Optimisation of BVS Implantation in Real World Experience - Imaging or Angiography Guided?

The 4th Revolution in PCI Symposium – Leave Nothing Behind
TCTAP - April, 27 August 2016

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Disclosures

- **Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below -**

Affiliation/Financial Relationship	Company
1. Grant/Research support	Abbott Vascular, St Jude Medical
2. Advisory/Honoraria	
3. Major Stock Shareholder/Equity	None
4. Royalty income	
5.Ownership/Founder	
6. Intellectual/Property Rights	
7. Other Financial Benefit	

- **No conflict of interest with reference to this talk or meeting**

ABSORB BVS in Real-world Practice – Optimising Outcomes

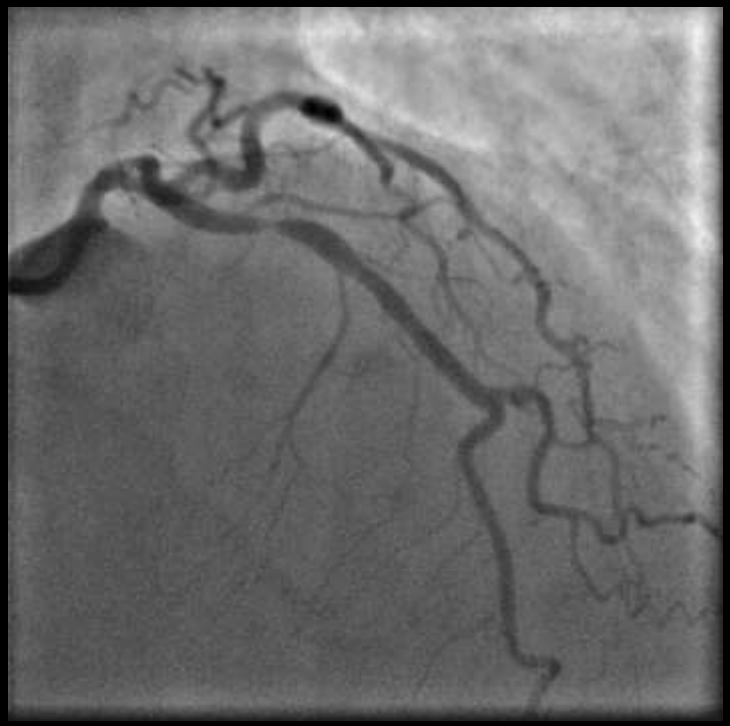
- Appreciate novel device features *(BUT its still a "stent" acutely!)*

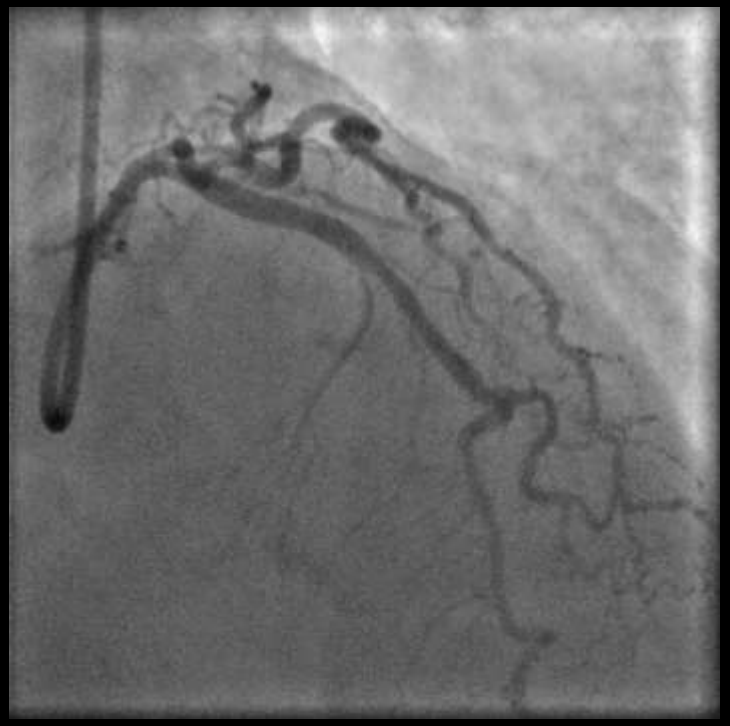
  → *5 key aspects (Ps) of scaffold implantation*

- Learning-curve - *do not start with complex disease*
- Meticulous technique *(sizing, preparation, post-dilatation)*
- Prolonged DAPT in complex disease
- Liberal OCT use

ABSORB BVS – On-label Indication

62 F, SAP, *Angio-guided Implantation*



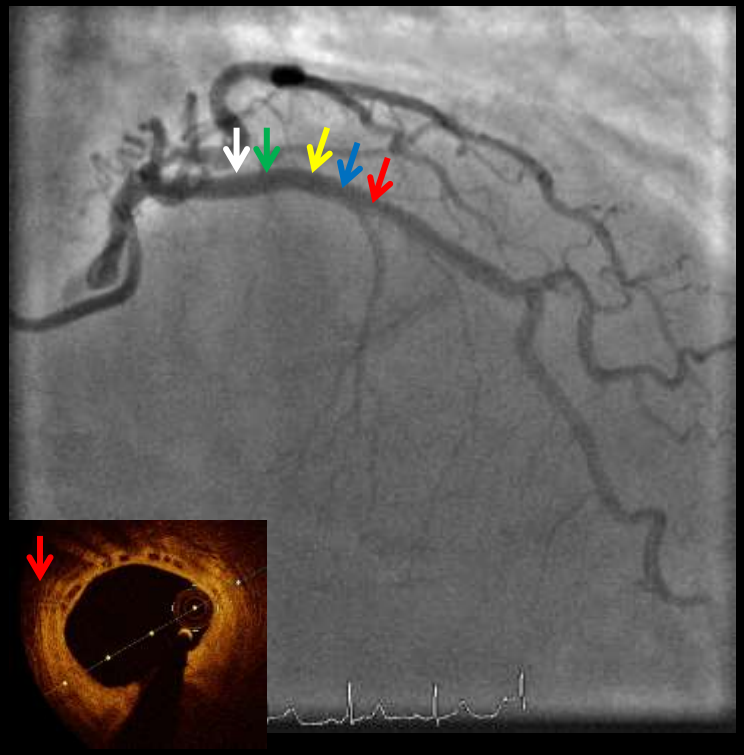


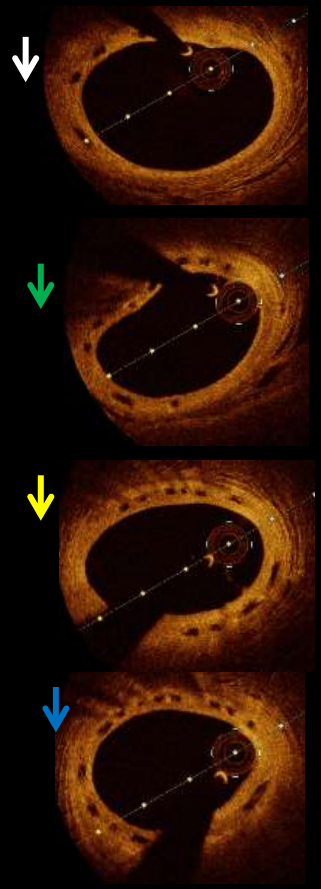
- 3.5 x 18 mm Absorb
- 3.75 mm NC

POW/EHC Absorb Registry - Case # 23

ABSORB BVS – Late OCT insights

30 mth post Absorb BVS



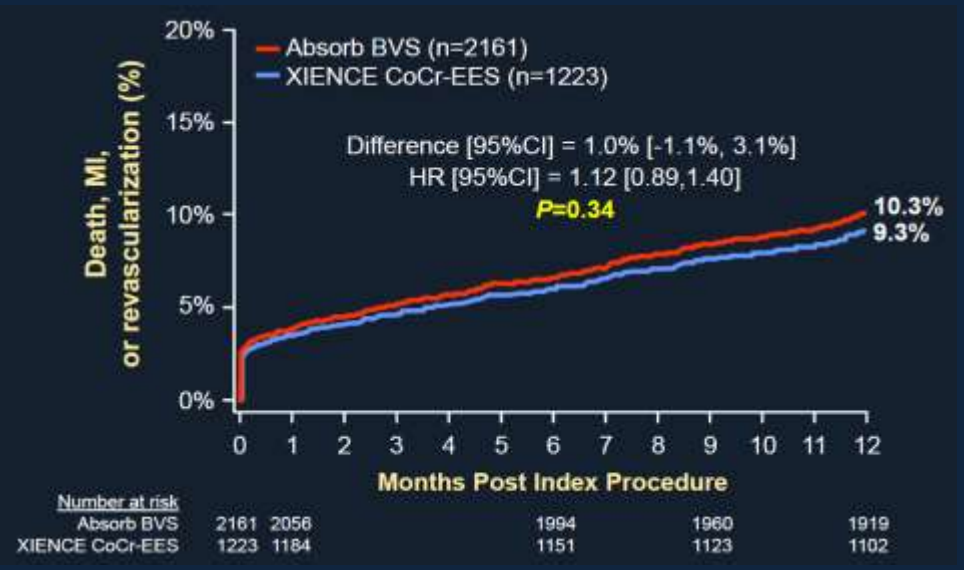


POW/EHC Absorb Registry - Case # 23

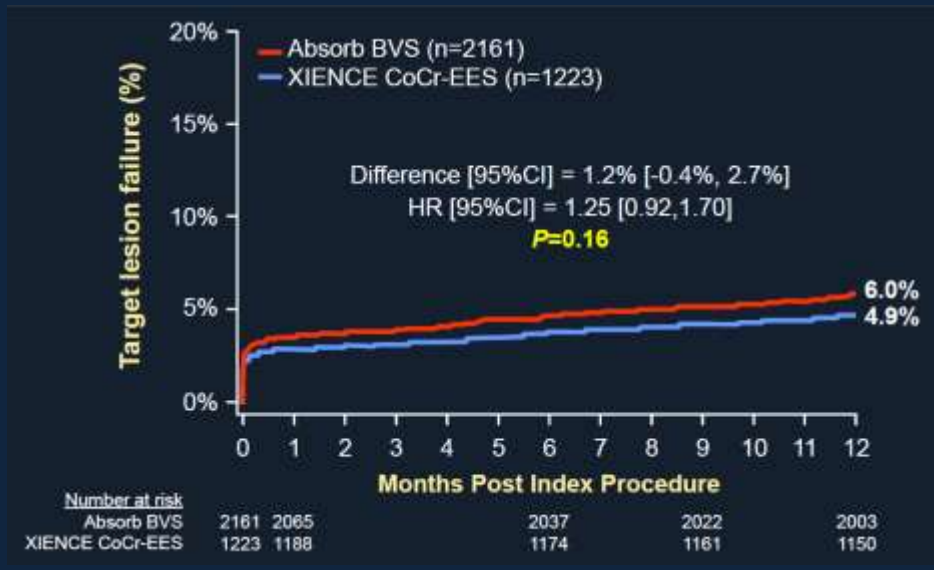
ABSORB 1-Year Meta-analysis
Outcomes in 3389 'On-label' patients

