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The comparison of early healing 1-month after PCI among CoCr-everolimus-eluting stent (EES), biodegradable polymer (BP)-EES and BP-sirolimus-eluting stent: Insights from OFDI and coronary angioscopy ☆

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ABSTRACT

Background: Third-generation stents with abluminal biodegradable polymer (BP) might facilitate early healing. Therefore, we compared early healing between second-generation and third-generation stents using coronary angioscopy (CAS) and optical frequency domain imaging [OFDI].

Methods: We prospectively enrolled 30 consecutive patients with stent implantation for acute coronary syndrome (cobalt chromium [CoCr] everolimus-eluting stent [EES] [n = 10], BP-EES [n = 10], and BP-sirolimus eluting stent [SES] [n = 10]). All patients underwent CAS and OFDI 1 month after initial percutaneous coronary intervention. On OFDI, the stent coverage (SC), thrombus, and peri-strut low intensity area (PLIA) were assessed. CAS findings were recorded for the grade of SC, grade of yellow color (YC), and grade of the thrombus (TG).

Results: On OFDI, the incidences of any thrombus at the 1-month follow-up were 70%, 80%, and 80% in the CoCr-EES, BP-EES, and BP-SES groups, respectively. The percentage of coverage was comparable among the groups (CoCr-EES 79.8 vs. BP-EES 79.9 vs. BP-SES 80.1%, P = 0.96). However, the number of struts with PLIA was numerically higher in the BP-SES group than in the CoCr-EES and BP-EES groups (46.4 ± 25.1 vs. 21.6 ± 13.2 vs. 22.0 ± 7.2%, P = 0.08). In the CoCr-EES, BP-EES, and BP-SES groups, mean grades of SC were 1.25 ± 0.5, 1.25 ± 0.5, and 0.85 ± 0.70 (P = 0.60); mean grades of YC were 0.75 ± 0.5, 0.80 ± 0.45, and 0.88 ± 0.37 (P = 0.65), and mean grades of TG were 1.00 ± 1.00, 1.20 ± 0.83, and 0.88 ± 0.64 (P = 0.75), respectively.

Conclusion: Third-generation stents are not inferior to second-generation stents regarding stent coverage. However, PLIA on OFDI was often observed with BP-SESs, indicating involvement of the fibrin component.

1. Introduction

Drug-eluting stents (DESs) have dramatically reduced the rate of in-stent restenosis and target revascularization by inhibiting neointimal hyperplasia [1]. However, delayed neointimal healing and incomplete endothelialization have gained attention as causes for late stent thrombosis (ST) with first-generation DESs [2–4].

Second-generation DESs were designed to overcome these limitations of first-generation DESs after improvement of the stent platform, the use of alternative anti-proliferative limus analogues, and development of biocompatible polymers [5]. In fact, stopping dual anti-platelet therapy (DAPT) at 3 months in selected patients after cobalt chromium (CoCr)-everolimus-eluting stent (EES) implantation of second-generation DESs was at least as safe as the prolonged DAPT regimen used in the historical control group [6]. Furthermore, third-generation stents were a newly developed DES with a bioresorbable polymer (resorbed within 3–4 months) coated only albuminally by applying special gradient technology. Currently, several papers have described the long-term outcome using these stents [7,8]. In addition, there is the possibility that third-generation stents might facilitate early switching from DAPT to single anti-platelet therapy (SAPT).

The recent development of light-based intravascular imaging with the improved resolution of optical frequency domain imaging (OFDI) was associated with increased capability to evaluate both acute stent implantation results [9] and aspects of the late healing process,

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including late malapposition [10], vessel remodeling, and strut coverage [11,12]. Thus, OFDI has emerged as an excellent tool for evaluating the time course of strut coverage.

Coronary angioscopy (CAS), as a tool of macroscopic pathology in living patients, can evaluate intra-stent status and the extent of atherosclerosis according to the presence of yellow plaque with direct and full-color vision. Yellow plaque, especially that of high yellow color grade, is regarded as vulnerable plaque, and it has been associated with future coronary events [13–18]. Furthermore, CAS provides morphological information of atherosclerotic plaque, thrombus, and vascular healing, such as the neointima after stent implantation [19,20].

