

PLENARY SESSION
DRUG ELUTING STENT SUMMIT-II

A PACLITAXEL-ELUTING STENT FROM INDIA :
INFINNium – SIMPLE 1 TRIAL RESULTS



Prof. D. S. Gambhir MD, DM

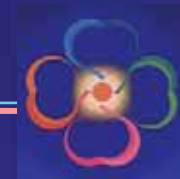
CEO & Director of Cardiology

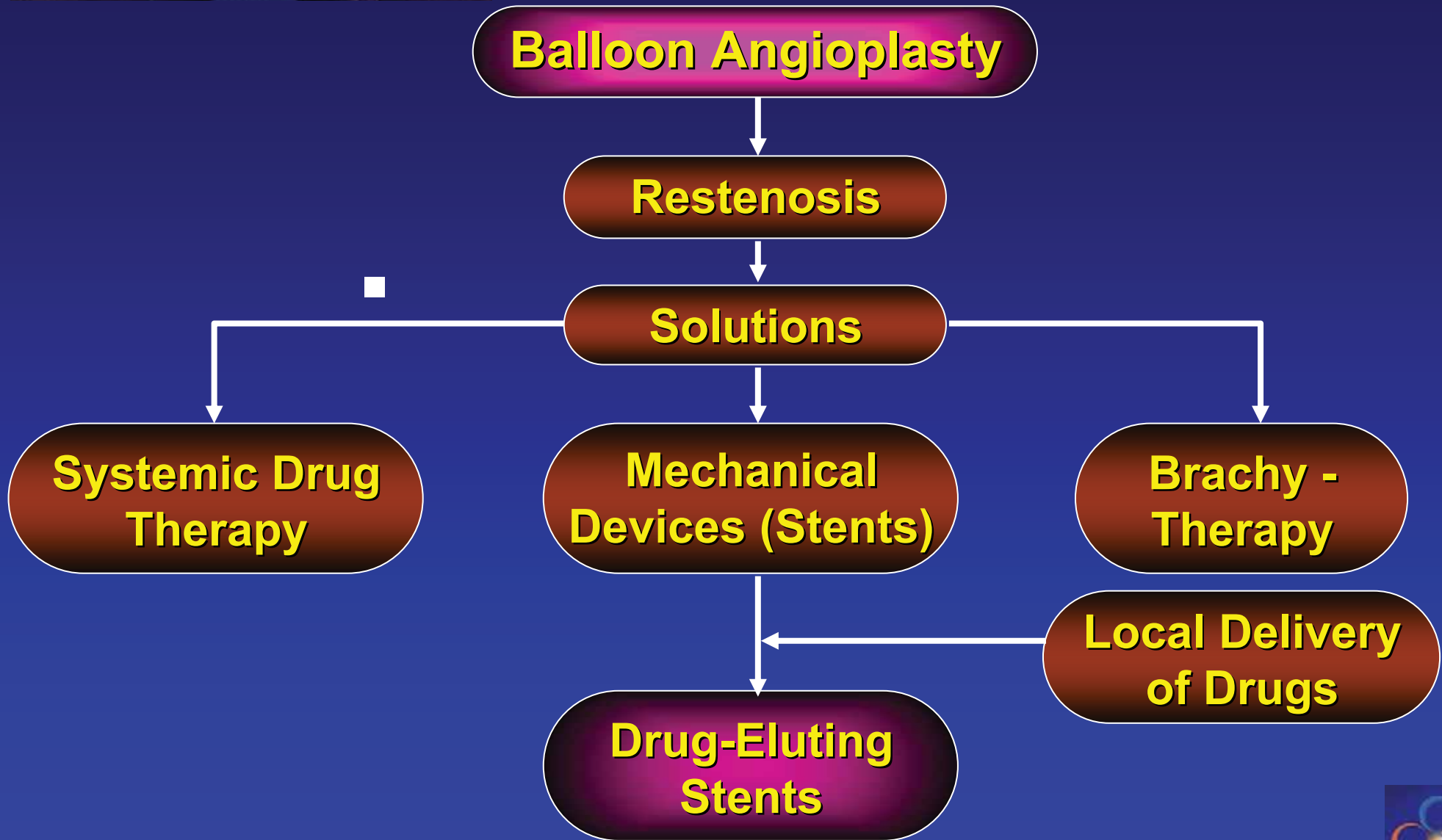
Kailash Heart Institute,

Noida - INDIA

ANGIOPLASTY SUMMIT 2004,
KOREA

April 29, 2004





Drug-Eluting Stents

**INFINNIIUM
(SMT)**

**CYPHER
(J&J)**

**TAXUS
(BSC)**

Efficacy

Established

Limitation

High Cost



Drug-Eluting Stents

CYPHER

**INFINNIUM
(SMTPL)**

TAXUS

A PACLITAXEL-ELUTING STENT FROM INDIA

**Results of SIMPLE-1 Trial in First 282 Patients
Treated by Infinnium Paclitaxel-Eluting Stent**



INFINNIIUM : PACLITAXEL-ELUTING STENT COMPOSITION

- **Stent Platform** → *Matrix*
Millennium stent
Slotted tube design
- **Antiproliferative Drug** → **Paclitaxel**
- **Drug Delivery Vehicle** → **Biodegradable
Polymers**
- **Drug Release** → **Slow**

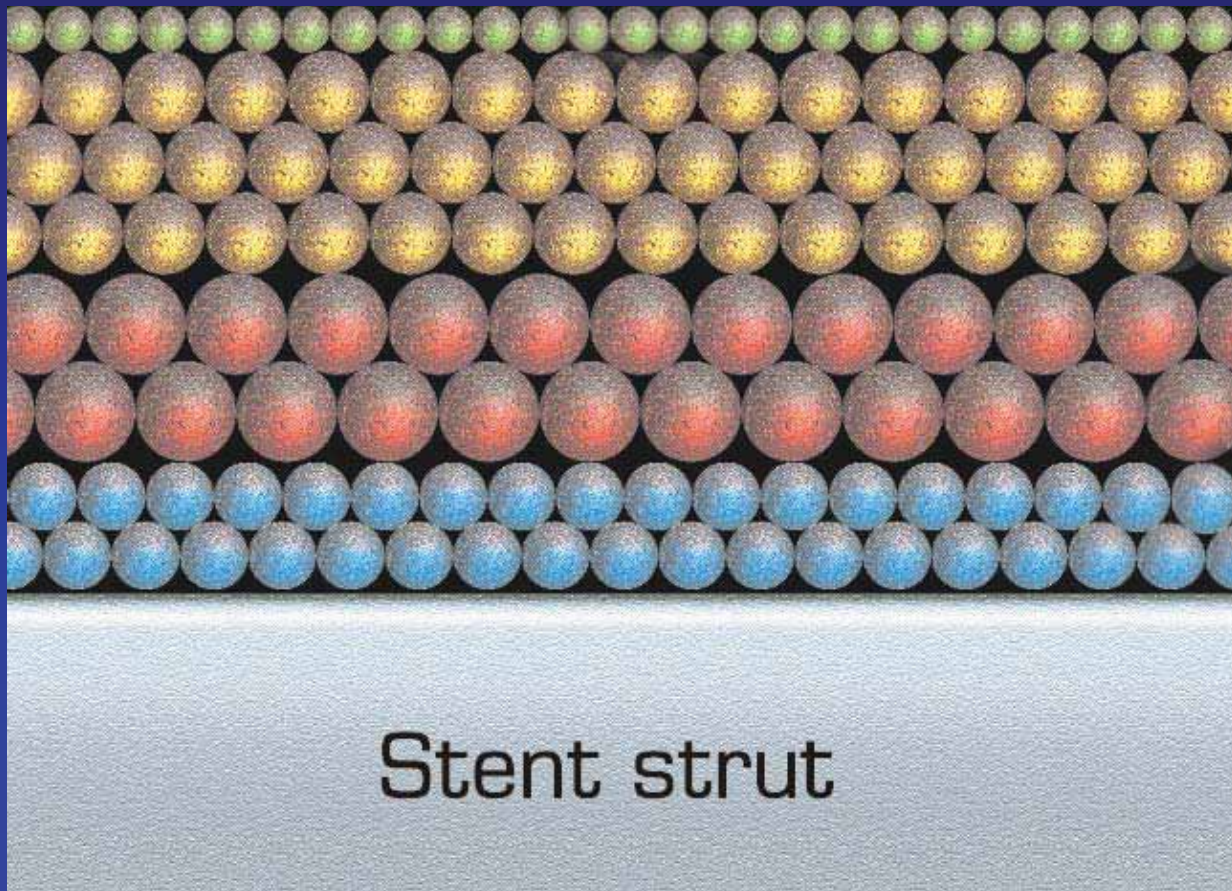


THE POLYMERS : BIODEGRADABLE

- **Four Different Polymers**
- **Selection Done by Known Medical Application and Favorable Screening *in vitro* and *in vivo***
- **Formulated Into Four Layers with Different Composition and Concentration in Each Layer**



PERCENTAGE PACLITAXEL IN DIFFERENT COATING LAYERS



← 0% (Protecting Layer)

← 33% (Fast Release)

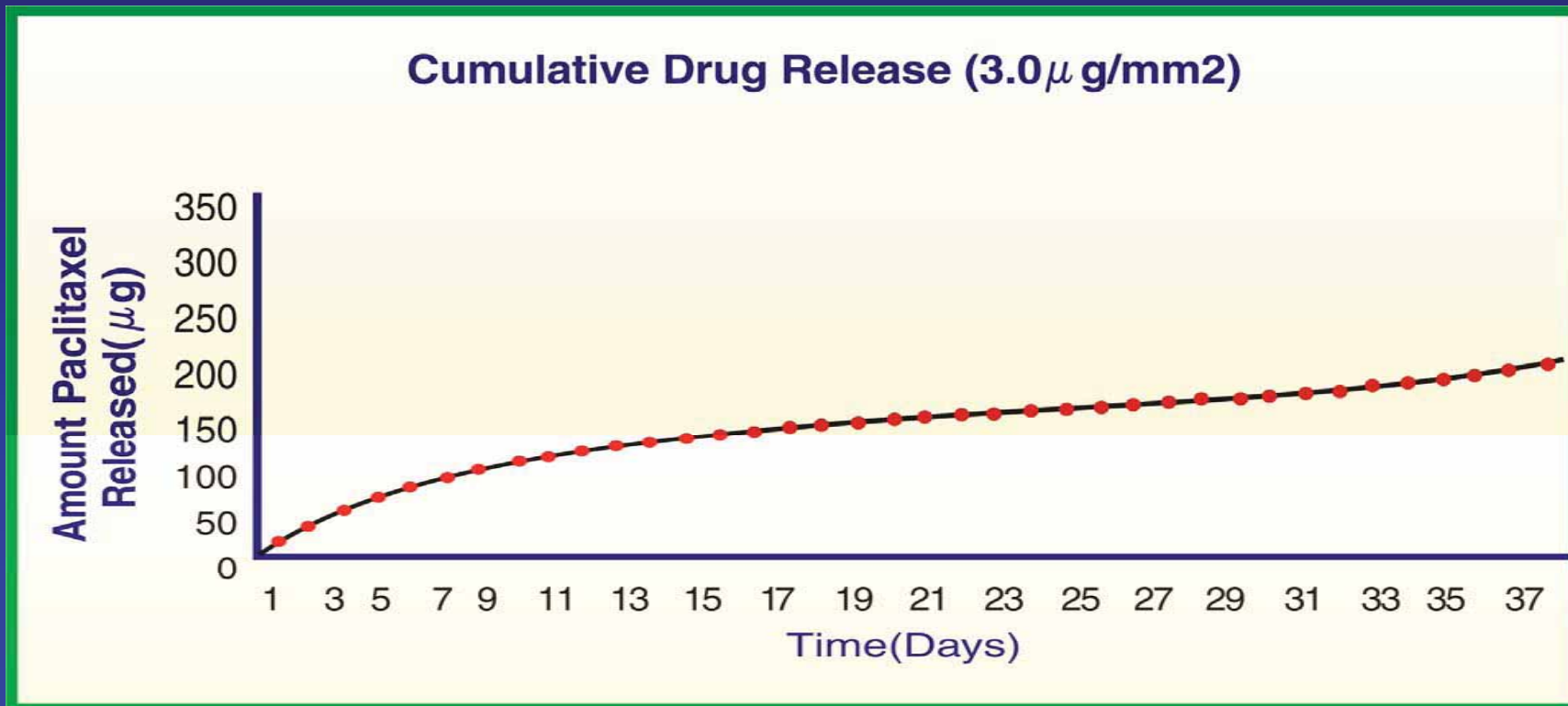
← 30% (Medium Release)

