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Mini focus on bioresorbable scaffolds

Bioresorbable scaffolds versus everolimus-eluting metallic stents: five-year clinical outcomes of the randomised ABSORB II trial

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Introduction

The Absorb™ bioresorbable everolimus-eluting scaffold (Abbott Vascular, Santa Clara, CA, USA) was designed to provide a transient vessel scaffold and everolimus elution followed by bioresorption of the polymer, aiming to restore coronary structure and functionality. Although randomised controlled trials comparing the bioresorbable scaffold with the XIENCE everolimus-eluting stent (Abbott Vascular) demonstrated non-inferiority of Absorb compared with XIENCE in target lesion failure (TLF) at one year, the excess of early, late, and very late scaffold thromboses raised safety concerns about the bioresorbable scaffold, leading to a halt of commercialisation of the product. Theoretically, device-related events should diminish after the completion of the bioresorption process (three years); however, clinical data beyond four years have not yet been reported in the context of the randomised controlled ABSORB II trial[1]. The objective of the current report is therefore to present comparative clinical results of the Absorb scaffold and XIENCE stents up to five years in this randomised trial.

Methods

Details of the study design, study device, procedure and clinical follow-up have been published elsewhere[2]. Briefly, 501 patients were randomly assigned to receive either the Absorb scaffold or the XIENCE stent in a 2-to-1 fashion. The primary endpoints were assessed by angiography at three-year follow-up. At the three-year visit, patients were re-consented for extended follow-up up to five years. Twenty patients refused to participate in the extended follow-up. Also, at five years, thirty-seven patients were removed early due to a lapse in the protocol renewal by the Polish Ethics Committee. All clinical events were adjudicated by an independent clinical event adjudication committee. Fisher's exact test was used to compare categorical variables. The Kaplan-Meier method was used to estimate the cumulative rates of events and the log-rank test was performed to examine the differences between groups.

Results

Five-year follow-up was available in 256 patients (76.4%) and 125 patients (75.3%) in the Absorb arm and the XIENCE arm,

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respectively. Between four and five years, 2 patients died and 3 patients were lost to follow-up. Twelve patients came back for five-year follow-up, but before the predefined five-year time window. Details of the patient flow are shown in **Figure 1**. Between four and five years, TLF was observed in 0.8% (2 patients) and 0.0% (0 patients) in the Absorb arm and the XIENCE arm, respectively (p=0.33). Also, myocardial infarction was observed in one patient in the XIENCE arm (0.8%, p=0.33) between years 4 and 5 of follow-up. The patient-oriented composite endpoint (PoCE) was observed in 3.7% (10 patients) and 2.3% (3 patients) in the Absorb and the XIENCE arm, respectively (p=0.46). Importantly, no definite stent or scaffold thrombosis was observed between four and five years in either arm.

The cumulative TLF rate was 11.8% (38 patients) and 5.6% (9 patients) in the Absorb arm and the XIENCE arm, respectively (p=0.033), whereas the five-year PoCE rate was 25.0% (80 patients) and 25.7% (41 patients), respectively (p=0.78) **(Figure 2)**. At the five-year visit, 17.8% and 12.7% of patients were on dual antiplatelet therapy (DAPT) (p=0.14), although the majority of patients remained on aspirin (72.2% and 69.3%, p=0.50). Individual components of the composite endpoint and a non-hierarchical analysis of clinical outcomes are presented in **Supplementary Table 1**.

The risk difference between the Absorb and XIENCE arms in terms of TLF and PoCE at five years was evaluated according to several baseline and lesion characteristics, as shown in **Supplementary Table 2** and **Supplementary Table 3**.

