2019 euro PCR

MeRes-1 Extend: Imaging and two-year clinical outcomes of thin strut sirolimus-eluting bioresorbable vascular scaffold in patients with coronary artery disease

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For The MeRes-1 Extend Investigators

Disclosure Statement of Financial Interest

I do have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation, they are:

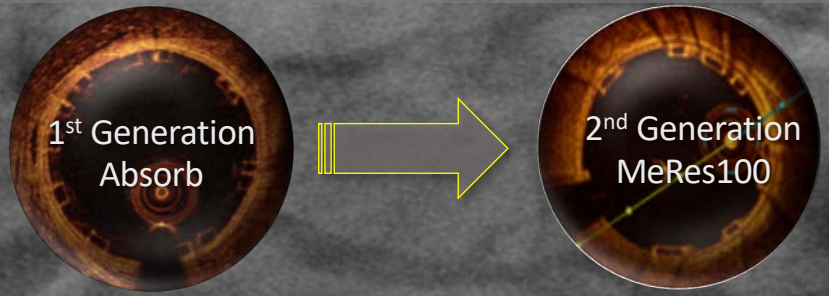
Affiliation/Financial Interest:	**Name of Organization:**
Scientific Advisor	Meril Life Sciences Pvt. Ltd.

BRS Under Siege – Due to Bulky 1st Gen BVS

- Large strut thickness
- Bulky, high profile device
- Compromised radiopacity
- Limited size matrix
- Storage conditions
- Shelf life constraints
- Increased dependence on imaging (IVUS/OCT)
- Difficult to re-cross
- Overlapping not ideal
- Learning curve
- Poor clinical performance in small diameter vessels (Scaffold Thrombosis)

