

Left Atrial Ridge Edema After VARIPULSE pulsed field ablation: Correlation With Early Peri-device leak

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Research Article

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Abstract

Background: Pulsed field ablation (PFA) combined with left atrial appendage occlusion (LAAO) is an emerging one-step strategy for atrial fibrillation. Current clinical studies mainly focus on procedural safety and recurrent arrhythmia, while subtle anatomical changes after PFA, especially alterations of the left atrial ridge, are rarely recognized. This cohort represents a preliminary real-world experience of one-stage PFA+LAAO using the VARIPULSE system in Chinese patients, where related anatomical morphological data remain scarce in domestic literature.

Methods: In this single-center retrospective cohort study, 40 consecutive patients underwent combined PFA and LAAO. LAA ridge thickness and LAA orifice diameter were measured via transesophageal echocardiography before and after ablation. The primary follow-up endpoint at 90 days was the presence of residual shunt of the LAA occluder. Periprocedural adverse events were analyzed descriptively as secondary outcomes.

Results:

Implant success was achieved in all 40 patients (100%), with no deaths, strokes, major bleeding events, or intervention-requiring pericardial effusions observed. No complications such as hemolysis, air-bubble stroke, phrenic nerve palsy, or coronary artery spasm occurred intraoperatively. All patients underwent pulmonary vein isolation (PVI) with VARIPULSE, followed by LAAO with Watchman FLX (21/40) or LACbes (19/40) guided by transesophageal echocardiography (TEE). Post-PFA, LAA ridge thickness increased significantly by 1.21 ± 0.50 mm ($P < 0.001$), $30.45 \pm 12.69\%$. At 90-day follow-up, complete sealing (0 mm peri-device leak) was achieved in 100% of patients, with no device-related thrombus (DRT) or embolization observed.

Conclusion: Combined PFA and LAAO was feasible with high implant success, low periprocedural complication rates, and favorable outcomes through 90 days. This integrated approach offers a promising “one-stop” strategy for patients with AF requiring rhythm control and stroke prevention. We observed a mean 30.45% increase in LAA ridge thickness immediately following PFA. This study provides preliminary anatomical evidence for postoperative structural changes after VARIPULSE PFA.

Introduction

Catheter ablation represents a well-recognized therapeutic option for individuals diagnosed with AF. Multiple randomized controlled trials have verified that this intervention outperforms antiarrhythmic medications in reducing arrhythmia recurrence, improving quality of life and reducing the risk of hospitalization ^[1, 2]. Separately, percutaneous LAAO can effectively reduce stroke events attributable to AF ^[2]. As a novel ablation modality, PFA achieves favorable safety and efficacy when used to perform PVI in patients with AF ^[3]. To date, there are relatively few published studies regarding the combination of PFA and LAAO. This study evaluated the efficacy and safety of combined PFA and LAAO procedures. PFA produces lesions via non-thermal cell death; theoretically, it induces less tissue edema

at the LAA ridge area compared with radiofrequency ablation or cryoablation [4, 5]. Therefore, this study evaluated LAA ridge thickness post-PFA and the occurrence of peri-device leak (PDL) on 90-day follow-up imaging.

Materials and methods

Study design and setting

This was a retrospective cohort study of consecutive patients undergoing combined PFA and LAAO procedures at Putuo Hospital (Shanghai University of Traditional Chinese Medicine) from January 2026 to June 2026. All patients were referred for LAAC based on clinical indication (Table 1).

Table 1
Baseline Characteristics

Clinical characteristics (N = 40) Value	
Age (Years)	70.8 ± 5.6
Female	47.1%
AF type	
Paroxysmal	64.7%
Persistent	35.3%
LVEF %	63.82 ± 6.80
BMI kg/m²	21.22 ± 2.46
CHA2DS2-VASc score	3.52 ± 1.08
HAS-BLED score	2.38 ± 0.80
Procedure strategy	
PVI-only	6(15%)
PVI+	34(85%)
Oral Anti-Coagulant	36(90%)
Vitamin K Antagonist	0
Antiarrhythmic drug	5(12.5%)
Values are presented as mean ± SD or n(%);LVEF,left ventricular ejection fraction;PVI,pulmonary vein isolation;AF,atrial fibrillation;	

