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# Serial Comparison of Neointimal Coverage between Two Different Concept Stents: Optical Coherence Tomographic Evaluation

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#### Abstract

Recently, two different concept drug-eluting stents including biolimus A9-eluting stents (BES) with biodegradablepolymer and everolimus-eluting stents (EES) with durable biocompatible-polymer are available. However, serial comparison of BES and EES on neointimal coverage is not fully investigated. We performed serial evaluation of neointimal coverage at 8 months (BES polymer remained) and 20 months follow-up (BES polymer absorbed) by optical coherence tomography (OCT) for 14 BESs and 10 EESs, and compared uncovered strut proportion (%Uncovered), malapposed strut proportion (%Malapposed) and average neointimal hyperplasia thickness (Ave-NHT), numbers of extra stent lumen (ESL) and multiple interstrut hollow (MIH) calculated by OCT between two DESs, at 8 months and 20 months follow-up, respectively. As a result. at 8 months, Ave-NHT of EES was significantly higher than BES (124  $\pm$  65 µm vs 83  $\pm$  47 µm, p<0.001) but %Uncovered and %Malapposed were similar between the two groups. At 20 months, %Uncovered and ESL of EES were significantly lower than BES (0.8  $\pm$  5.7% vs 4.8  $\pm$  12.7%, p<0.001 and 0.86  $\pm$  1.28 vs 0.09  $\pm$  0.16, p=0.043) and Ave-NHT of EES was significantly higher than BES (185  $\pm$  88 µm vs 90  $\pm$  46 µm, P<0.001). In conclusion, EES showed favorable neointimal healing compared to BES.

**Keywords:** Coronary artery disease; Drug-eluting stent; Everolimuseluting stent; Biolimus a9-eluting stent; Optical coherence tomography

#### Introduction

First generation drug-eluting stents (DES) had dramatically reduced restenosis and target vessel revascularization after percutaneous coronary intervention (PCI) compared to bare metal stents (BMS) [1,2]. However, first generation DESs had durable and non-biocompatible polymer, and their polymer could induce chronic inflammation and result in delayed neointimal coverage which may cause very late stent thrombosis (VLST) [3,4]. At present, second generation DESs including biodegradable-polymer coated biolimus A9-eluting stents (BES) whose polymer will be absorbed within twelve months, and biocompatible durable-polymer coated everolimuseluting stents (EES) are available. BES showed better clinical outcome as compared to sirolimus-eluting stents, which is first generation DES, in LEADERS trial [5]. Moreover, strut coverage evaluated by optical coherence tomography (OCT) at 9 months follow-up to be more complete in patients with BESs as compared to SES [6]. EES also showed better clinical outcome compared to first generation DES [7,8]. We previously reported that EES showed better neointimal coverage at bifurcation compared to first generation DESs including sirolimus-, paclitaxel-, and zotalolimus-eluting stents, by OCT study [9]. Some reports showed that angiographic and clinical outcomes after BES implantation was noninferior to that after EES implantation, [10,11] but, serial comparison of these two types of second generation DES: BES and EES, in terms of neointimal coverage is not fully investigated. In the present study, we compared the neointimal characteristics of BES and EES by serial OCT evaluation.

#### Methods

#### **Study population**

Eleven patients with 14 BESs (NoboriTM; Terumo, Tokyo, Japan) and eight patients with 10 EESs (Xience VTM; Abbott Vascular, Santa Clara, CA, USA or PROMUSTM; Boston Scientific, Natick, MA, USA) who had undergone serial evaluation of neointimal coverage at 8 months (BES polymer still remained) and 20 months follow-up (BES polymer was already absorbed) by OCT, were prospectively enrolled. Medical ethics committee of Osaka Rosai Hospital approved this study and we obtained written informed consent from all study patients.