The present study investigated and compared early healing at 1 month after percutaneous coronary intervention (PCI) among CoCr-EES, biodegradable polymer (BP)-EES stent, and BP-sirolimus-eluting stent (SES).

2. Methods

2.1. Study population

Thirty consecutive patients who underwent stent implantation (the CoCr-EES [XIENCE Alpine™; Abbott Vascular, Santa Clara, CA, USA], N = 10; BP-EES [Synergy™; Boston Scientific Corporation, Marlborough, MA, USA], N = 10; and BP-SES [Ultimaster™; Terumo Corp., Tokyo, Japan], N = 10) for acute coronary syndrome (ACS) were prospectively enrolled. Patients had ischemic chest discomfort with ST-segment elevation or depression of >0.5 mm or T-wave inversion in 2 or more leads. Acute myocardial infarction was diagnosed by increased troponin T levels, serum levels of creatine phosphokinase (more than twice the upper limit of normal), and creatine phosphokinase-MB fraction (>10% of the total creatine kinase). Patients without elevation of the creatine kinase-MB fraction were classified as having unstable angina.

Patients with the following criteria were excluded: cardiogenic shock, left main coronary artery disease, extremely tortuous or heavily calcified vessels, intolerance to antiplatelet drugs, in-stent restenosis after DES implantation, overlapped stenting, multiple stenting, and severe chronic kidney disease (estimated glomerular filtration rate < 30 mL/min/1.73 m^2).

2.2. Ethical statement

Our study was approved by our institutional ethics review board, and all participants provided written informed consent about this protocol for the use of their data in our prospective analysis.

2.3. Procedure of PCI

Patients who had undergone emergent PCI in this study presented to the emergency room with suspected ACS. Aspirin (200 mg) was administered orally in the emergency room, followed by a daily maintenance per oral dose of 100 mg thereafter. In addition, patients received prasugrel at a loading dose of 20 mg, respectively, with daily maintenance per oral doses of 3.75 mg for prasugrel thereafter. DAPT was continued for at least 1 year after PCI. Furthermore, unfractionated heparin was administered intravenously to achieve an activated clotting time of 200–250 s during PCI. A 6-French (F) arterial sheath and a transradial or transfemoral artery approach were used. Angiography was performed using a 6-F guiding catheter to identify the site of the culprit lesion. A 0.014-inch coronary guidewire was passed through the lesion. First, thrombus aspiration was performed when any thrombus was observed on angiography. The pre-dilatation procedure were also performed to obtain forward flow if necessary. Subsequently, after intravascular evaluation by intravascular ultrasonography (IVUS) or OFDI based on an operator's discretion, a stent was implanted at the site of culprit plaque. However, the use of stents was randomized. Finally, post-dilatation procedures were also performed based on the IVUS or OFDI assessment.

2.4. Image acquisition by OFDI at 1 month after initial PCI

The Fastview catheter (Terumo Corp., Tokyo, Japan) was positioned distally to the implanted stent segment. The automatic injector filled with flash media (i.e., contrast or a mixture with saline) was connected to the standard y-piece of the guiding catheter. After confirming the correct position of the Fastview catheter by fluoroscopy and that the guiding catheter was selectively engaged into the ostium of the coronary artery by fluoroscopy, the artery was cleared of blood by the automatic injection of flash media at a flow rate of 4–5 mL/s. After sufficient clearance of the artery, automated pullback was started at a speed of 20 mm/s with a frame rate of 160 frames/s. Pullback was stopped after visualization of the complete coronary segment. OFDI analysis was performed using a dedicated offline review system by the independent experienced staff.

