

Update on BVS

I. Sheiban

University of Torino

**Director Interventional Cardiology
Pederzoli Hospital
Pescheria del Grada (Verona)/ Italy**

e-mail: isheiban@gmail.com

What are the expectations from Bioabsorbable stents

Bioabsorbable stent would avoid or overcome the above-mentioned downsides of metal in the artery.

Bioabsorbable stents would avoid the loss of (and perhaps restore) normal vasomotion improve persistently abnormal endothelial function, and permit vessel remodeling not possible within the metallic stent cage.

Will not compromise future CABG if needed

Reduce late stent thrombosis

What About Recent Clinical Data ?

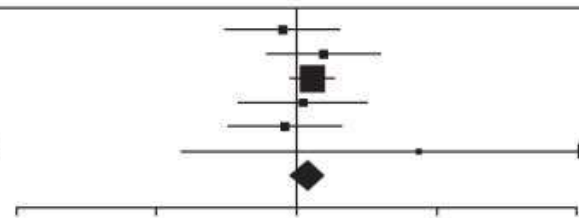
Meta-Analysis of 6 RCT ABSORB Series and EVERBIO II and TROFI II

A Target lesion failure

	BVS		EES		Weight (%)	Fixed-effects odds ratio (95% CI)
	Events	Total	Events	Total		
ABSORB China	8	238	10	237	9.3	0.79 (0.31-2.03)
ABSORB II	16	335	5	166	9.6	1.55 (0.61-3.92)
ABSORB III	102	1313	41	677	63.9	1.29 (0.09-1.85)
ABSORB Japan	11	265	5	133	7.3	1.11 (0.38-3.19)
EVERBIO II	9	78	11	80	9.4	0.82 (0.32-2.09)
TROFI II	1	95	0	96	0.5	7.47 (0.15-376.35)
Overall	147	2324	72	1389	100	1.20 (0.90-1.60)

Heterogeneity: $\chi^2=2.71$, $df=5$; $p=0.74$; $I^2=0\%$
 Test for overall effect: $Z=1.25$; $p=0.21$
 Random-effects odds ratio 1.20 (95% CI 0.90-1.60)

TLF

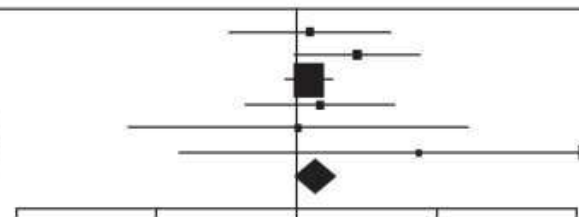


B Myocardial infarction

	BVS		EES		Weight (%)	Fixed-effects odds ratio (95% CI)
	Events	Total	Events	Total		
ABSORB China	5	238	4	237	6.1	1.25 (0.33-4.66)
ABSORB II	15	335	2	166	10.1	2.71 (0.97-7.56)
ABSORB III	90	1313	38	677	74.5	1.23 (0.84-1.79)
ABSORB Japan	9	265	3	133	7.2	1.48 (0.44-4.98)
EVERBIO II	1	78	1	80	1.4	1.03 (0.06-16.55)
TROFI II	1	95	0	96	0.7	7.47 (0.15-376.35)
Overall	121	2324	48	1389	100	1.36 (0.98-1.89)

Heterogeneity: $\chi^2=2.80$, $df=5$; $p=0.73$; $I^2=0\%$
 Test for overall effect: $Z=1.86$; $p=0.06$
 Random-effects odds ratio 1.36 (95% CI 0.98-1.89)

MI

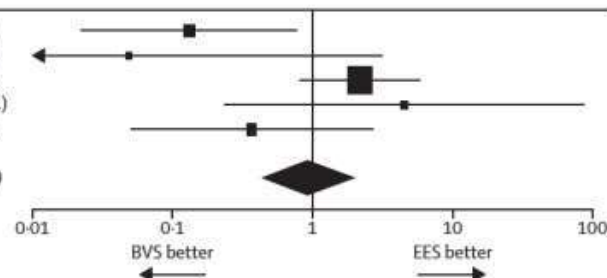


C Death

	BVS		EES		Weight (%)	Fixed-effects odds ratio (95% CI)
	Events	Total	Events	Total		
ABSORB China	0	238	5	237	18.0	0.13 (0.02-0.77)
ABSORB II	0	335	1	166	3.2	0.05 (0.00-3.15)
ABSORB III	15	1313	3	677	58.1	2.18 (0.82-5.81)
ABSORB Japan	2	265	0	133	6.4	4.51 (0.24-85.41)
EVERBIO II	1	78	3	80	14.2	0.37 (0.05-2.68)
TROFI II	0	95	0	96		Not estimable
Overall	18	2324	12	1389	100	0.95 (0.45-2.00)

Heterogeneity: $\chi^2=11.47$, $df=4$; $p=0.02$; $I^2=65\%$
 Test for overall effect: $Z=0.14$; $p=0.89$
 Random-effects odds ratio 0.59 (95% CI 0.12-2.74)

Death



Meta-Analysis of 6 RCT

ABSORB Series and EVERBIO II and TROFI II

A Target lesion revascularisation

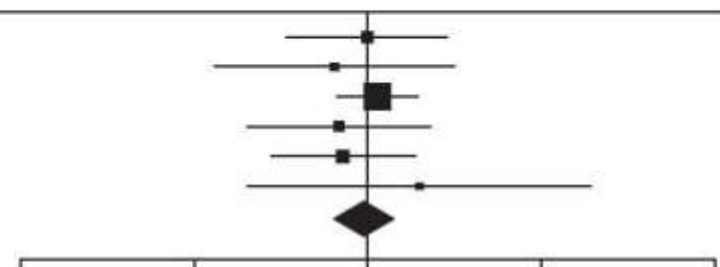
	BVS		EES		Weight (%)	Fixed-effects odds ratio (95% CI)
	Events	Total	Events	Total		
ABSORB China	7	238	7	237	13.2	1.00 (0.34-2.88)
ABSORB II	4	335	3	166	5.9	0.64 (0.13-3.12)
ABSORB III	42	1313	19	677	51.6	1.14 (0.67-1.95)
ABSORB Japan	7	265	5	133	10.1	0.68 (0.20-2.31)
EVERBIO II	8	78	11	80	16.3	0.72 (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: $\chi^2=1.69$, $df=5$; $p=0.89$; $I^2=0\%$

Test for overall effect: $Z=0.16$; $p=0.87$

Random-effects odds ratio 0.97 (95% CI 0.66-1.43)

TLR



B Definite or probable stent thrombosis

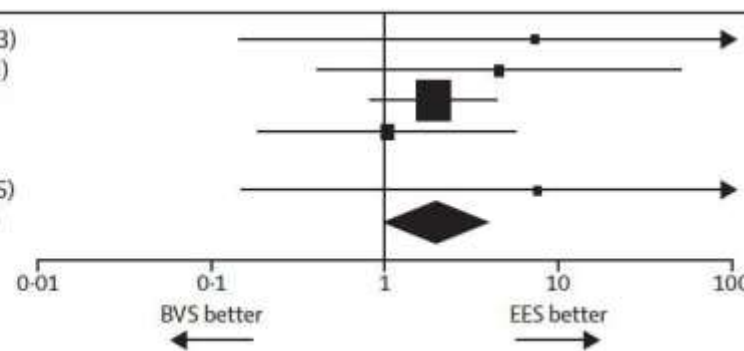
	BVS		EES		Weight (%)	Fixed-effects odds ratio (95% CI)
	Events	Total	Events	Total		
ABSORB China	1	238	0	232	3.1	7.21 (0.14-363.23)
ABSORB II	3	335	0	166	8.2	4.49 (0.04-49.92)
ABSORB III	20	1301	5	675	69.1	1.89 (0.82-4.34)
ABSORB Japan	4	262	2	133	16.5	1.02 (0.18-5.58)
EVERBIO II	0	78	0	80		Not estimable
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: $\chi^2=1.90$, $df=4$; $p=0.75$; $I^2=0\%$

Test for overall effect: $Z=1.96$; $p=0.05$

Random-effects odds ratio 1.99 (95% CI 1.00-3.98)

ST



Meta-Analysis of 6 RCT

ABSORB Series and EVERBIO II and TROFI II

A In-device late lumen loss

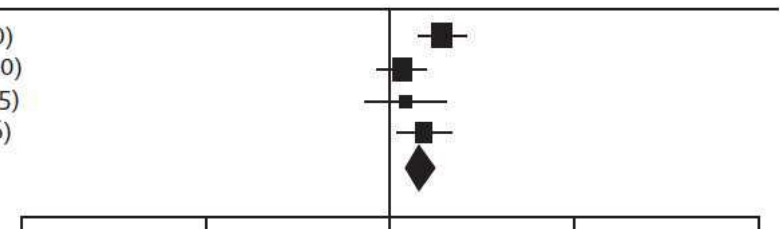
	BVS			EES			Weight (%)	Mean difference (95% CI)
	Mean (SD)	Total		Mean (SD)	Total			
ABSORB China	0.24 (0.39)	240		0.10 (0.32)	246	33.3	0.14 (0.08 to 0.20)	
ABSORB Japan	0.19 (0.31)	272		0.16 (0.33)	137	30.4	0.03 (-0.04 to 0.10)	
EVERBIO II	0.28 (0.39)	75		0.24 (0.32)	103	11.6	0.04 (-0.07 to 0.15)	
TROFI II	0.17 (0.24)	94		0.08 (0.28)	98	24.7	0.09 (0.02 to 0.16)	
Overall		681			584	100	0.08 (0.05-0.12)	

Heterogeneity: $\chi^2=6.19$, $df=3$; $p=0.10$; $I^2=52\%$

Test for overall effect: $Z=4.42$; $p<0.0001$

Random-effects mean difference 0.08 (95% CI 0.03-0.13)

