Bioresorbable Vascular Scaffolds will become systematic ?

Contra

« Do the job and disappear ! »

« Do the job ???......... »

« … and disappear ??? »

Gérard Finet MD PhD

Department of Cardiology and Interventional Cardiology
Cardiovascular Hospital - Hospices Civils de Lyon
INSERM Unit 1060 CARMEN
Claude Bernard University Lyon 1
Lyon - France

gerard.finet@univ-lyon1.fr

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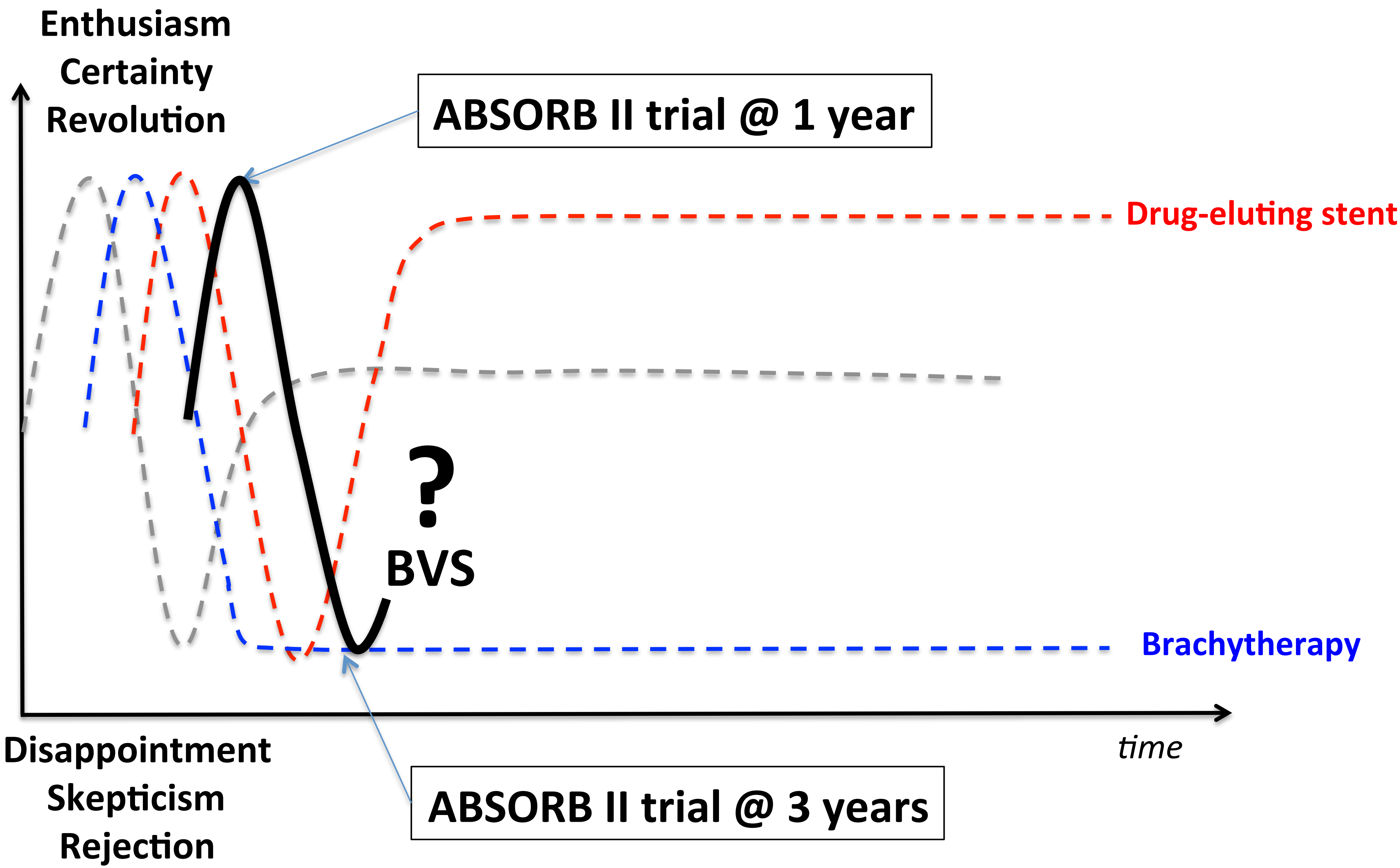
Royalty Income: **no**