Regarding the stented segment, the lumen and stent areas, strut coverage, malapposition, incidence of any thrombus, and peri-strut low intensity area (PLIA) were evaluated according to previous report (Fig. 1A–D) [21]. PLIA was defined as a region around the stent struts with a homogeneous lower intensity than surrounding tissue on OFDI images without signal attenuation. The %strut coverage was calculated as follows: (the number of covered struts) × 100 / (the number of all observed struts). The %malapposition was also assessed as follows: (the number of struts with malapposition) × 100 / (the number of all observed struts). PLIA was defined as a peri-strut region of homogeneous lower intensity observed on OFDI without signal attenuation. The %PLIA was calculated as follows: (the number of struts surrounded by PLIA) × 100 / (the number of all observed struts). Thrombus was defined as the presence of any thrombus. Finally, the calcification score was determined as follows: 0, no calcification; 1, <1 quadrant; 2, ≥1 but <2 quadrants; 3, ≥2 quadrants but <3 quadrants; and 4, ≥3 quadrants.

2.5. Image acquisition by CAS at 1 month after initial PCI

CAS (Smart-i™ type S11; iHeart Medical Co., Ltd., Tokyo, Japan) was used to evaluate the stented segment (Fig. 2A–D). Manual pullback images of the left coronary artery (6 cc/s, total 40 cc) and right coronary artery (4 mL/s, total 40 cc) by CAS was recorded during continuous infusion of contrast media by the autoinjector. According to a previous report [22], yellow color (0: white, 1: slightly yellow, 2: yellow, and 3: intensive yellow) and stent coverage: (0: no coverage, 1: poor coverage, and 2: complete coverage) were assessed. In addition, the thrombus grade was defined as follows: 0, no thrombus; 1, several spotty thrombi; and 2, thrombus extending between the struts. CAS analysis was performed by the independent experienced staff.

2.6. Statistical analyses

All statistical analyses were performed using SPSS, version 22 (IBM Japan, Tokyo, Japan).

Continuous data with a non-normal distribution are presented as means ± standard deviations, and categorical data are presented as counts and percentages. Differences among the CoCr-EES, BP-EES and BP-SES groups were evaluated using a Kruskal-Wallis analysis for nonparametric data followed by multiple comparisons with Dunn's method and χ^2 or Fisher's exact test for categorical data. A two-sided P-value < 0.05 was considered statistically significant in all analyses.

