

DCB

Future Mainstream of Niche Device ?

Franz X. Kleber MD FESC
Professor of Medicine
Charité University Medicine Berlin

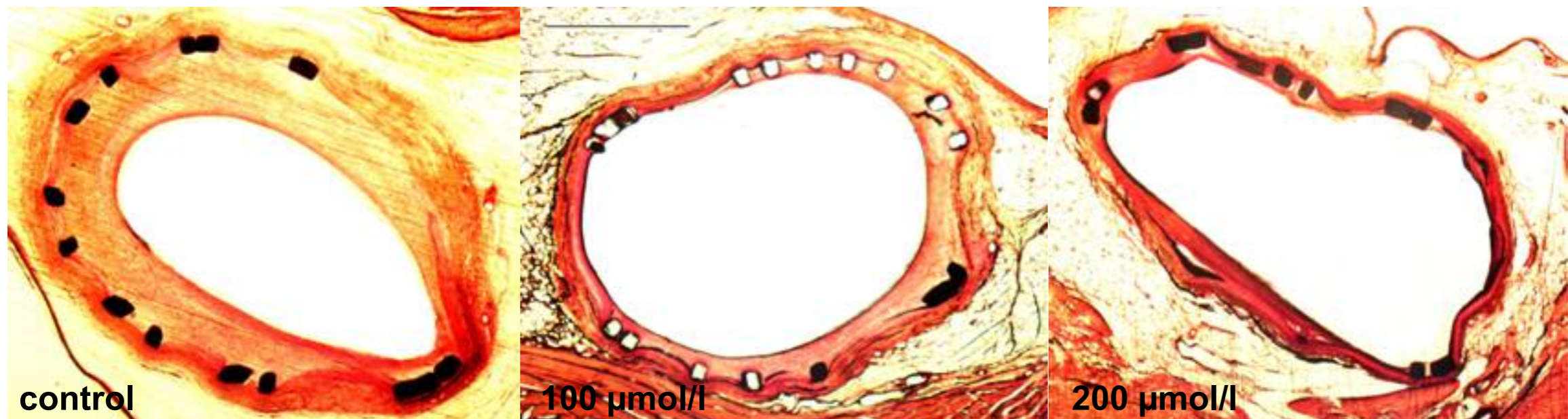
TCT AP Seoul April 24, 2013

Intracoronary Iopromide Paclitaxel

Table 3. Histomorphometry of Stented Porcine Coronary Arteries After 28 Days

	Control	Iopromide Paclitaxel		p
		ic 100 $\mu\text{mol/l}$	ic 200 $\mu\text{mol/l}$	
n	16	10	6	
Injury score	0.87 \pm 0.12	0.88 \pm 0.15	0.92 \pm 0.07	0.723
EEL area (mm^2)	6.03 \pm 1.37	6.14 \pm 0.81	5.51 \pm 0.19	0.516
Luminal area (mm^2)	2.33 \pm 0.76	2.94 \pm 1.11	3.78 \pm 0.44	0.004
Area stenosis (%)	59 \pm 13	51 \pm 17	31 \pm 10	0.001
Neointimal area (mm^2)	3.69 \pm 1.38	3.19 \pm 1.17	1.73 \pm 0.62	0.008
Maximal neointimal thickness (mm)	0.77 \pm 0.39	0.50 \pm 0.23	0.29 \pm 0.24	0.011

Injury score, external elastic lamina (EEL) area, luminal area, area stenosis, neointimal area, and maximal neointimal thickness. Histomorphometric measurements of the three cross-sectional planes were averaged to obtain a mean value per stent.



J Am Coll Cardiol 2003; 42: 1415-20

In Stent Restenosis

late lumen loss

6 mo in stent resten

12 months MACE

uncoated

0.74

10/23

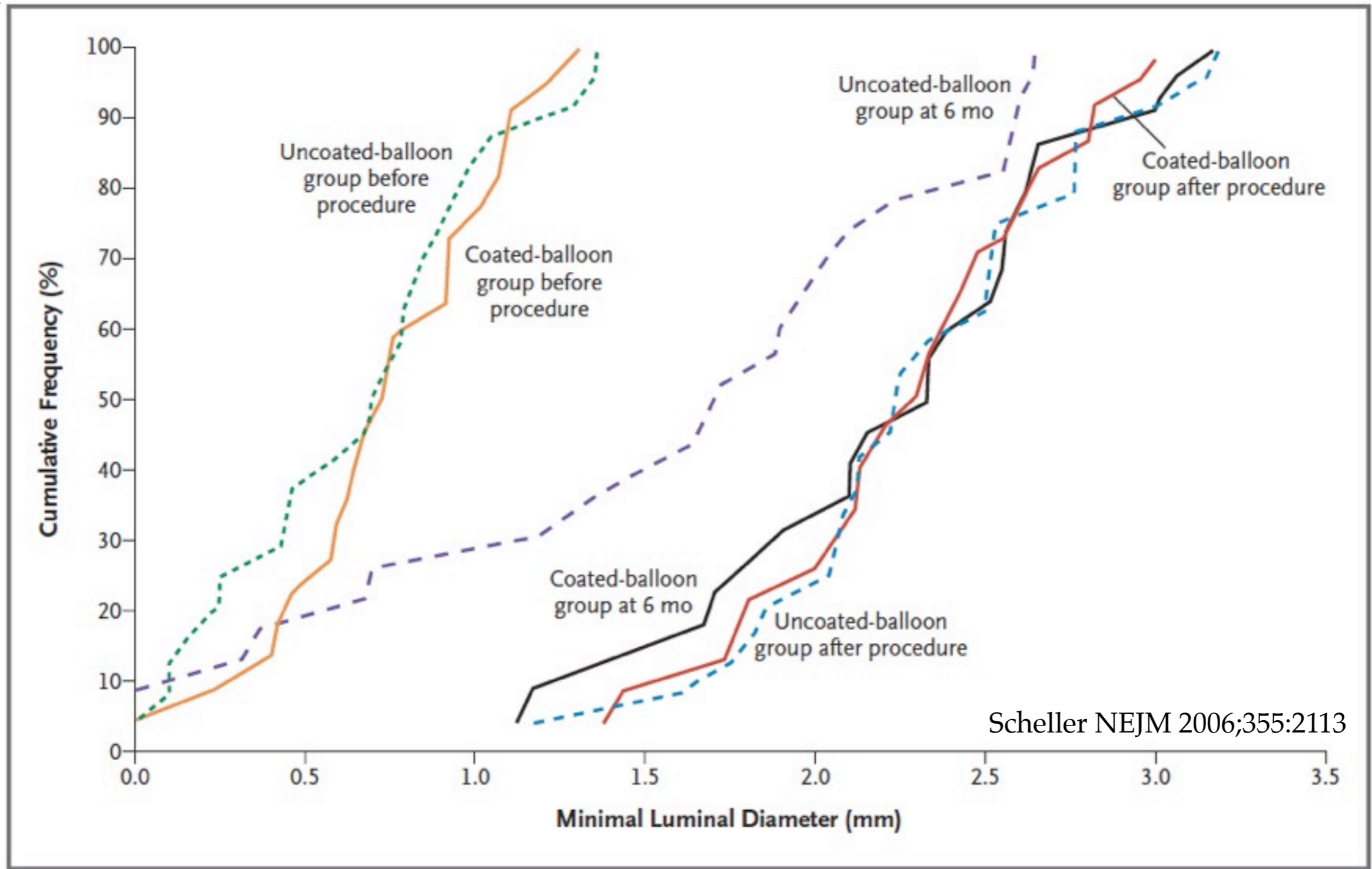
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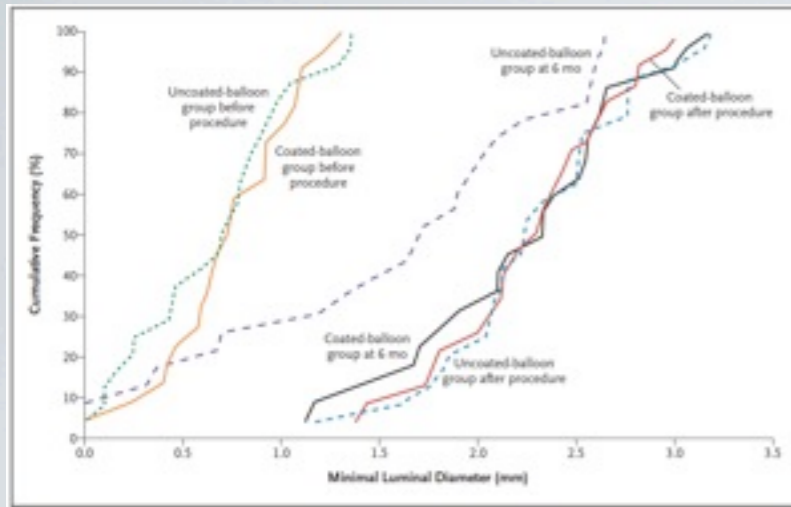
paclitaxel c.

