Safety and Feasibility of an Intravascular Optical Coherence Tomography Image Wire System in the Clinical Setting

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Optical coherence tomography (OCT) is a fiber-optic technology that enables high-resolution intracoronary imaging. The aim of this study was to evaluate the safety and feasibility of intracoronary imaging with OCT in the clinical setting; 76 patients with coronary artery disease from 8 centers were enrolled. The OCT imaging system (ImageWire, Light Imaging Inc., Westford, Massachusetts) consists of a 0.006 inch fiber-optic core that rotates within a 0.016 inch transparent sheath. OCT imaging was performed during occlusion of the artery with a compliant balloon and continuous flushing. Intravascular ultrasound (IVUS) imaging was performed in the same segments. We assessed the safety and feasibility of the OCT imaging, compared with IVUS. Vessel occlusion time was 48.3 ± 13.5 seconds and occlusion-balloon pressure was 0.4 ± 0.1 atmospheres. Flushing with lactated Ringer's solution was performed at a rate of 0.6 ± 0.4 ml/s. No significant adverse events, including vessel dissection or fatal arrhythmia, were observed. Procedural success rates were 97.3% by OCT and 94.5% by IVUS. The OCT image wire was able to cross 5 of 6 tight lesions that the IVUS catheter was unable to cross. Of the 98 lesions in which both OCT and IVUS were successfully performed, OCT imaging had an advantage over IVUS for visualization of the lumen border. Minimum lumen diameter and area measurements were significantly correlated between OCT and IVUS imaging ($r = 0.91$, $p < 0.0001$ and $r = 0.95$, $p < 0.0001$, respectively). In conclusion, this multicenter study demonstrates the safety and feasibility of OCT imaging in the clinical setting. **(Am J Cardiol 2008;101:562–567)**

Intravascular optical coherence tomography (OCT) is an optical analogue of intravascular ultrasound (IVUS) that provides high-resolution (10 to 15 μm) cross-sectional images of the coronary arteries. Previous single-center studies demonstrated the ability of OCT to visualize the microscopic structures of the coronary artery,[1–8] however, an inherent limitation of this technique is the need to displace blood during imaging acquisition because red blood cells cause multiple scattering and substantial signal attenuation of the OCT source light.[5,8,9] In several previous studies, displacement of blood was accomplished mostly through intermittent saline flushes through the coronary guide catheter, but this technique allows only a few seconds of image acquisition time, which precludes the imaging of long arterial segments.[5,8,9] The motorized pullback OCT image wire system (M2 OCT system and ImageWire, LightLab Imaging, Inc., Westford, Massachusetts) consists of a 0.016 inch image wire that is used with a balloon occlusion and flushing catheter (Helios Occlusion Balloon Catheter, LightLab Imaging, Inc., Westford, Massachusetts) (Figure 1). This OCT image wire system may offer the ability to image longer arterial segments.[10] This Japanese multicenter study was conducted to evaluate the safety and feasibility of this OCT imaging system in the clinical setting.

Methods

This multicenter study involved 8 medical centers (Appendix) and was conducted between December 2004 and May 2005. The study protocol was approved by the ethics committee at each participating institution, and written informed consent was obtained from all patients. Patients were eligible for the study if they were 20 to 75 years old, were not pregnant and were protected against pregnancy during the study, and underwent diagnostic coronary angiography and/or percutaneous coronary intervention (PCI). PCI cases included balloon angioplasty, cutting balloon angioplasty, and stenting. Both OCT and IVUS imaging were performed in a single target lesion in a native coronary artery with a stenosis <99% of the lu-

