

**Are Asian Patients Different ? -
Updates Of Biomatrix Experience In Regional Settings:
BEACON II (3 Yr F up) &
Biomatrix™ Single Center Experience (Indonesia)(Final 5 Yr F up)**



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BEACON II Registry

Trial Design (PI: Prof. Tian-Hai Koh)

Prospective, Asia-Pacific, observational registry assessing clinical outcomes in Real World, All-Comers patients receiving BioMatrix™ DES

Key Enrollment Criteria:

- Native coronary arteries and SVG
- Target Vessel Diameters: ≥ 2.5 – ≤ 4.0 mm
- No limit to lesion length
- No limit to number of treated lesions or vessels
- No limit to disease / lesion pathology

(except lesion at Protected / Unprotected Left Main)

BioMatrix™
N = 497

Patients enrolled from 12 Asia Pacific Sites

Clinical Follow-Up Time points

30 d

3 mo

6 mo

12 mo

2-5 yr

Primary Endpoint:

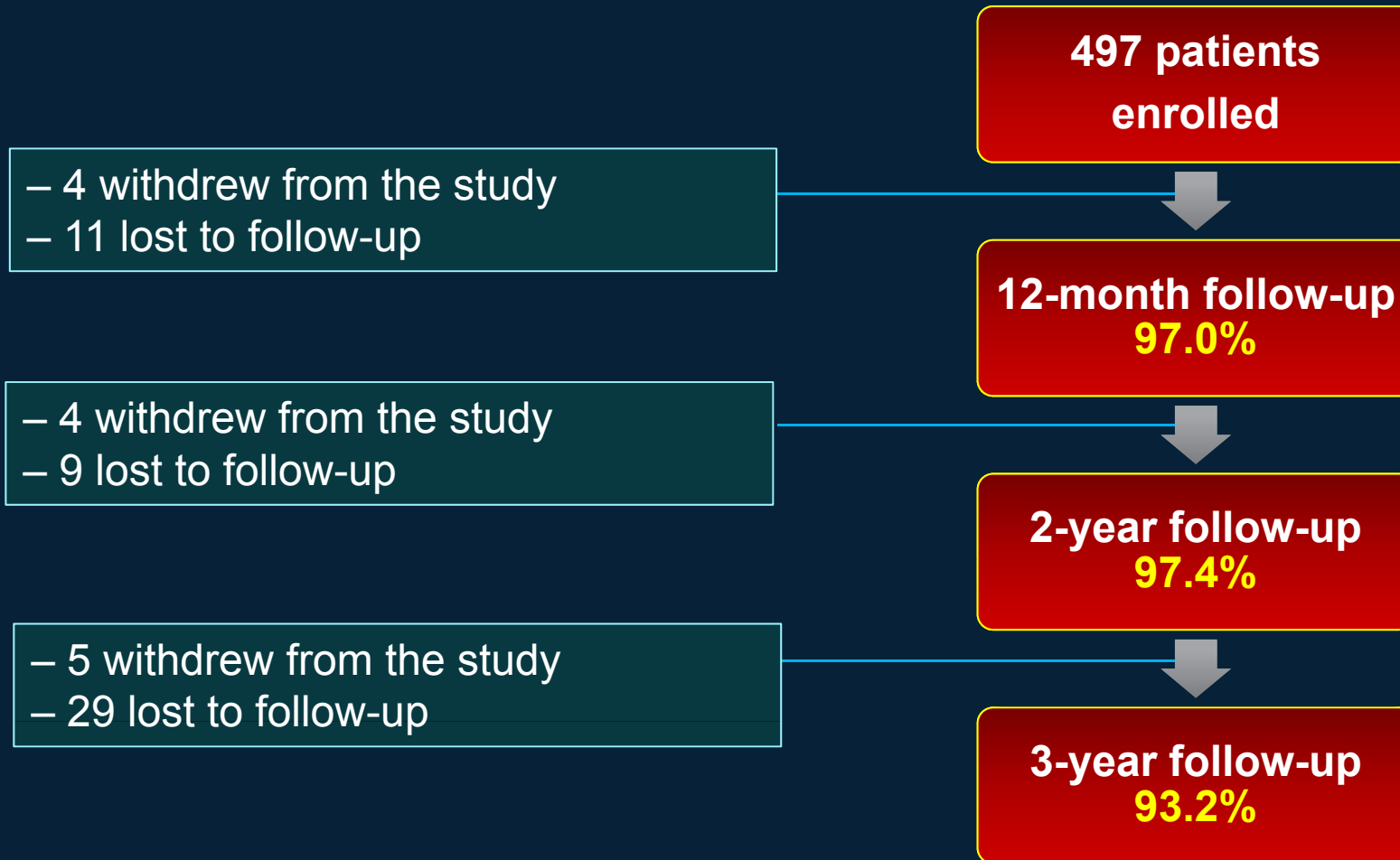
- **MACE at 12 month**
(Cardiac Death, Q-Wave & Non Q-Wave MI, Ischemia Driven TLR)

Key Secondary Endpoints:

- Ischemia driven **TLF and TLR at 12 months**
- Rates of **definite stent thrombosis** (ARC Definition) up to 5 years
- **MACE** at 30d, 90d, 6m, 12m and 2-5y

Anti-Platelet Therapy recommended for 6 months (Highly recommended for 12 months)

Patient Flow



Patient Demographics

	N = 497 pts
Gender (♂)	80 %
Age (years)	60 ± 8.8
Diabetes	33 %
Hypertension	62 %
Hypercholesterolemia	74 %
History of Smoking	46 %
Family History of CAD	29 %
Prior MI	39 %
Previous PCI	28 %
Previous CABG	5.5 %

Patient Characteristics

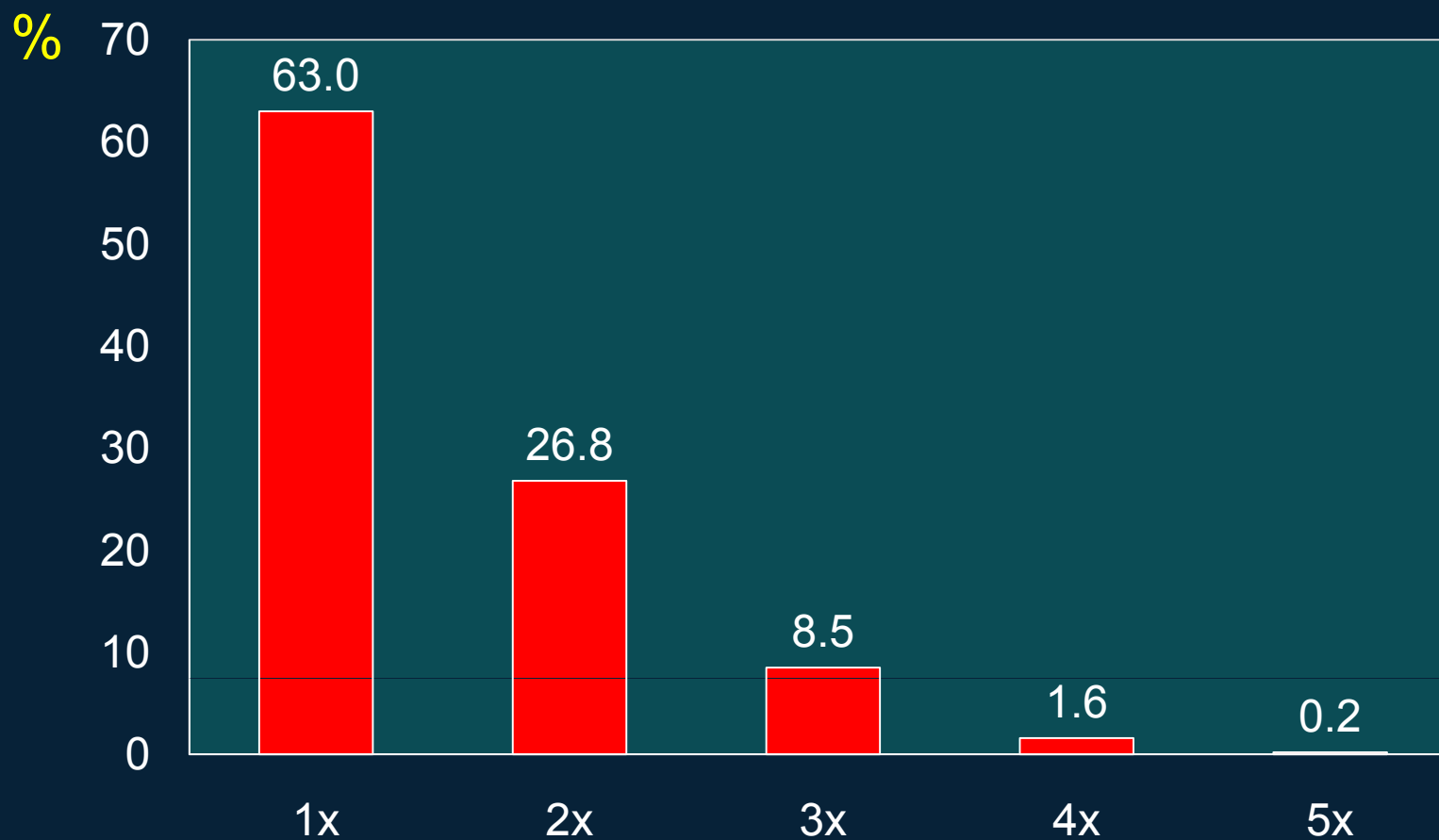
	N = 497 pts
Stable Angina	54%
Unstable Angina	30%
CCS Class	
I	29%
II	40%
III	21%
IV	11%
LVEF %	52 ±14
LVEF < 30%	6.8%

