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ORIGINAL PAPER

Procedure planning and device positioning for left atrial appendage occlusion: insights from multi detector-row computed tomography with 3D fusion

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Abstract

To compare planned and achieved device position in patients undergoing left atrial appendage occlusion (LAAO). It is unclear how devices used for LAAO position themselves compared to what is planned. All patients undergoing LAAO at our institution had pre- and post-procedural multi detector-row computed tomography (MDCT) at 3 months (N = 52). Using dedicated software, both datasets were fused to superimpose the left atria in all planes. The effective device position was traced on the post-procedural MDCT and then imported in the pre-procedural dataset to allow comparisons. Planned and effective landing zones were compared with respect to size, location and orientation. The device's final position was in a significantly larger landing zone than planned (452 ± 174 vs. 351 ± 112 mm^2 for effective and planned landing zones, respectively, paired t-test: $p < 0.0001$), resulting in significantly less-than-intended area oversizing (41 ± 31 vs. 12 ± 28%, $p < 0.0001$). In terms of device orientation, there was a difference of 19.7° between the planned and effective landing zones ($p < 0.0001$). The Amplatzer device had a shallower-than-planned position in 70% of cases, whereas the Watchman device had a deeper-than-planned position in 75% of cases ($p = 0.04$). Incomplete occlusion was found in 17 patients (33%). In a multivariable model, oversizing at the effective landing zone was the only MDCT independent predictor of incomplete occlusion (OR: 0.96 per 1% increment, 95% CI 0.95–0.98, $p = 0.009$). MDCT fusion showed that LAAO device position and orientation are different than planned, and this is associated with incomplete occlusion of the LAA.

Keywords Left atrial appendage occlusion · Incomplete occlusion · Multi detector-row computed tomography · Device position

Abbreviations

LAAO	Left atrial appendage occlusion
MDCT	Multi detector-row computed tomography
HU	Hounsfield unit

Introduction

Left atrial appendage occlusion (LAAO) has markedly changed the landscape of stroke prevention for patients with atrial fibrillation, providing an alternative to those with a contra-indication to anticoagulation therapy [1]. As with other structural interventions, multi detector-row computed tomography (MDCT) has proven to be a valuable tool in the refinement of this new technology, for both pre-procedural planning and post-procedural surveillance. Thanks to its excellent three-dimensional resolution, MDCT can be used in the pre-procedural phase to assess LAA anatomy, detect the presence of thrombus, and measure device landing zone in order to select the appropriate prosthesis size and fluoroscopic viewing angles [2, 3]. In the post-procedural phase, MDCT allows the assessment of device position and is a sensitive tool to evaluate for incomplete occlusion of the LAA [3–6].

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Incomplete occlusion of the LAA is found in 44–69% of patients, depending on whether images are acquired in a delayed (venous) phase in addition to the arterial phase [7]. In cases of incomplete occlusion, MDCT can provide insight into the mechanisms of this finding [8]. While the clinical consequences of incomplete occlusion remain uncertain, it does have an impact on patient management, as most will remain on oral anticoagulants for a longer period of time [5, 7, 9, 10].

It is also unclear if incomplete occlusion of the LAA is the result of suboptimal device positioning (i.e. the device is released in a different location and orientation than planned) or suboptimal planning (i.e. the device is positioned as planned, but this still results in incomplete occlusion because of inappropriate sizing or landing zone assessment).

A potential use of MDCT which has yet to be explored is the fusion of pre- and post-procedural exams. By superimposing and comparing pre-procedural planning lines to post-procedural device position, we could better understand how devices behave in comparison to what was expected. This could bring further insight in the mechanisms of incomplete occlusion, and in turn, allow for better planning and device sizing. In this study, we describe a new method to fuse pre- and post-LAAO MDCT datasets, and compare expected and achieved results. We then describe how these results relate to the occurrence of incomplete LAA occlusion.

Methods

Patients and procedure

The MDCT data of consecutive patients with non-valvular atrial fibrillation and contra-indications to oral anticoagulation undergoing LAAO at our institution were retrospectively analyzed. All patients had pre-procedural MDCT for device sizing and determination of optimal fluoroscopic viewing angles. In addition, all patients underwent post-procedural MDCT at 3 months to assess device position and the presence of incomplete occlusion.

All procedures were performed under general anesthesia with transesophageal echocardiography guidance, according to previously described techniques [11]. Both the Amplatzer (Cardiac Plug and Amulet) and Watchman devices were used. After implantation, the presence of incomplete occlusion was assessed by transesophageal echocardiography and angiography. Patients were discharged with dual antiplatelet therapy (aspirin + clopidogrel) for 3 months, then lifelong aspirin. Clinical follow-up was obtained at 1 year. This study was approved by our institution's review committee and patients gave informed consent.

Acquisition

Dual-source MDCT was performed in spiral/helical acquisition mode with retrospectively electrocardiogram-gated reconstruction, with tube voltage of 100 or 120 kV and tube current according to patient size. For acquisition of the MDCT dataset, 80–100 mL of contrast (370 mg iodine/mL) was injected at a rate of 4 mL/s. The scan range extended from the neck to the diaphragm and image acquisition was performed in a cranio-caudal direction. MDCT data were reconstructed in 10%-intervals throughout the cardiac cycle images with a slice thickness of 0.6 mm and an increment of 0.4 mm.

