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A randomized trial comparing two stent sizing strategies in coronary bifurcation treatment with bioresorbable vascular scaffolds – The Absorb Bifurcation Coronary (ABC) trial

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ABSTRACT

Background: Limited information is available on the use of Bioresorbable Vascular Scaffold (BVS) in bifurcations involving significant side branches. When treating bifurcation disease with metal stents, the recommendation is to choose a stent diameter based on the distal main vessel diameter. Whether this sizing strategy is applicable to BVS is currently unknown.

Methods: We randomised 37 patients undergoing elective PCI for 'false' bifurcation disease (Medina 0,1,0; 1,0,0; 1,1,0) to receive BVS based either on proximal or distal reference diameters. Optical Frequency Domain Imaging (OFDI) measurements were performed pre BVS insertion to obtain proximal and distal reference diameters and post implantation. BVS size was chosen according to the proximal or distal reference diameter as per randomisation. Implantation was performed using the PSP technique tailored to bifurcation stenting. OFDI was repeated post implantation to confirm satisfactory expansion and apposition.

Results: Baseline demographics between the two groups were similar. Patients were aged 62.8 ± 3.3 years; 76% were male. Mean side branch diameter was 2.24 ± 0.13 mm. TIMI III flow in the main vessel was achieved in all cases. Side branch occlusion occurred in 1 case (2.7%). In the distal-sizing arm, there was a greater incidence of significant malapposition (>300 μm) at the proximal end of the scaffold on OCT (2.3% versus 0.8%, p 0.023). The incidence of distal edge dissections was numerically greater in the proximal-sizing group but this was not statistically significant (31.3% vs 11.8%, p 0.17).

Conclusion: Both proximal and distal sizing strategies have similar procedural complication rates when using the ABSORB BVS to treat coronary bifurcations. However a proximal sizing strategy is associated with less malapposition and may be preferable.

1. Introduction

Bifurcation lesions are present in 15–20% of patients undergoing PCI [1]. Despite their fairly common frequency, clinical outcomes remain unsatisfactory. Major adverse event rates range between 3 and 15% [2]. The provisional strategy is now widely accepted as the bifurcation technique of choice but metal caging of a sizeable side branch (SB) can obstruct blood flow resulting in myocardial ischaemia [3]. The emergence of bioresorbable technology has provided a new treatment option. Potential benefits include late unjailing of the side branch and restoration of the bifurcation anatomy after complete resorption. Randomised controlled trials have excluded patients with reasonably sized SB (>2 mm in diameter) [4,5].

Choosing the right size of bioresorbable vascular scaffolds (BVS) for bifurcation stenting is crucial to avoid complications. With metal stents, it is generally recommended to choose the stent size according to the distal vessel diameter and to perform the proximal optimisation technique to ensure good apposition at the proximal end [6]. However bioresorbable scaffolds are more delicate devices. Aggressive dilatation beyond the recommended limits can easily fracture hoops and connectors. This is particularly relevant in bifurcations where there can be a sizeable discrepancy between the proximal and distal diameters. In suitable anatomies, another strategy is to select the scaffold according to proximal MV diameter and to deploy at low pressure in order to avoid damaging the distal vessel, followed by adequate post-dilatation of the proximal segment. Which of these two strategies is better when using BVS is currently unknown.

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2. Methods

2.1. Study design and population

The ABC one trial was a single centre, randomised comparison of two sizing strategies when using the ABSORB BVS for the treatment of 'false' bifurcation disease. The trial included patients who required elective percutaneous coronary intervention for stable angina or were listed for staged PCI following previous coronary angiography. The inclusion criteria was the presence of 'false' bifurcation disease (Medina type 1,1,0 or 1,0,0 or 0,1,0) with >70% stenosis in the main vessel and a side branch diameter > 2 mm on visual assessment. Major exclusion criteria were acute presentation either with unstable angina or acute coronary syndrome, bifurcation disease involving the left main stem and chronic total occlusion of either the main vessel or side branch. The clinical investigational plan, consent form and all amendments to these study documents were reviewed and approved by the South East Coast (Brighton and Sussex) Research Ethics Committees (REC). Patients were recruited at the Royal Sussex County Hospital between February 2016 and March 2017. Patients who fulfilled the inclusion and exclusion criteria and consented to the study were randomised in randomly permutated blocks of randomly varying lengths [2,4,6]. Fig. 1 charts the progress of patients through the phases of the randomised trial.

