Real World BVS Implantation - OCT Guided or Angiography Guided?

TCTAP Pre-workshop Course IV. - Imaging
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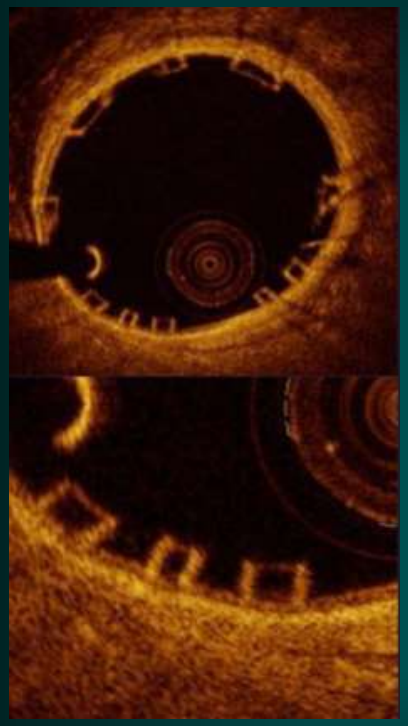
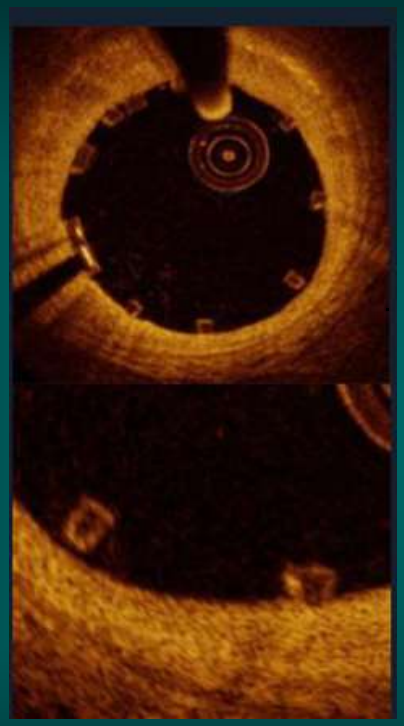
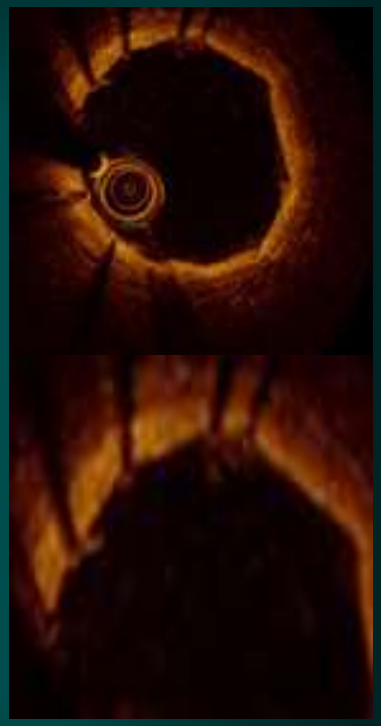
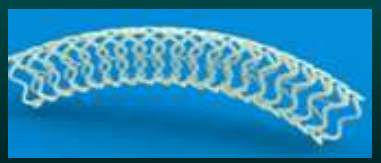
Disclosures

- **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**

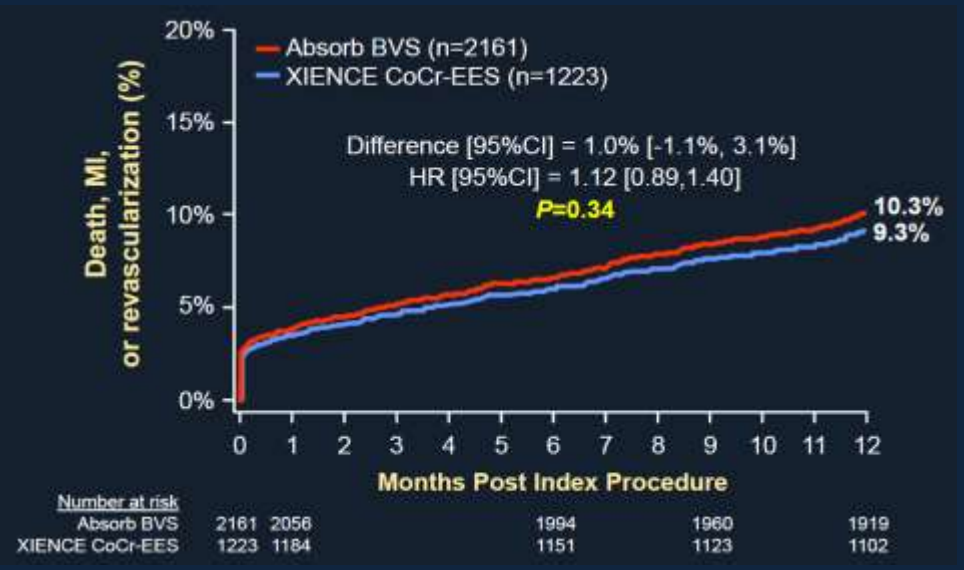
BRS Platforms and OCT Characterization

ABSORB	DESOLVE	FANTOM	XIENCE DES
			
			

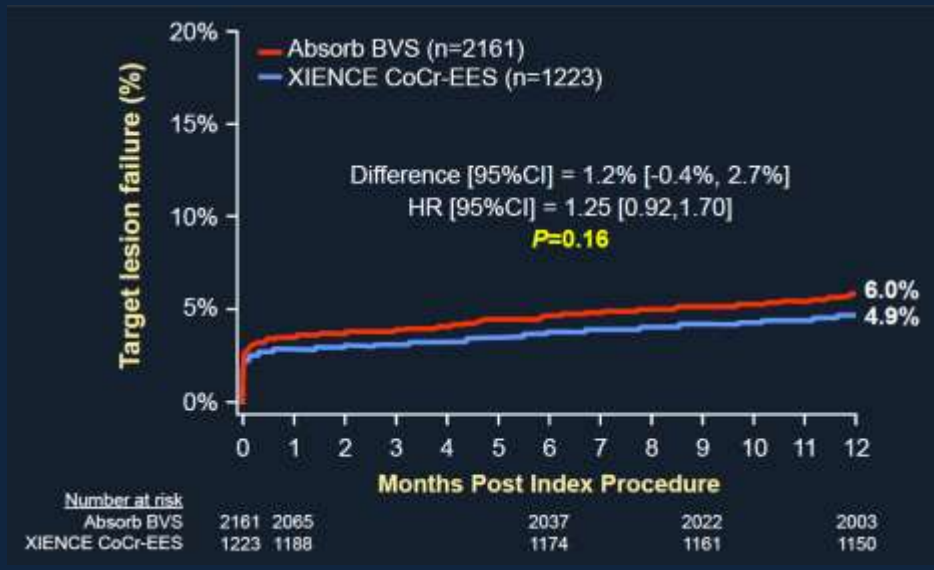
ABSORB 1-Year Meta-analysis
Outcomes in 3389 'On-label' patients

ABSORB II, ABSORB Japan, ABSORB China, ABSORB III

PoCE: Death, MI or Revascularization (pooled)



