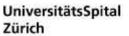


BVS Scaffold Thrombosis The Role of OCT



Evelyn Regar Heart Center University Hospital Zürich Zürich, Switzerland





BVS-Thrombosis at Day 2 after PCI LAD :

Zhang BC et al. JACC Cardiovasc Interv . 2016

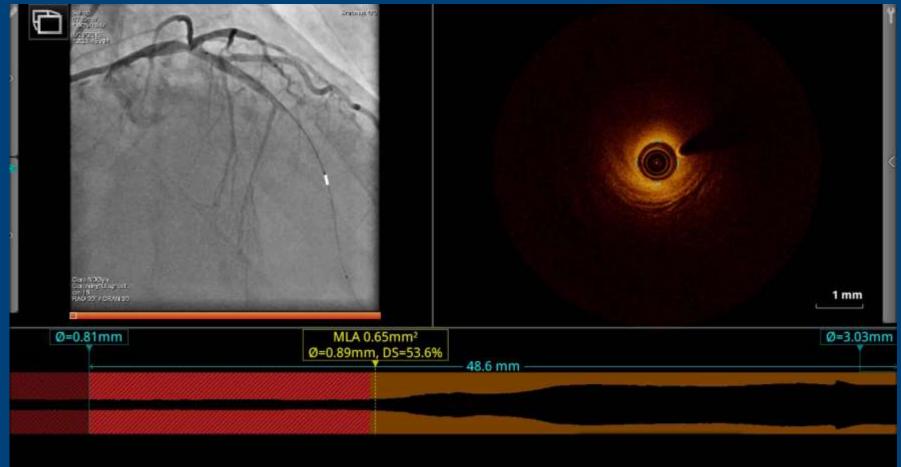
BVS-Thrombosis at Day 2 after PCI LAD (BVS 3.5/18mm):



LAD: Event

Zhang BC et al. JACC Cardiovasc Interv . 2016

BVS-Thrombosis at Day 2 after PCI LAD (BVS 3.5/18mm):



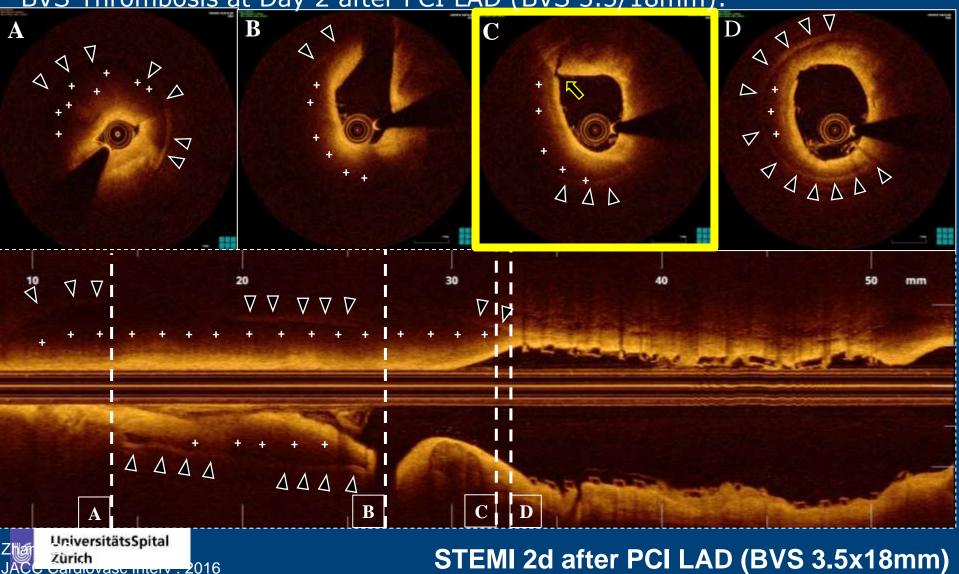
Optisi St.Jude

Zhang BC et al. JACC Cardiovasc Interv . 2016

STEMI 2d after PCI LAD (BVS 3.5x18mm)

2016

BVS-Thrombosis at Day 2 after PCI LAD (BVS 3.5/18mm):