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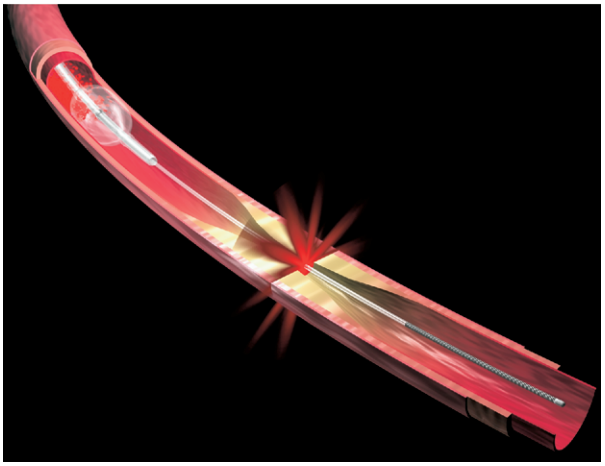

Figure 1. Schematic of the motorized pullback OCT image wire system. This system consists of a 0.016 inch image wire with a balloon occlusion and flushing catheter.

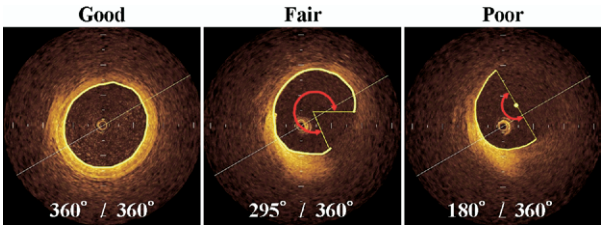

Figure 2. Grading of visibility of the lumen border in OCT imaging: good = visible on entire circumference; fair = ≥75% of circumference; poor = <75% of circumference.

minal diameter and measuring <20 mm in length (per visual estimate on angiography) during diagnostic coronary angiography or before and after PCI. Major criteria for exclusion were acute myocardial infarction (within the previous 72 hours), ejection fraction <30%, and a target lesion in an ostium, a bifurcation, a left main coronary artery, or a vessel with thrombus or severe calcification.

The coronary artery was cannulated with a 6Fr or 8Fr guiding catheter under fluoroscopic guidance by the femoral approach. After baseline coronary angiography and intracoronary injection of 200 μg nitroglycerine, IVUS imaging was performed and was followed by OCT imaging.

OCT images were obtained with a M2 OCT system (LightLab Imaging, Inc., Westford, Massachusetts) that operates at a central wavelength of 1310 nm. Based on the principles of low-coherence interferometry, the OCT system produces images with an axial resolution of 15 μm and a lateral resolution of 25 μm. An optic probe (ImageWire, LightLab, Westford, Massachusetts), with dimensions similar to those of a coronary guide wire, delivers light to the tissue and collects the light reflected from the tissue. The image wire consists of a 0.006 inch (0.15 mm) fiber-optic core that rotates inside a sheath with a diameter of 0.016 inch (0.41 mm).

To deliver the image wire and remove blood from the target lesion, an over-the-wire occlusion balloon catheter was used. The diameter of the catheter shaft was 4.4Fr and the balloon, designed for low-pressure inflation, was thin-walled polyurethane with a diameter of 3.8 mm at 0.3 atmospheres (≤8.5 mm at 1.0 atmospheres) and a length of 6.5 mm. Lactated Ringer's flushing solution was injected through the central inner lumen, which is shared with the image wire, and exits from the distal tip.

The OCT imaging procedure started with advancing the tip of a 0.014 inch (0.36 mm) coronary guide wire into the distal coronary artery. The occlusion catheter was then advanced over the wire until the balloon was positioned proximal to the lesion. After the guide wire and OCT image wire were exchanged, lactated Ringer's solution was continuously flushed through the central lumen of the occlusion catheter by a power injector, and the balloon was inflated gradually by a custom inflation device until blood flow was fully occluded. Motorized pullback OCT imaging was performed at a rate of 1.0 mm/s for a length of 30 mm. Images were acquired at 15 frames/s and were digitally archived. The images were saved in the OCT image system console and then saved on a compact disk for off-line analysis. During the procedure, electrocardiographic and hemodynamic features were carefully monitored.

