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Optical Frequency Domain Imaging Versus Intravascular Ultrasound in Percutaneous Coronary Intervention (OPINION Trial)

Results From the OPINION Imaging Study

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ABSTRACT

OBJECTIVES The authors sought to clarify how intravascular ultrasound (IVUS) and optical coherence tomography affect percutaneous coronary intervention (PCI) with current-generation drug-eluting stents in a pre-specified substudy of the OPINION (OPtical frequency domain imaging versus INtravascular ultrasound in percutaneous coronary interventiON) trial, a multicenter, prospective, randomized, noninferiority trial comparing optical frequency domain imaging (OFDI)-guided PCI with IVUS-guided PCI.

BACKGROUND The impact of these 2 imaging modalities in guiding PCI remains unknown.

METHODS Of 829 patients enrolled in the OPINION trial, 106 were included in the present imaging substudy. Their PCI was guided by either IVUS or OFDI, but all patients were imaged by both modalities after PCI and by OFDI at 8 months. Angiographic, OFDI, and IVUS images were analyzed by independent core laboratories, and statistical analysis was done independently by a dedicated institution.

RESULTS A total of 103 patients underwent either OFDI-guided (n = 54) or IVUS-guided (n = 49) PCI. Immediately after PCI, OFDI-guided PCI was associated with a smaller trend of minimum stent area (5.28 ± 1.65 mm^2 vs. 6.12 ± 2.34 mm^2; p = 0.088), fewer proximal stent-edge hematomas (p = 0.04), and fewer irregular protrusions (p = 0.014) than IVUS-guided PCI. At 8 months, the neointima area tended to be smaller in the OFDI-guided PCI group than in the IVUS-guided PCI group (0.56 ± 0.30 mm^2 vs. 0.80 ± 0.65 mm^2; p = 0.057), although the percentage of uncovered struts was significantly higher in the OFDI-guided PCI group than in the IVUS-guided PCI group (6.97 ± 7.03% vs. 4.67 ± 6.43%; p = 0.039). The minimum lumen area was comparable in both groups (p = 0.18).

CONCLUSIONS There were several differences in local findings between OFDI- and IVUS-guided PCI as expected given the different protocols for stent sizing in the 2 groups. The minimum lumen area at the 8-month follow-up was comparable, suggesting that OFDI- and IVUS-guided PCI are similarly feasible using the current-generation drug-eluting stents. (OPtical frequency domain imaging versus INtravascular ultrasound in percutaneous coronary interventiON; NCT01873222) (J Am Coll Cardiol Img 2018;11:111–23) © 2018 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

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ABBREVIATIONS AND ACRONYMS

DES = drug-eluting stent(s)

IVUS = intravascular ultrasound

MLA = minimum lumen area

MSA = minimum stent area

OCT = optical coherence tomography

OFDI = optical frequency domain imaging

PCI = percutaneous coronary intervention

Intravascular ultrasound (IVUS) guidance for percutaneous coronary intervention (PCI) using drug-eluting stents (DES) reduces stent thrombosis, myocardial infarction, and major adverse cardiac events within 1 year after PCI compared with conventional angiography guidance (1). Optical coherence tomography (OCT) has a >10 × higher resolution than that of IVUS, and offers more detailed information on microstructural findings (e.g., intrastent tissue protrusion, incomplete stent apposition, and stent-edge dissection) during PCI (2). Optical frequency domain imaging (OFDI) (Lunawave, Terumo Corporation, Tokyo, Japan) is the most recent intravascular imaging device based on OCT technology. It enables rapid image acquisition of a long coronary segment (up to 150 mm, 40 mm/s) within a few seconds. Based on this, OFDI can be a useful alternative PCI guide, and is expected to improve the PCI procedure for optimal stent deployment (3).

SEE PAGE 124

The OPINION (OPtical frequency domain imaging versus INtravascular ultrasound in percutaneous coronary interventiON) trial compared OFDI-guided PCI with IVUS-guided PCI (4). In this trial, OFDI-guided PCI (n = 414) was noninferior to IVUS-guided PCI (n = 415) for the primary endpoint of target vessel failure (a composite of cardiac death, target vessel-related myocardial infarction, and ischemia-driven target vessel revascularization) at 12 months (5.2% vs. 5.1%; $p_{noninferiority} = 0.042$, respectively) (5). There are, however, only limited data regarding how, and to what extent, these 2 imaging modalities affect PCI with current-generation DES.

Herein we report a pre-specified OPINION imaging study comparing acute and midterm arterial response to OFDI-guided PCI with IVUS-guided PCI by analyzing OFDI and IVUS imaging immediately after stenting (after PCI), and OFDI imaging at the 8-month follow-up.

METHODS

STUDY DESIGN AND POPULATION. OPINION is a prospective, multicenter, randomized, active-controlled, open-label, parallel group, noninferiority trial comparing OFDI-guided PCI with IVUS-guided PCI with a second-generation DES for the primary endpoint of target vessel failure (defined in the previous text) at 12 months. Patients admitted to 42 hospitals in Japan between June 10, 2013, and July 1, 2014 (Online Appendix), were included. An independent data and safety monitoring committee monitored the safety, and Wakayama Medical University (Wakayama, Japan), one of the clinical sites, coordinated the trial. The Translational Research Informatics Center (Kobe, Japan) undertook data management, statistical analysis, and site management. Adult patients (20 to 85 years of age) scheduled for PCI with a second-generation DES to a de novo native coronary artery lesion were eligible for inclusion. Patients with myocardial infarction in the previous 3 months, cardiogenic shock, congestive heart failure, chronic kidney disease (estimated glomerular filtration rate <30 ml/min/1.73 m^2 or serum creatinine level >1.5 mg/dl), hemodialysis or peritoneal dialysis, 3-vessel disease, left main coronary artery disease, aorto-ostial lesion arising within 3 mm of the origin of a coronary artery, chronic total occlusion, small vessel disease (reference vessel diameter <2.5 mm), coronary bypass graft, in-stent restenosis, or planned surgery within 1 year were not eligible. Patients were randomly assigned to 1 of 2 groups, receiving either OFDI- or IVUS-guided PCI with a second-generation DES. The randomization using a web-based randomization software (eClinical Base, Translational Research Informatics Center, Kobe, Japan) was stratified by age, history of diabetes, and participating cardiovascular centers (Online Appendix) (4). Among 829 patients enrolled in the OPINION trial, the first 106 consecutive patients at 7 pre-selected study sites were included in the present exploratory imaging study (**Figure 1**). Patients were excluded from this subanalysis if they were considered ineligible by the investigator in charge, or if additional diagnostic imaging by OFDI or IVUS after PCI, or by OFDI at 8-month follow-up angiography, would be difficult for them. All participants provided written informed consent. Local research ethics boards approved the study protocol.

