

ORIGINAL RESEARCH

EMERGING TECHNOLOGIES AND INNOVATIONS

Accuracy of IVUS-Based Machine Learning Segmentation Assessment of Coronary Artery Dimensions and Balloon Sizing



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ABSTRACT

BACKGROUND Accurate intravascular ultrasound (IVUS) measurements are important in IVUS-guided percutaneous coronary intervention optimization by choosing the appropriate device size and confirming stent expansion.

OBJECTIVES The purpose of this study was to assess the accuracy of machine learning (ML) automatic segmentation of coronary artery vessel and lumen dimensions and balloon sizing.

METHODS Using expert analysis as the gold standard, ML segmentation of 60 MHz IVUS images was developed using 8,076 IVUS cross-sectional images from 234 patients, which were randomly split into training (83%) and validation (17%) data sets. The performance of ML segmentation was then evaluated using an independent test data set (437 images from 92 patients). The endpoints were the agreement rate between ML vs experts' measurements for appropriate balloon size selection, and lumen and acute stent areas. Appropriate balloon size was determined by rounding down from the mean vessel diameter or rounding up from the mean lumen diameter to the next balloon size. The difference of lumen area $\geq 0.5 \text{ mm}^2$ was considered as clinically significant.

RESULTS ML model segmentation correlated well with experts' segmentation for training data set with a correlation coefficient of 0.992 and 0.993 for lumen and vessel areas, respectively. The agreement rate in lumen and acute stent areas was 85.5% and 97.0%, respectively. The agreement rate for appropriate balloon size selection was 70.6% by vessel diameter only and 92.4% by adding lumen diameter.

CONCLUSIONS ML model IVUS segmentation measurements were well-correlated with those of experts and selected an appropriate balloon size in more than 90% of images. (JACC Adv 2023;2:100564) © 2023 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

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**ABBREVIATIONS
AND ACRONYMS****AI** = artificial intelligence**CNN** = convolution neural network**DES** = drug-eluting stent(s)**DSC** = dice similarity coefficient**IoU** = intersection over union**IVUS** = intravascular ultrasound**ML** = machine learning**PCI** = percutaneous coronary intervention

Intravascular ultrasound (IVUS) is used to guide percutaneous coronary intervention (PCI) in treating coronary artery disease,^{1,2} and IVUS guidance has improved patient outcomes in both short- and long-term follow-up compared with angiography alone.³⁻⁷ The 2021 American Heart Association/American College of Cardiology and Society of Cardiovascular Angiography and Interventions Guideline for Coronary Artery Revascularization and the 2018 guidelines from the European Society of Cardiology give a Class 2a recommendation for IVUS guidance in patients undergoing coronary stent implantation.^{8,9} However, the real-world usage of IVUS guidance remains low despite its benefits.^{10,11} One possible reason is the lack of physician education leading to misinterpretation of IVUS images.¹² IVUS measurements must be accurate in the clinical setting.

The medical field is taking advantage of artificial intelligence (AI) technology with regard to diagnostic imaging interpretation. We hypothesized that intravascular imaging could also benefit from AI. Fully automatic assessment of vessel geometry such as lumen, vessel wall, and plaque burden using IVUS should greatly facilitate diagnosis and treatment planning by reducing the time and effort needed to manually obtain key measurements. Several image segmentation technologies based on traditional filter design and pattern recognition for automatic IVUS image segmentation have been developed over the decades, but with limited success and/or adoption.¹³

Recent advancements in deep machine learning (ML) technologies with convolution neural networks (CNNs) have provided a potential solution to this challenge.¹⁴⁻¹⁷ The key difference between the new CNN and traditional pattern recognition is the increase in the “depth” of the network, providing millions of parameters that can be trained to match the input with desired output to mimic the capability of an expert. This study aimed to assess the accuracy of ML automatic segmentation of coronary artery vessel and lumen dimensions and balloon sizing using high-definition (HD) IVUS images.

METHODS

STUDY DATA SET. Two separate data sets were pre-specified. The first data set was used for training and validation, and the second data set was used for independent testing. All IVUS images were taken using the HD 60 MHz IVUS OptiCross IVUS catheter paired with the iLab Polaris Multi-Modality Guidance System

