FFR and IVUS Guided DES Implantation in Long Diffuse Lesions

Can We Reach Optimal DES Expansion With Conventional Stent Delivery System in Long Diffuse Lesion?

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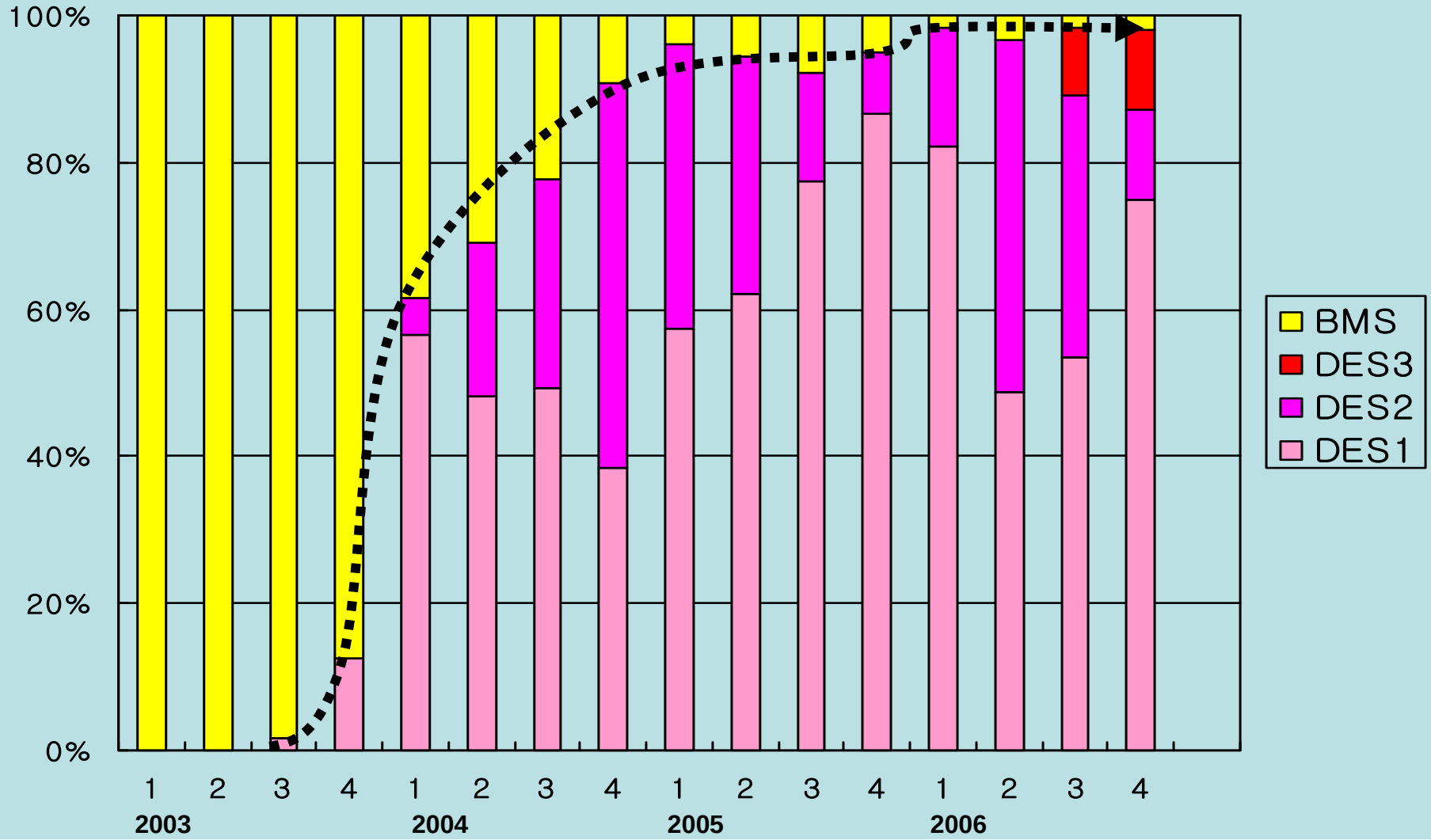
Are Drug-Eluting Stents Changing Your Daily Practice?

After 24 months of DES for all patients, the point of no return has been reached and we will not come back to bare stent.

Thank you

DES Penetration in Ajou University Medical Center



DES changes our pattern of PCI

We are getting more aggressive ..

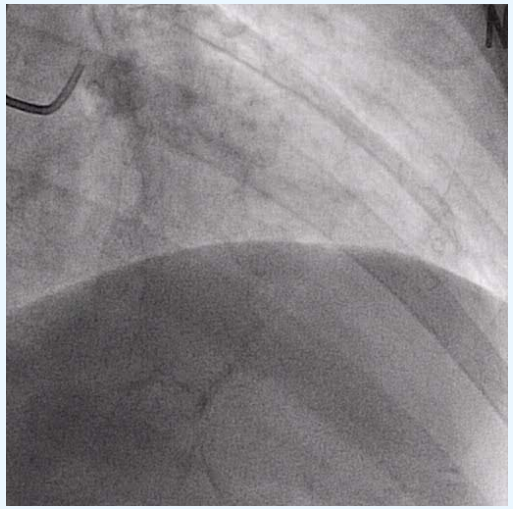
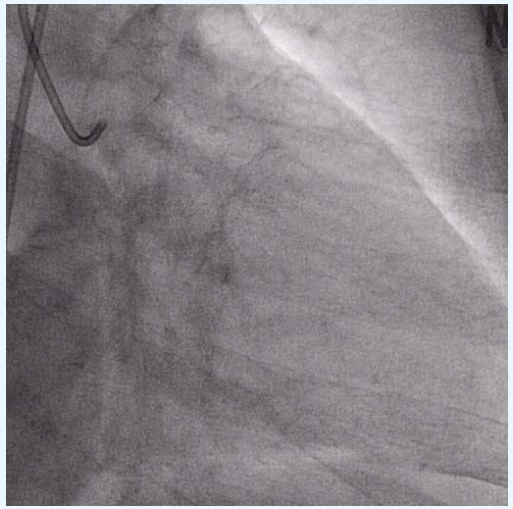
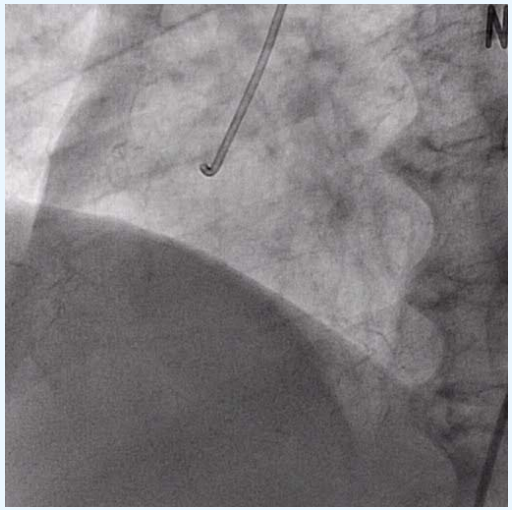
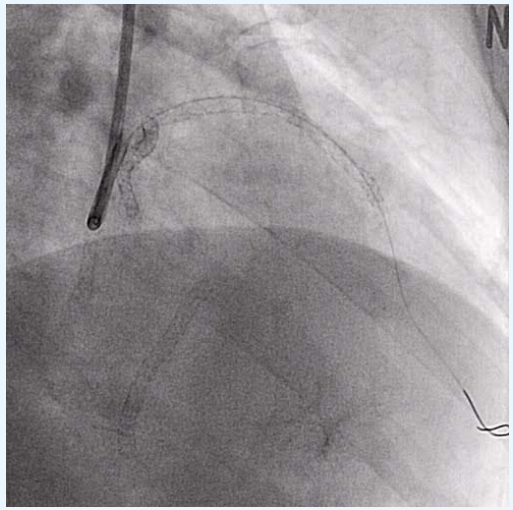
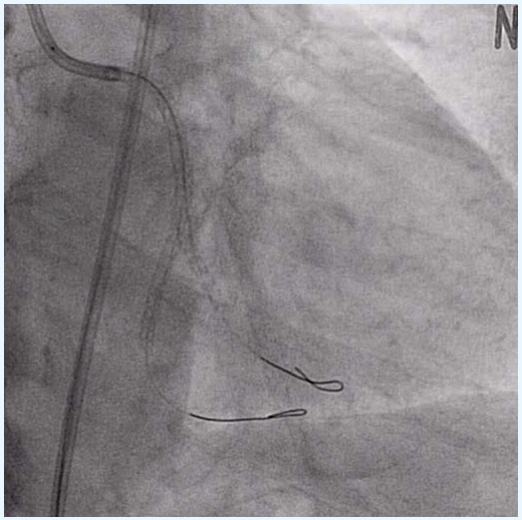
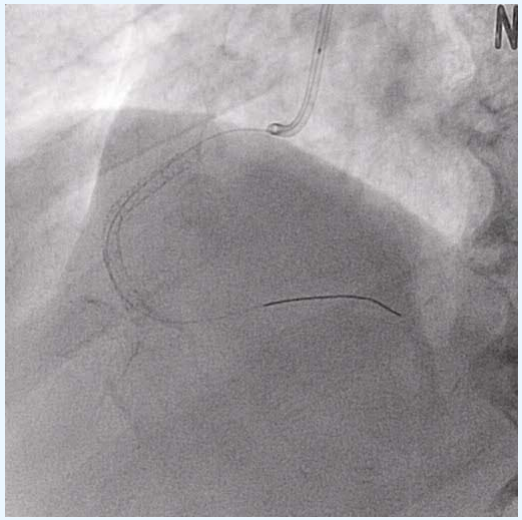
Complex Lesions

Long Diffuse Lesions

Small Vessels

Diabetic Patients

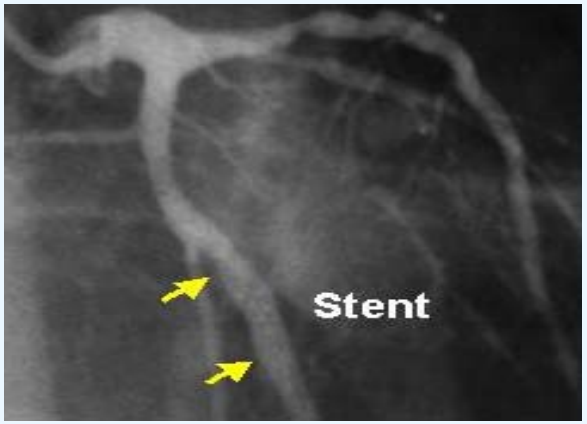
DES Mania .. Metal Jacket ..
Do we have optimal stent expansion in every stent?

