Research Square

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Safety and Feasibility of a Balloon-based Pulsed Field Ablation System for Catheter Ablation of Paroxysmal Atrial Fibrillation

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Research Article

Keywords: Pulsed field ablation, Atrial fibrillation, Pulmonary vein isolation, Catheter ablation, balloon-based

Posted Date: May 4th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-9302807/v1

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Additional Declarations: No competing interests reported.

Version of Record: A version of this preprint was published at Journal of Interventional Cardiac Electrophysiology on August 19th, 2026. See the published version at https://doi.org/10.1007/s10840-026-02417-4.

Abstract

Aims

Pulsed field ablation (PFA) is a growing ablation modality for pulmonary vein isolation (PVI) in atrial fibrillation (AF) patients. This study assesses the 6-month safety and effectiveness of a balloon-based PFA system.

Methods and results

The study is a prospective, single-center, pre-market study. A total of 56 patients with drug-refractory paroxysmal (PAF) were enrolled between November 2024 to September 2025, which underwent PVI with the balloon-based PFA system. Study endpoints were the rate of primary serious adverse events as well as acute procedural effectiveness and 6-month freedom from recurrence. Acute effectiveness was achieved in 100% (231/231) of treated PVs (100% of patients, 56/56) with 33 ± 5.5 PFA applications/patient. Procedure, fluoroscopy, and transpired ablation times were 89.0 ± 30.7, 24.2 ± 8.3, and 20.0 ± 12.0 min, respectively. There was 1 (1.8%; 1/56) primary serious adverse events. One patient developed intraoperative gastrointestinal bleeding due to TEE-induced mechanical injury. The rate of freedom from documented atrial arrhythmias was 92.9% through 6-months post-index procedure.

Conclusion

The study primary results demonstrate the safety and effectiveness of the balloon-based PFA system to perform PVI in PAF.

Background

Atrial fibrillation (AF) is a prevalent clinical cardiac arrhythmia characterized by chaotic atrial electrical activity leading to rapid and irregular atrial contractions. AF not only severely impairs patients' quality of life but also causes severe complications, most prominently stroke, thromboembolism, and heart failure. Catheter ablation has become the first-line therapy for rhythm control of AF[1–2], with radiofrequency ablation (RFA) and cryoablation being the most widely used modalities. However, both conventional ablation approaches have inherent limitations: RFA is associated with significant intraoperative pain and thermal conduction-induced injury to adjacent tissues (esophagus, phrenic nerve, coronary arteries) leading to severe complications such as atrial-esophageal fistula; cryoablation carries risks of phrenic nerve palsy, along with low ablation efficiency and prolonged procedural duration[3–4]. Thus, exploring a safer, more effective, and efficient therapeutic strategy for AF has become a research hotspot in cardiovascular medicine.

Pulsed Field Ablation (PFA), an emerging ablation technology, is increasingly applied in AF treatment. It ablates myocardial tissue via irreversible electroporation while preserving critical epicardial structures including the esophagus and phrenic nerve[5–8]. Recent clinical studies have demonstrated its efficacy comparable to RFA and cryoablation, and consistent evidence confirms the superior safety of PFA systems, especially in reducing adjacent organ injury caused by energy conduction[9–11]. However, with the expanding application of PFA in AF catheter ablation, challenges have emerged, including inadequate tissue contact accuracy, and risks of severe hemolysis and renal failure. Given the differences in structural and waveform design among PFA systems, each new device requires rigorous evaluation of these specific factors. This study aimed to assess the safety and feasibility of a balloon-based PFA system (EnChannel Medical) for catheter ablation of paroxysmal AF.