0.03 mm

1/22 patients

4 %





DCB Treatment of ISR

Scientific Evidence - Data Base

- Paccocath ISR I
- Paccocath ISR II
- Paccocath long term follow up
- PEPCAD II
- Habara
- PEPCAD DES
- ISAR-DESIRE III

Scheller NEJM 2006
 Scheller CRC 2008
 Scheller JACC Interv 2012
 Unverdorben Circulation 2009
 Habara JACC Interv 2011
 Rittger JACC 2012
 Byrne Lancet 2012

DCB in small vessels data base

Trial	n	Additional	Late Lumen	Restenosis	TLR
	(DCB)	BMS (%)	Loss (mm)	(%)	(%)
PEPCAD I ¹³	114	26.7	0.32±0.41	17.3	12.8
PICCOLETTO ⁵²	28	34.5	1.37±0.62	32.1	32.1
BELLO ³⁵	90	21.1	0.08±0.38	10.0	7.8

Table 2: Prospective trials with drug coated balloons (DCB) in coronary small vessel disease (SVD). TLR target lesion revascularization. BMS bare metal stent.

Unverdorben CRC 2010
Cortese Heart 2010
Latib JACC 2012

DCB in Bifurcations database:

- World Wide Registry (13 %)
- Debiut Study (Paclitaxel without carrier or shellac)
- PEPCAD V (in DCB only is segment LLL 0.04mm)

conclusion:

Wöhrle Jacc 2012

Stella Cath Cardiovasc Interv 2012

Mathey Eurointervention 2011

- treatment with DCB only is promising and may be considered, appears save, more data needed
- no placement of DCB through stent struts

DCB + BMS database:

- PEPCAD I (BMS)
- World Wide Registry (BMS)
- PERFECT (EPC Stent)
- PEPCAD IV (Diabetes; vs. Taxus)
- PEPCAD III (BMS on DCB vs Cypher)
- Gutierrez (OCT)

Unverdorben CRC 2010

Wöhrle JACC 2012

Wöhrle Heart 2011

Ali Eurointervention 2011

Gutierrez-Chico Eurointervention 2011

conclusion:

combination is safe as long DCB is longer than stent
preferred BMS first, DCB thereafter

Duration of Antiplatelets

- ISR: 4 weeks
- DCB only: 4 weeks
- DCB+BMS: 3 months
- Bifurcations/ DCB only: 4 weeks
- Bifurcations DCB+Stent: 6-12 months

Does it make sense to revive old ideas?
Is PCI with DCB only a step backwards?
Acute Results after Stenting look better!
We fear acute vessel closure after PTCA alone!

