

# A novel wide-band dielectric imaging system for electro-anatomic mapping and monitoring in radiofrequency ablation and cryoablation

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## ABSTRACT

**Background and Objectives:** A novel wide-band dielectric mapping system, named as KODEX-EPD (EPD Solutions, Philips, Best, the Netherlands), was effectively used in the EA mapping for atrial fibrillation (AF) ablation. To date, only a few studies have concentrated on the application of the KODEX-EPD system for ablating supraventricular tachycardia or ventricular premature beats (VPBs) in human models. This study aims to assess the applicability and efficiency of a novel three-dimensional electro-anatomic (EA) mapping system to improve the success rate of ablation. **Methods:** This study included 11 consecutive patients who underwent ablation after EA mapping with the KODEX-EPD system. **Results:** All surgeries were successfully performed using the KODEX-EPD system, including 6 cases who underwent ablation of paroxysmal supraventricular tachycardia (PSVT), 2 cases who received ablation of VPBs from right ventricular outflow tract (RVOT), and 3 cases who underwent cryoablation of AF. For ablation of PSVT or VPBs, the operation time was 31.4 (range, 24.0–38.0) min, in which a median operation time of 2.9 min was used to create anatomic images, and the median fluoroscopic dose was 7.4 mGy. For ablation of AF, the operation time was 56.0 (range, 49.0–62.0) min, in which a median of 4.3 (range, 3.4–5.2) min was used for constructing left atrium map, and the median fluoroscopic dose was 15.0 mGy. The operation time and the fluoroscopic dose were greatly shortened for all surgeries. **Conclusion:** The KODEX-EPD system is an effective and safe tool to guide the EA mapping, leading to improvement in the success rate of ablation. It can promote the ablation process with the reduced fluoroscopic dose, and it is also a promising tool for complex surgeries.

**Key words:** KODEX-EPD, catheter ablation, three-dimensional imaging, dielectric mapping, arrhythmia, atrial fibrillation, supraventricular tachycardia, premature ventricular beat

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## INTRODUCTION

The novel wide-band dielectric mapping (KODEX-EPD) system (EPD Solutions, Philips, Best, the Netherlands) measures changes in electric field gradients induced by intracardiac electrodes to enable catheter localization and real-time three-dimensional (3D) cardiac mapping.<sup>[1,2]</sup> An electric field is formed with the patches on the body

surface. Using a set of electric field signs at each location of the catheter, the 3D electro-anatomic (EA) map of the chamber can be created to locate the catheter in real time.<sup>[3,4]</sup> The KODEX-EPD system was innovatively reported in radiofrequency ablation (RFA) or cryoablation of atrial fibrillation (AF). Several studies have concentrated on the applicability of the KODEX-EPD system in cryoablation.<sup>[4-8]</sup> Novel applications of

the KODEX-EPD in pacemaker implantation have also been recently reported.<sup>[9,10]</sup> However, there are only a few studies concerning the utility of the KODEX-EPD system for the ablation of ventricular premature beats (VPBs) and paroxysmal supraventricular tachycardia (PSVT) in human models.

In the present study, we aimed to assess the applicability and efficacy of the KODEX-EPD system for cardiac EA mapping (including atrium and ventricle) and ablation for VPBs and PSVT. In addition, we studied the reliability of the KODEX-EPD occlusion tool software to detect real-time pulmonary vein occlusion and to avoid contrast injection for cryoballoon ablation of AF.

## METHODS

### Study population

Data of a total of 11 consecutive patients undergoing RFA for symptomatic PSVT, VPB, and drug-refractory paroxysmal or persistent AF from October 2020 to December 2021 were retrospectively analyzed. The KODEX-EPD system was used to perform real time, *in vivo* 3D cardiac mapping. All patients signed the written informed consent form before enrollment. The study was approved by the Ethics Committee of the First Affiliated Hospital of China Medical University (AF-SOP-07-1.0-01), and it was conducted in accordance with the Declaration of Helsinki.

