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Imaging outcomes of bioresorbable scaffold overlap: an optical coherence tomography analysis from the ABSORB EXTEND trial

Yohei Sotomi[1], MD; Pannipa Suwannasom[1,2,3], MD; Chiung-Jen Wu[4], MD; Hiroki Tateishi[2], MD, PhD; Wai-Fung Cheong[5], PhD; Wei-Ying Zhao[5], PhD; Susan Veldhof[5], RN; Robbert J. de Winter[1], MD, PhD; Joanna J. Wykrzykowska[1], MD, PhD; Vasim Farooq[6], MD, PhD; Alexandre Abizaid[7], MD, PhD; Patrick W Serruys[8], MD, PhD; Yoshinobu Onuma[2]*, MD, PhD; on behalf of the ABSORB EXTEND trial investigators

1. Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands; 2. ThoraxCenter, Erasmus Medical Center, Rotterdam, The Netherlands; 3. Northern Region Heart Center, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand; 4. Division of Cardiology, Department of Internal Medicine, Kaohsiung Chang Gung Memorial Hospital and Chang Gung University College of Medicine, Kaohsiung, Taiwan; 5. Abbott Vascular, Santa Clara, CA, USA; 6. Institute of Cardiovascular Sciences, Manchester Academic Health Sciences Centre, University of Manchester and Manchester Heart Centre, Manchester Royal Infirmary, Central Manchester University Hospitals NHS Trust, Manchester, United Kingdom; 7. Instituto de Cardiologia Dante Pazzanese, Sao Paulo, Brazil; 8. International Centre for Circulatory Health, NHLI, Imperial College London, London, United Kingdom

KEYWORDS

- bioresorbable scaffold
- optical coherence tomography
- overlap

Abstract

Aims: The purpose of this study was to assess the vascular response and vessel healing of overlapped Absorb scaffolds (Abbott Vascular, Santa Clara, CA, USA) compared to non-overlapped devices in human coronary arteries as assessed by optical coherence tomography (OCT) in the same treated segment.

Methods and results: The ABSORB EXTEND (NCT01023789) trial is a prospective, single-arm, open-label clinical study which enrolled 800 patients. The planned overlap OCT subgroup in the ABSORB EXTEND trial was analysed and two-year OCT follow-up was performed in seven patients. In cross-section level analysis at baseline, lumen and abluminal scaffold areas were larger in overlap segments than in non-overlap segments, whereas the endoluminal scaffold area was similar. At two-year follow-up, lumen area and endoluminal scaffold areas were similar in both segments despite the neointimal area being larger in the overlap segments. The neointimal coverage was essentially fully complete in both non-overlap (99.4±0.8%) and overlap segments (99.8±0.4%) at two-year follow-up.

Conclusions: The imaging results of this small OCT subgroup analysis in the ABSORB EXTEND trial demonstrated substantial vessel healing and vascular response in the overlap segments of Absorb at two-year follow-up comparable to the non-overlap segments.

**Corresponding author: Thoraxcenter, Ba-583, 's Gravendijkwal 230, 3015 CE Rotterdam, The Netherlands. E-mail: yoshinobuonuma@gmail.com*

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Introduction

Overlapping of Absorb scaffolds (Absorb BVS; Abbott Vascular, Santa Clara, CA, USA) is generally associated with a number of issues. 1) Technically, thick struts (157 µm) could hinder implantation of the second Absorb device, which could result in difficult scaffold delivery or disruption of struts. 2) Overlap might be associated with an increased risk of periprocedural myocardial infarction. In the ABSORB II trial (n=501), treatment with overlapping devices was the only independent determinant of periprocedural myocardial infarction (odds ratio: 5.07, 95% CI: 1.78-14.41, p=0.002)[1]. 3) Animal studies have suggested delayed coverage of overlapping struts. In a juvenile porcine model, the overlapped Absorb scaffolds showed more delay in tissue coverage than non-overlapped scaffolds[2].

The segments with overlapped scaffolds (overlap segments) are possibly associated with delayed healing and greater neointimal growth compared to the segments with no overlapped scaffolds (non-overlap segments), which could result in smaller luminal dimension at follow-up[2]. However, the vessel healing and vascular response at segments with overlapped Absorb BVS in human coronary arteries have, thus far, not been precisely evaluated by optical coherence tomography (OCT).

The purpose of the current study was to assess by OCT the vascular response and vessel healing in the Absorb scaffold overlap segments compared to the non-overlap segments in human coronary arteries.

Methods

STUDY DESIGN

The ABSORB EXTEND trial is a prospective, single-arm, open-label clinical study that has enrolled 812 patients at up to 100 global sites (NCT01023789). Details on the study and the study device (Absorb BVS; Abbott Vascular) have been described previously[3] **(Table 1)**. Initially, a subset of up to 50 patients who received planned overlapping Absorb BVS at selected sites with OCT capability was planned to be included in the OCT subgroup. In this OCT subgroup, OCT imaging after the BVS implantation and at two-year follow-up was mandated in all patients. Despite the initial plan to include 50 patients with planned overlapping, the actual OCT subgroup included only 14 patients. The main reasons were: i) the small number of sites due to limited availability of OCT at the time of the study initiation in 2009; ii) the premature termination of the study; iii) the low patient consent rate due to invasive imaging follow-up. The need for planned overlapping of BVS was determined by the investigator at the time of the index procedure. The research ethics committee of each participating institution approved the protocol and all enrolled patients provided written informed consent before inclusion.

