

Optical Coherence Tomography for Lesion Assessment

A focus on pre-PCI imaging.

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Optical coherence tomography (OCT) is an intravascular imaging technology that employs an optical source for image acquisition, allowing high-resolution (10–20 μm) analysis of the coronary vasculature. The development of this imaging tool over the last decade, along with European CE Mark approval in March 2009 and US Food and Drug Administration approval in April 2010, has led to a dramatic increase in the number of operators and institutions using this technology. In many ways, early experience with this technology mimics the early experience with intravascular ultrasound (IVUS) 2 decades earlier, and as a still-emerging innovative imaging modality, much of the published clinical experience and research in this field involves observational data from registries or single sites. As such, the role of OCT for lesion assessment prior to percutaneous coronary intervention (PCI) is evolving and remains largely unsettled. This article focuses on recent findings and novel insights gained from OCT and explores how these findings may apply to new approaches to lesion assessment that diverge from long-held concepts of PCI.

THE BASICS OF IMAGING WITH OCT

The high-resolution, detailed visualization of plaque components and morphology with OCT allows the ability to distinguish between the fibrous, lipid, and calcified components of an atherosclerotic plaque.^{1,2} Moreover, OCT can determine vascular dimensions with a greater degree of accuracy than is possible with IVUS. This has been demonstrated in vitro using a coronary phantom model in which frequency domain OCT showed fewer measurement errors and a smaller discrepancy between maximum lumen diameter and minimal lumen diameter compared

with IVUS. It has also been demonstrated in clinical data in which OCT measurements, especially in smaller-caliber vessels, were shown to correlate more closely than IVUS with fractional flow reserve (FFR) measurements.^{3,4} OCT allows for accurate determination of fibrous cap thickness, thereby enabling in vivo identification of the presence of thin-cap fibroatheroma (TCFA).⁵ However, given the limited penetration of OCT within the vessel wall, the ability to image the external elastic membrane is often obscured in patients with coronary atherosclerosis, resulting in an inability to rely on measurements of true vessel dimension or quantify plaque burden in assessing a target lesion.⁶ As such, the use of OCT for lesion assessment before PCI must incorporate a strategy in which these two parameters, vessel dimension and plaque burden, commonly used for IVUS-based lesion assessment, are eliminated.

Comparison With IVUS

After an entire generation of conflicting IVUS studies,^{7,8} recent data from a large registry and two randomized trials provide a coherent and consistent message regarding the potential role for IVUS, and perhaps other intravascular imaging, in guiding contemporary PCI. A meta-analysis by Zhang et al, which incorporated more than 29,000 patients, revealed that IVUS guidance was associated with improved clinical outcomes, especially in patients with acute coronary syndromes (ACSs) and complex lesions.⁹ In a randomized trial of IVUS versus angiographic guidance with drug-eluting stents (DESs) in long lesions, 1-year major adverse cardiac event (MACE) rates showed a trend toward improvement but not statistical significance in the intention-to-treat analysis with IVUS, but when analyzed based on actual IVUS use, MACE rates improved from 8.1% to 4%.¹⁰ Similarly, in

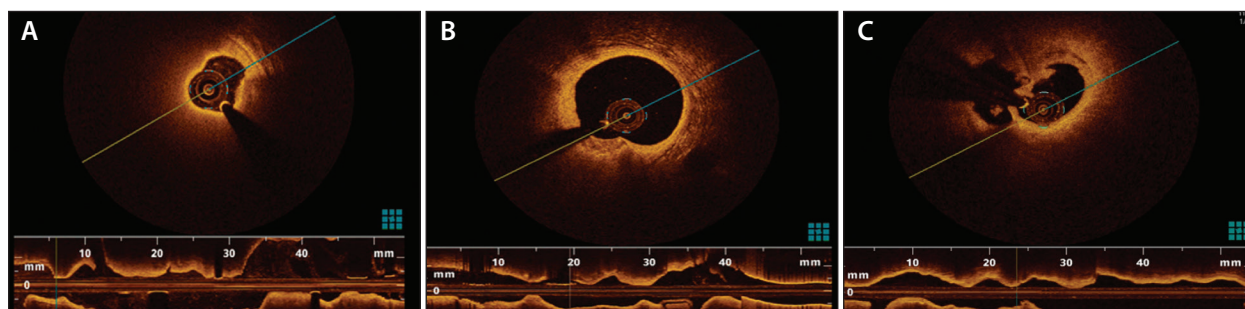


Figure 1. Acute coronary syndrome OCT pre-PCI lesion findings. TCFA with > three quadrants lipid plaque (A). ACS related to erosion of calcified nodule at lumen surface, visible at inferior lumen border of this image (B). TCFA with plaque rupture and ulceration. Remnant of ruptured fibrous cap is visible, with thrombus (C).