### Preoperative preparation

Echocardiography or cardiac computed tomography (CT) scan was performed preoperatively. Seven patches were placed on patient's body surface, producing an electric field with the wideband (10–100 kHz) across his thorax. By comparing the potential difference between the intracardiac catheter electrode and the reference sensor from the right leg, the electric field line distribution in the heart was measured to locate the catheter and construct the anatomic map with or without physical contact between the catheter and cardiac wall. All procedures were conducted in accordance with the routine surgical guidelines of AF, VPB, and PSVT.<sup>[11–14]</sup>

### Cardiac imaging

The KODEX-EPD system created high-resolution images of cardiac anatomy by exploiting the distinct dielectric properties of biological tissue. It provided fast, real-time, and accurate images without rectifications.<sup>[5,8]</sup> The KODEX-EPD allowed a flat 3D view of the entire chamber – the panoramic view (PANO view) – to present anatomic details and accurately facilitate ablation surgeries. The internal structure of the cardiac chamber was clearly shown with the PANO view to confirm the definitive ablation target.<sup>[15]</sup>

### Endpoints

The primary endpoint of the study was the successful rate of surgeries, guided with the 3D images of the KODEX-EPD. The secondary endpoints included the following items: (1) procedural parameters, such as the operation time and fluoroscopic dose; (2) procedure-related complications, defined as death, transient ischemic attack, stroke, pericardial tamponade or pericardial effusion, bleeding requiring blood transfusion, etc.

## RESULTS

### Procedural parameters

All procedures were completed successfully, including 6 cases who underwent ablation of PSVT, 2 cases who received ablation of VPBs from right ventricular outflow tract (RVOT), and 3 cases who underwent cryoablation of AF. Patients' data are shown in Table 1. For ablation of PSVT or VPB, median operation time was 31.4 (range, 24.0–38.0) min, and median fluoroscopic dose was 7.4 (range, 5.0–14.0) mGy, in which a median of 2.9 (range, 2.0–4.0) min was used for mapping. For cryoablation of AF, median operation time was 56.0 (range, 49.0–62.0) min, and median fluoroscopic dose was 15.0 (range, 13.0–17.0) mGy, in which a median of 4.3 (range, 3.4–5.2) min was used to map the left atrium (Table 1). Additionally, the average fluoroscopic dose for catheter ablation with CARTO 3 (Biosense Webster Inc., Irvine, CA, USA) or cryoablation with angiography of pulmonary veins (PVs) was 60.0 (range, 50.0–63.0) mGy and 256.0 (range, 226.0–298.0) mGy in our center (data were not shown), respectively. High-resolution anatomic images were successfully built and the fluoroscopic dose used for cryoablation with the KODEX-EPD system was greatly reduced, compared with other traditional mapping methods ( $P < 0.05$ ). All the 11 surgeries were carried out without any complications.

### 3D imaging of RVOT

The 3D images of RVOT and endocardial or epicardial views are shown in Figure 1. Electrocardiogram (ECG) of 2 patients showed VPB from RVOT. The ablation catheter was delivered into RVOT and used for constructing 3D maps of passing chambers of the heart with KODEX-EPD. Under the guidance of multi-channel recorder and ECG in KODEX, ablation target was accurately located in the map. At last, all patients successfully underwent ablation. After 6 months of follow-up, no frequent VPB was found in 24 h Holter monitoring.