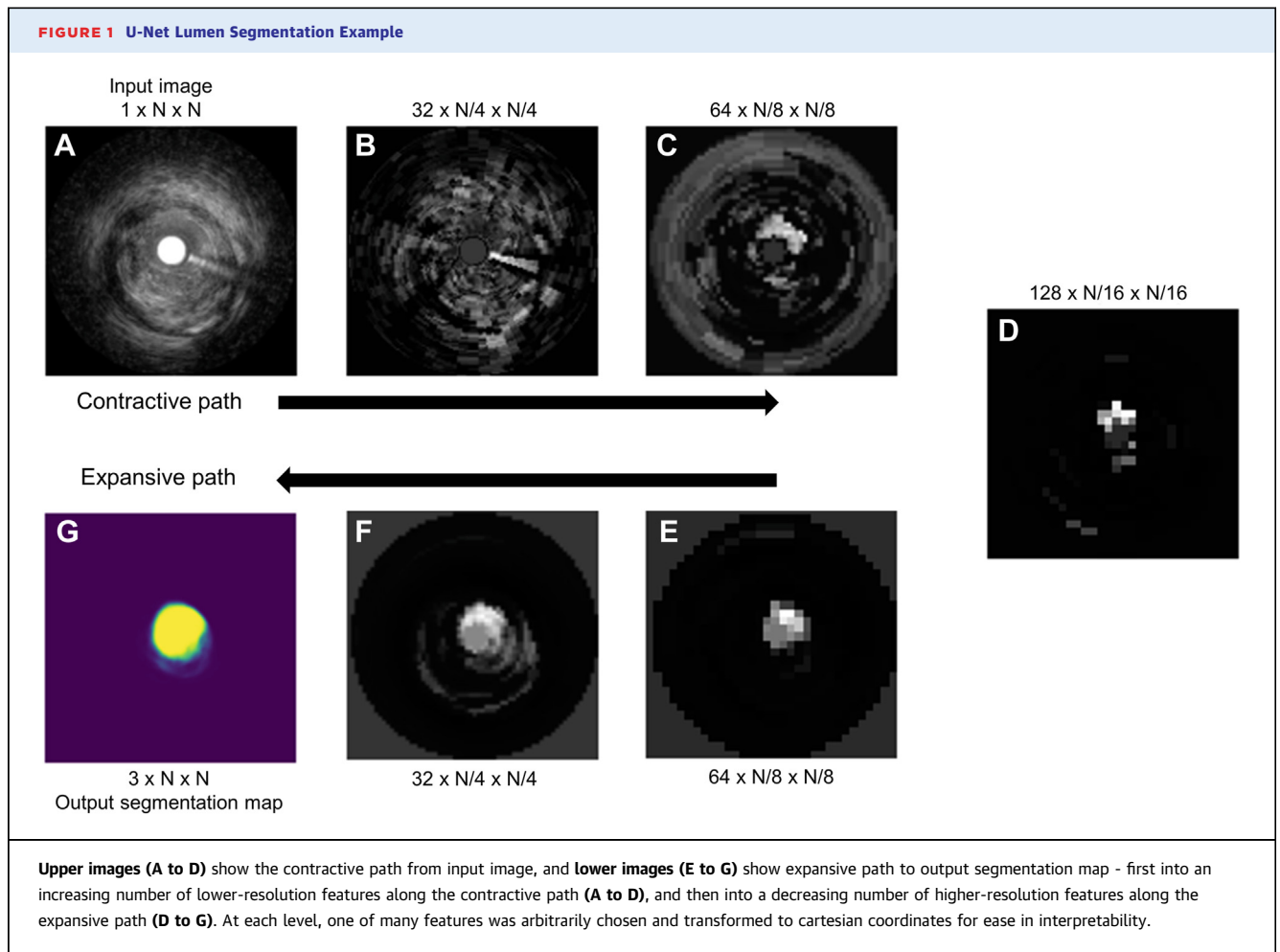
(Boston Scientific Corporation). IVUS was performed in a standard manner using an automated transducer pullback at 0.5 or 1.0 mm/s with a 40 mm or longer pullback length. The first data set included 8,076 IVUS cross-sectional images from 234 patients located in Asia, Europe, or the United States; and the second data set included 437 cross-sectional images from 92 patients from the United States. Of note, images from each institution including U.S. sites were included in either the first or second data set, but not both. The Institutional Review Board of all sites approved the study protocol and patient consent was waived due to minimal risk.

IVUS IMAGE ANALYSIS. In both the first and second data sets, the lumen or stent and vessel areas were analyzed by experts using a preloaded Polaris simulator. In the first data set, the analysis was done for the entire vessel; whereas in the second data set, the analysis was done at the minimum lumen area site, minimum stent area site if stented, and proximal and distal reference sites. Proximal and distal reference sites were the least plaque burden within 5 mm of the edge of the lesion but before any major side branch (>1.5 mm in diameter). Mean lumen and vessel diameters were calculated from the lumen or vessel area.

IVUS U-NET MODEL DEVELOPMENT. The ML segmentation algorithm was trained using expert analysis as the gold standard. In the first data set, the training data set (83% of images) and validation data set (17% of images) were randomly selected; and the IVUS images from one patient were either in the training or validation data set, but not both. In addition, image argumentation techniques were applied to eliminate the effect from IVUS image variations such as brightness and the orientation of an IVUS cross-section image.

Among various types of CNNs, the “U-Net” has been one of the most successful ML architectures for biomedical image segmentation. An example of U-Net lumen segmentation has been shown in [Figure 1](#). The input for the model was a resized IVUS image as a contractive path, which is to enhance the object of interest by losing other details while the output of the model was the mask image as an expansive path to create vessel, lumen, and stent areas separately with a high-resolution segmentation map. In the end, the output segmentation masks had the same resolution as the input image. Representative images have been shown in [Figure 2](#).

PRIMARY ENDPOINT. The primary endpoint was the agreement rate of appropriate balloon size selection between ML vs expert analysis at the individual slice



level in an independent data set. First, the appropriate balloon size was determined by rounding *down* from the mean *vessel* diameter to the next balloon size. If the ML chosen balloon size was different from the expert, the appropriate balloon size was then determined by rounding *up* from the mean *lumen* diameter to the next balloon size.¹⁸ The endpoint was repeated at the lesion level.

Because the post-PCI absolute lumen or stent area is the most powerful parameter to be associated with the long-term outcome, we set the secondary endpoint as the agreement rate in lumen area between ML vs expert analysis using a difference of $<0.5 \text{ mm}^2$ as an acceptable cutoff in IVUS frames having lumen area $<9.0 \text{ mm}^2$.^{19,20} In other words, a difference of $\geq 0.5 \text{ mm}^2$ in lumen area measurement was considered as clinically significant in a $\leq 3.5 \text{ mm}$ angiographic vessel. In addition, the agreement rate in the acute stent area was assessed using the same acceptable cutoff used for the lumen area. As an exploratory analysis, we evaluate interobserver