OCT METHODOLOGY

The image acquisition was performed with the C7-XR™ imaging console and the Dragonfly™ intravascular imaging catheter (both St. Jude Medical, St. Paul, MN, USA). Analysis of the OCT images was performed with the QCU-CMS software (Medis medical imaging systems, Leiden, The Netherlands), using the methodology for BVS analysis described in a previous publication[4]. All analyses were performed at 1 mm longitudinal intervals within the non-overlap segment, and at 0.2 mm intervals within the overlap segment. In addition, the analysis for scaffold coverage was performed at 0.2 mm intervals in the whole scaffold segment.

Details of the OCT analysis are illustrated in **Figure 1**. Definitions of OCT parameters were described in a previous publication[4]. Specifically, in overlap segments at baseline, the struts of the first (outer) and second (inner) scaffolds could appear stacked or overhanging. The struts of the inner scaffold could look malapposed in a cross-section, but that does not necessarily indicate absence of contact with other structures, since such struts are touching the other scaffold **(Figure 1)**[5]. As a surrogate for vessel stretch, the abluminal side of the outer scaffold area ratio was calculated as the ratio of mean abluminal scaffold area of the outer scaffold in the overlap segment to the mean abluminal area of the single scaffold implanted in the adjacent non-overlap segments (5 mm of both sides). The endoluminal scaffold area ratio was also computed in the same way. At two years, the scaffold has already lost its mechanical integrity and could present late discontinuities, as expected from the bioresorption process[6]. Therefore, it is not always possible to differentiate the two layers of struts in an overlap segment. In the current study, the analysis delineated the inner and outer contour of the struts without distinction of the two scaffolds. Wherever two struts were overhanging or stacked, the

Table 1. Diameter of target vessel(s), length of target lesion(s) and Absorb BVS size used.

Target vessel diameter	Length of target lesion(s)	BVS size to be used
Distal Dmax and proximal Dmax		
≥2.0 mm and ≤3.0 mm	≤14 mm	Single 2.5×18 mm
	>14 mm and ≤22 mm	Single 2.5×28 mm
	>22 mm and ≤28 mm	Two overlapping 2.5×18 mm
≥2.5 mm and ≤3.3 mm	≤14 mm	Single 3.0×18 mm
	>14 mm and ≤22 mm	Single 3.0×28 mm
	>22 mm and ≤28 mm	Two overlapping 3.0×18 mm
≥2.0 mm and ≤2.5 mm (distal Dmax)	>22 mm and ≤28 mm	Overlapping 2.5×18 with 3.0×18 mm
≥3.0 mm and ≤3.3 mm (proximal Dmax)		

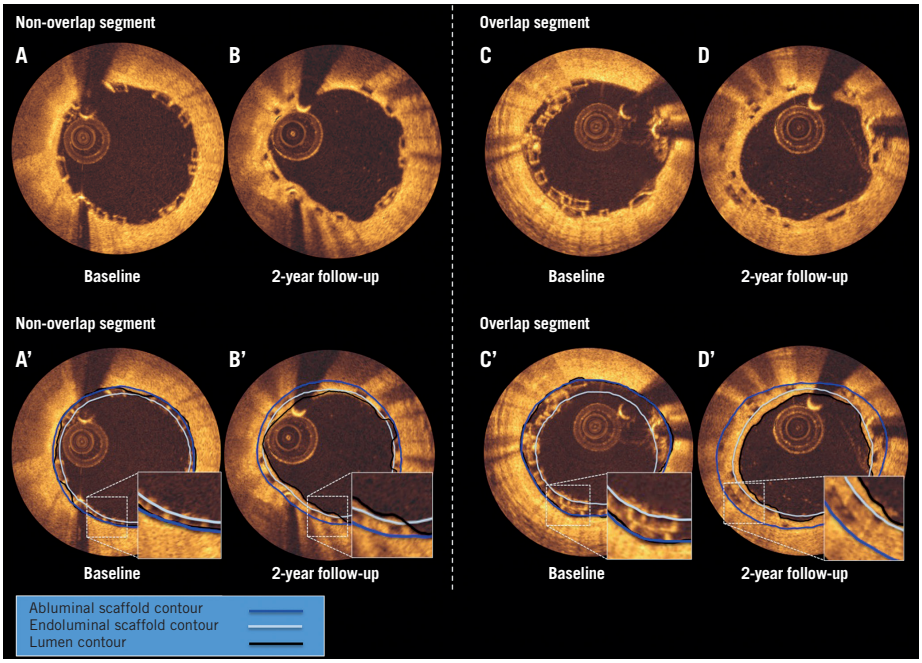

Figure 1. *OCT methodology. A) – D) Baseline and follow-up OCT images in the non-overlap and overlap segments, respectively. In the non-overlap segment, the previously published methodology was applied (A', B')[4]. In the overlap segment, the endoluminal scaffold contour was drawn using the midpoint of the endoluminal black core border of "inner struts" at baseline (C') and follow-up (D'). The abluminal scaffold contour was drawn using the midpoint of the abluminal black core border of "outer struts" at baseline (C') and follow-up (D').*

