From a DES to a BMS -Biodegradable Polymer Technology:

A Single Center Clinical Experience Using Biolimus A9™-Eluting Stent with Biodegradable Polymer

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Faculty Disclosure

I have no financial relationships to disclose!

Background: LEADERS out to 3-Years

1. *Overall population*

   With respect to MACE, Cardiac Death, MI & Clinically-indicated TVR, noninferiority of BES vs SES in all-comers population was sustained up to 3 years

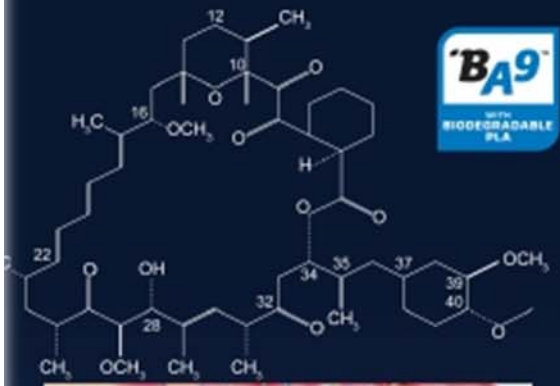
2. *Subgroup analysis*

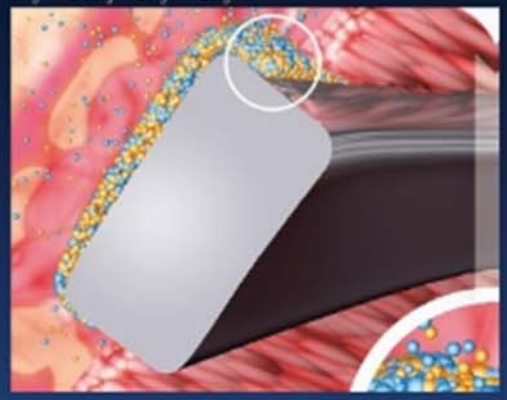
   Significant reduction of MACE with BES compared to SES in STEMI patients – (9.6% vs 20.7%)

3. *Very Late Stent Thrombosis*

   - *Definite VLST events were rare*
   - *No VLST events in BES patients b/w 2 & 3 year clinical FU*

Biolimus-A9™ Eluting Stent





- Biolimus is a semi-synthetic sirolimus analogue with **10x higher lipophilicity** and similar potency as sirolimus.
- Biolimus is immersed at a concentration of 15.6 μg/mm into a biodegradable polymer, polylactic acid, and applied solely to the **abluminal stent surface** by a fully automated process.
- Biolimus is co-released with polylactic acid and completely desolves into carbon dioxide and water after **a 6-9 months period**.
- The stainless steel stent platform has a strut thickness of 120 μm with a **quadrature link** design.

BioMatrix™ Single Center Registry

- ***Prospective, observational Single center registry*** *assessing clinical outcomes in* ***Real World, All-Comer*** *receiving BioMatrix™ DES* ***307 patients with 417 lesions*** *b/w Feb.2010 and Mar., 2011.*
- *No limit to the number of treated lesions, vessels, or lesion length and age of patients*
- ***Exclusion:***

  Contraindications to antiplatelet agents

  Short life expectance & serious medical illness

  Lack of patient' consent
- *Angiographic Follow-up @ 6 month*

  Clinical Follow-up @ 30 day, 6, 9 & 12 month
- ***Primary Endpoint:*** *TVR*
- ***Secondary Endpoints:*** *CV death, MI, TLR, stent thrombosis(ARC)*

  Late loss & binary restenosis
- ***DAPT*** *recommended for 6 month at least, & ASA indefinitely*

Patient Characteristics

Patients	n(%)307	LEADERS (n=857)
Age(yr)	67	65
Male sex	188(61%)	75%
Diabetes mellitus	107(34%)	26%
Hypertension	228(74%)	74%
Hyperlipidemia	147(47%)	65%
Current smoker	101(32%)	24%
Cerebrovascular disease	174(56%)	NA
Previous PCI/CABG	4(1.3%)	36%/10%
Renal insufficiency	47(15%)	NA
Ejection fraction (%)	61%	56%
Chronic stable angina	227(74%)	45%
Acute coronary syndrome	80(26%)	55%

NA=not available

Lesion Characteristics

Lesions(N=417)		LEADERS
Multivessel disease(±LM stenosis)	91(21.8%)	24.4%
LM stenosis	9(2%)	1.6%
Thrombotic lesion	40(9.6%)	NA
Small vessel(<2.5mm)	72(17.4%)	68%(<2.75mm)
Total occlusion(±thrombotic)	64(15.3%)	12%
Chronic(CTO)	40(9.6%)	NA
Bifurcation lesion(side branch>2mm)	87(20.8%)	30%
Ostial lesion	37(8.9%)	NA
Restenotic lesion	7(1.7%)	5%
Severe calcification	42(9.8%)	13%
Long lesions(≥25mm)	93(22.5%)	30.6%

NA=not available

Procedural Results

Lesions	N=417	LEADERS
Procedural success rate[1]	100%	98.6%
Number of stents per lesion	1.3±0.6	1.3±0.7
Number of stents per patient	1.7±0.5	NA
Total stent length per lesion (mm)	24.7±15.5	24.7±15.5
Total stent length per patient (mm)	33.4±27.1	NA
Maximal stent diameter per lesion (mm)	3.1±0.7	3.0±0.4
Maximal pressure (mmHg)	16.0±4.0	NA
Use of IVUS	12(3%)	NA
Use of glycoprotein IIb-IIIa inhibitors	25(8%)	NA

