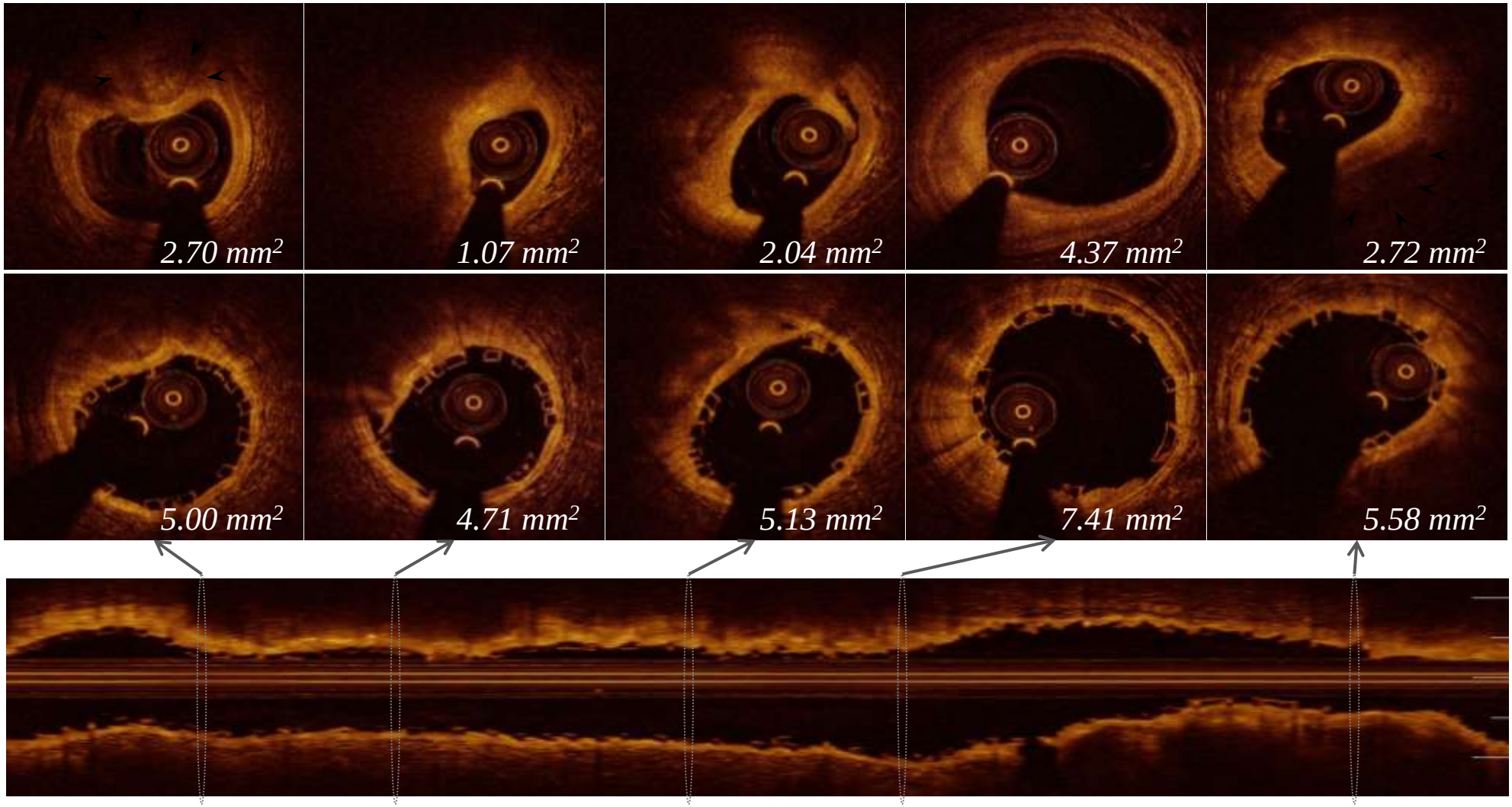
The Critical Role of Lesion Preparation for BRS:
Effect of plaque morphology, components and novel devices



Giulio Guagliumi, MD, FESC

CONFLICT OF INTEREST

GIULIO GUAGLIUMI, MD

RESEARCH/EDUCATIONAL GRANTS THROUGH THE HOSPITAL

- ABBOTT VASCULAR
- BOSTON SCIENTIFIC
- ST. JUDE MEDICAL

CONSULTING

- BOSTON SCIENTIFIC
- ST. JUDE MEDICAL

JACC: CARDIOVASCULAR INTERVENTIONS
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PUBLISHED BY ELSEVIER

VOL. 9, NO. 1, 2016
ISSN 1936-8798/$36.00
http://dx.doi.org/10.1016/j.jcin.2015.09.021

EDITORIAL COMMENT

Who Is Thrombogenic: The Scaffold or the Doctor? Back to the Future!*

Antonio Colombo, MD,† Neil Ruparelia, MB BS, DPHIL‡†

- Recent meta-analyses have raise concerns regarding a higher incidence of scaffold thrombosis when compared to metallic DES

  Lipinski M et al. J Am Coll Cardiol Intv 2016;9: 12-24

  Cassese et al. Lancet 2015

- Mechanical properties of BRS are inherently different from permanent metallic stent

  Onuma Y, Serruys P. Circulation 2011;123:779-97

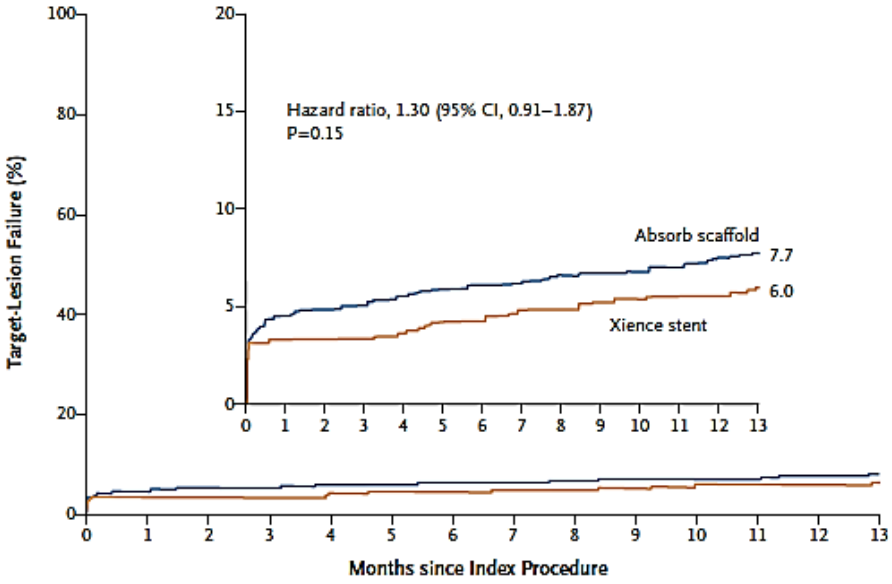
- The design of current DES have evolved becoming more forgiving toward procedural optimization
- On the contrary, current BRS are less forgiving to suboptimal implantation due to its limits