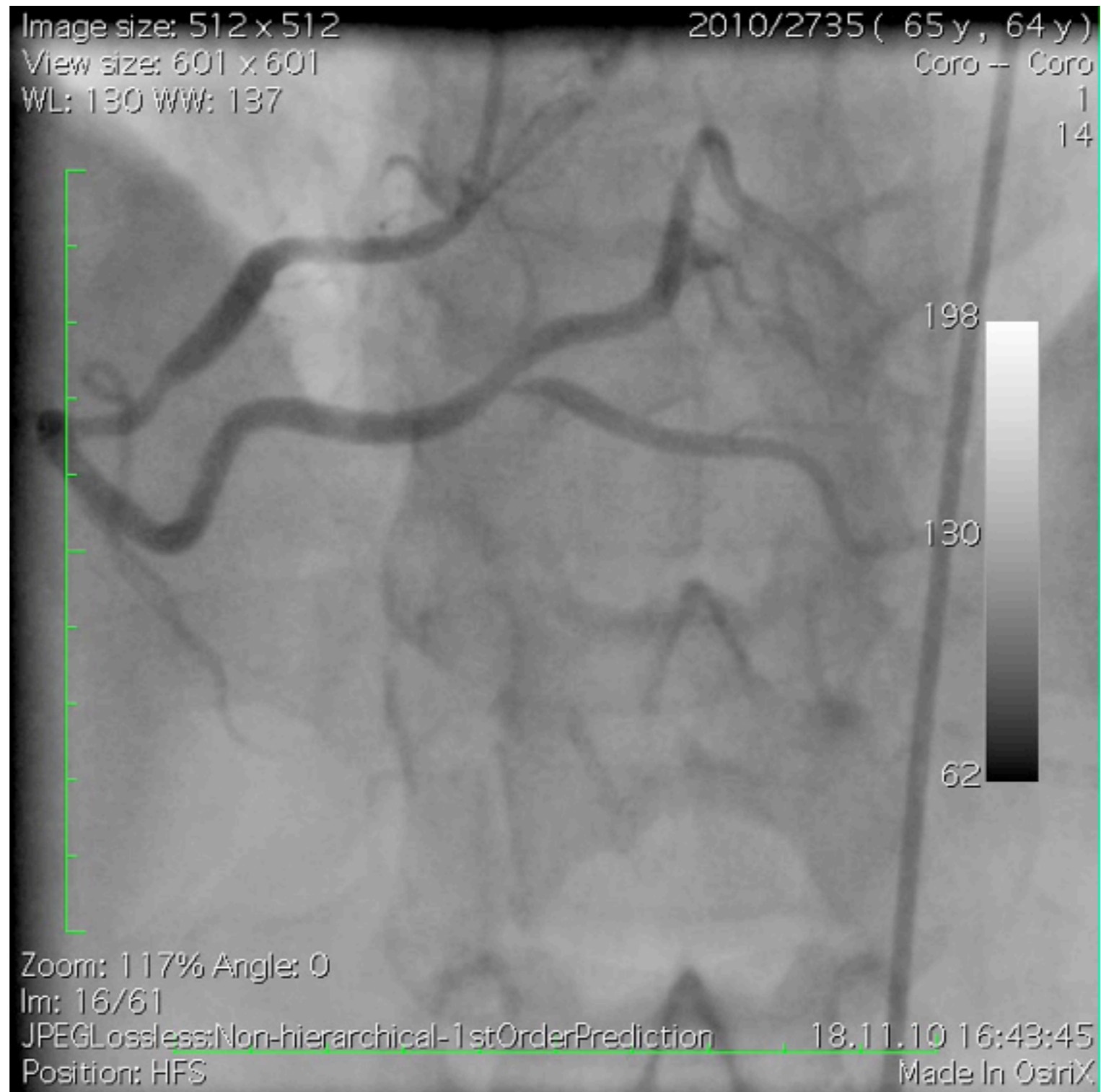


There are numerous successful examples
for a successful revival of old ideas
provided the flaws of the old ideas are overcome

Limitations of PTCA

**recoil, dissection, acute closure,
negative vessel remodeling
(shrinkage and neointimal proliferation)**

positive remodeling in bifurcational treatment



RCA Bifurcation Lesion

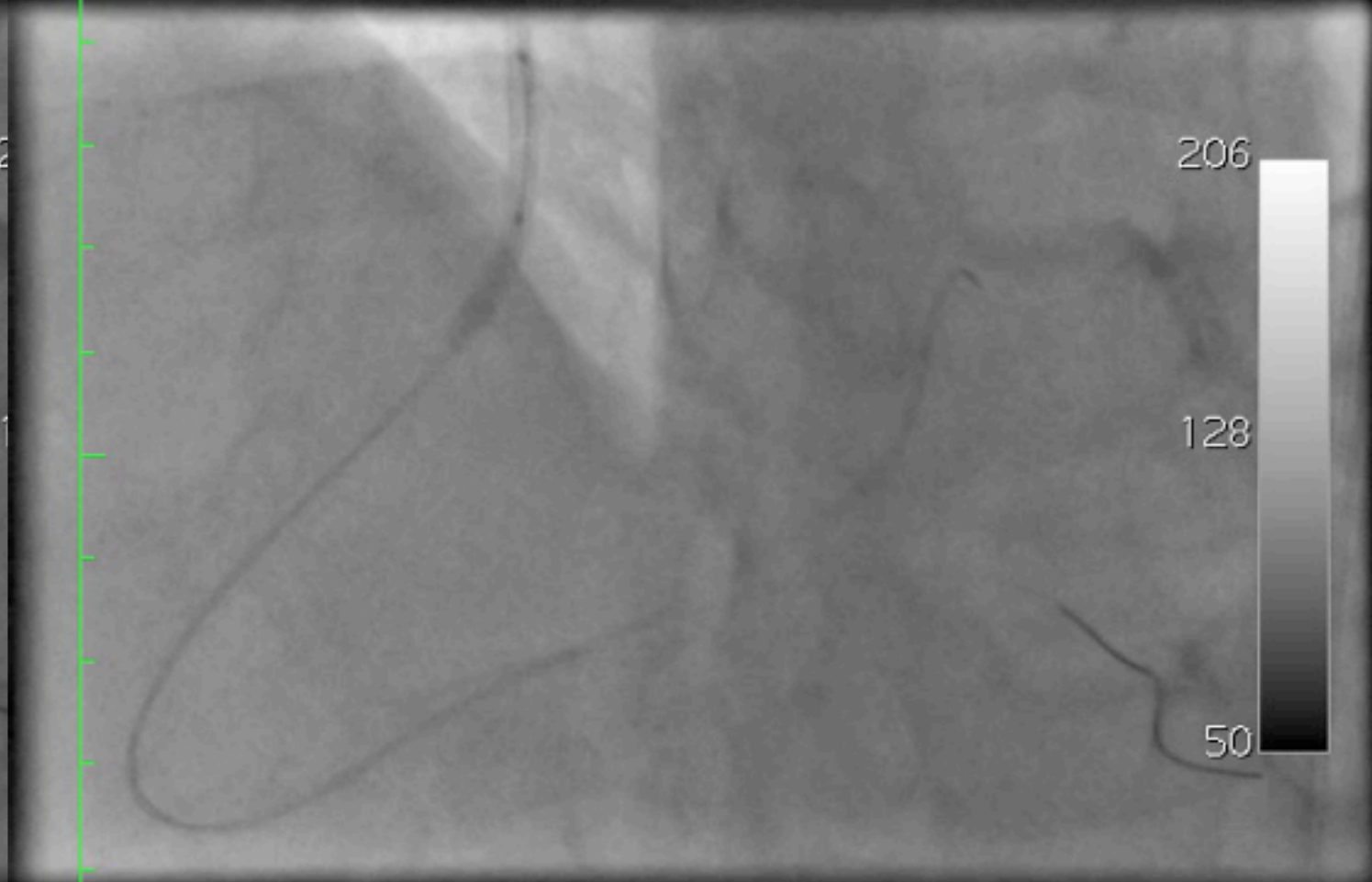
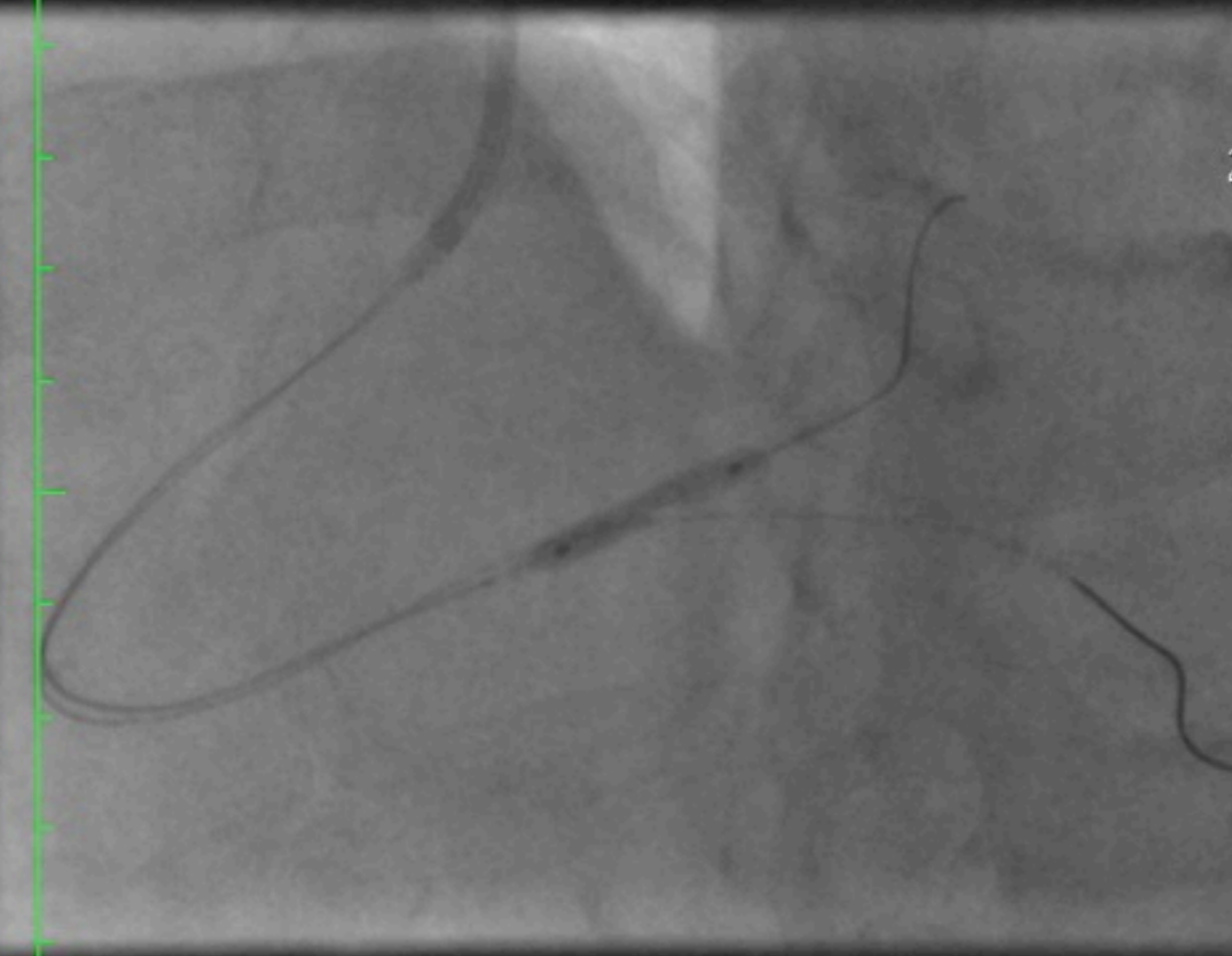