Methods

A total of 56 patients with paroxysmal AF who underwent their first PFA treatment at TEDA International Cardiovascular Hospital from November 2024 to September 2025 were enrolled. The inclusion criteria were: (1) aged 18–75 years, regardless of gender; (2) diagnosed with symptomatic paroxysmal AF (terminating spontaneously within 7 days of onset or with treatment, documented by electrocardiogram, ambulatory electrocardiography, or implantable devices within 1 year before enrollment); (3) poor response to or intolerance of at least one Class I or III antiarrhythmic drug (AAD); (4) willingness to comply with follow-up protocols and provision of written informed consent. The exclusion criteria included: (1) persistent AF (duration > 7 days); (2) AF caused by electrolyte imbalance, thyroid disease, reversible or non-cardiac etiologies; (3) re-ablation for rapid atrial arrhythmias; (4) confirmed atrial flutter or atypical atrial flutter; (5) left atrial diameter > 47 mm on echocardiography; (6) previous left atrial ablation or cardiac surgery (including left atrial appendage occlusion); (7) implantation of permanent pacemaker, biventricular pacemaker, loop recorder/insertable cardiac monitor (ICM), or any implantable cardioverter-defibrillator; (8) anticoagulation contraindications or history of coagulation/bleeding disorders; (9) severe pulmonary disease, pulmonary arterial hypertension, or pulmonary disease with severe dyspnea and blood gas abnormalities; (10) artificial heart valve, NYHA Class III/IV heart failure, left ventricular ejection fraction (LVEF) < 40%, atrial/ventricular septal defect occlusion, atrial myxoma, or left atrial appendage device/occlusion; (11) history of myocardial infarction, unstable angina, percutaneous coronary intervention, cardiac surgery, heart failure hospitalization, pericarditis, or pericardial effusion within 3 months preoperatively; (12) history of cerebral infarction, transient ischemic attack, or documented thromboembolism within 6 months preoperatively; (13) malignant tumor history or expected survival < 12 months; (14) mental disorder with inability to cooperate independently; (15) lactation, pregnancy, or planned/potential pregnancy; (16) acute/severe systemic infection or significant liver/renal dysfunction. All patients provided informed consent, and the study was approved by the Ethics Committee of TEDA International Cardiovascular Hospital ([2024]1018-2).

Preoperative preparations included transthoracic echocardiography for cardiac structure and function, measurement of cardiac biomarkers, liver/renal function, routine blood, and coagulation tests;

pulmonary vein computed tomography angiography (CTA) within 48 h to clarify pulmonary vein morphology; transesophageal echocardiography (TEE) to exclude left atrial/appendage thrombus. Routine anticoagulation with non-vitamin K antagonist oral anticoagulants (NOACs) was administered, with a 12-h withholding preoperatively; patients fasted for 8 h preoperatively.

The investigational balloon PFA system consisted of a PFBalloon catheter (11 Fr shaft, 12 pairs of evenly distributed flexible electrodes on the balloon surface, EnChannel Medical, China, Fig. 1), a PFA generator(NanoAblate, EnChannel Medical, China, Fig. 1), and a 13 Fr deflectable sheath（Linkman, EnChannel Medical, China）. The balloon was filled with a saline-contrast medium mixture for fluoroscopic visualization, ensuring adequate electrode-tissue contact and minimizing blood pool exposure. PFA therapy was delivered as bipolar biphasic pulsed electric fields without R-wave gated pulse sequences between consecutive electrode pairs. All procedures were performed under general anesthesia: two 6F sheaths were implanted via the left femoral vein for a 10-pole coronary sinus (CS) electrode and a right ventricular electrode; transseptal puncture was performed via the right femoral vein, with immediate heparin sodium administration (1000 IU/kg) to maintain activated clotting time (ACT) at 250–350 s. A multipolar mapping catheter was used to create a pre-ablation three-dimensional geometry with voltage mapping of the LA. The mapping catheter was then removed. The PFA catheter was advanced into the left atrium after air evacuation, and ablation was performed at the pulmonary vein antrum and ostium (left superior/inferior, right superior/inferior pulmonary veins) .The balloon was fully inflated to achieve tight apposition for antral ablation 2 applications were delivered at the initial position, followed by a 15° rotation for 2 additional applications (Fig. 2, Fig. 3). The balloon was then partially deflated and advanced to the pulmonary vein ostium(forming a heart-shaped configuration), where two applications were delivered, followed by another 15° rotation for 2 additional applications (Fig. 2, Fig. 3). Accordingly, the standard dosing protocol consisted of 8 applications per pulmonary vein. Ablation parameters were bipolar, biphasic waveform on a microsecond scale ± 750 V with one pulse per train and four pulse trains per application, including 700-ms pause time between trains, totaling about 2.1 seconds per application. Pulmonary vein isolation was confirmed by bidirectional conduction block after a 20-min waiting period (Fig. 4), with additional energy delivery for residual connections if needed.

