

OCT Compared With IVUS in a Coronary Lesion Assessment

The OPUS-CLASS Study

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OBJECTIVES The aim of this study was to investigate the reliability of frequency domain optical coherence tomography (FD-OCT) for coronary measurements compared with quantitative coronary angiography (QCA) and intravascular ultrasound (IVUS).

BACKGROUND Accurate luminal measurement is expected in FD-OCT because this technology offers high resolution and excellent contrast between lumen and vessel wall.

METHODS In 5 medical centers, 100 patients with coronary artery disease were prospectively studied by using angiography, FD-OCT, and IVUS. In addition, 5 phantom models of known lumen dimensions (lumen diameter 3.08 mm; lumen area 7.45 mm²) were examined using FD-OCT and IVUS. Quantitative image analyses of the coronary arteries and phantom models were performed by an independent core laboratory.

RESULTS In the clinical study, the mean minimum lumen diameter measured by QCA was significantly smaller than that measured by FD-OCT (1.81 ± 0.72 mm vs. 1.91 ± 0.69 mm; $p < 0.001$) and the minimum lumen diameter measured by IVUS was significantly greater than that measured by FD-OCT (2.09 ± 0.60 mm vs. 1.91 ± 0.69 mm; $p < 0.001$). The minimum lumen area measured by IVUS was significantly greater than that by FD-OCT (3.68 ± 2.06 mm² vs. 3.27 ± 2.22 mm²; $p < 0.001$), although a significant correlation was observed between the 2 imaging techniques ($r = 0.95$, $p < 0.001$; mean difference 0.41 mm²). Both FD-OCT and IVUS exhibited good interobserver reproducibility, but the root-mean-squared deviation between measurements was approximately twice as high for the IVUS measurements compared with the FD-OCT measurements (0.32 mm² vs. 0.16 mm²). In a phantom model, the mean lumen area according to FD-OCT was equal to the actual lumen area of the phantom model, with low SD; IVUS overestimated the lumen area and was less reproducible than FD-OCT (8.03 ± 0.58 mm² vs. 7.45 ± 0.17 mm²; $p < 0.001$).

CONCLUSIONS The results of this prospective multicenter study demonstrate that FD-OCT provides accurate and reproducible quantitative measurements of coronary dimensions in the clinical setting. (J Am Coll Cardiol Img 2013;6:1095–104) © 2013 by the American College of Cardiology Foundation

Optical coherence tomography (OCT) is a high-resolution intracoronary imaging technology based on near-infrared interferometry. The spatial resolution of OCT is 10 to 20 μm , which is approximately 10 times greater than that of intravascular ultrasound (IVUS). Recently, a new-generation frequency domain optical coherence tomography (FD-OCT) has been developed to overcome limitations of conventional time-domain optical coherence tomography (TD-OCT). FD-OCT provides a high frame rate

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(100 frame/s), which enables imaging of long coronary segments within a few seconds in combination with rapid spiral pullback (20 mm/s) and contrast injection through a guiding catheter. This technology is safe and feasible for evaluating coronary atherosclerosis (1). Several studies have shown excellent ability of FD-OCT to qualitatively assess coronary plaque morphologies (1). However, the accuracy of quantitative FD-OCT measurement has not been fully elucidated. Accurate coronary measurement is important in the guidance of percutaneous coronary intervention (PCI). QCA is the standard method for estimating lumen diameter stenosis in the atherosclerotic lesion. IVUS is also widely used for measurement of absolute cross-sectional luminal areas. The aim of the present study was to investigate the reliability of FD-OCT for coronary measurements compared with QCA and IVUS.

ABBREVIATIONS AND ACRONYMS

- FD** = frequency domain
- IVUS** = intravascular ultrasound
- MLA** = minimum lumen area
- MLD** = minimum lumen diameter
- OCT** = optical coherence tomography
- PCI** = percutaneous coronary intervention
- QCA** = quantitative coronary angiography
- TD** = time-domain

METHODS

Study population. A total of 100 patients with coronary artery disease were prospectively enrolled in 5 medical centers. After coronary angiography, FD-OCT and IVUS were performed in 20 patients at pre-PCI, in 60 patients at both pre-PCI and post-

stent deployment, and in 20 patients at stent follow-up. Patients with a left main coronary artery lesion, coronary bypass graft lesion, chronic total occlusion, minimum lumen diameter (MLD) <1.5 mm, reference vessel diameter >4 mm, extremely tortuous vessel, coronary artery containing target imaging lesion which had previous coronary bypass graft, or renal insufficiency with serum creatinine >2.0 mg/dl were excluded. This study was approved by the institutional review boards of the institutions in which the procedures were performed, and all patients provided written informed consent before cardiac catheterization.

Coronary imaging. QCA, FD-OCT, and IVUS were performed via 6-F guiding catheters. All patients received an intracoronary bolus injection of nitroglycerine (0.2 mg) before each coronary imaging.