Lesion Morphology & Characteristics

N = 742 Target Lesions	
Bifurcation Lesion (side branch > 2mm)	14%
with moderate/severe calcification	4.3%
Moderate/Severe Calcification	24%
Long Lesions > 20 mm	31%
Small Vessels < 2.75 mm	34%
Total Occlusion	9.3%
De Novo Lesions	95 %

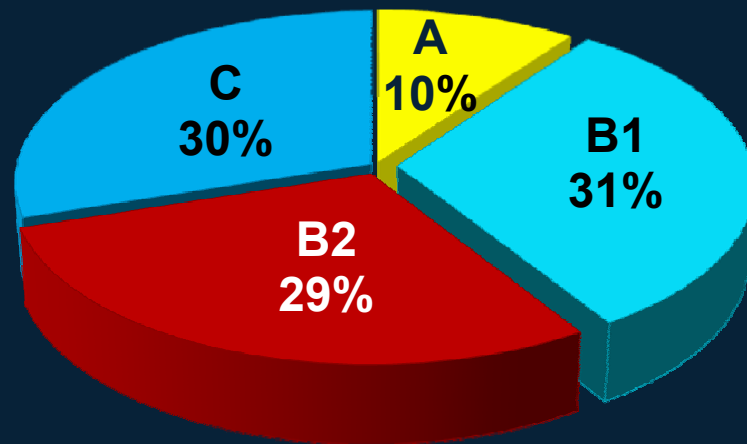
Lesions Treated Per Patient (ITT)

Mean # of target lesions per patient = 1.49 ± 0.74
Total Target Lesions = 742 Total Patients Treated = 497

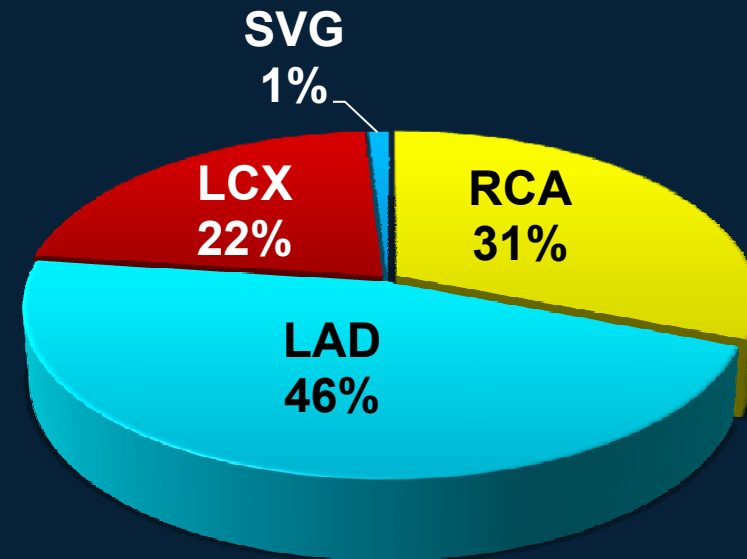


Target Lesion (n=742)

ACC/AHA Classification



Location



Procedural Characteristics

Mean Lesion Length	18.7mm (\pm 9.7)
Mean Stent Length	19.3mm (\pm 6.0)
Stents per Target Lesion	1.16 \pm 0.47
Device Success ¹	98.5%
Lesion Success ¹	98.7%
Procedural Success ¹	97.8%

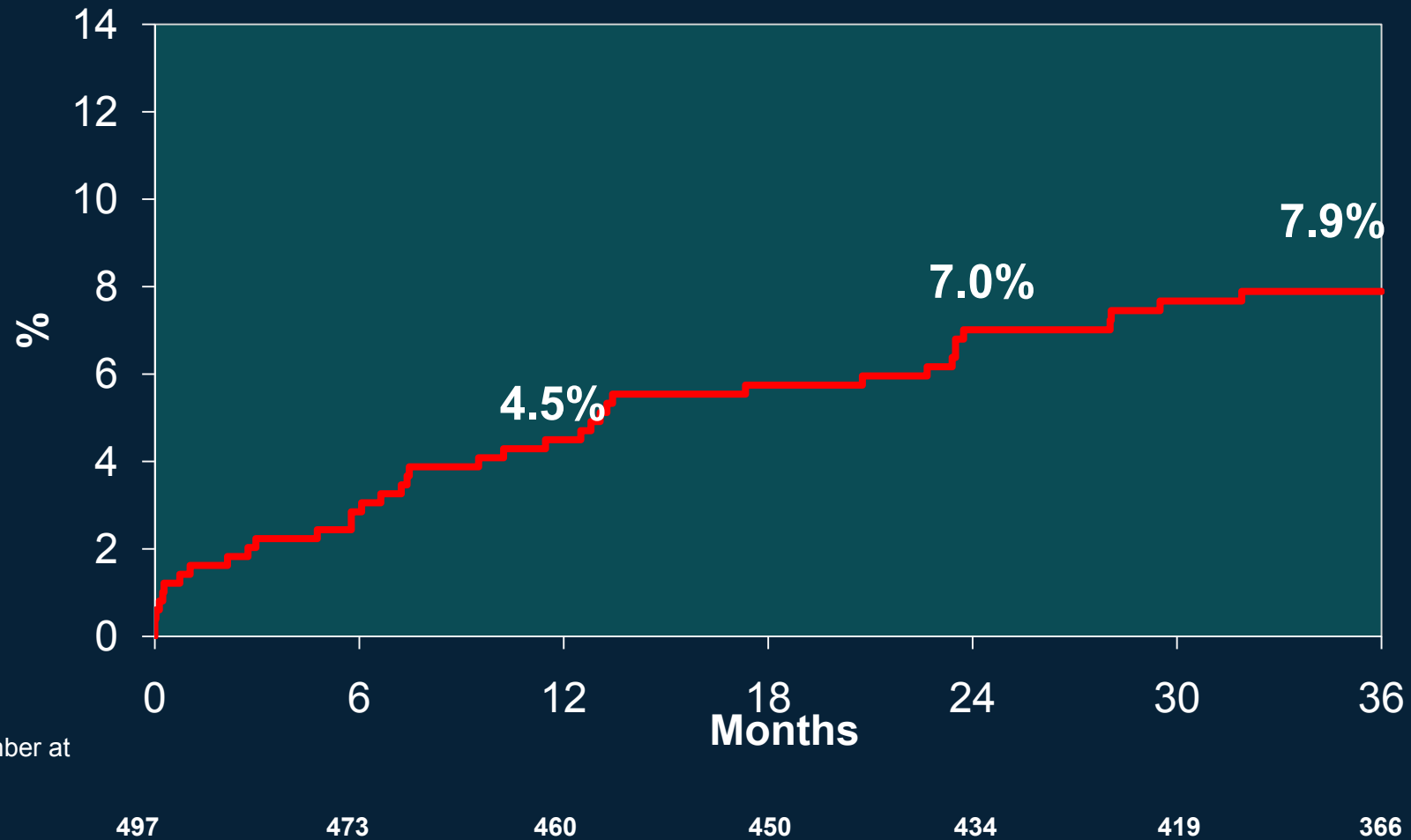
¹ **Device Success** defined as achievement of a final residual in-stent diameter stenosis of < 30% (visual estimate), using the BioMatrix DES.

Lesion Success defined as attainment of < 30% in-stent residual stenosis of the target lesion using any percutaneous method.

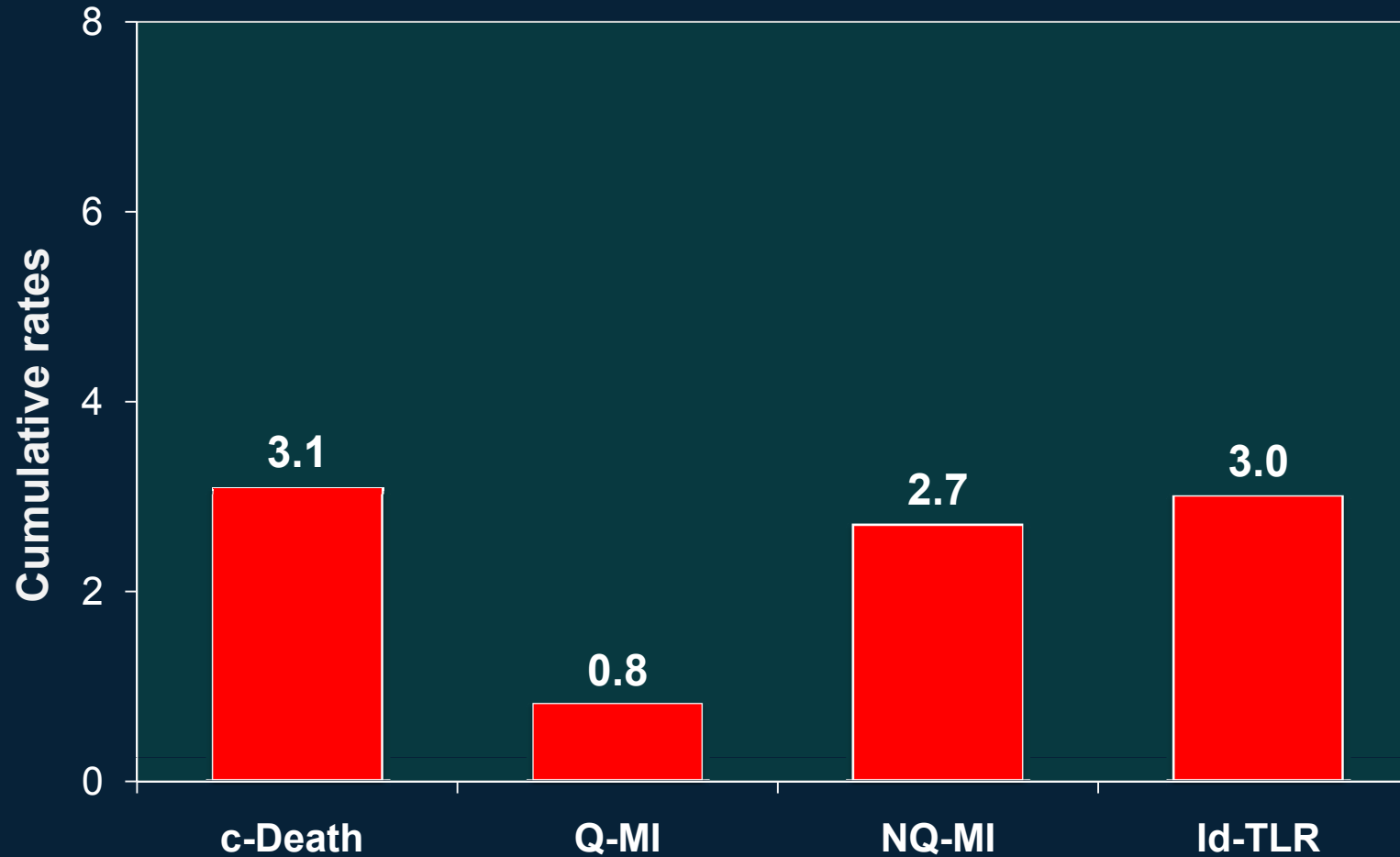
Procedural Success defined as achievement of Device Success without the occurrence of in-hospital MACE.

