14 Clinical Evidence of Optical Coherence Tomography-Guided Percutaneous Coronary Intervention

Seung-Yul Lee, Yangsoo Jang,
and Myeong-Ki Hong

Although the guideline of the European Society of Cardiology has recommended that optical coherence tomography (OCT) may be considered in selected patients during percutaneous coronary intervention (PCI) [1], data regarding OCT guidance are limited (Table 14.1). In this chapter, clinical evidences and benefits of OCT-guided PCI will be discussed.

14.1 Lesional Assessment

The accurate measurement of lumen dimensions is important for assessing the severity of coronary stenoses. In the study comparing the lumen measurement obtained ex vivo in human coronary arteries using intravascular ultrasound, OCT and histomorphometry, and in vivo in patients using intravascular ultrasound and OCT with and without balloon occlusion, both intravascular ultrasound and OCT overestimated the lumen area compared with histomorphometry (mean difference 0.8 mm^2 for OCT and 1.3 mm^2 for intravascular ultrasound) [3]. The lumen dimensions in vivo obtained using intravascular ultrasound were larger than those obtained using OCT (mean difference 1.67 mm^2 for intravascular ultrasound relative to OCT with balloon occlusion and 1.11 mm^2 relative to OCT without balloon occlusion) [3]. OCT has a moderate diagnostic efficiency in identifying hemodynamically severe coronary stenoses with fractional flow reserve (FFR) ≤ 0.80 measured with pressure wire (sensitivity = 82%, specificity = 63%) [4]. The optimal cutoff value associated with FFR ≤ 0.80 was 1.95 mm^2 of minimal lumen area [4]. Like intravascular ultrasound, the

Table 14.1 Recent recommendations regarding the usage of optical coherence tomography (OCT) during percutaneous coronary intervention

Recommendations	Class of recommendation	Level of evidence
European Society of Cardiology [1]		
OCT to assess mechanisms of stent failure	IIa	C
OCT in selected patients to optimize stent implantation	IIb	C
ACCF/AHA/SCAI [2]		
Not documented		

ACCF American College of Cardiology Foundation; *AHA* American Heart Association; *SCAI* Society for Cardiovascular Angiography and Interventions

S.-Y. Lee
Department of internal Medicine, Sanbon Hospital, Wonkwang University College of Medicine, Gunpo, South Korea

Y. Jang • M.-K. Hong (✉)
Division of Cardiology, Severance Cardiovascular Hospital, Yonsei University College of Medicine, Seoul, South Korea
e-mail: mkhong61@yuhs.ac

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Table 14.2 Optical coherence tomographic criteria for defining severe coronary stenosis evaluated by fractional flow reserve (FFR)

Authors	No. of lesions	FFR	Minimal lumen area	Sensitivity	Specificity
Shiono et al. [5]	62	0.75	1.91 mm^2	94%	77%
Gonzalo et al. [4]	61	0.80	1.95 mm^2	82%	63%
Pawlowski et al. [6]	71	0.80	2.05 mm^2	75%	90%
Reith et al. [7]	62	0.80	1.59 mm^2	76%	79%