BVS-Thrombosis at Day 2 after PCI LAD (BVS 3.5/18mm):



After implantation of distal overlapping BVS 3.5x23mm & 2.5x12mm

Zhang BC et al. JACC Cardiovasc Interv . 2016

STEMI 2d after PCI LAD (BVS 3.5x18mm)

Device Failure

BVS Thrombosis

Coronary Interventions

OPEN

Angiographic and Optical Coherence Tomography Insights Into Bioresorbable Scaffold Thrombosis Single-Center Experience

Antonios Karatusos, MD, PhD: Nicolas Van Mieghem, MD, PhD; Nienke van Ditzhuijzen, MSc; Cordula Felix, MD; Joust Daemen, MD, PhD; Arosachska Autar, MD; Yoshinobu Omanu, MD, PhD; Mie Karata, MD, PhD; Roberto Diletti, MD; Marco Valgimigli, MD, PhD; Floris Kauer, MD; Heleen van Beusekom, MD, PhD; Peter de Jaegero, MD, PhD; Felix Zigluta, MD, PhD; Robert-Jan van Geaus, MD, PhD; Evelyn Regar, MD, PhD

Weigen Angelergen, Mark Paris, Mark Wall, Sander Mark and Mark Mark Mark Break & Lagran, 2017 PAIR System, 2018, 2018, 2018, 2018.

Main Pathomechanisms

- Incomplete lesion coverage
- Underexpansion &
- Malapposition

Operator Failure

Seems to be triggered by implantation technique and thus, potentially avoidable

Device Failure

BVS Thrombosis

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY © 2016 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION PUBLISHED BY ELSEVIER

Bioresorbable Coronary Scaffold Thrombosis

Multicenter Comprehensive Analysis of Clinical Presentation, Mechanisms, and Predictors

Serban Puricel, MD,^a Florim Cuculi, MD,^b Melissa Weissner, MTA,^c Axel Schmermund, MD,^d Peiman Jamshidi, Tobias Nyffenegger, MD,^b Harald Binder, PHD,^e Holger Eggebrecht, MD,^d Thomas Münzel, MD,^c Stephane Cook, Tommaso Gori, Dorr MED CHIR, PHD^c

Multi-center, all comer registry, n=1305 pts

Operator Failure

"can be reduced by \approx 70% using a specific implantation technique"



Puricel S et al. J Am Coll Cardiol 2016

VOL. 67, NO. 8, 20

0

%

Kaplan-Meier Estimate,

2

3

4

0

200

ISSN 0735-1097/\$

http://dx.doi.org/10.1016/j.jacc.2015

In-BVS Thrombosis

3%

at 12m

400

Days

600

800

Emphasis on implantation technique:



Scaffold diameter must not be too SMALL

Scaffold diameter must not be too LARGE

Scaffold length must not be too SHORT

Scaffold expansion must be OPTIMAL



If BVS Diameter Is Selected Too SMALL:



If BVS Diameter Is Selected Too SMALL: Struts Can Break!

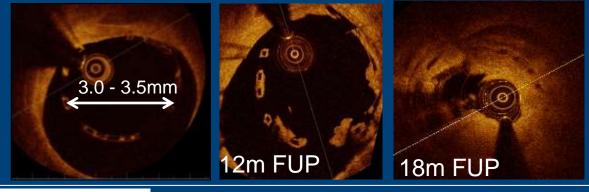
Key issue with the ABSORB scaffold Limited range of expansion 2.5 mm scaffold → up to 3.0mm 3.0 mm scaffold → up to 3.5mm 3.5 mm scaffold → up to 4.0mm



If BVS Diameter Is Selected Too SMALL: Struts Can Break!

Key issue with the ABSORB scaffold Limited range of expansion 2.5 mm scaffold → up to 3.0mm 3.0 mm scaffold → up to 3.5mm 3.5 mm scaffold → up to 4.0mm

Beyond that range, struts can break when postdilated.





Onuma Y et al. J Am Coll Cardiol Intv 2014;7:1400-11.

