Impact of Frequency-Domain Optical Coherence Tomography Guidance for Optimal Coronary Stent Implantation in Comparison With Intravascular Ultrasound Guidance

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Background—Frequency-domain optical coherence tomography (FD-OCT) is a novel, high resolution intravascular imaging modality. Intravascular ultrasound (IVUS) is a widely used conventional imaging modality for achieving optimal stent deployment. The aim of this study was to evaluate the impact of FD-OCT guidance for coronary stent implantation compared with IVUS guidance.

Methods and Results—A total of 70 patients with de novo coronary artery lesions and either unstable or stable angina pectoris were enrolled in this randomized study (optical coherence tomography [OCT] group: n=35, IVUS group: n=35). In the OCT group, stent implantation was performed under FD-OCT guidance alone and final stent expansion was evaluated by IVUS. In the IVUS group, conventional IVUS guidance was used and final stent apposition was evaluated by FD-OCT. There were no significant differences regarding the procedural, fluoroscopy time, and contrast volume. Although device and clinical success rates also were similar, the visibility of vessel border was significantly lower in the OCT group (P<0.05). Minimum and mean stent area and focal and diffuse stent expansion were smaller (6.1±2.2 mm versus 7.1±2.1 mm, 7.5±2.5 versus 8.7±2.4 mm, 64.7±13.7% versus 80.3±13.4%, 84.2±15.8% versus 98.8±16.5%, P<0.05, respectively), and the frequency of significant residual reference segment stenosis at the proximal edge was higher in the OCT group (P<0.05). Incomplete apposed struts in both groups were similar (P=0.34).

Conclusions—FD-OCT guidance for stent implantation was associated with smaller stent expansion and more frequent significant residual reference segment stenosis compared with conventional IVUS guidance. (Circ Cardiovasc Interv. 2012;5:193-201.)

Key Words: optical coherence tomography ■ intravascular ultrasound ■ optimal stenting

Optimal stent deployment remains an important issue for coronary stenting and is associated with a lower incidence of restenosis and stent thrombosis. Some studies suggest that optimal stent deployment using intravascular ultrasound (IVUS) achieves a lower target vessel revascularization rate and better clinical outcomes compared with angiographic guidance. Optical coherence tomography (OCT) is a light-based, high-resolution intracoronary imaging modality that has the potential of improving clinical outcomes after intervention. Recently, frequency-domain optical coherence tomography (FD-OCT) has become commercially available and is considered a feasible and safe technique for guidance of percutaneous coronary intervention (PCI). However, it is not fully known whether FD-OCT has the potential to replace IVUS in coronary intervention with stent implantation. This study was designed to compare FD-OCT guidance with IVUS guidance for stent implantation in a prospective patient cohort to gain further insight into this potential.

Methods

Patient Selection

This study was designed as a prospective, single center study from March 2010, to November 2010. After baseline angiograms had been obtained, patients eligible for this study were randomly assigned to either (1) OCT guided PCI, or (2) IVUS guided PCI. Random assignments to the treatment groups were distributed in sealed envelopes. The study was open label, as blinding was not possible for either investigator or subject.

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WHAT IS KNOWN

- Optimal coronary stent implantation using intravascular ultrasound (IVUS) can potentially improve clinical outcome.
- Frequency-domain optical coherence tomography (FD-OCT) is an alternate intracoronary imaging modality that provides very high resolution images.

WHAT THE STUDY ADDS

- A direct comparison of FD-OCT and IVUS guidance for coronary stent implantation.
- FD-OCT guidance was associated with smaller stent expansion than seen following IVUS guidance.

Inclusion criteria consisted of patients with (1) symptomatic ischemic heart disease, and (2) a de novo lesion in the native coronary circulation detected by coronary angiography and planned stent implantation. Exclusion criteria were (1) left main coronary artery disease, (2) totally occluded lesion, (3) diffuse lesion (lesion length ≤25 mm analyzed by quantitative coronary angiography [QCA]), (4) bifurcation lesion, (5) lesion of large vessel (reference vessel diameter ≥3.5 mm analyzed by QCA), (6) lesion of severe tortuous vessel, (7) cardiogenic shock, (8) left ventricular ejection fraction ≤30%, (9) serum creatinine ≥2 mg/dL, (10) ST elevation myocardial infarction, and (11) when use of aspirin, ticlopidine, or heparin was contraindicated. This study was approved by the institutional review board with written informed consent obtained from all patients.