Hierarchical MACE

Cardiac Death / MI / Id-TLR

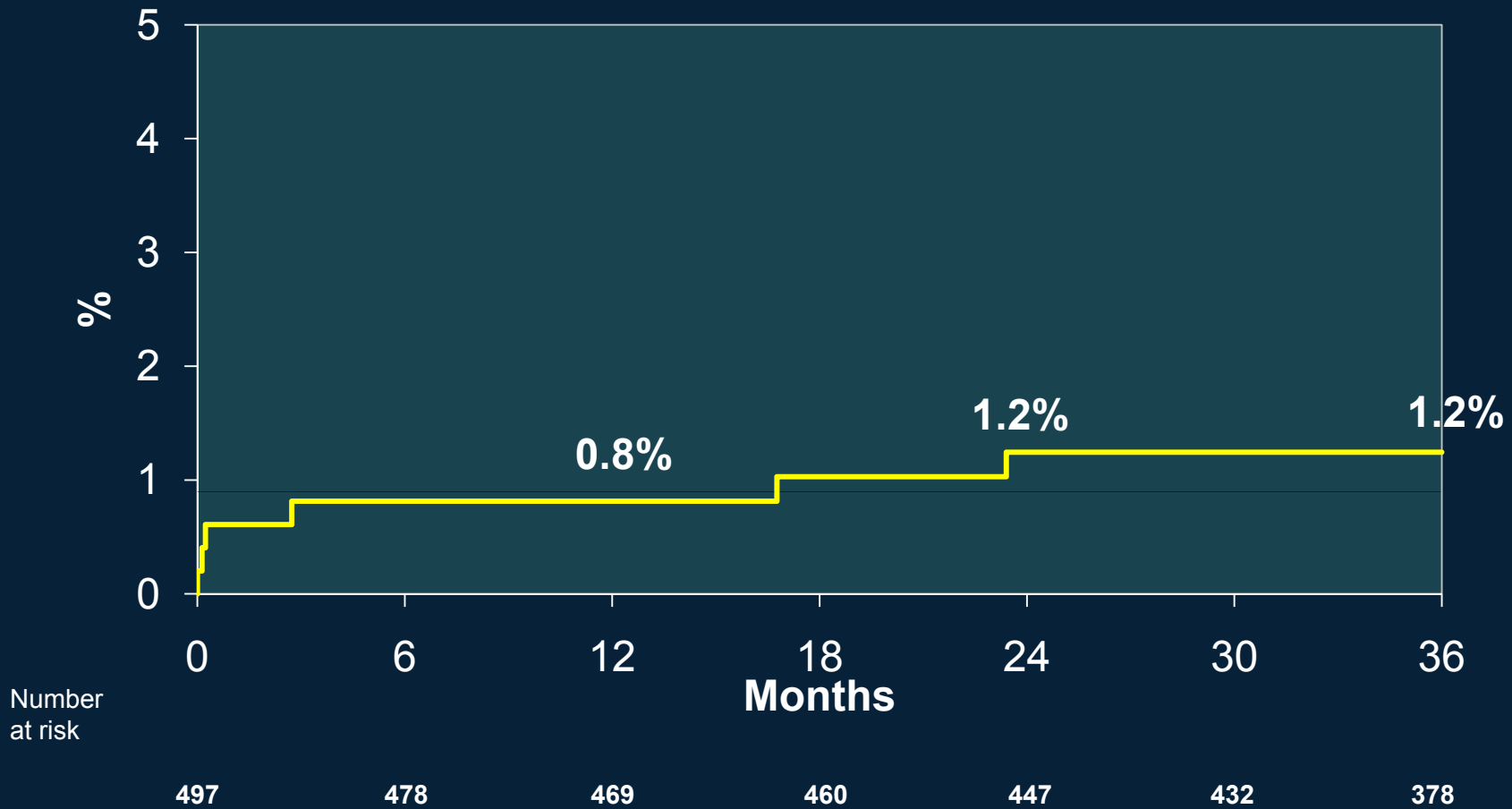


3-Year MACE Components



MACE defined as a composite of Cardiac death, MI (Q and Non-Q wave) and ischemia driven TLR
All event rates are Kaplan-Meier cumulative incidence rates

Definite Stent Thrombosis (ARC Defined)



Definite Stent Thrombosis (ST) (ARC Defined)

N= 497	0 - 30 Days		31-180 Days	181-360 Days	361 -1080 Days	Total Definite Stent Thrombosis
	Acute Thrombosis	Sub-Acute Thrombosis	Late Stent Thrombosis		Very Late Stent Thrombosis	
Definite Stent Thrombosis	1 (0.2%)	3 (0.6%) ¹	1 (0.2%)	0	2 (0.4%) ²	7 (1.4%) ³

No VLST in native coronary arteries for BioMatrix™ – VLST limited to SVGs!

¹ Excluded one secondary definite ST occurring after 14 days in a patient who had an earlier ST at 07 days

² Excluded two secondary definite ST: a) an ST occurring after 879 days in a patient who had a VLST at 503 days and b) an ST occurring after 941 days in a patient who had a VLST at 702 days

³ Excluded the secondary STs mentioned in 1 & 2

Conclusion

- BEACON II registry suggests an **excellent safety profile up to 3 Year** for BioMatrix™, when used in routine clinical practice in an Asian population with a **low MACE*** rate of **7.9%§**
- Definite VLST
 - *Although this was an all-comers registry, **definite very late stent thrombosis events were rare (0.4%)§***
 - ***No VLST events occurred in patients where a BioMatrix™ was implanted in native coronary arteries***
- Such a positive safety profile is particularly of note in an **all-comers registry** population.

* Hierchical MACE

§ All event rates are Kaplan-Meier cumulative incidence rates

BioMatrix™ Single Center Registry (Indonesia) Real World Patients (PI: T. Santoso)

Prospective, Single Center Registry

Real world cases

Exclusions:

- Contraindications to anti-platelets
- Patients with short life expectancy & serious concomitant disease (advanced cancer, etc)
- Lack of patient's consent

BioMatrix™
N=302 pts

Medistra Hospital

Clinical Follow-up

30d 6 mo 9 mo 12 mo 24 mo 36 mo 48 mo 60 mo

Angiographic Follow-up at 6 mo

(Dr. A. Wong & T.H. Koh, NHC, Singapore)

Primary Endpoint:	TVR at 6 & 12 months
Key Secondary Endpoints:	MACE at 30 days, 6 & 12 mo In-segment late loss & restenosis at 6 mo
Antiplatelet therapy	ASA indefinitely (unless contraindicated) Clopidogrel 300 mg (loading), then 75 mg for 6 months