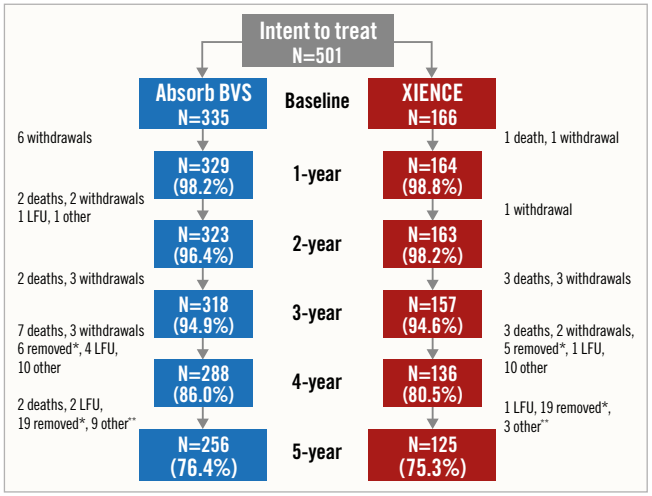
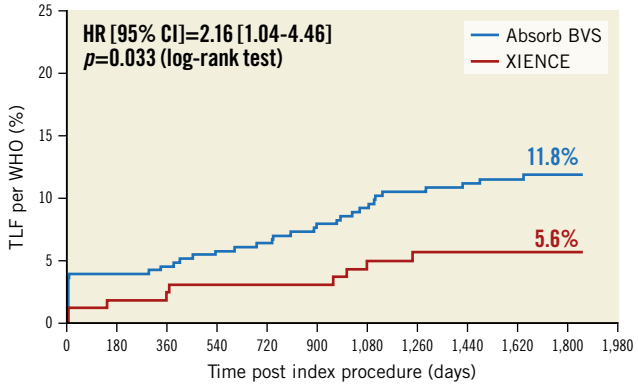


Figure 1. *Flow chart of the ABSORB II study at five-year follow-up. LFU: lost to follow-up. * The Polish Ethics Committee approval of the ABSORB II trial ended on 31 December 2016. Considering this, subject data past 31 December 2016 from the Poland site were removed from the 5-year ABSORB II analysis. ** Between 4 and 5 years, 12 patients were counted as "other." 1 patient refused to return for the 5-year visit. There were 11 patients who had completed 4-year visits but their 5-year visits occurred before the allowable window and therefore they are counted as removed without a 5-year visit.*

Discussion

The main findings of this extended follow-up of the ABSORB II trial are: i) there was no additional device thrombosis between four and five years; ii) the device-oriented composite endpoint and the PoCE remained low in both arms.

In previous randomised trials comparing Absorb and XIENCE, Absorb reached the primary endpoint in terms of TLF; however, the increased rate of scaffold thrombosis up to three years was considered to be a safety concern. The device was therefore withdrawn from commercial sale. Some studies planned to continue clinical follow-up up to seven years (e.g., COMPARE ABSORB) to investigate the potential very long-term benefit of the Absorb scaffold versus XIENCE metallic stents. The current results are encouraging in that very long-term risks of scaffold thrombosis and TLF are diminishing after completion of the degradation of the bioresorbable scaffold (3 years). Indeed, the five-year results of the ABSORB III trial also indicated the safety of the Absorb BVS beyond three years after implantation[3].



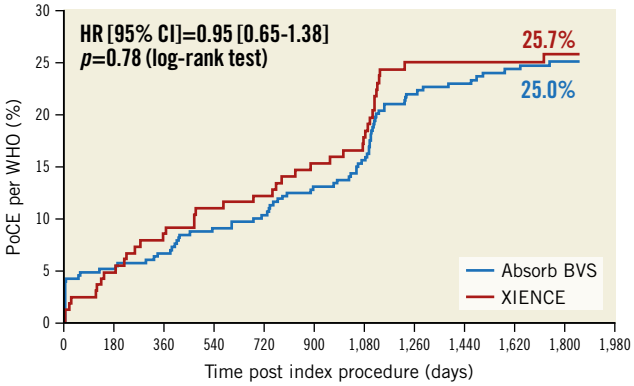


Figure 2. *Target lesion failure and patient-oriented composite endpoint up to five years. TLF (target lesion failure): cardiac death, target vessel myocardial infarction, and clinically indicated target lesion revascularisation. PoCE (patient-oriented composite endpoint): death, any myocardial infarction, and all revascularisation. Myocardial infarction was adjudicated according to the WHO definition. HR: hazard ratio; CI: confidence interval; BVS: bioresorbable vascular scaffold; WHO: World Health Organization*