the randomized multicenter IVUS-XPL trial conducted in more than 1,400 patients with long lesions, the use of IVUS-guided DES implantation compared to angiography alone resulted in a lower MACE rate at 1 year.¹¹

Can these data supporting IVUS guidance be used to justify OCT guidance for PCI? Although this question remains unanswered in regard to clinical trial outcome data, there is at least indirect evidence that OCT may provide the same type of benefit in guiding PCI. The recently published ILUMIEN II study, which compared IVUS guidance for PCI from the ADAPT-DES study to OCT guidance for PCI from the ILUMIEN I registry, demonstrates nearly identical assessments of stent minimal lumen area (MLA), which has been determined to be the strongest procedural predictor of stent thrombosis and restenosis.¹² Because achieving greater stent luminal dimensions with IVUS guidance has been associated with improved event-free survival compared to angiographic guidance alone, it is tempting to conclude that OCT PCI guidance can provide similar benefit. However, it would be premature to draw such a conclusion before the results of ILUMIEN III, a randomized trial designed to directly address this question, are available.

Comparison With FFR

FFR is widely accepted, based on a series of studies demonstrating impressive clinical outcomes, as the standard for determining the hemodynamic significance of coronary stenoses and as a guide to decision making for PCI.¹³⁻¹⁵ The clinical data supporting IVUS for this purpose are based on several studies with acceptable event rates in patients for whom intervention was deferred based on IVUS MLA $\geq 4 \text{ mm}^2$, resulting in an American College of Cardiology/American Heart Association class IIb recommendation.¹⁶ However, comparisons of IVUS MLA measurements with FFR show only a moderate correlation, with area under the curve values of 0.68 to 0.80.¹⁷⁻¹⁹ In comparison with IVUS, OCT can provide more accurate and reproducible MLA measurements; recently, an OCT-derived MLA threshold

of 1.95 mm^2 has been shown to have a moderate ability to identify an $\text{FFR} \leq 0.80$.²⁰ Lesions with OCT-derived MLA $> 1.95 \text{ mm}^2$ are unlikely to be hemodynamically significant, based on the moderate sensitivity (82%) and high negative predictive value (80%) of this threshold.⁴ Nonetheless, due to poor specificity and positive predictive value, an OCT-derived MLA $< 1.95 \text{ mm}^2$ cannot be used to justify intervention in the absence of additional functional assessment. In addition, an MLA threshold of 1.62 mm^2 may be more appropriate in small vessels $< 3.0 \text{ mm}$ in diameter, with this threshold having a significantly higher area under the curve by receiver-operating characteristic analysis (0.77 vs 0.63; $P = .04$) when compared to IVUS.⁴

Despite these favorable findings, the existence of overwhelming evidence for functional lesion assessment with FFR makes the likelihood of strict, absolute anatomic criteria with OCT as a surrogate for functional significance unlikely to become a first-tier option.^{17,21,22} Additionally, the long-term clinical safety of deferring PCI in the setting of an OCT-derived MLA $> 1.95 \text{ mm}^2$ has not been determined. Randomized trials with clinical outcomes will be needed to define and validate the optimal OCT-derived MLA thresholds against FFR, and at present, we do not advocate for OCT use as the sole method for decision making regarding PCI.