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

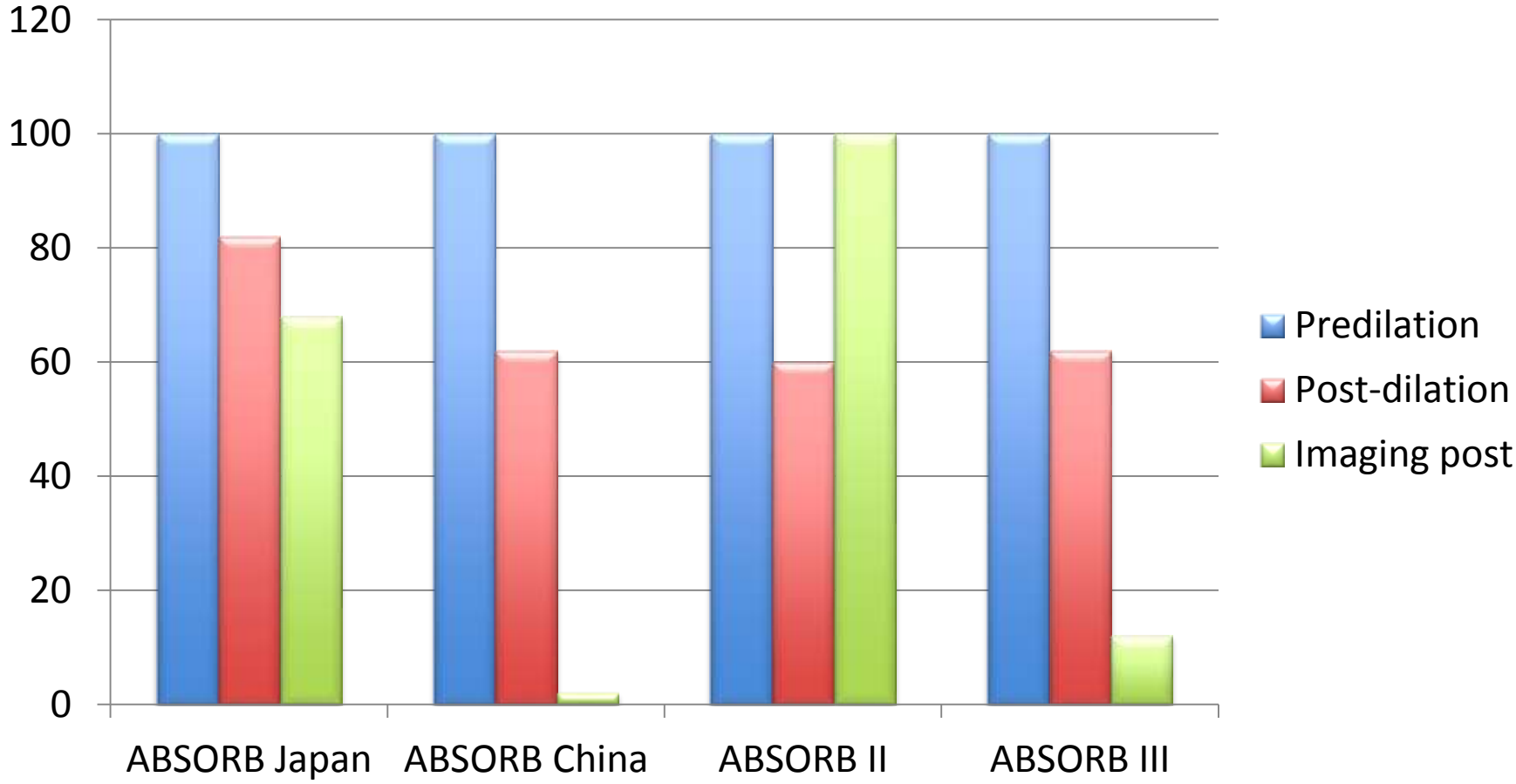
Everolimus-Eluting Bioresorbable Scaffolds for Coronary Artery Disease

