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# Discrepancy between frequency domain optical coherence tomography and intravascular ultrasound in human coronary arteries and in a phantom in vitro coronary model



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## ABSTRACT

Background: This purpose of this study is to evaluate, concomitantly with quantitative coronary angiography (QCA), the potential discrepancy between frequency domain optical coherence tomography (FD-OCT) and intravascular ultrasound (IVUS) measurements in a phantom coronary model and in human coronary arteries within and outside stented segments.

Methods: FD-OCT and IVUS images sequentially obtained from a phantom coronary model and 57 stented human coronary arteries were compared between each other and with QCA.

Results: Lumen area (LA) by IVUS was 10.1% larger ( $6.43\pm0.09~\text{mm}^2$ ) while by FD-OCT was similar ( $5.78\pm0.09~\text{mm}^2$ ) to actual phantom LA ( $5.72~\text{mm}^2$ ); IVUS vs. FD-OCT stent area (SA) was 4.2% larger. In human coronary artery, diameter by QCA was smaller than by IVUS and OCT in reference (by 10.5% and 3.5%, both p < 0.001) and stented (3.6%, p < 0.001; and 1.7%, p = 0.012) segments. IVUS vs. FD-OCT distal reference LA was significantly larger ( $6.19\pm2.18~\text{mm}^2$  vs.  $5.49\pm2.49~\text{mm}^2$ , p < 0.001, respectively), and SA was numerically larger ( $7.42\pm2.28~\text{mm}^2$  vs.  $7.22\pm2.48~\text{mm}^2$ , p = 0.059) with larger discrepancy in reference (11.3%) than stented (2.7%) segments. IVUS vs. FD-OCT correlation for diameter was significantly higher for stented than reference segments ( $8^2=0.8670~\text{vs}$ ) vs. 0.7351, p = 0.047), while numerically higher for area ( $8^2=0.8663~\text{vs}$ ) vs. 0.7806, p = 0.157).

Conclusions: In phantom model and human coronary arteries, IVUS vs. FD-OCT measurements were larger, particularly in non-stented than stented segments, and diameter was smaller by QCA vs. IVUS or FD-OCT. Despite undefined clinical significance, said discrepancy warrants consideration.

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# 1. Introduction

In coronary artery measurement to inform stent size selection and to optimize stent deployment during percutaneous coronary intervention (PCI), both intravascular ultrasound (IVUS) and optical coherence tomography (OCT) have benefits over simple coronary angiography [1, 2]. However, studies have shown that IVUS depict significantly larger diameter and area compared to time domain (TD)-OCT with obstructive technique [3–5] and the more recent frequency domain (FD)-OCT with non-occlusive technique [5–7]. The size discrepancy between the modalities might interfere adequate stent sizing during the procedure. This study evaluated, in conjunction with quantitative coronary angiography (QCA), the nature, magnitude and mechanism of the discrepancy

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between FD-OCT and IVUS measurements in a phantom coronary model and in human coronary arteries both within and outside stented segments.

## 2. Material and methods

2.1. Study population — phantom model and human coronary artery

To evaluate accuracy of FD-OCT and IVUS measurements in vitro, cylindrical plastic coronary model with stent was used. Sirolimus-eluting stent (Cypher $^{\rm IM}$  stent, Cordis, Johnson and Johnson, Miami Lakes, Florida, USA; 2.5 mm in diameter; 33 mm long) was implanted in a 2.70 mm lumen diameter plastic model using inflation for 30 s at a rated pressure of 16 atm.

The in vivo study retrospectively enrolled consecutive patients with coronary artery disease who had undergone percutaneous coronary intervention following standard protocol with drug eluting stent implantation after which both FD-OCT and IVUS were performed. Inclusion criteria were complete pullback and >70% analyzable frames in both modalities [7]. Cases with 1. bifurcation lesions in which the side branch occupied more than 45° of the cross section; 2. poor FD-OCT or IVUS images due to heavy calcification or artifact; and 3. left main coronary lesion, were excluded to avoid other factors that might have an effect on measurement error and cause further size discrepancy of the

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two modalities. A total of 57 stented lesions were included. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institution's human research committee.