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



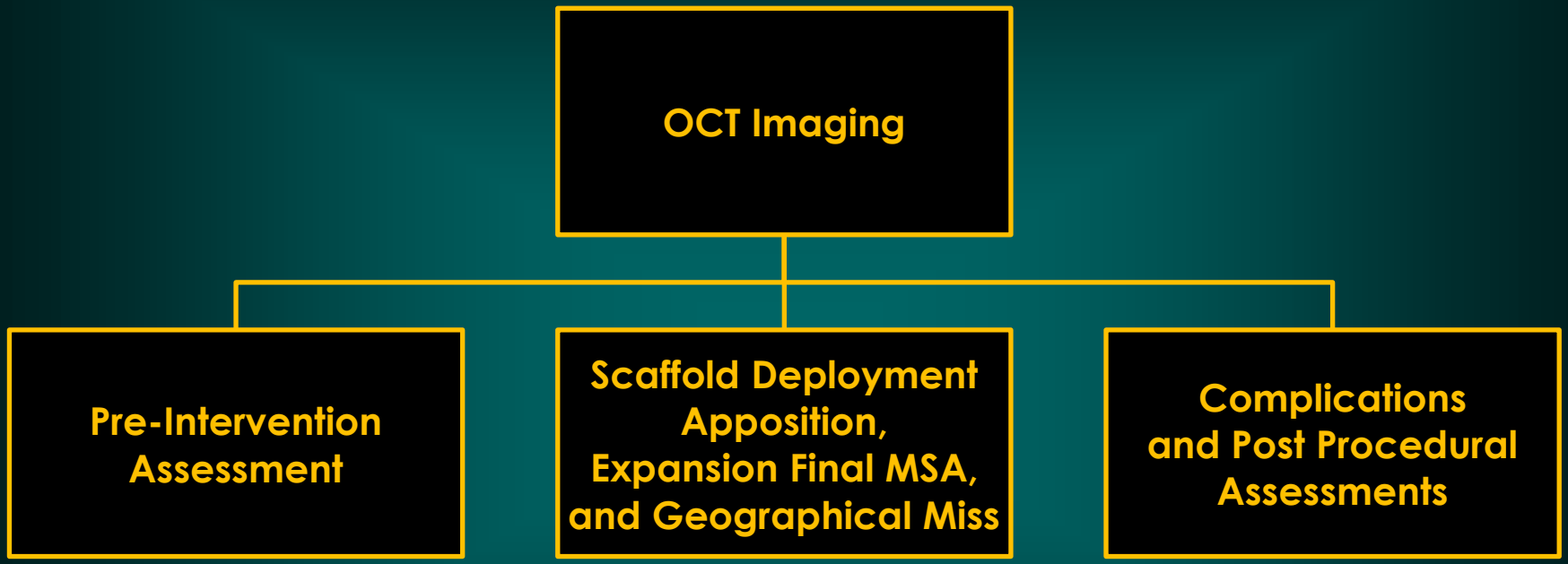
IVUS or OCT guidance/procedure – 23.9 % Absorb vs 20.3% Xience Co-Cr EES P<0.02

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

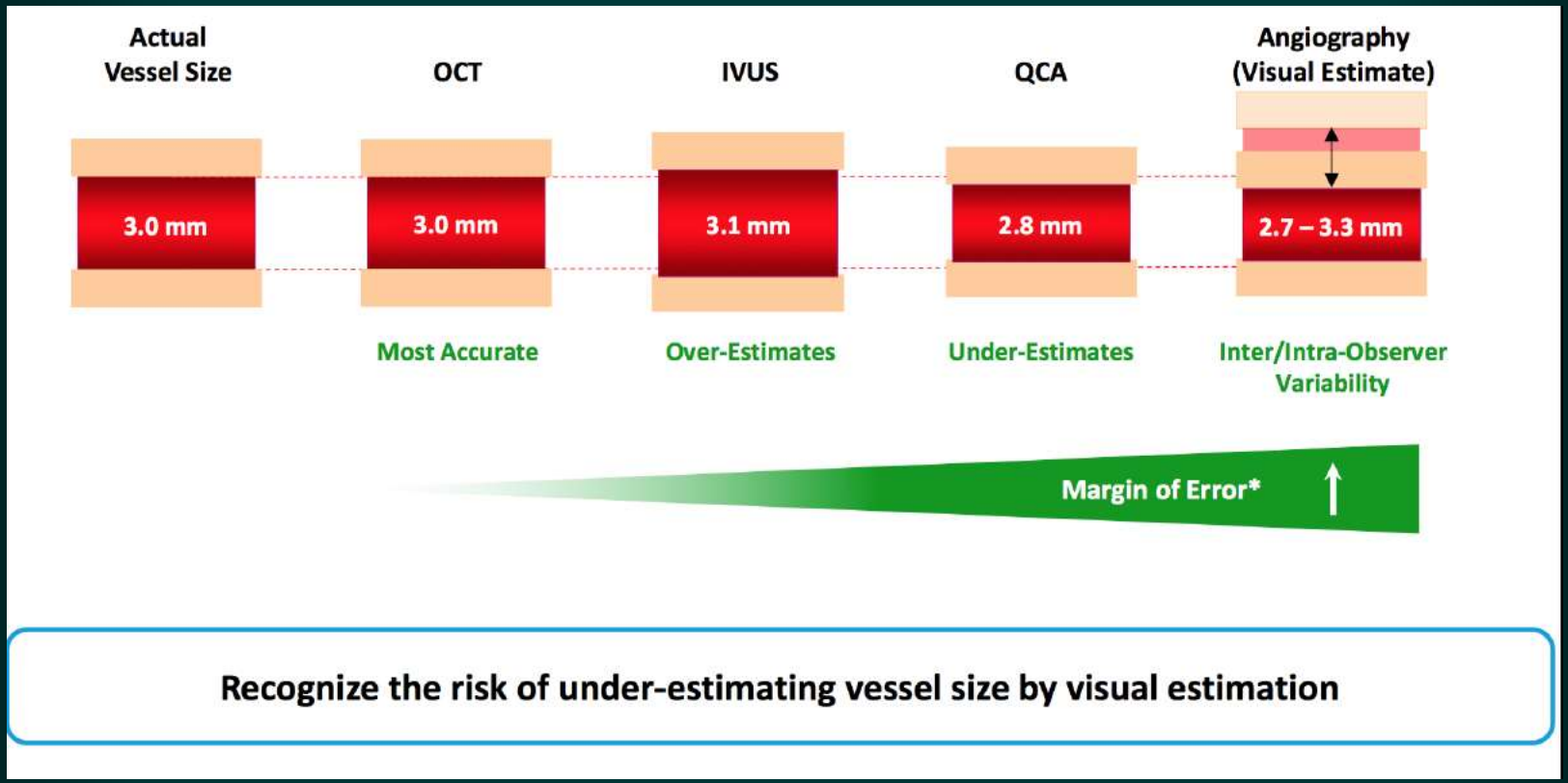
OCT imaging Guidance - BRS Implantation

What Have We Learnt?