Dataset analysis

Two investigators (MS, MC) analyzed data independently to ensure reproducibility. Fusion of pre- and post-procedural MDCT was performed using the software Integrated Registration on AW workstation (GE Healthcare, Chicago, USA). The 30% phase of both studies were superimposed (pre-procedural in grayscale and post-procedural in heatmap), and adjusted semi-automatically to have the left atria coincide in all three planes (Fig. 1). The planning lines of device landing zone used during the procedure were present in the pre-procedural MDCT dataset. Briefly, these were defined as follows [3]. For both devices, the ostium of the LAA was defined as the line that connects from the pulmonary vein ridge superiorly to the inferior junction of the LA/LAA at the circumflex artery. For the Amplatzer devices, the landing zone is located 10 mm (for ACP) and 12–15 (for Amulet) inside the LAA, relative to the ostium. For the Watchman, the landing zone is located at least 2 mm inside the pulmonary vein ridge superiorly, with the same inferior border as the ostium.

First, we traced the device area on the post-procedural MDCT (Fig. 2a). For the Amulet or Amplatzer Cardiac Plug, we traced this at the mid-height of the lobe, and for the Watchman, we used the widest part of the device, as per manufacturer recommendation. We compared this measurement to nominal device size in order to assess device compression and circularity.

Next, this device tracing was imported into the pre-procedural MDCT (Fig. 2b). The LAA on the pre-procedural MDCT was measured at this location. This measurement was called the effective landing zone (Fig. 2c). This effective landing zone was compared to the planned landing zone in terms of size, depth and orientation in a 3D volume reconstruction (Fig. 2d).

Finally, the presence of incomplete occlusion was assessed on the post-procedural MDCT, while using the fused volumes as a reference for region of interest

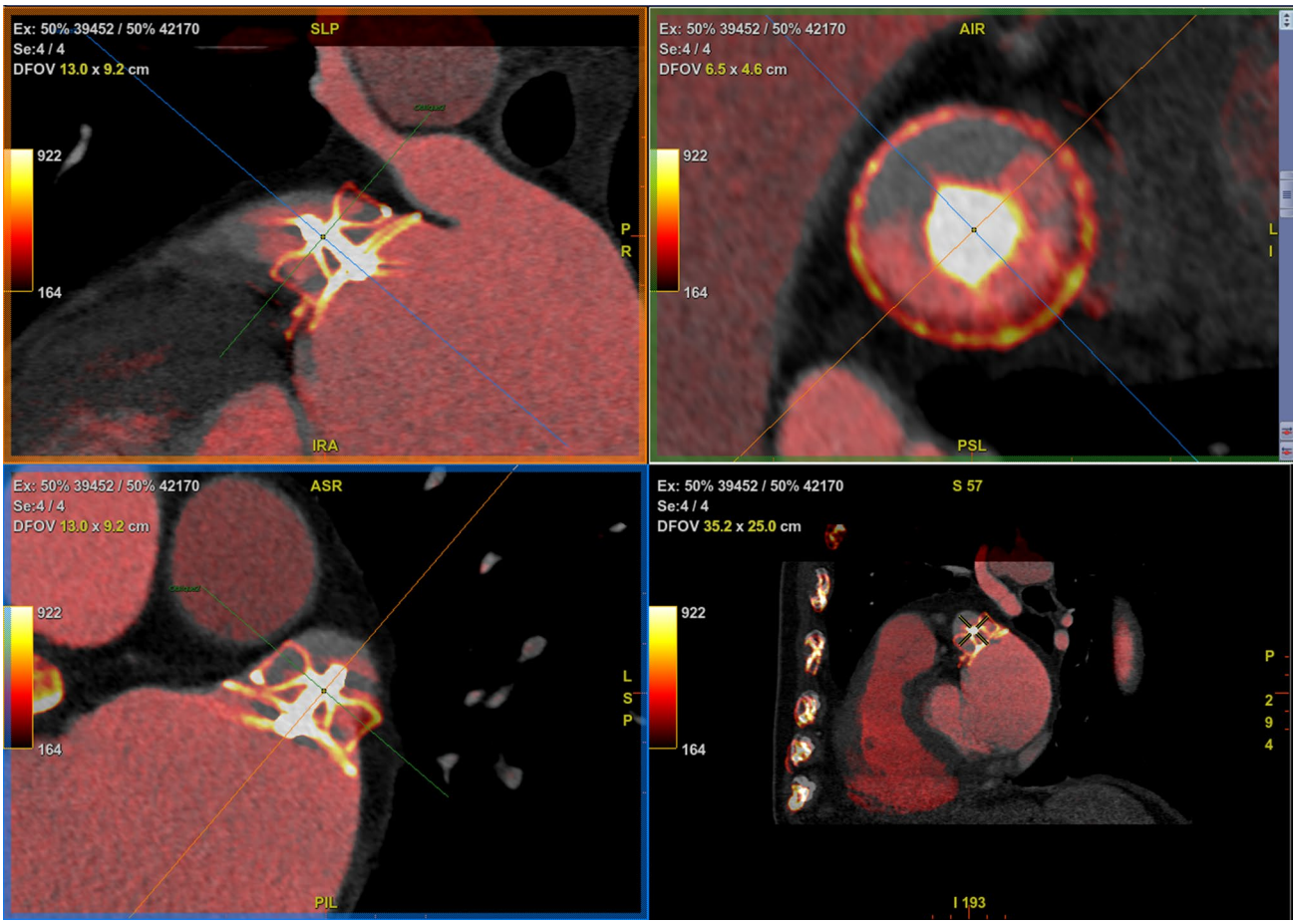


Fig. 1 Example of fused pre- and post-procedural MDCT. The pre-procedural MDCT is seen in usual grayscale. The post-procedural MDCT (with implanted Amplatzer device) is overlaid in heatmap colors. Both datasets are aligned in all three planes as shown in top right, top left and bottom left views (3D multiplanar reconstruction) with the borders of the left atrium superimposed