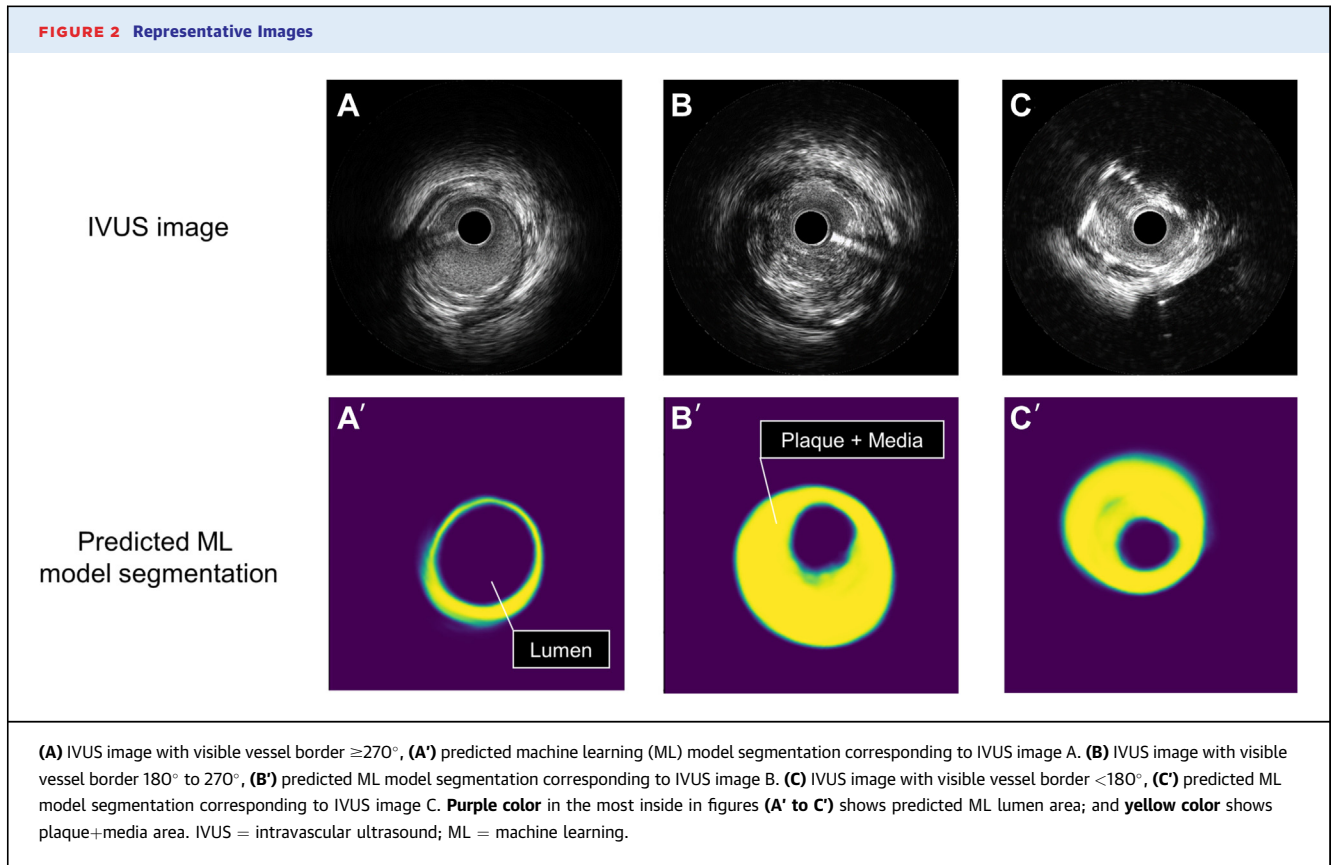
variability of lumen and vessel area measurements between 2 interventional cardiologists and compared them with those obtained between ML and expert analysis.

STATISTICAL ANALYSIS. The primary and secondary endpoints were descriptive and shown as the rate of agreement between ML vs expert analysis. The metrics used for the evaluation were the mean intersection over union (IoU) and dice similarity coefficient (DSC), common evaluation metrics for semantic image segmentation, which first computed the IoU and DSC for each semantic class and then computed the average over classes. IoU and DSC were defined as follows:

$$\text{IoU} = \frac{\text{true positives}}{(\text{true positives} + \text{false positives} + \text{false negatives})}$$

$$\text{DSC} = \frac{2 \times \text{true positives}}{(2 \times \text{true positives} + \text{false positives} + \text{false negatives})}$$

To assess the practical validity, the agreement and correlation of the lumen, vessel, and stent areas between the ML model segmentation and the



expert analysis were assessed by Pearson correlation coefficient, and mean differences were visualized by scatter and Bland-Altman plots. Continuous variables were expressed as mean \pm SD or 95% CI. Interobserver variability of lumen and vessel areas was tested between ML analysis vs expert analysis, and between 2 interventional cardiologists in 40

randomly selected IVUS images using an intraclass correlation coefficient. A P value < 0.05 was considered to indicate statistical significance. The statistical analyses were performed using EZR statistics version 4.0.2 (R Foundation for Statistical Computing).

RESULTS

ACCURACY OF IVUS-BASED ML SEGMENTATION. In the first data set used for training and validation ($n = 8,076$), the mean areas of the lumen and vessel were $7.5 \pm 3.9 \text{ mm}^2$ and $15.2 \pm 6.6 \text{ mm}^2$, respectively. The diagnostic performance of the ML model segmentation has been summarized in **Table 1**. The ML model segmentation correlated well with expert segmentation for the training data set with a mean IoU of 0.92 ± 0.05 and 0.94 ± 0.04 , correlation coefficients of 0.992 (95% CI: 0.991 - 0.992) and 0.993 (95% CI: 0.993 - 0.994), and mean differences of $-0.09 \pm 0.51 \text{ mm}^2$ and $-0.12 \pm 0.78 \text{ mm}^2$ for lumen and vessel areas, respectively (**Table 1**).

A total of 437 IVUS images in 92 patients were labeled by expert analysis in an independent data set. Of 437 IVUS images, 42 images (9.6%) were within the

TABLE 1 Performance of the Machine Learning-Based Segmentation Against Observers on the Training and Validation Set

	Overall (N = 8,076)	Training (n = 6,669)	Validation (n = 1,407)
Lumen area			
Intersection over union	0.92 ± 0.05	0.92 ± 0.05	0.91 ± 0.06
Dice similarity coefficient	0.96 ± 0.03	0.96 ± 0.03	0.95 ± 0.03
Correlation coefficient	0.991 (0.991-0.991)	0.992 (0.991-0.992)	0.984 (0.983-0.986)
Mean difference	-0.08 ± 0.52	-0.09 ± 0.51	-0.05 ± 0.56
Vessel area			
Intersection over union	0.94 ± 0.04	0.94 ± 0.04	0.93 ± 0.06
Dice similarity coefficient	0.97 ± 0.02	0.97 ± 0.02	0.96 ± 0.03
Correlation coefficient	0.991 (0.991-0.991)	0.993 (0.993-0.994)	0.976 (0.974-0.979)
Mean difference	-0.11 ± 0.88	-0.12 ± 0.78	-0.02 ± 1.26

