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# Letters

RESEARCH LETTER

## Decisional Impact of CT-Based 3D Computational Modeling in Left Atrial Appendage Occlusion

The PRECISE LAAO

Left atrial appendage occlusion (LAAO) is a well-accepted alternative to oral anticoagulants in the prevention of stroke and systemic thromboembolism in patients with atrial fibrillation. The 3-dimensional (3D) anatomical complexity and interindividual variability of the left atrial appendage render 2-dimensional (2D) imaging modalities suboptimal for an adequate assessment. Inappropriate device selection or implantation can result in device embolization, residual peridevice leaks, and device-related thrombus, which are all associated with adverse clinical outcomes.[1] FEops HEARTguide (FEops) is a Food and Drug Administration-approved and Conformité Européenne-marked artificial intelligence-enabled simulation technology suite that uses computed tomography (CT)-based 3D computational modeling to assess host-device interactions.[2] The potential benefits of this technology compared to the standard of care (SoC) are still unknown. Therefore, we designed the PRECISE LAAO (Preprocedural Assessment of Anatomy and Device Sizing With CT and 3D Simulation in Left Atrial Appendage Occlusion; NCT04640051) with the Amplatzer Amulet (Abbott), an investigator-initiated, prospective, multicenter, self-controlled case study.

Ethics committees approved the study, and patients provided written informed consent. Preprocedural CT scans were uploaded into the FEops portal, and computational simulations were performed independently by FEops. SoC preprocedural assessments were conducted at the discretion of the 6 participating centers. The implanting teams came to a first Amulet size decision (Decision SoC), which was irrevocably registered on the case report form. They could only then access the results of the FEops simulations for the first time and come to a second Amulet size decision (Decision FEops). The teams then proceeded to implant any Amulet device at their discretion (Implanted Device) under transesophageal echocardiography (TEE) guidance. The study's primary objective was to compare the concordance of Decision SoC vs Decision FEops with Implanted Device. The statistical tests are 2-sided, and $P < 0.05$ was considered statistically significant using IBM SPSS Statistics 29 (IBM Corp).

Of 115 eligible patients (July 2021-April 2023), 102 were included in the final analysis. The mean age was 76.2 ± 8.1 years, with a $CHA_2DS_2$-VASc score of 4.4 ± 1.3 and a HAS-BLED score of 2.9 ± 1.0. Device implantation was successful in 100 patients (98.0%). SoC used CT in 42 patients (41.2%), 3D TEE in 31 patients (31.4%), and 2D TEE in 95 patients (93.1%). The primary outcome, concordance with Implanted Device, was 59.8% (n = 61) for Decision SoC and 90.2% (n = 92) for Decision FEops ($P < 0.0001$) (**Figure 1A**). FEops induced a change in size selection from SoC in 35 (34.3%) patients (**Figure 1B**), which was correct (or concordant with Implanted Device) in 33 (32.4%) patients. Size adjustments after considering FEops included an upsizing in 20 patients (19.6%) and a downsizing in 15 patients (14.7%). If CT was part of SoC, FEops still induced a correct device change in 15 patients (35.7% of those 42 patients).

SoC pre/periprocedural assessment in LAAO varies widely across the globe, and although TEE is the most widely used imaging modality, evidence is increasing in favor of CT. The PRO3DLAAO (Prospective, randomized comparison of 3-dimensional computed tomography guidance versus TEE data for left atrial appendage occlusion) study demonstrated greater accuracy of CT in device selection on the first attempt compared to 2D TEE (92% vs 27%; $P = 0.01$).[3] In SWISS-APERO (Comparison of Amplatzer Amulet and Watchman Device in Patients Undergoing Left Atrial Appendage Closure), CT was associated with more frequent complete LAA occlusion without complications both at the procedure and at 45 days compared to TEE.[4] The randomized PREDICT-LAA (The Value of FEops HEARTguide Patient-Specific Computational Simulation in the Planning of Percutaneous Left Atrial Appendage Closure with the Amplatzer Amulet Device) study demonstrated that CT-based 3D