Procedure

The protocol of the procedure during PCI is shown in Figure 1. Implanted stents ≤3.5 mm were drug-eluting, and 4.0 mm were bare metal.

Frequency Domain-Optical Coherence Tomography Guidance for Stent Implantation

The protocol of the FD-OCT guided PCI procedure is shown in Figure 1. In the OCT group, preprocedural FD-OCT was performed within the target segment. Distal protection device was deployed (Figure 2) when 1 of the following findings was observed: (1) thrombus, (2) plaque rupture, or (3) thin cap fibroatheroma. Stent size and deployment pressure also were determined by the obtained OCT image. When lumen border at both (proximal and distal) reference segments could not be detected, balloon dilatation (1.5 mm diameter) for imaging was performed. When vessel and lumen border at both reference segments could be measured, reference sites were decided by the site with the largest lumen, either proximal or distal to the target lesion and with plaque burden of less than 50%, but within the same segment. Stent length was decided by measuring from distal to proximal reference site, and stent diameter was decided by measuring proximal and distal reference lumen diameter. Alternatively, when vessel border could not be measured, reference sites and stent size (length and diameter) were determined by angiography (Figure 3). Stent deployment pressure was determined by measuring the vessel diameter at minimum lumen area (MLA) site in accordance with the compliance chart of the stent delivery balloon, when vessel border at MLA site could be measured. When FD-OCT could not determine vessel border at MLA site, stent deployment pressure was decided by angiography (Figure 4). Balloon angioplasty before stent implantation was left to the discretion of the operator. After angiographic success (defined as diameter stenosis <30% with thrombolysis in myocardial infarction-3 flow by visual assessment), iterative FD-OCT was performed to evaluate stent expansion and apposition. Poststent balloon dilatation was determined in accordance with the obtained image. Additional inflation with a larger noncompliance balloon was performed when the following findings were observed: (1) residual plaque burden at minimum stent area (MSA) site >50%, (2) MSA <90% of the distal reference vessel lumen area, and (3) incomplete stent apposition (ISA).8,9 Balloon size and pressure were decided by each finding, and the largest balloon size was selected when several findings were observed (Figure 5). If additional inflation was required, FD-OCT pullback was performed again after postdilatation. Finally, IVUS pullback also was performed to assess stent expansion. During the

![Figure 1](https://example.com/figure1.png)

Figure 1. The protocol of the procedure. FD-OCT indicates frequency-domain optical coherence tomography; IVUS, intravascular ultrasound.
procedure, OCT images were evaluated with criteria for thrombus,
plaque rupture, and thin-cap fibroatheroma, as previously reported.10

Intravenous Ultrasound Guidance for Stent Implantation

The protocol of the IVUS guided procedure is shown in Figure 1. Preprocedural IVUS was performed within the target segment. A distal protection device was deployed (Figure 2) when 1 of the following findings was observed: (1) thrombus, (2) plaque rupture, or (3) attenuation plaque. Stent size and deployment pressure also were decided by IVUS image. The protocol for determining stent diameter, length, and deployment pressure was the same as the FD-OCT guided procedure (Figures 3 and 4). After angiographic success, iterative IVUS was performed to evaluate stent expansion and apposition. The decision for postballoon dilatation was made in accordance with the obtained IVUS image. The protocol of deciding to use postballoon dilatation was also the same as the FD-OCT guided procedure (Figure 5). If additional inflation was required, IVUS pullback was performed again after postdilatation. During the procedure, IVUS images were evaluated with criteria for ISA, thrombus, plaque rupture, and attenuated plaque, as previously reported.11,12

The procedural, fluoroscopy time, and contrast media volume were measured from guiding catheter insertion to removal after final angiogram. OCT and IVUS images were recorded after administration of 100 to 200 µg of nitroglycerin. These catheters were advanced >5 mm beyond the lesion/stent and were automatically pulled back to a point >5 mm proximal to the lesion/stent. All patients received dual antiplatelet drugs (aspirin 100 mg/d and ticlopidine or clopidogrel) prior to the procedure. A 300 mg loading dose of clopidogrel before the procedure was administered if patients were not pretreated. An intra-arterial bolus of 8000 units of heparin was administered prior to the PCI, and activated coagulation time was maintained at >300 seconds during the procedure. All PCI procedures were performed via the radial artery approach by 2 operators (M.H. and T.K.).