Angiograms were obtained from a standard series of 6 to 8 projections for the left coronary artery and 2 to 3 projections for the right coronary artery. All images were stored on a CD-ROM for offline analysis.

FD-OCT imaging was performed using the C7-XR OCT imaging system (LightLab Imaging/St. Jude Medical, Westford, Massachusetts). After a Z-offset adjustment, an FD-OCT image catheter was advanced distally to the target lesion over a 0.014-inch conventional angioplasty guidewire. After the catheter placement, preheated contrast media at 37°C was flushed through the guiding catheter at a rate of 3 to 4 ml/s for approximately 3 to 4 s by using an injector pump. When a blood-free image was observed, the FD-OCT imaging core was pulled back over a longitudinal distance up to 54 mm at a rate of 20 mm/s by using standalone electronic control of the pullback motor. FD-OCT images were stored digitally for subsequent analysis.

IVUS imaging was performed using a commercial scanner (Atlantis SR Pro, Boston Scientific Corporation, Maple Grove, Minnesota) that consisted of a 40-MHz transducer. The IVUS catheter was advanced beyond the target lesion and withdrawn to

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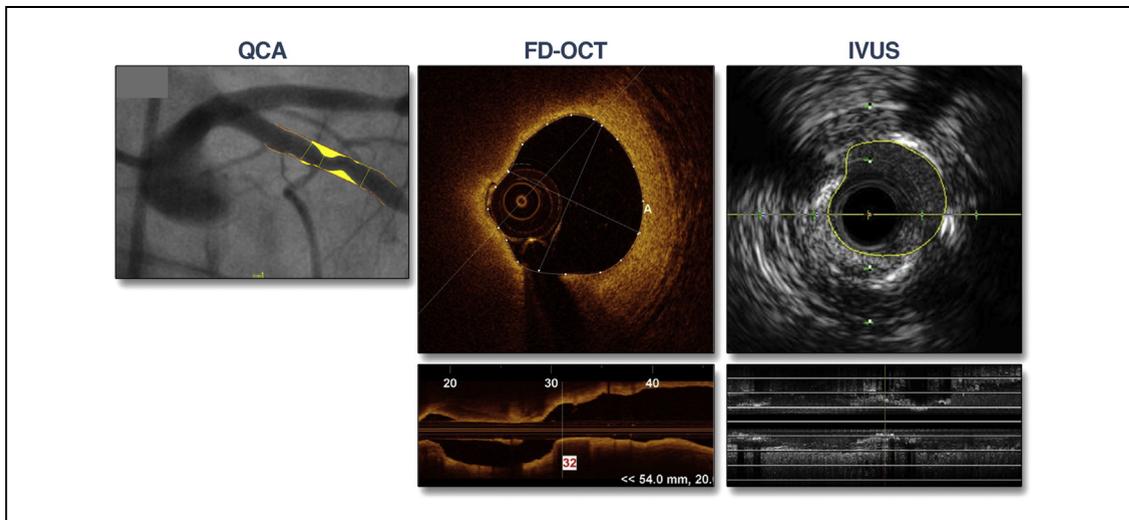


Figure 1. In Vivo Measurements of Lumen Dimensions by QCA, FD-OCT, and IVUS

In this representative case, frequency domain optical coherence tomography (FD-OCT) and intravascular ultrasound (IVUS) was performed for the proximal circumflex coronary artery stenosis of which minimum lumen diameter (MLD) was 1.59 mm in quantitative coronary angiography (QCA). MLA measured using FD-OCT and IVUS was 2.75 mm² and 3.50 mm² (MLD was 1.87 mm and 2.13 mm), respectively.

the aorto-ostial junction at a pullback speed of 0.5 mm/s automatically. The IVUS images were recorded onto a DVD for offline analysis.

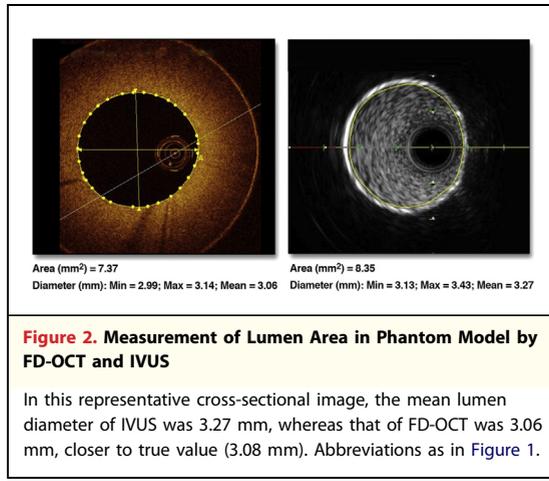
Quantitative image analysis. Image analysis was performed by an independent core laboratory (Cardiocore, Tokyo, Japan) (Fig. 1). QCA was performed with the CMS Medis system (Medis, Leiden, the Netherlands). The MLD was averaged from the 2 orthogonal projections without foreshortening.

