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Anatomical accuracy of the KODEX-EPD novel 3D mapping system of the left atrium during pulmonary vein isolation: A correlation with computer tomography imaging

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Abstract

Background: A novel 3D mapping system (KODEX-EPD, EPD Solutions) enables catheter localization and real-time 3D cardiac mapping.

Objective: To evaluate left atrium (LA) anatomical mapping accuracy created by the KODEX-EPD system during pulmonary vein isolation (PVI) compared with gold standard computed tomography (CT) images acquired from the same patients before the procedure.

Methods: In 15 consecutive patients who underwent PVI, 3D mapping of the LA was created on the KODEX-EPD system using the Achieve catheter. Pulmonary vein (PV), posterior wall, and appendage anatomy and diameters, were compared to the CT 3D reconstruction measured on the CARTO 3 system. Measurements were done independently by two physicians in each method. Linear correlation and agreement between CT and EPD measurements were assessed by Spearman correlation and Bland-Altman plot.

Results: Mean LA mapping time was 7.7 ± 3.6 min. Very high interobserver correlation was found for both EPD and CT measurements (Spearman $r = .9$). High correlation ($r = .75$) was found between CT and EPD measurements. Bland-Altman plot method revealed that measurements assessed by EPD were slightly higher than those assessed by CT. Mean difference was 3.5 mm, $p < .01$. In 2 (13.5%) patients each, disagreement regarding the presence of a left common PV and a right middle accessory vein anatomy was seen.

Conclusion: The new KODEX-EPD mapping system allows quick and accurate mapping of the LA with high correlation to CT imaging. Some differences in left common and accessory right middle vein anatomy were seen.

KEYWORDS

anatomy, KODEX-EPD, left Atrium, mapping, pulmonary vein isolation

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1 | INTRODUCTION

The KODEX-EPD system (EPD Solutions, a Philips company) is a novel dielectric, real-time, in vivo cardiac mapping and navigation system which registers shifting voltage and electric field measurements, as electrode-containing catheters move within an electric field produced by removable body surface patches. This process rapidly generates three-dimensional (3D) images of cardiac anatomy without the need for direct physical contact between the catheter and the endocardial surface. The KODEX-EPD system also simultaneously displays the real-time 3D location and movements of any type of diagnostic or therapeutic catheter, even standard electrophysiology catheters lacking location sensors, by sensing voltages generated on the catheter electrodes by the induced electric field.[1]

In the first validation study, the anatomy created by the KODEX-EPD system in 4 swine was compared to a gold standard computed tomography (CT) image, and a qualitive comparison of human left atrial anatomy was made.[1] The study found the KODEX-EPD system created an accurate map, comparable with the CARTO 3 map. Measurement of the pulmonary vein (PV) ostia using Kodex-EPD imaging and CARTO 3 mapping revealed a high level of concordance with angiographic visualization as assessed with contrast injection and fluoroscopy.[2] The use of the KODEX-EPD system for atrial fibrillation (AF) ablation has been reported in a few case reports[3–5] and one study evaluated the accuracy of the systems' occlusion tool software accuracy during pulmonary vein isolation (PVI) using Cryoballoon (CB) (Medtronic Inc.).[6]

In the current study we sought to compare the anatomical accuracy of the left atrium (LA) created by the EPD system using the Achieve catheter during PVI procedures, to the gold standard CT Image obtained from the same patient before the procedure.

2 | METHODS

2.1 | Study population

Patients with standard guideline-based indications for AF ablation were prospectively enrolled in the study. All patients underwent a first ablation procedure using CB technique.

Exclusion criteria were: age <18 years, permanent AF, contrast media allergies, kidney injuries, previous AF ablation, hyperthyroidism, left atrial thrombus, and cryoglobulinemia.

All patients were enrolled in our medical center (Shaare Zedek Medical Center, Jerusalem) from January 2020, since the system (KODEX-EPD—Philips) was delivered in Israel in limited market release phase 2.

The study protocol was approved by the local ethics committee and written informed consent from all patients was obtained before each procedure.

2.2 | CT image acquisition

Cardiac CT was performed in all patients to image PV anatomy and to rule out left atrial thrombus before the procedure. CT angiography (CTA) protocol. After 4 h fasting state, all patients underwent ECG-gated CTA (SOMATON Force, Siemens) before the procedure. A bolus of 60–100 cc of iodinated contrast (Iopamiro, Bracco) was injected in a rate of 4.5–5.5 ml/s according to body weight, and a gated prospective scan was performed during breath hold, obtaining images at inspiratory phase and mid diastole. Images were reconstructed using the following parameters: 0.6 mm slice thickness with 50% overlap, Bv36 filter and 3 iterations. For the purpose of ruling out LA appendage thrombus, additional delayed scan was acquired 45 s after the first scan. The radiation dose was approximately 2–2.5 mSv per patient.

