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Techniques to Optimize the Use of Optical Coherence Tomography: Insights from the Manufacturer and User Facility Device Experience (MAUDE) Database☆

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ABSTRACT

Background/purpose: Optical coherence tomography (OCT) is a high-resolution intravascular imaging modality used to assess coronary arteries and as an adjunctive tool for optimization of percutaneous coronary interventions. Overall, the rate of complications and adverse events related to intravascular imaging is low. Limited data exist on the most commonly reported complications and modes of failure related to the use of OCT. Therefore, we analyzed the post-marketing surveillance data from the Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database to assess the reported complications and failure modes for OCT and reviewed techniques to optimize device use.

Methods/materials: The MAUDE database was queried for all event reports involving coronary OCT devices. Two independent reviewers identified 49 device reports included in the final analysis. Modes of failure and device-related patient complications were assessed.

Results: Of the 49 cases with reported device-related issues, 6.1% involved malfunction prior to insertion of the OCT catheter, and 30.6% of reported events did not result in an associated patient-related adverse event. The most commonly reported adverse events included coronary dissection and difficulty removing the catheter within a previously stented segment. No events of contrast-induced nephropathy were reported.

Conclusions: Findings from the MAUDE database highlight the modes of device-related events associated with OCT. Device issues are uncommon, and as a result, users should be aware of optimal techniques to prevent and minimize adverse events related to device use.

1. Introduction

Optical coherence tomography (OCT) is an intravascular imaging modality used to evaluate coronary arteries and optimize percutaneous coronary interventions (PCI). Using light-based technology, OCT provides a 360-degree cross-sectional high-resolution image of a coronary artery. Use of OCT has been associated with improved clinical outcomes in large registry databases with increasing use over time, though overall utilization remains less than 1% of all PCIs in the United States [1–3].

Initial coronary OCT technology incorporated time-domain OCT, with balloon occlusion proximal to the segment of interest and injection of flush media during a prolonged pullback to achieve blood displacement for image acquisition. The technology, however, was limited by its increased risk for endothelial injury and myocardial ischemia, and had limited clinical use [4]. Current generation OCT systems utilize frequency-domain imaging which enables faster image acquisition rates and pullback speeds. This obviates the need for balloon occlusion

Abbreviations: OCT, optical coherence tomography; PCI, percutaneous coronary interventions; MAUDE, Manufacturer and User Facility Device Experience; MDR, medical device reports; FDA, Food and Drug Administration; MLA, minimum lumen area; MLD, minimum lumen diameter; IVUS, intravascular ultrasound; IFU, instructions for use; EEL, external elastic lamina.

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and allows image acquisition with injection of contrast through the guide-catheter to displace blood during pullback. With improved safety profile and usability, frequency-domain OCT has become the standard OCT imaging modality in use today [5,6].

Though complications related to OCT are rare, there are limited post-approval surveillance data on the clinical safety of OCT. The objective of this study was to assess the modes of failure and most commonly reported malfunctions and adverse events related to coronary OCT as reported in the Manufacturer and User Facility Device Experience (MAUDE) database and review techniques to reduce the likelihood of these complications [7].

2. Materials and methods

2.1. Study device

The Ilumien Optis Dragonfly Imaging Catheters (Abbott Vascular, Santa Clara, CA) are intended for the intravascular imaging of coronary arteries and are indicated in patients who are candidates for PCI with intended use in vessels ranging from 2.0 to 3.5 mm in diameter [8]. The inner rotating fiber optic imaging core emits near infrared light to the tissue and receives the reflected light, which is combined and processed by the Ilumien Optis System software to construct an OCT image. It is manipulated by a stainless steel torque wire visible under fluoroscopy and can be pulled back automatically through the tube of the external sheath. The external sheath completely covers the rotating imaging core and, consequently, the artery is not exposed to any moving parts during automated imaging pullback.

The Dragonfly Optis catheter is a rapid-exchange dual-lumen OCT imaging catheter with a tip that tapers to a 2.7-F diameter. It is compatible with a 6-F or larger guiding catheter and offers fast acquisition, with automated pullback 2 to 3 s in duration. The Dragonfly Optis catheter is the most contemporary version of OCT available from the Dragonfly family of catheters and incorporates a rapid exchange tip. Prior versions of the OCT catheter have included the C7 Dragonfly, Dragonfly Duo, and Dragonfly JP catheters.