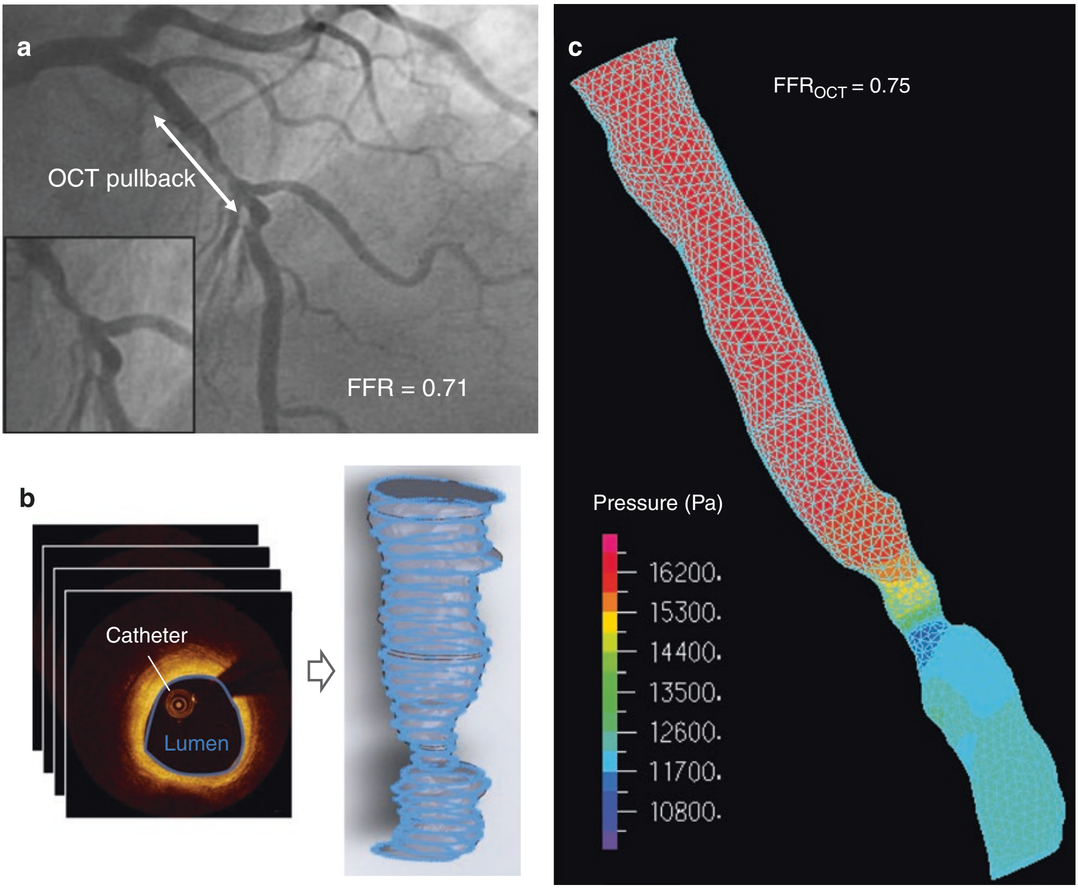

Fig. 14.1 Representative images of computational flow dynamics model and fractional flow reserve (FFR) simulation. Coronary angiography (**a**) showed a moderate stenosis (*arrows*) of the proximal segment of left anterior descending artery. The measured FFR of the lesion was 0.71, indicating functionally significant stenosis. After three-dimensional reconstruction (**b**) was performed using optical coherence tomography (OCT), computational flow dynamics model was applied to the acquired geometry (**c**). The calculated FFR of the lesion was 0.75

assessment of OCT is not specific for identifying severe stenoses, thus limiting the positive predictive value [4]. Table 14.2 summarizes the cut-off values of OCT-derived minimal lumen area that correspond to functionally significant stenosis. Recently, an OCT study reported that there was a moderate correlation between OCT-derived FFR measurements using computational fluid dynamics algorithm and direct FFR measurements using pressure wire (r = 0.72, $p < 0.001$) in patients with intermediate coronary stenosis in the left anterior descending coronary