Ownership/Founder: **no**

Intellectual Property Rights: **yes**

Other Financial Benefit: **no**

The stages of development of new techniques

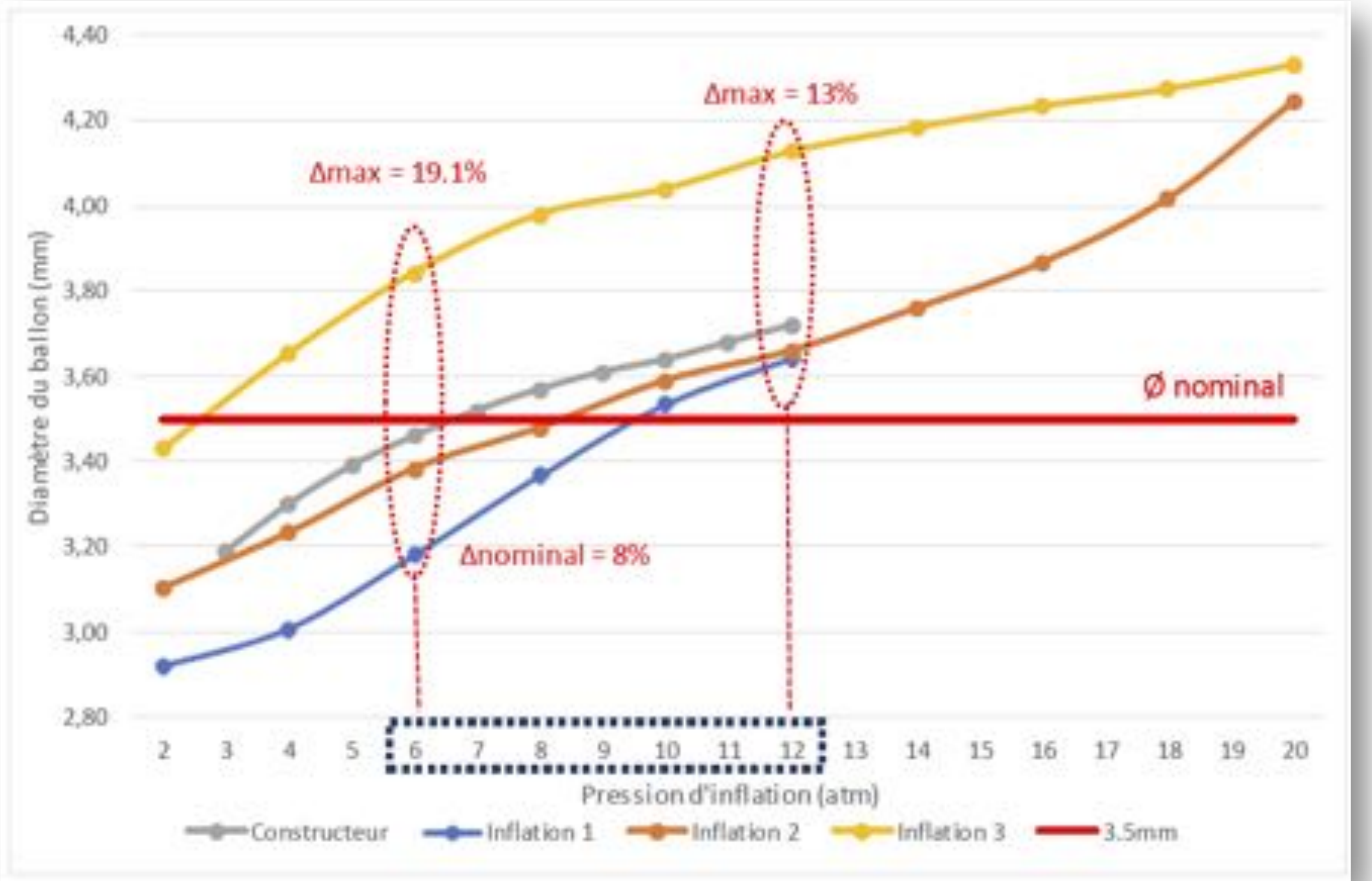


ABSORB II trial at baseline

Lancet 2014

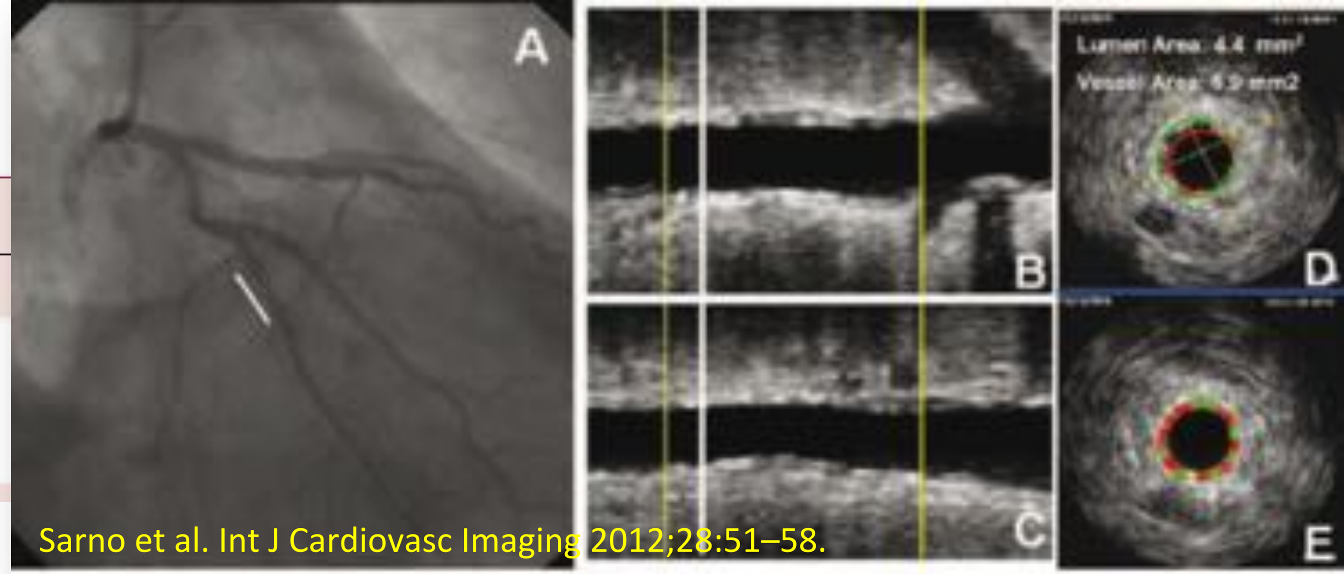
	Bioresorbable scaffold group	Metallic stent group	p value
Procedural details			
Number of lesions	364	182	..
Balloon dilatation prior to device implantation	364 (100%)	180 (99%)	0·11
Planned overlap with the same type of device	56 (15%)	20 (11%)	0·16
Unforeseen additional implantation with the same device	14 (4%)	11 (6·0)	0·25
More than one study device implanted	70 (19%)	27 (15%)	0·21
Nominal size of study device (mm)	3·01 (0·31)	3·05 (0·28)	0·10
Balloon dilatation after device implantation	221 (61%)	107 (59%)	0·67
Nominal diameter of balloon used (implantation or post-dilatation; mm)	3·08 (0·34)	3·16 (0·36)	0·02
Maximum balloon pressure used (implantation or post-dilatation; atm)	14·23 (3·43)	15·03 (3·33)	0·01
Expected diameter of balloon used (implantation or post-dilatation; mm)	3·29 (0·35)	3·35 (0·37)	0·15
Angiographic acute recoil of device following implantation per device (mm)	0·19 (0·19)	0·19 (0·18)	0·85
Diameter stenosis			
Pre-procedure percent diameter stenosis (%)	59% (11)	60% (12)	0·30
Post-procedure in-stent/in-scaffold percent diameter stenosis (%)	16% (7)	10% (5)	<0·001
p between pre-procedure and post-procedure	<0·001	<0·001	
Post-procedural curvature, cm^{-1}	0·29 (0·23)	0·24 (0·19)	0·02

Ballon compliant : 3.5 * 15 mm



Cellier G et Finet G – Personal data

In-scaffold or stent assessment
Co-primary endpoints
Vasomotion (mm)
In-stent or scaffold late loss (mm)



Sarno et al. Int J Cardiovasc Imaging 2012;28:51–58.

ABSORB II trial @ 1 years

Lancet 2014

	Bioresorbable scaffold group (n=335)	Metallic stent group (n=166)	p value
Outcomes			
All deaths	0	1 (1%)	0·33
Cardiac deaths	0	0	1·00
All target-vessel revascularisation	8 (2%)	8 (5%)	0·15
Clinically indicated target-vessel revascularisation	6 (2%)	6 (4%)	0·23
Composite secondary endpoints			
Cardiac death, all myocardial infarction, clinically indicated target-vessel revascularisation (target-vessel failure)	18 (5%)	8 (5%)	0·78
Thrombosis endpoints			
Definite scaffold or stent thrombosis	2 (0·6%)	0	1·00

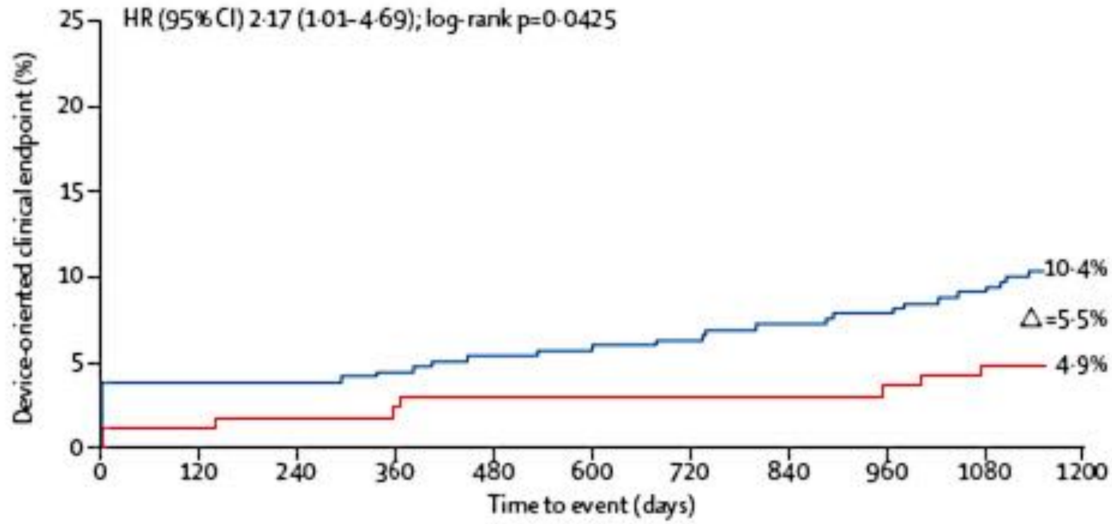
ABSORB II trial @ 3 years

Lancet 2016

	Absorb group	Xience group	p value
Secondary endpoints			
All deaths	8/325 (2%)	6/161 (4%)	0·57
Cardiac deaths	3/325 (1%)	3/161 (2%)	0·40
All target lesion revascularisation	24/325 (7%)	8/161 (5%)	0·31
Clinically indicated target lesion revascularisation	20/325 (6%)	3/161 (2%)	0·0360
Composite secondary endpoints			
Cardiac death, target vessel myocardial infarction, and clinically indicated target lesion revascularisation (target lesion failure; device-oriented composite endpoint)	34/325 (10%)	8/161 (5%)	0·0425
Thrombosis endpoints			
Definite scaffold or stent thrombosis	8/320 (3%)	0/159	0·06
Acute (0–1 day)	1/335 (<1%)	0/166	1·0
Sub-acute (2–30 days)	1/334 (<1%)	0/166	1·0
Late (31–365 days)	0/329	0/164	1·0
Very late (>365 days)	6/329 (2%)	0/164	0·19