abluminal (endoluminal) border of the outer (inner) struts was used to define the abluminal (endoluminal) scaffold contour **(Figure 1)**.

With respect to coverage analysis, when the coverage thickness (the shortest distance from the lumen contour to the endoluminal border of the strut black core) was ≥30 µm in polymeric struts, the strut was defined as a covered strut. To allow full visualisation of the spatial distribution of neointimal thickness and coverage status in the overlapping devices, "spread-out-vessel graphs" – a visual representation of the vessel as if it had been cut along the reference angle (0°) and spread out on a flat surface – were created based upon previously described methodologies[7].

CLINICAL FOLLOW-UP

Definitions of all clinical endpoints have been described elsewhere[3]. All study endpoint events were adjudicated by an independent clinical events committee (CEC), according to either protocol definitions and/or the Academic Research Consortium (ARC) definitions. All adverse events were reported to an independent data and safety monitoring board (DSMB), which reviewed the data to identify any safety issues related to the conduct of the study.

STATISTICAL ANALYSIS

The normality of distribution of continuous data was examined with the Shapiro-Wilk test. Continuous variables with normal distribution are expressed as means±standard deviations and those with unequal variance are expressed as medians and interquartile ranges (25th and 75th percentiles). Categorical variables are expressed as numbers and frequencies. Group means for continuous variables with normal and non-normal distributions were compared using the Student's t-test and the Mann-Whitney U test, respectively. Categorical variables were compared using the χ^2 test or Fisher's exact test, where appropriate. A mixed linear model with an assumed Gaussian distribution was used for the comparisons of continuous variables to take into account the clustered nature of >1 struts and cross-sections analysed from the same lesion, which might result in unknown correlations among measurements within the clusters. Statistical significance was assumed at a probability (p)-value of <0.05. All statistical analyses were performed with SPSS, Version 22.0.0 (IBM Corp., Armonk, NY, USA).

Results

In the whole ABSORB EXTEND trial (N=812), a total of 14 patients were enrolled in the planned overlap population (OCT subgroup). In these 14 patients, one patient died due to a non-cardiac cause, and 13 patients underwent two-year clinical follow-up. The median duration of follow-up was 748 (729-755) days. The baseline OCT data of one patient were not analysable due to the poor image quality. Two-year invasive OCT follow-up was performed in only seven patients.

PATIENT DEMOGRAPHIC DATA AND PROCEDURAL DATA

The baseline characteristics of the patients and procedural data are summarised in **Table 2**. A sensitivity analysis comparing the baseline characteristics of patients with and without OCT surveillance at follow-up demonstrated that there was no significant difference between these cohorts.

Table 2. Patient characteristics.

Variables	N=14
Baseline characteristics	
Age (years)	62±9
BMI (kg/m^2)	27.3±4.3
Male sex, n (%)	12 (85.7)
Current smoker, n (%)	2 (14.3)
Any diabetes, n (%)	1 (7.1)
Diabetes treated with insulin, n (%)	0 (0)
Hypertension requiring medication, n (%)	7 (50.0)
Hypercholesterolaemia requiring medication, n (%)	7 (50.0)
Prior MI, n (%)	2 (14.3)
Stable angina, n (%)	13 (92.9)
Unstable angina, n (%)	1 (7.1)
Lesion data	
Lesion location LAD/LCX/RCA	5/5/4
Lesion class (ACC/AHA) A/B1/B2/C	0/6/7/1
Angulation (≥45°), n (%)	1 (7.1)
Calcification (moderate or severe), n (%)	2 (14.3)
Bifurcation, n (%)	3 (21.4)
Eccentric, n (%)	14 (100)
Pre-procedure thrombus, n (%)	0 (0)
Procedural data	
Predilatation, n (%)	14 (100)
Balloon diameter (mm)	2.61±0.28
Balloon pressure (atm)	13.7±3.2
Post-dilatation, n (%)	9 (64.3)
Compliant balloon, n (%)	4 (29)
Non-compliant balloon, n (%)	5 (36)
Balloon diameter (mm)	3.14±0.17
Balloon pressure (atm)	17.3±4.0
Device, n (%)	
2.5×18; 2.5×18 mm	1 (7.1)
3×18; 3×18 mm	12 (85.7)
3.5×18; 3.5×18 mm	1 (7.1)
Bail-out with XIENCE PRIME (3.5×18 mm), n (%)	2 (14.3)
Side branch occlusion, n (%)	1 (7.1)
Overlap length (mm) by post-procedural OCT	4.0 [2.0, 7.4]
Acute success, n (%)	14 (100)
QCA data	
Pre-procedural lesion length (mm)	15.1 [8.2, 21.0]
Pre-procedural RVD (mm)	2.5 [2.26, 2.55]
Pre-procedural DS%	56.9±14.8
Post-procedural in-device DS%	18.0±6.3
In-device acute gain (mm)	0.99±0.39

