

CASE BASED HOT TOPICS

BVS: passato, presente e futuro?

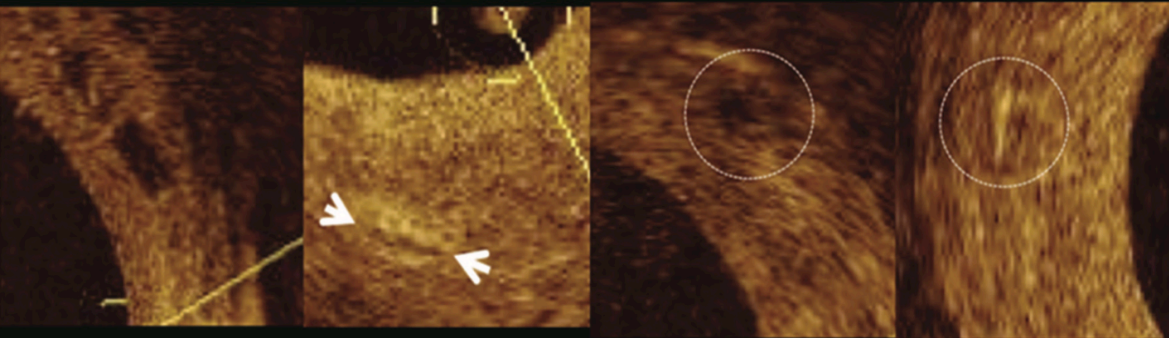
Fezzi Simone MD Msc
University of Verona



BVS – THE PAST

HYPE FOR ABSORB

Classification with OCT



Preserved box

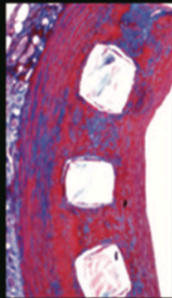
Open box

Dissolved black box

Dissolved bright box

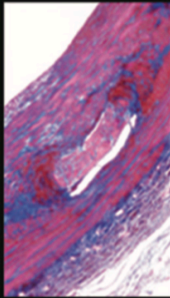
Classification with histology

Category 1



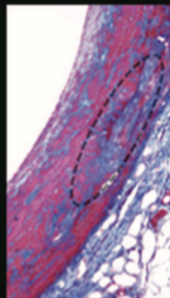
Open acellular regions with well defined borders, filled with hyaline material (2 years)

Category 2



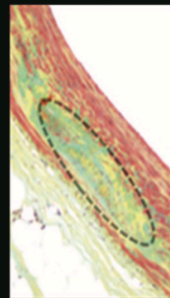
Defined accretion of hyaline, material separated by extracellular matrix and cell

Category 3



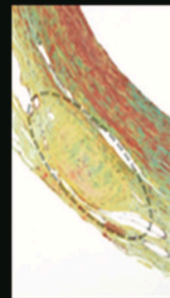
Region of low to moderately cellular connective tissue, cells poorly arranged, lacking hyaline material

Category 4

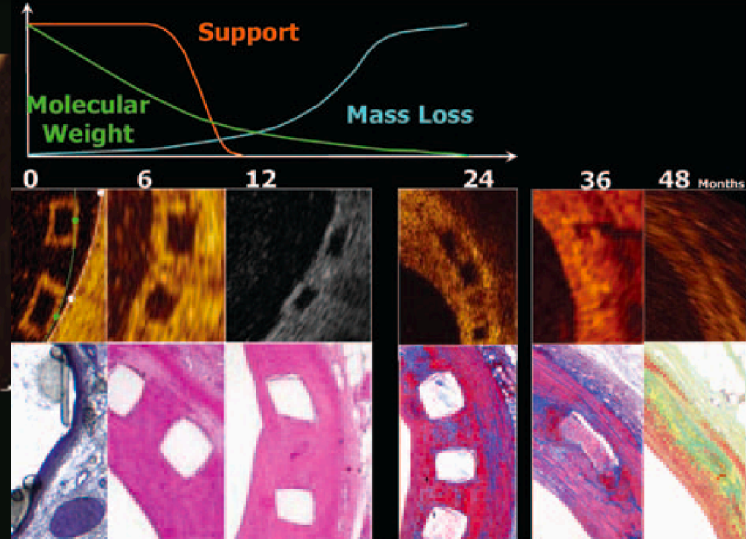


Poorly circumscribed regions of dense connective tissue with moderate to low cellularity, cells not regularly arranged

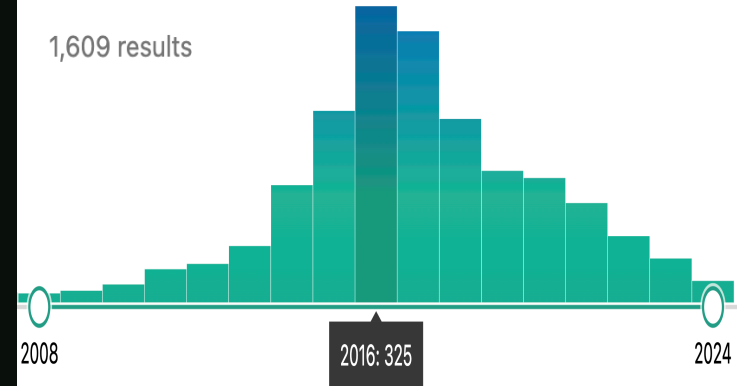
Category 5



Circumscribed area of dense connective tissue with low cellularity, cells typically arranged in circumferential pattern