Patient & Procedure Characteristics

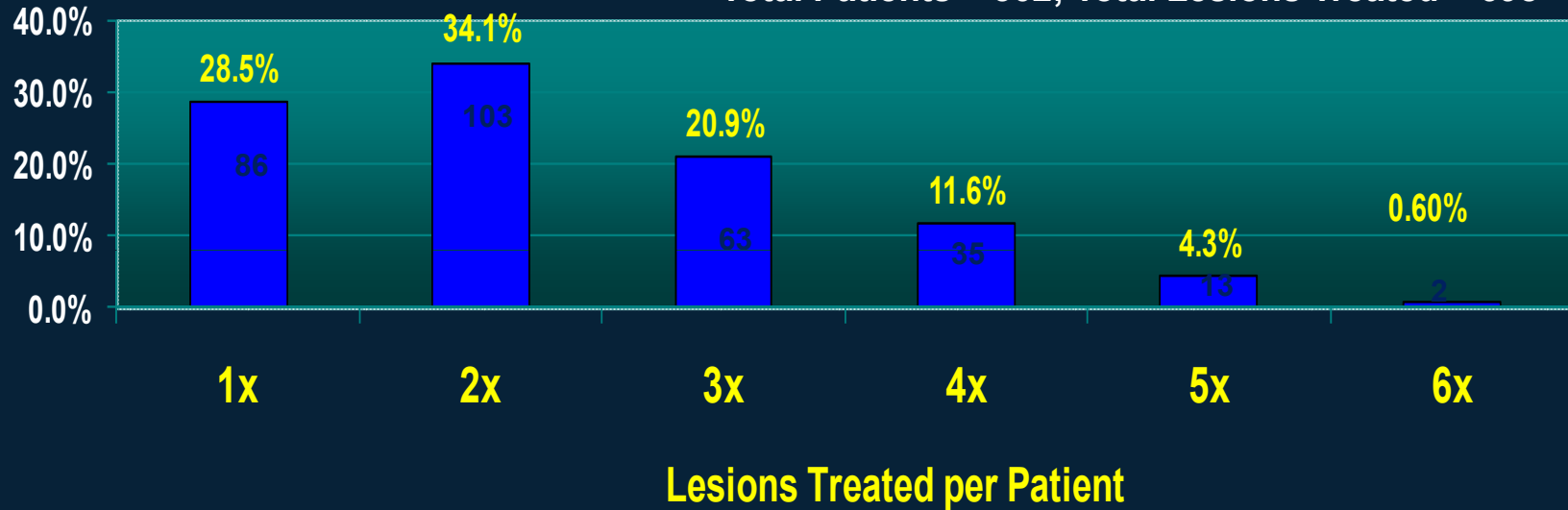
No of patients	302
No of lesions	548
No of stents	588
Male:female ratio	210/92
Mean age (years)	59.5 ± 10.0
Clinical diagnoses:	
■ Stable angina (AP)	136 (45%)
■ Unstable AP	62 (20.5%)
■ Acute myocardial infarction (MI)	13 (4.3%)
■ Recent AMI	13 (14.3%)
■ Silent ischemia	78 (25.8%).

■ Device Success	100.0%*
■ Lesion Success	99.8% **
■ Procedure Success	99.3% *

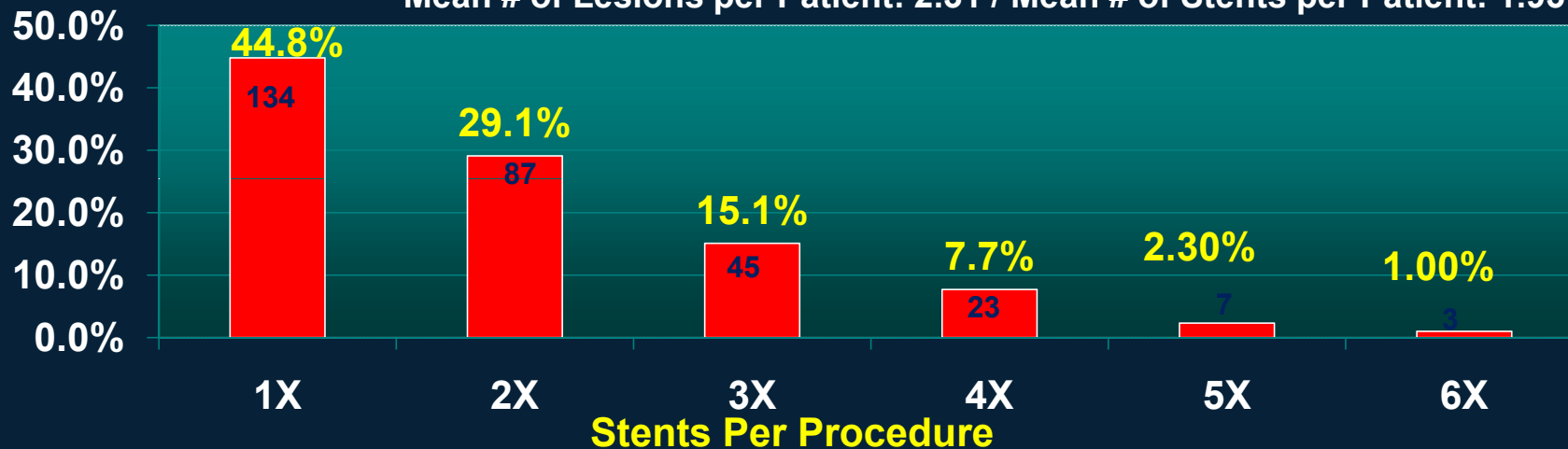
*Target Lesions ; ** All Lesions; Device Success: achievement of <50% residual in-segment % DS with assigned stent. Lesion Success: achievement of <50% residual in-segment % diameter stenosis; Procedure Success: device success & without 30-day MACE.

No of Treated Lesions & No of Stents

Total Patients = 302; Total Lesions Treated = 698



Mean # of Lesions per Patient: 2.31 / Mean # of Stents per Patient: 1.95



BioMatrix™ Stents Were Implanted In The Following Complex Patient & Lesion Types

		BEACON II
■ Types B2/C	393 (79.5%)	58.9%
■ Multivessel disease (\pm LM stenosis)	183 (60.1%)	<57.3%*
■ Small vessel < 2.5 mm	154 (51.0%)	34.0%#
■ Long lesion (> 25 mm)	114 (37.7%)	31.9%†
■ Calcification	97 (32.1%)	23.6%
■ Diabetes mellitus	83 (27.5%)	31.4%
■ Bifurcation lesion	69 (22.8%)	13.9%
■ Chronic total occlusion	29 (9.6%)	9.3%
■ Thrombus	18 (6.0%)	ND
■ LM stenosis	16 (5.3%)	0.0%
■ Old saphenous vein graft	12 (4%)	1.1%
■ Instent restenosis	10 (3.3%).	5.7%

BEACON II: *single stent procedure; # < 2.75 mm; † \geq 20 mm

Comparison With BEACON II & the LEADERS Trial*

	BEACON II 497 pts	Indonesian SC 302 pts	LEADERS* 850 pts
Age (yrs)	59.6	59.5 ± 10.0	65 ± 11
Male (%)	80.3	69.5	75
Diabetes (%)	33.0	27.5	26
Number of lesions per patient	1.4	2.31	1.5
Lesions per patient (%)	57.3% single stent		
- 1 lesion	--	28.5	63
- 2 lesions	--	34.1	29
- ≥ 3 lesions	--	37.4	8
Multivessel disease (%)	--	60.1	24
Acute coronary syndrome	30.4	24.8	55
Long lesions (%)	31.9 (≥20 mm)	37.7 (>25 mm)	31 (>20mm)
Small vessels (%)	34.0 (< 2.75 mm)	51 (<2.5 mm)	68 (≤2.75 mm)