2.3 | Ablation procedure

The procedures were conducted under general anesthesia after 6 h fasting state. After transseptal catheterization, the CB catheter was introduced into the LA via a 12F steerable sheath (FlexCath Advance; Medtronic, Inc.). Mapping of the PVs and LA was performed with an inner lumen circular mapping catheter (Achieve; Medtronic, Inc.). The mapping catheter was advanced in each PV ostium and positioned as proximal as possible to provide PV potentials recording. Mapping was performed by fluoroscopy or navigation, dependent on physician's preference. The LA and PV ostia were reconstructed with the use of the circular mapping catheter on the navigation system (Kodex-EPD Navigation system, version 1.4.6a and 1.4.7). A 28-mm CB catheter (Arctic Front Advance; Medtronic Inc.) was inflated, then advanced and positioned at each PV antrum. The standard set of lesions included the isolation of the left superior PV first, followed by the left inferior PV, right inferior PV (RIPV), and right superior PV. To avoid phrenic nerve injury, all CB applications on right PVs were done while monitoring phrenic nerve function. Target application time was 180–240 s.

2.4 | KODEX-EPD system

The KODEX-EPD system was used to image anatomy and to navigate in the LA. KODEX-EPD system technical characteristics have been already described.[1,2] The EPD system is respiration and cardiac movement gated—to end expirium and end diastole. Briefly, the system creates high-density images of cardiac anatomy by exploiting the distinct dielectric properties of biological tissue, measuring voltages between the body surface sensors (patches) and the catheters connected to the system in the blood pool. The system receives and analyzes the subtle electrical field transmission and reflection among skin patches and all catheter electrodes as they are manipulated in the cardiac chambers. Structures such as the endocardial atrial surface, cardiac veins, and heart valves cause marked gradients in the electrical field. This “bending of the electrical field” is sensed by the system and used to calculate the geometric characteristics of the 3D image. A transformation function, transforming the voltages (in millivolts) recorded off the indwelling catheter's electrodes to x, y, z coordinates (in millimeters), is being calculated every few seconds throughout the process of imaging the cardiac chamber until the operator decides the imaging is complete. With this technique, the KODEX-EPD system can collect anatomic information without actual physical surface contact, a few millimeters ahead of the catheter electrodes (5–10 mm), resulting in a certain kind of “far-field imaging.” KODEX spatial resolution was assessed in-vitro, using an accurate robotic arm, KODEX ability to distinguish between two very close spatial locations (“clouds”) of an ablation catheter's tip electrode was determined repeatedly with increasingly smaller robotic steps (1 → 0.5 → 0.3 → 0.2 mm). KODEX spatial resolution was determined as 0.27 ± 0.06 mm, with a location precision of 0.18 ± 0.09 mm. KODEX PU (processing unit) continuously collects spatial data at 100 Hz sampling rate. In a characteristic 10 min KODEX imaging, within which a detailed image of the mapped chamber can usually be achieved, approximately 60 000 data points are being collected. This raw data undergoes preprocessing in the workstation, whereby 10%–20% of the points are being filtered out (due to noise, outliers, systematic bias and drift). A typical KODEX imaged chamber is variable and comprises up to 14 000 points which is the upper computational power. There is an additional cost for using the added technology provided by the EPD system. Other than the cost of the system there is the cost of the Body Surface Sensors (patches) and feature keys.

2.5 | Measurement technique

KODEX-EPD measurements were made using both a posterior-anterior (PA) and the panoramic (PANO) view. First, vein anatomy, including anatomical variations of left common PV or the presence of an accessory PV was determined. Second, the route of the vein was followed from distal to proximal and the plain where the vein arises from the atria was marked on the 3D atria shell reconstruction. Then, the PV and appendage os longest length and width at a 90° angle to it were measured by taking the longest length and width (Figure 1). Third, superior, inferior, right and left posterior wall lines were measured, connecting the most upper points of the superior veins