If BVS Diameter Is Selected Too LARGE



If BVS Diameter Is Selected Too LARGE **Increased Risk For Failure (TLF & ST)**

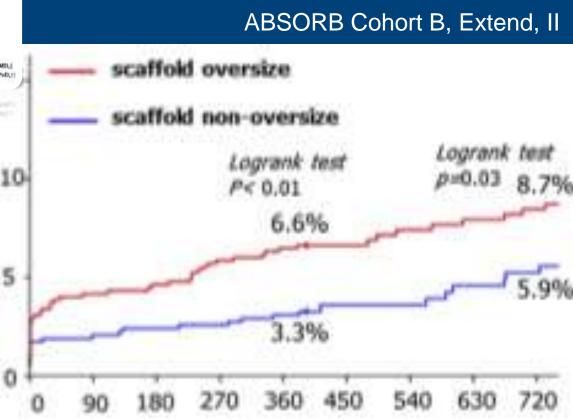
Relation Between Bioresorbable Scaffold Sizing Using QCA-Dmax and Clinical Outcomes at 1 Year in 1,232 Patients From 3 Study Cohorts (ABSORB Cohort B. ABSORB EXTEND, and ABSORB II)

Yoki hibibashi, MD, PuD," Shimpei Nakatani, MD," Yubei Sotomi, MD,/ Pannipa Suwannasom, MD," Maik J. Grundeken, MD.; Hector M. Garcia-Garcia, MD, PaD,* Antonio L. Bartorelli, MD.; Robert Whithearn, MD.; Bernard Chevalier, MD, 9 Alexandre Abizaid, MD, Pr/D,# John A. Gemiston, MB, CaB, Pr/D,** Hichard J. Rapora, Pr/D, 1 Sasan Veldhof, RN, J. Yoshinobu Onoma, MD, PvD, * Patrick W. Serroys, MD, PvD

> ncidence of cardiac death, MI & TLR (%) death, MI &

5

TLR: Target Lesion Revascularization ST: Scaffold Thrombosis

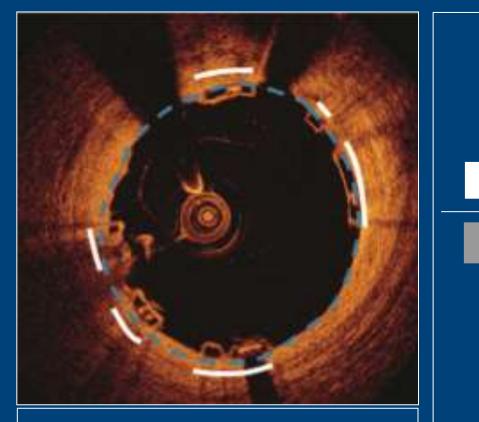


Follow-up (days)



CC CardioVasc Interv 2015:8(13): 1715-26

If BVS Diameter Is Selected Too LARGE: The Scaffold Footprint Is Large



Footprint (%) =

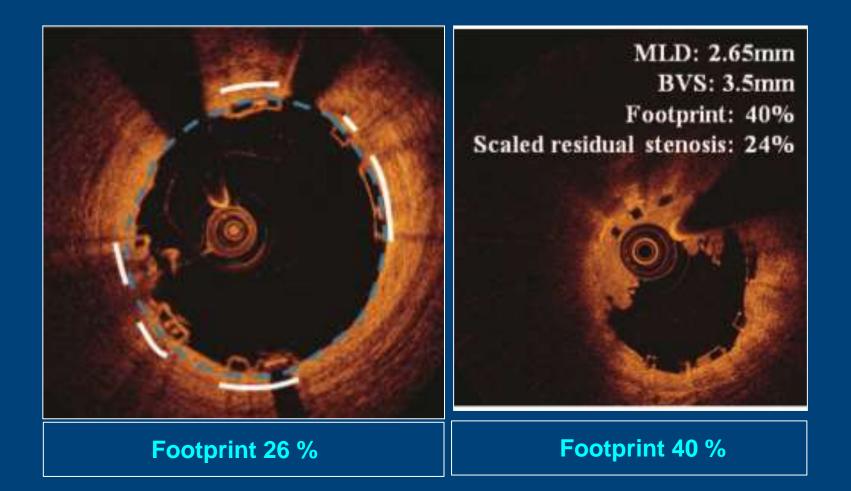
fraction covered by struts

lumen circumference

Footprint 26 %



If BVS Diameter Is Selected Too LARGE: The Scaffold Footprint Is Large





Puricel S et al. J Am Coll Cardiol 2016

If BVS Diameter Is Selected Too LARGE: Large Footprint & Association To Thrombosis