The Absorb bioresorbable scaffold was designed to be bioresorbed by three years. Gas chromatography analysis in preclinical models demonstrated that, by 36 months, poly-l-lactide (PLLA) becomes undetectable[4]. The healing process of the vessel continues after biodegradation of polymer with connective tissues infiltrating into the histological void, previously occupied by the polymer[5]. At four years, the integration of the scaffold is almost complete, which is reflected in the surge of light intensity imaged by optical coherence tomography (OCT)[6]. Although case reports have described persistence of struts beyond three years, preclinical studies have indicated that such findings probably reflect only a delayed cellularisation of the matrix occupying the resorbed scaffold struts[6]. It was previously hypothesised that beyond the point of resorption the vessel would recover its physiological capacity and its native structure. Five-year results of the first-in-man ABSORB cohort B study, in which bioresorbable scaffolds had been implanted in simple stenotic lesions, showed low restenosis and low major adverse cardiac event rates, especially after the first three years[7]. Invasive imaging follow-up studies up to five years demonstrated stable lumen dimensions from midterm (24 or 36 months), suggesting the long-term efficacy of the bioresorbable scaffold in a selected population[7]. In the current ABSORB II trial, the absence of scaffold thrombosis and diminished event rates between three and five years are in line with the observations made in animal studies.

Limitations

This study has several limitations. The study was not powered for the clinical endpoint, and hence these data remain hypothesis-generating. Since the original study design was limited to follow-up up to three years, 20 patients refused to participate in this extended follow-up at the time of re-consenting. Imaging follow-up at three years might have contributed to the increase of PoCE in both arms at around that time.

Conclusion

In conclusion, this extended follow-up of the randomised ABSORB II trial demonstrates the absence of scaffold/stent thrombosis from four years to five years, and very low additional events beyond three years, the time point of full scaffold resorption. In the present study, the advantage of a bioresorbable scaffold over a metallic stent was not demonstrated, suggesting that an improved version of the bioresorbable scaffold is needed to justify its clinical use.

Impact on daily practice

The long-term follow-up of the ABSORB II randomised controlled trial demonstrated the absence of very late scaffold thrombosis between four and five years.

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Conflict of interest statement

P. Serruys is a member of the Advisory Board of Abbott Vascular, and reports personal fees from Biosensors, Micel Technologies, Sino Medical Sciences Technology, Philips/Volcano, Xeltis, and HeartFlow, outside the submitted work. B. Chevalier was a consultant for Abbott Vascular and reports personal fees from Abbott Vascular, during the conduct of the study; he reports other from Colibri, and personal fees from Biotronik, Medtronic, and Terumo, outside the submitted work. M. de Sousa Almeida reports that his institution received fees as part of its participation in the ABSORB II trial but not himself. A. Cequier reports grants and personal fees from Abbott Vascular and Biosensors, grants from Boston Scientific, Biomenco, Cordis, OrbusNeich, and the Spanish Society of Cardiology, personal fees from Biotronik and Medtronic, outside the submitted work. M. Sabaté reports the following conflicts of interest outside the submitted work: consultant for Abbott Vascular and iVascular. S. Windecker has received research and educational grants to the institution from Abbott, Amgen, Bayer, BMS, Boston Scientific, Biotronik, CSL Behring, Medtronic, Edwards, Polares and Sinomed. G. Campo reports grants from Boston Scientific, AstraZeneca, Medis, and Sahajanand Medical Technologies, outside the submitted work. D. Dudek reports having received speaker fees, being on the advisory board of and being an investigator for Abbott. R. Rapoza is a full-time employee of Abbott Laboratories, the sponsor of this trial. N. West is employed by Abbott Vascular. The other authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Table 1. Outcomes at 5 years.

Supplementary Table 2. Comparison of risk of TLF between the Absorb BVS and the XIENCE stent according to baseline, angiographic, and imaging characteristics.

Supplementary Table 3. Comparison of the risk of PoCE between Absorb BVS and XIENCE according to baseline, angiographic, and imaging characteristics.

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Supplementary data

Supplementary Table 1. Outcomes at 5 years.