RCA Bifurcation Lesion

Image size: 512 x 512
View size: 601 x 601
WL: 128 WW: 156
X: 118 px Y: 501 px Value: 65.00
Z: 0.00 mm Y: 0.00 mm Z: 0.00 mm

2011/44 (65 y, 64 y)
Coro RL
Image size: 512 x 512
View size: 601 x 601
WL: 128 WW: 156

2011/44 (65 y, 64 y)
Coro RL -- Coro R



Zoom: 117% Angle: 0
Im: 14/42

JPEGLossless:Non-hierarchical-1stOrderPrediction
Position: HFS

07.01.11

Zoom: 117% Angle: 0
Im: 1/54

JPEGLossless:Non-hierarchical-1stOrderPrediction
Position: HFS

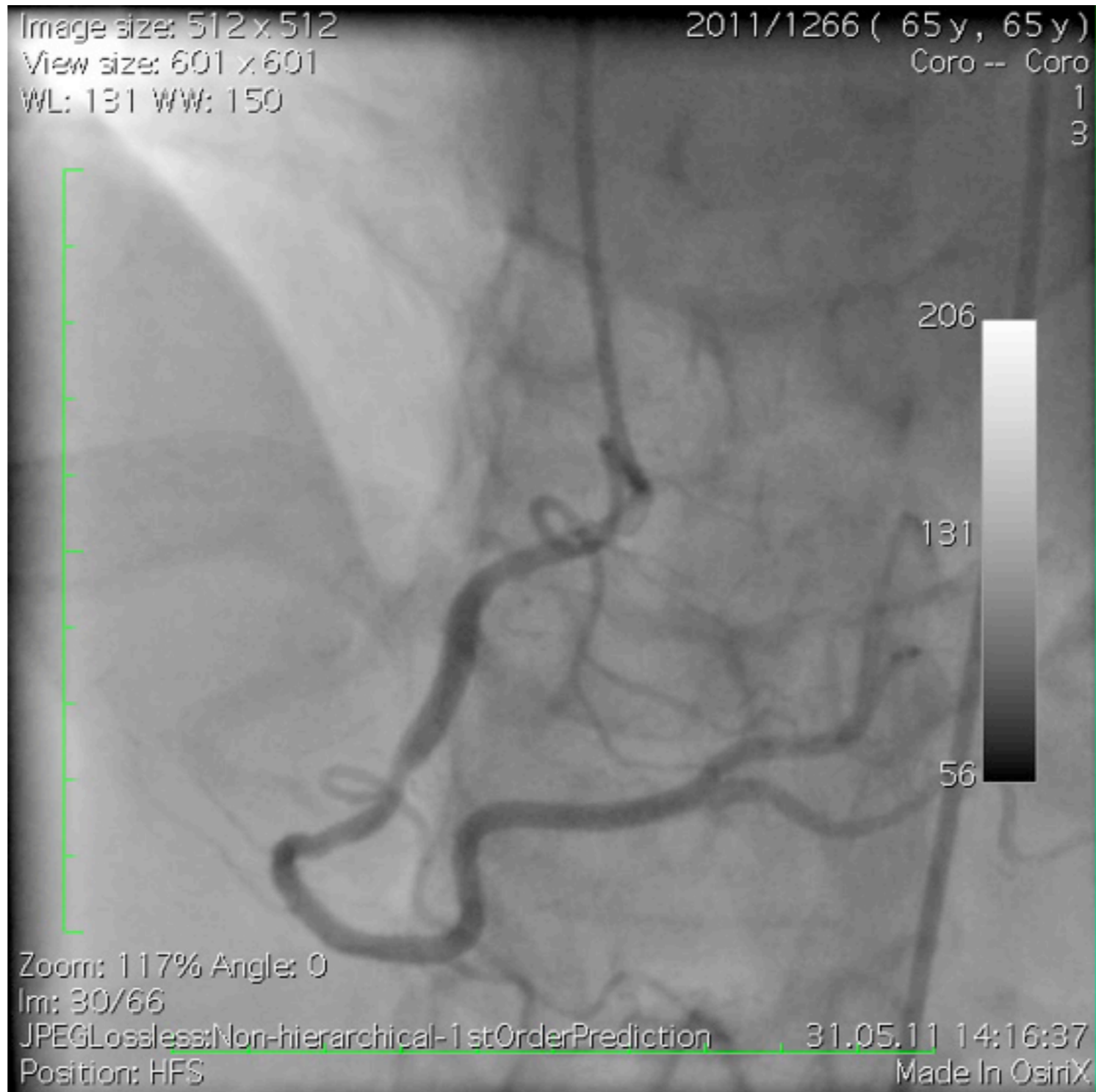
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Made In Osiri