Correct Sizing + Post-dilatation

BRS – Insights from Intravsacular Imaging

Vessel Sizing Techniques



Recognize the risk of under-estimating vessel size by visual estimation

BRS – Insights from Intravsacular Imaging

OCT offers advantages - SIZING

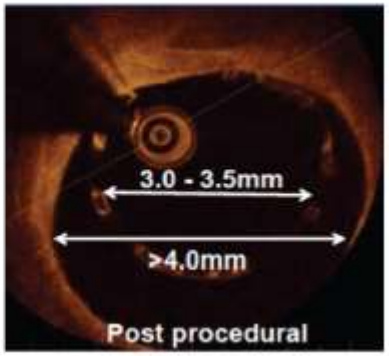
Small malapposition

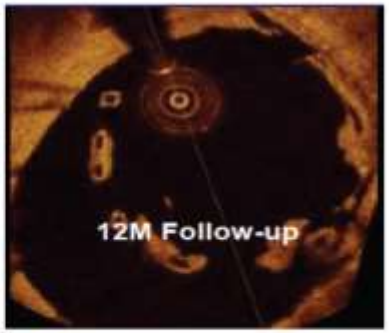
- Correctable by post dilatation
- Resolve at FUP

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

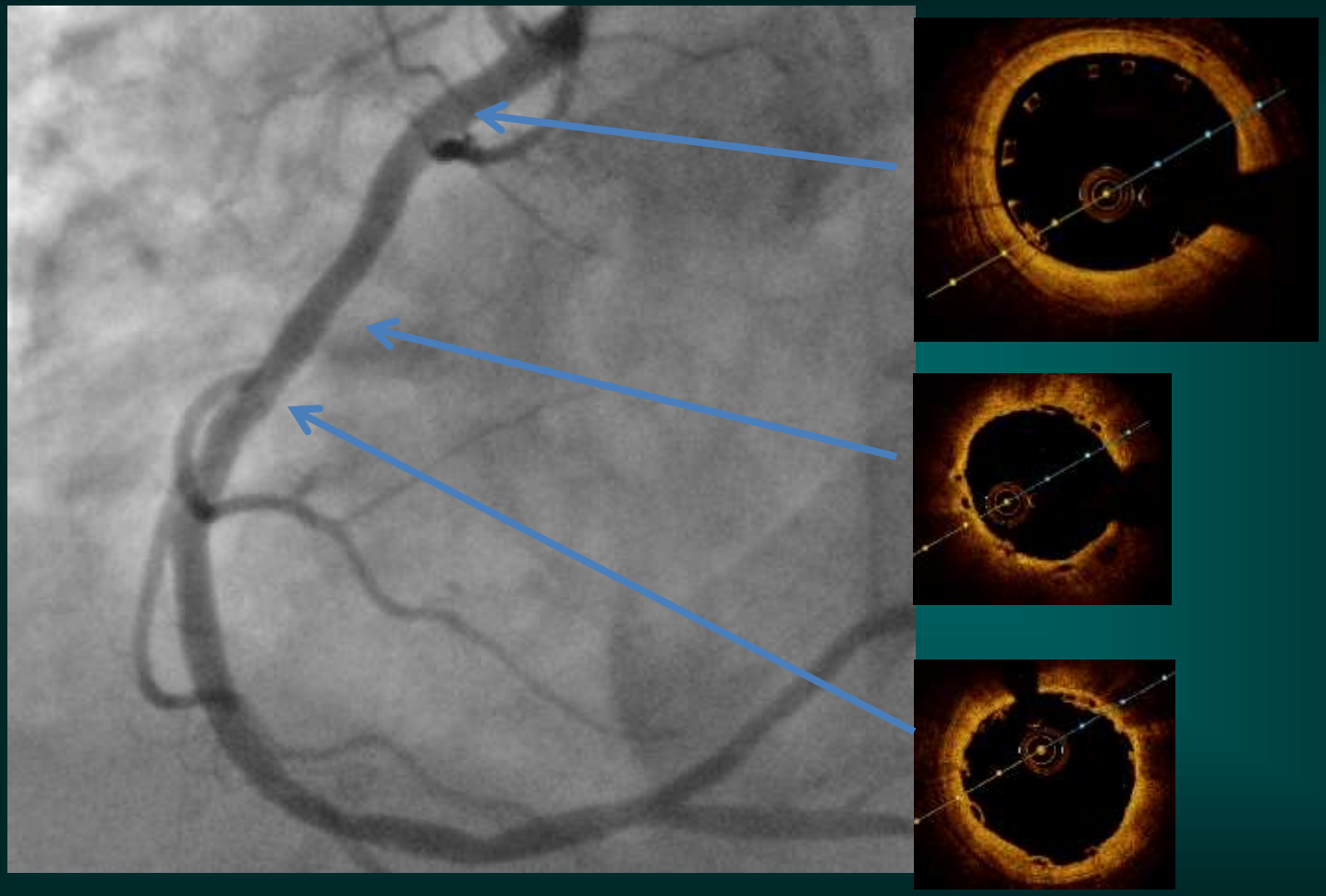
Bioresorbable Scaffolds – Sizing

61 M, Inferior STEMI, lysis, < 24 hr angiogram

3.0 x 28 mm BVS/3.5 mm NC

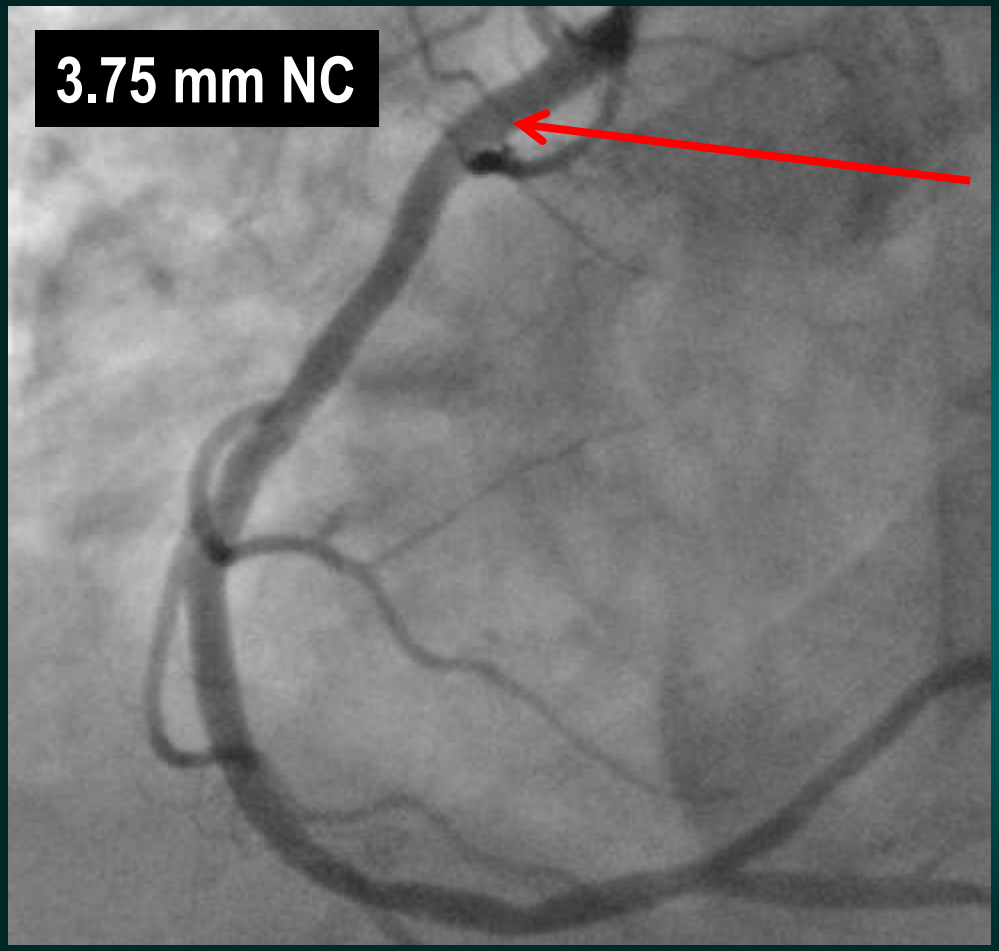
Bioresorbable Scaffolds – Sizing

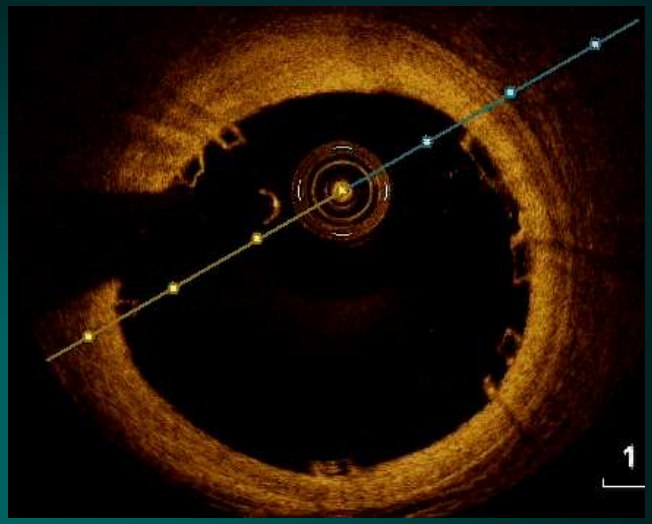
61 M, Inferior STEMI, lysis, < 24 hr angiogram



Bioresorbable Scaffolds – Sizing

61 M, Inferior STEMI, lysis, < 24 hr angiogram