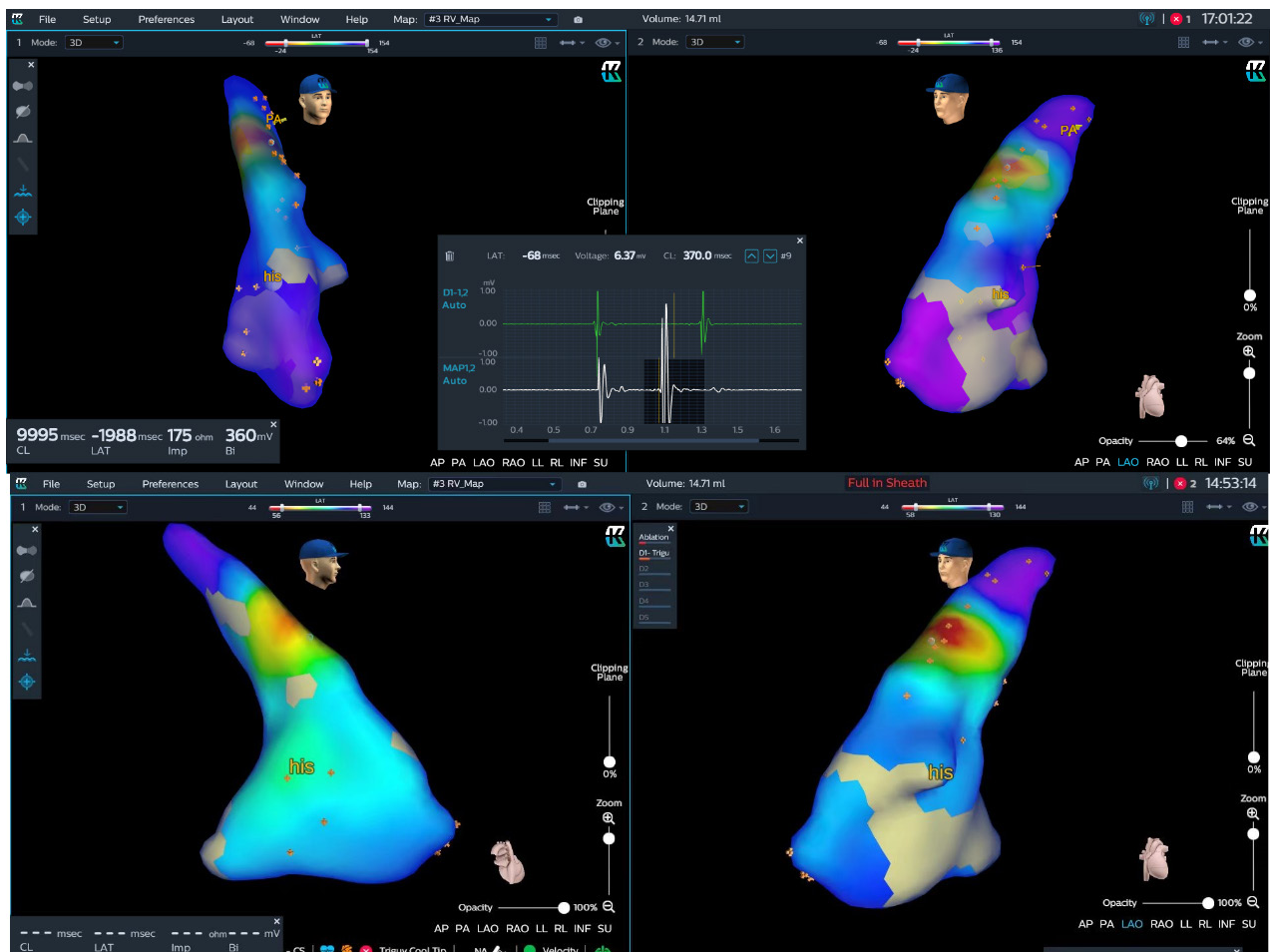
### 3D imaging of the right atrium

An irrigated ablation catheter (Triguy, TPT Medical Co., Ltd., Shenzhen, China) was used to establish the anatomic model (Figure 2) of coronary sinus, right atrium, and