## 2.2. FD-OCT and IVUS image acquisition

FD-OCT imaging was performed after stent deployment using the C7XR Imaging System with a 2.7 French Dragonfly imaging catheter (LightLab Imaging, St Jude Medical, St Paul, Minnesota, USA). Intracoronary nitroglycerin 200  $\mu$ g was injected. During image acquisition, contrast was flushed continuously at a rate of 4 to 6 mL/s for a total volume of 20 mL/pullback into the vessel through the guide catheter to clear  $\mu$  blood in the coronary artery. Images were acquired with automated 20 mM/s pullback.

The IVUS image was acquired after stent deployment using a single 40 MHz transducer within a 3.2 French short monorail sheath (Atlantis® SR Pro Imaging Catheter, Boston Scientific, Natick, Massachusetts, USA). Intracoronary nitroglycerin 200 µg was administered before the procedure. The catheter was placed 10 mm distal to the target lesion. Motorized constant velocity (0.5 mm/s) pullback was used to display the artery retrograde to the coronary ostium. The location of the catheter transducer was documented at the initiation of pullback with angiography.

## 2.3. Post-stenting FD-OCT and IVUS image analysis

Quantitative FD-OCT and IVUS analyses were performed by two independent experienced analysts. IVUS images were analyzed with commercially available software (echoPlaque, Indec Systems, Mountain View, California), and FD-OCT images with LightLab OCT imaging proprietary software (LightLab Imaging). Post-stenting images were analyzed at 1 mm intervals for 5 mm within the stent starting from its distal edge. Measurements of the distal native vessel were also performed at 1 mm intervals for 5 mm length starting from the first segment outside the distal stent edge. All FD-OCT images were matched with corresponding IVUS images according to the distance from the distal stent edge. To quantify size discrepancy between the FD-OCT and IVUS measurements, relative difference percentage [(IVUS measurement value – FD-OCT measurement value) divided by IVUS measurement value] was calculated and compared with previous studies [5]. Representative cases of phantom and human coronary artery measurements are displayed in Fig. 1.

## 2.4. Post-stenting quantitative coronary analysis

To compare FD-OCT and IVUS measured mean and QCA diameters, post-stenting coronary angiograms were analyzed using Clinical Measurements Solutions system (CAAS 5.7 QCA system, Pie Medical, Maastricht, The Netherlands). The automatic edge detection program determines the vessel contours by assessing brightness along scan lines perpendicular to the vessel center. Post-stenting QCA was performed retrospectively by an independent analyst supervised by an expert physician. Best image at end-diastolic frame was selected to measure, well visualizing stent site and distal reference lumen

with minimal foreshortening and branch overlap. For the estimation of distal stent diameter, distal edge of the stent was selected and five counts of diameter at an interval of 1 mm to the proximal side was measured, and same counts of distal reference diameter were measured at 1 mm intervals in the distal reference segment immediately after the distal stent edge

## 2.5. Statistical analysis

The statistical analyses were performed using SPSS software package (version 18.0 for windows; SPSS Inc., Chicago, Illinois, USA). Continuous variables are presented as mean  $\pm$ standard deviation, and categorical variables as counts and percent frequencies. For the comparison of FD-OCT and IVUS measurements, the diameter and area at the reference segment and the stent site were analyzed using paired t test. All tests were two-sided and p-values of < 0.05 were considered statistically significant. For all paired measurements, agreement between FD-OCT and IVUS measurements as well as with QCA from the matched images was investigated using a simple regression analysis and expressed as a Bland-Altman plot depicting the difference between each pair of measurements in the v-axis and the average of both techniques in the x-axis with reference lines for the mean difference. The correlation coefficients among FD-OCT, IVUS and QCA were compared using the Fisher r-to-z transformation. Inter-observer agreement and intraobserver agreement were estimated for both FD-OCT and IVUS measurements. Interobserver agreement was analyzed by blind measurement from two independent observers. To assess intra-observer agreement, independent analysis was blindly performed twice by one of the observers.

#### 3. Results

# 3.1. Phantom coronary model

FD-OCT showed similar lumen diameter (LD) (phantom 2.70 mm vs. FD-OCT 2.71  $\pm$  0.02 mm) and lumen area (LA) (phantom 5.72 mm² vs. FD-OCT 5.78  $\pm$  0.09 mm²) as actual phantom size in the reference segment. In contrast, IVUS measurements were larger for LD (2.87  $\pm$  0.02 mm, p < 0.001), and LA (6.43  $\pm$  0.09 mm², p = 0.001) when compared to FD-OCT measurements. In the stented segment, stent diameter (SD) measured by IVUS was larger than that measured by FD-OCT (FD-OCT 2.36  $\pm$  0.04 vs. IVUS 2.42  $\pm$  0.04, p < 0.001), as was stent area (SA) (FD-OCT 4.37  $\pm$  0.12 vs. IVUS 4.56  $\pm$  0.15, p < 0.001) (Fig. 2 A and B).