Intervention and procedure

All procedures were performed under general anesthesia with transesophageal echocardiography (TEE). First, a single transseptal puncture was performed, followed by PFA-based PVI or PVI + utilizing the VARIPULSE system (Johnson & Johnson). After successful isolation of all pulmonary veins was confirmed by entrance block, the transseptal sheath was exchanged for a 14-Fr Watchman delivery system. Subsequently, LAAO was performed with the Watchman FLX or LACbes device under TEE guidance. Device size was determined according to the maximum left atrial appendage orifice diameter measured at imaging angles of 0°, 45°, 90°, and 135°. Prior to deployment, adequate device positioning, stable fixation validated by the tug test, and satisfactory sealing (peri-device leak $\leq$ 3mm on color Doppler imaging) were confirmed.

Measurement of LAA ridge thickness

LAA ridge thickness, defined as the distance between the left superior pulmonary vein orifice and the left atrial appendage at the carina crest, was measured via TEE at the 90 plane by two independent cardiologists immediately before PFA and after PFA (prior to LAAO) (Fig. 1,A,B). Measurements were performed perpendicularly to the carina axis at the carina crest, and the mean value of three consecutive measurements was recorded for analysis.

Outcomes and follow-up

All patients completed the 90-day clinical follow-up after the procedure. Follow-up imaging with contrast-enhanced cardiac computed tomography at 90 days was performed in all patients to evaluate device position, PDL, and device-related thrombus(DRT)(Fig. 1,C,D). Complete LAA sealing discontinued oral anticoagulation (OAC) and switched to single antiplatelet therapy, while those with those with significant PDL (> 3 mm) continued OAC until repeat imaging verified full occlusion.

Statistical analysis

Baseline and procedural characteristics were summarized via frequency tables. Normally distributed continuous variables were presented as mean $\pm$ standard deviation, while non-normal continuous data were reported as median (interquartile range). Between-group comparisons for normal continuous variables adopted the student's t-test, and the Mann-Whitney U test was applied for non-normal continuous variables. Categorical variables were analyzed using the chi-square test or Fisher's exact test as indicated. A paired t-test was utilized to compare pre- and post-ablation LAA ridge thickness. All statistical analyses were conducted with SPSS 29.0 (IBM).

Results

Study Participants

Between January 2026 and June 2026, a total of 40 consecutive patients with AF underwent PFA with combined LAAO. Baseline characteristics are summarized in Table 1. The mean age was 70.8 ± 5.6 years; 47.1% were women, and 35.3% had persistent AF. The mean CHA₂DS₂-VASc score was 3.52 ± 1.08 and the mean HAS-BLED was 2.38 ± 0.80 . The majority of patients were treated with a DOAC (36/40), and were on antiarrhythmic drug therapy.

Procedure Parameters

Detailed procedural information is provided in Table 2. Device implantation succeeded in 40/40 patients (100%). Notably, no procedures were terminated due to landing zone edema. Among the completed procedures (N = 40), PVI combined with left atrial posterior wall ablation was achieved in 85% of cases. Intraoperative metrics revealed a median procedural time of 77.01 minutes and median fluoroscopy time of 18.77 minutes. The mean size of Watchman FLX or pro implanted devices was calculated as 26.15 ± 4.71 mm. The LACbes perimeter was 31.54 ± 4.18 mm. Acute procedural seal was achieved in all implants (100%). No deaths, strokes, major bleeding events, pericardial effusions requiring intervention, device embolization, or vascular access complications were observed. No complications such as hemolysis, air-bubble stroke, phrenic nerve palsy, or coronary artery spasm occurred intraoperatively.