← 36% (Slow Release)

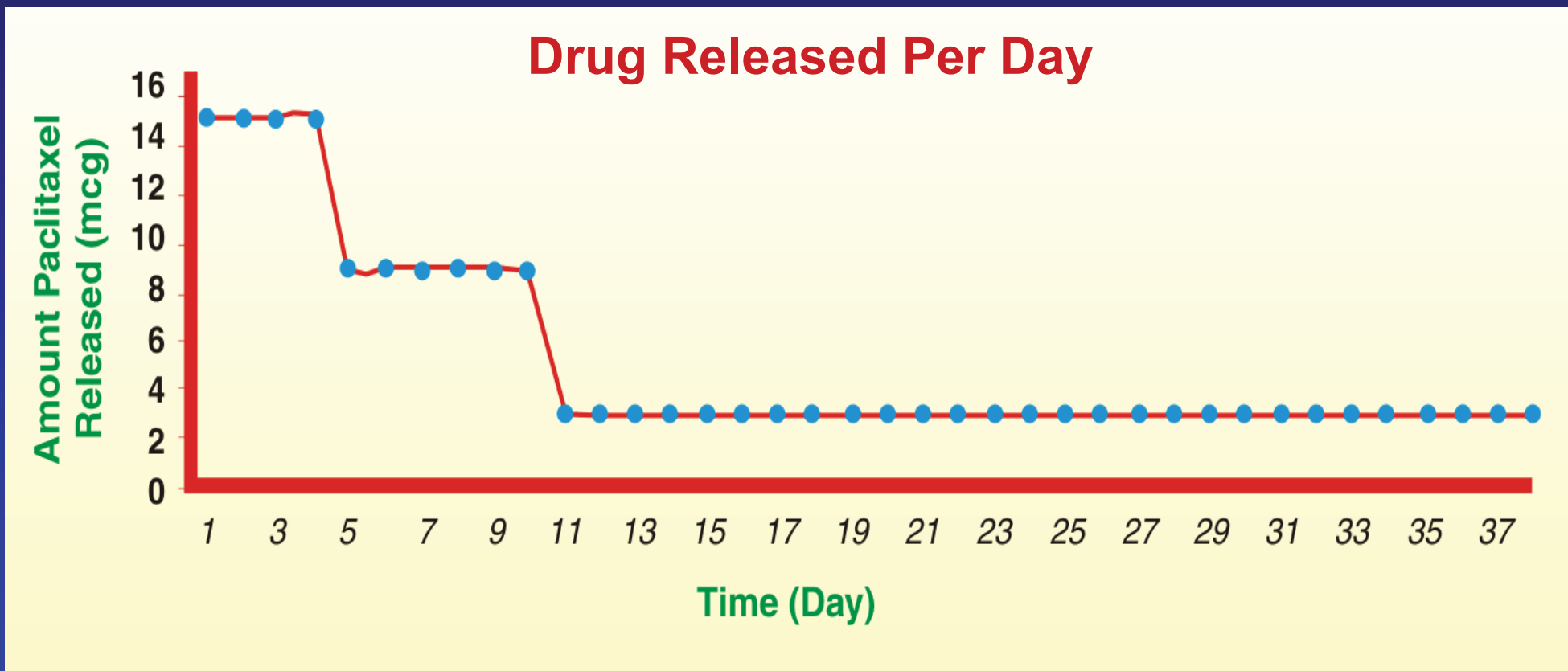


DRUG LOADING AND RELEASE : 16MM STENT

- **Total Drug Content** : 180 μg
- **Drug Content in Relation to Stent Surface Area** : 3 $\mu\text{g}/\text{mm}^2$



CONTROLLED RELEASE PATTERN OF PACLITAXEL FROM POLYMER MATRIX





CLINICAL DATA

Safety and Efficacy of InfinniumM **A Paclitaxel-Eluting (SIMPLE 1) Stent**

Multicentric Open Label Registry

Results in First 282 Patients

SIMPLE 1 : DEMOGRAPHIC DATA

- **No. of Patients** : **282**
- **Period of Implant** : **Aug.02 – Feb. 03**
(7 months)
- **Age (Years)**
 - ◆ **Range** : **26 – 86**
 - ◆ **Mean** : **53.2**
- **Sex Distribution**
 - ◆ **Males** : **234 (83%)**
 - ◆ **Females** : **48 (17%)**



SIMPLE 1 : RISK FACTOR PROFILE

- **Diabetes** : 94 (33.3%)
- **Hypertension** : 83 (29.4%)
- **Dyslipidemia** : 70 (24.8%)
- **Smoking** : 53 (18.8%)

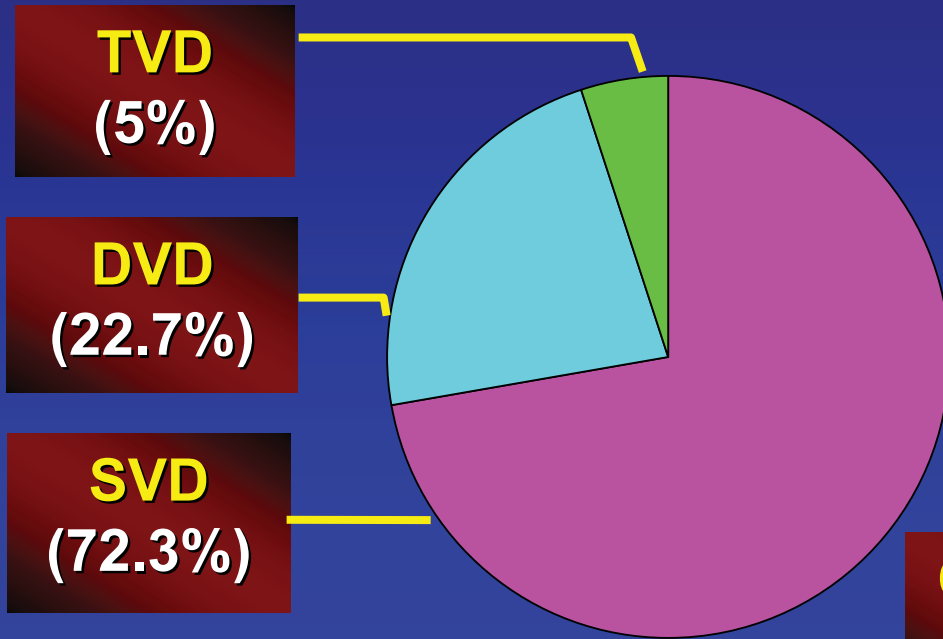
- **Single** : 105 (37.2%)
- **Multiple** : 126 (44.7%)
- **None** : 51 (18.1%)