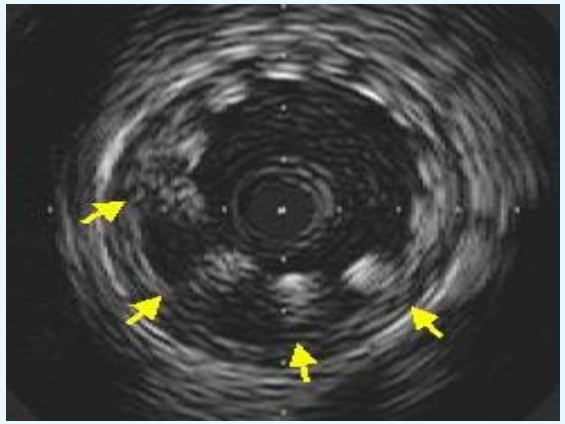
Evaluation of Stent Expansion in Long Diffuse Lesion

No expert can be perfect with visual assessment…

Optimal DES expansion and apposition is important ..



Under angiography, the stent *appears* fully expanded/apposed



Using IVUS, the stent demonstrates *sub-optimal* expansion/apposition

- Optimal expansion and uniform apposition facilitates drug delivery [2,3,4,5]
- Incomplete apposition may contribute to stent thrombosis[1]
- Stent underexpansion may increase risk for restenosis and TLR [6,7]

1. Cheneau, et al. Circulation 2003;108;43-47
2. Creel, et al. Circulation 2000;86:879.
3. Hwang, et al. Circulation 2001;104:600-605
4. Leon, M. *The basic "tips and tricks" for DES implantation;* TCT 2003 presentation
5. The TAXUS Stent Directions for Use
6. Fitzgerald, et al. Circulation 2000; 102:523-530
7. Fuji, et al. Circulation 2004; 109: 1085-1088

Predictors of Restenosis and Target Vessel Revascularization after SES Implantation

Clinical variables
Diabetes
Angiographic variables
Small reference vessel diameter
Ostial location
Non–left anterior descending artery lesion
In-stent restenosis
Procedural variables
Long stent length
Small stent diameter or minimal stent area (MSA) by IVUS

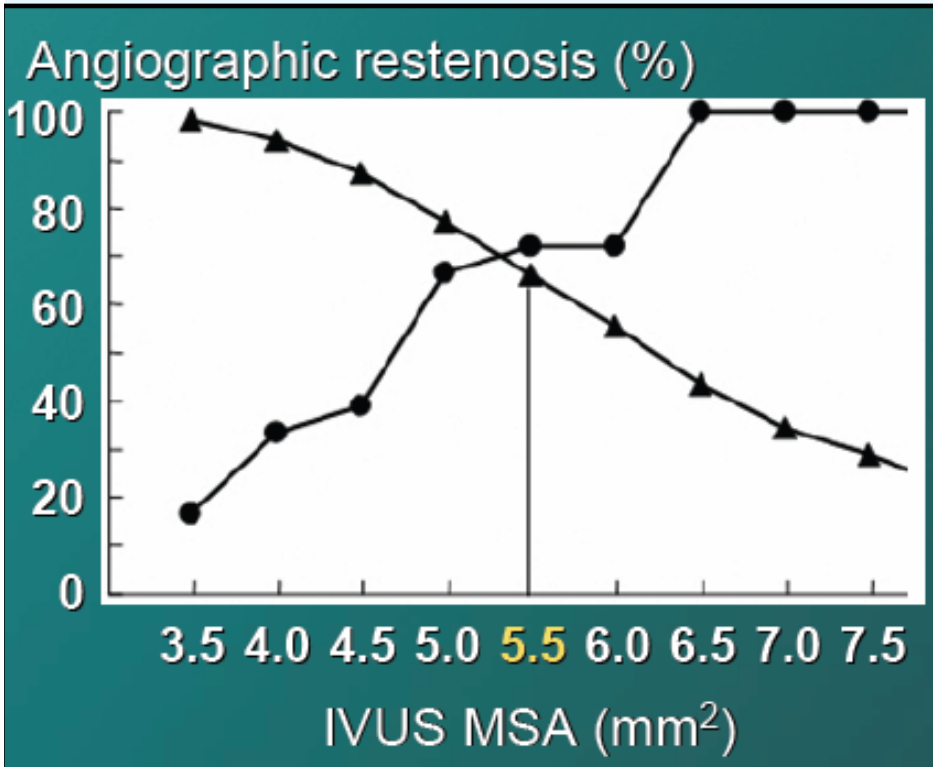
BR Brodie. J Interven Cardiol 2006;19:43–50)

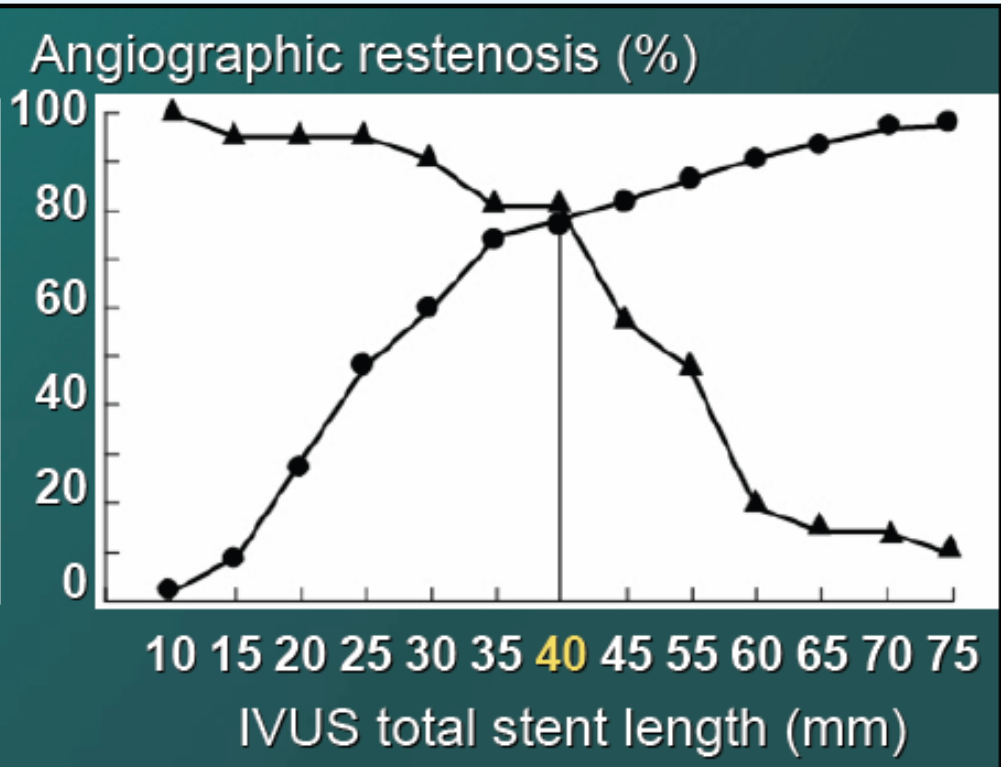
Predictors of Drug-Eluting Stent Thrombosis

- Clinical variables
  - Diabetes
  - Renal failure
  - Low ejection fraction
- Angiographic variables
  - Bifurcation lesions
- Procedural variables
  - Use of multiple stents
  - Use of long stents
  - Small final stent area (MSA) by IVUS
  - Stent underexpansion
  - Residual reference segment stenosis
- Postprocedural variables
  - Premature discontinuation of antiplatelet therapy

BR Brodie. J Interven Cardiol 2006;19:43–50)

Predictors of angiographic restenosis in 550 patients with 670 native artery lesions in patients treated with Cypher Stents

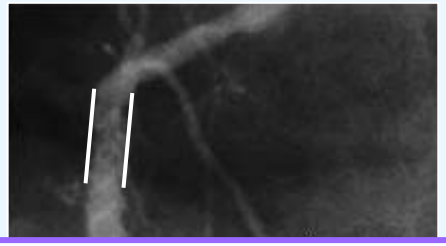




	<5.5mm²	≥5.5mm²
≤40mm	2.4%	0.4%
>40mm	17.7%	8.6%

(Hong et al. Euro Heart J 2006;27:1305-10)

POSTIT Trial
Verification of BMS expansion by IVUS



Post-dilatation with **non-compliant balloons** double the rate of optimum stent deployment

Optimal stent deployment* is only achieved in 29% of patients with current stent delivery systems; usually due to inability of stent delivery balloon to expand fully the stent to nominal size.

*MSD≥90% of average reference lumen diameter

POSTIT Trial, Brodie et al, Catheterization and Cardiovasc Int 2003;59:184

DES Expansion without Postdilation

Table IV. IVUS quantitative assessment

	SES (n = 133)	PES (n = 67)	*P*
Reference segment			
Minimal stent diameter (mm)	3.2 ± 0.3	3.1 ± 0.4	.7
Minimal stent cross-sectional area (mm^2)	6.1 ± 1.6	6.2 ± 1.9	.5
IVUS/manufacturer's predicted stent diameter (%)	75.6 ± 10.3	74.6 ± 11.0	.5
IVUS/manufacturer's predicted stent cross-sectional area (%)	66.0 ± 16.2	65.4 ± 18.1	.4

- **The DES achieved only 75% of predicted MSD and 66% of predicted MSA.**
- **This was similar form SES and PES.**
- **24%-28% of DES did not achieve a final MSA of 5.0 mm^2.**

Jose de Ribamar Costaet al. Am Heart J 2007;153:297-303

DES Expansion with Incremental Delivery Pressures

Table 3
Comparison of postintervention IVUS parameters at different delivery pressures

