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Original Research

Impact of Artificial Intelligence-Enhanced Optical Coherence Tomography Software on Percutaneous Coronary Intervention Decisions

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ABSTRACT

Background: Integration of intravascular imaging into percutaneous coronary intervention (PCI) workflow demands physician time and expertise. Artificial intelligence (AI)-enabled software that automates the identification of key intravascular imaging parameters has the potential to streamline physician workflow, increase accuracy, and reduce variability in PCI planning decisions. This study investigated if AI-enabled software, Ultreon (Abbott), compared with traditional software, AptiVue (Abbott), improved physician decision-making accuracy, variability, and efficiency in optical coherence tomography (OCT)-based PCI planning.

Methods: In this multireader, multicase study, 30 interventional cardiologists of varying OCT imaging experience evaluated 21 pre-PCI OCT pullbacks using both Ultreon and AptiVue platforms. Physician PCI planning decisions about lesion morphology, length, and diameter were compared to published best practices. Decision accuracy, variability, and time efficiency were assessed using statistical models.

Results: Physician OCT-based planning decisions were more accurate using Ultreon compared to AptiVue in the identification of calcium severity by 1.77 (95% CI, 1.27-2.50; $P < .001$), vessel preparation strategy by 2.00 (95% CI, 1.12-3.4; $P = .018$), and stent diameter by 2.83 (95% CI, 1.79-4.50; $P < .001$). Physicians exhibited less variability in assessments using Ultreon, especially for distal and proximal stent landing zone, and planned stent length ($P < .0001$). The efficiency of OCT assessments was improved with Ultreon, reducing the duration of OCT assessments by 0.5 minutes ($P < .0001$). The benefits were observed irrespective of the physician's prior OCT experience.

Conclusions: Physician OCT-based PCI planning decisions were more accurate, less variable, and more efficient with AI-enhanced Ultreon software. This could potentially aid in the fuller adoption of intravascular imaging in PCI workflow.

Introduction

Intravascular imaging guidance of percutaneous coronary intervention (PCI) is associated with multiple benefits,[1–3] yet adoption is limited.[4] Integrating intravascular imaging into PCI workflow requires physician time and expertise, both potential barriers to more fulsome adoption.[5] Frameworks such as the MLD MAX (where MLD stands for plaque Morphology, lesion Length, vessel Diameter, and MAX for Medial dissection, stent Apposition, and stent eXpansion) workflow can help physicians focus on relevant optical coherence tomography (OCT) parameters,[6–8] but still do not obviate expertise requirements for image interpretation. Enhancing image interpretation software with artificial intelligence (AI) could address this gap.[9] AI-enabled software could allow physicians to identify OCT parameters relevant to PCI more consistently and accurately while reducing image interpretation time.

Ultreon (Abbott), an AI-enabled software platform, highlights OCT features relevant to planning PCI to assist user's decision-making (Figure 1). It was developed to provide better insights through automation and an improved workflow compared to the previous software version, AptiVue (Abbott) (Supplemental Table S1). AI automation facilitates PCI planning within the MLD MAX framework by automatically detecting calcium relevant to plaque modification, identifying appropriate stent landing zones relevant to selecting a stent length, and automatically detecting lumen and external elastic lamina (EEL) relevant to selecting a stent diameter.

In this study, we ask physicians to plan a stenting strategy with both Ultreon and AptiVue software platforms. We compare the accuracy,

Abbreviations: AI, artificial intelligence; EEL, external elastic lamina; MLD MAX, plaque Morphology, lesion Length, vessel Diameter, Medial dissection, stent Apposition, stent eXpansion; OCT, optical coherence tomography; PCI, percutaneous coronary intervention.

Keywords: accuracy; artificial intelligence; drug-eluting stent; efficiency; innovation; optical coherence tomography.