2.2. Definitions

The primary end point was defined as the successful placement of the BVS with <50% residual stenosis and TIMI III flow in both the main vessel and side branch at the end of the procedure (procedural success). Device success was defined as a final diameter stenosis of <50% in the scaffolded segment by Quantitative Coronary Angiography (QCA). The secondary endpoints included the degree of malapposition, geometrical distortion and presence of edge dissections on Optical Coherence Tomography (OCT) at the end of the procedure. A strut was considered to be malapposed if its outer border was not in contact with the vessel wall. Malapposition was considered to be significant if the perpendicular distance between the midpoint of the abluminal edge and the vessel wall was >300 μm. The Eccentricity Index (EI), defined as the ratio between the minimum and maximal diameter of the scaffold within a single frame, was used to assess scaffold distortion. An edge dissection was defined as a breach of luminal surface present within 5 mm of the scaffold edge. It was considered to be major if additional stenting was required.

2.3. Procedure

All patients had dual antiplatelet treatment prior to the procedure. The decision to insert a wire in the side branch was left at the discretion of the operator. Pressure wire measurements were performed before pre-dilatation. Lesion preparation was then undertaken using a balloon sized to the distal reference vessel in order to avoid excessive wall injury distally. OFDI was performed to obtain the diameter of the proximal and distal main vessel. The operator was informed of the randomisation strategy and the appropriate size of BVS was chosen. The scaffold was deployed progressively according to standard manufacturer recommendations. Following insertion of the BVS, the proximal optimisation

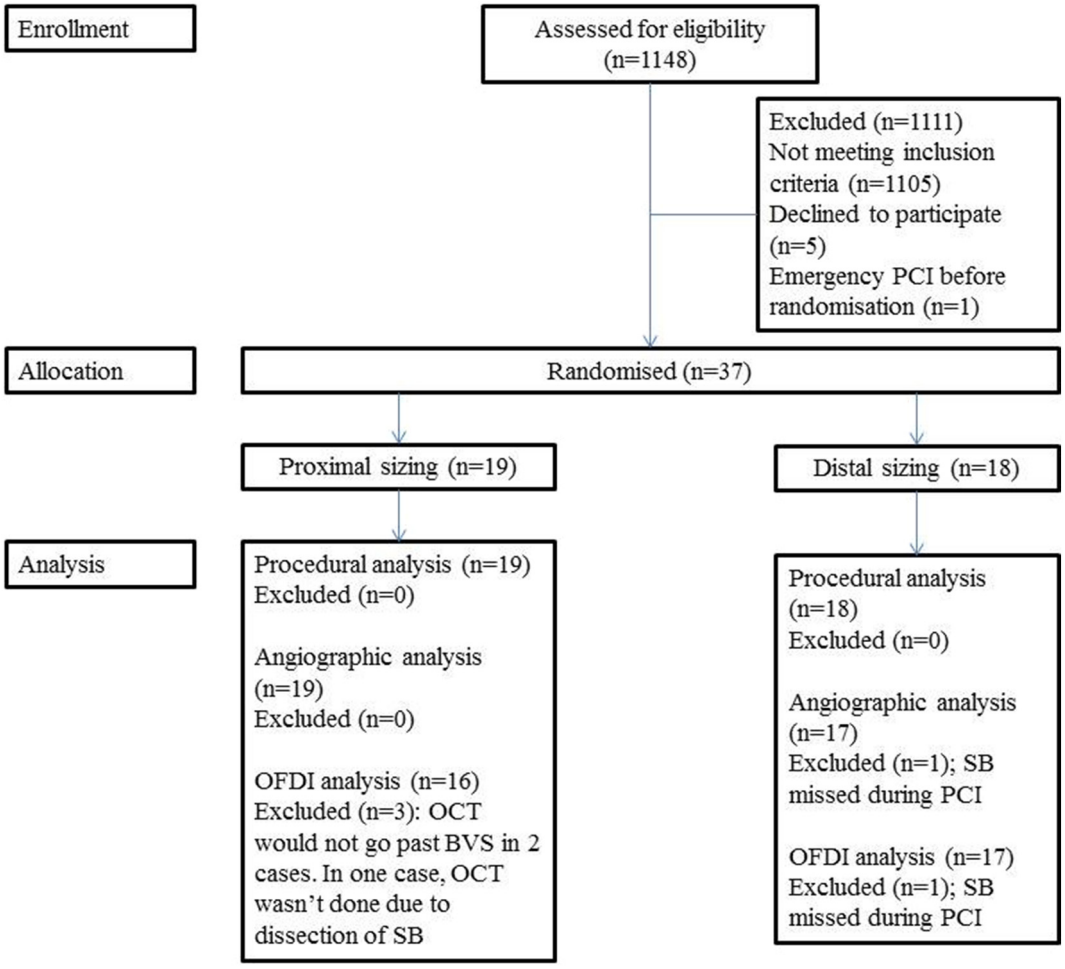

Fig. 1. Patient flow diagram.