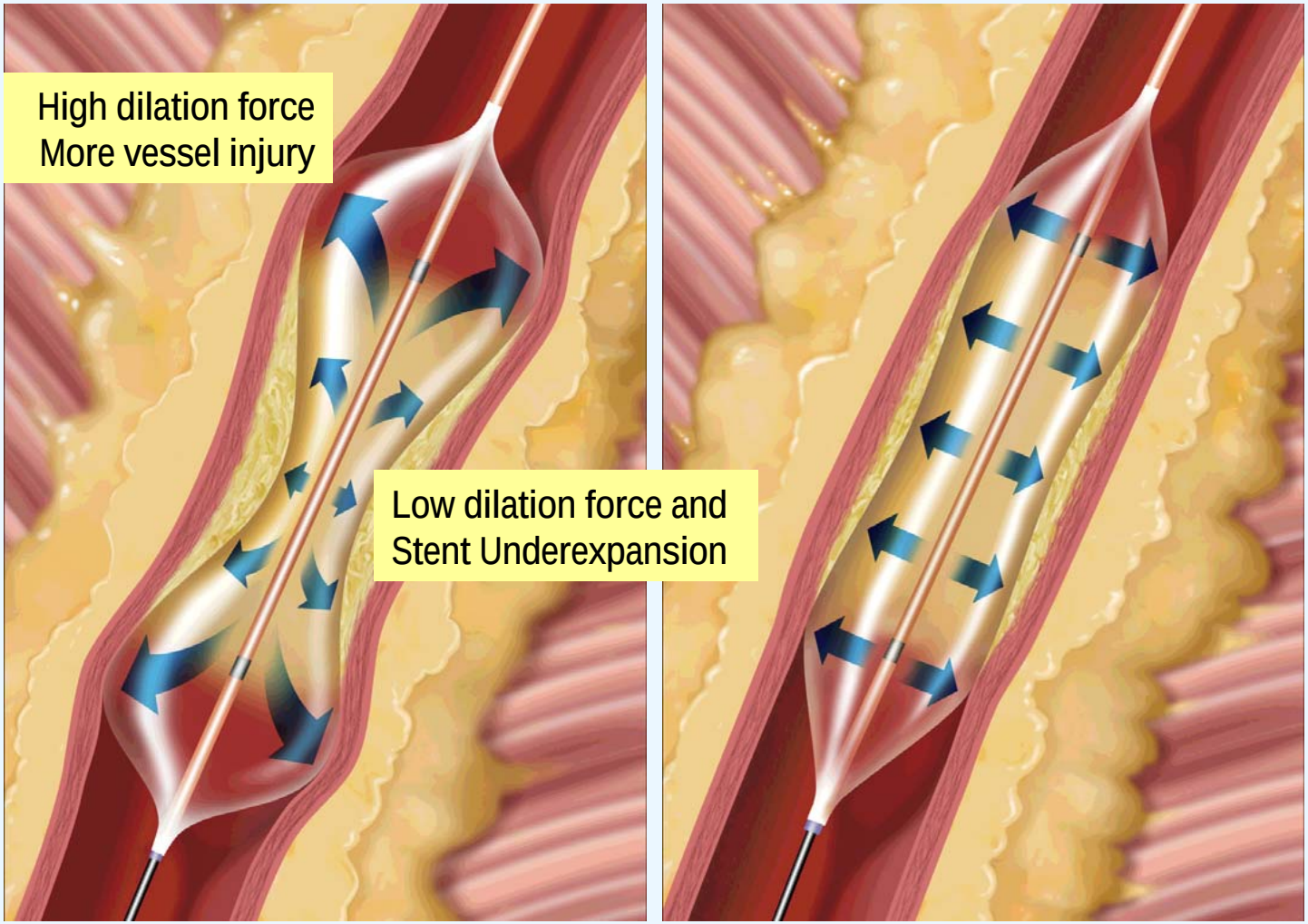
Variable	SES (n=46)	PES (n=41)	P value
14 atm			
Min stent CSA (mm^2)	5.0±1.4	5.6±2.1	.15
Max stent CSA (mm^2)	6.9±1.9	8.0±2.4	.007
Min stent diameter (mm)	2.34±0.33	2.40±0.50	.46
Max stent diameter (mm)	2.93±0.37	3.35±0.50	<.0001
Axial stent symmetry	0.73±0.11	0.69±0.13	.08
Radial stent symmetry	0.80±0.09	0.72±0.09	<.0001
Underexpansion	37/46 (80.4%)	26/41 (63.4%)	.08
20 atm			
Min stent CSA (mm^2)	6.4±1.7	6.0±2.0	.30
Max stent CSA (mm^2)	8.0±1.9	8.4±2.3	.44
Min stent diameter (mm)	2.64±0.34	2.51±0.44	.16
Max stent diameter (mm)	3.20±0.38	3.45±0.48	.01
Axial stent symmetry	0.82±0.11	0.70±0.10	.0004
Radial stent symmetry	0.83±0.08	0.73±0.08	<.0001
Underexpansion	22/46 (47.8%)	9/26 (34.6%)	.28

*** Stent Underexpansion by MUSIC criteria**

A Javaid et al. Cardiovascular Revascularization Medicine 7 (2006) 208– 211

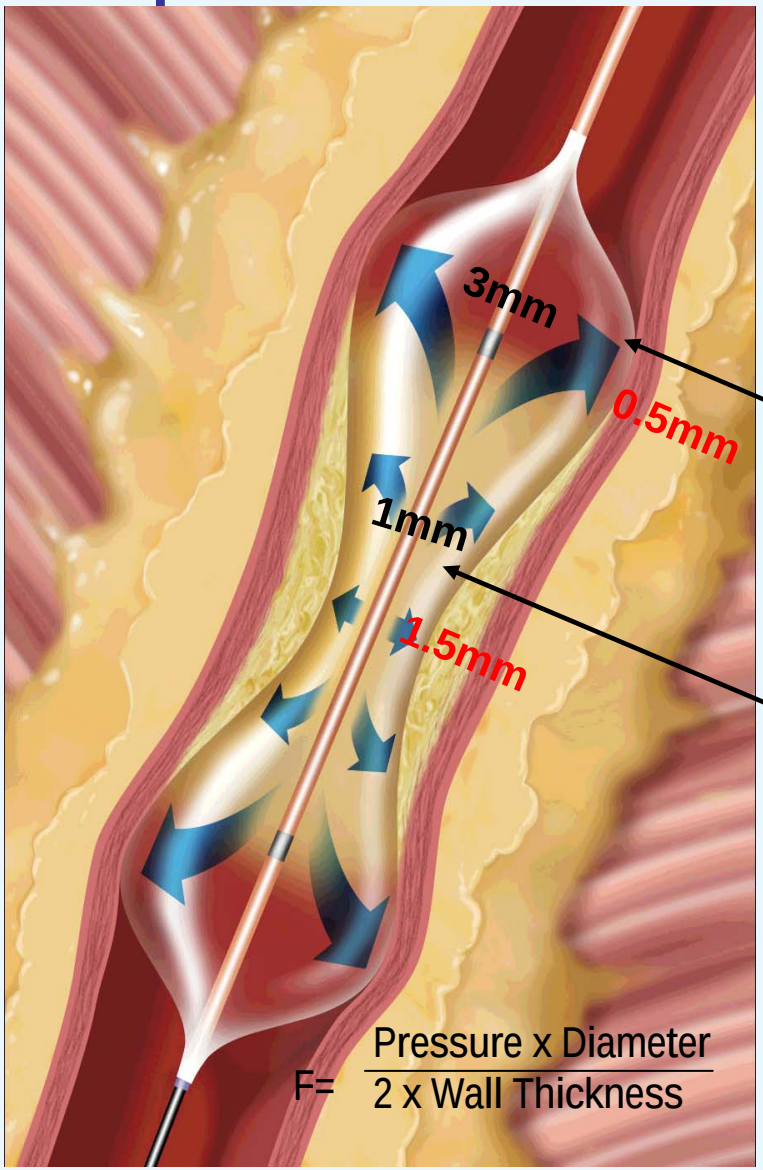
Mechanism of Suboptimal Stent Expansion
Balloon compliance and dilation force

Compliant/Semi-Compliant | **Non Compliant**



$$F = \frac{\text{Pressure x Diameter}}{\text{2 x Wall Thickness}}$$

Mechanism of Suboptimal Stent Expansion
Inflation pressure and dilatation force



Inflation pressure = 10 atm

Dilation force varies from

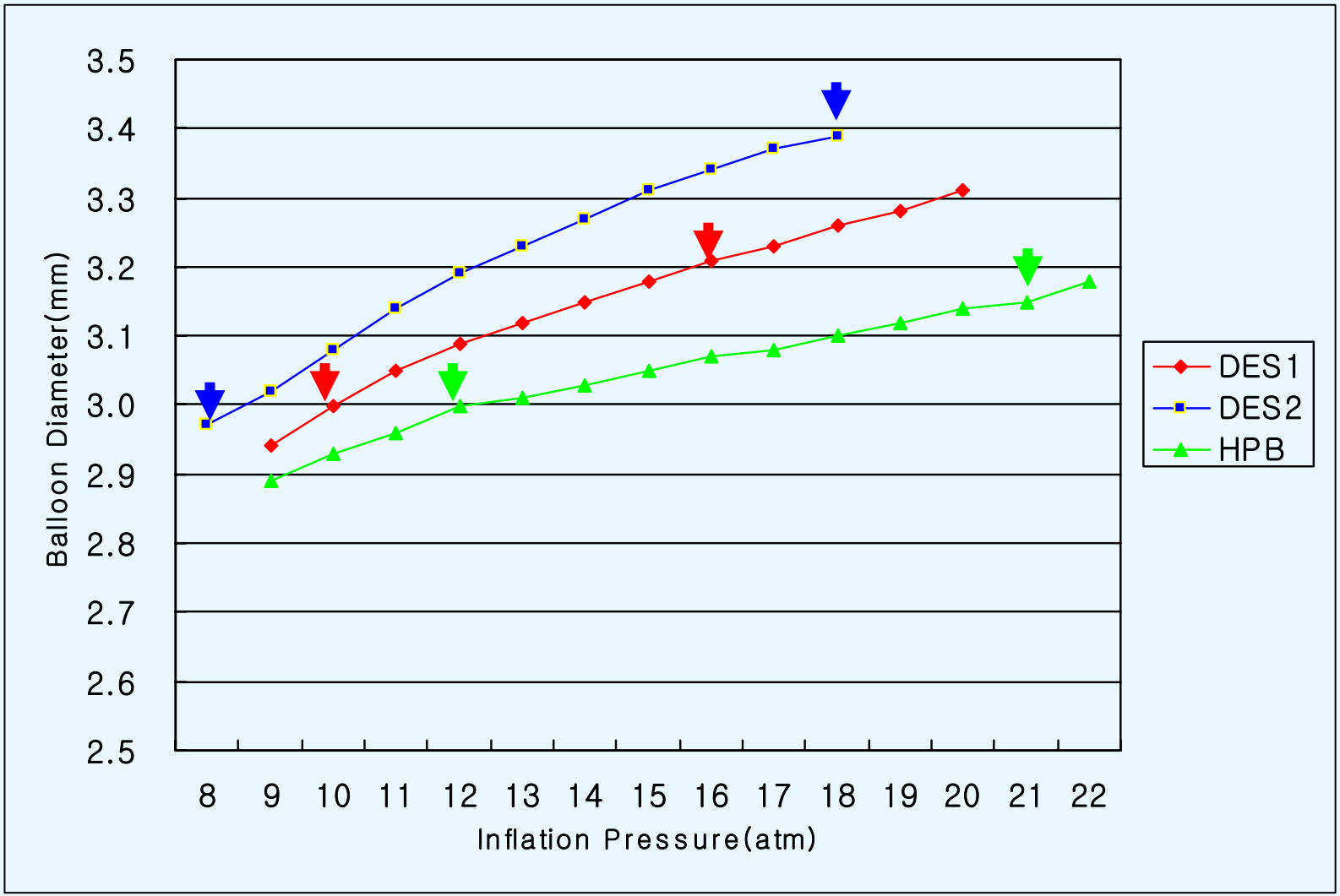
10x3/2x0.5 = 30 atm

to

10x1/2x1.5 = 3.3 atm

X 10 Dilatation Force

Compliance of current DES delivery system



Long Diffuse Lesion
FFR and IVUS-guided DES Implantation

- PCI with current semi-compliant stent delivery system (SDS) in long diffuse lesion may result in stretching of the balloon around the lesion rather than concentrating the force at the lesion and cannot achieve optimal stent expansion at culprit site.