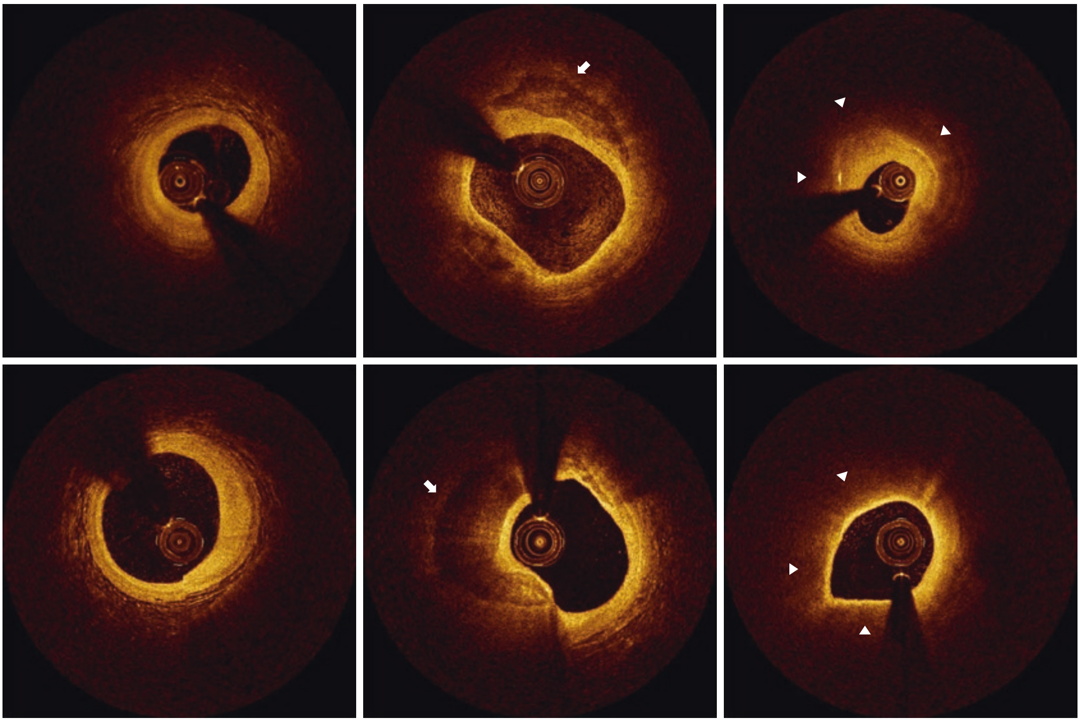

Fig. 14.2 Morphological features of fibrotic (*left panel*), fibrocalcific (*middle panel*), and lipid-rich (*right panel*) plaques at the segment with minimal lumen area. Fibrotic plaques had high backscattering and relatively homogeneous optical signal. Fibrocalcific plaques showed signal-poor heterogeneous region with well-delineated borders, being consistent with calcium (*arrows*). Lipid-rich plaques demonstrated signal-poor regions with poorly delineated borders, indicating lipid (*arrowheads*)

artery, as represented in Fig. 14.1 [8]. This OCT approach without use of pressure wire may be useful for evaluating the simultaneous functional and anatomic severity of coronary stenosis [8]. However, further studies are required to establish its feasibility and effectiveness. In contrast to determination of functionally significant severity of coronary artery, the OCT examination is reliably sensitive and specific for characterizing different types of atherosclerotic plaques: fibrous, fibrocalcific, and lipid-rich plaques (Fig. 14.2) [9, 10]. Morphological features detected by OCT were associated with the occurrence of post-interventional complications. The presence of thin-cap fibroatheroma identified by OCT was a predictor of post-PCI myocardial infarction [11]. Figure 14.3 represents a typical case that showed post-PCI myocardial infarction in patient treated with elective stent implantation.

14.2 Stent Optimization

The optimal OCT criteria for stent deployment have not been established yet. In the CLI-OPCI (Centro per la Lotta contro l'Infarto-Optimisation of Percutaneous Coronary Intervention) study, the reference lumen narrowing had to be greater than 4 mm^2, and the stent-lumen distance, namely, malapposed distance, had to be less than 200 μm for optimal stenting [12]. However, this study was retrospective, and the decision as to whether to perform further actions if the OCT criteria were not satisfied was left at the operator's discretion [12]. In the multicenter, random-