technique (POT) was performed with a non-compliant (NC) balloon. Post dilatation of the distal portion of the scaffold was performed with a NC balloon of the same diameter as the distal vessel. If the side branch was not compromised, this marked the end of the stenting procedure. In case of SB compromise after POT, the first line strategy was to open the cell at the ostium of the side branch using an undersized NC balloon (<2.5 mm). POT was then repeated with a larger balloon in the proximal main vessel. Routine Final Kissing Balloon Inflation (FKBI) was not recommended but mini-FKBI ('snuggle balloon dilatation') with minimal overlap was performed if deemed necessary. Stenting of the side branch or conversion to complex 2 scaffold strategies were to be utilised only as bail-out. An OFDI pullback was performed in the main vessel to confirm adequate strut apposition and exclude major dissections. In case of significant malapposition, further inflation with either larger balloons and/or higher pressures was performed. Any correction was followed by another OFDI run to confirm satisfactory resolution of complications. Pressure wire measurements were repeated before final angiographic pictures. The pressure wire measurements formed part of a substudy of this trial and are not reported in this study.

2.4. Angiographic assessment

QCA analysis was performed offline using the Cardiovascular Angiography Analysis System (CASS; Pie Medical Imaging, Maastricht, Netherlands). Measurements were done in end-diastolic frames. The scaffolded segment was analysed in matched angiographic views before and after the interventional procedure. The following parameters were computed: proximal and distal main reference vessel diameter (RVD), lesion length, minimum luminal diameter (MLD) and diameter stenosis (DS) of both the main vessel and side branch. The in-stent parameters are reported at after scaffold implantation. Three dimensional reconstruction of the bifurcation was performed and the bifurcation angle, defined as the angle between the SB and distal segment of the main vessel, is presented.

2.5. OCT analysis

OCT imaging was performed using the FastView catheter R and the Lunawave coronary imaging console (Terumo Corporation, Tokyo, Japan). The OFDI catheter was carefully advanced over a guidewire beyond the target area. While contrast was continuously injected at a rate of 4 ml/s, OFDI images of the main vessel were acquired at a rate of 160 frames/s with a pullback speed of 20 mm/s. OCT analysis was performed offline using software provided by Terumo. The scaffold and edge segments (5 mm on either side of the scaffold) were analysed at 1 mm intervals. Frame by frame analysis was conducted in cross-sections where the side branch was visible. Measurements were performed in accordance to previously published expert recommendations on the use of OCT in investigating the ABSORB BVS [7].

2.6. Statistical analysis

The ABC-1 trial was a pilot study designed to provide preliminary information on the performance of the ABSORB BVS in bifurcations. The sample size was chosen based on an estimate of the number of patients likely to fit the inclusion criteria with a recruitment course of 1 year. Categorical outcomes are presented in frequency and absolute numbers. Continuous data is presented either as mean with standard deviation. Analysis was performed with the SPSS software (version 24, SPSS Inc., Chicago, Illinois). Test for normality was performed using the Shapiro-Wilk test. Comparison between the two treatment arms was done using Mann-Whitney test for continuous data and Chi-squared test for categorical variables. Since no formal hypothesis testing was planned in this feasibility study, the p values presented are exploratory and should be cautiously interpreted.

3. Results

3.1. Baseline characteristics of cohort

Thirty-seven patients were enrolled. The baseline characteristics of the cohort are presented in Table 1. The mean age of patients was 62.8 years and 76% were male. Patient characteristics between the two interventional arms were similar. Over 80% of treated lesions involved the LAD/D1 bifurcation. B2/C lesions were present in 65% of cases.