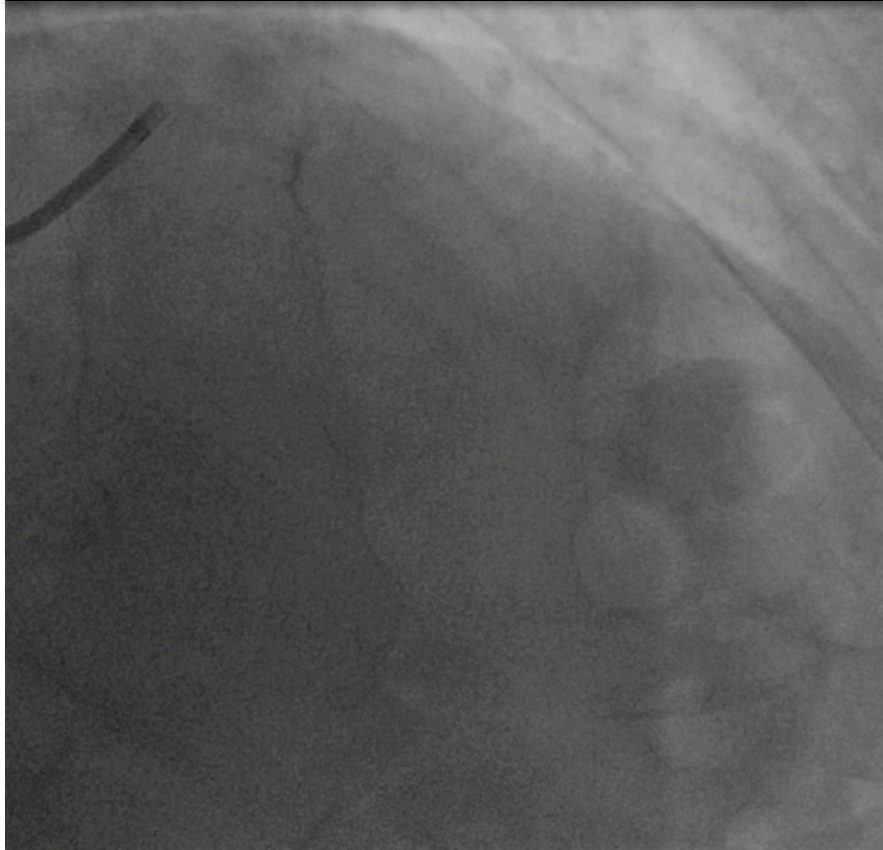


1,609 results

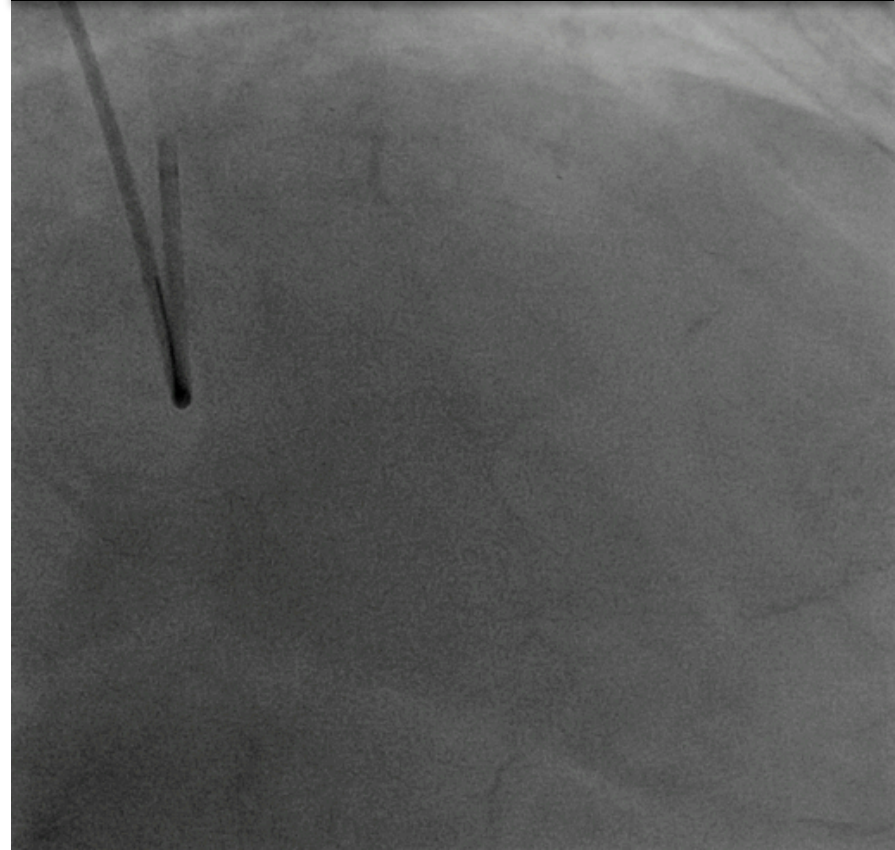


HYPE FOR ABSORB

BASELINE - 2015

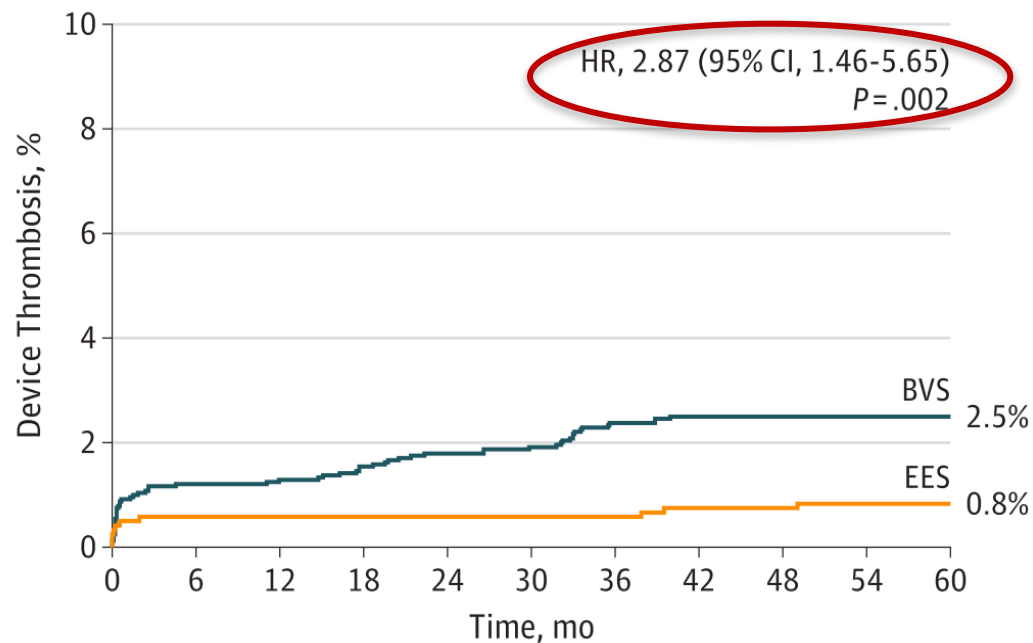


2019



Study	Comparator	Design/n of patients	Primary endpoint	Angio F-up (m)/ Late Lumen Loss (mm)	Long Term F-up (y)	TLF/MACE (%)			Sc Thromb (%)
						BRS (%)	DES (%)	p	BRS (%)
II ABSORB II	XIENCE EES	Mechanistic; 2:1 RCT; single blind; 256:125	 Negative	3Y; 0.37 vs 0.25 mm; (p-non inf 0.78)	5Y	11.8	5.6	0.033	3.0
III ABSORB III	XIENCE EES	Powered for clinical outcomes; 2:1 RCT; single blind; 1322:686	 Positive	-	5Y	17.5	15.2	0.15	2.5
IV ABSORB IV	XIENCE EES	Powered for clinical outcomes; 1:1 RCT; double blind; 1296:1308	 Positive	-	5Y	17.5	14.5	0.03	1.7
ABSORB JAPAN	XIENCE Prime/ Xpedition	Powered for clinical outcomes; 2:1 RCT; single blind; 266:134	 Positive	13M; 0.13 ± 0.30 vs 0.12 ± 0.32; (p-non inf 0.001)	5Y	11.0	7.9	0.33	3.8
ABSORB CHINA	XIENCE V	Powered for clinical outcomes; 1:1 RCT; open label; 231:239	 Positive	12M; 0.19 ± 0.38 vs 0.13 ± 0.38; (p-non inf 0.001)	5Y	15.9	13.1	0.002	2.2
AIDA	XIENCE Prime/ Xpedition	Powered for clinical outcomes; 1:1 RCT; single blind; 924:921	 Positive	-	5Y	14.9	13.7	0.356	4.8
COMPARE ABSORB	XIENCE EES	Powered for clinical outcomes; 1:1 RCT; single blind; 848:822; 1670/2100 intended	 Positive 12M TLF; Non-inferiority; Superiority 3-y mark	-	7Y	15.1	13.1	0.24	2.8