In -device LL



B In-segment late lumen loss

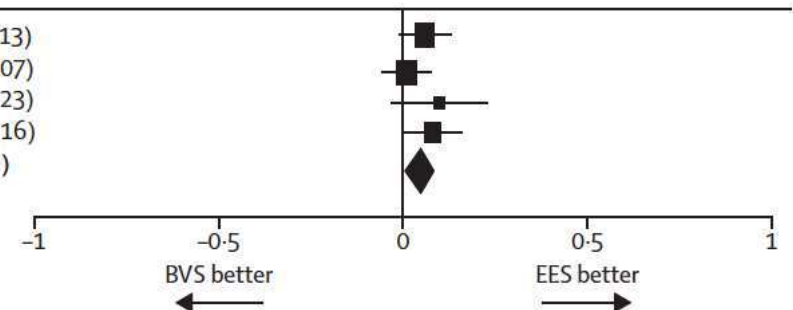
	BVS			EES			Weight (%)	Mean difference (95% CI)
	Mean (SD)	Total		Mean (SD)	Total			
ABSORB China	0.19 (0.40)	240		0.13 (0.37)	246	31.9	0.06 (-0.01 to 0.13)	
ABSORB Japan	0.13 (0.30)	272		0.12 (0.32)	137	36.2	0.01 (-0.05 to 0.07)	
EVERBIO II	0.30 (0.44)	75		0.20 (0.43)	103	8.9	0.10 (-0.03 to 0.23)	
TROFI II	0.14 (0.28)	94		0.06 (0.29)	98	23.0	0.08 (-0.00 to 0.16)	
Overall		681			584	100	0.05 (0.01-0.09)	

Heterogeneity: $\chi^2=2.67$, $df=3$; $p=0.45$; $I^2=0\%$

Test for overall effect: $Z=2.54$; $p=0.01$

Random-effects mean difference 0.05 (95% CI 0.01-0.09)

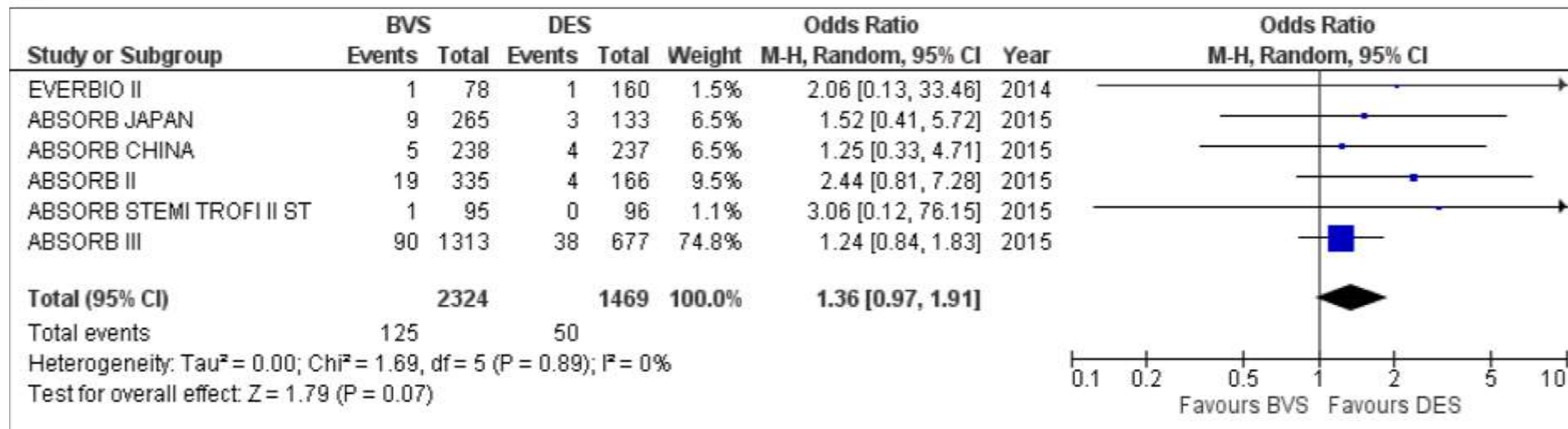
In -segment LL



openheart Use of bioresorbable vascular scaffold: a meta-analysis of patients with coronary artery disease

Mohamed Farag,^{1,2} Nikolaos Spinthakis,¹ Diana A Gorog,^{1,2,3} Abhiram Prasad,⁴ Keith Sullivan,² Zaki Akhtar,¹ Neville Kukreja,¹ Manivannan Srinivasan¹

C MI



Test for overall effect using fixed-effect model: Z = 1.87 (P = 0.06)

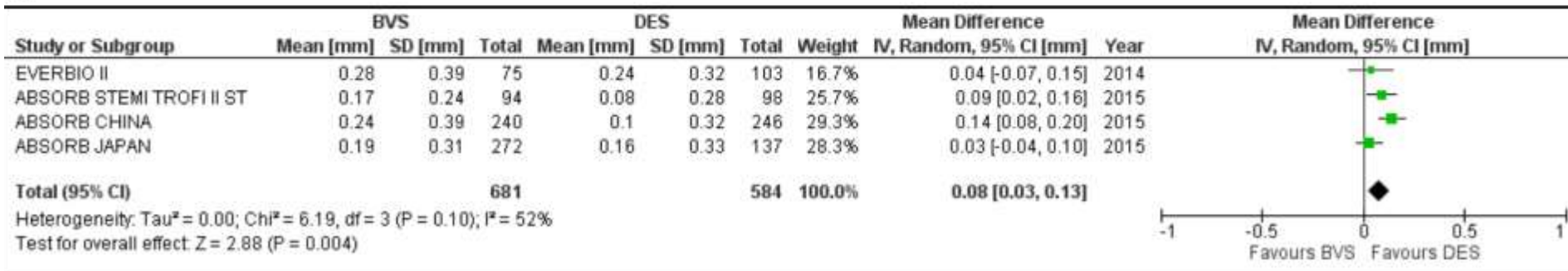
Downloaded from <http://openheart.bmj.com/> on April 6, 2017 - Published by group.bmj.com

Interventional cardiology

openheart Use of bioresorbable vascular scaffold: a meta-analysis of patients with coronary artery disease

Mohamed Farag,^{1,2} Nikolaos Spinthakis,¹ Diana A Gorog,^{1,2,3} Abhiram Prasad,⁴ Keith Sullivan,² Zaki Akhtar,¹ Neville Kukreja,¹ Manivannan Srinivasan¹

C : LLL





Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard



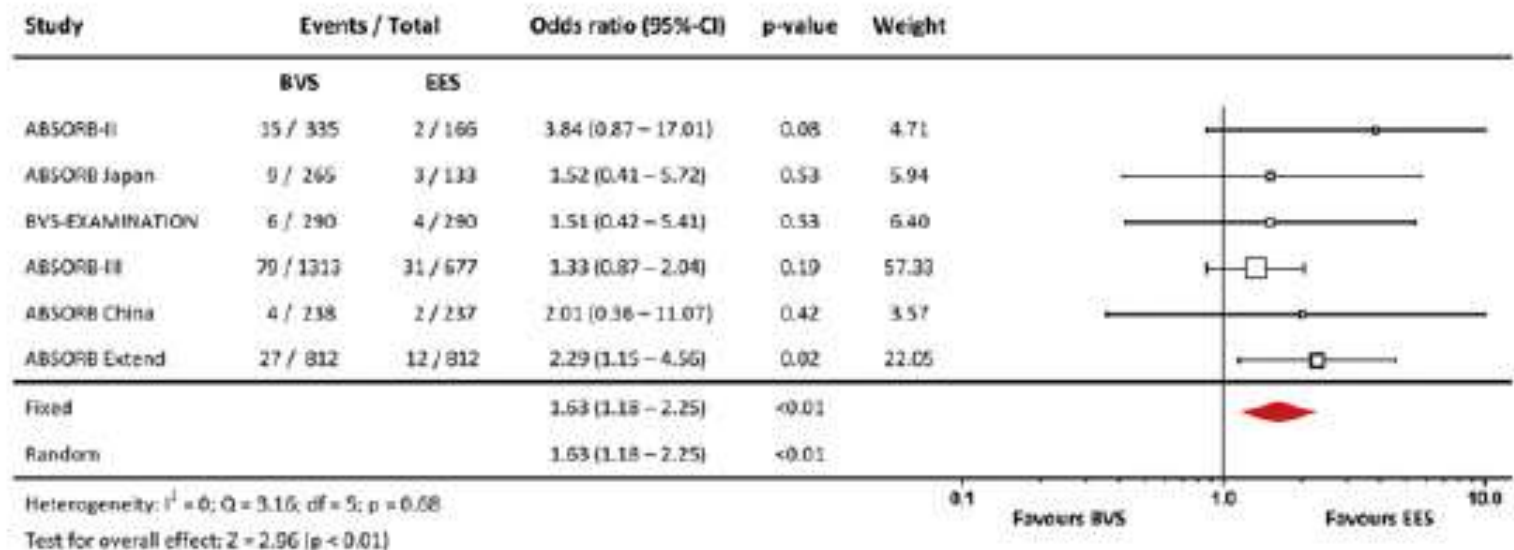
Review

Safety and efficacy of everolimus-eluting bioresorbable vascular scaffolds versus durable polymer everolimus-eluting metallic stents assessed at 1-year follow-up: A systematic review and meta-analysis of studies☆



Bertrand N. Mukete ^{a,1}, Liefke C. van der Heijden ^{b,1}, Kenneth Tandjung ^b, Hassan Baydoun ^a, Kapil Yadav ^a, Qusai A. Saleh ^a, Carine J.M. Doggen ^c, Nidal Abi Rafeh ^a, Thierry H. Le Jemtel ^a, Clemens von Birgelen ^{b,c,*}