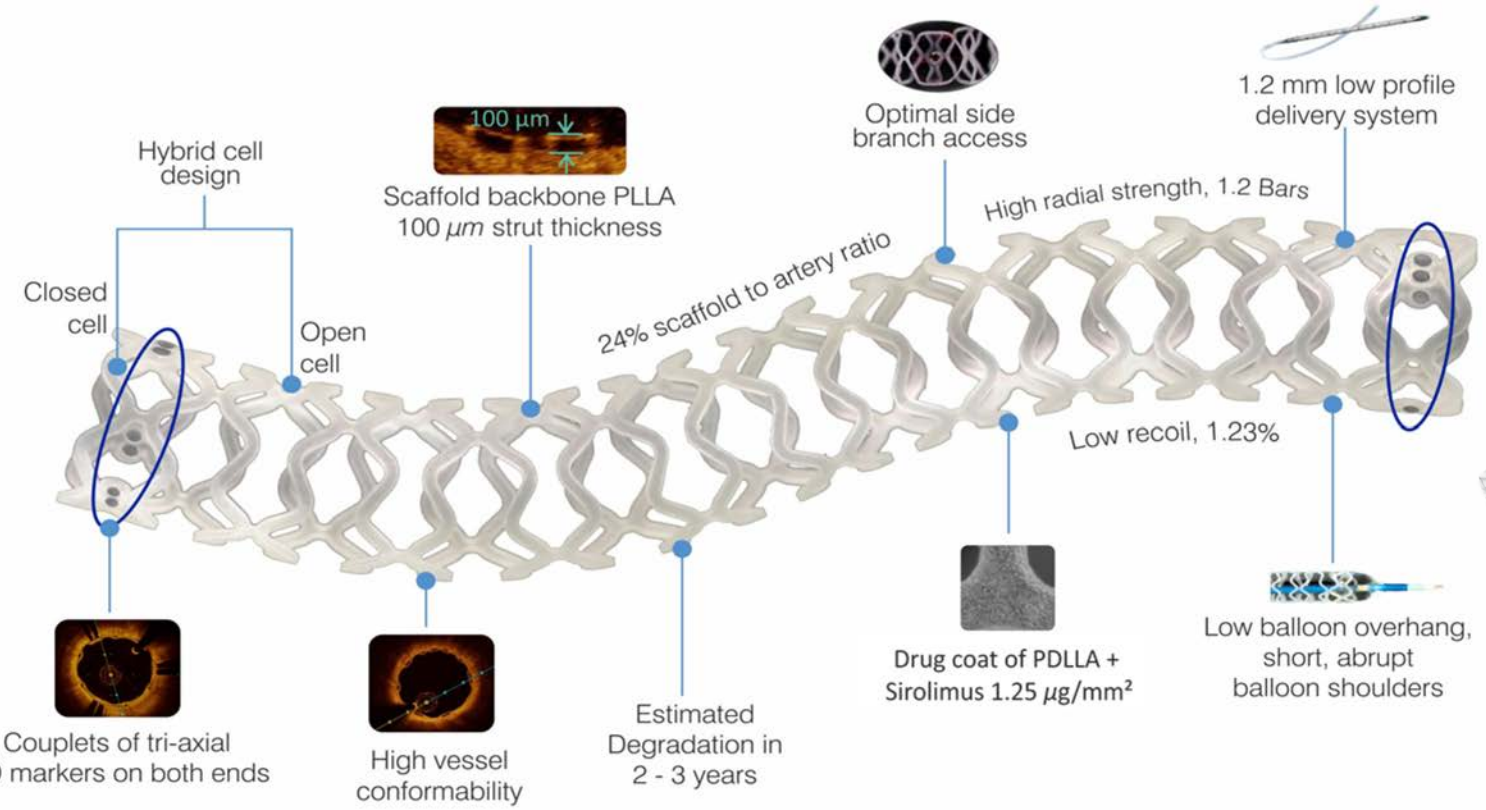
Drivers of BRS Adoption

Acute Performance & Long Term Safety and Efficacy



- Reduced strut thickness, profile for deliverability
- Large size matrix to cover multitude of morphologies
- Ability to treat lesions across clinical spectrum
- No increase in Tx duration or hardware consumed
- Regular Cath-lab storage conditions & long shelf life

MeRes100 (100µm BRS)
Sirolimus-Eluting Bioresorbable Vascular Scaffold



MeRes100 - BRS
Global Clinical Program

MeRes-1[1] (n=108)
FiM, Single, denovo lesions.
13 Indian Sites

MeRes-1 Extend[2] (n=64
Single, denovo lesions
8 Global Sites

MeRes100 Global[3] (n=2,000)
All comers, real world registry.
100 participating sites global.

MeRes-Evolve[4] (n=800)
RCT MeRes100 Vs XIENCE
30 participating sites global

MeRes100-China[5] (n=1,242)
RCT 242:242 MeRes100 Vs XIENCE
+ 800 MeRes100. 1 year MACE, ST

MeRes100-US/JPN[6] (n=2,000)
RCT MeRes100 Vs XIENCE
1 year MACE, ST

>5,000 Patients
Global Clinical Program

1-2. Achieved Primary Objective 3-6. Planning phase.

MeRes-1 Extend
Study Design

First-in-man safety and efficacy in patients with single, de-novo coronary lesion (in up to 2 vessels) treated by a single MeRes100 scaffold up to 24mm length

Clinical follow-up

N = 64	30-day	6-months	1-year*	2-years	3-years
Clinical follow-up	64	64	**64**	64	64
Angiographic follow-up	-	32	-	32	-
OCT follow-up	-	24	-	-	24

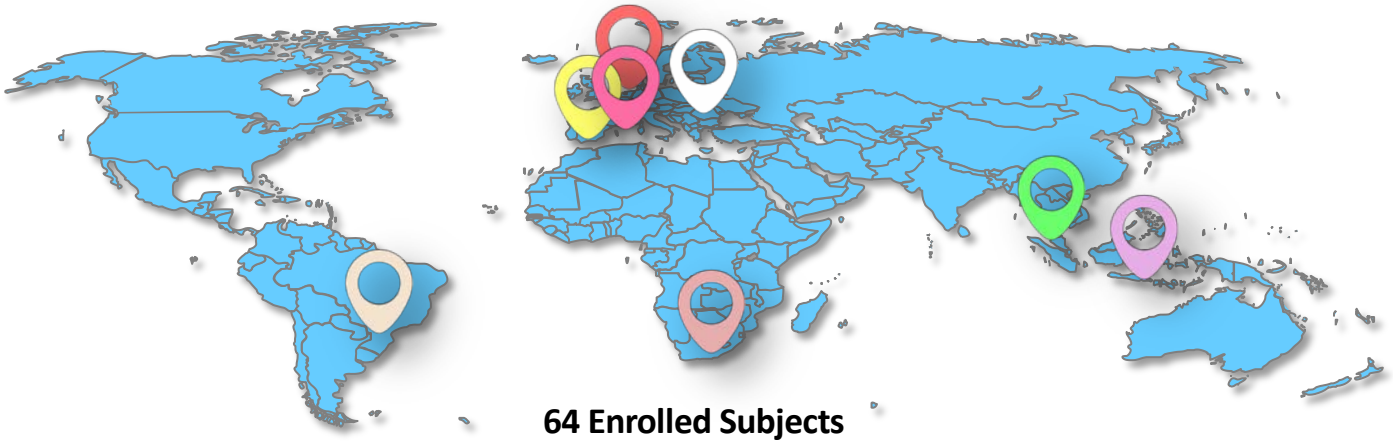
*QCA, OCT follow-up

Diameters – 2.75, 3.00, 3.50 mm
Length – 19, 24 mm

PI – **Dr. Alexandre Abizaid, Dante Pazzanese, Sao Paulo**
Core Labs
Angiographic – Cardiovascular Research Center, Sao Paulo, Brazil
OCT – Cardialysis, Rotterdam, The Netherlands
Data Management
CRO – JSS, New Delhi, India

***1-year data presented during EuroPCR 2018**

MeRes-1 Extend
Sites



64 Enrolled Subjects

Dr. Alexandre Abizaid, Sao Paulo	Dr. Sasko Kedev, Skopje
Dr. Robert-jan Van Geuns, Rotterdam	Dr. Rosli Mohd. Ali, Kuala Lampur
Dr. Bernard Chevalier, Paris	Dr. Teguh Santoso, Jakarta
Dr. Angel Cequier, Barcelona	Dr. Farrel Hellig, Johannesburg