Postoperatively, patients remained recumbent for 12 h, with routine antiarrhythmic and anticoagulant therapy consistent with RFA/cryoablation. Perioperative complications (puncture-related complications, bleeding, thromboembolism, phrenic nerve injury, cardiac tamponade, cerebral infarction, esophageal injury, death) were monitored. Scheduled follow-up occurred at 30 days, 3 and 6 months. Follow-up is ongoing and will complete at the 12-month visit for all patients. A 90-day blanking period was observed after the index ablation procedure. Medication adjustments, cardioversions, and one repeat ablation procedure utilising the PFBalloon system were allowed during the blanking period without being considered a primary effectiveness endpoint failure. At 30 days, patients were reminded to discontinue antiarrhythmic drugs (AADs) unless clinically justified. Subjects must be off all Class I and III AADs prescribed for AF/AFL/AT after the blanking period.

A 12-lead electrocardiogram (ECG) was performed at the 30 days and 6-month visit. At 3 months, a 24-h Holter monitor was administered. Clinically significant AF recurrence was defined as documented AF, atrial flutter, or atrial arrhythmia lasting > 30 s.

Statistical analysis was performed with SPSS 22.0 (IBM Corp., Armonk, NY, USA). Normally distributed continuous variables were expressed as **mean ± standard deviation (x ± s)**, non-normally distributed variables as median (interquartile range), and categorical variables as n (%). Paired t-tests were used for preoperative-postoperative comparisons of normally distributed variables. A two-sided $P < 0.05$ was considered statistically significant.

Results

A total of 56 patients (mean age 62.4 ± 8.7 years) underwent successful ablation with the investigational PFA system. The baseline characteristics included 67.8% male, mean BMI 26.3 ± 3.3 kg/m², mean CHA_2DS_2-VASc score 1.8 ± 1.2, mean LVEF 63.1 ± 4.3%, and mean left atrial diameter 37.6 ± 3.6 mm; the most common comorbidities were hypertension (58.9%), coronary heart disease (37.5%), and diabetes (16.1%). Patient characteristics are summarized in Table 1.

The mean procedural duration was 89.0 ± 30.7 min, mean fluoroscopy time 24.2 ± 8.3 min, and mean ablation time (first to last energy delivery) 20.0 ± 12.0 min. The mean number of energy deliveries per patient was 33.0 ± 5.4, with 8.9 ± 3.4, 8.0 ± 0.1, 8.7 ± 1.8, and 8.1 ± 0.5 deliveries for the left superior, left inferior, right superior, and right inferior pulmonary veins, respectively. Procedural characteristics are summarized in Table 2.

For efficacy, acute electrical isolation was achieved in all 231 pulmonary veins (100% success rate), with no acute reconnection observed. All patients completed 6-month follow-up, 92.9% of the patients free from documented atrial arrhythmias. All of the 4 patients received repeat procedure, and 2 of the patients remained PVs isolated. The reasons for effectiveness endpoint failure are summarized in Table 3. There were 8 patients (14.3%, 8/56) used propafenone after procedure, and 4 patients (7.1%, 4/56) used propafenone/amiodarone after the blanking period (2 propafenone; 2 amiodarone).