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Figure 1.
Graphical User Interface difference between Ultreon and AptiVue. Ultreon display provides guided workflow screens for morphology (top left) and sizing (top right) compared to the AptiVue display (bottom). Compared to AptiVue, Ultreon display provides additional augmentation to aid in stent planning: (**A**) automated calcium detection over the user set threshold is displayed on the angio image to match the automated detection display in the lumen profile (**B**), calcium arc is displayed in orange on the 2D cross-section (**B**) with total angle in degrees calculated frame-by frame, maximum calcium thickness is automatically detected and displayed in millimeters frame-by-frame (**C**) and the location of maximum thickness is denoted by a white indicator on the 2D cross-section (**D**), frames with at least 180° of external elastic lamina (EEL) detection are denoted by a white dashed line in the lumen profile to aid in stent landing zone selection (**E**), and mean EEL diameter is displayed in the 2D cross-section frame-by-frame when at least 180° of EEL is detected to aid in stent diameter selection (**F**).

variability, and efficiency of these decisions across a range of physician expertise in OCT interpretation to gain insight into the additive value of AI-enhanced software.

Methods

Study design

This is a multireader, multicase (MRMC) study executed prospectively with 30 interventional cardiologists evaluating 21 pre-PCI OCT pullbacks obtained previously from the LightLab Initiative[6] designed to evaluate the impact of AI and prior OCT imaging experience on accuracy, variability, and efficiency of physician treatment decision-making. Physicians performed offline evaluations of pre-PCI OCT pullbacks assessing "MLD" from the MLD MAX workflow[7,8,10] over a series of 4 test sessions occurring on separate days with each session dedicated to a single software version (Ultreon 1.0 Software [Ultreon] or AptiVueE.5 Software [AptiVue]), with each software session repeated once. The order of the 21 pullbacks was randomized for each of the 120 test sessions according to a prespecified test plan (21 pullbacks × 2 software × 3 user groups × 10 physicians per user group × 2 replicates).

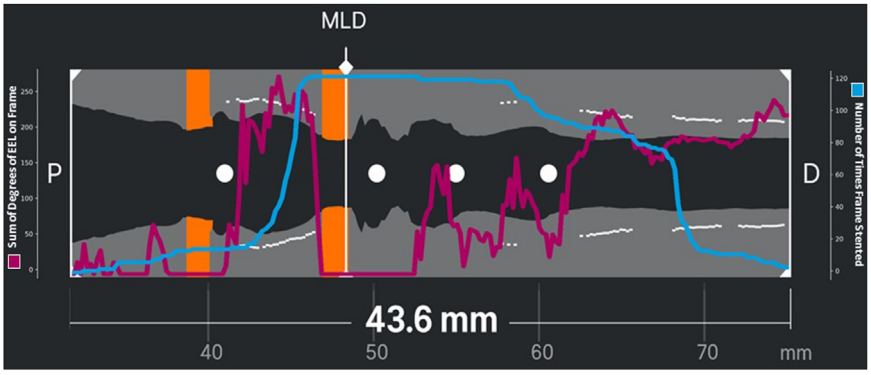


Figure 2.
Overlay of physician stent plan on optical coherence tomography pullback. Longitudinal view of optical coherence tomography pullback in Ultreon where the orange vertical bars identify frames with calcium greater than 180° arc length, white dots identify side branches, and white lines identify external elastic lamina (EEL) visualization greater than 180° arc length overlayed with the sum of visible EEL degrees (purple) and the total number of physician assessments that placed a stent over the frame number region (blue). Each pullback was assessed a total of 120 times (30 physicians × 2 software × 2 replicates).

The test sessions were conducted between October 14, 2021, through March 16, 2022, involving 30 physicians with varying OCT imaging experience defined by OCT use within the last 12 months. Each OCT experience group consisted of 10 physicians: new (0-5 OCT-guided PCI), occasional (6-34 OCT-guided PCI), and routine (35+ OCT-guided PCI) all of whom did not have previous exposure to Ultreon. Institutional review board approval was not required due to the retrospective, offline nature of the study.