3.2. Procedural characteristics

Table 2 shows the procedural characteristics of the trial. Predilatation was performed in all cases. The average pressure at which the scaffold was deployed did not differ between the two sizing groups. Post dilatation was performed in all proximal segments and in 59% of distal ones. Distal randomisation was associated with a smaller BVS size ($p = 0.007$). In proximal sizing strategy, the proximal RVD resulted in the use of a larger scaffold in 12 out of 19 patients. In 1 case, the distal diameter (3.26 mm) was comparable to the largest available BVS (3.5 mm). In 6 cases, the difference between scaffold and proximal and distal RVDs was similar which meant that sizing strategy did not affect the choice of scaffold. POT was carried out with a relatively bigger balloon with respect to BVS dameter in the distal cohort ($p = 0.026$). Three patients had BVS expansion beyond the recommended 0.5 mm above the BVS diameter with no adverse sequelae (1 mm overexpansion in 2 cases and 0.75 mm overexpansion in 1 case). OFDI imaging was done before BVS implantation in all cases and in 95% of cases at the end of the procedure. A single stent strategy was used in all cases. SB dilatation was performed in 2

Table 1
Patient demographics and clinical features.

	Proximal sizing (n = 19)	Distal sizing (n = 18)
Patient		
Demographics		
Age	64.2 (9.1)	61.7 (10.4)
Gender (male)	73.7 (14)	77.8 (14)
Body mass index (kg/m^2)	26.2 (4.4)	31.2 (5.8)
Clinical characteristics		
Hypertension	42.1 (8)	55.6 (10)
Hyperlipidaemia	47.4 (9)	55.6 (10)
Current smoker	10.5 (2)	22.2 (4)
Diabetes mellitus	10.5 (2)	27.8 (5)
Family history of IHD	26.3 (5)	44.4 (8)
Previous MI	21.1 (4)	38.9 (7)
Previous PCI	26.3 (5)	38.9 (7)
Previous CABG	0	0
Stable angina	73.6 (14)	61.1 (11)
Staged procedure		
Target vessel		
Bifurcation site		
Left anterior descending artery	84.2 (16)	83.3 (15)
Left circumflex artery	15.8 (3)	5.6 (1)
Right coronary artery	0	11.1 (2)
Medina classification		
0,1,0	47.4 (9)	44.4 (8)
1,0,0	5.3 (1)	11.1 (2)
1,1,0	47.3 (9)	44.4 (8)
ACC - AHA lesion classification		
A	10.5 (2)	5.6 (1)
B1	15.8 (3)	38.9 (7)
B2	31.6 (6)	16.7 (3)
C	42.1 (8)	38.9 (7)
Moderate/severe calcification	31.6 (6)	27.8 (5)

IHD - ischaemic heart disease; MI - myocardial infarction; PCI - percutaneous coronary intervention; CABG - coronary artery bypass graft; AHA - American Heart Association; ACC - American College of Cardiology.
Data is presented as mean (SD) or frequency (n).

Table 2
Procedural characteristics.

	Proximal sizing	Distal sizing	p value
Lesion preparation			
Predilatation	100 (19)	100 (18)	
Max balloon diameter	2.6 (±0.2)	2.6 (±0.3)	0.94
Max balloon length	14.9 (±2.8)	14.1 (±3.7)	0.34
OFDI measurements			
Proximal RVD (mm)	3.50 (±0.53)	3.30 (±0.37)	0.36
Distal RVD (mm)	2.76 (±0.44)	2.76 (±0.55)	1
Proximal-distal RVD diameter (mm)	0.74 (±0.59)	0.54 (±0.49)	0.36
BVS			
Diameter (mm)	3.2 (±0.3)	2.89 (±0.39)	0.007
Length (mm)	23.3 (±4.8)	21.8 (±5.5)	0.48
Inflation pressure (atm)	13.4 (±3.0)	13.4 (±2.6)	0.99
Post dilatation			
Proximal post dilatation	100 (19)	100 (18)	
POT	84.2 (16)	94.4 (17)	0.32
Balloon diameter for POT - BVS diameter	0.3 (±0.2)	0.5 (±0.2)	0.026
Maximal diameter (mm)	3.6 (±0.3)	3.4 (±0.4)	0.2
Maximal length (mm)	7.8 (±2.4)	8.8 (±3.1)	0.39
Post dilatation pressure	17.8 (±3.3)	14.3 (±2.5)	0.06
NC balloon	100 (19)	100 (18)	
Distal postdilatation	78.9 (15)	38.9 (7)	0.031
Maximal diameter (mm)	3.3 (±0.9)	2.9 (±1.2)	0.45
Maximal length (mm)	6.9 (±1.5)	10.7 (±3.9)	0.03
Post dilatation pressure	16.5 (±3.7)	13.1 (±3.0)	0.12
NC balloon	100 (19)	100 (18)	
Bifurcation technique			
MV stent only	100 (19)	100 (18)	
BVS SB fenestration	5.2 (1)	0	0.32
KBI	0	5.6 (1)	0.3
Conversion to double strategy	0	0	
Intravascular imaging			
Preimplant OCT	100 (19)	100 (18)	
Postimplant OCT	89.4 (17)	100 (18)	0.16
Procedural outcome			
Device success	100 (19)	100 (18)	
Procedural success	89.4 (17)	94.4 (17)	0.58
TIMI III flow in MV	100 (19)	100 (18)	
TIMI III flow in SB	100	88.9 (16)	0.14
SBO (end of procedure)	0	5.6 (1)	0.3