RCA Bifurcation Lesion



RCA Bifurcation Lesion: 4 months result



Dissection: Classification by NHLBI

PTCA revisited: acute vessel closure

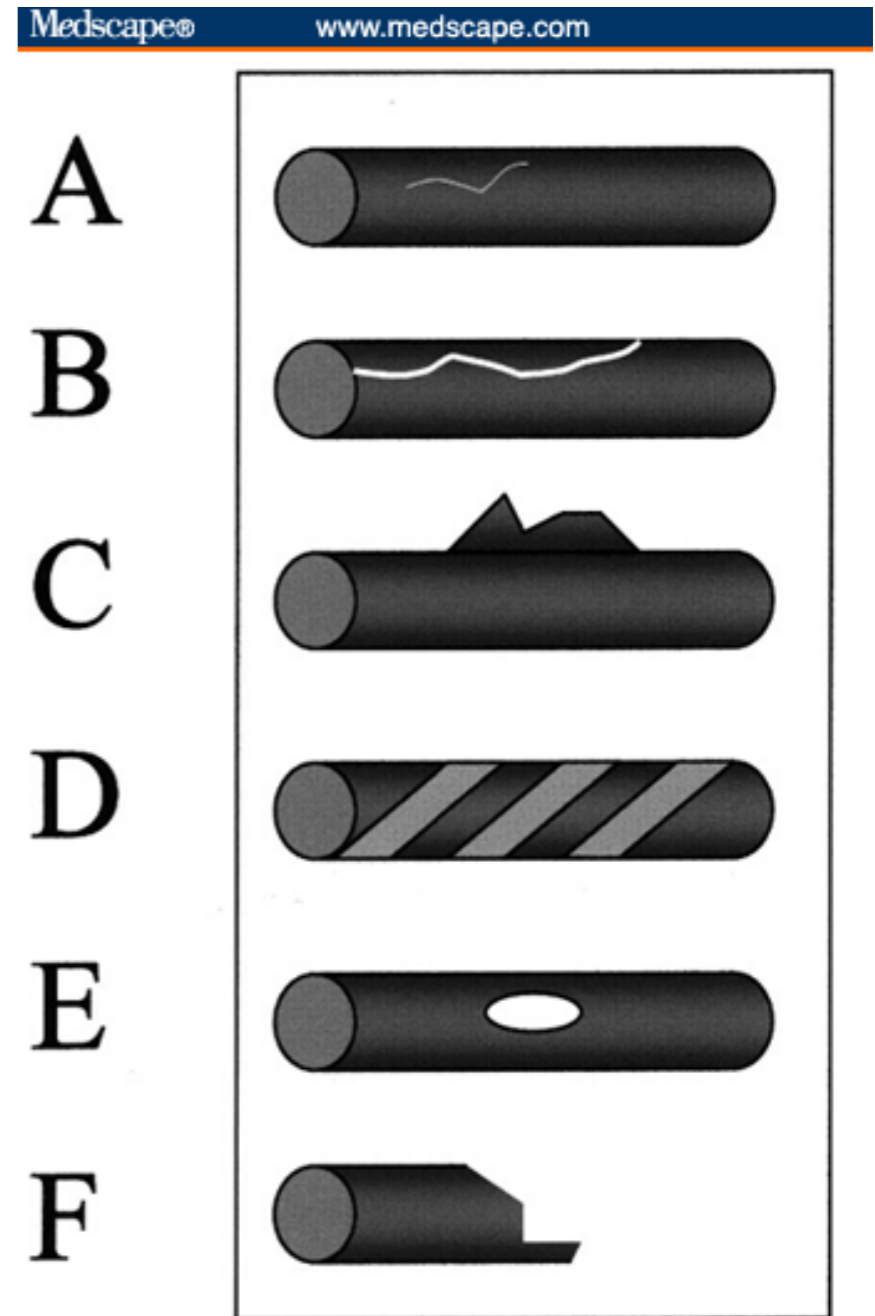
Dissection has been classified by NHLBI in the pre stent era

Types A to F have been differentiated
Types A and B are considered benign

Type A: minor radiolucent areas within the coronary lumen with little or no persistence

Type B: parallel tracts or double lumen separated by contrast during injection with minimal or no persistence after dye clearance

Type C-F Persistent dye outside lumen, spiral dissection, severe filling defects, abrupt vessel closure



