

The latest update: Invasive Imaging

Imaging-Guidance for Bioresorbable Scaffold Implantation



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Disclosure

 The institution Erasmus MC receives research support from St. Jude Medical and consultancy fees from Boston Scientific.

Imaging Guidance for BVS Implantation Update – What's New in 2016?

Device Failure

BVS Thrombosis

Coronary Interventions

(10)

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

Martin Martinetti, Bart Martinetti, Martinetti and Martinetti and Martinetti Prime da Sangara, MIC PARS 2146, 2040, 2010, 2010.
Historic San Yun Linnes, MIX, PARS Toulys, Bagas, MIX, PARS

Main Pathomechanisms

Erasmus MC

- Incomplete lesion coverage
- Underexpansion &
- Malapposition

Operator Failure

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

Karanasos A et al. Circ Cardiovasc Intervent 2015.

Imaging Guidance for BVS Implantation Update – What's New in 2016?

Device Failure

BVS Thrombosis

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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"

VOL. 67, NO. 8, 20

0

%

Kaplan-Meier Estimate,

2

3

0

ISSN 0735-1097/\$

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

200

Erasmus MC

In-BVS Thrombosis

3%

at 12m

400

Days

600







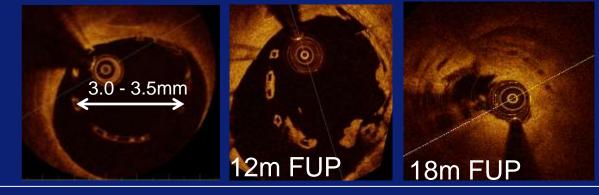
Scaffold diameter must not be to LARGE

Scaffold expansion must not be OPTIMAL

If BVS Diameter Is Selected Too SMALL:

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.

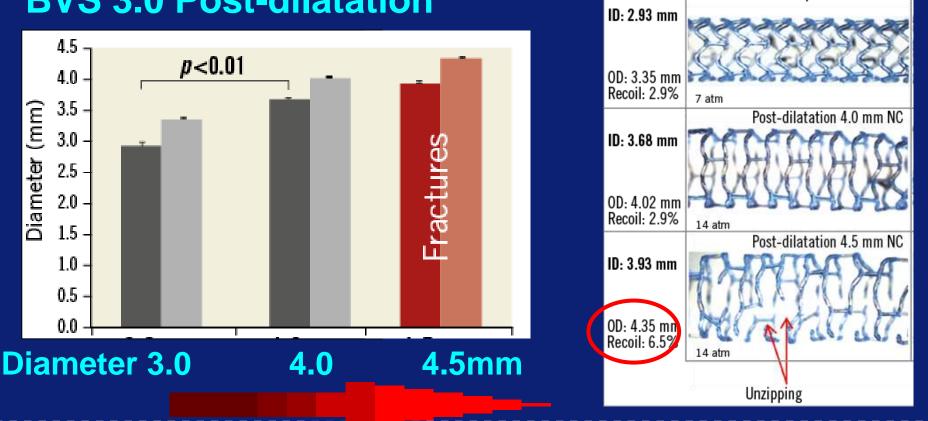


Onuma Y et al. J Am Coll Cardiol Intv 2014;7:1400-11.

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

BVS overexpansion: in vitro post-expansion experiments

BVS 3.0 Post-dilatation



ID: 1.04 mm

0D: 1.36 mm

Nominal pressure 3.0 mm

Foin N et al. EuroIntervention 2016;11:1389-1399



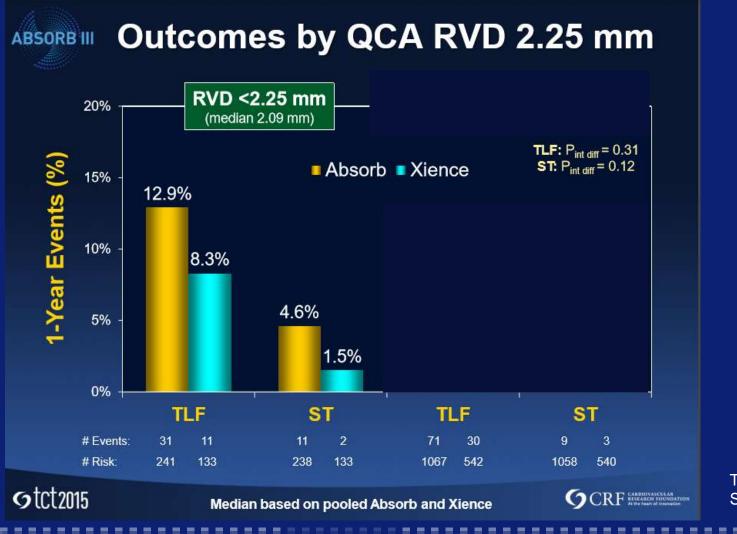
ABSORB Baseline Lesion Characteristics (QCA)