Clinical outcomes - non-hierarchical events up to 5 years			
	Absorb BVS	**XIENCE**	***p*-value**
	N=335	**N=166**	
Death, n (%)	13 (4.6)	7 (5.1)	0.82
Cardiac	5 (1.8)	4 (2.9)	0.48
Vascular	1 (0.4)	0 (0.0)	1.00
Non-cardiovascular	7 (2.5)	3 (2.2)	1.00
Myocardial infarction, n (%)	27 (9.5)	6 (4.3)	0.07
Q-wave	10 (3.5)	2 (1.4)	0.35
Non-Q-wave	18 (6.3)	4 (2.9)	0.14
Revascularisation - non-hierarchical events up to 5 years			
All revascularisations, n (%)	59 (20.7)	34 (24.6)	0.36
All TLR	28 (9.8)	8 (5.8)	0.16
ID-TLR	23 (8.1)	3 (2.2)	0.02
All NTL-TVR	18 (6.3)	14 (10.1)	0.16
All NTVR	30 (10.5)	20 (14.5)	0.24
Clinical outcomes - non-hierarchical events from 4 years to 5 years			
Death, n (%)	2 (0.8)	0 (0.0)	1.00
Cardiac	0 (0.0)	0 (0.0)	1.00
Vascular	0 (0.0)	0 (0.0)	1.00
Non-cardiovascular	2 (0.8)	0 (0.0)	1.00
Myocardial infarction, n (%)	0 (0.0)	1 (0.8)	0.33
Q-wave	0 (0.0)	0 (0.0)	1.00
Non-Q-wave	0 (0.0)	1 (0.8)	0.33
All revascularisations, n (%)	8 (3.1)	2 (1.6)	0.51
All TLR	2 (0.8)	1 (0.8)	1.00
All NTL-TVR	4 (1.6)	0 (0.0)	0.31
All NTVR	4 (1.6)	1 (0.8)	1.00
Scaffold/stent thrombosis up to 5 years			
Definite ST 0-1,853 days, n (%)	8 (3.0)	0 (0.0)	0.057
Acute/subacute (0-30 days)	2 (0.6)	0 (0.0)	1.00
Late (31-365 days)	0 (0.0)	0 (0.0)	1.00
Very late (366-1,853 days)	6 (1.8)	0 (0.0)	0.19
Very late between 4- and 5-year follow-up	0 (0.0)	0 (0.0)	1.00
Definite/probable ST 0-1,853 days, n (%)	9 (3.4)	0 (0.0)	0.03
Acute/subacute (0-30 days)	2 (0.6)	0 (0.0)	1.00
Late (31-365 days)	1 (0.3)	0 (0.0)	1.00

Very late (366-1,853 days)		6 (1.8)	0 (0.0)	0.19
Very late between 4- and 5-year follow-up		0 (0.0)	0 (0.0)	1.00
Post-procedure usage of antiplatelet medication up to 5 years				
On aspirin, n (%)	At 1 year	320 (95.8)	158 (95.2)	0.75
	At 5 years	241 (72.2)	115 (69.3)	0.50
On DAPT, n (%)	At 1 year	270 (81.3)	134 (80.7)	0.87
	At 2 years	87 (26.2)	43 (25.9)	0.94
	At 3 years	88 (26.5)	40 (24.1)	0.56
	At 4 years	69 (20.8)	24 (14.5)	0.09
	At 5 years	59 (17.8)	21 (12.7)	0.14

Data are presented as n (%).
BVS: bioresorbable vascular scaffold; ID-TLR: ischaemia-driven TLR; NTL-TVR: non-target lesion TVR; NTVR: non-target vessel revascularisation; TLR: target lesion revascularisation; TVR: target vessel revascularisation

Supplementary Table 2. Comparison of risk of TLF between Absorb BVS and XIENCE according to baseline, angiographic, and imaging characteristics.

Outcomes	Absorb BVS	XIENCE	*p*-value	Relative risk BVS vs XIENCE [95% CI]	*p*-value for interaction
TLF up to 5 years					
AI					
AI ≤0.3	11.7% (11/94)	5.4% (5/92)	0.1903	2.15 [0.78, 5.96]	0.7728
AI >0.3	16.2% (27/167)	9.5% (4/42)	0.3396	1.70 [0.63, 4.59]	
EI					
EI ≥0.7	14.8% (28/189)	5.4% (7/129)	**0.0100**	2.73 [1.23, 6.06]	**0.0180**
EI <0.7	13.9% (10/72)	40.0% (2/5)	0.1707	0.35 [0.10, 1.17]	
PSP					
Fulfilling PSP criteria	10.0% (1/10)	14.3% (1/7)	1.0000	0.70 [0.05, 9.41]	0.4139
Not fulfilling PSP criteria	13.5% (37/275)	6.1% (8/131)	**0.0282**	2.20 [1.06, 4.60]	
RVD					
Small vessel (≤2.5 mm)	17.1% (21/123)	10.5% (6/57)	0.3693	1.62 [0.69, 3.80]	0.5032
Not small vessel (>2.5 mm)	10.5% (17/162)	3.8% (3/80)	0.0852	2.80 [0.84, 9.27]	
Age					
≤60	13.2% (17/129)	4.3% (3/70)	0.0507	3.07 [0.93, 10.13]	0.3561
>60	13.5% (21/156)	8.8% (6/68)	0.3798	1.53 [0.64, 3.61]	
Sex					
Male	14.7% (32/218)	7.0% (8/114)	0.0503	2.09 [1.00, 4.39]	0.9949
Female	9.0% (6/67)	4.2% (1/24)	0.6707	2.15 [0.27, 16.95]	
Diabetes mellitus					
DM	20.0% (13/65)	15.8% (6/38)	0.7931	1.27 [0.53, 3.06]	0.1699
Non-DM	11.4% (25/220)	3.0% (3/100)	**0.0172**	3.79 [1.17, 12.25]	
TLF from 4 years to 5 years					
AI					
AI ≤0.3	0.0% (0/85)	0.0% (0/83)	1.0000	NA	1.0000
AI >0.3	1.3% (2/151)	0.0% (0/38)	1.0000	NA	
EI					
EI ≥0.7	0.6% (1/171)	0.0% (0/118)	1.0000	NA	NA
EI <0.7	1.5% (1/65)	0.0% (0/3)	1.0000	NA	

