

Beyond ISR Treatment Viewpoint of a European CONSENSUS Group

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Drug Coated Balloons for treatment of coronary artery disease – updated recommendations from a Consensus Group

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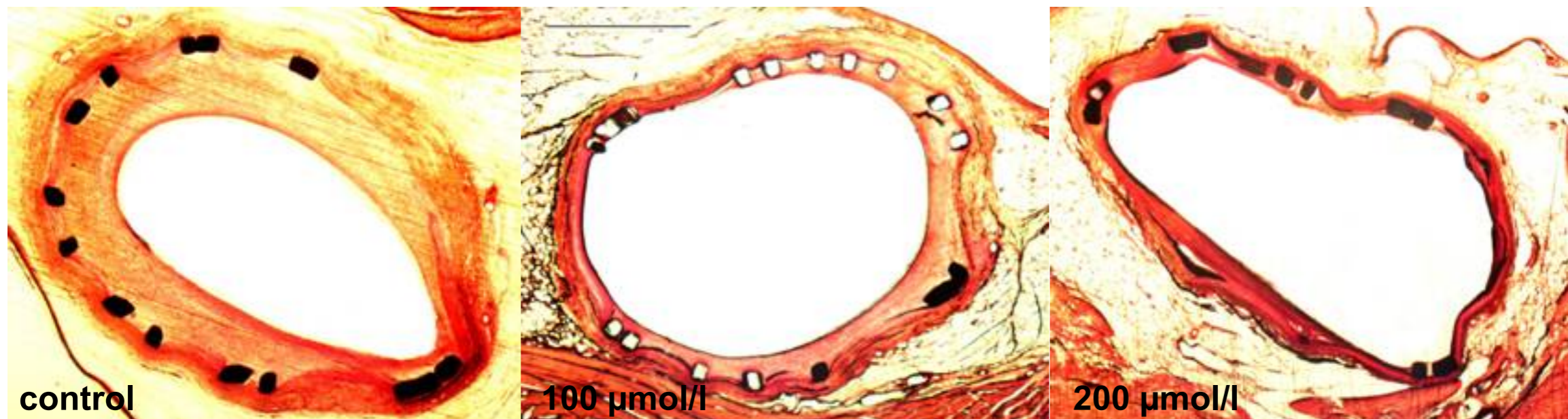
14 Klinische und Experimentelle Interventionelle Kardiologie, Klinik für Innere Medizin III, Universitätsklinikum des Saarlandes, Homburg/Saar, Germany

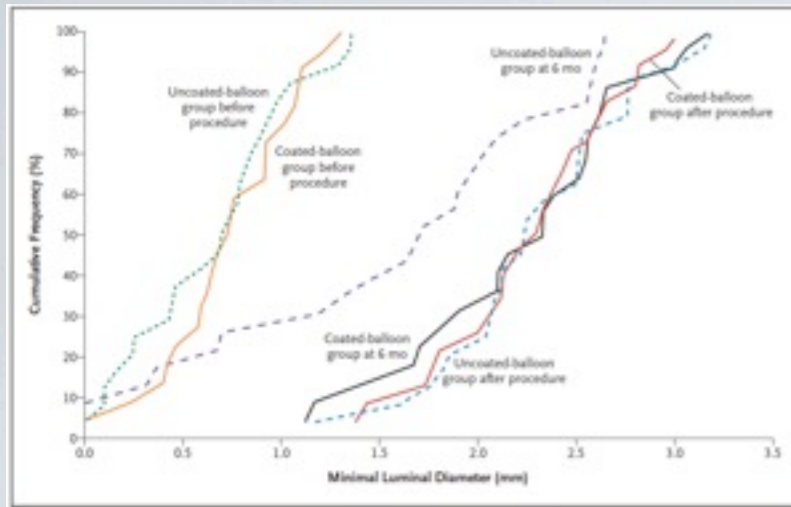
Intracoronary Iopromide Paclitaxel

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.