	BVS Thrombosis	Control		
	N=42	N=84	р	HR (95% CI)
MLD (mm)	2.39±0.58	2.85±0.49	0.001	0.05 (0.01-0.28)
RVD (mm)	2.93±0.58	3.41±0.52 0.	0.002	0.13 (0.04-0.46)
DS (%)	19±12	16±7	0.071	1.05 (0.10-1.10)
Max.FootPrint (%)	43±0.11	35±6	0.001	1.20 (1.08-1.33)
SRS (%)	0.21±0.18	0.07±0.14	0.001	1.71 (20.0-146)

QCA Predictors of BVS thrombosis (post procedure)

Max FP = Maximum footprint: the scaffold outer surface area divided by actual arterial surface area calculated from the MLD

Universitiitišipitas al stenosis

Zürich

ionship between MLD and nominal BVS diameter.

Puricel S et al. J Am Coll Cardiol 2016

If BVS Length Is Selected Too SHORT: The Lesion Is Not Covered Completely



If BVS Lenght Is Selected Too SHORT: An Additional Scaffold Is Needed...



If BVS Lenght Is Selected Too SHORT: Scaffold Overlap Increases Risk for MI!

Predictors for Periprocedural MI

Incidence and Potential Mechanism(s) of Post-Procedural Rise of Cardiac Biomarker in Patients With Coronary Artery Narrowing After Implantation of an Everolimus-Eluting Bioresorbable Vascular Scaffold or Everolimus-Eluting Metallic Stent ۲

Yaho Nahanda, Mith, Nardy, Yakada Hilemannan, Mith, Nardy, Yilkang Handanan, Mith, Yahoo Lawano, Mith, Yangang Isanamananan, MitV, Haho J. Ganavalinan, Hill, Yana Hang, Giao, Mit, Nardy, Ya Honna H, Ganala Ganza, Kato, Jinfe, Hal, Yana Himon, Mitk, Yaho, Yaho, Jinfe, Manaha Hantah, Mit, Yaho, Yi Hinfero, Habaja, Han, Ya Aadoona, Kamahan, Kin Michard, Balla, Hannan, Hannan Hannah, Mitt, Yaho, Ya Hanhando, Daman, Mito, Hadoona, Kamahan, Kin Michard, Balla, Ballan, Hannah Ganashin, Mito, Mito, Handanahan, Jinto, Yahanda, Ki Manan, Jinto, Han, Yanahan, Yahanan, Ki Hanan, Yahanda, Yahama, Yahanan, Ki Yahana, Yahama, Yahana, Yahana, Yahama, Yah