ABSORB II, ABSORB Japan, ABSORB China, ABSORB III

PoCE: Death, MI or Revascularization (pooled)



DoCE (TLF): Cardiac Death, MI or ID-TLR (pooled)



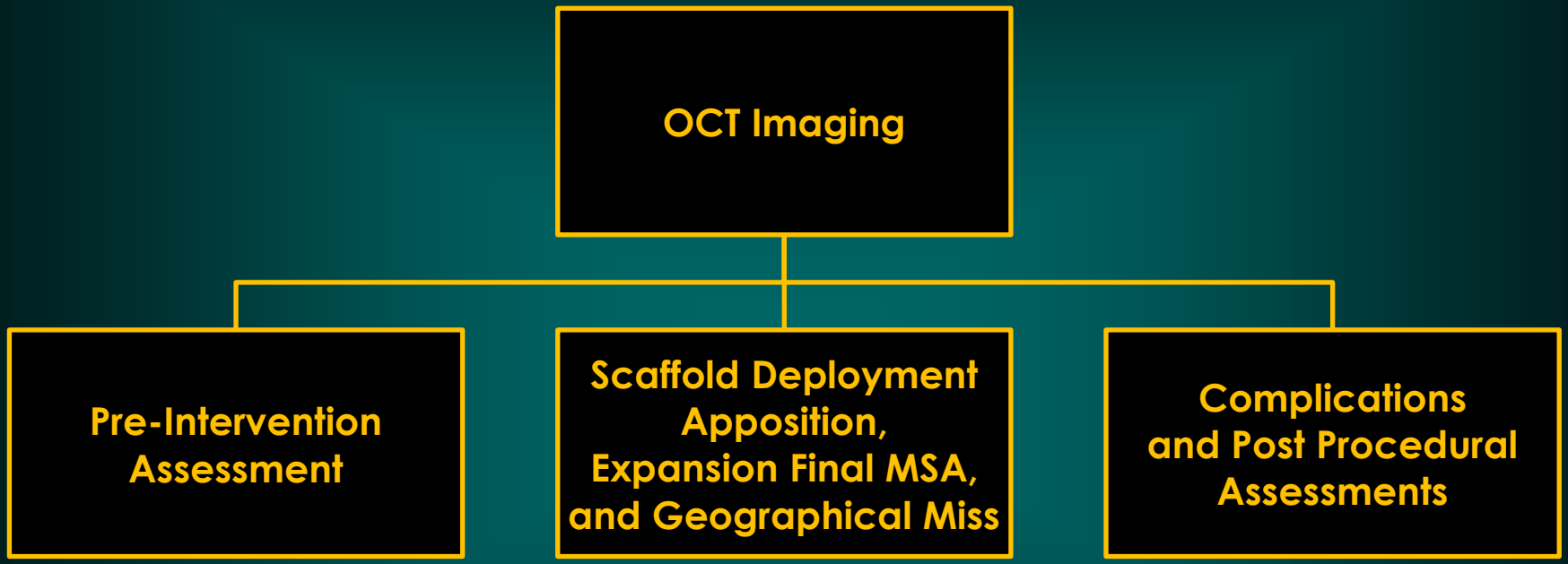
IVUS or OCT guidance/procedure – 23.9 % Absorb vs 20.3% Xience Co-Cr EES P<0.02

Stone et al Lancet 2016

OCT imaging Guidance - BRS Implantation

What Advantages over Angiographic Guidance?

OCT imaging Guidance - BRS Implantation



- Plaque characteristics - *preparation*
- Identify proximal and distal reference segments to select scaffold length
- Measure vessel diameter to select scaffold size – *esp 2.5 mm*

- Apposition
- Expansion – *final MSA*
- Lesion coverage *(geographic miss?)*

- Edge dissections
- Tissue protrusion/thrombus

OCT imaging Guidance - BRS Implantation

OCT offers advantages - SIZING

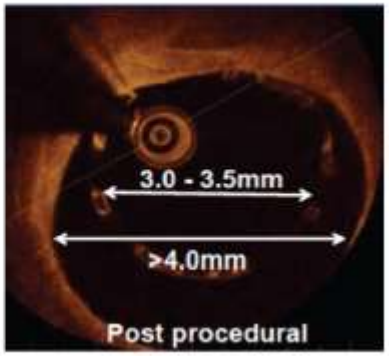
Small malapposition

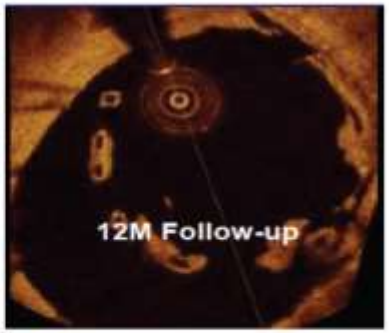
- Correctable by post dilatation
- Resolve at FUP

Large malapposition

- Uncorresctable (persistent at FU)
- Overexpansion by a large balloon

→ Acute disruption





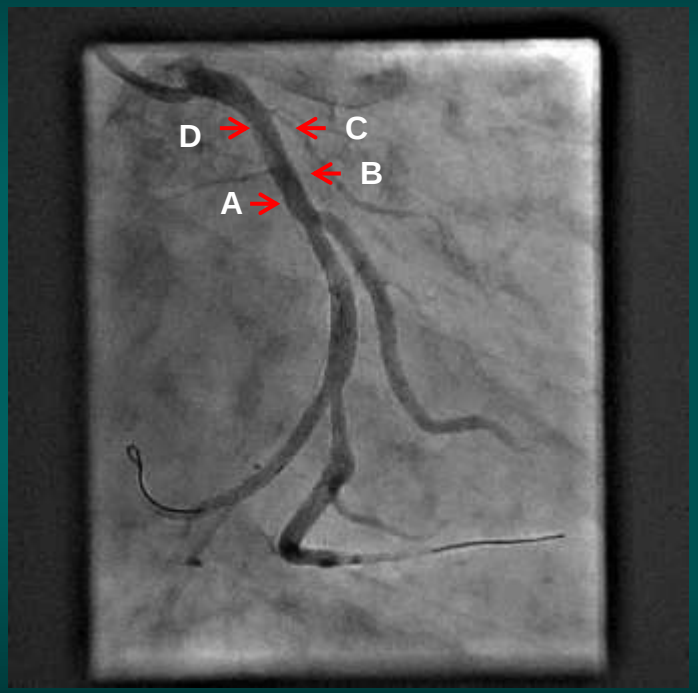
Max Diameter at landing zone (angio)	<2.5mm	2.5-3.3mm	>3.3mm	-
Edge dissection	61.5%	33.3%	11.1%	*p* 0.05
>5% Malapposition	7.7%	36.7%	66.7%	*p* 0.02

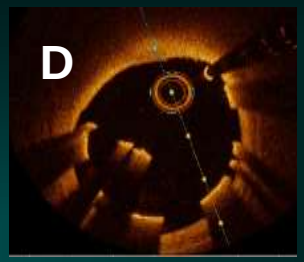
Gomez-Lara J et al Eurointerv. 2012; 8:214

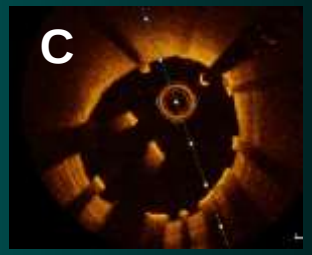
Bioresorbable Scaffolds – Sizing

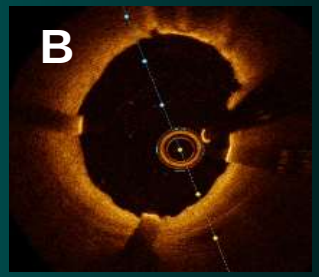
Malapposition cannot be detected by angiography

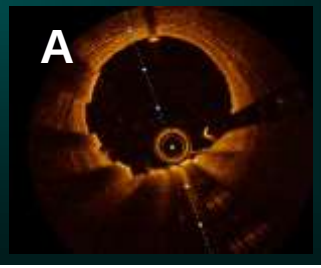
3.0 x 18 mm REVA FANTOM Scaffold











OCT after failure to cross with NC balloon

POWH/EHC Fantom II Trial - Case # 6

OCT imaging Guidance - BRS Implantation

What Have We Learnt?