For safety, there was 1 patient (1.8%, 1/56) with stroke 28 days post-procedure requiring hospitalization. No death, cardiac tamponade, phrenic nerve injury, renal failure, or other PFA-related serious adverse events (SAEs) were observed (Table 4). One patient developed intraoperative gastrointestinal bleeding due to TEE-induced mechanical injury to the esophagogastric fundal mucosa, which was successfully managed with hemostatic clipping. Perioperative laboratory tests showed mild, transient changes in red blood cell count, hemoglobin, and hematocrit ($P < 0.05$), with no statistically significant alterations in serum creatinine and urea ($P > 0.05$); total bilirubin and LDH increased slightly at 1 day postoperatively ($P = 0.0095$) with no clinical jaundice. No clinically significant hemolysis was observed (Table 5).

Discussion

This single-center prospective exploratory study evaluated the safety and feasibility of a domestically developed balloon-based PFA system (EnChanel Medical) for catheter ablation of paroxysmal AF. The key findings are: (1) the system achieves a 100% acute PVI success rate with no acute reconnection; (2) 92.9% 6-month freedom from clinically significant AF recurrence; (3) a good safety profile with 1.8% PFA-related severe complications; (4) low risks of hemolysis and renal injury, with mild and transient perioperative changes in hematological parameters. These results provide important clinical evidence for the safety and efficacy of this domestic PFA system, supporting its potential clinical application for paroxysmal AF.

Safety of the Balloon-based PFA System

The most prominent advantage of PFA over conventional thermal ablation is its non-thermal irreversible electroporation mechanism, which selectively ablates myocardial tissue while preserving the structural and functional integrity of adjacent non-myocardial tissues (esophagus, phrenic nerve, coronary arteries) [12–14]. This fundamental advantage is the core reason for the low incidence of adjacent organ injury in PFA. In this study, no phrenic nerve injury, esophageal injury, or atrial-esophageal fistula was observed, consistent with the results of previous PFA studies. The balloon-based "one-shot" ablation mode reduces the frequency of catheter manipulation in the left atrium, thereby lowering the risk of cardiac tamponade and other procedural-related complications. Notably, no cardiac tamponade occurred even with relatively low operator familiarity with this novel system, suggesting a low procedural risk and a short learning curve for electrophysiologists—an important advantage for clinical promotion[14].

Hemolysis is a major potential safety concern of PFA, mainly related to energy delivery in the blood pool, the number of energy releases, and the degree of electrode-tissue contact[15,16]. Severe hemolysis may lead to acute renal failure, which has been reported in some PFA studies. In this study, the balloon-based catheter minimizes electrode-blood contact through tight tissue apposition, resulting in no clinically significant hemolysis. Perioperative laboratory tests showed only mild changes in red blood cell count, hemoglobin, hematocrit, total bilirubin and LDH with no significant alterations in renal function parameters (creatinine, urea), indicating a low risk of hemolysis and renal injury.

Efficacy of the Balloon-based PFA System

Pulmonary vein isolation is the gold standard for AF catheter ablation, and the acute PVI success rate is a key indicator of ablation efficacy. In this study, the 100% acute PVI success rate is consistent with the results of other balloon-based PFA studies, which is mainly due to the balloon catheter's advantages of uniform electrode distribution and tight tissue contact—these features ensure complete ablation of pulmonary vein myocardial sleeves and avoid ablation gaps caused by inadequate electrode-tissue contact.

The 92.9% 6-month freedom from clinically significant AF recurrence in this study is higher than the results of previous large-scale PFA trials (66.2%–86.2%)[14,17–20]. Several factors may contribute to this superior mid-term efficacy: (1) the study population was strictly limited to paroxysmal AF patients with a

relatively small left atrial diameter (mean 37.9 ± 2.9 mm), who have a better ablation prognosis than patients with persistent AF or large left atrial diameter; (2) the short 6-month follow-up period may lead to overestimation of efficacy, and long-term follow-up (≥ 1 year) is needed to confirm chronic efficacy; (3) the small sample size of this exploratory study may also contribute to the high AF-free survival rate, and large-sample multicenter studies are required for validation.