PROCEDURES. Detailed procedures were described previously (4). In the OFDI-guided PCI group,

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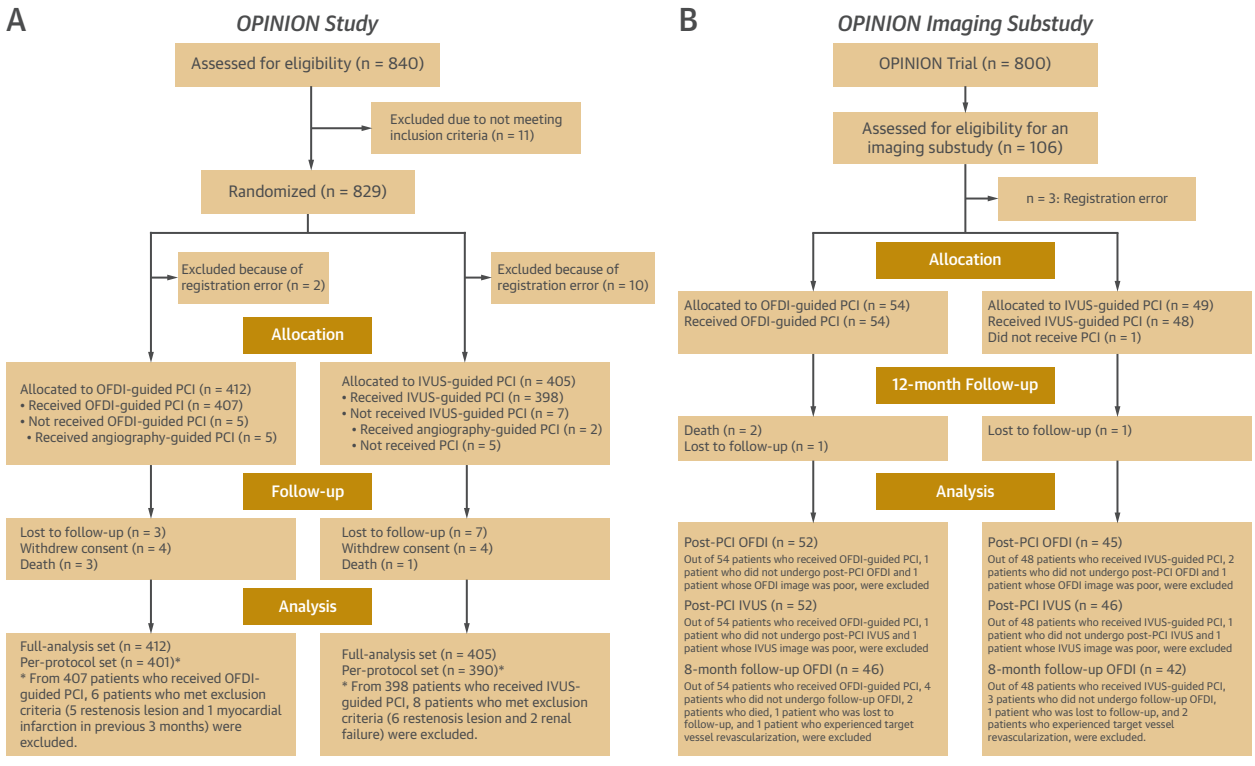
FIGURE 1 Trial Profile

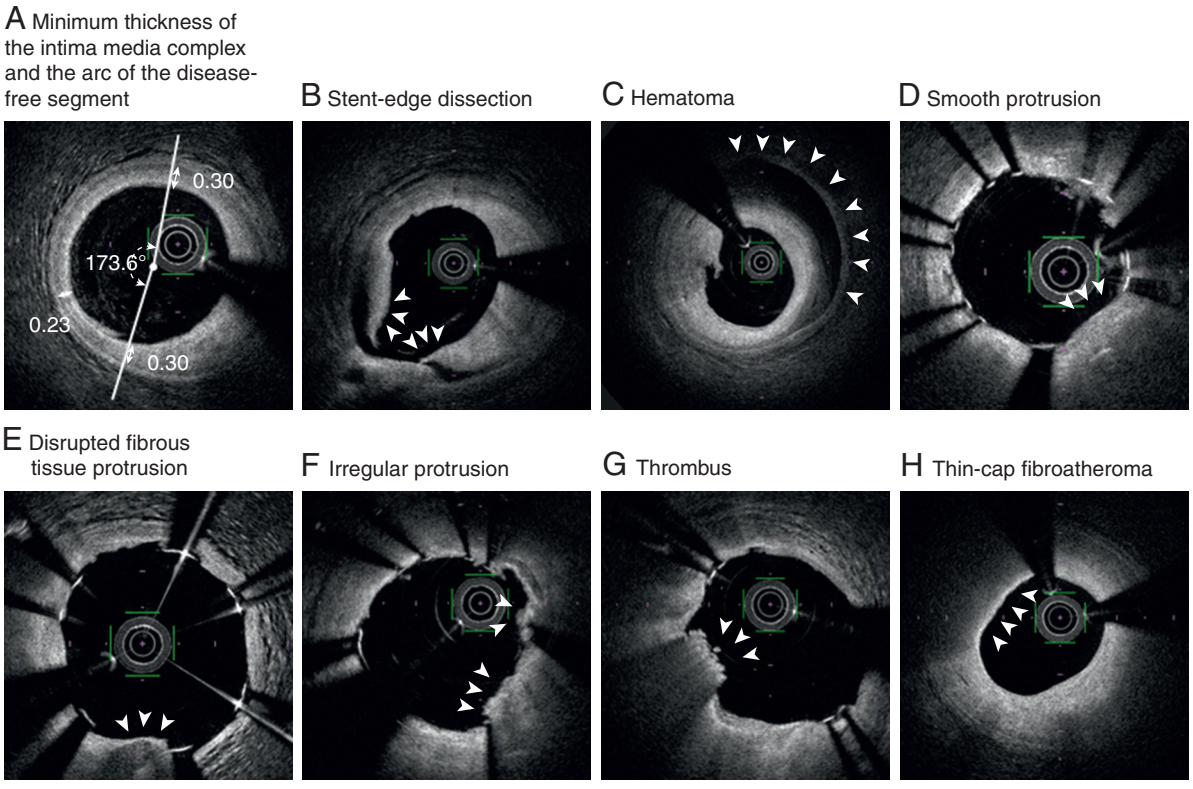


(A) OPINION study. **(B)** OPINION imaging substudy. IVUS = intravascular ultrasound; OFDI = optical frequency domain imaging; OPINION = OPtical frequency domain imaging versus INtravascular ultrasound in percutaneous coronary interventiON; PCI = percutaneous coronary intervention.

proximal and distal reference sites were set at cross sections adjacent to the target lesion that had the most normal appearance and were free of lipidic plaque. Stent diameter was determined by measuring the lumen diameter at the proximal and distal reference sites, and stent length was determined by measuring the distance from the distal to the proximal reference site. In the IVUS-guided PCI group, proximal and distal reference sites were set at cross sections adjacent to the target lesion that had the largest lumen and a plaque burden of <50%. Stent diameter was determined by measuring the vessel diameter (approximated by the external elastic membrane diameter) at the proximal and distal reference sites, and stent length was determined by measuring the distance from the distal to proximal reference site. Stents were implanted using the standard technique under OFDI or IVUS guidance. Immediately after stent implantation, post-dilation was allowed on the basis of the angiographic findings. After stent implantation and/or post-dilation, acute results were evaluated by iterative intravascular imaging. When incomplete stent expansion, incomplete stent apposition, asymmetric stent expansion, plaque or thrombus protrusion with the potential to provoke flow disturbance, or stent-edge dissection with the potential to provoke flow disturbance were identified, additional procedures were performed, if deemed safe and feasible, followed by further intravascular imaging.