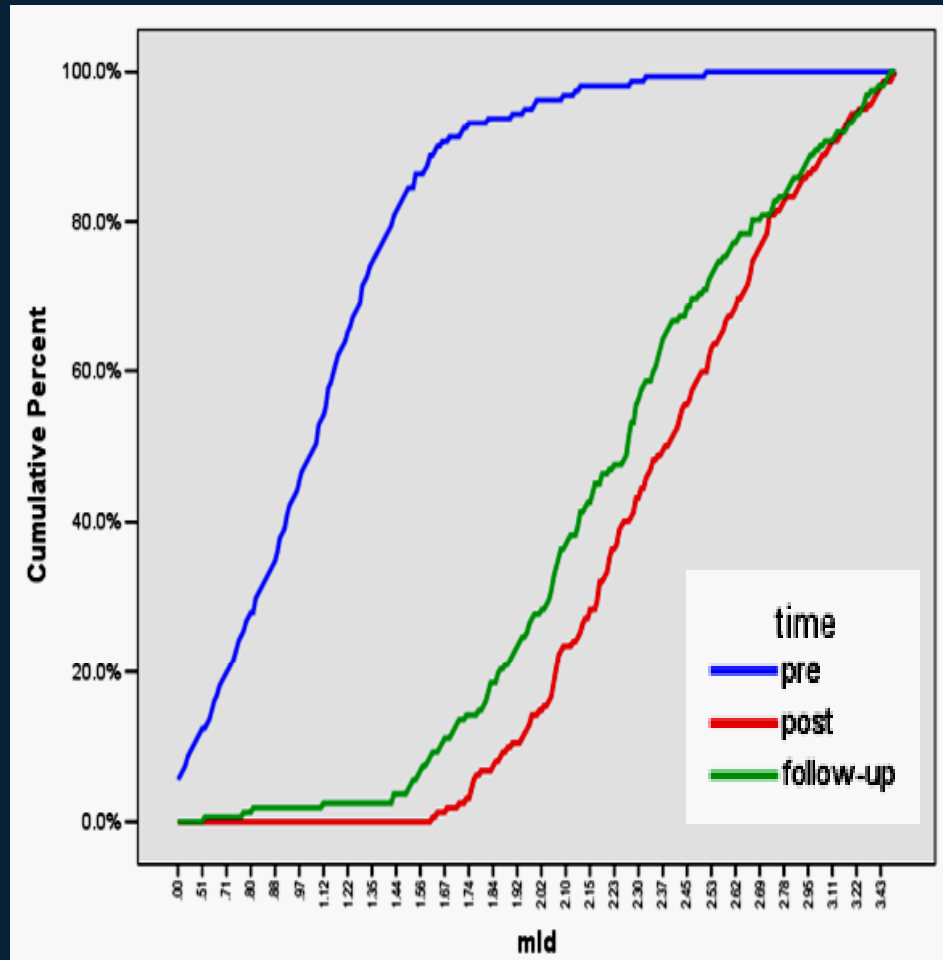
* Biomatrix group

#Windecker S. et al. Lancet 2008; 372:1163-73

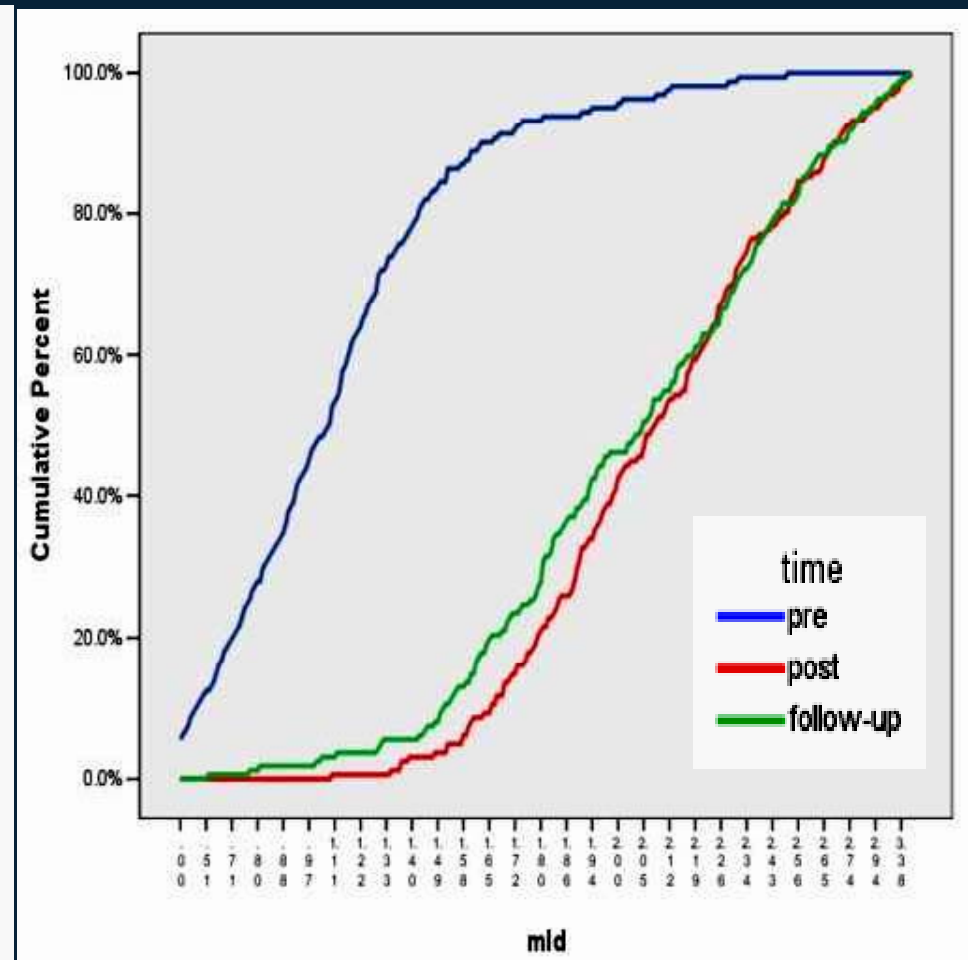
	Pre-procedural	Post-procedural	Follow-up
RVD, mm	2.63	2.65	2.68
MLD, mm	1.05	2.14	2.07
DS, %	60.2	19.0	22.8
Stent MLD, mm	--	2.44	2.28
In-stent DS, %	--	7.7	15.1
Late loss, mm			
- In segment	--	--	0.07
- In-stent	--	--	0.16
Restenosis (n lesion=163)			
- In-segment	--	--	7 (4.3%)
- In-stent	--	--	5 (3.1%)
Restenosis (n patient=104)			
- In-segment	--	--	6 (5.8%)
- In-stent	--	--	5 (4.8%)

Cumulative Frequency Curve

In-stent



In-segment



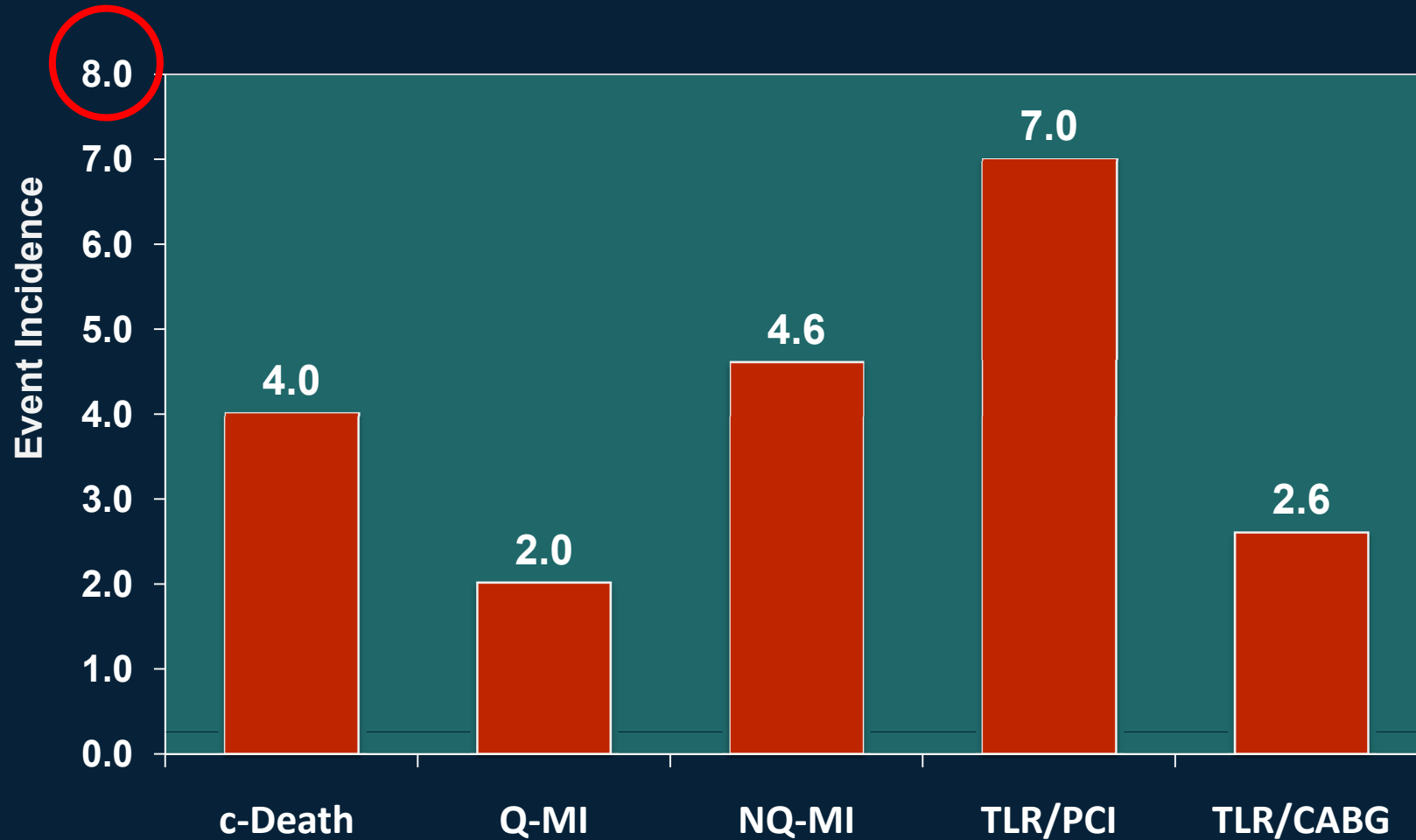
	Indonesian SC (n = 302)	LEADERS* (n = 850)
<i>Preprocedural</i>		
- RVD, mm	2.63	2.60
- DS, %	60.2	64.6
<i>Procedural</i>		
- # stent per lesion		1.3 ± 0.7
- Stent length per lesion, mm	24	24.7
- Device success, %	100	95.8
- Lesion success, %	99.8	98.6
<i>Angiographic follow-up</i>		
Late loss, mm		
- In- segment	0.07	0.08
- In-stent	0.16	0.13
Restenosis, %		
- In-segment	4.3	6.7
- In-stent	3.1	5.5