#### **OCT procedure**

The OCT system used in present study consisted of a computer, a monitor display, and time-domain OCT system (Model M2 Cardiology Imaging system; St. Jude Medical, St. Paul, MN, USA) or frequency-domain OCT system (C7-XRTM; St. Jude Medical), an occlusion balloon catheter (HeliousTM; Goodman Corp, Nagoya, Japan) to remove blood and a 0.016 inch wire-type imaging catheter (Imaging Wire TM; St. Jude Medical) in case of usage of Model M2 system, and Dragonfly TM. imaging catheter (St. Jude Medical) in case of usage of C7-XRTM. We analyzed continuous cross-sections at 1 mm longitudinal interval within stented segment in standard maneuver as previously reported [12]. Two independent observers blinded to patient's information analyzed digitally stored OCT data.

## **OCT** evaluation

After PCI, 8 months and 20 months follow-up OCT were performed. We excluded restenotic lesion (lumen diameter>50% stenosis by angiogram), stent-in stent, and cross-sectional image with major side branch (>2.0 mm in diameter), overlap stents segment, and

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poor image. We performed OCT evaluation every 1 mm cross-sectional image, and compared three OCT parameters, including uncovered strut proportion (%Uncovered), malapposed strut proportion (%Malapposed), and averaged neointimal hyperplasia thickness (Ave-NHT) calculated by OCT between BES and EES, at 8 months and 20 months follow-up, respectively. Uncovered strut was defined as a strut whose any part exposed to the lumen [13-15]. Malapposed struts was defined as a strut with the distance between the center of strut blooming and the adjacent lumen border  $\ge 100 \ \mu m$  in EES, and  $\ge 150$ µm in BES, considering their polymer and strut thickness, respectively. %Uncovered and %Malapposed were calculated as follows: %Uncovered or %Malapposed = (the number of uncovered or malapposed struts/ observed struts in the same cross-section)  $\times$  100. Ave-NHT was defined as mean value of neointimal hyperplasia thickness on each strut in the same cross-section. Moreover, we evaluated the numbers of extra stent lumen (ESL) and multiple inter-strut hollow (MIH) in the same stent, which were considered as predictive factors of VLST [16,17]. MIH was defined as a lumen outside the stent strut with the depth  $\geq$  500 µm16 and ESL as a lumen outside the stent strut with the depth<500 µm. We counted numbers of ESL or MIH in each stent, and calculated ESL index and MIH index. ESL index and MIH index were defined as follows; ESL index or MIH index = (total number of ESL or MIH in the same stent / total observed cross-sections in the same stent). Representative images of ESL and MIH were shown in Figure 1.

## Statistical analysis

All continuous values were expressed as mean ± SD (standard deviation). To compare numerical data between two groups, Welch's t test was used. P value<0.05 was considered to be statistically significant. Inter-observer reproducibility of the OCT analysis was assessed by Lin's concordance correlation [18]. All calculations were performed by using commercially available statistical package (JMP® 11; SAS Institute, Inc., Cary, NC, USA).

# Results

We analyzed 11 patients with 14 BESs (250 cross-sections / 2243 struts at 8 months, 260 cross-sections / 2061 struts at 20 months followup), and 8 patients with 10 EESs (154 cross-sections / 1269 struts at 8 months, 158 cross-sections / 1229 struts at 20 months follow-up). Patients' characteristics were shown in Table 1. The prescription of renin-angiotensin system blockers of patients with EES was significantly higher than that of patients with BES, but there were no significant differences of the other parameters between two groups. Angiographic characteristics were shown in Table 2. Left anterior descending artery lesion of BES group had a tendency to be higher than that of EES but not significant. There were no significant differences of the other parameters between two groups.

# **OCT findings**

Serial OCT findings of BES and EES: Serial (8 months and 20 months) OCT findings of BES and EES were shown in Figure 2. In BES, the incidences of %Uncovered and %Malapposed were decreased from 8 months (BES polymer still remained) to 20 months (BES polymer was already absorbed) but not significant (5.8%  $\pm$  13.3 vs. 4.8  $\pm$  12.7% in %Uncovered, p=0.39 and  $0.9 \pm 5.0\%$  vs.  $0.4 \pm 3.5\%$  in %Malapposed, p=0.17). Ave-NHT was similar from 8 months to 20 months ( $83 \pm 47$  $\mu$ m vs. 90 ± 49  $\mu$ m, p=0.10). ESL and MIH indices were numerically decreased but did not show the significant differences between 8 and 20 months (1.6  $\pm$  2.6 vs. 0.9  $\pm$  1.3 in ESL, p=0.33, and 0.03  $\pm$  0.67 vs.  $0.01 \pm 0.04$  in MIH, p=0.43) (Figure 2a). In EES, on the other hand, the incidence of %Uncovered significantly decreased, and Ave-NHT was significantly increased from 8 months to 20 months ( $8.0 \pm 15.6\%$  vs. 0.8 $\pm$  5.7% in %Uncovered, p<0.001 and 124  $\pm$  65 µm vs. 185  $\pm$  88 µm in Ave-NHT, p<0.001). The incidence of % Malapposed was similar ( $0.4 \pm$ 3.7% vs. 0.6  $\pm$  6.7%, p=0.69). ESL index was very rare and numerically