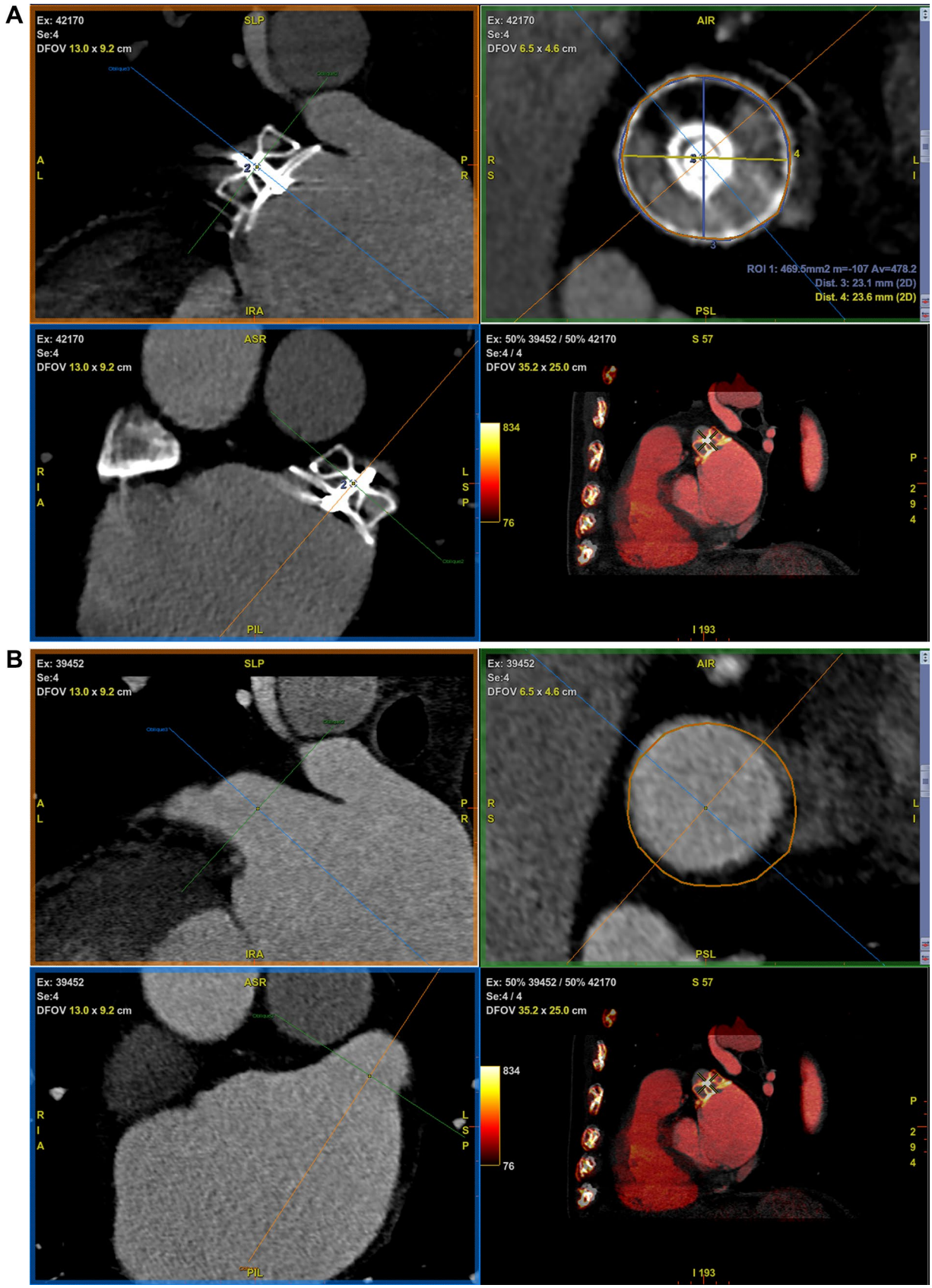
selection (Fig. 3). This was done according to previously described techniques [12]. Linear attenuation coefficient (Hounsfield units, HU) was measured both in the LA and in the LAA and values were compared, along with a qualitative assessment, to determine the presence of incomplete occlusion. A difference of < 50 HU between the LA and LAA indicated incomplete occlusion, as suggested by other authors [12]. In cases of uncertainty, cases were reviewed and consensus was achieved between two investigators. In cases of incomplete occlusion, we attempted to identify the mechanism by which contrast reached the LAA behind the device.