ABSORB II trial @ 3 years

Lancet 2016



	Time after index procedure (days)					
	0	37	194	393	758	1151
Absorb						
Number at risk	335	318	318	312	300	282
% event rate	2·10	3·90	3·90	4·80	6·90	10·40
% SEM	0·80	1·10	1·10	1·20	1·40	1·70
Xience						
Number at risk	166	164	161	158	156	149
% event rate	1·20	1·20	1·80	3·00	3·00	4·30
% SEM	0·80	0·80	1·00	1·30	1·30	1·60

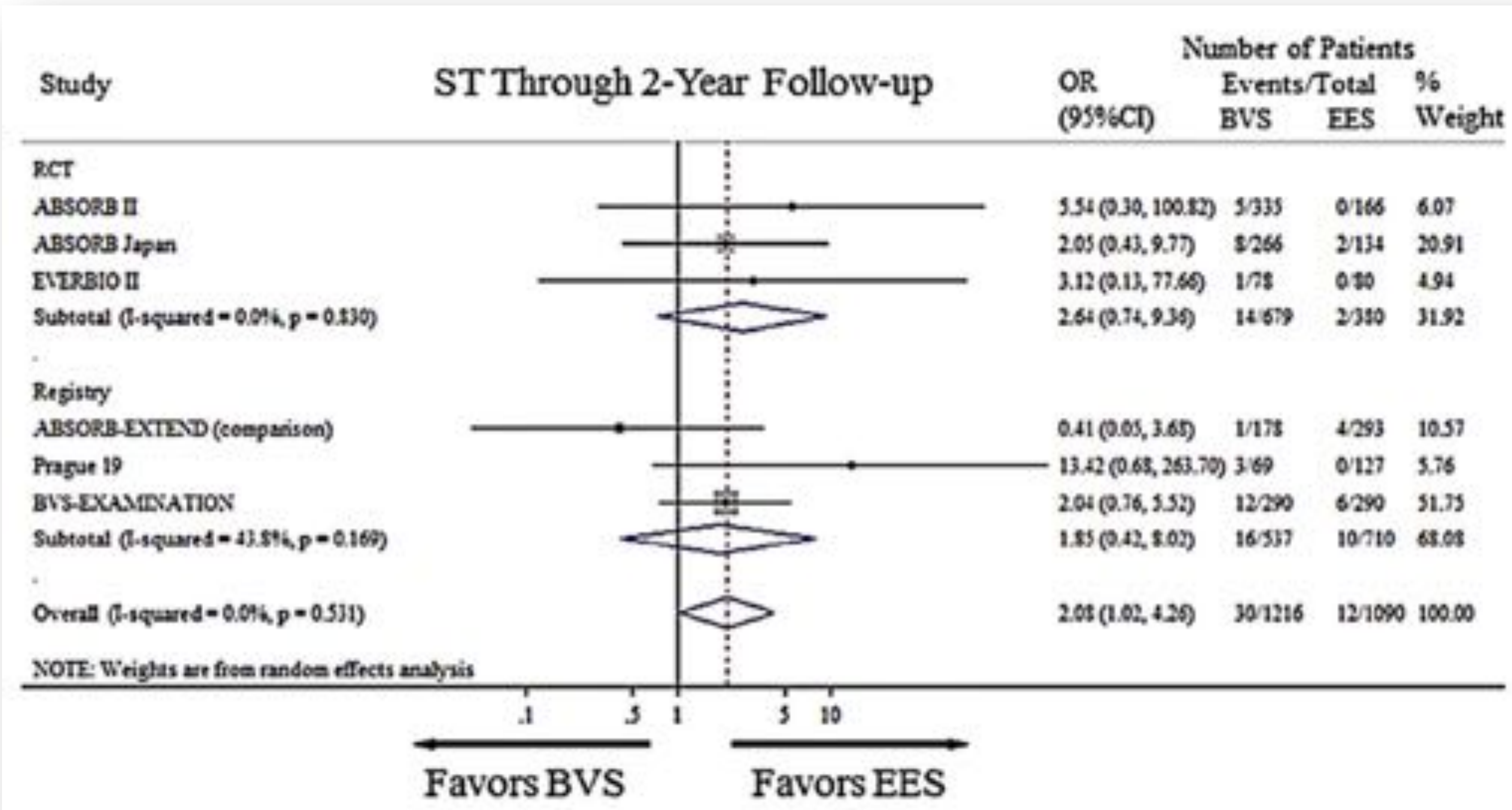
Kaplan-Meier curves for the device-oriented composite clinical endpoints

The device-oriented composite endpoint was cardiac death plus myocardial infarction attributable to target vessel plus clinically indicated target lesion revascularisation.

Very Late Scaffold Thrombosis of Bioresorbable Vascular Scaffold

Systematic Review and a Meta-Analysis

Toshiaki Toyota, MD,[a] Takeshi Morimoto, MD, PhD,[b] Hiroki Shiomi, MD,[a] Yusuke Yoshikawa, MD,[a] Hidenori Yaku, MD,[a] Yugo Yamashita, MD,[a] Takeshi Kimura, MD[a]



J Am Coll Cardiol Intv 2017;10:27–37

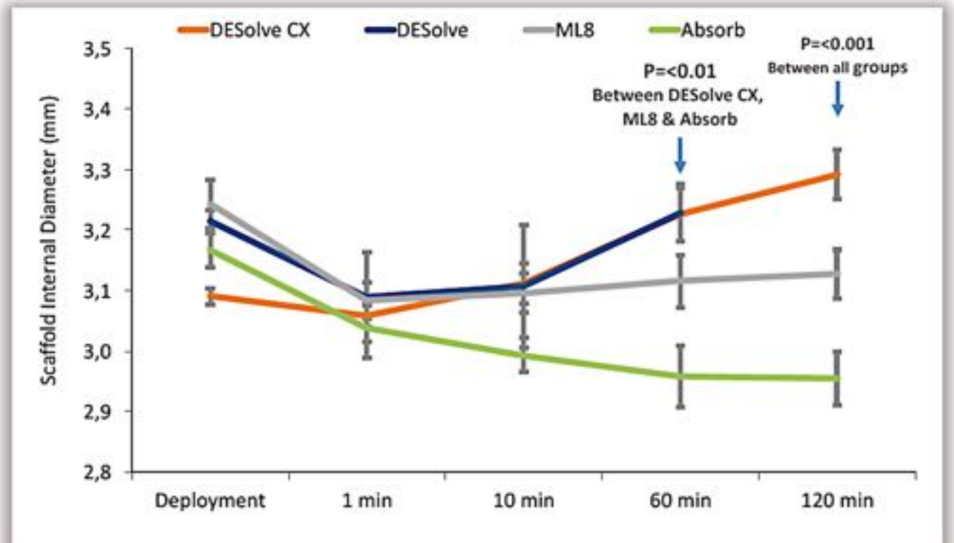
Mechanical properties and degradation time for different polymers

Polymer Composition	Tensile Modulus of Elasticity, GPa	Tensile Strength, MPa	Elongation at Break, %	Degradation Time, mo
Poly (L-lactide)	3.1–3.7	60–70	2–6	>24
Poly (D,L–lactide)	3.1–3.7	45–55	2–6	12–6
Poly (glycolide)	6.5–7.0	90–110	1–2	6–12
50/50 D,L-lactide/glycolide	3.4–3.8	40–50	1–4	1–2
82/18 L-lactide/glycolide	3.3–3.5	60–70	2–6	12–18
70/30 L-lactide/ε–caprolactone	0.02–0.04	18–22	>100	12–24
Cobalt chromium	210–235	1449	~40	Biostable
Stainless steel 316L	193	668	40+	Biostable
Nitinol	45	700–1100	10–20	Biostable
Mg alloy	40–45	220–330	2–20	1–3