NA=not available

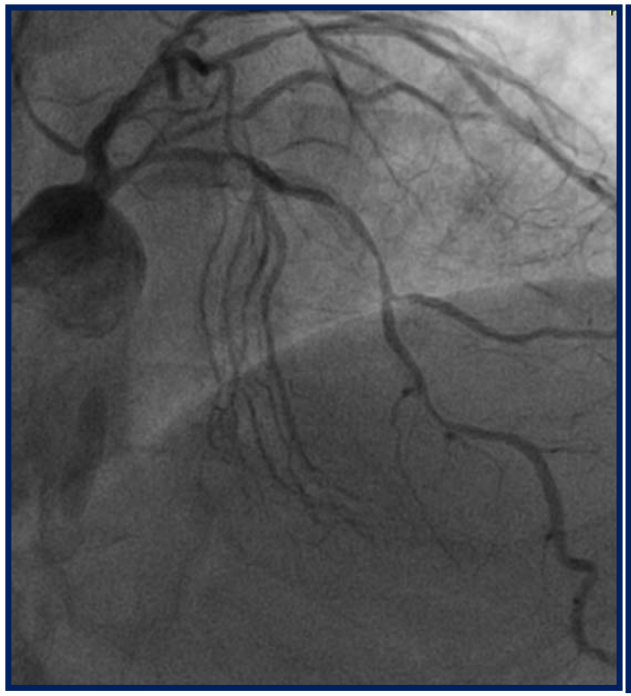
[1]Procedural Success: achievement of final in-stent diameter stenosis of <30%(visual estimate) by using any percutaneous method, without the Occurrence of in-hospital MACE

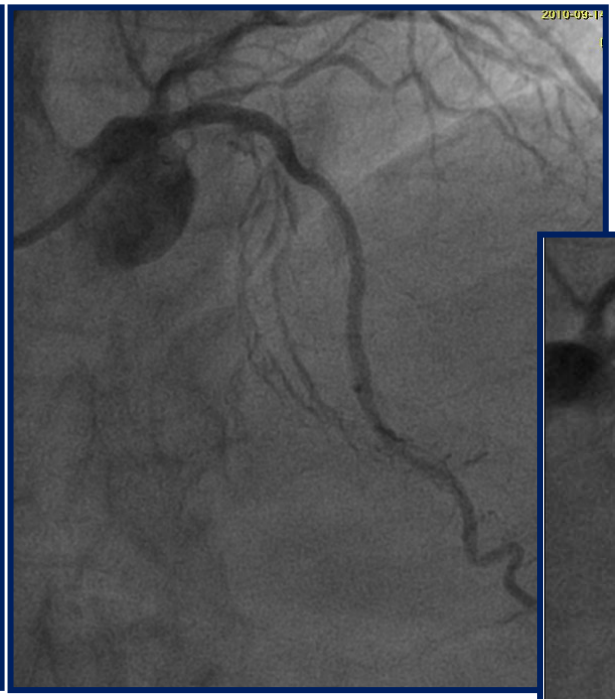
Procedural Results

Quantitative Coronary Analysis	N=417	LEADERS
Reference vessel diameter(mm)	3.07±0.47	2.6
Minimal luminal diameter(mm)		
In-stent	2.83±0.56	2.33
In-segment	2.83±0.57	2.03
Diameter stenosis(%)		
In-stent	7.8±5.7	15.09
In-segment	7.9±5.3	23.32
Acute gain(mm)		
In-stent	**2.53±0.57**	**1.41**
In-segment	**1.49±0.55**	**1.11**

CASE 1: Multivessel Disease

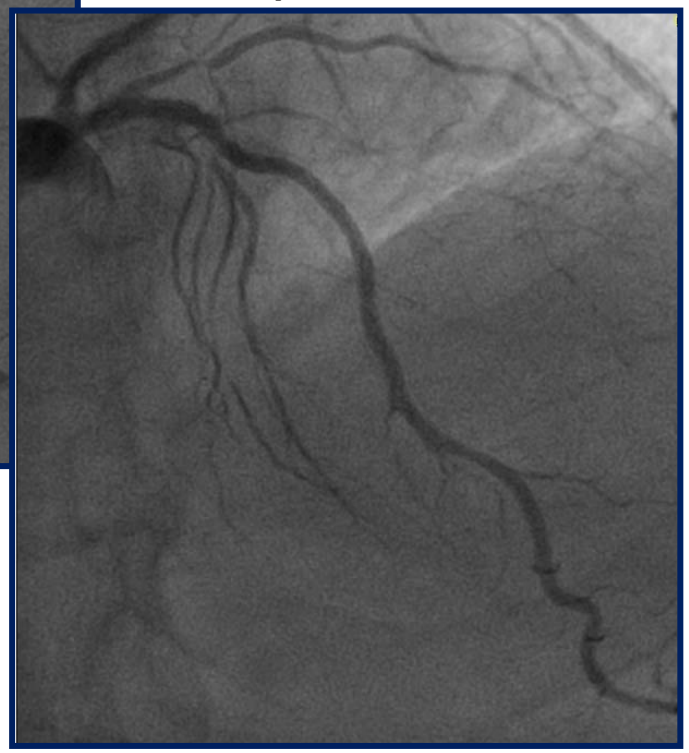
Diffuse, calcified LAD stenosis & prox. RCA stenosis





Baseline

Final:
After Placement of
3 overlapping BioMatrix™
(3.0/28, 2.75/28 &
2.5/24mm), 3.0/18mm for RCA