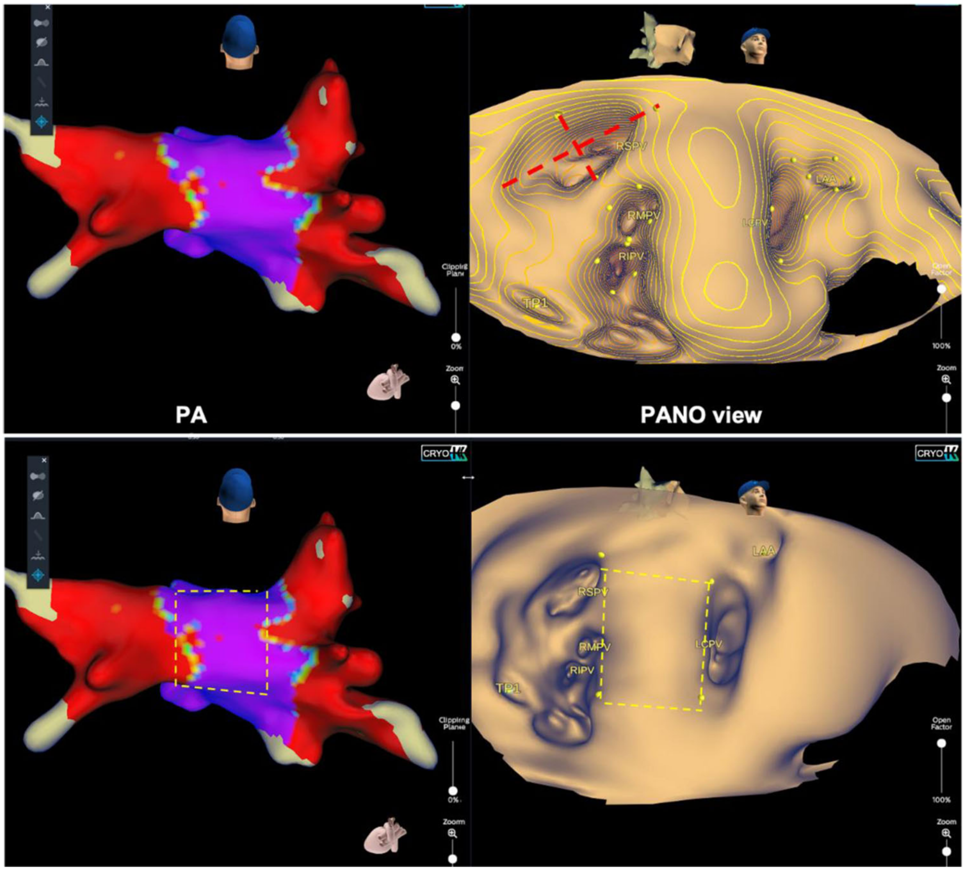

FIGURE 1 An example of the measurement technique on the KODEX-EPD posterior-anterior and PANO images. The anatomy demonstrated a left common PV and an early branch of the RIPV. Upper panel: PV and appendage os length and width diameters measured at an approximately 90° angle, between the yellow dots. The red lines demonstrate the measurement of the RSPV. Lower panel: superior, inferior, right and left posterior wall lines were measured, connecting the most upper points of the superior veins ostia and the most lower points of the inferior veins ostia, demonstrated with the yellow dashed lines. PV, pulmonary vein; RSPV, right superior PV

ostia and the most lower points of the inferior veins ostia measured at a PA view (Figure 1).

CT images were measured using a 3D image on the CARTO auto-segmentation module using the same process. For the posterior wall line measurements, the points were placed sequentially, while leaving the last point in the same location when measuring the next line, hence using the exact same points for all the lines (Figure 2).

All measurements were done independently by two physicians in each method. The mean value of the two measurements was used for comparing both systems.

2.6 | Statistical analysis

Continuous data are described as mean ± *SD*, if normally distributed, or as median (first; third quartile). Categorical data are described with absolute and relative frequencies.

Linear correlation and agreement between CT and EPD measurements were assessed by Spearman correlation and Bland-Altman plot. All statistical tests were two sided and $p < .05$ was considered statistically significant. SPSS software was used for all statistical analyses (IBM SPSS statistics for