- Visual angiographic estimation of stenosis may poorly correlate with anatomic and physiologic significance.

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Long Diffuse Lesion
FFR and IVUS-guided DES Implantation

- Evaluate the incidence of suboptimal stent expansion with current drug SDS in long diffuse lesion.
- Evaluate effectiveness of post-stent adjuvant high-pressure non-compliant balloon dilatation.
- Identify the factors which was related with the suboptimal stent expansion.

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Long Diffuse Lesion
FFR and IVUS-guided DES Implantation

- Inclusion Criteria
  - 41 consecutive angina patients, 47 de novo lesions
  - % DS on QCA >50% with evidence of myocardial ischemia
  - Stent length > 32mm
  - Informed consents for IVUS and FFR measurement.

- Exclusion Criteria
  - Restenotic lesion
  - Acute myocardial infarction or prior myocardial infarction
  - LV dysfunction: LVEF < 55%
  - Left main disease
  - Significant cardiac arrhythmia hampering physiologic study

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Long Diffuse Lesion
FFR and IVUS-guided DES Implantation

Pre PCI	Stenting with SDS (at RBP: 16-18 atm)	Adjunctive High Pressure (Quantum at 20-22 atm) *if Post Stent FFR<0.95*
IVUS FFR	IVUS FFR	IVUS FFR

Pressure measurement: RADI Medical System, Uppsala, Sweden

IVUS: 40MHz Atlantis™ SR Pro, Galaxy 2 Ultrasound Imaging System, Boston Scientific Corporation, Natick, MA, USA

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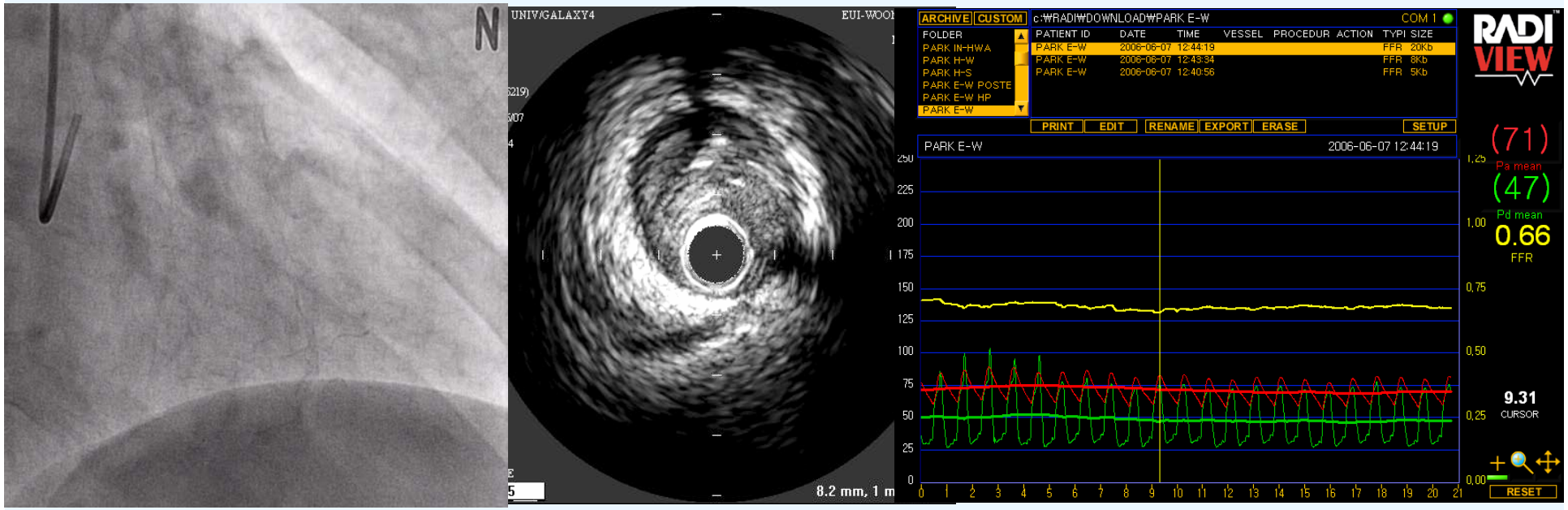
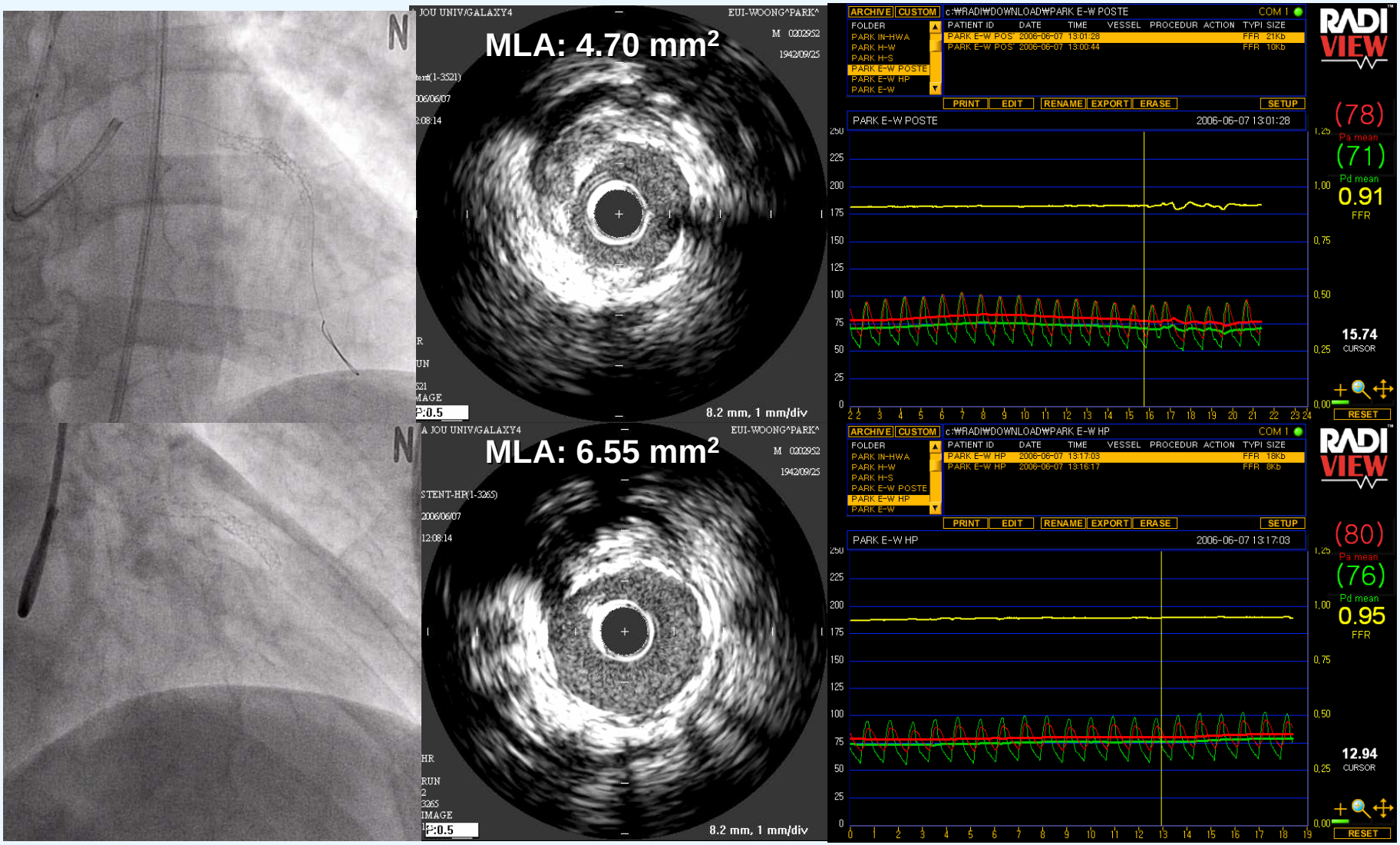
63 y-o Male, Unstable Angina



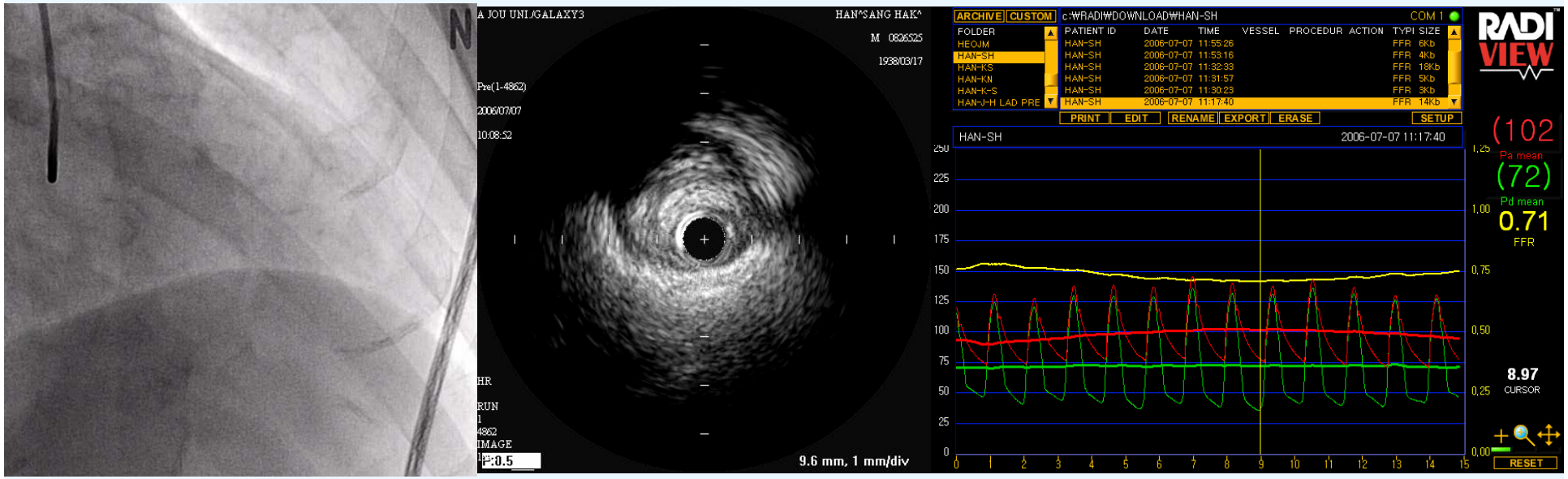
MLD	**0.72 mm**	**MLA**	**1.15 mm^2**
DS	**77.0%**	**%AS**	**87.6 %**
Lesion length	**38 mm**	**Plaque Burden**	**89.3%**