NC - non compliant; RVD - reference vessel diameter; POT - proximal optimisation technique; MV - main vessel; SB - side branch; KBI - kissing balloon inflation; SBO-side branch occlusion.
Data is presented as mean (SD) or frequency (n).

cases – the first because of angiographic pinching of the SB ostium and the second to improve flow after SB dissection.

Overall procedural success rate was 92%. There were two cases of periprocedural MI (PMI) in the proximal arm. The first case was due to dissection of the side branch during manipulation of the pressure wire after BVS deployment (Post PCI pressure wire measurement was mandated in the research protocol). TIMI III flow in the SB was restored after dilatation of the BVS cell across the side branch. The second case was deemed to be due to distal plaque embolization as both the main vessel and side branch were patent at the end of the procedure. In the distal arm, there was one case of PMI due to side branch occlusion (SBO) and distal main vessel dissection after predilatation. TIMI III flow was achieved in the main vessel after BVS deployment but flow along the occluded side branch could not be restored.

3.3. Angiographic results

Table 3 shows the results of the QCA analysis. Mean side branch diameter in the cohort was 2.24 mm. Comparable acute luminal gains were achieved in the proximal arm (1 mm) and distal arm (1.02 mm). In general, luminal size was underestimated on QCA when compared to OCT measurements. The side branch ostium was narrower after the PCI procedure irrespective of the sizing strategy (SB ostial stenosis of 44% post PCI versus 24% pre PCI. p = 0.007). We were able to reconstruct the 3-dimensional geometry of the bifurcation in 26 out of the 37 cases. There was no significant change in bifurcation angle after PCI in either arm (p = 0.86).

Table 3
Angiographic characteristics before and after PCI.

	Proximal sizing	Distal sizing	p value
Pre PCI			
Proximal RVD (mm)	3.18 (±0.49)	2.98 (±0.51)	0.23
Distal RVD (mm)	2.58 (±0.36)	2.43 (±0.51)	0.29
MLD (mm)	1.24 (±0.37)	1.14 (±0.39)	0.51
DS (%)	57 (±12)	56 (±13)	0.62
Lesion length (mm)	18.90 (±9.28)	15.87 (±7.29)	0.36
SB ostial diameter (mm)	1.85 (±0.45)	1.54 (±0.31)	0.023
SB RVD (mm)	2.30 (±0.46)	2.18 (±0.25)	0.35
SB stenosis (%)	20 (±15)	28 (±16)	0.05
Bifurcation angle (°)	67 (±24)[a]	57 (±23)[b]	0.25
Post PCI			
Proximal RVD (mm)	3.23 (±0.38)	3.09 (±0.35)	0.3
Distal RVD (mm)	2.77 (±0.33)	2.54 (±0.39)	0.05
In device MLD (mm)	2.24 (±0.39)	2.16 (±0.40)	0.62
In device DS(%)	20 (±18)	16 (±8)	0.27
SB ostial diameter (mm)	1.40 (±0.53)	1.07 (±0.43)	0.09
SB RVD (mm)	2.31 (±0.41)	1.81 (±0.76)	0.14
SB stenosis (%)	38 (±21)	51 (±23)	0.09
Bifurcation angle (°)	61 (±24)[a]	58 (±25)[b]	0.66

RVD - reference vessel diameter; SB - side branch; DS - diameter stenosis; MLD - minimum luminal diameter.
Data is presented as mean (SD) or frequency (n).
[a] n = 13.
[b] n = 13.

3.4. OFDI analysis post implantation

Table 4 outlines the intracoronary characteristics in each group from OCT. Performing an OFDI after scaffold implantation changed management in a quarter of cases (Table 5). In seven cases (20%), significant malapposition was evident after POT and further postdilatation with a bigger balloon was necessary. In two cases (6%), OFDI identified significant distal dissections which were successfully treated with further stenting. Fig. 2 illustrates a typical example of the OCT images after bifurcation stenting with the ABSORB BVS. Sizing strategy did not have a significant impact on the overall scaffold geometry as assessed by the Eccentricity Index (p = 0.48). Strut embedment was numerically higher in the proximal arm on both sides of the bifurcation segment.