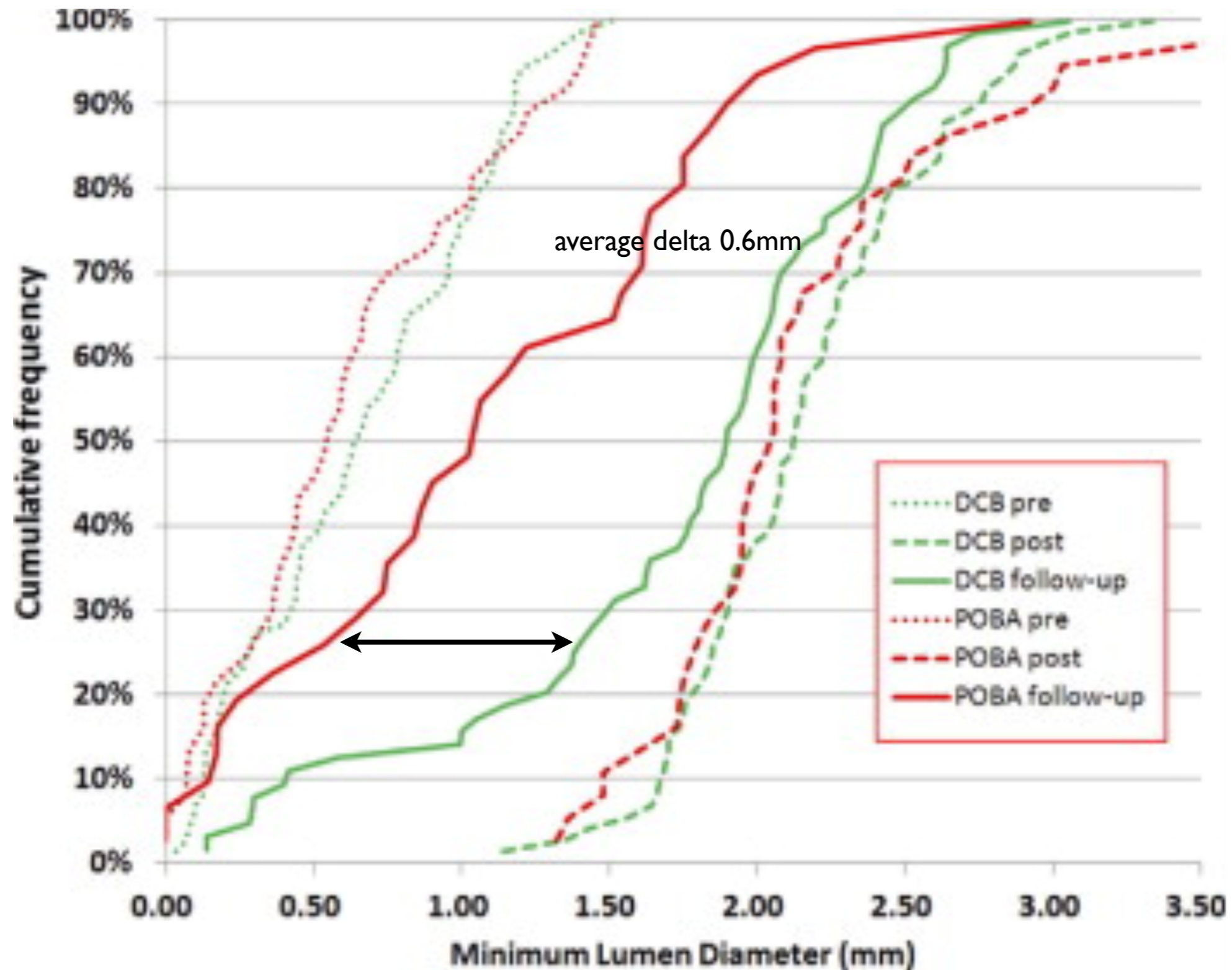
DCB Treatment of ISR

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

PEPCAD DES



**TLR in DCB World Wide Registry
1 %