Stephen G. Ellis, M.D., Dean J. Kereiakes, M.D., D. Christopher Metzger, M.D.,

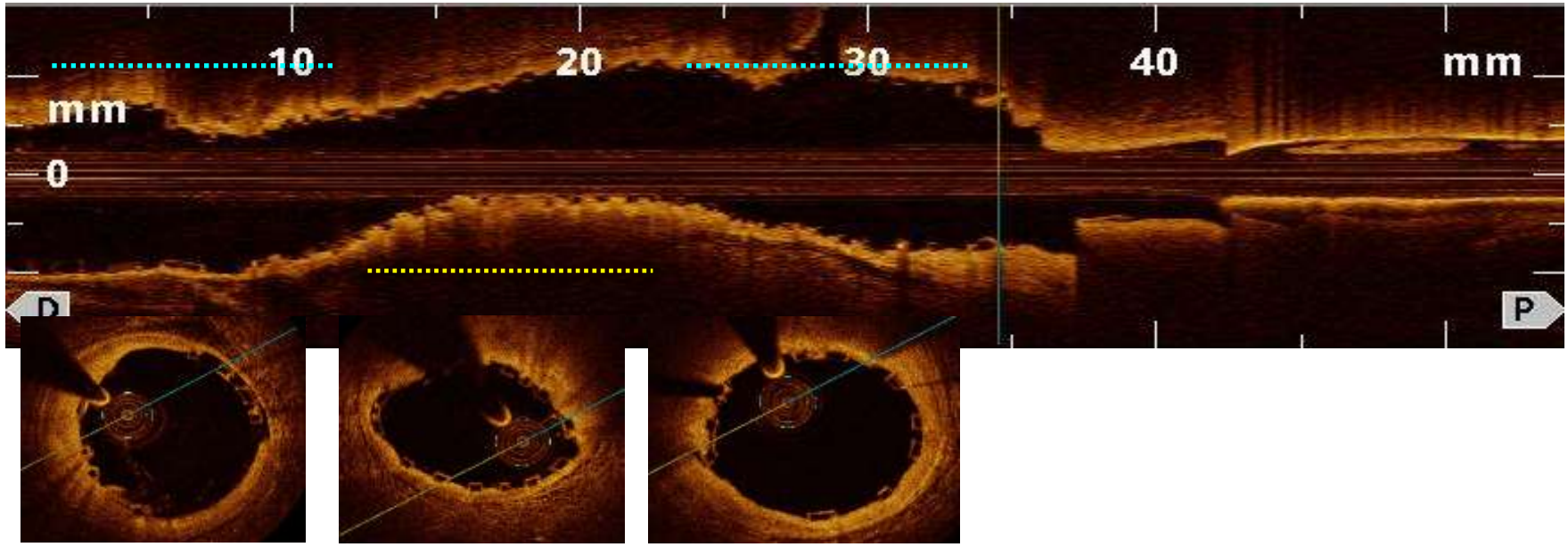


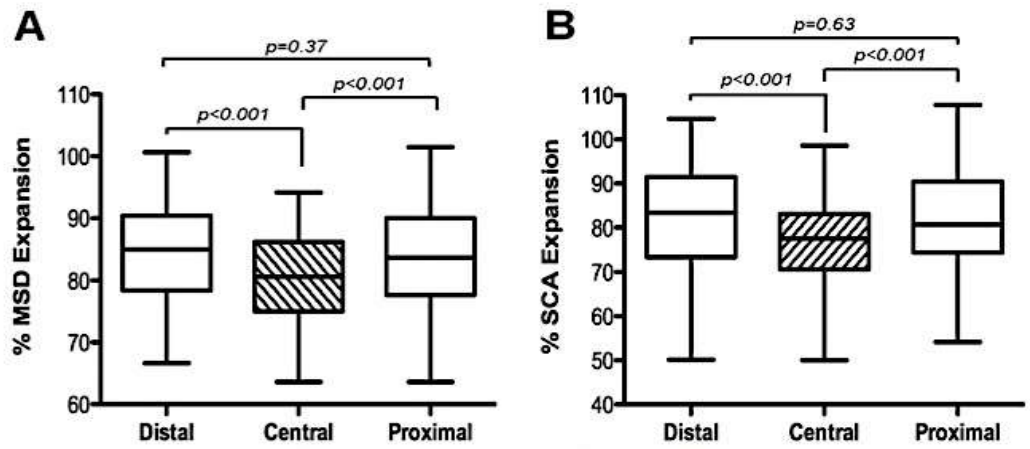
ACUTE GAIN Data presented in mean ± SD	Absorb Scaffold	Xience Stent	*P*
ABSORB II	1.15±0.40	1.46±0.4	<0.001
ABSORB III	1.45±0.45	1.59±0.44	<0.001
ABSORB Japan	1.46±0.40	1.65±0.40	<0.0001
ABSORB China	1.51±0.03	1.59±0.03	<0.04
Device success per lesion* *Stone GW et al. Pooled meta-*	95.6%	99.4%	<0.0001

Lesion Approach in Recent Studies



Scaffold expansion: prox, central, distal segments





Brown AJ, West NEJ et al. Catheter Cardiovasc Interv 2014; 84: 37-45

JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 8, NO. 6, 2015

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC.
http://dx.doi.org/10.1016/j.jcin.2014.12.244

Clinical, Angiographic, Functional, and Imaging Outcomes 12 Months After Implantation of Drug-Eluting Bioresorbable Vascular Scaffolds in Acute Coronary Syndromes

Tommaso Gori, MD, PhD,* Eberhard Schulz, MD,* Ulrich Hink, MD,* Madeleine Kress,* Nadja Weiers,*

Patient Characteristics (n=133)	
Clinical Presentation (UA, NSTEMI, STEMI)	26(19.6%), 57(42.9%), 50(37.6%)
Procedural characteristics (n=166)	
Pre-dilation	100%
Post-dilation	19(11%)

QCA Results *	**Prox Scaffold Edge**	**In-scaffold**	**Distal Scaffold Edge**
% Diameter Stenosis			
After implantation	8±7	16±8	9±8
At follow-up	9±7	18±13	9±7

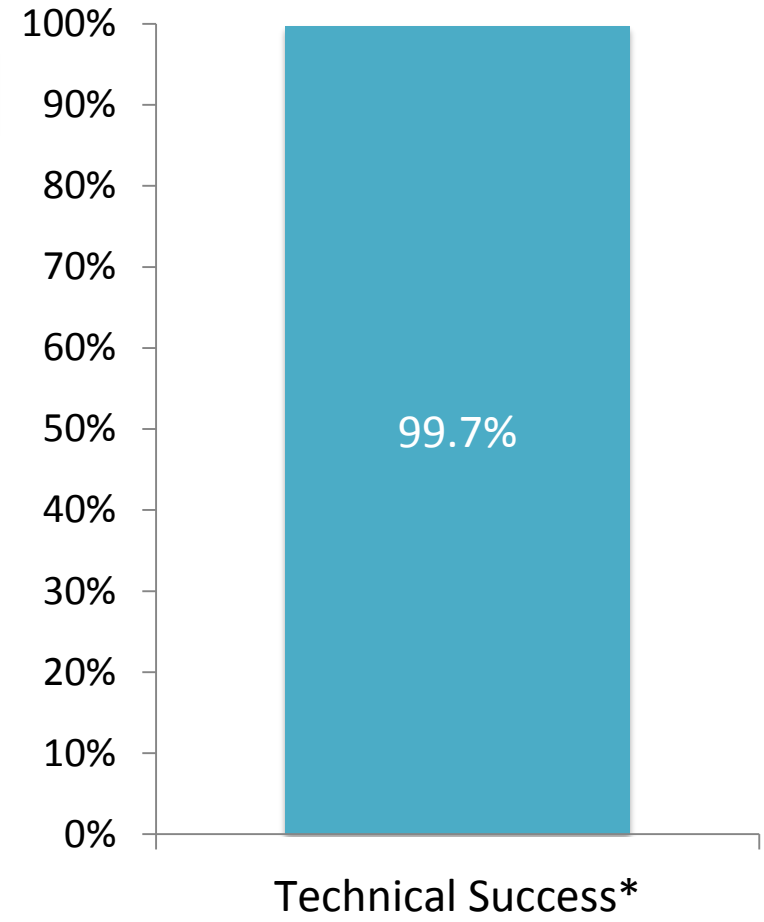
** online appendix*

ABSORB REGISTRIES

Lesion characteristics	ASSURE N=183	GHOST N=1189	ABSORB FIRST N=1801	EXPAND n-=200
B2/C (%)	64,6%	52,2%	46,7%	41,1%
Bifurcation lesion (%)	14,1%	23,1%	11,9%	29,1%
CTO (%)	4%	6,7%	10,5%	5,8%
Calcified lesion (%)	15,7%	0%	20,04%	45,8%
Lesion length (mm)	15 +/- 11	19,4 +/- 14,4	18,2 +/- 8,2	25,4+/- 13,5
Procedural characteristics				
Pre-dilatation	100%	95,9%	94,3%	89,2%
Post-dilatation	12,5%	52,3%	48,3%	50,2%

GHOST EU
Procedural characteristics

Pre-Dilatation	1670/1736 (96.2%)
Cutting balloon	21/1723 (1.2%)
Scoring balloon	47/1722 (2.7%)
Residual DS ≥ 40% after pre-dilatation	254/911 (28%)
Post-Dilatation	908/1736 (52.3%)
Mean scaffold Length/Les (n=1722)	27.6±16.7
N. of scaffold/Les	1.28±0.64
Overlapping/Les	364/1736 (21%)
OCT	206/1498 (14%)
IVUS	240/1498 (16%)