OCT pullbacks

Pre-PCI OCT pullbacks were all 75 mm in length and obtained using 5 frames per mm over 2.1 secs for OCT and were required to have adequate image quality with angiographic coregistration. Pullbacks with complex anatomical features (bifurcation lesions requiring 2-stent treatment, chronic total occlusions, in-stent restenosis, lesions longer than 38 mm, lesions located in the left main or a bypass graft) were excluded so as to not confound data interpretation or prompt physician recollection of prior treatment plan responses (Supplemental Figure S1). A total of 21 pre-PCI pullbacks were selected with varying degrees of calcification and lesion lengths (Supplemental Table S2).

OCT software training

Physicians were trained on the software used in the test session prior to the start of the OCT pullback evaluations by Abbott Vascular Field Clinical Specialists (FCS). Training content and method of delivery were standardized for all physicians ensuring the only variable was their prior experience with AptiVue (Supplemental Methods). Training content included OCT image interpretation (terminology, vessel, and lesion morphology), software navigation (specific for Ultreon or AptiVue), MLD MAX clinical decision-making, and instructions for data collected from the pullback evaluations.

Data collection

Physicians assessed OCT pullbacks for MLD (Supplemental Table S3) on demonstration OCT laptops containing either the Ultreon or AptiVue software. Their responses were recorded first via manual data entry on paper forms and then transcribed into Microsoft Forms (Microsoft) by Abbott FCS and independently verified. After training was completed, the FCS did not provide guidance to physicians during the OCT pullback assessment.

Primary end points

The primary end points for this study are as follows: physician decision accuracy, variability, and interpretation time of OCT pullbacks.

Criteria for assessment accuracy were based on guidance from MLD MAX workflow (Supplemental Methods); these logistical rules were applied to the per-frame AI output to generate the ground truth. Accuracy was determined by comparing the physician decisions to the ground truth (Supplemental Figures S2-S5). Variability was based on the assessment of variance, and efficiency was based on the length of time measured to assess the pullback and provide the treatment plan.

Statistical analysis

Accuracy was evaluated using a logistic mixed-effect model for binomial outcomes. Variability was evaluated using variance component analysis with a log-linear variance model. Efficiency was evaluated using a linear mixed-effect model. We estimated a minimum sample size of 80 OCT pullback evaluations per experience group would have 90% power to provide evidence of statistical significance. The details of the statistical methods are included in Supplemental Methods. Continuous variables are expressed as mean and SD. Categorical variables are expressed as counts and percentages. Statistical analyses and

Table 1. Accuracy of physician assessment and treatment plan per MLD MAX criteria by physician experience.

Assessment	AptiVue N = 1259[a]			Ultreon N = 1260		
	New[a] n = 419	Occasional n = 420	Routine n = 420	New n = 420	Occasional n = 420	Routine n = 420
Calcification severity	196/419 (47%)	204/420 (49%)	244/420 (58%)	236/420 (56%)	240/420 (57%)	258/420 (61%)
Vessel preparation	369/419 (88%)	371/420 (88%)	378/420 (90%)	386/420 (92%)	388/420 (92%)	394/420 (94%)
Distal stent edge landing zone	359/419 (85%)	360/420 (86%)	365/420 (87%)	363/420 (86%)	374/420 (89%)	374/420 (89%)
Proximal stent edge landing zone	248/419 (59%)	244/420 (58%)	232/420 (55%)	246/420 (59%)	258/420 (61%)	253/420 (60%)
Stent diameter	347/419 (83%)	378/420 (90%)	377/420 (90%)	388/420 (92%)	392/420 (93%)	390/420 (93%)

Values are n/N (%).
MLD MAX, plaque Morphology, lesion Length, vessel Diameter, Medial dissection, stent Apposition, stent eXpansion.
[a] In 1 assessment, the physician stated he would not stent the lesion; hence, an accuracy assessment could not be performed.

Table 2. Odds ratios for accuracy of fixed-effect factors.