Analysis at a strut level showed that there were numerically more malapposed struts in the distal arm. There was a higher incidence of significant proximal edge malapposition (>300 μm) in the distal arm (2.3% v 0.8%, p 0.023) Even though there was a trend towards more distal edge dissections in the proximal arm (31.3% vs 11.8%),with one patient requiring additional PCI to seal the dissection flap, this increased incidence did not reach statistical significance (p 0.17). There was one case of scaffold disruption in the distal arm caused by KBI in a 2.5 mm BVS with two 2.0 mm NC balloon.

4. Discussion

The main findings of our study are: 1) Treating bifurcations with the ABSORB BVS using a provisional strategy is feasible and associated with good procedural outcomes. 2) A distal sizing strategy is associated with more proximal malapposition on intravascular imaging but both approaches have similar clinical complication rates.

To our knowledge, this is the first prospective trial of two sizing strategies of a bioresorbable scaffold in coronary bifurcations.

Table 4
OFDI measurements after BVS insertion.

	Proximal sizing	Distal sizing	p value
Plaque composition			
Fibrous (%)	6.3 (1)	0	0.3
Fibroatheroma (%)	31.3 (5)	47.1 (8)	0.35
Fibrocalcific (%)	62.5 (10)	52.9 (9)	0.58
Segment analysis			
Proximal segment			
Mean flow area (mm^2)	8.19 (±2.39)	7.85 (±1.62)	0.9
Min flow area (mm^2)	7.20 (±2.22)	6.92 (±1.60)	0.96
Mean scaffold area (mm^2)	8.71 (±2.36)	8.32 (±1.65)	0.96
Min scaffold area (mm^2)	7.73 (±2.11)	7.33 (±1.67)	0.9
Mean luminal diameter (mm)	3.20 (±0.46)	3.15 (±0.32)	0.90
Min luminal diameter (mm)	3.00 (±0.45)	2.95 (±0.34)	0.93
Mean EI	0.88 (±0.05)	0.89 (±0.05)	0.81
Embedment depth (μm)	31 (±33)	24 (±17)	0.3
Distal segment			
Mean flow area (mm^2)	6.58 (±1.58)	6.16 (±1.72)	0.42
Min flow area (mm^2)	5.50 (±1.60)	5.01 (±1.25)	0.33
Mean scaffold area (mm^2)	7.40 (±1.65)	6.87 (±1.79)	0.35
Min scaffold area (mm^2)	6.24 (±1.76)	5.68 (±1.31)	0.4
Mean luminal diameter (mm)	2.87 (±0.34)	2.77 (±0.38)	0.44
Min luminal diameter (mm)	2.62 (±0.38)	2.51 (±0.31)	0.3
Mean EI	0.87 (±0.04)	0.87 (±0.05)	0.69
Embedment depth (μm)	52 (±32)	40 (±18)	0.15

EI - eccentricity index.
Data is presented as mean (SD) or frequency (n) unless stated otherwise.

4.1. Procedural issues

Despite the bulkier scaffold, our post procedural complication rate when using this device in a provisional strategy is comparable to those of metal stents [3]. The high rate of intracoronary imaging, predilatation and post dilatation in our study is likely to account for this. It is now widely recognised that correct implantation technique is pivotal to reduce complication rates with the ABSORB BVS. The three critical components of implantation are summarized by the acronym PSP [8] where P stands for Predilatation with a NC balloon with a 1:1 balloon: vessel ratio, S implies careful Sizing of the vessel preferably with intravascular imaging and the final P stands for Postdilatation with a NC balloon to high pressure. Whether the same principle can be extended to bifurcation lesions is unknown and formed part of the rationale for our study. We adjusted the PSP implantation protocol for use in a bifurcation anatomy. Post dilatation was performed in all proximal segments. However this was not necessary in all distal segments due to the tapering nature of the bifurcation anatomy. Since the implanted scaffold was imaged at the end of the procedure, we determined the need for distal post dilatation based on the final OCT image.