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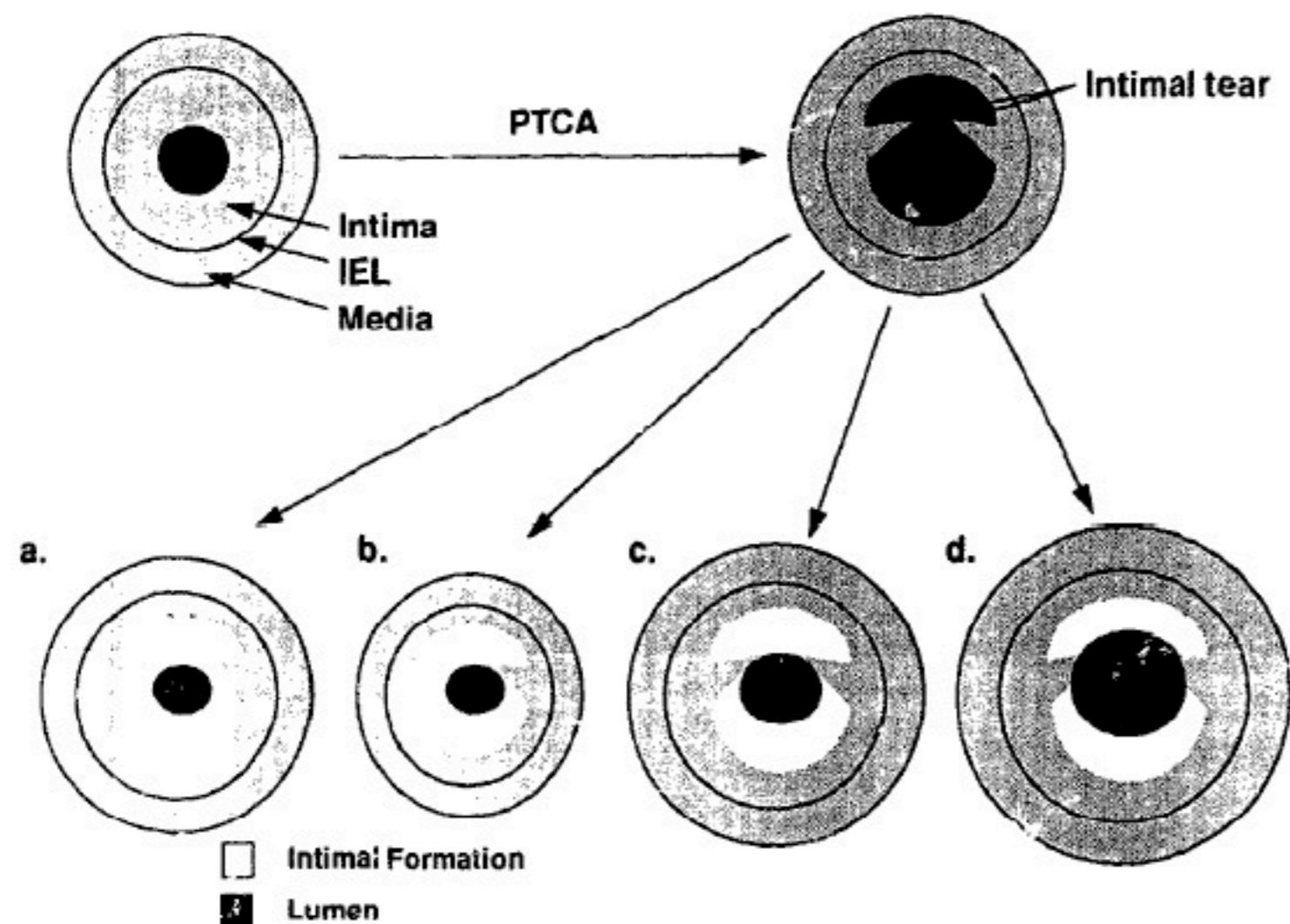
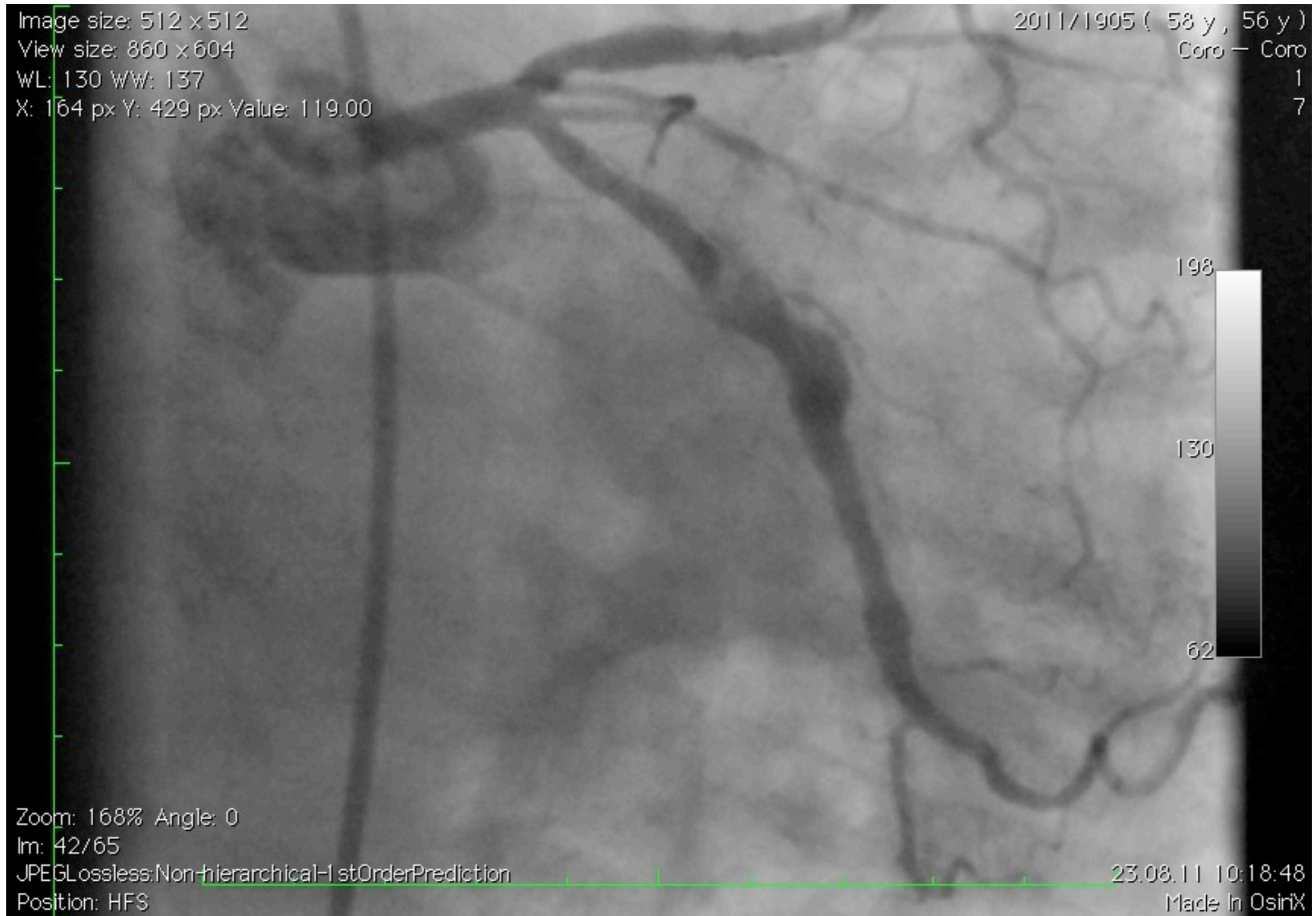


Figure 1. Expanded paradigm of restenosis after angioplasty. Several possible responses to balloon injury are illustrated. The classical paradigm (a) is intimal formation with no remodeling. If vascular constriction occurs (b), even minimal amounts of neointima may result in restenosis. A moderate amount of compensatory enlargement (c) may accommodate neointima with less lumen narrowing. Augmented compensatory enlargement (d) may result in a widely patent artery despite significant intimal formation. IEL = internal elastic lamina; PTCA = percutaneous transluminal coronary angioplasty.