Late Lumen Loss in Bello for DCB only
0.03 mm**

Coronary Balloon Overstretch Model in Pigs, intrapericardial Paclitaxel

Influence on Intimal Area, External Elastic Membrane Area and Vessel Size

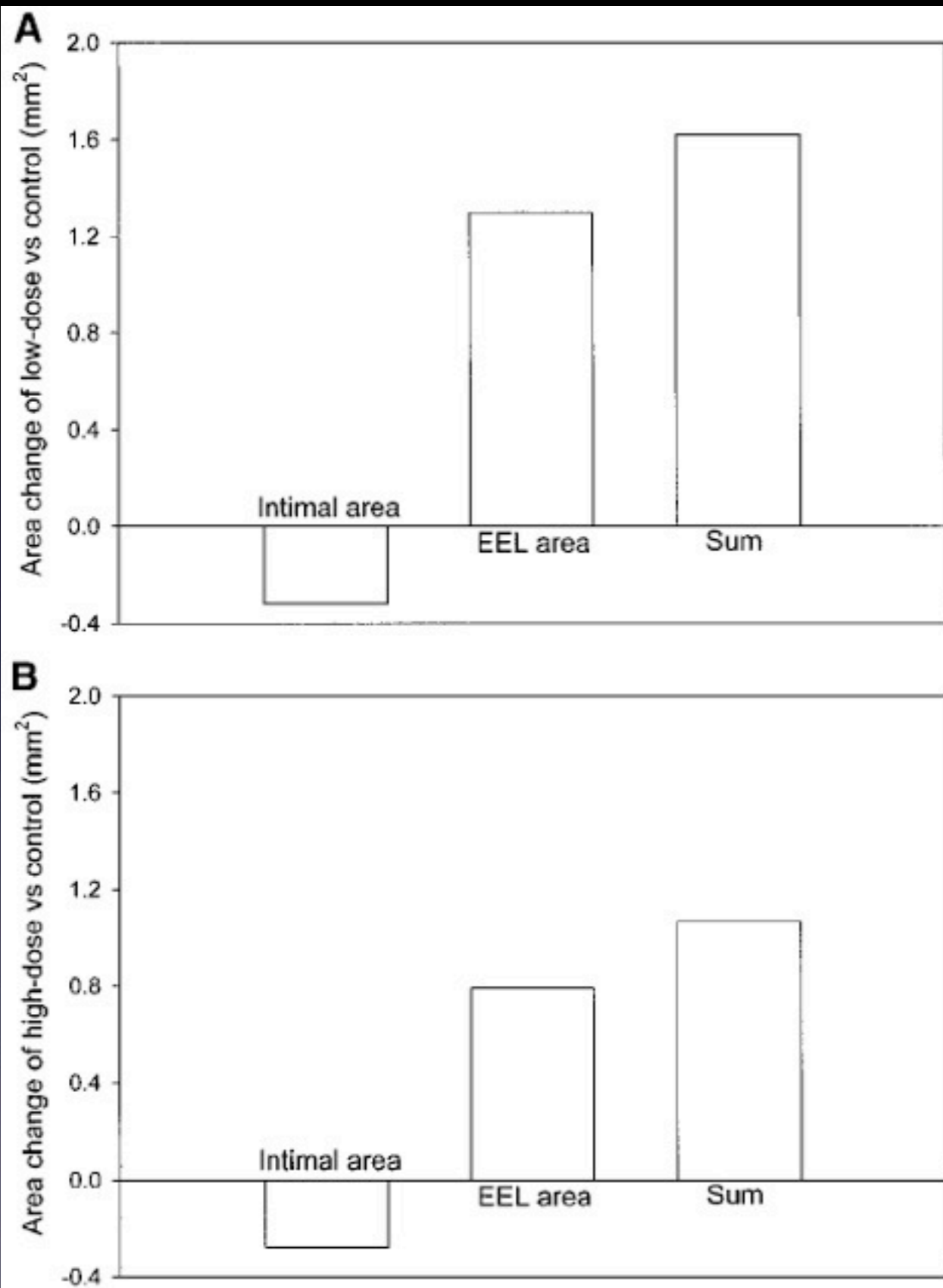
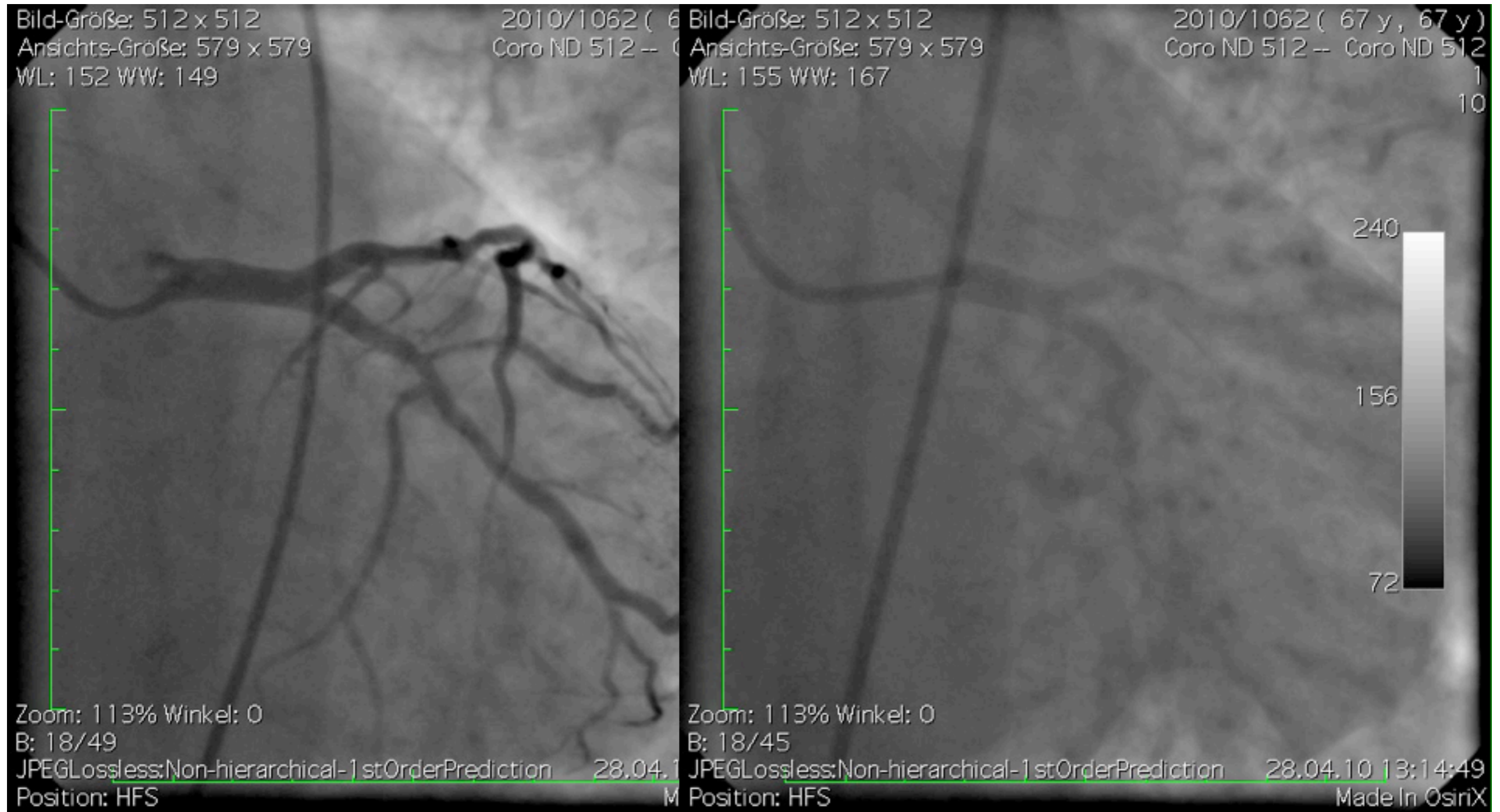
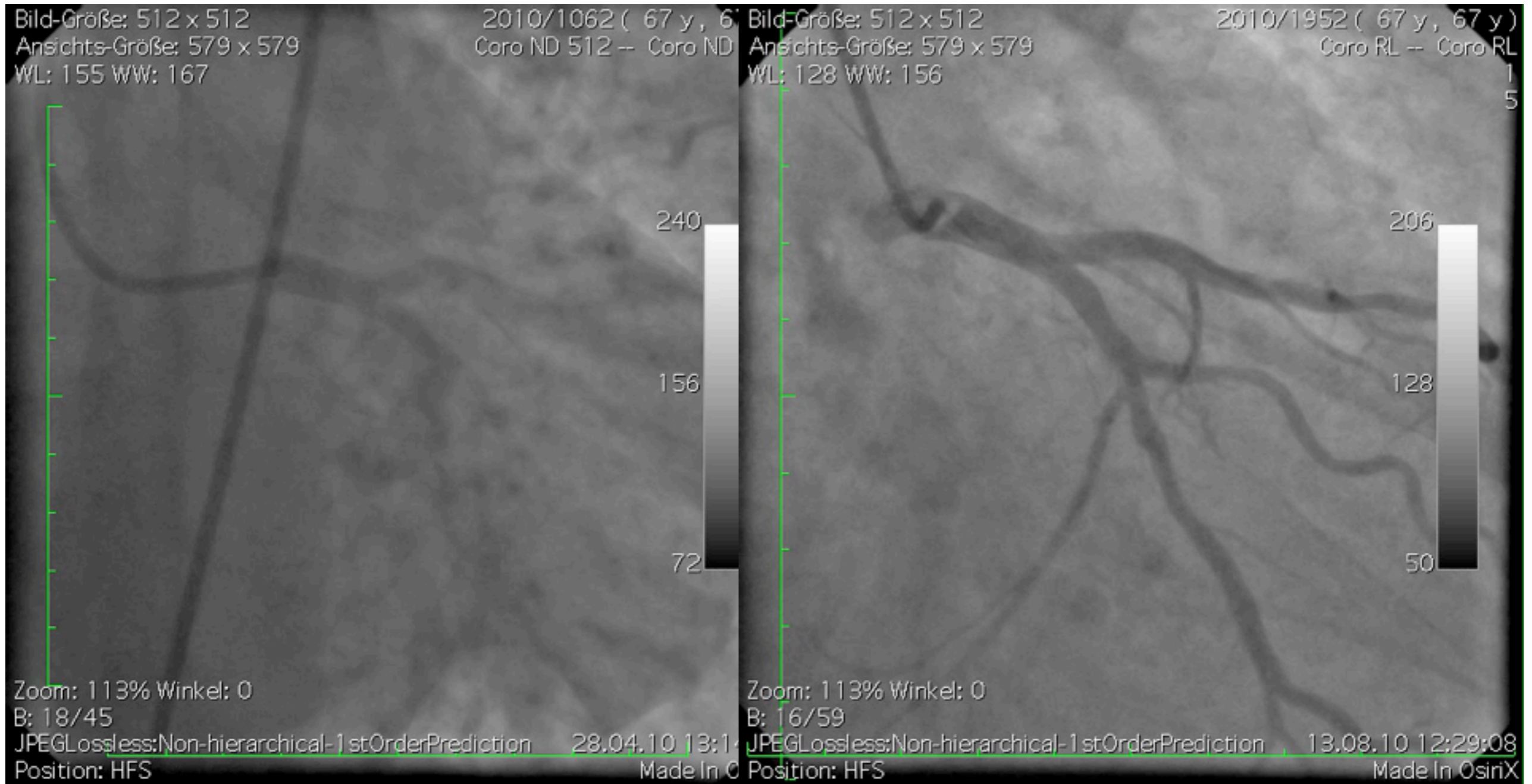