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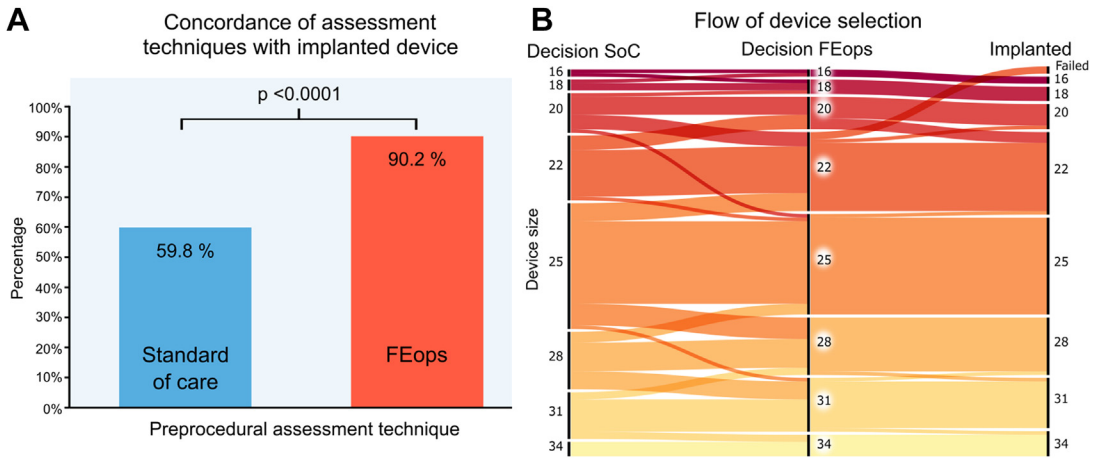
**FIGURE 1 Decisional Impact of FEops on Device Size Selection**




(A) Concordance between the preprocedural assessment techniques and the implanted device. (B) A Sankey diagram showing the decisional flow of the device selection induced by FEops.

computational modeling with FEops compared to standard CT-based planning reduced mis-sizings (3.0% vs 16.5%, respectively; $P < 0.01$), device repositioning, procedure time, and contrast medium, with a trend for an improved procedural outcome (contrast leakage distal of the Amulet lobe and/or the presence of device-related thrombus observed in 41.8% in the standard group vs 28.9% in the FEops group; $P = 0.08$).[5]

The current study corroborates a positive decisional impact of FEops by inducing a correct device change in almost 1 of 3 patients compared to SoC in daily clinical practice. CT-based FEops simulation could be considered as the current standard in LAAO.

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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.

## REFERENCES

**1.** Alkhouli M, Du C, Killu A, et al. Clinical impact of residual leaks following left atrial appendage occlusion: insights from the NCDR LAAO registry. *JACC Clin Electrophysiol*. 2022;8(6):766–778.

**2.** Bavo AM, Wilkins BT, Garot P, et al. Validation of a computational model aiming to optimize preprocedural planning in percutaneous left atrial appendage closure. *J Cardiovasc Comput Tomogr*. 2020;14(2):149–154.

**3.** Eng MH, Wang DD, Greenbaum AB, et al. Prospective, randomized comparison of 3-dimensional computed tomography guidance versus TEE data for left atrial appendage occlusion (PRO3DLAAO). *Catheter Cardiovasc Interv*. 2018;92(2):401–407.

**4.** Galea R, Aminian A, Meneveau N, et al. Impact of preprocedural computed tomography on left atrial appendage closure success: a Swiss-Apero trial subanalysis. *JACC Cardiovasc Interv*. 2023;16(11):1332–1343.

**5.** De Backer O, Iriart X, Kefer J, et al. Impact of computational modeling on transcatheter left atrial appendage closure efficiency and outcomes. *JACC Cardiovasc Interv*. 2023;16(6):655–666.