Quantitative Coronary Angiography

Offline QCA was conducted using the view that revealed the highest degree of stenosis. Severity of coronary stenosis was measured using the Cardiovascular Measurement System (CMS-MEDIS Medical Imaging System). Angiograms were analyzed before intervention, after stent deployment, and after intervention for every patient. Lesion length, reference diameter, minimal luminal diameter, and diameter stenosis were calculated by a single operator who was
Figure 4. The protocol defining stent deployment pressure. MLA indicates minimum lumen area; MSA, minimum stent area.

blinded to clinical characteristics. Analysis of angiographic frames was performed in the end diastolic stage.

**Optical Coherence Tomography Imaging and Analysis**

Optical coherence tomography imaging was performed using the OCT imaging system (CT OCT System). Contrast media was flushed continuously through the guiding catheter during image acquisition. Motorized pullback OCT imaging was performed at a pullback rate of 20 mm/s throughout the lesion/stent. Images were acquired at 100 frames(s) and digitally archived. All OCT images were reviewed, and quantitative OCT analysis was performed using LightLab OCT Imaging proprietary software (LightLab Imaging) by an independent, experienced observer who was blinded to clinical and angiographic lesion characteristics. Cross-sectional OCT images were analyzed at 1 mm intervals (every 5 frames). ISA was defined as >1 stent strut clearly separated from the vessel wall without any tissue behind the strut not associated with any side branch and having a distance over 0.2 mm.

**Intravascular Ultrasound Imaging and Analysis**

All IVUS studies were performed using an automated motorized pullback (0.5 mm/s) with a commercially available imaging system (40-MHz IVUS Catheter, Boston Scientific Corporation). All IVUS images were reviewed and evaluated for quantitative parameters using commercially available software (echoPlaque, Indec Systems Incorporated) by an independent, experienced analyst who was blinded to clinical and angiographic lesion characteristics. Measurements of external elastic membrane (EEM), lumen, plaque and media (EEM-lumen CSA), and stent cross-sectional area (CSA) were performed every 1 mm within the stent and for the 5 mm long reference sites proximal and distal to the stent sites. Plaque burden was plaque and media CSA divided by EEM CSA. Residual plaque burden at MSA site was (EEM-stent CSA) divided by EEM CSA. Mean reference lumen CSA was the average of proximal and distal reference lumen CSAs. Focal stent expansion was MSA divided by mean reference lumen CSA. Diffuse stent expansion was mean stent CSA divided by mean reference lumen CSA. The proximal and distal reference segments were measured at the most normal looking cross sections within 5 mm proximal or distal to the stent, but before any side branch. Furthermore, for the analysis of residual reference segment stenosis, the 1 mm slices closest to either edge of the stent were analyzed.

**Study End Points and Definitions**

The primary end point of the study was stent expansion analyzed by IVUS. The secondary end points were (1) the frequency of residual stent-edge plaque burden >50% analyzed by IVUS (defined as significant residual reference segment stenosis), (2) the frequency of incomplete apposed stent struts detected by FD-OCT, (3) visibility of the lumen border and the vessel border, (4) total procedural time, (5) total fluoroscopy time, (6) total contrast media volume, (7) device success rate, and (8) clinical success rate.

The visibility of the lumen border and the vessel border by FD-OCT and IVUS were evaluated at both reference sites and MSA site before and after intervention and classified into 2 grades, (1) good, equaling ≥75% (270°) of visible circumference, and (2) poor, equaling <75% (270°) of visible circumference.

Device success for FD-OCT and IVUS was defined as successful imaging obtained when devices crossed through the lesion to the distal location. Clinical success was defined as device success with a final lesion diameter stenosis <30% without in-hospital major adverse cardiac event, including death, myocardial infarction (MI), or target vessel revascularization. An MI was defined as any postprocedural creatine kinase elevation to >2 times normal. Q-wave MI was defined as MI in the presence of new Q-wave on ECG in 2 contiguous leads. Similarly, non–Q-wave MI was defined as MI without new Q-wave on ECG. In addition, we compared other complications, such as (1) life-threatening arrhythmia, (2) coronary dissection, (3) prolonged and severe vessel spasm, and (4) distal embolus.

**Statistical Analysis**

Sample size calculation was based on the assumption that focal stent expansion is 10% higher in the IVUS-guided group than in the OCT-guided group (80±14% versus 70±14%). With a 2-sided α-level of 0.05 and a power of 80%, 32 patients were required in each group. To accommodate 10% for possible missing investigations and withdrawals, the sample size was increased to 35 patients per group. In addition, we referred to previous studies about device feasibility and safety. Categorical variables are expressed as numbers (percentages). Continuous variables are expressed as
mean±standard deviation. Comparisons between groups were performed with 2-tailed Student t test for continuous variables and with χ² or Fisher test for categorical variables. Linear regression and the Bland-Altman tests were performed to evaluate correlation between FD-OCT and IVUS in measurements of minimum stent area and mean stent area. A probability value of <0.05 was considered statistically significant.