In addition to the post-PCI imaging by an allocated imaging modality, the OFDI-guided PCI group underwent post-PCI IVUS, and the IVUS-guided PCI group underwent post-PCI OFDI. Both groups underwent follow-up angiography with OFDI 8 months after the index procedure. Details of the OFDI and IVUS procedures are given in the Online Appendix. Coronary angiograms were performed in a standard fashion, and an independent core laboratory (Cardiocore, Tokyo, Japan) performed the analysis for the parameters described (4).

FIGURE 2 Representative OFDI Images



(A) Measurement of minimum thickness of the intima-media complex and arc of the disease-free segment. **(B)** Stent-edge dissection. **(C)** Hematoma. **(D)** Smooth protrusion. **(E)** Disrupted fibrous tissue protrusion. **(F)** Irregular protrusion. **(G)** Thrombus. **(H)** Thin-cap fibroatheroma.

The recommended antiplatelet regimen was aspirin (>81 mg/day) indefinitely and thienopyridine (75 mg/day clopidogrel) for 12 months.

STUDY OUTCOMES. The primary endpoint of the OPINION imaging study was the minimum stent area (MSA) by OFDI post-PCI. The secondary endpoints included: 1) percentage of malapposed struts; 2) frequency of edge dissection by OFDI post-PCI; 3) percentage of uncovered struts; and 4) minimum lumen area (MLA) at the 8-month follow-up OFDI.

OFDI AND IVUS ANALYSIS. Off-line OFDI analysis was performed using dedicated software (Terumo Corporation) in an independent core laboratory at Kobe University Graduate School of Medicine (Kobe Cardiovascular Core Analysis Laboratory, Kobe, Japan), blinded to the clinical presentation, lesion, procedural characteristics, and randomization. Details of the OFDI and IVUS analysis are provided in the Online Appendix. In addition to the standard evaluation, the minimum thickness of the intima-media complex, and the arc of the disease-free segment (defined as a segment whose minimum thickness of intima-media complex is <300 μm) (6) within 1 mm from the stent edges, were measured in the adjacent proximal and distal reference segments (**Figure 2A**).

Every frame was assessed qualitatively to evaluate stent-edge dissection, in-stent dissection, hematoma, plaque protrusion, thin-cap fibroatheroma at the reference segment, and thrombus (2,7,8) (**Figure 2**) (Online Appendix). In-stent tissue protrusion was divided into 3 categories: smooth, disrupted fibrous tissue, and irregular (**Figures 2D to 2F**) (Online Appendix), as previously described (8).

Volumetric IVUS measurements were performed using planimetry software (echoPlaque, Indec Systems Inc., Santa Clara, California) using a standard method (Online Appendix) (9). All OFDI and IVUS parameters were pre-specified by the core laboratory, except for the minimum thickness of the intima media complex, and the arc of the disease-free segment.

We also assessed visibility of the vessel border by OFDI and IVUS at both reference sites and the MLA site before and after intervention by classifying into 2 grades: 1) ≥270° of visible circumference; and 2) <270° of visible circumference (10).

CLINICAL OUTCOMES. Clinical follow-up in the OPINION trial was scheduled at discharge and at 8 and 12 months after the PCI to evaluate target vessel failure (defined in the Introduction), cardiac death, myocardial infarction, target vessel-related myocardial infarction, ischemia-driven target vessel revascularization, ischemia-driven target lesion revascularization, major adverse cardiac event (a composite of cardiac death, myocardial infarction, or ischemia-driven target lesion revascularization), stent thrombosis, stroke, and contrast medium-induced nephropathy (Online Appendix). The endpoint events were adjudicated by the independent and blinded clinical event assessment committee, and the clinical event data were independently reviewed by 3 experts.

STATISTICAL ANALYSIS. We compared categorical data with the Fisher exact test, and continuous data with Wilcoxon rank-sum test. All reported p values are 2-sided, with values <0.05 taken to be significant. All statistical analyses were conducted with SAS software, version 9.3 (SAS Institute, Cary, North Carolina).

RESULTS

PATIENT FLOW. Between June 10, 2013 and July 1, 2014, 829 patients were randomized to receive OFDI-guided (n = 414) or IVUS-guided (n = 415) PCI (**Figure 1A**). Of these, 106 were enrolled in the imaging study between June 25, 2013, and April 16, 2014. Three patients were excluded due to registration error. The 103 remaining patients were randomized to undergo either OFDI-guided (n = 54) or IVUS-guided (n = 49) PCI. Post-PCI OFDI and IVUS were available in 97 and 98 patients, respectively; 8-month follow-up OFDI was available in 88 patients (**Figure 1B**), and serial OFDI analysis was available in 85 patients (**Figure 1B**).

COMPARISON OF BASELINE CHARACTERISTICS IN THE IMAGING SUBGROUP AND THE NONIMAGING PATIENTS IN THE OPINION TRIAL. There was no difference in the baseline clinical characteristics between the imaging subgroup and the nonimaging patients in the OPINION trial, except for a lower percentage of obese patients in the imaging subgroup (Online Table 1). The percentage of left anterior descending artery lesions and heavily calcified lesions was significantly higher in the imaging subgroup than in the nonimaging subgroup. Regarding procedural characteristics, the post-dilation percentage and maximum inflation pressure were significantly lower and the percentage of biolimus-eluting stent use was significantly higher in the imaging subgroup than in the nonimaging patients (Online Table 2). Clinical outcomes were not different between the 2 groups (Online Table 3).

COMPARISON OF BASELINE CHARACTERISTICS IN THE OFDI- AND IVUS-GUIDED PCI GROUPS IN THE OPINION IMAGING SUBSTUDY. Patient clinical characteristics were well balanced between the OFDI- and IVUS-guided PCI groups (Online Table 1). As expected, the OFDI-guided PCI group had a significantly smaller stent diameter than the IVUS-guided PCI group (2.92 ± 0.41 mm vs. 3.11 ± 0.39 mm; p = 0.01) (Online Table 2); otherwise, there was no statistical difference in patient, lesion, or procedural characteristics between the groups. Quantitative coronary angiography analysis showed no significant difference between the groups, although the IVUS-guided PCI group had a numerically greater acute gain than did the OFDI-guided PCI group (Online Table 4).

