CARDIOVASCULAR SUMMIT

TCTAP 2015

April 28-May1 , 2015 Seoul. Korea

Bioaresorbable Vascular Scaffold (BVS) for Bifurcation PCI

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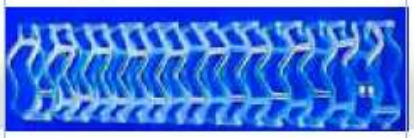
BVS Undergone Clinical Evaluation

Company / Device	Design of the biorsorbable device	Strut thickness, (μ m)	Polymer / Drug	Absorption time	Late loss, (mm)
Kyoto Medical/ Igaki-Tamai		170	PLLA	2 years (y)	0.48 (6m)
Biotronik / DREAMS		125	Mg alloy (AMS-4) / sirolimus	4 to 6 months (m)	0.68 (6m)*
Abbott / ABSORB BVS		150	PLLA / everolimus	2y	0.19 (6m)
Reva Medical / ReSolve		200	Tyrosine poly carbonate with iodine / sirolimus abluminal	2y	1.81 (6m)
-/ BTI		200	Salicylic acid into polymer (PLA or adipic acid) / sirolimus	6m	NA
Elixir / DESolve		150	PLLA / novolimus	1 to 2y	NA

Potential Advanteges :

- The “liberation” of the treated vessel from its “metallic cage” and the subsequent reactivation of the physiological processes of vasomotion, vascular remodelling and late lumen enlargement.
- The potential elimination/integration into the vessel wall of the polymeric struts from jailed side-branches after the completion of the bioresorption process.
- The superior conformability and flexibility compared to conventional metallic stents, thereby leading to a less altered distribution of the tissue biomechanics and preservation of the vessel geometry.
- The potential long-term beneficial edge vascular response.
- The elimination of the late acquired or persistent malapposition, which has been implicated in causing thrombotic events with conventional metallic devices.

Side branch jailing &BVS

- **The SB jailing during provisional T-stenting with the BVS seems to have a benign behaviour compared to metallic stents.**
- **At 2-year follow up post BVS implantation, the polymeric struts disappear at the side branch ostium, with evidence of integration into the underlying tissue and, in some cases, causing a membranous neocarina.**
- **Feasibility of crossing the polymeric struts of the BVS using 3D OCT**

Okamura T, et al . Eur Heart J. 2010; 31: 2179.
Gogas BD et al JACC Cardiovasc Interv. 2011; 4:1149-1150.
van Geuns RJ et al Int J Cardiol. 2011; 153: e43-45.

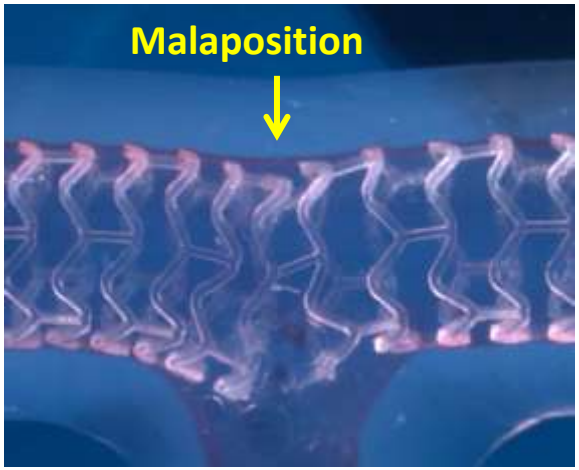
Limitations

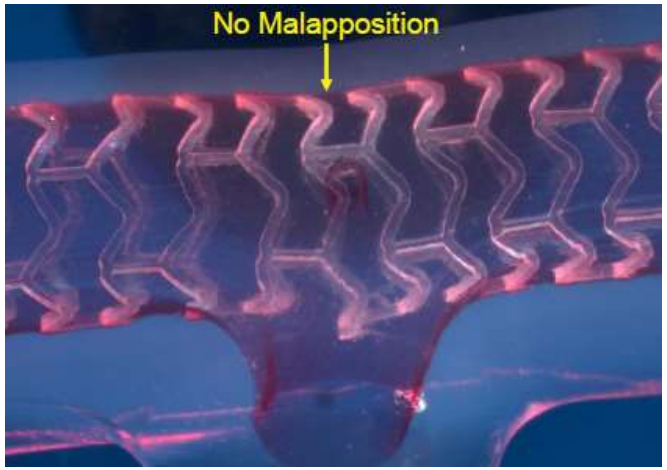
- Limited expansion
- Reduced radial strength
- Possible fracture
- Strut thickness