Absorb (N=1322) (L=1385)	Xience (N=686) (L=713)	p-value
68.7%	72.5%	0.08
1.0 ± 0.2	1.0 ± 0.2	0.38
95.1%	96.1%	0.32
4.8%	3.9%	0.36
44.5%	42.2%	0.31
29.2%	27.2%	0.35
26.2%	30.6%	0.03
12.60 ± 5.41	13.12 ± 5.82	0.05
		0.36
m 18%	19%	0.39
		0.11
65.3 ± 12.5	65.9 ± 11.7	0.24
	$(N=1322) \\ (L=1385) \\ 68.7\% \\ 1.0 \pm 0.2 \\ 95.1\% \\ 4.8\% \\ 44.5\% \\ 29.2\% \\ 26.2\% \\ 12.60 \pm 5.41 \\ n \\ 18\%$	$\begin{array}{c c} (N=1322) & (N=686) \\ (L=1385) & (L=713) \\ \hline 68.7\% & 72.5\% \\ 1.0 \pm 0.2 & 1.0 \pm 0.2 \\ 95.1\% & 96.1\% \\ 4.8\% & 3.9\% \\ \hline 44.5\% & 42.2\% \\ 29.2\% & 27.2\% \\ 26.2\% & 30.6\% \\ 12.60 \pm 5.41 & 13.12 \pm 5.82 \\ \hline 18\% & 19\% \\ \hline \end{array}$