OFDI AND IVUS FINDINGS POST-PCI. **Table 1** shows the post-PCI OFDI results. Likely due to the stent sizing protocol, the MSA and mean stent area measured by OFDI tended to be smaller in the OFDI-guided PCI group than in the IVUS-guided PCI group. The mean stent expansion index and frequency of cases with optimal stent expansion were numerically lower in the OFDI-guided PCI group than in the IVUS-guided PCI group, although not statistically different. The frequency of malapposed struts, malapposed area, and malapposed volume were similar (**Table 1**).

The frequency and quantitative variables of plaque protrusion by post-PCI OFDI were comparable (**Table 1**). The frequency and mean number of irregular protrusions were, however, significantly lower in the OFDI-guided than in the IVUS-guided PCI group (**Table 1**).

In adjacent reference segments, although percent plaque volume and the frequency of lesions with residual stent-edge plaque burden >50% assessed by IVUS were comparable (**Table 2**), the minimum thickness of the intima-media complex was thicker and the arc of the disease-free segment was significantly smaller in the OFDI-guided PCI group than in the IVUS-guided PCI group by OFDI (**Table 1**). Post-PCI OFDI showed that the frequency of stent-edge dissection was similar, but the frequency of proximal

TABLE 1 OFDI Results After PCI

	OFDI-Guided (n = 54)	IVUS-Guided (n = 49)	p Value
In-stent segment			
3D analysis			
Stent volume, mm^3	139.9 (111.7–184.3)	158.1 (123.1–220.8)	0.33
Lumen volume, mm^3	142.7 (113.4–188.9)	164.1 (126.4–232.9)	0.27
2D analysis			
Length, mm	23.1 (18.0–26.0)	19.0 (15.9–27.5)	0.47
Mean stent area, mm^2	6.36 (4.95–7.68)	6.68 (5.91–8.79)	0.054
Minimum stent area, mm^2	5.17 (4.06–6.29)	5.63 (4.76–7.52)	0.088
Mean lumen area, mm^2	6.45 (5.22–7.82)	7.07 (6.14–9.14)	0.037
Minimum lumen area, mm^2	5.28 (4.05–6.25)	5.62 (4.69–7.69)	0.099
Stent expansion index	0.82 (0.71–0.94)	0.89 (0.81–0.99)	0.17
Cases with stent expansion index of >0.8	26 (61.9)	28 (77.8)	0.15
Stent malapposition			
Stent with malapposition	38 (73.1)	38 (84.4)	0.22
Location of malapposition			
Proximal edge	17 (32.7)	15 (33.0)	1.00
Distal edge	6 (11.5)	7 (15.6)	0.77
Stent body	29 (55.8)	29 (64.4)	0.41
Mean number of malapposed struts	7.0 (0.0–18.5)	7.0 (1.0–20.0)	0.45
Malapposed strut, %	3.02 (0.00–7.15)	2.22 (0.75–8.57)	0.48
Stent malapposition volume, mm^3	1.09 (0.15–4.38)	1.11 (0.37–4.78)	0.46
Mean stent malapposition area, mm^2	0.05 (0.01–0.14)	0.04 (0.02–0.15)	0.41
Tissue protrusion			
Stent with tissue protrusion	44 (84.6)	41 (91.1)	0.37
Mean number of tissue protrusions	5.00 (2.00–6.00)	4.00 (2.00–7.00)	0.87
Length of tissue protrusion, mm	1.12 (0.84–1.39)	1.01 (0.79–1.27)	0.43
Tissue protrusion volume, mm^3	2.28 (1.38–3.77)	2.34 (1.28–3.96)	0.83
Mean tissue protrusion area, mm^2	0.10 (0.06–0.15)	0.09 (0.07–0.16)	0.99
Maximum tissue protrusion area, mm^2	0.14 (0.09–0.18)	0.16 (0.11–0.20)	0.25
Maximum tissue protrusion thickness, mm	0.22 (0.18–0.25)	0.24 (0.19–0.28)	0.13
Classification of tissue protrusion			
Smooth protrusion	39 (75)	29 (64)	0.275
Disrupted fibrous tissue protrusion	35 (67)	28 (62)	0.672
Irregular protrusion	25 (48)	33 (73)	0.014
Irregular protrusion			
Mean number of irregular protrusions	0.00 (0.00–2.00)	2.00 (0.00–2.00)	0.025
Maximum irregular protrusion length, mm	0.00 (0.00–0.32)	0.23 (0.00–0.36)	0.087
Maximum irregular protrusion area, mm^2	0.00 (0.00–0.26)	0.16 (0.00–0.27)	0.098
Maximum irregular protrusion thickness, mm	0.00 (0.00–1.46)	1.14 (0.00–1.52)	0.087
Thrombus			
Stents with thrombus	24 (46.2)	27 (60.0)	0.22
Mean number of thrombi	0.00 (0.00–1.00)	1.00 (0.00–1.00)	0.29
Length of thrombus, mm	0.00 (0.00–1.25)	0.89 (0.00–1.39)	0.16
Maximum thrombus area, mm^2	0.00 (0.00–0.23)	0.17 (0.00–0.27)	0.16
Maximum thrombus thickness, mm	0.00 (0.00–0.40)	0.30 (0.00–0.43)	0.34
In-stent dissection			
Stent with in-stent dissection	39 (75.0)	37 (82.2)	0.46
Mean number of dissections	2.00 (0.50–4.00)	2.00 (1.00–5.00)	0.15
Length of dissection, mm	0.55 (0.13–0.94)	0.73 (0.44–1.01)	0.22
Maximum dissection length, mm	0.37 (0.09–0.58)	0.41 (0.24–0.63)	0.44

Continued on the next page

stent-edge dissection with intramural hematoma was significantly lower in the OFDI-guided PCI group (0 cases) than in the IVUS-guided PCI group (4 cases) (Table 1). In the proximal reference segment, the minimum thickness of the intima-media complex was thinner and the arc of the disease-free segment was significantly greater in cases with stent-edge dissection with hematoma than with others (Figure 3).