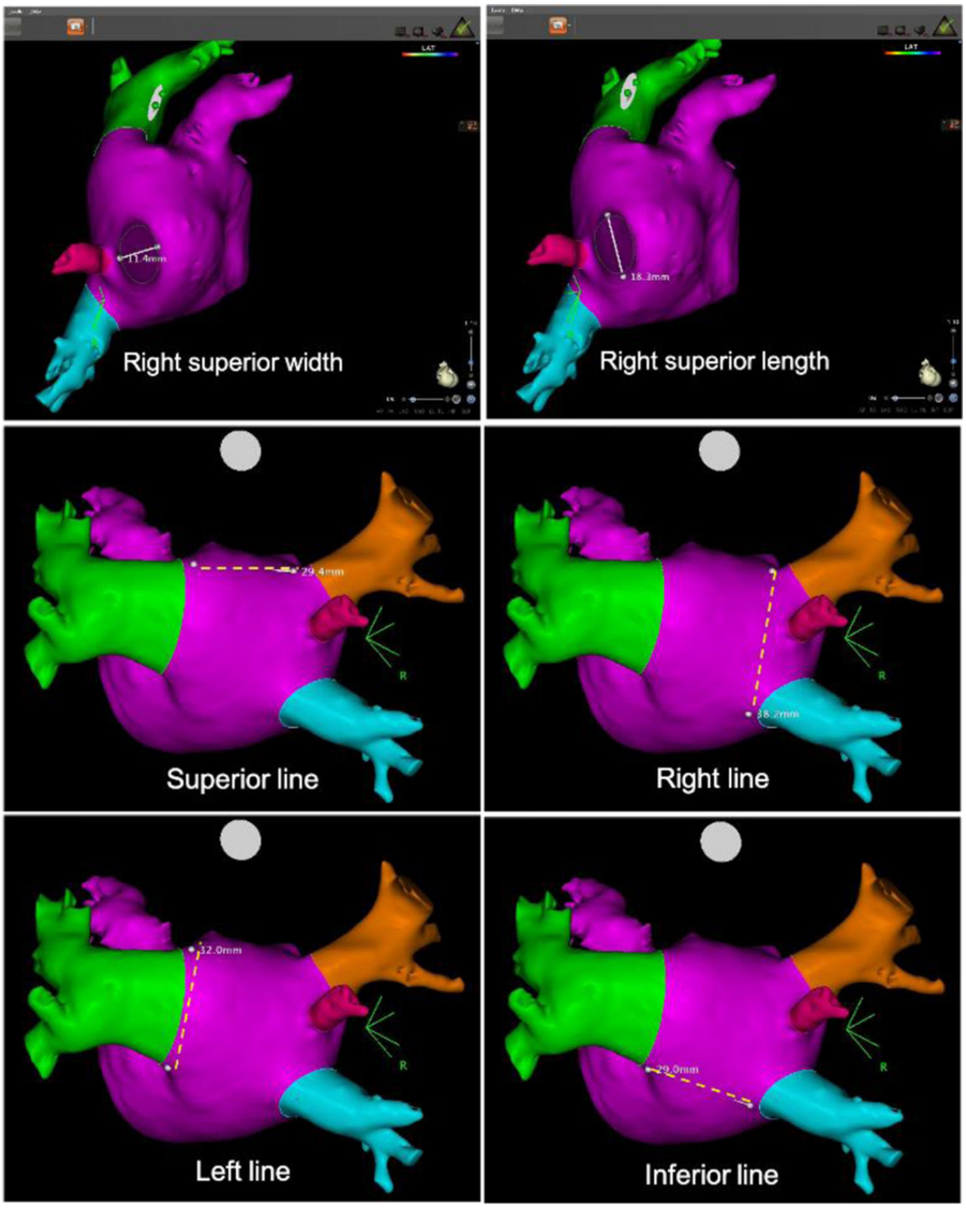

FIGURE 2 An example of the measurement technique on the CT images of the same patient shown in Figure 1. Measurements were performed using a 3D image on the CARTO auto-segmentation module. Anatomy demonstrated a LCPV and a separate right middle PV. Upper panel: RSPV length and width diameters measured at an approximately 90° angle. Middle and lower panel: Posterior wall line measurements are shown (white dashed lines), the measurement points were placed sequentially (white dots), while leaving the last point in the same location when measuring the next line, hence using the exact same points for all the lines. CT, computed tomography; LCPV, left common pulmonary vein; PV, pulmonary vein; RSPV, right superior PV

windows, version 24, IBM cooperation, Armonk, NY, USA, 2016).

3 | RESULTS

Fifteen consecutive patients were enrolled between 01/2020 and 11/2020. All patients presented with paroxysmal AF. Baseline patient characteristics are presented in Table 1. CT was performed in a median of 6 [2,9] days before the procedures. CT scan was performed in sinus rhythm in 10 (67.7%) patients. EPD mapping was performed in sinus rhythm in 11 (73.3%) patients. In 5 (33.3%) patients CT and EPD was not performed during the same rhythm. In 7 and 8 patients the KODEX-EPD versions used were 146a and 147, respectively.