Study Limitations

This study has several limitations that should be noted when interpreting the results. First, this is an exploratory single-center study with only 56 patients enrolled, which may limit the generalizability of the results. Rare complications (e.g. atrial-esophageal fistula, coronary artery spasm) cannot be effectively evaluated due to the small sample size. Second, only 6-month efficacy and safety were evaluated; long-term follow-up (≥ 1 year) is needed to confirm the chronic efficacy, PVI persistence, and long-term complication incidence. Third, no electrophysiological re-mapping was performed during follow-up to evaluate PVI persistence; AF recurrence was only based on non-invasive electrocardiographic monitoring, which may underestimate the actual recurrence rate.

Conclusions

This balloon-based PFA system (EnChannel Medical) exhibits an excellent safety profile and high feasibility for paroxysmal AF ablation, with no PFA energy-related severe complications. It achieves a 100% acute pulmonary vein isolation success rate and 92.9% 6-month freedom from clinically significant AF recurrence, demonstrating reliable acute and short-term chronic efficacy. Long-term follow-up and multicenter randomized controlled trials are warranted to further validate its long-term efficacy and safety, and to compare it with other ablation modalities and PFA systems.

Declarations

Disclosure

The balloon-based PFA system study is sponsored by EnChannel Medical.

Author Contribution

PZ W wrote the main manuscript text. JJ L designed the study. K Z and JL B finished the procedure. XH D, S Y, LC T and ZZ Q contributed to data collection, data analyses. Z L and YH M contributed to interpretation. All authors reviewed the manuscript.

Acknowledgments

This work was supported by the Science Foundation of Tianjin Binhai New Area Health Commission(2023BWKQ012) and Tianjin Key Medical Discipline Construction Project

(Grant No. TJYXZDXK-3-035C).

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Tables

Tables 1 to 5 are available in the Supplementary Files section.

Figures

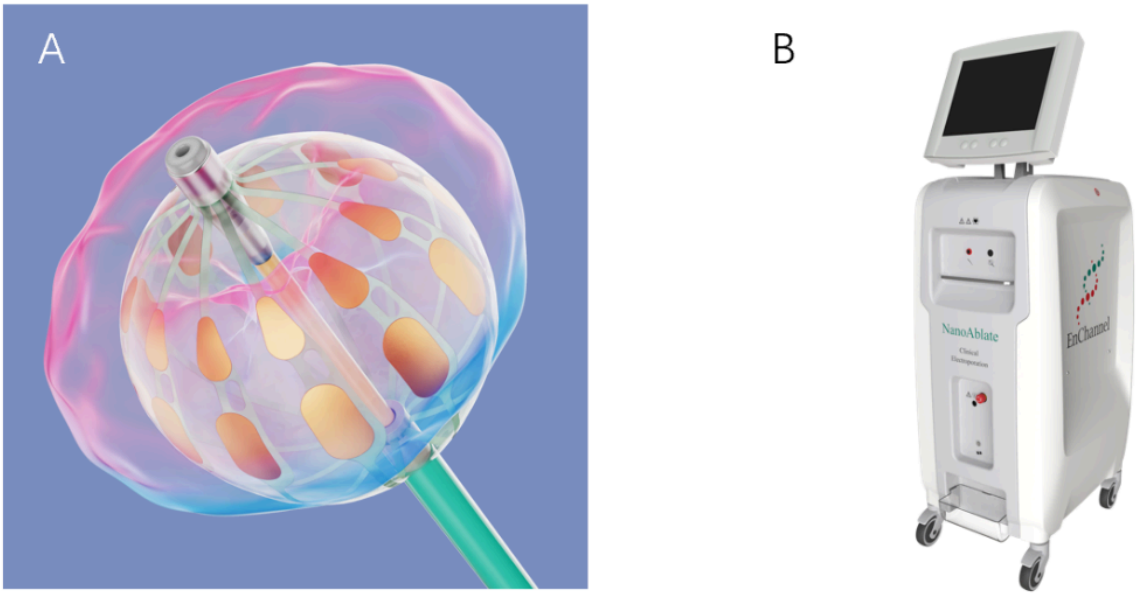


Figure 1

A, PFBalloon catheter (11 Fr shaft, 12 pairs of evenly distributed flexible electrodes on the balloon surface，EnChannel Medical，China). B, PFA generator，NanoAblate，EnChannel Medical，China，.