Results

Patient and Angiographic Characteristics
Seventy patients were enrolled in this study from March 2010, to November 2010. In accordance with the protocol, 35 patients in the OCT group and 35 patients in the IVUS group underwent PCI. There were no protocol deviations. Baseline demographics, clinical data, and angiographic characteristics, including QCA findings, are shown in Table 1. The 2 groups were well matched for patient characteristics and showed similar angiographic characteristics.

Procedural Outcomes
Procedural outcomes are listed in Table 2. Total procedural, fluoroscopy time, and total contrast media volume were similar between the groups. In addition, the device and clinical success rates also were similar. No complications associated with the imaging procedure were observed in either group and there were no significant differences between the 2 groups with respect to complications during the PCI procedure. Q-wave MI was observed for 1 patient in both groups (the patient in the OCT group was due to side branch occlusion and the patient in the IVUS group was due to distal embolus). In addition, non–Q-wave MI was observed for 1 patient in the OCT group and 4 patients in the IVUS group (all of them were attributed to distal embolus). The 2 groups showed similar visibility in visualization of lumen border. On the other hand, in terms of the visibility of vessel border, IVUS imaging had a significant advantage over OCT imaging before and after intervention (P<0.05). With regard to the procedural variables, there was no significant difference about preballoon dilatation, including the frequency, balloon diameter, and pressure. In addition, no patient in either group had balloon dilatation for image, because in all patients lumen border could be detected at both reference segments at the first preprocedural image. Although there was no significant difference for implanted stent size, deployment pressure was higher in the IVUS group. The frequency and pressure of postballoon dilatation also was significantly higher in the IVUS group (P<0.05). The frequency of distal protection device deployment was significantly higher in the OCT group (P=0.03).

Analysis of Quantitative Coronary Angiography, Intravascular Ultrasound, and Optical Coherence Tomography
Quantitative coronary angiography, IVUS, and OCT findings at final examination are presented in Table 3. In QCA analysis, minimal luminal diameter after PCI was similar between the 2 groups. However, the diameter stenosis was smaller in the IVUS group (7.7±5.8% versus 5.0±4.5%, P<0.05). In IVUS analysis of stent expansion, MSA and mean stent area were larger in the IVUS group (6.1±2.2 mm² versus 7.1±2.1 mm² and 7.5±2.5 mm² versus 8.7±2.4 mm², P<0.05). In addition, both focal and diffuse stent expansion were also larger in the IVUS group (64.7±13.7% versus 80.3±13.4% and 84.2±15.8% versus 98.8±16.5%, P<0.01). At MSA site, residual plaque burden was larger in the OCT group than the IVUS group.