TABLE 1 Baseline characteristics

	***n* = 15**
Age	57.5 ± 13.9
Sex, male	10 (66.7%)
BMI	28.1 ± 4.1
HTN	5 (33.3%)
DM	1 (6.7%)
CAD	2 (13.3%)
Vascular disease	2 (13.3%)
CVA/TIA	1 (6.7%)
CHF	1 (6.7%)
LVEF	57.7 ± 6.1
LA diameter mm	45.3 ± 9.3
CHA2DS2-VASC	1.4 ± 1.4
CHA2DS2-VASC 0	4 (26.7%)
CHA2DS2-VASC 1	5 (33.3%)
CHA2DS2-VASC 2	3 (20%)
CHA2DS2-VASC 3	1 (6.7%)
CHA2DS2-VASC 4	0 (0%)
CHA2DS2-VASC 5	1 (6.7%)
Paroxysmal AF	12 (80%)
Persistent AF	3 (20%)
Beta blocker	10 (66.7%)
AAD Ic	5 (33.3%)
AAD III	7 (46.7%)

Abbreviations: AAD, antiarrhythmic drug; AF, atrial fibrillation; BMI, body mass index; CAD, coronary artery disease; CHF, congestive heart failure; CVA/TIA, cerebrovascular accident/transient ischemic attack; DM, diabetes mellitus; ICD, implantable cardioverter defibrillator; LA, left atrium; LVEF, left ventricular ejection fraction.

Mean LA mapping time was 7.7 ± 3.6 min. Mean number of anatomical mesh points (used for creation of LA anatomy) was 10 053 ± 5000, mean number of electric data points contributing to the anatomical mesh was 480 615 ± 58 812. A movie demonstrating the creation of the left atrial geometry in the KODEX-EPD system is presented in the supplementary data. Mean procedural LA mapping and PV isolation time (from the entrance to the withdrawal of the Achieve catheter from the LA) was 63.6 ± 14 min. After left atrial imaging, CRYO-PVI was achieved in all patients. Additional creation of a cavotricuspid isthmus line to ablate typical atrial flutter was done in one patient. No procedure-related complications occurred.

Very high interobserver correlation was found for both EPD and CT measurements (Spearman $r = .9$, $p < .01$). High correlation ($r = .75$, $p < .01$) was found between CT and EPD measurements. Bland-Altman plot method revealed that measurements assessed by EPD were slightly higher than those assessed by CT. Mean difference was 3.5 mm, $p < .01$ (Figure 3A,B). Correlation was nonsignificantly higher in the subgroup of patients in whom CT scan was performed 6≥ compared with ≥7 days before the EPD mapping, spearman $r = .758$ versus .726, $p = .62$; respectively. A trend for significantly higher correlation was seen in patients in whom the CT scan and EPD mapping were performed in the same rhythm compared with those who were not in the same rhythm, spearman $r = .787$ versus .659, $p = .07$; respectively. All measurements on both systems are shown in Table 2.

In 2 (13.5%) patients, disagreement between the KODEX-EPD and CT imaging regarding a LC PV anatomy was seen, in 1 patient KODEX-EPD system demonstrated a LC anatomy while the CT demonstrated a separate PV os of the superior and inferior PVs, and in the second patient vice versa. In 2 (13.5%) patients, disagreement regarding right middle accessory vein anatomy was seen, in 1 patient KODEX-EPD system demonstrated a superior branch to the RIPV while the CT demonstrated a separate right middle PV os, and in the second patient vice versa. In addition, in 1 patient of the pre-CRYO and post-CRYO anatomical map differed (Figure 4A,B).

4 | DISCUSSION

The KODEX-EPD is a new 3D mapping system with several possible advantages. It provides high quality real time dielectric and voltage-based catheter navigation and imaging. A wide variety of diagnostic and ablation catheters can be used with the system with no need for specific adjustments. In addition, it can create CT like images without the need for direct catheter tissue contact. This capability allows for fast and safe anatomical recontraction of different heart chambers and in particular the LA during PVI procedures.