Data are expressed as mean±standard deviation, number (frequency), and median [interquartile range]. BMI: body mass index; DS%: percent diameter stenosis; LAD: left anterior descending artery; LCX: left circumflex artery; MI: myocardial infarction; OCT: optical coherence tomography; QCA: quantitative coronary angiography; RCA: right coronary artery; RVD: reference vessel diameter

QUANTITATIVE OCT FINDINGS AT BASELINE AND TWO-YEAR FOLLOW-UP

Table 3 shows the quantitative OCT findings at baseline in 13 patients at lesion level and cross-section level analyses. At cross-section level analysis, no significant difference in endoluminal scaffold area was observed (6.31±1.18 mm^2 vs. 6.29±0.97 mm^2, p=0.568) between overlap and non-overlap segments.

Table 4 tabulates the quantitative OCT findings at baseline and two-year follow-up in seven patients with both baseline and follow-up OCT data. The time interval to OCT follow-up was 742 (724-754) days. At two-year follow-up, both non-overlap and overlap segments presented with a similar lumen area, abluminal scaffold area, endoluminal scaffold area, flow area, and neointimal area in lesion-level analysis.

Serial changes of abluminal/endoluminal scaffold areas and the flow area between the overlap segment and its margin (10 mm) are illustrated in the graph of **Figure 2** (representative case 6 in **Figure 3**). Serial changes of all the cases (margin: 5 mm) are shown in **Figure 3**. Post-dilatation was performed in five out of the seven patients. Abluminal and endoluminal scaffold area ratios were 1.12±0.07 and 1.03±0.06, respectively. Outward vessel enlargement was still maintained at two-year follow-up despite being after the disappearance of scaffold radial strength (12 months).

Regarding the strut coverage analysis, 7,828 struts in non-overlap segments and 1,801 struts in overlap segments were analysed. The neointimal coverage was almost completed in both segments at two-year follow-up (coverage rate in non-overlap segment vs. overlap segment, 99.4±0.8% vs. 99.8±0.4%, p=0.360).

Table 3. Baseline OCT data (13 cases).

	Non-overlap segment (N=13*)	Overlap segment (N=13*)	*p*-value
Baseline			
Total number of struts, n	2,571	4,382	
Number of struts per lesion, n	198±52	337±267	0.077
Lesion level analysis	**N=13**	**N=13**	
Lumen area (mm^2)	7.00±0.92	7.96±1.37	0.046
Abluminal scaffold area (mm^2)	7.30±0.96	8.04±1.19	0.095
Endoluminal scaffold area (mm^2)	6.31±0.86	6.35±1.07	0.926
Strut core area (mm^2)	0.20±0.03	0.43±0.06	<0.001
Flow area (mm^2)	6.80±0.90	7.53±1.36	0.118
Cross-section level analysis	**N=339**	**N=324**	
Lumen area (mm^2)	6.98±1.26	7.94±1.24	<0.001
Abluminal scaffold area (mm^2)	7.29±1.30	8.01±1.10	<0.001
Endoluminal scaffold area (mm^2)	6.31±1.18	6.29±0.97	0.568
Strut core area (mm^2)	0.20±0.08	0.44±0.16	<0.001
Flow area (mm^2)	6.78±1.24	7.50±1.22	<0.001

Data are expressed as mean±standard deviation and number. *The OCT baseline data (case 14) were not analysable due to poor quality of image.

Table 4. Serial OCT data post-procedure and at 2-year follow-up (7 cases).

	Baseline	2-year follow-up	*p*-value
Strut analysis			
Number of struts per lesion, n			
Non-overlap segment	175±59	1,118±197	–
Overlap segment	283±265	257±74	–
p-value¶	0.351	<0.001	
Number of uncovered struts per lesion, n			
Non-overlap segment	–	7.0±9.4	–
Overlap segment	–	0.9±1.7	–
p-value¶	–	0.163	
Coverage rate (%)			
Non-overlap segment	–	99.4±0.8	–
Overlap segment	–	99.8±0.4	–
p-value¶	–	0.360	
Lesion level analysis			
Non-overlap segment	N=7	N=7	
Overlap segment	N=7	N=7	
Lumen area (mm^2)			
Non-overlap segment	6.98±1.18	5.58±2.01	0.138
Overlap segment	8.25±1.73	6.09±2.30	0.071
p-value¶	0.133	0.663	
Abluminal scaffold area (mm^2)			
Non-overlap segment	7.33±1.23	8.02±2.52	0.529
Overlap segment	8.26±1.50	9.23±3.16	0.476
p-value¶	0.233	0.445	
Endoluminal scaffold area (mm^2)			
Non-overlap segment	6.34±1.09	6.81±2.20	0.619
Overlap segment	6.56±1.35	7.48±2.84	0.453
p-value¶	0.744	0.632	
Strut core area (mm^2)			
Non-overlap segment	0.20±0.04	0.21±0.05	0.804
Overlap segment	0.41±0.07	0.36±0.10	0.284
p-value¶	<0.001	0.004	
Flow area (mm^2)			
Non-overlap segment	6.78±1.15	5.58±2.01	0.195
Overlap segment	7.84±1.71	6.09±2.30	0.133
p-value¶	0.197	0.663	

