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ORIGINAL RESEARCH

EMERGING TECHNOLOGIES AND INNOVATIONS

FEops HEARTguide Patient-Specific Computational Simulations for WATCHMAN FLX Left Atrial Appendage Closure

A Retrospective Study

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ABSTRACT

BACKGROUND Three-dimensional transesophageal echocardiography (3D-TEE) is the primary imaging tool for left atrial appendage closure planning. The utility of cardiac computed tomography angiography (CCTA) and patient-specific computational models is unknown.

OBJECTIVES The purpose of this study was to evaluate the accuracy of the FEops HEARTguide patient-specific computational modeling in predicting appropriate device size, location, and compression of the WATCHMAN FLX compared to intraprocedural 3D-TEE.

METHODS Patients with both preprocedural and postprocedural CCTA and 3D-TEE imaging of the LAA who received a WATCHMAN FLX left atrial appendage closure device were studied (n = 22). The FEops HEARTguide platform used baseline CCTA imaging to generate a prediction of device size(s), device position(s), and device dimensions. Blinded (without knowledge of implanted device size/position) and unblinded (implant device size/position disclosed) simulations were evaluated.

RESULTS In 16 (72.7%) patients, the blind simulation predicted the final implanted device size. In these patients, the 3D-TEE measurements were not significantly different and had excellent correlation (Pearson correlation coefficient (r) ≥ 0.90). No patients had peridevice leak after device implant. In the 6 patients for whom the model did not predict the implanted device size, a larger device size was ultimately implanted as per operator preference. The model measurements of the unblinded patients demonstrated excellent correlation with 3D-TEE.

CONCLUSIONS This is the first study to demonstrate that the FEops HEARTguide model accurately predicts WATCHMAN FLX device implantation characteristics. Future studies are needed to evaluate if computational modeling can improve confidence in sizing, positioning, and compression of the device without compromising technical success. (JACC Adv 2022;1:100139) © 2022 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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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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ABBREVIATIONS AND ACRONYMS

3D = 3-dimensional

CCTA = cardiac computed tomography angiography

ICE = intracardiac echocardiography

LAAC = left atrial appendage closure

Left atrial appendage closure (LAAC) is an alternative treatment to oral anticoagulation in nonvalvular atrial fibrillation patients who are at high risk of stroke and unsuitable for anticoagulation.[1] LAAC is a safe procedure with a low procedure-related complication rate; however, complete LAAC is not always achieved.[2] Adding to this challenge is the considerable anatomic variation in the LAA which increases procedural complexity. Both cardiac computed tomography angiography (CCTA) and transesophageal echocardiography (TEE) are used to assess the 3-dimensional (3D) anatomy of the LAA.[3,4] CCTA, however, is increasingly used in the preprocedural evaluation and for planning of LAAC and allows for patient-specific computational models to be generated.[4,5] Computational modeling can potentially optimize procedural success by anticipating issues with LAA orifice area and depth, which determines optimal device sizing as well as the number and location of accessory lobes, which may determine optimal device positioning. Additionally, it has the ability to simulate the interaction between the device and LAA tissue which aids in the prediction of final device configuration.

The FEops HEARTguide platform (FEops NV) is cloud-based and uses the virtual twin technology based on patient-specific digital replicas of the heart to aid the clinician with procedural planning and device sizing. The aim of our study was to evaluate the accuracy of implantation prediction of device size, position, and compression, generated with the FEops HEARTguide patient-specific computational model for LAAC with the WATCHMAN FLX device (Boston Scientific)[6] compared to the actual device characteristics as determined by intraprocedural TEE. The primary hypothesis was that the FEops simulated device implantation will accurately represent the interaction of the device with LAA tissue and anatomy.

TABLE 1 Baseline Left Atrial Appendage Sizing: Intraprocedural TEE and FEops CCTA Measurements

	Intraprocedural TEE	FEops CCTA	Mean Difference	Paired *t*-Test *P* Value
Area-based diameter (mm)	21.45 ± 4.39	21.54 ± 4.81	−0.09 ± 1.95	0.83
Perimeter-based diameter (mm)	22.11 ± 4.29	22.12 ± 4.89	−0.01 ± 2.13	0.98
Maximum diameter (mm)	24.40 ± 4.34	24.17 ± 5.20	0.23 ± 3.45	0.76
Minimum diameter (mm)	19.13 ± 5.22	19.91 ± 4.80	−0.79 ± 2.39	0.14

Values are mean ± SD.
CCTA = cardiac computed tomography angiography; TEE = transesophageal echocardiography.