Table 1. Patient and Angiographic Characteristics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>OCT Group (n=35)</th>
<th>IVUS Group (n=35)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Value</td>
<td>Value</td>
<td></td>
</tr>
<tr>
<td>Male gender</td>
<td>29 (82.9%)</td>
<td>26 (74.3%)</td>
<td>0.76</td>
</tr>
<tr>
<td>Age, y</td>
<td>67.6±9.7</td>
<td>67.4±8.0</td>
<td>0.95</td>
</tr>
<tr>
<td>Hypertension*</td>
<td>11 (31.4%)</td>
<td>9 (25.7%)</td>
<td>0.6</td>
</tr>
<tr>
<td>Hyperlipidemia†</td>
<td>15 (42.9%)</td>
<td>21 (60%)</td>
<td>0.15</td>
</tr>
<tr>
<td>Diabetes mellitus‡</td>
<td>11 (31.4%)</td>
<td>9 (25.7%)</td>
<td>0.6</td>
</tr>
<tr>
<td>Smoker</td>
<td>7 (20.0%)</td>
<td>3 (8.6%)</td>
<td>0.31</td>
</tr>
<tr>
<td>Family history</td>
<td>9 (25.7%)</td>
<td>9 (25.7%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>Previous MI</td>
<td>3 (8.6%)</td>
<td>3 (8.6%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>1 (2.9%)</td>
<td>1 (2.9%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>Previous PCI</td>
<td>6 (17.1%)</td>
<td>4 (11.4%)</td>
<td>0.73</td>
</tr>
<tr>
<td>Clinical presentation</td>
<td>Stable angina</td>
<td>32 (91.4%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td></td>
<td>31 (88.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unstable angina</td>
<td>3 (8.6%)</td>
<td>4 (11.4%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>Target vessel</td>
<td>LAD</td>
<td>14 (40%)</td>
<td>0.47</td>
</tr>
<tr>
<td></td>
<td>17 (48.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LCX</td>
<td>8 (22.9%)</td>
<td>11 (31.4%)</td>
<td>0.42</td>
</tr>
<tr>
<td>RCA</td>
<td>13 (37.1%)</td>
<td>7 (20%)</td>
<td>0.11</td>
</tr>
<tr>
<td>Lesion location</td>
<td>Proximal</td>
<td>10 (28.6%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td></td>
<td>10 (28.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mid</td>
<td>23 (65.7%)</td>
<td>23 (65.7%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>Distal</td>
<td>2 (5.7%)</td>
<td>2 (5.7%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>Lesion type</td>
<td>Type A</td>
<td>1 (2.9%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td></td>
<td>1 (2.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type B1</td>
<td>8 (22.9%)</td>
<td>5 (14.3%)</td>
<td>0.54</td>
</tr>
<tr>
<td>Type B2</td>
<td>24 (68.6%)</td>
<td>25 (71.4%)</td>
<td>0.79</td>
</tr>
<tr>
<td>Type C</td>
<td>2 (5.7%)</td>
<td>4 (11.4%)</td>
<td>0.67</td>
</tr>
<tr>
<td>QCA analysis</td>
<td>Preselion length, mm</td>
<td>11.9±5.0</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>13.4±5.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pereferece diameter, mm</td>
<td>2.7±0.5</td>
<td>2.8±0.4</td>
<td>0.84</td>
</tr>
<tr>
<td>Preminimum lumen diameter, mm</td>
<td>1.1±0.3</td>
<td>1.1±0.5</td>
<td>0.82</td>
</tr>
<tr>
<td>Pre % diameter stenosis, %</td>
<td>58.6±6.9</td>
<td>61.8±9.9</td>
<td>0.12</td>
</tr>
</tbody>
</table>

Data are presented as mean±1 SD, or No. of patients/arteries (percentage). OCT indicates optical coherence tomography; IVUS, intravascular ultrasound; MI, myocardial infarction; CABG, coronary artery bypass surgery; PCI, percutaneous coronary artery intervention; LAD, left anterior descending artery; LCX, left circumflex artery; RCA, right coronary artery; QCA, quantitative coronary angiography.

*Hypertension was defined as a systolic blood pressure ≥140 mm Hg, diastolic blood pressure ≥90 mm Hg, or use of an antihypertensive drug.
†Hyperlipidemia was defined as a total cholesterol level ≥240 mg/dL or medication use.
‡Diabetes was defined as diet-controlled or oral agent-treated or insulin-treated.
Table 2. Procedural Outcomes

<table>
<thead>
<tr>
<th></th>
<th>OCT Group (n=35)</th>
<th>MUS Group (n=35)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total procedural duration, min</td>
<td>40±16.4</td>
<td>47.0±17.6</td>
<td>0.09</td>
</tr>
<tr>
<td>Total fluoroscopy time, min</td>
<td>20.4±8.4</td>
<td>24.8±10.4</td>
<td>0.05</td>
</tr>
<tr>
<td>Total contrast media volume, mL</td>
<td>130.0±57.9</td>
<td>146.9±60.0</td>
<td>0.24</td>
</tr>
<tr>
<td>Device success</td>
<td>35 (100%)</td>
<td>35 (100%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>Clinical success</td>
<td>32 (91.4%)</td>
<td>30 (85.7%)</td>
<td>0.71</td>
</tr>
</tbody>
</table>

Complications

- Death | 0 (0%) | 0 (0%) | >0.99   |
- Emergency revascularization | 0 (0%) | 0 (0%) | >0.99   |
- Q-wave myocardial infarction | 1 (2.9%) | 1 (2.9%) | >0.99   |
- Non-Q-wave myocardial infarction | 1 (2.9%) | 4 (11.4%) | 0.36    |
- Life-threatening arrhythmia | 0 (0%) | 0 (0%) | >0.99   |
- Coronary dissection | 1 (2.9%) | 0 (0%) | >0.99   |
- Prolonged and severe vessel spasm | 0 (0%) | 0 (0%) | >0.99   |
- Distal embolus | 1 (2.9%) | 5 (14.2%) | 0.2     |