FD-OCT analysis was performed with the LightLab OCT console software (LightLab Imaging/St. Jude Medical). The Z-offset was adjusted again before the FD-OCT analysis. By visual screening for all contiguous frames, 3 candidate frames were selected for measurement of minimum lumen area (MLA). MLA was determined as the smallest lumen area in the candidate frames. MLD was defined as the mean diameter of the lumen at the MLA site. Initially, 1 observer (S.N.) performed FD-OCT measurements, which were compared with IVUS measurements. Subsequently, images were analyzed again by another observer (K.K.) to assess interobserver reproducibility of FD-OCT measurements.

IVUS analysis was performed after FD-OCT analysis. IVUS images were analyzed with the echo-Plaque software (INDEC, Santa Clara, California). MLA and MLD were estimated at the same location in FD-OCT and IVUS. To obtain corresponding images of IVUS and FD-OCT, the measured

distances from at least 2 landmarks, such as side branches, calcifications, and/or stents, were used as references. Initially, 1 observer (K.H.) performed IVUS measurements, which were compared with FD-OCT measurements. Subsequently, images were analyzed again by another observer (M.A.) to assess interobserver reproducibility of IVUS measurements.

Qualitative image analysis. The FD-OCT and IVUS images at post-PCI were analyzed qualitatively. Qualitative analysis was performed by 2 observers in FD-OCT (S.N. and K.K.) and IVUS (K.H. and M.A.), respectively. When there was any discordance between the 2 observers, a consensus reading was obtained. Qualitative analysis determined the presence or absence of intrastent tissue protrusion, incomplete stent apposition, stent edge dissection, and intrastent thrombus. Intrastent tissue protrusion was defined as prolapse of tissue between stent struts extending inside a circular arc connecting adjacent struts in both the FD-OCT and IVUS images. Incomplete stent apposition was defined as a distance between the center reflection of the strut and the vessel wall of greater than the actual stent thickness +20 μm (FD-OCT resolution limit) in the FD-OCT images, and it was identified as a clear separation between at least 1 stent strut and the vessel wall in the IVUS images. Stent edge dissection was defined as disruption of the luminal vessel surface at the edge segments in both the FD-OCT and IVUS images. Thrombus was defined as a protruding mass beyond the stent strut into the lumen with significant



attenuation behind the mass in the FD-OCT images, and it was defined as an irregular low echoic mass, often mobile and extruding into the vessel lumen, and sometimes becoming detached from the vessel wall in the IVUS images.

Phantom model. In addition to the *in vivo* study, we evaluated the accuracy of FD-OCT and IVUS measurements using an *in vitro* phantom model (Fig. 2). A circular, polytetrafluoroethylene plastic arterial model (lumen diameter 3.08 mm; lumen area 7.45 mm²; length 10.00 mm; Lightlab Imaging/St. Jude Medical) was used. For the FD-OCT examination, the arterial model was filled with contrast media by using a 3-ml syringe. After a Z-offset adjustment, the FD-OCT image catheter was advanced into the model. The FD-OCT images were acquired during motorized pullback of the catheter (20 mm/s) through the model. For the IVUS examination, the arterial model was filled with whole human blood by using a 3-ml syringe. The IVUS catheter was introduced into the model and pulled back automatically (0.5 mm/s) for image acquisition. Single pullback data of both FD-OCT and IVUS were obtained from each of the 5 medical centers. Three optimal image frames were selected from each pullback, and lumen areas were measured in the independent core laboratory. The FD-OCT (n = 15) and IVUS (n = 15) measurements were compared with the actual model lumen areas and with each other.

Statistical analysis. Categorical variables were presented as percentages, with comparisons using the McNemar test. Continuous variables were presented as mean \pm SD and were compared by using the paired *t* test. Values of *p* < 0.05 were considered to be significant. The relationships between the measurements (FD-OCT vs. IVUS, FD-OCT vs. QCA,

Table 1. Patient Clinical Characteristics (N = 100)

Age, yrs	66 \pm 10
Men	81
Coronary risk factor	
Hypertension	72
Dyslipidemia	62
Diabetes mellitus	38
Current smoker	51
Target imaging vessel	
LAD	50
LCX	15
RCA	35

Values are mean \pm SD or %.

LAD = left anterior descending coronary artery; LCX = left circumflex coronary artery; RCA = right coronary artery.

IVUS vs. QCA, and interobserver comparison) were investigated using a simple regression analysis. The agreements between the measurements were expressed in Bland-Altman plots. The Bland-Altman plot depicted the differences of each pair of measurements versus their mean values with reference lines for the mean difference of all paired measurements. The limits of agreement were defined as mean \pm 1.96 SD of absolute difference.