L= number of lesions

Stone G et al. Presented at TCT 2015

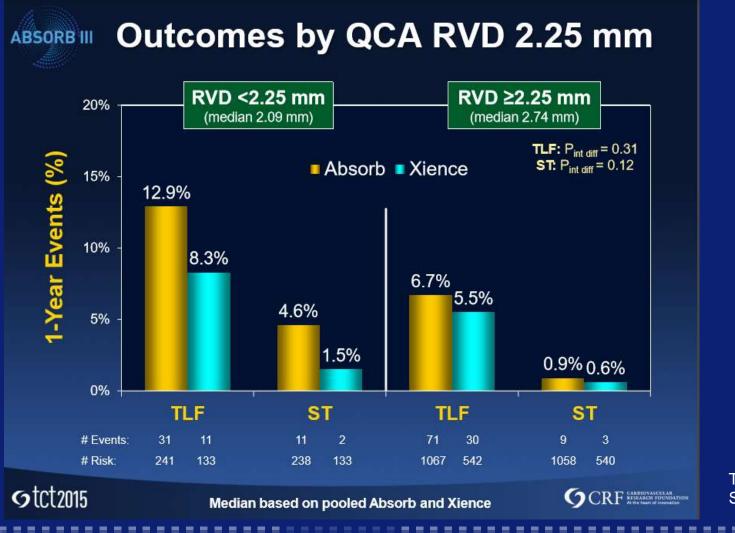




TLF: Target Lesion Failure ST: Scaffold Thrombosis

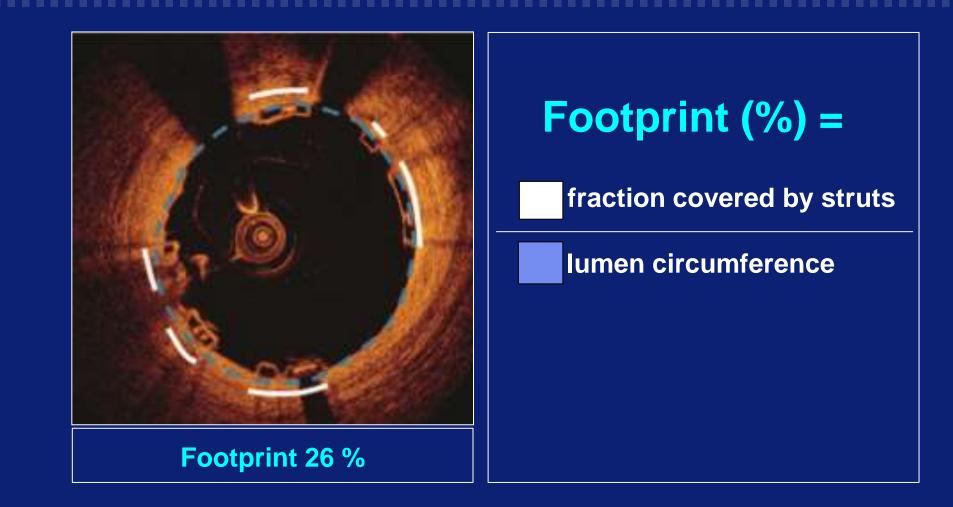
Stone G et al. Presented at TCT 2015



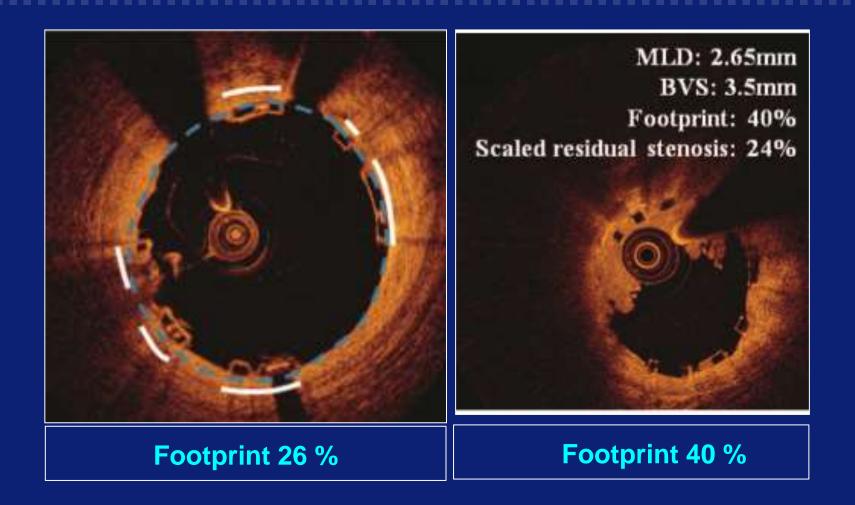


TLF: Target Lesion Failure ST: Scaffold Thrombosis

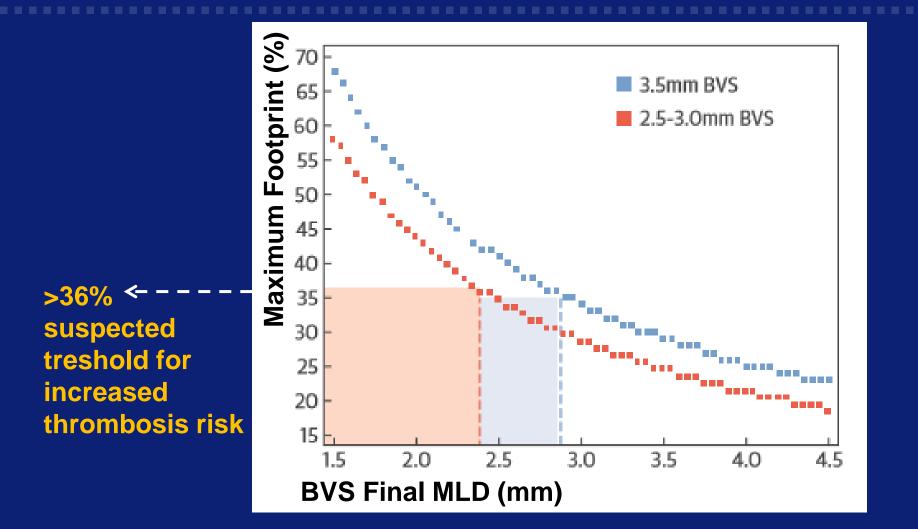
Stone G et al. Presented at TCT 2015



Puricel S et al. J Am Coll Cardiol 2016



Puricel S et al. J Am Coll Cardiol 2016



	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	0.002	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

SRS=Scaled residual stenosis
 expresses the relationship between MLD and nominal BVS diameter.

Puricel S et al. J Am Coll Cardiol 2016



The Problem Really Is....

Angiography Is A Poor Tool

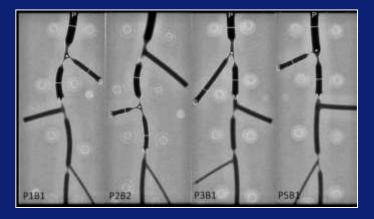
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Angiography Is A Poor Tool To Visualize Coronary Dimensions



Visual assessment of stenosis severity is poor! poor validity and high variability



<u>36 experts</u> assessed % stenosis in phantom lesions

- Overestimated = 49 %
- Underestimated = 26 %
- Exact = 25%

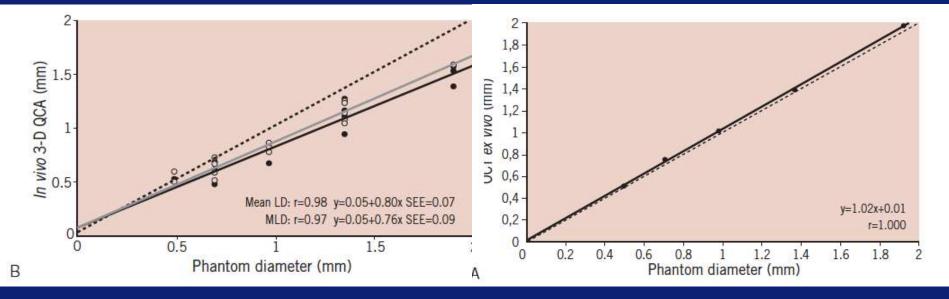
Girasis et al; Catheterization and Cardiovascular Interventions 79:361–368 (2012)

Angiography Is A Poor Tool To Visualize Coronary Dimensions





OCT provides the correct lumen dimension.