Y. Onuma and P. W. Serruys. Circulation. 2011;123:779-797

BVS Recoil over time

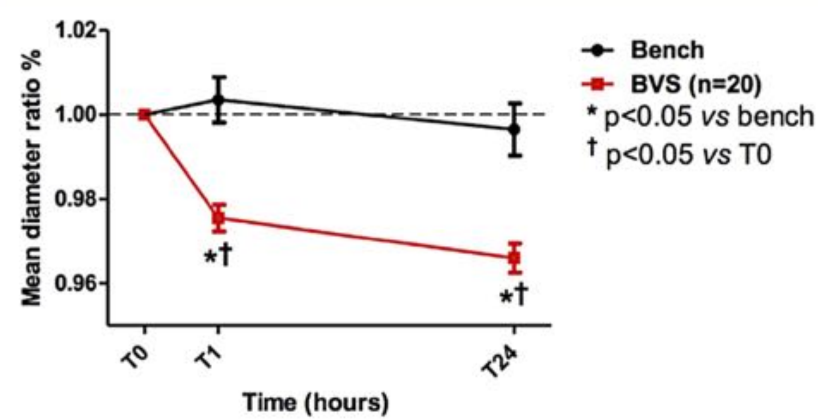
- 6% @ 2h



Orminston J. EBC 2016

- 4% @ 24h

FIGURE 5 **Analysis of Late Recoil in Absorb Bioresorbable Vascular Scaffold at 1 and 24 h**

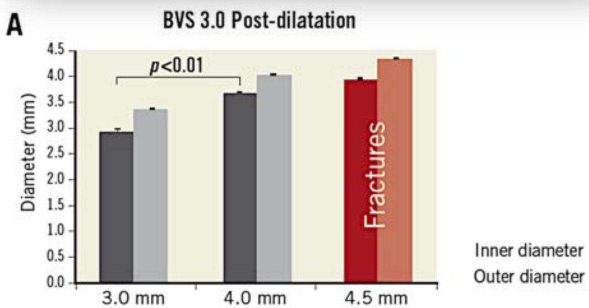


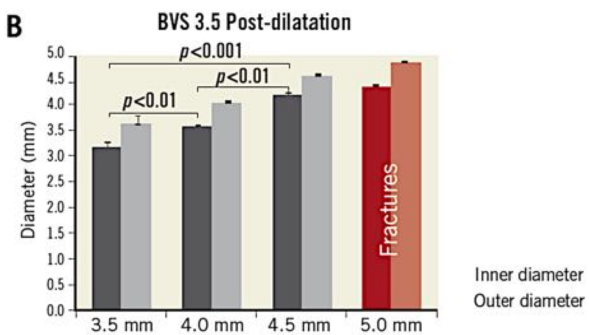
Variations in mean diameter ratio calculated between diameters (bioresorbable vascular scaffold [BVS] and bench model) at 1 and 24 h compared with reference diameters immediately following re-POT. POT = proximal optimizing technique.

Derimay F et al. J Am Coll Cardiol Intv 2016

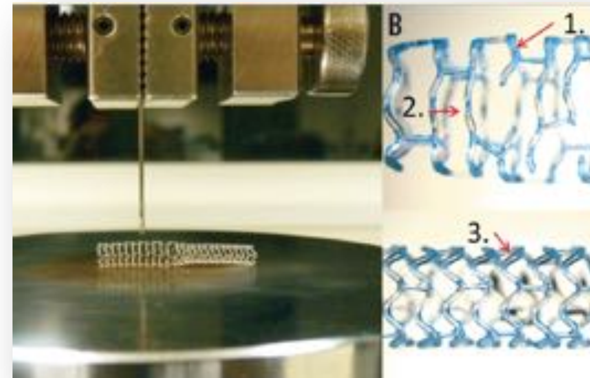
Bioabsorbable vascular scaffold overexpansion: insights from *in vitro* post-expansion experiments

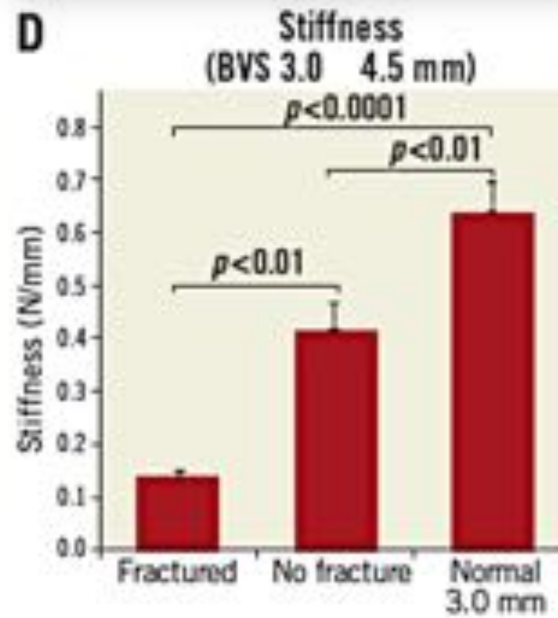
BVS overexpansion without constraining models