6 month f/up:
No restenosis

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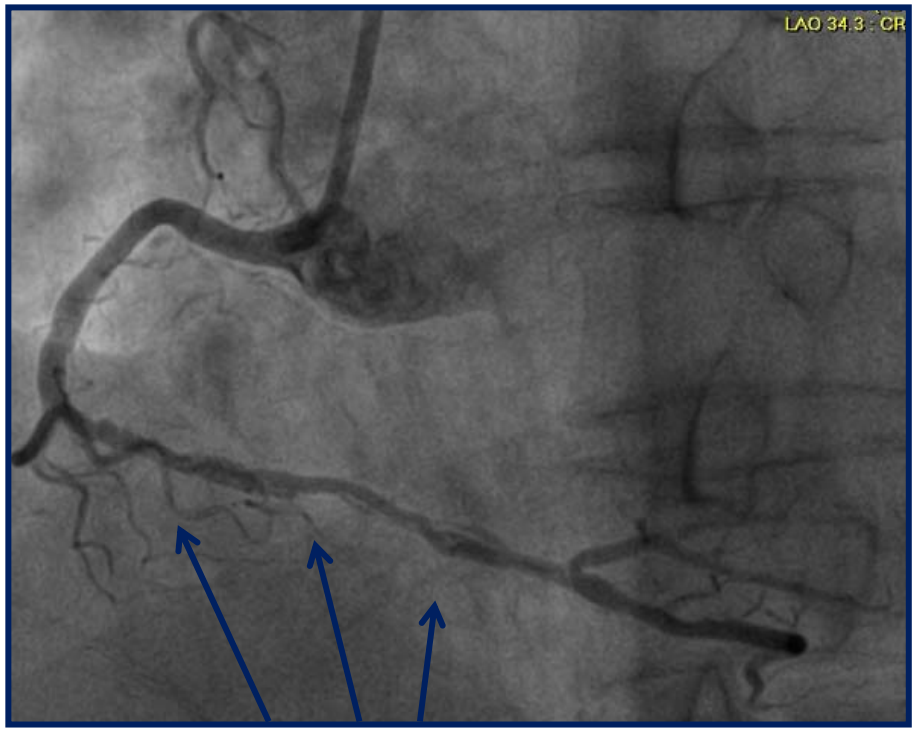
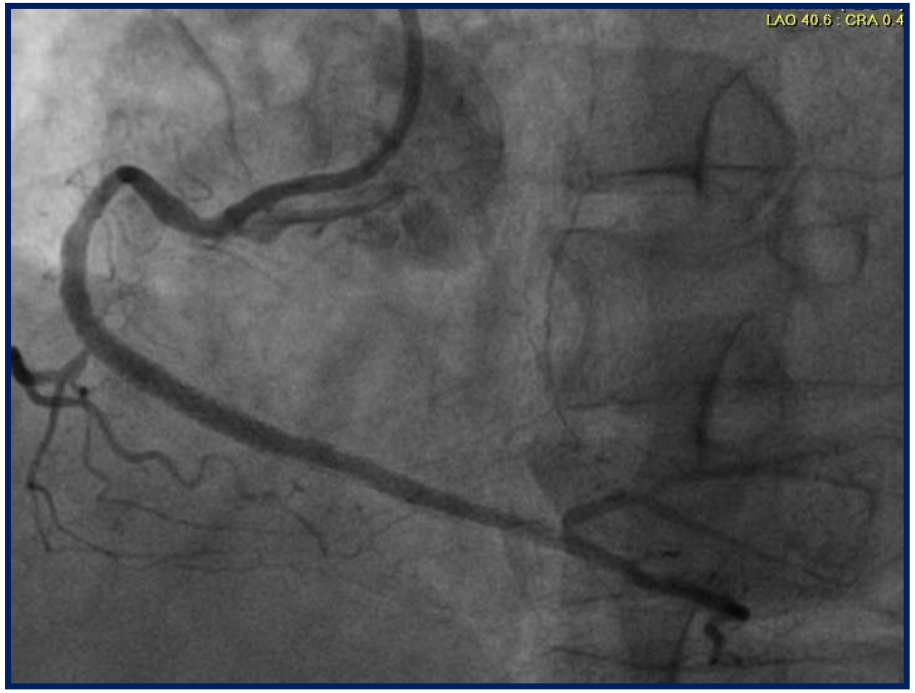
CASE 2: Restenotic Lesion

ISR with Diffuse, total occlusion of distal RCA



Baseline: diffuse stenosis of
Distal RCA with organized thrombus
Or spontaneous dissection

Final: After Placement of 2
overlapping Endeavor
(3.0/30 & 2.75/30mm)



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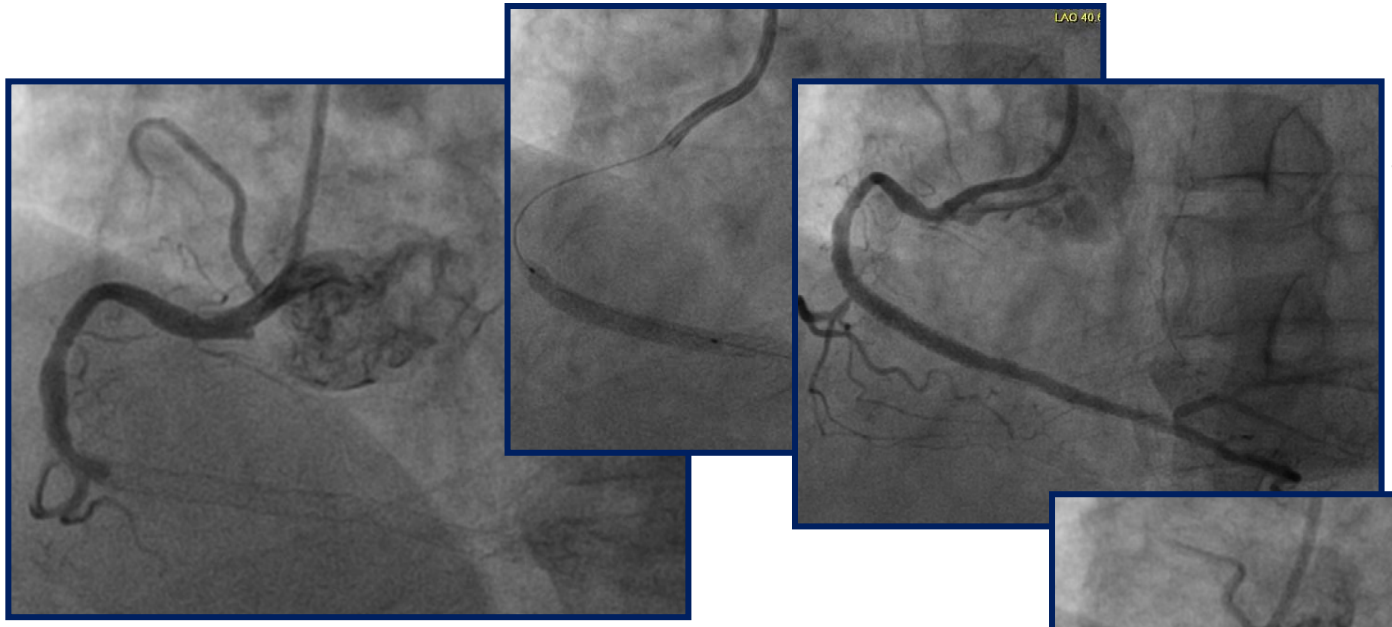
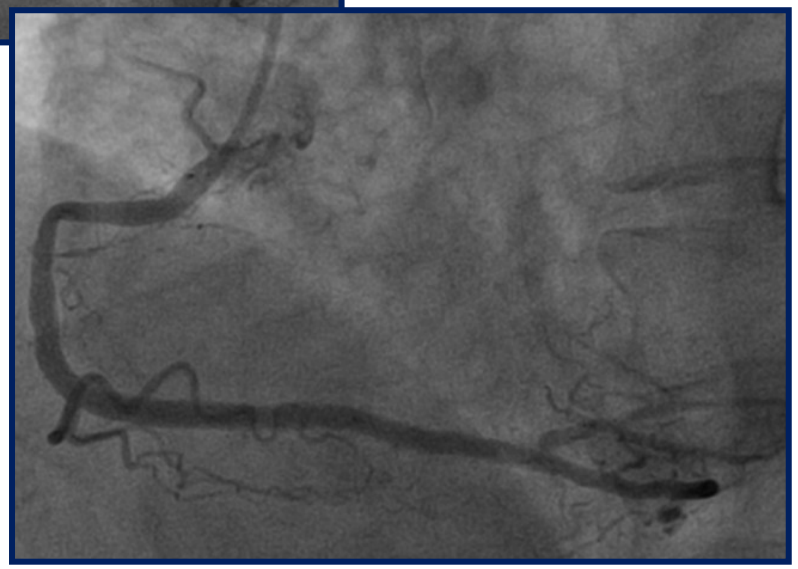