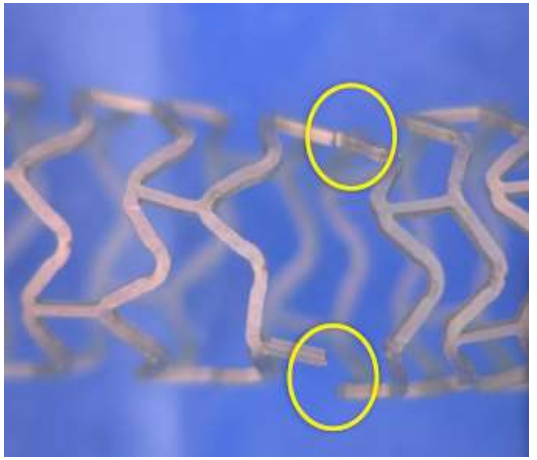
BVS in Bifurcation

2.5 mm balloon in side branch taken to nominal pressure

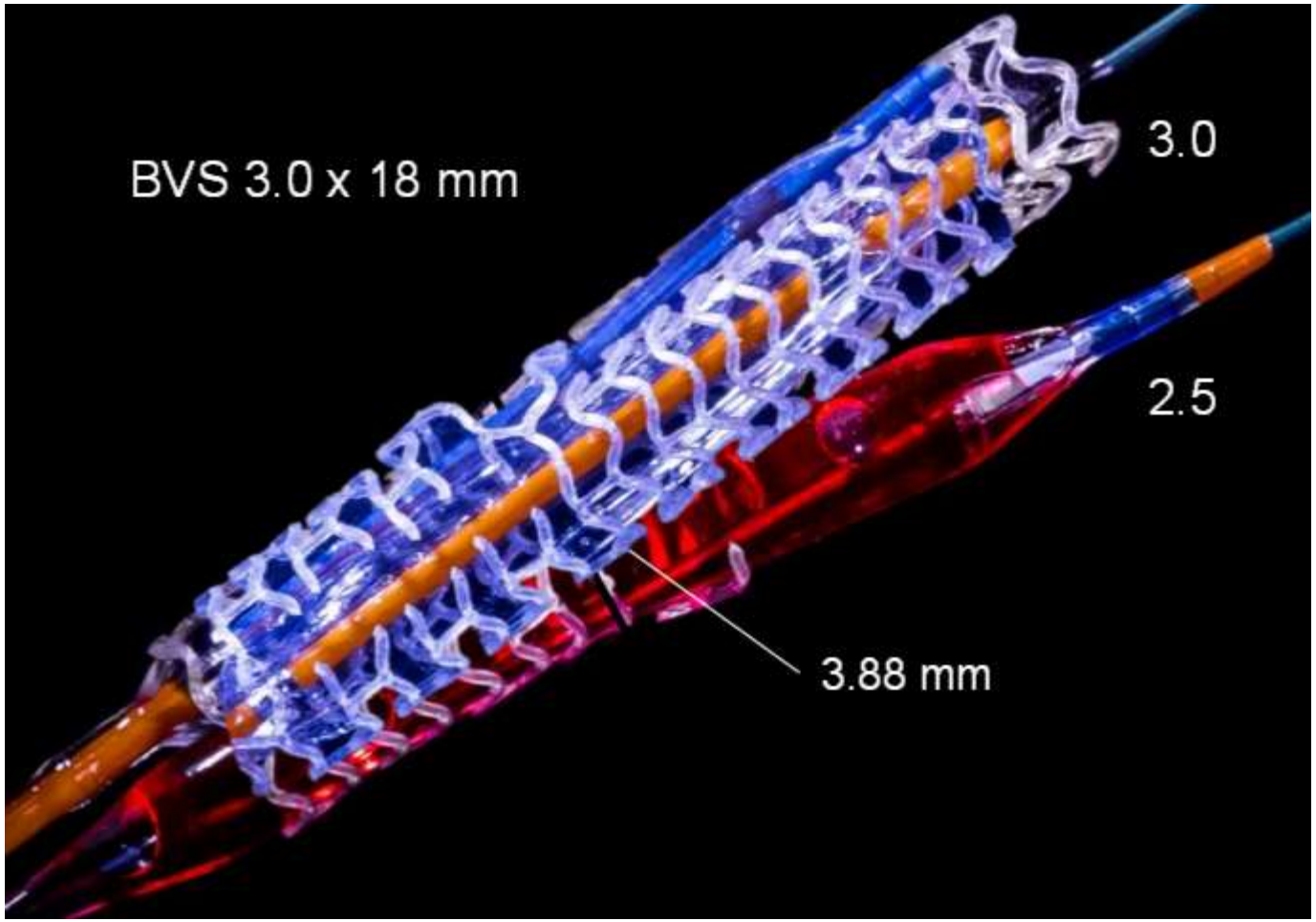
2.5 mm balloon in side branch taken to nominal pressure, deflated, then 3.0 x 18 mm delivery system balloon taken to 16 atm for post-dilatation