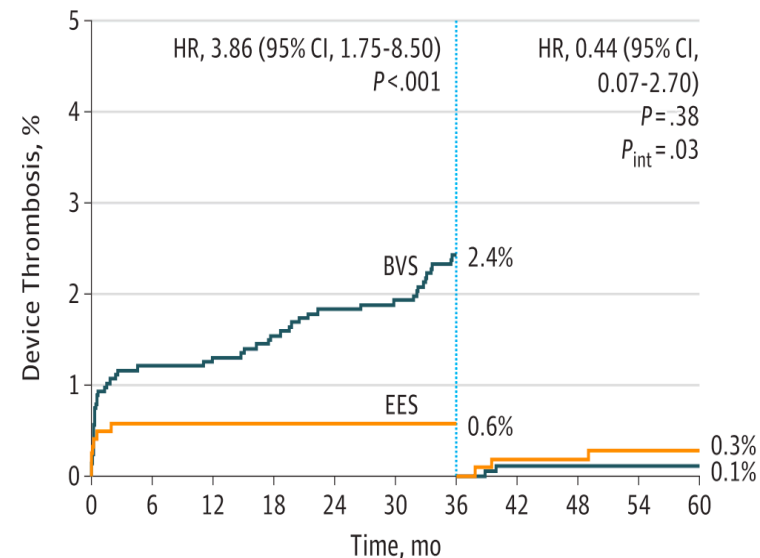
ABSORB II-III-JAPAN-CHINA



No. at risk

BVS	2161	2107	2079	2043	2021	1984	1943	1891	1840	1757	943
EES	1223	1202	1188	1167	1154	1131	1116	1088	1065	1024	536

D Device thrombosis between 0-3 y and 3-5 y



No. at risk

BVS	2161	2107	2079	2043	2021	1984	1984	1931	1877	1792	960
EES	1223	1202	1188	1167	1154	1131	1121	1094	1070	1029	536



**BRS are currently not recommended
for clinical use outside of clinical studies**

Class III

Level C



1. Randomized trials

ABSORB II, ABSORB III,
ABSORB Japan, ABSORB China,
AIDA



2. Meta-analyses

Pooled analyses including
ABSORB trials,
TROFI II, and EVERBIO II



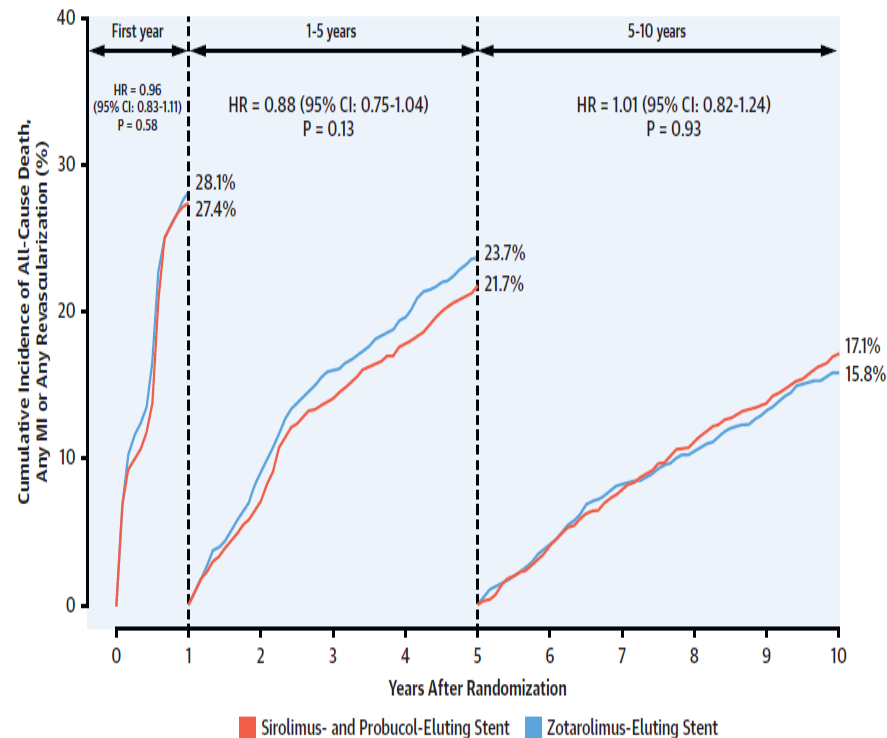
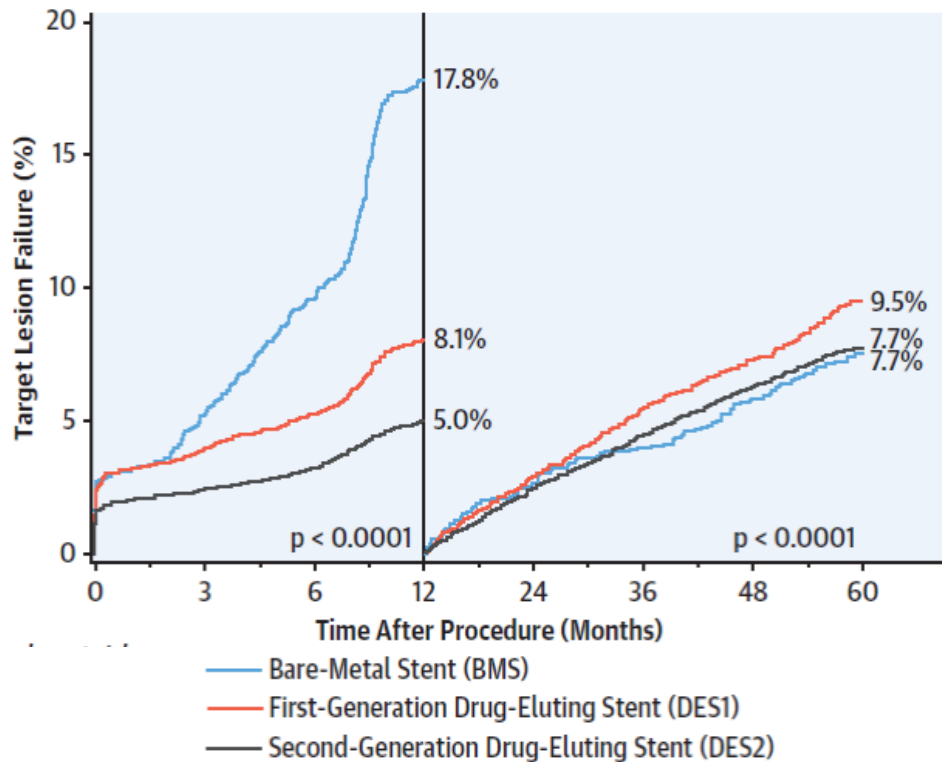
3. Key takeaway

The ESC recommendation
against BRS is derived from
evidence centered on
the Absorb platform.

BVS – THE PRESENT

De novo lesions – rationale for leave-nothing behind ?

Event rate: 3.3% per year after first year



BRS RATIONALE AND NEED?