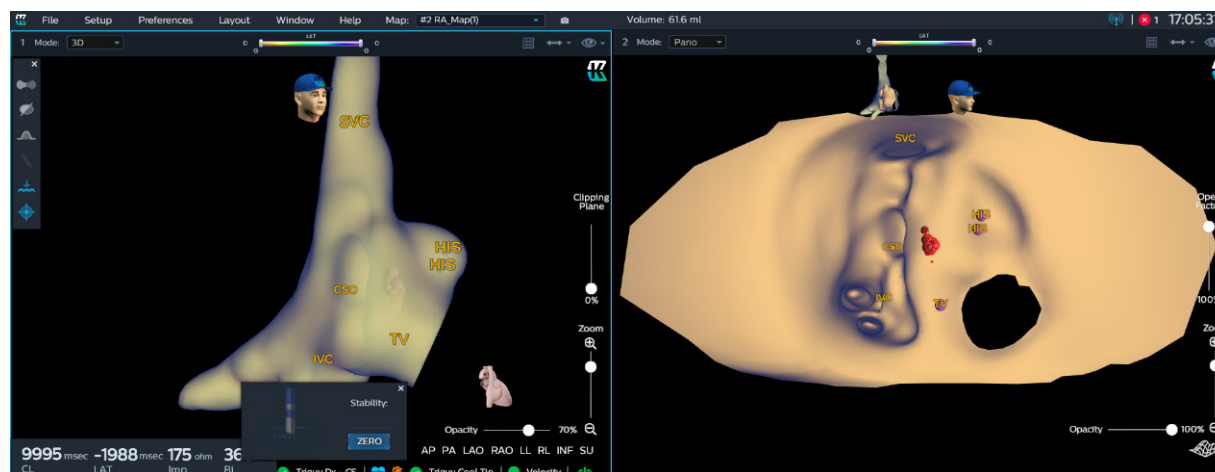
**Table 1: Patients' clinical characteristics**

Patient No.	Age, (years)	Gender	Weight (kg)	Height (cm)	Symptom time (month)	Diagnosis	Medical history	Total procedure time (min)	Total fluoroscopic dose (mGy)	Mapping time with KODEX-EPD (min)
1	59	Female	65	170	24	AF	Amiodarone	49	13	14
2	41	Female	67	164	240	AVRT	Diltiazem, metoprolol, verapamil	24	6	2
3	50	Male	84	168	7	AF	Propafenone	57	15	17
4	41	Female	65	165	3	VPB	Metoprolol	36	5	2
5	49	Male	79	168	6	AVNRT	Metoprolol	36	14	3
6	48	Male	75	170	36	AVRT	Metoprolol	31	7	2
7	60	Male	80	180	84	AF	Bisoprol, propafenone, amiodarone	62	17	17
8	17	Male	84	182	24	VPB	Metoprolol, propafenone	28	6	4
9	41	Male	72	170	72	AVNRT	Metoprolol	25	6	2
10	67	Female	70	158	60	AVNRT	Metoprolol	38	7	4
11	31	Female	65	172	1	AVNRT	No	33	8	4

AF: atrial fibrillation; AVNRT: atrioventricular nodal reentrant tachycardia; AVRT: atrioventricular reentrant tachycardia; VPB: ventricular premature beat; KODEX-EPD: novel wide-band dielectric mapping.



**Figure 1: KODEX map of one patient with ventricular premature beats. The anatomic map of RVOT and right ventricle were plotted. The earliest target was clearly located at the septum of RVOT, with early fragmentation potential in the ECG lead window. After two seconds of ablation, ventricular premature beats disappeared. his: His bundle; RVOT: right ventricular outflow tract.**