MeRes-1 Extend
Key Eligibility Criteria

Key Inclusion Criteria

- Age >18 years
- Maximum 2 lesions in native coronary arteries (1 lesion/vessel)
- Reference vessel diameter 2.75-3.50mm
- Lesion length ≤ 20 mm
- Stenosis ≥ 50% & < 100%. TIMI ≥ 1
- Type A/B1 lesions

Key Exclusion Criteria

- Acute MI <7 days of Tx
- History of PCI or CABG
- LVEF ≤ 30%
- Ostial lesion (within 3mm)
- Lesion location in left main
- Lesion within 2 mm of origin of LAD, LCX
- Moderate to severe calcification, aneurysm
- Bifurcation, Side branch >2mm in diameter
- Extreme tortuosity, angulation ≥ 90°
- Creatinine ≥ 1.3 mg/dL

Major Clinical Endpoints

- **Safety**
  - Primary Endpoint:
    - MACE at 6-months (Cardiac death, MI, ID-TLR)
  - Secondary Endpoints:
    - Device & procedure success
    - Scaffold thrombosis (ARC defined)

- **Efficacy**
  - QCA: Late lumen loss (in-scaffold/in-segment)
  - OCT: Minimum lumen area (flow area), NIH area

Baseline Characteristics in the ITT Population

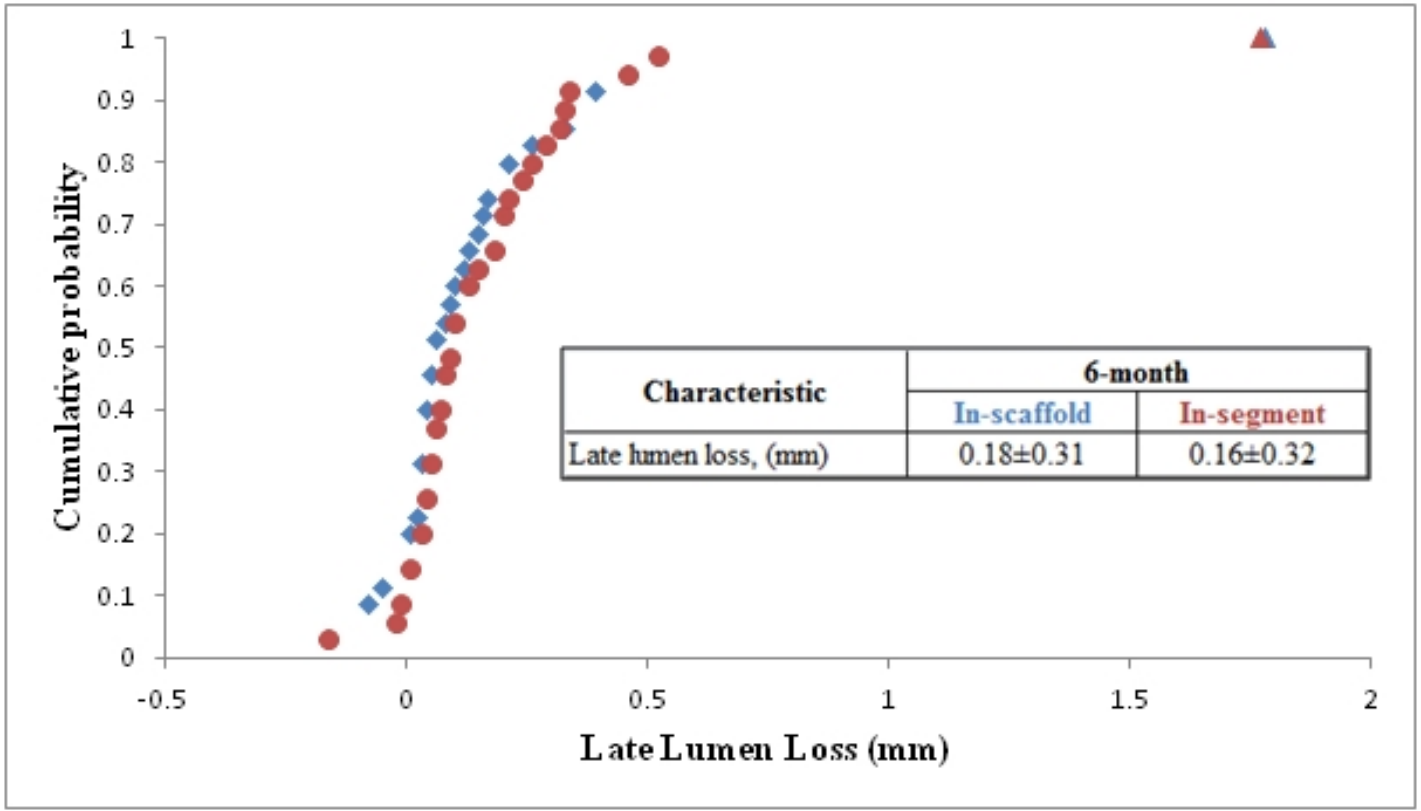
Variables	n = 64 Patients
Age (years), mean ± SD	58.30±9.02
Male, n (%)	44 (68.8)
Current smokers, n (%)	23 (35.94)
Diabetes mellitus, n (%)	17 (26.56)
Dyslipidemia, n (%)	31 (48.44)
Hypertension, n (%)	49 (76.56)
Previous myocardial Infarction, n (%)	18 (28.13)
Clinical presentation, n (%)	
Stable angina	44 (68.75)
Unstable angina	6 (9.38)
Silent ischemia	14 (21.88)
LVEF (%)	59.61±8.75