C) Target vessel myocardial infarction

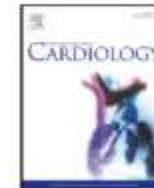




Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard



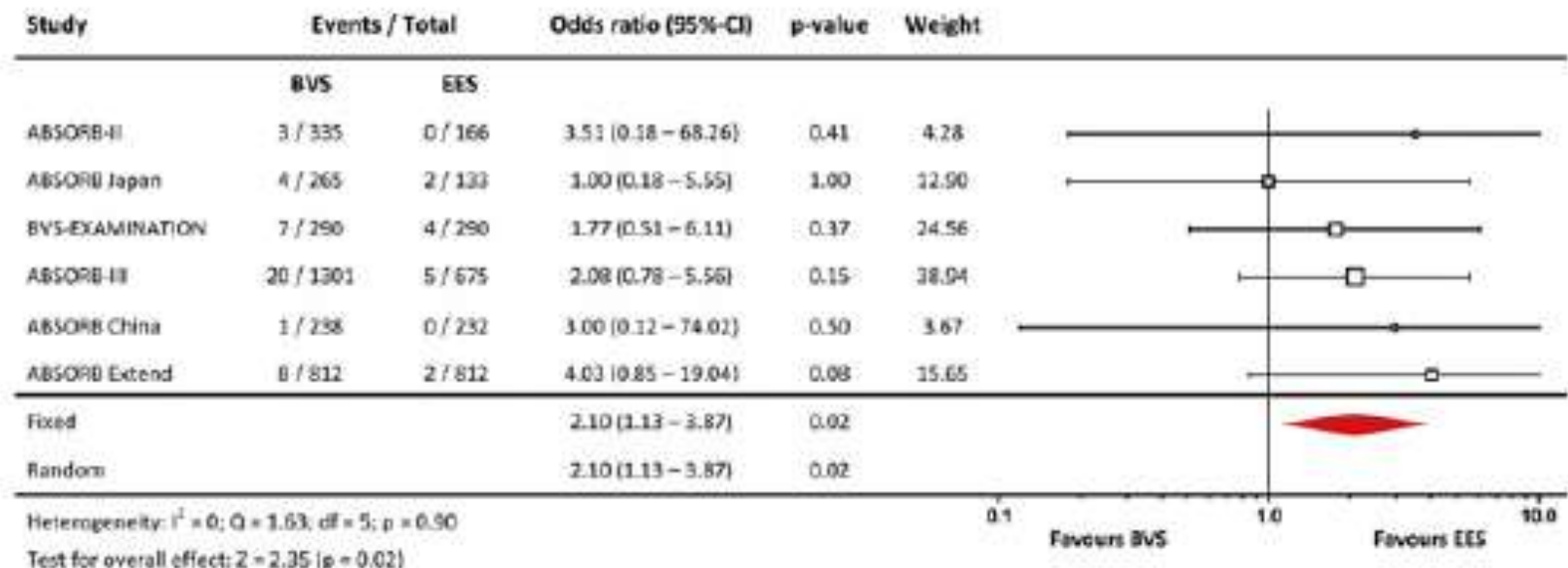
Review

Safety and efficacy of everolimus-eluting bioresorbable vascular scaffolds versus durable polymer everolimus-eluting metallic stents assessed at 1-year follow-up: A systematic review and meta-analysis of studies☆



Bertrand N. Mukete ^{a,1}, Liefke C. van der Heijden ^{b,1}, Kenneth Tandjung ^b, Hassan Baydoun ^a, Kapil Yadav ^a, Qusai A. Saleh ^a, Carine J.M. Doggen ^c, Nidal Abi Rafeh ^a, Thierry H. Le Jemtel ^a, Clemens von Birgelen ^{b,c,*}

F) Definite-or-probable scaffold/stent thrombosis



Corc Origi
 Tw
 elu
 Rame
 Auth
 Abs

JAC
 Volum
 DOI: 10.1016/j.jacc.2016.11.016

Eurol
 Official Journal of European Association of Percutaneous Cardiovascular Interventionalists

AMERICAN COLLEGE OF CARDIOLOGY

Articles & Issues
 For A
 Search all JCI Journals

Home / Archives

Journal
 April 2017
 DOI: 10.1016/j.jacc.2016.11.016
 Just Accepted

Outcomes with everolimus eluting stents
 Insights from randomized trial
 Sripal Bangalore, MD, PhD, et al.

Everolimus

THE LANCET

Online First Current Issue All Issues Special Issues Multimedia Information for Authors

All Content Search Advanced Search

Volume 387, No. 10025, p1277-1289, 26 March 2016

Articles

1-year outcomes with the Absorb bioresorbable scaffold in patients with coronary artery disease: a patient-level, pooled meta-analysis

Prof Gregg W Stone, MD, Prof Runlin Gao, MD, Takeshi Kimura, MD, Dean J Kereiakes, MD, Prof Stephen G Ellis, MD, Yoshisaba Onuma, PhD, Wal-Fung Cheong, PhD, Jennifer Jones-McMears, PhD, Xiaolu Su, MS, Zhen Zhang, PhD, Prof Patrick W Serruys, PhD

Published: 26 January 2016

DOI: [http://dx.doi.org/10.1016/S0140-6736\(16\)00029-9](http://dx.doi.org/10.1016/S0140-6736(16)00029-9)

Summary Full Text Tables and Figures References Supplementary Material

2016-2017 :

7 meta-analysis (mostly at study level) :

Efficacy is comparable to Metallic DES

Safety : BVS are associated with significantly higher stent thrombosis

primary endpoint
 126,526 patients
 terms of ST with
 the risk of ST co
 than that of BP-f
 probable ST with
 BVS showed low

Results Seve
 (n=3,261) ve
 EES, risk of t
 confidence i
 vs. 0.7%, ARI
 BVS. There v
 for ST assoc
 year) period:

Conclusion t
 thrombotic r

Conclu
 2 years

Findings

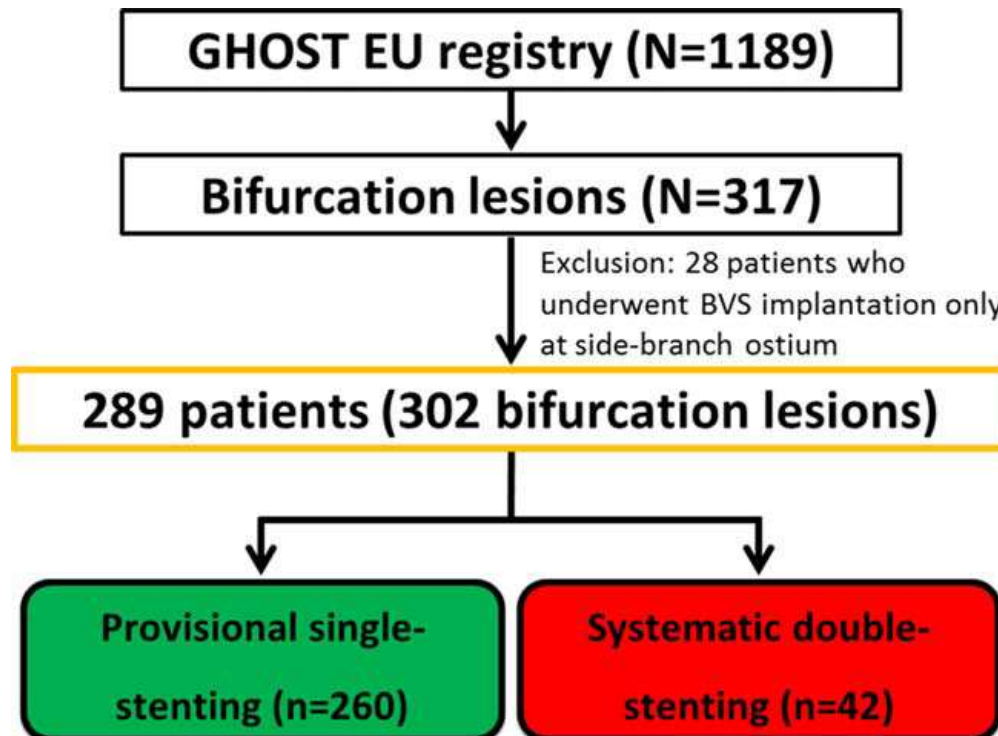
The summary treatment effect for the 1-year relative rates of the patient-oriented composite endpoint did not differ significantly different between BVS and CoCr-EES (relative risk [RR] 1.09 [0.89-1.34], p=0.38). Similarly, the 1-year relative rates of the device-oriented composite endpoint did not differ between the groups (RR 1.22 [95% CI 0.91-1.64], p=0.17). Target vessel-related myocardial infarction was increased with BVS compared with CoCr-EES (RR 1.45 [95% CI 1.02-2.07], p=0.04), due in part to non-significant increases in per-procedural myocardial infarction and device thrombosis with BVS (RR 2.09 [0.92-4.75], p=0.08). The relative rates of all-cause and cardiac mortality, all myocardial infarction, ischaemia-driven target lesion revascularisation, and all revascularisation did not differ between BVS and CoCr-EES. Results were similar after multivariable adjustment for baseline imbalances, and were consistent across most subgroups and in sensitivity analysis when two additional randomised trials with less than 1 year of follow-up were included.

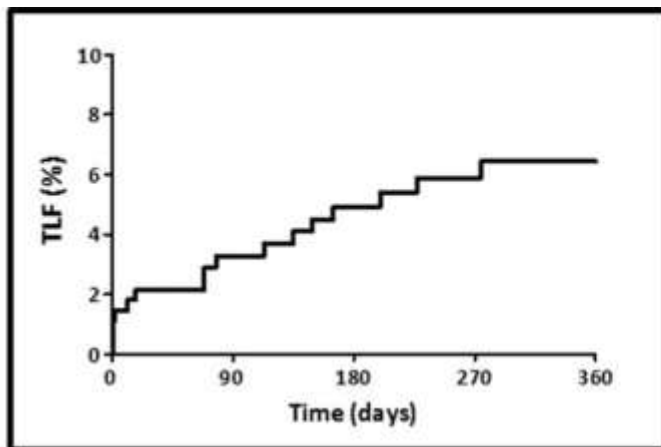
Interpretation

In this meta-analysis, BVS did not lead to different rates of composite patient-oriented and device-oriented adverse events at 1-year follow-up compared with CoCr-EES.