	Baseline	2-year follow-up	*p*-value
Lesion level analysis			
Neointimal area (mm^2)			
Non-overlap segment		2.24±0.63	
Overlap segment		2.78±0.85	
p-value¶		0.206	
Cross-section level analysis			
Non-overlap segment	N=174	N=211	
Overlap segment	N=143	N=142	
Lumen area (mm^2)			
Non-overlap segment	6.89±1.50	5.56±2.20	<0.001
Overlap segment	8.12±1.55	5.69±1.96	<0.001
p-value¶	<0.001	0.735	
Abluminal scaffold area (mm^2)			
Non-overlap segment	7.24±1.56	8.02±2.76	<0.001
Overlap segment	8.18±1.33	8.69±2.68	0.001
p-value¶	<0.001	0.001	
Endoluminal scaffold area (mm^2)			
Non-overlap segment	6.27±1.40	6.81±2.42	<0.001
Overlap segment	6.52±1.21	7.01±2.43	<0.001
p-value¶	0.030	0.834	
Strut core area (mm^2)			
Non-overlap segment	0.20±0.08	0.21±0.09	0.788
Overlap segment	0.40±0.13	0.35±0.15	0.015
p-value¶	<0.001	<0.001	
Flow area (mm^2)			
Non-overlap segment	6.69±1.47	5.56±2.20	<0.001
Overlap segment	7.72±1.54	5.69±1.96	<0.001
p-value¶	<0.001	0.735	
Neointimal area (mm^2)			
Non-overlap segment	–	2.25±0.95	–
Overlap segment	–	2.65±0.81	–
p-value¶	–	<0.001	–
Abluminal scaffold area ratio (overlap vs. non-overlap)	1.12±0.07	–	–

Data are expressed as mean±standard deviation and number.
¶ Non-overlap segment vs. overlap segment

Spread-out-vessel graphs represent the spatial distribution of the neointimal thickness and coverage status along each overlap segment and non-overlap segments at two-year follow-up **(Figure 4)**.

ADVERSE EVENTS

The rate of ischaemia-driven (ID) major adverse cardiac events (all cardiac death, all myocardial infarction, or ischaemia-driven target lesion revascularisation) at two years was 0% in the OCT subgroup. Preprocedural and post-procedural blood sample tests for cardiac enzymes (creatine kinase, creatine kinase-myocardial band, and troponin) were performed in 12 (85%) patients, and the periprocedural myocardial infarction rate (per protocol criteria) was 0%. Of the 14 patients, 13 patients were on dual antiplatelet therapy at one year (one patient discontinued the treatment before one year), and three patients were still on dual antiplatelet therapy at two years. One patient died due to a non-cardiac cause 345 days after the index procedure. Two patients underwent ID non-target vessel revascularisation by PCI 188 days and 409 days after the index procedure, respectively. One patient underwent non-ID target lesion revascularisation by PCI 707 days after the index procedure due to in-scaffold restenosis.