7 month f/up:
ISR, diffuse,
total Occlusion

Final: After Sequential ballooning & Placement of BioMatrix™ 3.0/28mm



6 month f/up:
No restenosis

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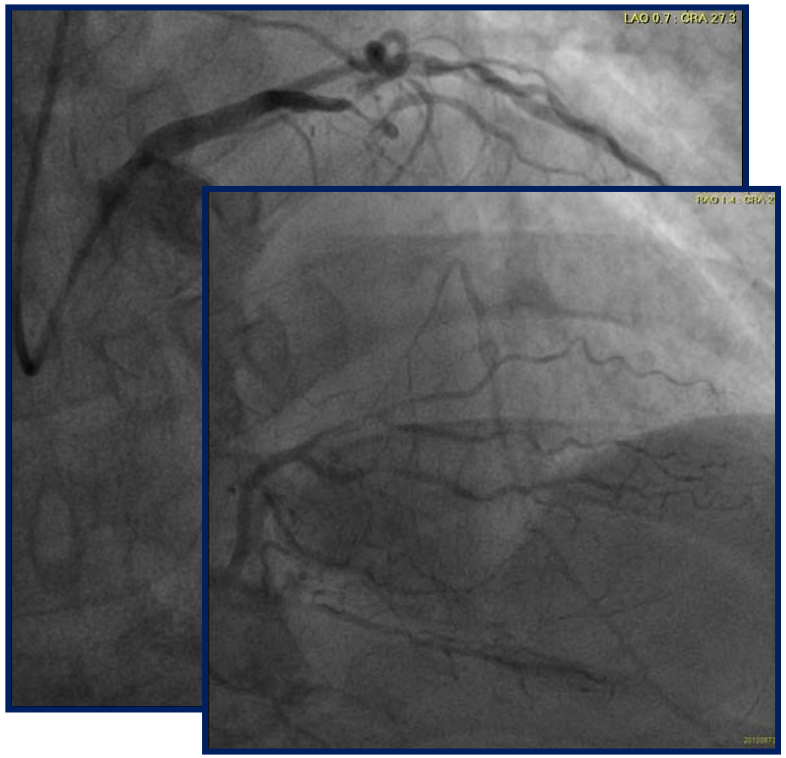
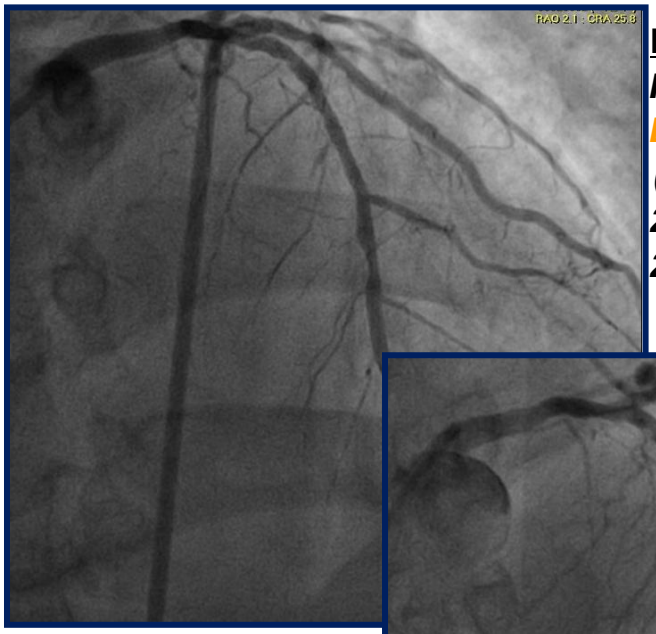
CASE 3: Chronic Total Occlusion