CB-based PVI was shown to be an effective and safe modality for the treatment of patients with symptomatic AF.[7,8] While most centers performing this ablation rely on 2D X-ray navigation alone, 3D navigation may offer farther advantages in terms of precise catheter location, lower patient and operator fluoroscopic exposure, and possibly also in terms of safety and efficacy. In addition, a novel

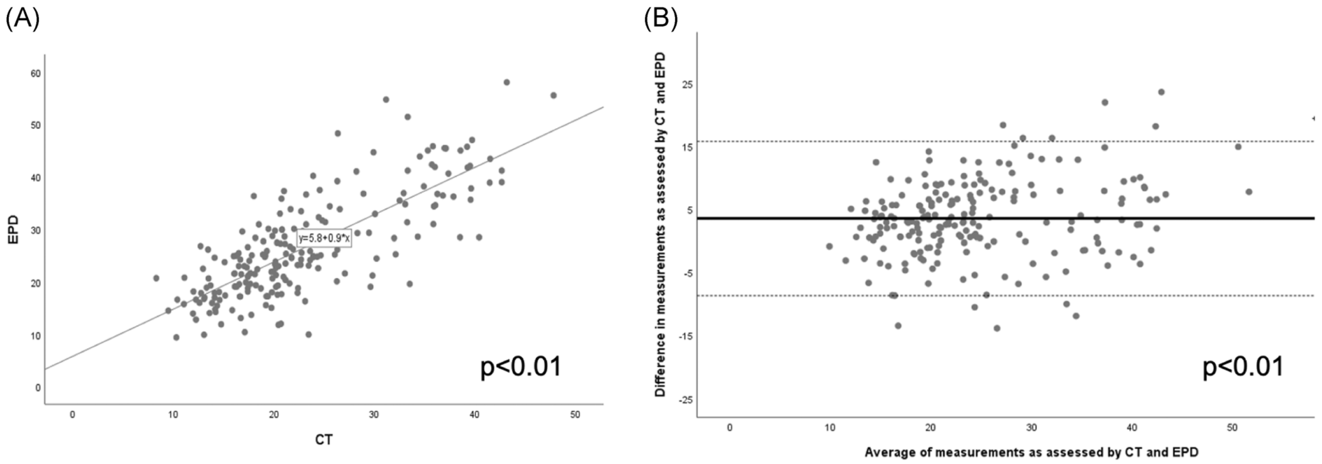

FIGURE 3 (A) Spearman correlation demonstrating a high correlation ($r = .75$) between CT and KODEX-EPD measurements, $p < .01$. (B) Bland-Altman plot method demonstrating the measurements assessed by the KODEX-EPD system were slightly higher than those assessed by CT, with a mean difference of 3.5 mm, $p < .01$. CT, computed tomography

TABLE 2 Comparison of mean measurements of CT versus KODEX-EPD

	CT			KODEX- EPD			
Site	*n*	Mean ± *SD*	Median [IQR]	*n*	Mean ± *SD*	Median [IQR]	*p* value
Left superior length	15	22.54 ± 6.0	20.95 [19.0–23.9]	15	27.94 ± 6.4	25.85 [24.0–30.1]	.001
Left superior width	15	15.59 ± 3.6	15.15 [13.3–16.6]	15	19.74 ± 3.9	18.80 [16.6–23.8]	.001
Left inferior length	13	19.45 ± 2.7	20.10 [17.5–21.0]	13	25.15 ± 4.4	24.15 [21.8–27.9]	.002
Left inferior width	13	13.60 ± 2.5	13.50 [12.1–15.6]	13	18.42 ± 3.1	18.05 [17.0–20.7]	.001
Right superior length	15	21.21 ± 2.9	21.55 [20.1–23.5]	15	25.93 ± 4.0	24.70 [22.7–29.9]	.005
Right superior width	15	17.21 ± 4.1	18.10 [12.7–20.7]	15	19.29 ± 4.3	18.80 [16.0–23.5]	.164
Right inferior length	15	19.95 ± 3.3	20.20 [16.8–22.7]	15	25.82 ± 4.9	24.65 [21.6–29.6]	.005
Right inferior width	15	17.88 ± 3.0	17.65 [15.9–19.9]	15	19.20 ± 4.4	18.15 [16.0–20.7]	.244
Left line	15	35.19 ± 4.9	35.90 [32.0–39.6]	15	36.78 ± 6.1	36.70 [31.4–41.0]	.650
Right line	15	34.86 ± 5.8	37.10 [30.1–39.2]	15	40.05 ± 5.6	40.60 [36.2–45.0]	.020
Superior line	15	27.79 ± 7.3	26.30 [21.1–34.3]	15	29.75 ± 9.1	28.70 [24.5–36.4]	.211
Inferior line	15	32.36 ± 7.7	32.10 [24.8–37.0]	15	40.38 ± 10.3	37.25 [31.7–47.0]	.003
Distance from post line to carina	11	16.48 ± 6.8	14.35 [12.1–17.3]	9	20.13 ± 11.7	15.45 [10.9–30.1]	.327
Appendage os length	9	24.46 ± 5.1	24.65 [19.8–28.4]	9	22.38 ± 3.4	21.60 [19.5–25.1]	.314
Appendage os width	9	19.81 ± 4.8	19.20 [16.4–22.7]	9	15.83 ± 3.4	16.30 [12.5–19.1]	.051