**Figure 2: KODEX map of atrioventricular junctional region. Three-dimensional map (left) and PANO view (right) of right atrium and atrioventricular junctional region were presented. After isoprenaline infusion, a typical atrioventricular nodal re-entry tachycardia was induced. The position of His bundle, coronary sinus orifice and the ablation mark were clearly marked in PANO view to indicate the ablation tissue. After 1.5 minutes of ablation (35W, 55°C), the arrhythmia was successfully ablated. PANO view clearly showed the right atrial endocardial view of atrioventricular junctional region. CSO: coronary sinus orifice; HIS: His bundle; IVC: inferior vena cava; SVC: superior vena cava; TV: tricuspid valve.**

tricuspid annulus in 6 PSVT patients. PANO views (Figure 2) of the right atrium were constructed subsequently. Then, the KODEX-EPD system rendered all major anatomic landmarks related to intracardiac catheter placement and navigation. Using 3D visualization, two diagnostic catheters (ten poles and four poles, respectively; Abbott Laboratories Inc., Chicago, IL, USA) were promptly placed into the coronary sinus and right ventricle without fluoroscopy. The EA map was used to reveal the activation and propagation sequence of cardiac electrical activity in the two PANO views.

### 3D imaging of the left atrium

The KODEX-EPD system clearly constructed 3D images of the left atrium and PVs for cryoablation in 3 AF patients. The map of the left atrium and PVs for one patient is shown in Figure 3. Tiny malformations of PVs could be clearly observed in a 3D image plotted by the KODEX-EPD system. The accuracy of the model was similar to that of preoperative CT venography of PVs.<sup>[3,16]</sup> Meanwhile, it could indicate whether the balloon completely blocked PVs or not, with changes of dielectric coefficients discerned by the annular electrode at the head of the balloon. This greatly reduced or even avoided the fluoroscopic exposure and the usage of the contrast agent. High-quality voltage images of left atrium before and after operation are attached in the Supplementary Material.

### Surgical results and complications

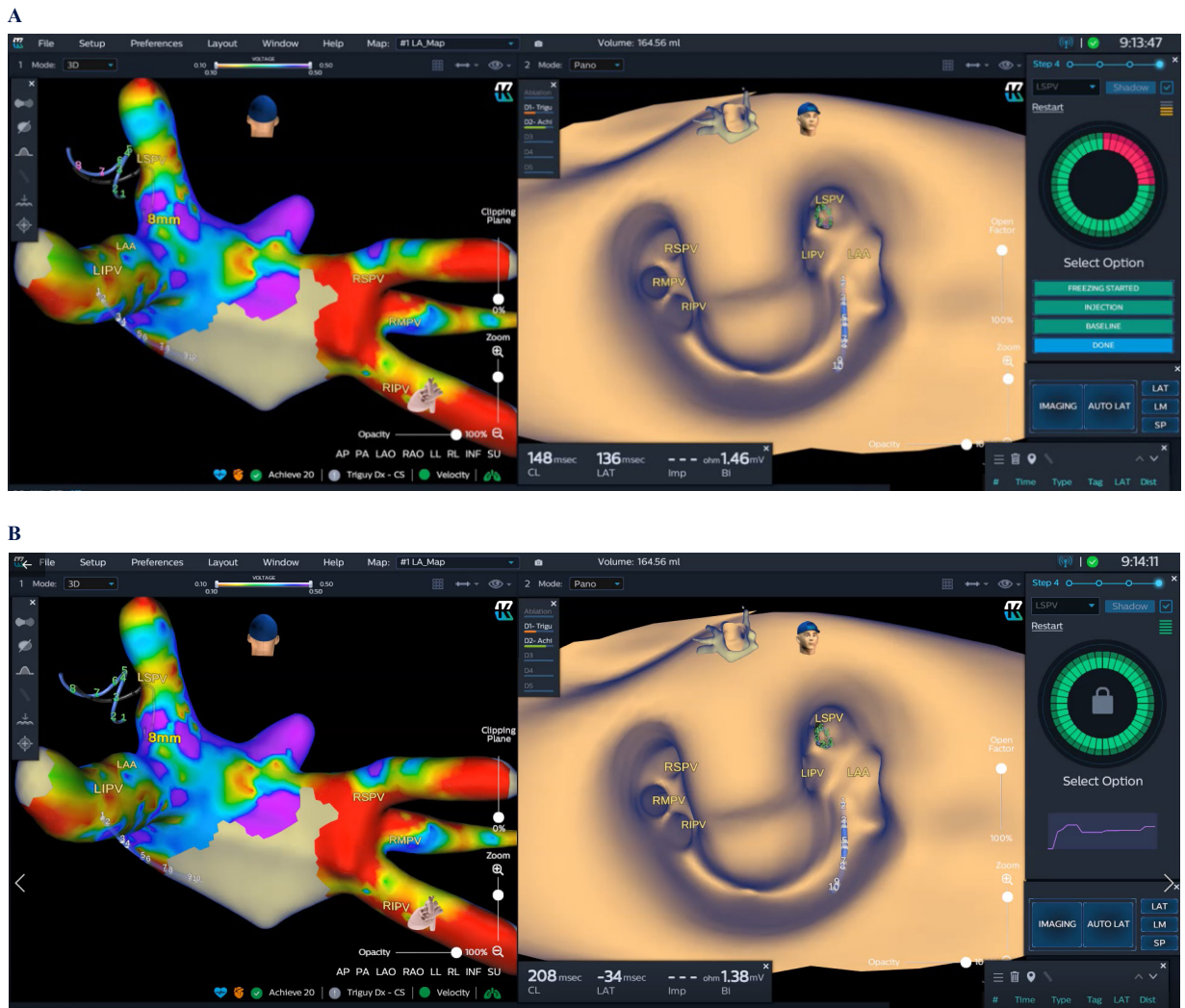
All the surgeries were successfully carried out. After 6–12 months of follow-up, all patients had no recurrent events of previously diagnosed arrhythmia, neither enlargement of cardiac chambers nor reduced ejection factors. The follow-up data of echocardiography are presented in Table 2.