Optimization of ABSORB Scaffold Implantation with OCT

OCT post successful BVS implantation by angiography

28% (8/29) required further intervention after OCT review

- 3/8 due to scaffold malapposition
- 5/8 due to scaffold underexpansion★

★< 80% mean prox/dist reference area

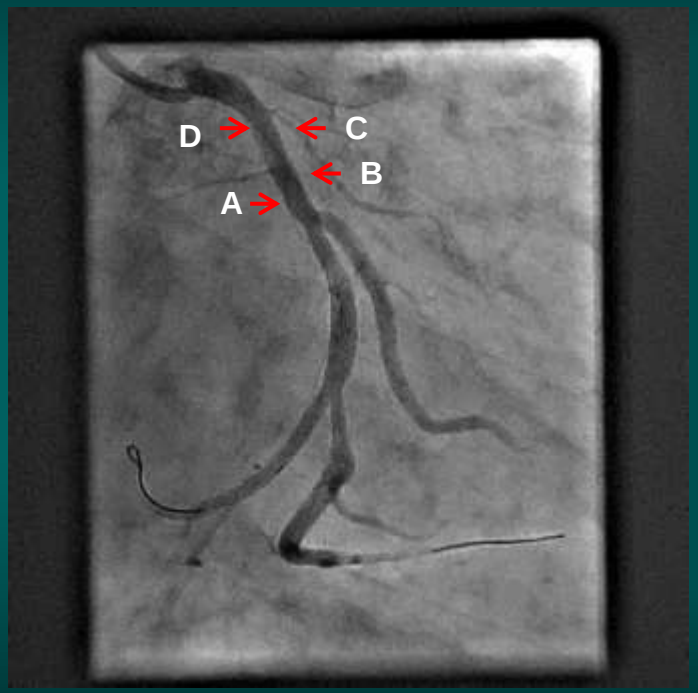
	Not requiring OCT optimisation (n=21)	Requiring OCT optimisation (n=8)	*p*-value
Lesion type			
A	10 (66%)	5 (33%)	0.49
B or C	11 (79%)	3 (21%)	0.49
Fluoroscopic time, min (SD)	18.9 (8.0)	26.0 (18.5)	0.16
Mean no. balloon inflations (SD)	8.7 (3.3)	16.5 (11.3)	<0.01
Length of procedure, min (SD)	83.7 (26.5)	113.7 (39.0)	<0.05

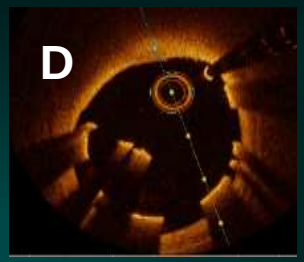
EuroIntervention 2015;10:1154-1159

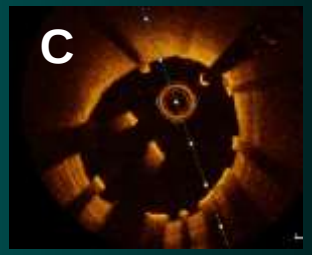
Bioresorbable Scaffolds – Sizing

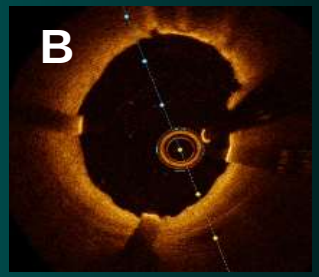
Malapposition cannot be detected by angiography