Figure 5. Induction of therapeutic remodeling after IPC delivery of paclitaxel. A and B, Area change of intima and EEL in LD (A) and HD (B) groups relative to control group. Sum refers to total effect on vessel enlargement.

RH female 67 yrs 1062 und 1952-2010 OM stenosis acute result



RH female 67 yrs 1062 und 1952-2010 OM stenosis Acute & 4 months result



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

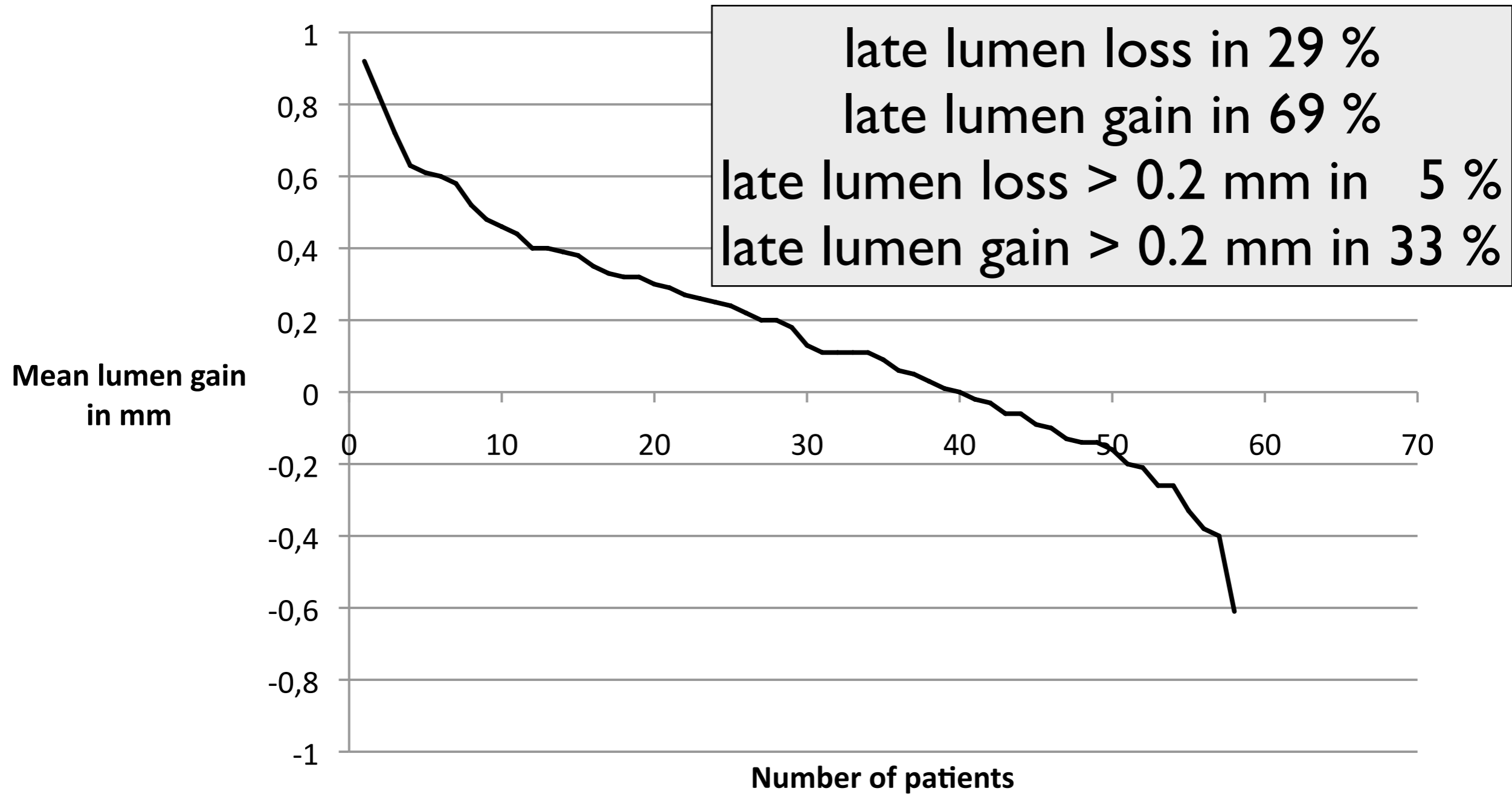
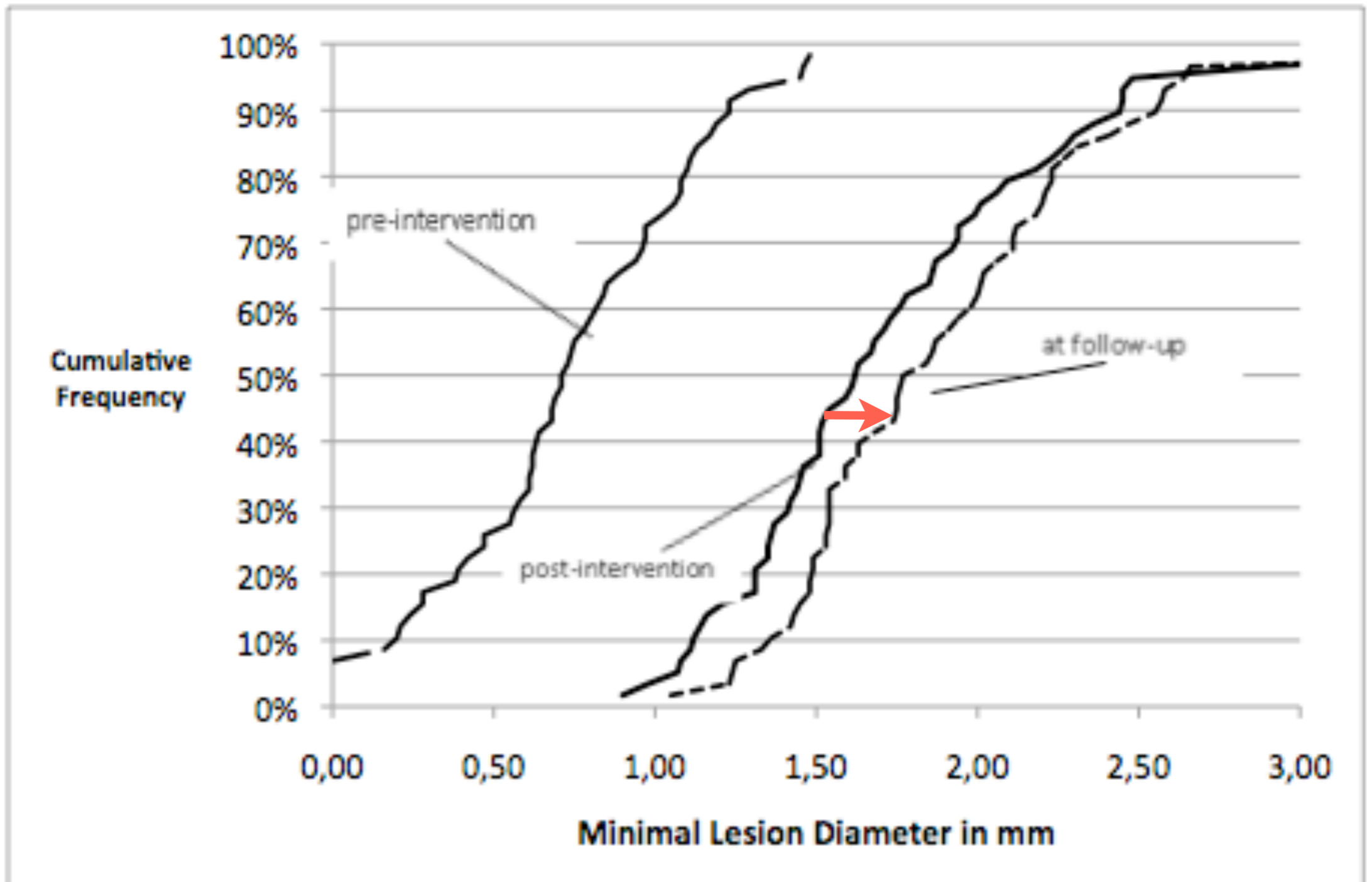
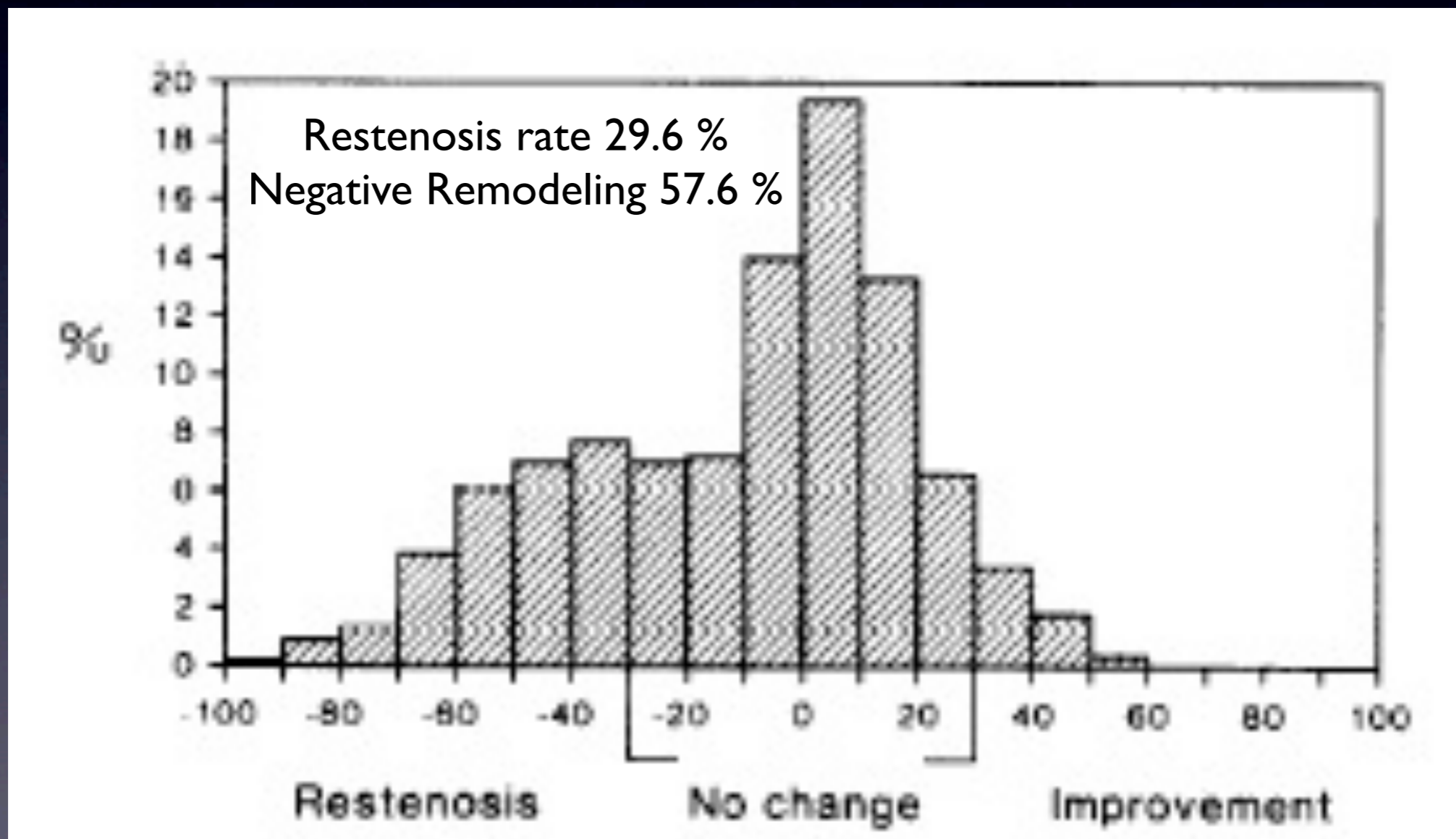