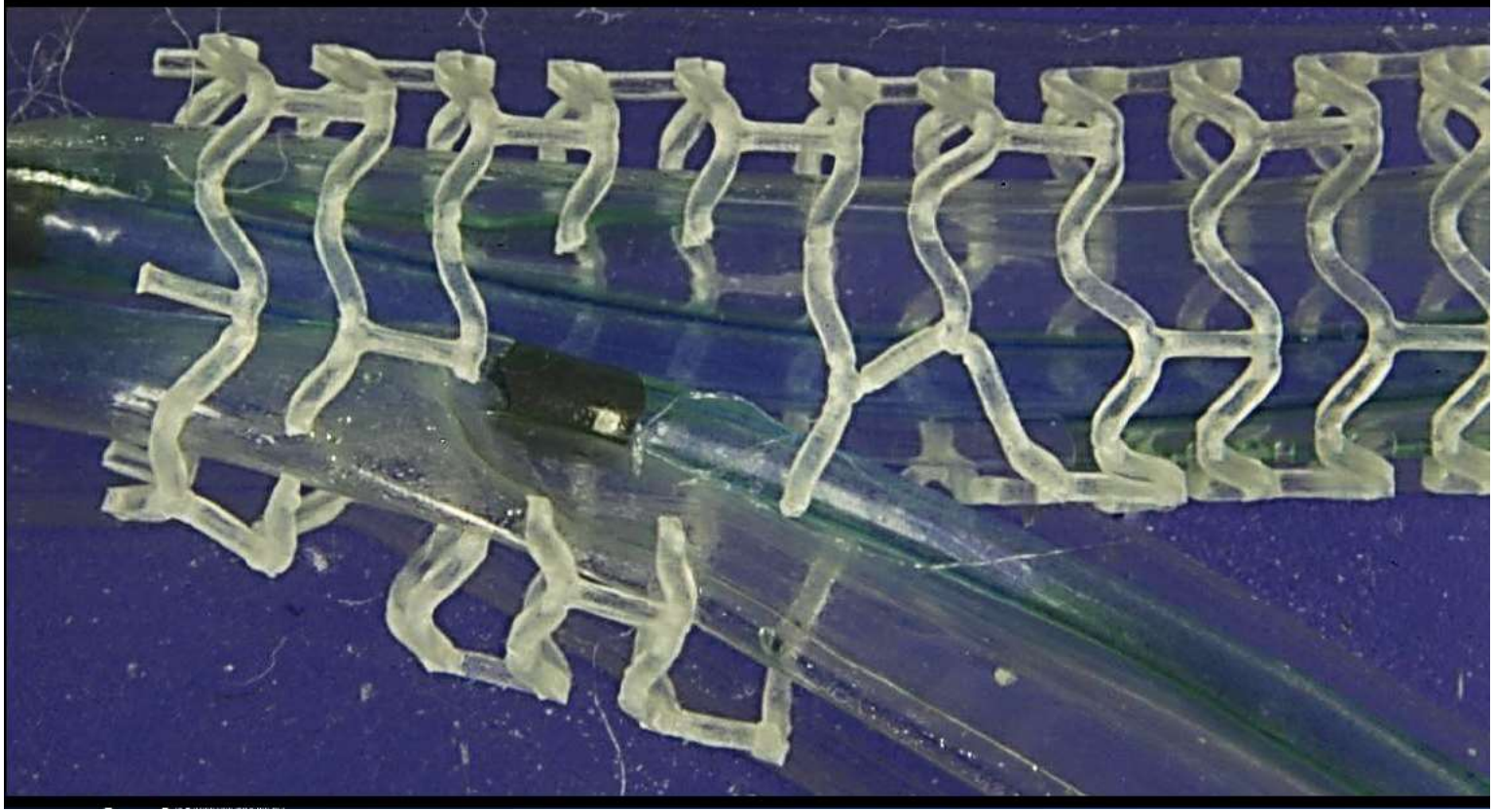
BVS in Bifurcation



After Kissing balloon

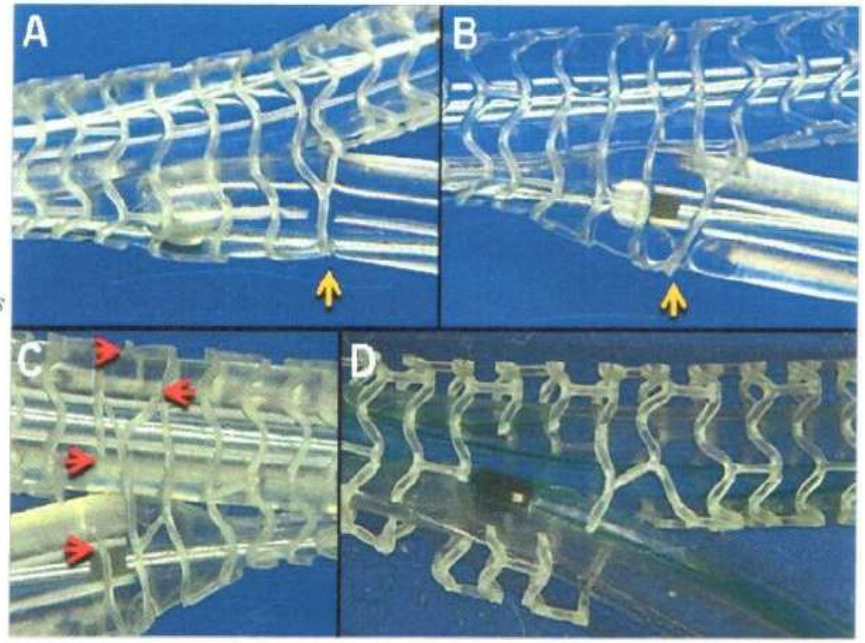
BVS in Bifurcation

Pressures above the safe threshold will cause strut fractures with possible severe scaffold disruption



BRS; Risk of strut fractures

Figure 4. *Mini-KBPD at low (5 atm) and high (>15 atm) balloon pressures. Panel A is a photograph of mini-KBPD with 3.0 mm NC balloons inflated slowly to 5 atm in a 3.0 mm Absorb scaffold showing that there were no strut fractures. The yellow arrow indicates a strut that is restraining balloon expansion at this pressure. In panel B, the simultaneous balloon inflation pressure was increased to 15 atm in the same scaffold. The SB balloon had prolapsed forward ("melon seeding") and the scaffold strut no longer restrained balloon expansion because, as shown in panel C, struts had fractured (red arrows). The photograph D shows a scaffold severely damaged by high-pressure mini-KBPD with multiple fractures.*