2.2. MAUDE database

The MAUDE database was queried for intravascular OCT devices. The MAUDE database is an electronic open-access database that stores medical device reports (MDR) submitted to the Food and Drug Administration (FDA) relating to adverse events or device complications. MAUDE reporters are classified into two categories: a) mandatory reporters (manufacturers, importers, and device user facilities), or b) voluntary reporters (health care professionals, patients and consumers). The MAUDE database is updated monthly and can be accessed electronically at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm. Each medical device report contains information on the device type, event date, whether the device was returned to the manufacturer, description of the event by the provider and the manufacturer's input. The MAUDE database is a passive surveillance system with voluntary physician reporting, and may provide insight into device-related complications and adverse events. Data extraction from the MAUDE database has been reviewed previously in detail [9]. The reporting of device-related adverse events pertaining to interventional cardiology devices has been published previously for a number of prior devices [10–13].

2.3. Data collection

The MAUDE database was last accessed on August 31, 2018. Two independent reviewers (ES,NK) queried the database for the time period January 1, 2001, to July 31, 2018, for coronary OCT devices by searching for the following event types: “injury”, “malfunction”, “death”, and “other” and brand name “Dragonfly” or product class “Optical Coherence Tomography, Intravascular Catheter”. The Dragonfly family of OCT intravascular imaging catheters are the only commercially approved coronary OCT devices currently available in the United States, with initial FDA approval on September 19, 2014 [14]. The search yielded a total of 51 device reports, with the initial device report occurring in 2011. All reports were screened and 49 reports were included for the final analysis, with 2 reports excluded as they did not involve an intravascular imaging-related device. Device reports were analyzed and categorized by modes of failure and device-related patient complications.

3. Results

The final study cohort included 49 reports of device-related events. The breakdown of specific catheters involved in device reports is presented in Fig. 1. Previous versions of OCT catheters that are no longer commercially available accounted for 31.3% of events reported. The currently available Dragonfly Optis catheter was listed in 45.8% of reported events, with the remaining catheter type not specified. Fig. 2 displays the number of reported device-related events by year, which did not demonstrate a linear trend of annually increasing events.

There were 15 (30.6%) reported events that did not result in an associated adverse event to the patient, and an additional 6.1% of reported device issues were recognized and occurred prior to insertion of the device into the body. The most commonly reported event type was dissection. Coronary dissections were reported in 26.5% of reported events. Reports of dissections were recognized prior to OCT in 2% of cases, and in vessels not assessed by OCT in another 2% of cases. One case that resulted in iatrogenic coronary dissection was reported to have occurred as a result of the operator recognizing that the minimum lumen area (MLA) was initially misinterpreted as the minimum lumen diameter (MLD), and stent size selection was consequently oversized.

Difficulty in removing the catheter occurred in 20.4% ($n = 10$) of reported events, 9 of which were reported as having occurred within a stented segment. Of the 7 reported cases involving damage to the OCT catheter during use, 4 reported intact removal of the imaging catheter. One case did not specify the device condition, and 2 cases involved retained components. Of the 2 cases with retained components, 1 involved a fractured distal tip of the Dragonfly Duo catheter. Retrieval using a snare technique was unsuccessful and the procedure was staged for re-attempt at a later date with no further data available. The other case required surgical intervention for retrieval of optic fiber components from a C7 Dragonfly catheter that was entrapped between two newly implanted stents. There were no reports of retained components from the current Dragonfly Optis catheter.

Four deaths occurred, 2 of which were not attributed to the OCT catheter. Of the other 2 cases, the first described successful OCT imaging following stent implantation with a well-apposed stent. Following OCT imaging, the patient experienced hemodynamic collapse and ventricular tachycardia. Resuscitative measures and attempt at revascularization of the vessel were unsuccessful, and the patient expired. The other case was complicated by left main coronary artery dissection that was seen during OCT pullback and treated with stent implantation. The patient, however, went into cardiac arrest and expired despite resuscitative efforts. The devices were not returned to the manufacturer for analysis in either case. Arrhythmia or conduction disturbances were reported in 9 cases, and 1 instance was published as a case report [15]. There were no reports of contrast-induced nephropathy. The complete list of reported patient-related adverse events occurring with device use is presented in Table 1.

