An update on bioresorbable coronary devices.

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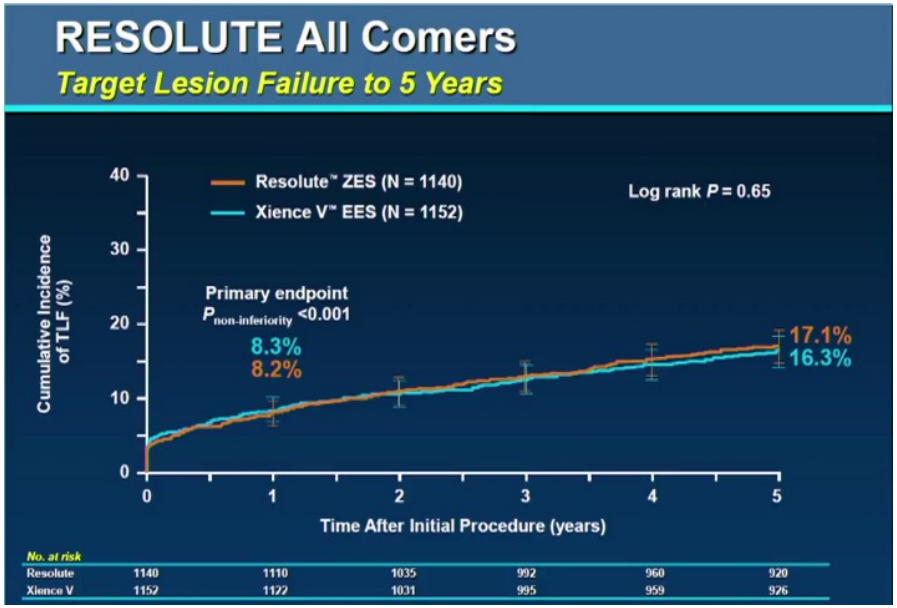
Bulgarian Bifurcation and Complex Coronary Interventions Course
22-23 January 2016 Tokuda Hospital, Sofia

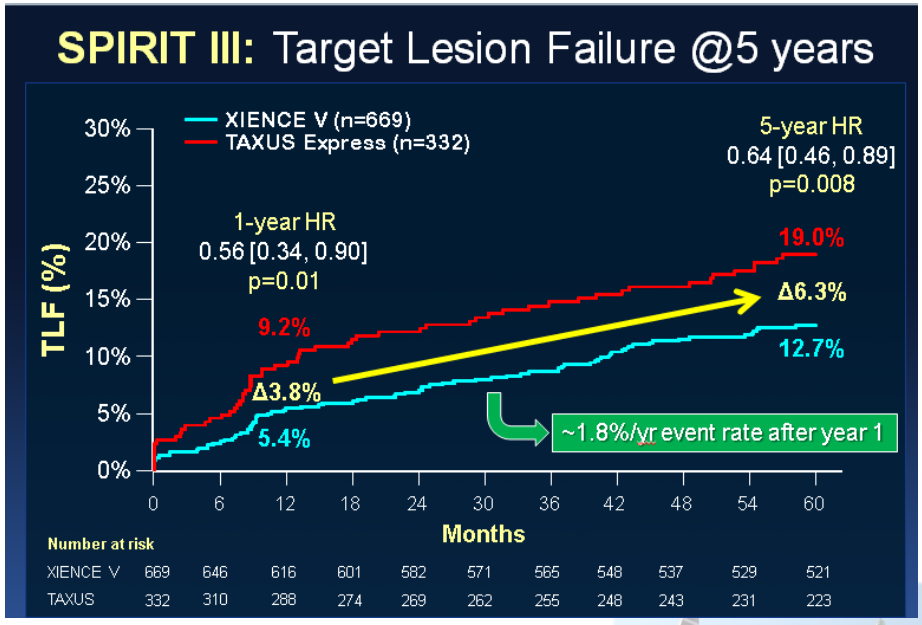
Long Term limitations of Permanent Metallic Implants

Continuous Increase in Events over Time with Current Generation DES



TLF = cardiac death, target vessel MI, or clinically-driven TLR

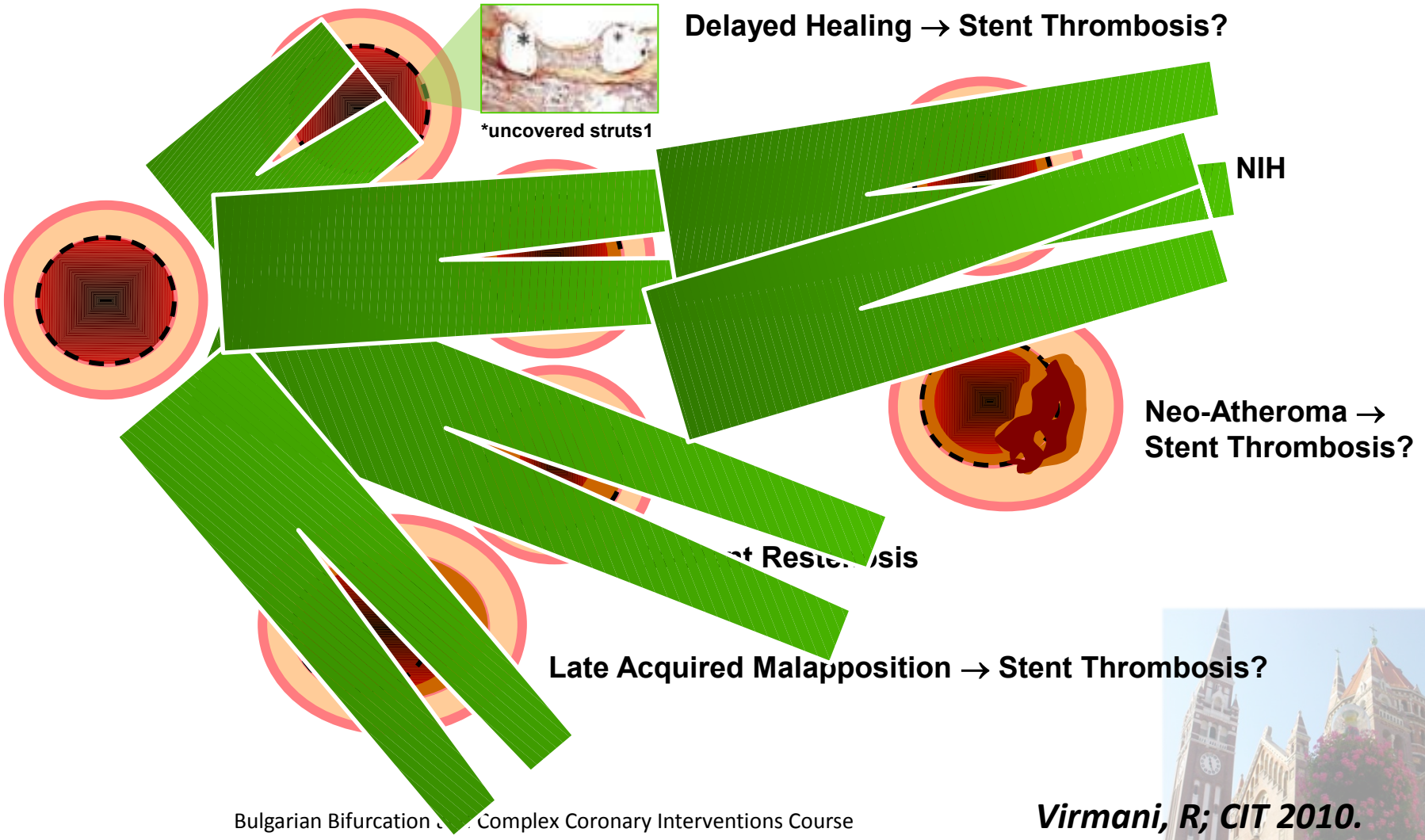
Windecker, PCR 2014



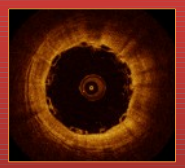
TLF = cardiac death, target vessel MI, or ischemic-driven TLR

Gada H, et al., J Am Coll Cardiol Intv 2013

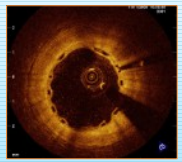
‘Caged’ (Stented) Vessel



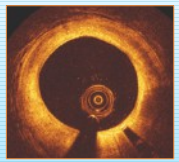
Virmani, R; CIT 2010.



Repair



Restore



Renew

Immediate revascularization

Restore natural vessel function, enabling vasodilation and remodeling

Sustained vessel wall patency and functionality

BMS & DES

Unique benefits of BRS only possible absent a permanent implant

RJ van Geuns, Cohort B OCT images

Potential advantages of BRS vs metallic stents

- Restored Vessel Function
- Late Lumen Gain
- Plaque Regression
- Non-Invasive Imaging (MSCT)
- Reintervention in the Treated Segment (CABG)

BRS under current development

Basic material	MAGNESIUM			OTHER		
Scaffold name	AMS	DREAMS 1.0	DREAMS 2.0	REVA BRS	REVA ReZolve	Ideal BioStent
Manufacturer	Biotronik, Berlin, Germany	Biotronik, Berlin, Germany	Biotronik, Berlin, Germany	Reva Medical Inc., San Diego, CA, USA	Reva Medical Inc., San Diego, CA, USA	Xenogenics Corp., Canton, MA, USA
Composition	Magnesium and rare earth metals	Magnesium and rare earth metals	Magnesium and rare earth metals	Desaminotyrosine polycarbonate	Desaminotyrosine polycarbonate	Poly-lactic anhydride containing 2 salicylic acid molecules linked to 1 sebacic acid molecule
Design of the latest generation	4-crown design	6-crown design	6-crown design	Slide-and-lock ("ratchet")	Slide-and-lock ("ratchet")	Tube with laser-cut voids
Thickness of strut, µm	165	120	150	204	122	200
Visualization	Latest generation with radiopaque markers			Fully radiopaque	Fully radiopaque	--
Special feature	Electronegative charge that emerges during degradation process has an antithrombotic function			--	--	Polymer causes less inflammation
Anti-proliferative drug elution	No	Paclitaxel	Sirolimus	Paclitaxel	Sirolimus	Sirolimus
Resorption time	2 mos	9-12 mos	--	2-3 yrs	2-3 yrs	15 mos
Status	Clinical evaluation	Clinical evaluation	Clinical evaluation	Clinical evaluation; CE trial ongoing	Clinical evaluation; CE trial ongoing	Clinical evaluation, pre-clinical evaluation of the thinner 2nd generation

Wiebe J., et., JACC 2014

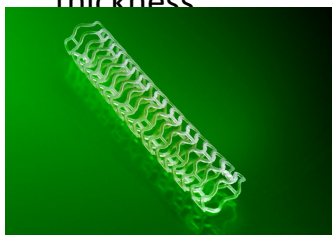
BRS under current development

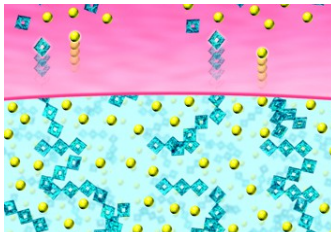
Basic material	POLY-LACTIC ACID								
Scaffold name	Igaki-Tamai Stent	Absorb BVS 1.0	Absorb BVS 1.1	DESolve 1st generation	DESolve 2nd generation	Amaranth	ART18Z BRS	Xinsorb BRS	Acute BRS
Manufacturer	Kyoto Medical Planning Co, Ltd, Kyoto, Japan	Abbott Vascular, Santa Monica, CA, USA	Abbott Vascular, Santa Monica, CA, USA	Elixir Medical Corp., Sunnyvale, CA, USA	Elixir Medical Corp., Sunnyvale, CA, USA	Amaranth Medical Inc., CA, USA	Arterial Remodeling Tech., France	Shandong HuaAn Biotech., Co. Ltd., China	OrbusNeich, Fort Lauderdale FL, USA
Composition	PLLA	PLLA	PLLA	PLLA	PLLA	PLLA	PLLA, PDLA	Poly-lactic acid, poly ε-caprolactone, poly-glycolic acid	PLLA, L-latic-co-ε-caprolactone, PDLA
Design of the latest generation	Zigzag helical coil	Out-of-phase sinusoidal hoops with links	In-phase zigzag hoops, cross-linked by bridges	Tubularly arranged hoops, linked by bridges	Tubularly arranged hoops, linked by bridges	Zigzag hoops, linked by bridges	Creep-resistant hinge	--	Helically linked double ring
Thickness of strut, μm	170	150	150	150	150	--	--	150–170	150
Visualization	Gold radio-paque markers at both ends	Radiopaque metal markers at both ends	Radiopaque metal markers at both ends	2 platinum radiopaque markers	2 platinum radiopaque markers	--	--	2 radiopaque markers	Radiopaque markers
Special feature	Self-expandable when heated	--	--	Minor malapposition is self-corrected	Minor malapposition is self-corrected	Consists of multiple layers	--	Radial strength is comparable to that of DES	Dual elution
Anti-proliferative drug elution	No	Everolimus	Everolimus	Myolimus	Novolimus	No	No	Sirolimus	Abluminal side: sirolimus Luminal: CD34+ antibodies
Resorption time	3 yrs	Up to 3 yrs	Up to 3 yrs	1 yr	1 yr	1–2 yrs	1.5–2 yrs	--	--
Status	CE mark (for peripheral use)	CE mark (for coronary use); randomized-controlled trial BVS vs. DES) is currently enrolling patients		CE mark (for coronary use)		Clinical evaluation, new version under dev.	Clinical evaluation	30 patients enrolled in FiM study	Pre-clinical evaluation