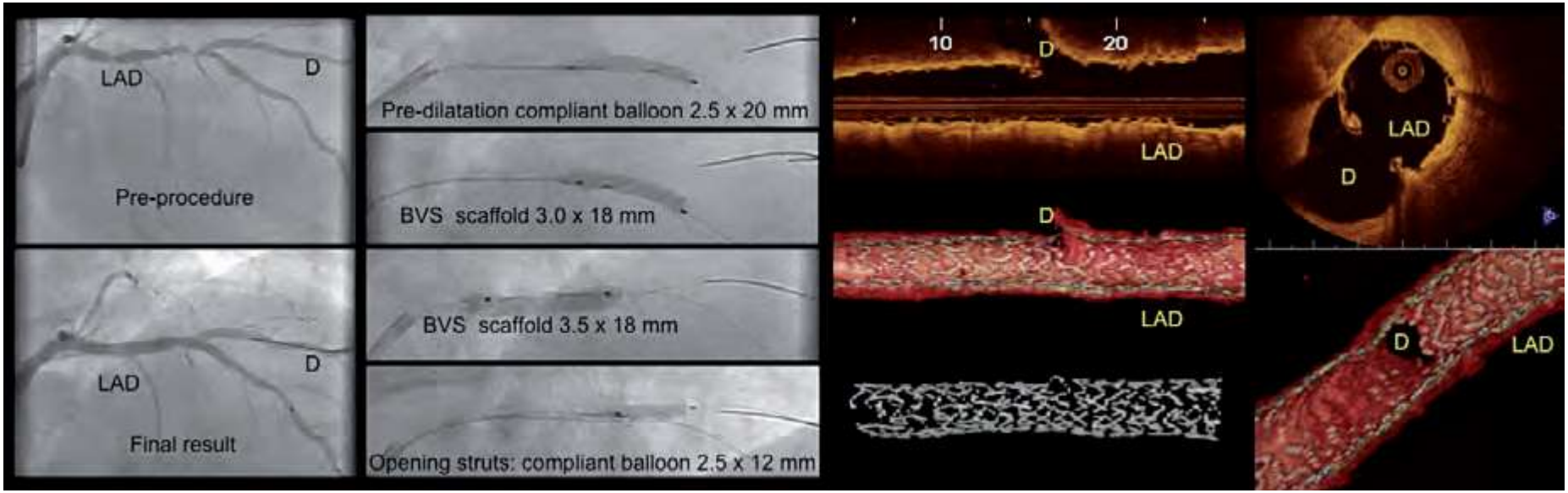


Ormiston et al. EuroIntervention; 2014, may: 10 online (published ahead of print)

Clinical Data ?