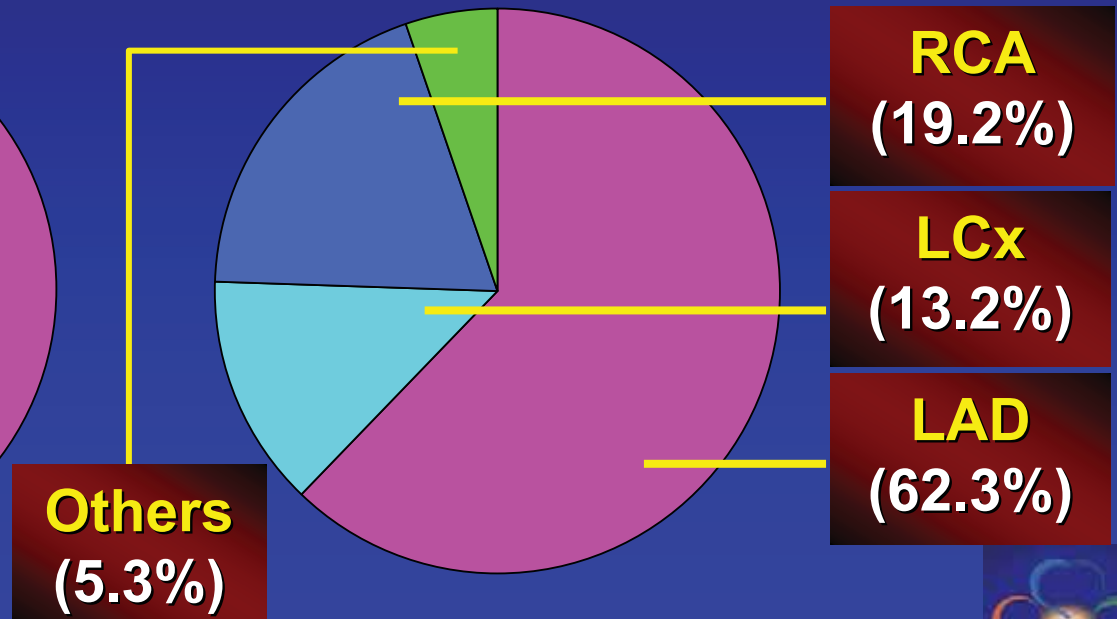
SIMPLE 1

CORONARY ARTERY PROFILE

Severity of CAD



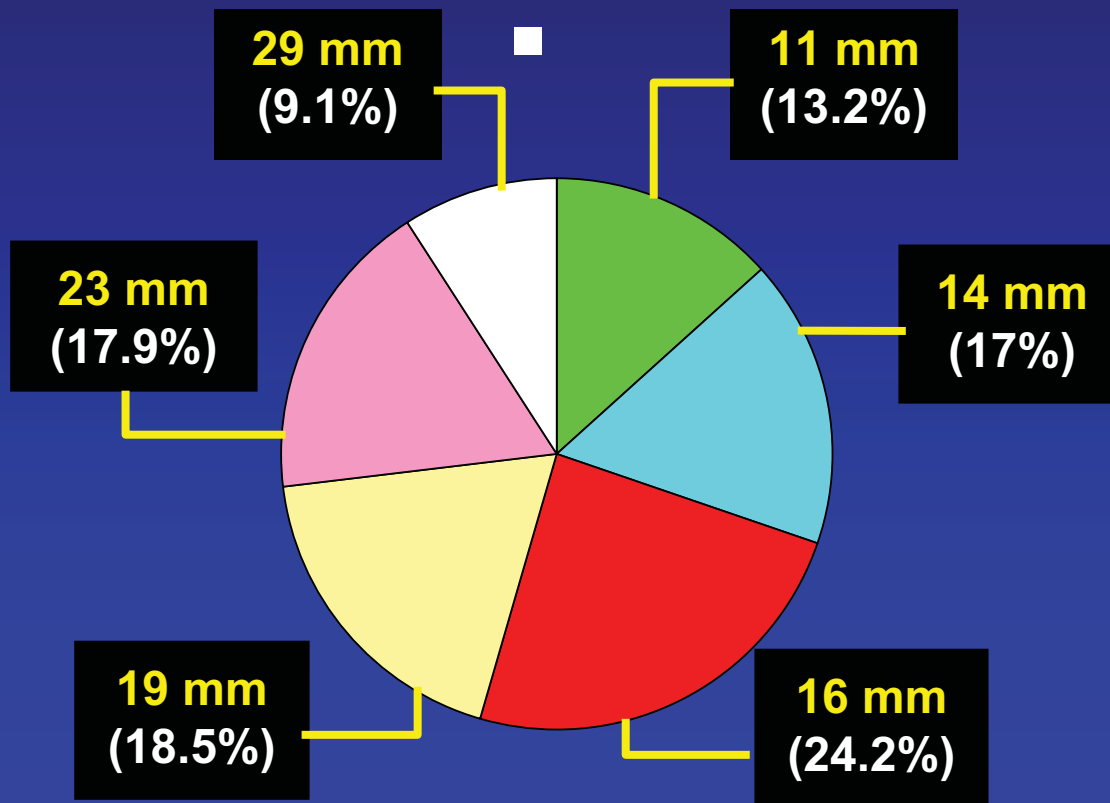
Target Vessel (N=318)



SIMPLE 1

INFINNIIUM STENTS USED (N = 318)

LENGTH



- **Average Stent Length = 18 mm**
- **Stent Length**
 - ◆ ≥ 16 mm = 69.8%
 - ◆ ≥ 19 mm = 45.6%



**FOLLOW-UP
SCHEDULE**

**Patients
(N = 282)**

Clinical

Angiographic

Number

All

First 100 Patients

Available

100%

Timings

**One, Three and
Six Months FU**

**Six Months Post-Implant
(Av. 6.35 Months)**



SIMPLE 1 : RESULTS

I. IN-HOSPITAL COMPLICATIONS



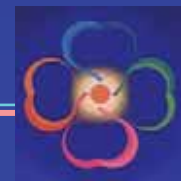
● Reocclusion of Target Vs.	:	2 (0.7%)
● Myocardial Infarction	:	1 (0.35%)
● Death	:	2 (0.7%)
● CABG	:	0



SIMPLE 1 : RESULTS (Contd...)

II. MACE AT ONE MONTH FU

● Subacute Thrombosis	:	6 (2.1%)
● Successful Re-PTCA	:	5 (1.8%)
● CABG	:	1 (0.35%)
● MI	:	1 (0.35%)
● Death	:	0
Overall	:	6 (2.1%)



SIMPLE 1 : RESULTS (Contd...)

III. MACE BETWEEN ONE AND SIX MONTHS

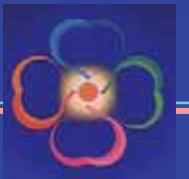
● Re-Intervention	:	2 (0.71%)
◆ Re-PTCA	:	2 (0.71%)
◆ CABG	:	0
● MI	:	1 (0.35%)
● Death	:	4 (1.42%)
◆ Cardiac	:	2 (0.71%)
◆ Non-Cardiac	:	2 (0.71%)
Overall	:	6 (2.12%)



SIMPLE 1 : RESULTS

IV. OVERALL MACE UPTO SIX MONTHS FOLLOW-UP

● Number of Patients	:	282
● MACE	:	14 (4.96%)
● Re-PTCA	:	7 (2.48%)
● Death	:	6 (2.12%)
◆ Cardiac	:	4 (1.42%)
◆ Non-Cardiac	:	2 (0.71%)
● MI	:	3 (1.06%)
● CABG	:	1 (0.35%)
Event-Free Survival	:	95%



SIMPLE 1

QUANTITATIVE CORONARY ANGIOGRAPHY

95 patients

**94 patients
material received**

**2 videos not
analyzable**

**92 patients
QCA analysis**

**2 patients not
analyzable**

**77 Patients
One vessel
disease**

**6 patients
Two vessel
disease**

**2 patient
Three vessel
disease**



SIMPLE 1

QCA : IN-STENT ANALYSIS

Patients = 85

N = 95 lesions

Lesion Length (mm)	11.9 ± 4.4
Reference Diameter (mm)	2.64 ± 0.54
MLD (mm) Pre	0.92 ± 0.43
Post	2.44 ± 0.40
FU	2.29 ± 0.70
Late Loss (mm)	0.19 ± 0.68
Late Loss Index	0.16 ± 0.49
Diameter Stenosis (%) FU	18.8 ± 18.7
Restenosis Rate (%)	6.3



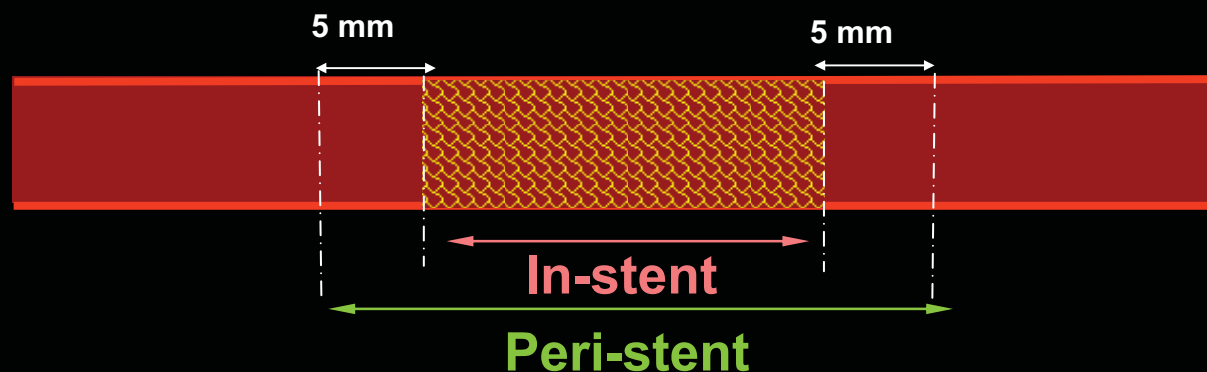
SIMPLE 1

QCA : PERISTENT ANALYSIS

Patients = 85

N = 95 lesions

MLD (mm) Post	2.07 ± 0.41
FU	1.99 ± 0.63
Late Loss (mm)	0.12 ± 0.59
Late Loss Index	0.11 ± 0.60
Diameter Stenosis (%) FU	28.7 ± 17.5
Restenosis Rate (%)	9.5



SIMPLE 1

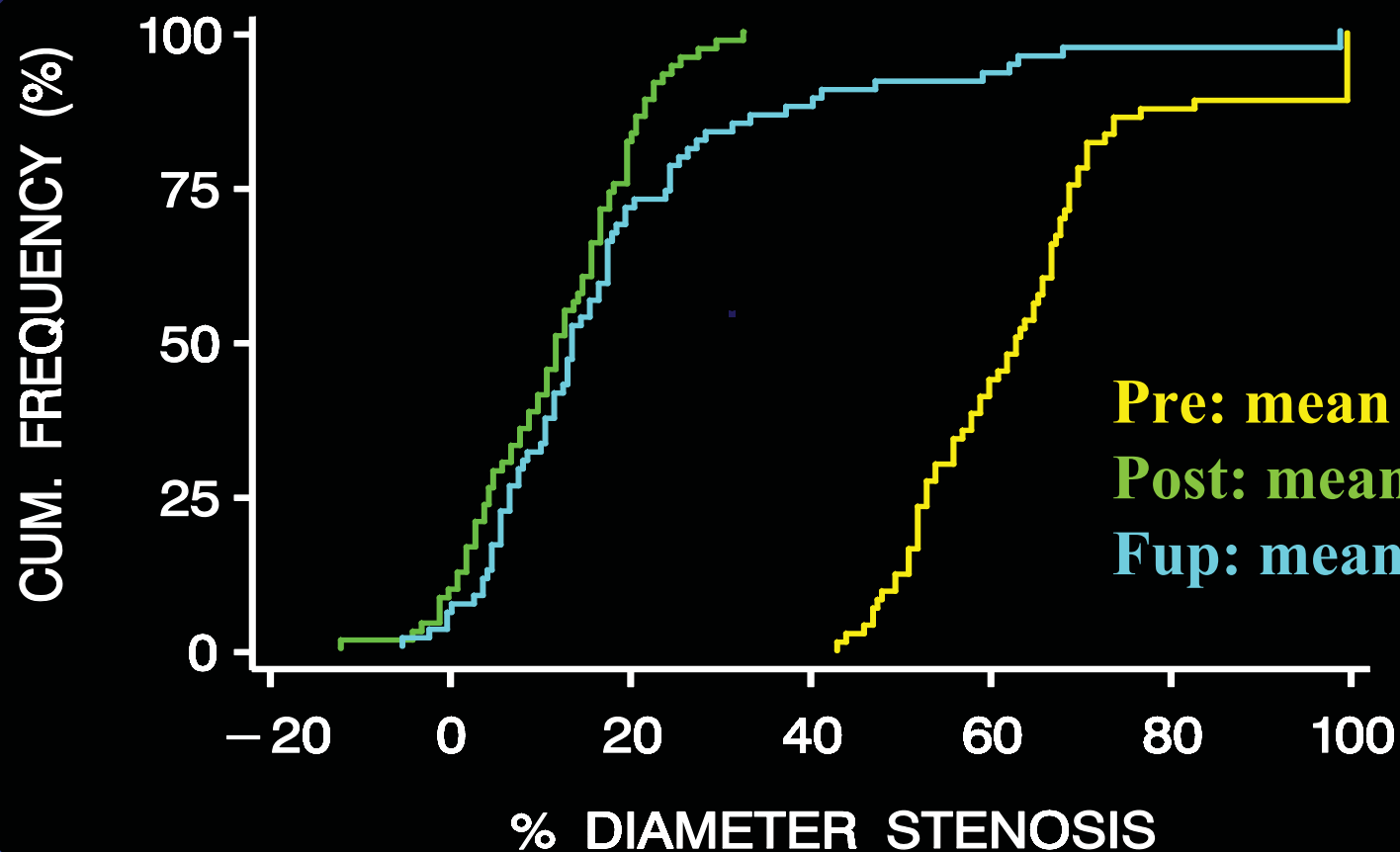
QCA ANALYSIS

	Proximal	In-Stent	Distal
MLD (Post)	2.55±0.54	2.44±0.40	2.17±0.49
MLD (Fup)	2.49±0.70	2.29±0.70	2.16±0.68
Late Loss	0.08±0.64	0.19±0.68	0.04±0.55
DS% (Post)	13.9±10.0	12.0±9.16	19.1±11.4
DS% (FUP)	16.7±18.2	18.8±18.7	20.1±17.2
Restenosis (%)	2.1	6.3	1.1