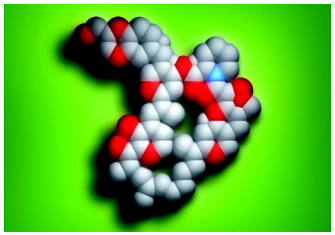
Wiebe J., et., JACC 2014

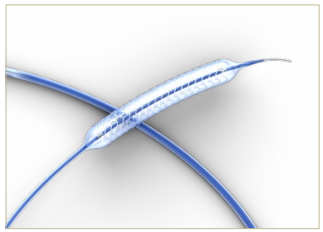
Absorb Bioresorbable vascular scaffold system

Bioresorbable Scaffold	Bioresorbable Coating	Everolimus	Enhanced Delivery System
· Poly (L-lactide) (PLLA) · Based on proven MULTILINK pattern · Naturally resorbed, fully metabolized* · 150 µm strut thickness	· Poly (D, L-lactide) (PDLLA) · Naturally resorbed, fully metabolized · 3 years to full resorption	· Similar dose density and release rate to the XIENCE family of products	· Improved push transmission · Improved ease of use · Broad patient applicability









Ongoing Absorb Studies

Randomized Controlled Clinical Trial

ALL-COMERS

GABI-R
Design: All-comers registry
N=5000
1˚: Safety & efficacy

FEAST Russia Registry
Design: All-comers registry
N=2500
1˚: 1-year MACE, TVF, Revascularization, ST, Peri-procedural MI, Angina

ABSORB FIRST
Design: Prospective, multi-center, global registry
N= ~1800
1˚: ST, CD, MI, revascularization, MACE, TLF, & TVF

GHOST EU
Design: All-comers registry
N=continuous enrollment
1˚: TVF

EVERBIO II
Design: Non-inferiority RCT EES vs BES vs BVS
N=240
1˚: Late lumen loss at 9 months

UK REGISTRY
Design: Prospective, single-arm, multi center, observational registry
N= 1000
1˚: RDS < 50% at procedure conclusion, MACE

AIDA
Design: RCT vs XIENCE
N=2690
1˚: 2-year TVF

FRANCE ABSORB
Feasibility: De novo lesions
N=2000
1˚: 1-year MACE

REPARA
Design: All-comers registry
N=1500
1˚: 1-year MACE

BVS EXPAND*
Design: All-comers registry
N=300
1˚: 1-year MACE

Kuwait Registry
Design: All-comers registry
N=200
1˚: Safety & efficacy

ASSURE
Design: All-comers registry
N=180
1˚: Safety & efficacy

ADDITIONAL LARGE RCTs

ABSORB CHINA
Design: RCT
N= ~440
1˚: In-segment late loss at 1 year

ABSORB JAPAN
Design: RCT
N= ~400
1˚: TLF at 1 year

ABSORB III
Design: RCT
N= ~2250
1˚: TLF at 1 year

ABSORB IV
Design: RCT
N= ~3000
1˚: Angina within 1 year

COMPLEX POPULATIONS

POLAR-ACS
Design: ACS registry
N=100
1˚: Safety, clinical device, procedure, success & in-hospital MACE

ISAR ABSORB MI
Design: Non-inferiority vs EES
N=260
1˚: % diameter stenosis at 6-8 months

PRAGUE 19
Design: STEMI (STEMI Killip I/II)
N=100
1˚: Clinical outcomes

TROFI II
Design: STEMI vs XIENCE
N=190
1˚: 6-month, neo-intimal healing score

ABSORB CTO
Feasibility: CTO
N=35
1˚: Safety & performance

PABLOS
Feasibility: Bifurcations
N=30
1˚: Device, procedural, main & side branches

IT-DISAPPEARS
Design: MVD and Long Lesion Registry
N=1000
1˚: Safety & efficacy

COMPARE ABSORB
Design: High risk for ISR
N=2100
1˚:TLF

PROSPECT
Design: RCT BVS vs OMT in unstable asymptomatic pts
N=900
1˚: 2-Yr IVUS MLA

SIMPLE TO MODERATELY COMPLEX POPULATIONS

ABSORB II
Design: Randomized 2:1 Absorb BVS:XIENCE
N=501
1˚: Vasomotion & lumen diameter after the index procedure & at 3 years

ABSORB COHORT B
Design: Allocated (non-randomized)
N=101
1˚: Safety & performance

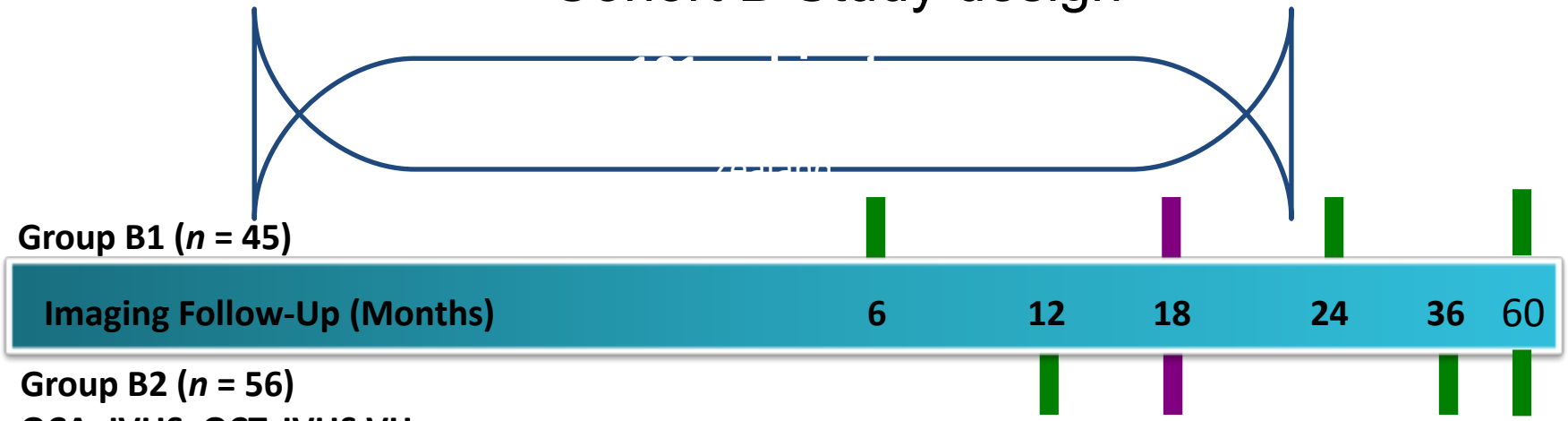
ABSORB EXTEND
Design: Prospective, single-arm, open-label clinical study
N=800
1˚: ID-MACE

*Excludes STEMI patients. ACS, acute coronary syndrome; MVD, multi-vessel disease; CTO, chronic total occlusion; MI, myocardial infarction RCT, randomized controlled trial; OMT, optimal medical therapy; EES, everolimus-eluting stents; BVS, bioresorbable vascular scaffold; STEMI, ST-segment–elevation myocardial infarction; MACE, major adverse cardiac events; ID-MACE, ischemia-driven major adverse cardiac events; TLF, target lesion failure; IVUS MLA, intravascular ultrasound minimal lumen area; TVF, target vessel failure; LAD, left anterior descending; FIM, first-in-man.

All comparative claims of catheter design improvements are based on internal studies versus Absorb BVS. Data and images on file at Abbott Vascular.

Absorb Clinical Update

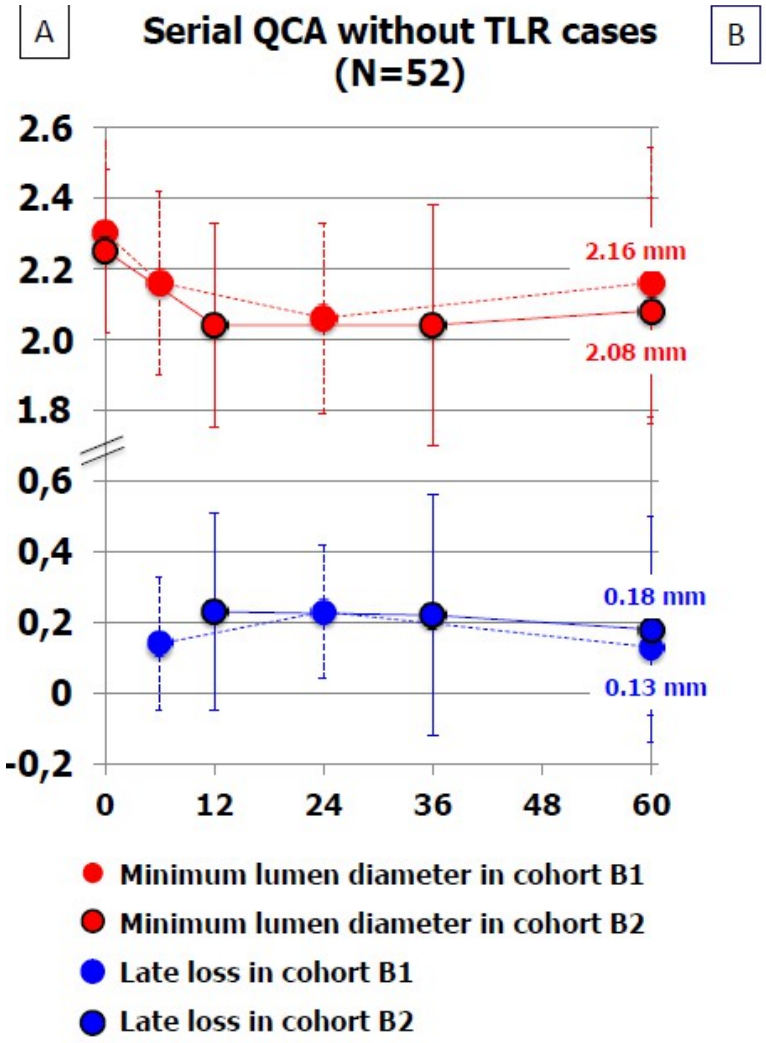
Cohort B Study design

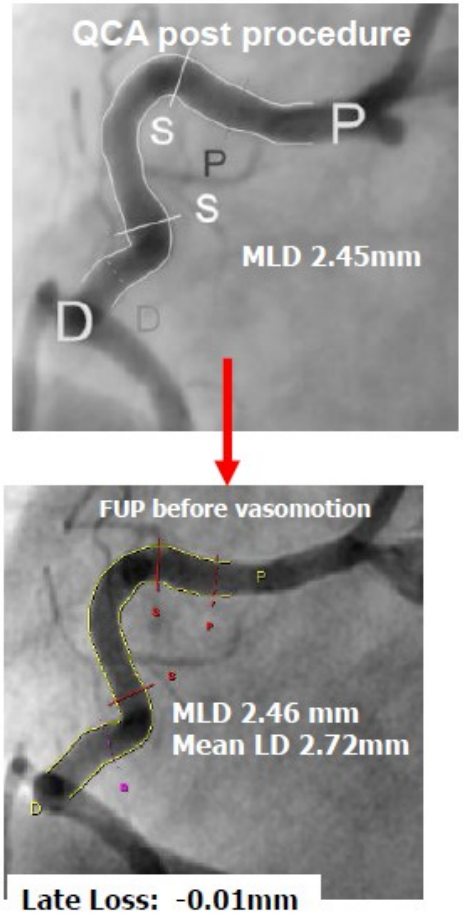


Study Objective	First In Man, Single Arm – safety/performance
Endpoints	Typical PCI clinical and imaging endpoints
Treatment	Up to 2 *de novo* lesions in different epicardial vessels Reference vessel diameter of 3.0 mm, lesions ≤ 14 mm in length
Device Sizes	3.0 x 18 mm devices