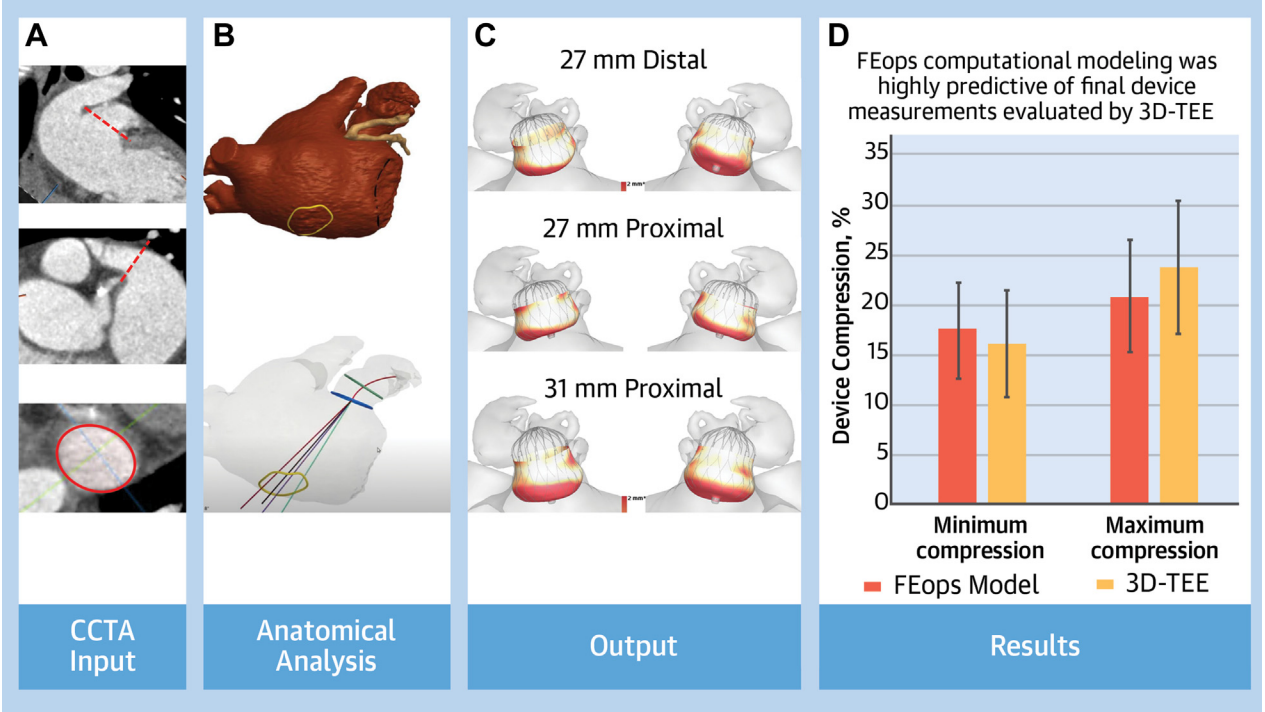
METHODS

STUDY POPULATION. Twenty-two sequential patients who had received a WATCHMAN FLX for LAAC and had both preprocedural and postprocedural CCTA scans available in addition to intraprocedural 3D-TEE were retrospectively included in this study. All patients were treated at the Columbia University Irving Medical Center. The Columbia Institutional Review Board approved this study. Prior to the LAAC, all patients underwent an electrocardiographically-gated CCTA with an Aquilion One 320-detector (Toshiba Medical Systems Corporation) scanner as per a previously described protocol.[7] WATCHMAN FLX implantation was performed under general anesthesia with TEE guidance. The final decision about implant size was made by the operator based on intraprocedural TEE images. Intraprocedural 3D-TEE images were analyzed using the TOMTEC software (TOMTEC Imaging Systems GmbH). Postprocedural CCTA scans were acquired 45 to 60 days after the procedure.

BASELINE LEFT ATRIAL APPENDAGE MEASUREMENTS. Preimplant LAA measurements were performed by both FEops (based on preprocedural CCTA) and intraprocedural 3D-TEE. Measurements included maximum LAA diameter, minimum LAA diameter, area-based diameter, and perimeter-based diameter. These measurements are provided in Table 1.