RESULTS

Patients and images. Baseline patient characteristics are shown in Table 1. There were no adverse events related to the imaging procedures. In 2 patients, the FD-OCT and IVUS catheter could not pass through the target lesion at pre-PCI. Eight pullbacks of FD-OCT were not evaluable due to incomplete blood clearance. Two pullbacks of IVUS contained artifacts that did not allow a proper image assessment. Eventually, 148 sets of FD-OCT/IVUS pullbacks were analyzed.

Quantitative analysis. Measurements of MLD by QCA, IVUS, and FD-OCT are shown in Figure 3. MLD by QCA was significantly smaller than that by FD-OCT (1.81 \pm 0.72 mm vs. 1.91 \pm 0.69 mm; *p* < 0.001), with a mean difference of 0.10 mm. MLD by IVUS was significantly greater than that by FD-OCT (2.09 \pm 0.60 mm vs. 1.91 \pm 0.69 mm; *p* < 0.001), with a mean difference of 0.18 mm. Figure 4 shows Bland-Altman analyses for the MLD. There were direct correlations and good agreements in MLD between FD-OCT and IVUS (*r* = 0.95, *p* < 0.001), between FD-OCT and QCA (*r* = 0.89, *p* < 0.001), and between IVUS vs. QCA (*r* = 0.87, *p* < 0.001).

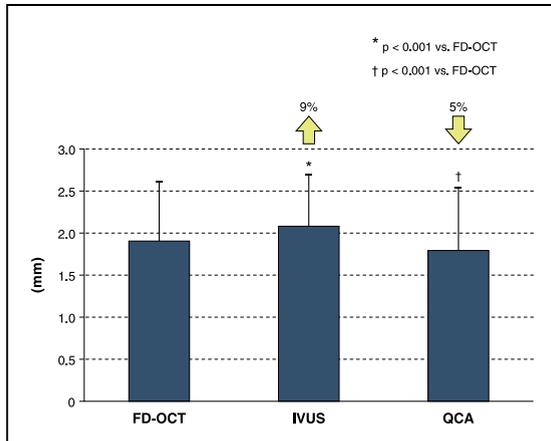


Figure 3. Measurements of MLD by FD-OCT, IVUS, and QCA

MLD by IVUS was greater than that by FD-OCT (relative reference 9%). MLD by QCA was smaller than that by FD-OCT (relative reference -5%). Abbreviations as in Figure 1.

Measurements of MLA by IVUS and FD-OCT are shown in Figure 5. MLA measured using IVUS was significantly greater than that according to FD-OCT ($3.68 \pm 2.06 \text{ mm}^2$ vs. $3.27 \pm 2.22 \text{ mm}^2$;

$p < 0.001$). The difference in measurements of MLA between IVUS and FD-OCT was significantly greater in nonstented segments compared with stented segments ($0.56 \pm 0.49 \text{ mm}^2$ vs. $0.25 \pm 0.87 \text{ mm}^2$; $p = 0.007$). Bland-Altman analyses for MLA are shown in Figure 6. There was a direct correlation and good agreement in MLA between FD-OCT and IVUS ($r = 0.95$, $p < 0.001$; mean difference 0.41 mm^2).

Interobserver reproducibility. Interobserver reproducibility for measurement of MLA is shown in Figure 7. Bland-Altman analysis revealed a direct correlation and good agreement between the measurements by 2 observers in both FD-OCT ($r = 0.999$, $p < 0.001$; mean difference 0.01 mm^2) and IVUS ($r = 0.994$, $p < 0.001$; mean difference 0.04 mm^2). The root-mean-squared deviation between measurements by the same observer was approximately twice as high for the IVUS measurements compared with the FD-OCT measurements (0.32 mm^2 vs. 0.16 mm^2).

Qualitative analysis. Table 2 summarizes the results the evaluation of the abilities of FD-OCT and IVUS to detect suboptimal lesion morphologies at