Table 2
Procedural Characteristics and Complication

Procedural Characteristics and Complication Value	
Procedural time(Excluding anesthesia and recovery duration)	77.01 ± 29.09
Fluoroscopy time	18.77 ± 4.52
Acute procedural success rate,n(%)	100
Acute appendage seal rate,n(%)	100
LAAC device type:WATCHMAN FLX or Pro	21
LAAC device type:LACbes	19
LAAC device size:WATCHMAN FLX or Pro,n(%)	21
20mm	3(7.5%)
24mm	5(12.5%)
27mm	7(17.5%)
31mm	5(12.5%)
37mm	1(2.5%)
40mm	0
LAAC device size:LACbes,n(%)	19
Small(18/20mm)	11(27.5%)
Medium(22/24/26mm)	6(15%)
Large(≥ 28 mm)	2(5%)
Pericardial effusion/tamponade	0
Stroke	0
Transient ischaemic attack	0
Death	0
Device embolization	0
Major bleeding events	0
Hemolysis, air-bubble stroke, phrenic nerve palsy, and coronary artery spasm	0
Values are presented as mean ± SD or n(%); LAAC, left atrial appendage occlusion;	

90-day Follow-up Outcomes

All patients completed 90-day follow-up. Clinical outcomes are summarized in Table 3. At 90 days, no deaths, strokes, major bleeding events, or intervention-requiring pericardial effusions were observed. One participant presented recurrent arrhythmia during the 90-day follow-up. 90 days after the procedure, successful complete sealing was verified for every patient. No occurrences of DRT or device embolization were recorded during follow-up.

Table 3
Clinical outcomes at 90 days follow-up

Clinical Outcomes Value	
Stroke/TIA	0(0)
Major bleeding	0(0)
Heart failure	0(0)
Pericardial effusion	0(0)
All-cause death	0(0)
Arrhythmia recurrence	1(2.5%)
Follow-up imaging	
CT	39(97.5%)
TEE	1(2.5%)
Device-related Outcomes at 90 days	
Complete seal	40
PDL > 5 mm	0
PDL > 3 mm to ≤ 5 mm	0
PDL ≤ 3 mm	0
DRT	0
Device embolization	0
Values are presented as n(%). TEE, transoesophageal echocardiography; CT, computed tomography; PDL, CT, computed tomography; DRT, Device related thrombosis.	

LAA Ridge Thickness

The baseline LAA ridge thickness measured immediately prior to PFA was 4.10 ± 0.71 mm. Post-procedurally, the thickness increased to 5.31 ± 0.89 mm. The mean thickness increment reached 1.21 ± 0.50 mm (95%CI: 0.96-1.47mm, $P < 0.001$), corresponding to a relative elevation of $30.45 \pm 12.69\%$.

Outcomes are summarized in Table 4 and Fig. 2. Ridge thickening was identified in all 40 enrolled patients.

Table 4
LAA Ridge Thickness

Ridge thickness	Before ablation	After ablation	P-value
	4.10 ± 0.71mm	5.31 ± 0.89mm	<0.001
Ridge thickness change percentage	N/A	30.45 ± 12.69%	N/A
LAA diameter	22.5 ± 3.8mm	21.2 ± 3.2mm	0.756
Values are presented as mean ± SD or n(%);LAA,left atrial appendage			

Discussion

The present single-center cohort study systematically evaluated the procedural feasibility, periprocedural safety, and short-term clinical outcomes of one-stop VARIPULSE pulsed field ablation combined with LAAO in patients with atrial fibrillation (AF), and quantified for the first time the immediate morphological changes of the pulmonary ridge after PFA in the Chinese population. The main findings of this study are as follows: (1) Combined PFA and LAAO therapy is safe, effective and feasible, with a 100% implantation success rate of occluder devices. (2) No complications such as hemolysis, air-bubble stroke, phrenic nerve palsy, or coronary artery spasm occurred intraoperatively. No adverse events including death, stroke, major bleeding, pericardial effusion or device embolization were observed during the perioperative period and follow-up. (3) All patients received oral anticoagulation for a minimum of 45 days, and anticoagulants were discontinued at 90 days after the procedure. No peri-device leak (PDL) > 3 mm or device-related thrombus was detected. (4) The ridge of the left atrial appendage exhibited a 30.45% swelling rate after PFA ablation. These findings strongly validate the clinical operability and short-term safety of this one-stop combined strategy, filling the gap of domestic clinical data regarding combined PFA and LAAO for AF treatment.