EY Park


MLA: 4.70 mm²
8.2 mm, 1 mm/div
PARK E-W POSTE
2006-06-07 13:01:28
(78)
Pa mean
(71)
Pd mean
0.91
FFR
15.74
CURSOR
MLA: 6.55 mm²
8.2 mm, 1 mm/div
PARK E-W HP
2006-06-07 13:17:03
(80)
Pa mean
(76)
Pd mean
0.95
FFR
12.94
CURSOR

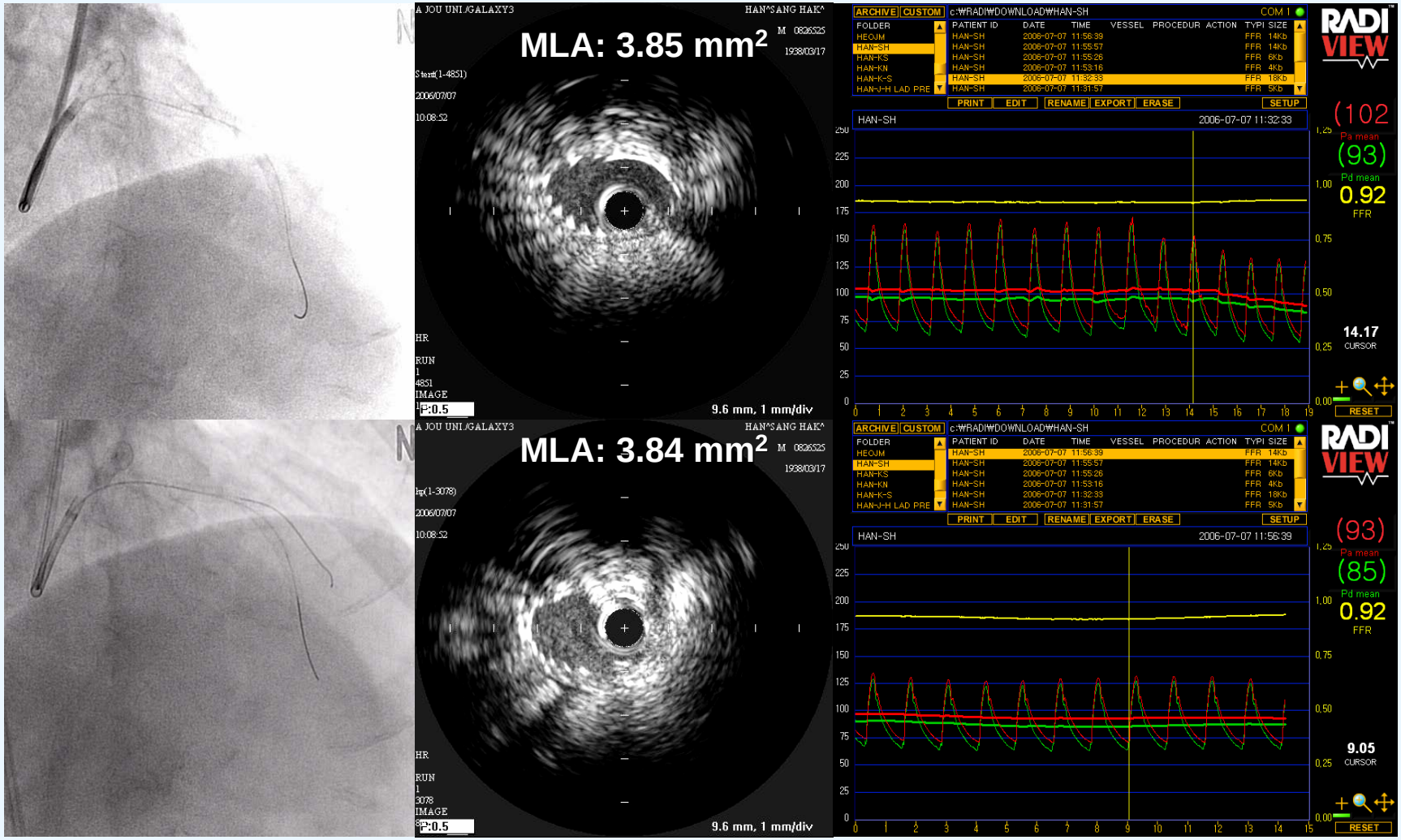
EY Park

69 y-o Male Stable Angina



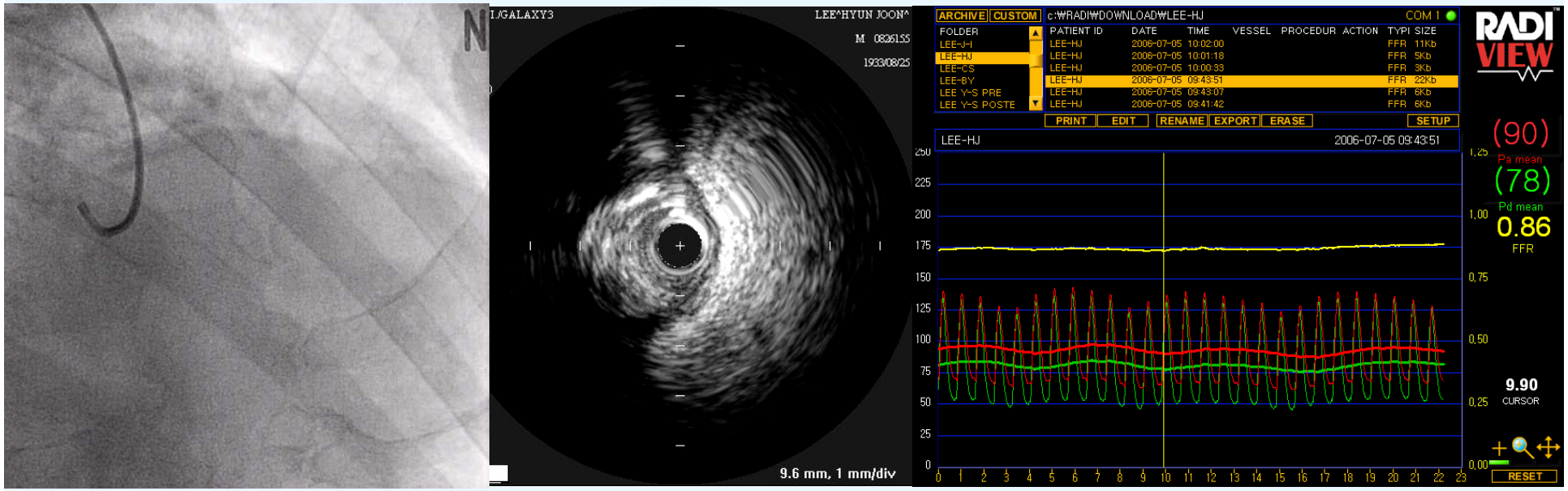
MLD	**0.58 mm**	**MLA**	**0.94 mm^2**
DS	**81.0%**	**%AS**	**87.7%**
Lesion length	**61 mm**	**Plaque Burden**	**90.3%**

SH Han

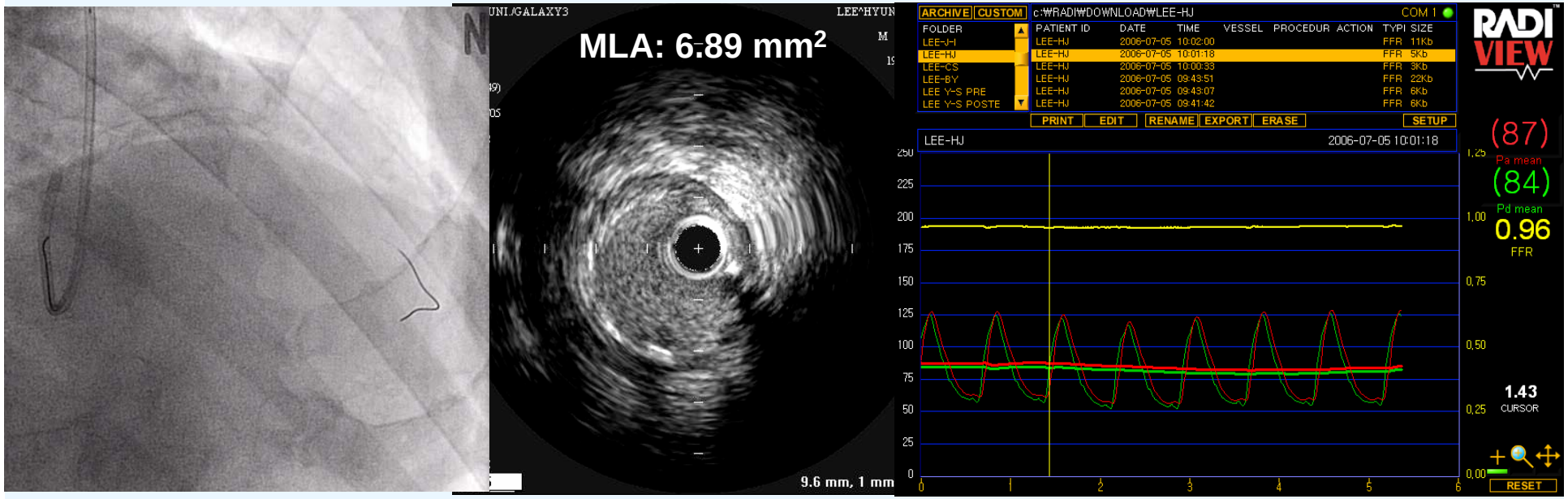

MLA: 3.85 mm²
9.6 mm, 1 mm/div
(102
(93)
0.92
FFR
14.17
MLA: 3.84 mm²
9.6 mm, 1 mm/div
(93)
(85)
0.92
FFR
9.05