Six devices were returned to the manufacturer for analysis, and all were determined to be functioning as intended. Of the 6 devices returned for assessment by the manufacturer, 5 were noted to have had stretching of the distal exit port; however, all retained the ability to successfully pass a guidewire through the port.

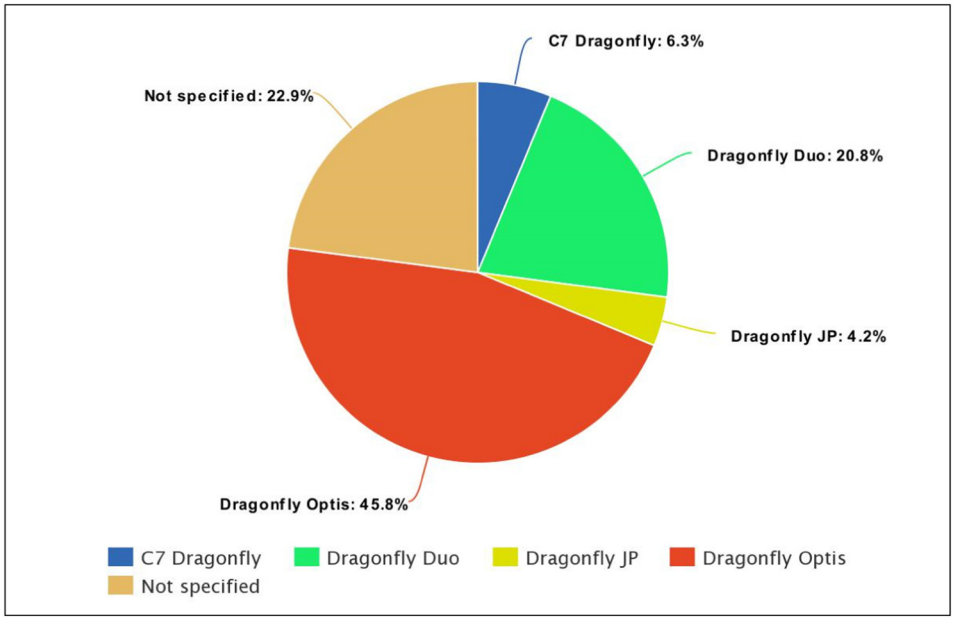

Fig. 1. Reported events by catheter type.

4. Discussion

The main findings of our study are: a) Device-related complications with OCT are uncommon, b) Reported OCT-related events often do not result in any harm to patients, and c) The most commonly reported modes of device-related issues include difficulty in removing the catheter (i.e., entrapment at the site of a recently placed stent) and identification of a coronary dissection.

There are limited data specific to the safety profile and associated device-related issues pertaining to OCT. Previous studies have demonstrated the safety of OCT with low rates of dissection, air embolism, and arrhythmia [4,16]. A large prospective registry found no differences in intravascular imaging related complications between OCT and intravascular ultrasound (IVUS), with no major adverse events or permanent patient harm observed [17]. A single-center study on the safety of OCT in a pediatric population reported no procedure-related events [18]. Reported adverse events from clinical trials assessing OCT have reinforced the safety of OCT, with low rates of associated adverse events. Dissection, perforation, thrombus, and acute vessel closure each occurred less than 1% of the time in the overall study population of the pivotal ILLUMIEN III trial [19]. The randomized controlled OPINION trial, comparing OCT with IVUS-guided PCI in 829 patients, reported a 0.7% rate of procedure-related complications in the OCT cohort with no significant difference compared with the IVUS comparator group [20]. Nearly half (44.9%) of the reported events in this study occurred prior to FDA approval, representing initial device use for many of the users. The increase in recent reported events in the MAUDE database is likely related to increased utilization [2,3].