LEAVE NOTHING BEHIND APPEALING IN YOUNG PATIENTS

- Diffuse and mu
- Option of future



DIAMETER MISMATCH CAUSING REGIONS OF STEP-UP OR STEP-DOWN

tions



LIMITATION OF THE NEOATHEROSCLER INFLAMMATORY I

- ACS
- Focal-vulnerable plaques

Need for prolonged intensity
and/or duration of antiplatelet
therapy



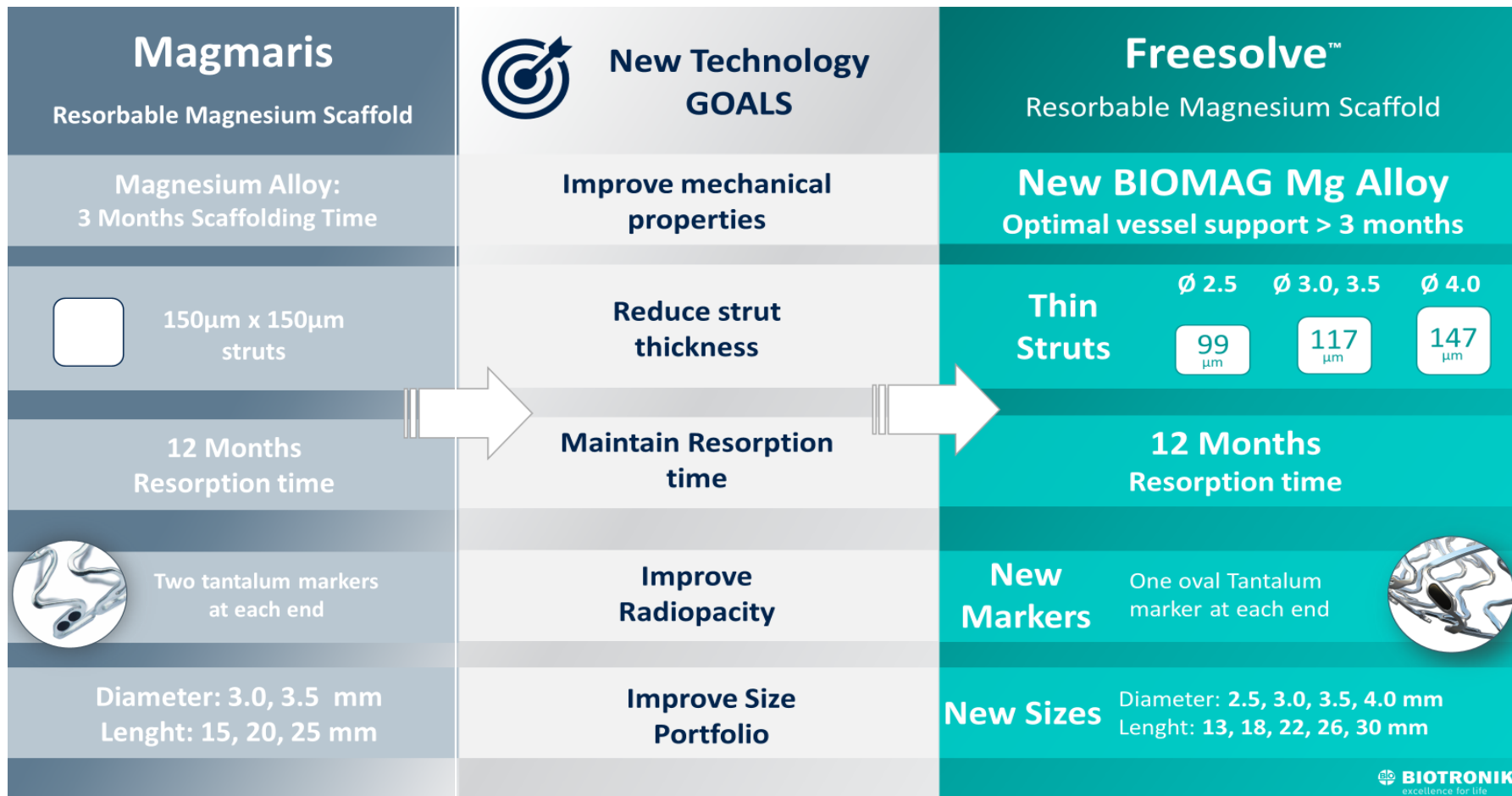
MECHANICS RESTORATION

otility and vascular pulsatility

ar angulation and curvature
ed when the scaffold loses its

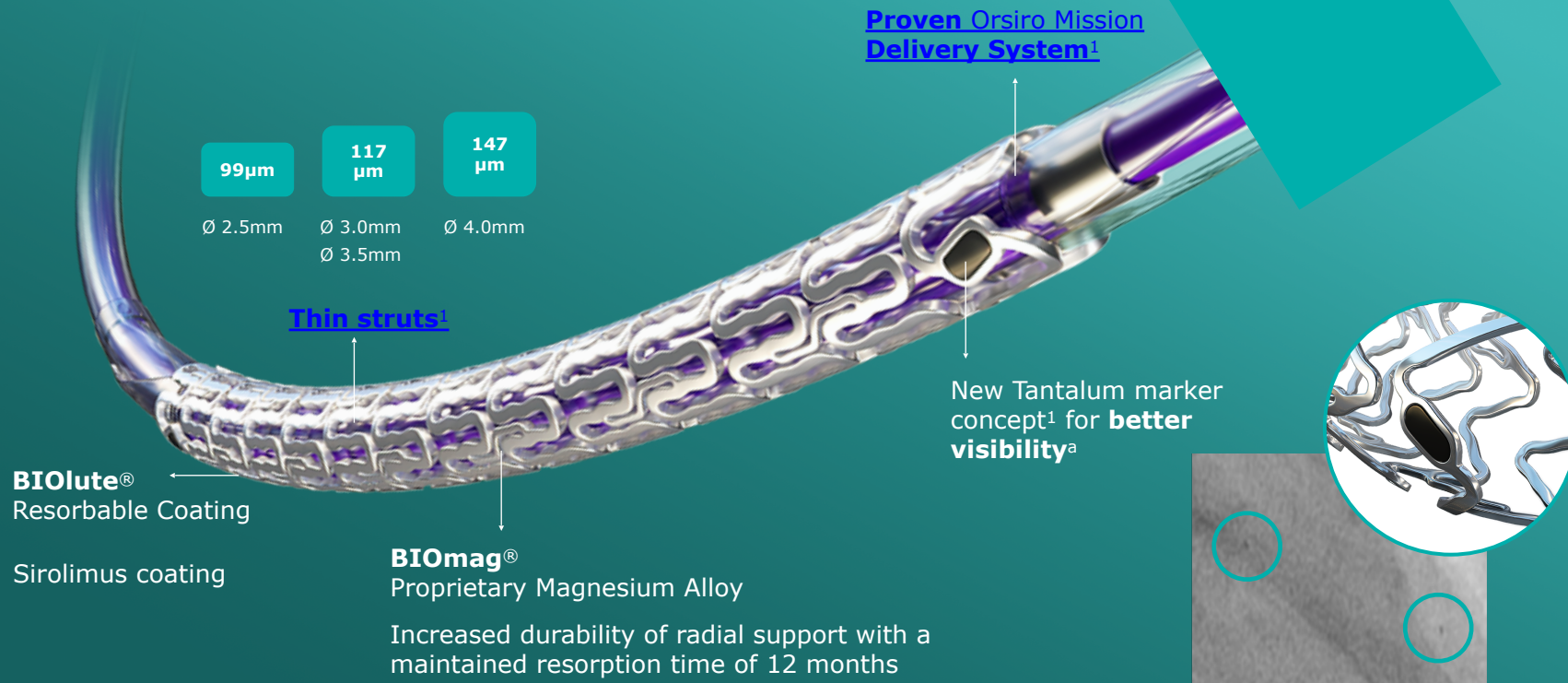
radial strength

RESORBABLE MAGNESIUM SCAFFOLDS



Freesolve® RMS

Device overview



a. BIOMAG-I case in normal cine projection, courtesy of Prof. Michael Haude, Rheinland Klinikum Neuss GmbH, Lukaskrankenhaus, Neuss, Germany. 1 Data on file.

RESORBABLE MAGNESIUM SCAFFOLDS

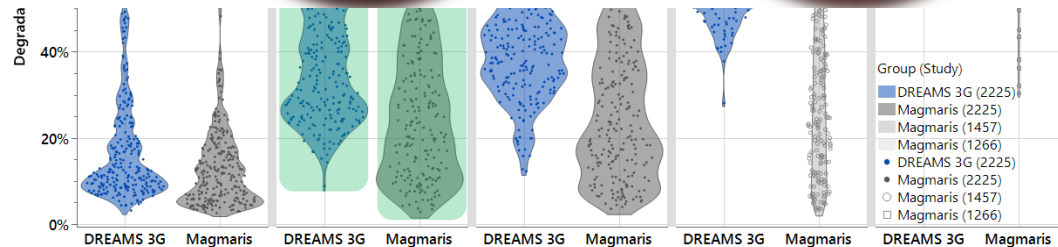
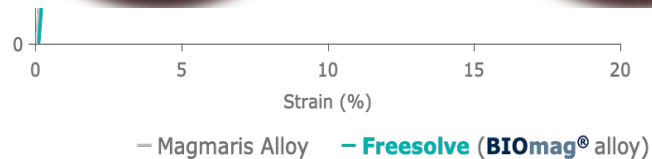
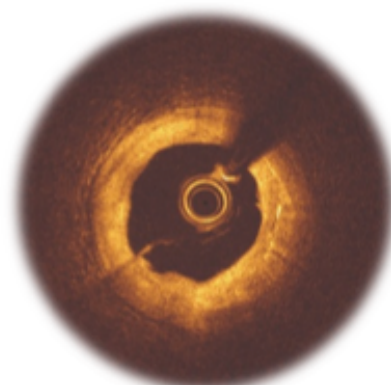
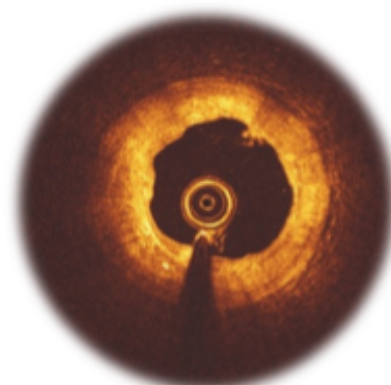
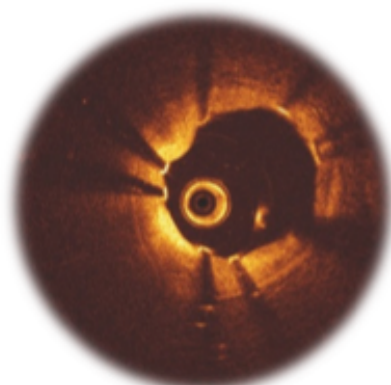
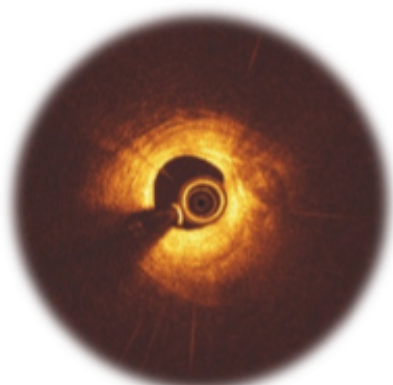
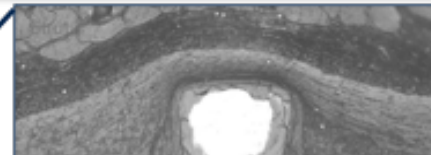
BIOmag® Proprietary Magnesium alloy