## DISCUSSION

The present study explored the safety, feasibility, and efficacy of using a novel wide-band dielectric mapping system (KODEX-EPD) to treat various arrhythmias, including PSVT, AF, and VPB (RVOT). The KODEX-EPD system can accurately guide the catheter location, and form real-time mapping of atrium, PV antrum, RVOT, and atrioventricular junctional region with valuable anatomic data.

The KODEX-EPD system constructs a high-resolution image of cardiac anatomy by measuring the distinct dielectric properties of heart with catheter moving within an electric field produced by body surface patches.<sup>[3,4]</sup> The heart, as a dielectric material, has dielectric coefficients and can be polarized by an applied electric field, storing and discharging energy.<sup>[17,18]</sup> Using this property, the KODEX-EPD system measures the dielectric properties and determines catheter location, as well as contact pressure.<sup>[2]</sup>

The KODEX-EPD system was first reported in the surgery of human atrial flutter and proved to be safe, feasible, and practical.<sup>[2]</sup> Several studies have subsequently reported the application of the KODEX-EPD system in the AF ablation.<sup>[4-8,19]</sup> AF is associated with significantly high morbidity and mortality.<sup>[20-22]</sup> The KODEX-EPD system was validated for accurate distance measuring and catheter positioning, capturing high-quality images.<sup>[23]</sup> It could construct 3D images of atrium with a quality non-inferior to that of CARTO 3 in human applications, and provide real-time images of mapping.<sup>[3,5]</sup> The real-time 3D and high-resolution imaging capability of the KODEX-EPD system revealed PV ostium structures that are critical in predicting



**Figure 3: KODEX mapping for AF cryoablation.** A 28 mm cryoballoon (Arctic Front Advance Pro; Medtronic), including the circular diagnostic catheter, was placed in the PV antrum. On the roof of the left atrium, there was a small diverticulum between the left and right superior PVs. Three branches were found for the right PV (left). When the cryoballoon occluded the pulmonary vein, “Select PV” displayed a circle with part of red color due to incomplete occlusion or leakage of contrast agent (A). If the PV was occluded completely, the “Select PV” displayed a circle of green color (B). AF: atrial fibrillation; PV: pulmonary vein; LAA: Left atrial appendage; LIPV: Left inferior pulmonary vein; LSPV: Left superior pulmonary vein; RIPV: Right inferior pulmonary vein; RMPV: Right middle pulmonary vein; RSPV: Right superior pulmonary vein.