SH Han

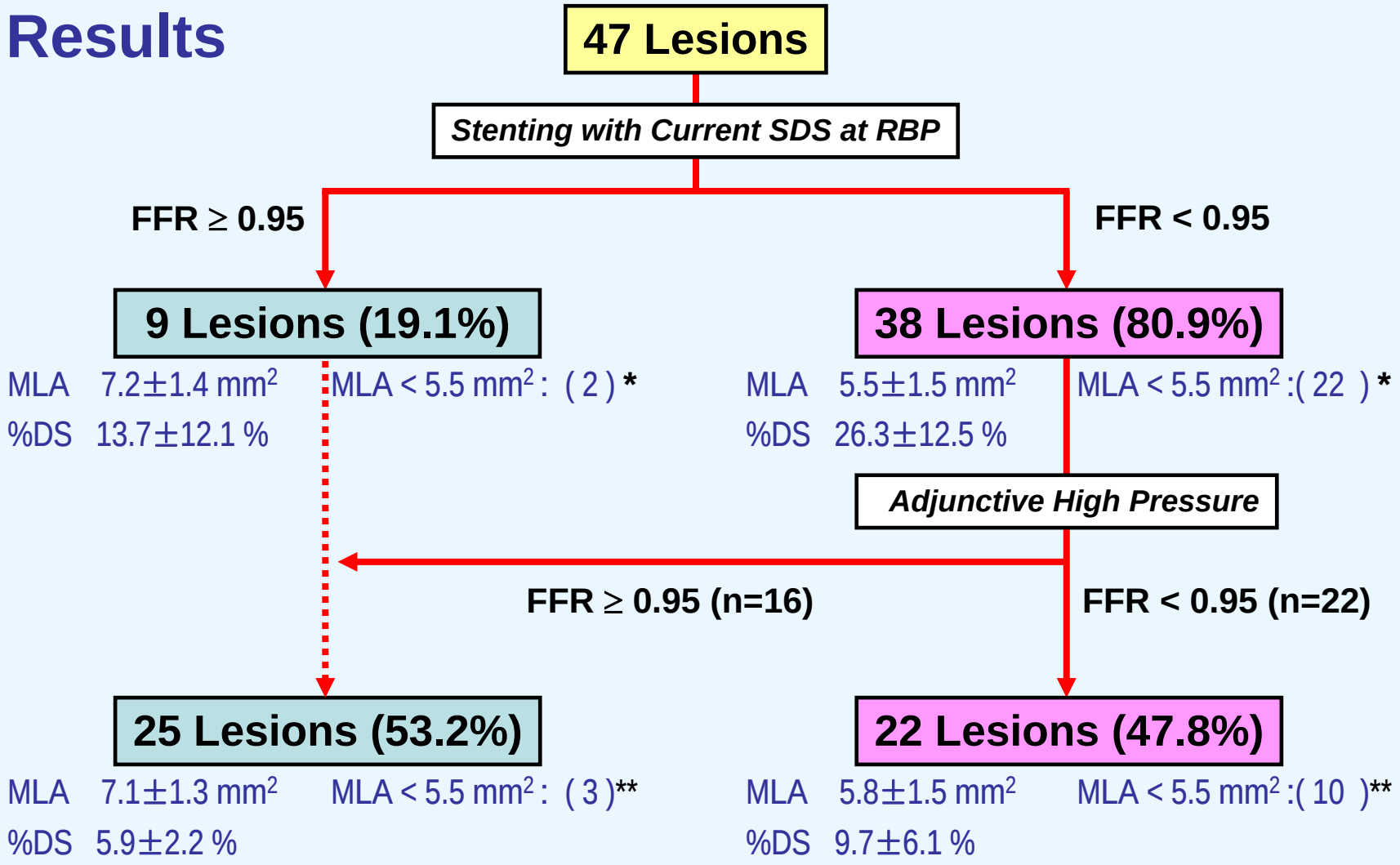
72 y-o Stable Angina



MLD	**0.70 mm**	**MLA**	**2.15 mm^2**
DS	**77.0%**	**%AS**	**72.7%**
Lesion length	**40 mm**	**Plaque Burden**	**80.5%**


MLA: 6.89 mm²
9.6 mm, 1 mm
ARCHIVE
CUSTOM
c:₩RADI₩DOWNLOAD₩LEE-HJ
COM 1
FOLDER
LEE-J-I
LEE-HJ
LEE-CS
LEE-BY
LEE Y-S PRE
LEE Y-S POSTE
PATIENT ID
DATE
TIME
VESSEL
PROCEDUR
ACTION
TYPI
SIZE
PRINT
EDIT
RENAME
EXPORT
ERASE
SETUP
LEE-HJ
2006-07-05 10:01:18
RADI VIEW
(87)
Pa mean
(84)
Pd mean
0.96
FFR
1.43
CURSOR
RESET

Results



*** 24/47 (52.7%) lesions could not reach MLA>5.5mm^2 on IVIS with SDS at RBP**

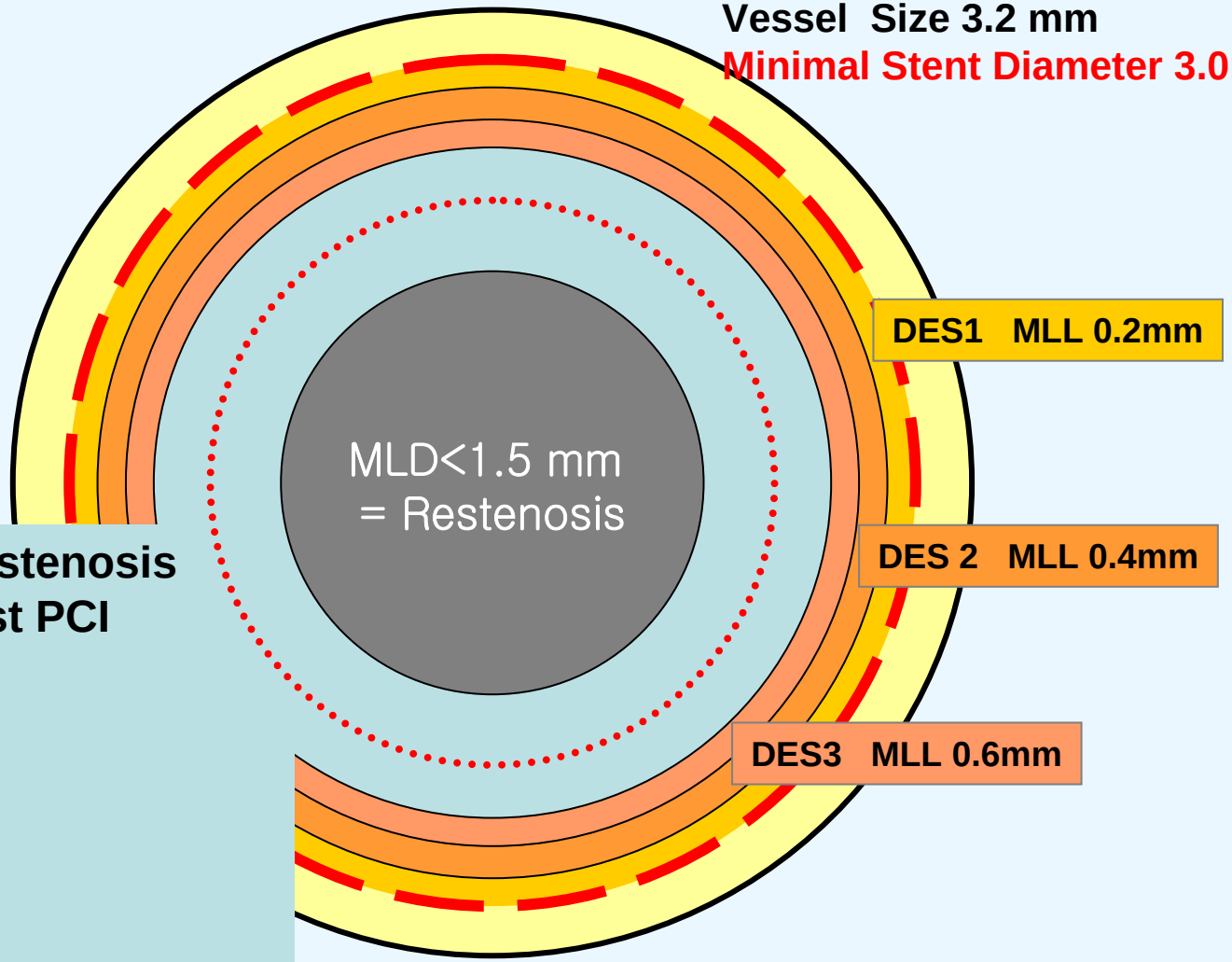
**** 13/47 (27.7%) lesions could not reach MLA>5.5mm^2 on IVIS after HP dilatation**

FFR and IVUS Criteria Reached ..

	Post Stent	Post HP
FFR>0.95	9 (19.1%)	25 (53.2%)
IVUS MSA >5.5mm^2	23 (47.3%)	38 (72.3%)
IVUS MUSIC*	12 (25.5%)	14 (29.8%)

* Final lumen CSA > 80% of the reference (or > 90% if minimal lumen CSA was < 9 mm^2)

Late Loss and "Headroom" to Restenosis in Patients FFR≥0.95



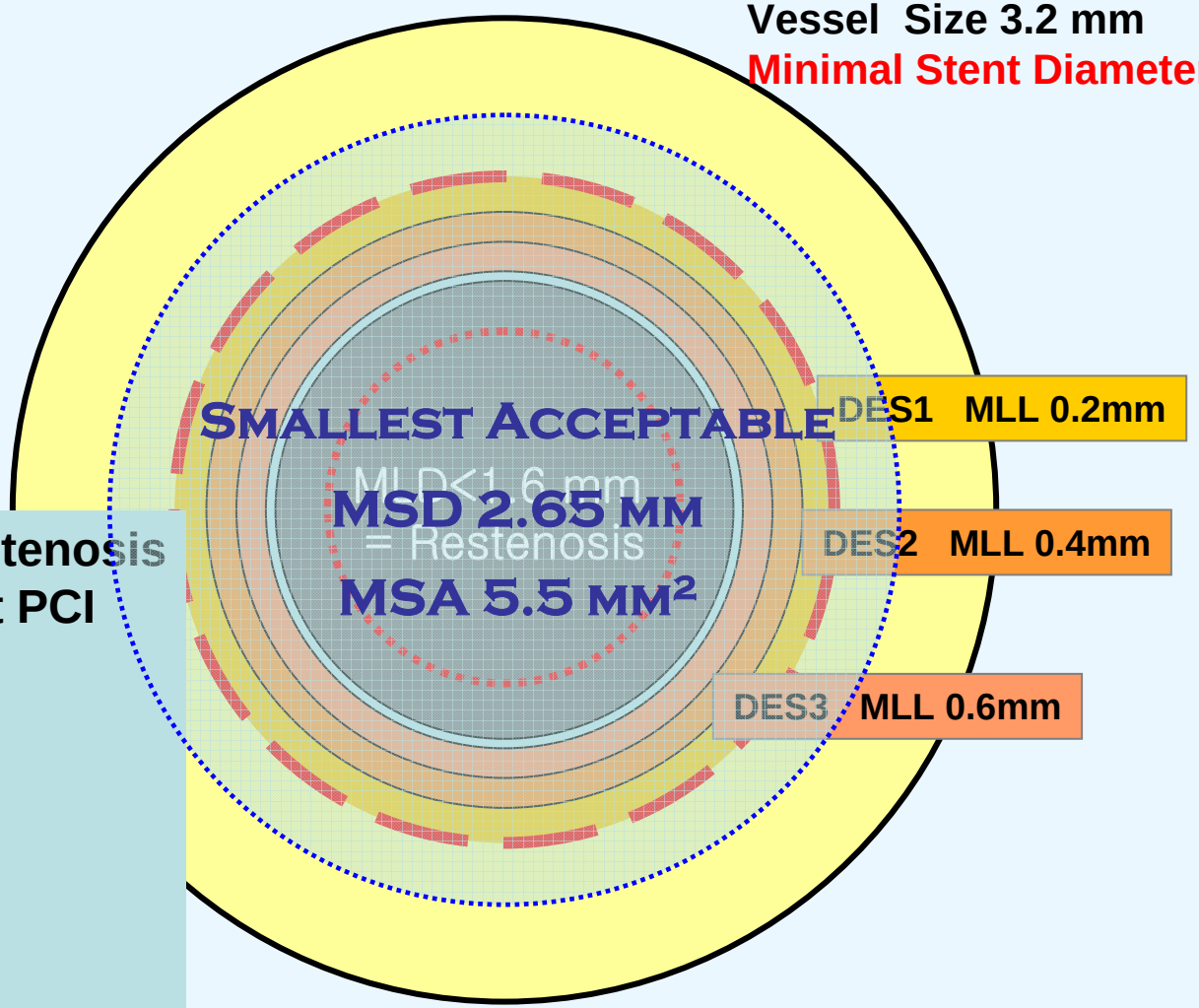
Headroom to Restenosis
1.5 mm after Post PCI