PRE-PROCEDURE

POST-PROCEDURE²

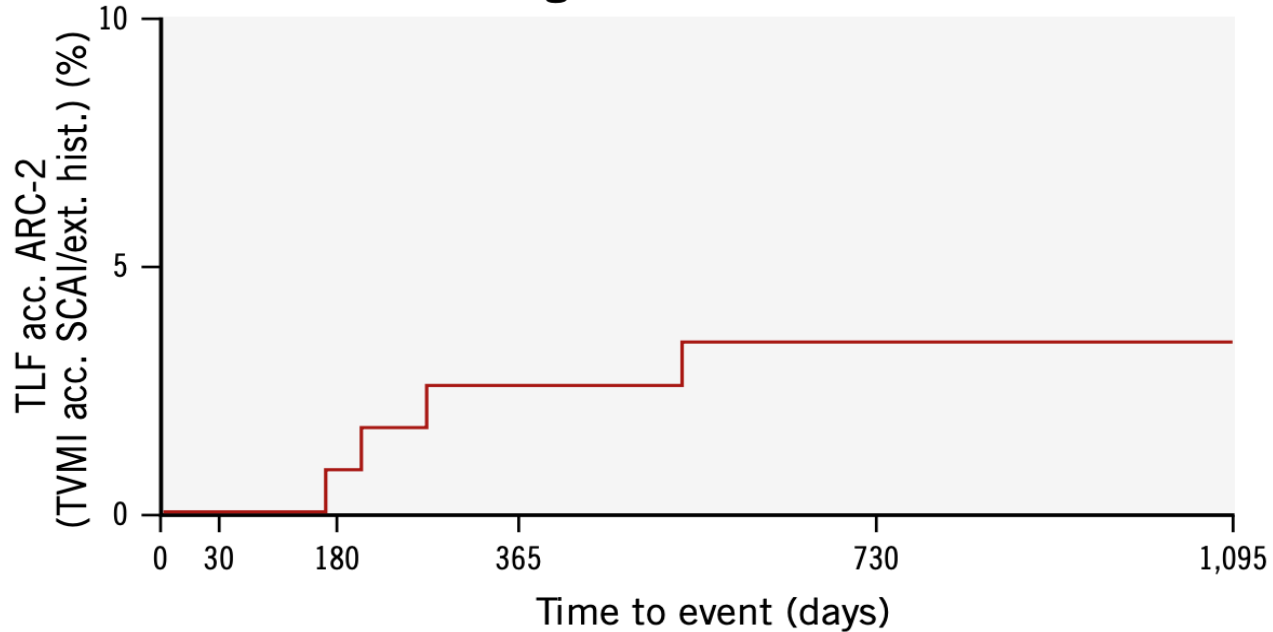
6M-FOLLOW UP

12M-FOLLOW UP²



116 patients
117 lesions

Target lesion failure

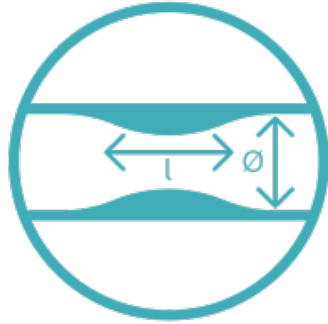


At risk	116	112	111	67
KM estimate	0%	2.6%	3.5%	3.5%
95% CI	0.0-0.0	0.8-7.9	1.3-9.0	1.3-9.0

The 4Ps Protocol



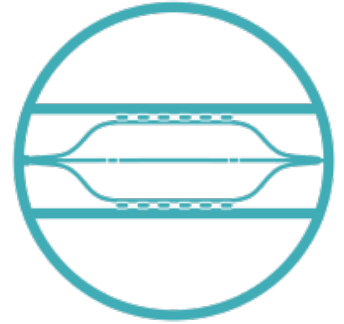
**Patient
Selection**



**Proper
Sizing**



**Pre-
Dilatation**



**Post-
Dilatation**



Patient Selection

IDEAL PATIENT SELECTION

Younger patients

Life expectancy >10 years



Long life expectancy



40s

50s

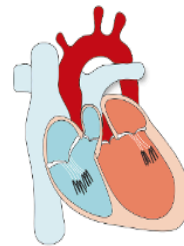
60s

PATIENTS TO AVOID

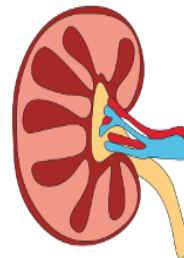
STEMI



HFrEF



Severe CKD



HBR



The 4Ps Protocol

IDEAL LESION SELECTION

Focal/short lesions (<28 mm)

Large caliber vessels (RVD 3.0-4.2 mm)

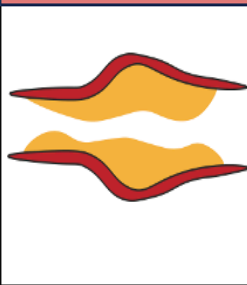


LESIONS TO AVOID

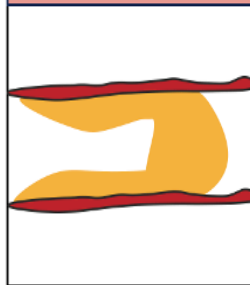
LEFT MAIN



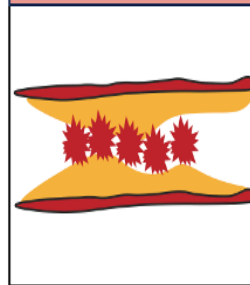
ECTATIC SEGMENTS
(RVD>4.2 mm)



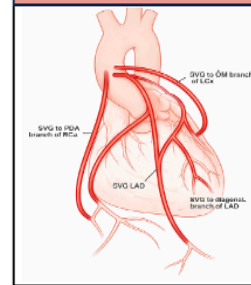
CTO



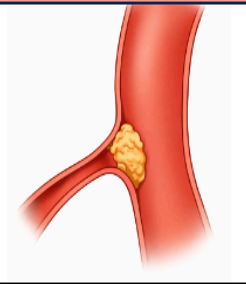
THROMBUS



CABG



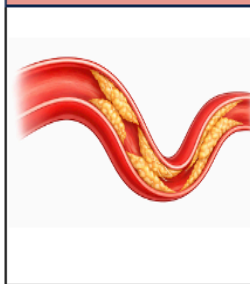
AORTO-OSTIAL



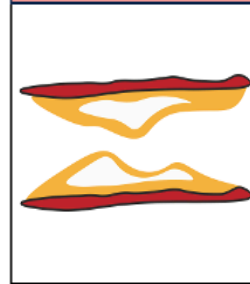
BIFURCATIONS
(SB treatment)



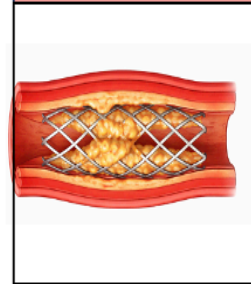
TORTUOUS
SEGMENTS



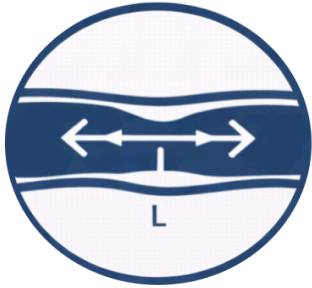
SEVERE
CALCIFICATIONS



ISR



OPTIMAL IMPLANTATION TECHNIQUE

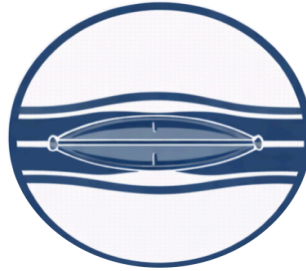


Proper Sizing

QCA underestimates vessel diameter by 0.25 mm

IVUS and/or OCT should be considered

- Plaque morphology
- Vessel sizing
- Proper lesion preparation
- BRS optimization



Pre-Dilatation

Pre-dilatation with NC balloon 1:1 ratio



Full expansion of NC balloon



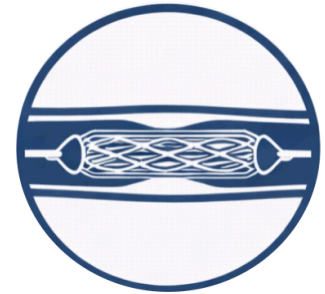
ANGIOGRAPHY

RESIDUAL STENOSIS

Visual estimation ≤ 20%



If not achieved, use Cutting/Scoring balloon



Post-Dilatation

Post-dilatation with NC balloon up to 0.5 mm larger than implanted BRS at high pressure (>16 atm)

IVUS and/or OCT ensure optimal expansion and apposition

Case presentation



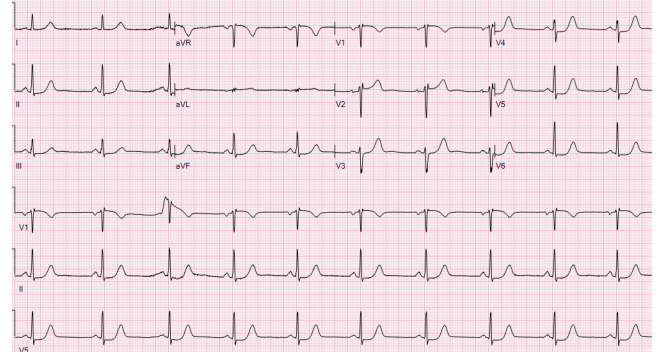
Female, 50 year-old

- Mild dyslipidaemia
- No relevant medical history

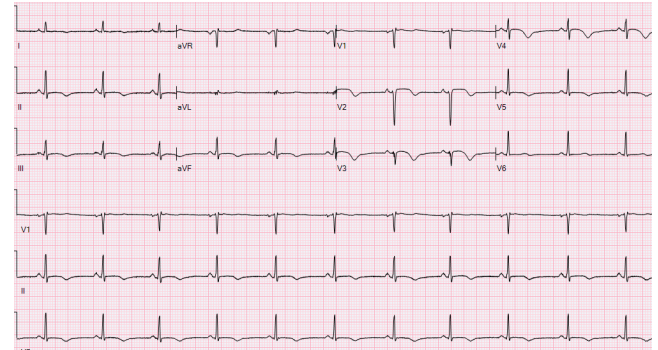
Admitted to CCU for NSTEMI-ACS
(symptomatic for chest pain)