TABLE 1 Continued

	OFDI-Guided (n = 54)	IVUS-Guided (n = 49)	p Value
Proximal reference segment			
Length, mm	5.06 (5.06–5.06)	5.06 (4.94–5.06)	0.14
Lumen volume, mm^3	34.4 (26.5–40.8)	35.5 (28.6–43.6)	0.39
Mean lumen area, mm^2	6.61 (5.10–8.38)	8.01 (5.57–9.41)	0.25
Minimum lumen area, mm^2	6.01 (4.16–7.62)	6.61 (4.54–7.94)	0.25
Minimum thickness of intima media complex, μm	282.0 (225.0–396.0)	244.0 (206.0–310.0)	0.07
Arc of disease-free segment, °	60.8 (0.0–103.7)	98.4 (0.0–135.0)	0.04
Thin-cap fibroatheroma	2 (4.3)	1 (2.6)	1.00
Calcification	22 (46.8)	18 (46.2)	1.00
Thrombus	6 (12.8)	6 (15.4)	0.76
Dissection	11 (23.4)	10 (25.6)	1.00
Length of dissection, mm	0.00 (0.00–0.00)	0.00 (0.00–0.38)	0.72
Dissection with hematoma	0 (0.0)	4 (10.3)	0.04
Distal reference segment			
Length, mm	5.06 (5.06–5.06)	5.06 (5.06–5.06)	0.42
Lumen volume, mm^3	24.1 (18.9–31.2)	24.0 (20.1–33.8)	0.52
Mean lumen area, mm^2	4.71 (3.64–6.02)	4.70 (3.73–6.77)	0.62
Minimum lumen area, mm^2	4.15 (2.76–5.55)	3.97 (3.06–5.62)	0.95
Minimum thickness of intima media complex, μm	265.0 (234.0–356.0)	237.5 (218.0–286.0)	0.02
Arc of disease-free segment, °	75.7 (0.0–97.2)	103.2 (62.4–129.5)	<0.01
Thin-cap fibroatheroma	1 (2.1)	0 (0.0)	1.00
Calcification	12 (25.5)	9 (21.4)	0.80
Thrombus	2 (4.3)	1 (2.4)	1.00
Dissection	4 (8.5)	5 (11.9)	0.73
Length of dissection, mm	0.00 (0.00–0.00)	0.00 (0.00–0.00)	0.60
Dissection with hematoma	0 (0.0)	1 (2.4)	0.47

Values are median (interquartile range) or n (%).
OFDI = optical frequency domain imaging; IVUS = intravascular ultrasound; PCI = percutaneous coronary intervention; 3D = 3-dimensional; 2D = 2-dimensional.

Regarding vessel border visibility, ≥270° of visible circumference at the MLA site and at the proximal and distal reference sites was significantly more frequent with IVUS than with OFDI (Online Table 5).

COMPARISON OF 8-MONTH OFDI FINDINGS AND 1-YEAR CLINICAL OUTCOMES. The number lost was comparable (OFDI-guided PCI group, n = 8; IVUS-guided PCI group, n = 7) and there were no significant differences in baseline patient characteristics between those lost and those retained (Online Table 6). Regarding lesion and procedural characteristics, the lost group had a trend toward a greater incidence of heavy calcification and rotablation use. Also, maximum inflation pressure was significantly higher in lost group as compared with the retained group (Online Table 7).

Table 3 summarizes the results of the 8-month follow-up OFDI. Mean neointima thickness and area tended to be smaller in the OFDI-guided PCI group than in the IVUS-guided PCI group. In cases available for serial OFDI examination, changes in the mean lumen area and lumen volume from post-PCI to the 8-month follow-up were significantly smaller in the OFDI-guided PCI group than in the IVUS-guided PCI group (average lumen area change 0.55 ± 0.73 mm^2 vs. 0.96 ± 1.02 mm^2, p = 0.035; average lumen volume change 10.2 ± 26.6 mm^3 vs. 24.4 ± 31.1 mm^3, p = 0.037). No statistical difference in MLA at the 8-month follow-up was noted between the groups.

The frequency of uncovered struts was significantly lower in the IVUS-guided PCI group than in the OFDI-guided PCI group. The frequency of malapposed struts at 8 months was similar between the 2 groups. Most of the dissections detected after PCI had healed, and stent-edge dissection remained in 2 reference segments only in the IVUS-guided PCI group (**Table 3**). One-year clinical data showed no significant difference between the 2 groups (Online Table 8).

COMPARISON OF OFDI AND IVUS POST-PCI FINDINGS. Stent length, MLA, and stent volume measured by OFDI were significantly correlated with those by IVUS (**Figure 4**). Bland-Altman plots of OFDI measurement in relation to IVUS measurement are also shown in **Figure 4**. Regarding the post-PCI qualitative

TABLE 2 IVUS Results After PCI

	OFDI-Guided (n = 54)	IVUS-Guided (n = 49)	p Value
In-stent segment			
Length, mm	22.8 (17.7–26.7)	20.3 (16.5–33.5)	0.50
Lumen volume, mm^3	137.3 (106.8–184.6)	159.0 (120.2–209.5)	0.27
Lumen volume index, mm^3/mm	6.45 (4.69–7.77)	6.65 (5.67–8.19)	0.21
Minimum lumen area, mm^2	5.42 (4.07–6.21)	5.53 (4.23–7.24)	0.23
Stent volume, mm^3	137.3 (108.6–184.8)	159.3 (119.3–212.9)	0.29
Stent volume index, mm^3/mm	6.42 (4.69–7.77)	6.67 (5.67–8.07)	0.21
Minimum stent area, mm^2	5.52 (3.96–6.21)	5.53 (4.23–7.24)	0.27
Persistent plaque volume, mm^3	169.5 (121.9–216.6)	161.5 (107.1–220.9)	0.73
Persistent plaque volume index, mm^3/mm	7.68 (5.25–9.61)	6.85 (5.23–9.42)	0.72
Percent persistent plaque volume, %	52.8 (48.8–57.3)	50.4 (45.4–55.4)	0.15
Vessel volume, mm^3	292.8 (238.4–378.3)	302.3 (230.5–423.8)	0.95
Vessel volume index, mm^3/mm	14.5 (10.3–16.7)	13.5 (10.9–17.4)	0.81
Tissue protrusion volume, mm^3	0.00 (0.00–0.16)	0.00 (0.00–0.27)	0.66
Tissue protrusion volume index, mm^3/mm	0.00 (0.00–0.01)	0.00 (0.00–0.01)	0.57
Proximal reference segment			
Length, mm	5.00 (5.00–5.00)	5.00 (5.00–5.00)	0.79
Lumen volume, mm^3	34.5 (29.8–41.5)	39.6 (30.8–47.1)	0.12
Lumen volume index, mm^3/mm	6.91 (6.00–8.30)	7.93 (6.17–9.96)	0.12
Minimum lumen area, mm^2	5.74 (4.50–7.13)	6.45 (4.99–8.18)	0.18
Plaque volume, mm^3	37.5 (29.9–50.6)	39.6 (31.0–44.1)	0.74
Plaque volume index, mm^3/mm	7.70 (6.04–10.13)	8.01 (6.19–8.83)	0.85
Percent plaque volume, %	52.0 (44.2–59.1)	48.7 (42.5–55.2)	0.31
Residual stent-edge plaque burden >50%	20 (50.0)	14 (38.9)	0.36
Vessel volume, mm^3	72.1 (60.3–93.9)	75.5 (62.6–88.8)	0.66
Vessel volume index, mm^3/mm	14.4 (12.3–18.8)	15.1 (12.5–18.6)	0.63
Calcification	26 (57.8)	21 (50)	0.52
Dissection	3 (6.7)	2 (4.8)	0.48
Dissection with hematoma	0 (0.0)	1 (2.4)	0.46
Distal reference segment			
Length, mm	5.00 (5.00–5.00)	5.00 (5.00–5.00)	0.77
Lumen volume, mm^3	28.1 (21.6–35.0)	29.1 (22.3–40.7)	0.55
Lumen volume index, mm^3/mm	6.06 (4.59–7.05)	5.92 (4.84–8.14)	0.68
Minimum lumen area, mm^2	5.22 (3.64–6.39)	4.91 (3.77–6.67)	0.81
Plaque volume, mm^3	21.9 (12.7–33.8)	19.0 (8.6–33.1)	0.36
Plaque volume index, mm^3/mm	4.39 (2.54–6.81)	3.97 (1.73–6.61)	0.33
Percent plaque volume, %	43.4 (27.9–52.5)	35.9 (27.4–46.9)	0.31
Residual stent-edge plaque burden >50%	13 (32.5)	6 (16.7)	0.18
Vessel volume, mm^3	51.4 (37.8–67.0)	46.2 (31.2–71.5)	0.42
Vessel volume index, mm^3/mm	10.3 (8.1–14.2)	9.7 (6.6–14.3)	0.41
Calcification	18 (38.3)	13 (32.5)	0.66
Dissection	3 (6.4)	3 (7.5)	0.58
Dissection with hematoma	0 (0.0)	1 (2.5)	0.46

Values are median (interquartile range) or n (%).
Abbreviations as in Table 1.