IVUS imaging was performed using a commercially available 3.2Fr, 40 MHz ultrasound catheter (Atlantis SR, Boston Scientific, Natick, Massachusetts). Pullback images were acquired at 0.5 mm/s over the entire length of the target lesion. All IVUS images were recorded on 0.5 inch, high resolution S-VHS videotape for off-line analysis.

A total of 76 patients from 8 centers were enrolled and underwent both OCT and IVUS imaging. Procedural outcomes of both imaging procedures were compared. All cardiac complications occurring during the procedure and ≤24 hours postprocedure were reported. Major complications included myocardial infarction, emergency revascularization, or death. Acute procedural complications were considered to be angiographic complications including acute vessel occlusion, dissection, thrombus formation, embolism, or vasospasm along the entire target artery, and significant arrhythmias requiring immediate treatment. Myocardial ischemia occurring during motorized pullback OCT or IVUS imaging was not considered to be a complication when electrocardiographic indications of ischemia resolved immediately after the imaging procedure.

An independent core laboratory reviewed all OCT and IVUS images (the Cardiovascular Imaging Center, Toyohashi, Japan). For the analysis, corresponding segments including the minimal lumen site were selected in both OCT and IVUS images in reference to the baseline coronary angiography.

OCT analysis was performed with proprietary OCT imaging software (LightLab Imaging, Inc., Westford, Massachusetts). The OCT measurements were calibrated based on the reflection of the OCT imaging wire, which is the standard calibration technique for this system. IVUS images were digitized with commercially available software for IVUS image analysis, which runs on an Intel Pentium-based PC system with Windows NT (NetraIVUS, ScImage Inc., Los Altos, California); 2 observers performed qualitative and quantitative analyses

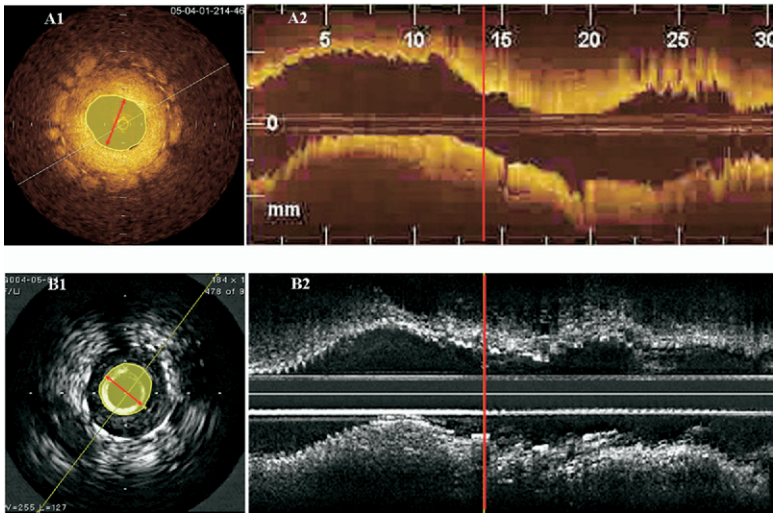

Figure 3. Measurements of minimal lumen diameter *(red arrows)* and lumen area *(yellow circles)* at the minimal lumen site by OCT *(A1)* and IVUS *(B1)*. Red lines in longitudinal images *(A2 and B2)* represent the corresponding cross-sectional sites.

Table 1
Patient demographics

Variable	n = 76
Age (yrs)	63.3 ± 7.7
Men	67 (88%)
Clinical presentation	
Stable angina pectoris	43
Unstable angina pectoris	14
Recent myocardial infarction	2
Healed myocardial infarction	9
Silent ischemia	4
Previous PCI	4
Risk factors	
Hypercholesterolemia*	50 (66%)
Diabetes mellitus†	32 (42%)
Hypertension‡	57 (75%)
Treated coronary artery	
LAD/LC/Right	30/19/27

* Hypercholesterolemia was defined as a total cholesterol level ≥240 mg/dl or medication use.

† Diabetes was defined as diet-controlled and treated with oral agent or insulin.