In vivo validation of a novel three-dimensional quantitative coronary angiography system (CardiOp-BTM): comparison with a conventional two-dimensional system (CAAS IITM) and with special reference to optical coherence tomography

electri Traccieda, MD, PHD; Willeen J, van das Garesen, MD, PHD; Mark Patterson, MMDP; huzur Tariwana, MD; Histon M, Garcia-Garria, MD, MDc; Evelyn Ingga, MD, PHD; urgen M, R. Liphart, Eliz, Anno-Marie Mangemeis; Gio Manrijle, Intarda J, Wontzel, PhD, urgen M, R. Liphart, Eliz, JARC, FESC.

Tschuchida et al. EuroIntervention

Angiography Is A Poor Tool To Visualize Lesion Length





19,19 mm

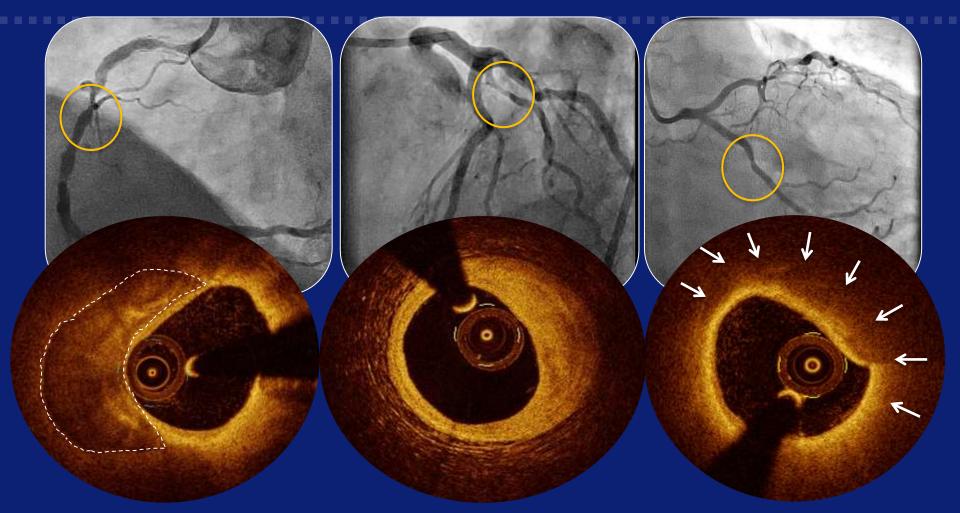
Courtesy J. Ligthart, EMC

21,01 mm

24,51 mm

Same vessel, different projections, different lengths.

Angiography Is A Poor Tool To Visualize Lesion Composition (Lesion Preparation?)