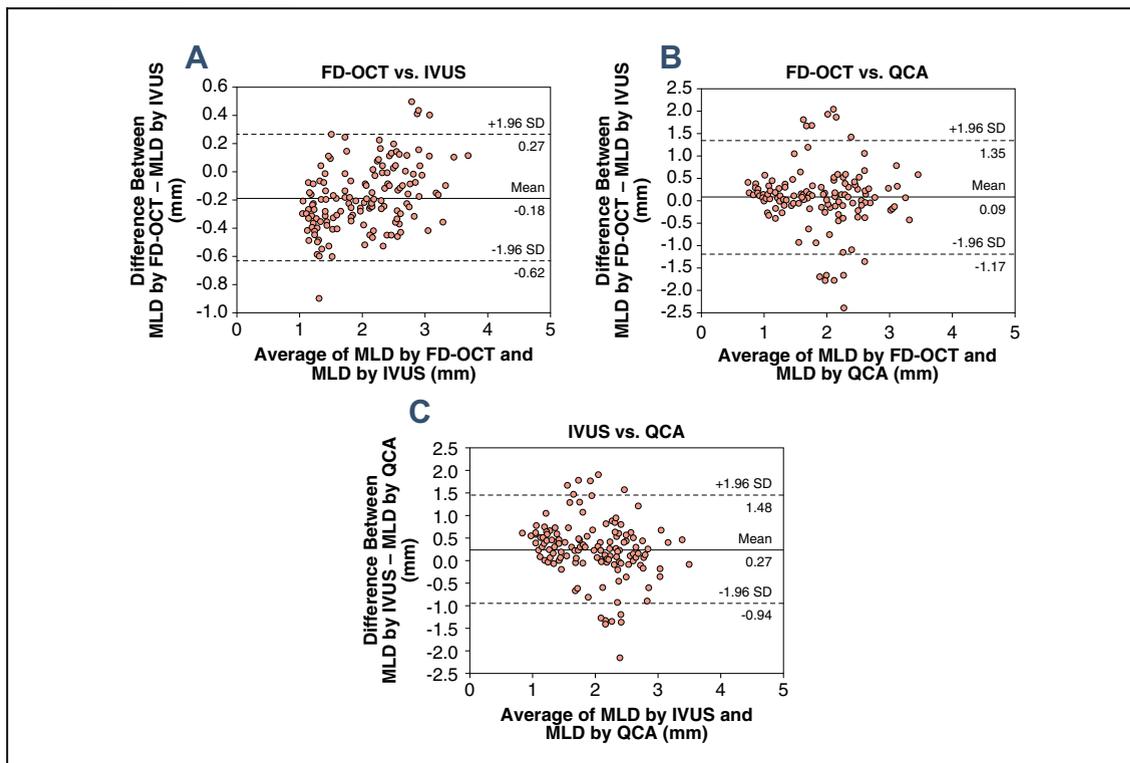
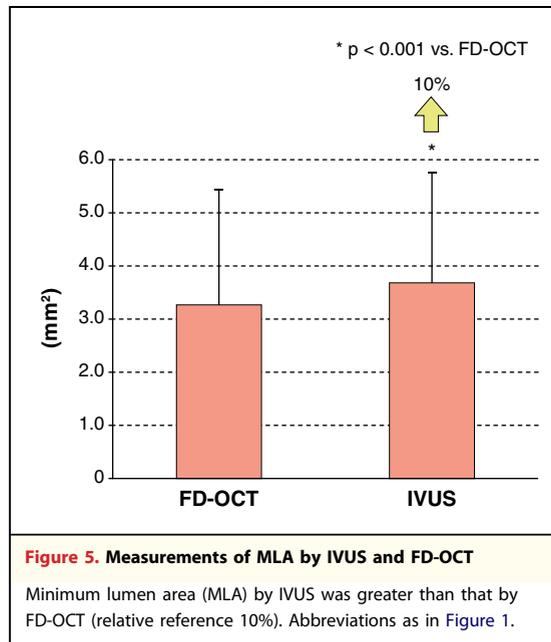


Figure 4. Bland-Altman Analysis for Measurements of MLD

There were direct correlations and good agreements for measurements of MLD (A) between FD-OCT and IVUS, (B) between FD-OCT and QCA, and (C) between IVUS and QCA. Abbreviations as in Figure 1.



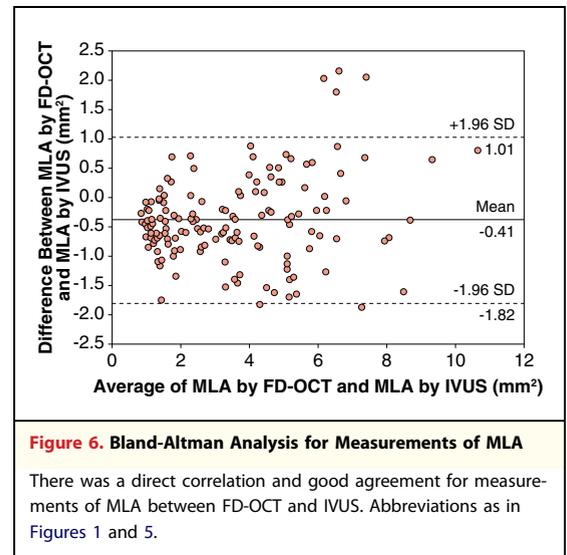
post-PCI. Intrastent tissue protrusion (95% vs. 18%; $p < 0.001$), incomplete stent apposition (39% vs. 14%; $p < 0.001$), stent edge dissection (13% vs. 0%; $p = 0.013$), and intrastent thrombus (13% vs. 0%; $p = 0.013$) were detected more frequently by FD-OCT compared with IVUS. Representative FD-OCT and IVUS images of suboptimal lesion morphologies after stenting are shown in Figure 8.

Phantom models. Figure 9 compares measurements of lumen area by IVUS and FD-OCT in the phantom models. The mean of the lumen areas measured using FD-OCT was equal to the actual lumen area of the phantom model. The mean and SDs of the lumen area of the phantom measured by using IVUS were significantly greater than those measured by using FD-OCT ($8.03 \pm 0.58 \text{ mm}^2$ vs. $7.45 \pm 0.17 \text{ mm}^2$; $p < 0.001$).