TCFA and High-Risk Lesions

Autopsy studies suggest that acute coronary events most commonly result from disruption of TCFA, lipid plaques with a thin, fibrous cap.^{2,23-28} OCT can quantify and identify TCFA, potentially allowing for better targeting of high-risk or potentially “vulnerable” plaques, and the accuracy of OCT identification of TCFA has been validated with histologic comparisons.²⁹ In a series of OCT clinical studies, Yonetsu et al determined that 95% of ruptured plaques contained a minimal fibrous cap thickness and most representative cap thickness of $< 80 \mu\text{m}$ and $< 188 \mu\text{m}$, respectively, with the best cut-offs for predicting rupture

determined to be $< 67 \mu\text{m}$ for minimal fibrous cap thickness and $< 151 \mu\text{m}$ for most representative cap thickness.³⁰ These criteria offer the potential to serve as threshold targets for future therapeutic efforts, as well as a marker for risk stratification.

Acute Coronary Syndrome

Recent experience with OCT imaging has led to the identification of imaging features associated with ACS, and the ability to distinguish such features in patients presenting with stable angina pectoris. Convincingly and reproducibly, these studies have revealed that the fibrous cap is significantly thinner, and TCFA is more frequently observed in ACS than in stable angina pectoris.^{1,31} Furthermore, OCT can also be employed in ACS to identify not only plaque rupture, but also fibrous cap erosion and the presence of calcified nodules (Figure 1).³² In a series of patients with ACS, Jang et al reported that the incidence of plaque rupture, erosion, and calcified nodule were approximately 44%, 31%, and 8%, respectively, with erosion being a frequent finding in non-ST-segment elevation myocardial infarction (NSTEMI) and in younger patients.³³ Kubo et al analyzed culprit lesions of 30 patients with an acute myocardial infarction (MI) and demonstrated that OCT can identify these characteristics more frequently compared with conventional imaging techniques (IVUS and coronary angiography).³²

Additionally, culprit lesion morphologies have been compared between STEMI and NSTEMI using OCT. In 89 patients with ACS, Ino et al concluded that plaque rupture, TCFA, and red thrombus were more often seen in STEMI

compared with NSTEMI. Although the MLA at the plaque rupture site was similar, the ruptured cavity area was significantly larger in STEMI with a greater likelihood of the ruptured plaque aperture facing upstream, against the direction of coronary flow.³⁴ This finding, while not likely to result in different treatment approaches at present, aids in our understanding of which lesion types are more likely to result in complete vessel occlusion and STEMI in ACS.

Predicting PCI Risk

The ability of OCT to define plaque morphology and characteristics adds value to angiography in predicting risks associated with PCI, including periprocedural MI (type IV, third universal definition of MI), which occurs due to distal embolization or side branch occlusion and which is associated with adverse outcomes after PCI.^{35,36} Porto et al identified TCFA as the strongest predictor of periprocedural MI, present in 76% of patients with an event, and Lee et al studied the relationship between pre-PCI plaque composition obtained using OCT and post-PCI cardiac troponin I elevations in 131 patients who underwent elective PCI, concluding that type B2/C lesions and the presence of OCT-defined TCFA can predict post-PCI MI in elective PCI patients. These patients may require adjunctive therapy during or after otherwise successful PCI.³⁷⁻³⁹ These investigators further explored characteristics associated with subclinical troponin elevation after PCI in 206 patients, demonstrating that the combination of even a mildly elevated troponin value on admission (cardiac troponin I $> 0.03 \text{ ng/mL}$) with the presence of a lesion site TCFA resulted in a 73% chance of a postprocedural troponin elevation of $> 5 \text{ ng/mL}$. It is clear