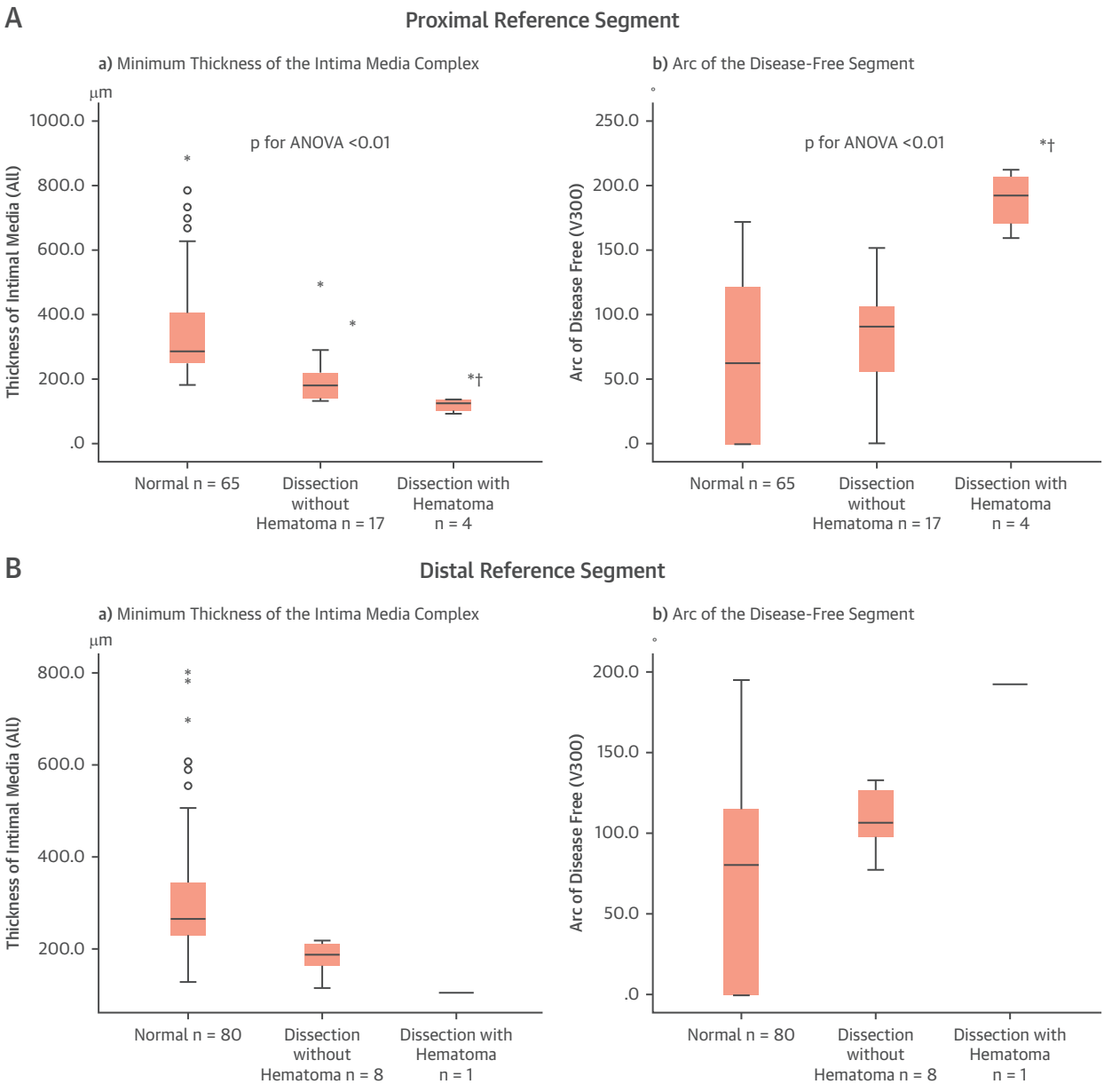
evaluation, OFDI detected more cases with stent-edge dissection as compared with IVUS (Tables 1 and 2).

DISCUSSION

Intravascular imaging is important in appropriate device sizing during PCI. In the present study, the imaging study protocol dictated a slightly, but significantly, smaller stent diameter in the OFDI-guided PCI group than in the IVUS-guided PCI group. The OFDI-guided PCI group had a trend toward a smaller MSA after PCI, with a numerically smaller mean stent expansion index than the IVUS-guided PCI group. Previous reports on the relationship between stent expansion and the imaging modality used are controversial. A single-center, prospective, randomized study (n = 35 for each group) showed that OCT-guided PCI was associated with smaller stent expansion than IVUS-guided PCI (10). In contrast, the ILUMIEN III: OPTIMIZE PCI (ILUMIEN III: OPtical Coherence Tomography [OCT] Compared to Intravascular Ultrasound [IVUS] and Angiography to Guide Coronary Stent Implantation: a Multicenter Randomized Trial in Percutaneous Coronary Intervention [PCI]) study comparing angiography-, IVUS-, and OCT-guided PCI, with the primary endpoint of post-PCI MSA, showed that post-PCI MSA with OCT-guided PCI was noninferior to that with IVUS-guided PCI (11). The difference between the ILUMIEN III trial and ours is probably due to different protocols for stent sizing. In the ILUMIEN III trial, OCT-guided stents were sized by referring to reference segment external elastic lamina measurements. In the OPINION trial, operators were recommended to decide stent diameter based on the lumen diameter at both reference sites for the OFDI-guided PCI group and based on the vessel diameter at both reference sites for the IVUS-guided PCI group. Therefore, it is theoretically reasonable to have a larger stent size and better stent expansion in the IVUS-guided PCI group than in the OFDI-guided PCI group. Such slight differences had, however, no influence on the clinical outcomes after PCI with a second-generation DES.