Abbreviation: CT, computed tomography.

occlusion tool and balloon visualization tool were also specifically developed for CB ablation when using the KODEX-EPD system.

To our knowledge, up to date, only 3 prior studies examined the system capabilities in creating 3D anatomical reconstruction of the heart chambers. Maurer et al.[2] described a comparison of the LA anatomy reconstructed on the KODEX-EPD system compared with the CARTO 3 system, and to fluoroscopy with contrast injection. A point-by-point electroanatomical mapping was performed using the ablation catheter, and at least 50 points per map were acquired. High correlation of KODEX-EPD images was demonstrated. However, the study was limited by the use of 2D images for comparison with a single diameter measurement, and that diameter cannot be assured in 2D fluoroscopy as overlap between anterior and more posterior segments is possible. In addition, relative low number of points were used for the creation of the CARTO anatomical mapping, render it to a lower resolution and accuracy, hence their study lacked comparison with a "gold standard" (i.e., CT image). Romanov et al.[1] used CT for comparison of KODEX-EPD images. However, it was used in a porcine model and only limited number of animals ($n = 4$) were studied. Rottner et al.[9] compared the KODEX-EPD PV ostial anatomy to

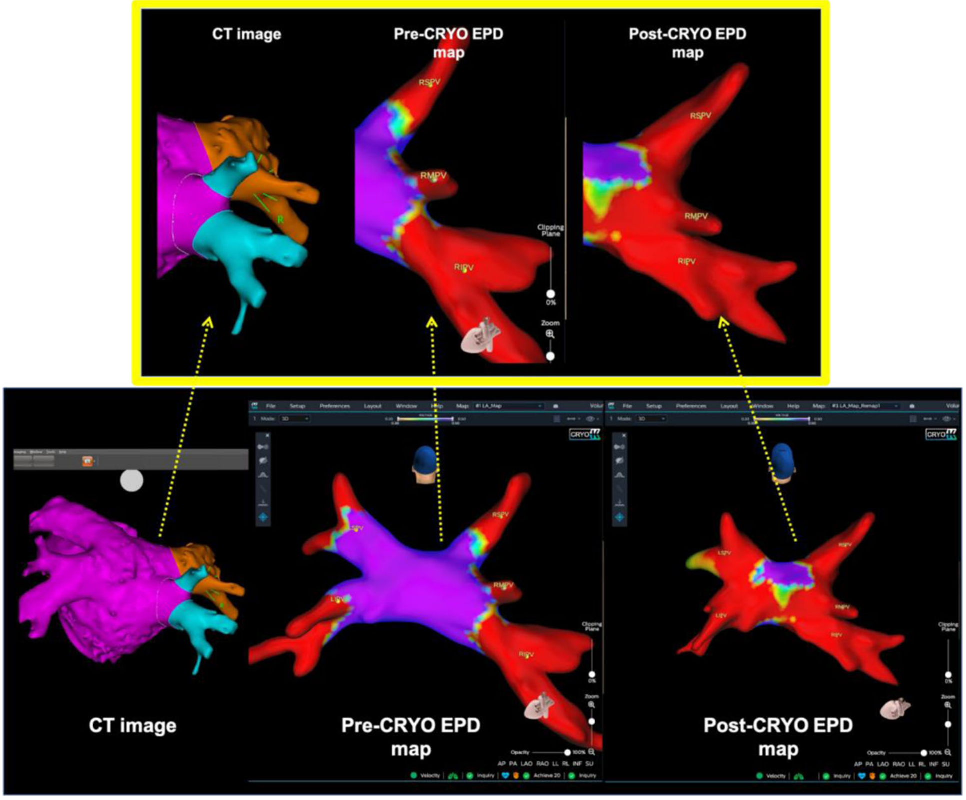

FIGURE 4 An example of disagreement regarding a right middle pulmonary vein anatomy. The CT demonstrated a superior branch to the right inferior PV while the KODEX-EPD system demonstrated a separate right middle pulmonary vein os. In addition, the pre-CRYO and post-CRYO anatomical map differed. The pre-CRYO map demonstrated a separate RMPV while the post-CRYO map demonstrated an early superior branch of the RIPV. CT, computed tomography; PV, pulmonary vein; RIPV, right inferior PV

fluoroscopy and found a good correlation of PV anatomy. The KODEX-EPD overestimated fluoroscopy measurements by approximately 2 mm compared to fluoroscopy. Thus, further studies are needed to test the usefulness of the KODEX-EPD system in creating accurate 3D anatomy.