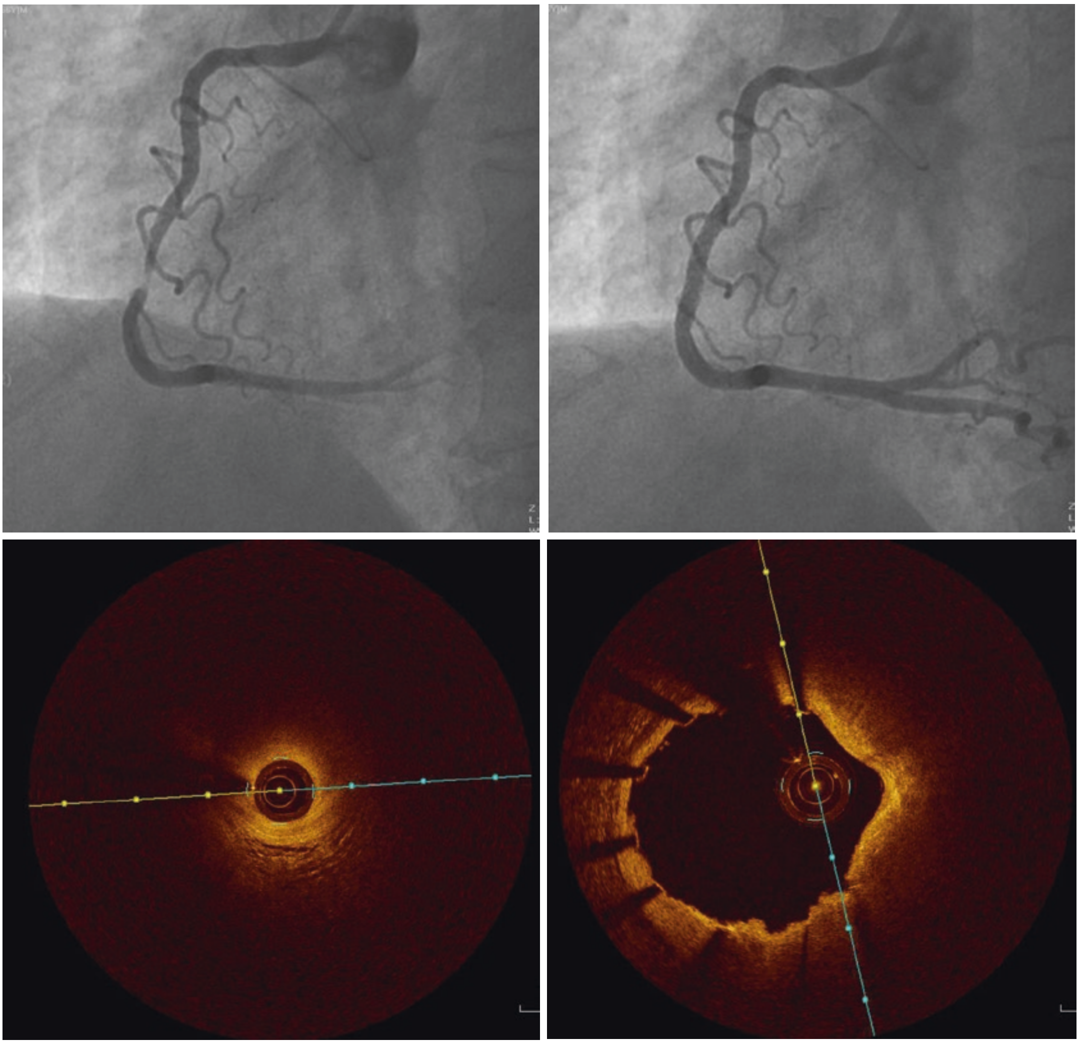

Fig. 14.3 A case showing post-interventional myocardial infarction after successful stent implantation. There was a tight narrowing at midportion of the right coronary artery (*left upper panel*). Pre-intervention optical coherence tomography (OCT) examination showed smallest lumen area with large amounts of lipid pool (*left lower panel*). Stent implantation was successfully performed without residual stenosis on angiogram (*right upper panel*) and with larger stent lumen area on post-intervention OCT examination (*right lower panel*). The level of CK-MB was elevated from 2.1 ng/mL pre-intervention to 22.7 ng/mL post-intervention

ized DOCTORS (Does Optical Coherence Tomography Optimize Results of Stenting) study [13], the guidelines for the procedural strategy incorporating OCT information were as follows: (1) additional balloon overdilations were to be performed in case of stent underexpansion (the ratio of in-stent minimal lumen area to reference lumen area was ≤ 80%), (2) management of malapposition or edge dissection was at the operator's discretion, and (3) additional stent implantations were to be performed to rectify incomplete lesion coverage. These methods of stent optimization led to a larger minimum lumen area compared with immediate post-stenting and subsequently improved the functional outcome assessed by FFR after PCI [13]. Table 14.3 summarizes the considerations for stent optimization using OCT.

Table 14.3 Criteria for optimal stent implantation

Comments
Achievement of adequate stent expansion (minimum lumen area or minimum stent area > 4–5 mm^2 or 80% of reference lumen area)
Avoidance of large stent malapposition (> 200 μm)
Complete lesion coverage with minimal residual plaque burden
No procedure-related complications (edge dissection, thrombosis, and others)