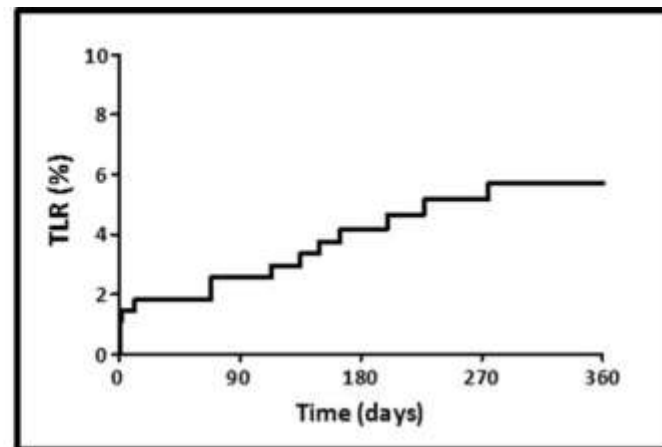
Bioresorbable Vascular Scaffold Use for Coronary Bifurcation Lesions: A Substudy from GHOST EU Registry

Toru Naganuma,^{1,2} MD, Antonio Colombo,¹ MD, Maciej Lesiak,³ MD, Davide Capodanno,⁴ MD, PhD, Tommaso Gori,⁵ MD, PhD, Holger Nef,⁶ MD, Giuseppe Caramanno,⁷ MD, Christoph Naber,⁸ MD, Carlo Di Mario,⁹ MD, Neil Ruparelia,¹ MD, Piera Capranzano,⁴ MD, Jens Wiebe,⁶ MD, Aleksander Araszkiwicz,³ MD, Salvatore Geraci,⁷ MD, Hiroyoshi Kawamoto,^{1,2} MD, Stelios Pyxaras,⁸ MD, Alessio Mattesini,⁹ MD, Thomas Münzel,⁵ MD, Corrado Tamburino,⁴ MD, PhD, and Azeem Latib,^{1*} MD

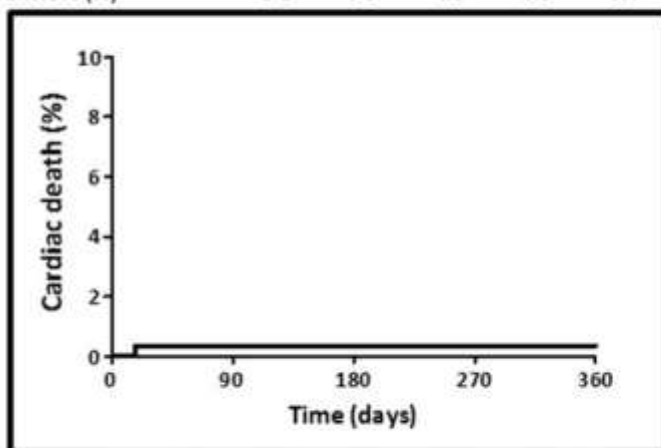




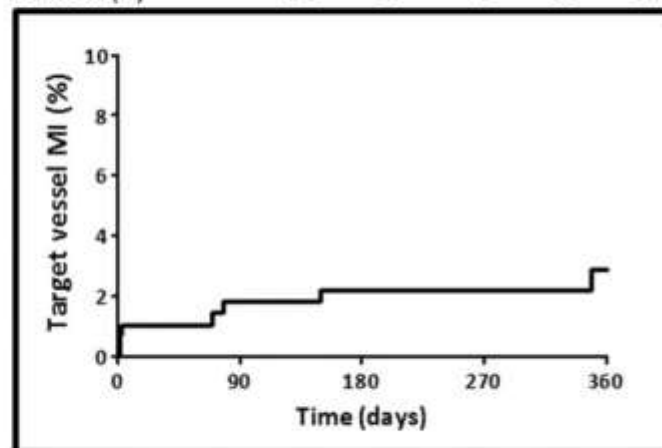
Time (days)	0	30	90	180	270	360
Number at risk	289	271	251	217	175	135
Event rate (%)		2.2	3.3	4.9	5.9	6.4



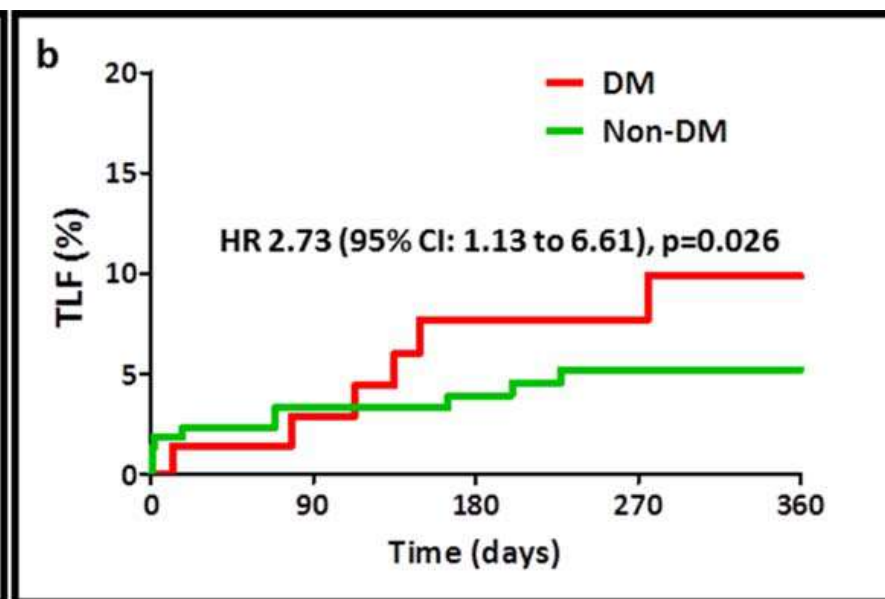
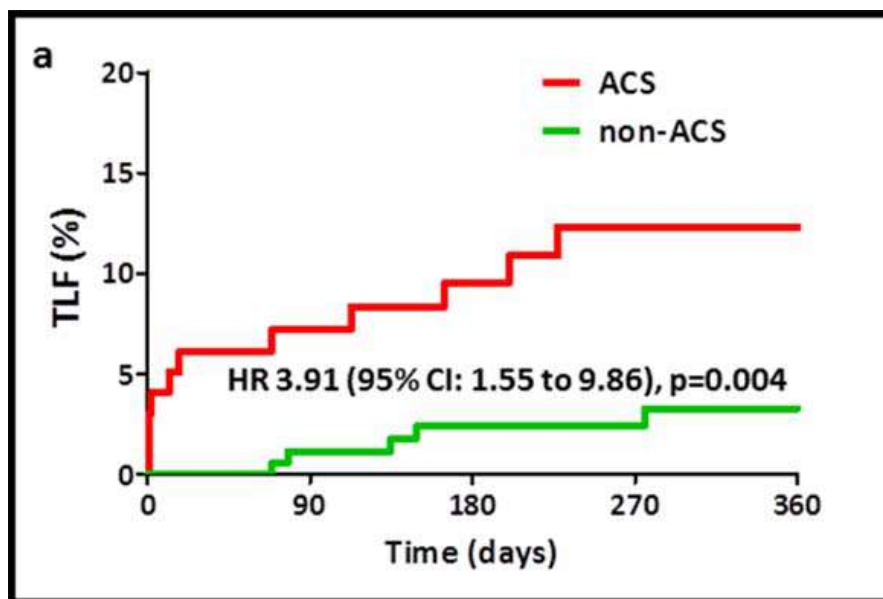
Time (days)	0	30	90	180	270	360
Number at risk	289	272	253	219	174	134
Event rate (%)		1.8	2.5	4.2	5.2	5.7



Time (days)	0	30	90	180	270	360
Number at risk	289	276	259	229	186	143
Event rate (%)		0.4	0.4	0.4	0.4	0.4



Time (days)	0	30	90	180	270	360
Number at risk	289	274	255	224	180	139
Event rate (%)		1.1	1.8	2.2	2.2	2.9



Time (days)	0	30	90	180	270	360
Number at risk						
ACS	99	90	85	73	59	49
Non-ACS	190	190	167	145	117	87
Event rate (%)						
ACS		6.1	7.2	9.5	12.3	12.3
Non-ACS		0	1.1	2.4	2.4	3.3

Time (days)	0	30	90	180	270	360
Number at risk						
DM	73	70	64	54	43	35
Non-DM	216	202	188	164	134	101
Event rate (%)						
DM		1.4	2.9	7.7	7.7	9.9
Non-DM		1.9	3.4	3.9	5.2	5.2

ISAR-ABSORB Registry

- 419 patients
- Routine angiographic surveillance 6–8 months.