Cumulative MACE event till 24-month follow-up

Events, n (%)	1-months N=62*	6-month N=62	12-month N=62	24-month N=62
MACE	**0 (0.0%)**	**1 (1.61 %)**	**1 (1.61 %)**	**1 (1.61 %)**
Cardiac death	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myocardial infarction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ID-TLR	0 (0.0%)	1 (1.61 %)	1 (1.61 %)	1 (1.61 %)
Scaffold thrombosis	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**
Non-cardiac death	0 (0%)	0 (0%)	0 (0%)	0 (0%)

***Data presentation is for PTE population**

Cumulative Frequency Distribution Curve for In-scaffold Late Lumen Loss



Characteristic	6-month	
	In-scaffold	In-segment
Late lumen loss, (mm)	0.18±0.31	0.16±0.32

Angio QCA – CRC, Sao Paulo, Brazil

Paired OCT Analysis (n=21 patients)

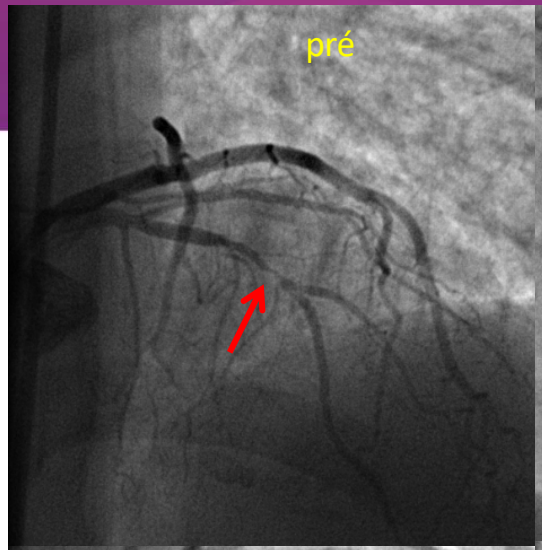
Characteristic	Post-procedure	6-month[#]
Mean flow area, (mm^2)	6.7±1.7	6.0±1.8
Minimum lumen area, (mm^2)	5.5±1.4	4.2±1.2
Mean scaffold area, (mm^2)	7.4±1.7	7.6±1.8
Minimum scaffold area, (mm^2)	6.1±1.5	5.9±1.4
Mean neointimal hyperplasia area, (mm^2)	-	1.5±0.5
Covered struts, (%)	**-**	**97.9±3.7**

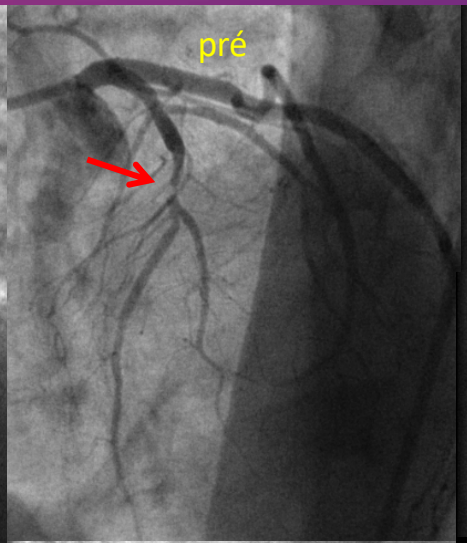
[#]6-month Clinical, Angiographic and OCT follow-up data was presented during TCT 2017

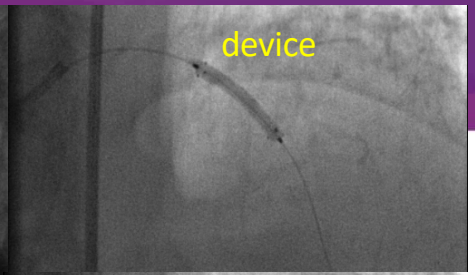
OCT– Cardialysis BV, Rotterdam, The Netherlands