- **Lab:** hs-troponin T elevation
(peak: 3411 ng/L)
- **Echo:** LV apical akinesia with
preserved LVEF. Mild-to-
moderate MR

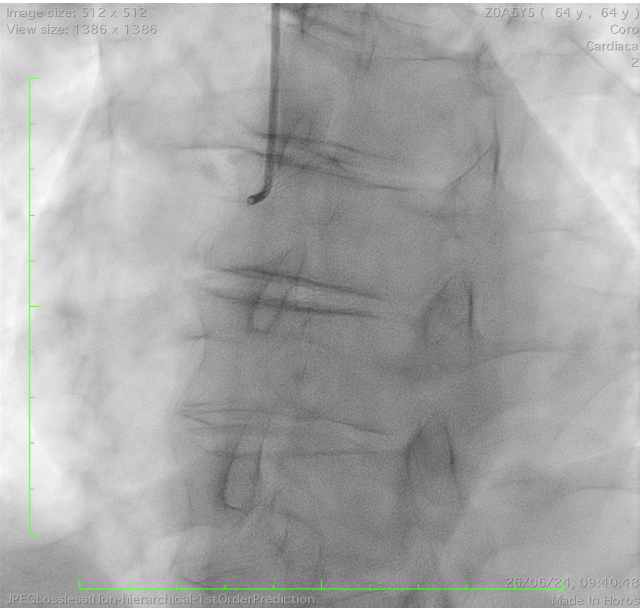
1° EKG



24-h from admission



Coronary angiogram



Left Anterior Descending PCI

PCI setting

- EBU 3.5 6 Fr
- Workhorse guidewire
- Thrombus aspiration



PCI planning



Thrombus?
SCAD?
Plaque rupture?

How to manage?

Imaging?

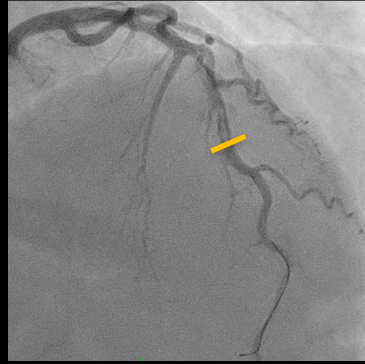
Stenting?

Left Anterior Descending - IVUS

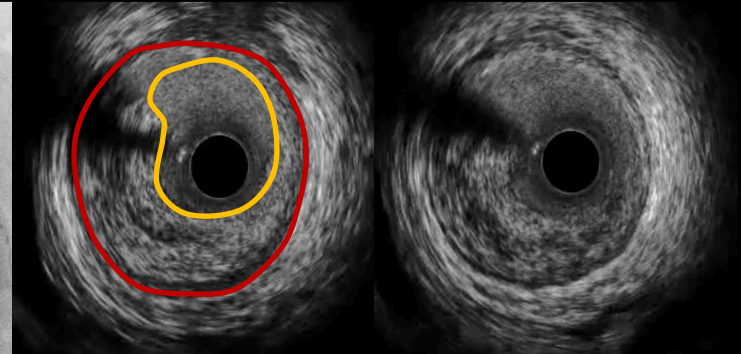
Frame 1



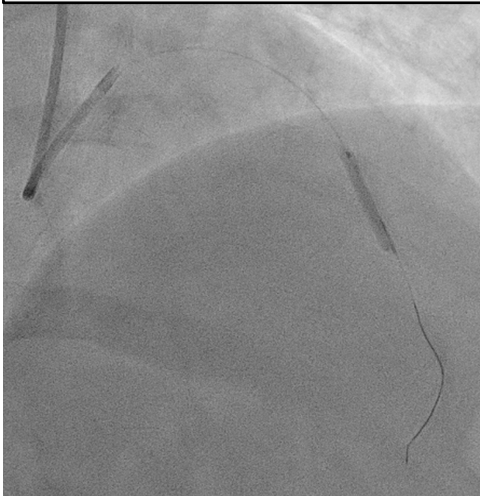
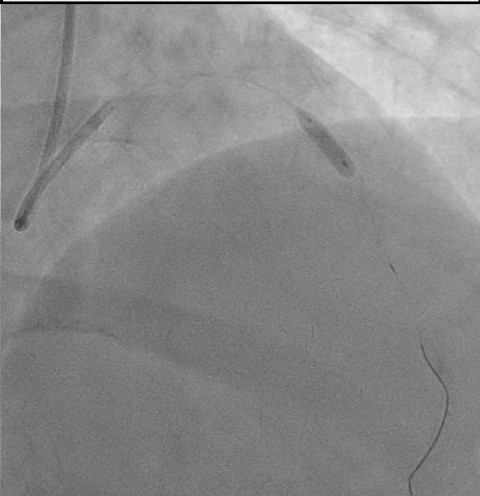
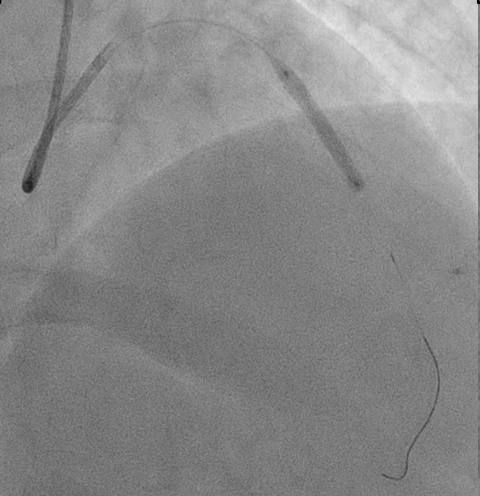
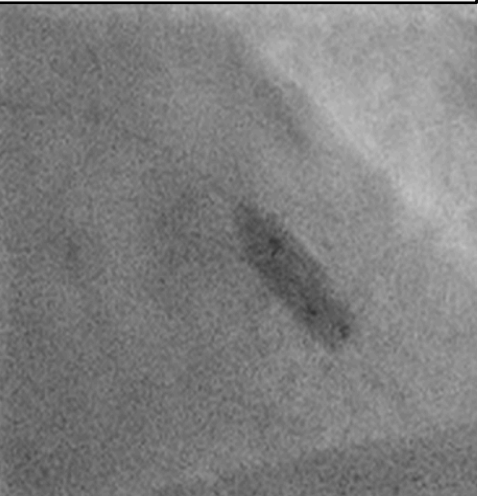
Distal thrombus in healthy segment



Proximal subocclusive ipoechogenic plaque



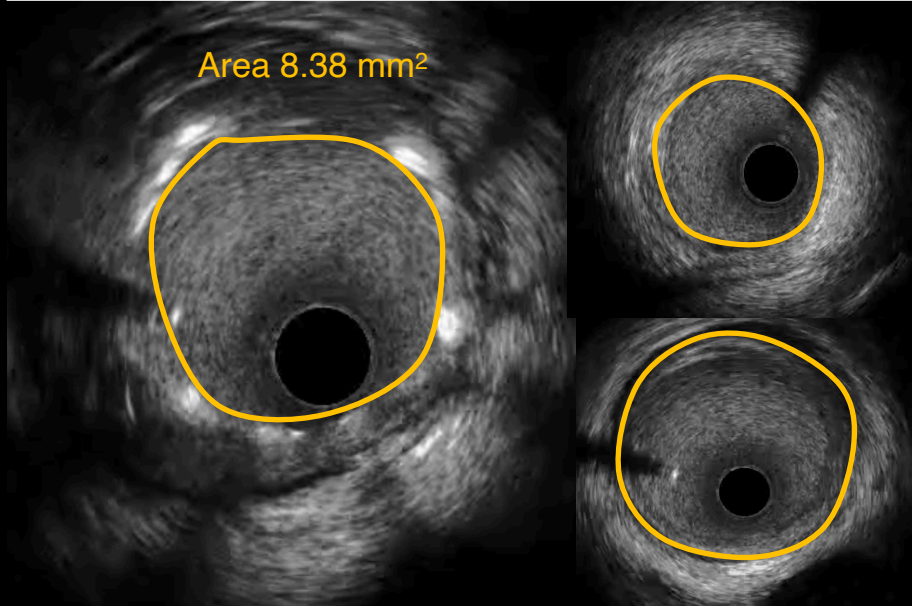
LAD – PCI

Lesion preparation		BRS deployment	
SC balloon 3.0x20 mm	NC 3.5x12 mm	Freesolve 3.5x22 mm	NC 4.0x15-4.0x8 mm
			