	Patients	Patients		
	419	419	6-month rate	12-month rate
Age (years)	66.6 ± 10.9			
Male sex	321 (76.6)			
Diabetes	132 (31.5)			
Diabetes (insulin-treated)	43 (10.3)			
Hypertension	361 (86.2)	Death	15	2.7
Hypercholesterolemia	281 (67.1)	Cardiac death	9	1.7
Current smoker	90 (21.5)	MI	11	2.4
Glomerular filtration rate < 60 mL/min	98 (23.8)	Death or MI	24	4.9
Body mass index (kg/m ²)	27.8 ± 4.8	Definite stent thrombosis	10	2.0
Left ventricular ejection fraction (%)	55.2 ± 9.4 ^a	Definite or probable stent thrombosis	12	2.4
Previous MI	109 (26.0)	Target lesion revascularization	33	4.2
History of coronary bypass surgery	18 (4.3)	Composite of death, MI, target lesion revascularization	49	7.3
Multivessel disease	319 (76.1)			
<i>Clinical presentation</i>				
Stable coronary artery disease	256 (61.1)			
Unstable angina	48 (11.5)			
Non-ST-elevation MI	80 (19.1)			
ST-elevation MI	35 (8.4)			

THE NEW ENGLAND JOURNAL OF MEDICINE

March 29, 2017 DOI: 10.1056/NEJMoa1614954

ORIGINAL ARTICLE

Bioresorbable Scaffolds versus Metallic Stents in Routine PCI

Joanna J. Wykrzykowska, M.D., Ph.D., Robin P. Kraak, M.D.,
 Sjoerd H. Hofma, M.D., Ph.D., Rene J. van der Schaaf, M.D., Ph.D.,
 E. Karin Arkenbout, M.D., Ph.D., Alexander J. Ijsselmuiden, M.D., Ph.D.,
 Joëlle Elias, M.D., Ivo M. van Dongen, M.D., Ruben Y.G. Tijssen, M.D.,
 Karel T. Koch, M.D., Ph.D., Jan Baan, Jr., M.D., Ph.D., M. Marije Vis, M.D., Ph.D.,
 Robbert J. de Winter, M.D., Ph.D., Jan J. Piek, M.D., Ph.D., Jan G.P. Tijssen, Ph.D.,
 and Jose P.S. Henriques, M.D., Ph.D., for the AIDA Investigators*

Table 1. Characteristics of the Patients at Baseline*

Characteristic	Scaffold Group (N=924)	Stent Group (N=921)
Age — yr	64.3±10.6	64.0±10.5
Male sex — no. (%)	670 (72.5)	700 (76.0)
Risk factors — no./total no. (%)		
Diabetes mellitus	171/924 (18.5)	153/921 (16.6)
Treated with oral medication	95/171 (55.6)	97/153 (63.4)
Treated with insulin	65/171 (38.0)	45/153 (29.4)
Hypertension	468/920 (50.9)	464/919 (50.5)
Hypercholesterolemia	344/915 (37.6)	350/914 (38.3)
Family history of coronary artery disease	451/886 (50.9)	469/886 (52.9)
Current smoker	248/867 (28.6)	273/861 (31.7)
History — no./total no. (%)		
Chronic renal failure	70/924 (7.6)	91/921 (9.9)
Ejection fraction <30%	22/910 (2.4)	17/900 (1.9)
Previous stroke or transient ischemic attack	46/923 (5.0)	58/921 (6.3)
Peripheral vascular disease	65/924 (7.0)	56/918 (6.1)
Previous myocardial infarction	166/924 (18.0)	172/921 (18.7)
Previous percutaneous coronary intervention	202/924 (21.9)	184/921 (20.0)
Previous bypass surgery	38/924 (4.1)	26/921 (2.8)
Clinical presentation — no. (%)		
ST-segment elevation myocardial infarction	240 (26.0)	225 (24.4)
Non-ST-segment elevation myocardial infarction	185 (20.0)	192 (20.8)
Unstable angina	70 (7.6)	87 (9.4)
Stable angina, documented ischemia, or both	361 (39.1)	370 (40.2)
Angiographically driven indication for PCI†	51 (5.5)	36 (3.9)
Other	17 (1.8)	11 (1.2)
SYNTAX score‡		
Mean	13.2±8.6	12.6±8.4

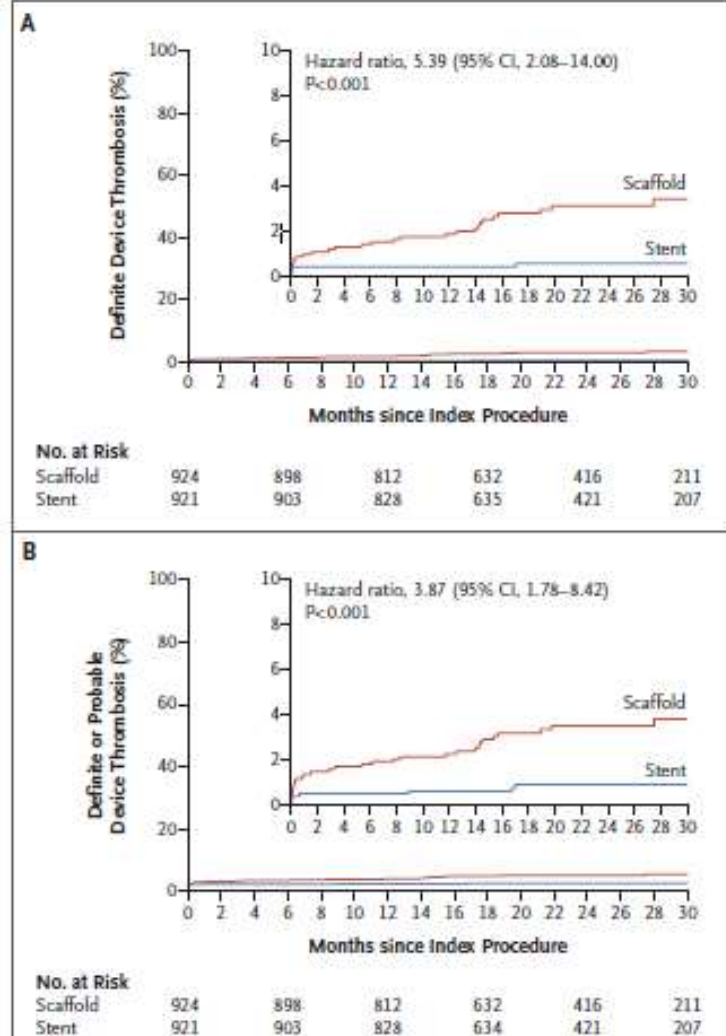
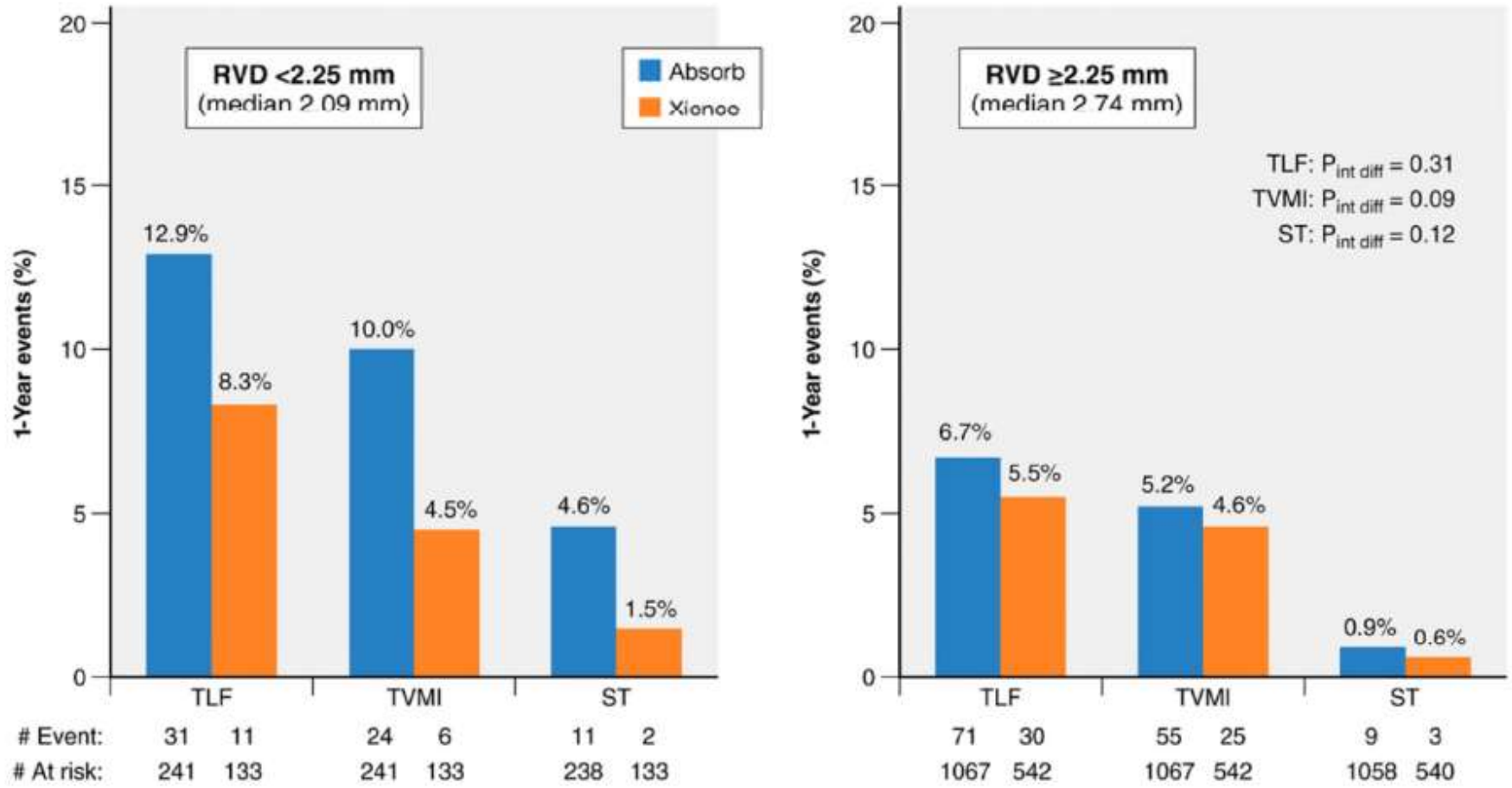