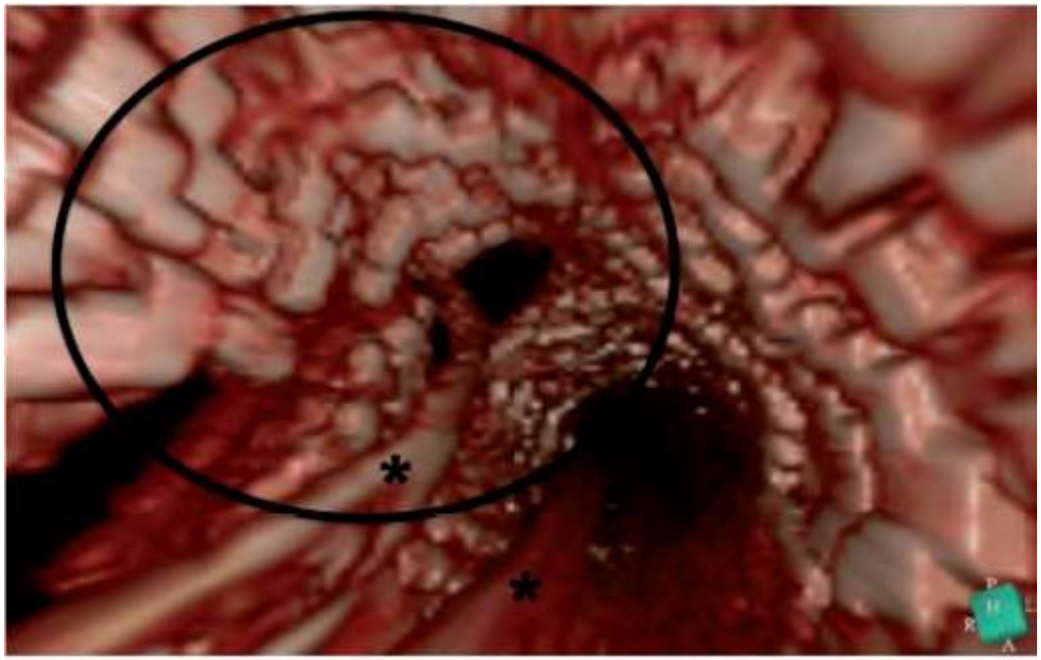
Bifurcation Lesion Treated with Provisional One-scaffold Approach

The main vessel (left anterior descending) is treated with two bioresorbable vascular scaffolds (BVS) (3.0 x 18.0 mm at the site of the bifurcation and 3.5 x 18.0 mm proximally. The ostium of the side branch is re-crossed and ballooned with a 2.5 x 12.0 mm balloon. The good final angiographic result is confirmed by two- and three-dimensional optical coherence tomography (OCT).



R Diletti and N M Van Mieghem*Interventional Cardiology Review*, 2013;8(2):93–5

Three-dimensional Optical Coherence Tomography Reconstruction of the Carina Treated with a Two-scaffold Culotte Technique



*The ostium of the side branch (within the light blue circle) illustrates the multiple scaffold layers with complete coverage of the carina. *coronary guidewire in the mother branch and side branch. I*

mage courtesy of Robert-Jan van Geuns.

BVS in Bifurcation

Milan Experience in BVS in Bifurcation lesions

	Bifurcation number (n = 64)	Utilized technique		Stent type		FKBI
				Main branch	Side branch	
Single-stenting	52	-		BVS	-	7
Double-stenting as a crossover from provisional strategy	1	TAP		BVS	DES (BVS could not pass through MB-BVS strut)	0
Systematic double-stenting	11	7 T-stenting	6	BVS	BVS	2
			1	BVS	DES	0
		4 mini-crush	2	BVS	BVS	1
			2	BVS	DES	0
Stenting only at SB-ostium	5	-		-	BVS	0

A. Latib , EBC meeting ,

Provisional T Stenting with BVS

Clinical data n=26	
Age, years	59 ± 12
Male gender	22 (85)
Hypertension	12 (48)
Diabetes mellitus	6 (23)
Hypercholesterolemia	12 (48)
Current smoking	15 (60)
Unstable	22 (85)
Multivessel disease	8 (30)
Left ventricular EF	63 ± 13

Data are expresed as n (%)

Baseline angiographic data n=26		
Location of the lesion, n (%)		
LAD-Dg LCx-Cx RCA	17 (65) 6 (23) 3 (12)	
Type of lesion, n (%)		
{1,1,1} {1,1,0} {1,0,1} {0,1,1} {1,0,0} {0,1,0} {0,0,1}	11 (42) 6 (23) 0 (0) 5 (19) 2 (8) 2 (8) 0 (0)	{_,_,1} 16 (61%)
QCA	**Main vessel**	**Side branch**
Lesion length, mm	21.9 ± 8.30	4.8 ± 2.1
Prox. reference diameter	2.97 ± 0.37	2.42 ± 0.3
Distal reference diameter	2.53 ± 0.38	
MLD, mm	1.13 ± 0.61	1.38 ± 0.41
DS,%	62 ± 19	42 ± 16