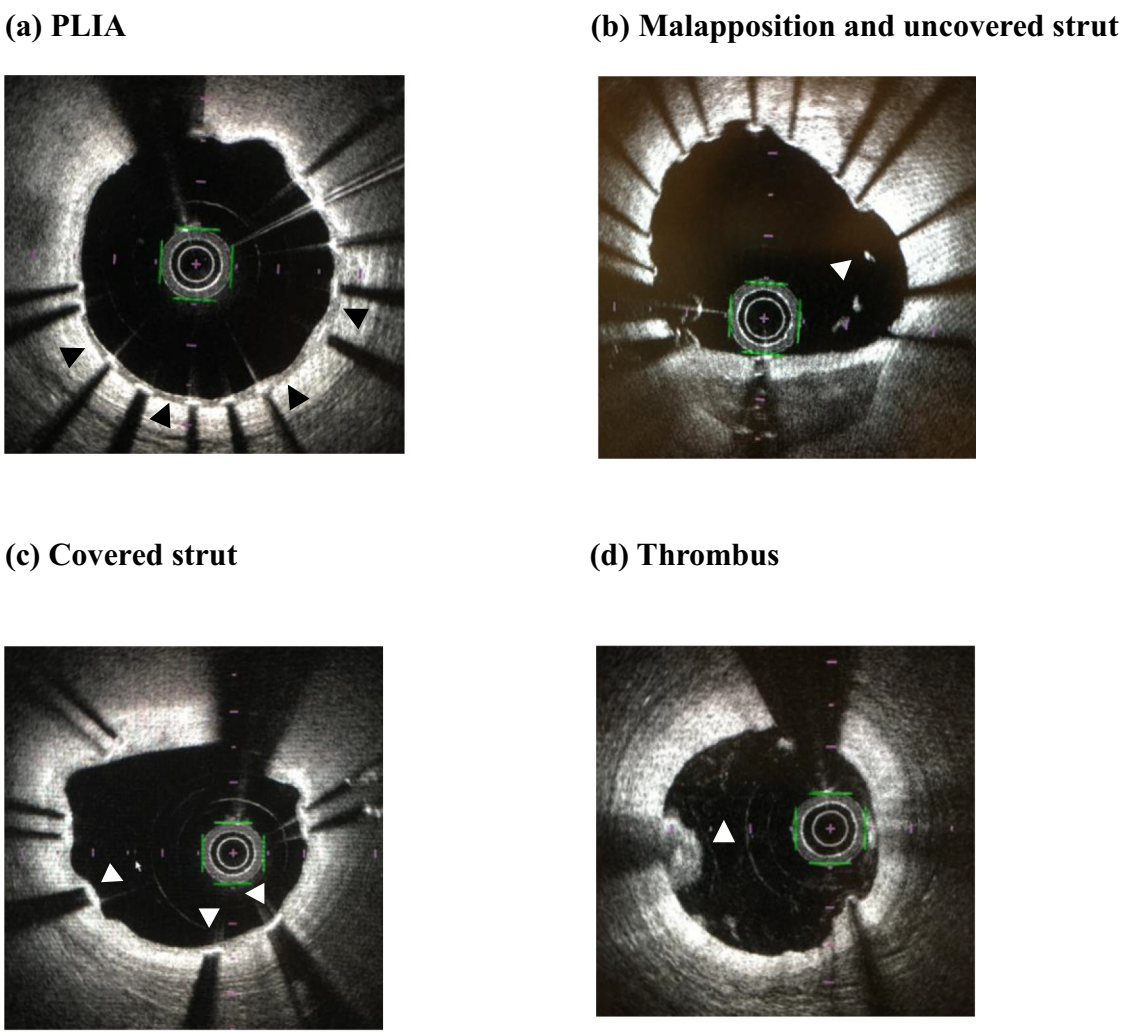

Fig. 1. Representative findings of optical frequency domain imaging. (A) The peri-strut low intensity area (PLIA) is shown (black arrowhead). PLIA was defined as a region around stent struts with a homogeneous lower intensity than surrounding tissue on optical coherence tomography images without signal attenuation. (B) Malapposition and the uncovered strut are shown (white arrowhead). (C) The covered strut is shown (white arrowhead). (D) The thrombus is shown (white arrowhead).

3. Results

3.1. Patient and PCI procedure characteristics among the three stents

In the CoCr-EES, BP-EES, and BP-SES groups, patients' mean ages were 70 ± 9, 69 ± 5, and 67 ± 9 years, respectively (P = 0.69) (Table 1). Respectively, men comprised 60, 70, and 70% of patients in the aforementioned groups. In addition, the presence of hypertension, dyslipidemia, and diabetes mellitus, and smoker status were similar among the three stents groups. There were also no significant differences in the culprit coronary artery, the angiographic data of the culprit lesion, and the incidences of pre-dilatation and post-dilatation, and diameter and length of the implanted stents (Table 2).

3.2. Difference in the CAS and OFDI findings at 1 month after PCI

There was no difference in the stent area among the three stent groups. No significant difference was also observed in the %strut coverage and %malapposition among the CoCr-EES, BP-EES, and BP-SES groups (79.8 ± 7.3 vs. 79.9 ± 8.9 vs. 80.1 ± 17.5%, P = 0.96; 9.1 ± 8.5 vs. 2.7 ± 2.3 vs. 3.5 ± 6.8%, P = 0.25, respectively) (Table 3). At least one thrombus per stent (strut coverage) was observed in about 80% of cases in all three stent groups. However, only %PLIA tended to be higher in the BP-SES group than in the CoCr-EES and BP-EES groups.

Using CAS, the yellow color score, stent coverage grade, and thrombus grade were observed. As shown in Table 4, there were no significant differences in the yellow color score, stent coverage grade, and thrombus grade among the three stent groups.

4. Discussion

The main findings of the present study are as follows: 1) there were no significant differences in %strut coverage on OFDI at 1 month after PCI, 2) there were no significant differences in CAS findings at 1 month after PCI, 3) and %PLIA tended to be higher in the BP-SES group than in the CoCr-EES and BP-EES groups.