‡ Hypertension was defined as a systolic blood pressure ≥140 mm Hg, diastolic blood pressure ≥90 mm Hg, or use of an antihypertensive drug.

LAD = left anterior descending; LC = left circumflex.

of OCT images and 2 other observers did the same analyses of IVUS images. Each observer was blinded to the results of the other 3 observers.

Qualitative measurements assessed in the study included visibility of the lumen border and of the vessel border at the minimal lumen site. The visibility of the lumen border and of the vessel border by OCT and IVUS were classified into 3 grades: (1) good = entire circumference visible, (2) fair = ≥75% of circumference visible, and (3) poor = <75% of circumference visible (Figure 2).

The quantitative measurements analyzed in both OCT and IVUS images included minimal lumen diameter and minimal lumen area. Measurements of minimal lumen diameter and minimal lumen area in OCT images were obtained as a reference to previous reports (Figure 3).[5,6,10,11] IVUS measurements were performed according to the American College of Cardiology Clinical Expert Consensus standards for acquisition, measurement, and reporting of IVUS studies.[12]

Table 2
Procedural success rates of optical coherence tomography (OCT) and intravascular ultrasound (IVUS) imaging

	OCT	IVUS	p Value
Overall (n = 110)	107 (97.3%)	104 (94.5%)	0.307
Diagnostic angiogram (n = 36)	36 (100%)	36 (100%)	1
PCI			
Before PCI (n = 40)	37 (92.5%)	34 (85.0%)	0.284
After PCI (n = 34)	34 (100%)	34 (100%)	1

To assess the reproducibility of measurements in OCT images, 15 cases were selected randomly and analyzed again by 2 independent observers. These measurements were compared to examine interobserver variability. To determine intraobserver variability, the images were measured again by the first observer at least 6 weeks after the initial measurement, and those 2 measurement sessions were compared.

Continuous variables are reported as mean ± SD, and categorical data are expressed as number or frequencies of occurrence. Statistical analysis was performed with StatView 5.0 software (SAS Institute Inc., Cary, North Carolina). Continuous variables were compared using paired *t* test. The chi-square test was used to compare frequency of occurrence. Ordered variables were compared using Wilcoxon signed-ranks test. Linear regression and the Bland-Altman tests were performed to evaluate correlation between OCT and IVUS in measurements of minimal lumen diameter and minimal lumen area. The intra- and interobserver agreement (reproducibility) was assessed by determining the mean ± SD of differences between observation and between observer, respectively. Significance was interpreted as a value of $p < 0.05$.

Table 3
Comparison of lumen border and vessel border visibility between optical coherence tomography (OCT) and intravascular ultrasound (IVUS) imaging

	Lumen Border		Vessel Border	
	OCT (n = 98)	IVUS (n = 98)	OCT (n = 98)	IVUS (n = 98)
Good	88	81	5	55
Fair	4	0	7	7
Poor	6	17*	86	36
p Value	0.037		<0.0001	

* IVUS catheter was wedged.

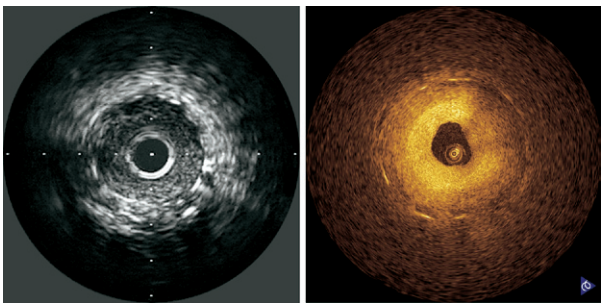

Figure 4. IVUS *(left)* and OCT images *(right)* of the lesion with tight stenosis. In the IVUS image, lumen border was unclear due to wedging of the IVUS imaging catheter. In contrast, lumen border was clearly visualized by OCT imaging.

Results

The clinical features of 76 patients (63.3 ± 7.7 years) who underwent both OCT and IVUS are listed in Table 1. The target vessel was the left anterior descending coronary artery in 30 patients, the left circumflex artery in 19 patients, and the right coronary artery in 27 patients.