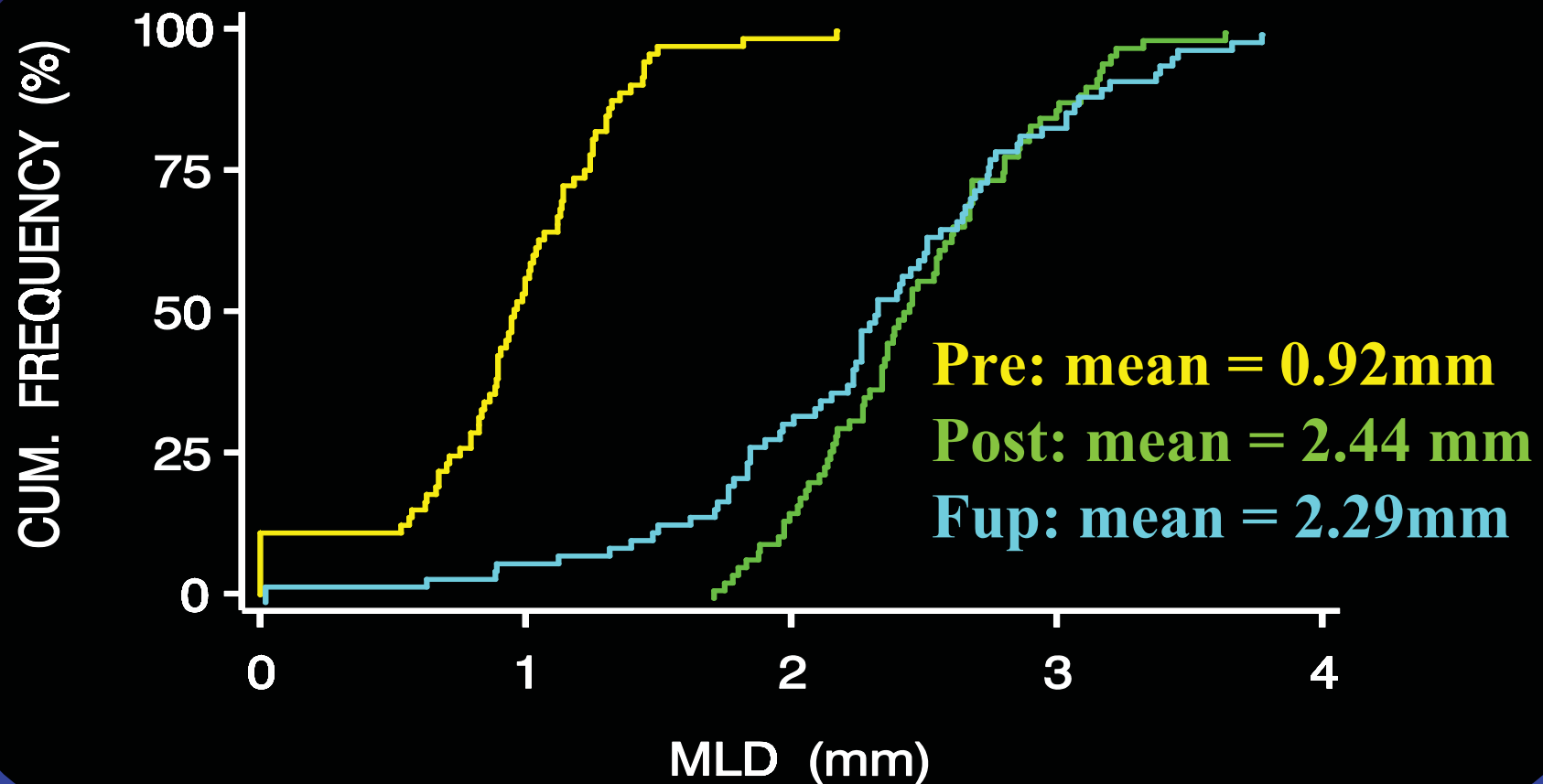
SIMPLE 1

IN-STENT ANALYSIS : CUMULATIVE FREQUENCY CURVE
DIAMETER STENOSIS : PRE-, POST PROCEDURE AND FUP



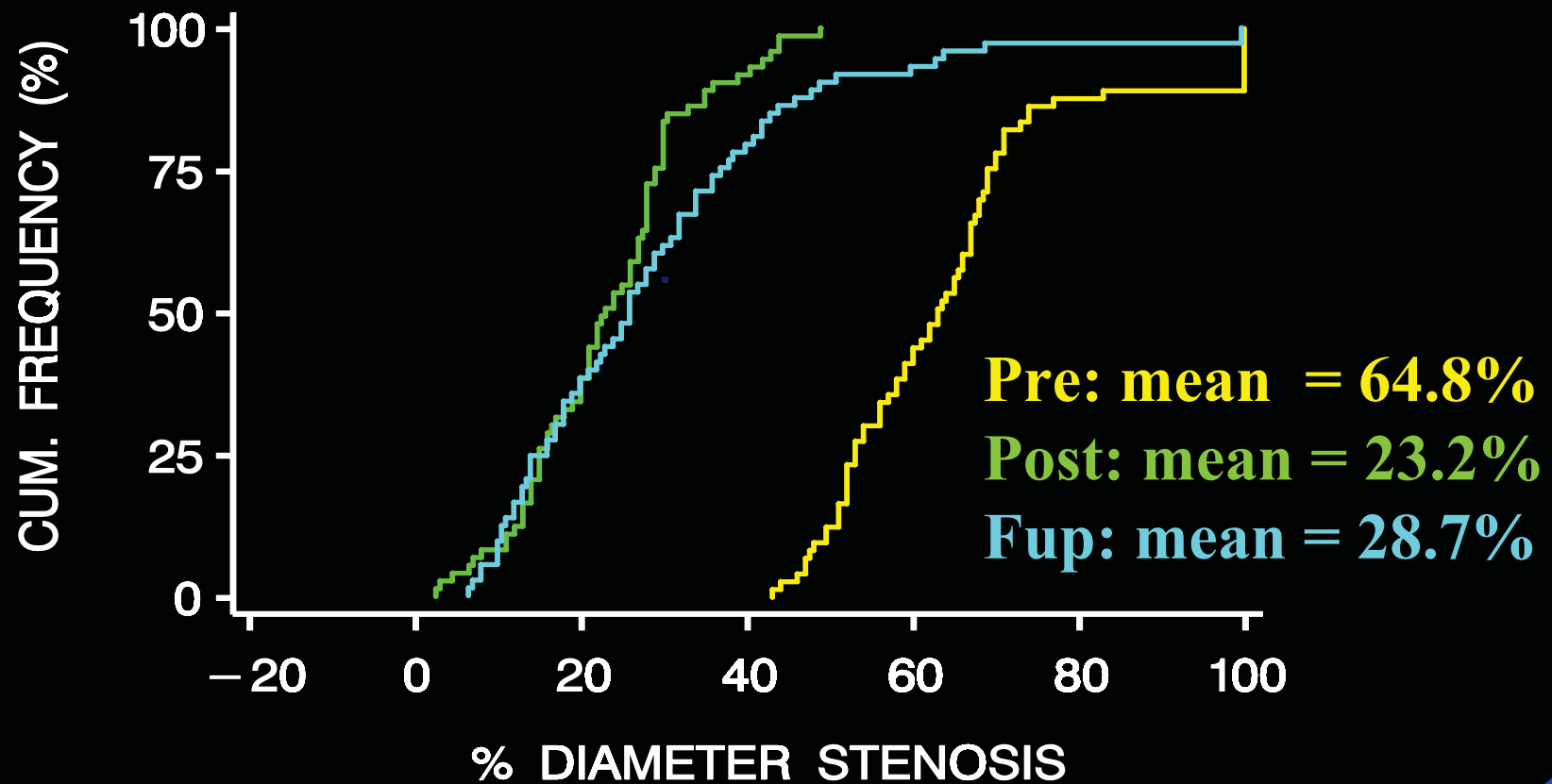
SIMPLE 1

IN-STENT ANALYSIS : CUMULATIVE FREQUENCY CURVE
MINIMAL LUMEN DIAM. : PRE-, POST PROCEDURE AND FUP



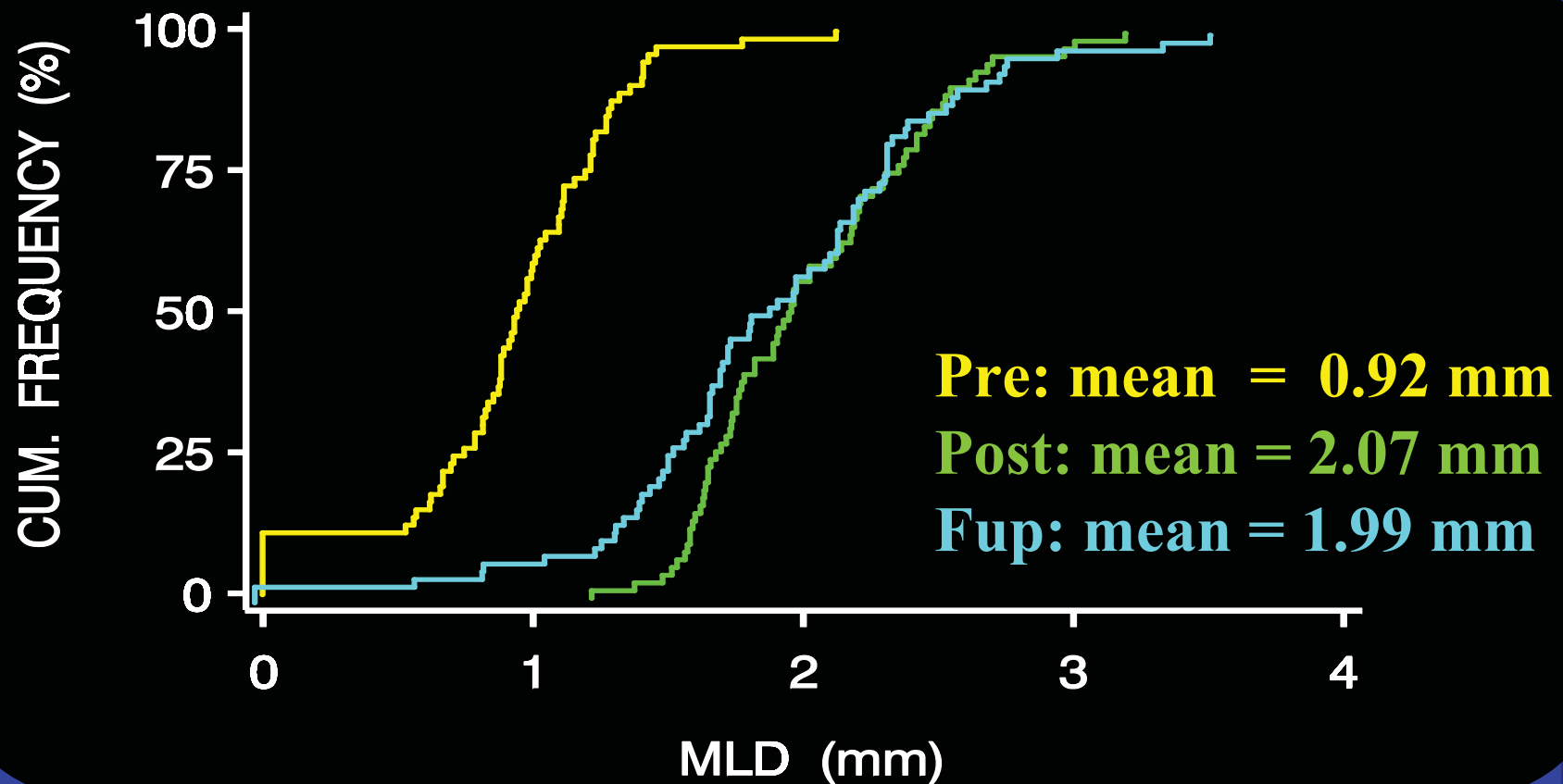
SIMPLE 1

PERI-STENT ANALYSIS : CUMULATIVE FREQUENCY CURVE