Accurate Sizing and Optimal Implantation in Small Vessels with 2.5 mm Scaffolds

ABSORB 1-Year Meta-analysis - Outcomes

ABSORB II, ABSORB Japan, ABSORB China, ABSORB III

	Relative risk (95% CI)	p value
Patient-oriented composite endpoint (death, myocardial infarction, or revascularisation)		
Diabetes present	1·39 (1·15–1·68)	0·0008
Previous cardiac intervention	1·40 (1·16–1·69)	0·0006
Number of target lesions (≥2 *vs* 1)	1·45 (1·16–1·82)	0·001
Any lesion with minimal luminal diameter <median (0·93 mm)*	1·37 (1·13–1·68)	0·002
Any lesion with reference vessel diameter <median (2·65 mm)*	1·23 (1·01–1·51)	0·04
Any ACC/AHA class B2 or C lesion (*vs* class A or B1)*	1·38 (1·11–1·73)	0·003
BVS (*vs* CoCr-EES)	1·10 (0·90–1·34)	0·29
Device-oriented composite endpoint (target lesion failure: cardiac death, target vessel-related myocardial infarction, or ischaemia-driven target lesion revascularisation)		
Diabetes present	1·56 (1·19–2·04)	0·002
Previous cardiac intervention	1·36 (1·03–1·78)	0·03
Any lesion with minimum luminal diameter <median (0·93 mm)*	1·37 (1·03–1·82)	0·03
Any lesion with reference vessel diameter <median (2·65 mm)*	1·52 (1·14–2·03)	0·005
Any ACC/AHA class B2 or C lesion (*vs* class A or B1)*	1·65 (1·19–2·28)	0·002
BVS (*vs* CoCr-EES)	1·23 (0·92–1·64)	0·14
Myocardial infarction, all		
Diabetes present	1·61 (1·20–2·15)	0·002
Previous cardiac intervention	1·60 (1·19–2·15)	0·002
Number of target lesions (≥2 *vs* 1)	1·47 (1·03–2·08)	0·04
Any lesion with minimum luminal diameter <median (0·93 mm)*	1·42 (1·04–1·95)	0·03
Any lesion with reference vessel diameter <median (2·65 mm)*	1·57 (1·13–2·16)	0·007
Any ACC/AHA class B2 or C lesion (*vs* class A or B1)*	1·68 (1·18–2·41)	0·003
BVS (*vs* CoCr-EES)	1·35 (0·98–1·87)	0·052

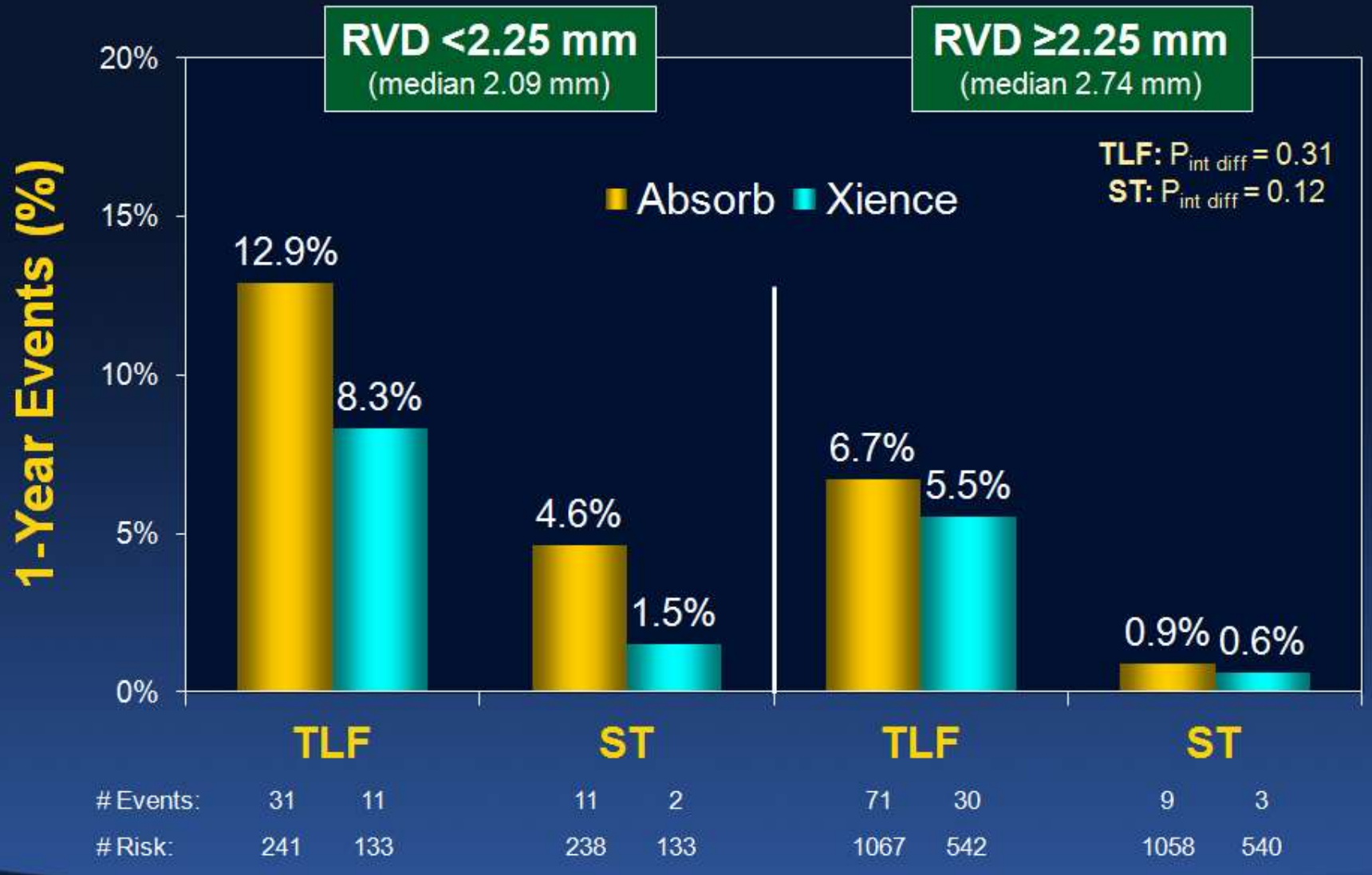
- **Independent baseline predictors of ischaemic events at 1 year by logistic regression**

- **Any lesion with reference vessel diameter < median (2.65mm) predictive of –**

  - **POCE (death, MI or revasc)**
  - **DOCE/TLF (cardiac death, TV-MI, ID-TLR)**
  - **All MI**

Stone et al Lancet 2016

Outcomes by QCA RVD 2.25 mm

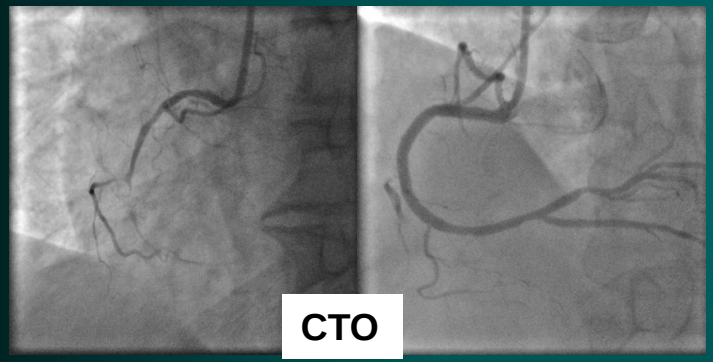


Median based on pooled Absorb and Xience

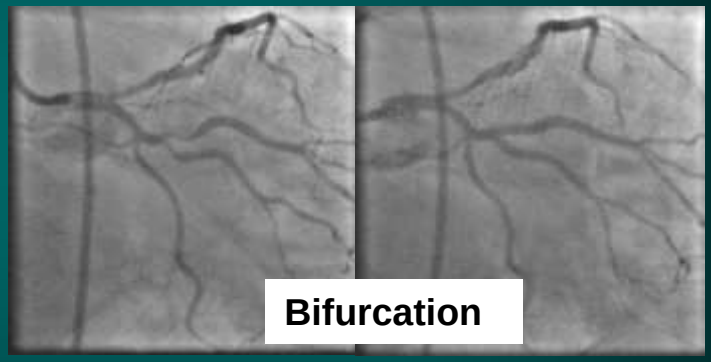
Absorb BVS Implantation – Real-world Disease