* Biomatrix group

Hierarchical MACE (5 Yr F-up) Cardiac Death / MI / Id-TLR



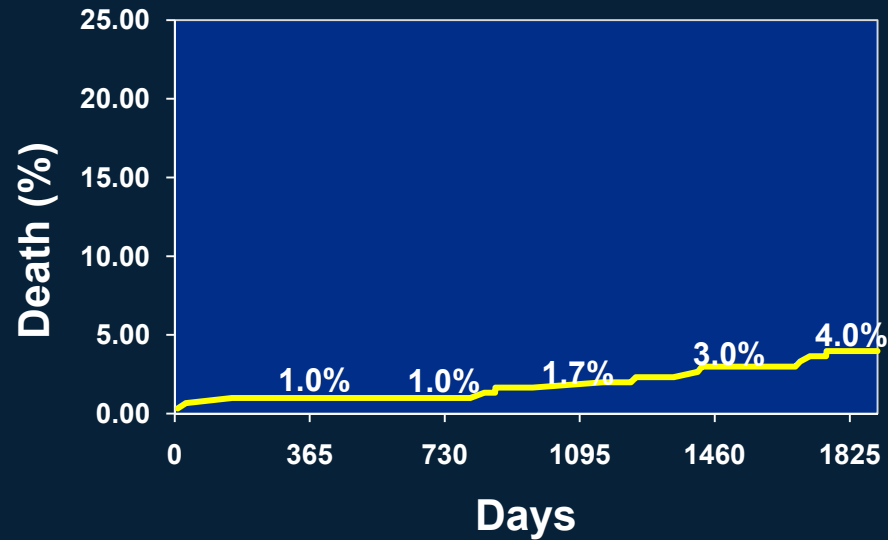
MACE Components @ 5 yrs



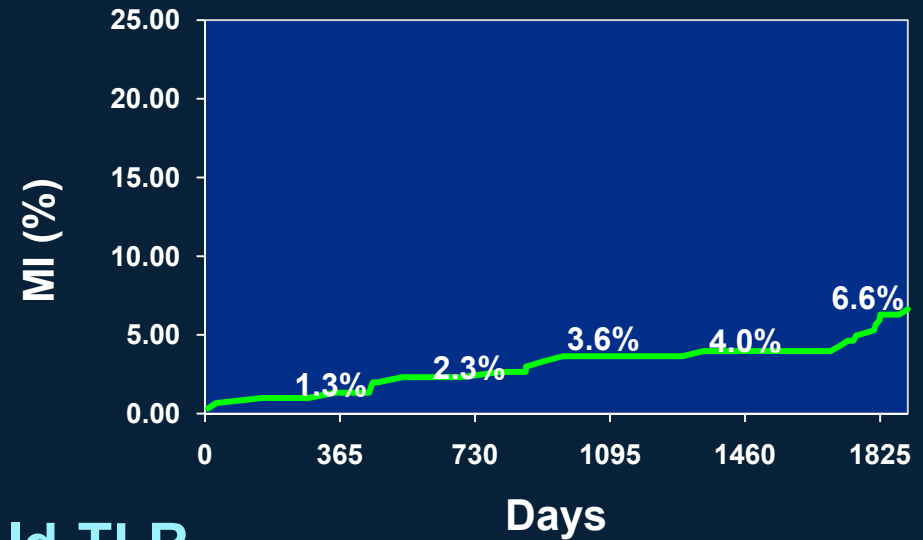
*MACE: Cardiac death, MI, TLR

KM Curves Of Individual End-points Of MACE Cardiac Death / MI / Id-TLR @ 5 Yr

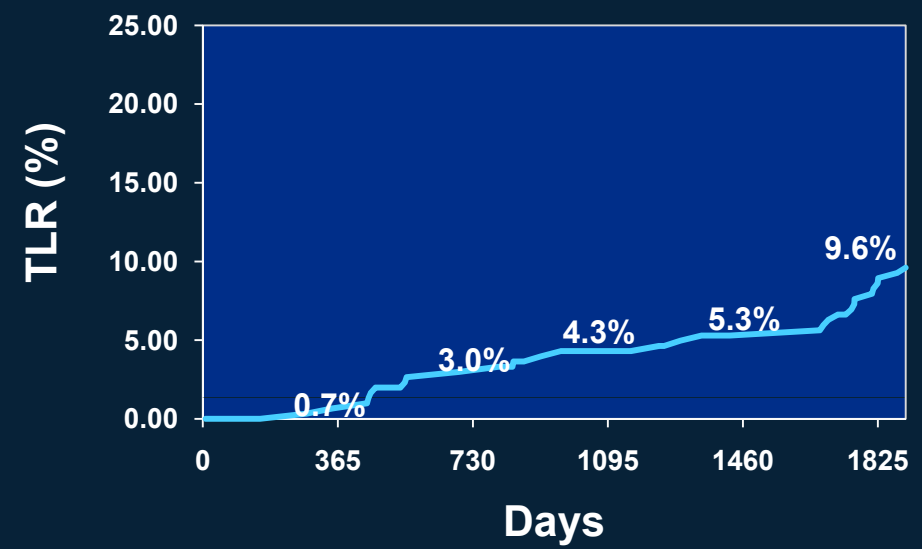
Cardiac Death



MI



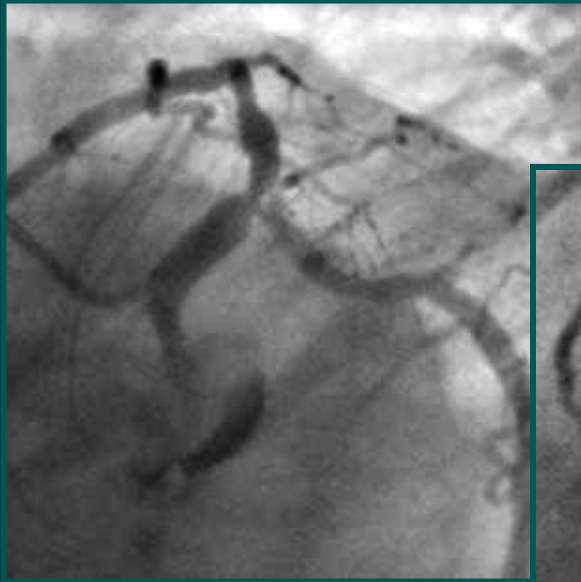
Id-TLR



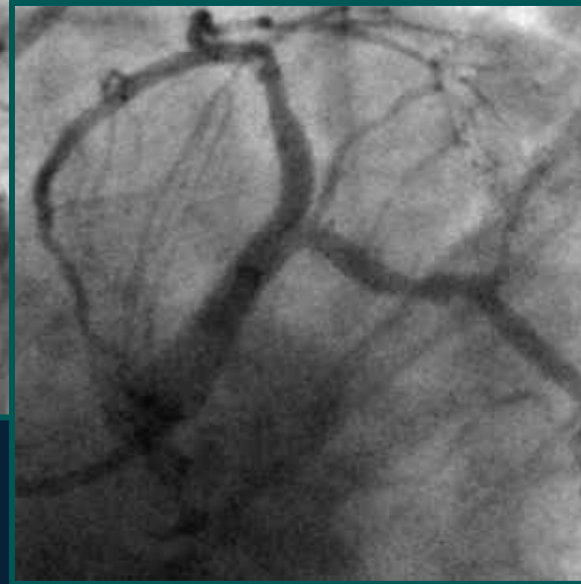
ARC Definite/Probable ST 4 Year Follow-up

	0 - 30 Days	31-180 Days	181 Days -1 yr	1y-5y	Total Definite Stent Thrombosis
	Early Stent Thrombosis	Late Stent Thrombosis		Very Late Stent Thrombosis	
N= 302					
Definite ST	0	0	0	0	0
Probable ST	1 (0.3%)	0	0	0	1 (0.3%)

Case 1: LM Bifurcation Stenosis (Kissing Stents)



Baseline:
LM bifurcation,
ostial LAD &
ostial LCX
stenoses



Final: After placement
of **2 Biomatrix stents**
(3.5/18 in LM-LAD &
3.0/14 in LM-LCX) with
kissing stent technique



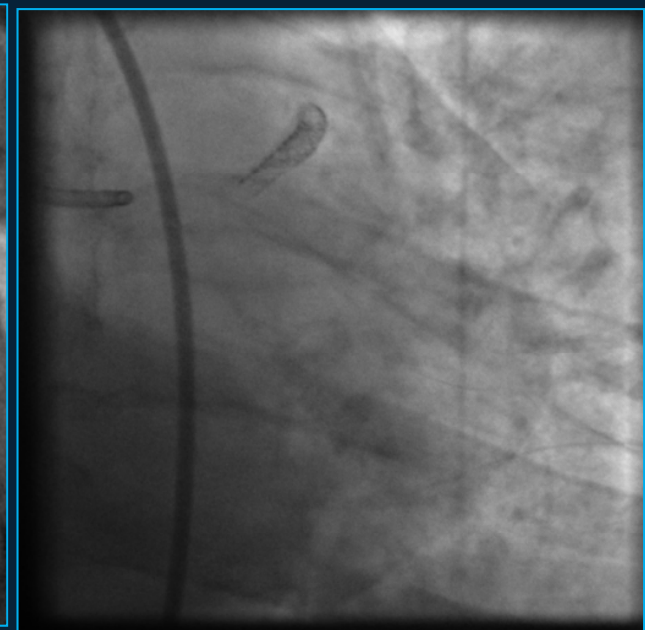
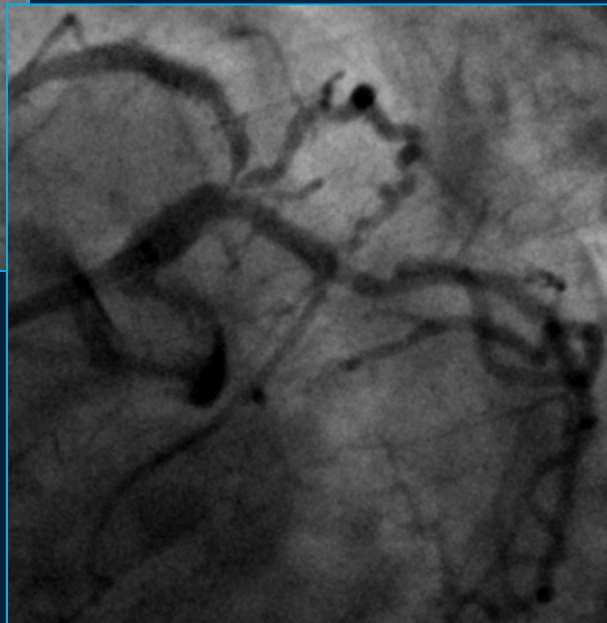
6 month f/up:
No restenosis