1.3 mm
1.1 mm
0.9 mm

0.5 mm in BMS
RV Size 3.0 mm

Late Loss and "Headroom" to Restenosis in Patients FFR<0.95

Vessel Size 3.2 mm
Minimal Stent Diameter 2.3mm

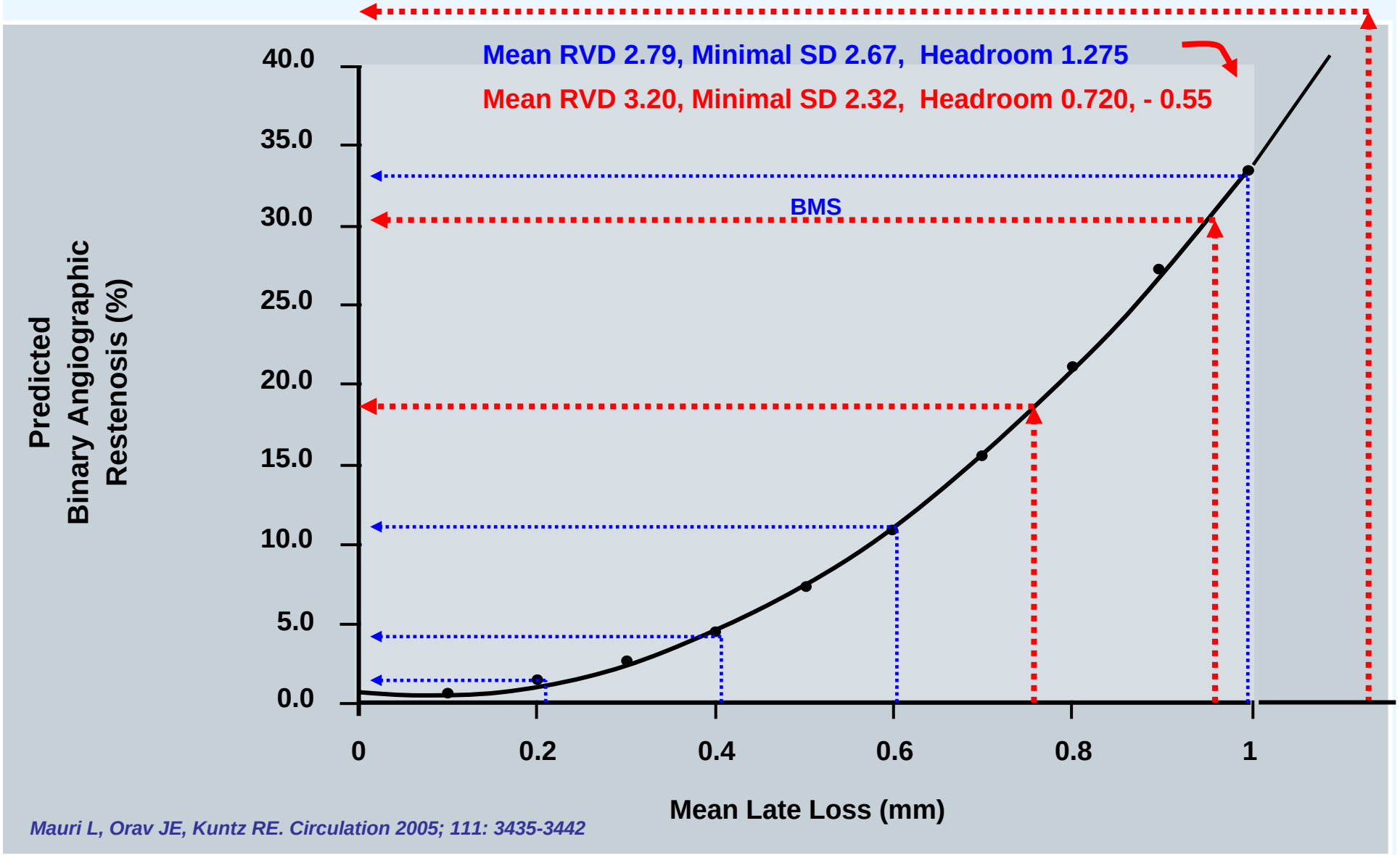


Headroom to Restenosis
0.7 mm after Post PCI

0.5 mm
0.3 mm
0.1 mm

-0.3 mm in BMS
RV Size 3.0 mm

Mean Late Loss and Risk of Restenosis



Mauri L, Orav JE, Kuntz RE. Circulation 2005; 111: 3435-3442

Angiographic and Procedural Findings

	Group A (FFR≥0.95, n=9)	Group B (FFR<0.95, n=38)	p Value
Pre-Stent			
MLD (mm)	0.57 ±0.11	0.59 ± 0.19	0.921
DS (%)	81.1 ± 4.5	81.5 ± 5.4	0.872
Post-Stent			
MLD (mm)	3.09 ± 0.23	2.32 ± 0.46	0.012
DS (%)	13.8 ± 12.1	26.3 ± 12.5	0.014
Reference Diameter (mm)			
Proximal	3.40 ±0.17	3.42 ±0.25	0.776
Distal	2.95 ±0.14	3.0 ±0.29	0.641
Lesion length (mm)	42.8 ±10.4	52.3 ±12.2	0.049
Stent number	1.64 ±0.50	1.95 ±0.55	0.096
Stent length (mm)	46.4 ± 13.9	56.9 ± 15.3	0.047

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IVUS Findings

	Group A (FFR≥0.95, n=9)	Group B (FFR<0.95, n=38)	p Value
Pre-stent			
MLA (mm^2)	2.65 ± 0.68	1.75 ± 0.69	0.001
AS (%)	71.3 ± 9.8	80.0 ± 10.6	0.030
Post-stent			
MLA (mm^2)	7.16 ± 1.64	5.57 ± 1.57	0.005
AS (%)	23.3 ± 12.3	36.2 ± 19.7	0.059
Ref Lumen Area(mm^2)	10.0 ±3.4	8.9 ±1.9	0.176
VA at Lesion(mm^2)	13.0 ±4.2	10.8 ±2.5	0.041
Plaque Burden	78.7 ±6.3	83.7 ±6.5	0.042
Ref Vessel Area (mm^2)	14.6 ± 4.4	13.3 ± 2.9	0.284
Remodeling Index	0.92 ±0.22	0.82 ±0.16	0.140

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Independent Predictor for Suboptimal Stent Expansion (FFR<0.95 or FFR≥0.95)

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	PLAQ_C	.502	1.116	.202	1	.653	1.652
	REMOD_IX	-.120	2.809	.002	1	.966	.887
	ECCENT	-3.706	2.720	1.857	1	.173	.025
	MINLA	-1.482	.685	4.682	1	.030	.227
	ST_LENGT	.019	.041	.213	1	.645	1.019
	Constant	4.057	3.453	1.380	1	.240	57.780

a. Variable(s) entered on step 1: PLAQ_C, REMOD_IX, ECCENT, MINLA, ST_LENGT.

By Multiple binary logistic regression analysis

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Independent Predictor for Suboptimal Stent Expansion (correlation with post-stent FFR)

Coefficients [a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	.933	.041		22.891	.000
	PLAQ_C	−.012	.012	−.154	−1.010	.320
	REMOD_IX	.001	.032	.005	.036	.972
	ECCENT	.024	.033	.095	.725	.474
	MINLA	.017	.008	.328	2.120	.042
	ST_LENGT	−.001	.000	−.351	−2.364	.024