Impact of oversizing on focal mechanical support





Foin N et al. EuroIntervention 2015

+ 0.5 mm

≤ 0.5 mm

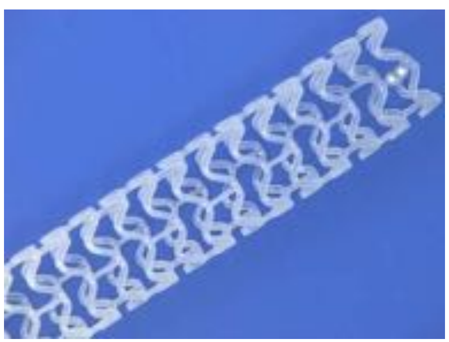
≤ 1.0 mm

≤ 0.5 mm

≤ 1.0 mm

1.04 ring/mm length
190 μm ring wide

0.87 ring/mm length
216 μm ring wide



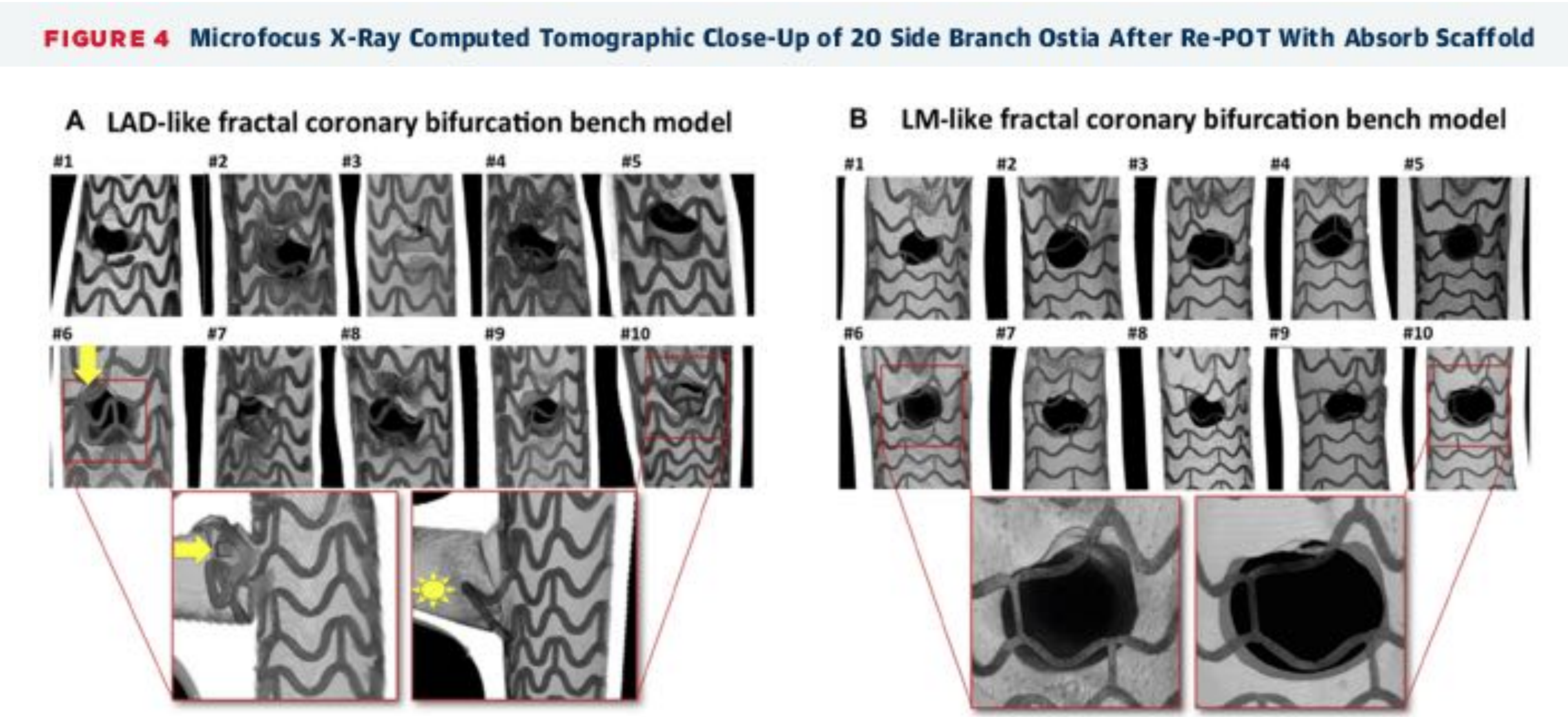
BVS 2.5 mm

BVS 3.0 mm

BVS 3.5 mm

157 μm Strut thickness
3 "peak-to-valley" connectors with 60 offset between rings

Sequential Proximal Optimizing Technique in Provisional Bifurcation Stenting With Everolimus-Eluting Bioresorbable Vascular Scaffold Fractal Coronary Bifurcation Bench for Comparative Test Between Absorb and XIENCE Xpedition



ΔD ($D_{MoV} - D_{MB}$) = 0.41 mm

BVS 2.5 x 24 mm

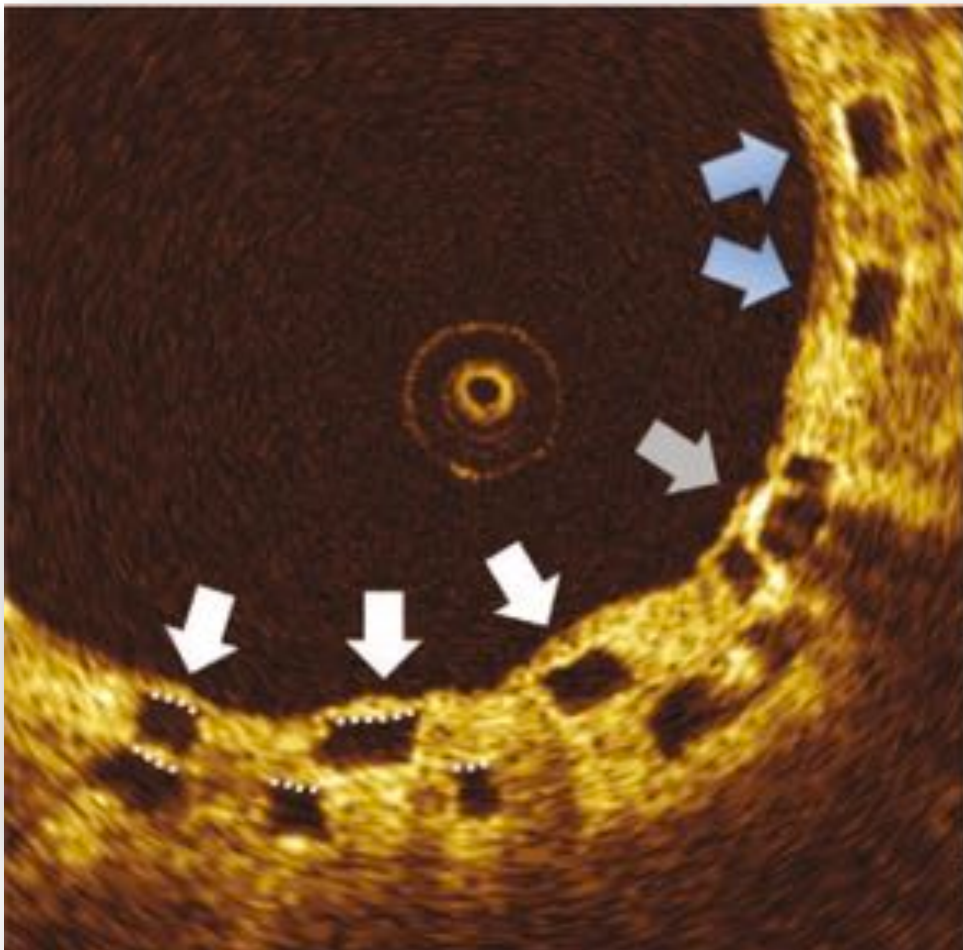
ΔD ($D_{MoV} - D_{MB}$) = 0.84 mm

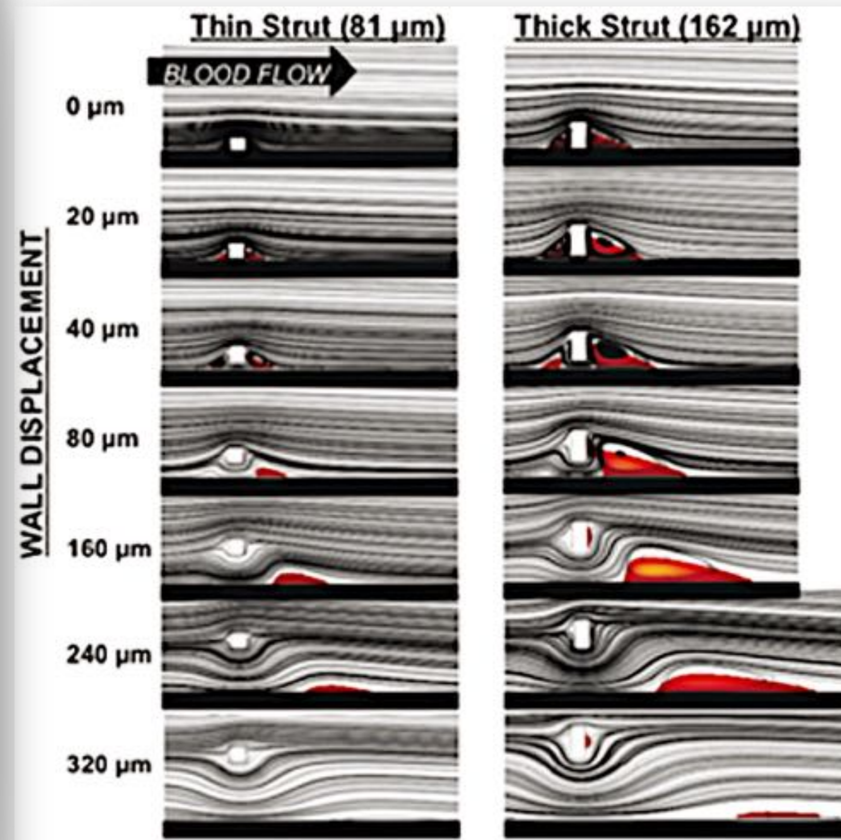
BVS 3.5 x 24 mm

Derimay F et al. J Am Coll Cardiol Intv 2016;9:1397–406

Stent Thrombogenicity Early in High-Risk Interventional Settings Is Driven by Stent Design and Deployment