14.3 Clinical Benefits

The CLI-OPCI study firstly evaluated 1-year clinical outcomes in matched patients between angiographic guidance alone and angiographic plus OCT guidance. The use of OCT was associated with a lower risk of cardiac death or myocardial infarction (odds ratio = 0.49, p = 0.037) [12]. This observational study suggested the potential usefulness of OCT-guided PCI compared to conventional therapy. The ILUMIEN I (Observational Study of OCT in Patients Undergoing FFR and PCI) was a prospective, nonrandomized, observational study of PCI procedural practice in a total of 418 patients (with 467 stenoses) undergoing intra-procedural pre- and post-PCI FFR and OCT [14]. Based on pre-PCI OCT findings, the procedure was altered in 57% of all stenoses by selecting different stent lengths, and further stent optimization based on post-PCI OCT findings was done in 27% of all stenoses using additional post-dilation or implantation of new stents [14]. With the decreases of stent malapposition, underexpansion, and edge dissection, the change in treatment strategy appeared to be associated with reduced rates of periprocedural myocardial infarction [14]. Although intriguing, these results need confirmation in randomized controlled trial to firmly establish the clinical benefit of OCT-guided PCI.

Several benefits including adequate stent expansion, improved strut coverage, or FFR after PCI were also noted in patients receiving OCT-guided PCI. According to the OCT substudy of the thrombectomy versus PCI alone (TOTAL) trial, OCT-guided primary PCI for ST segment elevation myocardial infarction was associated with a larger final stent minimum lumen diameter compared to angiographic guidance (2.99 ± 0.48 mm versus 2.79 ± 0.47 mm, $p < 0.0001$) [15]. Although this study was statistically underpowered to detect a difference in clinical outcomes in OCT-guided patients, these findings suggested that OCT had the potential to improve clinical outcomes in patients undergoing PCI [15]. The ILUMIEN II study retrospectively compared OCT guidance with intravascular ultrasound guidance in propensity scores matched population and demonstrated that stent expansion was comparable between OCT- and intravascular ultrasound-guided patients [16]. Recently, the ILUMIEN III randomized trial tested whether or not OCT-based stent sizing strategy would result in a minimum stent area similar to or better than that achieved with intravascular ultrasound guidance and better than that achieved with angiography guidance alone [17]. In this trial, stent diameter was determined according to measurements of the external elastic lamina in the proximal and distal reference segments, and stent length was determined as the distance from distal to proximal reference site using the OCT automated lumen detection feature [17]. After stent implantation, high-pressure or larger noncompliant balloon inflation was performed to achieve a minimum stent area of at least 90% in both the proximal and distal halves of the stent relative to the closest reference segment [17]. Regarding minimum stent area, OCT guidance was non-inferior to intravascular ultrasound guidance, but not superior. OCT guidance was also not superior to angiography guidance [17]. Accordingly, these data warrant a large-scale randomized trial to establish whether or not OCT guidance results in superior clinical outcomes to angiography guidance [17].

Another study investigated the impact of OCT guidance on follow-up stent strut coverage after drug-eluting stent implantation. In this randomized trial, OCT-guided PCI significantly reduced the incidence of uncovered stent struts at 6 months compared to angiography-guided PCI (the percentage of uncovered struts, 1.6% versus 4.5%, p = 0.0004) [18]. This finding was accompanied with lower percentage of malapposed struts at 6 months in patients undergoing OCT guidance (0.19% versus 0.98%, p = 0.027) [18].