Fixed-effect factor	Calcification severity	Vessel preparation	Distal EEL	Proximal EEL	Stent diameter
Software (Ultreon)	1.77 (1.27-2.5) (< .001)	2.00 (1.12-3.4) (.018)	1.16 (0.65-2.1) (.62)	0.94 (0.61-1.4) (.765)	2.83 (1.79-4.5) (< .001)
Experience (occasional)	1.10 (0.62-2.0) (.74)	1.20 (0.42-3.3) (.751)	0.97 (0.45-2.1) (.93)	0.89 (0.56-1.4) (.642)	2.03 (1.17-3.5) (.012)
Experience (routine)	1.98 (1.11-3.5) (.020)	1.50 (0.53-4.3) (.439)	1.17 (0.54-2.5) (.69)	0.68 (0.42-1.1) (.100)	1.92 (1.11-3.3) (.019)
Software (Ultreon) × Experience (occasional)	0.96 (0.60-1.5) (.849)	1.0 (0.47-2.3) (.909)	1.7 (0.73-3.9) (.22)	1.51 (0.82-2.8) (.185)	0.57 (0.29-1.1) (.111)
Software (Ultreon) × Experience (routine)	0.69 (0.43-1.1) (.119)	1.10 (0.48-2.5) (.837)	1.36 (0.58-3.2) (.47)	1.75 (0.96-3.2) (.067)	0.54 (0.28 -1.1) (.076)

Values are odds ratio (95% CI) (*P* value).
EEL, external elastic lamina.

sample size justification were conducted using R Version 4.2.2 (R Core Team 2022), NCSS PASS (NCSS, LLC), and JMP statistical software (JMP Statistical Discovery, LLC). A *P* value $< .05$ was considered statistically significant.

Results

The study resulted in 2520 assessments as planned. Figure 2 visually depicts the stenting treatment plan from 120 assessments for a single OCT pullback in the study.

Accuracy

Table 1 shows Ultreon had a higher proportion of accurate assessments compared to AptiVue. Table 2 presents the results of the mixed effects model, which includes the odds ratios for the accuracy of fixed-effect factors of software and prior OCT imaging experience as predictors and their interactions. The main effect of software indicated that Ultreon had improved odds of accuracy compared to AptiVue for calcification severity at 1.77 (95% CI, 1.27-2.50; $P < .001$), vessel preparation strategy at 2.00 (95% CI, 1.12-3.4; $P = .018$), and stent diameter at 2.83 (95% CI, 1.79-4.50; $P < .001$). However, the distal and proximal stent edge landing zones were not significant. Moreover, the study found that OCT experience significantly improved the odds of accuracy for occasional and routine users compared to new users. For stent diameter, the improvement was statistically significant at 2.03 (95% CI, 1.17-3.50; $P = .012$) and 1.92 (95% CI, 1.11-3.0; $P = .019$), respectively. For calcification severity, OCT experience significantly improved the odds of accuracy for routine users by 1.98 (95% CI, 1.10-2.50; $P = .0203$). Other fixed effects did not have a significant odds ratio. However, interaction terms between software and OCT experience levels showed no significant difference in accuracy between software for more OCT experience levels compared to the new experience level.

Variability

Table 3 shows a statistically significant percentage of reduction, on average, in variability with Ultreon for physician assessments: distal stent landing zone, proximal stent landing zone, and planned stent length by 15%, 24%, and 17%, respectively ($P < .0001$ for each). No difference in variability was observed for the planned stent diameter ($P = .2914$). The analysis also presented that Ultreon has 25% less variance in OCT assessment duration compared to AptiVue ($P < .0001$).