Values are mean \pm SD or mean (95% CI).

stent, of which 33 images had new stents; and 395 (90.4%) were in a non-stented segment. The mean areas of the lumen and vessel were $6.8 \pm 4.0 \text{ mm}^2$ and $12.7 \pm 5.8 \text{ mm}^2$, respectively. A strong correlation of the lumen area was found between the ML model segmentation and the expert analysis with a mean difference of -0.10 ± 0.54 (correlation coefficient: 0.991 [95% CI: 0.989-0.993], $P < 0.001$) (Table 2, Figures 3A and 3B). Similarly, a strong correlation of the vessel area was found between the ML model segmentation and the expert analysis with a mean difference of 0.29 ± 1.47 (correlation coefficient: 0.967 [95% CI: 0.960-0.973], $P < 0.001$) (Table 2, Figures 3C and 3D). When the vessel area was categorized into 3 groups stratified by visible vessel border, the images having a larger visible vessel border ($\geq 270^\circ$) had less difference when compared to those having a less visible vessel border ($< 180^\circ$) (mean: -0.02 ± 0.50 vs 0.75 ± 2.59 , $P = 0.02$) (Figure 4).

There was a similarly good intraclass correlation coefficient for measurements of lumen and vessel areas between ML and expert analysis (95% CI: 0.998-0.993) and between 2 interventional cardiologists (95% CI: 0.996-0.996), respectively. The mean difference of lumen area between ML and expert and between 2 cardiologists was -0.04 ± 0.43 and -0.13 ± 0.55 , respectively ($P = 0.47$). The mean difference of vessel area was 0.01 ± 1.03 and 0.29 ± 0.86 , respectively ($P = 0.13$) (Supplemental Figure 1).

PRIMARY AND SECONDARY ENDPOINT. The primary endpoint was the agreement rate of appropriate balloon size selection between ML vs expert analysis in an independent data set. Using mean vessel diameter, the rate of agreement was 70.6%, and adding mean lumen diameter, the overall rate of agreement was 92.4% (primary endpoint) (Figure 5, Central Illustration). If only images with visible vessel border $< 180^\circ$ were applied, it was 45.5%, if only images with visible vessel border $\geq 180^\circ$ and $< 270^\circ$ were applied, it improved to 68.9%; and if only images with visible vessel border $\geq 270^\circ$ were applied, it was further improved to 80.7%. By adding the assessment of mean lumen diameter, the rate of appropriate balloon size chosen by ML was improved to 85.2% in visible vessel border $< 180^\circ$, 91.9% in visible vessel border $\geq 180^\circ$ and $< 270^\circ$, and 95.3% in visible vessel border $\geq 270^\circ$.

Because balloons and stents come in 0.25 mm sizes, differences in diameter measurements < 0.25 mm could be considered as acceptable. When a difference of 0.25 mm in the lumen and/or vessel

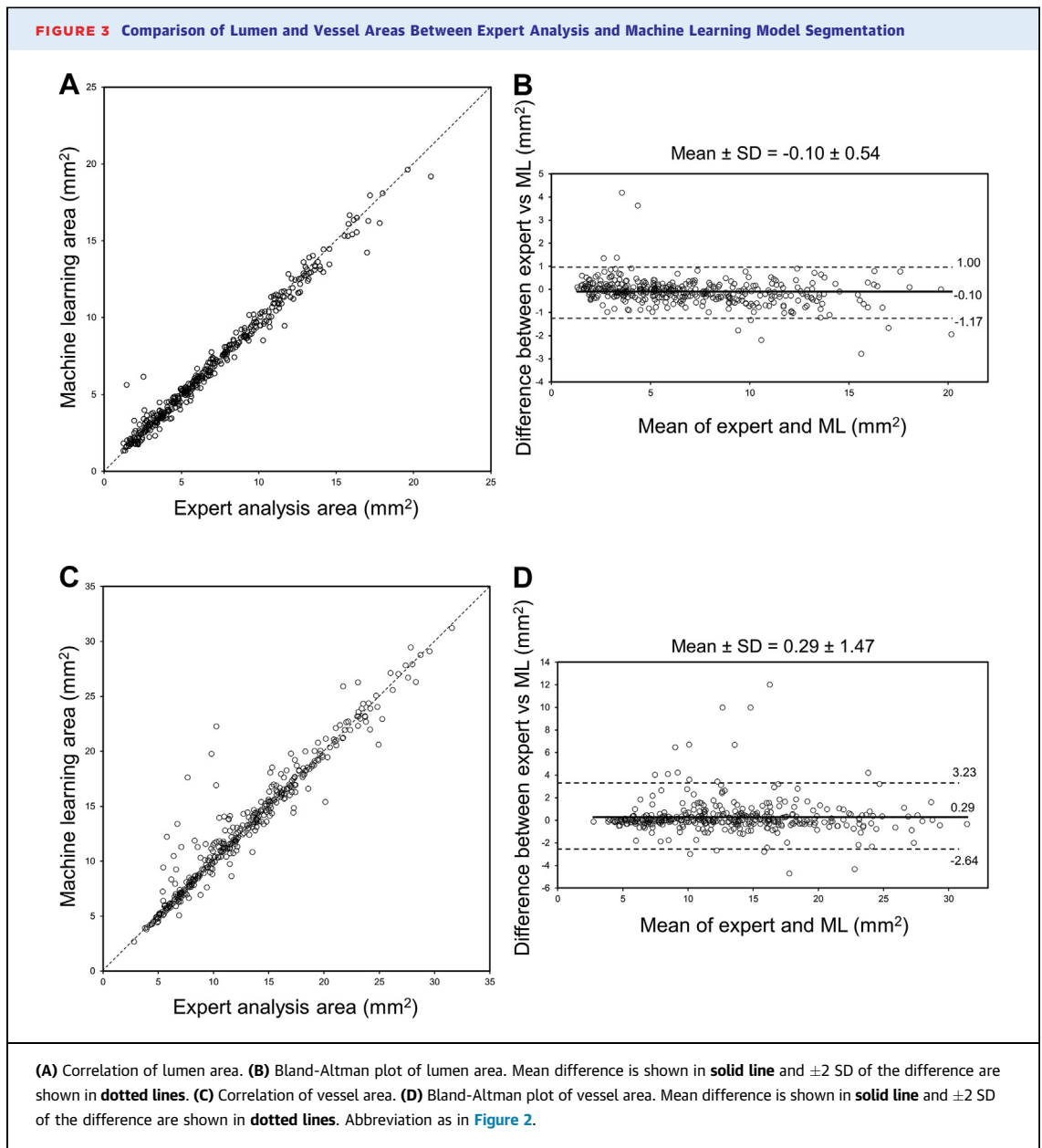
TABLE 2 Correlation Between Machine Learning and Expert Analysis in an Independent Data Set