Device-related adverse events can result from device malfunction, patient and procedural factors, or operator-related technique. It is often the interplay of multiple factors that contributes to an adverse event. Recognizing patient characteristics that increase the likelihood of device-related complications is vital and should occur for each patient when determining whether a device should be used. Operator

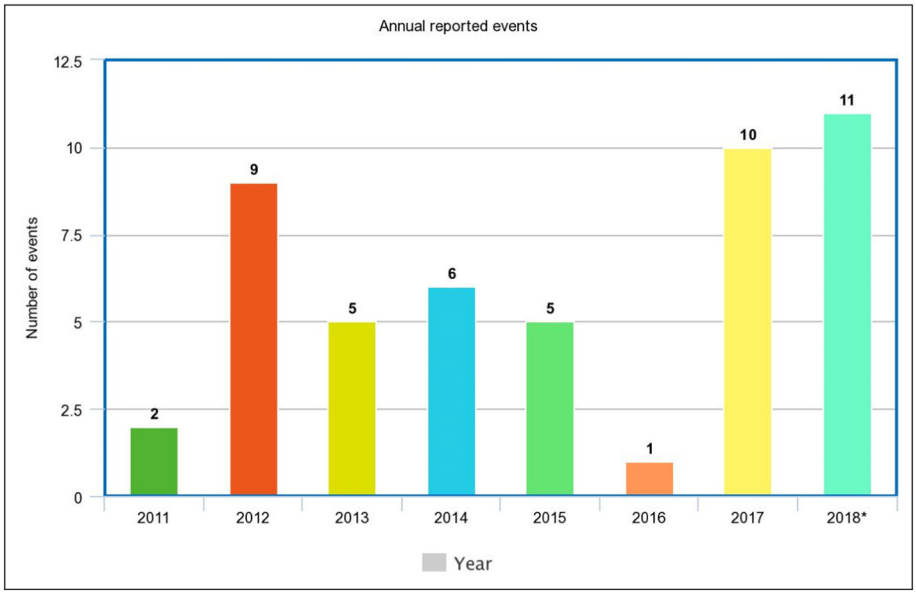

Fig. 2. Number of reported events by year. Reported events from 2018 did not include a complete year and were collected through July 31, 2018.

Table 1
Modes of device-related complications and adverse events. Some event reports represented multiple complications and adverse events for the same patient.

Modes of device-related event	N (%)
Malfunction prior to insertion into the body	3 (6.1)
No associated patient-related adverse event reported	15 (30.6)
Difficulty removing device	10 (20.4)
Within a stented segment	9 (18.4)
At the site of a non-stented segment	1 (2.0)
Damage to stent reported, requiring additional stent implanted	1 (2.0)
Possible allergic reaction to contrast media	1 (2.0)
Contrast flushing difficulty	3 (6.1)
In setting of thrombus	1 (2.0)
Vessel occluded with catheter insertion, prior to imaging	4 (8.2)
Catheter malfunction reported on console, device removed without incident	1 (2.0)
Fracture/Damage to device	7 (14.3)
Device removed intact	4 (8.2)
Retrieved with snare device	1 (2.0)
Retrieved surgically	1 (2.0)
Not specified	1 (2.0)
Dissection	13 (26.5)
Dissection present prior to OCT	1 (2.0)
Dissection in vessel not assessed by OCT	1 (2.0)
MLA recognized as having been misinterpreted as the MLD, and stent subsequently oversized	1 (2.0)
Air emboli	2 (4.1)
Arrhythmia	9 (18.4)
Ventricular fibrillation	7 (14.3)
Ventricular tachycardia	2 (4.1)
Death	4 (8.2)
Death not attributed or related to the OCT catheter	2 (4.1)

MLA, minimum lumen area; MLD, minimum lumen diameter; OCT, optical coherence tomography
Data are n (%)

experience and technique also play an important role in device-related procedures. Recognition of optimal acquisition techniques can mitigate future events.

Sufficient post-market data for interventional devices has been a concern for some time and is an important factor to help prevent future events [21]. The MAUDE database aids post-market surveillance; however, it is significantly limited by the voluntary and inconsistent nature of data input. Improved comprehensive reporting of events can help improve the ability for this database to provide insight into device-related events. Complications related to OCT are exceedingly rare, as demonstrated in this database analysis and based on prior literature. Recognition of the most commonly encountered issues is important to minimize and mitigate potential adverse outcomes.