In our study, we have demonstrated that the adoption of a PSP protocol tailored to bifurcation disease is feasible and associated with low complication rates. The comparable rate of peri-procedural complications between treatment arms is perhaps unsurprising since the methods of implantation except for BVS size were broadly similar. We originally intended to perform POT only in the distal arm as in theory, choosing a larger BVS similar based on the proximal vessel diameter would obviate the need for postdilatation. However we found that even with proximal sizing, strut malapposition in the proximal segment was often present on post implant OCT despite satisfactory angiographic appearances. This highlights the importance of intracoronary imaging with this technology. In fact, abnormalities detected on OCT after scaffold deployment led to a change in management in approximately one in four cases. Other studies have confirmed the importance of intracoronary imaging even after satisfactory angiographic appearance when using the ABSORB BVS [9,10].

Table 5
Complications on intravascular imaging.

	Proximal sizing	Distal sizing	p value
Scaffold analysis			
Scaffold disruption	0	6 (1%)	0.33
Edge dissection			
Proximal	6.3 (1)	11.8 (2)	0.58
Distal	31.3 (5)	11.8 (2)	0.17
Post implant OFDI changing management	29 (5)	24 (4)	0.62
Malapposition needed dilatation	24 (4)	18 (3)	0.61
Dissection needed stent	6 (1)	6 (1)	0.97
Strut level analysis			
Total no. of struts analysed	17,835	19,367	
Total no of malapposed struts			
Whole segment	4.8 (858)	6.4 (1231)	0.18
Proximal segment	3.1 (552)	4.5 (862)	0.23
Distal segment	1.7 (306)	1.9 (369)	0.29
Total no of significantly malapposed struts (>300 μm)			
Whole segment	0.8 (142)	2.3 (451)	0.023
Proximal segment	0.8 (142)	2.3 (451)	0.023
Distal segment	0	0	

Data is presented as frequency (n) unless stated otherwise.

4.2. Scaffold and bifurcation geometry

The final geometry of the metal stent or scaffold after implantation exerts an influence on clinical outcomes. In a subset analysis of the ABSORB II trial, post procedural eccentricity in BVS was related to higher event rates [11]. In our study, we did not find a difference in scaffold eccentricity index between the two sizing strategies. This is perhaps not unexpected. While bigger BVS were chosen in the proximal arm, the eccentricity index is a ratio of diameters and thus less dependent on absolute scaffold dimensions. Plaque composition (in particular calcific content) affects the final geometry of a scaffold and these were similar in both arms. Finally the method of lesion preparation with respect to balloon inflation size and pressures was comparable in both arms. One would thus expect equivalent plaque modification and consequently, the scaffold to be accommodated in a similar manner within a stenotic lesion.

Bifurcation PCI can change the 3-dimensional structure of the bifurcation segment [12]. Bifurcation with metal stents 'stiffens' the artery and typically decreases the angle between the distal main vessel and side branch. This phenomenon has been observed after both single and complex stenting [13]. The resulting artificial configuration may adversely affect local haemodynamics leading to restenosis long term. In contrast to studies with metal stents, we did not observe any significant change in bifurcation angle before and after PCI with the ABSORB BVS [14]. The more conformable BVS may better preserve the natural architecture of the bifurcation particularly in a provisional strategy [15].

4.3. Edge dissections

Contrary to our expectations, we did not observe a statistically significant increase in distal edge dissections when using a bigger scaffold in a proximal sizing strategy. In both groups, the balloon size and inflation pressures used for post dilatation of the distal bifurcation segment was similar. This may be more important than actual scaffold size in determining the risk of damage to the distal vessel. Interestingly, more post dilatation was performed within the distal segment in the proximal sizing group. The fact that post dilatation was guided by OCT may explain that unusual occurrence. Our overall dissection rate of 30.3% is actually lower than in the ABSORB B OCT substudy (36.5%) where the lesions were far less complex [16]. The clinical relevance of