	Correlation Coefficient	95% CI	P Value	Mean Difference	SD
At slice level (n = 437)					
Lumen area	0.991	0.989-0.993	<0.001	-0.10	0.54
Vessel area	0.967	0.960-0.973	<0.001	0.29	1.47
Stent area	0.982	0.966-0.990	<0.001	0.05	0.46
Mean lumen diameter	0.985	0.981-0.987	<0.001	-0.01	0.13
Mean vessel diameter	0.965	0.958-0.972	<0.001	0.06	0.23
At lesion level (n = 92)					
Lumen area	0.994	0.990-0.996	<0.001	-0.20	0.41
Vessel area	0.987	0.981-0.992	<0.001	0.18	0.81
Mean lumen diameter	0.986	0.979-0.991	<0.001	-0.03	0.10
Mean vessel diameter	0.982	0.973-0.988	<0.001	0.04	0.15

diameters was considered as a cutoff value, 94.4% of the lumen and 88.9% of vessel diameters were within ± 0.25 mm difference (Figure 6). When only images with visible vessel border $\geq 270^\circ$ were included, 97.9% of the images were with ± 0.25 mm difference; when images with visible vessel border $\geq 180^\circ$ and $< 270^\circ$ were included, 89.2% had a ± 0.25 mm difference; and when images with visible vessel border $< 180^\circ$ were included, 63.6% had a ± 0.25 mm difference (Supplemental Figure 2). The prevalence of ≥ 0.5 mm of larger balloon size was observed in 5.3%, which was mostly found in the images with visible vessel borders $< 180^\circ$. Using multivariable linear regression to predict the errors of balloon sizing including the presence of myocardial bridge, vessel diameter by expert, vessel location in left anterior descending, and vessel visibility, vessel visibility was independently associated with the errors of balloon sizing (Table 3).

The secondary endpoint was an 85.5% agreement rate in lumen area between ML vs expert analysis using a difference of $< 0.5 \text{ mm}^{219,20}$ as an acceptable cutoff difference in lesions with lumen area $\leq 9.0 \text{ mm}^2$ (Figure 7). When 5% difference of lumen area was applied for all lumen areas, 76.2% were in agreement; and when lumen area difference $< 0.5 \text{ mm}^2$ or 5% difference of lumen area was applied, 86.3% were in agreement. There were only 33 images with new stents. When the acute stent area was compared between ML vs expert analysis using a difference of $< 0.5 \text{ mm}^2$ as a cutoff, the agreement rate was 97.0% (Central Illustration).

LESION LEVEL ANALYSIS. When we consider the clinical setting, the balloon sizing should be done based on the distal reference vessel diameter first,

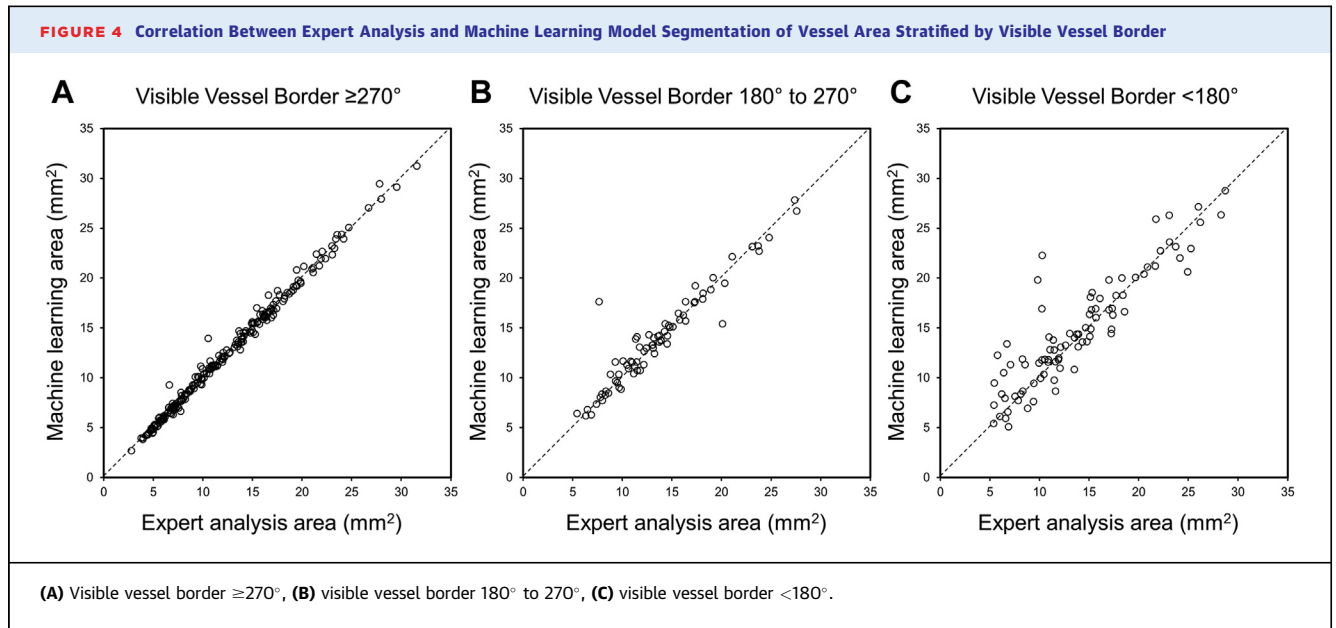


and then lumen diameter if visible vessel border $<180^\circ$. If distal reference is not available, either proximal reference or minimum lumen area sites should be chosen. When we applied this algorithm to the most representative 92 lesions in 92 patients (ie, one lesion per patient), the agreement rate of balloon or stent sizing was 76.1% by using mean vessel diameter and 91.3% by using both vessel and lumen diameters. Lesion level correlation between ML and expert analysis is consistent with slice level analysis ([Table 2](#), [Supplemental Figure 3](#)). Moreover, when we calculate the rate of the different sizing

when using distal or proximal references or the minimum lumen area site in the same lesion, more than 90% of the lesions had different sizing depending on the anatomic location chosen.