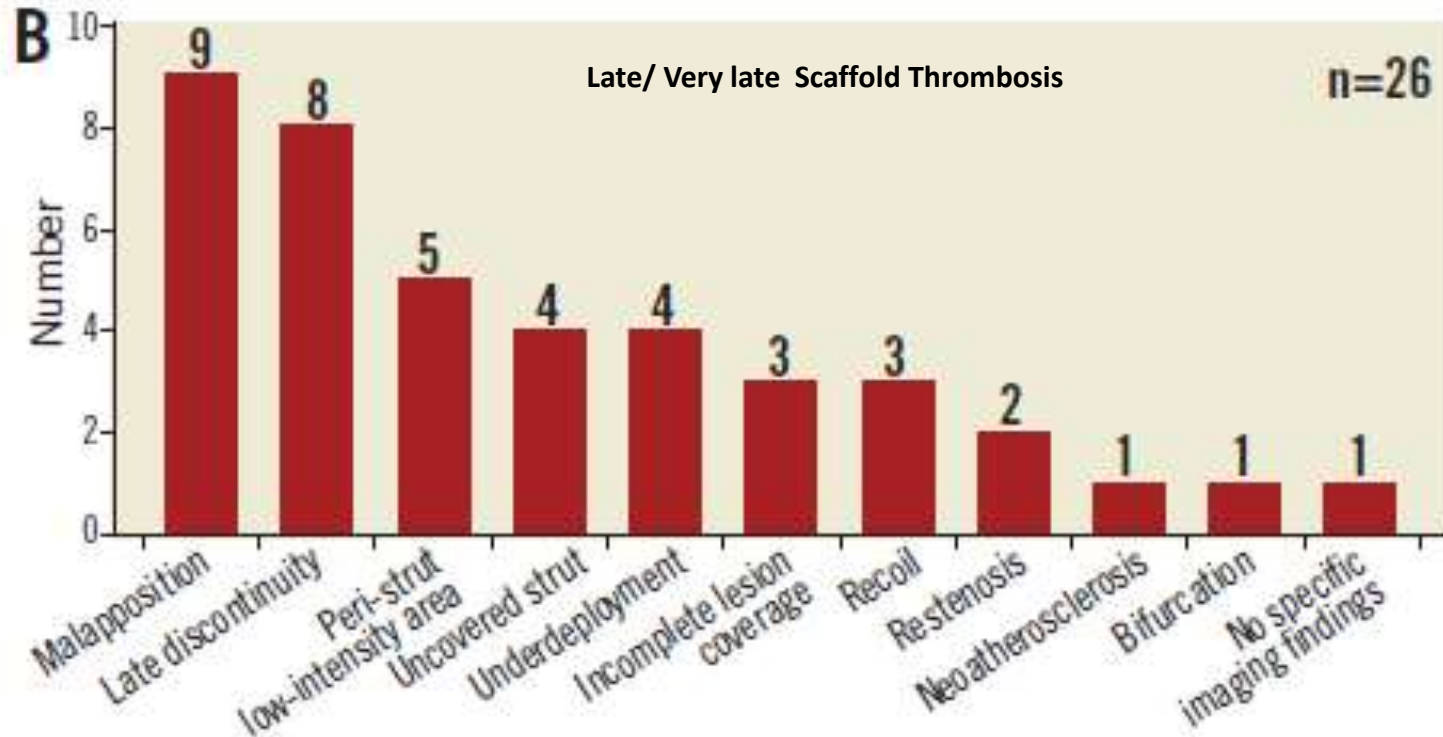
Figure 2. Kaplan–Meier Curves for Definite or Probable Device Thrombosis. Shown are the event rates of definite device thrombosis (Panel A) and definite or probable device thrombosis (Panel B) through 30 months among the patients randomly assigned to receive bioresorbable vascular scaffolds or metallic stents. In each panel, the inset shows the same data on an enlarged y axis.

More Clinical Events to 1 year in smaller vessels - ABSORB III trial.



Median based on pooled Absorb and Xience

Possible mechanical causes of scaffold thrombosis: insights from case reports with intracoronary imaging



RCT	pre-	post-dilatation	ACS	B2/C	Calc.	Bif.	TLR	ScT
EVERBIO II (N=78)	~40%	~10%	37	30			8 (10)***	0 (0.0)
ABSORB TROFI II (N=95)	~50%	~20%	100		5		1 (1.1)	1 (1.1)
ABSORB II (N=335)	~60%	~20%	20	46	13 [†]	*	4 (1.0)	3 (0.9)
ABSORB China (N=238)	~60%	~20%	65	75	18 [†]	50 [†]	7 (2.9)	1 (0.4)
ABSORB III (N=1,322)	~60%	~20%	27	69	5	*	42 (3.2)	20 (1.5)
ABSORB Japan (N=266)	~60%	~20%	10	76	35 [†]	*	7 (2.6)	4 (1.5)
Cohort study	pre-	post-dilatation	ACS	B2/C	Calc.	Bif.	TLR	ScT
ASSURE (N=183)	~10%	~5%		65	16	3	5 (2.8)	0 (0.0)
Gori et al (N=150)	~10%	~5%	100					3 (2.0)*
BVS-EXAMINATION (N=290)	~40%	~15%	100				5 (1.7)	7 (2.4)
POLAR-ACS (N=100)	~40%	~15%	100	58			1 (1.0)	1 (1.0) [†]
GHOST-EU (N=1,189)	~50%	~20%	47	51		23	25 (2.5)**	23 (2.1)**
MICAT (N=1,305)	~50%	~20%	69	38		11		32 (3.0)
BVS EXPAND (N=249)	~50%	~20%	59	38	42	21	NA (3.4)	NA (1.7)
AMC registry (N=135)	~50%	~20%	50	67	11	15	8 (6.3)**	0 (0.0)**
ABSORB EXTEND (N=768)	~60%	~20%	27	44	13		11 (1.5) [†]	4 (0.7)
ISAR-ABSORB (N=419)	~60%	~20%	39	49		13	33 (9.1)	12 (3.1)
Markovic et al (N=236)	~60%	~20%	44	81			7 (2.2)	0 (0.0)
Costopoulos et al (N=108)	~60%	~20%	48		35	18	1 (0.9)	1 (0.9)
RAI registry (N=122)	~60%	~20%	100			4	5 (4.1)**	3 (2.5)**
ESHC-BVS (N=100)	~60%	~20%	44	56	16	4	4 (4.0)	1 (1.0)
Tanaka et al (N=264)	~60%	~20%	14	75	23	47	14 (6.6) [†]	3 (1.2)

What determines long-term outcomes using fully bioresorbable scaffolds - the device, the operator or the lesion?



Kyohei Yamaji, MD, PhD; Lorenz Räber, MD, PhD; Stephan Windecker*, MD

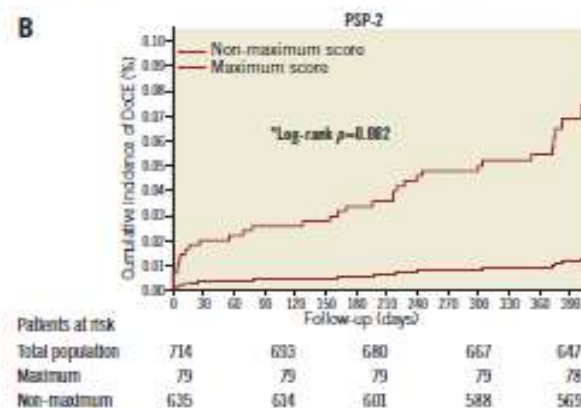
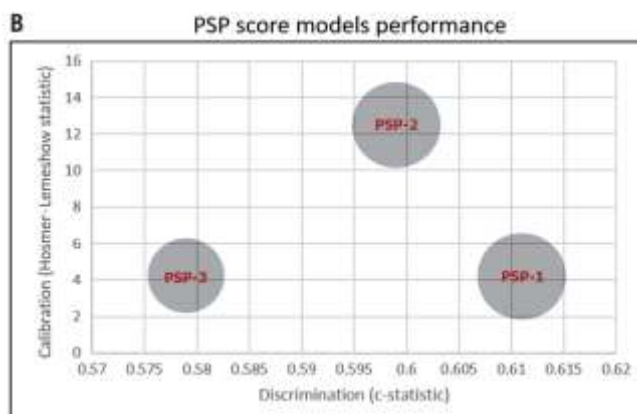
Department of Cardiology, Bern University Hospital, Bern, Switzerland

Optimised implantation strategy		
Correctable	Uncertain whether correctable	Not correctable
Malapposition Incomplete lesion coverage Underexpansion Acute disruption Overlap Acute recoil Uncovered struts Bifurcation	Late discontinuity Late recoil Restenosis	Peri-strut low intensity area Neoatherosclerosis

Predilation, sizing and post-dilation scoring in patients undergoing everolimus-eluting bioresorbable scaffold implantation for prediction of cardiac adverse events: development and internal validation of the PSP score

A PSP score models estimation

	PSP-1	PSP-2	PSP-3
Prediction	Not performed=0 Performed=0.63	Not performed or residual stenosis $\geq 30\%$ =0 Residual stenosis <30%=1.56	Not performed=0 Performed=0.63
	Incorrect=0 Correct*=1.96		
Scaffold sizing			
Post-dilation	Not performed, over-expanded* or performed with a 1:1 NC balloon**=0 Performed with a NC balloon >1:1*=1.93	Not performed, over-expanded* or performed with a 1:1 NC balloon**=0 Performed with a NC balloon >1:1*=1.93	Not performed, over-expanded*, or performed with a 1:1 NC balloon pressure <16 atm=0 Performed with a NC balloon pressure ≥ 16 atm=1.06
	Maximum score	4.51	5.45



Clinical outcomes of a real-world cohort following bioresorbable vascular scaffold implantation utilising an optimised implantation strategy

Table 4. Clinical outcomes at 1 and 2 years.