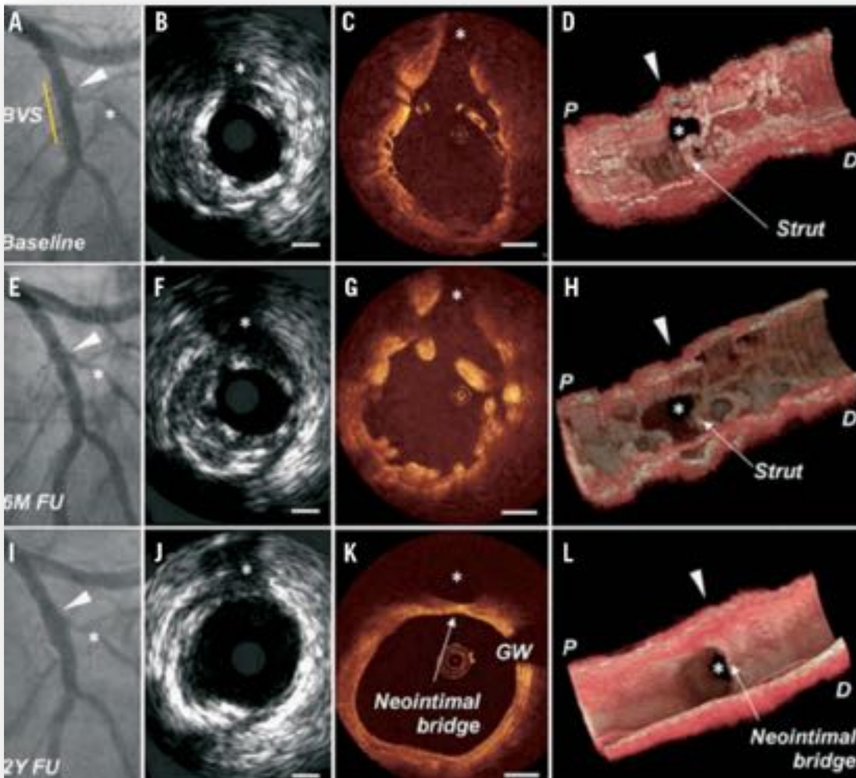
Kolandaivelu et al. Circulation. 2011;123:1400-1409.