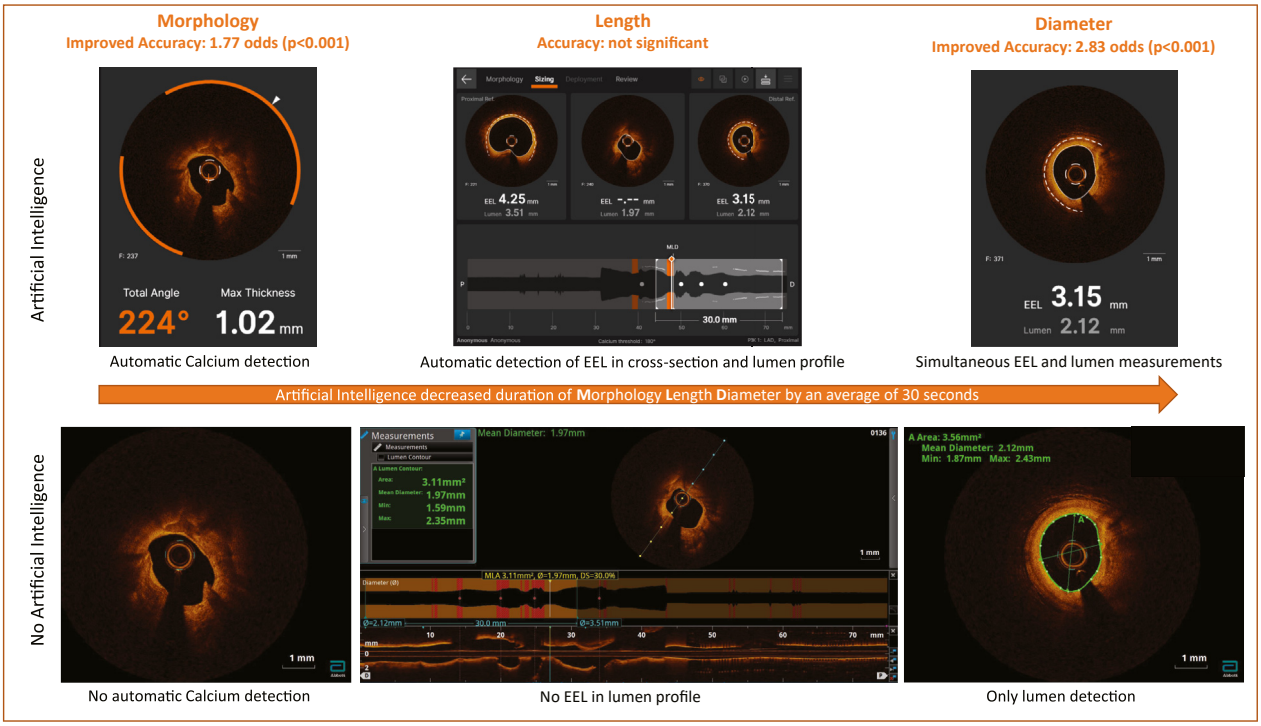
Efficiency

Supplemental Figure S6 visually shows the difference in OCT assessment duration identified as significant through the linear mixed model with the least square mean estimates of AptiVue (2.3 minutes) to Ultreon (1.8 minutes) ($P < .0001$).

Table 3. Variability between software types for OCT assessments of continuous outputs.

Assessment	Parameter estimate[a]	*P* value
Distal stent landing zone	1.157006	< .0001
Proximal stent landing zone	1.243052	< .0001
Planned stent length, mm	1.176803	< .0001
Planned stent diameter, mm	0.969301	.2914
Duration of OCT assessment, min	1.255186	< .0001

OCT, optical coherence tomography.
[a] Parameter estimates are the exp (estimate) where parameter estimates >1 correspond to lower variability for Ultreon compared to AptiVue.



Central Illustration.
Multi-reader, multi-case study of 30 interventional cardiologists evaluating 21 pre-PCI OCT pullbacks in 4 test sessions with and without AI-enhanced OCT software in PCI planning using the Morphology Length and Diameter algorithm. In the top row, AI enhanced calcium detection, external elastic lamina in cross section and lumen profile for length assessment and simultaneous external elastic lamina and lumen measurements for diameter assessment are shown. AI enhanced software was associated with increased accuracy, reduced variability and improved efficiency of planning decisions.

Discussion

This is the first study to investigate the potential benefits of AI-enhanced software on OCT-based PCI planning decisions. We identified 3 key findings: (1) physician accuracy of OCT-based MLD MAX PCI planning decisions improved with AI-enhanced Ultreon software; (2) variability in physician MLD MAX decision-making was reduced with AI-enhanced Ultreon software; (3) decision time was reduced with AI-enhanced Ultreon software. Importantly, physician accuracy was independent of experience level using the AI-enhanced Ultreon software in comparison to the conventional AptiVue platform (Central Illustration).