ABSORB Cohort B

Angiographic follow up to 5 years



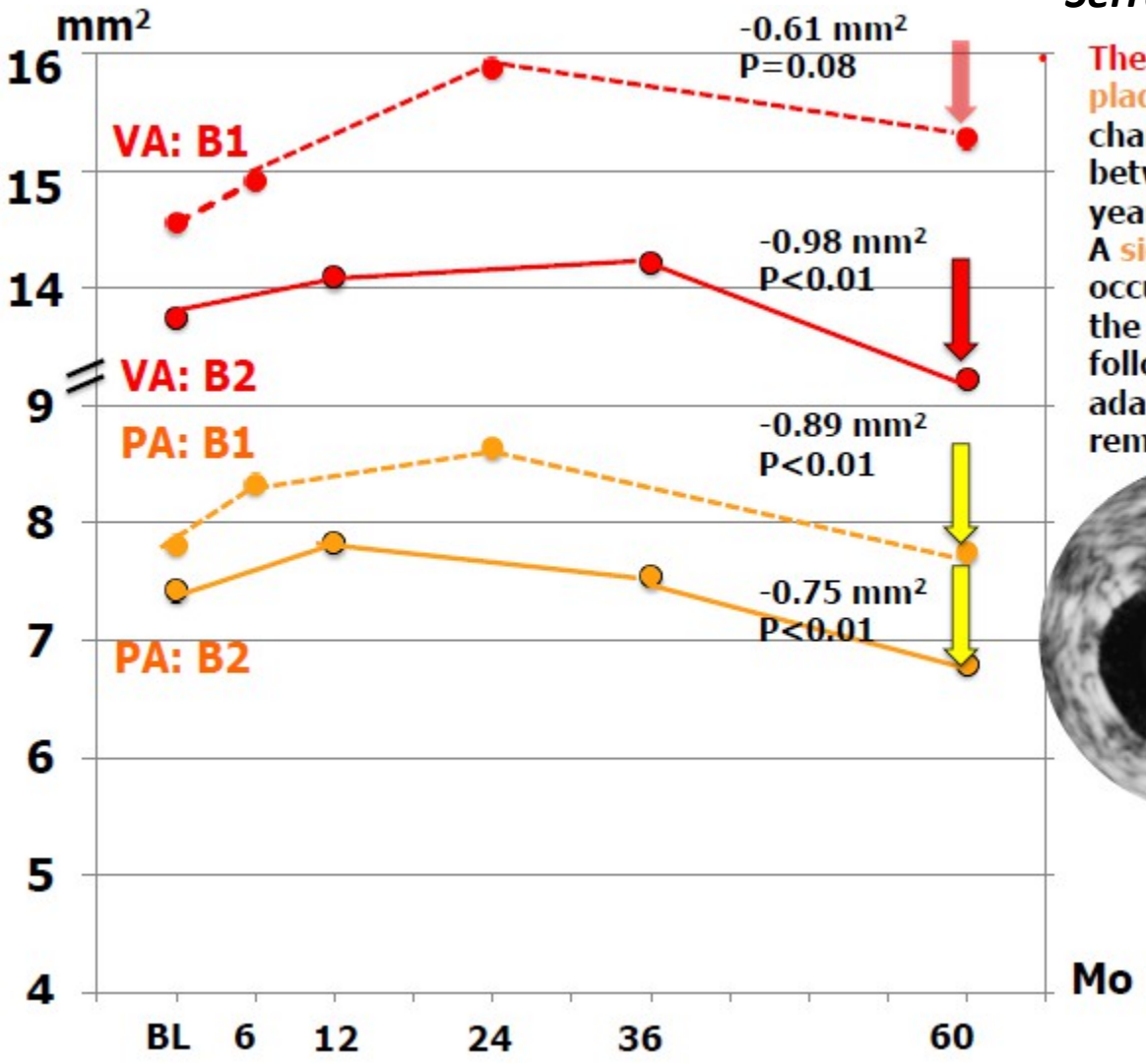


Serruys PW, et al., Gulf PCR 2015

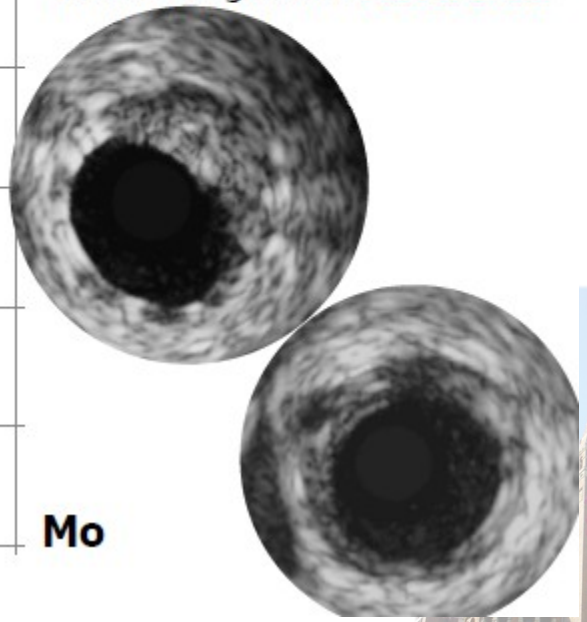
ABSORB Cohort B

IVUS follow up to 5 years

Serruys PW, et al., Gulf PCR 2015

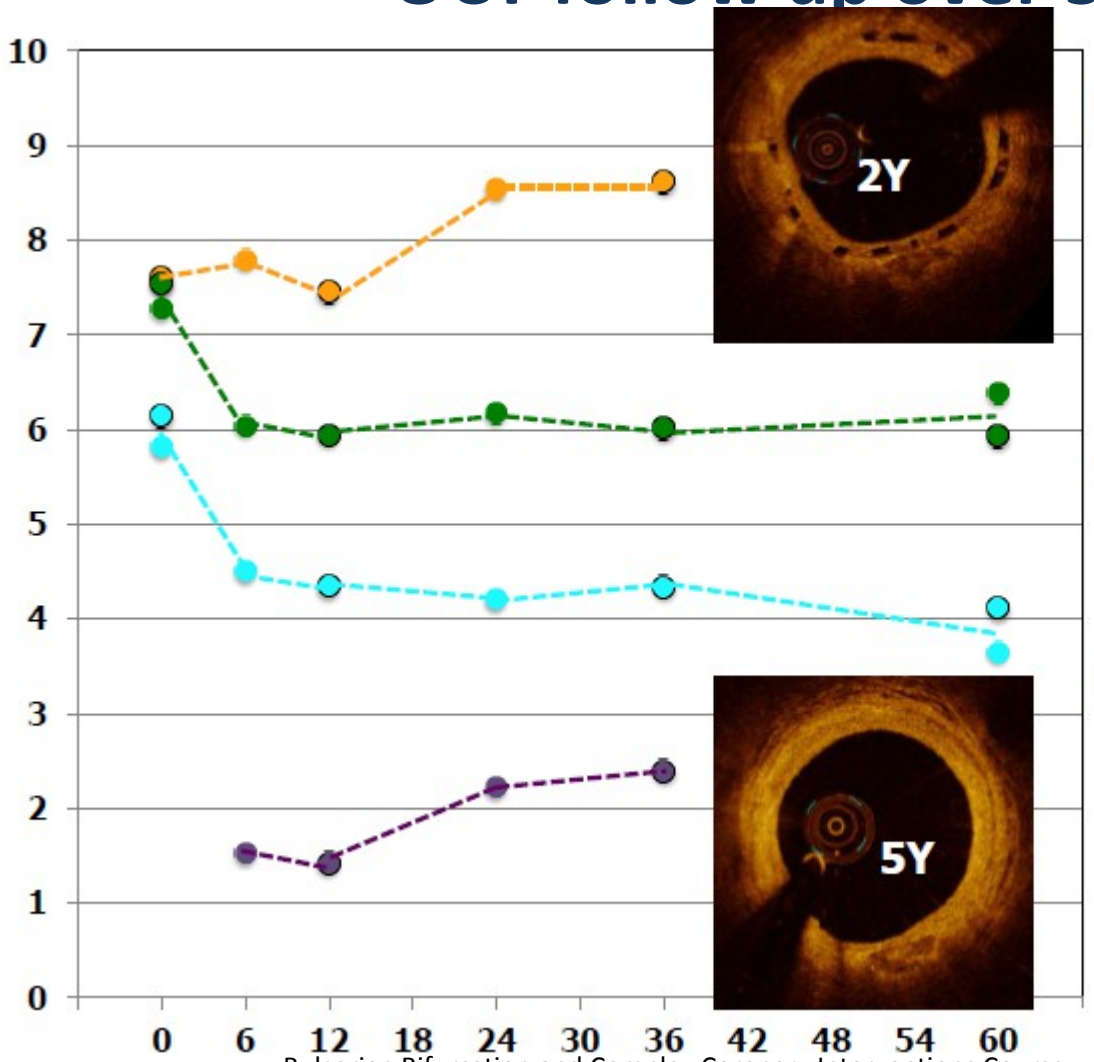


The Vessel area and total plaque area show a biphasic change with an increase between the first and second year.
A significant plaque reduction occurs in B1 and B2 between the second and fifth year follow-up accompanied by an adaptive and constrictive remodeling of the vessel area.



ABSORB Cohort B

OCT follow up over 5 years



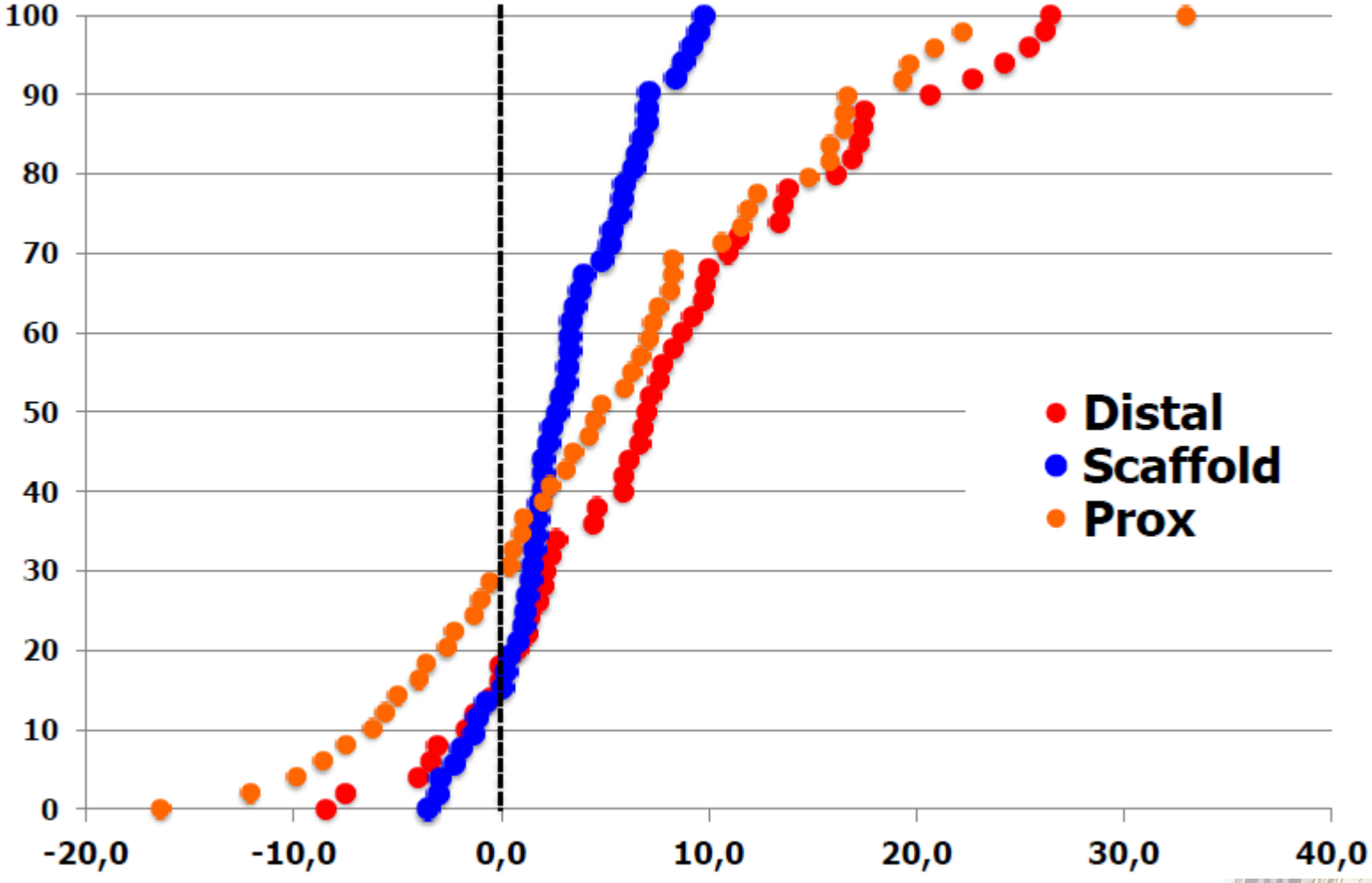
- On OCT, the mean and minimum scaffold area increased significantly in the first 3 years. Thereafter struts are no longer discernible at 5 years.
- The mean lumen area and minimal lumen area were stable from 1 year to 5 years.
- The neointima between and on top of struts are no longer measurable at 5 years since the struts are not discernible on OCT at 5 years.