ESL

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Figure 1: Representative images of extra stent lumen (ESL) and multiple inter-strut hollow (MIH). ESL was defined as a lumen outside the stent strut with the depth<500 µm, and MIH was defined as a lumen outside the stent strut with the depth  $\geq$  500 µm.

	BES 14 stents / 11patients	EES 10 stents / 8patients	P value
Age	64 ± 11	69 ± 6	0.28
Male n (%)	10 (91)	7 (88)	0.23
Hypertension n (%)	5 (45)	7 (88)	0.10
Diabetes n (%)	4 (36)	3 (38)	0.76
Dyslipidemia n (%)	3 (27)	5 (63)	0.76
Hyperuricemia n (%)	2 (18)	1 (13)	0.86
Smoking n (%)	5 (45)	1 (13)	0.86
Prior MI n (%)	1 (9)	0 (0)	0.38
Prior PCI n (%)	10 (91)	7 (88)	0.81
Prior CABG n (%)	0 (0)	0 (0)	1.00
Prior CVA n (%)	2 (18)	1 (13)	0.34
PAD n (%)	0 (0)	1 (13)	0.34
DAPT (%)	93%	100%	0.23
Statin (%)	91%	100%	0.23
RASB (%)	7%	50%	0.02
CCB (%)	64%	63%	0.15
Beta-blocker (%)	27%	50%	0.29

BES: Biolimus A9-Eluting Stents; CABG: Coronary Artery Bypass Grafting; CCB: Calcium Channel Blocker; CVA: Cerebrovascular Accident; DAPT: Dual Antiplatelet Therapy; EES: Everolimus-Eluting Stents; MI: Myocardial Infarction; PAD: Peripheral Artery Disease; PCI: Percutaneuos Coronary Intervention; RASB: Renin-Angiotensin System Blocker

Table 1: Baseline characteristics.

	BES 14 stents / 11patients	EES 10 stents / 8patients	p value
Culprit Lesion			
LAD / RCA / LCX	11/1/2	4/5/2	0.06
ACS n (%)	2 (18%)	2 (25%)	0.15
Stent diameter (mm)	2.96 ± 0.37	2.83 ± 0.26	0.38
Stent length (mm)	21.4 ± 5.0	20.8 ± 4.7	0.80
AHA/ACC type B2/C lesion n (%)	12 (86%)	7 (64%)	0.20

ACS: Acute Coronary Syndrome: AHA/ACC: American Heart Association/ American College of Cardiology; BES: Biolimus A9-Eluting Stents; EES: Everolimus-Eluting Stents; LAD: Left Anterior Descending Artery; LCX: Left Circumflex Artery; RCA: Right Coronary Artery

Table 2: Angiographic characteristics.

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Figure 2: Serial OCT findings of BES and EES. (a) In biolimus A9-ejuting stent (BES), the incidences of uncovered strut proportion (%Uncovered) and malapposed strut proportion (%Malapposed) were decreased from 8 months to 20 months but not significant. Average neointimal thickness (Ave-NHT) was similar between 8 months and 20 months. Extra stent lumen (ESL) and multiple interstrut hollow (MIH) indices were numerically decreased from 8 months to 20 months but not significant. (b) In everolimus-eluting stent (EES), the incidence of uncovered strut proportion (%Uncovered) significantly decreased, and Average neointimal thickness (Ave-NHT) was significantly increased from 8 months to 20 months. The incidence of malapposed strut proportion (%Malapposed) was similar between 8 months and 20 months. Extra stent lumen (ESL) index was very rare and numerically decreased. There were no multiple interstrut hollow (MIH) at both 8 and 20 months. CS, cross-section; 8M, 8 months; and 20M, 20 months.