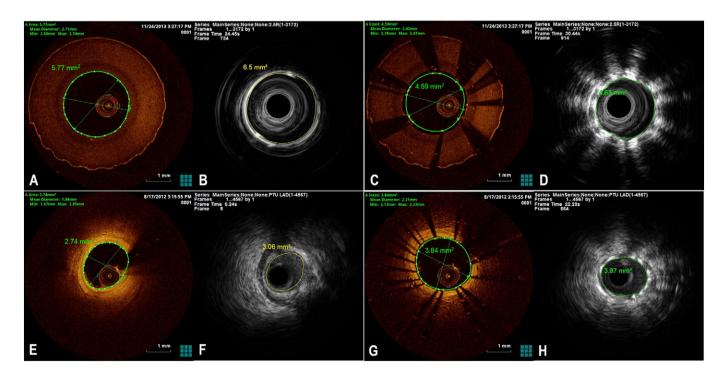


Fig. 1. Representative images of FD-OCT and IVUS at the same segment of phantom reference (A and B), phantom stent (C and D), human coronary artery (E and F), and human coronary artery with stent (G and H).

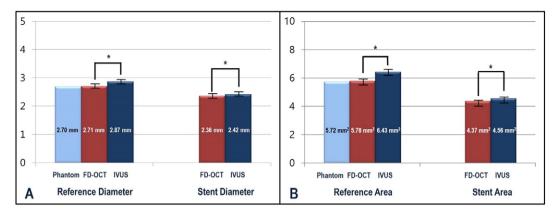


Fig. 2. Comparisons of diameter and area among actual phantom size (light blue), and FD-OCT (red) and IVUS (dark blue) measurements at the non-stented reference site (A) and stented segment (B) of phantom coronary model. (\*, p < 0.001; FD-OCT, frequency domain optical coherence tomography; IVUS, intravascular ultrasound).

# 3.2. Human coronary arteries

Among 57 patients (mean age, 65 years; 65% male), each of 285 matched images from 5 mm distal stent segments and 5 mm distal reference segments were investigated. Left anterior descending artery (LAD) was most commonly treated (73.7%). In human coronary arteries, IVUS depicted larger diameter than FD-OCT in the distal reference segment (2.77  $\pm$  0.49 mm vs. 2.57  $\pm$  0.60 mm, p < 0.001) and in the stented segment (3.05  $\pm$  0.45 mm vs.2.99  $\pm$  0.49 mm, p = 0.003). The difference in mean diameter was more prominent in the distal reference segment (7.2%) than in the stented segment (2.0%). When compared with IVUS and FD-OCT measured diameter, QCA measured diameter in the reference segment (2.48  $\pm$  0.57 mm) was smaller than that by IVUS by 10.5% (p < 0.001) and by OCT by 3.5%(p < 0.001). In the stented segment, QCA measured diameter (2.94  $\pm$ 0.50 mm) was smaller than IVUS by 3.6% (p < 0.001) and OCT by 1.7%(p = 0.012) (Fig. 3A). Mean distal reference LA by IVUS measurement was also significantly larger than by FD-OCT (6.19  $\pm$  2.18 mm<sup>2</sup> vs.  $5.49 \pm 2.49 \text{ mm}^2$ , p < 0.001). Mean SA was numerically larger by IVUS measurement as compared with FD-OCT measurement (7.42  $\pm$ 2.28 mm<sup>2</sup> vs.  $7.22 \pm 2.48$  mm<sup>2</sup>, p = 0.059). The difference in mean area by FD-OCT and IVUS measurements was more pronounced at the reference (11.3%) than stented (2.7%) segments (Fig. 3B). Bland-Altman plot showed greater difference between FD-OCT and IVUS measurements at the reference than stented segments (Fig. 4). In addition, correlation between FD-OCT and IVUS measurements was significantly higher in the SD than in the reference segment LD (stented segment diameter  $R^2 = 0.8670$ , reference segment diameter  $R^2 = 0.7351$ , p = 0.047), while the correlation was numerically higher in the SA than in the reference segment LA (stented segment area  $R^2 = 0.8663$ , reference segment area  $R^2 = 0.7806$ , p = 0.157) (Fig. 5).