Case 2: LM Trifurcation With Proximal LAD Instant Restenosis & Ostial Intermediate Branch Stenosis

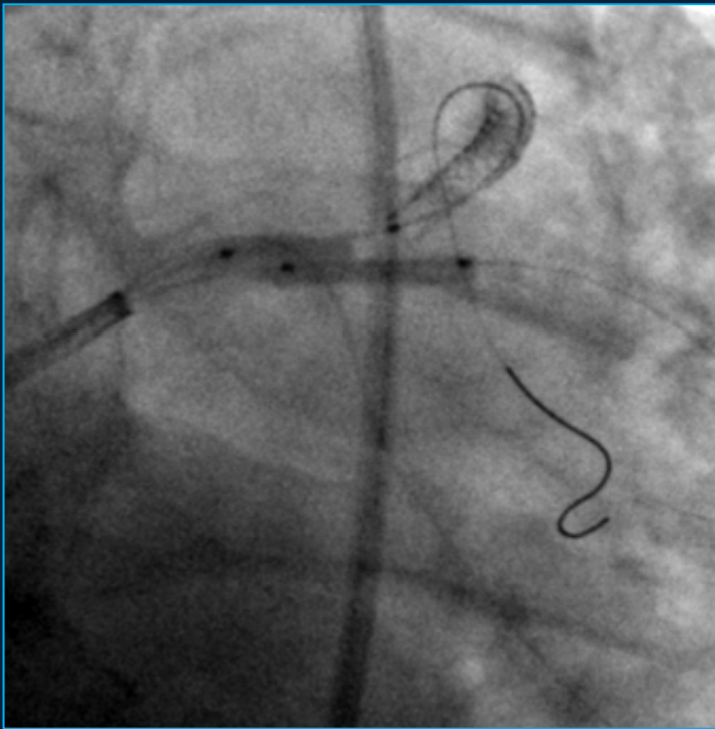


Baseline (Medina 0,1,1,0):

- Instant restenosis LADp
- Ostial LAD & intermediate branch stenosis



Case 2: LM Trifurcation With Proximal LAD Instant Restenosis & Ostial Intermediate Branch Stenosis

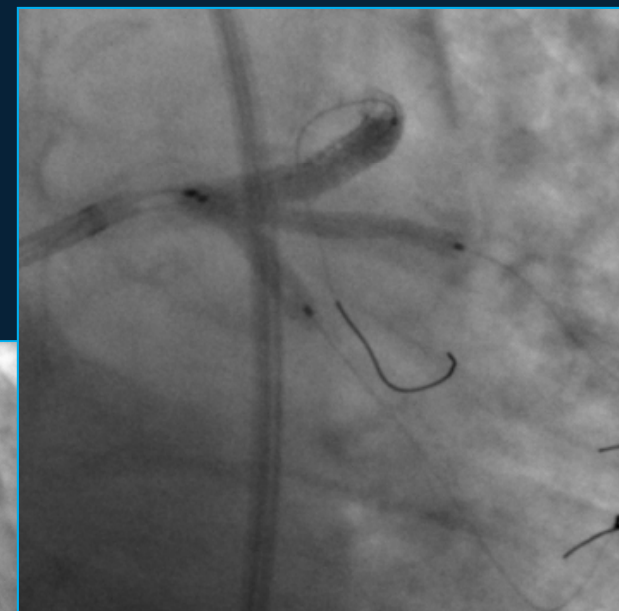
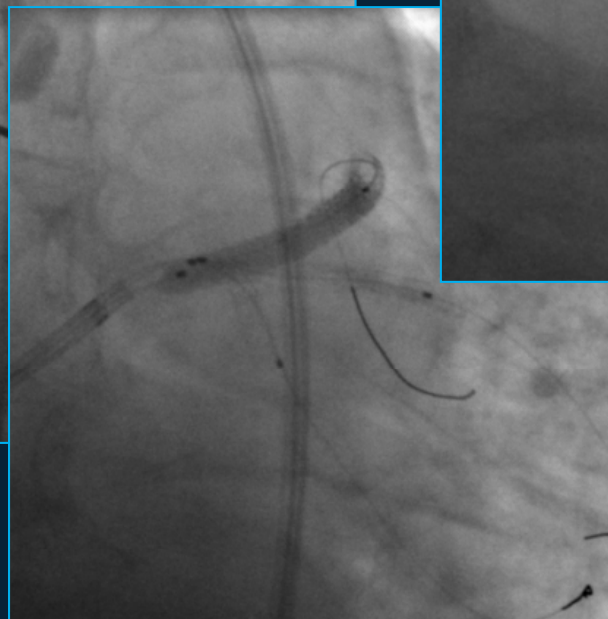
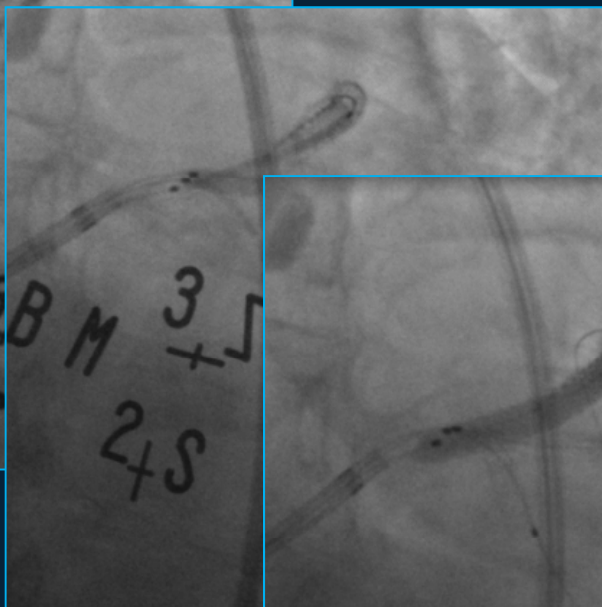
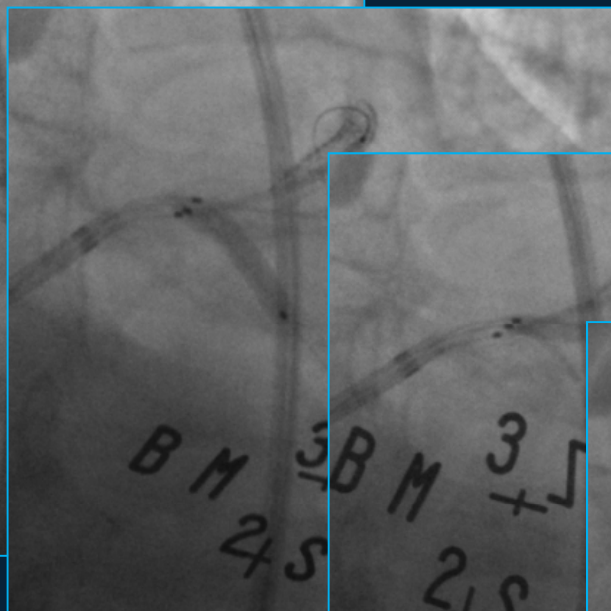
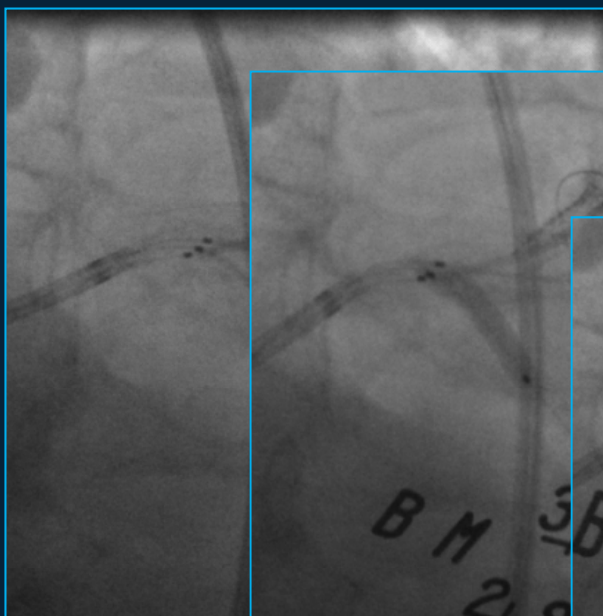