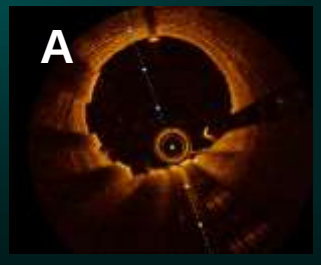
3.0 x 18 mm REVA FANTOM Scaffold











OCT after failure to cross with NC balloon

POWH/EHC Fantom II Trial - Case # 6

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

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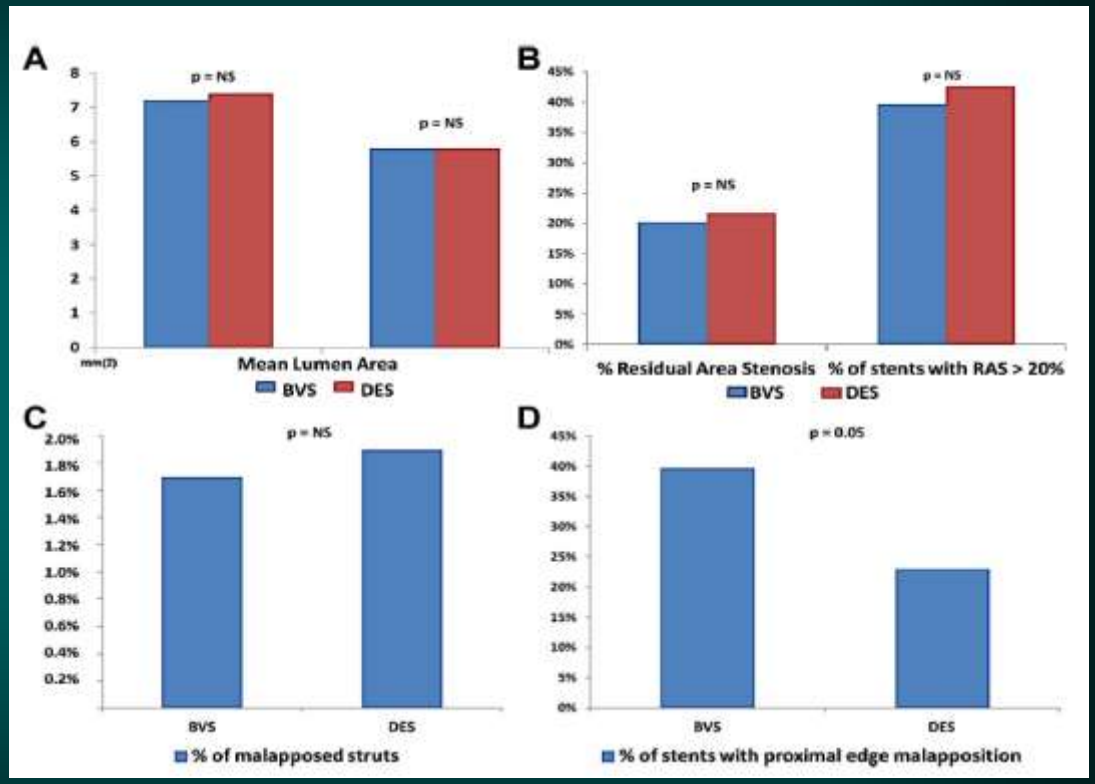
Matteo Ghione, MD,* Juan C. Rama-Merchan, MD,* Alessandro Lupi, MD,‡
Nicola Viceconte, MD,* Alistair C. Lindsay, MD, PhD,* Ranil De Silva, MD, PhD,*
Nicolas Foin, PhD,§ Toru Naganuma, MD,§ Serafina Valente, MD,†
Antonio Colombo, MD, PhD,‖ Carlo Di Mario, MD, PhD*
London, United Kingdom; Florence, Novara, 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



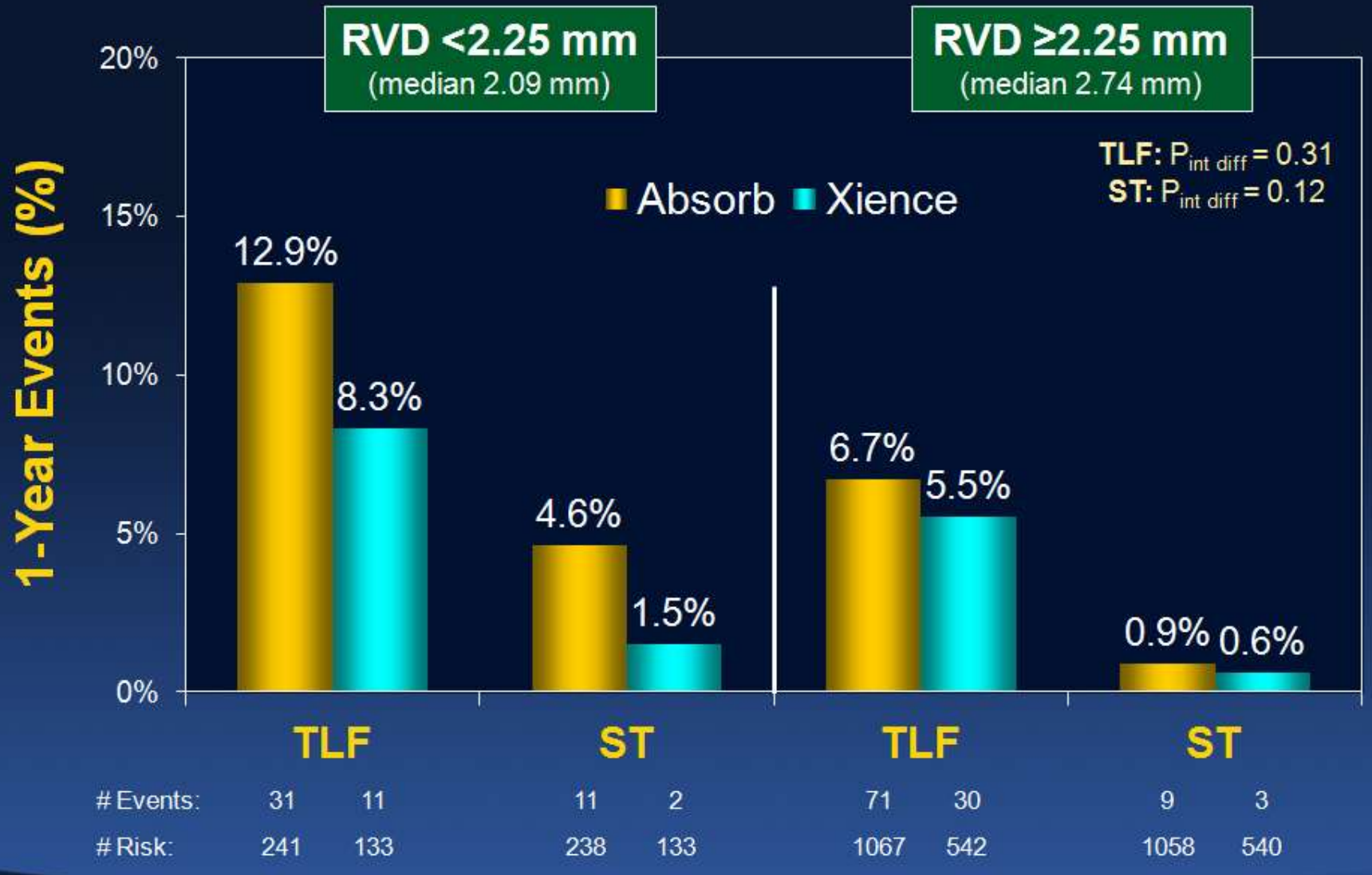
Mattesini et al JACC Cardiovasc Int 2014;7(7):241-50

OCT imaging Guidance - BRS Implantation

What Have We Learnt?