*BVS diameter was selected according to proximal vessel diameter

A. Medina , EBC Meeting , London ; 2013

Provisional T Stenting with BVS

Primary success (one patient needed SB stenting)	100%
IN HOSPITAL	**KB n=26**
Non-Q-wave MI	1 (4%)*
Death	0
Sub-acute BVS thrombosis (PAMI)	1 (4%)
FOLLOW-UP (7 ± 3 months)	
Recurrent infarction	0
Death (all causes)	0
Need of TLR	0
BVS thrombosis	0
Total MACE	**2 (8%)**

* troponin elevation within 48 h post-procedure of 5 ULN with either symptoms of myocardial ischemia, new ischemic ECG changes, or documented complications during the procedure

Angio-CT was performed at follow-up (n = 25). No restenosis

Medina 0,0,1 Bifurcation -BVS

Vessel / Lesion characteristics	N = 8
DIA	2
Ostial Cx	3
OM	3
Calcification (moderate/heavy)	3
Vessel reference diameter	2.7 ± 0.2 mm
Lesion length	11.2 ± 6.0 mm
Diameter stenosis	75.8 ± 13.4 mm
Scaffold diameter	2.9 ± 0.4 mm
Scaffold length	21.3 ± 4.7 mm
IVUS / OCT	4

BVS in Bifurcation

4-month Cinical FU

n=43	Discharge – end of FU
All cause death	1
Cardiac death	0
Myocardial infarction	0
Target lesion revascularization	0
Target vessel revascularization	0
Stent thrombosis (any as of ARC)	0
Target vessel failure	0

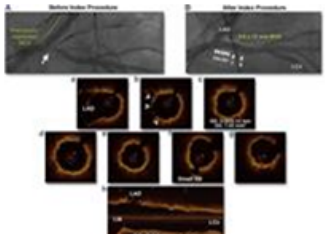
M Lesiak , Poznan, Poland
at EBC Meeting , London

JACC Journals
[JACC: Cardiovascular Imaging] Volume 7, Issue 8, August 2014

Delayed Disruption of a Bioresorbable Vascular Scaffold

Toru Naganuma, MD; Azeem Latib, MD; Vasileios F. Panoulas, MD; Katsumasa Sato, MD; Tadashi Miyazaki, MD; Antonio Colombo, MD
J Am Coll Cardiol Img. 2014;7(8):845-847. doi:10.1016/j.jcmg.2014.01.021

A 59-year-old man underwent percutaneous coronary intervention for a focal lesion at the ostium of the left circumflex artery (LCX) with a 3.5 × 12.0 mm everolimus-eluting Absorb bioresorbable vascular scaffold (BVS) (Abbott Vascular, Santa Clara, California). This was followed by post-dilation with a 3.5-mm double-layered OPN NC (SIS Medical AG, Winterthur, Switzerland), which allowed super high-pressure dilation (presumed balloon diameter: 3.85 mm at 30 atm) (Figure 1ab). Post-procedural optical coherence tomography (OCT) showed excellent results without evidence of scaffold disruption (Figure 1ab). At 6 months, the patient underwent repeat coronary angiography due to recurrence of exertional angina. This showed severe focal restenosis of the BVS at LCX ostium (Figure 1ab). The OCT revealed significant neointimal hyperplasia within a disrupted (Figure 1ab) and severely recoiled scaffold (reduction in scaffold area from 7.45 mm^2 to 5.01 mm^2 in Figure 1ab). Because of a concomitant significant lesion at distal left main artery ([LM]; lumen area: 3.98 mm^2), the T-stenting technique was successfully performed with a 3.5 × 18.0 mm BVS from the LM into the left anterior descending artery and a 3.0 × 12.0 mm drug-eluting stent in the LCX ostium.