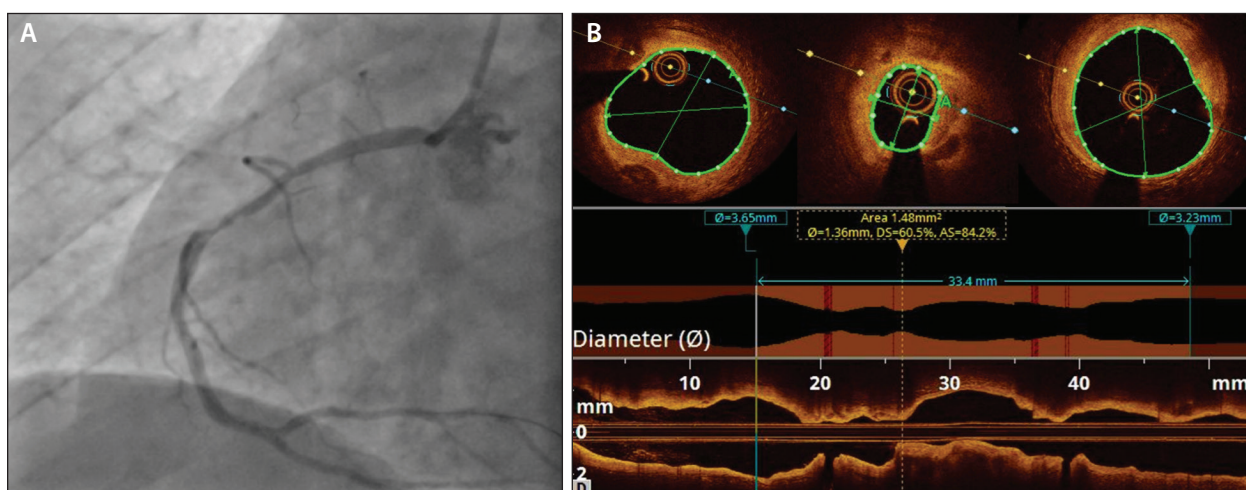


Figure 2. Example of OCT use for lesion length assessment. Angiogram of long segment of proximal mid-right coronary artery disease (A). OCT images of (from left to right) distal reference, MLA, and proximal reference frames, allowing stent sizing to match proximal and distal reference lumen areas (B). Longitudinal view, below individual frames, allows accurate lesion length measurement, which in this case, led to the selection of a 3.25- X 33-mm stent.

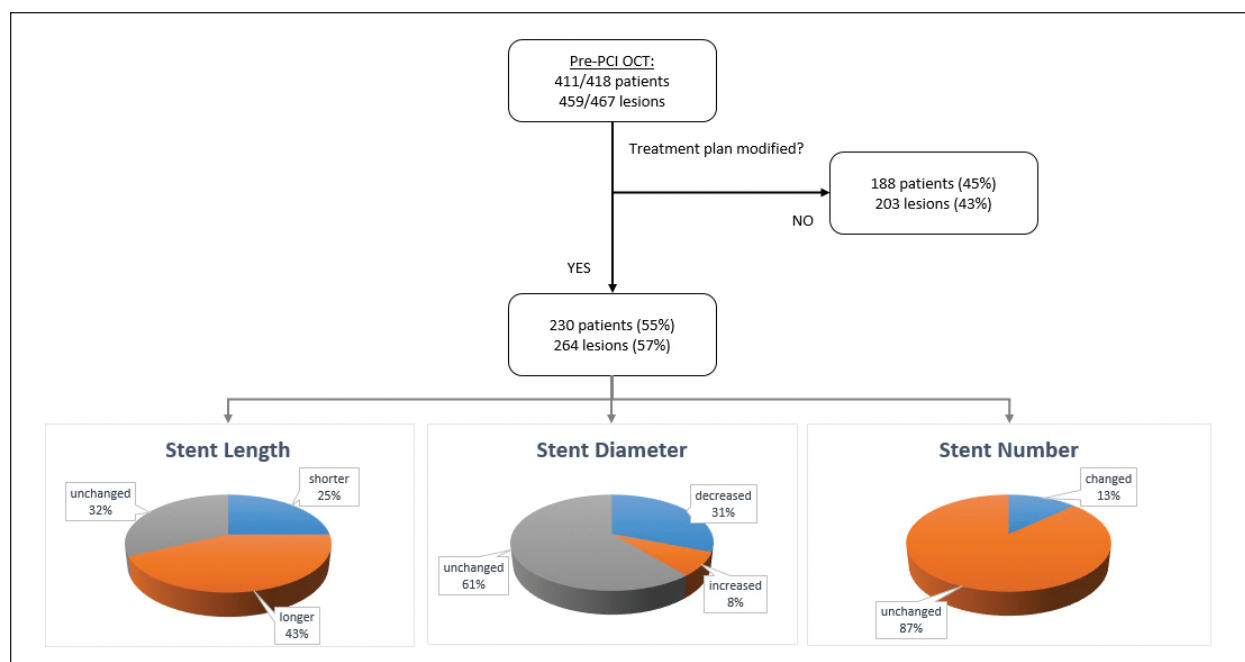


Figure 3. Treatment decisions affected by pre-PCI OCT in the ILUMIEN I study. Of the 411 patients (459 lesions) in which pre-PCI OCT images were obtained, the treatment plan was modified in 55% of patients and 57% of lesions. Treatment plan change manifested as a change in stent length in 68%, stent diameter in 39%, and number of stents in 13%.