PSP					
Fulfilling PSP criteria	0.0% (0/10)	0.0% (0/6)	1.0000	NA	1.0000
Not fulfilling PSP criteria	0.8% (2/248)	0.0% (0/119)	1.0000	NA	
RVD					
Small vessel (≤2.5 mm)	1.8% (2/112)	0.0% (0/51)	1.0000	NA	NA
Not small vessel (>2.5 mm)	0.0% (0/146)	0.0% (0/73)	1.0000	NA	
Age					
≤60	0.9% (1/117)	0.0% (0/65)	1.0000	NA	NA
>60	0.7% (1/141)	0.0% (0/60)	1.0000	NA	
Sex					
Male	0.5% (1/198)	0.0% (0/104)	1.0000	NA	NA
Female	1.7% (1/60)	0.0% (0/21)	1.0000	NA	
Diabetes mellitus					
DM	0.0% (0/53)	0.0% (0/31)	1.0000	NA	1.0000
Non-DM	1.0% (2/205)	0.0% (0/94)	1.0000	NA	

TLF is defined as a composite of cardiac death, target vessel MI, and clinically driven TLR.
Asymmetry index (AI) was calculated per lesion as (1 - minimum scaffold/stent diameter/maximum scaffold/stent diameter), based on intravascular ultrasound.
Eccentricity index (EI) was calculated as the ratio of minimum and maximum scaffold/stent diameter per cross-section, based on intravascular ultrasound.
PSP (predilation, sizing and post-dilation) is defined as fulfilling all of the following three criteria; 1) optimal predilation (balloon to core laboratory-derived reference vessel diameter ratio ≥1:1); 2) vessel size selection (reference vessel diameter ≥2.25 mm and ≤3.75 mm); 3) post-dilation (with a non-compliant balloon at ≥18 atm and larger than the nominal scaffold diameter, but not by >0.5 mm larger).
Denominator of all columns excludes subjects who are truly lost to follow-up, defined as subjects who are removed at a given time point without any PoCE (all death, all MI, all revascularisation) event.
Bold digits indicate statistical significance (p-value <0.05).
AI: asymmetry index; BVS: bioresorbable vascular scaffold; DM: diabetes mellitus; EI: eccentricity index; MI: myocardial infarction; NA: not applicable; PSP: predilation, sizing and post-dilation; RVD: reference vessel diameter; TLF: target lesion failure; TLR: target lesion revascularisation

Supplementary Table 3. Comparison of risk of PoCE between Absorb BVS and XIENCE according to baseline, angiographic, and imaging characteristics.