BVS in Bifurcation

Early (before 6 months), late (6-12 months) and very late (after 12 months) angiographic scaffold restenosis in the ABSORB Cohort B trial

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GUEST EDITOR: **Rafael Beyar, MD, DSc, MPH, Director**, *Rambam Health Care Campus, Women's Division/Dr Phillip and Sara Gotlieb Chair, Department of Medicine and Biomedical Engineering, Technion, Israel*

KEYWORDS

- bioresorbable scaffold
- everolimus
- intravascular imaging
- long-term follow-up
- restenosis

Abstract

Aims: The long-term follow-up of the first-in-man ABSORB Cohort B trial showed that angiographic binary restenosis can occur early, late or very late after implantation of the Absorb everolimus-eluting bioresorbable vascular scaffold (Absorb BVS). Since the mechanical support of the scaffold decreases during bioresorption, the mechanism of in-segment restenosis (ISR) of the Absorb BVS might be different from that of metallic stents. The objective of the current analysis was to review the multimodality imaging of cases with binary restenosis to elucidate the mechanism of ISR after Absorb BVS implantation.

Methods and results: The ABSORB Cohort B trial enrolled 101 patients with a maximum of two *de novo* coronary lesions. At the three-year imaging and clinical follow-up, there were six cases of in-segment binary restenosis: two early ISR (<6 months), one late ISR (6-12 months) and three very late ISR (>12 months). Three of these ISR cases seemed to be induced by anatomical or procedural factors. In the other three cases, intravascular imaging (IVUS/OCT) demonstrated that the main mechanism of restenosis was significant intra-scaffold tissue growth, while the structural circularity and diameter of the scaffold were not affected.

Conclusions: Early and late restenosis after implantation of the Absorb bioresorbable scaffold could be related to anatomical or procedural factors. In this small cohort of patients late or very late restenosis seems to be attributed to pure intra-scaffold tissue growth without extrinsic encroachment of the scaffold.

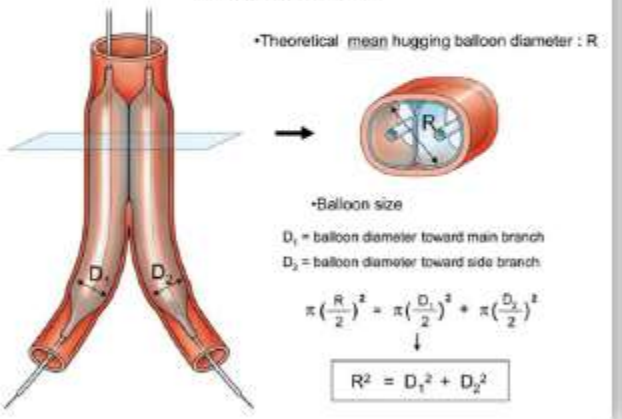
From the company :

ABBOT Recommendations for the BVS ABSORB

DO NOT PERFORM THIS TECHNIQUE!

- Simultaneous balloon inflations will cause mechanical disruption of proximal scaffold rings, if kissing balloons are over-sized
- Mechanical Disruption of Ring = *impact* radial strength
- Mechanical Disruption of Link = *no impact* on radial strength

Mitsudo Formula



Example:

D_1 = 3.32 mm — Main Branch Balloon

D_2 = 2.81 mm — Side Branch Balloon

R = 4.36 mm — Kissing Balloons

SEVERE OVER-EXPANSION

Morino, Y., et al. *Circ J.* 2008; 72: 886-892.

*Kissing balloon technique is considered off-label and techniques referenced must be indicated by physician only.

Abbott Vascular

Final Remarks

- **Bench tests on BVS in bifurcations confirm the fragility of the device. Damage or fracture of the stent can occur easily**
- **Need to lear more if *connection fracture* may impact the outcome.. Surely *stent integrity is important;***
- **In case of use BVS for bifurcation treatment (off label Use) be *extremely cautious* when crossing the struts and in selecting the device (wires, balloon m stents…) the strategy, follow the guidelines for BVS implantation, keep it easy (no need for complex procedures).**
- **Clinical data on BVS in bifurcation are very limited and do not allow to draw conclusions, Need for more solid data**