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

Outcomes by QCA RVD 2.25 mm



Median based on pooled Absorb and Xience

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 –**

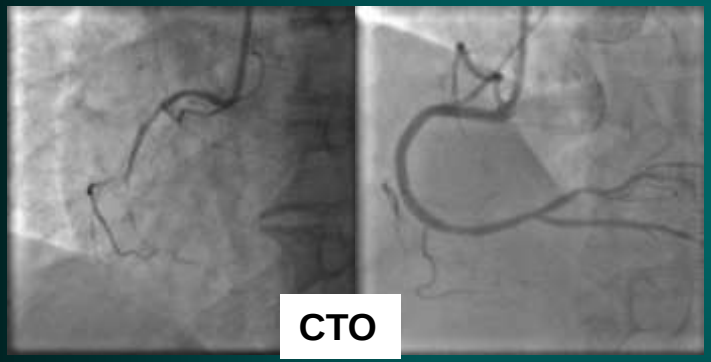
  - **POCE (death, MI or revasc)**
  - **DOCE/TLF (cardiac death, TV-MI, ID-TLR)**
  - **All MI**

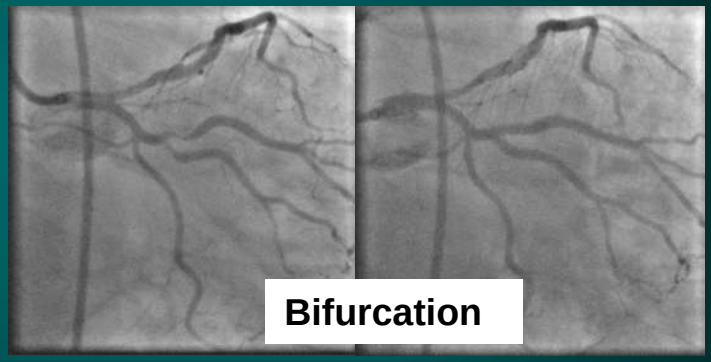
Stone et al Lancet 2016

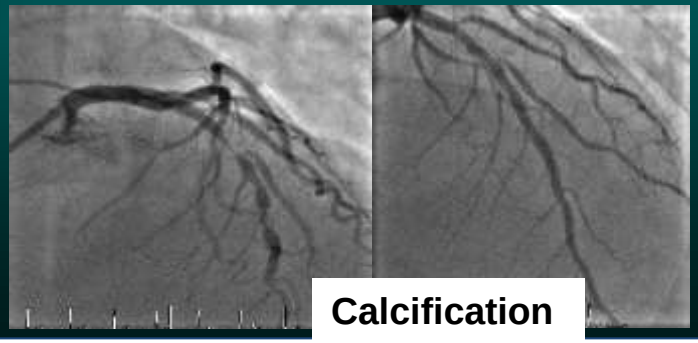
Absorb BVS Implantation – Real-world Disease


ACS/STEMI


Long lesion


CTO


Bifurcation


Calcification

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/IVUS use (%)	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

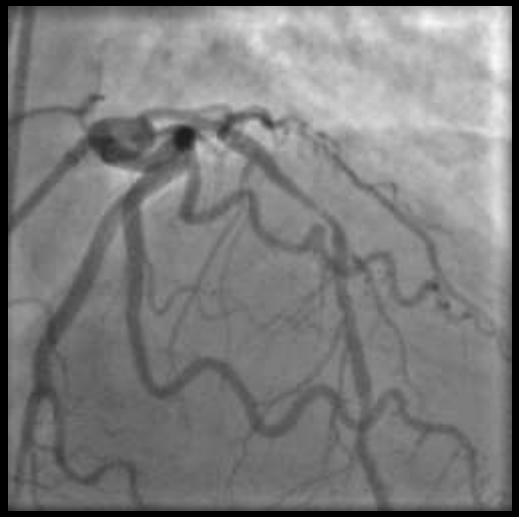
HLC 2015, J Inv Cardiol 2015

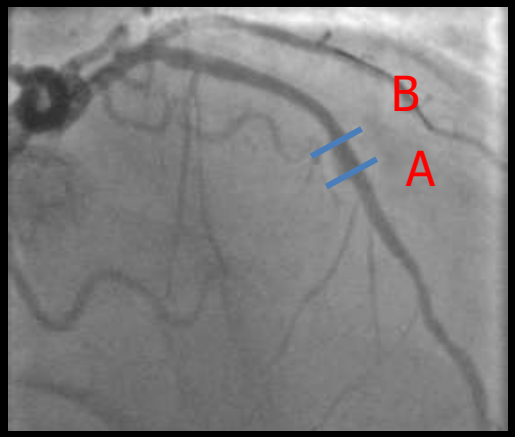
OCT imaging Guidance - BRS Implantation

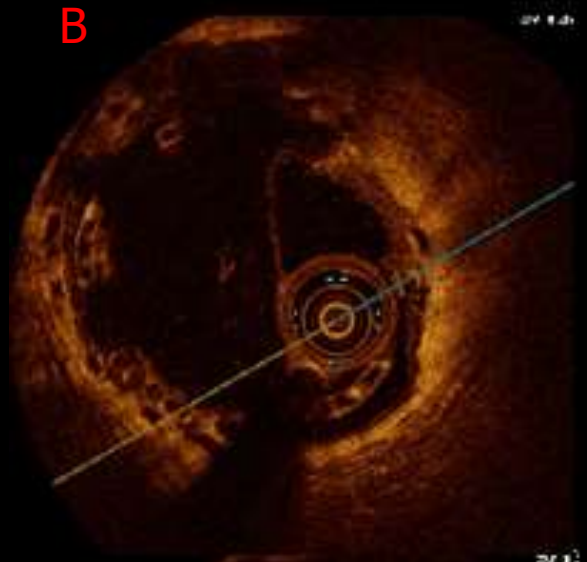
What Have We Learnt?