Mo

Serruys PW, et al., Gulf PCR 2015

ABSORB Cohort B

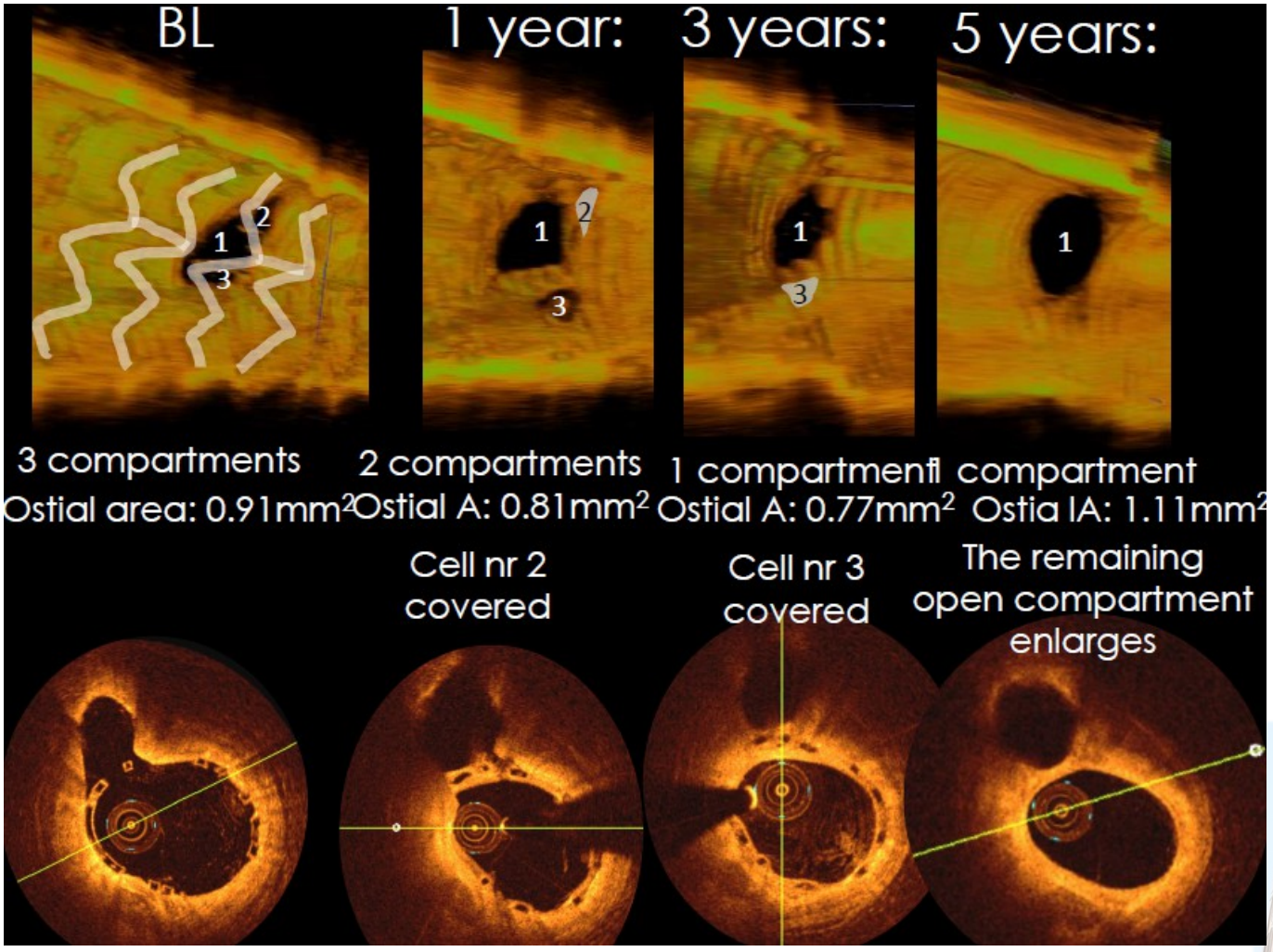
Vasomotion test (relative changes in lumem di on



Serruys PW, et al., Gulf PCR 2015

ABSORB Cohort B

Side branch jail through five years

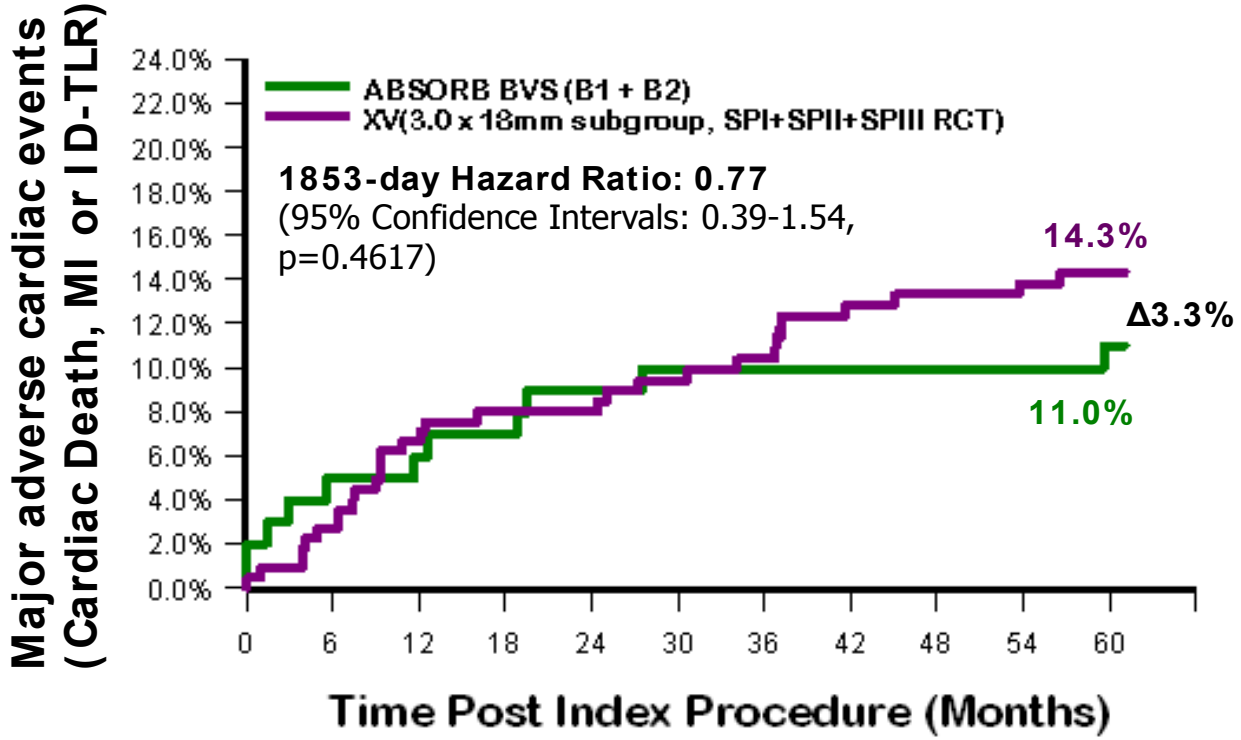


Serruys PW, et al., Gulf PCR 2015

Absorb clinical update

ABSORB Cohort B

KM Estimate of MACE Rate in Patients Treated with Absorb vs. Patients Treated with a Single 3.0x 18 mm Metallic XIENCE V



Serruys PW, et al., TCT 2015

Absorb Clinical Update

ABSORB III – Trial Design

Prospective, Multi-Center, Randomized Clinical Trial
2:1 Randomization Absorb versus XIENCE
n = 2,000 patients

Absorb	XIENCE
n = 1322	n = 686

Primary Endpoint	Target Lesion Failure at 1 year, powered for non-inferiority in 2000 clinical follow-up subjects
Powered Secondary Endpoints	Site diagnosed angina at 1 year test for superiority of Absorb to XIENCE (n = 2000) • Nitrate-induces vasomotion at 3 years by QCA, superiority of Absorb to XIENCE (n = 200) • Mean lumen area change from post-procedure to 3 years by IVUS, superiority of Absorb to XIENCE (n = 150) • Diabetic subgroup to support diabetic indication of Absorb

Kereiakes D, et al., TCT 2015

Absorb Clinical Update

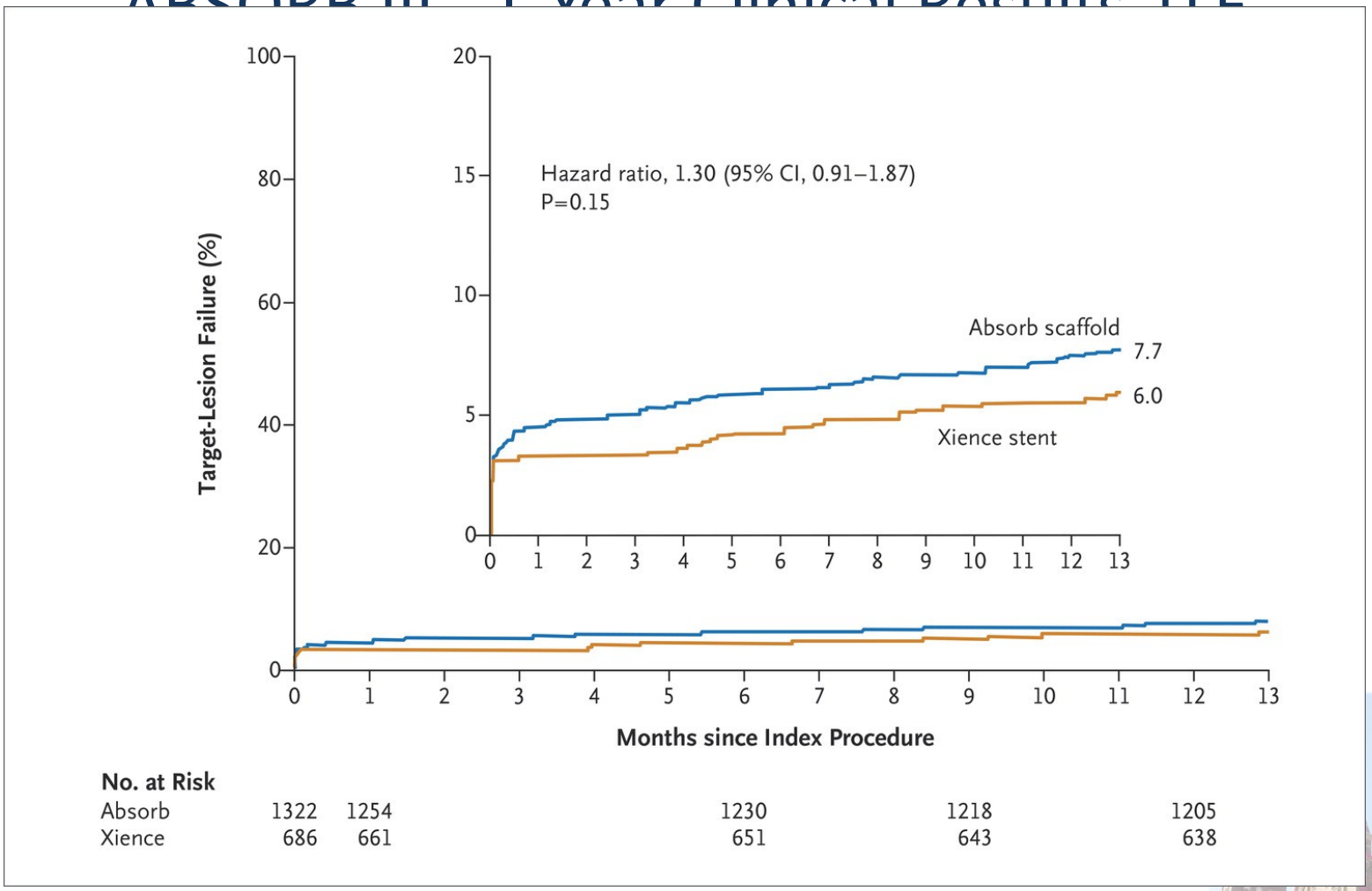
ABSORB III - Patient/Lesion Demographics

	Absorb (N=1322 patients)	XIENCE (N=686 patients)	P-value
All Diabetes, %	31.5%	32.7%	0.60
Prior PCI	38.7%	38.0%	0.75
Stable Angina, %	57.3%	60.8%	0.13
Unstable Angina, %	26.9%	24.5%	0.25
B2/C lesions, %	68.7%	72.5%	0.08
Lesion Length (mm)	12.60	13.12	0.05
RVD <2.25	18%	19%	0.39

Kereiakes D, et al., TCT 2015

Absorb Clinical Update

ABSORB III – 1 Year Clinical Results TLF



Ellis SG et al. N Engl J Med

Absorb Clinical Update

ABSORB III - 1-Year Clinical Results

1 Year Clinical Outcomes	Absorb N=1,322	XIENCE N=686	P-Value	
TLF	7.8%	6.1%	0.16	**Primary Endpoint**
ID-TLR	3.0%	2.5%	0.50	
TV-MI	6.0%	4.6%	0.18	
Cardiac Death	0.6%	0.1%	0.29	
Definite/Probable ST	1.5%	0.7%	0.13	**Not powered**
Angina (self-reported)	18.3%	18.4%	0.92	**Secondary Endpoint**

In vessels ≥2.25 mm by QCA*, ST = 0.9% versus 0.6% for Absorb versus XIENCE, respectively (P=0.12)

*The majority of patients (83%) in ABSORB III had vessels ≥2.25 mm

Clinical outcomes at 1 year demonstrated comparable safety and efficacy between Absorb and XIENCE in a large, pivotal randomized clinical trial