4.1. The importance of healing after stent implantation

First-generation DES implantation has been associated with an increased risk of late ST and very late ST because of a delayed healing response with slower strut coverage [23]. Consequently, the prolonged duration of DAPT was recommended [24]. However, currently, the development of DESs with biocompatible polymers (second-generation DESs) and abluminal coated polymer (third-generation DESs) has been associated with a dramatic decrease in ST risk [6,25], leading to the recommendation of a shorter duration of DAPT in the guidelines [26]. There are still few reports on early healing at 1 month after PCI using

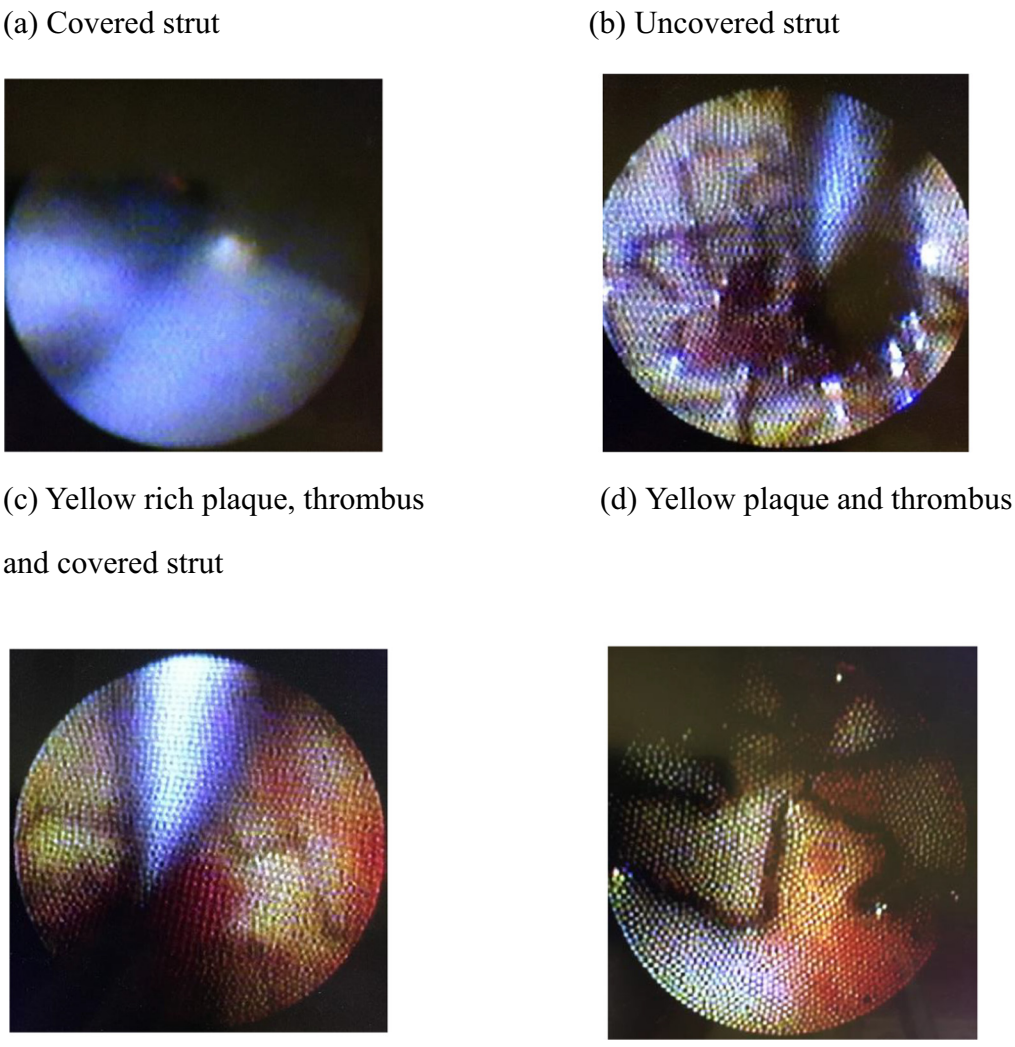

Fig. 2. Representative findings of coronary angioscopy. (A) The covered strut is shown without yellow plaque. (B) The uncovered strut and several spotty thrombi are shown. (C) The covered strut is covered by yellow, rich plaque, and thrombi are shown. (D) Yellow plaque and thrombi are shown.