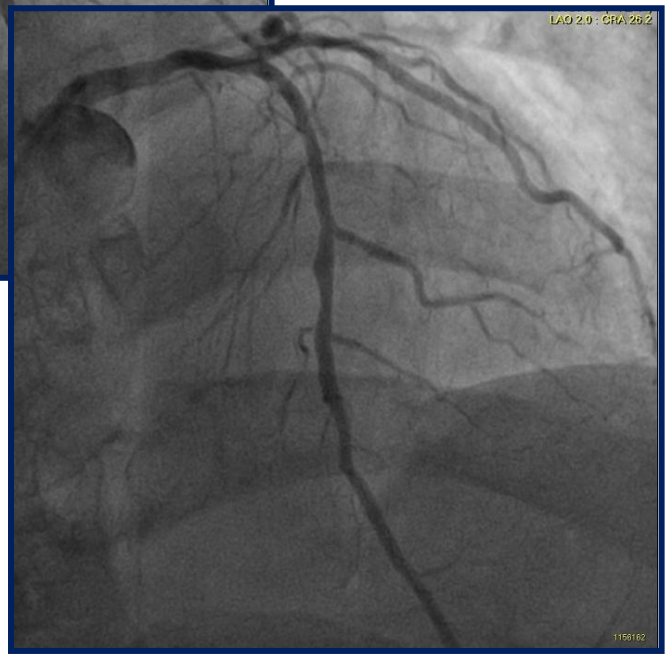
with LAD CTO & Diffuse stenosis of LCX



***Baseline**: prox. LAD CTO with good collateral flow from RCA*



Final: *After Placement of BioMatrix™ (3.0/28, 2.75/18mm) 2.75/18mm for LCX*



***8 month f/up**:*
No restenosis

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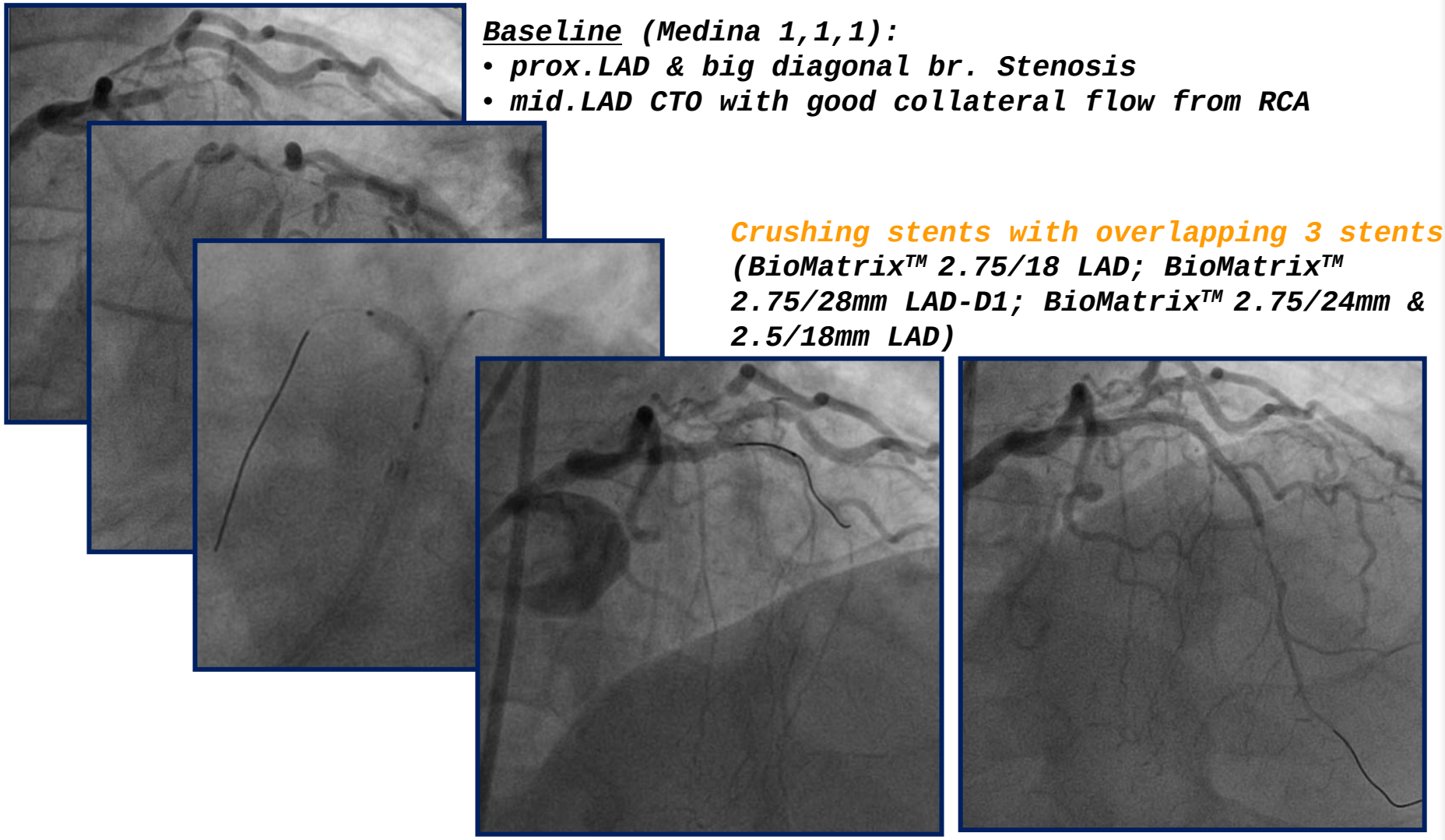
Case 4: LAD Bifurcation Stenosis

With mLAD CTO



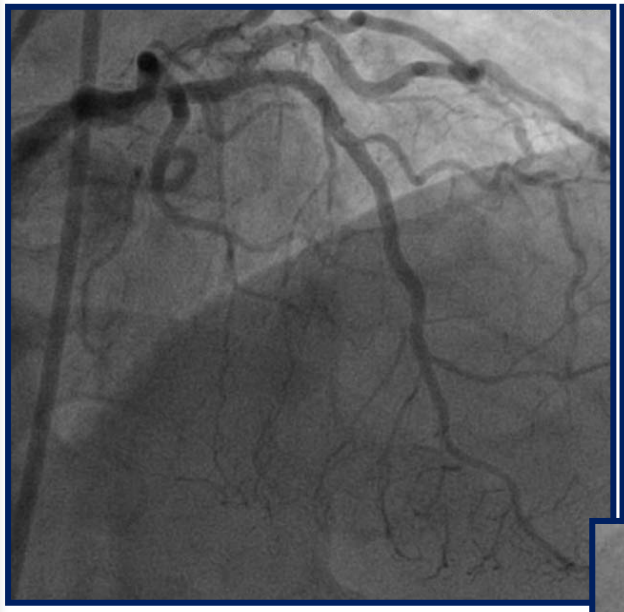
Baseline *(Medina 1,1,1):*

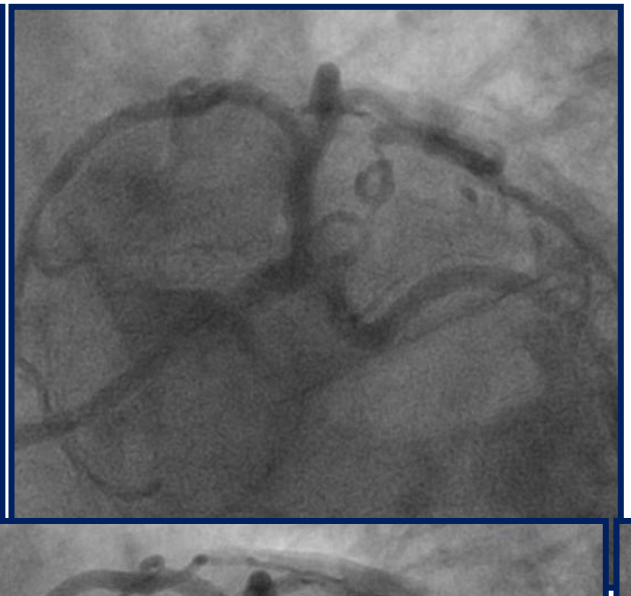
- *prox.LAD & big diagonal br. Stenosis*
- *mid.LAD CTO with good collateral flow from RCA*