N=264 patients	1 year	2 years
TLF	17 (7.9%)	22 (11.6%)
Cardiac death	3 (1.3%)	4 (2.0%)
Target vessel MI	4 (1.8%)	4 (1.8%)
TLR	14 (6.6%)	19 (10.4%)
All-cause death	6 (2.8%)	7 (3.5%)
Any myocardial infarction	5 (2.3%)	5 (2.3%)
TVR	17 (8.0%)	25 (13.8%)
Definite/probable ST	3 (1.2%)	3 (1.2%)

Event rates estimated using Kaplan-Meier analysis. MI: myocardial infarction; ST: scaffold thrombosis; TLF: target lesion failure; TLR: target lesion revascularisation; TVR: target vessel revascularisation

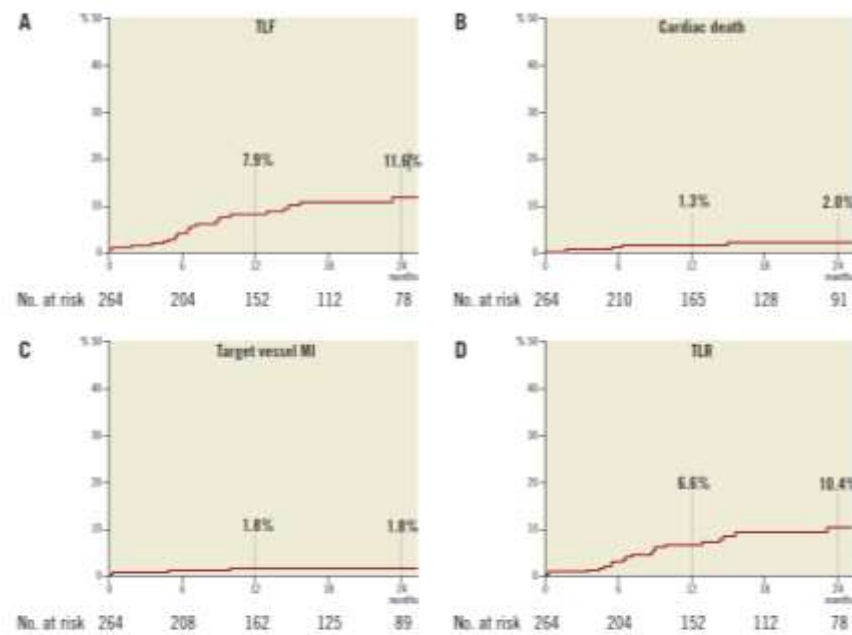
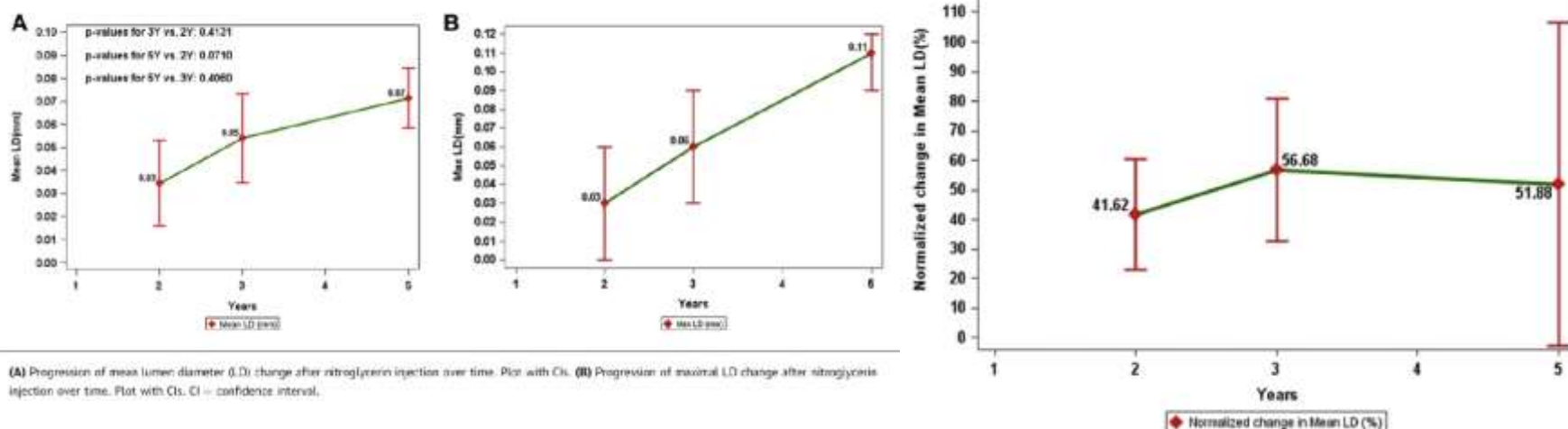


Figure 1. Kaplan-Meier curves. A) Target lesion failure. B) Cardiac death. C) Target vessel myocardial infarction. D) Target lesion revascularisation.

Vasomotor Response to Nitroglycerine Over 5 Years Follow-up After Everolimus Eluting Bioresorbable Scaffold Implantation

Dariusz Dudek, MD, PhD,^a Lukasz Rzeszutko, MD, PhD,^b Yoshinobu Onuma, MD, PhD,^c Yohei Sotomi, MD,^d Rafał Depukat,^b Susan Veldhof, RN,^e Divine Ediebah, MS,^e Peter Staehr, MD,^f Wojciech Zasada, MD, PhD,^g Krzysztof P. Malinowski, MS,^h Grzegorz L. Kaluza, MD, PhD,ⁱ Patrick W. Serruys, MD, PhD^j

FIGURE 1 LD Change Over Time



(A) Progression of mean lumen diameter (LD) change after nitroglycerine injection over time. Plot with CIs. (B) Progression of maximal LD change after nitroglycerine injection over time. Plot with CIs. CI = confidence interval.

At 5 years : No improvement in response to NTG using mean lumen diameter change by QCA. Only the maximal LD change increased significantly.

Moreover , the degree of response to NTG remained lower than in adjacent segments.

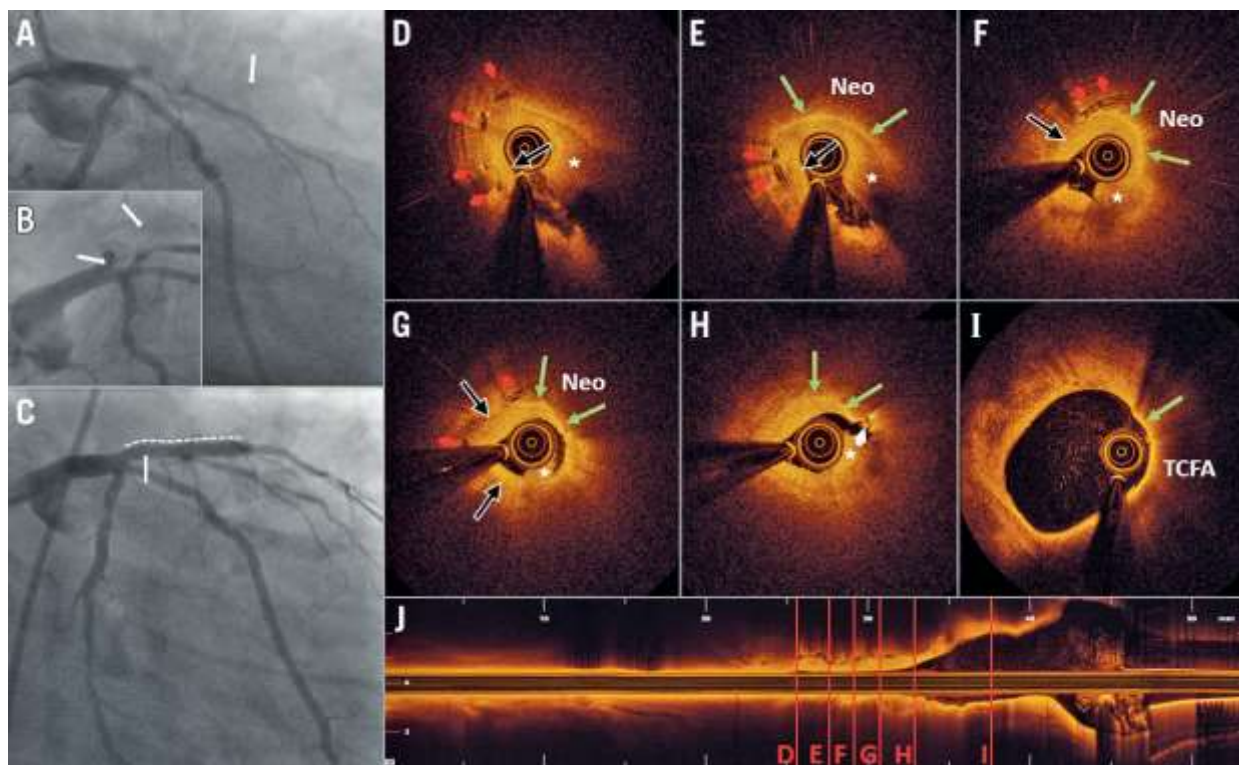
Neoatherosclerosis: an emerging and conceptually unexpected cause of very late bioresorbable vascular scaffold failure



Nick Hiltrop^{1*}, MD; Walter Desmet^{1,2}, MD, PhD, FESC; Tom Adriaenssens^{1,2}, MD, PhD;
Johan Bennett^{1,2}, MD

1. Department of Cardiovascular Medicine, University Hospitals Leuven, Leuven, Belgium; 2. Department of Cardiovascular Sciences, KU Leuven, Leuven, Belgium

This paper also includes supplementary data published online at: http://www.pcronline.com/eurointervention/113th_issue/331