ACS/STEMI

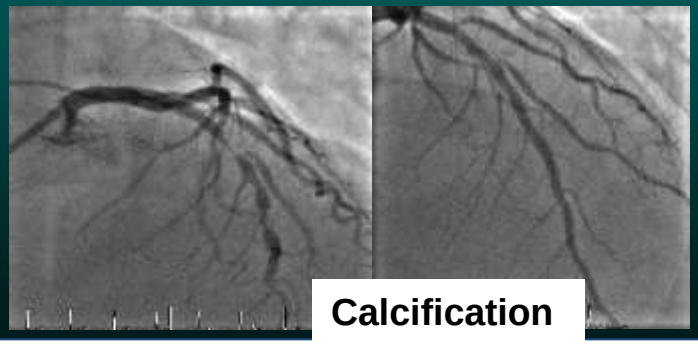
Long lesion



CTO



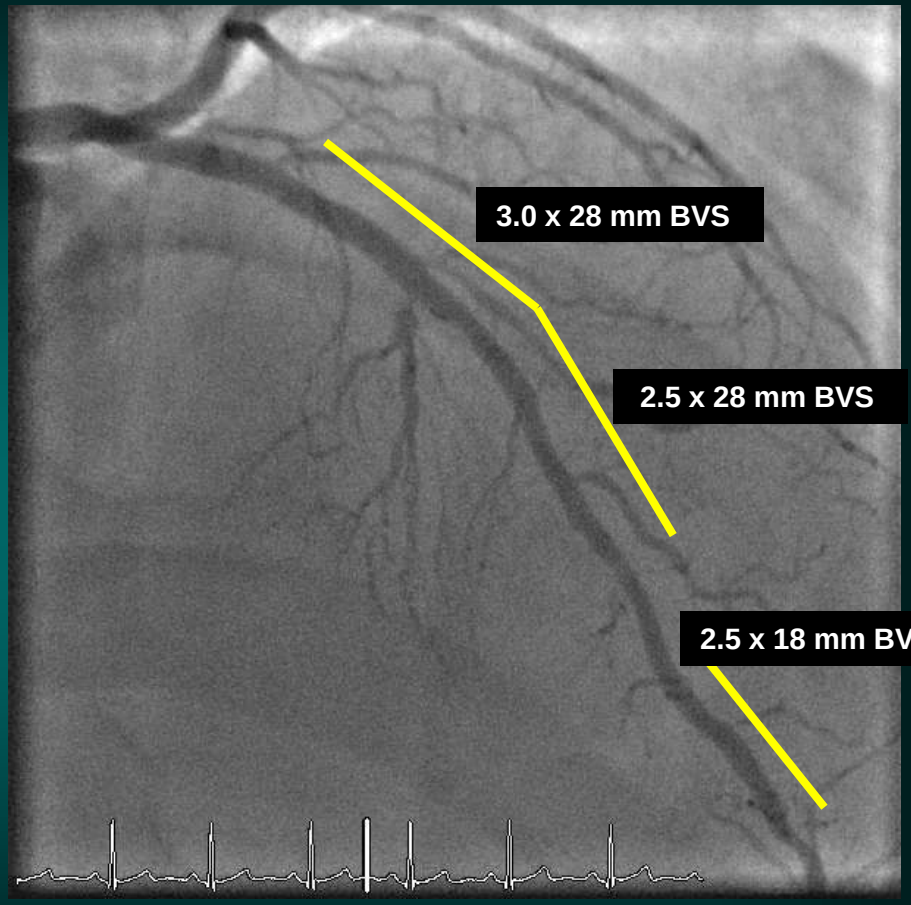
Bifurcation



Calcification

Diffuse, Long Segment Disease – Angiographic Guided BVS Implantation

36 Male, 2/12 limiting angina, Smoker, + FH



POW/EHC Absorb Registry - Case # 11

Diffuse, Long Segment Disease – Angiographic Guided BVS Implantation

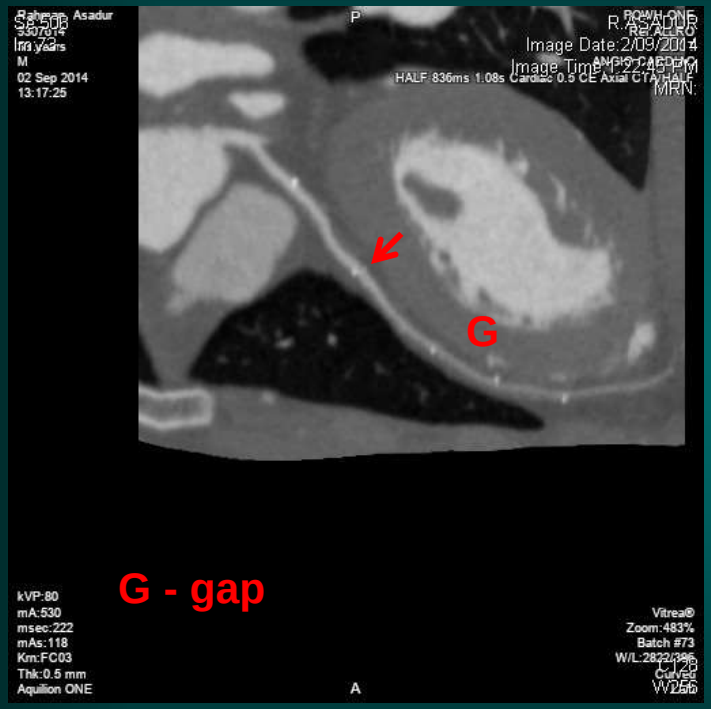
36 Male, 2/12 limiting angina, Smoker, + FH

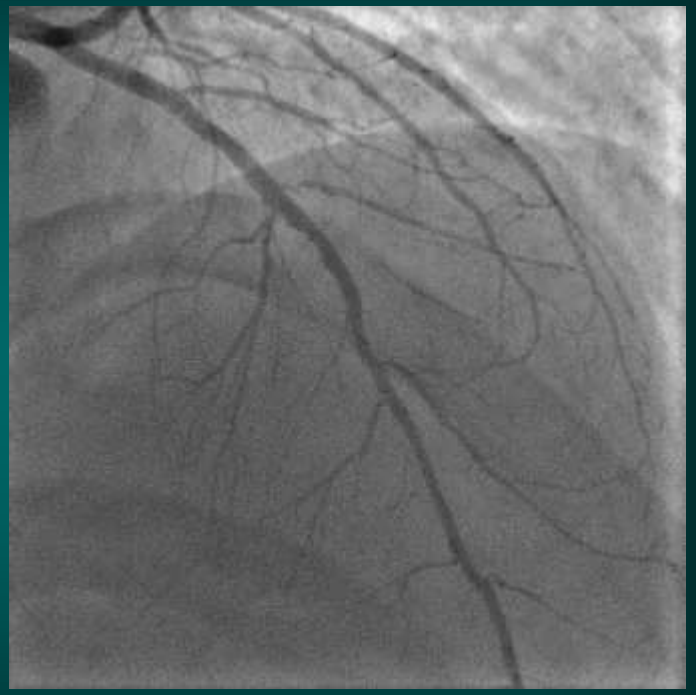
POW/EHC Absorb Registry - Case # 11

Diffuse, Long Segment Disease – Angiographic Guided BVS Implantation

36 Male, 2/12 limiting angina, Smoker, + FH

30 month F/up – CTCA and invasive





POW/EHC Absorb Registry - Case # 11

Eastern Heart Clinic/Prince of Wales Hospital
Real-World BVS Experience

Base-line Demographics - Dec 2010 - Dec 2015

N	295 (312 procedures)
Age (yrs/range)	59 (18-83)
Male (%)	76
DM (%)	20
Hypertension (%)	73
Prior MI (%)	19
Hyperlipidaemia (%)	85
CKD (%)	7
Prior PCI (%)	21
Prior CABG (%)	9

Eastern Heart Clinic/Prince of Wales Hospital
Real-World BVS Experience

Procedural Details

CTO (%)	7.5
Long lesions (%)	29
Bifurcations (%)	19
Moderate/severe calcification (%)	26
B2/C lesion complexity(%)	57

Eastern Heart Clinic/Prince of Wales Hospital Real-World BVS Experience

Procedural Details (3)

Pre-dilatation (%)	100
Scaffold overlap (%)	27
Multi-vessel BVS (%)	13
Total scaffolds (%)	472
Scaffolds/patient (n/range)	1.6 (1-5)
OCT (%)	18
Rotablator/scoring balloon (%)	4
NC balloon post-dilatation (%)	99

Eastern Heart Clinic/Prince of Wales Hospital Real-World BVS Experience

Clinical Outcomes

100 % 30 d, 73% 12 mth, 49% 24 mth	
Peri-procedural non-Q MI n (%)	9 (3.1)
Deaths n (%)	3 (1.0)
Cardiac Deaths n (%)	1 (0.3)
TVR n (%)	9 (3.1)
TLR n (%)	7 (2.4)
MACE n (%)	18 (6.1)
Scaffold thromboses – Definite/probable n (%)	3 (1.0)
Scaffold thromboses – Possible n (%)	1 (0.3)
MI (spontaneous) n (%)	3 (1.0)

EBC 2014, CSANZ 2015

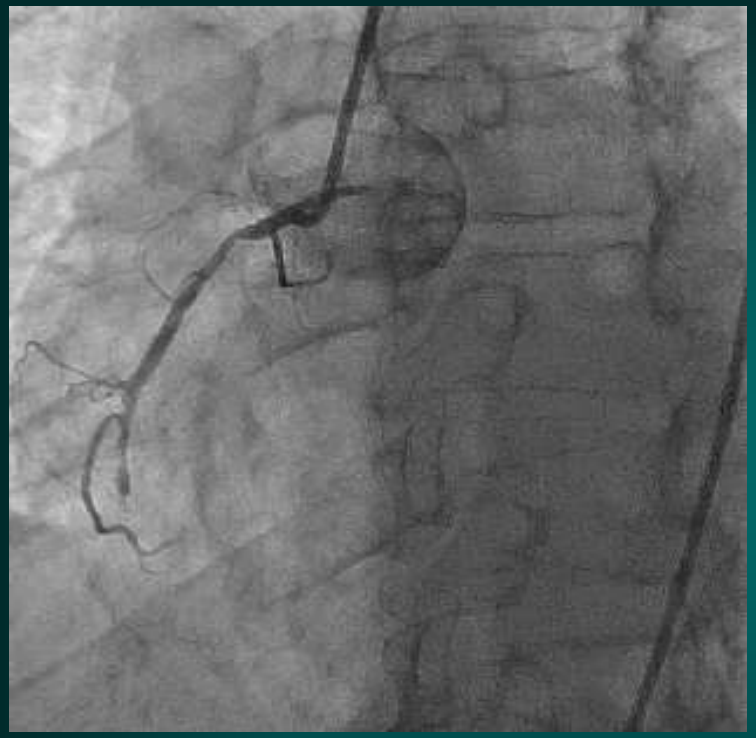
Eastern Heart Clinic/Prince of Wales Hospital Real-World BVS Experience

Clinical Outcomes – First 100 pts 12 mths

152 lesions, 167 scaffolds, mean age 62.1 (19-83) yrs	In-hospital	30 days	12 months
Deaths n	0	0	0
Non-fatal MI Q n	0	0	1
Non-fatal MI non-Q n	0	0	1
TVR n	0	0	6
TLR n	0	0	4
Scaffold thromboses n	0	0	1
Scaffold dislodgement n	0	0	0
MACE n	0	0	4