FEops COMPUTATIONAL MODELING. Twenty-five preprocedural CCTAs were anonymized and uploaded to the FEops HEARTguide platform with FEops blinded to the final implantation result. The received images were then further processed using the Mimics software (Materialise) to extract 3D patient-specific anatomical reconstructions and landmarks for the procedure. This, in combination with the device's mechanical material properties, serves as input for the blinded computational analysis. The deep learning algorithms that are used for segmentation, point detection, curve detection, and plane detection have been previously described.[8] Three of the CCTAs submitted to FEops did not have sufficient quality for computational modeling. The WATCHMAN FLX devices were virtually implanted into the patient-specific anatomy using finite-element computational simulation. The processed output that was returned predicted device compression and positioning for a range of device sizes, as well as LAA wall apposition plots and deformation visualization. The landing zone is defined from the simulations. The simulations aim to place the plane of maximum diameter of the LAA closure device at or just distal to the LAA ostium

CENTRAL ILLUSTRATION **FEops HEARTguide Platform Workflow and Prediction Results**



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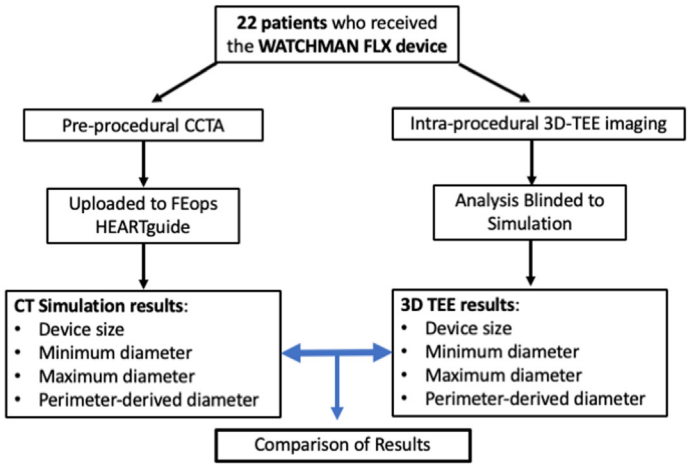
(A) The preprocedural cardiac computed tomography angiography (CCTA) is uploaded to the web-based platform. The received images are further processed using Mimics. **(B)** Several different trajectories are modeled to access the appendage as coaxial as possible with the centerline of the left atrial appendage. **(C)** As output, several options in terms of device size and position are provided in addition to left atrial appendage apposition plots, deformation visualization, and device measurements. **(D)** FEops modeling resulted in accurate prediction of the final device measurements when compared to intraprocedural 3D transesophageal echocardiography (TEE).

when possible, as stated in the instructions for use from Boston Scientific. The distance between the WATCHMAN FLX device and the nearest LAA wall was reported as a wall apposition plot, with red indicating a distance of at least 2 mm between the device and the nearest LAA wall (**Central Illustration**). For each device size and position, minimum diameter, maximum diameter, area-derived diameter, and perimeter-derived diameter were calculated. Simulations were performed using the Abaqus/Explicit finite-element solver (Dassault Systèmes). These results were compared to intraprocedural 3D-TEE measurements. Device deformation was evaluated by measurement of device minimum and maximum compression. Device minimum compression was calculated as: [(device size − device maximum diameter)/device size] × 100. Device maximum compression was calculated as: [(device size − device minimum diameter)/device size] × 100.

Two different FEops analyses were performed. The first is a blinded FEops analysis in which only the preprocedural CCTAs were measured by the FEops model and compared to the intraprocedural TEE, post device deployment images (**Figure 1**). The blinded simulation included the final implanted device size in 16 patients (72.7%). A subsequent optimized FEops analysis was performed using the 45- to 60-day post-device-deployment CCTA in which the implant size was disclosed. This nonblind "optimized" simulation was performed to test the model's ability to mimic the actual implant. Representative images of the FEops computational simulation, 3D-TEE images, and post-procedural CCTA are presented in **Figure 2**.

FIGURE 1 Study Design



This was a retrospective study that included patients who had a WATCHMAN FLX left atrial appendage closure device implanted and preprocedural cardiac computed tomography angiography (CCTA) and intraprocedural transesophageal echocardiography (TEE) images available. These data were compared to the FEops computational simulation results. CT = computed tomography.

STATISTICAL ANALYSIS. Statistical analyses were performed using Stata Version 12.1 (StataCorp). Data are presented as mean ± SD. The mean difference was calculated as: $\frac{1}{n}\sum_{i=0}^{n}(TEE\ measurement_i - FEops\ measurement_i)$. In cases that had both proximal and distal simulations, the average of the two was compared to the observed intraprocedural TEE measurements. A paired comparison between the observed and predicted measurements was performed using a paired Student's *t*-test. A linear regression analysis was used to assess the relationship between the observed (TEE) and the blinded, predicted (FEops model) measurements. Bland-Altman analysis and Pearson correlations were used to evaluate the accuracy of the blinded computational model predictions compared to 3D-TEE. For Bland-Altman analysis, the Bradley-Blackwood F-test of equality of means and variances was used to evaluate the significance of bias. Stata packages "aaplot" and "concord" were used for linear regression and Bland-Altman analysis.[9,10] A *P* value of <0.05 was considered statistically significant.