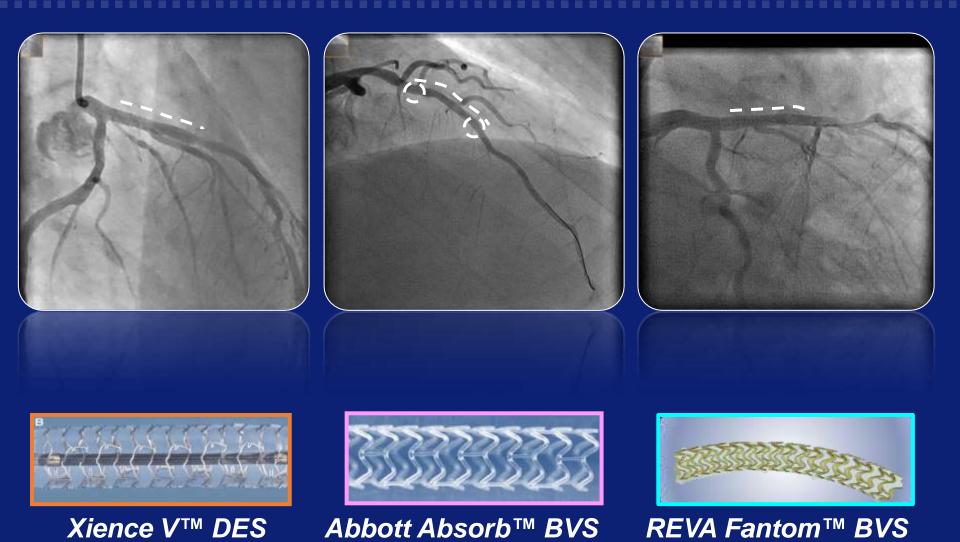


Fibrous

Lipid-rich Fibroatheroma

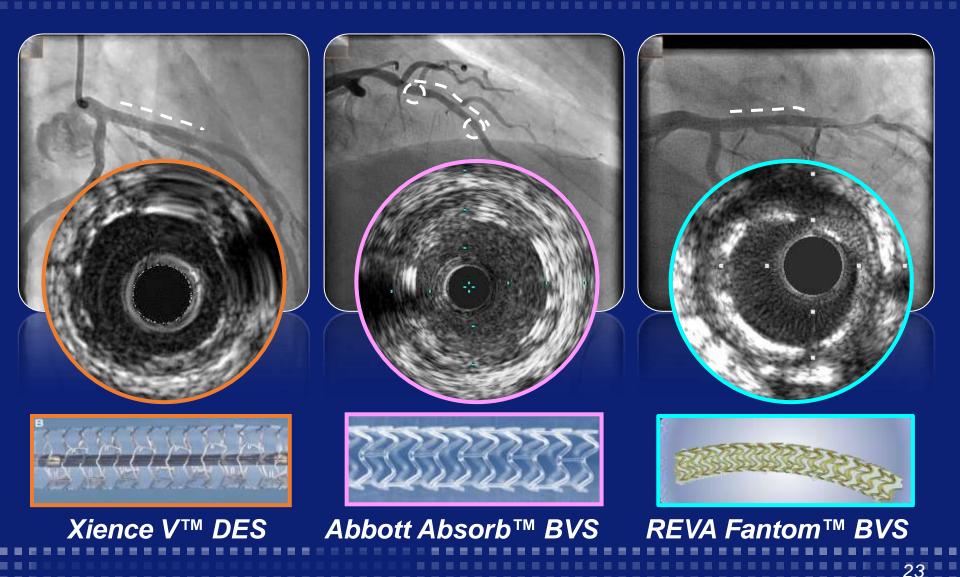
Angiography Is A Poor Tool To Visualize Stents & Scaffolds





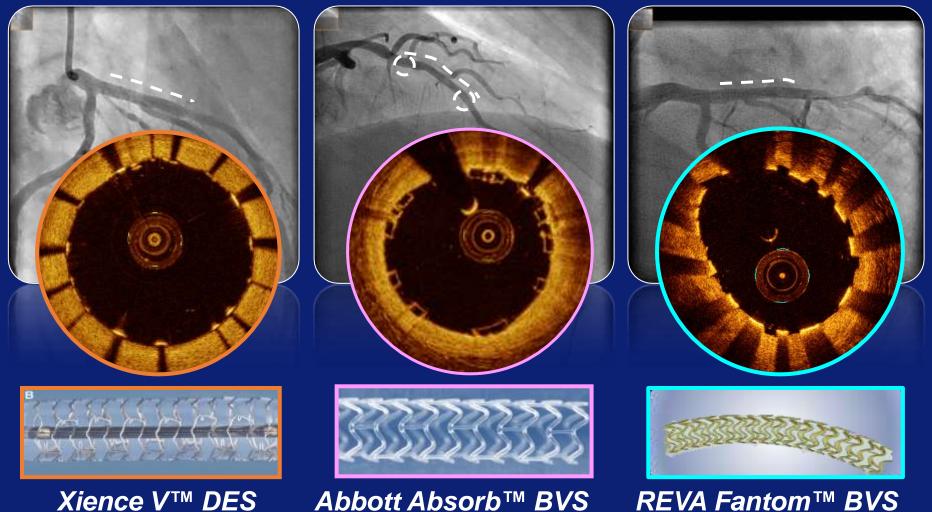
Angiography Is A Poor Tool IVUS Can Visualize Stents & Scaffolds





Angiography Is A Poor Tool OCT Can Visualize Stents & Scaffolds





Abbott Absorb[™] BVS REVA Fantom[™] BVS



A Solution....