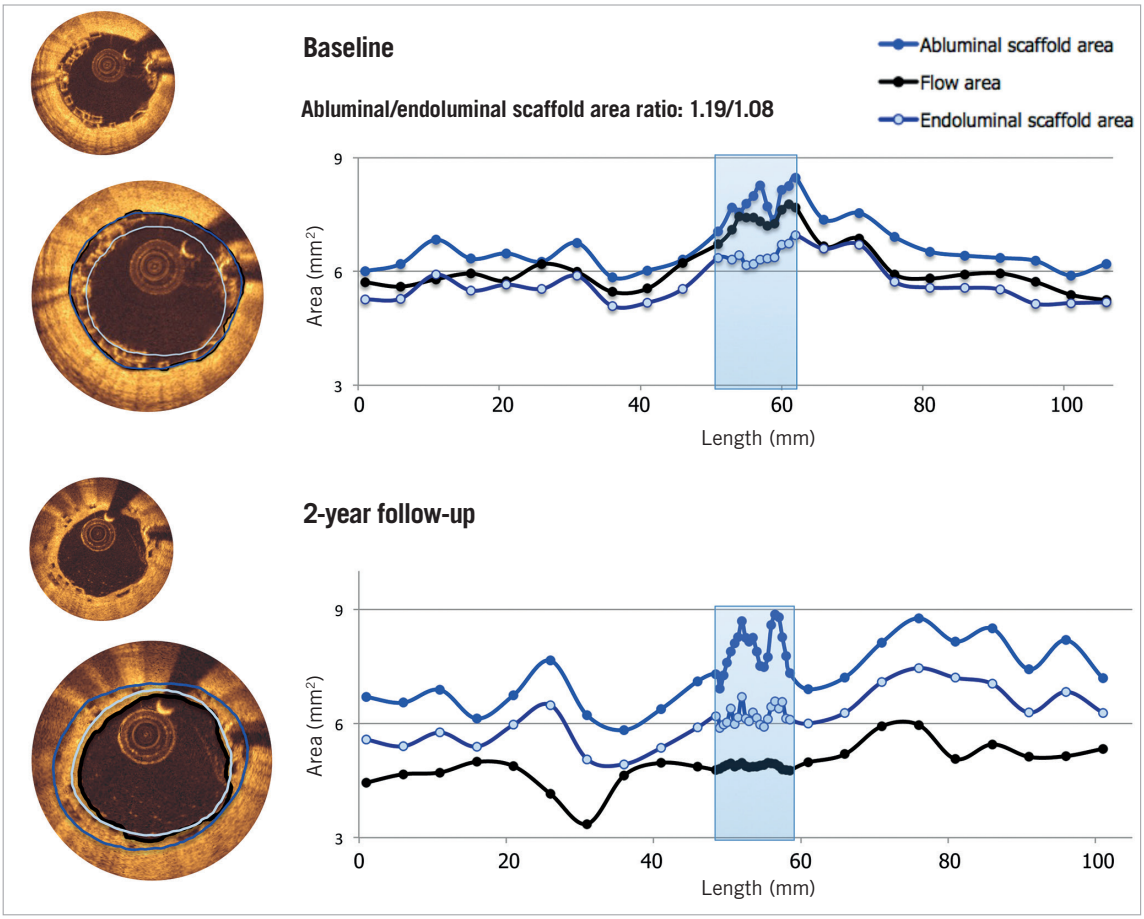

Figure 2. *Vessel-scaffold interaction in overlap and non-overlap segments. Vessel-scaffold interaction in overlap and non-overlap segments of a representative case (case 6 in Figure 3) is indicated with OCT analysis images. The horizontal axis indicates the length of the lesion from distal to proximal. The vertical axis indicates the area of each cross-section (black: flow area; dark blue: abluminal scaffold area; light blue: endoluminal scaffold area). The overlap segment (blue shadow) and both 10 mm margins are illustrated.*

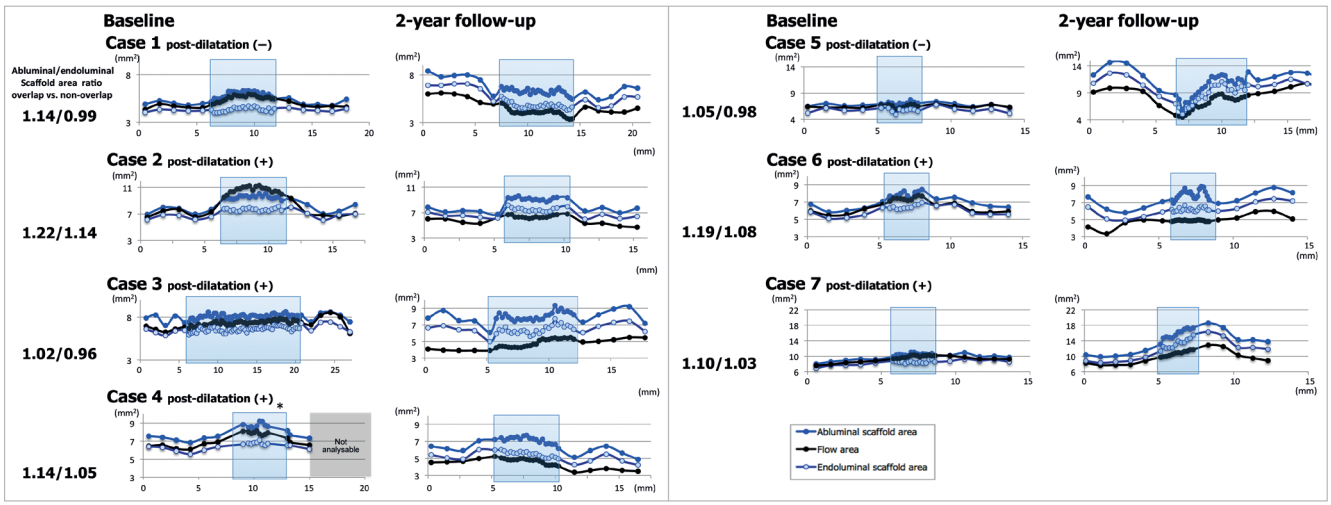

Figure 3. *Vessel-scaffold interaction in all cases. Vessel-scaffold interactions in overlap (blue shadow) and non-overlap segments of all the cases are shown. The horizontal axis indicates the length of the lesion from the distal to proximal. The vertical axis indicates the area of each cross-section (black: flow area; dark blue: abluminal scaffold area; light blue: endoluminal scaffold area). The overlap segments and both 5 mm margins are illustrated. * In case 4, some cross-sections in the overlap segments and proximal site of the scaffolded lesion were not analysable due to insufficient image quality.*