Our study is the first to systematically compare gold standard 3D CT imaging to high density KODEX-EPD LA mapping using a multipole catheter, which enabled the creation of a detailed LA map in humans. We found high correlation between the 2 modalities when measuring both os diameters (of PVs and LAA) as well as in distance measurements along the posterior wall. Of note, measurements with the KODEX-EPD systems were on average 3.5 mm longer. A finding that probably has no significant clinical implication. This finding is in accordance with the measurements performed by Rottner,[9] who demonstrated ana approximate 2 mm wider diameter in the KODEX-EPD map. A possible explanation is that image acquisition of the CT and EPD was not performed in the same rhythm (sinus vs. AF) in 5 (33.3%) patients. In addition, since the KODEX-EPD system can collect anatomic information without actual physical surface contact, a few millimeters ahead of the catheter electrodes, resulting in a certain kind of "far-field imaging," it is possible this technology may add a few millimeters to the anatomy. Notably, the excellent inter-observer measurements with KODEX-EPD suggest high reliability of this mapping system. With a multiple electrode catheter, like the 8–10 electrode Achieve spiral mapping catheter, acquisition time is potentially shorter. The anatomical correctness and extent of anatomical details are potentially higher with such a catheter as there's a higher likelihood that the cardiac chamber walls will be fully interrogated. However, imaging quality depends on many factors including mapping style and catheter manipulation skills. For KODEX-EPD 3D image to be truly high-resolution, as imaging is based on advanced statistics and computation, the operator needs to continuously acquire data by gently wiggling the catheter and reaching a large variety of different catheter angulations. An experienced EP operator can easily generate high-density left atrial images after a very short learning curve.

KODEX-EPD dielectric-based imaging can safely and accurately be performed in the vast majority of patients. Nevertheless, morbid-obesity patients (body mass index ≥40) can sometimes be challenging.

As with all other electro-anatomical mapping systems, the best mapping results are obtained when the patient is in sinus rhythm or being paced. KODEX-EPD imaging during AF is doable but may require a longer session.

A novel finding of the current study relates to the several instances of disagreements of accessory right sided vein anatomy and the presence of left common PVs. The KODEX-EPD system constantly measures changes in electrical field, these changes (electrical field gradients) occur at chamber borders and ostia of veins including the PVs. Using this data, the system creates anatomical reconstruction of the PVs and their ramifications without the need for direct catheter tissue contact. It may well be that the accuracy of anatomical recontraction based on these electrical gradients needs further fine tuning to constantly match the CT (which we consider the gold standard). Again, whether this finding is clinically significant needs further assessment. In our cases we were able to occlude and isolate all veins with no significant difficulty despite these disagreements.

5 | LIMITATION

The study is limited by a small sample size, nevertheless multiple measurements were performed on each reconstructed LA and compared to the CT image. Also, most patients had routine anatomy, therefore whether the disagreements regarding PV ramifications are clinically relevant cannot be answered by the current study. CT acquisition was performed during inspirium, while EPD is gated to the end experium. Finally, median CT imaging timing was 6 days before the ablation procedure and in 5 patients, rhythm at CT and ablation was different. Nevertheless, despite these limitations, a very high correlation was found between CT and EPD measurements, whether it could have been even better cannot be answered by the current manuscript. In addition, the finding of several cases of anatomical disagreement does not seem to be related to the above-mentioned limitations, however, it should be validated in larger studies.

6 | CONCLUSION

Using the Achieve catheter the KODEX-EPD systems is able to reconstruct the LA anatomy with high accuracy and within few minutes of mapping. Disagreement in PV ramifications were found, whether it may have clinical significance needs further exploration.

CONFLICT OF INTERESTS

Yoav Michowitz received lecture fees from Biosense Webster and consultation fees from EPD-Philips. David J. Orenstein is an employee of EPD solutions, a Philips company. All other authors have no conflict of interests to report that are relevant to the current manuscript.

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SUPPORTING INFORMATION

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