DISCUSSION

There were 2 main findings of this study. First, FD-OCT provided accurate measurements of coronary lumen with excellent intraobserver reproducibility. Compared with FD-OCT, QCA measured smaller lumen diameters and IVUS measured larger lumen areas, although the correlations among these 3 methods were high. Second, FD-OCT was much more sensitive in detecting intrastent tissue protrusion, incomplete stent apposition, stent edge dissection, and intrastent thrombus compared with IVUS.

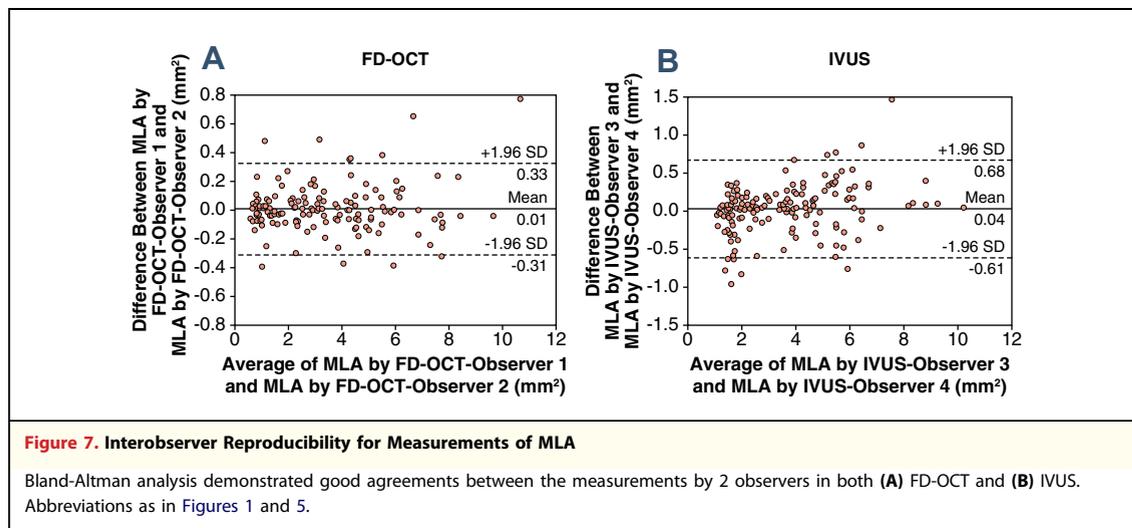
Accuracy of FD-OCT measurement. Accurate luminal measurement is expected in OCT because this



technology offers high resolution and excellent contrast between lumen and vessel wall. However, a few previous studies have reported conflicting results for the OCT morphometry.

Some phantom models have shown accurate measurements of OCT. Sawada et al. (2) demonstrated that the TD-OCT measurements of diameter and area of the phantom models were identical to the actual values when the image wire was positioned in the center of the lumen. Tsuchida et al. (3) revealed that the TD-OCT measurement correlated well with the actual lumen dimension (relative SD 1.8%, $r = 1.000$, intercept 0.01, slope 1.02) when OCT was performed in a plexiglass phantom manufactured with a precision of 10 μm . In a single-laboratory pilot study, Tahara et al. (4) found that FD-OCT measurements had excellent correlations with actual phantom dimensions (concordance correlation coefficient ≥ 0.9958). The present study demonstrated that FD-OCT measurements were more accurately reflective of the true phantom dimensions than IVUS. Our results are in line with previous phantom studies which showed that OCT provided closer measurement to the actual phantom dimension.

An additional vivo study by Gonzalo et al. (5) found that both TD-OCT and IVUS overestimated lumen area compared with histology. In fixed human coronary arteries, the lumen area obtained by using TD-OCT and IVUS was larger than that obtained by using histomorphometry: relative reference 28% for TD-OCT and 40% for IVUS. The proposed explanation was removal of water content from histology specimens causing vessel shrinkage and thereby falsely lowering luminal areas.