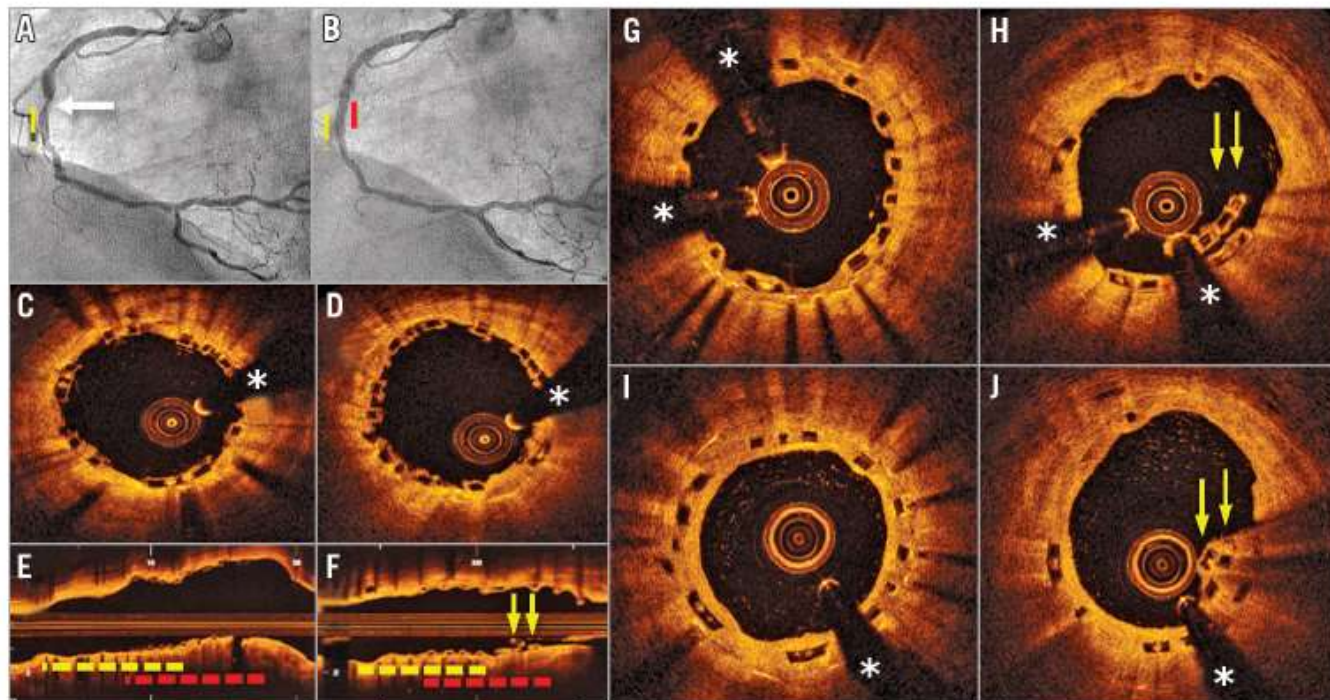


Delayed fracture of a bioresorbable vascular scaffold implanted for in-stent restenosis

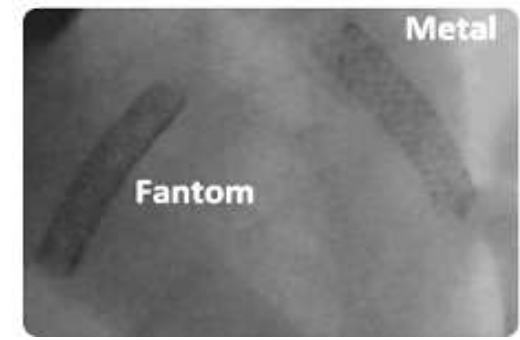
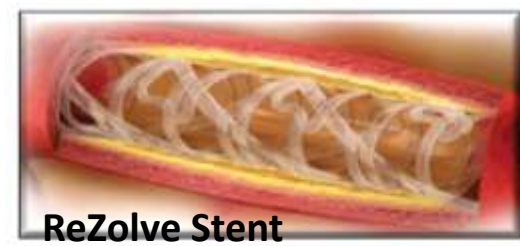
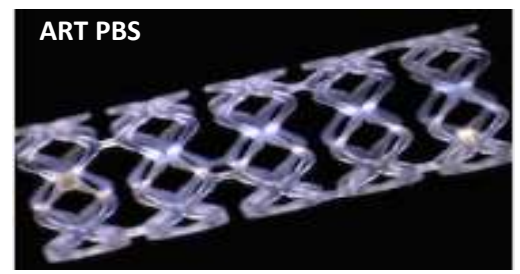
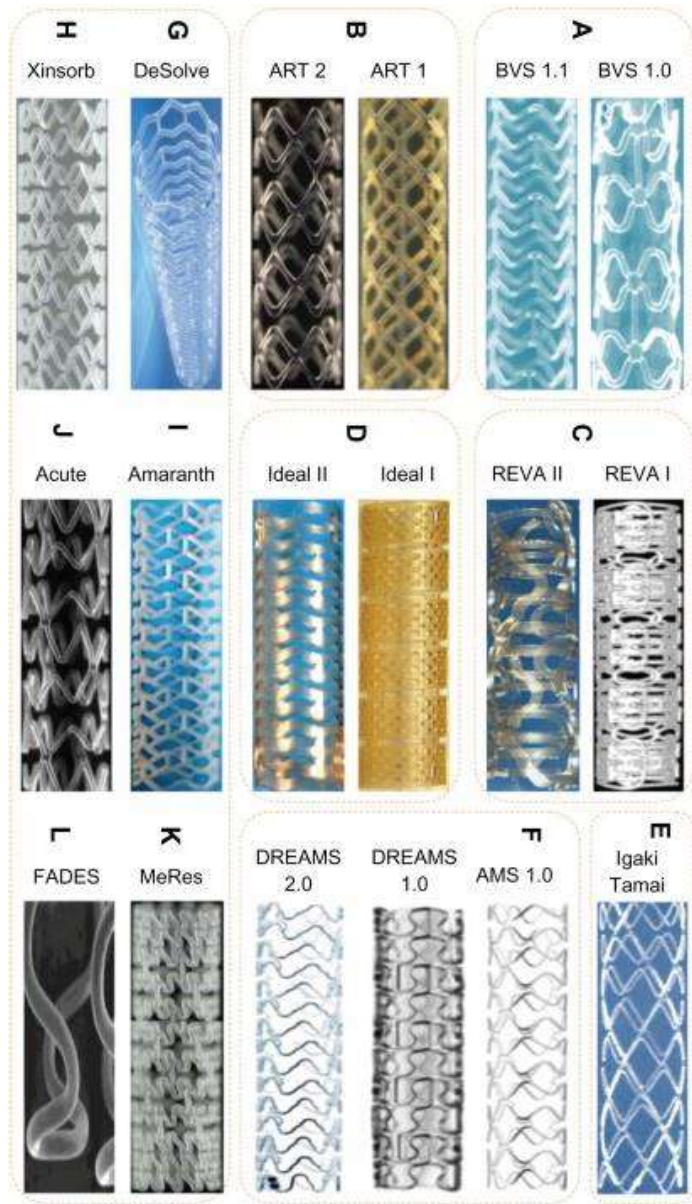


Teresa Bastante, MD; Javier Cuesta, MD; Fernando Rivero, MD;
Marcos García-Guimaraes, MD; Amparo Benedicto, MD; Fernando Alfonso*, MD, PhD

Department of Cardiology, Hospital Universitario de La Princesa, Madrid, Spain



A 61-year-old woman presented with effort angina one year complete neointimal coverage of the fractured BVS (Panel I,



BVS technology advancement is expected to further improve the clinical outcome

ABSORB



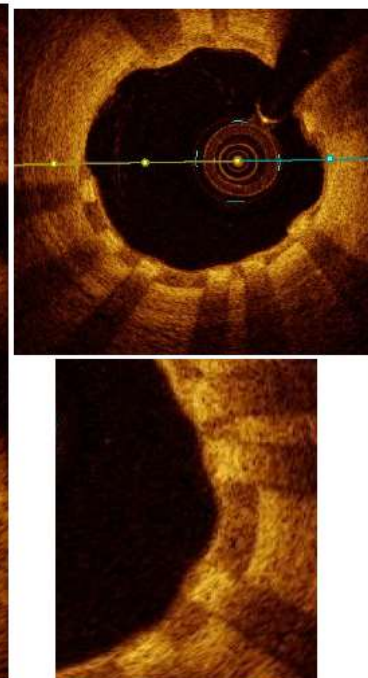
- Preserved box appearance
- Low backscattering strut core is easily identified embedded into the NIH tissue.

DESolve



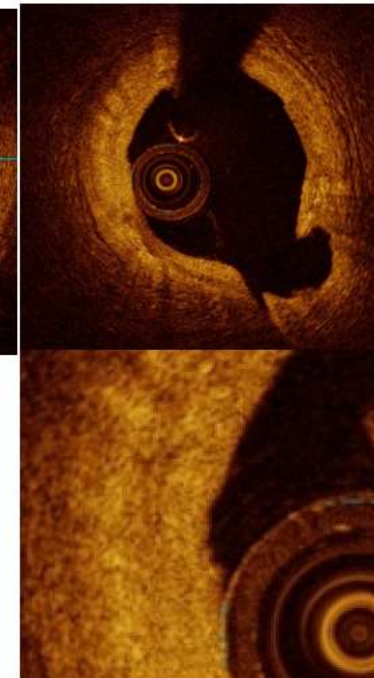
- Most struts retain their box-shaped appearance.
- Some struts present advanced degradation w/ diffuse boundaries.

Fantom



- Low backscattering long strips, locking system and backbone are easily recognized embedded into the NIH tissue.

Mirage



- High backscattering struts have an optical signal intensity close to that of fibrotic tissue, their identification difficult when embedded into NIH

Closing Remarks

- **Data Confirm that efficacy of BVS is comparable to II generation metallic DES**
- **Safety (ST) still a concern (nearly 3%). However; the improvement of our knowledge about scaffolding and particularly about the appropriate implantation technique seems to reduce significantly ST –**
- **There is a trend toward vasomotor recovery over time which is consistent with the progressive degradation and bioresorption of the scaffold; however, the degree of response to NTG remained lower than in adjacent segments.**
- **Next generation is expected to improve mechanical characteristics and consequently the clinical outcome**
- **At the present time , with the available devices expansion of angiographic indications should be considered as investigational and should not be encouraged**