4.1. Coronary artery dissection

Because of its high resolution, OCT use may allow for the identification of coronary artery dissections not otherwise appreciated with angiography alone. In the ILUMIEN III trial, there was a 1% post-PCI dissection rate in the OCT cohort with no perforations [19]. As with any guidewire or catheter used in the coronary arteries, dissection may occur with use. In the ORBITA trial, for instance, 4.2% of patients who underwent invasive physiologic assessment in the control arm crossed over to an intervention because of a wire-related complication during the diagnostic assessment [22]. Whenever an OCT imaging catheter is being advanced or withdrawn from a coronary artery, it should be moved slowly and with fluoroscopic guidance as per the instructions for use (IFU) [23]. If resistance is encountered, movement should be stopped, and further evaluation with fluoroscopy should occur. Per the device indications, the Dragonfly imaging catheter should not be used in vessels less than 2.0 mm in diameter.

During contrast flushing, care must be taken to avoid deep guide catheter intubation, which could increase the risk for coronary artery dissection. In cases where a significant dissection has occurred, no further OCT imaging should occur until the dissection has been appropriately treated. Further contrast injection into an untreated major coronary artery dissection should be avoided and definitive treatment should preferably be guided by IVUS imaging.

4.2. Air embolism

Two reported cases involved air embolism. One of the cases was secondary to an improperly prepared and purged catheter and this resulted in the direct injection of air into the coronary artery during the imaging run. In the second reported event, an atypical resistance was appreciated during purging. It is essential, prior to use, to properly prepare the imaging catheter according to the IFU. Before inserting the device into the body, purge the device and flush with contrast media until at least 3 drops have exited the distal tip. After device preparation, the catheter can be inserted into the body and delivered to the target vessel of interest on “standby view”. Prior to initiating device pullback, the presence of air in the catheter should be excluded and assessed each time. A representative image of air in the catheter is demonstrated in Fig. 3. If air is recognized, “live view” should be toggled to “standby view”, and the catheter should be removed from the body. Preparation of the imaging catheter with contrast should occur prior to re-insertion. In the event air has been injected during contrast injection, intracoronary vasodilators should be administered in addition to supportive care. If blood is noticed in the catheter lumen, it should be purged using the 3 mL syringe that attaches to the Optis system. A small amount of contrast should then be injected through the guide catheter to evaluate blood clearance and, if adequate, a pullback can be initiated.

4.3. Catheter entrapment

In cases of catheter entrapment following stent implantation, catheter removal should be performed under continuous fluoroscopic assessment. Catheter entrapment is typically associated with underexpanded stents. This often can be mitigated by attempting complete stent expansion and apposition prior to post-PCI imaging, in addition to appropriate lesion preparation when warranted prior to stent implantation. When significant calcium has been appreciated with pre-PCI intravascular imaging, judicious use of atherectomy may help to avoid stent underexpansion [24]. Prior to OCT pullback following stent implantation, effort should be made to optimize apposition of the distal stent struts to minimize likelihood of entrapment. If resistance is encountered when removing or advancing the catheter, further assessment with fluoroscopy should occur before continuing to move the catheter.

4.4. Coronary artery spasm, thrombus and no-reflow

Appropriate intracoronary vasodilator therapy is important prior to use of OCT imaging catheters to minimize vessel spasm and optimize image acquisition. Vasodilators should be administered again once the device has been switched to “live view” with contrast media to ensure adequate blood clearance and optimal guide position. During “live view”, the imaging catheter rotates within the inner sheath with a layered protection of a fluid-filled lumen and an outer sheath, transmitting images from the catheter lens to the Optis display console. Appropriate therapeutic anticoagulation should always be maintained during device use. Per the IFU, OCT should be avoided in cases where a large burden of thrombus has already been visualized with angiography, as OCT image quality may be impaired in this setting.