To use the gold standard

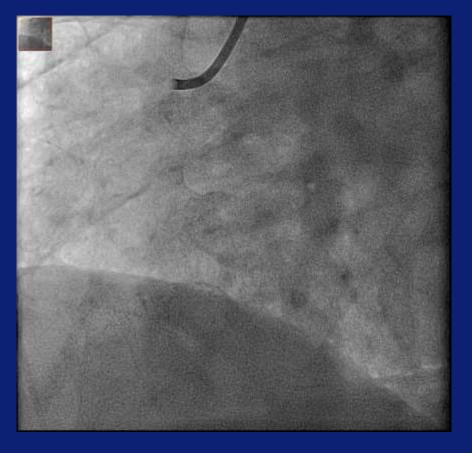
for the assessment of vascular dimensions for the visualization of BVS

Invasive coronary imaging: IVUS & OCT

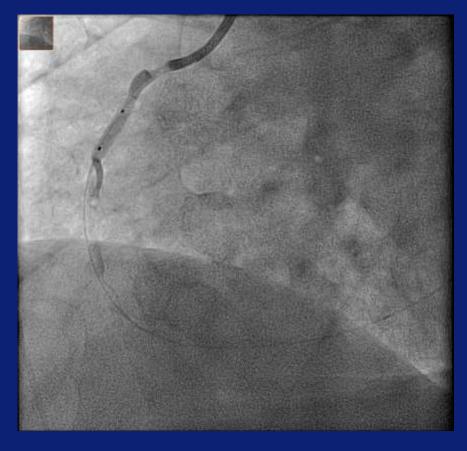
OCT To Guide BVS Implantation



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

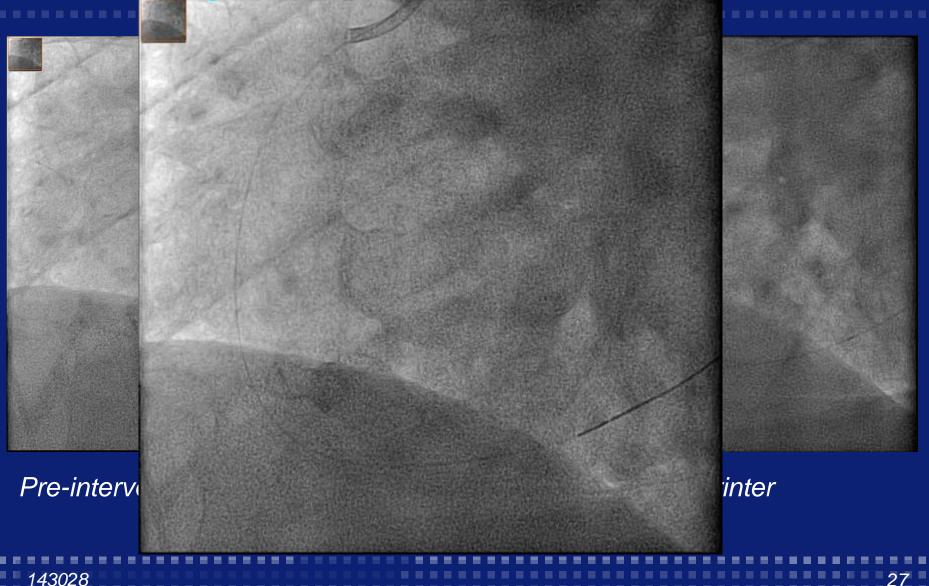


Pre-interventional



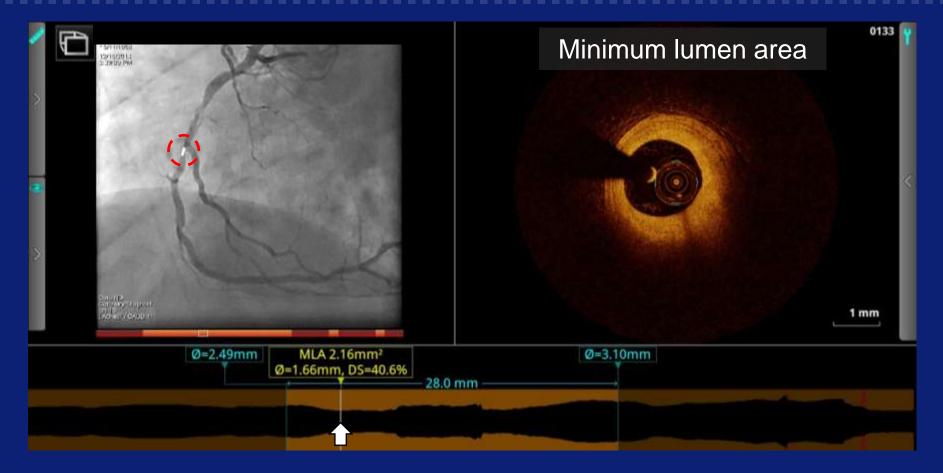
Predilation with Sprinter 2.5x10 mm balloon