This clinical performance aligns with the growing body of evidence supporting the safety and efficacy of this combined approach. Prior case reports and small series have established the procedural feasibility of this “one-stop” strategy, demonstrating high acute success with Watchman FLX or LACbes devices despite observable tissue changes from PFA [6–8]. Larger prospective studies have subsequently reinforced these findings, reporting high implant success rates and favorable safety outcomes, including low rates of pericardial effusion, stroke, and major bleeding [9, 10]. The absence of major adverse events such as cardiac tamponade or device embolization is particularly noteworthy, as these represent the most feared complications in LAAO procedures. The established safety profile of PFA in minimizing collateral damage to surrounding structures, such as the esophagus and phrenic nerve, may contribute to the overall safety of the combined approach [11, 12].

Measurement of LAA ridge thickness in this study was performed only based on immediate preprocedural and postprocedural TEE assessments, without long-term dynamic follow-up. Several studies have documented that thermal ablation-induced thickness of the LAA ridge may precipitate delayed peri-device leak^[13–15]. Since PFA does not induce immediate tissue necrosis^[5, 16], acute tissue swelling is presumed to be milder, rendering this modality more suitable for combined procedures. We observed a marked increase in LAA ridge thickness after PFA (mean increased by 1.21mm or 30.45%). Nevertheless, this effect was inferior to that of PVI with Farapulse (2.72mm or 69.4%)^[17]. This difference may be attributed to the more extensive electric field coverage of pulmonary vein antrum and more sufficient electric field exposure of the LAA ridge by Farapulse pulsed field ablation, thereby resulting in more significant acute edema of the LAA ridge. Surprisingly, no PDL was observed in patients undergoing combined PFA and LAAO. LAA ridge edema had no adverse impact on the stability and occlusion effect of Watchman FLX devices and LACbes. This observation may be attributable to the relatively localized and milder tissue edema induced by VARIPULSE PFA, which is predominantly confined to the LAA ridge. This critical finding resolves the potential clinical concern that periprocedural atrial tissue changes may compromise LAAO efficacy, and provides objective morphological evidence for the safety of matching PFA with LAAO implantation.

Limitations

This study has several inherent limitations that should be acknowledged. First, it was a single-center, retrospective observational study with a relatively small sample size of 40 patients, which may limit the generalizability of the findings and introduce potential selection bias. Second, the follow-up duration was limited to 90 days after the combined procedure; long-term efficacy and safety outcomes, including late device-related thrombus, recurrent atrial fibrillation, long-term peri-device leakage, and long-term thromboembolic events, remain unclear and require extended follow-up. Third, this study only quantified the immediate thickening of the LAA ridge after PFA, and did not further explore the dynamic changes in ridge thickness during long-term follow-up, as well as the potential correlation between anatomical thickening and long-term procedural prognosis. In addition, the absence of a control group (such as patients undergoing radiofrequency ablation combined with LAAO or simple LAAO) prevented further verification of the unique advantages and safety characteristics of the VARIPULSE PFA combined LAAO one-stop procedure. Finally, all operations were performed by experienced physicians in a specialized cardiovascular center, and the safety and operability of this combined strategy in primary and secondary hospitals need to be further validated by multi-center studies.

Conclusion

This single-center retrospective study demonstrates that the one-stop combination of VARIPULSE pulsed field ablation and Watchman FLX or LACbes left atrial appendage occlusion is a highly feasible, safe, and effective strategy for patients with atrial fibrillation. The combined procedure yields a 100% implant success rate with no major periprocedural adverse events, and achieves complete device sealing

without peri-device leakage, device-related thrombus, or embolization at the 90-day follow-up. Although pulsed field ablation induces significant immediate LAA ridge thickening the an averaging 30.45%, this acute morphological change does not compromise LAAO device stability or sealing performance. These findings support the clinical applicability and short-term safety of this integrated one-stop modality, providing novel morphological and clinical evidence for its wider adoption in comprehensive atrial fibrillation management.

Abbreviations

AF
atrial fibrillation
PFA
pulsed field ablation
LAAO
left atrial appendage occlusion
LAAC
left atrial appendage closure
CA
catheter ablation
PDL
peri-device leak.