Good lumen border visibility

Prior to intervention
- At proximal reference | 35 (100%) | 35 (100%) | >0.99   |
- At MLA site | 34 (97.1%) | 31 (88.6%) | 0.36    |
- At distal reference | 35 (100%) | 35 (100%) | >0.99   |

Postintervention
- At MSA site | 35 (100%) | 35 (100%) | >0.99   |

Good vessel border visibility

Prior to intervention
- At proximal reference | 22 (62.9%) | 35 (100%) | <0.001  |
- At MLA site | 3 (8.6%) | 33 (94.3%) | <0.001  |
- At distal reference | 22 (62.9%) | 35 (100%) | <0.001  |

Postintervention
- At MSA site | 4 (11.4%) | 33 (94.3%) | <0.001  |

Procedural detail

Preballoon dilatation
- Frequency of preballoon dilatation | 33 (94.3%) | 30 (85.7%) | 0.43    |
- Preballoon diameter, mm | 2.9±0.5 | 3.0±0.5 | 0.48    |
- Preballoon pressure, atm | 10.0±3.6 | 11.0±3.9 | 0.34    |

Stent
- Drug-eluting stent | 32 (91.4%) | 34 (97.1%) | 0.61    |
- Bare metal stent | 3 (8.6%) | 1 (2.9%) | 0.61    |
- Stent length, mm | 16.5±4.2 | 17.6±5.4 | 0.33    |
- Stent diameter, mm | 3.1±0.5 | 3.0±0.4 | 0.78    |
- Stent deployment pressure, atm | 9.8±2.4 | 14.2±3.4 | <0.001  |

Postballoon dilatation
- Frequency of postballoon dilatation | 21 (60%) | 30 (85.7%) | 0.03    |
- Postballoon diameter, mm | 3.4±0.6 | 3.2±0.4 | 0.3     |
- Postballoon pressure, atm | 13.5±3.4 | 16.1±4.7 | 0.03    |
- Frequency of distal protection | 8 (22.9%) | 1 (2.9%) | 0.03    |

Data are presented as mean±1 SD, or No. of lesions (percentage).

OCT indicates optical coherence tomography; IVUS, intravascular ultrasound; MLA, minimal lumen area; MSA, minimum stent area; atm, atmosphere.

Table 3. Quantitative Coronary Angiography, Intravascular Ultrasound, and Optimal Coherence Tomography Analysis

<table>
<thead>
<tr>
<th></th>
<th>OCT Group (n=35)</th>
<th>MUS Group (n=35)</th>
<th>P Value</th>
</tr>
</thead>
</table>
| QCA analysis
- Postreference diameter, mm | 3.0±0.5  | 3.0±0.5  | 0.56    |
- Postminimum lumen diameter, mm | 2.8±0.5 | 2.9±0.4 | 0.22    |

Postprocedural IVUS analysis

- Minimum stent area, mm² | 6.1±2.2 | 7.1±2.1 | 0.04    |
- Mean stent area, mm² | 7.5±2.5 | 8.7±2.4 | 0.04    |
- Focal stent expansion, % | 64.7±13.7 | 80.3±13.4 | 0.002  |
- Diffuse stent expansion, % | 84.2±15.8 | 98.8±16.5 | 0.003  |
- Mean reference lumen area, mm² | 9.2±3.3 | 9.1±3.1 | 0.98    |
- EEM at MSA site, mm² | 12.9±5.2 | 12.6±4.3 | 0.82    |
- Residual plaque burden at MSA site, % | 50.7±11.3 | 41.8±9.1 | <0.001  |

Proximal 1 mm edge
- EEM, mm² | 16.6±5.6 | 16.3±5.8 | 0.81    |
- Lumen area, mm² | 9.4±3.4 | 10.2±4.2 | 0.39    |
- Plaque burden, % | 42.2±11.6 | 36.5±8.6 | 0.02    |
- Residual stent-edge plaque burden >50% | 8 (22.9%) | 1 (2.9%) | 0.03    |

Distal 1 mm edge
- EEM, mm² | 14.1±6.0 | 12.2±4.4 | 0.16    |
- Lumen area, mm² | 8.9±4.1 | 8.0±2.6 | 0.29    |
- Plaque burden, % | 36.5±9.4 | 33.3±6.4 | 0.09    |
- Residual stent-edge plaque burden >50% | 3 (8.6%) | 1 (2.9%) | 0.61    |

Postprocedure OCT analysis
- No. of analyzed cross sections | 14.4±4.3 | 14.1±3.6 | 0.76    |
- No. of analyzed struts | 100.1±45.7 | 107.5±35.2 | 0.45    |
- Minimum stent area, mm² | 5.7±2.1 | 6.9±2.4 | 0.03    |
- Mean stent area, mm² | 7.2±2.8 | 8.4±2.4 | 0.06    |
- Frequency of incomplete stent apposition, % | 0.4±0.7 | 0.6±0.8 | 0.34    |
- Frequency of CSs with ISA struts/stent, % | 2.5±4.2 | 3.9±5.3 | 0.23    |

Data are presented as mean±1 SD, or No. of lesions (percentage).