Both OCT and IVUS imaging procedures were performed in 36 patients during diagnostic catheterization, in 40 patients before PCI, and in 34 of 40 patients who had PCI after PCI.

Overall procedural success rates of OCT and IVUS, defined as successful acquisition of a pullback image, were not statistically different (97.3% and 94.5%, respectively; Table 2). Both OCT and IVUS were performed successfully in all cases during diagnostic catheterization and after PCI. Before PCI, procedural failures occurred in 3 cases with OCT and in 6 cases with IVUS because the device was unable to cross a tight stenosis in 1 of the 3 OCT failures and in all 6 of IVUS failures; the OCT image wire was able to cross 5 of 6 tight stenoses that the IVUS catheter could not cross. In 2 of 3 OCT failures, imaging was not performed due to transient ST elevation while advancing the occlusion-flushing catheter. These electrocardiographic changes resolved immediately after catheter removal.

The mean vessel occlusion time was 48.3 ± 13.5 seconds, and the mean occlusion balloon pressure was 0.4 ± 0.1 atmospheres. Flushing of lactated Ringer's solution was performed at a rate of 0.6 ± 0.4 ml/s.

Some transient events, such as chest discomfort, brady- or tachycardia, and ST-T changes on electrocardiogram, were observed during OCT or IVUS imaging, all of which resolved immediately after the procedure. Neither hemodynamic instability nor ventricular tachyarrhythmia was observed. There were no major complications, including myocardial infarction, emergency revascularization, or death. In addition, acute procedural complications, which included acute vessel occlusion, dissection, thrombus formation, embolism, or vasospasm along the entire procedure-related artery, were not observed.

Visibility of the lumen border and of the vessel border at the minimal lumen site were compared in the 98 lesions in which both OCT and IVUS procedures were performed successfully. Poor visibility of the lumen border was observed in 17 procedures (17.3%) by IVUS imaging due to wedging of the imaging catheter compared with 6 procedures (6.1%) by OCT imaging due to insufficient blood removal ($p = 0.037$, Table 3). Figure 4 shows the IVUS and the OCT image of the lesion with tight stenosis. In visualization of the vessel border, IVUS imaging had a significant advantage over OCT imaging ($p < 0.0001$).

Minimal lumen diameter and minimal lumen area measured by OCT were significantly correlated with those measured by IVUS ($r = 0.91$, $p < 0.0001$ and $r = 0.95$, $p < 0.0001$, respectively; Figure 5). However, both measurements by OCT were significantly smaller than those by IVUS (2.2 ± 0.7 vs 2.3 ± 0.6 mm, $p = 0.008$; 5.2 ± 2.8 vs 5.6 ± 2.6 mm^2, $p < 0.0001$, respectively).

The intraobserver correlation coefficients for minimal lumen diameter and minimal lumen area were 0.999 and 0.999, with percent errors of 2.0 ± 1.1% and 2.5 ± 2.4%, respectively. The interobserver correlation coefficients for minimal lumen diameter and minimal lumen area were 0.997 and 0.998, with percent errors of 2.7 ± 2.1% and 4.6 ± 6.8%, respectively.

Discussion

Although several single-center studies have shown that OCT was superior to IVUS in visualization of microscopic structures of the coronary arteries,[4,5,7,13,14] an inherent limitation of this technique is the need to displace blood during OCT image acquisition.[5,8,9] Therefore, it is important to evaluate the safety of this technique in a clinical setting.

The procedural success rate of the OCT image wire system was high and comparable with that of IVUS. In addition, the low crossing profile of the OCT image wire enabled the accessing 5 of the 6 tight lesions that the IVUS catheter could not cross. In our study population, no major complications or adverse events were observed. The short- and long-term safety of IVUS has been shown previously in large multicenter registries.[13,15,16] As such, a comparable survey is needed to demonstrate the safety of the OCT imaging system.