# 3.3. Inter- and intra-observer reproducibility

In OCT measurements, inter- and intra-observer agreement for reference lumen diameter and area, and stent diameter and area was 0.9936 [95% confidence interval: 0.9887–0.9964] and 0.9989 [0.9981–0.9994]; 0.9953 [0.9917–0.9973] and 0.9986 [0.9974–0.9992]; 0.9955 [0.9921–0.9975] and 0.9984 [0.9972–0.9991]; and 0.9966 [0.9941–0.9981] and 0.9988 [0.9978–0.9993], respectively. The corresponding values for IVUS measurements were: 0.9766 [0.9588–0.9867] and 0.9984 [0.9971–0.9991]; 0.9749 [0.9559–0.9858] and 0.9985 [0.9973–0.9991]; 0.9943 [0.9899–0.9967] and 0.9978 [0.9960–0.9987]; and 0.9952 [0.9915–0.9973] and 0.9981 [0.9967–0.9989], respectively.

## 4. Discussion

The findings of this study are as follows: 1) diameter and area measured by FD-OCT were similar to real phantom model values, while those by IVUS were larger; 2) in human coronary arteries, IVUS vs. FD-OCT demonstrated larger diameter and area compared in

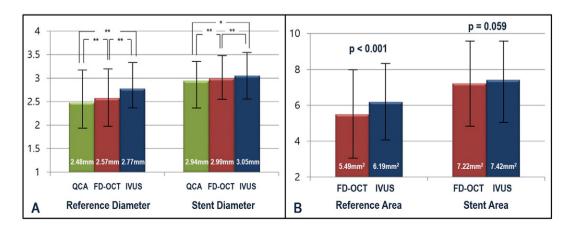


Fig. 3. Comparisons of diameter (A) and area (B) among FD-OCT (red), IVUS (dark blue) and QCA (green) measurements at the non-stented reference site and stented segment of human coronary artery. (QCA, quantitative coronary angiography; FD-OCT, frequency domain optical coherence tomography; IVUS, intravascular ultrasound; \*, p < 0.05; \*\*, p < 0.001).

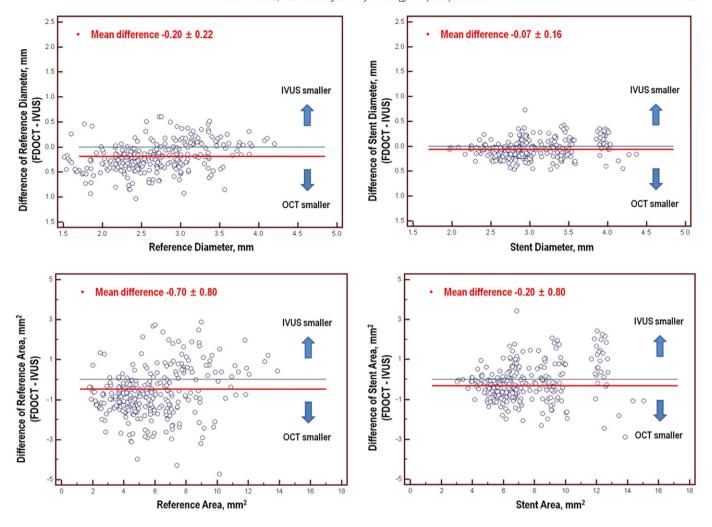


Fig. 4. Bland-Altman plots of differences between reference (left) and stent (right) diameter (upper panel) and area (lower panel) between IVUS and FD-OCT. (IVUS, intravascular ultrasound; OCT, optical coherence tomography).

both reference and stented segments; 3) the IVUS vs. FD-OCT measurement discrepancy was more prominent in reference than stented segments which can be affected by physiologic vascular response; and 4) lumen dimensions were larger by IVUS and FD-OCT than QCA in human coronary arteries.