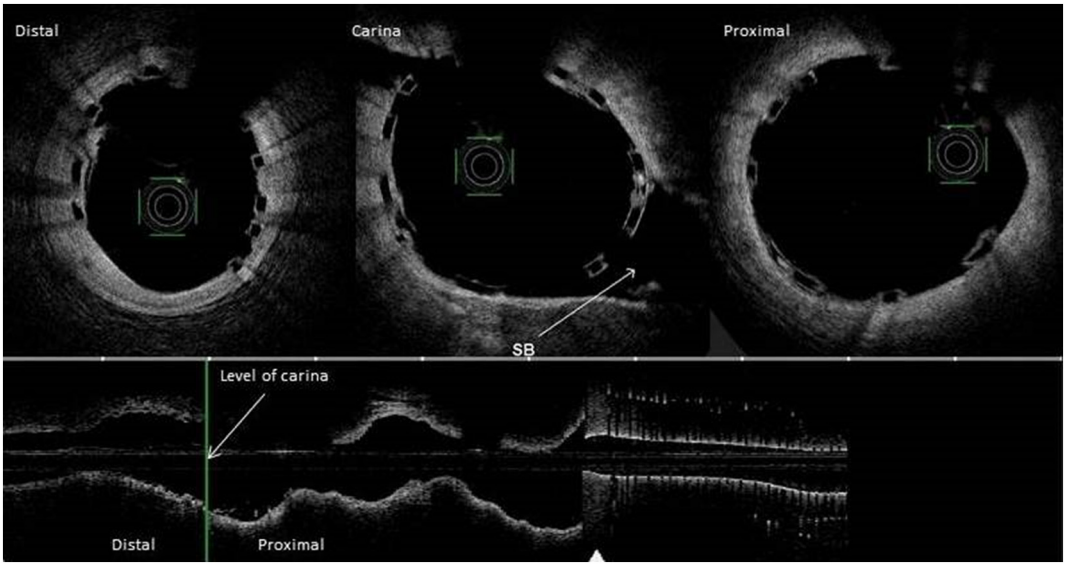

Fig. 2. OFDI images of bifurcation stenting of the LAD/Diagonal system with the ABSORB BVS.

edge dissections detected on intracoronary imaging is still unclear. In study using IVUS, there was no difference in clinical outcomes in patients with edge dissection compared to those without [17]. Conversely, other studies have found a link between the presence of these dissections and development of subacute stent thrombosis [18]. Even though the ABSORB B OCT cohort had a high dissection rate, only 1 adverse event (periprocedural MI) was directly attributed to a dissection. As intravascular imaging especially OCT is increasingly utilised in the future, the exact clinical significance and optimal management of small edge dissections should become clearer.

4.4. Malapposition

A greater malapposition burden was observed with the smaller BVS in the distal arm even after OCT guided optimisation. The same effect occurs in metal stents. However in the latter case, the discrepancy in main vessel size can be overcome by liberal post dilatation proximally. On the other hand, the safe expansion limit of the ABSORB BVS restricts the magnitude of postdilatation and by proxy the ability to correct proximal malapposition. The significance of ISA is still contentious. Acute ISA has been linked to delayed or absent strut coverage at follow-up [19], both of which are known risk factors for stent thrombosis. Other studies have failed to show a significant relationship between either ISA after DES implantation or at follow up and adverse outcomes [20]. The small rate of adverse events with current generation of stents makes it difficult to precisely quantify the risk of ISA. The answer should become clearer with more widespread use of intravascular imaging.

5. Limitations

Since this was a pilot study, it was not powered to detect statistically significant differences. Cardiac enzymes were not routinely measured and thus periprocedural MI may have been underdiagnosed in our cohort. As previously mentioned, we did not adhere to our original plan of performing POT only in the distal sizing arm as we were guided by the intracoronary scaffold appearance during each case for optimal expansion and apposition. This may have mitigated treatment effects between the two arms. The limited availability of BVS sizes (2.5, 3.0 and 3.5 mm) restricted their usefulness in our trial. In 4 cases randomised to distal sizing, the largest BVS available (3.5 mm) was similar to the diameter of the distal vessel. In 6 cases randomised to proximal sizing, the difference between stent diameter and proximal and distal diameters were the same. Scaffold choice was independent of randomisation in those cases.

6. Conclusion

With the appropriate implantation technique and adjunctive imaging, the use of bioresorbable vascular scaffolds in a provisional strategy across large side branches is safe and feasible. While procedural complication rates from the two sizing strategies are comparable, the proximal sizing strategy results in less malapposition and may be more advantageous. The risk of underdeployment with scaffold malapposition in distal sizing needs be carefully weighed against the risk of overdeployment with scaffold damage in proximal sizing. Long term imaging follow up is needed to see whether the potential benefits of scaffold resorption, especially across jailed side branches, materialise.

Declaration

I acknowledge that all the above authors meet the authorship criteria and that they are all in agreement with the manuscript.

Disclosures

ABSORB scaffolds were provided free of charge by Abbott Vascular. The OFDI imaging catheters were provided free of charge by Terumo Inc. Neither companies had any role in the study beyond the provision of consumables outlined above.

Disclosure statement

The authors report no financial relationships or conflicts of interest regarding the content herein.

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