Scaffold Overlap and Long lesions

Absorb BVS Scaffold – Long Overlap and Malapposition





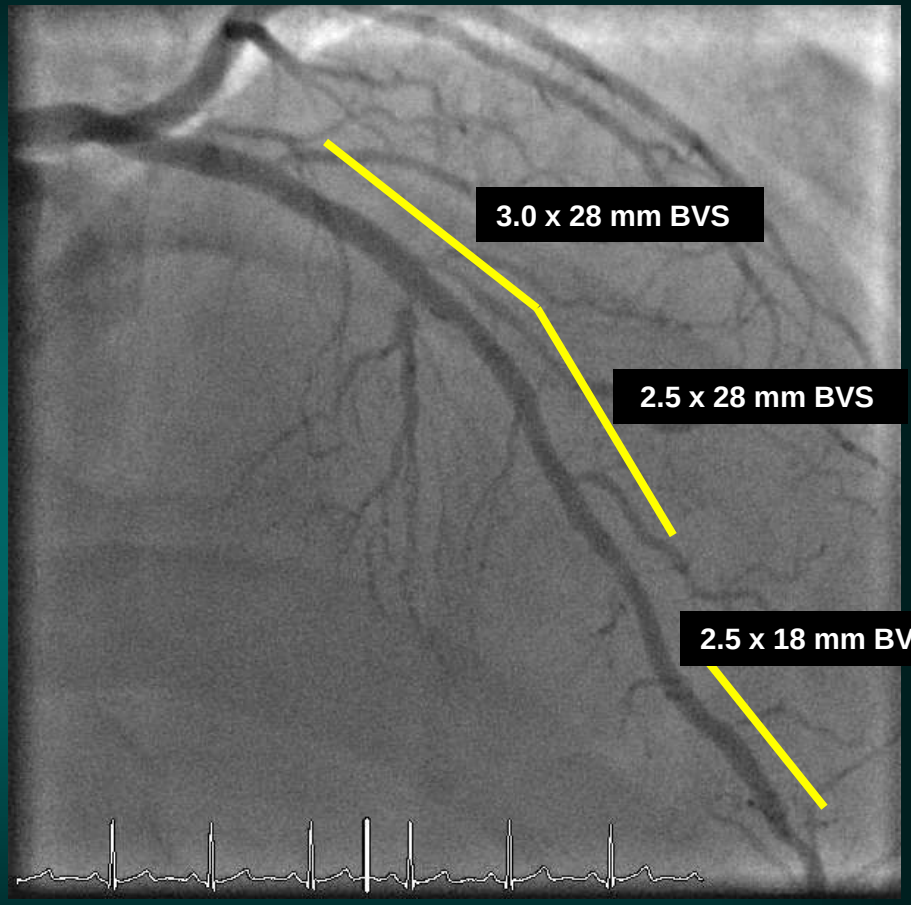


3.5 x 28 mm + 3.0 x 18 mm BVS

POW/EHC Absorb Registry - Case # 183

Diffuse, Long Segment Disease – Angiographic Guided BVS Implantation

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

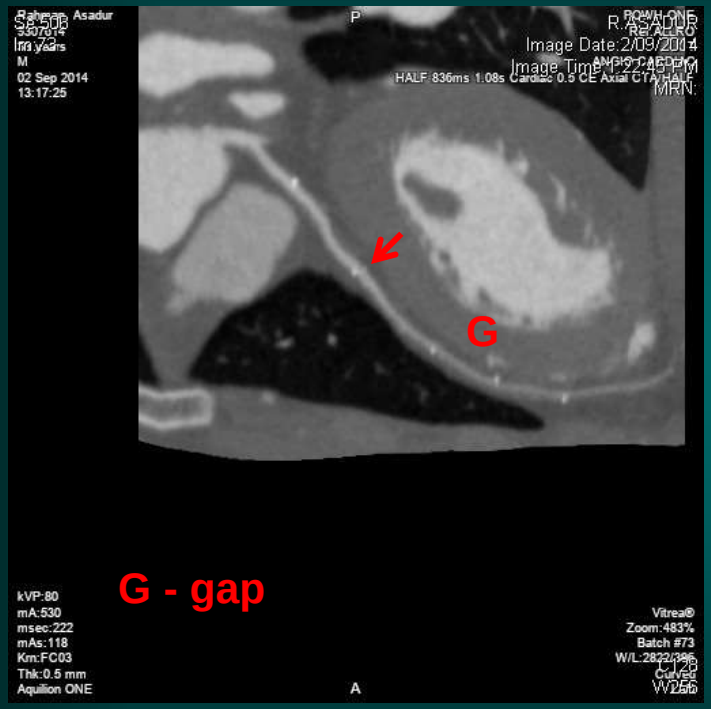


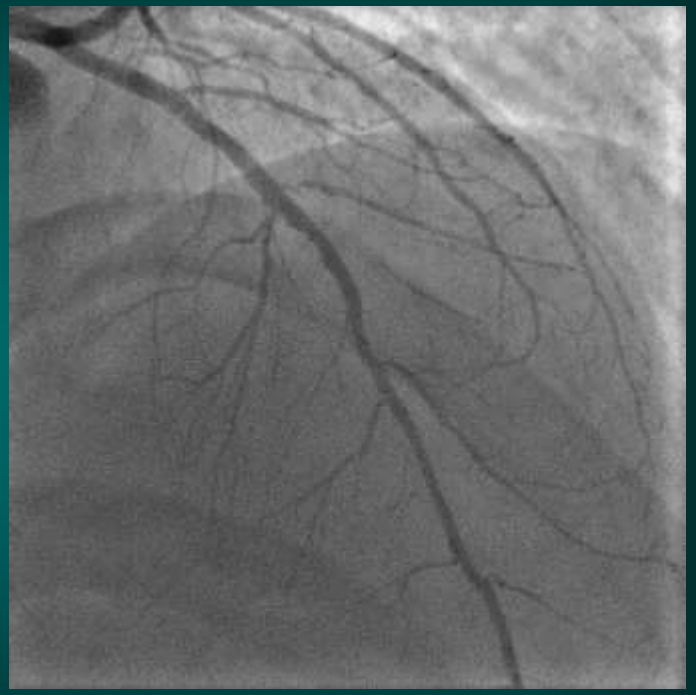
POW/EHC Absorb Registry - Case # 11

Diffuse, Long Segment Disease – Angiographic Guided BVS Implantation

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

30 month F/up – CTCA and invasive





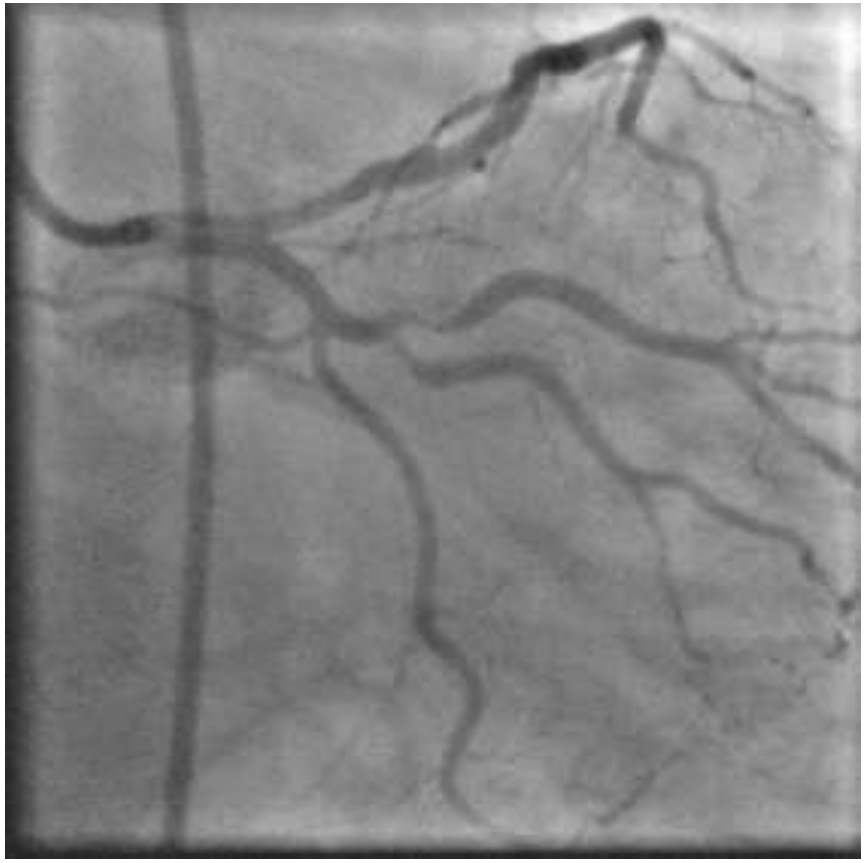
POW/EHC Absorb Registry - Case # 11

OCT imaging Guidance - BRS Implantation

What Have We Learnt?