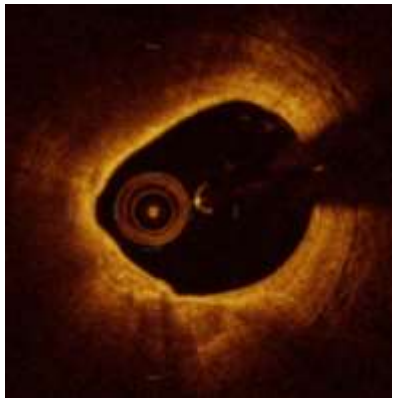


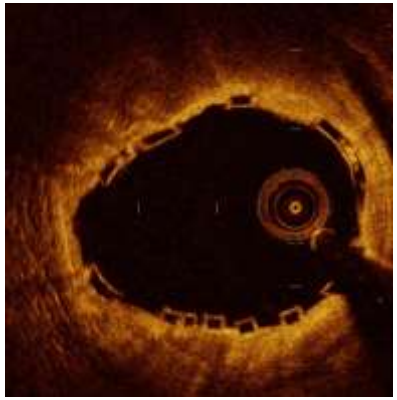
* ***Residual in-scaffold diameter stenosis < 30%***

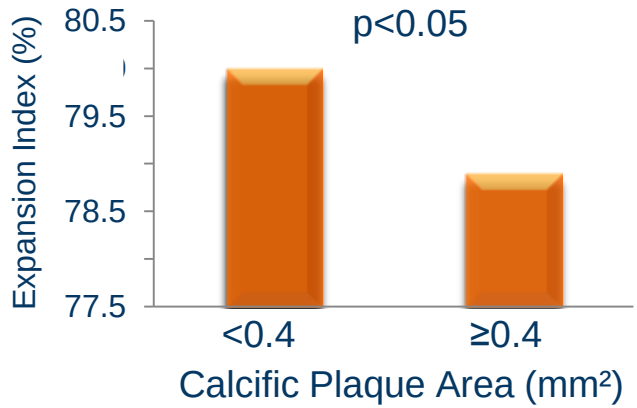
The effect of coronary artery plaque composition, morphology and burden on Absorb bioresorbable vascular scaffold expansion and eccentricity — A detailed analysis with optical coherence tomography

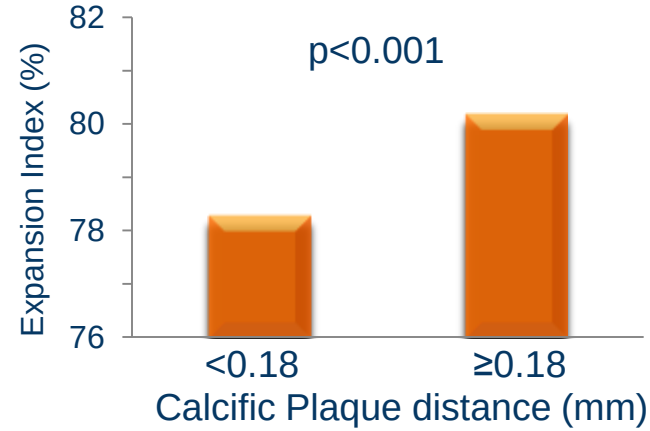
Elizabeth Shaw [a,b], Usaid K. Allahwala [a], James A. Cockburn [a], Thomas C.E. Hansen [a], Jawad Mazhar

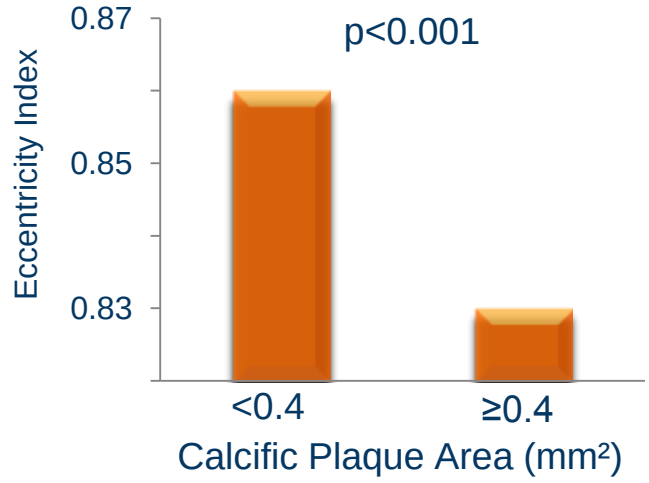
Calcific Plaque Effect on Scaffold Expansion and Eccentricity