Statistics

Continuous variables were expressed as mean ± standard deviation, and categorical variables were reported as frequencies. For comparison between categorical variables, Fisher's exact test was used, and an independent-sample t-test or a Wilcoxon test were used to compare continuous values that were normally or not normally distributed, respectively. Predictors of incomplete occlusion were determined using a forward stepwise multivariable logistic regression model, including all variables with univariate p-value < 0.20. The von Mises-Fisher distribution was not assumed for directional data given angle between planned and effective landing zone were < 180°. The statistical analysis was performed using R, version 3.5.0. The threshold for statistical significance was 0.05.

Results

Between October 2013 and January 2017, 52 consecutive patients underwent LAAO for non-valvular atrial fibrillation at our institution. All patients underwent pre- and post-procedural MDCT at a mean of 98 ± 40 days after the procedure. Mean age was 77.3 ± 7.1 and almost three-quarters of patients were men (Table 1). CHADS-VASc and


A
Ex: 42170
Se:4
DFOV 13.0 x 9.2 cm
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IRA
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Dist. 4: 23.6 mm (2D)
PSL
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S 57
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◀ **Fig. 2** Steps to compare post-procedural device position to pre-procedural planning. **a** Post-procedural MDCT dataset. After obtaining an *en face* view of the device (top right), the area of the mid-portion of the device lobe is traced (orange line). **b** Pre-procedural MDCT dataset. The device tracing line is imported in the fused pre-procedural dataset. **c**. Pre-procedural MDCT dataset. The LAA dimensions are traced at this location (effective landing zone, blue line). **d** Fused MDCT datasets. In a 3-D volume reconstruction focused on the device, the planned device landing zone (pink line) is compared to the effective device landing zone (orange line) in terms of size, depth and orientation

HASBLED scores were 3.9 ± 1.4 and 3.6 ± 1.2, respectively. All patients had at least one contra-indication to anticoagulation, with major bleeding occurring in almost three-quarters of patients. More than two-thirds of patients had a previous stroke, TIA or thrombo-embolic event. Forty-four (84%) patients received an Amplatzer device (Cardiac Plug or Amulet) and the remaining 8 patients received a Watchman device.

Procedural success with device release was 100%, and there were no peri-procedural strokes or device embolizations. There were 3 (5.8%) pericardial effusions requiring