both CAS and OFDI. However, in the present study, three stent groups already had about 80% strut coverage, which might indicate a good healing response in strut coverage. In fact, in several studies that investigated patients at 3 months after PCI, the healing outcome of these three stent types was improved [27–31]. Herein, there was no significant difference in OFDI findings and CAS findings, except for PLIA on OFDI. Considering these results, third-generation stents are not inferior to second-generation stents in early healing. However, attention should be paid to the slight difference in PLIA on OFDI findings. According to a previous study, optical density measurements revealed a significant difference between fibrin-covered and neointima-covered coronary stent struts [12]. PLIA on OCT in the long term has been reported to consist of proteoglycan with enriched inflammatory cells [32,33]. Therefore, based on these reports, physicians should avoid considering

Table 1
Baseline characteristics.

	CoCr-EES (N = 10)	BP-EES (N = 10)	BP-SES (N = 10)	P value
Clinical presentation				0.79
STEMI	5	4	2	
NSTEMI	3	4	5	
Unstable angina	2	2	3	
Age (years)	70 ± 9	69 ± 5	67 ± 9	0.69
Male/female (n)	6/4	7/3	7/3	0.75
Body weight (kg)	72 ± 7	61 ± 3	65 ± 8	0.11
Hypertension	8(80)	7(70)	9(90)	0.53
Dyslipidemia	6(60)	7(70)	7(70)	0.75
Diabetes mellitus	4(40)	5(50)	3(30)	0.61
Smoking, ever	3(30)	4(40)	5(50)	0.45

Data are presented as means ± SD or the number (percentage).STEMI, ST elevated myocardial infarction; NSTEMI, non-ST elevated myocardial infarction.

Table 2
PCI procedure.

	CoCr-EES (N = 10)	BP-EES (N = 10)	BP-SES (N = 10)	P value
LAD/LCX/RCA (n)	5/2/3	4/2/4	4/3/3	0.98
Thrombus aspiration	5 (50)	4 (40)	3 (30)	0.79
Pre-dilatation	6 (60)	6 (60)	7 (70)	0.79
Stent diameter (mm)	3.0 ± 0.8	3.0 ± 0.7	2.8 ± 0.4	0.51
Stent length (mm)	25.4 ± 3.5	23.2 ± 4.7	26.2 ± 5.4	0.37
Post dilatation	6 (60)	6 (60)	4 (40)	0.64
Final TIMI flow				0.61
0	0	0	0	
1	0	0	0	
2	0	1	1	
3	10	9	9	

Data are expressed as number (%) or means ± SD. QCA, quantitative coronary angiography; MLD, minimum lumen diameter; TIMI, thrombolysis in myocardial infarction.

Table 3
OFDI findings 1 month after PCI.

	CoCr-EES (N = 10)	BP-EES (N = 10)	BP-SES (N = 10)	P value
OFDI findings				
Stent area (mm^2)	7.8 ± 3.2	6.9 ± 3.5	6.8 ± 2.2	0.62
% strut coverage	79.8 ± 7.3	79.9 ± 8.9	80.1 ± 17.5	0.96
% PLIA	21.6 ± 13.2	22.0 ± 7.2	46.4 ± 25.1	0.08
%Malapposition	9.1 ± 8.5	2.7 ± 2.3	3.5 ± 6.8	0.25
Calcification grade	0.8 ± 0.7	0.5 ± 0.4	0.2 ± 0.2	0.18
Any thrombus per stent (%)	70	80	80	0.83

Data are expressed as means ± SD. PLIA, peri-strut low intensity area.