Declarations

Ethics approval and consent to participate

This retrospective observational study was reviewed and approved by the Putuo Hospital, Shanghai University of Traditional Chinese Medicine; Ethics reference number. Ethics Committee (PTEC-A-2026-57(S)-1). The requirement for individual informed consent was waived due to the retrospective nature of this study. All procedures were performed in accordance with the Declaration of Helsinki.

Consent for publication

Written consent for publication was not required for this retrospective de-identified dataset. No identifiable patient information is included within this manuscript.

Funding Declaration

No funding was received for conducting this study.

Availability of data and materials

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Conflict of interest

The authors declare no conflict of interest.

Authors' contributions

K. L. and R.W. contributed to data analysis. K.L. and J.J. drafted the manuscript. Y.Z. and Z.L. provided guidance on the study concept and critically reviewed the manuscript. M.W. and Q.D. contributed to patient screening and clinical data collection. All authors read and approved the final manuscript.

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None

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Figures

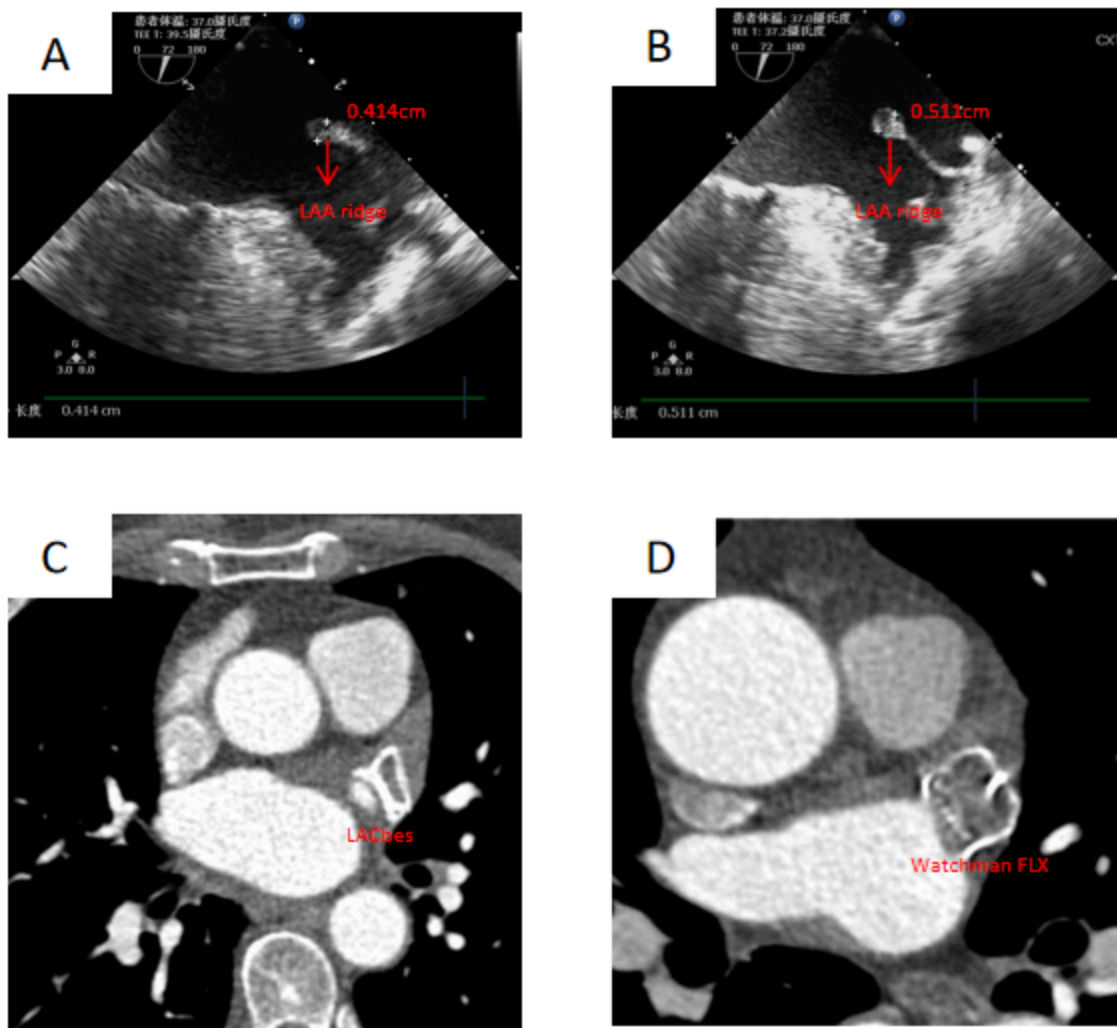


Figure 1

Measurement of LAA ridge thickness:(A) Pre-ablation; (B) Post-ablation,Transesophageal echocardiography demonstrated significant immediate thickening of the LAA ridge after PFA, increasing from 4.10 ± 0.71 mm to 5.31 ± 0.89 mm (mean increment $30.45 \pm 12.69\%$, $P < 0.001$);Follow-up CT at 3 months to confirm device position and seal:(C) LACbes; (B) Watchman FLX or pro

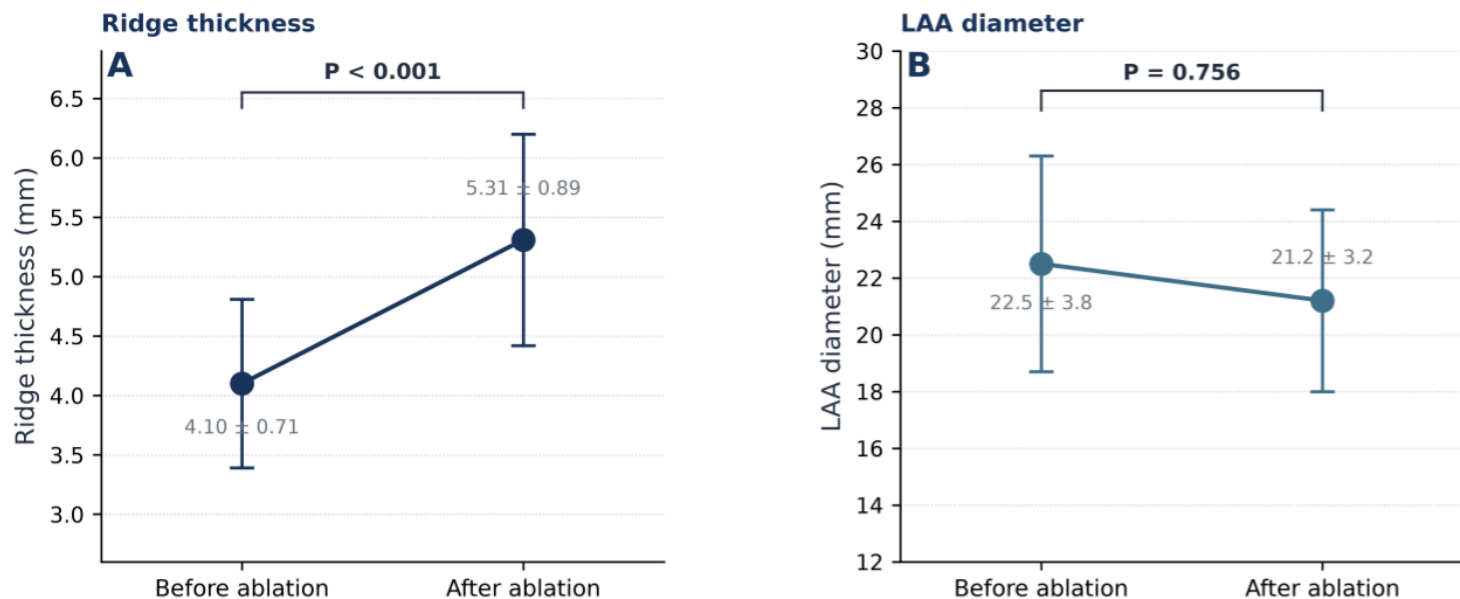


Figure 2

Changes in LAA ridge thickness and LAA orifice diameter before and immediately after PFA. (A) Significant acute thickening of the LAA ridge was observed after ablation. (B) No statistically significant difference in LAA orifice diameter was detected pre versus post ablation.