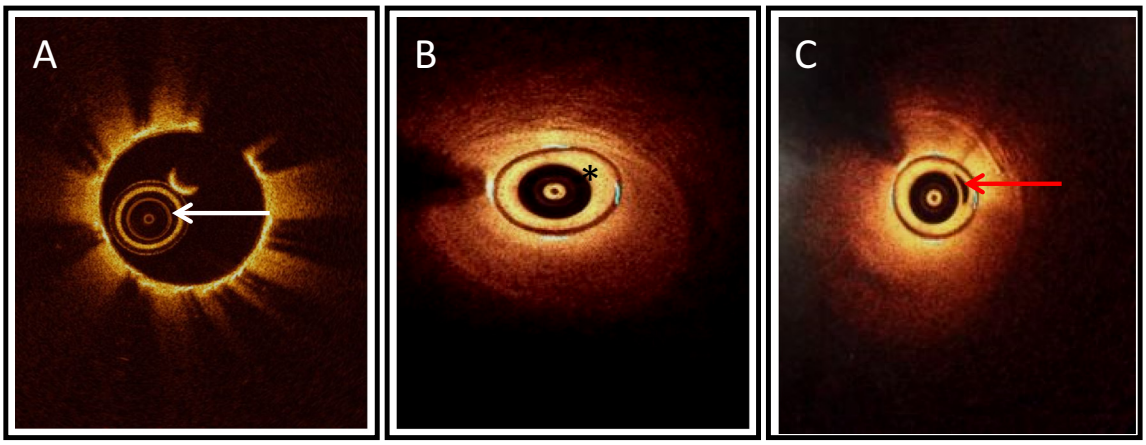

Fig. 3. Representative side-by-side comparison of OCT catheter with varied catheter preparation. A) OCT cross-section image with optimal preparation of the catheter, demonstrated by a circumferential solid black circle (white arrow). B) OCT cross-section image with blood present circumferentially in the catheter (asterisk). C) OCT cross-section image demonstrating the presence of air in the catheter (red arrow).

4.5. Vessel and lumen measurements

While extensive measurements and quantitative analysis can be performed on the images acquired from an OCT pullback, there are a few basic measurements and variables that must be understood prior to safe use. Familiarity with the imaging console is essential to avoid user error, as inaccurate image interpretation can lead to complications. In the lumen profile section of the Optis monitor, 3 boxes will appear after imaging acquisition with automated measurements representing the distal reference, minimal lumen area, and proximal reference, respectively (Fig. 4). In the ILUMIEN III trial, the external elastic lamina (EEL) was identified and used for stent sizing in approximately 75% of cases [19]. Improvement in EEL recognition with enhanced training and experience is being evaluated in ongoing studies.

4.6. Catheter failure

If the Optis display console indicates that the imaging catheter has failed, the catheter should be removed under fluoroscopic guidance prior to dismissing the error message. Once removed from the body, the catheter should be disconnected from the drive motor optical controller and can be replaced with a new imaging catheter.

4.7. Contrast-induced nephropathy

While concern for increased contrast usage is frequently cited as an explanation for limited OCT use, no reported events of acute renal insufficiency related to OCT were present in the MAUDE database. Additionally, in the OPINION trials, while contrast use was increased with OCT use, this was not associated with any cases of contrast-induced nephropathy [19]. Nonetheless, as with all procedures utilizing agents with potential for nephrotoxicity, contrast should be used judiciously. With an upfront OCT-guided strategy, the number of angiographic images necessary can be reduced, and simultaneous angiography may be obtained with each OCT pullback. Whether this can lead to a reduction in contrast use with routine OCT imaging in clinical practice can be addressed in future studies.

4.8. Limitations

This study has a number of important limitations, many of which are inherent to a retrospective database analysis. Significant variations in reporting exist, which may make certain types of events under- or over-reported. There may be a tendency to report more severe events, with minor events less likely to trigger an event report by a physician.