Figure 2: Minimal Lesion Diameters at pre-, post-intervention and at follow-up

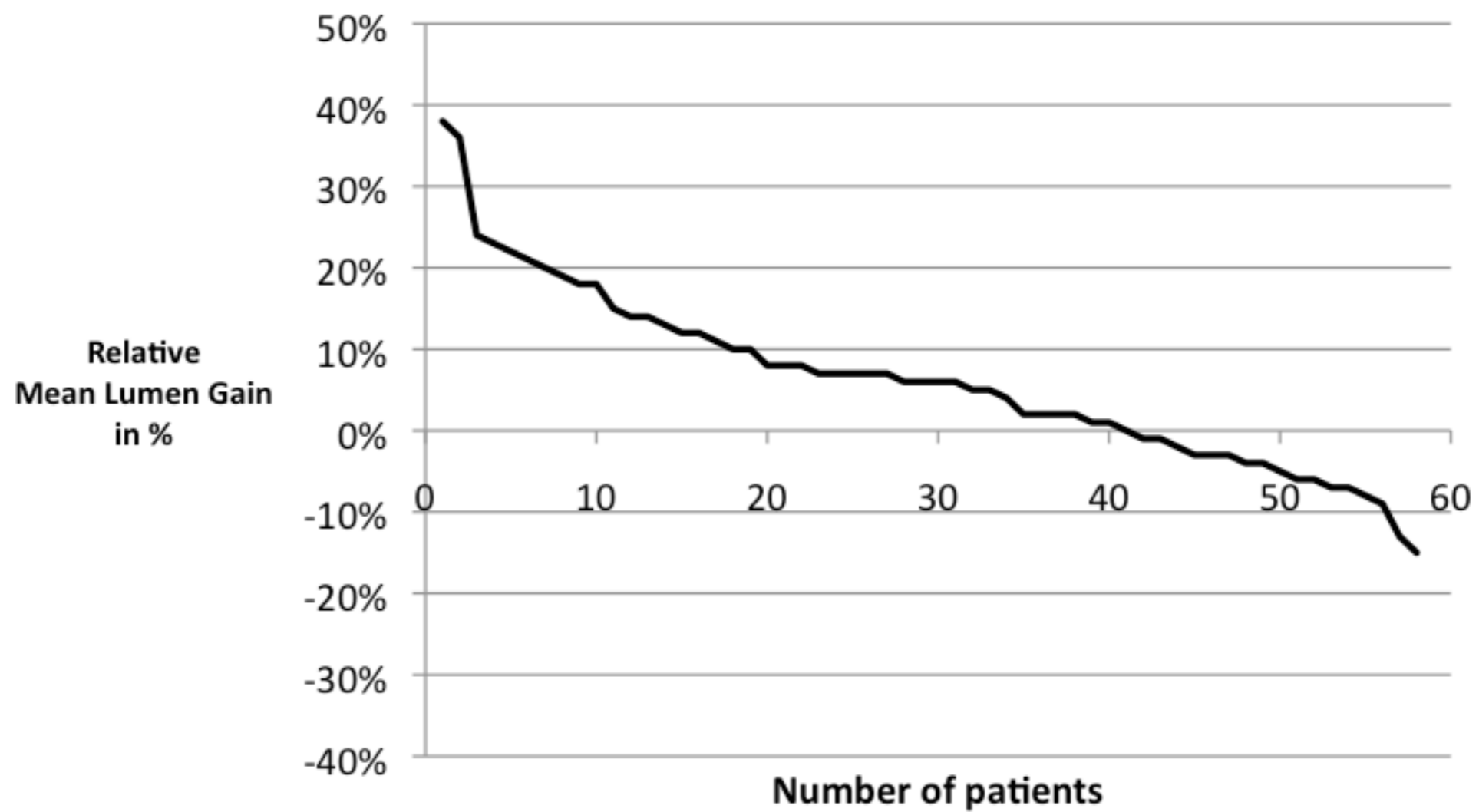


Restenosis (188 days n = 557)

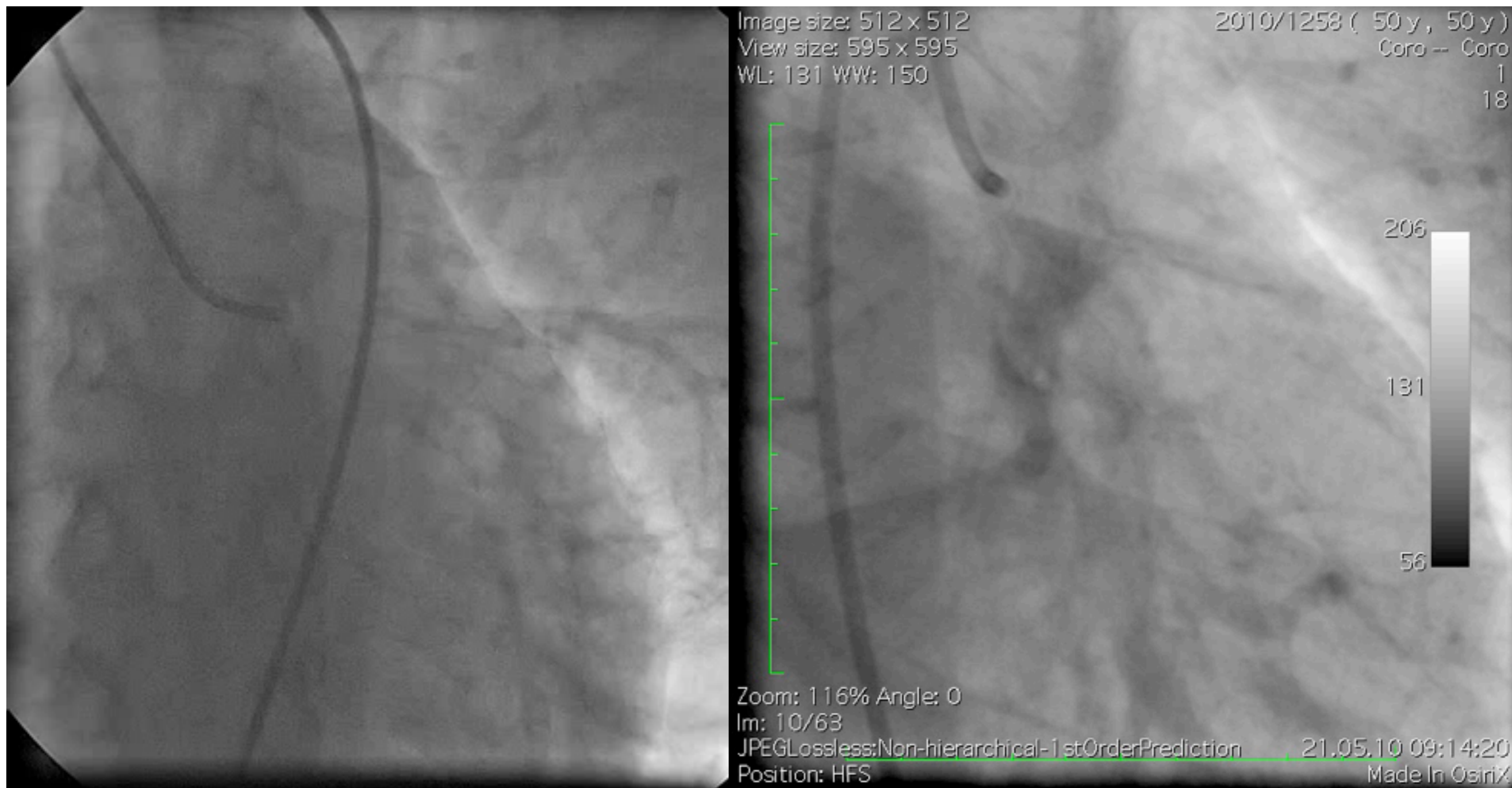
defined as an increase of 30 % in stenosis grade from end of procedure to follow up