RESULTS

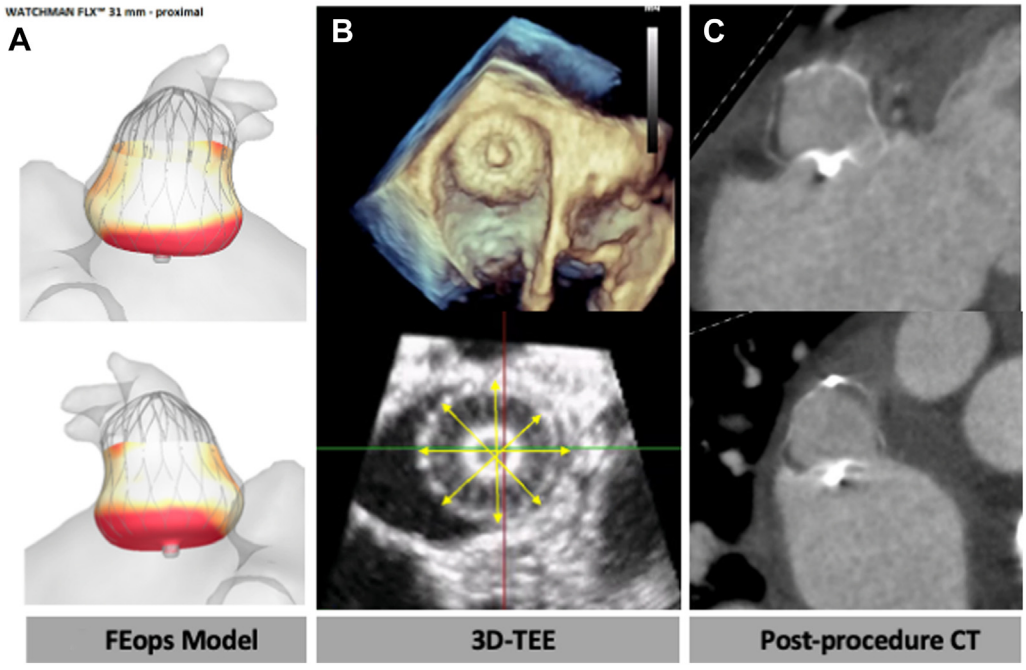
PATIENT POPULATION. The age of our cohort was 74.2 ± 8.8 years, and 81.8% (n = 18) were male. The CHA_2DS_2-VASc Score was 4.3 ± 1.9, and HAS-BLED Score was 4.0 ± 1.1. Comorbidities included heart failure (n = 6, 27.3%), coronary artery disease (n = 14, 63.6%), peripheral arterial disease (n = 2, 9.1%), hypertension (n = 22, 100%), diabetes mellitus (n = 7, 31.8%), and chronic kidney disease (n = 15, 68.2%). Fifteen patients (68.2%) had a prior bleeding event.

Table 1 summarizes the preprocedural LAA TEE and FEops baseline LAA CCTA measurements; there was no statistically significant difference between TEE and FEops CCTA measurements for any of the parameters. There was additionally no statistically significant difference in minimum or maximum LAA diameter between the site CCTA analysis and the FEops baseline LAA CCTA analysis (minimum diameter 20.51 ± 5.40 mm vs 21.13 ± 4.79 mm, $P = 0.20$; maximum diameter 25.05 ± 5.29 mm vs 25.03 ± 5.49 mm, $P = 0.96$).

PROCEDURAL RESULTS. The size of the WATCHMAN FLX devices implanted included the following: one 20 mm (4.5%), three 24 mm (13.6%), four 27 mm (18.2%), eight 31 mm (36.4%), and six 35 mm (27.3%). There were 4 patients in whom 1 recapture of the device was required (18.2%). The reasons for recapture were change in device size (n = 1) and repositioning (n = 3). There were no complications and no peri-device leaks documented.

COMPUTATIONAL MODELING. The blinded analysis was performed in 16 of the 22 patients (72.7%) in whom the final implanted device size was simulated by the FEops computation model. Of those with the implanted device size simulated, 13 patients (81.3%) had a simulated position that was comparable to that in the postoperative CCTA scan. For the remaining cases, the exact implanted position was not provided by the blind simulations. For the blinded simulation, the FEops model (predicted) and 3D-TEE (observed) measurements had a Pearson correlation coefficient (r) ≥0.90 and a nonsignificant difference by paired *t*-test (Table 2, Figure 3). Additionally, the mean difference between the TEE and FEops predicted measurements was <1 mm. The Bland-Altman plots for agreement between the 3D-TEE observed measurements and FEops blinded analysis demonstrated excellent agreement for all measures and are shown in Figure 4. There was no significant bias for area-based diameter (bias 0.4 ± 1.4, $P = 0.06$), perimeter-based diameter (bias 0.5 ± 1.4, $P = 0.08$), and maximum diameter (bias 0.3 ± 1.3, $P = 0.11$). For the 6 patients in whom the FEops model did not analyze the final implant size, a larger device size was always chosen for the actual implant. Further review of the CT and intraprocedural TEE imaging demonstrated that the intraprocedural TEE measured a larger maximum diameter than CT