Kereiakes D, et al., TCT 2015

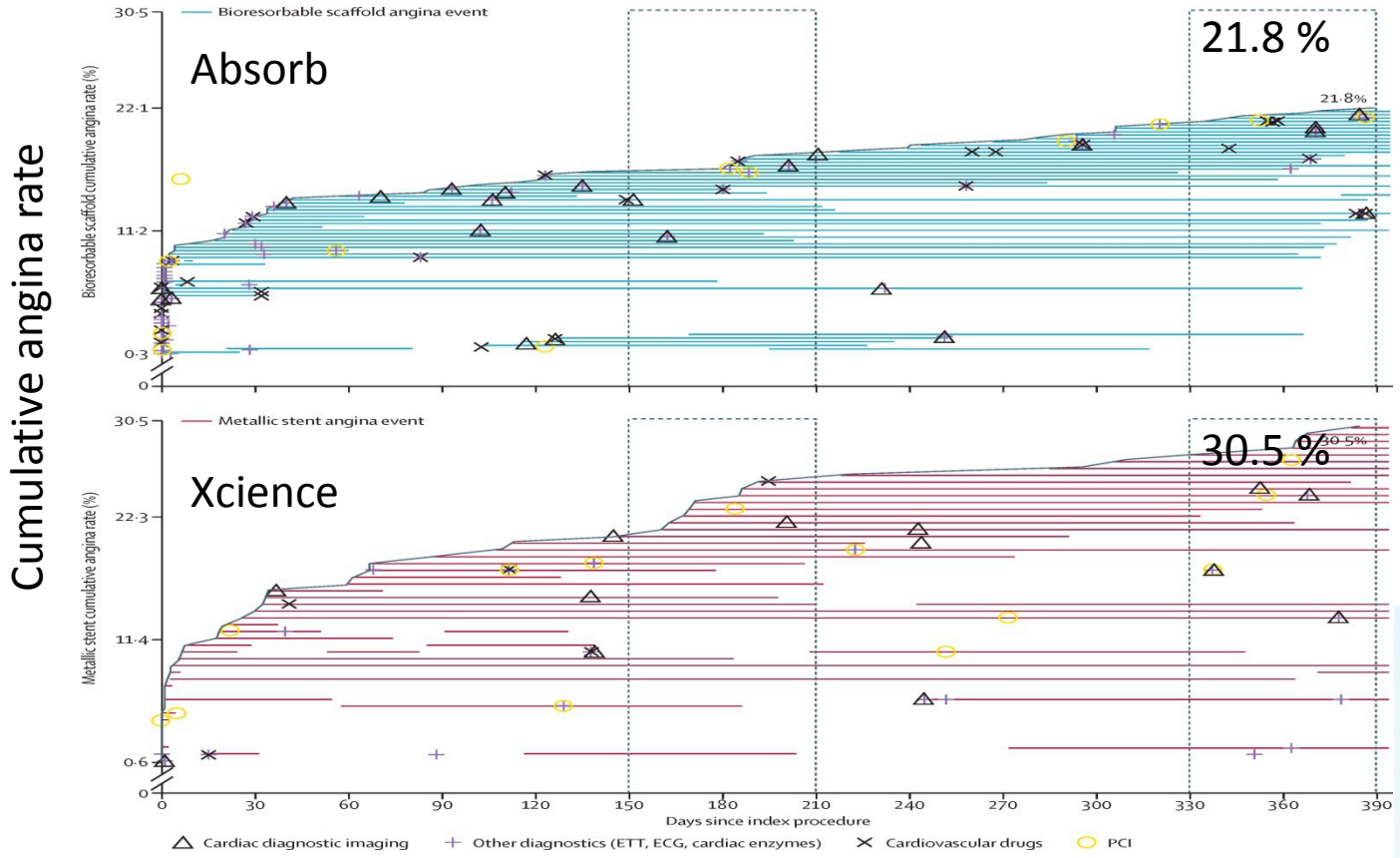
Residual angina after successful PCI (20%)

- Multiplex etiology:
  - Non cardiac origin
  - Incomplete revascularization/restenosis
  - Stent fracture
  - Endothel dysfunction
  - Impaired vasomotion
  - Neurogenic pain from endoluminal penetration of thin struts

Absorb Clinical Update

Absorb II/ angina reporting

New or worsening angina through adverse event reporting occurred less in Absorb than in Xience.



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Serruys PW, et al., Lancet 2015

BRS stent thrombosis

Initial experience and clinical evaluation of the Absorb bioresorbable vascular scaffold (BVS) in real-world practice: the AMC Single Centre Real World PCI Registry

Robin P. Kraak, MD; Mariëlla E.C.J. Hassell, MD; Maik J. Grundeken, MD; Kar
Jose P.S. Henriques, MD, PhD; Jan J. Piek, MD, PhD; Jan Baan Jr, MD, PhD; Ma
E. Karin Arkenbout, MD, PhD; Jan G.P. Tijssen, PhD; Robbert J. de Winter, MD,
Joanna J. Wykrzykowska*, MD, PhD

Eurointervention 2014

Percutaneous coronary intervention with everolimus-eluting bioresorbable vascular scaffolds in routine clinical practice: early and midterm outcomes from the European multicentre GHOST-EU registry

Davide Capodanno[1], MD, PhD; Tommaso Gori[2], MD, PhD; Holger Nef[3], MD; Azeem Latib[4], MD;
Julinda Mehilli[5], MD; Maciej Lesiak[6], MD; Giuseppe Caramanno[7], MD; Christoph Na
Carlo Di Mario[9], MD; Antonio Colombo[4], MD; Piera Capranzano[1], MD; Jens Wiebe[3],
Aleksander Araszkiewicz[6], MD; Salvatore Geraci[7], MD; Stelios Pyxaras[8], MD; Alessi
Toru Naganuma[4], MD; Thomas Münzel[2], MD; Corrado Tamburino[1], MD, PhD

Eurointervention 2015

AMC single center real world registry

- 135 patients, 159 lesions
- Stable angina (47%), ACS (53%)
- More complex population (67% type B2/C lesion)
  - Bifurcation (15%)
  - CTO (8%)
  - Calcified (11%)
  - Ostial (3%)
  - Thrombus (9%)
- IVUS/OCT (5-20%)

Kraak RP., et al., Eurointervention 2014

AMC single center real world registry

Table 4. Clinical outcomes.

	Total cohort (N=134)		Cohort without Tryton (N=124)	
Outcome	30-day*	6-month*	30-day*	6-month*
Cardiac death	0 (0%)	1 (0.8%)	0 (0%)	1 (0.8%)
Myocardial infarction	3 (2.2%)	4 (3.0%)	3 (2.4%)	4 (3.3%)
CABG	0 (0%)	0 (0.0%)	0 (0%)	0 (0.0%)
Target lesion revascularisation	4 (3.0%)	8 (6.3%)	3 (2.4%)	6 (5.0%)
Target vessel revascularisation	6 (4.5%)	11 (8.5%)	4 (3.3%)	8 (6.6%)
Any revascularisation¶	11 (8.2%)	18 (14%)	10 (8.1%)	16 (13%)
Definite stent thrombosis	3 (2.2%)	4 (3.0%)	3 (2.4%)	4 (3.2%)
Probable/possible stent thrombosis	0 (0%)	0 (0.0%)	0 (0%)	0 (0.0%)
TVF (cardiac death, MI or TVR)	6 (4.5%)	11 (8.5%)	4 (3.3%)	8 (6.6%)

*Estimated Kaplan-Meier cumulative event rates. ¶Any revascularisation included scheduled staged procedures of non-target vessels and target vessel revascularisation. Values are n (%). MI: myocardial infarction; TVF: target vessel failure; TVR: target vessel revascularisation

Historic data of best second/third generation metallic DES ST rate of ~ 0.5%

Kraak RP., et al., Eurointervention 2014

GHOST EU multi center real world registry

- 1189 patients,
- Stable angina (53%), ACS (47%)
- More complex population (51% type B2/C lesion)
  - Bifurcation (26.7%)
  - CTO (7.8%)
  - ISR (3.4%)
  - Ostial (6.1%)
  - Thrombus (18.3%)
- IVUS/OCT (14.4%-13.8%)

Capodanno P., et al., Eurointervention 2015

GHOST EU multi center real world registry

Table 3. Kaplan-Meier estimates of cardiac events at follow-up.

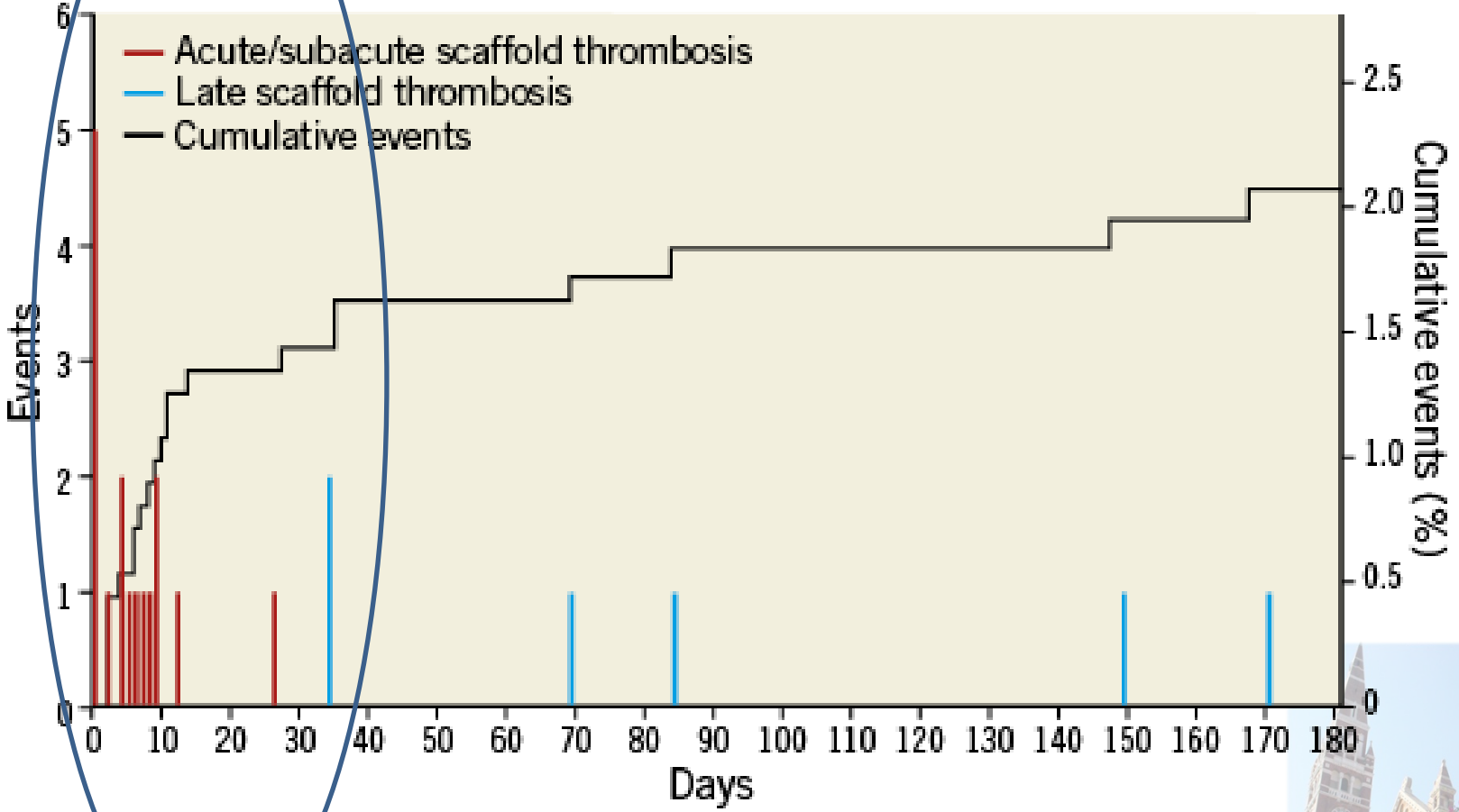
Efficacy and safety measures	30-day	6-month
TLF	2.2%	4.4%
TVF	2.3%	4.9%
All death	0.8%	1.3%
Non-cardiac death	0.2%	0.3%
Cardiac death	0.6%	1.0%
Any MI	1.4%	2.7%
Target vessel MI	1.1%	2.0%
TVR	1.6%	4.0%
TLR	1.1%	2.5%
ARC ST definite/probable	1.5%	2.1%

Numbers are reported as Kaplan-Meier estimates. The device-oriented composite endpoint (TLF) includes cardiac death, myocardial infarction (MI) related to target vessel and clinically driven target lesion reintervention (TLR). Target vessel failure (TVF) includes cardiac death, MI related to target vessel and clinically driven target vessel reintervention (TVR). ARC: Academic Research Consortium; ST: scaffold thrombosis

Historic data of best second/third generation metallic DES ST rate of ~ 0.5%

Capodanno P., et al., Eurointervention 2015

GHOST EU multi center real world registry



Capodanno P., et al., Eurointervention 2015

Everolimus-eluting bioresorbable vascular scaffolds versus everolimus-eluting metallic stents: a meta-analysis of randomised controlled trials

Salvatore Cassese, Robert A Byrne*, Gjin Ndrepepa, Sebastian Kufner, Jens Wiebe, Janika Repp, Heribert Schunkert, Massimiliano Fusaro, Takeshi Kimura, Adnan Kastrati*