TABLE 5 Predictors of Per-Protocol PMI								
	Univariate Logistic Regression		Multivariate Model (I, II, III, IV,V and Device Type)					
	OR (95% CI)	p Value	OR (95% CI)	p Value				
Patient-related factors								
Age, yrs	1.02 (0.96-1.07)	0.56	-	-				
Male	1.21 (0.34-4.37)	0.77	-	-				
Body mass index, kg/m ²	0.94 (0.81-1.08)	0.36	-	-				
Current smoker	1.71 (0.57-5.11)	0.34	-	-				
Hypertension requiring treatment	0.43 (0.15-1.22)	0.11	-	-				
Dyslipidemia requiring treatment	0.57 (0.20-1.64)	0.30	-	-				
Any diabetes mellitus	0.48 (0.11-2.16)	0.34	_	-				
Unstable angina	0.94 (0.26-3.40)	0.93	-	-				
Lesion-related factors assessed by angiography								
Pre-procedural diameter stenosis, %	0.98 (0.93-1.02)	0.28	-	-				
Pre-procedural minimal lumen diameter, mm	1.38 (0.28-6.72)	0.69	-	-				
Pre-procedural reference diameter, mm	0.48 (0.12-1.92)	0.30	-	_				
Obstruction length, mm	0.99 (0.92-1.08)	0.85	-	_				
Pre-procedural curvature, cm ⁻¹	0.20 (0.19-2.16)	0.19	-	-				
Lesion-related factors assessed by grayscale IVUS								
Pre-procedural minimal lumen area, mm ²	0.78 (0.35-1.70)	0.53	-	-				
Pre-procedural EEM, mm ²	0.99 (0.86-1.16)	0.98	-	_				
Pre-procedural mean total plaque area in treated region, mm ²	1.05 (0.88-1.27)	0.58	-	-				
Pre-procedural total plaque volume in treated region, mm ³	1.00 (1.00-1.01)	0.22	-	-				
Pre-procedural plaque burden in treated region, %	1.03 (0.99-1.07)	0.14	-	-				
Lesion-related factors assessed by IVUS-VH								
Pre-procedural dense calcium, mm ²	1.86 (0.15-23.83)	0.63	-	-				
Pre-procedural necrotic core, mm ²	1.16 (0.34–3.99)	0.81	-	-				
Pre-procedural fibrotic tissue, mm ²	1.33 (0.70-2.51)	0.39	-	-				
Pre-procedural fibro-fatty tissue, mm ²	0.92 (0.63-1.34)	0.67	-	-				
Treatment with overlapping devices	5.32 (1.88-15.05)	<0.01	5.07 (1.78-14.41)	0.002				
Post-dilation	1.18 (0.40-3.50)	0.77	-	-				
Bail-out	3.79 (0.45-31.96)	0.22	-	-				
Expected balloon diameter of the last balloon, mm	3.06 (0.76-12.33)	0.12	-	-				
Dashes indicate that there were no applicable data. Ω — confidence interval; NUS — intravascular ultrasound; OR — odds ratio; VH — virtual histology; other abbreviations as in Tables 1 and 4.								

Multivariate

Treatment with Overlapping Devices

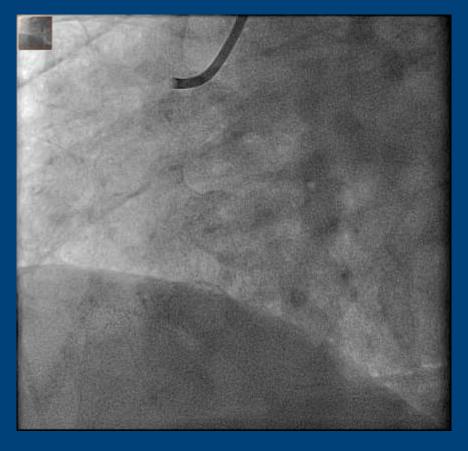
OR

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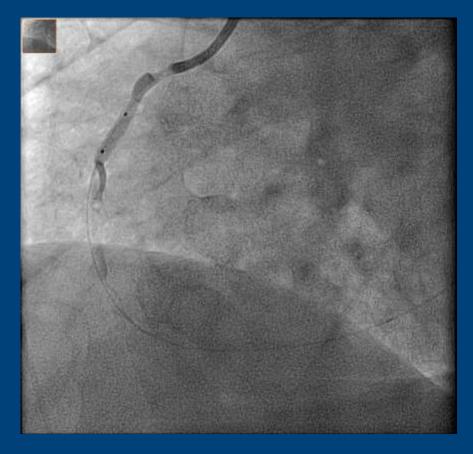
CC CardioVasc Interv 2015:8(13): 1053-63