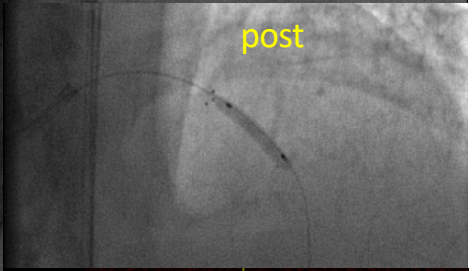
Case #1

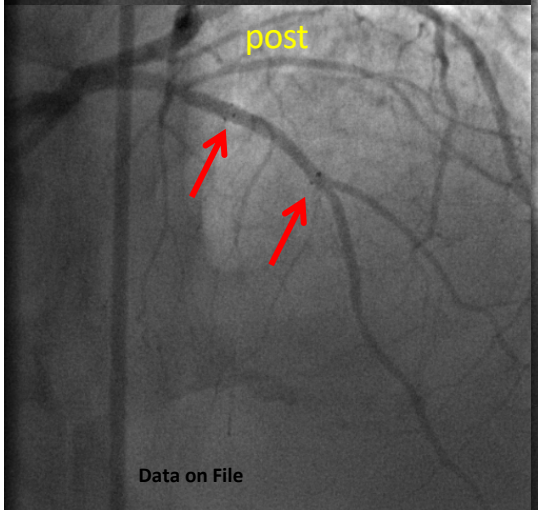
MeRes100 + OCT Imaging…

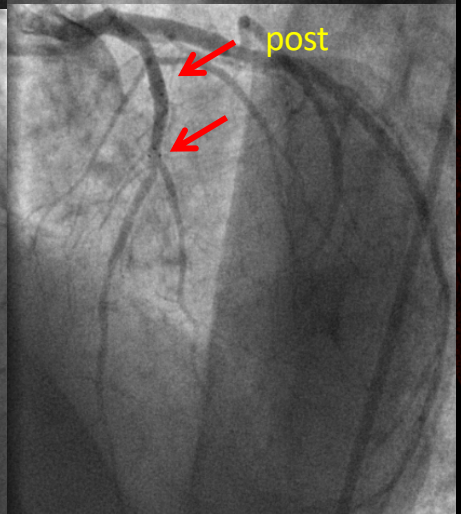


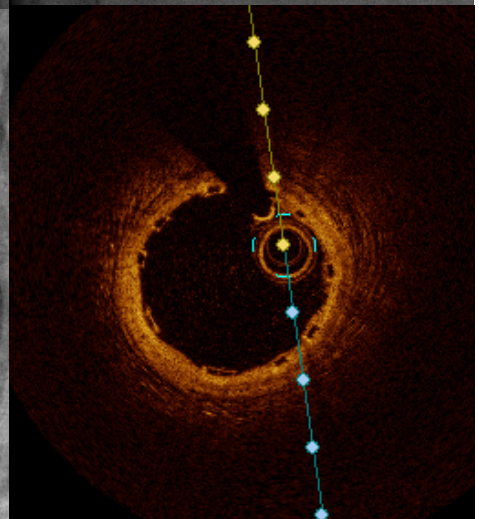


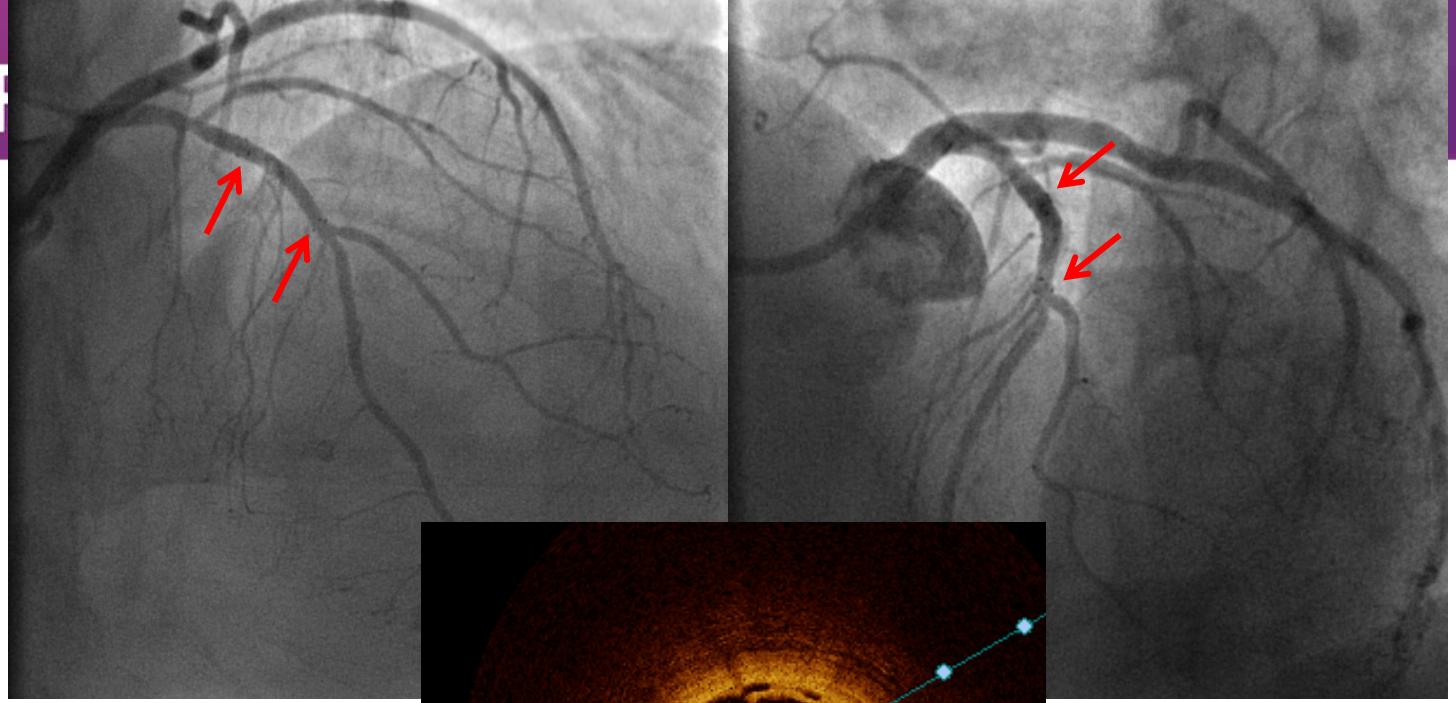