DISCUSSION

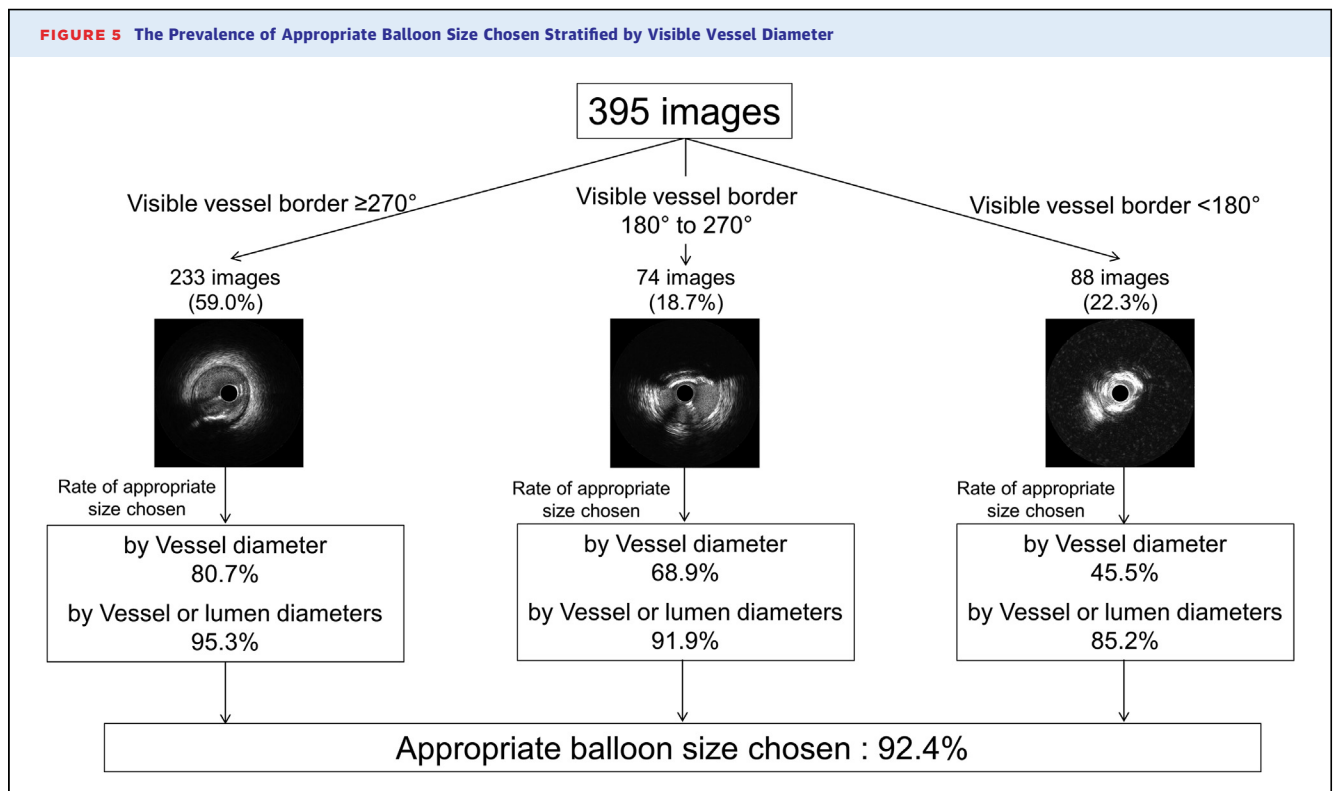
The main findings of this study were that the ML model segmentation of lumen, vessel, and stent areas was strongly correlated with those obtained by manually labeled segmentation. Better visibility of vessel border was associated with more accurate