Coronary hematoma is a rare but unfavorable complication potentially leading to adverse clinical events after PCI. In a previous study (905 patients) that identified 72 hematomas in 68 patients, the presence of hematoma was associated with a high rate of non-Q-wave myocardial infarction (26% at 1 month) after PCI (12). Also, the cumulative (in-hospital and 1-month) target vessel revascularization rates were higher in patients with hematoma than in those without (6.3% vs. 1.9%; p = 0.046) (12). In the ILUMIEN III trial, untreated edge dissections were more frequent after IVUS- and angiography-guided PCI than after OCT-guided PCI, although the prognostic significance of proximal edge dissection might be minimal (13). In the present study, the incidence of stent-edge dissection with hematoma was significantly higher in the IVUS-guided PCI group than in the OFDI-guided PCI group. An intramural hematoma occurs as a result of a dissection to the media or adventitia. Therefore, greater stent expansion

FIGURE 3 **Comparison of Post-PCI OFDI Findings in Adjacent Reference Segments in Relation to Dissection and Hematoma**



(A) Proximal reference segment. **(B)** Distal reference segment. **(a)** Minimum thickness of the intima-media complex. **(b)** Arc of the disease-free segment. *$p < 0.01$ versus normal. †$p < 0.01$ versus dissection without hematoma.

relative to the reference segment by IVUS-guided PCI might induce this phenomenon. Another possibility might be different selection of the landing zone. In the present study, the minimum thickness of the intima-media complex was thicker and the arc of the disease-free segment was significantly smaller in the adjacent reference segments of the OFDI-guided PCI group than in those of the IVUS-guided PCI group. Also, there were significantly fewer lesions with ≥270° of visible circumference at the proximal and distal reference site with OFDI than with IVUS (Online Appendix). A previous study showed that the media behind atherosclerotic plaque is less than one-half of the thickness of the normal wall and is more scarred than normal vessels (14). Therefore, once medial dissection occurs, hematoma formation and

TABLE 3 OFDI Results at the 8-Month Follow-Up

	OFDI-Guided (n = 54)	IVUS-Guided (n = 49)	p Value
In-stent segment			
3D analysis			
Stent volume, mm^3	140.1 (109.2–214.9)	158.8 (118.0–223.4)	0.49
Lumen volume, mm^3	131.2 (101.8–192.7)	147.4 (104.2–191.8)	0.69
Neointima volume, mm^3	12.0 (6.5–20.5)	16.2 (7.0–22.8)	0.34
Cross-section–based analysis			
Length, mm	22.7 (17.8–28.0)	19.0 (16.3–28.2)	0.28
Mean stent area, mm^2	6.66 (4.92–7.84)	7.20 (6.24–8.74)	0.055
Minimum stent area, mm^2	5.37 (3.82–6.02)	5.77 (5.19–7.61)	0.024
Mean lumen area, mm^2	6.33 (4.77–7.39)	6.34 (5.37–7.87)	0.24
Minimum lumen area, mm^2	4.81 (3.26–5.92)	5.04 (4.43–6.24)	0.18
Mean stent eccentricity index	0.92 (0.89–0.93)	0.91 (0.90–0.93)	0.64
Mean neointima area, mm^2	0.46 (0.36–0.76)	0.62 (0.40–1.06)	0.057
Mean neointima thickness, μm	0.07 (0.05–0.10)	0.08 (0.06–0.13)	0.078
Stent malapposition			
Stent with malapposition	18 (39.1)	15 (35.7)	0.83
Location of malapposition			
Proximal edge	6 (13.0)	3 (7.1)	0.49
Distal edge	0 (0.0)	2 (4.8)	0.22
Stent body	15 (32.6)	13 (31.0)	1.00
Malapposed strut, %	0.00 (0.00–0.47)	0.00 (0.00–0.26)	0.62
Stent malapposition volume, mm^3	1.00 (0.10–2.02)	0.33 (0.01–1.59)	0.31
Mean stent malapposition area, mm^2	0.03 (0.00–0.08)	0.01 (0.00–0.07)	0.36
Uncovered struts, %	4.05 (1.56–11.26)	2.16 (0.70–7.33)	0.039
Proximal reference segment			
Length, mm	5.06 (4.94–5.06)	5.06 (4.94–5.06)	0.95
Lumen volume, mm^3	33.4 (22.9–41.1)	33.5 (27.7–43.8)	0.52
Mean lumen area, mm^2	6.65 (4.41–8.08)	7.04 (5.47–8.94)	0.49
Minimum lumen area, mm^2	5.86 (3.65–7.46)	6.29 (4.80–7.79)	0.24
Dissection	0 (0.0)	1 (2.5)	0.49
Distal reference segment			
Length, mm	5.06 (4.94–5.06)	5.06 (5.06–5.06)	0.53
Lumen volume, mm^3	24.4 (19.1–29.0)	26.6 (22.6–32.8)	0.11
Mean lumen area, mm^2	4.84 (3.74–5.94)	5.39 (4.18–6.81)	0.22
Minimum lumen area, mm^2	4.41 (2.75–5.16)	4.72 (3.07–5.71)	0.36
Dissection	0 (0.0)	1 (2.4)	0.48

Values are median (interquartile range) or n (%).
Abbreviations as in Table 1.