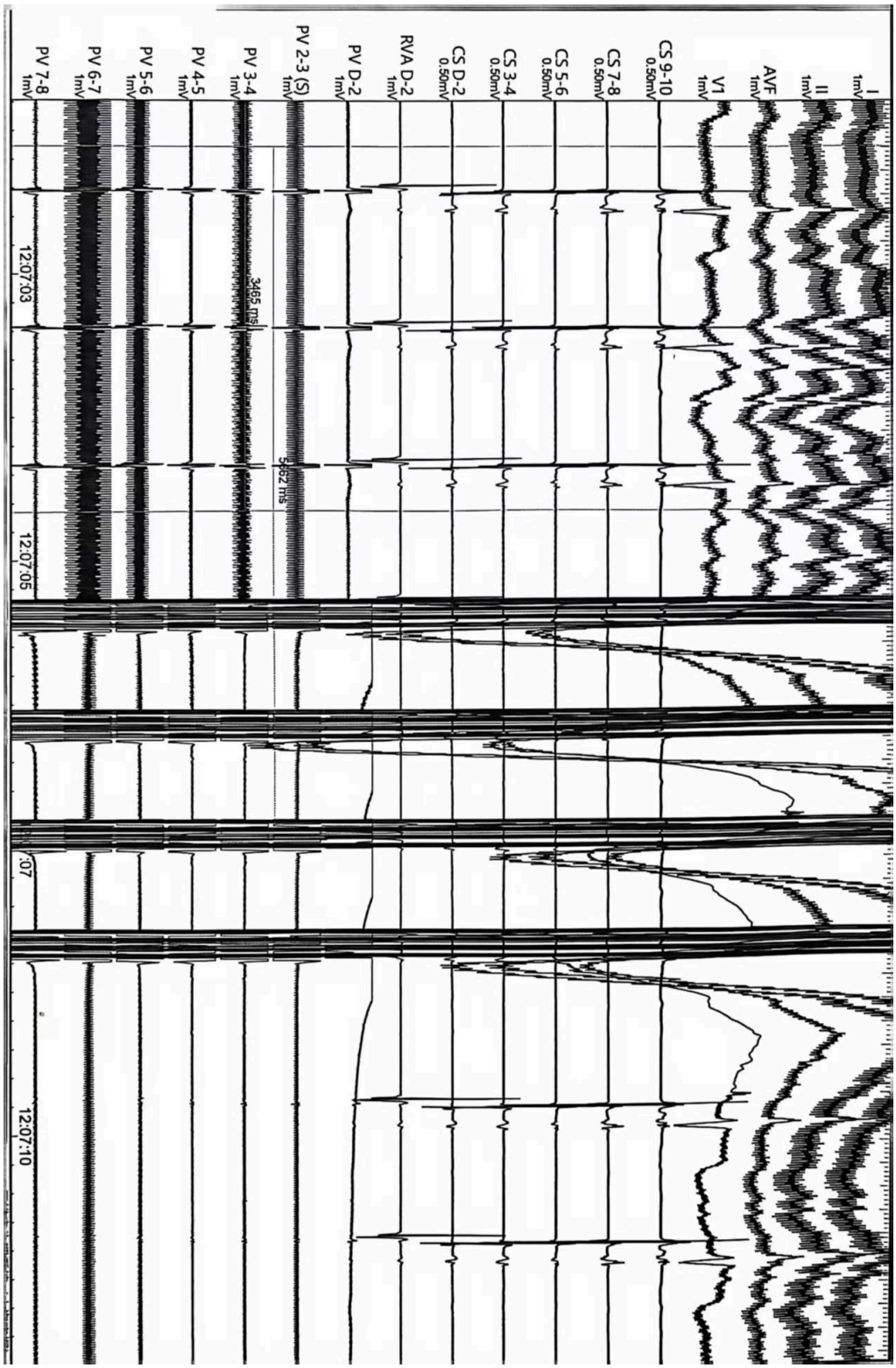


Figure 2

Pulmonary vein potential disappeared after ablation.