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decreased (0.25  $\pm$  0.36 vs. 0.09  $\pm$  0.16, p=0.20). There were no MIH at both 8 and 20 months (Figure 2b).

Comparison of OCT findings between BES and EES: We compared OCT findings between BES and EES at 8 months to 20 months, respectively. At 8 months (BES polymer still remained), Ave-NHT of EES was significantly higher than that of BES ( $124 \pm 65 \mu m vs.$  $8.3 \pm 47 \mu m$ , p<0.001), but %Uncovered ( $8.0 \pm 15.6\%$  vs.  $5.8 \pm 13.3\%$ , p=0.155) and %Malapposed ( $0.4 \pm 3.7\%$  vs.  $0.9 \pm 5.0\%$ , p=0.190) were similar between EES and BES. In addition, ESL and MIH indices were similar between EES and BES (0.4  $\pm$  0.4 vs.1.6  $\pm$  2.6, p=0.115 and 0 vs. 0.03  $\pm$  0.07), although there was no MIH in EES (Figure 3a). At 20 months (BES polymer was already absorbed), %Uncovered of EES was significantly lower than that of BES (0.8  $\pm$  5.7% vs. 4.8  $\pm$  12.7%, p<0.001), and Ave-NHT of EES was significantly higher than that of BES (185  $\pm$  88 µm vs. 90  $\pm$  46 µm, p<0001). %Malapposed was similar between two groups ( $0.6 \pm 6.7\%$  vs.  $0.4 \pm 3.5\%$ , p=0.721). In addition, ESL index of EES was significantly lower than that of BES ( $0.09 \pm 0.16$ vs.  $0.86 \pm 1.28$ , p=0.043). MIH was very rare in both group, especially there was no MIH in EES (Figure 3b).

**Inter-observer reproducibility:** Lin's concordance correlations for the evaluation of the inter-observer reproducibility was 0.987 for Ave-NHT. This data suggested almost perfect agreement between the two observers. As the assessment of the strut apposition, coverage and neointimal characteristics including ESL and MIH, when two persons' opinion did not suit, it was discussed and determined.

## Discussion

In this study, we showed the followings; (1) On EES, %Uncovered significantly decreased, and Ave-NHT of EES significantly increased from 8 months to 20 months, while, on BES, there were no significant differences of all OCT parameters from 8 months to 20 months. (2) With comparison between EES and BES, at 8 months Ave-NHT of EES was significantly higher than that of BES, and at 20 months %Uncovered and the frequency of ESL of EES were significantly lower, and Ave-NHT of EES was significantly higher than those of BES.

In this study, uncovered strut proportions assessed by OCT of EES and BES were similar at 8 months (short-term) follow up ( $8.0 \pm 15.6\%$ with EES vs.  $5.8 \pm 13.3\%$  with BES, p=0.155). These data corresponded to the previous published data which were reported Tada et al. (4.9% with EES vs. 10.7% with BES, p=0.34) [19]. On the other hand, Kubo et al. reported that the percentage of uncovered struts (3  $\pm$  7% with EES vs.  $9 \pm 10\%$  with BES, p<0.001) and the percentage of malapposed struts (0.2  $\pm$  0.8% with EES vs. 1.3  $\pm$  2.8% with BES, p=0.006) were significantly lower in EES than BES, and mean neointima thickness in EES was significantly higher than BES (105  $\pm$  82  $\mu$ m with EES, 91  $\pm$  80 µm with BES, p<0.001) at 8-12 months (short to mid-term) [12]. In our study, at 20 months (mid-term), both DESs showed more advanced neointimal healing on %Uncovered ( $0.8 \pm 5.7\%$  with EES and  $4.8 \pm 12.7$ with BES, respectively), on %Malapposed ( $0.6 \pm 6.7\%$  with EES and 0.4 $\pm$  3.5% with BES, respectively) as compared to those of 8-12 months (short to mid-term) data reported by Kubo et al. [12] %Uncovered: 3  $\pm$  7% with EES and 9  $\pm$  10% with BES, respectively and %Malapposed:  $0.2 \pm 0.8\%$  with EES and  $1.3 \pm 2.8\%$  with BES). Ave-NHT of EES at 20 months indicated also advanced neointimal healing (185  $\pm$  88  $\mu$ m), as compared to that of 8-12 months (short to mid-term) data reported by Kubo et al. [12] (105  $\pm$  82  $\mu$ m with EES). With regard to ESL, in our data, ESL index with both BES and EES numerically decreased from 8to 20-month follow-up (mid-term). Similarly, Konishi et al., reported about favorable neointimal healing of BES from 6- to 12 month follow-