that OCT-defined TCFA allows better assessment of the risk of periprocedural myonecrosis for elective PCI and is a better predictor of post-PCI MI than angiographic lesion type or patient demographic variables. However, without studies that address pharmacologic approaches or stenting strategies that demonstrate the ability to decrease the incidence of periprocedural MI, the question of how to incorporate these findings into clinical practice remains unanswered.

LONG LESION ASSESSMENT

Even in the DES era, long stent length has been associated with adverse clinical events and higher restenosis rates.⁴⁰ Although it remains unclear whether this is related to more diffuse vascular disease or excessive stent length, the accuracy of OCT stent length assessment provides a mechanism to match stent length to lesion length in a manner that can potentially limit this occurrence. In addition, patients with long coronary lesions often require multiple overlapping DESs and might be at a higher risk of stent thrombosis due to multiple DES layers exposing the vessel wall to higher doses of drug and polymer, resulting in impaired arterial healing.⁴¹ The ODESSA trial randomized 77 patients and investigated the rate of uncovered/malapposed struts in overlap versus nonoverlap segments in conjunction with sirolimus-eluting stents, paclitaxel-eluting stents, zotarolimus-eluting stents, or bare-metal stents at 6-month follow-up

with OCT. These data reveal a reduced efficacy of DESs at overlapped regions with a heterogeneous vascular response according to DES type.⁴² Other studies have reported similar findings, including an analysis from the SIRTAX trial that identified regions of stent overlap as a source of MACE.⁴³⁻⁴⁵ These findings demonstrate the potential value of OCT imaging to correctly identify and measure lesion length for procedural planning and to limit or eliminate stent overlap (Figure 2).

OUTCOMES WITH PRE-PCI OCT USE

There is an emerging body of nonrandomized registry data on outcomes after the incorporation of preprocedural OCT imaging. These data include two moderate-sized multicenter OCT registries that have laid the groundwork for future randomized trials in this field. The ILUMIEN I trial is the largest prospective, nonrandomized, multicenter, observational study of patients undergoing PCI with FFR and OCT.⁴⁶ ILUMIEN I explored the effect of OCT on physician decision making with respect to coronary interventions. Patients underwent elective PCI for stable angina, unstable angina, or NSTEMI, as well as pre- and post-PCI FFR and OCT, with investigators asked to declare a PCI strategy based on angiographic data alone, prior to incorporating preprocedural imaging results. After stents were placed, postprocedural FFR and OCT were