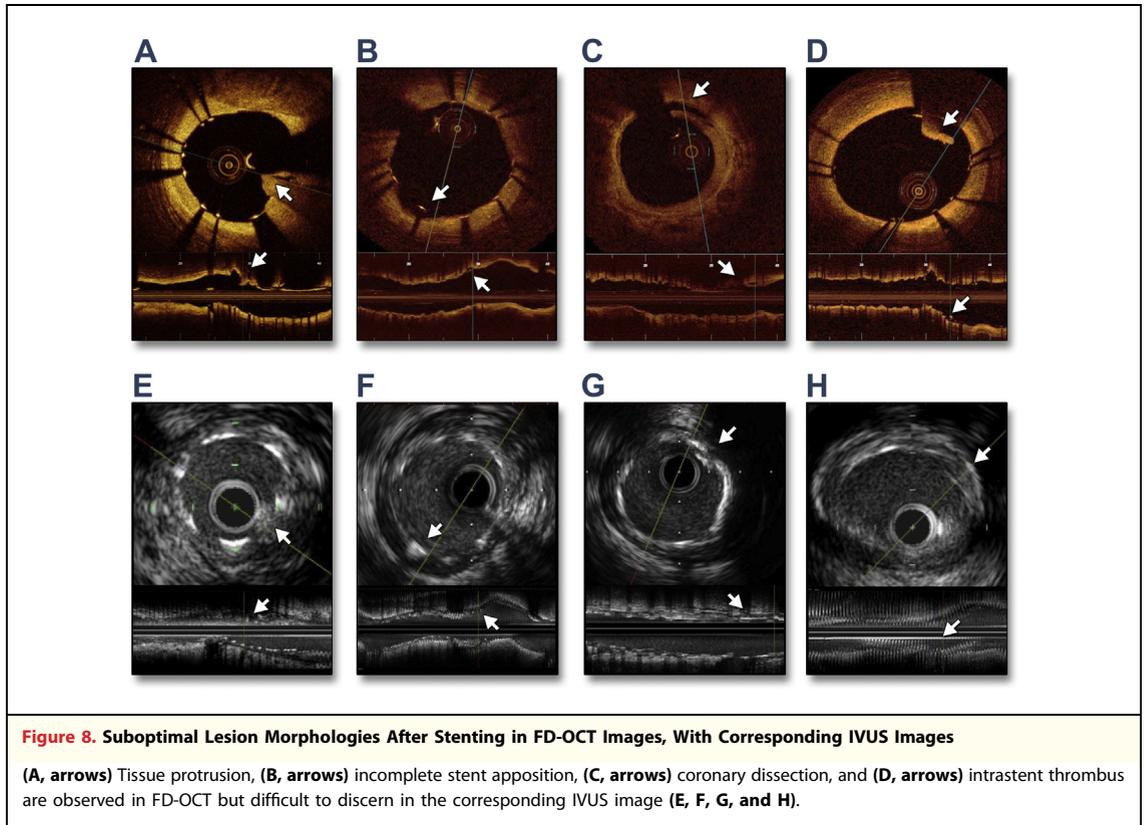
Several in vivo studies have compared luminal measurements between OCT and IVUS. Kawase et al. (6) performed measurements on stented pig arteries and demonstrated no differences in lumen areas and volumes between TD-OCT and IVUS. However, other studies consistently reported that lumen dimensions measured by OCT were significantly smaller than that by IVUS. In a clinical study by Yamaguchi et al. (7), the MLD and MLA measured by TD-OCT were significantly correlated with those measured by IVUS but the measurements by OCT were significantly smaller than those by IVUS (relative reference -4.3% and -7.1%, respectively). Capodanno et al. (8) showed that lumen area measured by TD-OCT using a non-occlusive imaging technique was significantly smaller than that by IVUS (relative reference -5.4%). Okamura et al. (9) demonstrated that MLA measured by a Terumo intravascular optical frequency domain imaging system (Terumo Corp., Tokyo, Japan) was smaller than that by IVUS (relative reference -6.7%) and larger than QCA (relative reference 40.3%).

One possible explanation for these measurement differences between OCT and IVUS is the fact that most previous studies were performed with TD-OCT, which requires proximal balloon occlusion. Balloon occlusion causes a decrease in coronary perfusion pressure that was not compensated by continuous flush injection, therefore causing partial vessel collapse. In support of this hypothesis, a previous TD-OCT study found that the lumen area obtained with proximal balloon occlusion technique was smaller than that obtained with a nonocclusive technique (relative reference -13%) (5). FD-OCT, however, does not require coronary occlusion for image acquisition. In addition, the size of the FD-OCT image catheter is similar to that of IVUS catheters. Therefore, the degree of coronary pressure depression and vessel collapse due to the imaging catheter is thought to be comparable between FD-OCT and IVUS. The difference in lumen measurements between the 2 techniques is not likely due to the imaging procedure of FD-OCT.

Another possible reason for this difference is the superior ability of OCT to visualize the lumen-intima interface compared with IVUS, therefore allowing OCT to visualize the true lumen dimensions and causing IVUS to overestimate. Supporting this theory is the fact that IVUS is known to overestimate lumen area. An experimental study reported that IVUS measurement was influenced by blood flow velocity, blood temperature, eccentric catheter placement, and the incidence angle of echo signal, which resulted in a $16 \pm 6\%$ increase in lumen area for phantoms and $14 \pm 9\%$ for human arteries in vitro (10). Furthermore, a clinical study showed that the lumen area measured using IVUS was larger than the values obtained

	FD-OCT	IVUS	p Value
Tissue protrusion	95	18	<0.001
Incomplete stent apposition	39	14	<0.001
Dissection	13	0	0.013
Thrombus	13	0	0.013

Values are %.
 FD-OCT = frequency domain optical coherence tomography; IVUS = intravascular ultrasound; PCI = percutaneous coronary intervention.



using 2 standard methods of QCA, such as edge detection and video-densitometry (11).