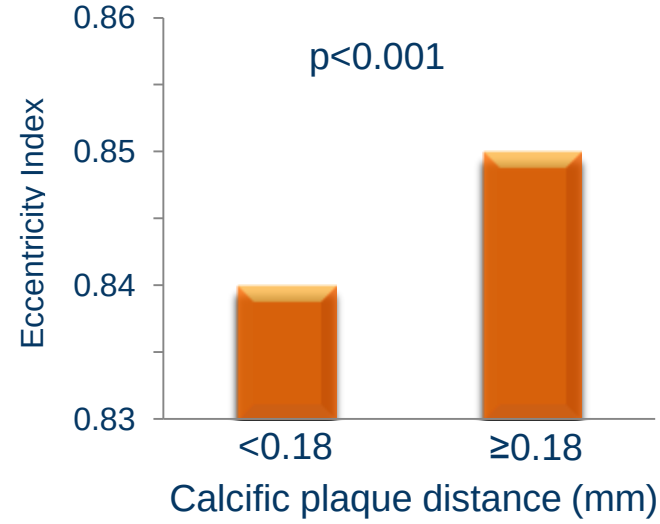






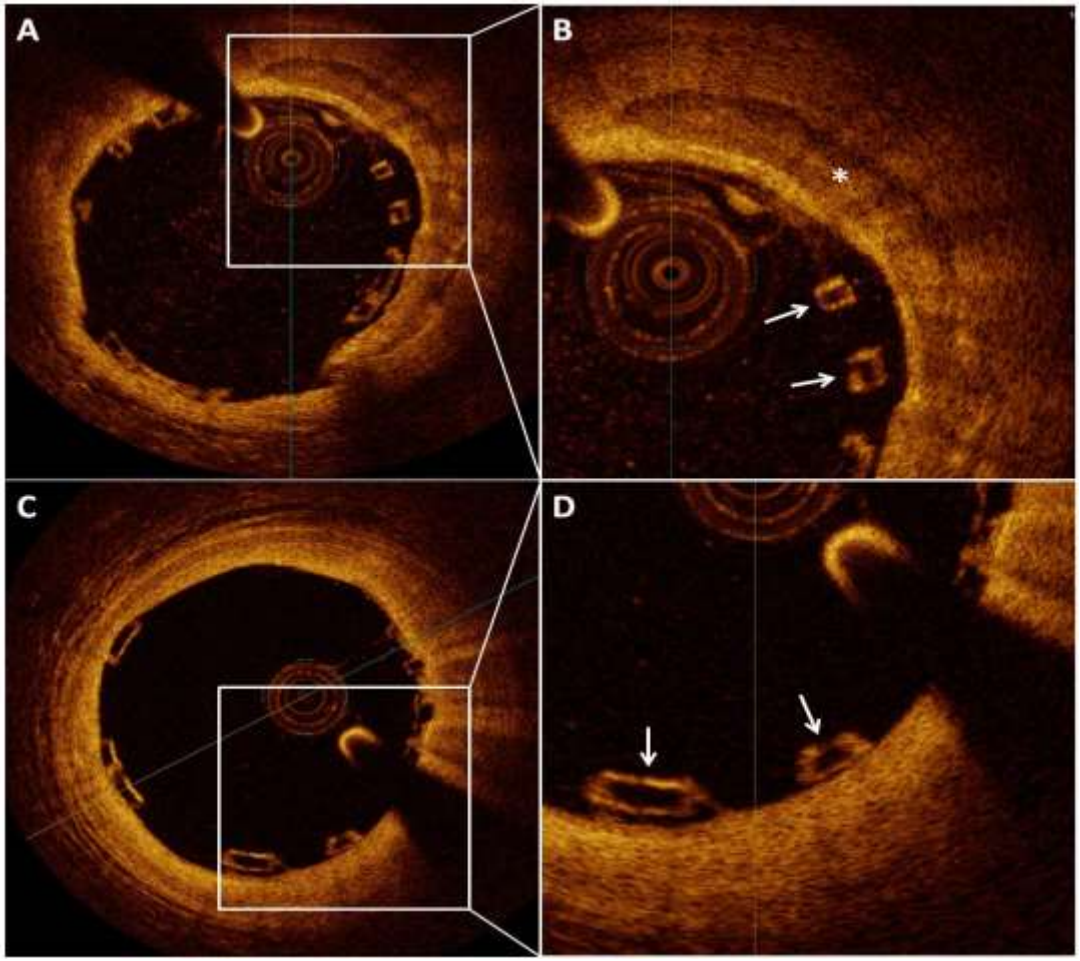


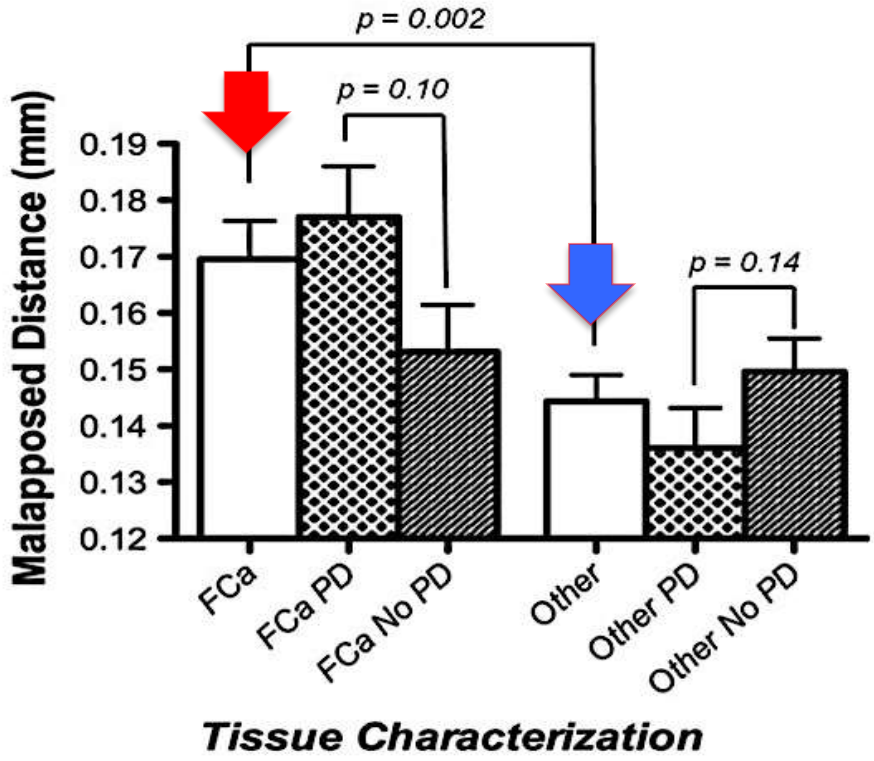




International Journal of Cardiology 2015;184:230-6

Calcium significantly increases strut malapposition





Brown AJ, West NEJ *et al. Catheter Cardiovasc Interv 2014; 84: 37-45*

Contemporary practice and technical aspects in coronary intervention with bioresorbable scaffolds: a European perspective

Corrado Tamburino[1], MD, PhD; Azeem Latib[2], MD; Robert-Jan van Geuns[3], MD; Manel Sabate[4], MD;

14 European centres with a high volume of BVS procedures

EuroIntervention 2015;11:45-52 published online ahead of print January 2015

BRS LESION PREPARATION		
How frequently do you perform **predilation before BVS** implantation?	30-60%	**14%**
	60-90%	**14%**
	> 90% of the cases	**71%**
What is your first choice **balloon for predilation** ?	**semi-**compliant	**50%**
	non-compliant	**50%**
How frequently do you **use scoring or cutting balloons** before BVS implantation?	<30% of the cases	**93%**
	30-60%	**7%**
Do you routinely use **intravascular imaging** to decide whether specific preparation is required?	Yes	**7%**
	No	**93%**

LESION PREPARATION

- Scaffold expansion
  - Less radial force
  - Inadequate lesion preparation may correlate with underexpansion