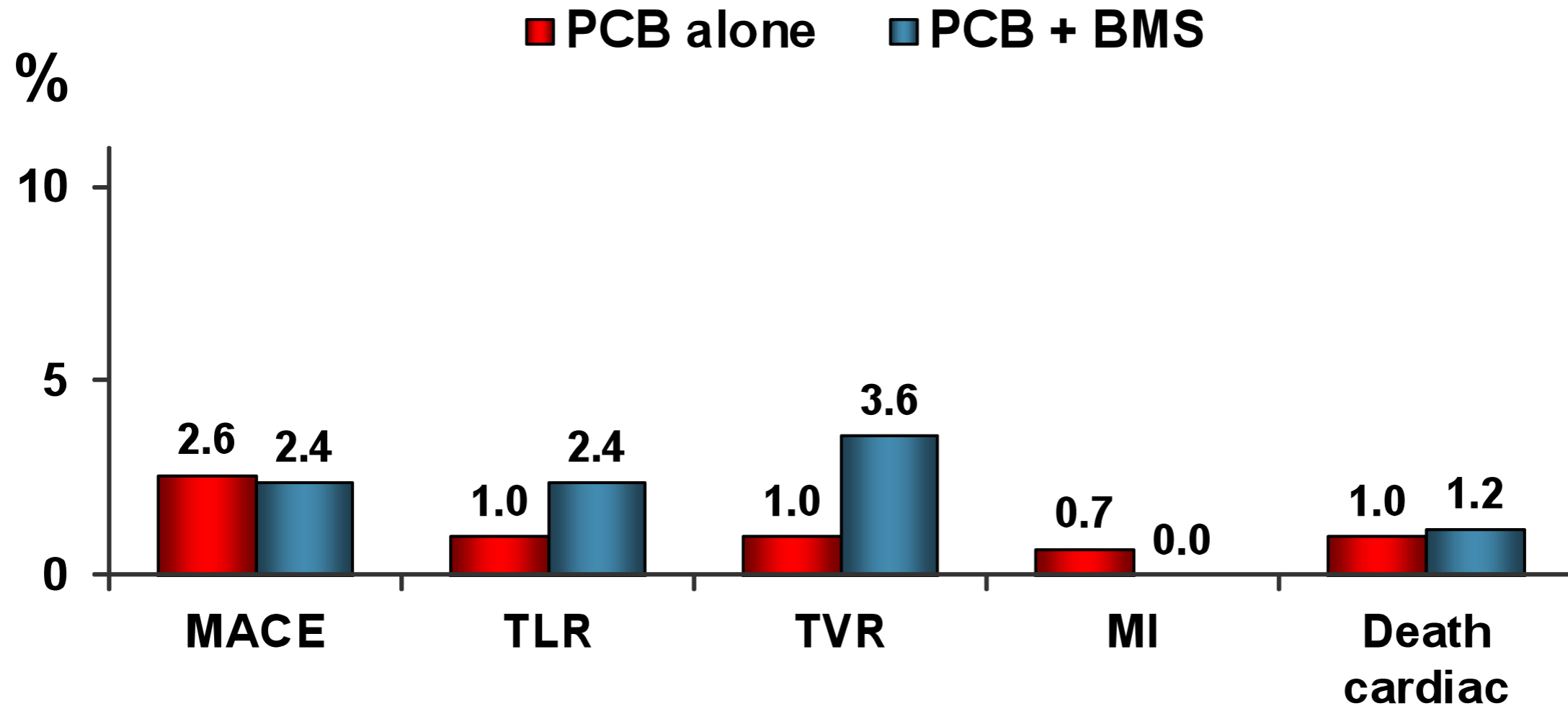
Male 58 yrs PTCA and DCB in peripheral CX artery acute result



Male 58 yrs PTCA and DCB in peripheral CX artery 10 weeks f.u.



Results after 9.8 months follow up



DCB World Wide Registry 9 months follow up Wöhrle JACC 2012; 60:11733-38

Table 1: Baseline Clinical and Angiographic Data

	Patients with small vessel de novo lesions (n=56)
Age, years	67.4±10.3
Male gender	82.1% (46)
Diabetes mellitus	33.9% (19)
Hyperlipidemia	82.1% (46)
Smoking	66.1% (37)
Hypertension	87.5% (49)
Number of diseased vessels	
1	17.9% (10)
2	37.5% (21)
3	44.6% (25)
Treated vessels	(n=58)
RCA	20.7% (12)
LCX	36.2% (21)
LAD	43.1% (25)
Lesion	(n=58)
Minimal diameter, mm	0.81±0.47
Length, mm	8.49±7.54
Reference diameter, mm	2.59±0.45
Diameter stenosis, %	69.1±14.0