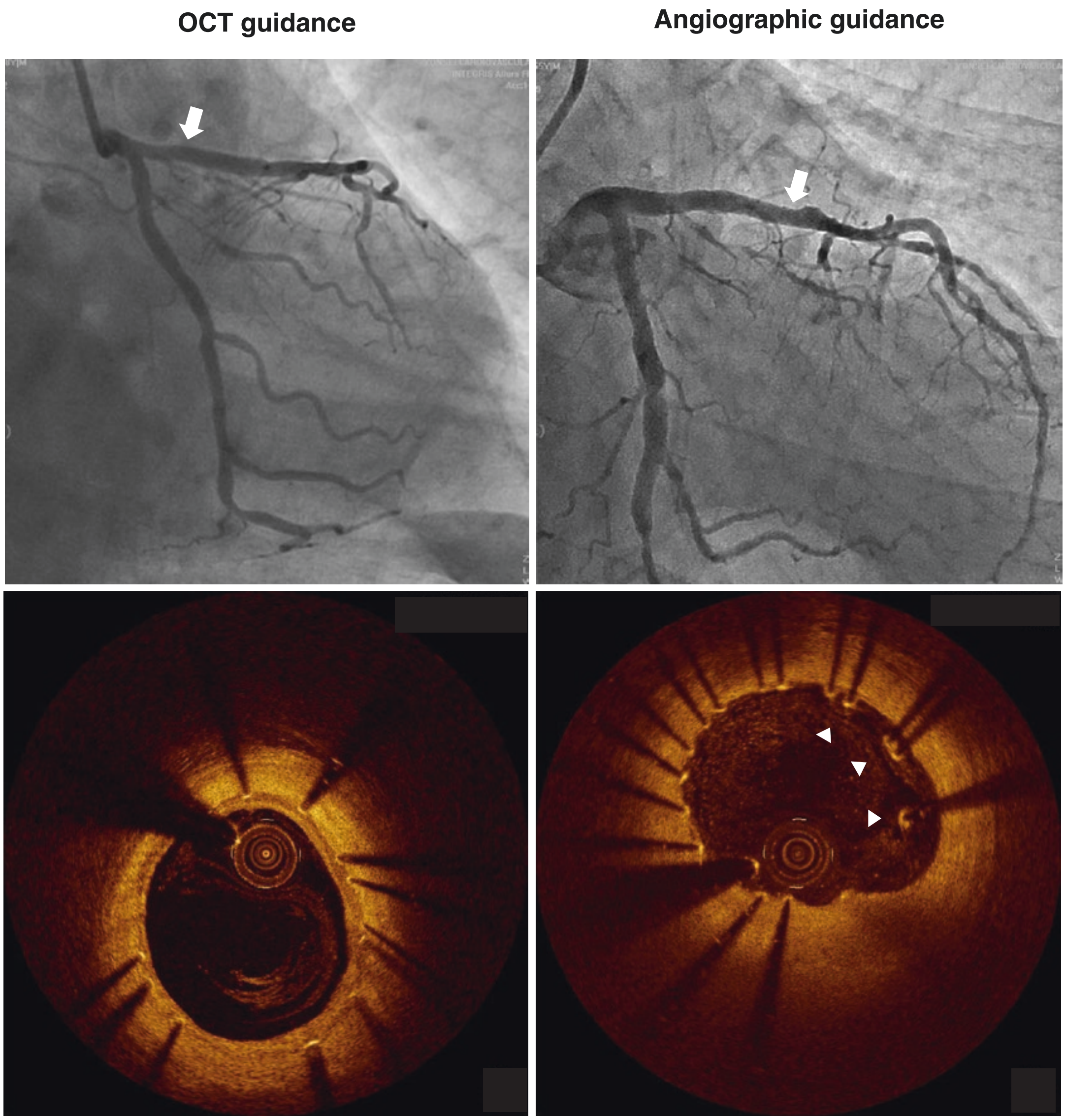

Fig. 14.4 Six-month follow-up after drug-eluting stent implantation. The shown optical coherence tomography (OCT) images were taken at the narrowest site on coronary angiography (*arrows*). Stent struts were almost covered in patients undergoing OCT guidance (*left panel*), while uncovered struts (*arrowheads*) were frequently noted in patients receiving angiographic guidance at stent implantation (*right panel*)

Given that delayed healing of implanted stents has been associated with stent thrombosis [19], this study demonstrates the possible benefit of OCT-guided PCI. Figure 14.4 shows representative cases of OCT versus angiographic guidance.

The use of OCT was related to the improved result of functional status after PCI. A randomized DOCTORS study involving 240 patients with non-ST segment elevation acute coronary syndromes compared OCT-guided PCI with angiography-guided PCI [13]. The OCT-guided group showed a higher value of post-procedural FFR compared with angiography-guided group (0.94 ± 0.04 versus 0.92 ± 0.05, $p = 0.005$) [13]. The OCT evaluation after stent implantation led to the more frequent use of post-stent overdilation

Table 14.4 Clinical benefits of optical coherence tomography (OCT) guidance during percutaneous coronary intervention