**Table 2: Preoperational and post-operational electrocardiograms and echocardiograms**

Patient No.	Preoperational materials				Post-operational materials			
	ECG	LA (mm)	LVdD (mm)	EF (%)	ECG	LA (mm)	LVdD (mm)	EF (%)
1	AF	42	50	58	SR	40	49	60
2	SR	39	53	63	SR	38	51	65
3	AF	40	46	57	SR	39	47	60
4	SR and VPB	29	41	67	SR	30	45	66
5	SR	35	56	57	SR	36	55	58
6	SR	34	43	67	SR	34	45	65
7	AF	42	47	67	SR	41	46	66
8	VPB	36	55	60	SR	35	54	61
9	Pre-excitation syndrome	36	48	61	SR	37	46	60
10	SR	37	42	63	SR	38	42	62
11	SR	33	47	67	SR	34	48	66

AF: atrial fibrillation; ECG: electrocardiogram; EF: ejection factor; LA: left atrium; LVdD: left ventricular end-diastolic dimension; SR: sinus rhythm; VPB: ventricular premature beat.

and identifying leaks of PV occlusion.<sup>[1,24]</sup> Cryoablation is a safe and effective method for PVI.<sup>[25,26]</sup> Complete occlusion of the antrum of the PV with the inflated balloon is the key in the surgical steps for AF cryoablation.<sup>[22,27,28]</sup> The KODEX-EPD system could indicate and guide the occlusion degree by measuring the changes of dielectric properties over the spiral mapping catheter during positioning of the balloon, rather than traditional fluoroscopic guidance of the cryoballoon-based PVI with contrast.<sup>[4,6]</sup> The KODEX-EPD system provides PANO view to indicate the degree of PV occlusion (green for full occlusion, red for partial occlusion) after 3D imaging even without any radiation or contrast.<sup>[1,24,29]</sup> In the conventional strategy without using 3D mapping, radiation dose and left atrial procedure time for AF cryoablation were reported to be 8,000 mGy and 50 min, respectively.<sup>[30]</sup> The use of contrast agents can lead to allergy or kidney injury.<sup>[31-33]</sup> The present study showed the reduced radiation dose and a short time required for mapping of the left atrium (Table 1) using the KODEX-EPD system. All cases of AF in the present study underwent cryoablation without any contrast. KODEX-EPD provided a good 3D image of the cardiac structure in real time.<sup>[29]</sup> High-quality images before and after surgery were advantageous to accurately evaluate the damage range and improve the success rate of freezing and assist physicians to make reliable clinical decisions.

Catheter ablation has been recommended as an effective modality for frequent VPBs, which are resistant to antiarrhythmic medications, leading to the reduced left ventricular ejection fraction.<sup>[14]</sup> The success rate of ablating VPB is highly variable due to its multiple origins, diversity of ventricular structure, and different underlying structural heart diseases. The KODEX-EPD system can produce the reconstructed 3D tomography of the heart without pre-acquired CT or other imaging methods. It can visualize any catheter and has the potential to characterize tissue. Images for the atrioventricular valves or ventricles in swine hearts captured with the KODEX-EPD system showed to be more similar to the CT images than CARTO 3's map.<sup>[3]</sup> The surgeon can navigate the catheter in real time and observe the position and orientation of the catheter during mapping. Based on the accurate activation mapping, the arrhythmogenic target could be promptly located to ablate with multiple anatomic images. To our knowledge, there are only a few studies about the application of the KODEX-EPD system for human VPB ablation. The present study included two patients with RVOT VPBs who successfully underwent RVOT mapping and ablation with the KODEX-EPD system. Dielectric imaging is a new approach that may improve some limitations of other EA mapping systems and has the potential to change the way of mapping and ablation.<sup>[2,34]</sup> It will help to improve the success rate of ventricular substrate ablation for VPBs

with exploiting specific dielectric properties of different tissues or even measuring myocardial thickness in the next version of KODEX-EPD.<sup>[35-38]</sup> The KODEX-EPD system is also an open platform that is compatible with validated electrophysiological catheters, providing CT-like images of cardiac anatomy.