DIAMETER STENOSIS : PRE-, POST PROCEDURE AND FUP

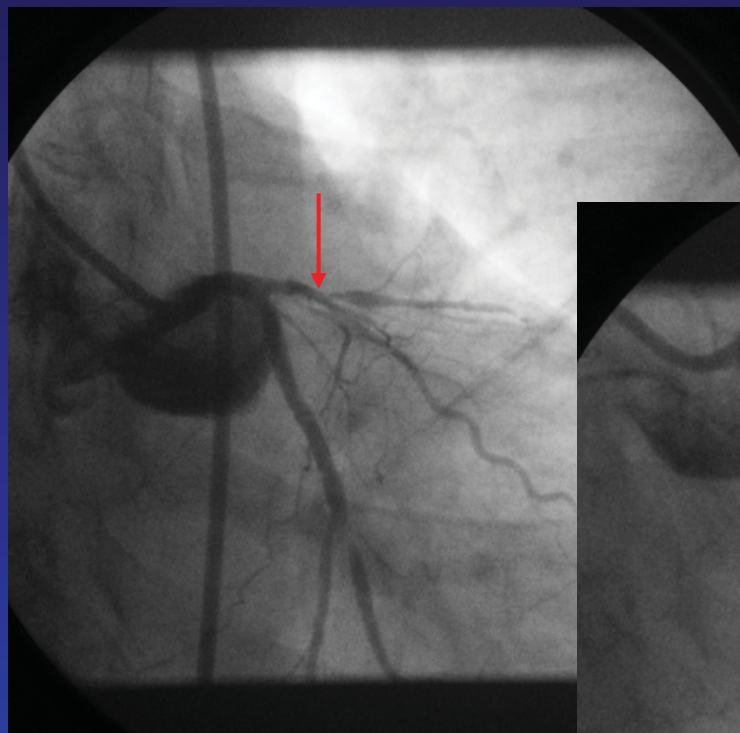


SIMPLE 1

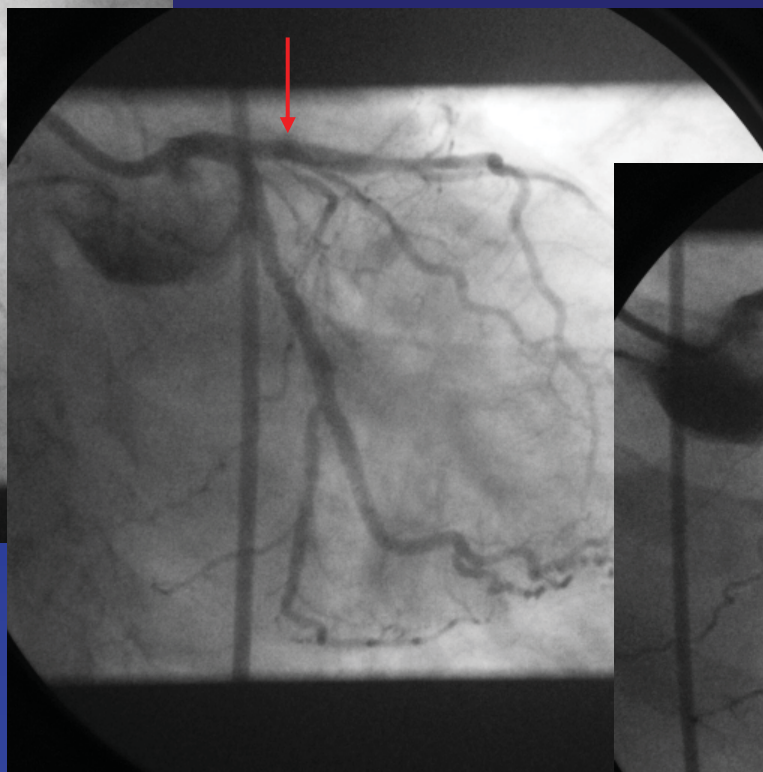
PERI-STENT ANALYSIS : CUMULATIVE FREQUENCY CURVE
MINIMAL LUMEN DIAM. : PRE-, POST PROCEDURE AND FUP



LAD OSTIAL STENOSIS TREATMENT BY **INFINNIUM** STENT

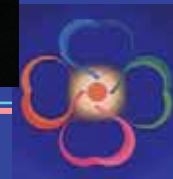
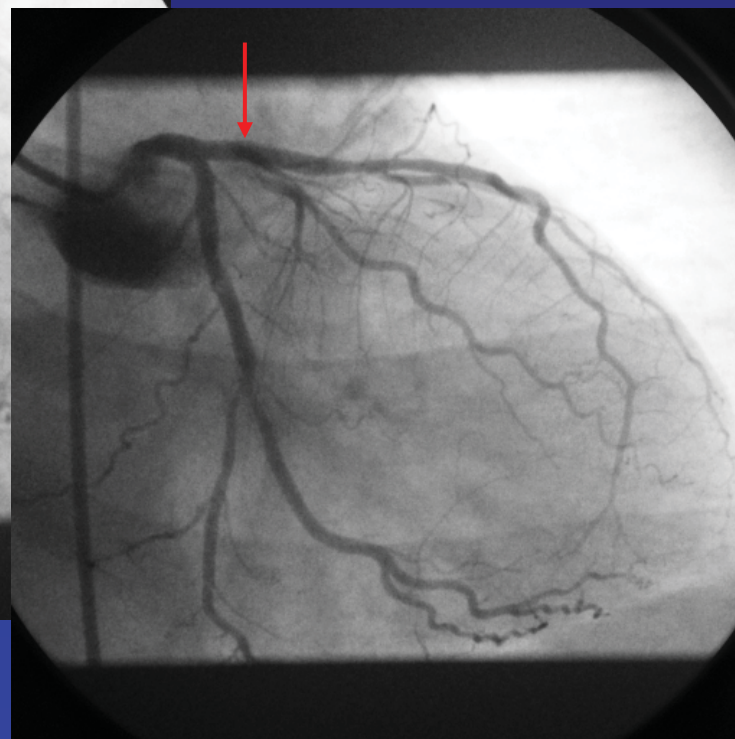