Authors	Main findings
Prati et al. [12]	Lower risk of cardiac death or myocardial infarction at 1 year, compared with angiographic guidance
Wijns et al. [14]	OCT-derived changes in treatment strategy were associated with the decrease of periprocedural myocardial infarction
Sheth et al. [15]	Larger minimum lumen diameter at post-intervention, compared with angiographic guidance
Maehara et al. [16]	Stent expansion was comparable between OCT and intravascular ultrasound guidance
Ali et al. [17]	OCT guidance using a specific reference segment external elastic lamina-based stent optimization strategy resulted in similar minimum stent area to that of intravascular ultrasound guidance
Kim et al. [18]	Lower rates of malapposed or uncovered struts at 6 months, compared with angiographic guidance
Meneveau et al. [13]	Higher fractional flow reserve at post-intervention, compared with angiographic guidance

in the OCT-guided group versus the angiography-guided group (43% versus 12.5%, $p < 0.0001$) with lower residual stenosis (7.0 ± 4.3% versus 8.7 ± 6.3%, $p = 0.01$) [13]. However, this functional benefit will translate into the clinical benefit remains to be determined [13]. Nevertheless, it has been previously shown that patients with a post-stent FFR of ≥ 0.90 had event rates of 4.9–6.2% at 6 months, compared with 20.3% in patients with post-stent FFR < 0.90 [20].

Based on the present studies, Table 14.4 summarizes the clinical benefits of OCT-guided PCI.

14.4 Specific Considerations

Left Main Diseases The use of OCT in left main diseases is challenging due to vessel size and anatomical access. OCT cannot adequately evaluate the large-sized vessel and aorto-ostial involvement because it needs to engage the guide catheter for removing the blood by contrast flushing. Although an observational study showed that frequency-domain OCT assessment of non-ostial left main diseases was feasible and provided high-quality imaging [21], data regarding OCT measurements of stenotic severity of left main diseases are currently limited. However, the OCT evaluation may be useful to optimize or guide PCI. Stent underexpansion or malapposition can be corrected to minimize restenosis or to facilitate the strut coverage of implanted stent. In a study comparing frequency-domain OCT with intravascular ultrasound, the OCT achieved imaging completeness less often, whereas it was more sensitive in detecting malapposition and edge dissections [22]. If kissing balloon angioplasty or two-stent techniques are necessary, the position of recrossing guidewire or the degree of stent distortion can be assessed by OCT, possibly improving the outcomes of stent therapy.

Bifurcated Lesions Based on high resolution, OCT provides additional information for treating bifurcated lesions. Three-dimensional OCT evaluation showed morphologic characteristics in jailed side-branch ostium. In lesions treated with single stent, the shape of the side-branch ostium changed from circular to elliptical after stent implantation [23]. The elliptical change of the side-branch ostium led to a larger minimal lumen area measured by OCT compared to minimal lumen area calculated by quantitative coronary angiography [23]. Given that three-dimensional OCT analysis may predict FFR more accurately rather than quantitative coronary angiography [24], the three-dimensional reconstruction using the most recent OCT system (ILUMIEN OPTIS OCT, St. Jude Medical) may be helpful to assess the stenotic severity of the side-branch ostium. OCT often detects vessel injuries or stent complications in bifurcated interventions, and it triggers additional procedures [25, 26]. In bifurcated lesions treated by provisional stenting, stent malapposition was more common at the proximal segment of main vessel and tissue prolapse at the distal segment of main vessel [25]. Stent malapposition was also associated with the location of wire recrossing at the side-branch ostium [26]. The OCT evaluation revealed that the wire passage via distal cell of the side-branch ostium reduced the rate of strut malapposition [26]. Thus, patients who were treated using OCT-guided recrossing had a lower number of malapposed stent struts compared to those treated with angiography guidance alone [26]. Figure 14.5 shows the case of ostial lesion of proximal segment of left anterior descending artery which was treated with single-stent implantation crossover the ostium of left circumflex artery and three-dimensional OCT reconstruction.

Safety and Feasibility Compared to previous OCT models, frequency-domain OCT system becomes more practical and less procedurally demanding [27, 28]. In a single-center registry, frequency-domain OCT was safe and feasible for PCI guidance [28]. The mean time of frequency-domain OCT pullback (from the setup to the completion of the pullback) was 2.1 min [28]. The procedure was almost successful, and major complications in terms of death, myocardial infarction, emergency revascularization, embolization, life-threatening arrhythmia, coronary dissection, prolonged and severe vessel spasm, and contrast-induced nephropathy were not noted [28]. In the randomized DOCTORS trial, there was no significant difference in the rate of procedural complications including periprocedural myocardial infarction and acute kidney injury between OCT and angiographic guidance [13]. However, the duration of OCT-guided procedures was longer than in those guided by angiography