Outcomes	Absorb BVS	XIENCE	*p*-value	Relative risk BVS vs XIENCE [95% CI]	*p*-value for interaction
PoCE up to 5 years					
AI					
AI ≤0.3	30.9% (29/94)	28.3% (26/92)	0.7492	1.09 [0.70, 1.70]	0.3009
AI >0.3	27.5% (46/167)	35.7% (15/42)	0.3432	0.77 [0.48, 1.24]	
EI					
EI ≥0.7	29.1% (55/189)	29.5% (38/129)	1.0000	0.99 [0.70, 1.40]	0.1715
EI <0.7	27.8% (20/72)	60.0% (3/5)	0.1542	0.46 [0.21, 1.04]	
PSP					
Fulfilling PSP criteria	40.0% (4/10)	57.1% (4/7)	0.6372	0.70 [0.26, 1.89]	0.5188
Not fulfilling PSP criteria	27.6% (76/275)	28.2% (37/131)	0.9061	0.98 [0.70, 1.37]	
RVD					
Small vessel (≤2.5 mm)	27.6% (34/123)	35.1% (20/57)	0.3821	0.79 [0.50, 1.24]	0.3236
Not small vessel (>2.5 mm)	28.4% (46/162)	26.3% (21/80)	0.7621	1.08 [0.70, 1.68]	
Age					
≤60	28.7% (37/129)	30.0% (21/70)	0.8711	0.96 [0.61, 1.50]	0.9526
>60	27.6% (43/156)	29.4% (20/68)	0.8717	0.94 [0.60, 1.47]	
Sex					
Male	29.8% (65/218)	31.6% (36/114)	0.8018	0.94 [0.67, 1.32]	0.7827
Female	22.4% (15/67)	20.8% (5/24)	1.0000	1.07 [0.44, 2.64]	
Diabetes mellitus					
DM	38.5% (25/65)	34.2% (13/38)	0.8326	1.12 [0.66, 1.92]	0.5038
Non-DM	25.0% (55/220)	28.0% (28/100)	0.5840	0.89 [0.61, 1.32]	
PoCE from 4 years to 5 years					
AI					
AI ≤0.3	2.4% (2/85)	2.4% (2/83)	1.0000	0.98 [0.14, 6.77]	0.7627
AI >0.3	4.0% (6/151)	2.6% (1/38)	1.0000	1.51 [0.19, 12.17]	
EI					
EI ≥0.7	1.8% (3/171)	2.5% (3/118)	0.6909	0.69 [0.14, 3.36]	NA
EI <0.7	7.7% (5/65)	0.0% (0/3)	1.0000	NA	

PSP					
Fulfilling PSP criteria	20.0% (2/10)	16.7% (1/6)	1.0000	1.20 [0.14, 10.58]	0.7769
Not fulfilling PSP criteria	3.2% (8/248)	1.7% (2/119)	0.5097	1.92 [0.41, 8.90]	
RVD					
Small vessel (≤2.5 mm)	2.7% (3/112)	5.9% (3/51)	0.3781	0.46 [0.10, 2.18]	NA
Not small vessel (>2.5 mm)	4.8% (7/146)	0.0% (0/73)	0.0983	NA	
Age					
≤60	2.6% (3/117)	4.6% (3/65)	0.6680	0.56 [0.12, 2.67]	NA
>60	5.0% (7/141)	0.0% (0/60)	0.1058	NA	
Sex					
Male	4.0% (8/198)	1.0% (1/104)	0.1714	4.20 [0.53, 33.14]	0.0823
Female	3.3% (2/60)	9.5% (2/21)	0.2750	0.35 [0.05, 2.33]	
Diabetes mellitus					
DM	7.5% (4/53)	3.2% (1/31)	0.6472	2.34 [0.27, 20.01]	0.6866
Non-DM	2.9% (6/205)	2.1% (2/94)	1.0000	1.38 [0.28, 6.69]	

PoCE is defined as a composite of all death, all MI (regardless of MI definition), and all revascularisation.
Asymmetry index (AI) was calculated per lesion as (1 - minimum scaffold/stent diameter/maximum scaffold/stent diameter), based on intravascular ultrasound.
Eccentricity index (EI) was calculated as the ratio of minimum and maximum scaffold/stent diameter per cross-section, based on intravascular ultrasound.
PSP (predilation, sizing and post-dilation) is defined as fulfilling all of the following three criteria; 1) optimal predilation (balloon to core laboratory-derived reference vessel diameter ratio ≥1:1); 2) vessel size selection (reference vessel diameter ≥2.25 mm and ≤3.75 mm); 3) post-dilation (with a non-compliant balloon at ≥18 atm and larger than the nominal scaffold diameter, but not by >0.5 mm larger).
Denominator of all columns excludes subjects who are truly lost to follow-up, defined as subjects who are removed at a given time point without any PoCE event.
AI: asymmetry index; BVS: bioresorbable vascular scaffold; DM: diabetes mellitus; EI: eccentricity index; MI: myocardial infarction; NA: not applicable; PoCE: patient-oriented composite endpoint; PSP: predilation, sizing and post-dilation; RVD: reference vessel diameter