LAD PCI

Proximal edge malapposition → optimization

Area 8.38 mm²

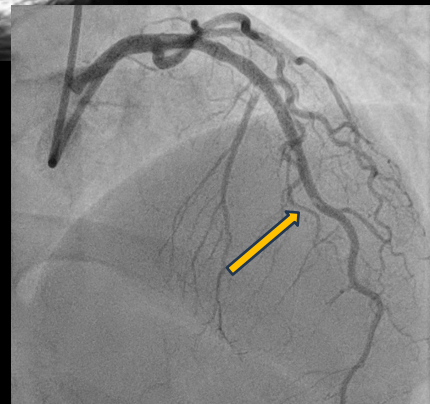


Distal ref area:
7.01 mm²

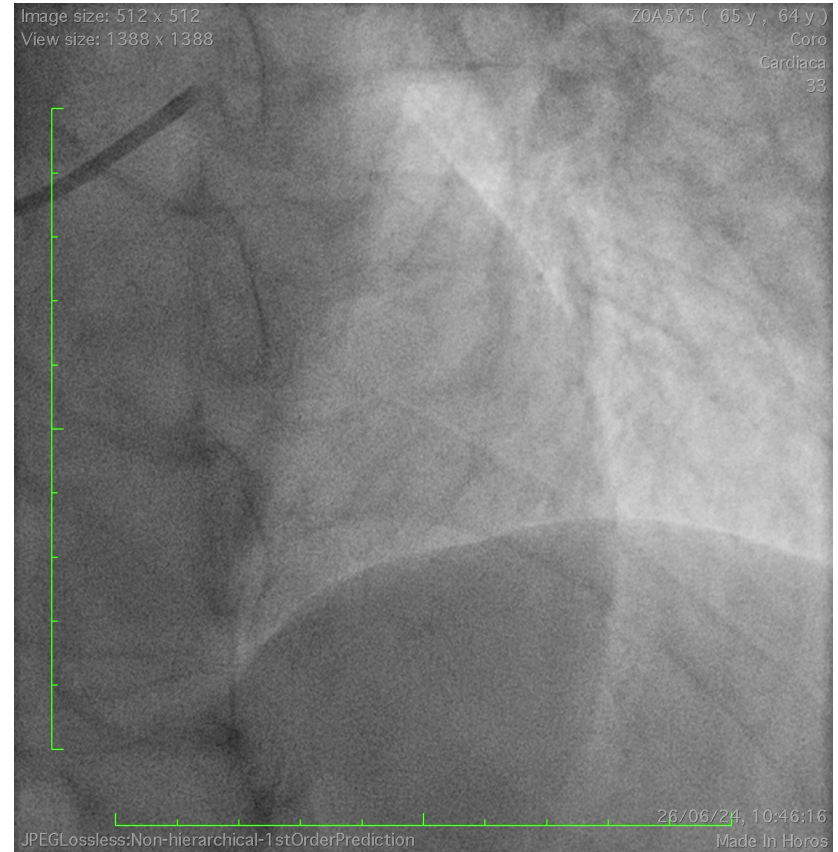
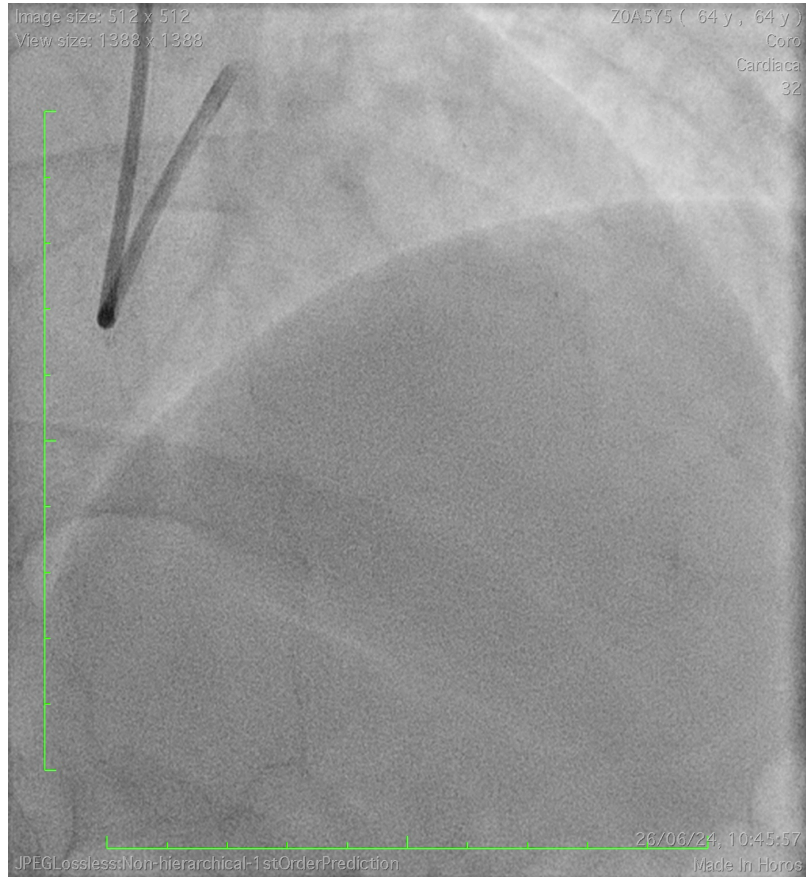
Proximal ref
area:
13.04 mm²

MSA: 83%

Residual focal distal thrombosis
(TIMI-3 flow)