FIGURE 2 Representative Case Example



(A) The FEops model predicted a size 31-mm device with proximal positioning, and this was ultimately the device size that was chosen. **(B)** Intraprocedural 3-dimensional transesophageal echocardiography (TEE) demonstrated the final device position to be similar to the FEops predicted model. No peridevice leak was visualized on the intraprocedural TEE. **(C)** The 45-day cardiac computed tomography angiography (CCTA) also demonstrated the final device position to be similar to the FEops-predicted model. The residual contrast opacification visualized inside the device on CCTA indicates incomplete endothelialization.

imaging in 3 of these patients, likely because the landing zone was chosen to be slightly more proximal. For the remaining, the device size(s) simulated was appropriate based on current sizing guidelines.

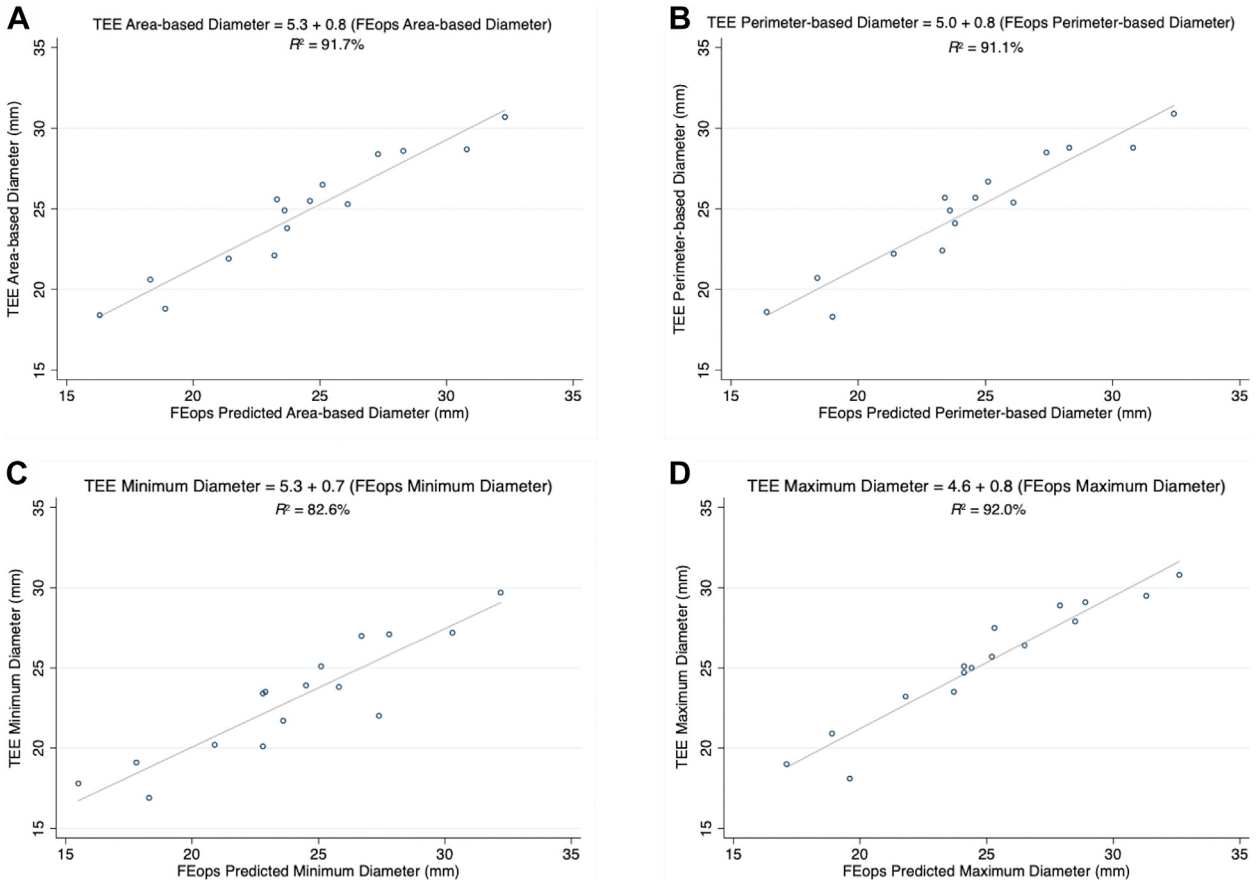
An "optimized" simulation was performed, matching the actual implanted device size and location, in 21 patients (95.5%). In 1 patient, the comparison with CCTA images was not possible, due to poor image quality. Compared to the observed measurements, the Pearson correlation coefficients were all ≥0.90 for all measurements. The minimum diameter was smaller by TEE than that in the optimized model; however, the mean difference was ~1 mm (Table 3).