PRE

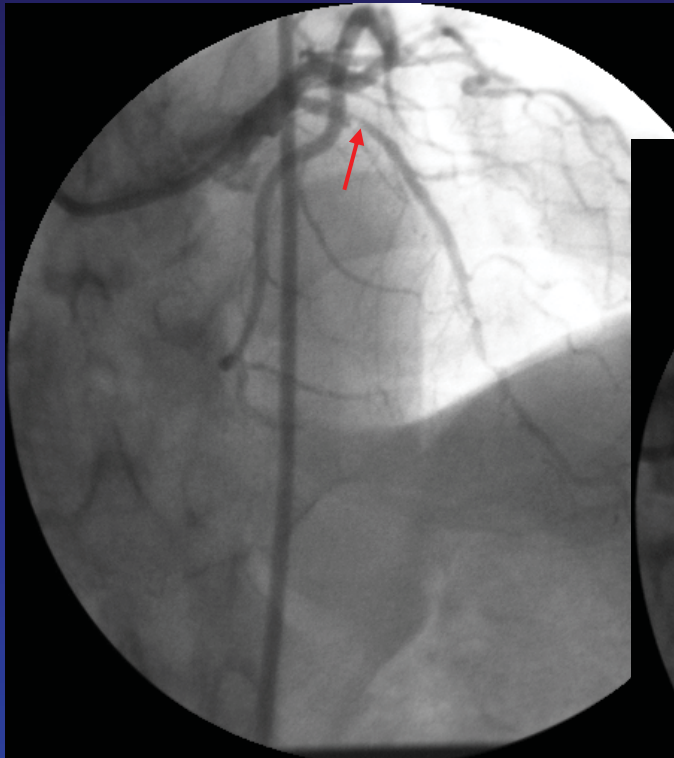


POST

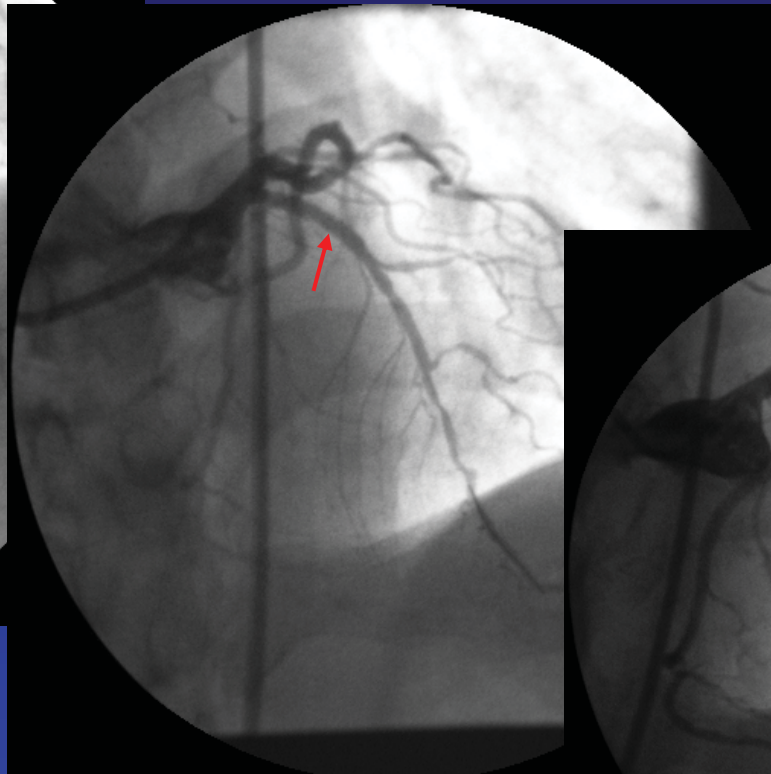
FUP



**PROXIMAL LAD STENOSIS
TREATMENT BY INFINNIUM STENT**

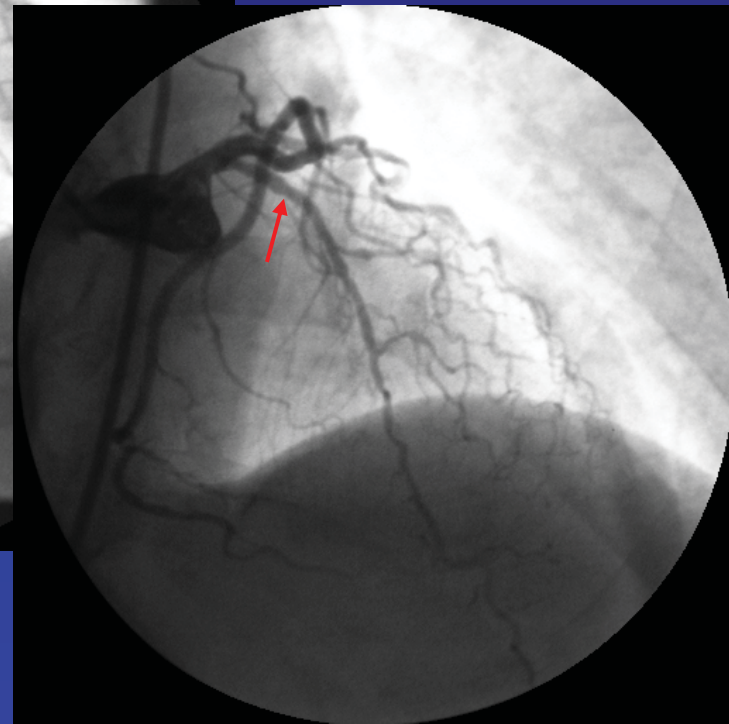


PRE

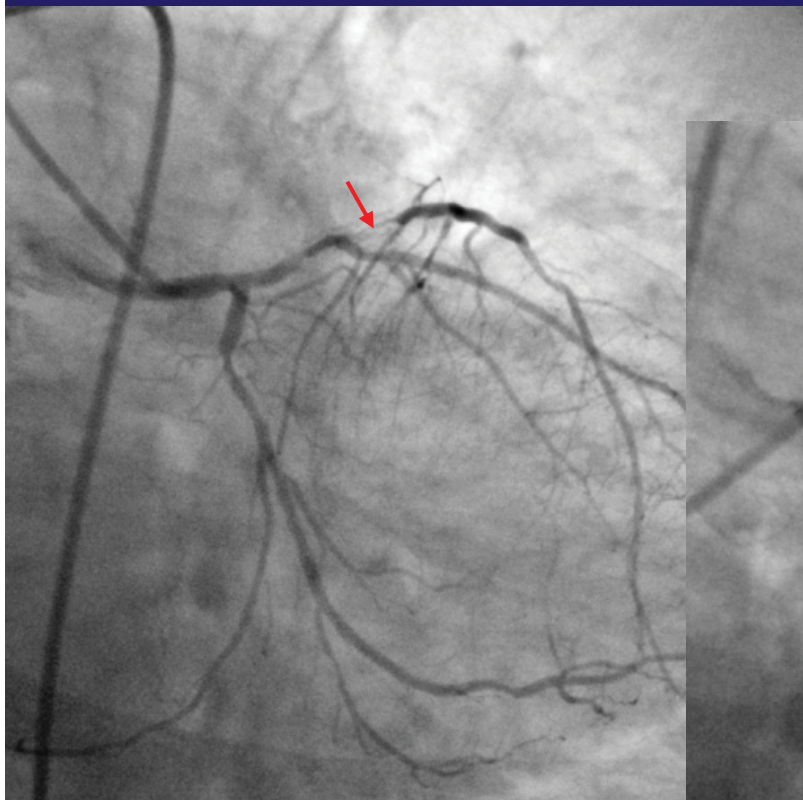


POST

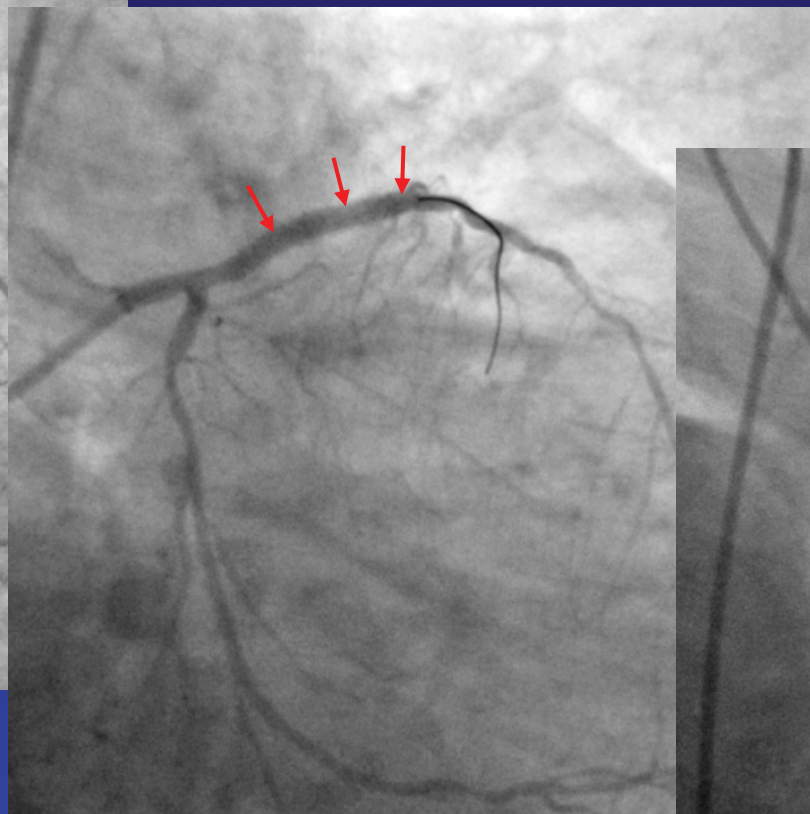
FUP



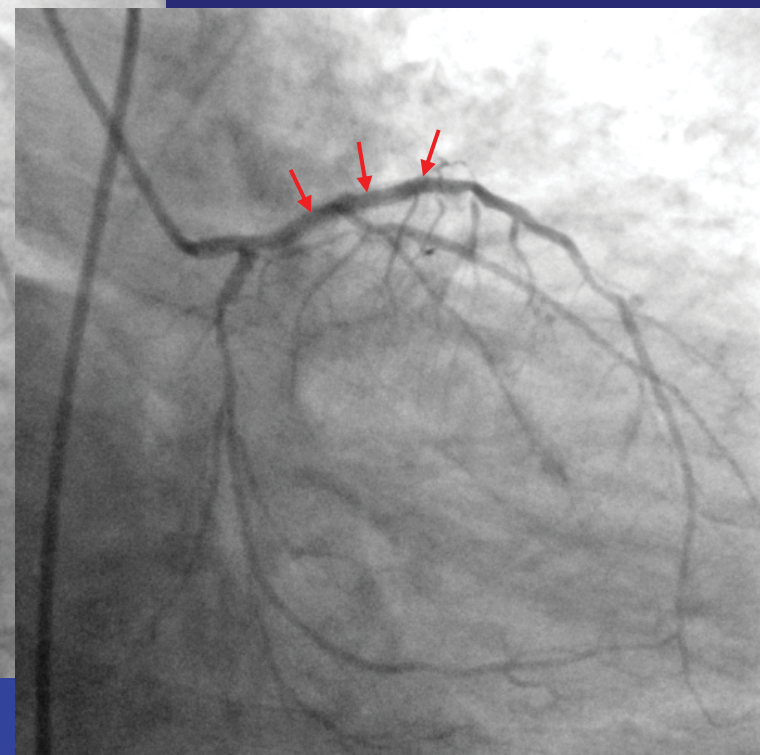
**INSTENT RESTENOSIS IN LAD
TREATMENT BY INFINNIUM STENT**