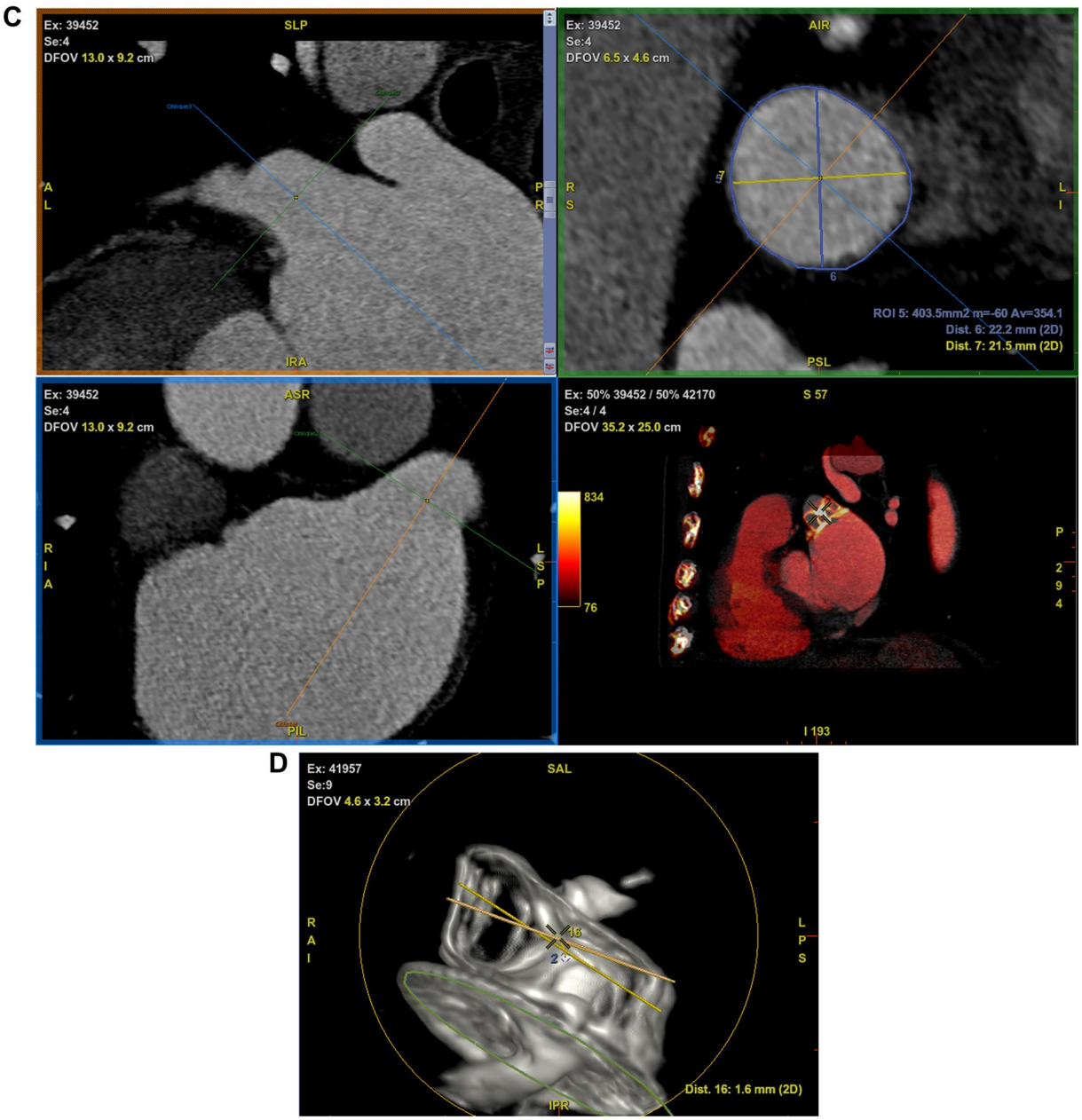

Fig. 2 (continued)

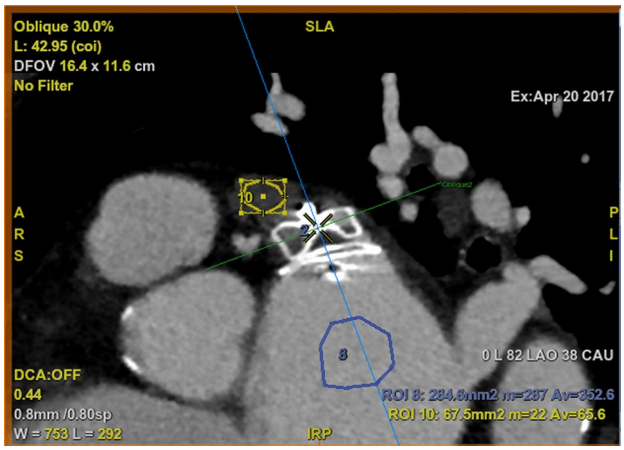

Fig. 3 Assessment of incomplete LAA occlusion. Linear attenuation coefficient (Hounsfield units, HU) was measured both in the LA (353 HU in this example) and in the LAA (66 HU in this example) on the post-procedural MDCT dataset. The fused pre-procedural MDCT was used to guide the positioning of the region of interest in the LAA

drainage, which did not result in other clinical events. Most patients were discharged on dual antiplatelet therapy (aspirin and clopidogrel) for a minimum duration of 3 months, and aspirin alone was given in 15 (28.8%) patients. No patients were discharged on oral anticoagulants.

MDCT characteristics and outcomes

MDCT fusion and dataset analysis was successful in all patients. The device's final position was in a significantly larger area than the planned landing zone (452 ± 174 vs. 351 ± 112 mm^2 for effective and planned landing zones, respectively, paired t-test: $p < 0.0001$, Table 2). This resulted in significantly less-than-intended oversizing (41 ± 31 vs. 12 ± 28%, for planned and effective area oversizing, respectively, paired t-test: $p < 0.0001$). In terms of device orientation, there was, on average, almost 20° difference between the planned and effective landing zones ($p < 0.0001$).

In almost two-thirds of patients, the effective landing zone was closer to the ostium of the LAA (i.e. shallower) than intended. This was significantly associated with the use of the Amplatzer device (N = 31/44 (70%) vs. 2/8 (25%) for Watchman; $p = 0.04$, Table 3).

Incomplete occlusion was found in 17 patients (33%). These patients had a higher linear attenuation coefficient in the LAA compared to those with complete occlusion (298.6 ± 131.3 vs. 79.3 ± 57.1 Hounsfield units respectively, $p < 0.001$, Table 2). The linear attenuation coefficient difference between the LA and LAA in patients with incomplete occlusion was 36.7 ± 62.9 Hounsfield units, compared to 282.6 ± 99.0 Hounsfield units in those with complete occlusion ($p < 0.001$). No device-related thrombus was identified.

Table 1 Baseline characteristics, procedural and clinical outcomes

Variable	(N = 52)
Age (years)	77.3 ± 7.1
Female sex	14 (26.9)
BMI (kg/m^2)	27.1 ± 4.4
CHADS-VASc score	3.9 ± 1.4
HASBLED score	3.6 ± 1.2
Previous major bleeding	37 (71.2)
Atrial fibrillation type	
Paroxysmal	25 (48.1)
Persistent or permanent	27 (51.9)
Hypertension	33 (63.5)
Diabetes mellitus	16 (30.8)
Previous stroke or TIA or thrombo-embolism	20 (38.5)
Coronary artery disease	10 (19.2)
Abnormal liver or renal function	14 (26.9)
GFR	59.0 ± 21.1
Device used	
Amplatzer Cardiac Plug or Amulet	44 (84.6)
Watchman	8 (15.4)
Intra-procedural complications	
Device embolization	0 (0)
Pericardial effusion requiring intervention	3 (5.8)
Stroke	0 (0)
Anti-thrombotic regimen at discharge	
Dual antiplatelet therapy	37 (71.2)
Single antiplatelet therapy	15 (28.8)
One-year follow-up	
Stroke or TIA	0 (0)
Death	0 (0)

Values are mean ± SD or n (%)

BMI body mass index, *TIA* transient ischemic attack, *GFR* glomerular filtration rate

When comparing fused MDCT characteristics of patients with and without incomplete occlusion, patients with incomplete occlusion had a trend for less planned oversizing (29 ± 25 vs. 47 ± 32%, $p = 0.05$, Table 2). Because of the larger-than-intended effective landing zone, this resulted in an effective undersizing of − 2 ± 24% in patients with incomplete occlusion, compared to an effective oversizing of 19 ± 27% in those with complete occlusion ($p = 0.009$). There was no significant difference between patients with complete and those with incomplete occlusion in terms of device type, relative depth of implant, orientation, area compression, and circularity index. For patients with an Amplatzer device, the angle between lobe and disk was numerically greater in patients with incomplete occlusion (13.7° ± 9.7° vs. 9.8° ± 5.3° respectively, $p = 0.09$).