In conclusion, the KODEX-EPD dielectric imaging system has the following advantages:

- (1) Based on the dielectric imaging mechanism, the KODEX-EPD system has the characteristics of high precision, good stability, and anti-interference ability. The KODEX-EPD system has a high spatial resolution to distinguish two points with a distance of at least 0.3 mm, even without catheter-tissue contact.<sup>[3]</sup>
- (2) The KODEX-EPD cryoablation occlusion tool helps to improve PVI by indicating PV occlusion degree during AF cryoablation. It significantly reduces operation time and fluoroscopic exposure and may promote AF cryoablation without administration of the contrast agent.<sup>[2,4,7,8]</sup>
- (3) The KODEX-EPD system continuously detects voltage changes of target chamber and locates the earliest ectopic activation point in real time using the local activation time and the propagation map. A 3D map produced by the KODEX-EPD system can be promptly and safely operated with multiple angles to locate the arrhythmogenic target.<sup>[5]</sup>
- (4) Unique visualization tool of the KODEX-EPD system, the PANO view, improves navigation and ablation procedures.<sup>[5,23]</sup>
- (5) Contact pressure of catheter can be obtained with the changes in dielectric coefficients by the KODEX-EPD system, even combined with ablation catheter without pressure-sensing function, leading to a reduction in the operation cost.
- (6) The KODEX-EPD system is highly compatible with other electrophysiological catheters.

## LIMITATIONS

Several limitations of the present study should be pointed out. First, it was a single-center study with a small sample size. However, this study showed a significant reduction in the fluoroscopic time and dose, suggesting that this novel KODEX-EPD system could be a novel zero fluoroscopic guidance tool for the most of electrophysiological surgeries. Second, during AF cryoablation, the catheter and balloon cannot be displayed in the constructed 3D image. Therefore, completely zero fluoroscopic exposure cannot be achieved during RFA. Third, there is only one simulated lead for the KODEX-EPD system to assist the mapping, which may cause errors in the mapping and highly depends on the operator's experience. Last but not least, tissue

information obtained through dielectric measurement and its value for RFA should be developed and validated.

## CONCLUSIONS

The novel wide-band dielectric KODEX-EPD mapping system can generate high-resolution 3D images in real time to guide RFA. It facilitates AF cryoablation with significantly reduced operation time and fluoroscopic dose. It has the potential to improve the ablation of VPB and PSVT. However, further studies with larger sample sizes are needed to confirm these findings.

## Supplementary Materials

Supplementary materials mentioned in this article are online available at the journal's official site only.

## Authors' Contributions

Sun Y, Chen Y, Zhang X, and Li J conceived and designed the research and drafted the manuscript. Li J and Chen Y collected the data. Li J, Chen Y, and Pang X completed the surgeries as the main surgeons. Jia H, Hua Y, Qiao L, Wang B, and Yu Y participated in surgeries and perioperative management. Yu B, Zhang X, and Chen Y assisted to draft the manuscript and made critical revision of the manuscript. All the authors read and approved the final manuscript.

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## Ethics Approval and Consent to Participate

The study was approved by the Ethics Committee of the First Affiliated Hospital of China Medical University (AF-SOP-07-1.0-01). All participants signed the written informed consent form to participate in this study.

## Conflict of Interest

Yingxian Sun is an Associate Editor-in-Chief of the journal. The article was subject to the journal's standard procedures, and peer review was handled independently of this editor and his research groups.

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