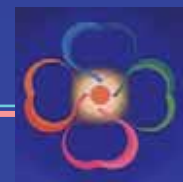
PRE



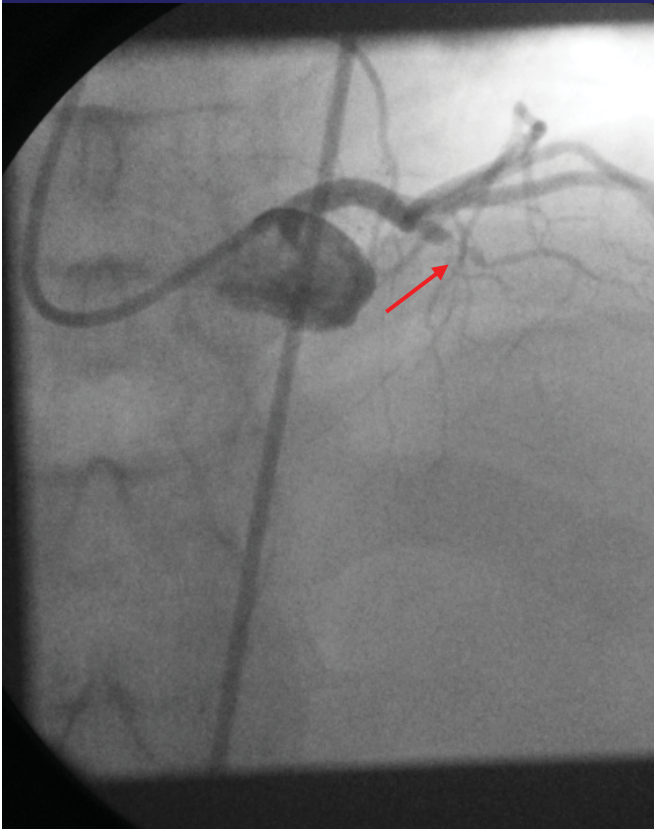
POST



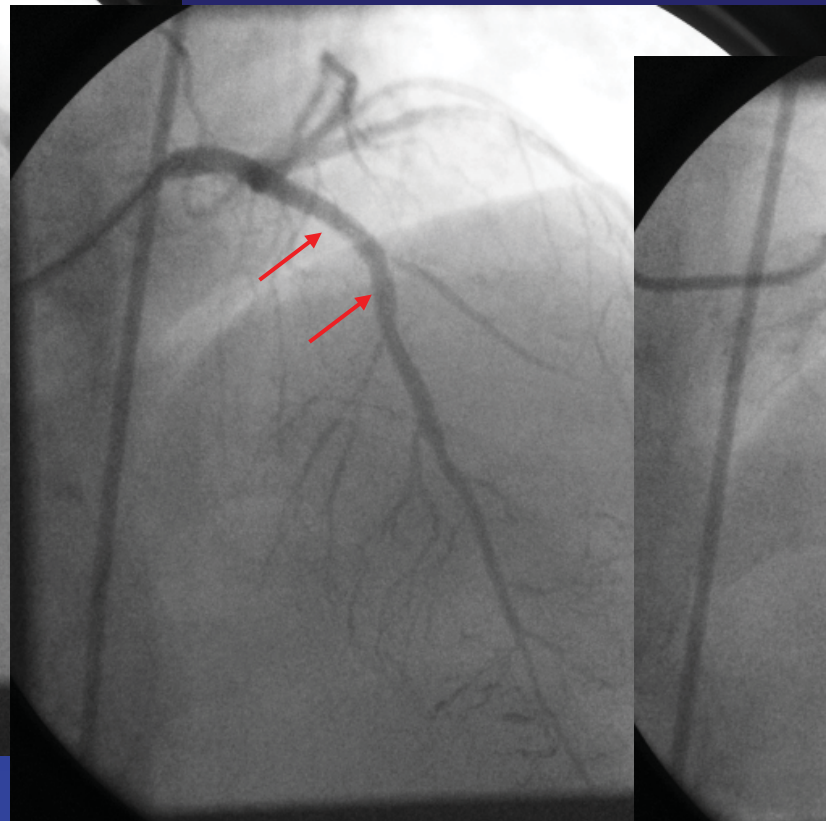
FUP



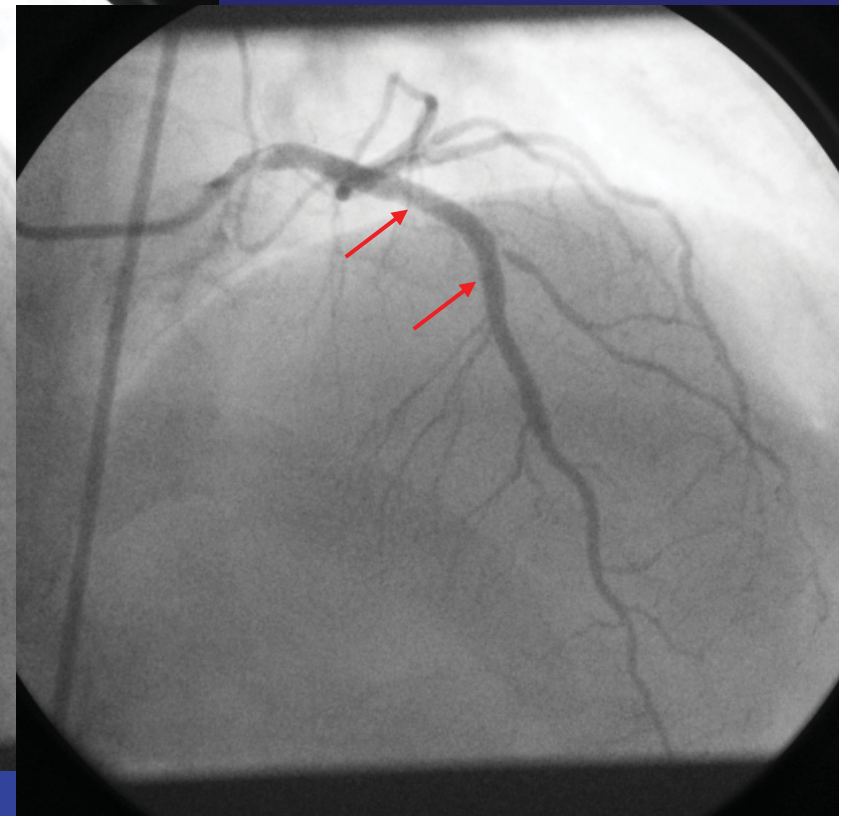
TREATMENT OF CTO IN LAD BY OVERLAPPING INFINNIUM STENTS



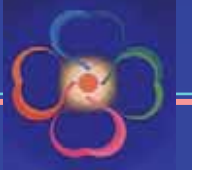
PRE



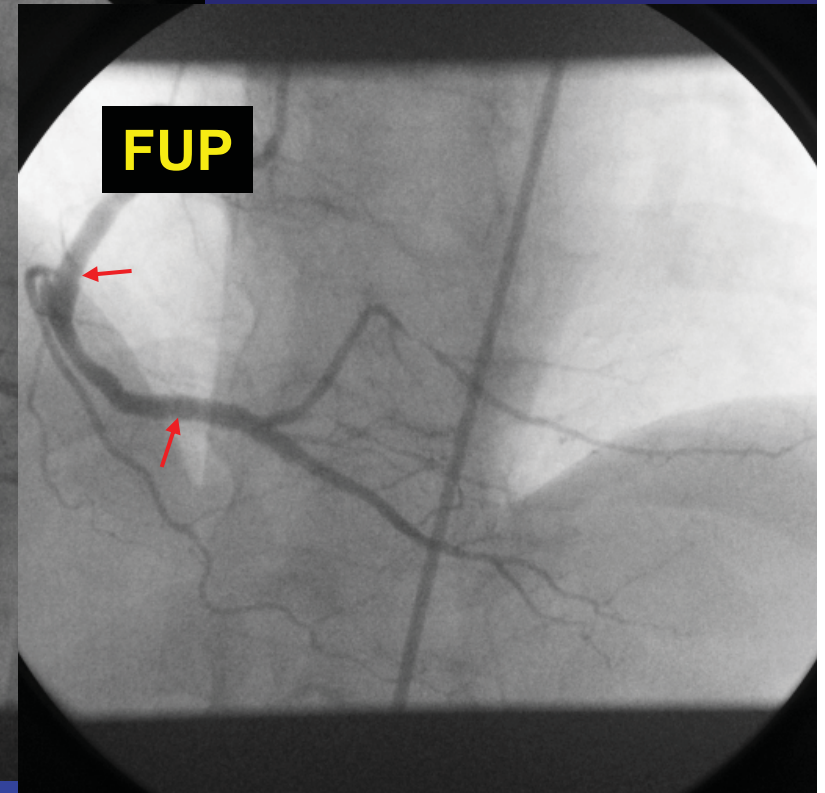
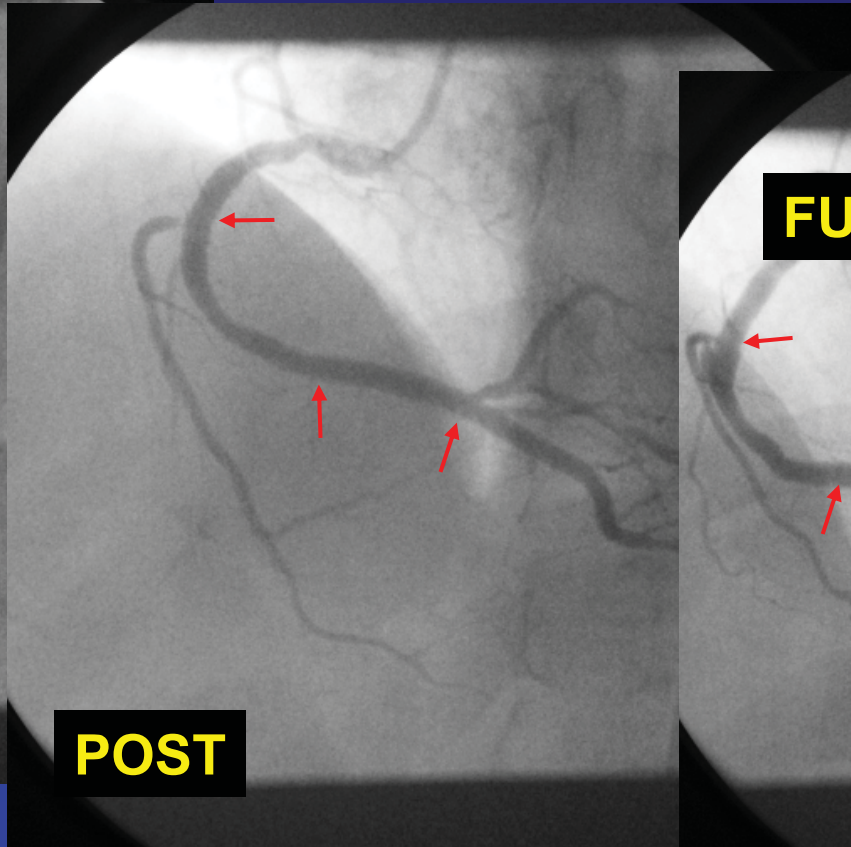
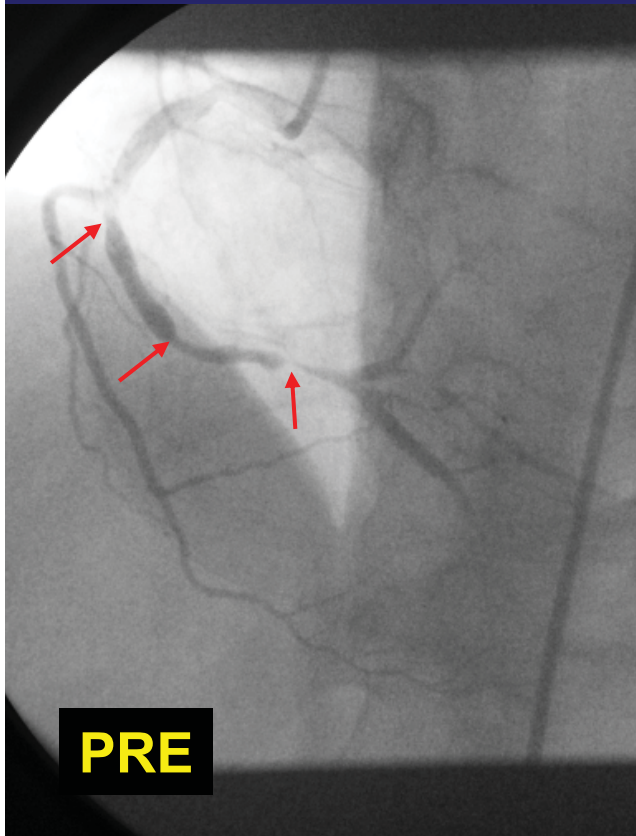
POST