Lancet 2015, dec

BRS VS EES

metanalysis of randomised controlled trialis

Randomized Controlled Clinical Trial

ALL-COMERS

GABI-R
Design: All-comers registry
N=5000
1˚: Safety & efficacy

FEAST Russia Registry
Design: All-comers registry
N=2500
1˚: 1-year MACE, TVF, Revascularization, ST, Peri-procedural MI, Angina

ABSORB FIRST
Design: Prospective, multi-center, global registry
N= ~1800
1˚: ST, CD, MI, revascularization, MACE, TLF, & TVF

GHOST EU
Design: All-comers registry
N=continuous enrollment
1˚: TVF

EVERBIO II
Design: Non-inferiority
RCT EES vs BES vs BVS
N=240
1˚: Late lumen loss at 9 months

UK REGISTRY
Design: Prospective, single-arm, multi center, observational registry
N= 1000
1˚: TLR < 50% at procedure conclusion, MACE

AIDA
Design: RCT vs XIENCE
N=2690
1˚: 2-year TVF

FRANCE ABSORB
Feasibility: De novo lesions
N=2000
1˚: 1-year MACE

REPARA
Design: All-comers registry
N=1500
1˚: 1-year MACE

BVS EXPAND*
Design: All-comers registry
N=300
1˚: 1-year MACE

Kuwait Registry
Design: All-comers registry
N=200
1˚: Safety & efficacy

ASSURE
Design: All-comers registry
N=180
1˚: Safety & efficacy

COMPLEX POPULATIONS

POLAR-ACS
Design: ACS registry
N=100
1˚: Safety, clinical device, procedure, success & in-hospital MACE

ISAR ABSORB MI
Design: Non-inferiority vs EES
N=260
1˚: % diameter stenosis at 6-8 months

PRAGUE 19
Design: STEMI (STEMI Killip I/II)
N=100
1˚: Clinical outcomes

TROFI II
Design: STEMI vs XIENCE
N=190
1˚: 6-month,
neo-intimal healing score

ABSORB CTO
Feasibility: CTO
N=35
1˚: Safety & performance

PABLOS
Feasibility: Bifurcations
N=30
1˚: Device, procedural, main & side branches

IT-DISAPPEARS
Design: MVD and Long Lesion Registry
N=1000
1˚: Safety & efficacy

COMPARE ABSORB
Design: High risk for ISR
N=2100
1˚:TLF

PROSPECT
Design: RCT BVS vs OMT in unstable asymptomatic pts
N=900
1˚: 2-Yr IVUS MLA

SIMPLE TO MODERATELY COMPLEX POPULATIONS

ABSORB II
Design: Randomized 2:1 Absorb BVS:XIENCE
N=501
1˚: Vasomotion & lumen diameter after the index procedure & at 3 years

ABSORB COHORT B
Design: Allocated (non-randomized)
N=101
1˚: Safety & performance

ABSORB EXTEND
Design: Prospective, single-arm, open-label clinical study
N=800
1˚: ID-MACE

ADDITIONAL LARGE RCTs

ABSORB CHINA
Design: RCT
N= ~440
1˚: In-segment late loss at 1 year

ABSORB JAPAN
Design: RCT
N= ~400
1˚: TLF at 1 year

ABSORB III
Design: RCT
N= ~2250
1˚: TLF at 1 year

ABSORB IV
Design: RCT
N= ~3000
1˚: Angina within 1 year

*Excludes STEMI patients. ACS, acute coronary syndrome; MVD, multi-vessel disease; CTO, chronic total occlusion; MI, myocardial infarction RCT, randomized controlled trial; OMT, optimal medical therapy; EES, everolimus-eluting stents; BVS, bioresorbable vascular scaffold; STEMI, ST-segment–elevation myocardial infarction; MACE, major adverse cardiac events; ID-MACE, ischemia-driven major adverse cardiac events; TLF, target lesion failure; IVUS MLA, intravascular ultrasound minimal lumen area; TVF, target vessel failure; LAD, left anterior descending; FIM, first-in-man.

All comparative claims of catheter design improvements are based on internal studies versus Absorb BVS. Data and images on file at Abbott Vascular.

BRS VS EES

metanalysis of randomised controlled trialis

TLR rate: BVS 3 % VS 0.3.3% EES (P=NS)

A Target lesion revascularisation

	BVS Events	BVS Total	EES Events	EES Total	Weight (%)	Fixed-effects odds ratio (95% CI)
ABSORB China	7	238	7	237	13·2	1·00 (0·34–2·88)
ABSORB II	4	335	3	166	5·9	0·64 (0·13–3·12)
ABSORB III	42	1313	19	677	51·6	1·14 (0·67–1·95)
ABSORB Japan	7	265	5	133	10·1	0·68 (0·20–2·31)
EVERBIO II	8	78	11	80	16·3	0·72 (0·28–1·87)
TROFI II	2	95	1	96	2·9	1·98 (0·20–19·29)
Overall	**70**	**2324**	**46**	**1389**	**100**	**0·97 (0·66–1·43)**

Heterogeneity: χ^2=1·69, df=5; p=0·89; I^2=0%
Test for overall effect: Z=0·16; p=0·87
Random-effects odds ratio 0·97 (95% CI 0·66–1·43)

ST rate: BVS 1.25% VS 0.5% EES (P=0.05)

B Definite or probable stent thrombosis

	BVS Events	BVS Total	EES Events	EES Total	Weight (%)	Fixed-effects odds ratio (95% CI)
ABSORB China	1	238	0	232	3·1	7·21 (0·14–363·23)
ABSORB II	3	335	0	166	8·2	4·49 (0·04–49·92)
ABSORB III	20	1301	5	675	69·1	1·89 (0·82–4·34)
ABSORB Japan	4	262	2	133	16·5	1·02 (0·18–5·58)
EVERBIO II	0	78	0	80		Not estimable
TROFI II	1	95	0	96	3·1	7·47 (0·15–376·35)
Overall	**29**	**2309**	**7**	**1382**	**100**	**1·99 (1·00–3·98)**

Heterogeneity: χ^2=1·90, df=4; p=0·75; I^2=0%
Test for overall effect: Z=1·96; p=0·05
Random-effects odds ratio 1·99 (95% CI 1·00–3·98)

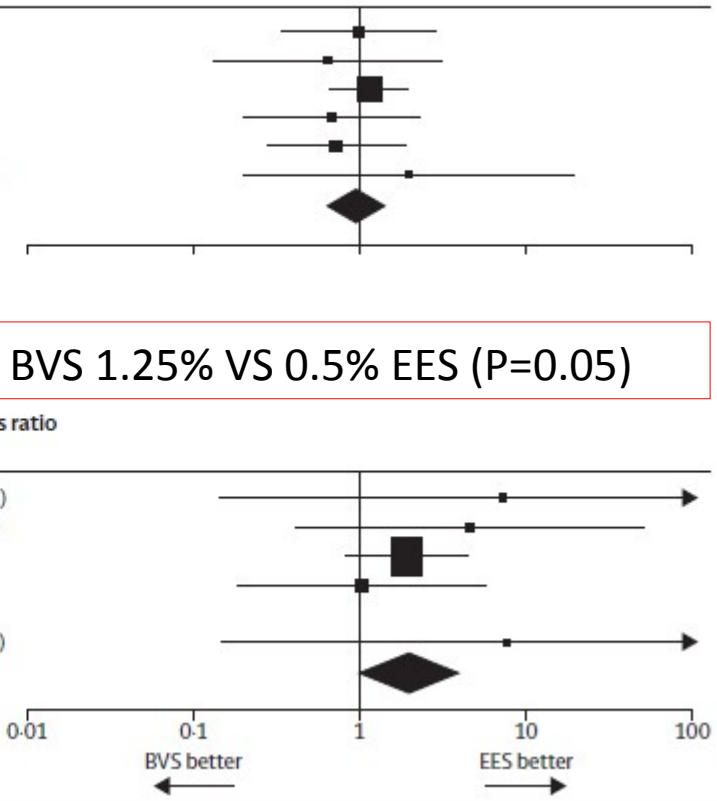


Figure 2: **Risk estimates of primary outcomes for BVS versus EES**

Cassese S., et al., Lancet 2015

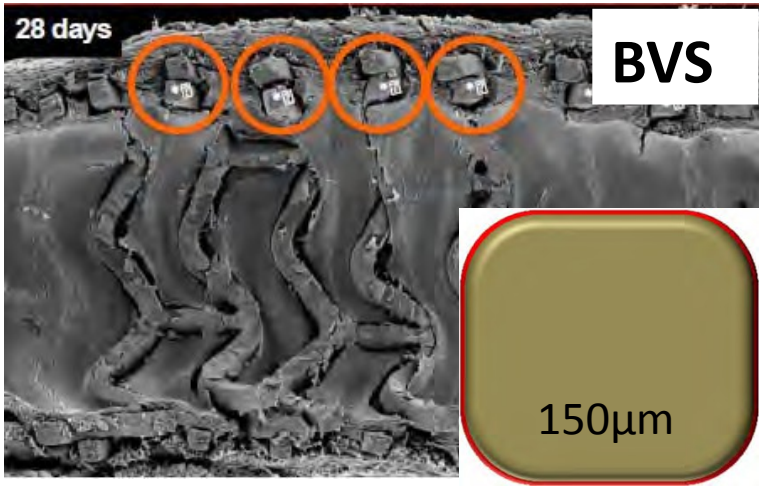
BRS thrombosis

- Case based OCT evaluation of ST revealed similar mechanic causes as with metallic stents:
  - malapposition
  - incomplete lesion coverage
  - stent fracture
  - edge dissection
- Premature DAPT termination

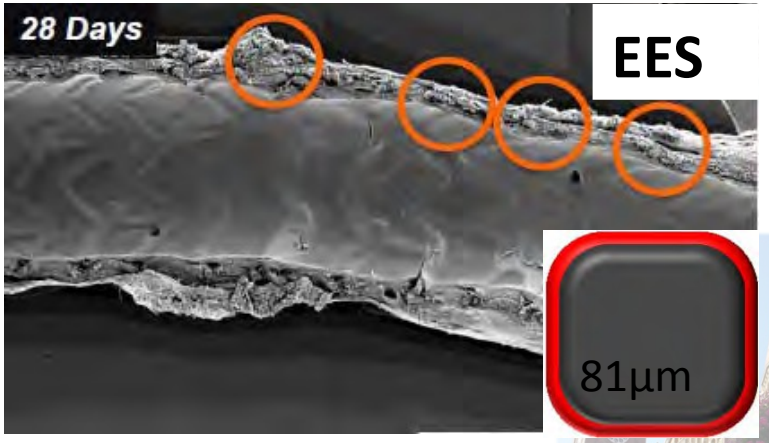
BRS thrombosis
Is it the scaffolds fault?

Thicker struts of ABSORB
associated with delayed healing
/endotheliazation

Incomplete coverage in porcine model



Complete coverage in porcine model



BRS thrombosis
Is it the operators fault?

- Inadequate experience with device
- Overconfidence in use/abuse of the device
- Expanding indications into complex anatomy, disregarding the inherent limitations of the device
  - CTO?
  - Extremely calcified lesions?

1. **P**repare the Lesion
2. **P**roperly Size the Vessel
3. **P**ost-Dilate with a Non-Compliant Balloon
4. **P**ay Attention to Expansion Limits

5 P rule

BRS in bifurcation lesions

Absorb everolimus-eluting bioresorbable scaffolds in coronary bifurcations: a bench study of deployment, side branch dilatation and post-dilatation strategies

John A. Ormiston[1,2,3]*, MBChB; Bruce Webber[1], MHSc; Ben Ubod[1], BSN; Mark W.I. Webster[1,2,3], MBChB; Jonathon White[2], MBChB

1. Mercy Angiography, Auckland, New Zealand; 2. Auckland City Hospital, Auckland, New Ze
School of Medicine, Auckland, New Zealand

Eurointervention 2015

When and how to use BRS in bifurcations?