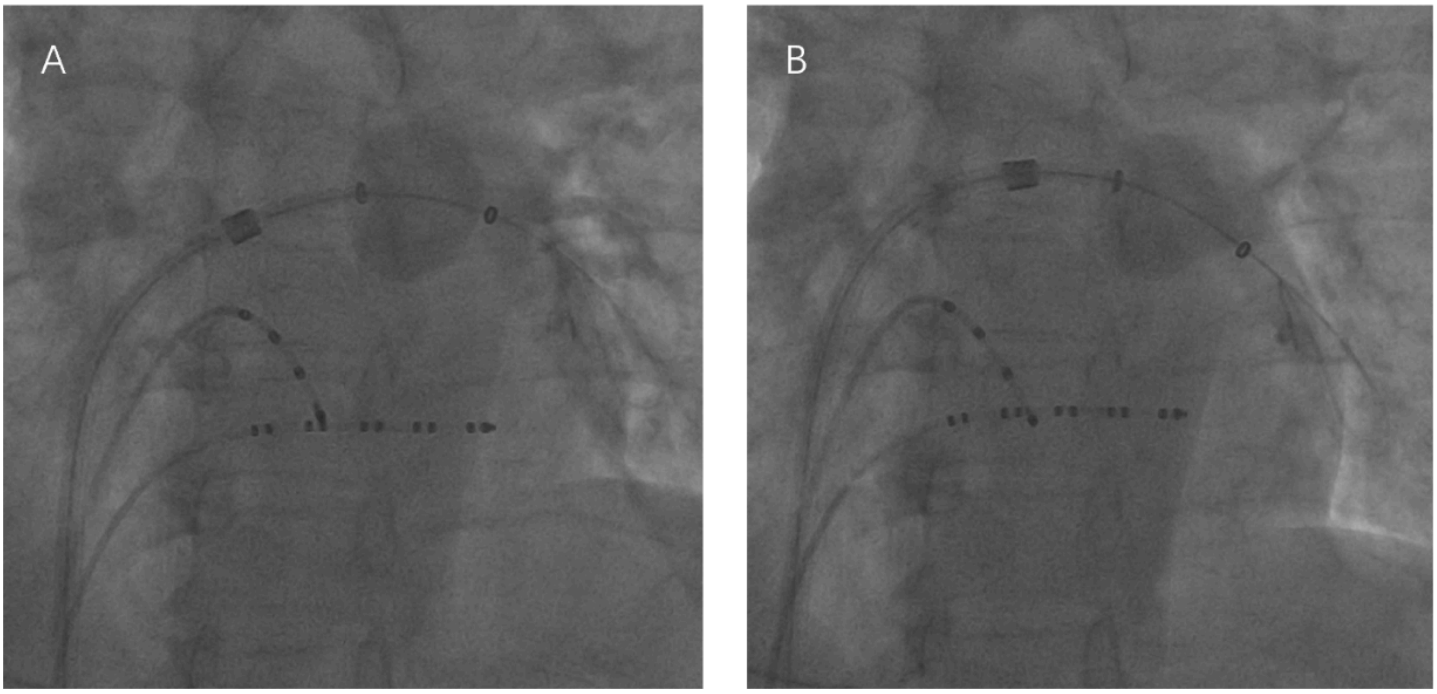


Figure 3

A, the balloon was fully inflated to achieve tight apposition for antral ablation. B, the balloon was partially deflated and advanced to the pulmonary vein ostium ablation (forming a heart-shaped configuration).