Brown et al. Cath Cardiovasc Interv 2014;84:37-45

Mattesini et al JACC Interv 2014:7:741-50

Danzi et al Cath Cardiovasc Interv 2015, 13 August, DOI: 10.1002/ccd.26148

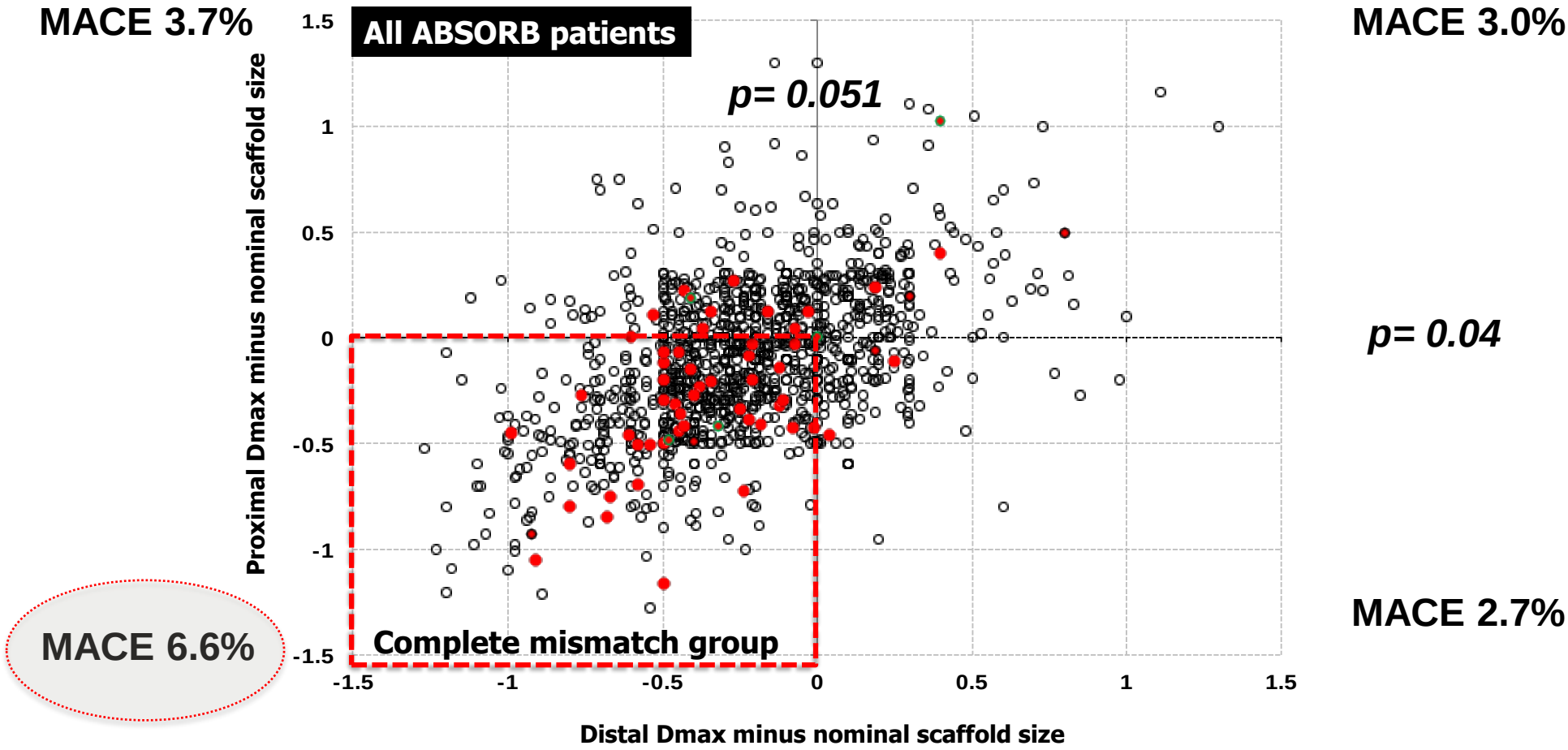
- **1:1 pre-dilation with NC or semi-compliant**
- **Low threshold for debulking devices in complex lesion settings**

VESSEL SIZING & SCAFFOLD SIZE

Do you routinely **size your vessel with balloons**?	**Yes**	**71%**
	No	**29%**
Do you routinely use **QCA for vessel sizing**	Yes	**14%**
	No	**86%**
Which vessel reference do you use ?	**Proximal**	**64%**
	Distal	**9%**
	Interpolated	**36%**
Do you routinely use **intravascular imaging for sizing**?	yes,IVUS	**0%**
	yes,OCT	**14%**
	No	**86%**

EuroIntervention 2015;11:45-52 published online ahead of print January 2015

Distribution of Dmax Prox and Dmax Distal related to the nominal device size in the ABSORB II, Extend and B (n=1248)



Ishibashi Y et al. J Am Coll Cardiol Intv 2015; 8: 1715-26

BRS OPTIMIZATION

How frequently do you **post-dilate the scaffold**?	<30% of the cases	**0%**
	30-60%	**14%**
	60-90%	**21%**
	> 90% of the cases	**64%**
Which **ballon size for post-dilation**?	Same size as BVS	**29%**
	0.25 mm larger	**14%**
	0.50 larger	**57%**
What is the typical **post-dil balloon pressure**?	< 12	**0%**
	13-16 atm	**50%**
	> 16 atm	**50%**
What is your **goal after scaffold** implantation?	**<10% residual stenosis**	**86%**
	<30% residual stenosis	**14%**
	<50% residual stenosis	**0%**

EuroIntervention 2015;11:45-52 published online ahead of print January 2015

IMPORTANCE OF POST-DILATION

- Acute lumen gain is lower for current BVS than metallic stents with similar pressures even in simplest lesion subsets
- High post-dilation rates (over 90%) and pressure (over 20 atm) were associated with lower rates of ST

Caiazzo et al. 2015,Int J Cardiol 2015; 201: 129-36

RISK WITH OVER-EXPANSION

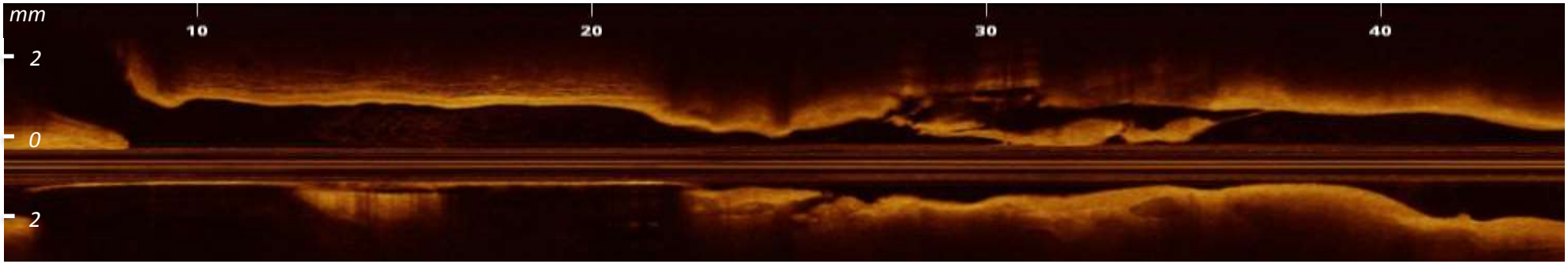
- Over-expansion might cause scaffold disruption (above limit, kissing balloon) and a focal loss of mechanical support

Foin et al. Eurointervention 2015, Jul 8; 11(3) Epub ahead of print

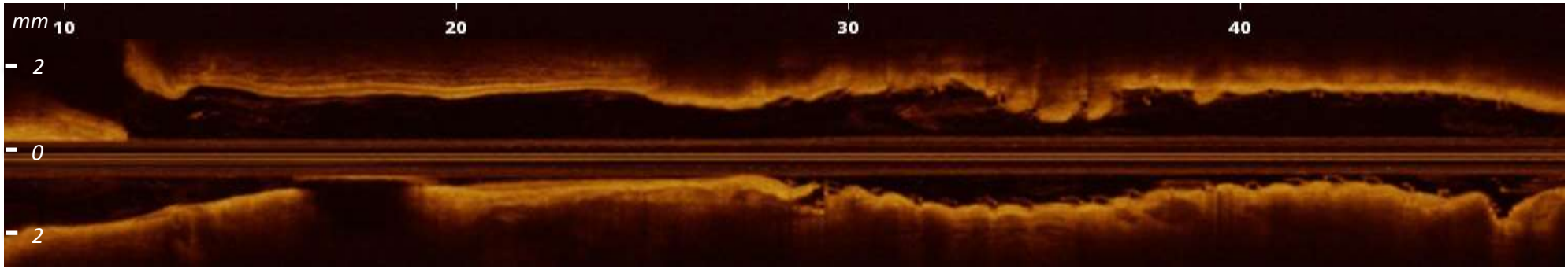
- **Non-oversized NC balloon with very high pressure**
- **Balloon/Scaffold diameter 1:1, max +0.5 mm**