OCT To Guide BVS Implantation

Case Example NSTEMI; 62 year old male, active smoker, CVA



Pre-interventional

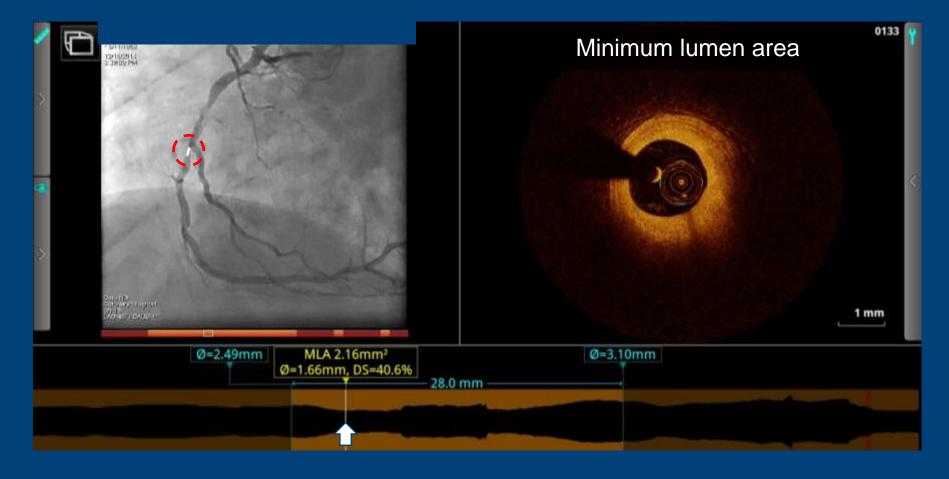


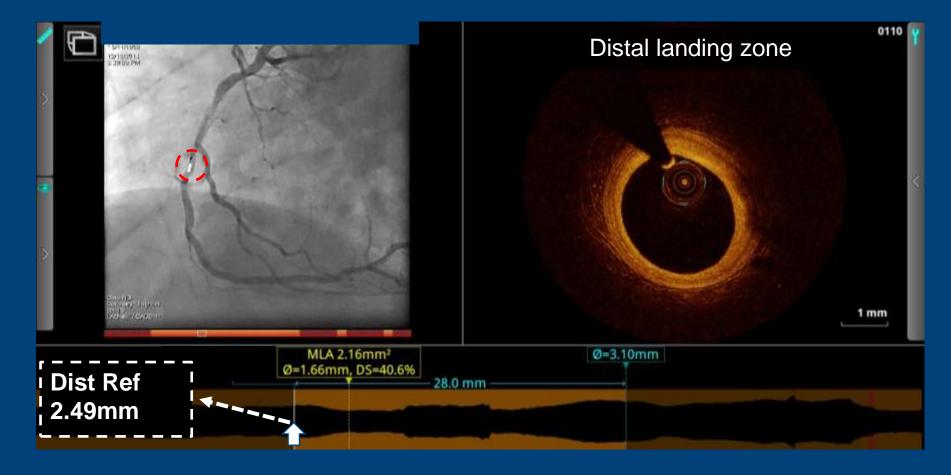
Predilation with Sprinter 2.5x10 mm balloon