Cumulative Frequency of Relative Mean Lumen Gain in % (N=58 patients)



NSTEMI 50 yrs Female ACS Angina at rest baseline and acute result



NSTEMI 50 yrs Female ACS Angina at rest acute and 4 months result



General principle of DCBonly, combination with BVS

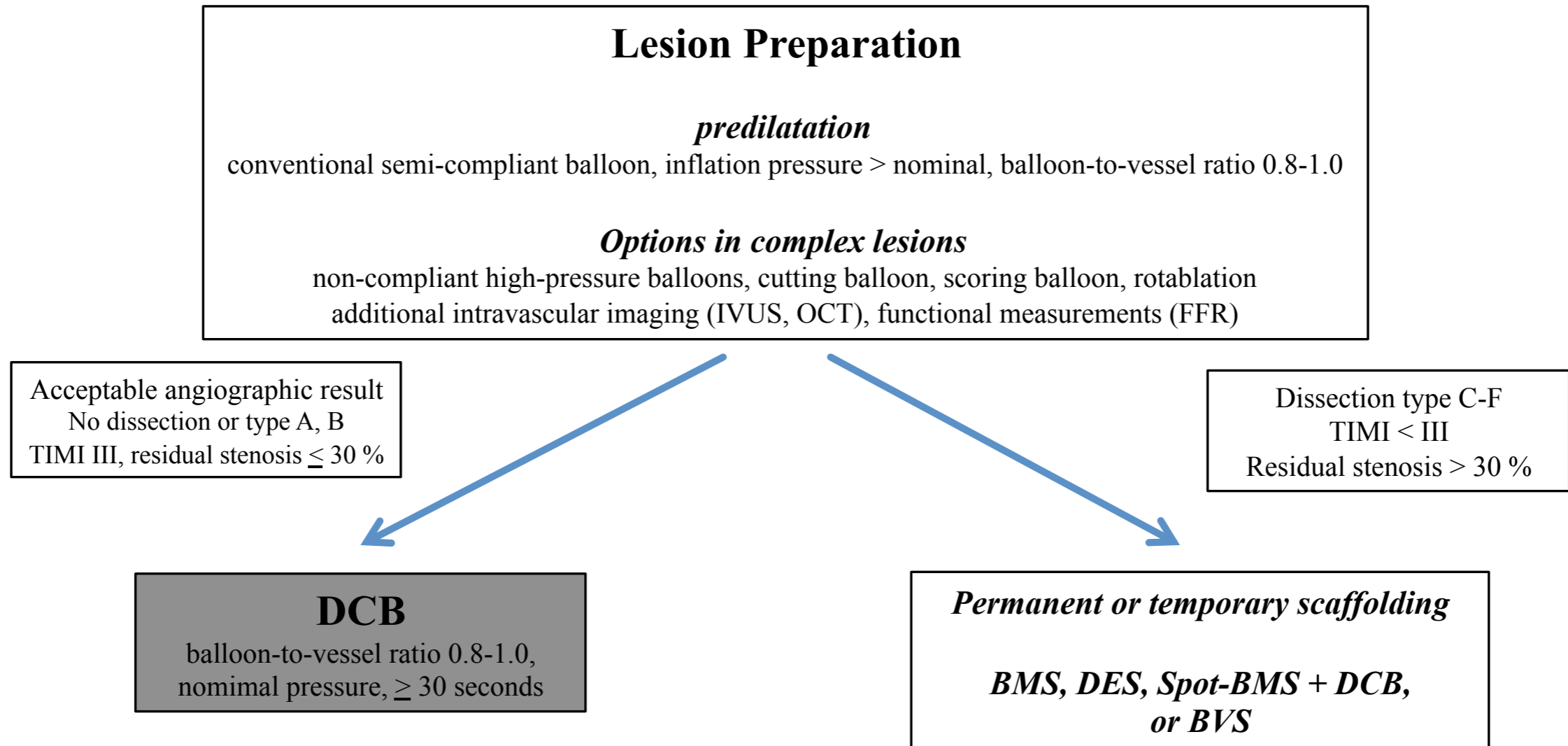


Figure 5

FXKleber for the DCB Consensus Group submitted 2013

Positive Remodeling seems to be
one of the mechanisms
active after DCB Angioplasty

This might represent a new paradigm in interventional
therapy of vascular disease

While looking at PTCA restenosis
and developing stents to overcome this
we exaggerated neointimal proliferation
and forgot about vessel remodeling

DCB and BAVS give us the opportunity
to rethink what we do