TABLE 2 Postimplant Device Diameters: FEops Blinded Simulation Results Compared to Intraprocedural 3D-TEE (N = 16)

	FEops Model	3D-TEE	Mean Difference	Paired *t*-Test *P* Value	Pearson Correlation Coefficient (r)	r *P* Value
Area-based diameter (mm)	24.21 ± 4.44	24.65 ± 3.71	−0.44 ± 1.39	0.24	0.96	<0.001
Perimeter-based diameter (mm)	24.27 ± 4.42	24.78 ± 3.77	−0.51 ± 1.39	0.18	0.95	<0.001
Minimum diameter (mm)	24.03 ± 4.49	23.03 ± 3.65	0.99 ± 1.92	0.06	0.91	<0.001
Maximum diameter (mm)	24.99 ± 4.31	25.33 ± 3.72	−0.34 ± 1.28	0.31	0.96	<0.001
Minimum compression (%)	17.26 ± 4.64	15.83 ± 5.27	1.43 ± 4.66	0.24	-	-
Maximum compression (%)	20.64 ± 5.44	23.43 ± 6.52	−2.78 ± 6.47	0.11	-	-

Values are mean ± SD.
TEE = transesophageal echocardiography.

FIGURE 3 **Linear Regression Analysis Between the Predicted vs Observed TEE Device Measurements in the Blinded FEops Model (N = 16)**



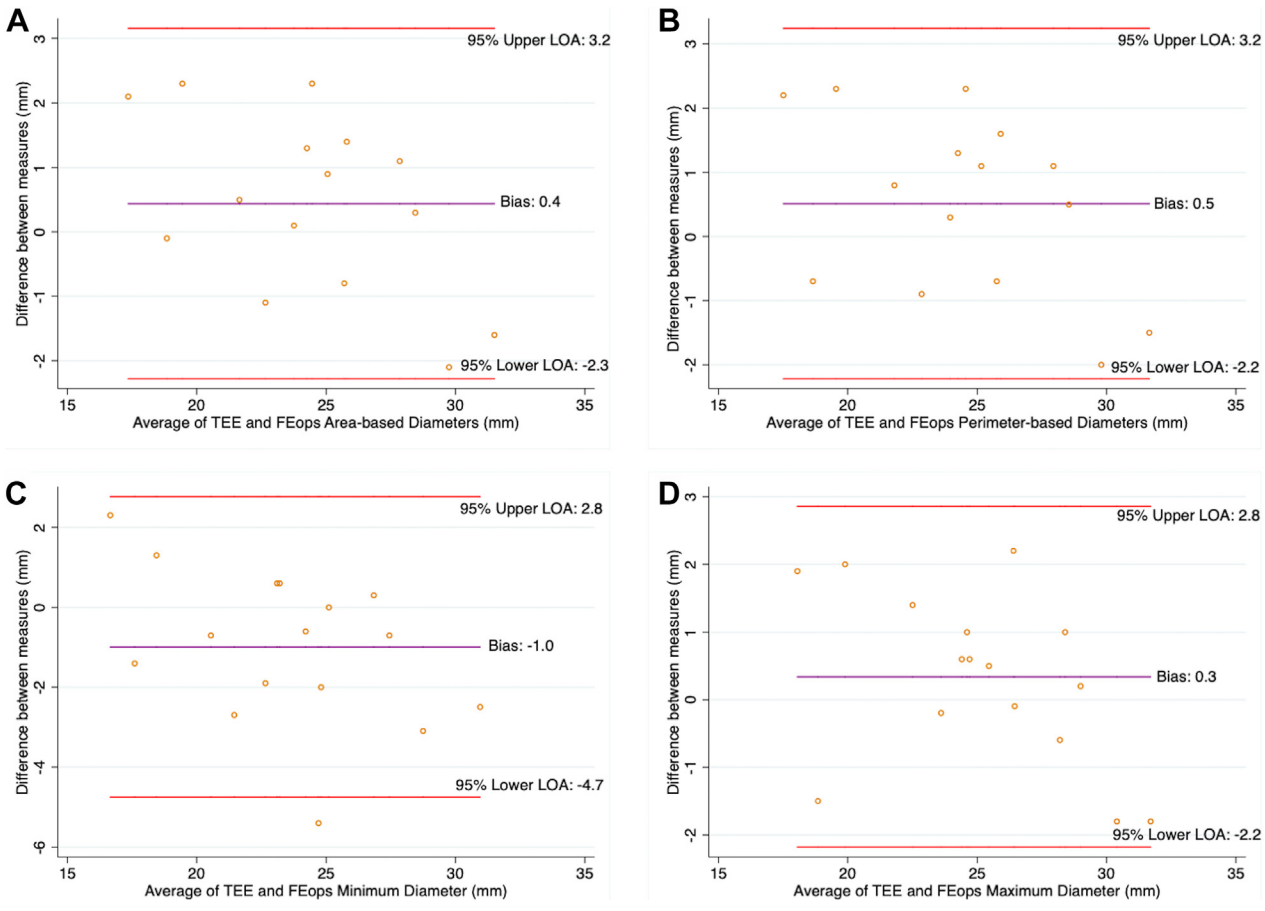
(A) Area-based diameter. **(B)** Perimeter-based diameter. **(C)** Minimum diameter. **(D)** Maximum diameter. TEE = transesophageal echocardiography.