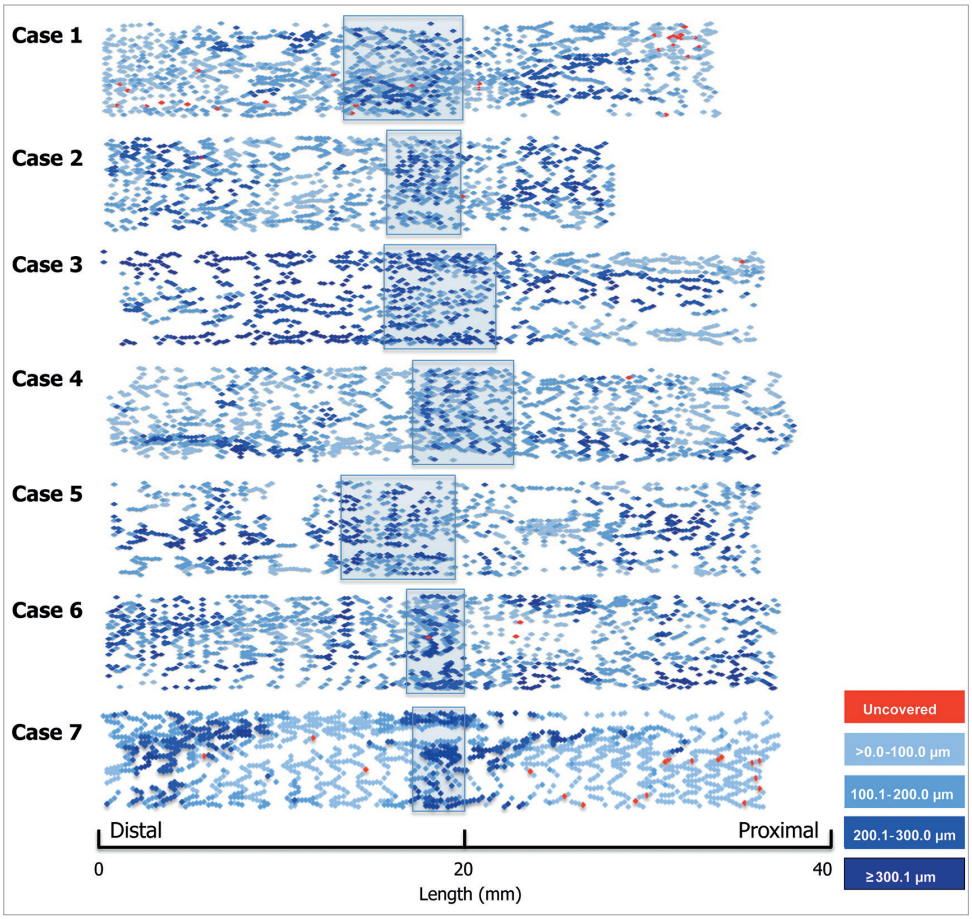

Figure 4. *The spatial distribution of the neointimal thickness and coverage status along each overlap segment and non-overlap segment at two-year follow-up. The horizontal axis indicates the distance from the distal edge of the implanted devices to the struts in the overlap and non-overlap segments. The vertical axis indicates the angle where the strut is located in the circular cross-section with respect to the centre of gravity of the vessel (0° to 360°). The neointimal thickness of each strut is colour-coded as indicated in the figure. Overlap segments (light blue square) show a mixture of light blue and dark blue, indicating the thinner neointima of "inner struts" and thicker neointima of "outer struts".*

Discussion

The major findings of the present study are: 1) post-procedure, both overlap and non-overlap segments presented a similar endoluminal scaffold area; 2) at two-year follow-up, the neointimal coverage of the BVS struts was almost completed both in overlap segments and in non-overlap segments; 3) the flow area in the overlap segments at two-year follow-up was not different from the flow area in the non-overlap segments, despite the neointimal response being greater in the overlap segments. Consequently, the treated segments showed a homogeneous lumen area through the scaffold segment.

LUMINAL DIMENSION AT THE OVERLAP SEGMENT

The lumen area at baseline was larger in the overlap segment than in the non-overlap segment. This could compensate for the greater neointimal growth at the overlap segment than at the non-overlap segment, resulting in the equivalent luminal dimensions at follow-up. As shown in **Figure 3**, post-dilatation aligned the scaffold endoluminal surface at the overlap segments, resulting in greater outward enlargement of the vessel due to double layers of struts compared to non-overlap segments. To maintain equivalent luminal dimension after neointimal coverage at an overlap segment as compared to non-overlap segments, appropriate post-dilatation might be necessary. However, the safety of this technique needs to be evaluated in further trials, since this technique could be a cause of coronary perforation[8].