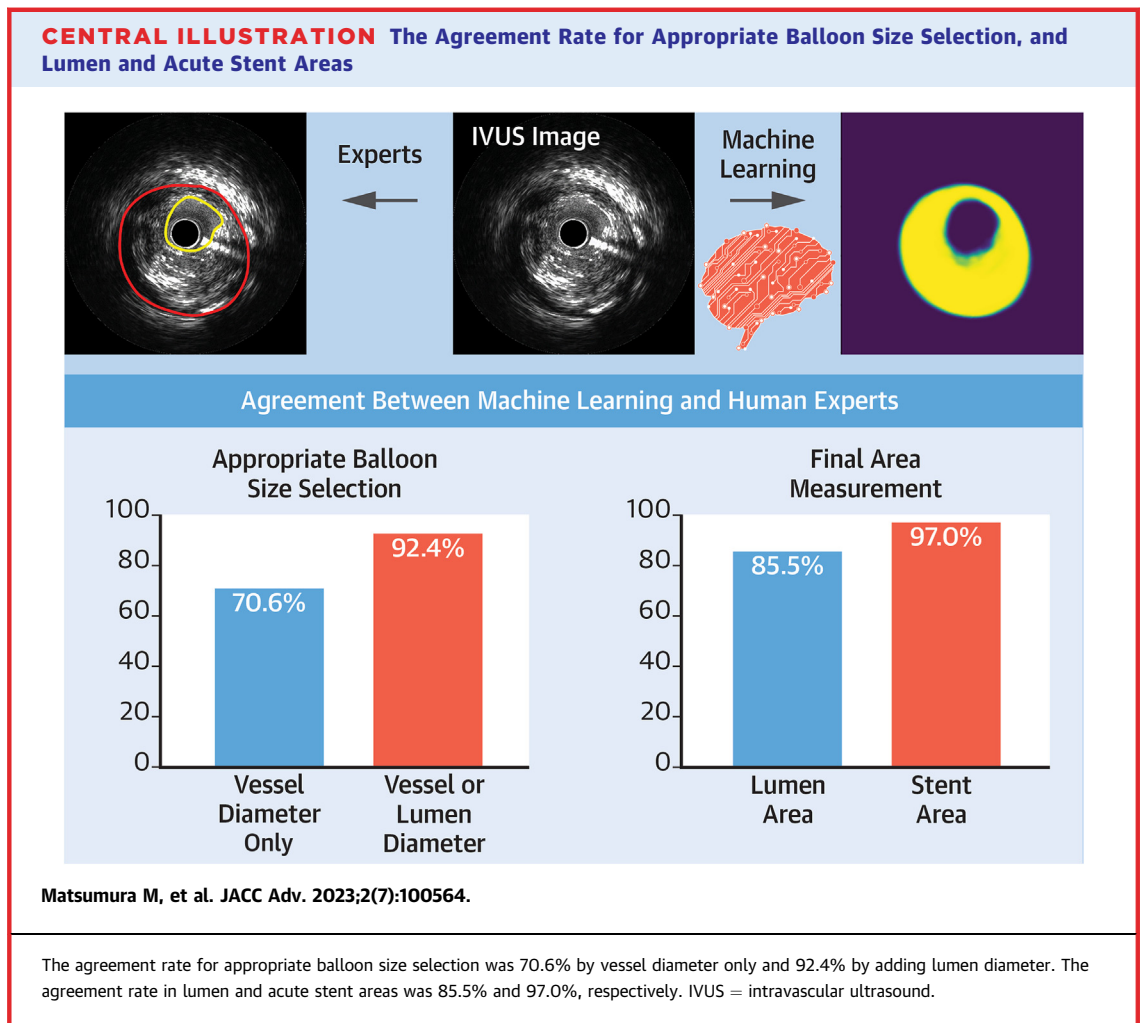


measurements of vessel area by ML model segmentation. Overall, appropriate balloon size was chosen in more than 90% of images by combining vessel and lumen ML measurements. Acceptable lumen and acute stent measurements were seen in more than 85% and 95% of images. The similar levels of SD for

both lumen and vessel areas between ML and expert and between 2 cardiologists indicated the capability of the ML model was approaching to that of a cardiologist.

Recent developments in AI have improved an automated, objective, and quantitative approach to

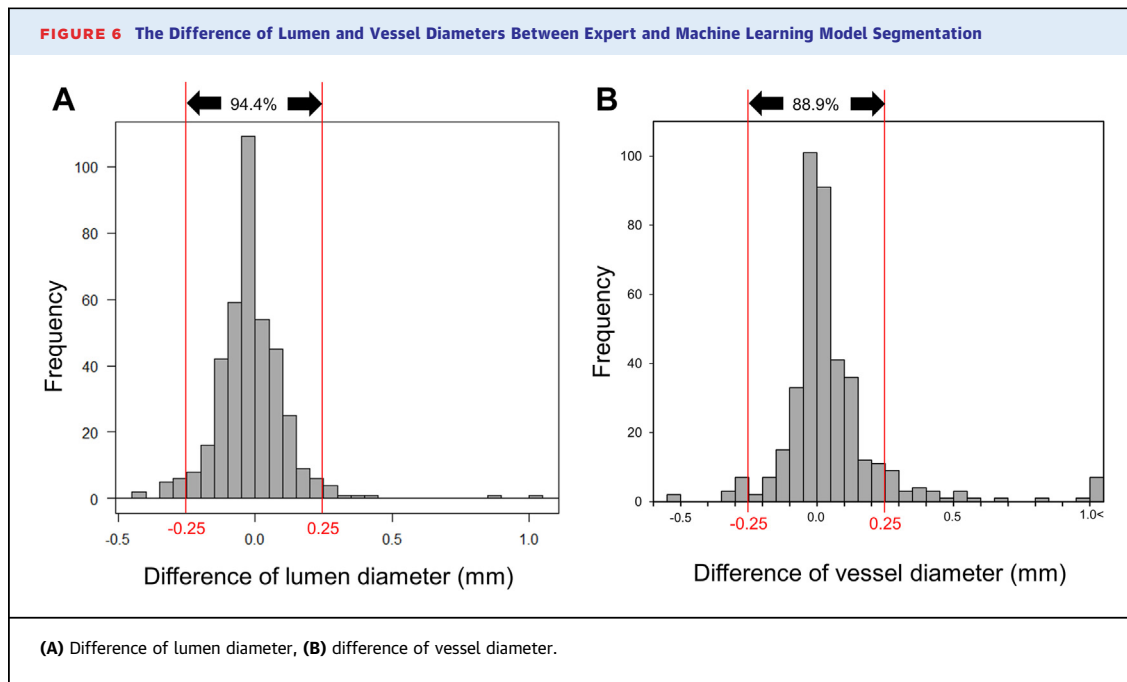




evaluating vessel dimensions with IVUS.¹⁴ Deep learning methods have been proposed to develop automated IVUS segmentation.^{21,22} Recent advancements of deep ML technologies with CNN have achieved relatively high performance for the segmentation of the lumen and vessel areas.^{15,23} Yang et al¹⁵ demonstrated that the IoU of vessel and lumen in the test data set was 0.86 and 0.90 using 20 MHz IVUS from 10 patients. Another study that used a full CNN with encoder/decoder networks with the main body being DeepLabv3 demonstrated that the mean IoU in the test data set was 0.88 using 40 to 45 MHz IVUS from 1,850 images.²³ Thus, ML measurements by HD IVUS suggested more accurate detection of lumen and vessel areas.