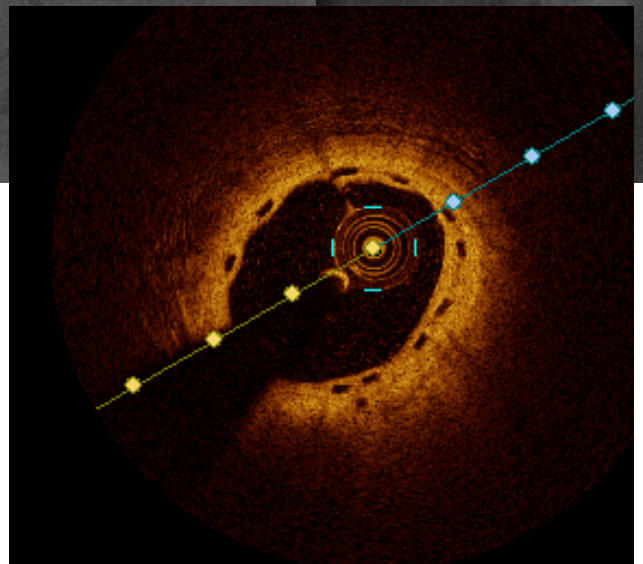












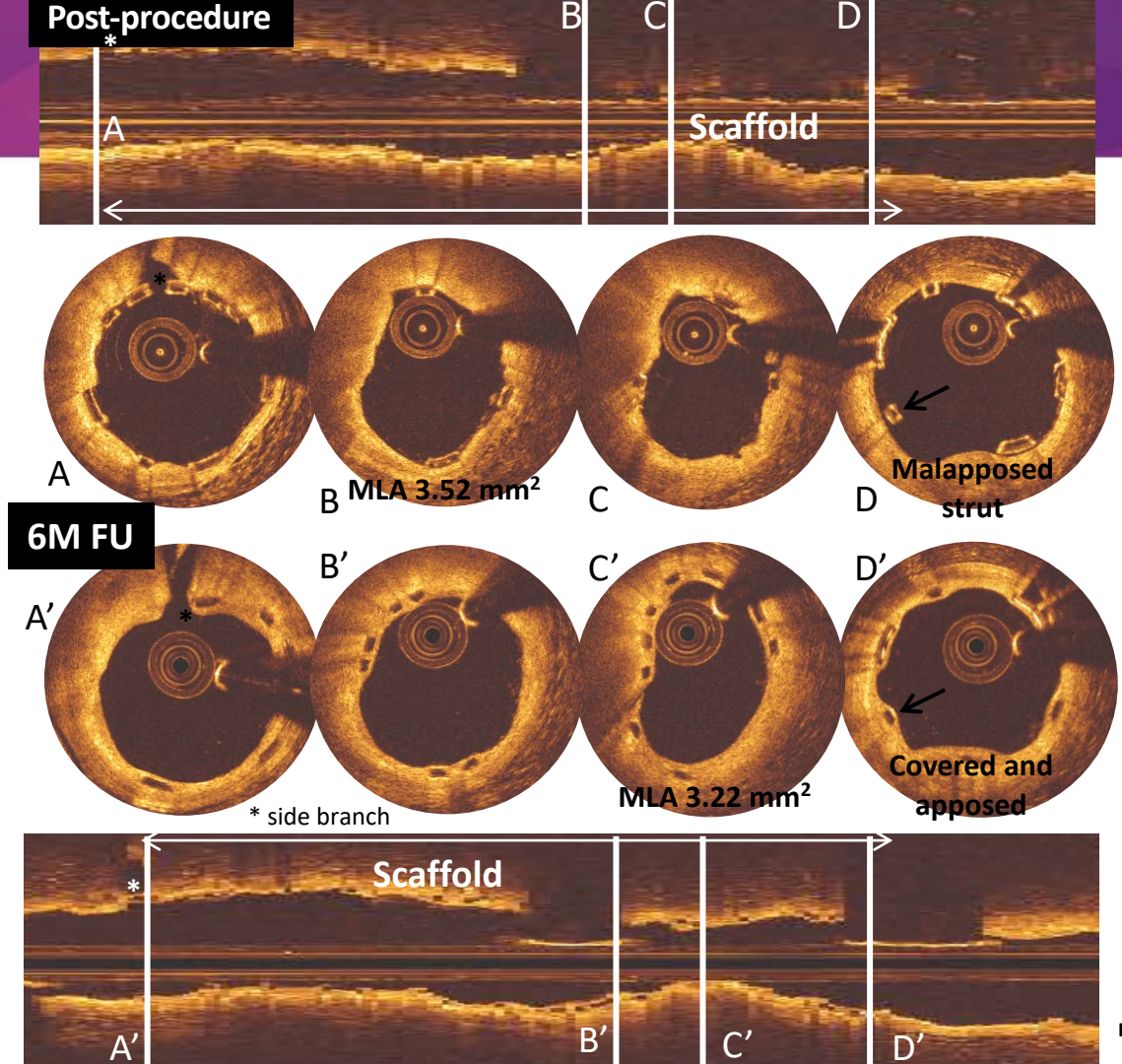
...Angio+OCT
Follow-up
At 6 months

Data on File

Case #2

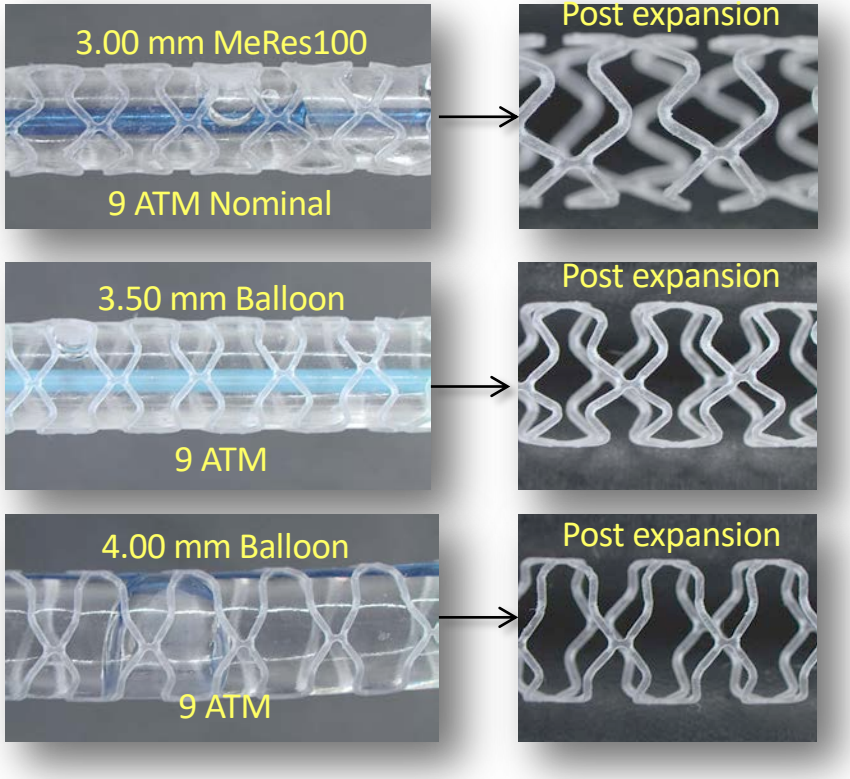
MeRes100 + OCT
Follow-up at
6 months

	Post-PCI	6-Month
Mean LA (mm^2)	4.56	4.28
Minimum LA (mm^2)	3.52	3.22
Mean SA (abluminal) (mm^2)	4.80	5.20
Minimum SA (abluminal) (mm^2)	3.92	4.43
Neointimal area (abluminal) (mm^2)	-	0.73



Data on File

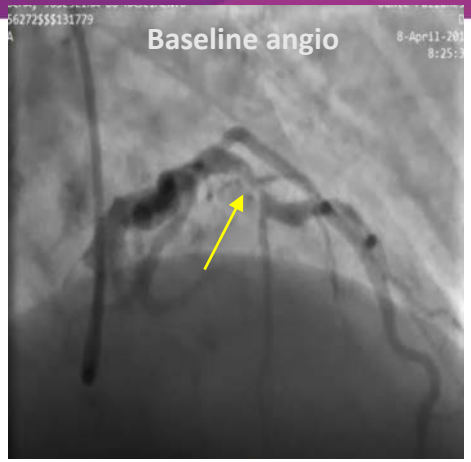
Not all BRS technologies are same..