Reproducibility of FD-OCT measurement. The high-resolution images of FD-OCT result in the excellent reproducibility of coronary measurements. Fedele et al. (12) reported that the average biases of

FD-OCT in the interobserver, intraobserver, and interpullback comparisons were $<0.15 \text{ mm}^2$ for the lumen area. Sources of variability were incomplete visualization of the vessel circumference, ambiguous luminal borders, and drift of internal catheter calibration (Z-offset). With its excellent accuracy and reproducibility of quantitative measurements, FD-OCT has great potential to become a valuable tool for evaluating lumen changes in response to specific pharmacologic or interventional treatments.

Assessment of coronary stenting by FD-OCT. Given the fine resolution at imaging depths $<1 \text{ mm}$, OCT is suited for stent visualization. A previous TD-OCT study showed that TD-OCT detected intra-stent tissue protrusion, incomplete stent apposition, stent edge dissection, and intrastent thrombus better than IVUS (13). The present study revealed that FD-OCT also had the capability to detect these suboptimal lesion morphologies after stenting. Further investigation is needed to assess the clinical implication of these detailed findings obtained by OCT.

Clinical implications. FD-OCT is becoming increasingly widespread as a clinical tool to assess coronary artery disease and guide PCI. Although a recent study by Habara et al. (14) found that

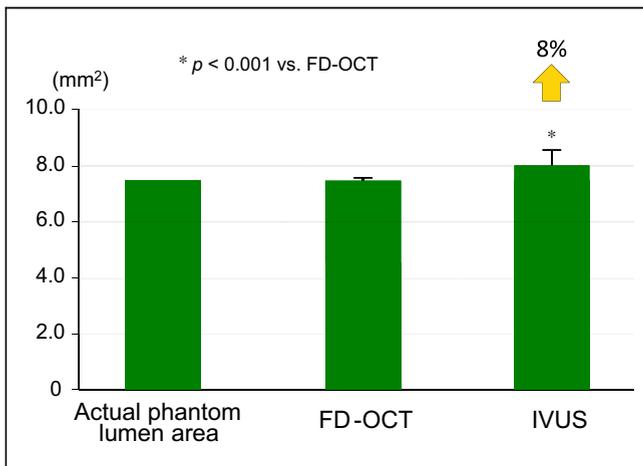


Figure 9. Measurements of MLA in Phantom Models by FD-OCT and IVUS
MLA by IVUS was greater than that by FD-OCT (relative reference 8%).
Abbreviations as in Figures 1, 5, and 7.

minimum stent area was smaller in FD-OCT-guided PCI compared with IVUS-guided PCI, knowledge of accuracy for FD-OCT measurements is essential when designing clinical trials and when considering FD-OCT findings as a surrogate marker of PCI optimization. Because FD-OCT has smaller lumen area measurements than IVUS, caution should be taken before using literature-validated IVUS parameters to assess lesion significance by FD-OCT. In addition, unlike IVUS, OCT has limited far-field penetration and thus is unable to reliably visualize the external elastic membrane, which may affect stent sizing. Thus, further studies are required to determine whether IVUS or OCT is better suited to improve clinical outcomes after stent implantation. Similar to the earlier days with IVUS, we will continue to learn more about this technique. Our results will form the basis of quantitative FD-OCT analysis in future clinical trials.

Study limitations. First, both FD-OCT and IVUS require keeping the guidewire in the vessel during image acquisitions. The shadow from the guide wire can affect measurements of lumen area. Second, the influence of coronary pulsation on lumen measurements was not assessed in the present study. Corresponding FD-OCT and IVUS images were not necessarily acquired during the same phase of cardiac cycle, because the pullback speed is different between the 2 techniques. Third, for the FD-OCT image acquisition, the injection rate of the contrast media was

chosen by the individual operator. Rapid injection increases shear stress, which could induce vasoconstriction. Fourth, we used 40-MHz IVUS transducers according to the previous comparison studies between TD-OCT and IVUS (6). Our results may be not applicable to IVUS images acquired by ultrasonic transducers that operate at frequencies significantly above or below 40 MHz, because the IVUS frequency can affect the spatial resolution. Finally, the QCA studies were performed using standard 2-dimensional analysis, which has a few well-known limitations. Recently developed 3-dimensional QCA has the potential to provide more reliable measurements of segment length and diameter.

CONCLUSIONS

This prospective multicenter study demonstrated that more accurate measurements of the coronary lumen may be achieved using FD-OCT compared with IVUS and angiography. These results indicate that FD-OCT provides reliable quantitative measurements of coronary dimensions in the clinical setting.

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