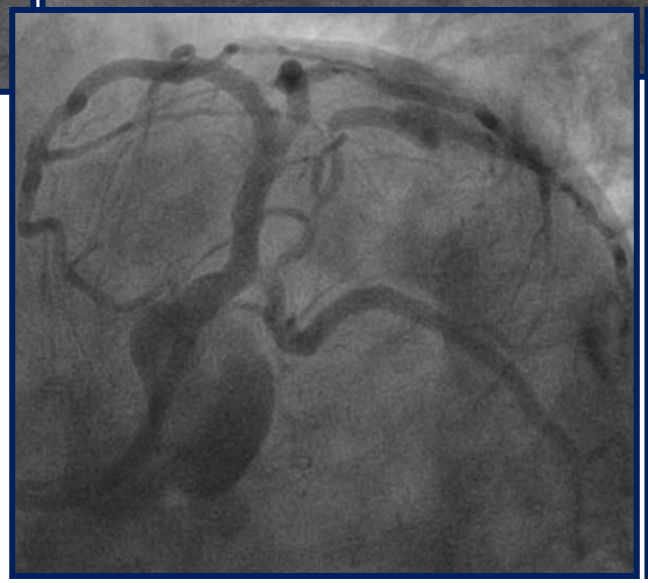
Crushing stents with overlapping 3 stents
(BioMatrix™ 2.75/18 LAD; BioMatrix™ 2.75/28mm LAD-D1; BioMatrix™ 2.75/24mm & 2.5/18mm LAD)

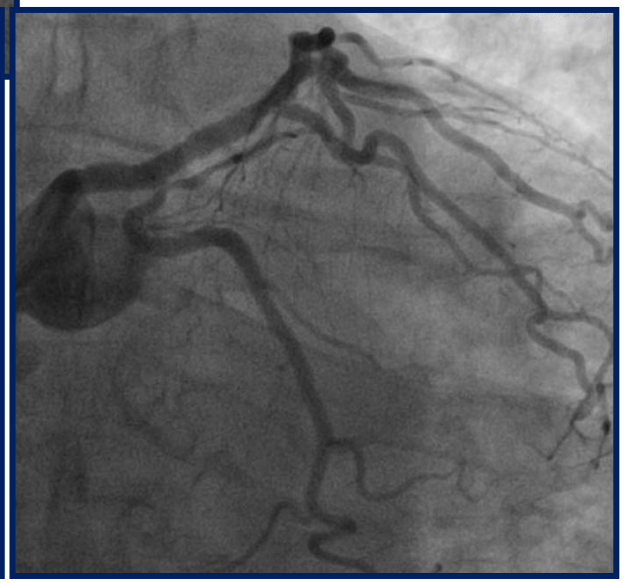
Case 4: LAD Bifurcation Stenosis

With mLAD CTO









***Final**: excellent result*

Total:
4 BioMatrix™

***7 month f/up**: No restenosis*

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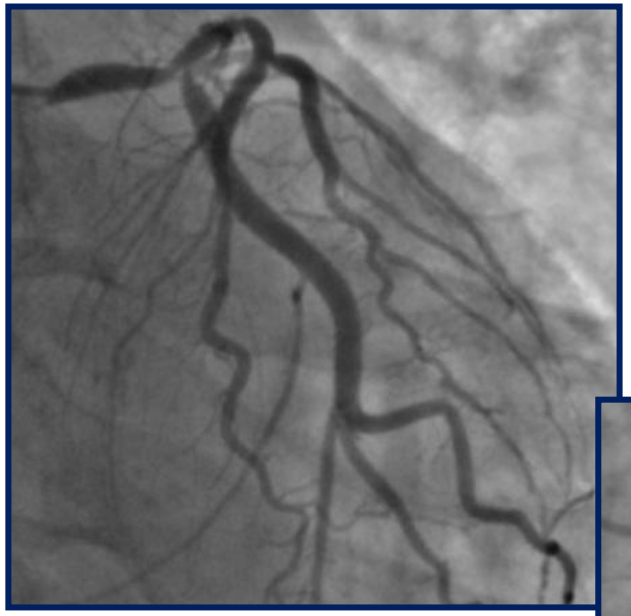
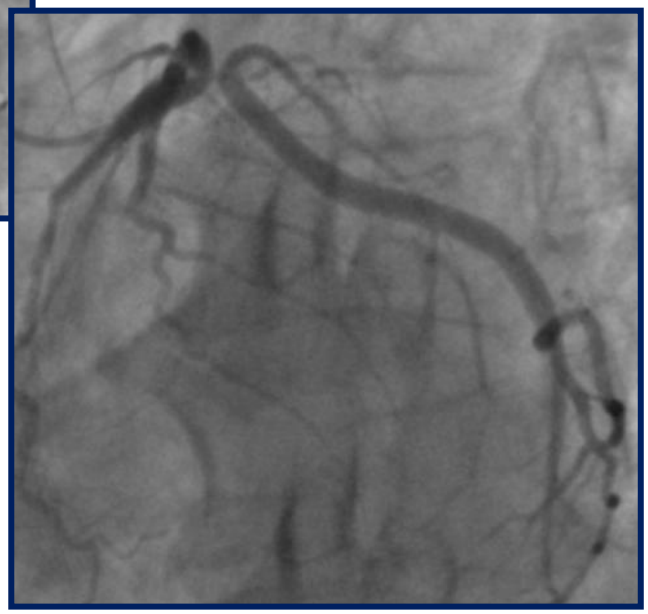
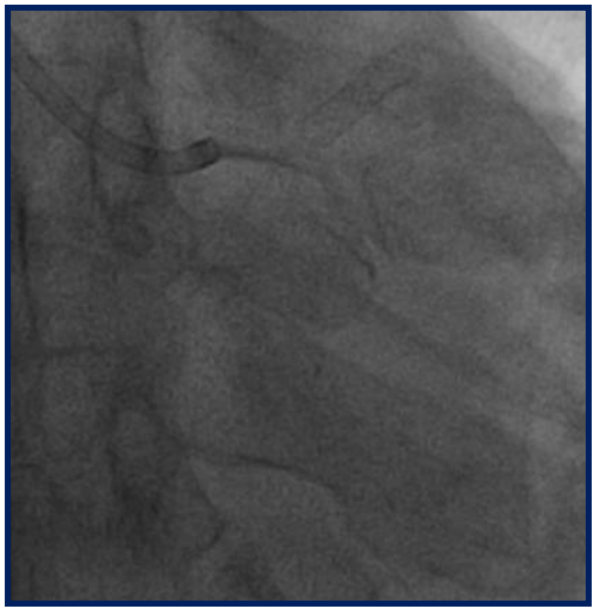
Case 5: LM Bifurcation Stenosis