struts surrounded by low-intensity material to have neointima coverage. In a case with a yellow color score of 0 on CAS, the discrimination between a neointima-covered strut and fibrin-covered strut has been reported to be difficult [34]. In the present study, there was no significant difference in the yellow color score despite the high incidence of PLIA in BP-SES. In other words, the present finding in BP-SES might indicate the involvement of a fibrin component. Late coronary DES thrombosis is associated with high morbidity and mortality and the increasing use of DES [35–38]. Furthermore, in pathological studies, Finn et al. observed that the percentage of uncovered stent struts represented the best morphometric predictor of late DES thrombosis [4]. Herein, %strut coverage at 1 month after PCI was almost 80% in all three stent groups, and there was no difference in %strut coverage. However, detection of the presence or absence of neointimal coverage may be potentially limited by the resolution of OFDI. Thus, struts classified as uncovered by OFDI might still have a very thin coverage of tissue of <10–20 μm, although the biological protection offered by such thin coverage is debatable. Additionally, analyses of fibrin-covered stent struts suggested that these may be rarely detected as uncovered stent struts by OFDI [12]. Furthermore, fibrin coverage of stent struts has been also observed in conditions associated with an increased risk of ST [2,39–41]. Therefore, both coronary imaging modalities such as OFDI and CAS may be needed for the evaluation of early healing after stent implantation.

The reason why the incidence of PLIA in the BP-SES group was higher remains unknown. However, differences in the polymer used for different DESs could cause varying degrees of inflammation [41]. Therefore, it is possible that biodegradation of the polymer coating after stent implantation might cause greater inflammation than a fluoropolymer, like the inflammation caused by bioresorbable vascular scaffolds [42]. Furthermore, sirolimus and similar compounds inhibit vascular smooth muscle cell proliferation and endothelial cell growth [43]. Therefore, a higher incidence of PLIA in the BP-SES group, indicating fibrin might be associated with these findings. Additionally, PCI procedures such as under-expansion have been known to be involved in neointimal proliferation and healing after stent implantation [44]. However, herein, there were no significant differences in the calcification grade before stent implantation, stent area after implantation, incidences of pre-dilatation and post-dilatation, and length and size of the implanted stent. Further, all patients underwent PCI for ACS.

Though all three stent types had a good long-term outcome, fibrin coverage of stent struts has been observed in conditions associated with an increased risk of ST as aforementioned. Therefore, in patients with a higher %PLIA who are switched from DAPT to SAPT early, such as at 1 month after PCI, it still remains unknown whether the incidence of ST increases. Therefore, new protocol studies involving larger populations and longer longitudinal follow-up periods will be needed in the future to clarify this issue.

Table 4
CAS findings 1 month after PCI.

	CoCr-EES (N = 10)	BP-EES (N = 10)	BP-SES (N = 10)	P value
CAS findings				
Yellow color score (n)				0.32
0	1	0	2	
1	6	6	7	
2	3	3	1	
3	0	1	0	
Stent coverage (n)				0.37
0	1	1	0	
1	9	9	10	
2	0	0	0	
Thrombus grade (n)				0.87
0	2	2	1	
1	6	6	8	
2	2	2	1	

5. Limitations

The limitations of this study are as follows. First, the number of study patients is relatively small though there are few reports on early healing (1-month) among CoCr-EES, BP-EES and BP-SES using both OFDI and CAS. Second, at initial procedure, the analysis of IVUS or OFDI was performed based on operator's discretion though the use of stent was randomized. The resolution of IVUS is even inferior to that of OFDI. Therefore, the difference of used device might affect the result of the present study. Third, the entire stented segment could not be evaluated, because angioscopic observation was performed in forward-viewing mode only. On the other hand, the entire stented segment was evaluated using OFDI. Fourth, although OFDI has high resolution (10–20 μm), it is still unable to make an accurate distinction between fibrin and neointimal hyperplasia, and to determine whether the neointima is covered by a layer of endothelial cells though the evaluation by CAS was also performed. Finally, OFDI and CAS in the present study were performed under DAPT 1-month after PCI. Therefore, no definite conclusion regarding the effect of a higher %PLIA and switching from DAPT to SAPT early after PCI on long-term outcome, such as ST, can be drawn from the present study findings, warranting the need for new protocol studies involving larger populations and longer longitudinal follow-up periods in the future.

6. Conclusions

Third-generation stents might not be inferior to second-generation stents regarding stent coverage. However, PLIA on OFDI was often observed with BP-SES, although there were no differences in CAS findings. This finding might indicate the involvement of a fibrin component. Therefore, the incidence of whether ST increases should be further investigated in patients with a higher %PLIA who are switched from DAPT to SAPT early after PCI.

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