**Predilatation of LAD &
intermediate branch ostiae**



Pinching of LCX ostium

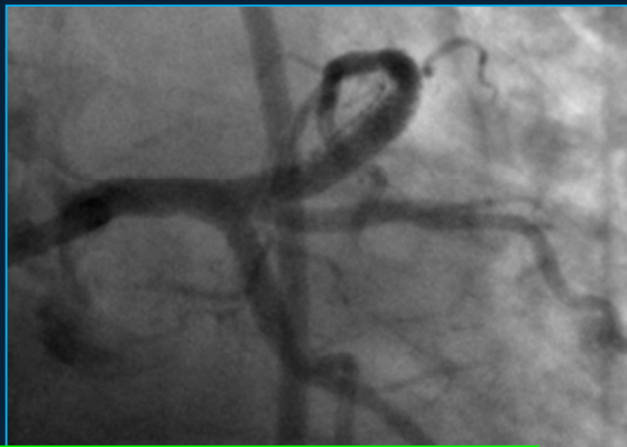
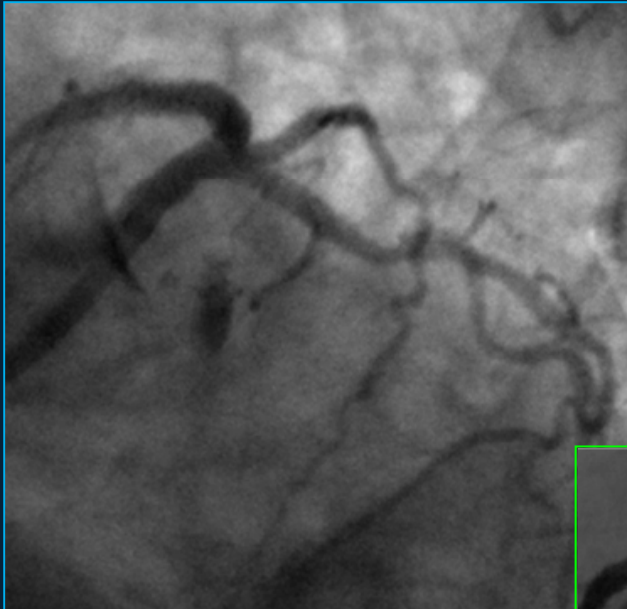
Case 2: LM Trifurcation With Proximal LAD Instant Restenosis & Ostial Intermediate Branch Stenosis



Triple kissing stent
(Biomatrix 3.5/28 mm
LM-LAD; Biomatrix
2.5/24 mm LM-interm;
Biomatrix 3.0/14 mm
LM-LCX)

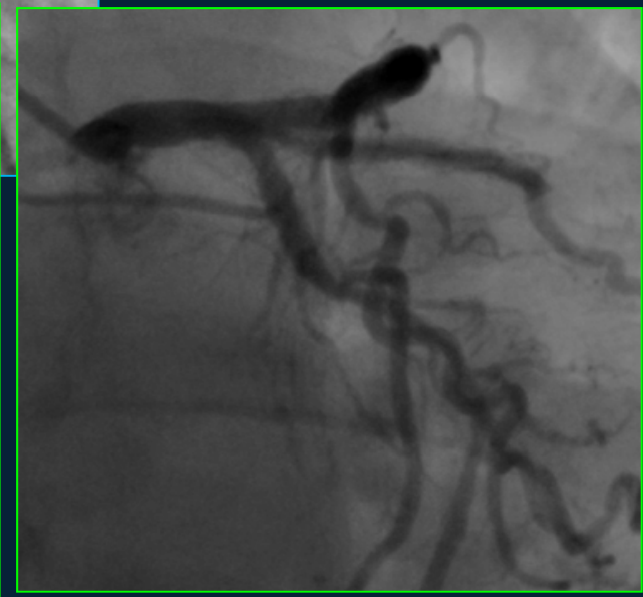
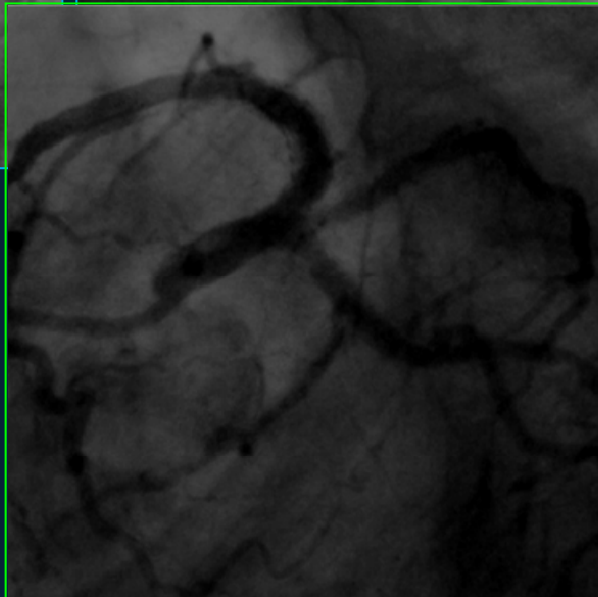
**Final triple kissing
balloon dilatation**

Case 2: LM Trifurcation With Proximal LAD Instant Restenosis & Ostial Intermediate Branch Stenosis

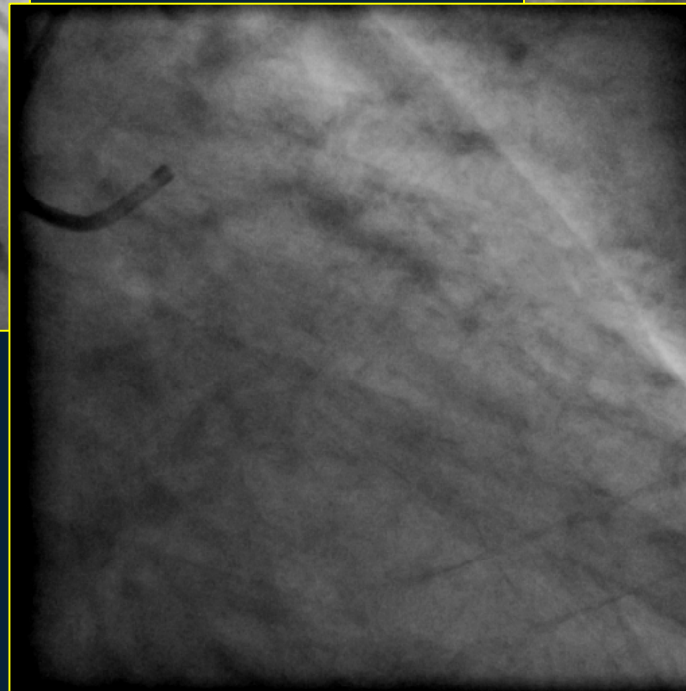


2 year f/up:
No restenosis

Final: Excellent result



Case 3: LM Trifurcation With Proximal LAD , Proximal LCX & Intermediate Branch Stenosis



Baseline

LM trifurcation stenosis &
90% stenosis of pLAD,
90% stenosis of pLCX,
70% stenosis of RI,

Case 3: LM Trifurcation

With Proximal LAD , Proximal LCX & Intermediate Branch Stenosis



Other stents:

BM 2.5/28 mm: pLAD

BM 2.8/28 mm: RI

BM 2.25/14 mm: pLCX



FINAL:

Triple kissing stent

BM 2.75/24 mm: LM-

LAD

BM 2.5/18 mm: LM-RI

BM 2.5/24 mm: LM-LCX

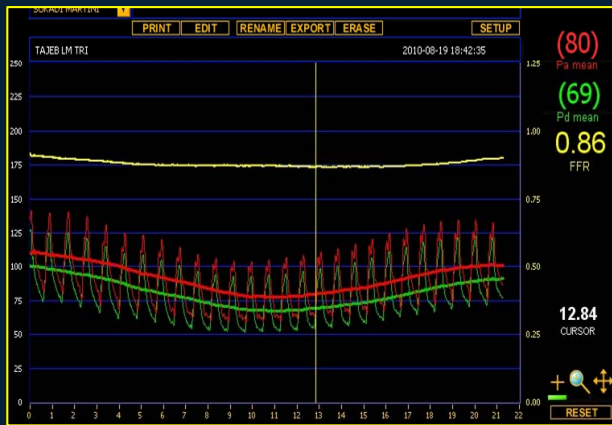


TOTAL:

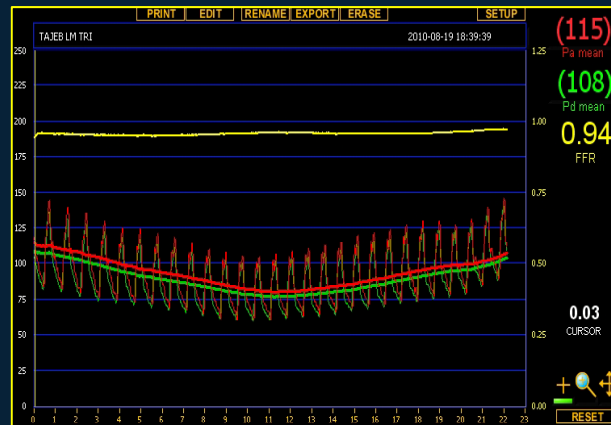
6 Biomatrix (BM)TM

Case 3: LM Trifurcation

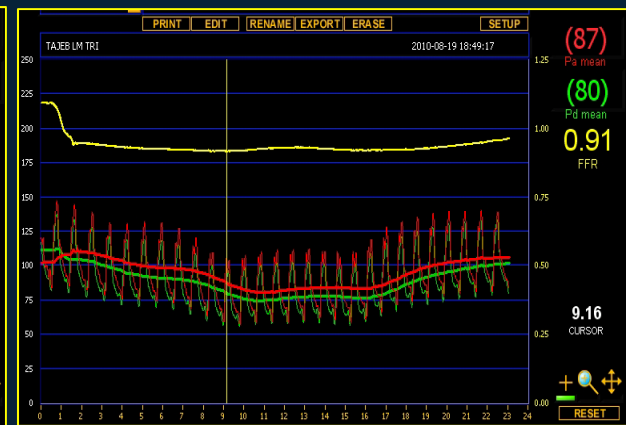
With Proximal LAD , Proximal LCX & Intermediate Branch Stenosis



FFR LAD = 0.86



FFR LCX = 0.94



FFR RI = 0.91

BIOMATRIX™:

Conclusion

The use of BioMatrix™ stent in **real world, complex Asian patients** has been demonstrated to be **safe and efficacious** up to 3-5 year follow-up with a **low incidence of MACE, TLR, stent thrombosis** as well as **low late loss and restenosis.**