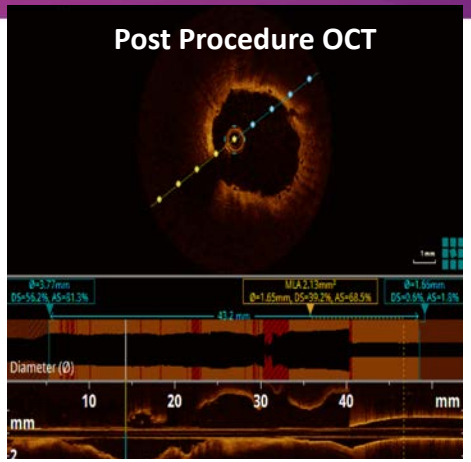


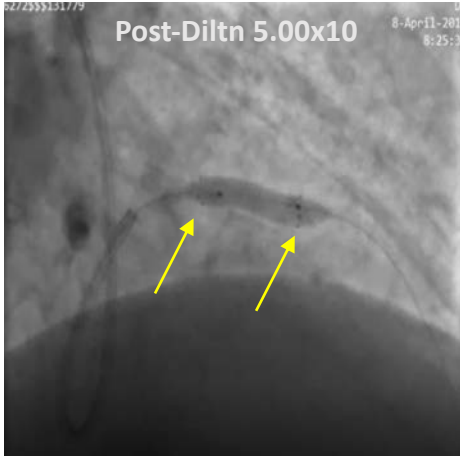
MeRes100 – Over Expansion

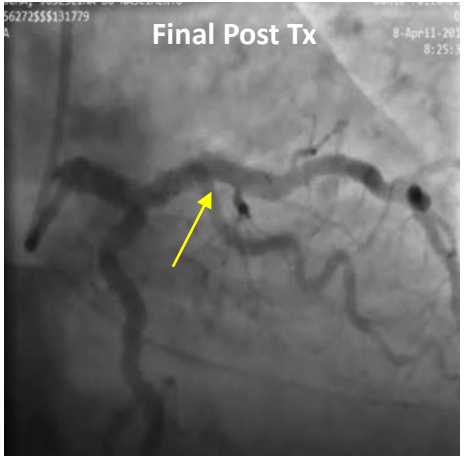
Bench study. Data on file at Meril Life Sciences Pvt. Ltd.

MeRes100 Case with high pressure post dilatation









Patient History

- 62Y/Female
- Stable Angina Class II
- Family history of CAD
- Previous MI >3months
- Smoker
- Diabetic Type II
- Hypertensive

Treatment Details

- Dt. of Tx – 8-Apr-2017
- Proximal LAD
- MeRes100 – 3.50x19
- Post-dil – 3.20x20 @ 30 atm
- 4.50x15 @ 26 atm;
- 5.00x10 # 12 atm

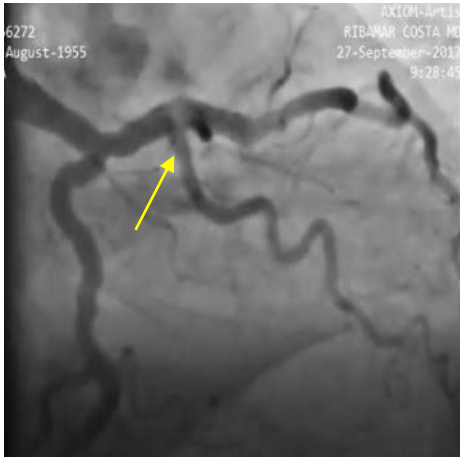
Follow-up Details

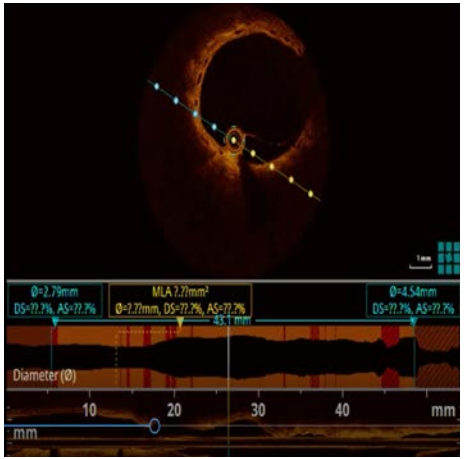
- No MACE, no ST
- Follow-up angio/OCT 6-months

Images courtesy by Dante Pazzanese, Brazil

MeRes100 Case is Patent at 6-months follow-up

6-month follow-up





- Fully patent vessel and scaffolded segment
- Positive remodeling of the lesion site
- Completely endothelialized struts
- No malapposition
- No strut fracture despite dilatation with 5.00 mm NC balloon
- Strong evidence of early degradation of struts

Conclusions

- MeRes-1 trial, the 1st human evaluation of novel 2nd generation MeRes100 BRS with 100µm struts has demonstrated high acute success as well as long term clinical success up to 2-years follow-up with very low MACE 1.87% (2, ID-TLR) and Zero Scaffold Thrombosis (ST). 3-year follow-up will be presented today.
- MeRes-1 Extend trial has **2-year follow-up with very low MACE 1.61%** (1, ID-TLR) and **Zero Scaffold Thrombosis (ST**).
- Serial QCA analysis demonstrated relatively **low late lumen loss (0.18±0.31 mm)** at 6-month, suggesting high efficacy on inhibiting NIH at late follow-up
- OCT subset analyses demonstrated sustained mean flow area and virtually **complete strut coverage (97.95±3.69)** at 6-months follow-up.
- Cases presented provide positive evidence that Not all BRS technologies are made same and we should look forward to lower strut thickness BRS technologies as future of PCI.

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Thank You

07-004

	Post-PCI	6-Month
Mean LA (mm^2)	4.56	4.28
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* side branch