DISCUSSION

Computational simulation provides a better understanding of device behavior within a procedure and would ideally predict device size, position, compression, and closure of the LAA, potentially resulting in the use of fewer devices, reduced procedure time and radiation exposure, and an increased LAA closure rate. This is the first study to demonstrate that with the incorporation of LAA tissue-device interaction characteristics, the current iteration of the FEops patient-specific computational model is able to accurately predict the implanted device size, position, and compression for WATCHMAN FLX LAAC using the preprocedural CCTA. Further training of the model using post-procedural CCTA and comparisons with 3D-TEE may even further improve the prediction model to ensure that the model includes the target simulated option in all patients.

The accuracy of the blinded FEops computational model was excellent with Pearson correlation coefficients ≥0.90 between the 3D-TEE and model estimates for all measurements. There was a small bias only for the minimum diameter (−1.0 ± 1.9, $P = 0.04$); however, this degree of bias is unlikely to have a clinically important impact. The chosen and implanted device size was one of the treatment scenarios modeled with the FEops HEARTguide platform in the majority of cases, and in cases where the final device size was not modeled, a larger device size was ultimately implanted as per operator preference for greater oversizing. It is important to note that more than 1 device size may be appropriate for any given LAA anatomy and can result in successful LAAC; however, depending on predicted placement (distal/

FIGURE 4 **Bland-Altman Plots for Postimplant Device Diameters: Intraprocedural 3D-TEE and FEops Blinded Stimulation Results**



(A) Area-based diameter ($P = 0.06$). **(B)** Perimeter-based diameter ($P = 0.08$). **(C)** Minimum diameter ($P = 0.04$). **(D)** Maximum diameter ($P = 0.11$). The **solid purple line** represents mean bias; the **solid red lines** represent the limits of agreement. LOA = limits of agreement; TEE = transesophageal echocardiography.

proximal) and LAA depth, 1 device size may be more suitable for a given anatomy. After careful review of these cases, we therefore believe that the FEops HEARTguide platform-predicted device size could have been used to achieve successful LAAC in all cases. Furthermore, it is possible that in some cases, a smaller device size could be a better fit with less protrusion into the left atrium.

In addition to accurate prediction of device implantation characteristics, CCTA-based patient-specific computational models, such as the FEops HEARTguide platform, have numerous benefits in terms of procedural planning. In addition to aiding the operator with understanding the tissue-device mechanical interaction in a patient's given anatomy, computational modeling provides simulation of multiple device sizes at a range of depths, thereby providing a better understanding of the available working depth. Furthermore, FEops modeling provides color apposition plots which can help with predicting leak or incomplete device sealing. Less residual leak has been observed on follow-up CCTA scans in patients who have had computational modeling as part of procedural planning.[11] Although the clinical impact of a peri-device leak <5 mm is controversial, this is important as patients with peri-device leak are more likely to remain on anticoagulation therapy which is associated with increased bleeding risk, especially in the LAAC population.[12,13]

There is growing interest in 3D intracardiac echocardiography (ICE) to guide LAAC as TEE is relatively invasive, typically requires anesthesia which can be less well-tolerated in elderly patients. The ICE technology has evolved, and the current 3D-ICE catheters are able to provide assessment of the LAA comparable

TABLE 3 Postimplant Device Diameters: FEops Nonblind, Optimized Size/Position Simulation Results Compared to Intraprocedural 3D-TEE (N = 21)