**Figure 3:** Comparison of OCT findings between BES and EES. (a) At 8 months, averaged neointimal thickness (Ave-NHT) of everolimus-eluting stent (EES) was significantly higher than that biolimus A9-ejuting stent (BES), but uncovered strut proportion (%Uncovered) and malapposed strut proportion (%Malapposed) were similar between EES and BES. extra stent lumen (ESL) and multiple inter-strut hollow (MIH) indices were similar between EES and BES, although there was no MIH in EES. (b) At 20 months, %Uncovered of EES was significantly lower than that of BES, and Ave-NHT of EES was significantly higher than that of BES. %Malapposed was similar between two groups. ESL index of EES was significantly lower than that of BES. MIH was very rare in both groups, especially there was no MIH in EES.

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up (short to mid-term) [20]. They reported that the frequency of stents with ESL in BES, nevertheless not significant, decreased from 6- to 12-month follow-up (short to mid-term) [20]. Accordingly, these data suggested that biocompatible durable-polymer coated EES showed more favorable neointimal healing as compared to biodegradable-polymer coated BES until mid-term (20 months).

Recent large-scale network meta-analysis demonstrated that biodegradable-polymer coated BESs were associated with similar rates of cardiac death/myocardial infarction (MI), MI, and target vessel revascularization compared with second-generation durable-polymer EESs comprised of cobalt-chromium or platinum-chromium, but showed higher rates of definite stent thrombosis than durable-polymer EES comprised of cobalt-chromium at 1-year follow-up [21]. OCT findings of present study, whose EESs were comprised of only cobaltchromium, could explain possible mechanism for meta-analysis just described. Biodegradable-polymer coated BES was expected to show favorable neointimal healing after polymer was absorbed, but durablepolymer coated EES was superior to biodegradable-polymer coated BES on neointimal coverage in this study. We consider the difference of strut thickness between BES and EES is one of the reasons for this unexpected result, namely, BES has thicker strut than that of EES (strut thickness is 135  $\mu m$  in BES, and 81  $\mu m$  in EES). We previously reported the efficacy of thin-strut DESs compared to thick-strut DESs [22]. It is suggested that thicker strut of BES, compared to thinner strut of EES, is disadvantage in neointimal healing.

In addition, Palmerini et al. demonstrated that EES treatment had the lower rate of stent thrombosis within 2 years of stent implantation as compared to BMS, which usually showed lower rate of stent thrombosis and higher rate of restenosis as compared to DES [23].

To the best of our knowledge, this is the first report showing serial and 20-month comparison of neointimal condition between EES and BES by OCT. According to our findings, EES may be considered as one of the most favorable DESs at present.

There were several limitations in this study. First, this study was retrospective, non-randomized, with small number of patients. Second, all patients underwent real serial OCT evaluation but every cross-sectional image of 8 months did not completely accord with the same cross-sectional image of 20 months because poor images were excluded. Third, clinical outcome such as major adverse cardiac events including cardiac death, target vascular revascularization, myocardial infarction, and stent thrombosis was not evaluated. Fourth, conventional OCT technology cannot distinguish between neointima and another material such as fibrin. Finally, the present study showed only mid-term result. Therefore, further larger studies in long-term will be needed to better prove the clinical significance of this study.

## Conclusion

From serial (8 months to 20 months) OCT evaluation, biocompatible durable-polymer coated EES showed more favorable neointimal healing as compared to biodegradable-polymer coated BES, which may be beneficial against VLST.

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