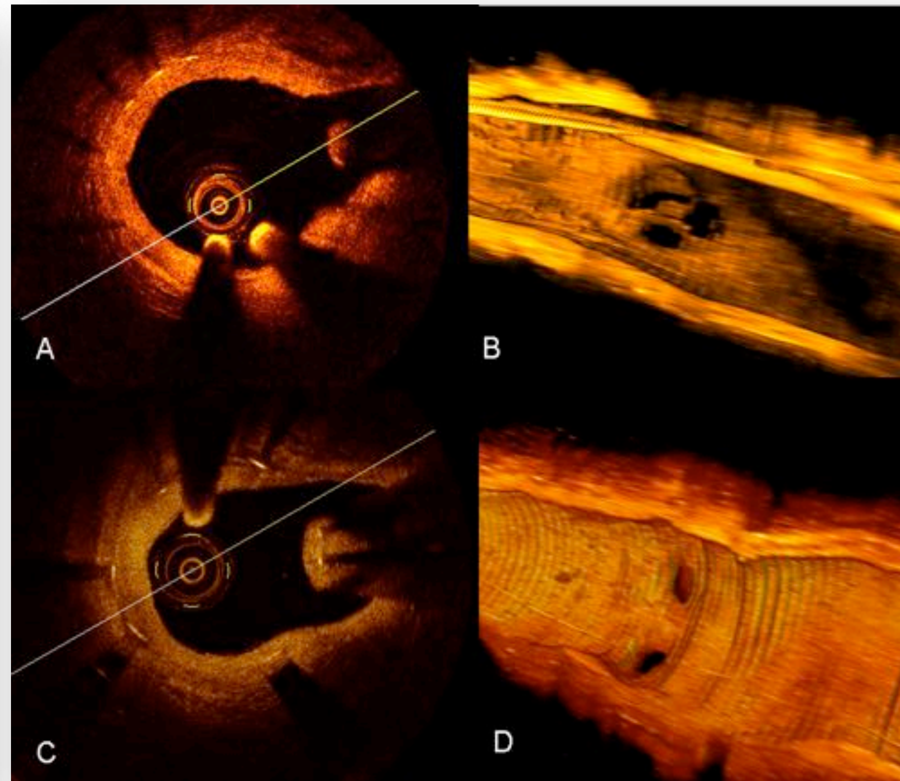


The fate of non-apposed bioabsorbable side branch struts

Neo-intimal bridge and tissue membrane

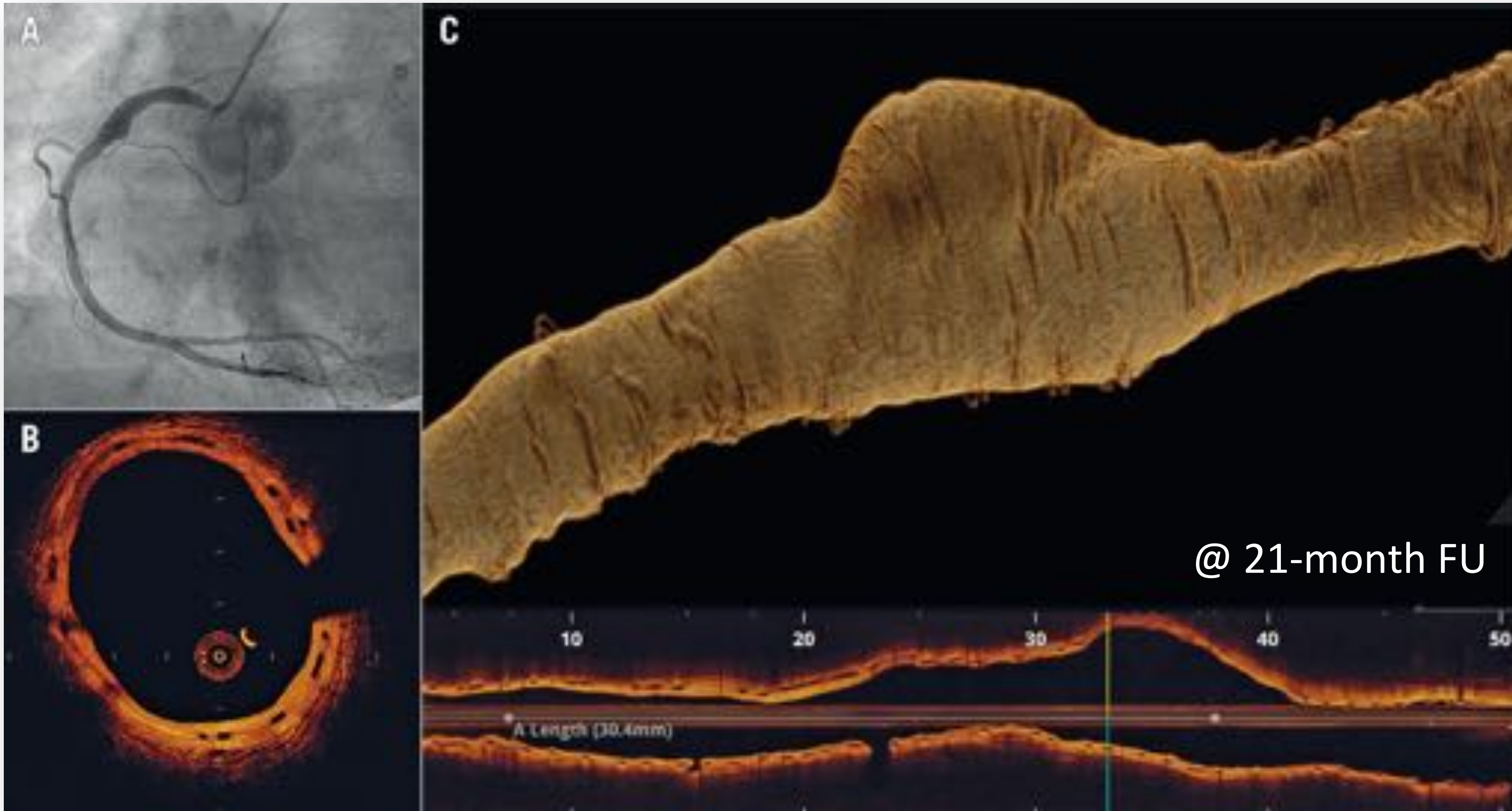


Kraak PR. EuroIntervention 2015;11:V188-V192



Courtesy of Dr Nicolas Foin

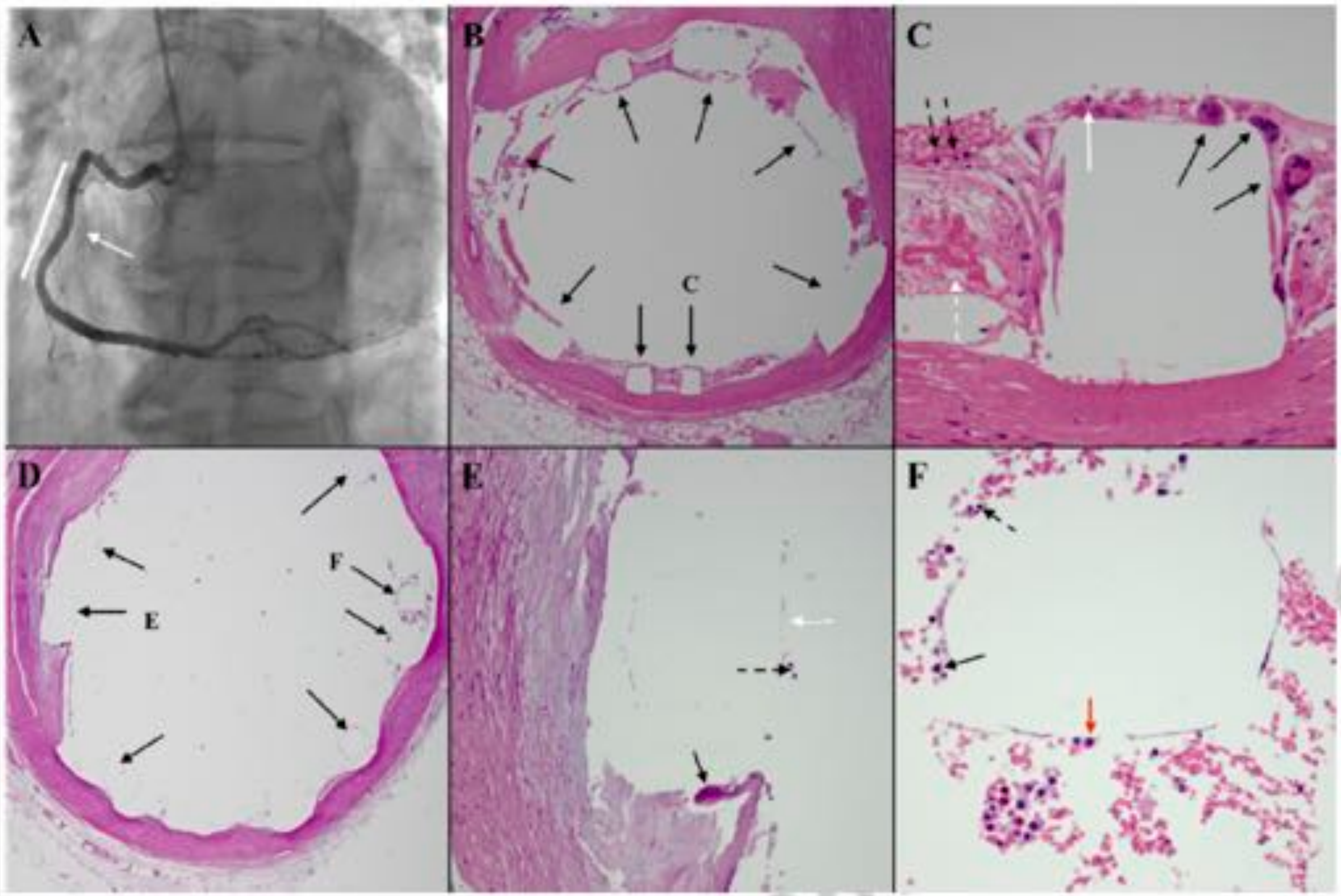
Acquired coronary artery aneurysm following treatment with bioresorbable vascular scaffolds



A 41-year-old female underwent deployment of two bioresorbable vascular scaffolds (BVS) (3.5•28 mm, 3.5•18 mm) (Abbott Vascular, Santa Clara, CA, USA) to a long segment of disease in the right coronary artery (RCA) as a staged intervention to bystander disease following a myocardial infarction. Due to a significant waist post deployment, post-dilation with 3.5•20 mm Pantera (Biotronik, Berlin, Germany) and 3.5•12 mm Quantum Apex™ (Boston Scientific, Marlborough, MA, USA) non-compliant balloons to 18 atm was required.

O'Gallagher K. EuroIntervention 2016;12:1174

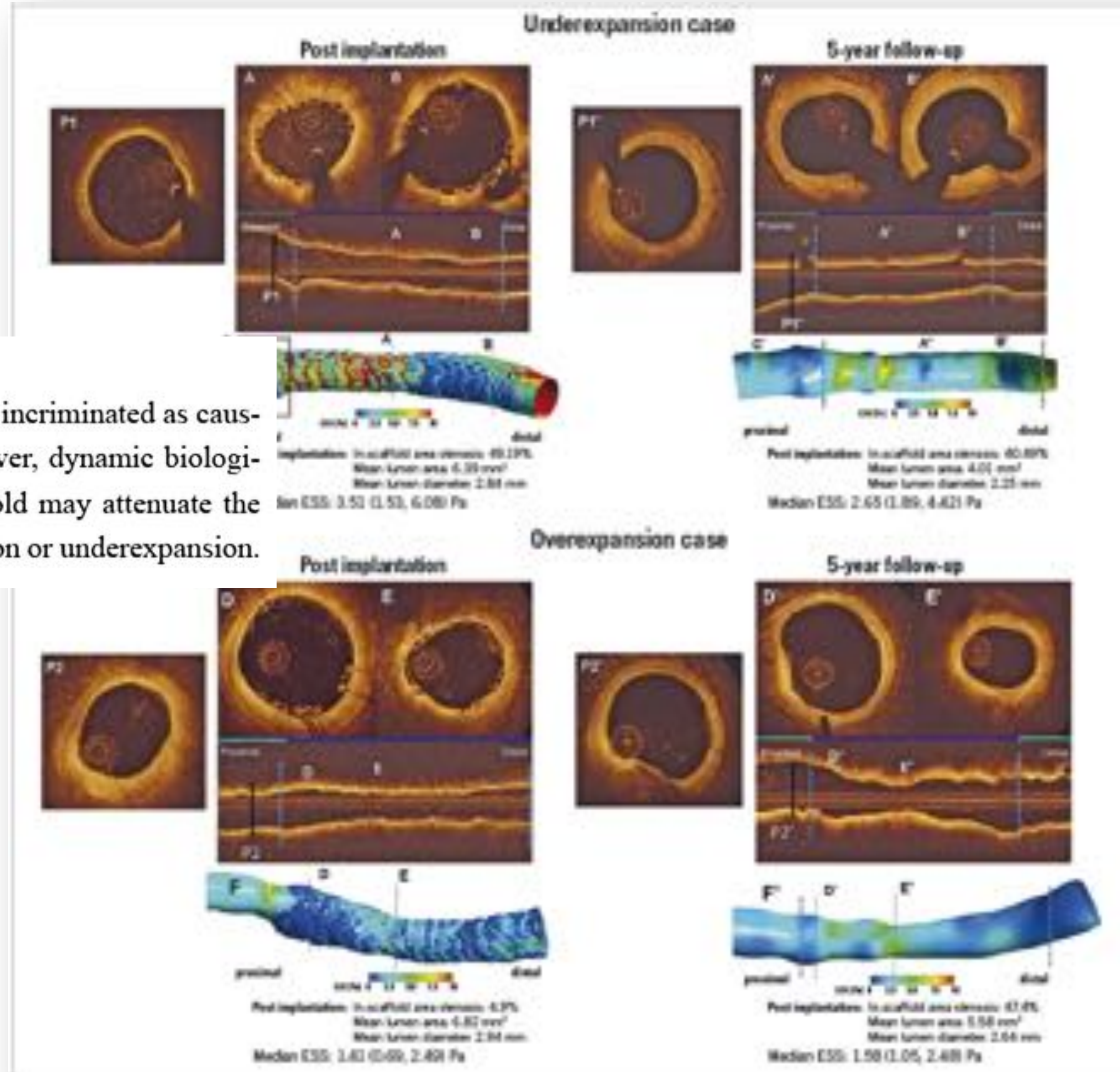
Evidence of acute giant cell reaction post bioresorbable vascular scaffold implantation



