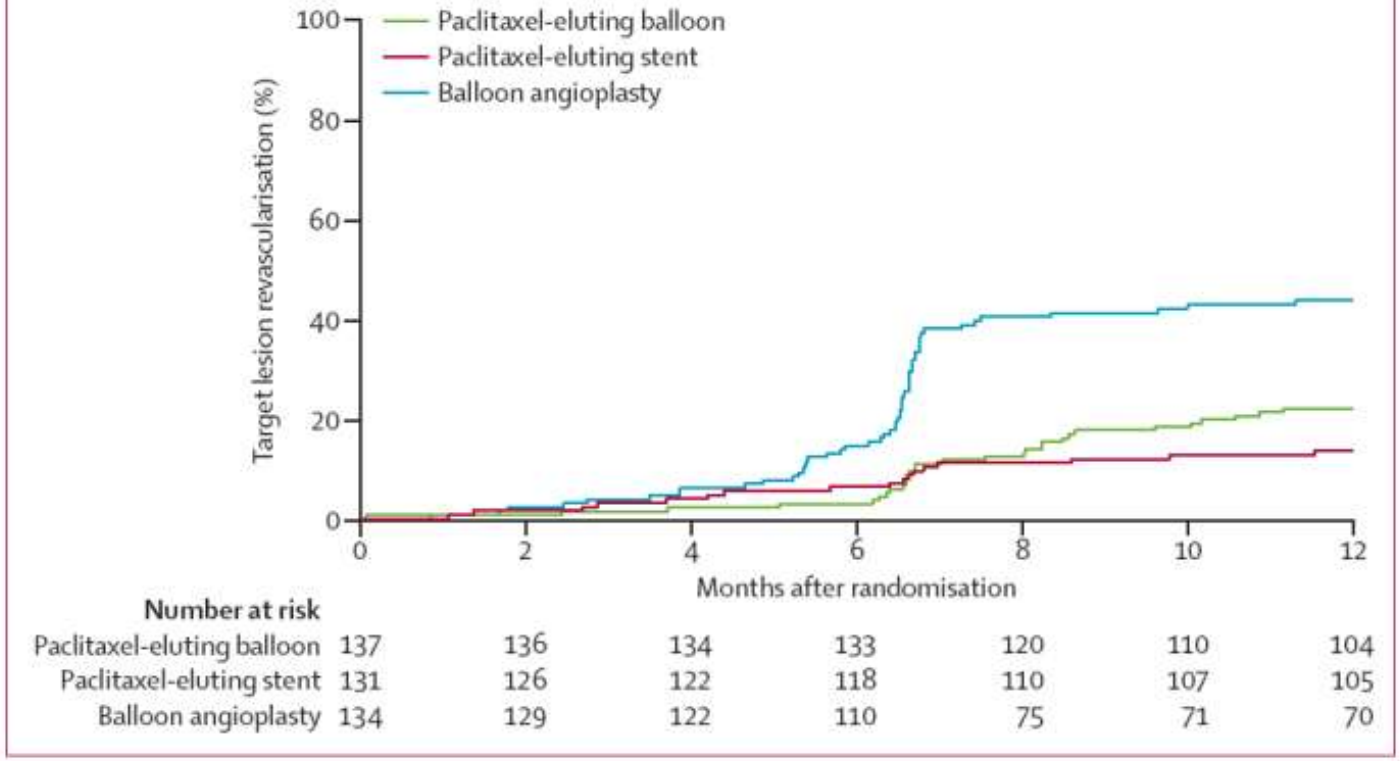


Lancet 2013; 381: 461–67

Primary endpoint: DS at 6–8 months

	PEB	PES	Balloon angioplasty
Lesions	147	142	127
Minimum luminal diameter (mm)	1·79 (0·74)	1·82 (0·74)	1·26 (0·75)
Diameter stenosis (%)	38·0% (21·5)	37·4% (21·8)	54·1% (25·0)
Recurrent binary restenosis	39 (27%)	34 (24%)	72 (57%)
Late lumen loss (mm)	0·37 (0·59)	0·34 (0·61)	0·70 (0·69)

Survival analysis curves for target lesion revascularisation



2014 ESC/EACTS Guidelines 2014

Recommendations	Class[a]	LoE[b]	Ref[c]
Disease progression and late graft failure			
Repeat revascularization is indicated in patients with severe symptoms or extensive ischaemia despite medical therapy if technically feasible.	I	B	54,143
PCI should be considered as a first choice if technically feasible, rather than re-do CABG.	IIa	C	
PCI of the bypassed native artery should be the preferred approach, if technically feasible.	IIa	C	
IMA, if available, is the conduit of choice for re-do CABG.	I	B	481
Re-do CABG should be considered for patients without a patent IMA graft to the LAD.	IIa	B	481
DES are recommended for PCI of SVGs.	I	A	489–495
Distal protection devices are recommended for PCI of SVG lesions if technically feasible.	I	B	484,485
Restenosis			
Repeat PCI is recommended, if technically feasible.	I	C	
DES are recommended for the treatment of in-stent restenosis (within BMS or DES).	I	A	501,502,508 511,524
Drug-coated balloons are recommended for the treatment of in-stent restenosis (within BMS or DES).	I	A	507– 511,524

Recurrent ISR within DES in DES?

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Take Home Messages

- **PCB has demonstrated safety and efficacy in the treatment of coronary in-stent restenosis in both BMS & DES.**

- **PCB is superior to balloon angioplasty and similar to early-generation DES in patients with BMS or DES in-stent restenosis.**

Take Home Messages

- **Currently, PCB is recommended for the treatment of in-stent restenosis (within BMS or DES) in the European guidelines (Class IA)**

- **However we need more data about the efficacy of PCB on specific situation like recurrent ISR in DES.**