HLC 2015, J Inv Cardiol 2015

ABSORB POWH Registry – Case # 201
50 M, STEMI – OCT guided



- ASA, Prasugrel, UFH - Thrombectomy + POBA
- 3.0 x 28mm, 3.0 x 28 mm, 3.5 x 28mm + 3.5 x 28 mm BVS – HP NB balloon
- Provisional PL/PDA bifurcation – step kiss

ABSORB POWH Registry – Case # 201
50 M, STEMI – OCT guided

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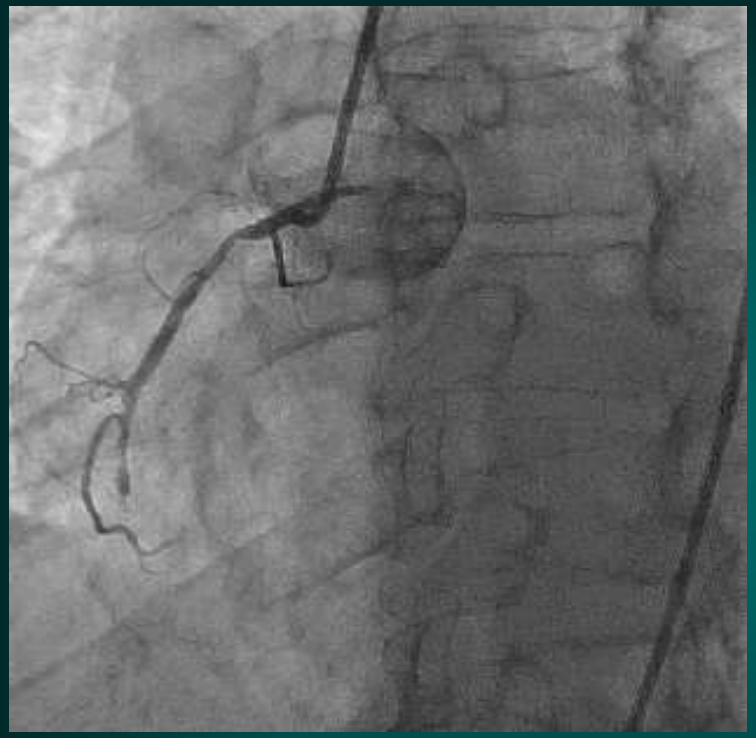

- ASA, Prasugrel, UFH - Thrombectomy + POBA
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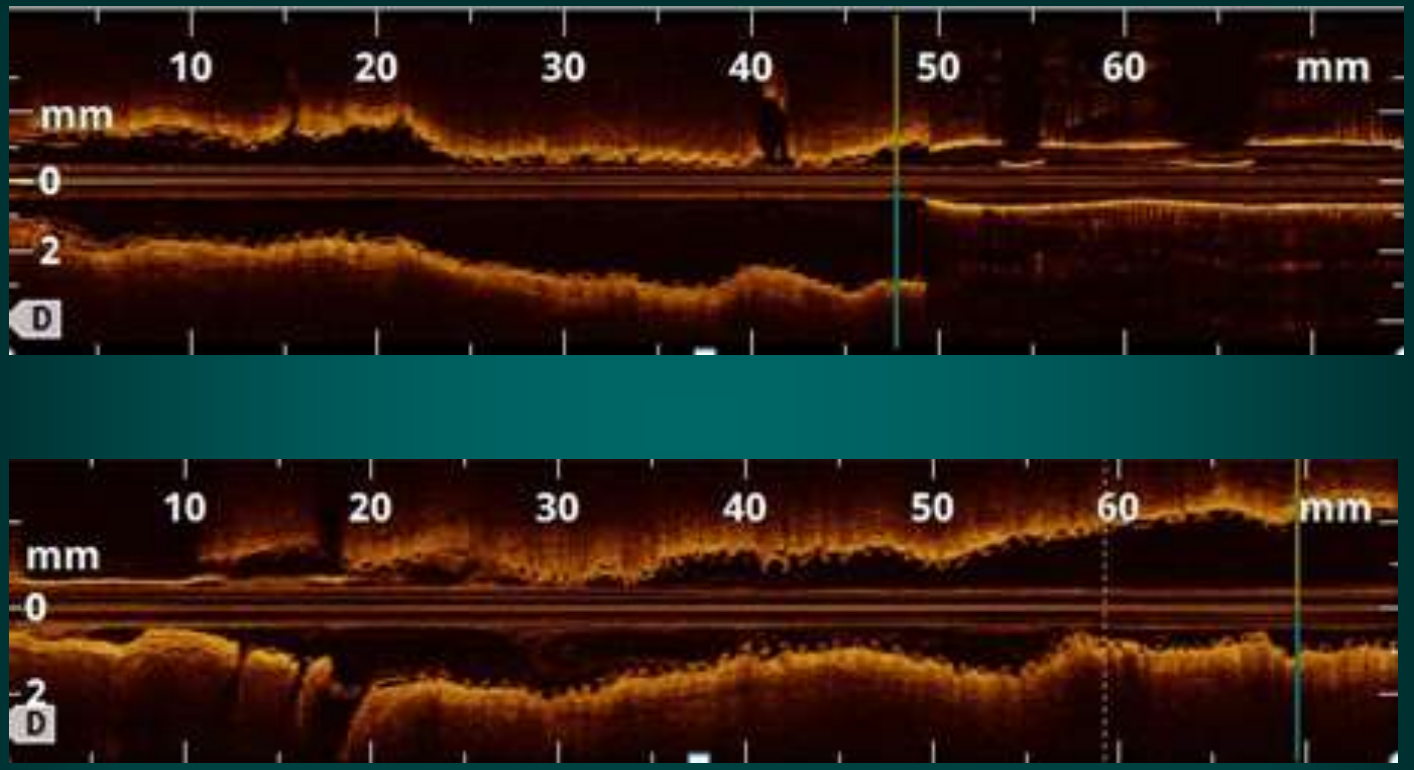
ABSORB POWH Registry – Case # 201
50 M, STEMI – OCT guided

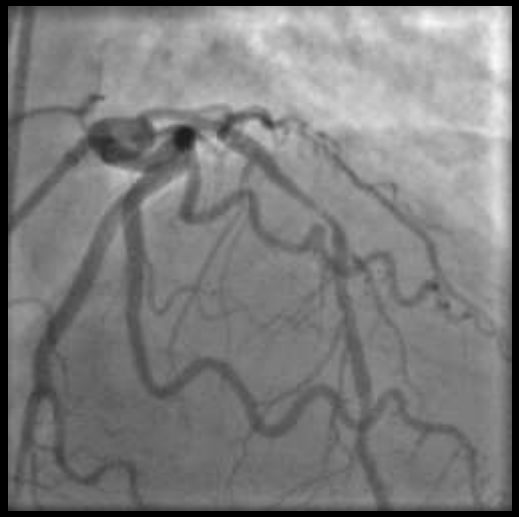


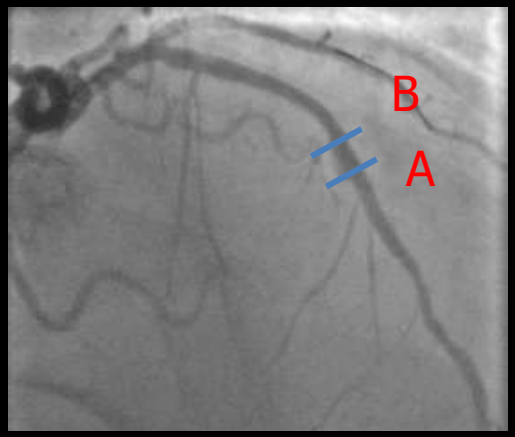
OCT imaging Guidance - BRS Implantation

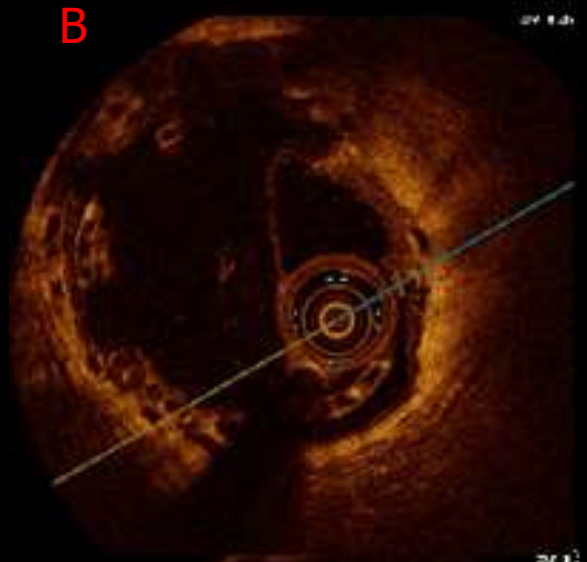
What Have We Learnt?