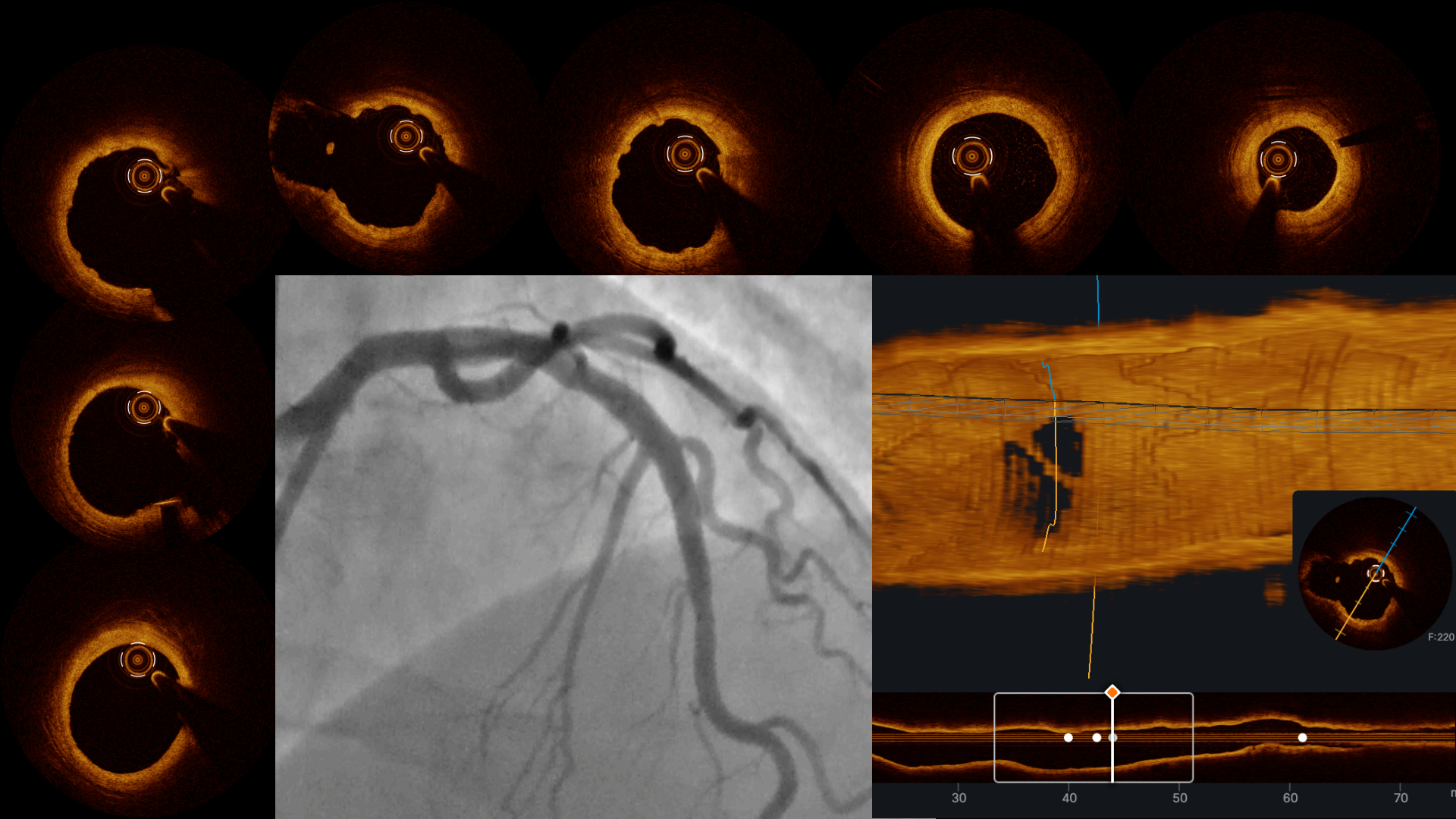


LAD PCI – Final result



LAD PCI – 15 months





BVS – THE FUTURE

BIOMAG-II STUDY DESIGN

Prospective, Randomized-Controlled, International, Multi-Center, Non-Inferiority Study



TCT 2027
PRESENTATION



DESIGN

- Prospective, randomized-controlled, international multi-center, non-inferiority study against **Xience family**



INDICATION

Freesolve is indicated for improving luminal diameter in the treatment of *de novo* native coronary artery lesions in patients with symptomatic coronary artery disease.



REFERENCE VESSEL DIAMETER

Between 2.5–4.2 mm
Maximum lesion length $\leq$ 28 mm



PRIMARY ENDPOINT



Target Lesion Failure (TLF)
at 12-month follow-up



ENROLLMENT COMPLETED

1859 SUBJECTS WITH *DE NOVO* CORONARY ARTERY STENOSIS



STUDY POPULATION

1859 patients
with *de novo* coronary artery stenosis

RANDOMIZATION (2:1)



FOLLOW-UP SCHEDULE

- 1-month Clinical FUP
- 6-month Clinical FUP
- 12-month Clinical FUP
PRIMARY CLINICAL ENDPOINT: TLF
- 2, 3, 4 and 5 years Clinical FUP

The BIOHYBRID Pilot Study

An RCT comparing hybrid strategy RMS/DCB vs DES only in long diffuse lesions

BIOHYBRID



Population
de novo diffuse
coronary lesions



Country / PI
Switzerland
Dr. Iglesias



Study Design
1:1 RCT comparing
hybrid strategy
RMS/DCB vs DES
only in long diffuse
lesions



Imaging
Angiography-
derived FFR
(FFRangio) at 12m



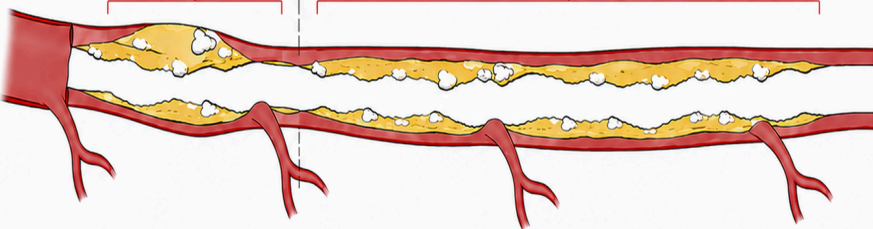
Primary Endpoint
Vessel-level delta
FFRangio values
between post-PCI
and 12-month
follow-up

BIOHYBRID

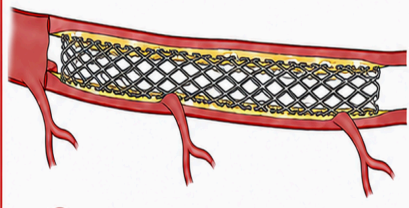
140

FOCAL PROXIMAL LESION

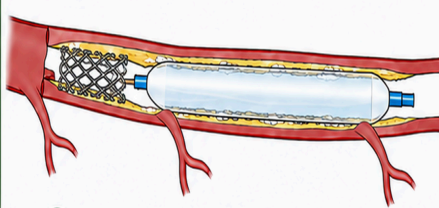
LONG DIFFUSE CRITICAL DISTAL LESION



DES-ONLY PCI ("FULL METAL JACKET")



DCB-ORIENTED PCI (HYBRID OR DCB-ONLY)



**140 subjects with
long diffuse lesions**



Hybrid arm:
Freesolve &
Pantera Lux



Conventional arm:
Orsiro Mission



**Control coronary angiography
and clinical follow-up
at 12 months**

The LEAVE NOTHING BEHIND Study

An RCT comparing DCB with bail-out BRS vs BRS strategy alone in a relatively young PCI population



LEAVE
NOTHING
BEHIND



Population

Relatively young
PCI population

Age 18–68 years



Eligibility

- De novo native coronary lesions
- RVD 2.75–4.0 mm
- Lesion length up to 30 mm
- Max 3 target lesions



Country / PI

Multicenter
international study

PI: Davide Capodanno



Study design

Prospective, randomized,
open-label, parallel-group

1:1 DCB + bail-out BRS
vs BRS alone



Primary endpoint

12-month TVF

MeRes100



MeRes100 at a glance

	Manufacturer	Meril Life Sciences
	CE mark	Yes
	Material	PLLA-based scaffold
	Strut thickness	100 µm
	Drug	Sirolimus



2256 relatively young
PCI patients



DCB arm

Mozec SEB
Bail-out MeRes100
if needed



BRS arm
MeRes100



Follow-up: 1 month, 6 months,
12 months, annual to 5 years



**Angiographic
substudy at
13 months**

PLLA – FURTHER DEVELOPMENTS

FIRESORB



AT A GLANCE



Manufacturer
MicroPort



Material
PLLA



Strut thickness
100–125 μ m



Drug
Sirolimus



FUTURE II

- Mechanistic 1:1 RCT
- N = 433 (215 BRS vs 218 EES)
- 12-month angiographic follow-up
- Late lumen loss: **0.17 mm**
- 1-year TLF/MACE: **0.9% vs 1.9%** (p=0.43)
- Scaffold thrombosis: **0.0%**

NEOVAS



AT A GLANCE



Manufacturer
Lepu Medical



Material
PDLLA



Strut thickness
170 μ m



Drug
Sirolimus



NeoVas Trial

- Mechanistic 1:1 RCT
- N = 560 (278 BRS vs 282 EES)
- 12-month angiographic follow-up
- Late lumen loss: **0.22 mm**
- 5-year TLF/MACE: **9.5%**
- Scaffold thrombosis: **1.5%**

Song L, Xu B, Chen Y, FUTURE-II Trial. JACC Cardiovasc Interv. 2021 Jul 12;14(13):1450-1462.

Xu K, Fu G, Wang X, Song L, The NeoVas Randomized Trial. JACC Cardiovasc Interv. 2025 Sep 8;18(17):2107-2115.

IRON IBS – FURTHER DEVELOPMENTS



AT A GLANCE



Manufacturer
Biotyx Medical



Material
Nitrided Iron



Strut thickness
50–60 μm



Drug
Sirolimus



Resorption time
~7 years

IRONMAN II



Mechanistic 1:1 RCT



N = 518 (258 BRS vs 259 EES)



24-month angiographic follow-up



Late lumen loss: 0.28 mm



2-year TLF/MACE: 7.4% vs 5.4%



p non-inferiority < 0.001



Scaffold thrombosis: 0.0% vs 0.4%

CONCLUSIONS



First-generation BRS, largely driven by Absorb data, showed **excess adverse events** and **scaffold thrombosis**.



New-generation scaffolds feature **thinner struts**, **improved materials**, and more **refined designs**.



Novel-generation MRS (Freesolve) has shown promising results in **BIOMAG-1**. The ongoing **BIOMAG-2** trial is currently evaluating the **non-inferiority** of this platform compared with EES.



Novel PLLA devices (MeRes100, NeoVas, Firesorb) and **iron-based IBS** have provided **convincing evidence** in mechanistic studies and will be **tested against DES in larger populations**.