Bifurcation lesions

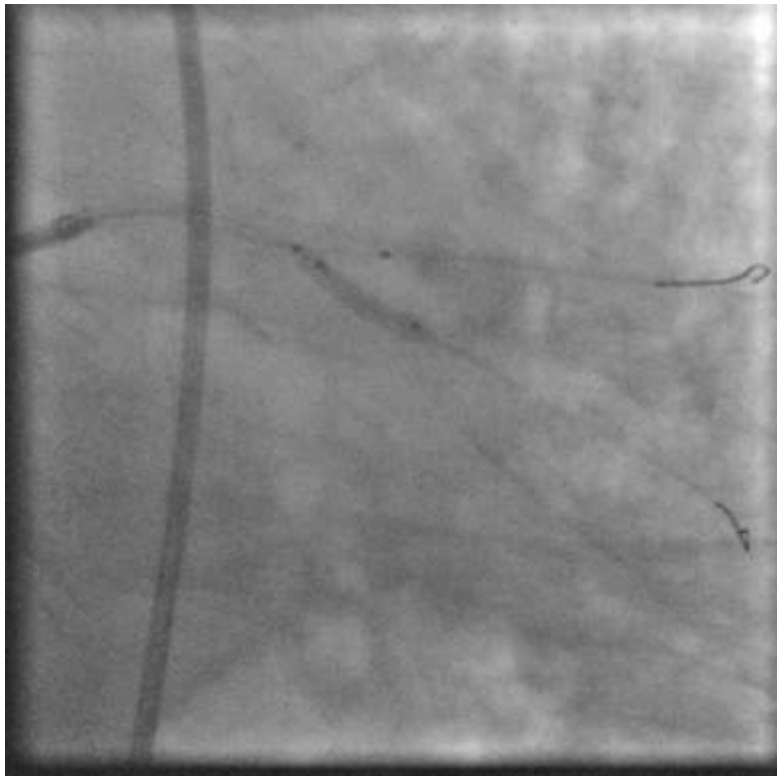
Bifurcation Circumflex Disease - Staged
53 yo male, recent RCA DES (STEMI – PPCI) + staged Absorb BRS x 3 LAD



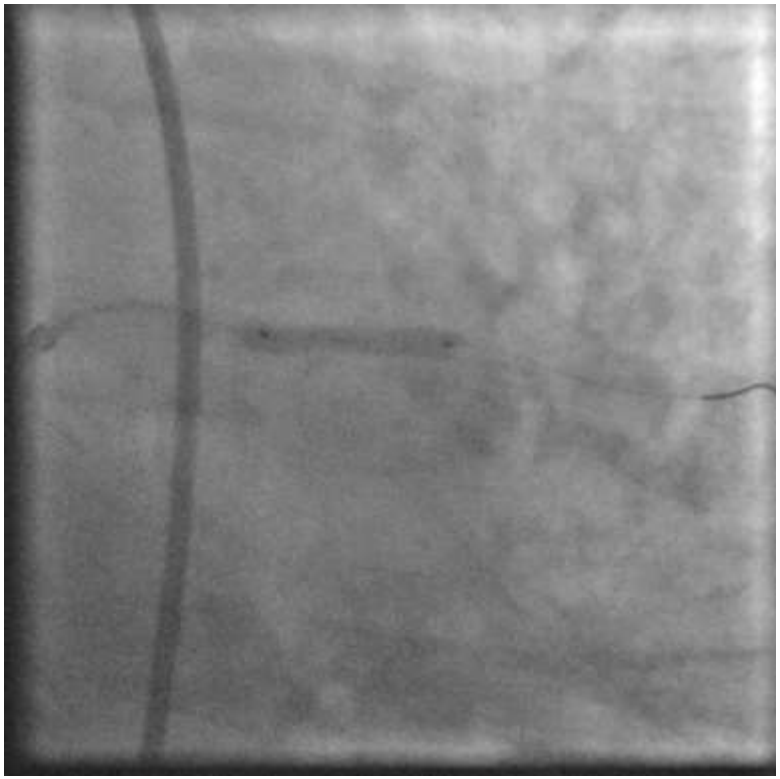
Set-up

POW/EHC Absorb Registry - Case # 118

Bifurcation Circumflex PCI – 53 yo male



2.5 x 12 mm Absorb



3.0 x 18 mm Absorb

Two scaffold strategy – Modified T with FKBI

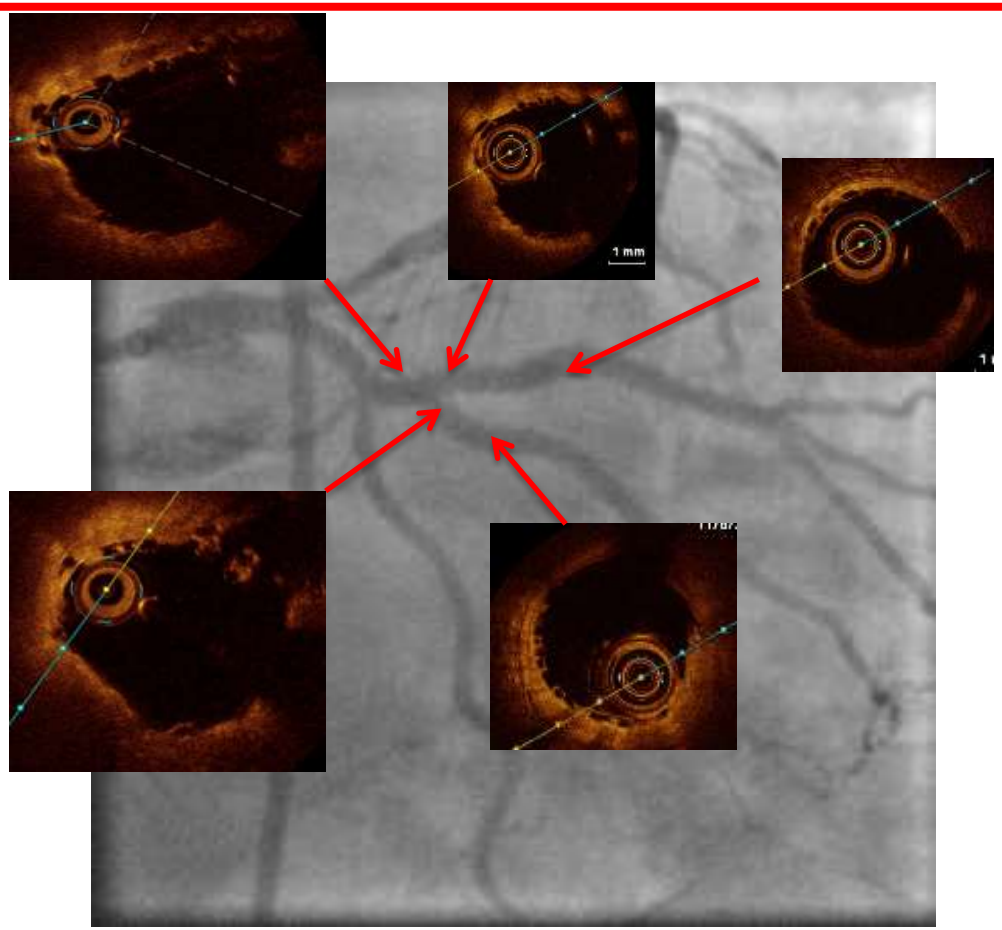
POW/EHC Absorb Registry - Case # 118

Bifurcation Circumflex PCI – 53 yo male

Final Result (OCT guided)

POW/EHC Absorb Registry - Case # 118

Bifurcation Circumflex PCI – 53 yo male



Final Result (OCT guided)

POW/EHC Absorb Registry - Case # 118

OCT imaging Guidance - BRS Implantation

What Have We Learnt?

Scaffold Failure

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

Angiographic and Optical Coherence Tomography Insights Into Bioresorbable Scaffold Thrombosis

Single-Center Experience

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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

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