These benefits are best understood by considering the relevance of AI enhancements within the OCT-based PCI planning decisions required of physicians. Ultreon AI enhancements include automated detection and quantification of calcium and EEL. Detecting calcium and EEL requires training and expertise.[13] For example, calcium must be distinguished from lipids and artefacts, both with similar optical characteristics.[14] Automated detection of calcium, and quantification of its arc streamlines physicians' decision-making around whether advanced lesion preparation is required by facilitating the differentiation of calcium from its mimickers. Similarly, automated detection of EEL allows the identification of safe landing zones (where more than 180° of EEL is present) and corresponding stent length between safe proximal and distal landing zones. This aids the physician's decision-making process in recognizing EEL and whether the safe landing zone threshold is met. Enhanced accuracy, reduced variability, and enhanced decision efficiency could be anticipated from these automated AI enhancements. Although stent diameter decisions can be derived from luminal diameters in both AptiVue and Ultreon platforms, automated detection of EEL and EEL-based vessel size measurement in the Ultreon platform may account for increased accuracy of stent diameter choice. Within the AptiVue platform, physicians may default to less accurate lumen sizing resulting in consistent but less accurate stent diameter choice.

Eye tracking data support these hypotheses.[15] Physicians took less time to focus on task-relevant information and less time to make PCI planning decisions in the Ultreon versus the AptiVue platform. This suggests that the AI-enhanced software allowed physicians to spend less time orienting and making sense of the cross-sectional imaging, leveraging the AI autodetection of calcium and EEL to jump to the quantifications required in PCI decision-making. These differences in eye movements and decision time were found among both experienced and less experienced physicians, consistent with the reduced variability in decision-making found in this study.

Not unlike other areas of medicine where AI is integrated into software, trained physician oversight to vet AI-enhanced output remains an important strategy to safeguard against errors.[9] Ultimately, PCI planning decisions are the responsibility of the physician whose expertise is important in leveraging AI-based software support. Although this study included physicians with a range of prior OCT-based PCI planning experience, the availability of AI enhancements does not obviate the need for physician training to ensure the AI interpretation is accurate and appropriately applied in OCT-based PCI planning decisions. This is particularly important among new users, where variability and accuracy of intravascular imaging interpretation may be more of a concern.[13]

Limitations

Several limitations warrant consideration. First, the use of retrospective offline review of OCT pullbacks does not fully capture the complexities of real-time decision-making. This simplification of the decision-making environment may underestimate the impact of AI enhancements as competing demands in the clinical environment are likely to strain physician attentional resources and decision-making. Second, this is not an outcomes study. As a result, the impact of AI

on patient outcomes is unclear. Third, although the accuracy of AI in detecting and quantifying plaque components is more accurate and consistent than the groups of experts,[16] there was no histologic confirmation of AI identification of calcium in this study. Fourth, the exclusion criteria limited the complexity of lesions used in this study. The incremental value of OCT-based AI software in physician decision-making around more complex lesions would not have been captured in this study. Finally, this study focused on OCT-based PCI planning decisions. We did not explore the integration of other sources of planning information including coronary CT scans or physiological pullbacks, which may be part of a comprehensive approach to PCI planning.

Conclusion

This study provides valuable insights into the potential benefits of integrating AI into intravascular imaging software for OCT-based PCI planning. Physicians using AI-enhanced software made PCI planning decisions using the MLD MAX framework that were more accurate, less variable, and more time efficient.

Acknowledgments

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Declaration of competing interest

Matthew Sibbald received honoraria from Abbott Vascular. Haley R. Mitchell and Jana Buccola are employees of Abbott Vascular. Natalia Pinilla-Echeverri is a consultant and speaker, received research grant support, and served on the advisory board for Abbott Vascular.

Funding sources

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Ethics statement and patient consent

Institutional review board approval was not required due to the retrospective, offline nature of the study. Deidentified and anonymized OCT pullbacks from the LightLabs Initiative were used with permission from the study team/sponsor.

Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at 10.1016/j.jscai.2024.102438.

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