The low profile motorized pullback OCT image wire system allowed observation of relatively long arterial segments (≤55 mm) and visualization of the lumen border of tightly stenosed lesions in which the IVUS catheter was wedged. The results of this study showed that the OCT image wire system had an advantage over IVUS in visualization of the lumen border. Poor visualization of the lumen border in 6 of the OCT cases was due to insufficient blood

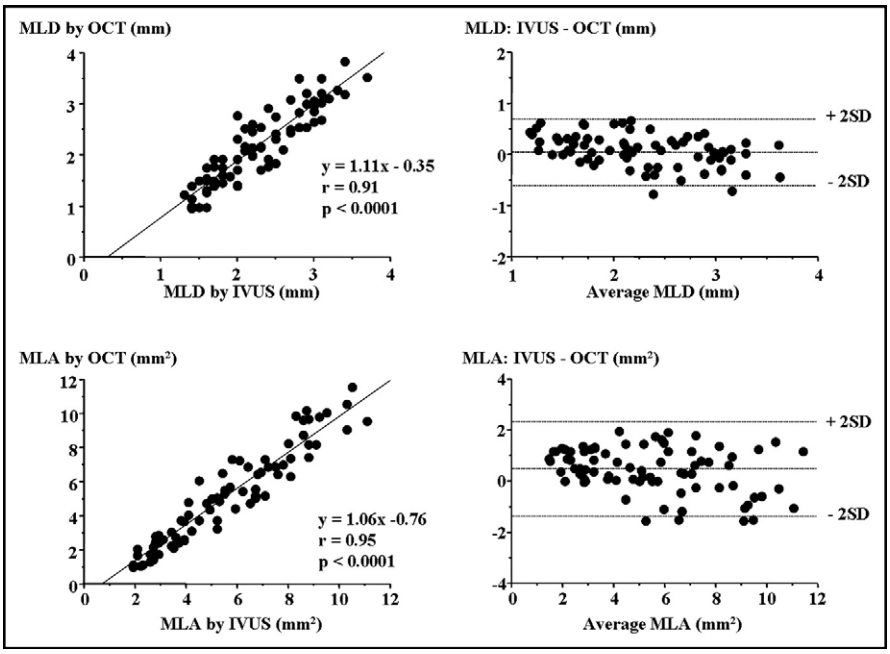

Figure 5. Comparison of minimal lumen diameter (MLD) and minimal lumen area (MLA) measured by OCT and IVUS imaging: correlations between OCT measurements and IVUS measurements *(left)* and Bland-Altman plots for OCTmeasurements versus IVUS measurements *(right)*.

removal during observation. Obtaining better quality images in these cases would have required complete vessel occlusion and a higher volume of physiologic saline or lactated Ringer's solution flush.[10] For visualization of the vessel border, OCT imaging was inferior to IVUS imaging. In OCT imaging, the main cause of poor visibility of the vessel border was insufficient penetration depth (<2 mm),[8,10] but in IVUS imaging, shadowing behind calcification was the main limiting factor.

Minimal lumen diameter and minimal lumen area measured by OCT were significantly correlated with those measured by IVUS. However, both measurements by OCT were smaller than those measured by IVUS; this may be related to the decrease in intracoronary pressure during OCT imaging resulting from vessel occlusion. Although the continuous flushing partially restores intracoronary pressure, some vessel narrowing is likely to occur in elastic arteries, particularly nonstented segments with less atherosclerotic disease. Although this potential source of measurement error deserves attention, the results of a previous animal study demonstrated that there were no significant differences in these measurements between OCT and IVUS in the stent-deployed segments.[10]

Several significant limitations of this study should be noted. First, this study was based on a relatively small, selected population of patients with stenosis <99% of the luminal diameter and length <20 mm. As such, a large population is needed to establish and refine clinical applications and the safety of the OCT imaging system.

Second, this study was not designed to evaluate potential advantages of OCT over IVUS resulting from an increase in resolution. Further analysis or a different study population will be necessary to evaluate the performance of OCT in these applications.

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Appendix

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