a. Dependent Variable: FFR_STEN

By Multiple linear regression analysis

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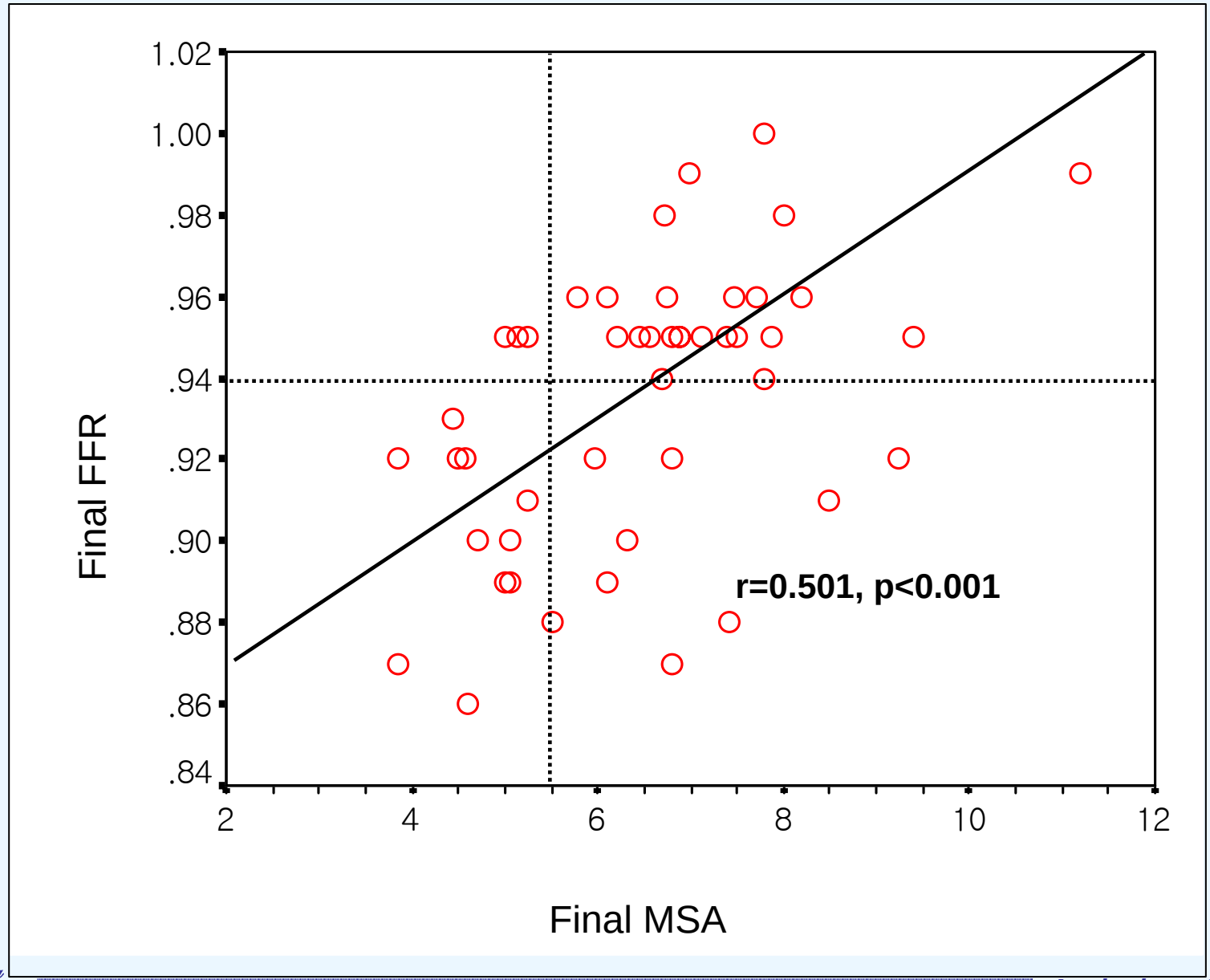
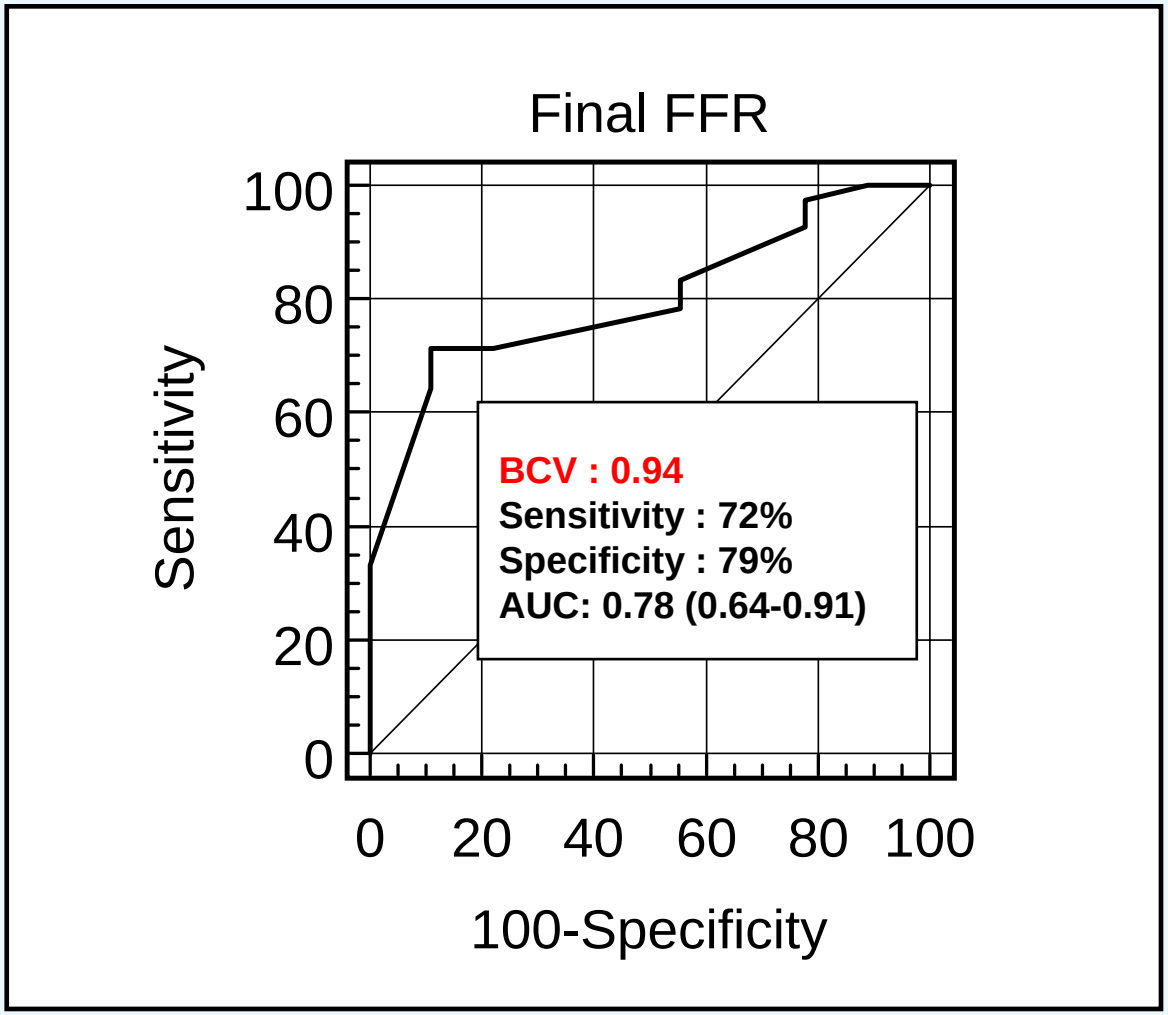
FFR vs. IVUS Minimal Stent Area



The Relation between Final FFR and MSA (BCV of FFR for MSA ≥5.5 mm^2)



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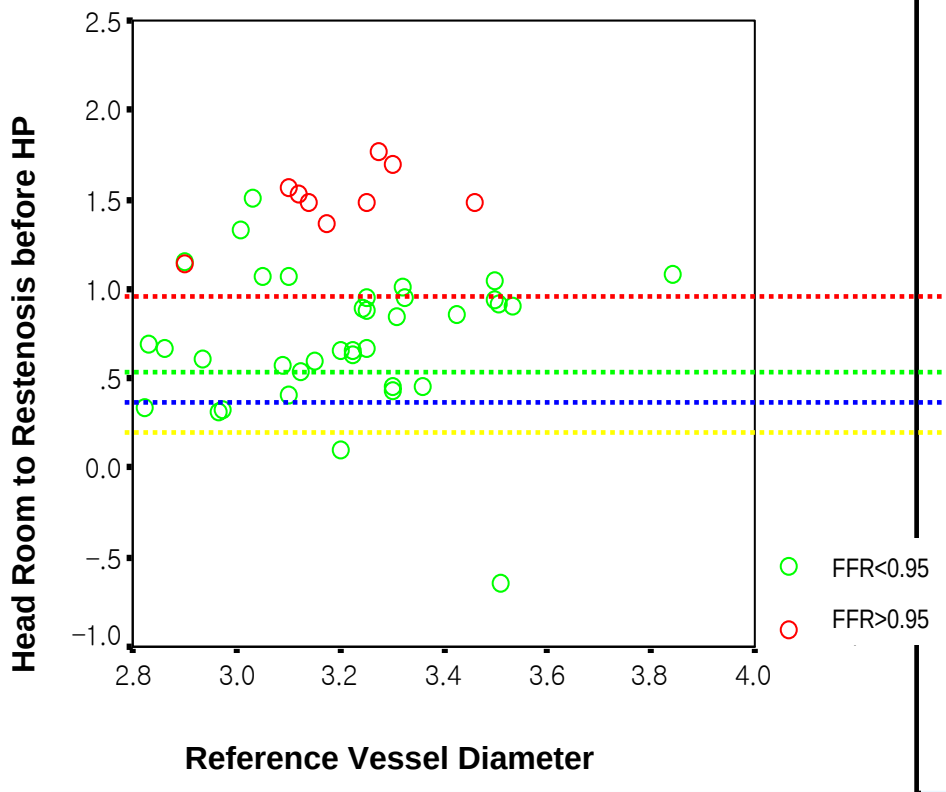
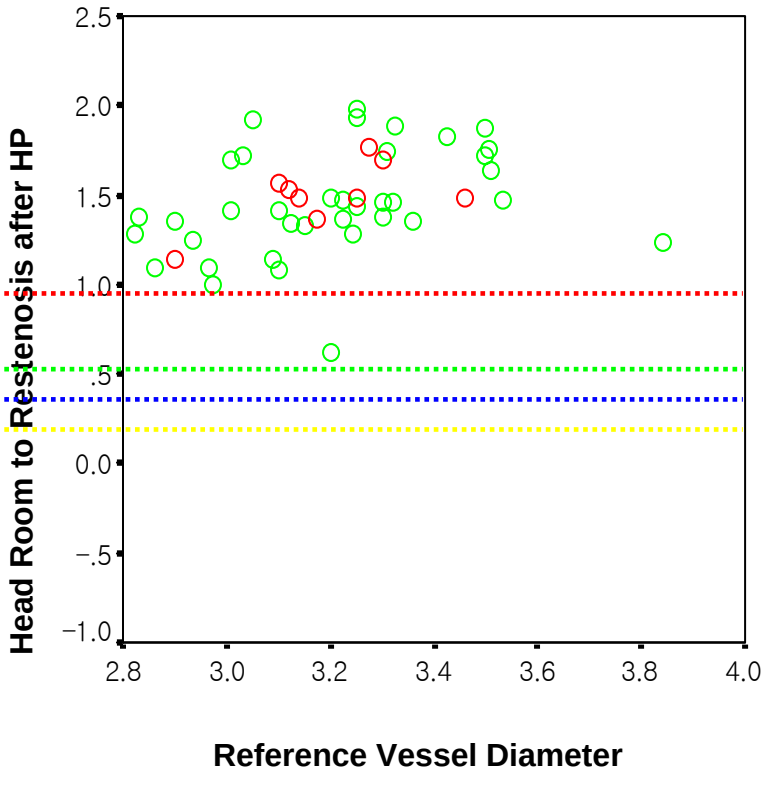
Effect of HP Dilatation on Headroom to Restenosis QCA Analysis





FFR and IVUS Criteria Reached were Inadequate with current SDS

	Post Stent	Post HP
FFR>0.95	9 (19.1%)	25 (53.2%)
IVUS MSA >5.5mm^2	23 (47.3%)	38 (72.3%)
IVUS MUSIC*	12 (25.5%)	14 (29.8%)

*** Final lumen CSA > 80% of the reference** (or > 90% if minimal lumen CSA was < 9 mm^2)

- Independent IVUS predictors for suboptimal stent expansion was minimal lumen area and lesion length.

- Best cut-off value of FFR for MSA>5.5mm^2 was 0.94

Conclusion

- Routine adjunctive high-pressure ballooning of DES might be required to achieve optimal functional and anatomic stent expansion, in number of long diffuse coronary stenoses.

- FFR and IVUS-guided PCI could potentially improve the procedural precision and decrease the rate of target vessel failure in DES era. However, the role of physiologic and IVUS study in DES era needs more randomized trials.

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DES Implantation in Long Diffuse Lesion

- Appropriate lesion preparation
- Adjunctive High Pressure Dilatation

Do not forget old lessons even in DES era.

- Do not believe your visual estimation
- Please do not avoid modern facilities of convenience