	FEops Model	3D-TEE	Mean Difference	Paired *t*-Test *P* Value	Pearson Correlation Coefficient (r)	r *P* Value
Area-based diameter (mm)	24.94 ± 3.96	24.65 ± 3.47	0.28 ± 1.34	0.36	0.94	<0.001
Perimeter-based diameter (mm)	25.01 ± 3.96	24.78 ± 3.52	0.23 ± 1.33	0.44	0.94	<0.001
Minimum diameter (mm)	24.63 ± 4.02	23.23 ± 3.44	1.39 ± 1.64	<0.001	0.91	<0.001
Maximum diameter (mm)	25.61 ± 3.80	25.46 ± 3.50	0.15 ± 0.96	0.47	0.97	<0.001
Minimum compression (%)	18.44 ± 19.10	14.57 ± 6.92	3.87 ± 19.86	0.37	-	-
Maximum compression (%)	21.72 ± 18.54	22.07 ± 8.38	−0.34 ± 18.83	0.93	-	-

Values are mean ± SD.
TEE = transesophageal echocardiography.

to that with TEE imaging.[14] ICE-guided LAAC obviates the need for anesthesia, potentially reducing procedure time, and multiple studies have demonstrated procedural feasibility.[15-17] Computational models in this setting have the potential to enhance preprocedural planning and could support a workflow where patients with a favorable anatomy, after ruling out thrombus by CCTA, are primarily selected for ICE-guided implantation. The patient-specific model results could help chose an appropriate device size and position prior to the procedure reducing the need for intraprocedural echocardiographic evaluation. Intraprocedural ICE imaging would instead focus on confirming the device position, compression, and ruling out peridevice leak. Furthermore, both the commercially available and approved LAAC devices in the United States require an understanding of the available LAA depth. CCTA is able to improve the spatial understanding of depth; however, it is often hard to judge how the device would be seated and if there is truly enough depth for device implantation. This depends on the inferior vena cava anatomy, the transseptal puncture, and the approach angle to the LAA. LAAC in LAA anatomy that has a wide ostium and shallow depth remains challenging; computational models can be especially helpful in patients with challenging anatomies such as these.

STUDY LIMITATIONS. This is an initial retrospective analysis on a single-center cohort. While the results from this study are encouraging, they are hypothesis-generating and need to be reproduced and confirmed in a larger, prospective study cohort. Additionally, there are a few limitations of the computational model used in this analysis that are worth noting. First, the FEops HEARTguide model is not validated for quantification of the peri-device leaks; however, it does provide color apposition plots through which potential leaks can be qualitatively assessed. Second, similar to other CCTA-based models, the FEops HEARTguide platform relies on the acquisition of adequate CT data for a model to be generated. Therefore, CT scans with a poor contrast quality or artifact may not allow modeling to be performed, and if performed, it may lead to inaccuracies. As we saw in our data set, there were 3 pre-CT and 1 post-CT scans that did not allow for modeling to be performed. Third, the model may provide a simulated device position that the operator is not able to achieve due to limitations of transseptal puncture or difficulty with sheath positioning. Last, the turnaround time for a full FEops analysis is approximately 24 hours; however, the technology is anticipated to become semi-automated in the future, which will decrease the turnaround time to ~30 minutes.

CONCLUSIONS

This is the first study to demonstrate that the FEops HEARTguide model accurately predicts WATCHMAN FLX device implantation characteristics. These results warrant further evaluation of this technology in larger prospective studies. Additionally, future studies are needed to evaluate the utility of computational modeling in reducing the number of closure devices per procedure and improving procedural efficiency without compromising technical success.

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Investigator on for two Gore trials: ASSURED and RELIEF. Dr Khalique is part of a corelab contracting with JenaValve, but has not received any direct compensation; has received consulting fees from Abbott Structural and Boston Scientific; and has received Speakers bureau fees from Edwards Lifesciences. Dr Hamid is part of a corelab contracting with JenaValve, but she has not received any direct compensation. Drs Bavo and De Beule are employees of FEops. Dr Hahn has received speaker fees from Abbot Vascular, Baylis Medical, Edwards Lifescience, and Philips Healthcare; institutional consulting contracts with no direct compensation for Abbott Structural, Edwards Lifesciences, Medtronic, Novartis, and Philips Healthcare; and equity with Navigate. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: CCTA is increasingly used in the preprocedural evaluation of and planning for left atrial appendage closure. CCTA can determine the left atrial appendage orifice area and left atrial appendage depth, which helps with determining the optimal device size. Additionally, CCTA allows for patient-specific computational models to be generated.

TRANSLATIONAL OUTLOOK: These data demonstrate the utility of patient-specific computational modeling in predicting final WATCHMAN FLX device configuration. Future studies are warranted to evaluate if computational modeling reduces the number of closure devices per procedure, improves procedural efficacy, and enhances operator confidence in device sizing.

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