Scaffold Overlap and Long lesions

Absorb BVS Scaffold – Long Overlap and Malapposition





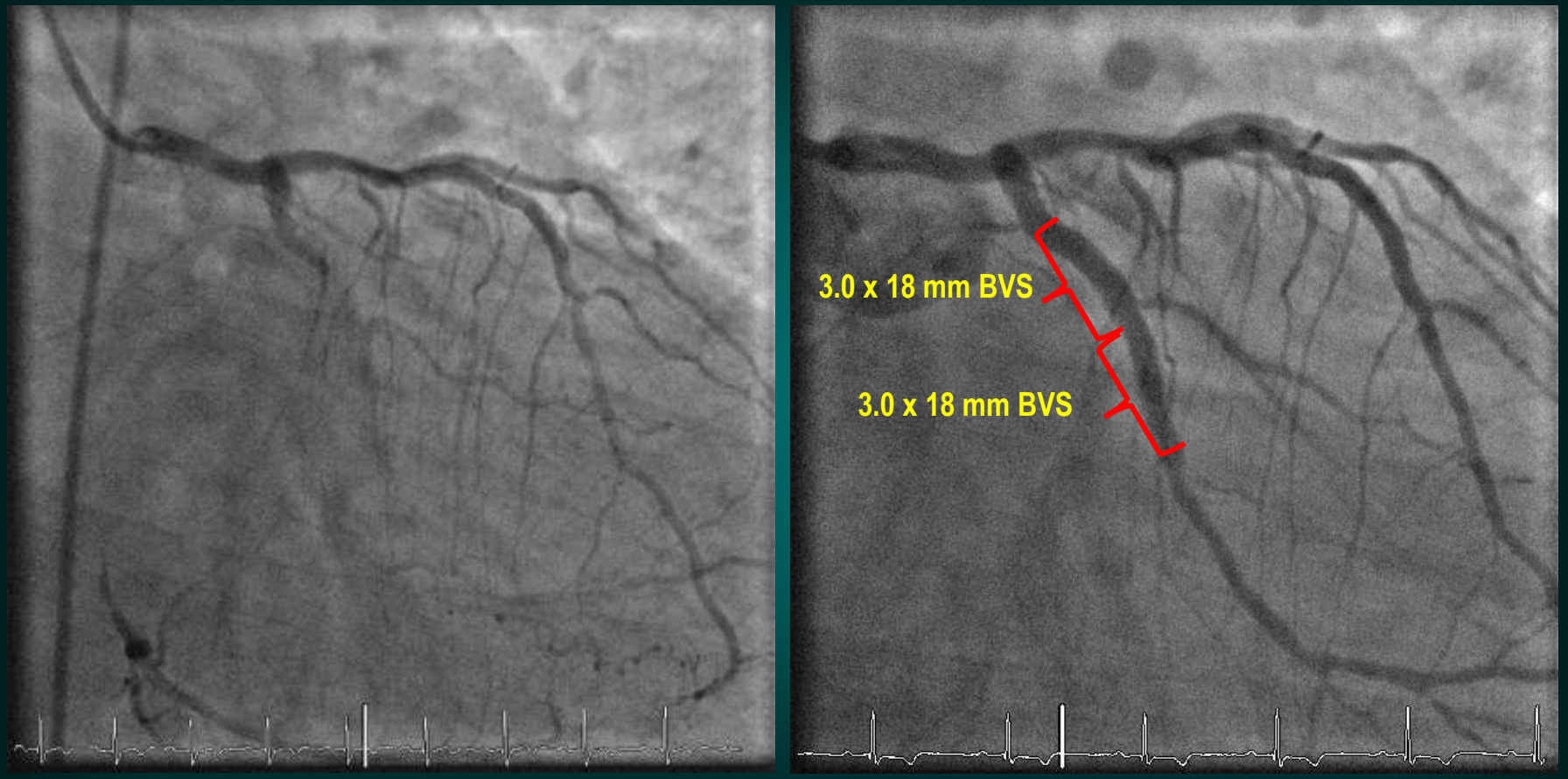


3.5 x 28 mm + 3.0 x 18 mm BVS

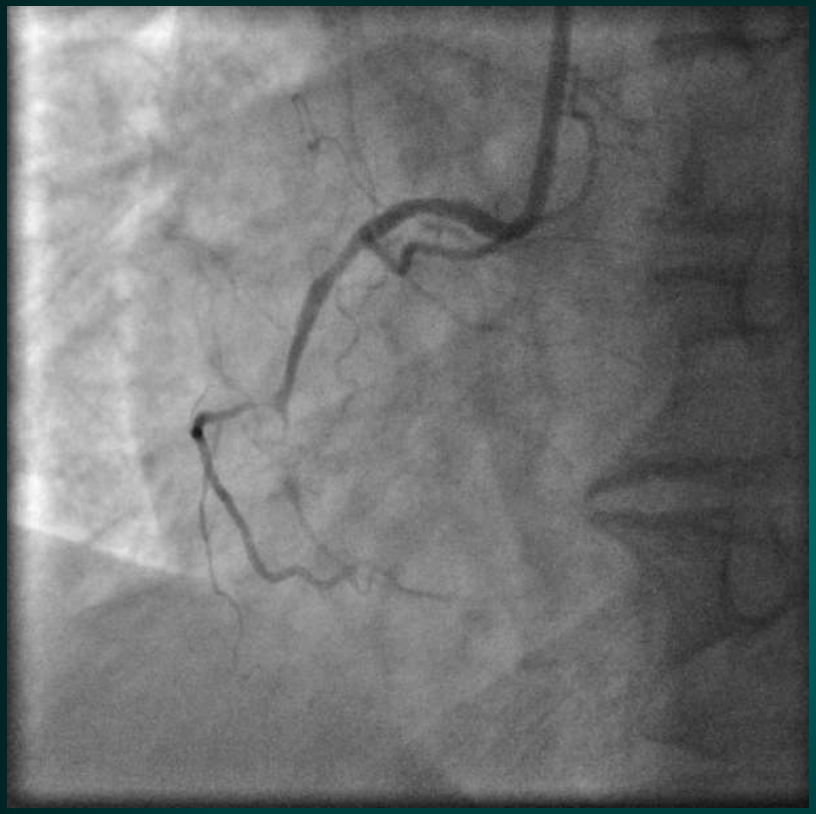
POW/EHC Absorb Registry - Case # 183

ABSORB POWH Registry – Case # 83 (47M)

CTO – Circumflex and RCA

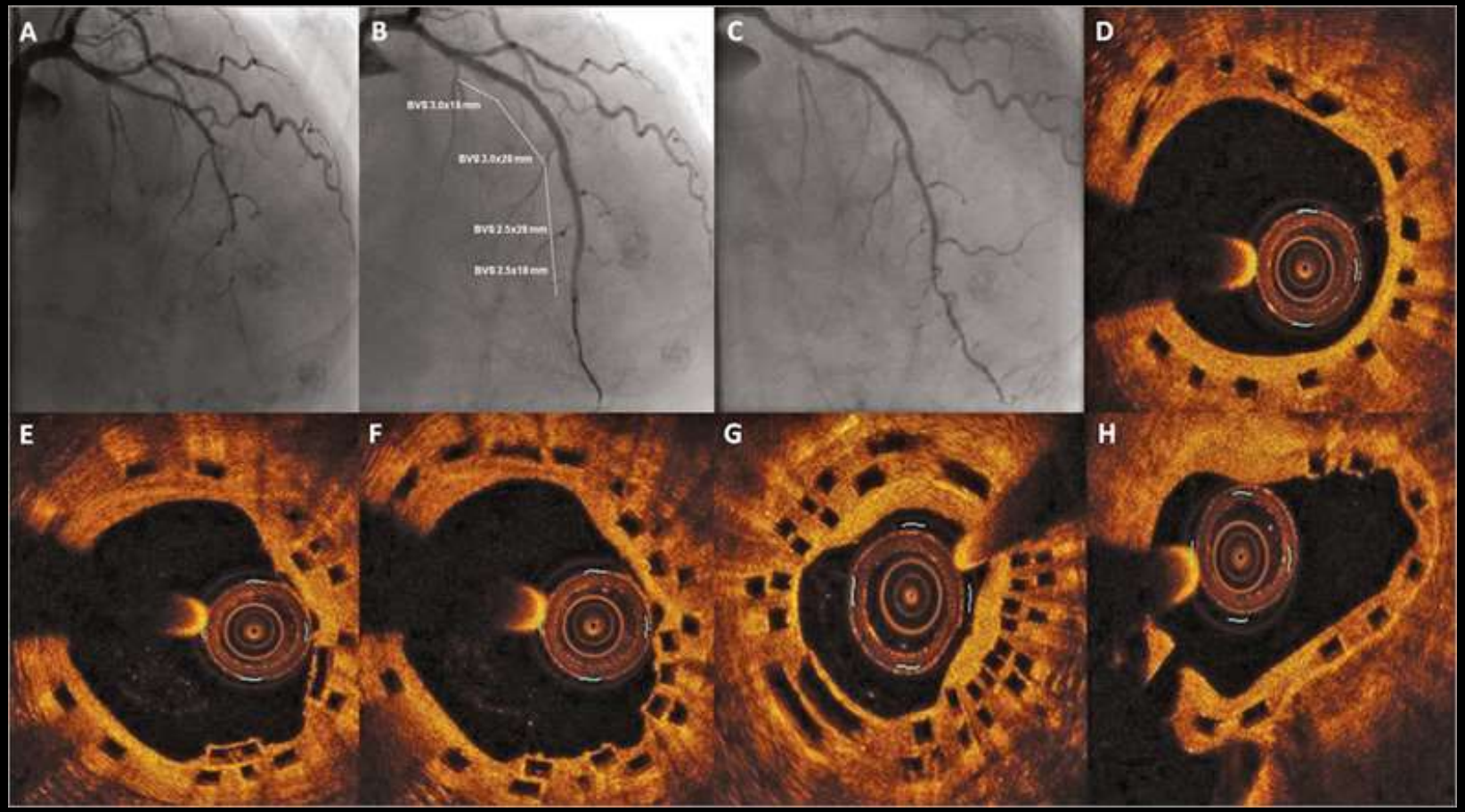


ABSORB POWH Registry – Case # 83 (47M)



Two BVS 3.5 x 28 mm Scaffolds
Post-dilated 3.5/3.75 mm NC balloons

Absorb BVS Scaffold – Long Overlap with Late OCT



EuroIntervention 2015;11:e1 published online e-article June 2015

"Full plastic jacket": 18-month follow-up after implantation of multiple overlapping bioresorbable vascular scaffolds