The role of intravascular imaging

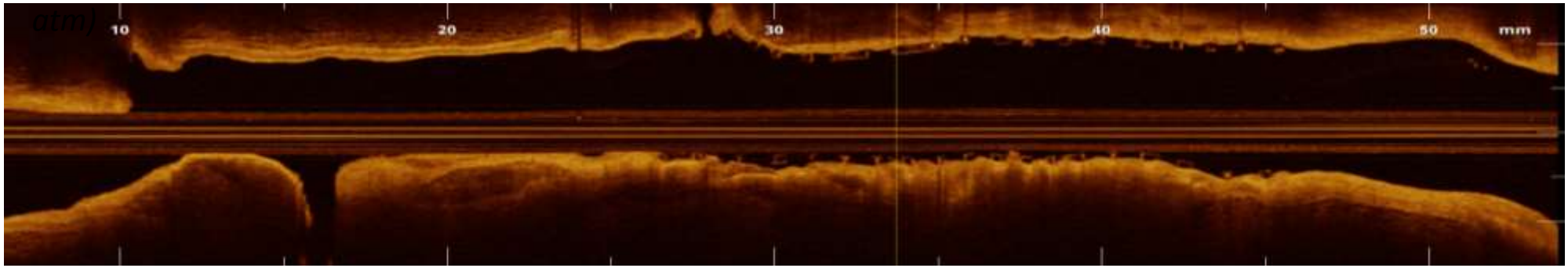
After pre-dilation with NC 1:1 balloon



After BVS implantation at 14 atm



After post-dilation with NC at HP (22 atm)



JACC: CARDIOVASCULAR INTERVENTIONS VOL. 7, NO. 7, 2014
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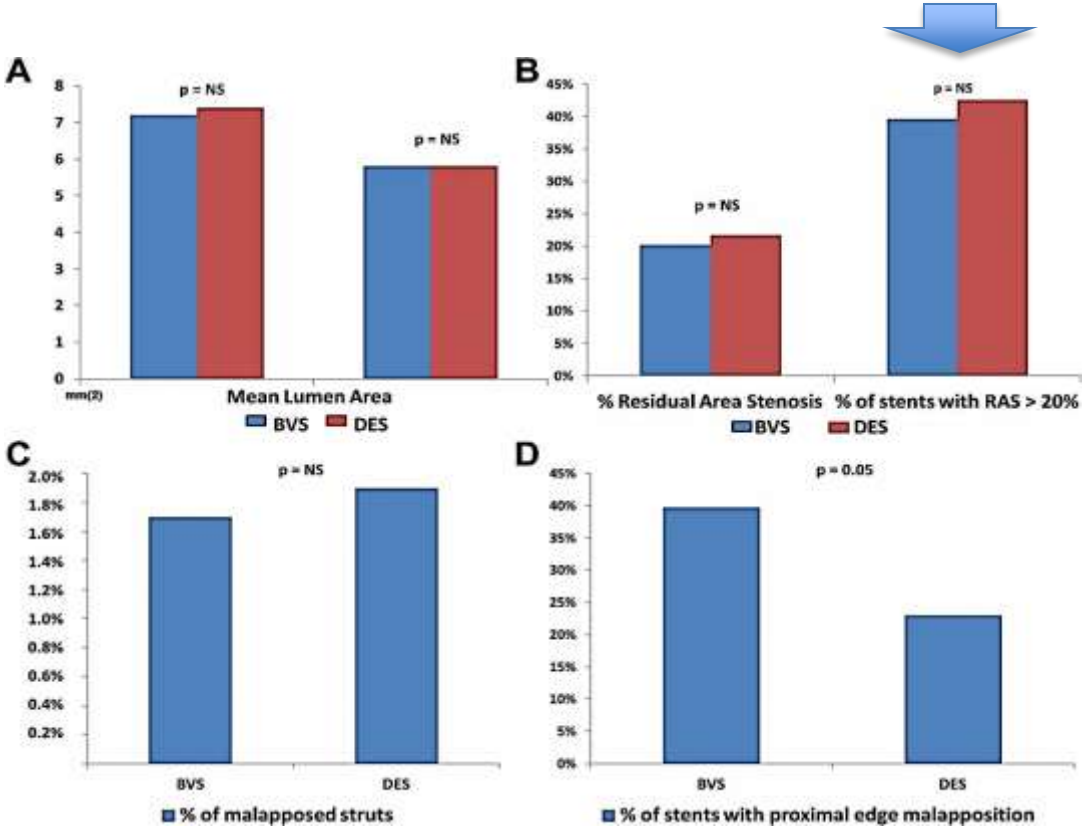
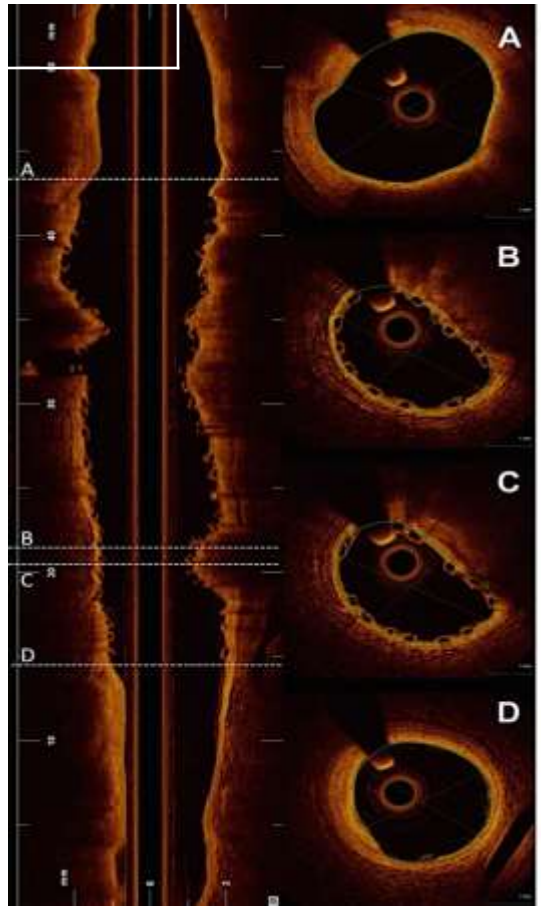
ABSORB Biodegradable Stents Versus Second-Generation Metal Stents

A Comparison Study of 100 Complex Lesions Treated Under OCT Guidance

Alessio Mattesini, MD,*† Gioel G. Secco, MD,*‡ Gianni Dall'Ara, MD,*

Lesion lenght, mm	**24.7 (14.2)**	**25.1 (10.6)**	**0.86**
Calcified, %	**31 (62.0)**	**37 (74.0)**	**0.28**