With proximal LAD ISR & ostial LCX stenosis





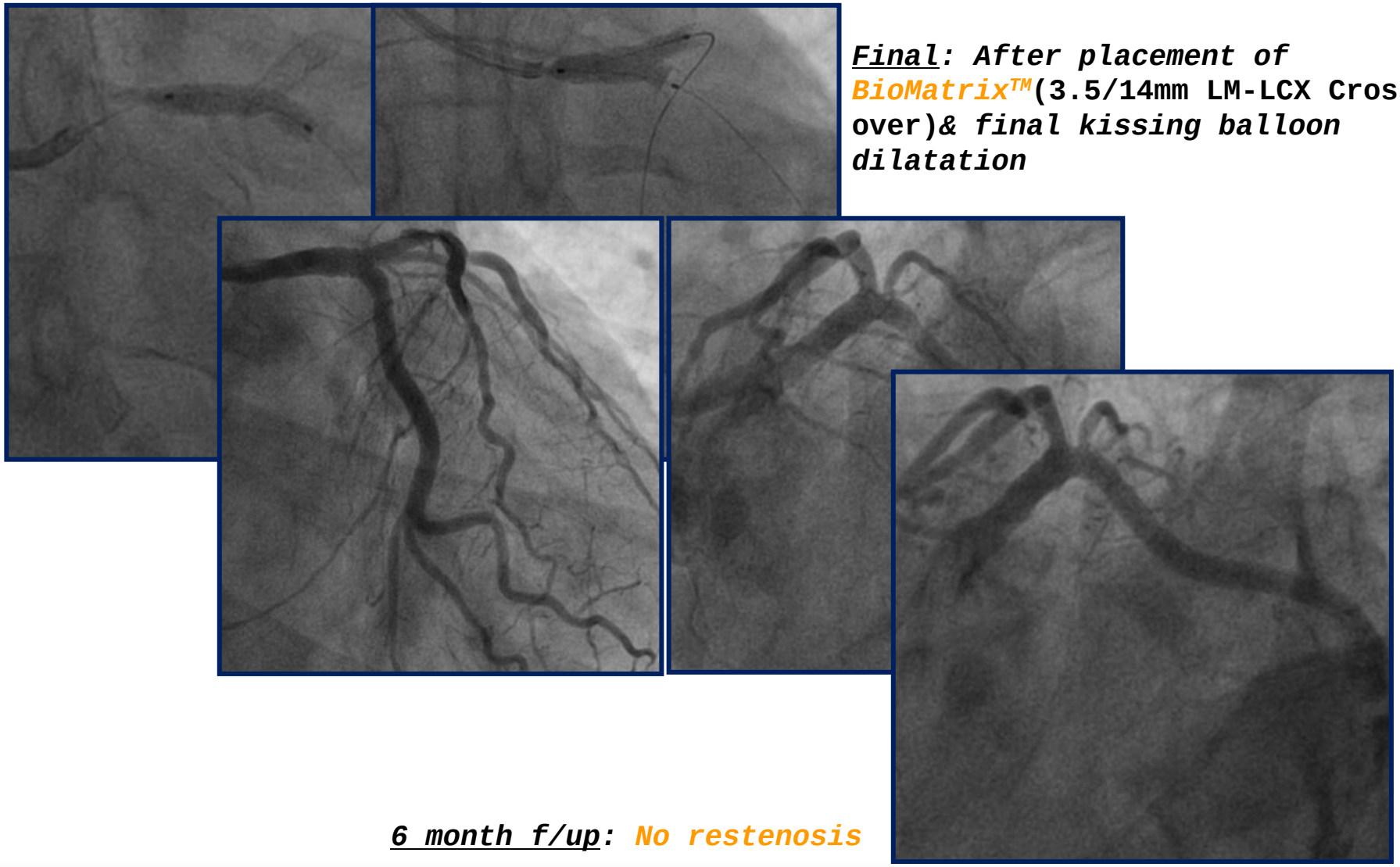


***Baseline** (Medina 1,1,1):*

- *In-stent restenosis pLAD*
- *Ostial LCX stenosis*

Case 5: LM Bifurcation Stenosis

With proximal LAD ISR & ostial LCX stenosis



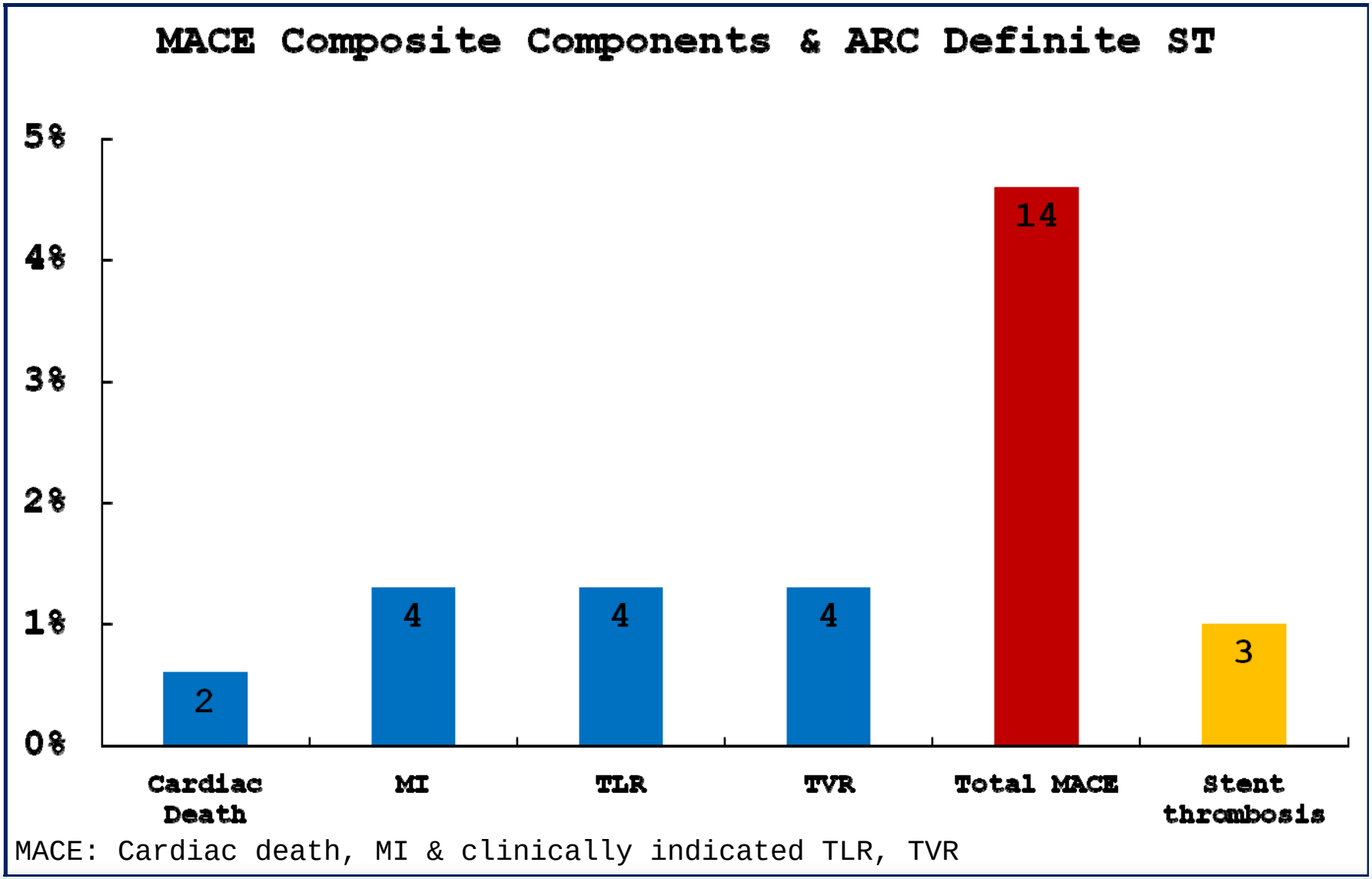
***Final**: After placement of BioMatrix™(3.5/14mm LM-LCX Cross-over)& final kissing balloon dilatation*

***6 month f/up**: No restenosis*

Angiographic Follow-up @ 6 months

Quantitative Coronary Analysis	N=135/417	LEADERS
Reference vessel diameter(mm)	3.06±0.57	2.82
Minimal luminal diameter(mm)		
In-stent	2.71±0.66	2.23
In-segment	2.72±0.57	2.01
Diameter stenosis(%)		
In-stent	11.6±10.7	20.9
In-segment	11.2±10.7	27.1
Late loss(mm)		
In-stent	**0.12±0.47**	**0.13**
In-segment	0.11±0.45	0.08
Binary restenosis		
In-stent	**3/102(3.0%)**	**3.1%**
In-segment	**1/102(1.0%)**	**1.1%**

12-month Safety Endpoints



MACE: Cardiac death, MI & clinically indicated TLR, TVR

Safety in Patients with Stroke

Outcomes (%)	Stroke (n=174)	Non-stroke (n=133)	P value
Death	0.6%(1)	1.5%(2)	<0.05
Cardiac death	0.6%(1)	0.8%(1)	NS
Myocardial infarction	1.2%(2)	1.5%(2)	NS
Any TLR	1.7%(3)	0.8%(1)	NS
Clinically indicated TLR	1.7%(3)	0.8%(1)	NS