IVUS and OCT provide better information than coronary angiography for coronary lesion assessment and stent optimization. However, because IVUS is a sound based imaging technique [8,9] and OCT is a light based imaging technique [10], the different characteristics of IVUS and OCT images can produce different size measurements in the same lesion [5–7]. Previous studies comparing TD-OCT and IVUS demonstrated smaller lumen by TD-OCT measurement. Proximal occlusion technique to obtain blood free space was an explanation for the smaller measurement by conventional OCT [3,11-13]. Recent studies also showed smaller FD-OCT estimations, even though they used contrast injection technique rather than proximal balloon occlusion [4,6,7]. The results from our study were mostly consistent with those of previous studies. Therefore, to evaluate the nature and mechanism of the discrepancy between FD-OCT, IVUS and QCA measurements, phantom coronary model and human coronary artery with and without stent were analyzed by 3 modalities sequentially.

Earlier studies showed significantly smaller size by QCA compared with OCT or IVUS measurements. The mechanisms of this phenomenon have been studied: 1) difficulty in image sequence selection with minimal foreshortening or overlap with other structures; 2) less accurate

border detection; and 3) insufficient vessel filling by contrast media during image acquisition [4,14–17].

In ex-vivo coronary artery, IVUS and FD-OCT both have shown larger diameter than the actual measurement of the pathologic specimen due to the shrinkage of the vessel during the preparation for histology [13, 18]. Therefore, the true size of the vessel could not be estimated using ex-vivo coronary artery and in vitro model has been used to estimate accuracy of FD-OCT and IVUS measurement. A recent study by Kubo et al. showed that minimum lumen area (MLA) by FD-OCT measurement was similar to the actual phantom silicon coronary model size. However, IVUS overestimated the size by 8%, which was in line with our observation [6]. In the current study, although FD-OCT depicted similar size with actual phantom coronary model, IVUS overestimated LD by 5.6% and LA by 10.1% compared to actual phantom size in the reference segment. In the stented segment of phantom model, SD and SA measured by IVUS were larger than those by FD-OCT by 2.5% and 4.2%, respectively. In human coronary artery, IVUS LD was 7.2% larger than FD-OCT LD in the distal reference segment, while SD was 2.0% larger. IVUS LA and SA were larger by 11.3% and 2.7% than FD-OCT measurement.

According to Bezerra et al., possible explanations for the size discrepancy between IVUS and FD-OCT are: 1) lumen discrimination — clear visualization with lesser blurring from the image attenuating material (e.g. calcium) by FD-OCT may allow more precise lumen identification than IVUS; 2) beating effect — faster pullback speed precludes selection of frames at maximum diastole in FD-OCT image; and 3) Dotter effect —

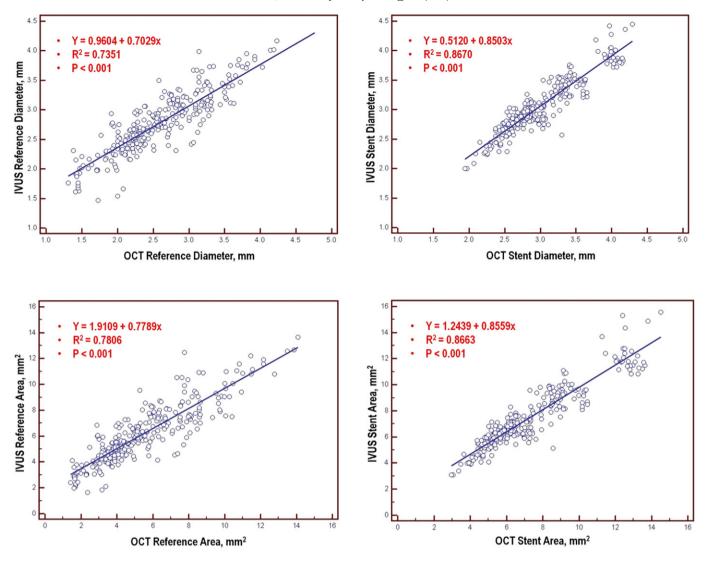


Fig. 5. Correlation between IVUS measured diameter and FD-OCT measured diameter at the reference segment and the stented segment (upper panel). Correlation between IVUS measured area and FD-OCT measured area at the reference segment and the stented segment (lower panel). Note correlation between IVUS and OCT measured diameter and area are greater at the stented segment than at the reference segment. (IVUS, intravascular ultrasound; OCT, optical coherence tomography).

the smaller caliber FD-OCT catheter (2.7 Fr) when compared with IVUS (3.2 Fr) may cause less stretch of the vessel in high-grade stenosis [7]. In real clinical practice, when dealing with coronary artery with stent, the

latter mechanisms might differentially contribute to the size discrepancy between FD-OCT and IVUS in each situation. Therefore, previous studies showed inconsistent results on the degree of size discrepancy