In a multivariable model, effective oversizing was the only MDCT independent predictor of incomplete occlusion

Table 2 MDCT characteristics and outcomes

Variable	All patients (n = 52)	Complete occlusion (n = 35)	Incomplete occlusion (n = 17)	p-value
Planned landing zone area (mm^2)	350.6 ± 111.9	341.0 ± 102.0	370.5 ± 131.0	0.40
Effective landing zone area (mm^2)	451.7 ± 174.2	428.1 ± 147.8	500.3 ± 215.7	0.16
Planned oversizing (%)	41 ± 31	47 ± 32	29 ± 25	0.05
Effective oversizing (%)	12 ± 28	19 ± 27	− 2 ± 24	0.009
Effective-planned oversizing (%)	− 29 ± 27	− 28 ± 22	− 31 ± 35	0.73
Relative depth of implant				0.76
Device position deeper than planned	19 (36.5)	13 (37.1)	6 (35.3)	
Device position shallower than planned	33 (63.5)	22 (62.9)	11 (64.7)	
Angle between planned and achieved device orientation (°)	19.7 ± 10.1	19.8 ± 10.1	19.5 ± 10.6	0.93
Device area compression (%)	91.5 ± 10.8	91.7 ± 12.5	91.1 ± 6.5	0.84
Device circularity index	1.07 ± 0.06	1.08 ± 0.07	1.06 ± 0.05	0.31
Device type				1
Cardiac Plug or Amulet	44 (84.6)	30 (85.7)	14 (82.4)	
Watchman	8 (15.4)	5 (14.3)	3 (17.6)	
Angle between lobe and disk (°)[a]	11.1 ± 7.1	9.8 ± 5.3	13.7 ± 9.7	0.09
Linear attenuation coefficient in LA (Hounsfield units)	353.2 ± 123.6	362.0 ± 106.1	335.3 ± 155.9	0.47
Linear attenuation coefficient in LAA (Hounsfield units)	151.0 ± 135.5	79.3 ± 57.1	298.6 ± 131.3	< 0.001
LA–LAA linear attenuation coefficient (Hounsfield units)	202.2 ± 146.1	282.6 ± 99.0	36.7 ± 62.9	< 0.001

Values are mean ± SD or n (%)

LA left atrium, *LAA* left atrial appendage, *MDCT* multi detector-row computed tomography

[a]Angle between lobe and disk applies only to patients receiving an Amplatzer Cardiac Plug or Amulet device (n = 44)

Table 3 MDCT characteristics stratified by device type

Variable	Amplazter (n = 44)	Watchman (n = 8)	p-value
Planned landing zone area (mm^2)	355.3 ± 109.8	325.1 ± 127.4	0.49
Effective landing zone area (mm^2)	473.5 ± 179.4	332.1 ± 63.8	0.03
Planned oversizing (%)	39.3 ± 19.5	50.6 ± 68.4	0.65
Effective oversizing (%)	7.7 ± 23.5	35.4 ± 39.5	0.009
Relative depth of implant			0.04
Device position deeper than planned	13 (30)	6 (75)	
Device position shallower than planned	31 (70)	2 (25)	
Angle between planned and achieved device orientation (°)	19.6 ± 10.5	20.3 ± 8.2	0.86
Device area compression (%)	90.2 ± 8.3	98.9 ± 19.0	0.24
Device circularity index	1.07 ± 0.06	1.09 ± 0.08	0.40

Values are mean ± SD or n (%)

MDCT multi detector-row computed tomography

(OR 0.96 per 1% increment, 95% CI 0.95–0.98, p = 0.009). The other independent predictor of incomplete occlusion was HAS-BLED score (OR: 0.50 per 1 point increment, 95% CI 0.26–0.95, p = 0.03).

When comparing MDCT characteristics of devices, while planned landing zone areas were similar between the Amplatzer and the Watchman devices, the effective landing zone was significantly larger in the Amplatzer group (473.5 ± 179.4 vs. 332.1 ± 63.8 mm^2, for Amplatzer and Watchman, respectively, p = 0.03, Table 3). This resulted in significantly less-than-intended oversizing in the Amplatzer group (7.7 ± 23.5 vs. 35.4 ± 39.5%, p = 0.009).