Any TVR	1.2%(2)	1.5%(2)	NS
Clinically indicated TVR	1.2%(2)	1.5%(2)	NS
MACE*	4.6%(8)	4.5%(6)	NS
Stent thrombosis	1.2%(2)	0.8%(1)	NS

* Cardiac death, MI, clinically indicated TLR, TVR
Stent thrombosis=#ARC definite or probable ST

BioMatrix™ Clinical Experience

	LEADERS			Single-Center		
Event	1 mo	9 mo	1 yr	1 mo*	9 mo*	1 yr*
N(cumulative)				274 (89%)	163 (53%)	28 (9.1%)
MACE			10.7%	2.2%	5.5%	0%
Death	0.8%	2.6%	3.2%	0.7%	0.6%	0%
-Cardiac	0.7%	1.6%	2.1%	0.7%		
-Non-cardiac	0.1%	1.0%	1.1%	0%	0.6%	
Q MI	0.4%	0.5%	0.5%	0.7%		
NQ MI	0.5%	5.3%	5.4%	0.7%	0%	0%
Any TLR	1.8%	5.4%	NA	0%	2.5%	0%
Any TVR	1.4%	4.4%	NA		2.5%	0%
Stent thrombosis	2.1%	0.5%	1.6%	1.1%	0%	0%

NA=not available, Stent thrombosis=#ARC definite or probable ST

*Non cumulative figure

Conclusion

- *Limitations of small sized nonrandomized, non-comparative study*
- *BioMatrix™ single-center registry represents:*
  - *All-comer patients following standard practice*
  - *No limit to lesion length, multi-vessels and multi-lesions*
  - *A patients population largely comparable to published study populations*
- *The use of BioMatrix™ in routine clinical practice has produced a excellent safety & efficacy profile with a*
  - *5% of MACE rate,*
  - *No additional ST after 1 month*