ABSORB Scaffolds vs Second-Generation DES

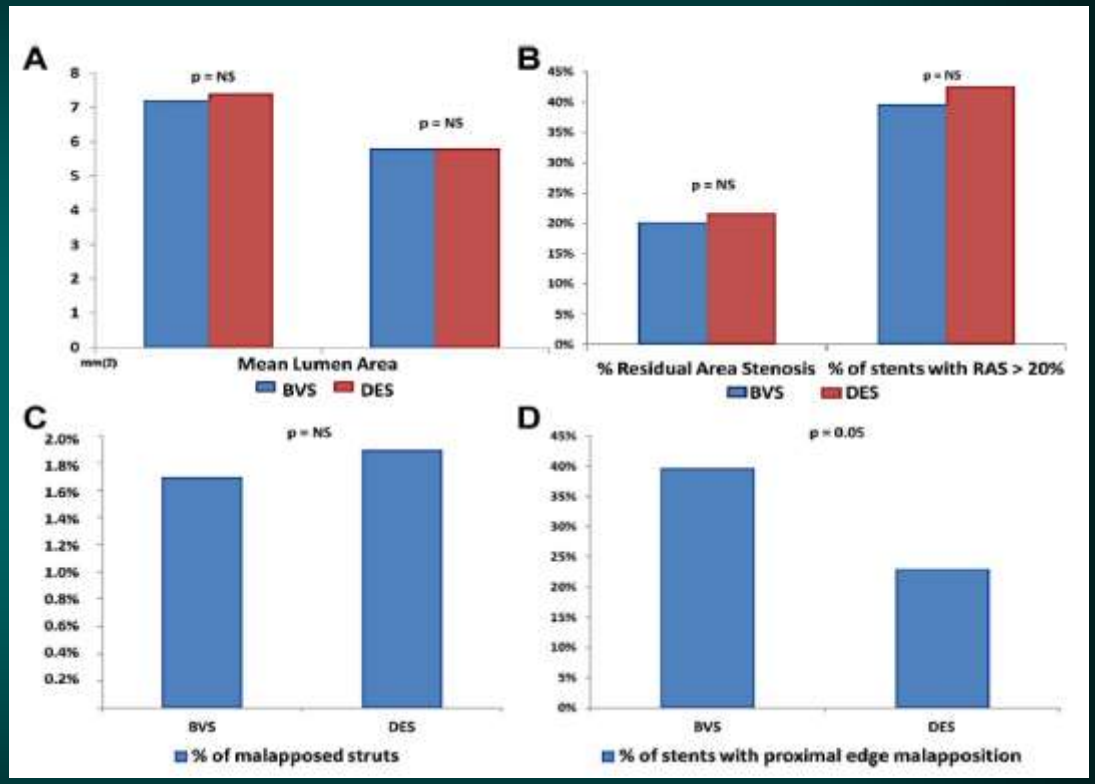
A Comparison Study of 100 Complex Lesion treated Under OCT Guidance

ABSORB Biodegradable Stents Versus Second-Generation Metal Stents

A Comparison Study of 100 Complex Lesions Treated Under OCT Guidance

Alessio Mattesini, MD,*† Gael G. Secco, MD,*† Gianni Dall'Ara, MD,*
Matteo Ghione, MD,* Juan C. Rama-Merchan, MD,* Alessandro Lupi, MD,‡
Nicola Viceconte, MD,* Alistair C. Lindsay, MD, PhD,* Ranil De Silva, MD, PhD,*
Nicolas Foin, PhD,§ Toru Naganuma, MD,§ Serafina Valente, MD,†
Antonio Colombo, MD, PhD,‖ Carlo Di Mario, MD, PhD*
London, United Kingdom; Florence, Novara, and Milan, Italy; and Singapore

	BVS (n=50)	DES(n=50)	*P*
Lesion lenght, mm	24.7 (14.2)	25.1 (10.6)	0.86
Calcified	31 (62.0)	37 (74.0)	0.28
Ostial	7 (14.0)	5 (10.0)	0.76
Bifurcation	17 (34.0)	23 (46.0)	0.30
In-stent restenosis	6 (12.0)	3 (6.0)	0.48



Mattesini et al JACC Cardiovasc Int 2014;7(7):241-50

OCT imaging Guidance - BRS Implantation

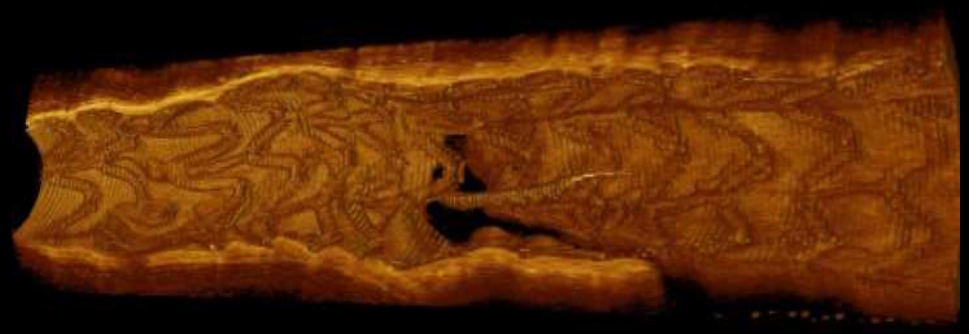
What Have We Learnt?

Bifurcation lesions

In-vivo Evaluation of Provisional Strategy for Absorb BVS in Bifurcation lesions – OCT Analysis

SB strut coverage by OCT *n=24*

- *Absorb BVS vs EES*
- *POT vs SB opening + Final POT (step kissing)*



Jepson N, Robaei R, Foin N

In-vivo Evaluation of Provisional Strategy for Absorb BVS in Bifurcation lesions – OCT Analysis

SB strut coverage by OCT (Absorb BVS vs EES)

		Xience		Absorb BVS	
		POT	**SBO + POT**	**POT**	**SBO + POT**
Malapposed strut in bifurcation (%)		26.4	17.6	17.7	12.3
Mal-apposed struts along entire device length (%)		9.3	3.6	3.9	3.3

No cases of scaffold/stent deformation, fracture or intra-luminal defects

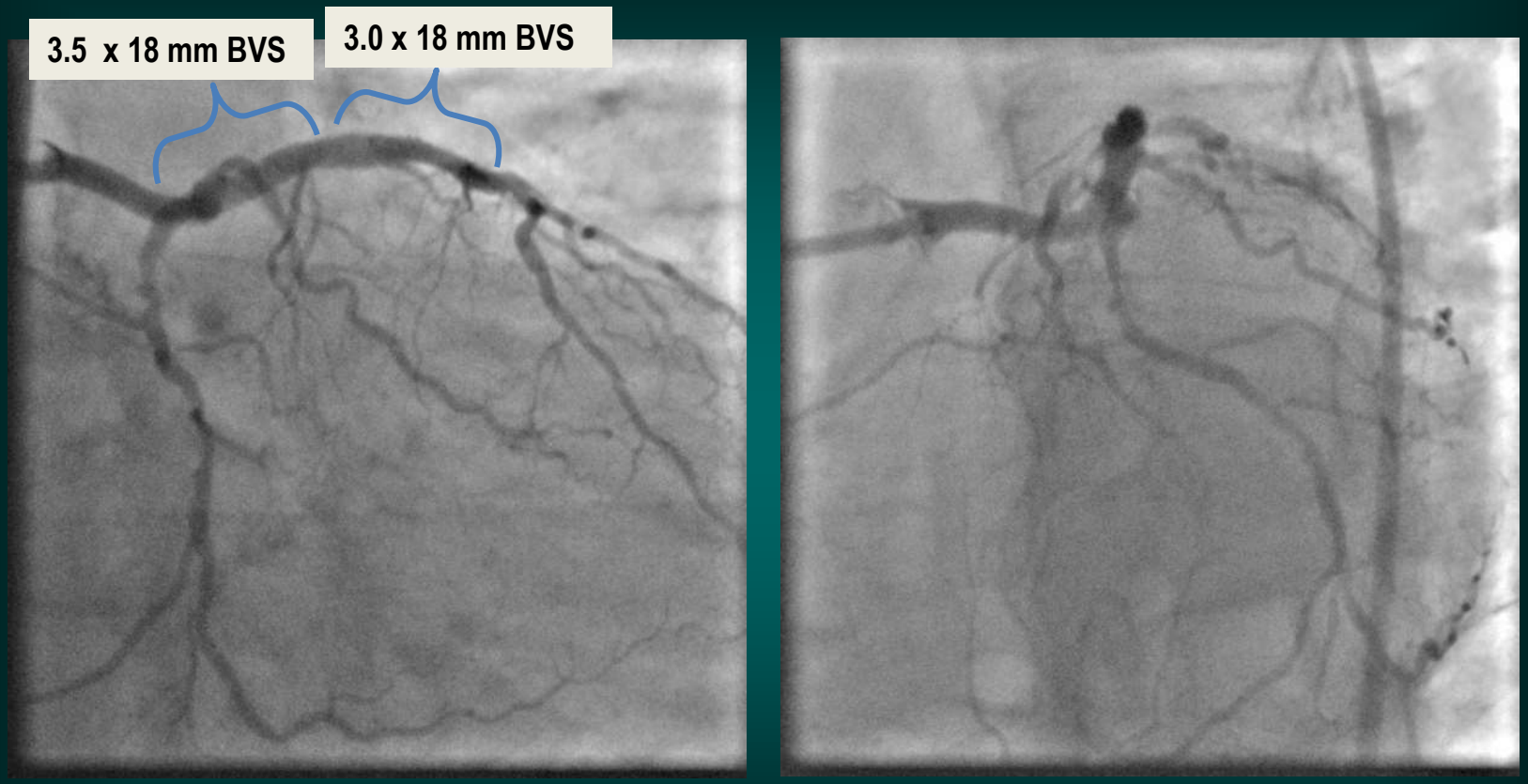
Jepson N, Robaei R, Foin N

OCT imaging Guidance - BRS Implantation

What Have We Learnt?