Cumulative Frequency of Mean Lumen Gain in mm (N=58 patients) at follow-up

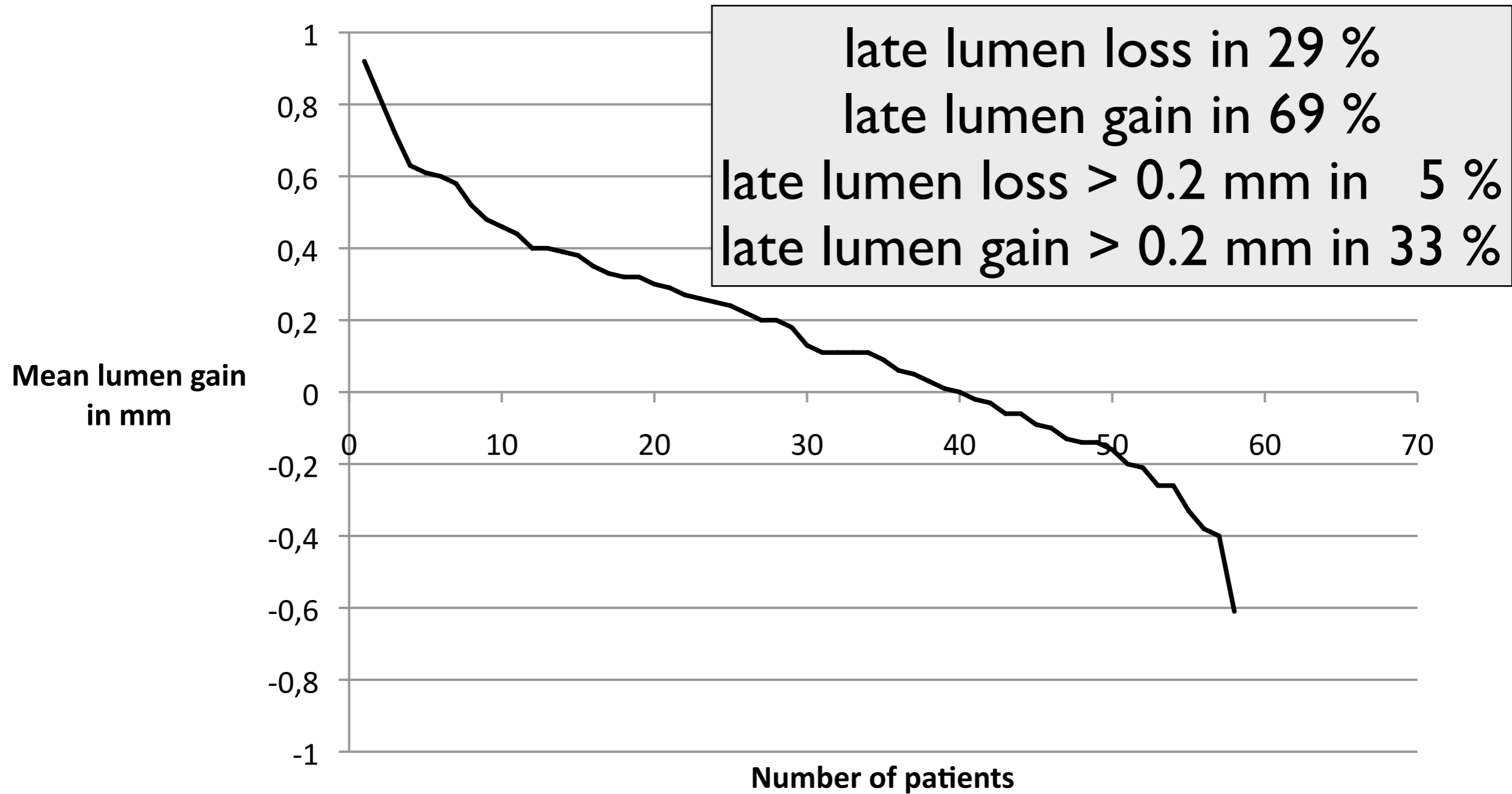
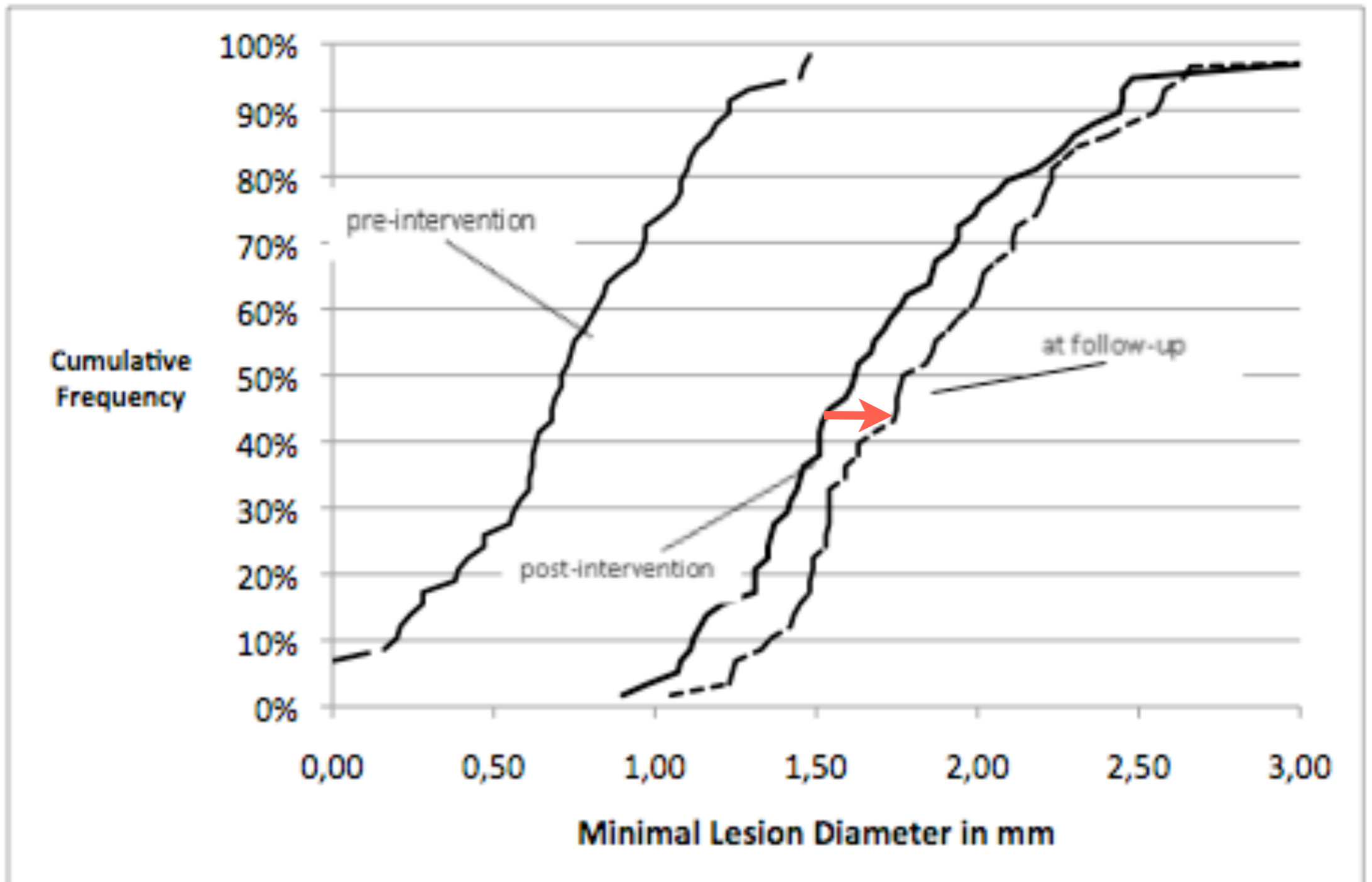


Figure 2: Minimal Lesion Diameters at pre-, post-intervention and at follow-up



How many patients do acutely need a stent during PCI?

Meta-Analysis of 10347 (5130 stent, 5127 PTCA) patients
in 23 trials randomized to stent or PTCA:

Cross over of 902 pts =
17 % from the PTCA group to stent group

In case of no flow-limiting dissection and an acceptable but not stent-like primary result, DCB use without additional stent implantation is recommended. We assume that this strategy will be applicable in up to 75 % of lesions depending on the complexity of coronary disease.

**DCB angioplasty is not a niche device
it has been shown to be superior to
other technologies in results or overall benefit,
in difficult indications like ISR, SVD and bifurcations.**

Stents are no more needed to prevent restenosis.