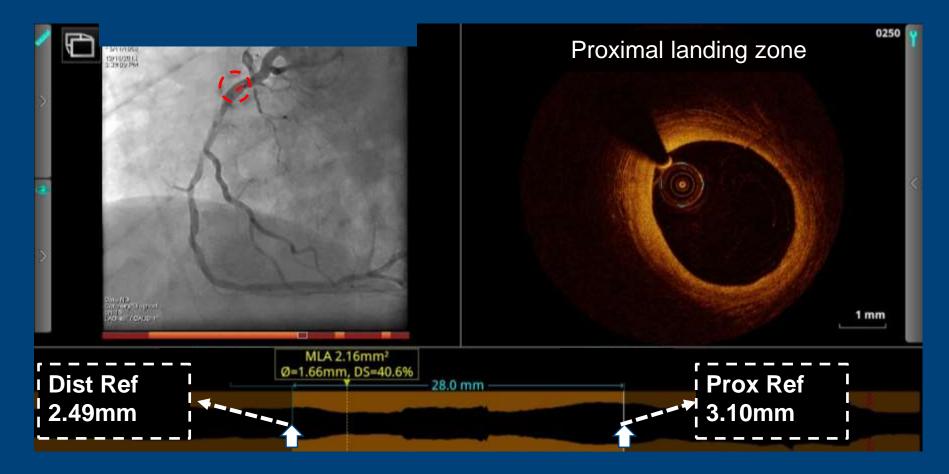
OCT To Guide BVS Implantation

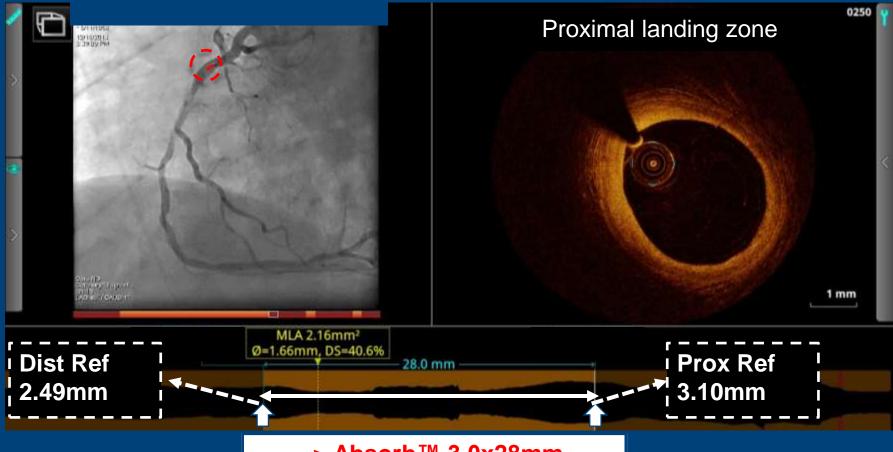
Case Example



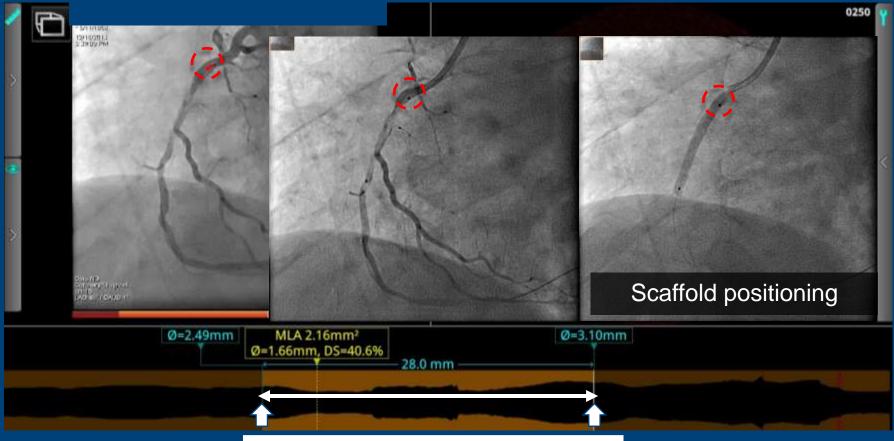




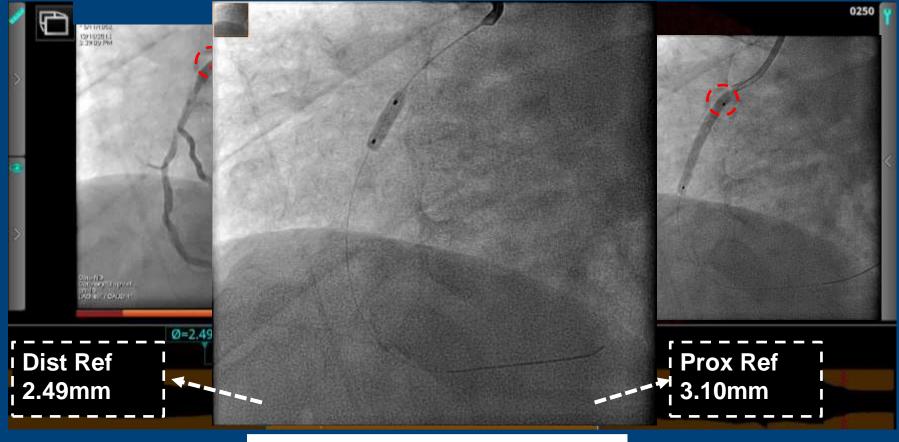




-> Absorb™ 3.0x28mm



-> Absorb™ 3.0x28mm



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		20.0 11111		

OCT To Guide BVS Implantation



Allows

 \checkmark to overcome intrinsic limitations of angiography.

Guidance of Implantation Procedure

Insights in Failure/ Thrombosis