Goran Stankovic[1]*, MD, PhD; Jens Flensted Lassen[2], MD, PhD

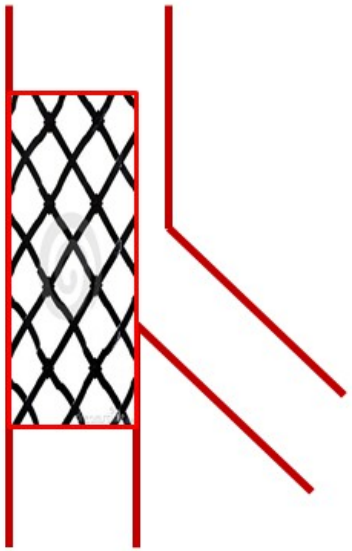
1. Department of Cardiology, Clinical Center of Serbia and Faculty of Medicine, University of Belgrade, Belgrade, Serbia;
2. The Heart Centre, Rigshospitalet, University Hospital of Copenhagen, Copenhagen, Denmark

Eurointervention 2015

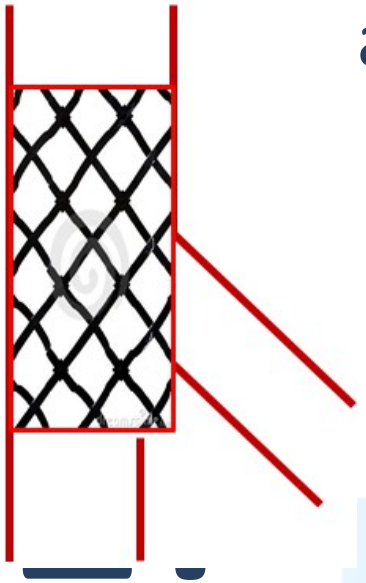
BRS in bifurcation lesions

One stent technique

A, Sizing according to distal branch



B, Sizing according to proximal anch

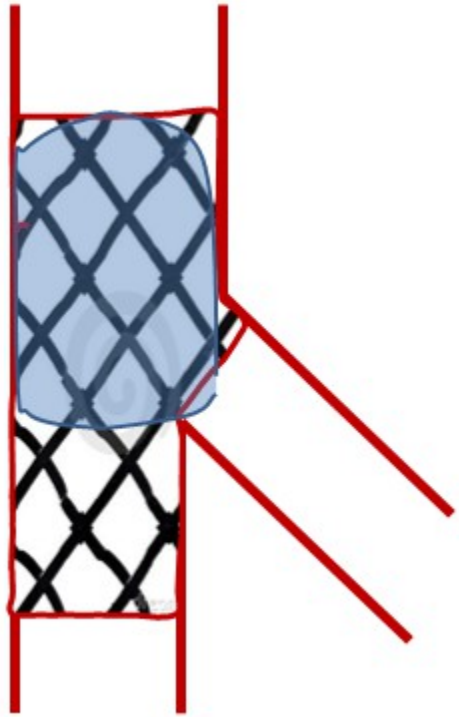


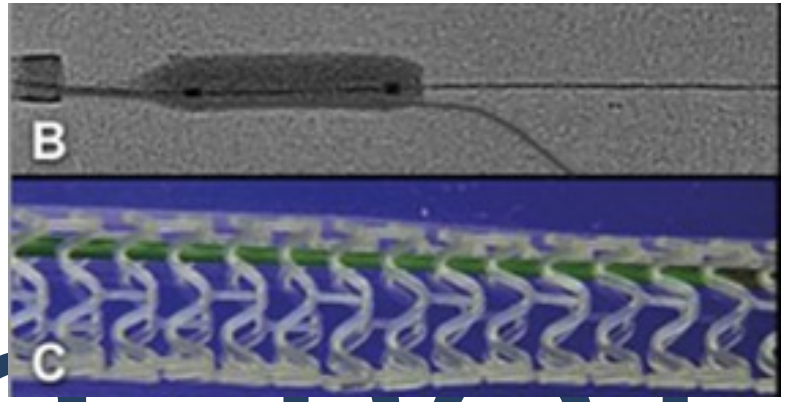
Absorb BRS should not be used in bifurcations in which the proximal MV diameter is greater than the maximal recommended diameter of the BRS

Selection of

BRS in bifurcation lesions

One stent technique





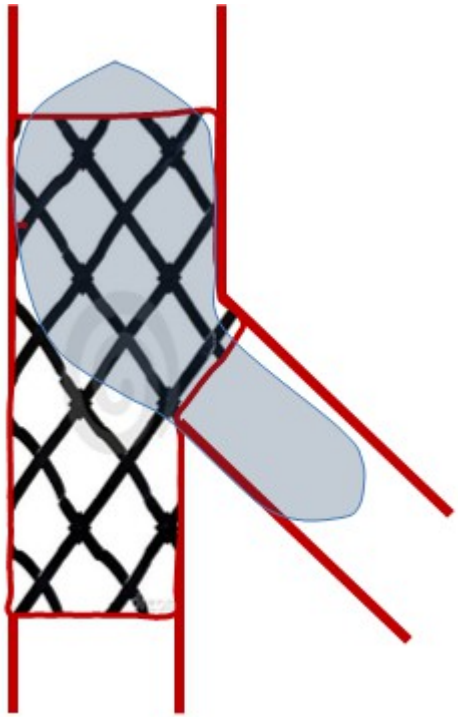
- Step 2: POT

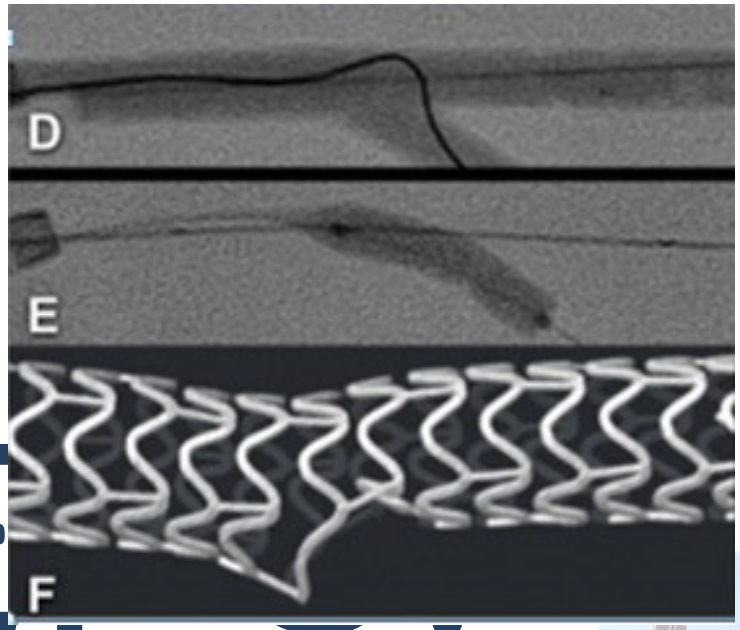
Ormistone JA, et al ., Eurointervention, 2015
Stankovic G, et al., Eurointervention , 2015

(proximal

BRS in bifurcation lesions

One stent technique





TE[illegible]

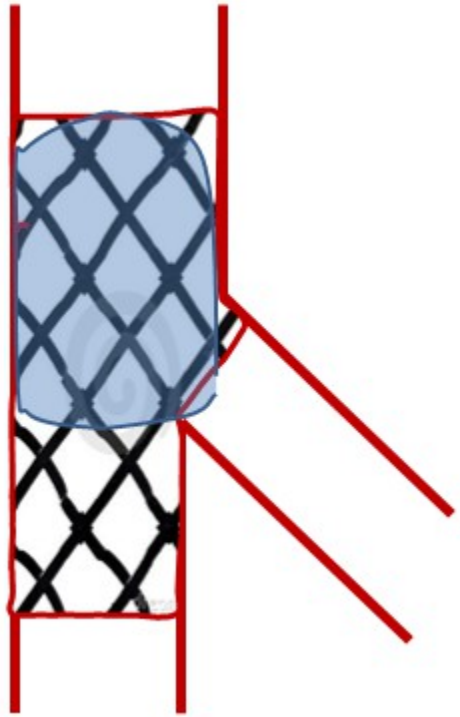
Ormistone JA, et al ., Eurointervention, 2015

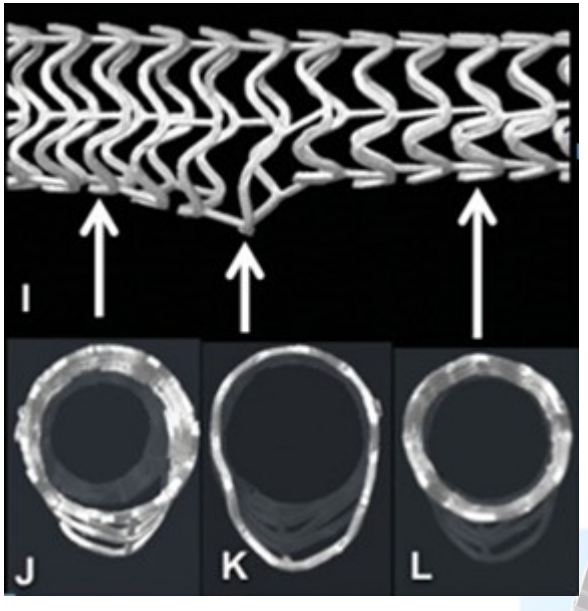
Stankovic G, et al., Eurointervention , 2015

Sidebranch

BRS in bifurcation lesions

One stent technique



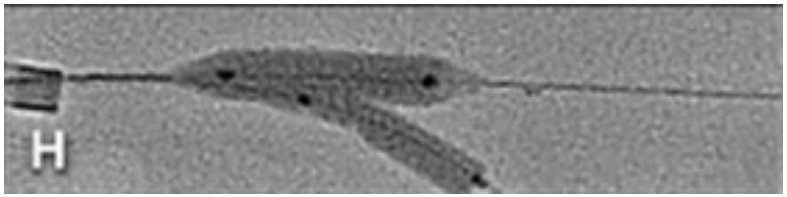


Ormistone JA, et al ., Eurointervention, 2015
Stankovic G, et al., Eurointervention , 2015

PSP technique

BRS in bifurcation lesions

One stent technique



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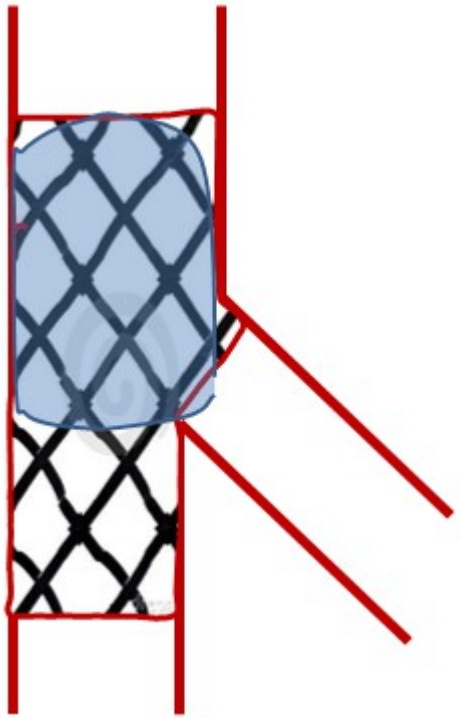


Ormistone JA, et al ., Eurointervention, 2015
Stankovic G, et al., Eurointervention , 2015

PKP technique

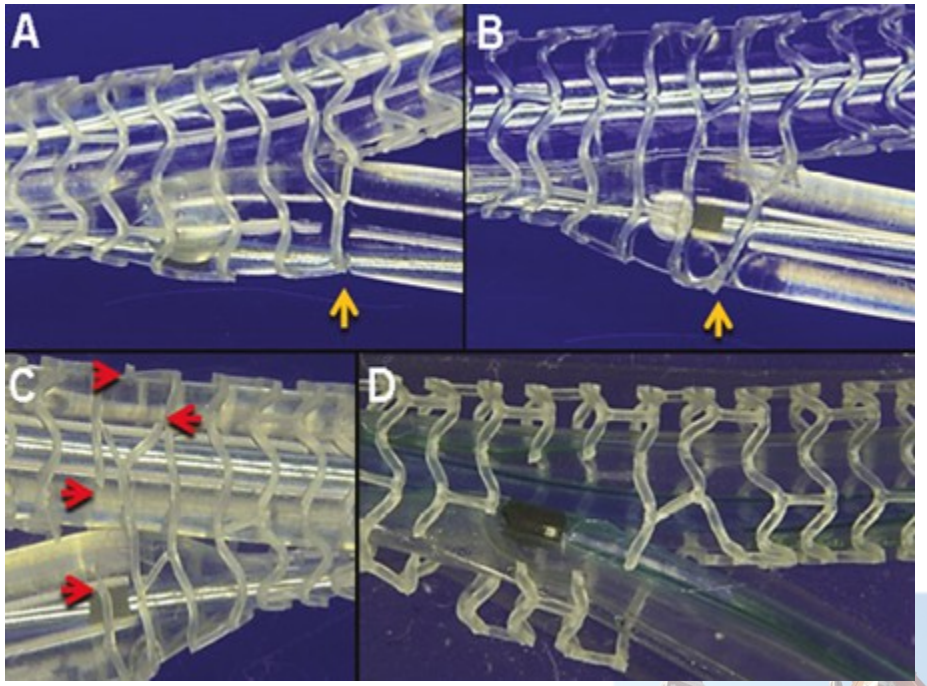
BRS in bifurcation lesions

One stent technique

3 mm ABSORB stent, 3 mm NCBalloon

Kissing balloon inflation: < 5 atm

Side branch dilation: < 10 atm.