FUP



TANDEM LESIONS IN MID AND DISTAL RCA TREATMENT BY TWO INFINNIUM STENTS



STENTING OF LONG LESION IN LAD AND BIFURCATION STENOSIS IN RAMUS

- **LAD Long Stenosis** : 70-80%
- **RAMUS (Bifurcation)** : 70-80%
- **Infinnium Stent**
 - LAD (Px / Mid) : 3 x 29 mm
 - LAD (Distal) : 2.5 x 29 mm
 - RAMUS (Sup. Br.) : 2.75 x 19 mm
 - (Inf. Br.) : 3 x 23 mm
- **Follow-up Angio After Six Months** : **No Restenosis in LAD and RAMUS**



COMPARISON WITH OTHER TRIALS ON DES

BASELINE CHARACTERISTICS

Feature	RAVEL	SIRIUS	TAXUS-II SR / MR	SIMPLE 1
● No. of Pts.	120	533	131 / 135	282
● Diabetics (%)	15.8	24.6	11 / 17	33.3%
● Lesion Length (mm)	9.6	14.4	10.5 / 10.7	11.9 ± 4.4
● RVD (mm)	2.60	2.78	2.78 / 2.73	2.64 ± 0.54



COMPARISON WITH OTHER TRIALS ON DES

CLINICAL AND QCA RESULTS

Feature	RAVEL	SIRIUS	TAXUS-II SR / MR	SIMPLE 1
● Late Loss (mm)	- 0.01	0.17	0.31 / 0.30	0.19
● Binary RS				
→ Instent	0	3.2	2.3 / 4.7	6.3
→ Persistent	0	8.9	5.5 / 8.6	9.5
● MACE upto 6 to 9 Months (%)	3.3	4.9	8.5 / 7.8	5%
TLR / TVR	0.8	3.9	7.7 / 6.2	

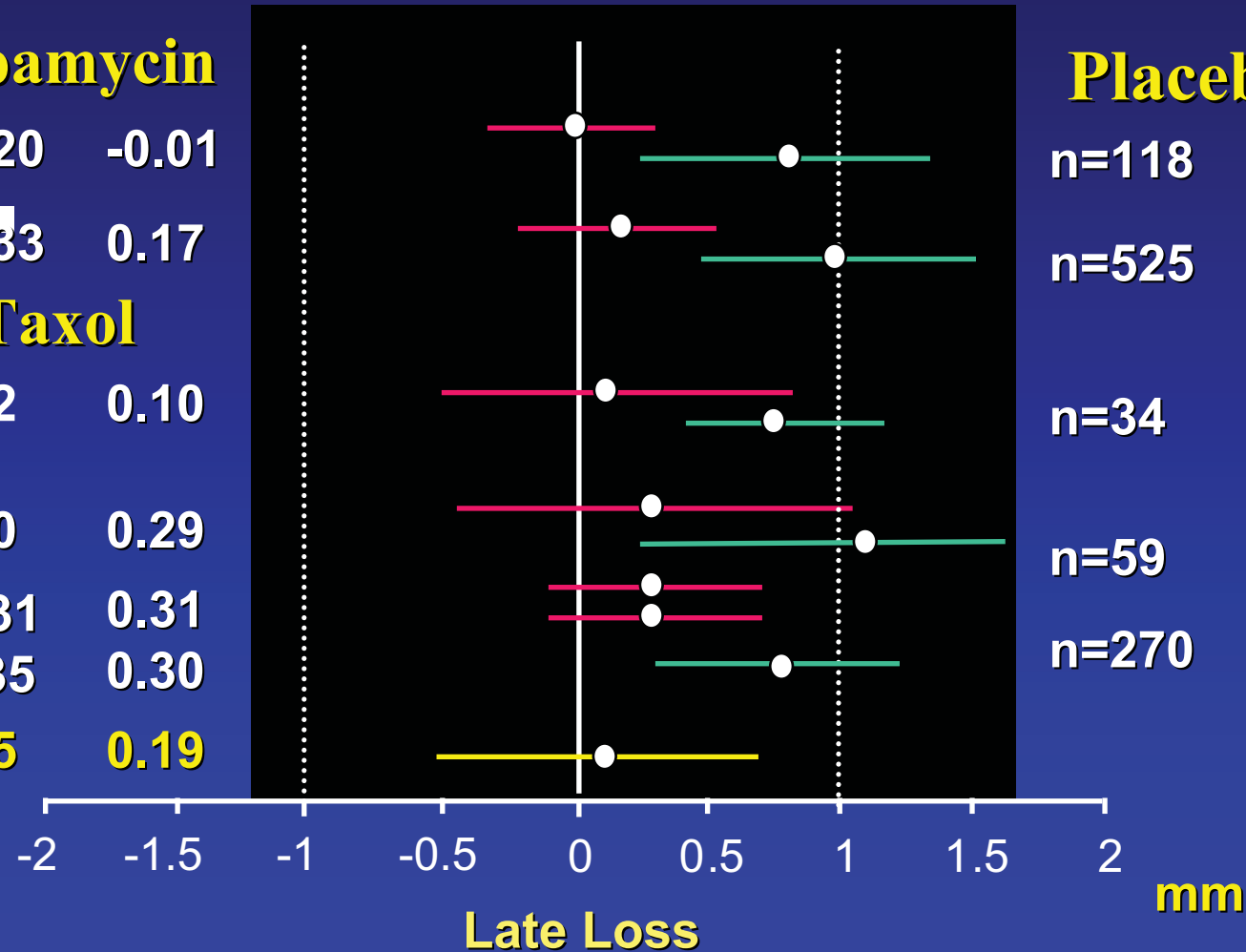


SIMPLE 1

LATE LOSS IN DRUG-ELUTING STENT TRIALS

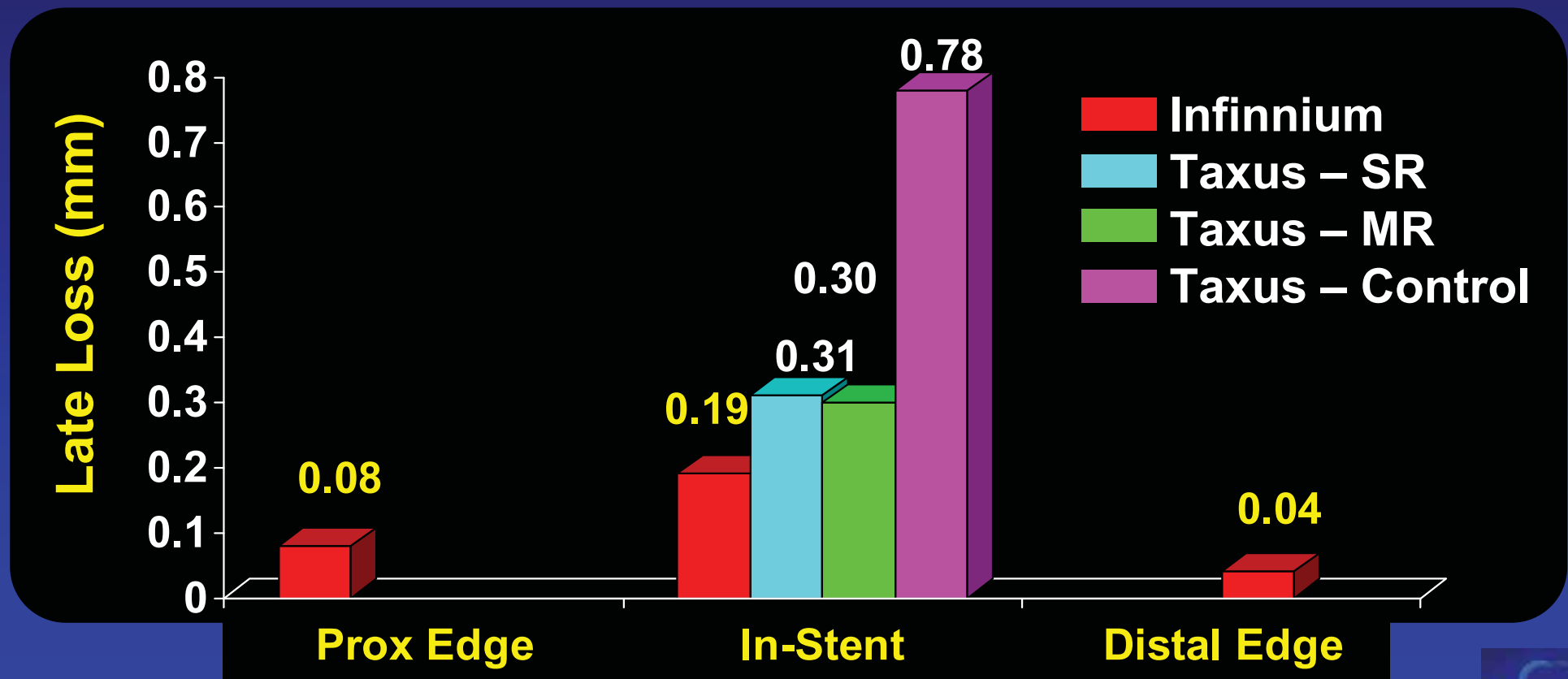
TRIAL		Rapamycin
RAVEL	n=120	-0.01
SIRIUS	n=533	0.17
		Taxol
ELUTES (Hi)	n=32	0.10
ASPECT (Hi)	n=60	0.29
TAXUS-II	SR n=131	0.31
	MR n=135	0.30
SIMPLE 1	n=95	0.19

	Placebo
n=118	0.80
n=525	1.00
n=34	0.73
n=59	1.04
n=270	0.78



SIMPLE 1

QCA : LATE LOSS IN COMPARISON WITH TAXUS II STENTED AREA AND EDGES



SUMMARY AND CONCLUSIONS

- **First Indigenously Designed and Evaluated DES from Asia**
- **Safety and Efficacy Comparable to Other DES**
 - Cypher and Taxus Marketed in World
- **SIMPLE 1 Registry : Data Collected from Non-Selective Implantation in Real World Lesions**
 - Smaller Vessels / Longer Lesions / Diabetics
- **Less Costly Compared to Cypher and Taxus**
- **Prospective, Multicentric Trial Planned to Start in May 2004**



ACKNOWLEDGEMENTS

Sincere Thanks

- **Sahajanand Medical Technologies** →
 - ◆ **Dhiraj Lal, Chairman** **Ms Varsha, Co-ordinator**
 - ◆ **Rajesh Vaishnav, Director** **Ms Richa, Co-ordinator**
 - ◆ **Manish Doshi, Director**
- **Cardialysis** →
 - ◆ **Prof. Patrick Serruys**
 - ◆ **Ms. Marie – angele Morel**
 - ◆ **Ms Patricia C. Otto-Terlouw**
- **Others** →
 - ◆ **Implanting Physicians**
 - ◆ **Patients for their Participation**