Although long-term data exist for the ABSORB BVS, the acute or short-term inflammatory response remains poorly understood. This is the earliest report of foreign body type giant cell reaction to ABSORB BVS in humans.

Schnorbus et al. Eurointervention 2017

Five-year follow-up of underexpanded and overexpanded bioresorbable scaffolds: self-correction and impact on shear stress



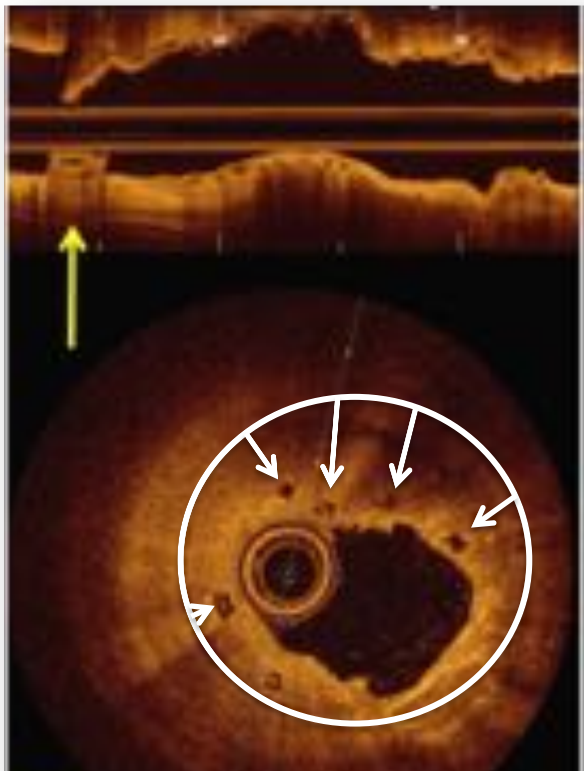
Practical implication

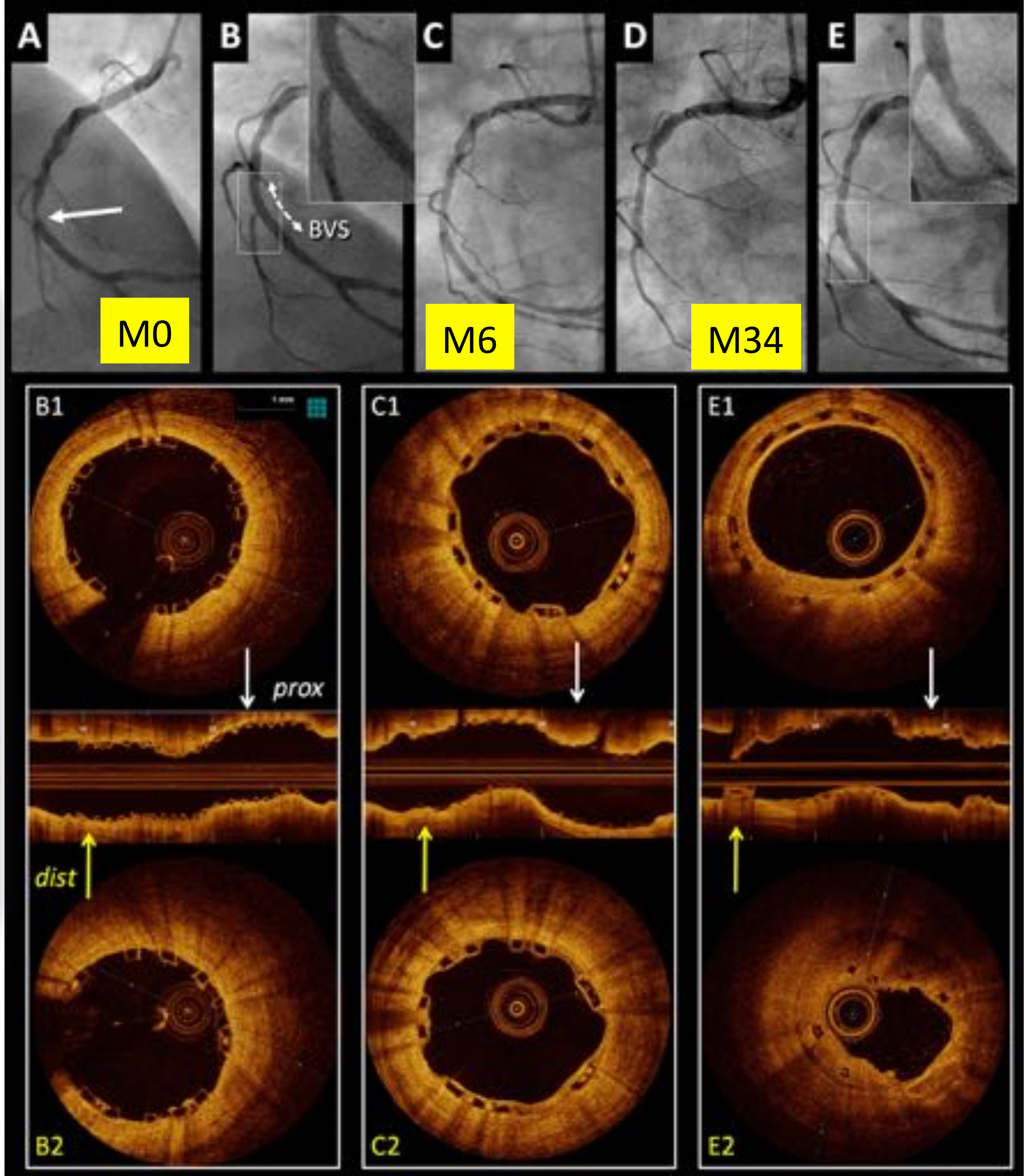
Underexpansion and overexpansion have been incriminated as causative factors of adverse cardiac events. However, dynamic biological interaction between vessel wall and scaffold may attenuate the adverse haemodynamic impact of overexpansion or underexpansion.

Torii et al. EuroIntervention 2017;12:2158-2159

Late BVS collapse

Scaffold dismantling





Courtesy of:
Dr G. Souteyrand
Pr. P. Motreff

Summary

1.	Patient’s preference not to have a permanent implant	*irrelevant*
2.	Allows non-invasive monitoring by coroscanner	**Yes** *(irrelevant)*
3.	Facilitates subsequent treatment with new stents	**Yes**
4.	Restoration of epicardial vasomotor activity	**No**
5.	Less late thrombosis (no chronic inflammation)	**No**
6.	Allows positive arterial remodeling	**No**
7.	Significantly superior clinical benefit	**No**

Ormiston J. Circulation Intervent 2009;2:255.

« Do the job ???... »

Poor mechanical properties

⇕

Scaffold underexpansion during implantation

« … and disappear ??? »

Late scaffold dismantling
(intraluminal scaffold collapse)

⇕

High late thrombosis