Ormistone JA, et al ., Eurointervention, 2015
Stankovic G, et al., Eurointervention , 2015

W

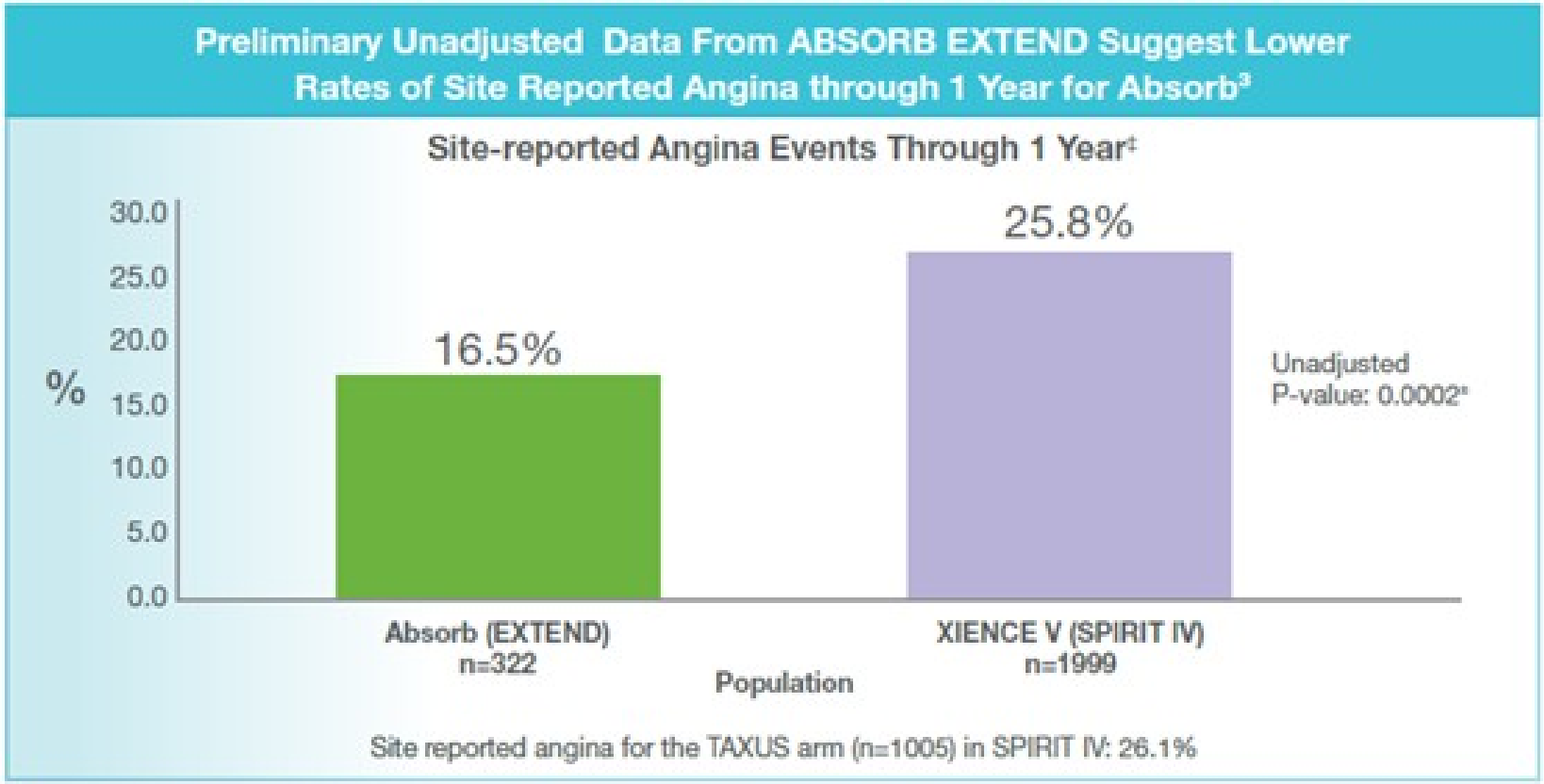
pressures

Conclusion

- BRS represent the new frontier in interventional cardiology and have shown acceptable safety and efficacy results in stable CAD patients.
- Caution is advised (stent thrombosis) before expanding indication of use into more complex lesions and in acute coronary syndromes.
- Further improvements to stent structure and absorption profile may translate into better fi

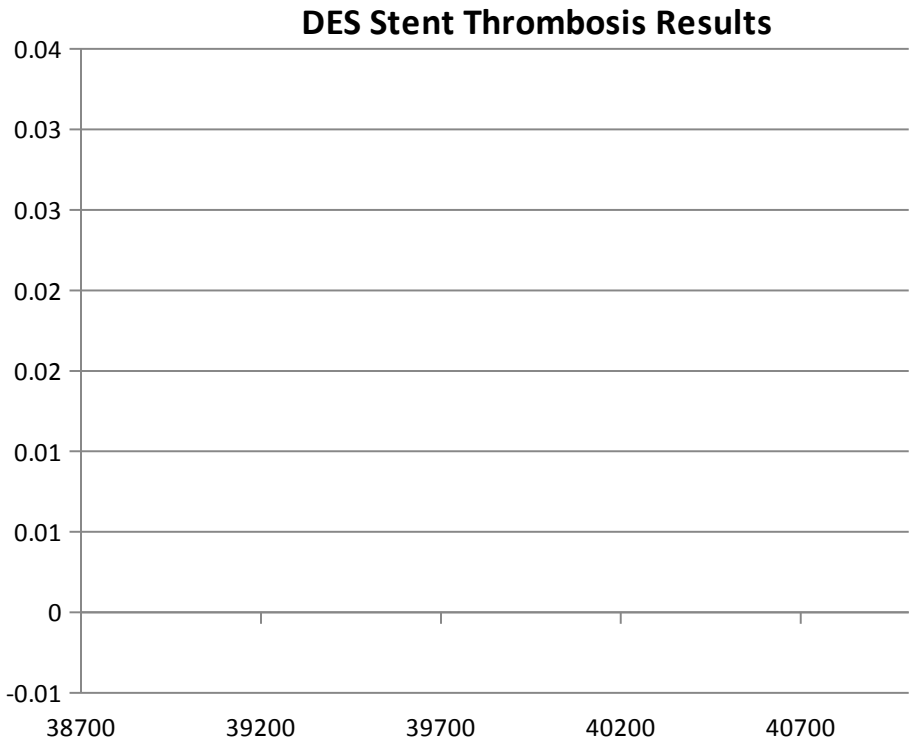

Thank you for
your attention!

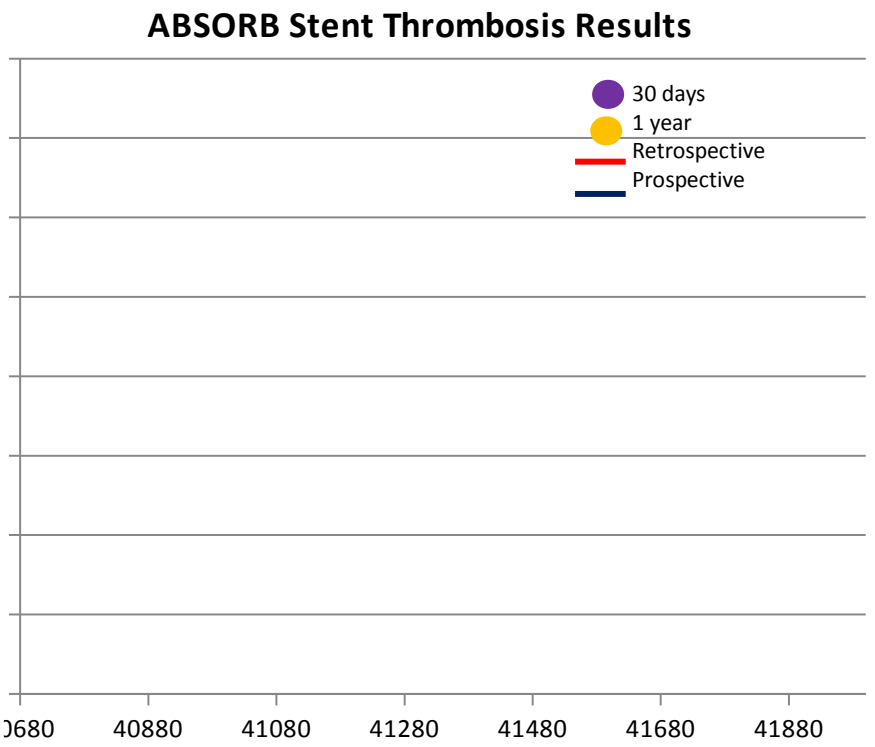
Absorb Clinical Update
Absorb EXTEND/ anigna reporting



Absorb scaffold thrombosis in perspective

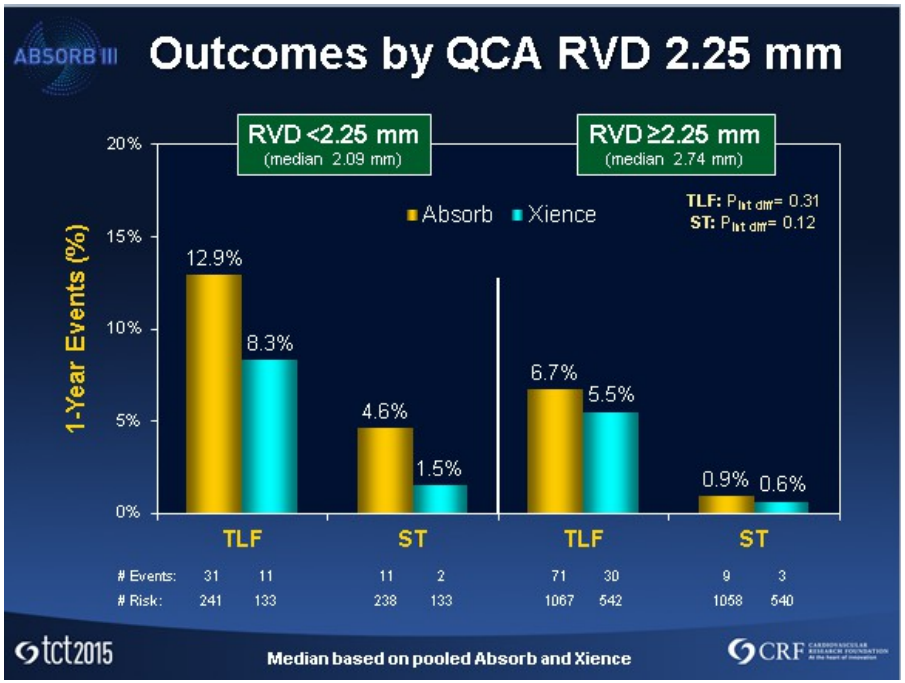
With experience there is a reduction in event rates with both metallic and

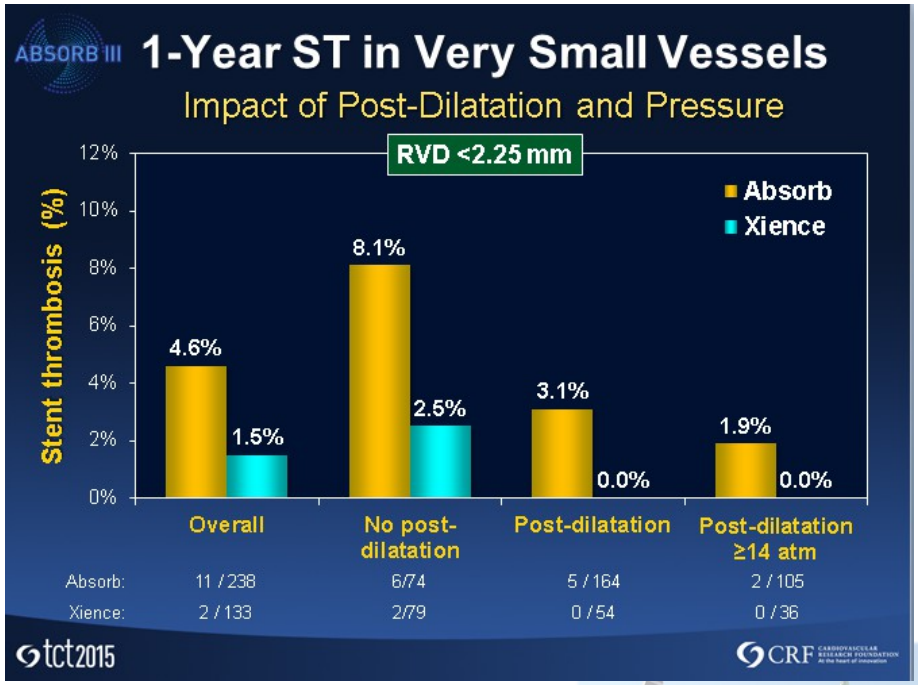




Absorb Clinical Update

ABSORB III - 1-Year scaffold thrombosis Results





Kereiakes D, et al., TCT 2015

Absorb Clinical Update

ABSORB III - 1-Year Clinical Results

1 Year Clinical Outcomes	Absorb N=1,322	XIENCE N=686	P-Value	
TLF	7.8%	6.1%	0.16	**Primary Endpoint**
ID-TLR	3.0%	2.5%	0.50	
TV-MI	6.0%	4.6%	0.18	
Cardiac Death	0.6%	0.1%	0.29	
Definite/Probable ST	1.5%	0.7%	0.13	**Not powered**
Angina (self-reported)	18.3%	18.4%	0.92	**Secondary Endpoint**

In vessels ≥2.25 mm by QCA*, ST = 0.9% versus 0.6% for Absorb versus XIENCE, respectively (P=0.12)

*The majority of patients (83%) in ABSORB III had vessels ≥2.25 mm

Clinical outcomes at 1 year demonstrated comparable safety and efficacy between Absorb and XIENCE in a large, pivotal randomized clinical trial

Kereiakes D, et al., TCT 2015