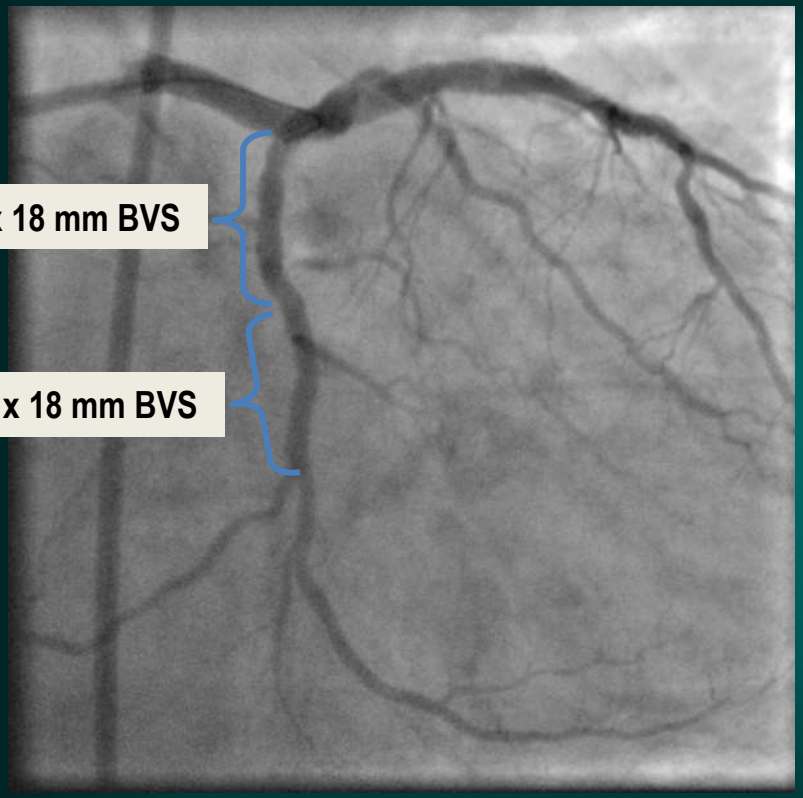
Tortuosity and Calcification

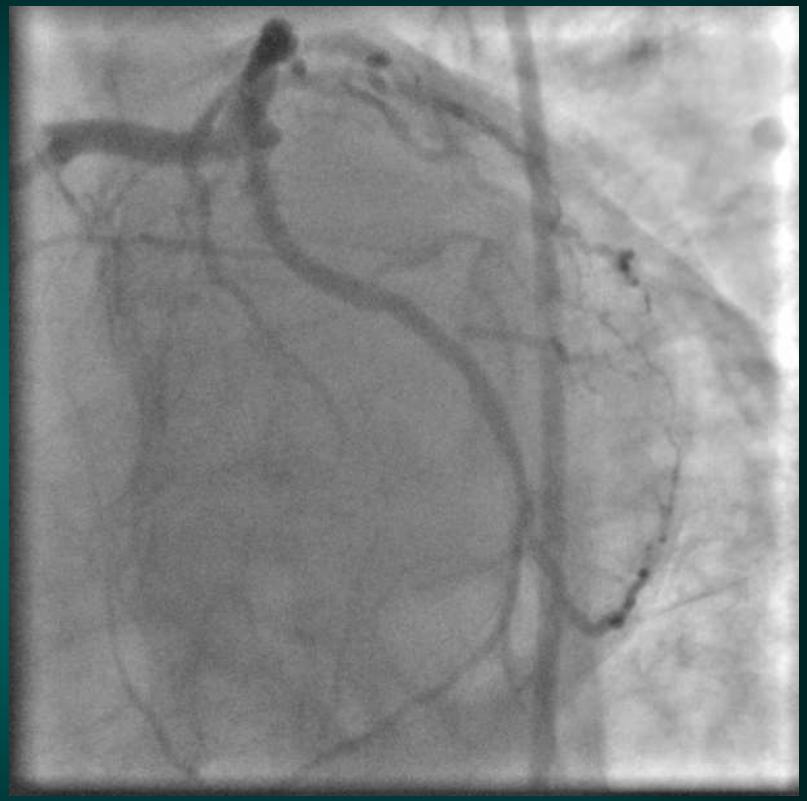
56 Male, unstable angina, hypertension, +FH



POW/EHC Absorb HREC Registry - Case # 79

56 Male, unstable angina, hypertension, +FH

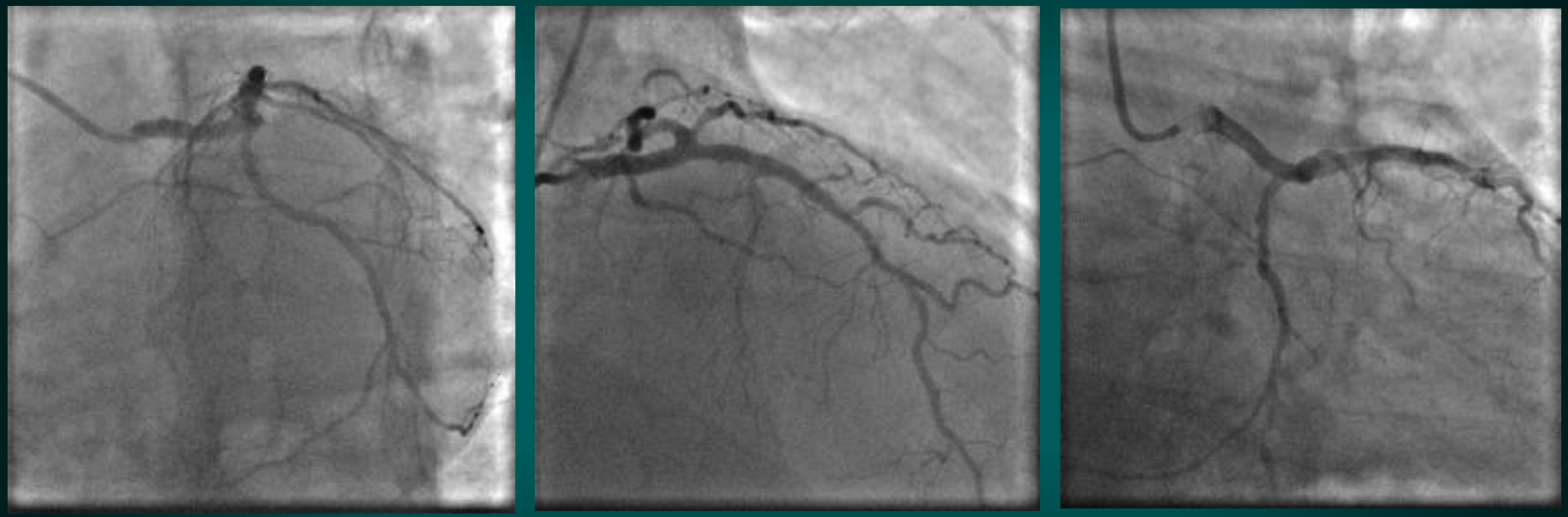




Angio-guided – OCT could not pass

POW/EHC Absorb HREC Registry - Case # 79

56 Male, unstable angina, hypertension, +FH
12 mth angiographic follow-up



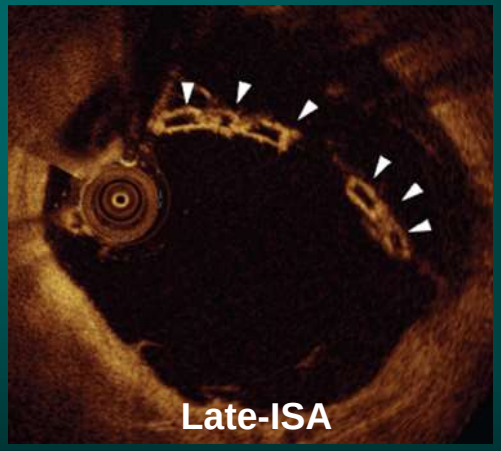
POW/EHC Absorb HREC Registry - Case # 79

OCT imaging Guidance - BRS Implantation

What Have We Learnt?

Scaffold Failure

•Neoatherosclerosis



Late-ISA

OCT imaging Guidance - BRS Implantation

Scaffold Failure

Angiographic and Optical Coherence Tomography Insights Into Bioresorbable Scaffold Thrombosis

Single-Center Experience

Antonios Karanasos, MD, PhD; Nicolas Van Mieghem, MD, PhD; Nienke van Ditzhuijzen, MSc; Cordula Felix, MD; Joost Daemen, MD, PhD; Anouchska Autar, MD; Yoshinobu Onuma, MD, PhD; Mie Kurata, MD, PhD; Roberto Diletti, MD; Marco Valgimigli, MD, PhD; Floris Kauer, MD; Heleen van Beusekom, MD, PhD; Peter de Jaegere, MD, PhD; Felix Zijlstra, MD, PhD; Robert-Jan van Geuns, MD, PhD; Evelyn Regar, MD, PhD

Main mechanisms of both early and late BVS thrombosis

- ***Incomplete lesion coverage***
- ***Under expansion***
- ***Malapposition***

Karanasos A et al Circ Cardiovasc Intervent 2015

OCT imaging Guidance - BRS Implantation

Scaffold Failure

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OCT reveals scaffold thrombosis associated with implantation technique

DEVICE FAILURE or OPERATOR FAILURE

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OCT imaging Guidance - BRS Implantation

OCT Imaging with BRS Therapy -

- Excellent results can be gained with BVS in a practice of predominant angiographic guidance in Real-world disease however OCT provides invaluable adjunctive insights
- Excellent imaging of strut/lumen interface (IVUS plaque:media volume, vessel area)
- Guide vessel preparation pre-BRS implant (plaque composition/distribution) and direct scaffold diameter, length and landing zones
- Ensure optimal expansion and apposition post-BRS deployment
- Resolve ambiguous angiographic appearance during/after implantation

OCT imaging Guidance - BRS Implantation

When to use OCT – ***in an absence of randomized data***

- OCT indications as per DES – planning and intra-procedural guidance
- Uncertainty in vessel sizing and final appearance
- Diffuse, small vessel disease
- Complex interventions – long lesions/overlaps, calcification, bifurcations, ISR
- Liberal use early in BVS experience
- BVS failure (scaffold thrombosis, restenosis)

Thank you for your attention

Whale Sharks – Ningaloo, Western Australia