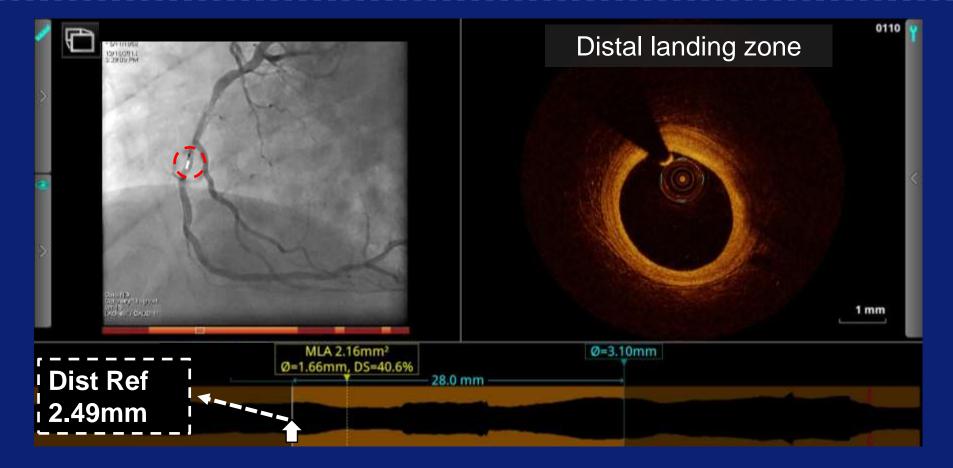
143028



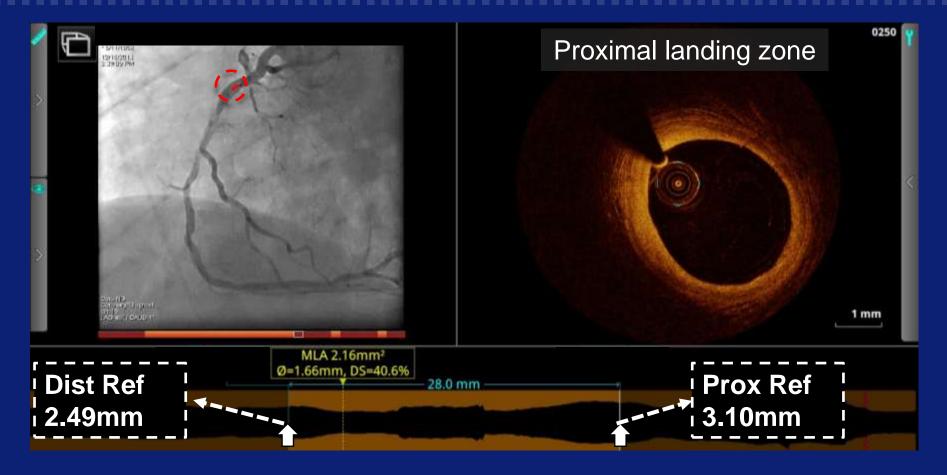


Representation of the true lumen dimensions based on automated rendering of the lumen in every cross section