We identified 4 mechanisms for the 17 cases of incomplete occlusion (Table 4, Fig. 4). First, disk malapposition could result from a partially protruding lobe into LA in the context of a shallow implant (n = 4, 23.5%). Second, in patients with a non-protruding lobe, disk malapposition was related to the angle between the lobe and the disk (n = 4,

Table 4 Mechanisms of incomplete occlusion

Variable	(N = 17)
Protruding lobe resulting in disk malapposition	4 (23.5)
Non-parallel disk and lobe resulting in disk malapposition	4 (23.5)
Incomplete coverage of LAA ostium by disk	3 (17.6)
Device off-axis with landing zone resulting in leak around device	2 (11.8)
Unclear	4 (23.5)

Values are n (%)

23.5%). In three patients (17.6%), the incomplete occlusion was related to the incomplete coverage of the LAA ostium by the disk, with the disk partially moving inside the LAA. In two patients (11.8%), the device was sufficiently off-axis with the landing zone to allow a leak around the device. Finally, in four patients, the mechanism of incomplete occlusion was unclear and likely related to incomplete endothelialization. Of the three patients with a Watchman device and incomplete occlusion, two had an unclear mechanism and one had a leak around an off-axis device.

Discussion

This proof-of-concept study is, to our knowledge, the first to use pre- and post-procedural MDCT fusion to compare planned and effective position and sizing for LAAO. The main findings are the following: (1) the device's end position is in a larger area than planned, and in a different orientation, resulting in less-than-intended oversizing; (2) incomplete occlusion was identified in one third of patients: these patients had less oversizing at the achieved landing zone compared to patients with complete occlusion; (3) both devices behaved differently: the Watchman's position was deeper than planned, whereas the Amplatzer's position was shallower than planned; (4) the discrepancy in device position led to different mechanisms of incomplete occlusion between devices.

These findings suggest that LAAO may be more complex to plan than other structural procedures, as devices do not conform uniformly with the appendage's highly variable anatomy. Transcatheter aortic valve replacement consists in implanting a cylindrical device in a relatively rigid tubular structure (the aortic annulus and root) that displays visible fluoroscopic landmarks. In comparison, LAAO consists in implanting a cylindrical or spherical lobe (with or without a disk) in a windsock, chicken wing, cactus or cauliflower structure that is thin-walled, has variable extent of pectinate muscles or trabeculations, and displays no fluoroscopic landmarks. These differences highlight, in our view, the procedure's complexity.

Our findings raise important questions with regards to the way we select devices and sizes for LAAO. It appears that devices position themselves in a location that is larger than intended, likely through a "path of least resistance". It is not clear if the selection of a larger device would result in better sealing. Rather, and this is especially true for the Amplatzer devices, a larger device may simply be more off-axis or shallower, resulting in paradoxically less oversizing and sealing. This is congruent with the findings of Jaguszewski and colleagues who reported significantly more incomplete occlusion in cases where the device had < 10% compression and was less coaxial to the LAA neck [5].

The fact that the Amplatzer devices are shallower than intended and the Watchman devices are deeper than intended probably results in different mechanisms of incomplete occlusion. For the Amplatzer, this often relates to incomplete coverage of the ostium because of device protrusion in the left atrium, whereas for the Watchman device, incomplete occlusion may more likely be related to poor coaxiality. The operator should be cognizant of these devices' properties and not hesitate to try different device sizes during the procedure in order to maximize coaxiality and sealing. Furthermore, the extent of pectinate muscles and trabeculations, which may be difficult to assess on MDCT, could alter device orientation upon implant. Accordingly, operators should use the pre-procedural MDCT landing zone measurements as a framework to have a range of appropriate device sizes. Further studies should strive to find ways to optimize device positioning relative to planning, and intra-procedural MDCT-fluoroscopy 3D fusion could represent an appealing approach in that regard [13].

Finally, MDCT was a good tool to assess the presence of incomplete occlusion, as we found a large difference in attenuation coefficients of the LAA between patients with and those without incomplete occlusion, similar to previous reports [6]. The rate of incomplete occlusion in our study is comparable to other reviews, which state a rate between 30 and 50% with the various percutaneous and surgical techniques [14]. The impact of incomplete occlusion remains difficult to assess, as most studies on the subject have limited power to detect thankfully rare events. However, data from the surgical literature show that incomplete occlusion after surgical ligation of the LAA is associated to thrombus formation and thrombo-embolism [14]. Whether these findings can be transposed to percutaneous techniques remains to be proven. Regardless, operators and imagers should strive to obtain the lowest rate of incomplete occlusion.