OCT indicates optical coherence tomography; IVUS, intravascular ultrasound; QCA, quantitative coronary angiography; EEM, external elastic membrane; MSA, minimal stent area; CSs, cross sections; ISA, incomplete stent apposition.

Although there was no significant difference regarding the plaque burden and the frequency of significant residual reference segment stenosis at the distal edge, those at the proximal edge were higher in the OCT group (44.2±11.6% versus 36.5±8.6% and 22.9% versus 2.9%, P<0.05). For OCT analysis of stent apposition, all OCT findings, including the frequency of ISA and cross sections with ISA/stent, were not significantly different between the groups.
Comparison and Correlation of the Minimum Stent Area and Mean Stent Area Between Frequency-Domain Optical Coherence Tomography and Intravascular Ultrasound

In all 70 cases, postprocedural MSA and mean stent area were evaluated by both FD-OCT and IVUS. MSA and mean stent area measured by FD-OCT were significantly correlated with those measured by IVUS ($r=0.96$, $P<0.001$ and $r=0.95$, $P<0.0001$; Figure 6). Focal and diffuse stent expansion measured by FD-OCT also were correlated with those measured by IVUS ($r=0.73$, $P<0.001$ and $r=0.70$, $P<0.0001$).

Discussion

The main findings of this study are (1) stent expansion showed an advantage in IVUS guidance, (2) there was no significant difference for stent apposition, and (3) although both devices showed similar accessibility (procedural time, fluoroscopy time, contrast material volumes, device, and clinical success), IVUS had a significant advantage over OCT in terms of the reduction of residual stent-edge plaque burden and visibility of vessel border. To our knowledge, this is the first report to compare between FD-OCT and IVUS guidance during coronary intervention for optimal stent implantation.

Despite drug-eluting stents having a proven higher effectiveness in reducing restenosis compared with bare metal stents, these stents are not free of restenosis and are limited by stent thrombosis. Optimal stent deployment remains an important issue in the coronary stenting and is associated with a lower incidence of restenosis and stent thrombosis. Some studies have suggested that IVUS guidance achieves a lower target vessel revascularization rate and better clinical outcomes after intervention compared with angiographic guidance for not only the bare metal stent era, but also the drug-eluting stent era due to optimal stent deployment.

Optical coherence tomography is a light-based intracoronary imaging modality, and having greater resolution than IVUS, visualizes microscopic structures of the coronary artery and has the potential of improving clinical outcomes after intervention. The development of FD-OCT, being able to image long coronary segments with greater scan depth in a
few seconds without occlusion of coronary flow, has made this technique widely applicable and is considered a feasible and safe technique for guidance of PCI. However, it is unknown whether FD-OCT has the potential to replace IVUS in a PCI procedure. To investigate the possibility, we designed this study to compare the new generation OCT system with IVUS for optimal stent implantation.

Previous IVUS studies revealed that stent underexpansion and residual reference segment stenosis has been associated with stent restenosis and thrombosis. Our results in this study showed MSA and mean stent area were smaller, and both focal and diffuse stent expansion was also smaller in the OCT group. Furthermore, significant residual reference segment stenosis at the proximal edge was also more frequently observed in the OCT group. In consideration of these factors, our results showed IVUS guidance has an advantage over FD-OCT guidance. In procedural analysis, stent deployment pressure and the frequency and pressure of postdilatation were lower in the OCT group. In addition, good vessel border visibility was more frequently observed in the IVUS group. Although IVUS could show the vessel border at the MLA/MSA site for about 94% of the patients, FD-OCT could show this only for approximately 10% of the patients. This difference in visibility of vessel border could contribute to the differences in stent size/deployment pressure, and frequency/balloon size/pressure of postballoon dilatation. When vessel border at MSA site was not detected, reference segment vessel size would be helpful for better stent expansion. However, complete visualization of vessel border at reference segment was not obtained in 37.1% of OCT group. In addition, positive/negative vessel remodeling of atherosclerotic lesion is occasionally observed and may affect procedural outcome. As over dilatation of the lesion with negative remodeling would lead to the coronary dissection/perforation, aggressive expansion would be avoided/restrained in the cases without complete vessel visualization. Taken together, these factors lead to a difference in stent expansion between IVUS and OCT group. Differences of stent deployment pressure or postdilatation might explain differences in area measurements between both techniques as previously reported, due to inherent differences and variable definitions used with both imaging techniques. Although stent area measured by FD-OCT and IVUS were similar in this study, the contribution of the difference in area measurement prior to stent implantation was not uncertain, and that is one of the limitations of this study. In terms of residual reference segment stenosis, plaque burden could only be measured in approximately 60% of the patients in the OCT group due to poor visibility of the vessel border at reference sites prior to intervention. More than 90% of patients could be measured in IVUS in the group. This disadvantage of FD-OCT could also contribute to unsatisfactory stent edge positioning.