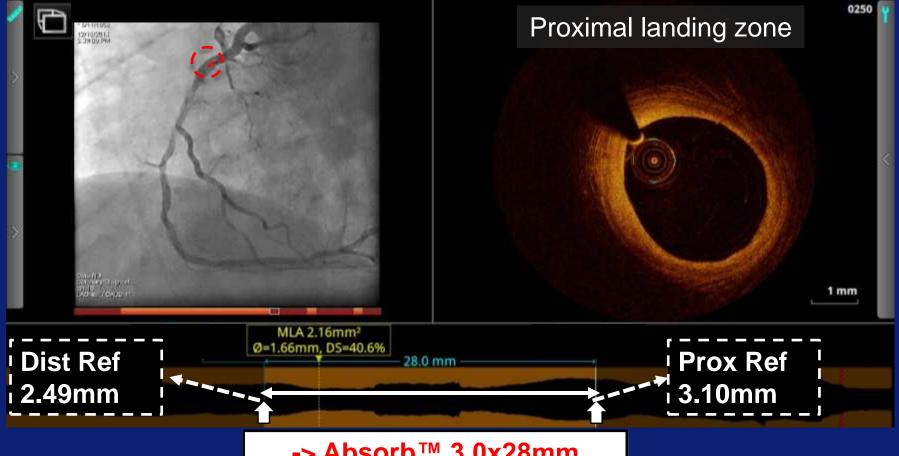






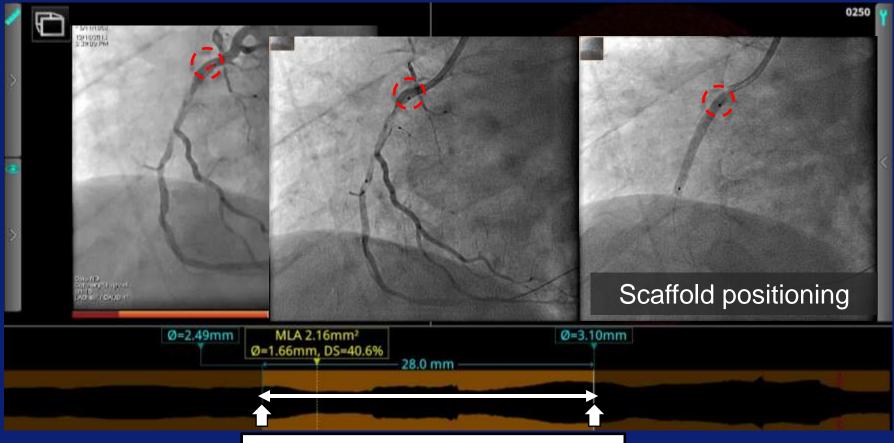
143028





-> Absorb[™] 3.0x28mm



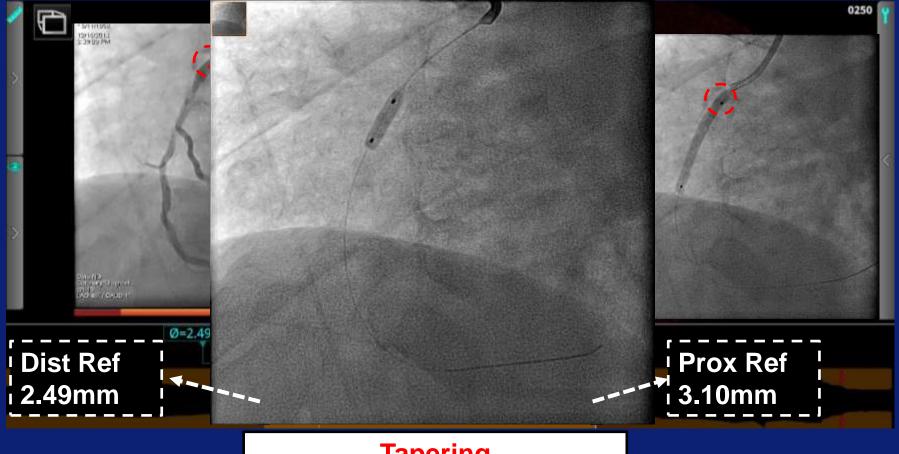


-> Absorb[™] 3.0x28mm



143028

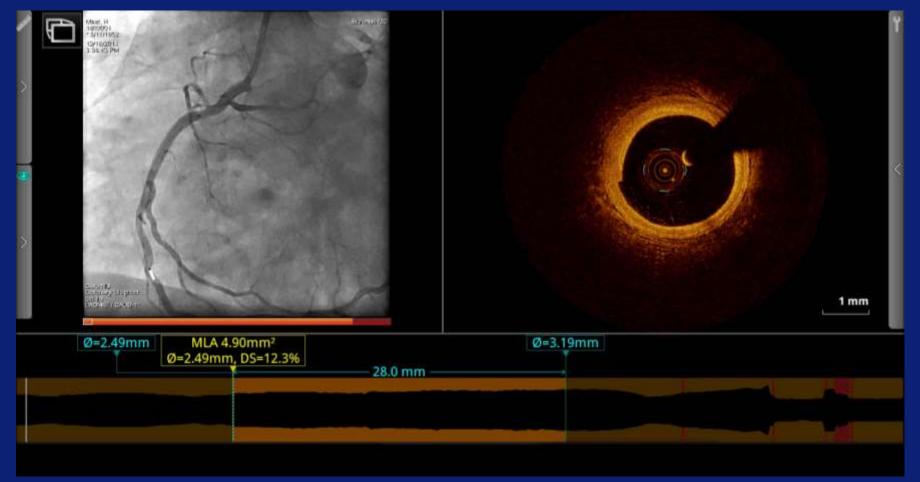




Tapering



34



Pullback 36mm/sec



Allows

- v to overcome intrinsic limitations of angiography.
- ✓ for optimal selection of BVS diameter, length & position.
- for rationale decision making regarding the need for lesion preparation & post dilatation.
- to achieve acute results that are comparable to DES.

Erasmus MC

Thank you for your attention!

PhD Students & Guest Researchers



Interventional Cardiology

J. Ligthart K. Witberg **R.J. van Geuns (BVS)** P. de Jaegere N. van Mieghem M. Valgimigli R. Diletti F. Zijlstra Experimental Cardiology H. van Beusekom

Hemodynamics Laboratory J. Wentzel F. Gijsen Bioengineering G. van Soest A.F.W. van der Steen

Imaging Group N. Bruining K. Sihan