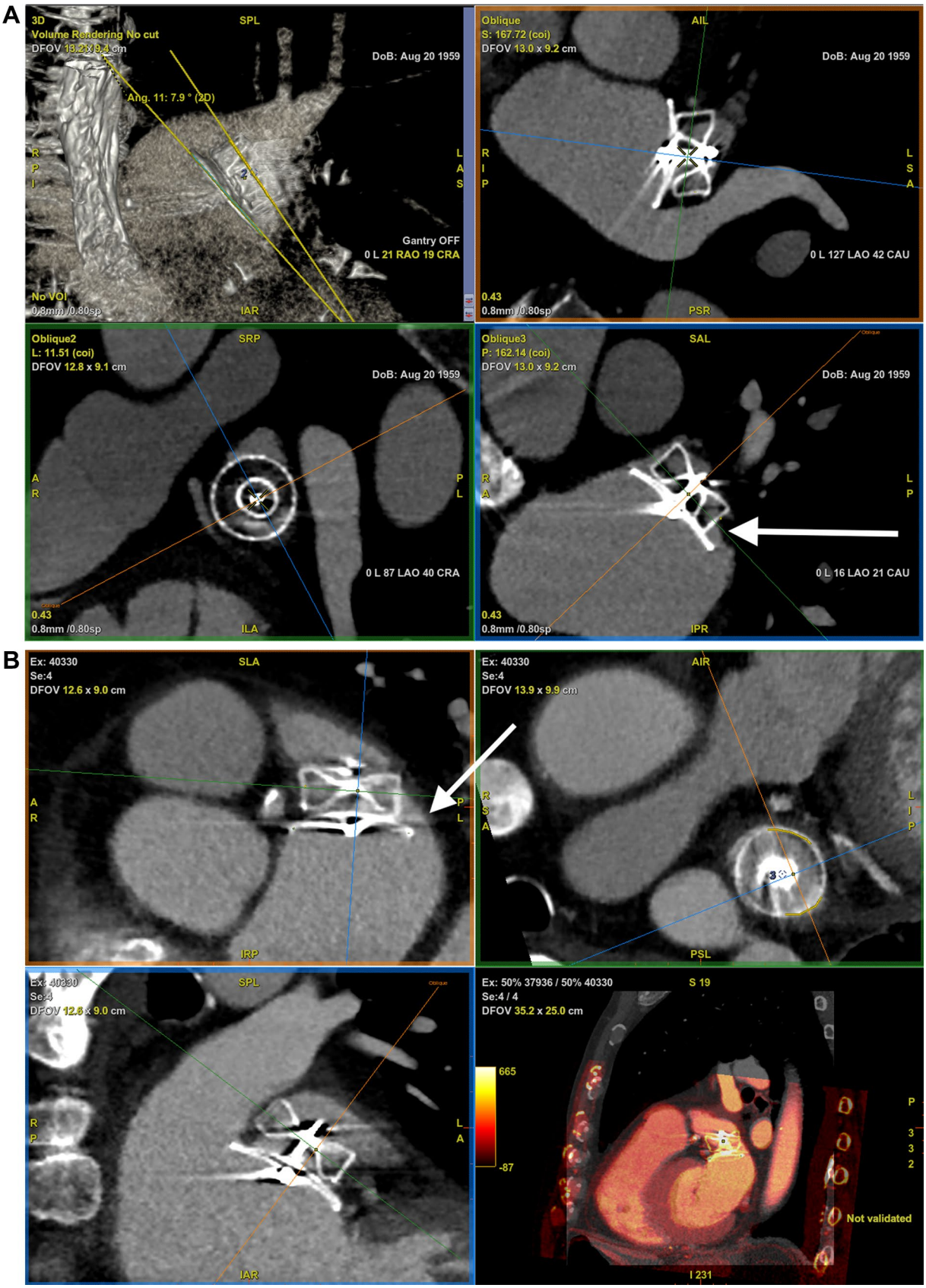

Fig. 4 Title: Mechanisms of incomplete LAA occlusion. **a** Device lobe partially protruding in the LA (arrow), with resulting disk malapposition. **b** Incomplete coverage of the LAA ostium be the device disk (arrow)

Limitations

As this was a small retrospective study, we lacked the power to evaluate the clinical impact of incomplete occlusion. We did not find a higher stroke rate in patients with incomplete occlusion, but our follow-up only extended to one year. That said, the purpose of this study was not to evaluate clinical outcomes, but rather to assess how the devices behave compared to what is planned. The number of patients that received a Watchman device is small, limiting comparisons between devices. The finding that the Watchman device had a deeper-than-planned position compared to the Amplatzer may be due to differences in landing zone definition rather than device characteristics. In addition, the only post-procedural MDCT was performed 90 days after the procedure, which is a generally accepted delay to assess incomplete occlusion. It is unknown if the device may have been positioned as planned during the procedure, and then moved in the days or weeks that followed. A late or venous MDCT phase was not systematically performed to assess for the presence of incomplete occlusion. The optimal methods and cutoffs for this remain poorly defined, and the clinical relevance of incomplete occlusion on late phase only is unclear. Finally, patients with incomplete occlusion did not systematically have repeat MDCT to assess if complete occlusion occurred in a delayed manner. It is possible for some patients with incomplete occlusion to convert to complete occlusion, most likely those with epithelization issues. In our study, this may be possible for the subgroup of patients with an unclear mechanism of incomplete occlusion (n = 4), as those with a clear etiology such as a gap between the device and the LAA ostium are unlikely to completely occlude.

Conclusions

In conclusion, in this proof-of-concept study, pre- and post-procedural MDCT fusion showed that LAAO device position and orientation were significantly different than planned, and this was associated to incomplete occlusion of the LAA. Further studies should investigate how to optimize procedural planning in order to reduce the rate of incomplete occlusion.

Perspectives

What's known?

MDCT is useful to plan left atrial appendage occlusion procedures, and to assess for the presence of incomplete occlusion when performed after the procedure.

What's new?

3D fusion of pre- and post-procedural MDCT datasets revealed that devices do not behave as planned. They tend to position themselves in landing zones that are larger than planned.

What's next?

Different device sizing algorithms should be tested in order to optimize positioning in an effort to reduce the rate of incomplete LAA occlusion.

Compliance with ethical standards

Conflict of interest Drs. Spaziano and Garot have received speaker fees from General Electric.

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