TECHNICAL ISSUES WITH OVERLAPPING ABSORB SCAFFOLDS

According to a European perspective for BVS use[9], keeping the overlap to a minimum to avoid delays in healing is mandated due to the relatively thick struts of the Absorb scaffold[2]. The thick struts of the Absorb scaffold could also hinder implantation of the second Absorb scaffold, which could result in difficulty in scaffold delivery or disruption of struts.

For an optimal overlapping of Absorb scaffolds, the "marker-to-marker" (~1 mm of overlap) and "scaffold-to-scaffold" (no overlap)

techniques are recommended by the European perspective[9]. In the marker-to-marker configuration, which appears to be the best to avoid gap restenosis, the second scaffold is advanced until the distal balloon markers line up with the proximal marker beads of the implanted scaffold. As such, the markers of the second scaffold will be adjacent to the markers of the deployed scaffold. Enhanced stent visualisation-guided implantation would also be helpful[10]. Attention should be paid to scaffold size selection and placement order (i.e., starting with the distal scaffold is preferred) to avoid damage at the overlap site.

In the ABSORB EXTEND trial, planned overlapping of scaffolds was permitted in lesions with an overlap of 1 mm to 4 mm. As a result, the overlap length obtained by post-procedural OCT was 4.0 mm (2.0, 7.4 mm) in this study population. Despite the overlap length being relatively longer than the expert recommendation, procedure success was achieved in all patients and no strut disruption was observed.

It is noteworthy that the endoluminal scaffold area in the overlap segments was similar to that in the non-overlap segments post-procedure (representative case [case 6] shown in **Figure 2**). Post-dilatation made the transition between overlap and non-overlap smooth, which consequently resulted in outward enlargement of the outer scaffold and vessel wall.

DELAYED COVERAGE AND GREATER NEOINTIMAL RESPONSE IN OVERLAPPING ABSORB SCAFFOLDS

In a juvenile porcine model, overlapping Absorb scaffolds showed more delay in tissue coverage than non-overlapping scaffolds[2]. It is likely that the larger strut thickness of the stacked-like Absorb scaffolds (approximately 300 μm) in overlap segments led to a greater neointimal response compared with that in non-overlap segments. Thicker, rectangular (non-streamlined) struts, characteristic of the Absorb, may theoretically increase the device area exposed to low endothelial oscillatory shear stress areas, leading to the local accumulation of growth factors, mitogenic cytokines, and platelets, which promote neointimal formation until a smooth lumen surface is achieved[11]. The delayed coverage of overlapping struts presumably results from that greater neointimal response which has a longer duration. Despite these concerns raised from the preclinical studies, overall coverage rate of the overlap segments at two-year follow-up was achieved in 99.8% of struts, a figure similar to that of the non-overlap segments. Lumen area was similar between overlap and non-overlap segments despite the greater neointimal response in the overlap segments. Despite a large abluminal scaffold area ratio (overlap segment versus non-overlap segment), exuberant neointima in response to barotrauma was not observed.

Study limitations

The first limitations are the small number of patients included in our study, low imaging follow-up rate (50%) and consequent selection bias, despite the data representing one of the largest early registries. The small sample size did not permit drawing any conclusions on clinical relevance. The second limitation is the follow-up timing. The OCT follow-up in this study was performed two years after the index procedure. The results confirmed the completed strut coverage at least at that time point. However, the serial changes of neointimal coverage of overlapping BVS struts in humans still remain to be elucidated. Lastly, the challenges of OCT assessment for overlapping segments should be acknowledged. Artefacts of OCT such as elongation and repetition could also interfere with the results[12]. Therefore, OCT results should be interpreted with caution.

Conclusions

Despite the expectation that overlapping scaffold struts would occupy more of the luminal area than non-overlapping struts, both overlap and non-overlap segments showed similar endoluminal areas post-implantation and good vessel healing and vascular response at two-year follow-up. The results from this small OCT substudy therefore support the feasibility of overlapping scaffolds when needed for longer lesions if acute lumen expansion is achieved similar to non-overlap segments using good implantation techniques.

Impact on daily practice

Results from the present OCT study might support the feasibility of overlapping scaffolds when needed for longer lesions if acute lumen expansion is achieved similar to non-overlap segments using good implantation techniques. Since the number of patients in our analysis was very limited, the results should be interpreted with caution, and further investigation in a prospective fashion might be necessary to elucidate the impact of overlapped Absorb scaffolds on clinical outcomes.

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Conflict of interest statement

Y. Sotomi is a consultant for GOODMAN and has received a grant from Fukuda Memorial Foundation for Medical Research and SUNRISE Lab. Y. Onuma and P. Serruys are members of the Advisory Board of Abbott Vascular. W-F. Cheong, W-Y. Zhao and S. Veldhof are employees of Abbott Vascular. The other authors have no conflicts of interest to declare.

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