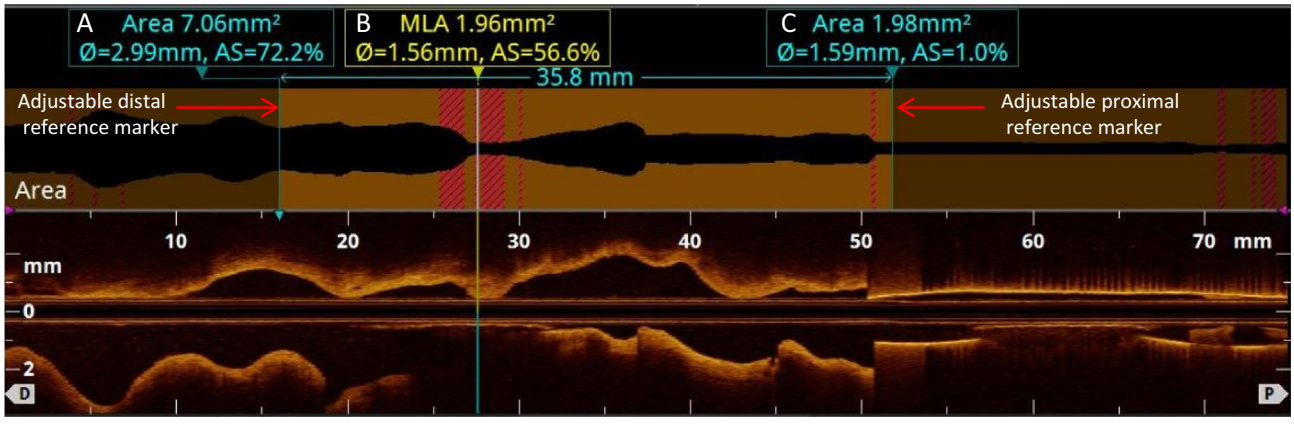

Fig. 4. Representative OCT lumen and longitudinal profile with automated measurements. The box on the left (A) represents measurements from the distal reference, whereas the box on the right (C) represents measurements from the proximal reference. The reference markers (red arrows) can be adjusted by the operator once a target landing zone for stent implantation has been identified, and measurements for the new references will automatically update. The middle box (B) provides automated localization of the minimum lumen area (MLA) with measurements from that site. Settings of displayed measurements in those boxes can be adjusted and customized to a user's specifications from the settings menu. By convention, the standard measurements displayed in the middle box are MLA, Ø and AS (area stenosis), with area, Ø and AS displayed in the outer boxes. Ø represents the lumen diameter at the region of interest. In this representative case example, the distal minimal lumen diameter is 2.99 mm and the minimum lumen area is 1.96 mm^2.

It is difficult to establish a cause-and-effect relationship between the reported device event and the adverse event in most cases. Many of the reported adverse events can occur during PCI without the adjunctive use of OCT, precluding the ability to attribute the event directly, and only, to the OCT. In this study, only 12.2% of devices were returned to the manufacturers for evaluation following the procedure, inhibiting a comprehensive analysis of the modes of failure from all reports. There was significant variability in the quality and completeness of individual reports, limiting what could be inferred. Events are not adjudicated and reporting is inconsistent. MAUDE is largely dependent upon voluntary reporting, and an unknown number of complications remain unreported or unrecognized. Conversely, adverse events caused by clinician's error may be misinterpreted as a device error and subsequently submitted to MAUDE. While open to worldwide reporters, the MAUDE database is maintained by the FDA, with English language entry input and, as a result, adverse events occurring outside the United States or involving non-English speaking physicians may be less likely to be reported. The MAUDE registry does not provide insight into the rates of event complications, as the precise number of coronary OCT catheters used during the study period is not known. Though the precise denominator is unknown, over 5000 devices have been used during the study period, indicating a reporting rate of less than 0.01% per OCT case. This supports the literature that device-related events are exceedingly uncommon. Nonetheless, complications can occur, and best practices and awareness of techniques to minimize adverse events are essential.

4.9. Future outlook

The ongoing randomized controlled multicenter trial ILUMIEN IV: OPTIMAL PCI (NCT03507777) will assess OCT in over 3600 participants and will be the largest intravascular imaging trial to date. Insights from ILUMIEN IV will help highlight any device-associated adverse events as well as add important data to the benefits and best uses of OCT in managing percutaneous coronary revascularization. Familiarity with OCT, appropriate patient selection, increased user experience and adherence to step-wise imaging algorithms and protocols can help reduce the likelihood of adverse events and minimize potential complications [25–27]. Complications relating to device use are rare, and recognition of common issues can help avoid adverse events.

5. Conclusions

OCT plays an important role in stent optimization with PCI. Our findings from the MAUDE database assessing reported events related to OCT supports the safety of OCT and highlight the most commonly reported device-related complications. Overall, reported major device related adverse events are exceedingly rare. An understanding of the mechanisms of OCT and best practices can help avoid and minimize the impact of any device-related issue.

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