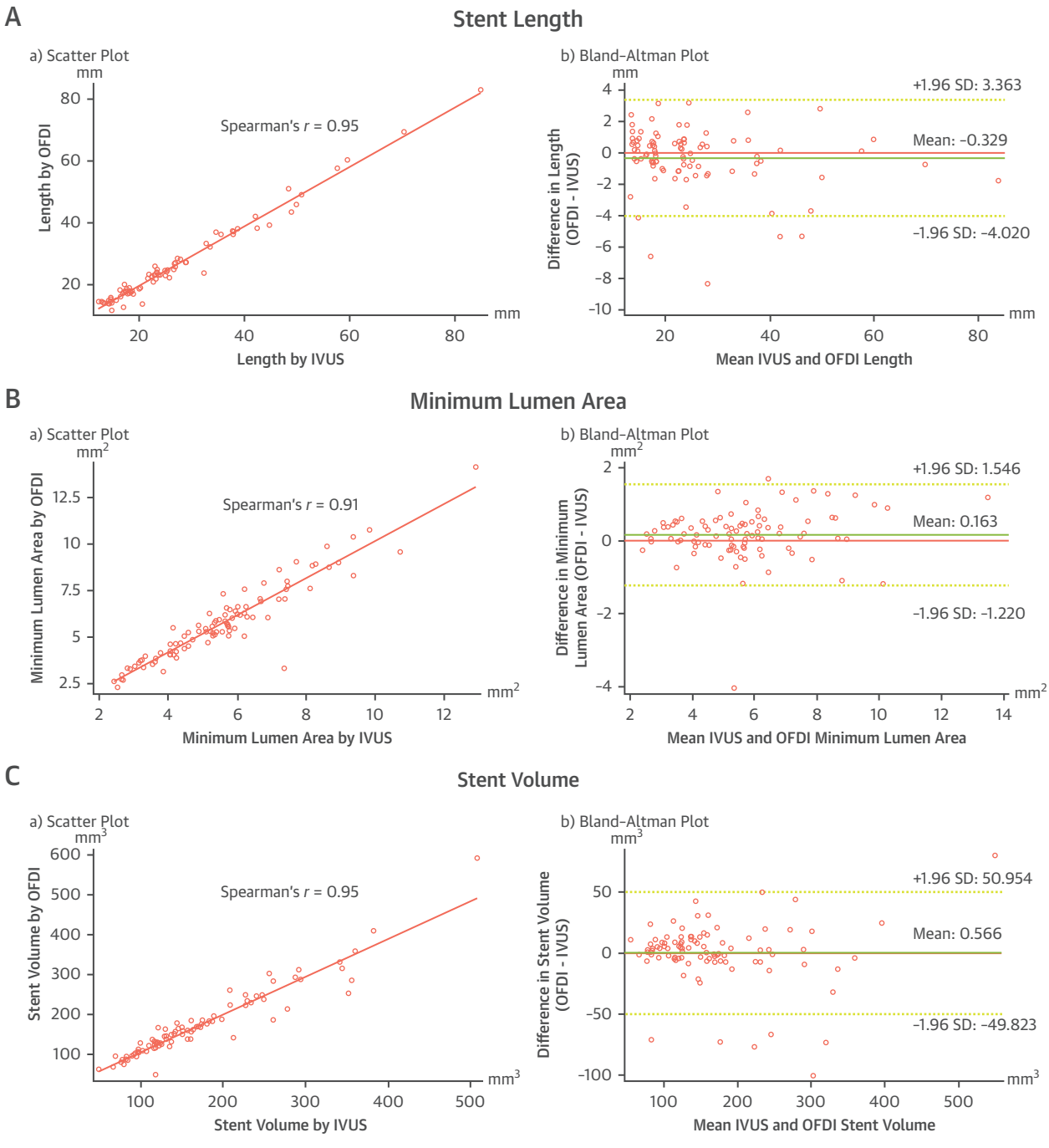
expansion is more likely to occur if the segment is less diseased (15). Thus, "normal to normal" IVUS-guided stent expansion might increase physiological stress at stent edges, thereby increasing the likelihood of stent-edge dissection with hematoma. Smooth stent landing by adjusting stent expansion to the lumen size with OFDI guidance might be preferable from a periprocedural safety perspective.

The presence of an irregular protrusion is considered to reflect the presence of moderate to severe vessel injury with a high likelihood of medial disruption and lipid core penetration. Soeda et al. (8) observed an irregular protrusion in 46.7% of patients with stable angina, and was an independent predictor of device-oriented clinical endpoints, including cardiac death, target vessel-related myocardial infarction, target lesion revascularization, and stent thrombosis. They showed that an irregular protrusion had a comparable impact to MSA on target lesion revascularization (8). In the present study, irregular protrusion incidence was significantly lower in the OFDI-guided PCI group than in the IVUS-guided PCI group. Previous pathological studies showed that lipid core penetration, deep vessel injury to the media, and necrotic core penetration by stent implantation can increase local inflammation and thrombogenicity, leading to increased risk for early restenosis and thrombosis (16,17). Therefore, the lower incidence of post-stent irregular protrusion observed in the OFDI-guided PCI group might be a positive aspect of this approach.

Neointima proliferation is one of the primary mechanisms of in-stent restenosis. In the present study, the average neointimal thickness and area tended to be smaller in the OFDI-guided PCI group than in the IVUS-guided PCI group. Serial OFDI analysis showed that the OFDI-guided PCI group had a significantly smaller late lumen area loss than the IVUS-guided PCI group. Generally, an inflammatory reaction occurs to repair local arterial injury induced by stenting, resulting in accelerated reactive neointimal growth within stents (18). A positive relationship between severity of the vascular injury and increased neointimal proliferation has been reported in animals (19) and humans (20,21) in lesions treated with a bare-metal stent and DES. These findings may support our speculation that IVUS-guided PCI could account for increased neointimal hyperplasia due to more aggressive stent sizing compared with OFDI-guided PCI. There was a significantly lower incidence of uncovered struts in the IVUS-guided PCI group than in the OFDI-guided PCI group. Recent studies show that uncovered struts might contribute to the occurrence of stent thrombosis (22). Nevertheless, considering that there was no significant difference in the occurrence of target lesion revascularization and stent thrombosis, the importance of such a slight difference in neointima proliferation and strut coverage might not be clinically significant, especially with the second-generation DES.

In the present study, post-PCI OFDI showed a tendency toward a greater MSA in the IVUS-guided PCI group than in the OFDI-guided PCI group, whereas post-PCI IVUS did not show such a difference. Previous studies consistently report that lumen area measured by IVUS was about 10% larger than actual phantom lumen area, whereas that measured by frequency domain-OCT is almost equal to actual

FIGURE 4 Scatter and Bland-Altman Plots



(A) Stent length. **(B)** Minimum lumen area. **(C)** Stent volume. Abbreviations as in Figure 1.

phantom lumen area (23,24). Although Kim et al. (24) observed a smaller discrepancy in stented (2.7%) than in reference (11.3%) segments of human coronary arteries, stent area measurements by IVUS and frequency domain-OCT in stented segments were different (7.42 ± 2.28 mm^2 vs. 7.22 ± 2.48 mm^2; p = 0.059). Considering the increased ability of OFDI to detect post-PCI abnormal findings (e.g., dissection, hematoma, and malapposed struts) and accurate measurement together, OFDI might have an

advantage for evaluating stent optimization immediately after PCI.

STUDY LIMITATIONS. First, this was an exploratory study without a statistical power calculation, and so it might be underpowered to detect potential differences between the OFDI- and IVUS-guided PCI. Second, although the imaging study was based on serially enrolled patients at pre-selected sites, the small sample size might increase the possibility of selection bias. Finally, the follow-up period was limited to 8 months, a time at which vessel healing in response to vessel wall injury by stenting may not be fully complete. Therefore, the present study is not powered for any conclusions regarding the long-term effects of IVUS- or OFDI-guided PCI. A further study with a longer follow-up period will be required to address this issue.

CONCLUSIONS

Detailed IVUS and OFDI analysis with a blinded comparison confirmed that there were several differences in local findings between OFDI- and IVUS-guided PCI, likely due to the different stent sizing protocols used. The MLA at the 8-month follow-up was comparable between the 2 groups, suggesting both OFDI- and IVUS-guided PCI can be similarly feasible for coronary intervention using the current-generation metallic DES.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: An IVUS-guided PCI may facilitate larger stent sizing and better expansion than OFDI-guided PCI, whereas OFDI-guided PCI may reduce the risk for stent-edge dissection with hematoma and irregular protrusion after stenting.

TRANSLATIONAL OUTLOOK: Further studies are needed to assess the generalizability of these observations to patients treated with a bioresorbable scaffold.

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KEY WORDS intravascular ultrasound, optical coherence tomography, optical frequency domain imaging, percutaneous coronary intervention

APPENDIX For the full list of OPINION investigators and supplemental materials, please see the online version of this paper.