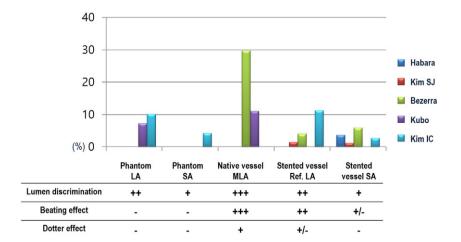


Fig. 6. Relative difference in percentage of mechanism contribution to difference between IVUS and FD-OCT measurements in previous studies and the present study. (IA, lumen area; SA, stent area; MLA, minimum lumen area; Relative difference percentage (%) =  $100 \times (IVUS \text{ measurement}) / IVUS \text{ measurement})$ .

which might be confounding to interventionists during clinical decision making.

Relatively different percentage contributions by the different mechanisms were seen in phantom, phantom with stent, human coronary artery reference site, MLA site and human coronary artery with stent in the previous and current study results (Fig. 6) [5-7,19]. In phantom coronary model, beating and Dotter effects were absent. Therefore, discrepancy can be only explained by blurring effect. Because stent struts provided a clear landmark to both FD-OCT and IVUS for lumen discrimination in contrast to the bare plastic material which appeared as a blurred lumen in the IVUS image, smaller discrepancy was observed in stented segment than in pure phantom segment. In human coronary artery, although current study did not include pre-interventional diseased segment, the size discrepancy and inter-study variation can be most exaggerated in the MLA site of native vessel, which was reported from 11.1% in the study by Kubo et al. [6] to 29.8% in that by Bezerra et al. [7]. Diverse plaque characteristics in MLA site including calcium can provide different lumen discrimination power. Narrow lumen area can augment beating and Dotter effects. In the reference segment of the stented vessel, lumen discrimination can be better than in the MLA site because of the relatively normal looking surface with lesser plaque.

The discrepancy between IVUS and FD-OCT was less pronounced and each measurement showed a stronger correlation in the stented than reference segment. In the stented segment, stent struts provide a clear landmark for lumen discrimination for both FD-OCT and IVUS. The beating effect is minimized in the stented segment because stent struts can provide enhanced radial strength during coronary systole and diastole. But in the reference segment, effect of stent strut nearby may provide some extent of radial strength, so the beating effect is less influenced than the native vessel MLA without effect of stent. Dotter effect might be almost absent both in the reference and stented segments with sufficient LA. Therefore, size discrepancy between FD-OCT and IVUS and inter-study variability are minimized when measuring stented segment which is least affected by those mechanisms. A previous report also showed attenuation of size discrepancy in the stented segment when compared to the reference native vessel site [5].

It is difficult to define the standard value of size discrepancy which can be universally applicable in clinical practice because of the high relative difference value and inter-study variability owing to the diverse contribution of size discrepancy mechanisms. Also, long-term clinical impact of those discrepancies might not be significant because of the numerically small difference among modalities. However, a better understanding of the mechanism underlying the measurement discrepancy between each modality in different situations can inform adequate device selection and result in a better coronary interventional procedure.

# 4.1. Study limitations

The present study has several limitations. First, it was a single center observational study with the inherent limitations of small number with possibility of selection bias. Second, the vessels studied had fairly simple lesions. Size discrepancy on complex lesions such as bifurcation lesion, side branch and bended lesions warrants further investigation. Third, the small number of the measurements in phantom coronary model might lack the statistical power to evaluate true size differences. Nevertheless, the size discrepancy estimated in phantom model was similar with the previous report, adding reliability of the results [6]. Fourth, there is no definite modality that can measure absolute vessel size. Furthermore, complex geometry of native coronary lesion and stented vessel as well as dynamic size change according to blood flow, temperature, and eccentric catheter placement may interfere with accurate measurement of definite vessel size [20]. Future devices which can measure real time vessel size without artifact should overcome the latter limitations.

## 5. Conclusions

Measurements were larger by IVUS than FD-OCT in phantom model and human coronary arteries, with greater difference in non-stented than stented segments. There is diversity in size discrepancy according to underlying mechanism, and operators should be cautious in applying FD-OCT and IVUS size criteria in different situations. Future investigations are warranted to elucidate the impact of size discrepancy among imaging modalities on clinical outcomes.

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# **Conflict of interest statement**

The authors have no conflict of interest.

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