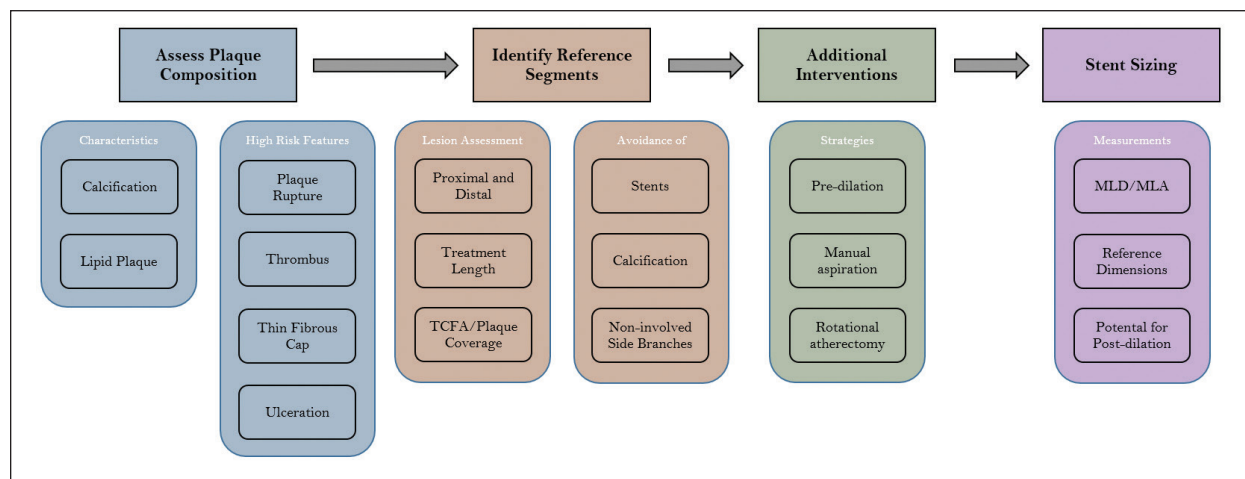


Figure 4. Algorithm for the approach to pre-PCI OCT. This proposed approach to assessment of lesions and guidance for stenting is designed for use with OCT prior to PCI. Plaque and vessel characteristics are assessed to guide operator decision making to optimize interventions. Abbreviations: MLA, minimum lumen area; MLD, minimum lumen diameter; TCFA, thin-cap fibroatheroma.

performed, and operators could then further optimize the stent result. Procedural decisions were altered in 57% of lesions (55% of patients) based on pre-PCI OCT, as demonstrated in Figure 3, and pre-PCI OCT was more likely to affect a change in treatment in patients with multivessel or multilesion single-vessel disease. The composite results of both pre- and post-PCI OCT affected management in a total of 68% of lesions (66% of patients). The rate of MACE was low both in-hospital and at 30 days.

More recently, the CLI-OPCI II study retrospectively evaluated patients who underwent stenting with at least one OCT assessment of the treated vessel performed at the end of the procedure.⁴⁷ Periprocedural OCT indications were left to the operator's discretion. Patients were followed to determine the effect of nonoptimal stent deployment on clinical outcomes. A total of 832 patients and 1,002 lesions were included. Nonoptimal stent deployment was noted in 31% of cases and was associated with a higher incidence of MACE, with in-stent MLA < 4.5 mm², dissection at the distal edge, and reference lumen area < 4.5 mm² in the presence of residual plaque identified as predictors of MACE. Although it is important to recognize its limitations as a retrospective, nonrandomized trial, and one that is focused on stent optimization, the identification of a reference area threshold of 4.5 mm² as a risk for MACE offers potential guidance for optimizing stent length based on preprocedural imaging and describes the importance of stent placement to cover reference regions with moderate lumen compromise. Although limited, these initial findings set the foundation for definitive studies to further investigate the role

that preprocedural OCT imaging may have on optimizing coronary interventions.

PRACTICAL ALGORITHM FOR PCI PROCEDURE PLANNING WITH OCT

Based on much of the data described previously, we currently use OCT to guide coronary intervention by incorporating both standard intravascular imaging findings (including assessments of lesion length, reference vessel size, lesion and side branch location) as well as OCT-specific characteristics (including plaque type and culprit lesion identification). This algorithm, outlined in Figure 4, begins with an assessment of plaque characteristics, including the presence and extent of calcification and lipid plaque, to aid in determining the need for vessel preparation. At this point, the presence of plaque rupture, thrombus, and thin fibrous cap are evaluated in an effort to identify high-risk features, while ensuring that the true culprit region is treated and planned for coverage. The third step of this algorithm involves determination of the reference segments, both proximally and distally, and calculating the proposed treatment length, with a focus on covering both the entire high-risk TCFA and lipid plaque comprising the lesion. Additionally, it is important to ensure that excessive stent length, stent overlap, and noninvolved side branches are avoided. Finally, the mean reference vessel lumen dimensions are identified for stent sizing with considerations including the need for postdilation if full stent expansion is not expected based on lesion characteristics and the possibility of matching proximal and distal portions of the stented segments to differing respective reference segments.

CONCLUSION

In a few short years, OCT imaging has become a valued tool for interventional cardiologists in guiding coronary intervention. Based on recent data supporting intravascular imaging procedural guidance for PCI, OCT has the similar ability to be used for procedural planning. Upcoming clinical trials with OCT will help to clarify this role. ■

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