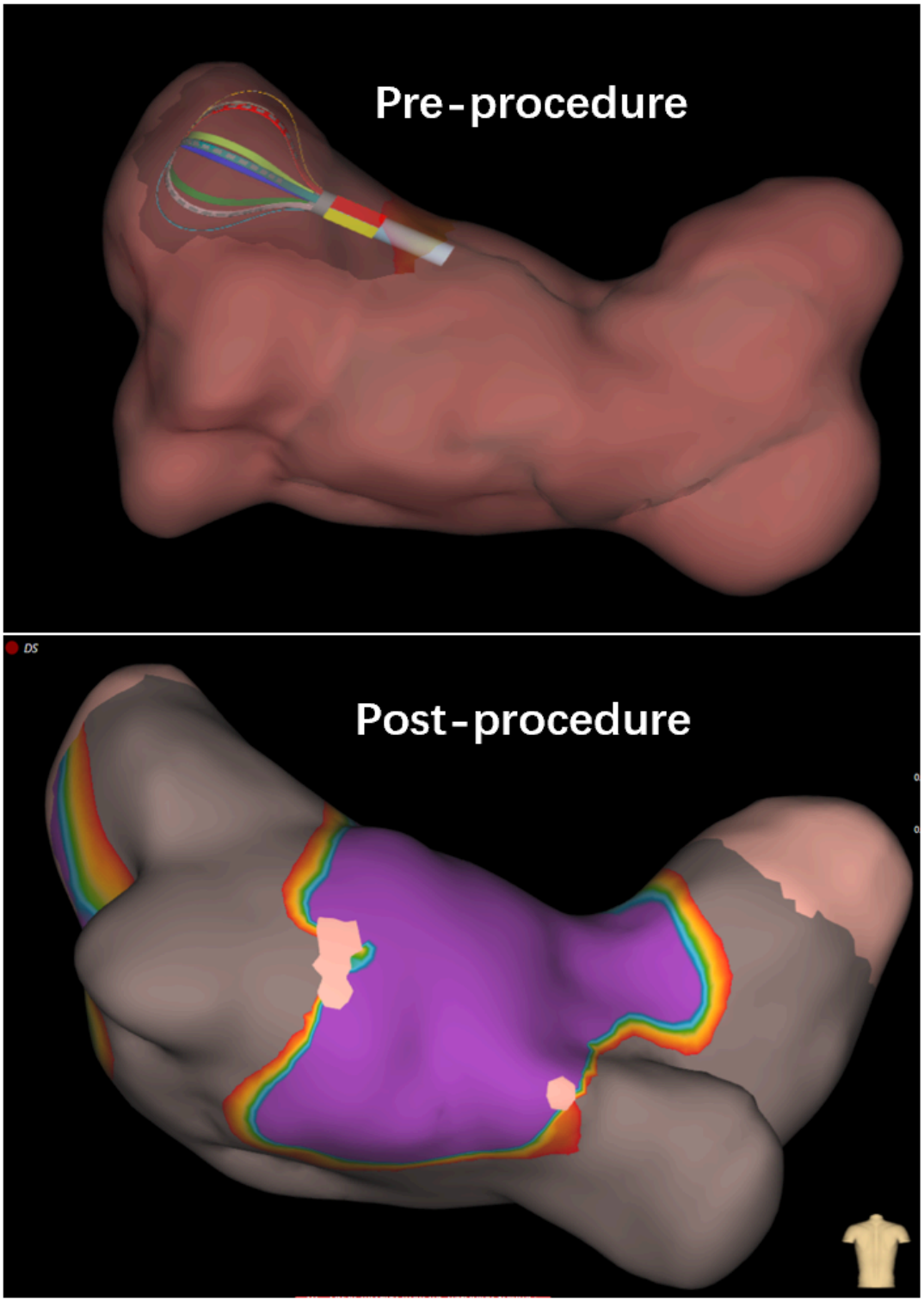


Figure 4

Legend not included with this version

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