In the drug-eluting stent (DES) era, intravascular imaging-guided stent or post-stent balloon sizing recommendations have been based on either: 1) vessel diameters of the proximal reference, distal

reference, or lesion site, usually rounded down by 0.25 mm; or 2) rounded up from the mean lumen diameter¹⁸ or by averaging the media-to-media diameters of the proximal and distal stent segments, as well as at the sites of maximal narrowing within the stent, and the value was rounded to the lower 0.00 or 0.50 mm.²⁴ Conversely, when lumen diameter was used, the expert consensus of the European Association of PCI suggested that a mean distal lumen reference-based sizing with rounding up by 0 to 0.25 mm may represent a safe and straightforward approach with subsequent optimization of the mid and proximal stent segments.⁹ It should be noted that about 15% of lesions may have negative remodeling with less plaque such that stent and/or balloon sizing by ML model segmentation considering not only vessel diameter but also lumen diameter could be more appropriate.²⁵



Numerous prior IVUS studies have reported that absolute minimum stent area, which is clinically the same meaning as minimum lumen area in the stented segment, is the most powerful predictor of clinical events, even in the contemporary DES era.^{26,27} Meta-analyses of randomized trials and registry data have shown significant major adverse cardiovascular event reductions with IVUS-guided PCI compared with angiography-guided PCI.²⁸⁻³⁰ The IVUS-XPL (Impact of Intravascular Ultrasound Guidance on the Outcomes of Xience Prime Stents in Long Lesions) study demonstrated that major adverse cardiovascular event reductions were significant with a hazard ratio of 0.50 (95% CI: 0.34-0.75) in the IVUS-guided cohort compared with the angiography-guided cohort at 5-year follow-up.⁷ In the ULTIMATE (Intravascular Ultrasound Guided Drug Eluting Stents Implantation in “All-Comers” Coronary Lesions) study, which used minimum lumen area in the stented segment as one of the optimal criteria, target vessel failure occurred in 47 patients (6.6%) in the IVUS-guided group and 76 patients (10.7%) in the angiography-guided group ($P = 0.01$), driven mainly by the decrease in clinically driven target vessel revascularization (4.5% vs 6.9%; $P = 0.05$) at 3-year follow-up.⁶ IVUS-guided DES implantation improves outcomes because of a significantly larger minimum stent area and minimum lumen diameter compared to angiography-guided PCI.^{5,18} Therefore, IVUS was beneficial in clinical settings not only for acute larger stent areas but also for long-term outcomes; and IVUS lumen and stent

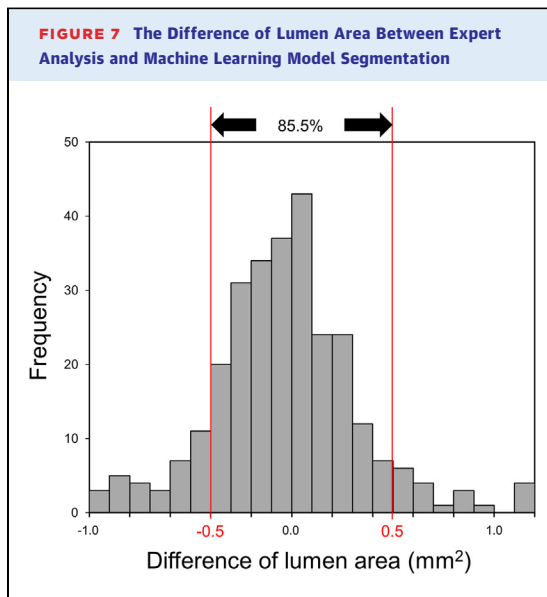
area measurements must be accurate. A survey of interventional cardiology fellows reported that independence and preparedness for practice was only 15% in all components of IVUS.¹² Thus, ML model segmentation might be helpful to generalize IVUS quantitative assessment as well as device selection with accuracy to overcome the lack of experience and/or education.

Lastly, the penetration rate of IVUS usage in daily practice is quite different among the regions.³¹⁻³⁴ The reasons for not using IVUS include finances and education.¹² Prior studies demonstrated that IVUS-guided DES implantation is likely to be cost-effective compared with angiography guidance alone.^{35,36} In terms of the lack of physician education, IVUS measurements must be accurate in the clinical setting because when an inappropriately large sized balloon or stent is chosen, there is a risk of perforation; or an inappropriately small sized balloon or

TABLE 3 Prediction of the Errors of Balloon Sizing Using Multivariable Linear Regression Model

	Regression Coefficient (95% CI)	P Value
Myocardial bridge	-0.03 (-0.14 to 0.08)	0.57
Vessel diameter by expert, mm	-0.01 (-0.04 to 0.01)	0.31
Vessel location in LAD	-0.03 (-0.08 to 0.01)	0.14
Vessel visibility >180°	-0.22 (-0.28 to -0.17)	<0.0001

LAD = left anterior descending.



stent is chosen, stent under-expansion is likely and may result in in-stent restenosis or thrombosis. To overcome the above, ML model segmentation can be very helpful for the physician to choose the appropriate balloon size in daily practice.

STUDY LIMITATIONS. First, the ML model was dedicated to just segmentation of lumen, vessel, and stent areas and did not function for qualitative assessment such as detecting dissection, malapposition, percent stent expansion, and calcified or attenuated regions, which would also be important in the clinical setting. Second, a separate test cohort was selected from one site; and it was relatively small, especially for the stent assessment. Multiple sites from around the world need to be tested to establish the ML model further. Third, we included only HD 60 MHz IVUS images; the constructed ML model was therefore not directly applicable to IVUS images obtained with lower frequency ultrasound signals that have a larger area compared to phantoms.³⁷

CONCLUSIONS

The ML model IVUS segmentation of lumen, vessel, and stent areas was strongly and positively correlated with those obtained in manually labeled expert analysis. More than 90% of images selected an appropriate balloon size by using both vessel and lumen diameters.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: During PCI, IVUS informs appropriate device sizing and good stent expansion to the operators to improve patient outcomes in both short- and long-term follow-up studies compared with angiography alone.

TRANSLATIONAL OUTLOOK: Correlation between ML and experts' lumen and vessel area measurements were excellent. The agreement rates between ML and experts' measurements for both appropriate balloon size selection and lumen measurements were about 90%. Extend ML to identify calcified or attenuated plaques which impact lesion preparation and post-PCI outcomes.

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KEY WORDS balloon sizing, convolution neural network, coronary artery, high-definition intravascular ultrasound, machine learning

APPENDIX For supplemental tables and figures, please see the online version of this paper.