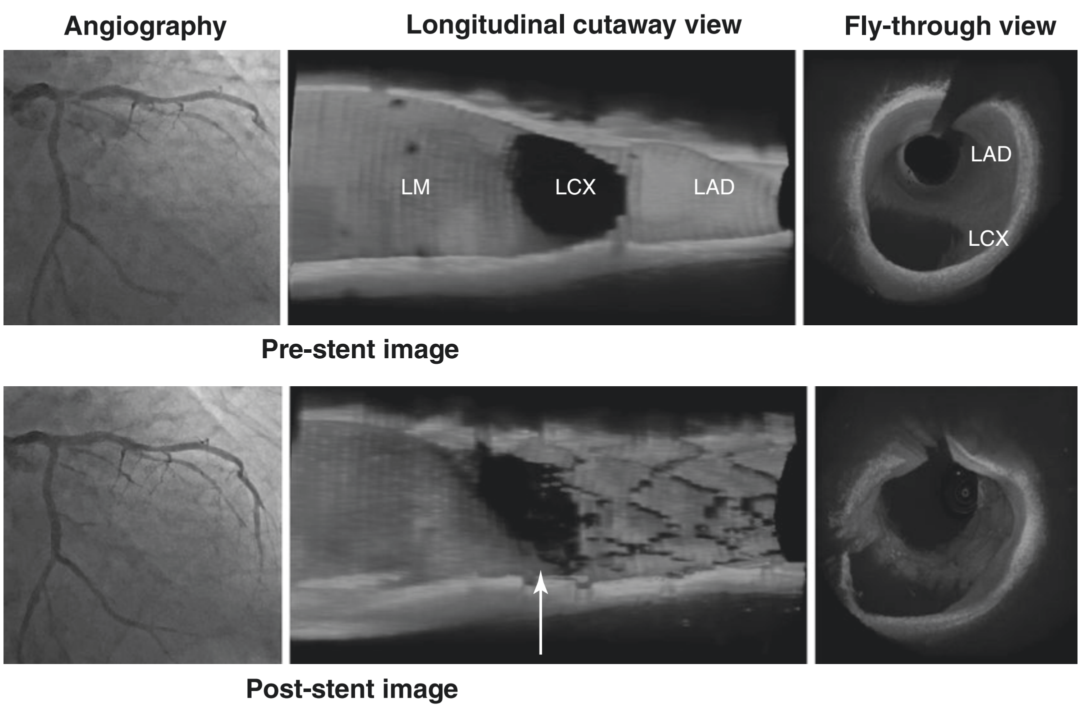

Fig. 14.5 Pre- and post-intervention angiogram and three-dimensional optical coherence tomographic (OCT) reconstructions. After stent implantation for ostial lesion of left anterior descending (LAD) artery, three-dimensional OCT reconstruction image clearly shows that proximal margin (*arrow*) of stent was protruded from LAD to left main (LM) coronary artery. LCX left circumflex artery

alone, with a greater fluoroscopy time [13]. In addition, the volume of contrast medium and the dose of radiation delivered were greater in patients receiving OCT guidance [13].

14.5 Summary

During PCI, the OCT evaluation has several advantages (Table 14.5). OCT can evaluate the severity and morphology of coronary atherosclerotic plaques and guide the proper treatment of coronary artery diseases. Various OCT findings affect the decision-making process of the physicians, leading to a change in interventional strategy. Compared to angiography guidance, OCT-guided PCI has a better stent expansion and FFR at the end of PCI and shows a lower percentage of uncovered or malapposed struts at follow-up. In complex lesions, detailed information derived from OCT helps to improve procedural outcomes. These beneficial findings were parallel to better outcomes of clinical end points in patients treated by OCT guidance. However, additional prospective studies are required to establish OCT guidance as standard use in patients with coronary artery diseases.

Table 14.5 Considerations for the usage of optical coherence tomography during percutaneous coronary intervention

Advantage
Good image resolution
Identification of morphometric characteristics of coronary atherosclerosis
Excellent visualization of stent apposition, dissection, and tissue prolapse
Evaluation of bioabsorbable stent
Disadvantage
Poor tissue penetration
Additional usage of contrast
Lesional limitations such as large-sized vessel (left main disease) or ostial stenosis
Insufficient clinical outcome data compared to intravascular ultrasound

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