Delayed or failed endothelial coverage of stent struts or ISA were reported as a pathological predictor of stent thrombosis. However, the current study showed a low and similar frequency of ISA between the 2 groups. The results indicated that there was no significant advantage of FD-OCT guidance regarding stent apposition.

With regard to accessibility, total procedural time, total fluoroscopy time, and total contrast media volume, device success rate and clinical success rate were compared, with parameters similar between the groups. In terms of procedural and fluoroscopy time, the improvement of the FD-OCT system with faster pullback speed and the shorter set-up time to completion of image acquisition might contribute to this result. Although FD-OCT requires flushing of contrast material to obtain images, there was no significant difference in total contrast media volumes. In IVUS guided PCI, the use of contrast media is required in certain situations (ie, to decide the proximal and distal reference position for stent implantation). This technical factor of IVUS guided PCI may contribute to the result. In addition, there was no significant difference in terms of device and clinical success. Concerning complications, we observed some MI patients (OCT group=2, IVUS group=5) during the PCI procedure. Except for 1 patient (side-branch occlusion) in the OCT group, all MIs were attributed to distal embolus after balloon/stent dilatation (without distal protection device). Although there was no significant difference, distal embolus was more frequently observed in the IVUS group (P=0.2), and distal protection device was significantly deployed in the OCT group (P=0.03). Due to its ability to address plaque components related to vulnerability, FD-OCT may have a role for assessing the risk of myocardial infarction. Hence, we consider that the FD-OCT system offers a major advantage of plaque characterization during PCI, which would be able to enhance the quality of PCI. Although there was no significant difference in this study, patients with complications were relatively small in both groups. Therefore, further investigations are warranted to assess its clinical safety.

Limitations

First, this study was designed as an open label randomized trial. Therefore, the operators were aware of the selected group and that may lead to bias. Second, the sample size was relatively small. Third, OCT has following inherent limitations: (1) pull back length is shorter than IVUS; (2) scan area is smaller than IVUS, and (3) flushing of contrast media is required for blood removal. In addition, only patients with a relatively short and single de novo lesion that was not contained within a large or tortuous vessel were enrolled. Therefore, the results might be difficult to generalize or to apply to less selected patients treated in different settings. The criteria for distal protection deployment according to the obtained image in this study were not supported by current evidence, and this might be one of the limitations. Further, FD-OCT has a limitation in that it cannot show a cross-sectional image frame in which the boundary shows a continuous arc of 360° relative to the center of the lumen due to guide wire artifact. Therefore, we could not analyze ISA in all stent struts, and this was a further limitation of this study. In addition, although stent area measurement was similar in both devices, differences in area measurements prior to stent implantation were not clear. Those differences might be associated with the result. Another limitation of this study is that our findings are compared for only short term outcome. Furthermore, although the optimization of stent expansion
may lead to improved outcomes, results from randomized trials in the era of drug-eluting stents are still lacking. Additional prospective investigations, including long term outcome, are needed with a larger number of patients.

Conclusion
Stent implantation with FD-OCT guidance showed similar accessibility compared with a conventional IVUS guided procedure. However, FD-OCT still has several essential basic limitations for optimal stent implantation due to the poor visibility of vessel border, which contributes to smaller stent expansion and more frequent significant residual reference segment stenosis compared with IVUS guidance.

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Disclosures
None.

References
Impact of Frequency-Domain Optical Coherence Tomography Guidance for Optimal Coronary Stent Implantation in Comparison With Intravascular Ultrasound Guidance


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