A: Proximal Reference Vessel Area (PRVA) = 10.8 mm²

B: Cross section with the Minimum Eccentricity Index =

(Minimum diameter/Maximum diameter) =

(2.34 mm/3.66 mm) = **0.64**

C: Minimal Lumen Area (MLA) = 6.9 mm²

Residual Area Stenosis =

(1- MLA/RVA*) X 100 =

(1-6.9mm²/ 8.9 mm²) X 100 = **22.5 %**

D: Distal Reference Vessel Area (DRVA) = 7.1 mm²

Reference Vessel Area (RVA) =

(PRVA + DRVA)/ 2 =

(10.8 mm² + 7.1 mm²) / 2 = **8.9 mm²**

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
VOL. 66, NO. 17, 2015

ISSN 0735-1097/$36.00
PUBLISHED BY ELSEVIER INC.
http://dx.doi.org/10.1016/j.jacc.2015.08.863

EDITORIAL COMMENT

Very Late Thrombosis After Bioresorbable Scaffolds

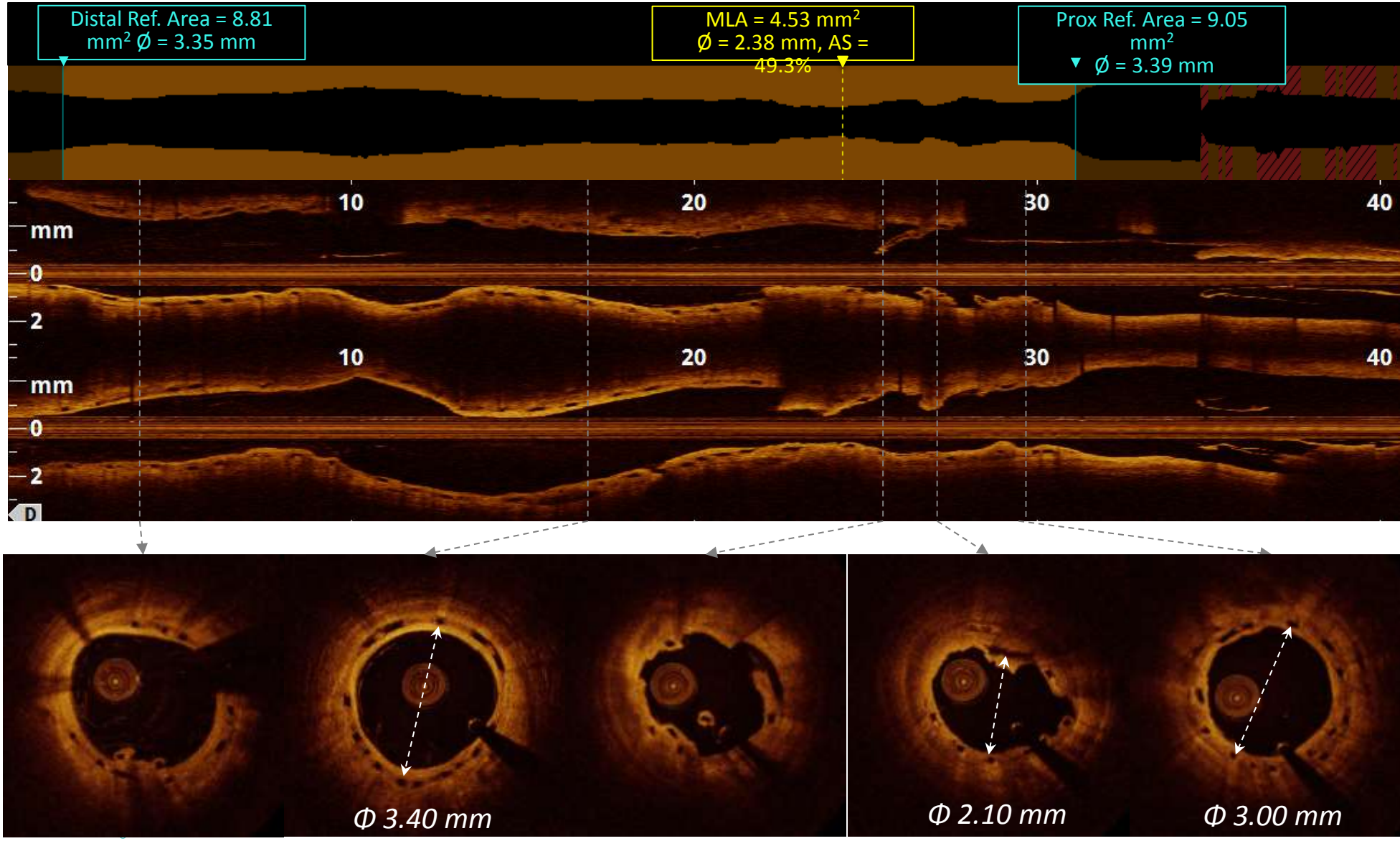
Cause for Concern?*

Gregg W. Stone, MD,† Juan F. Granada, MD‡

" However, the BVS **visually appear under-expanded in all 4 cases**, as confirmed by the **residual angiographic diameter stenosis ranging from 18.6% to 26.7%**. Careful lesion preparation (pre-dilation) and optimal scaffold expansion (post-dilation with non-compliant balloons at high pressure) are required to maximize lumen gain with first-generation BVS".

Very Late BVS Thrombosis 18 months

The role of accurate sizing and complete expansion



*Bioresorbable Vascular Scaffold (BVS Abbott Vascular) are not approved for sale in United States

INTRAVASCULAR IMAGING: PRE/POST-PROCEDURE USE

To Assist Sizing

BVS requires more careful sizing (more difficult to correct after deployment)

Undersize → Malapposition → ST risk

Raber et al. JACC 2015, 66: 1901-14
Karanasos et al. Circ Cardiovasc Interv: 2015: 8 e002369

Oversize → Increased foot print → Worse clinical outcomes
SB occlusion

Kawamoto et al. JACC Intv 2016; 9:299-300
Ishibashi et al. JACC Intv 2015:8;1715-1723
Muramatsu et al. JACC Intv 2013:6;247-57

To avoid, detect and correct

Underexpansion (*even after HP post-dil in fibrocalcific lesions: lesion preparation!*)

Edge inury: *possible due to agressive pre- and post- dilatation*

Malapposition

Low threshold for intravascular imaging especially in complex settings

THE CRITICAL ROLE OF LESION PREPARATION FOR BVS:

PRACTICAL CONSIDERATIONS

1. **BVS** should not be implanted into lesions that cannot be adequately prepared
2. **P**repare the lesion with 1:1 NC (or semi-compliant) balloon to reference diameter
3. **U**se intravascular imaging or the pre-dilation balloon for sizing (QCA tends to underestimate)
4. **P**roperly select scaffold diameter relative to proximal ref. vessel diameter (but check tapering!)
5. **L**ow threshold for debulking devices in complex lesions settings (diffuse, fibro-calcific)
6. **P**ost-dilate with high pressure non-compliant balloon (a maximum of nominal scaffold size + 0.5 mm, making sure that full expansion is achieved)
7. **P**rescribe dual anti-platelet therapy for no less then 6 months and preferably for 12 months

Scaffold is important, but doctor is also important.