

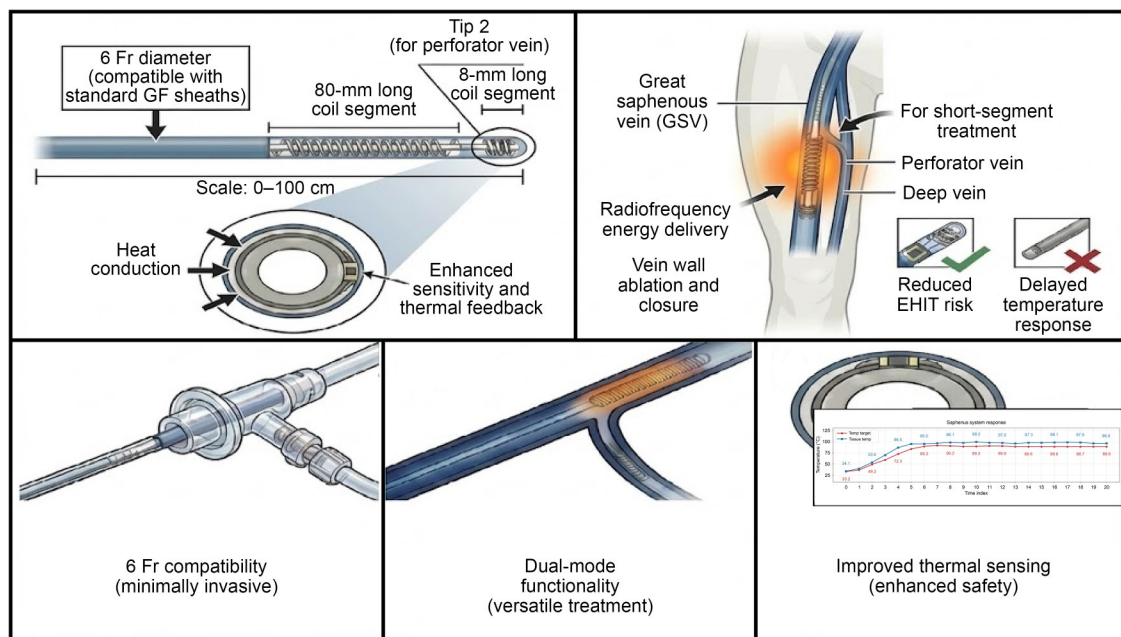


A dual-mode radiofrequency ablation catheter with advanced thermal sensing for saphenous and perforator vein insufficiency: a preclinical study on goats

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Graphical abstract



We developed a novel radiofrequency ablation (RFA) catheter system, Saphenus, to address limitations of existing devices such as heat injury risk and incompatibility with 6 French (Fr) sheaths used in Chinese hospitals. The key innovations include a 6 Fr diameter, a dual-mode design (8 mm for perforating veins (PVs) and 80 mm for the great saphenous vein (GSV)), and an enhanced temperature sensing mechanism for improved thermal feedback. In vitro tests and

experiments on goats demonstrate that the Saphenus system achieves effective vessel occlusion. Moreover, post-operative ultrasound and histopathological analysis have confirmed successful occlusion of all targeted veins without recanalization; such results are comparable to the control groups, but with reduced thermal damage. Overall, the proposed system provides a safe, effective, cost-efficient, and minimally invasive treatment for lower extremity venous

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insufficiency, which is particularly suited for clinical settings in China.

1 Introduction

Endovenous RFA is a leading minimally invasive treatment for lower extremity varicose veins, which has demonstrated superior efficacy and safety to other modalities such as sclerotherapy and laser therapy [1–4]. The procedure utilizes a bipolar catheter to deliver thermal energy (80–120 °C), thereby inducing endothelial destruction and fibrosis to occlude the vein; it has achieved a five-year GSV occlusion rate of 66.7% [5], as depicted in Fig. 1. While the Medtronic RFA system (which includes ClosureFAST and ClosureRFS) is widely used [6–8], it faces challenges under domestic Chinese Diagnosis-Related Group (DRG) payment models, leading to higher costs. It also carries technical and safety issues, such as a high risk of endovenous heat-induced thrombosis (EHIT) caused by slow temperature feedback from centrally located sensors [9, 10], incompatibility with the standard 6 Fr sheaths used in Chinese hospitals, and catheter lengths that are unsuitable for PVs.

To address these clinical and economic needs, we developed a novel RFA system for Chinese clinical settings, which brings three main innovations: (1) a reduced catheter diameter of 6 Fr that fits standard domestic sheaths; (2) a dual-function design featuring an 8-mm distal segment for perforating veins and an 80-mm main segment for GSV treatment;

(3) an optimized temperature sensor position combined with a thinner coating to enhance thermal sensitivity and transfer efficiency. These improvements allow for effective ablation at lower temperatures, significantly reducing the risk of heat penetration injury and EHIT, while also accommodating domestic clinical practices.

2 Methods

2.1 Radiofrequency ablation catheter design

The structure of the catheter sequentially includes—from the distal end to the proximal end—a glue tip, a heating segment, a main body tube, a handle device, a connection cable, and a connector. Internally, the heating segment consists of an alloy wire wound into a coil, with its surface covered by an insulating outer sleeve made of polyethylene terephthalate (PET) to achieve radiofrequency heating.

A temperature measurement device, which includes a platinum–iridium alloy temperature sensing ring and a temperature sensor, was installed at the deployment interval. Additionally, the device is fixed with adhesive to ensure that the sensor tip is isolated from the coil. Compared to the Medtronic systems, the proposed device can monitor the vascular wall temperature in real time more closely, as shown in Figs. 2a and 2b.

This radiofrequency closure catheter adopts a dual-mode design featuring two heating segment configurations: a distal 8 mm segment and a main 80 mm segment. Switching

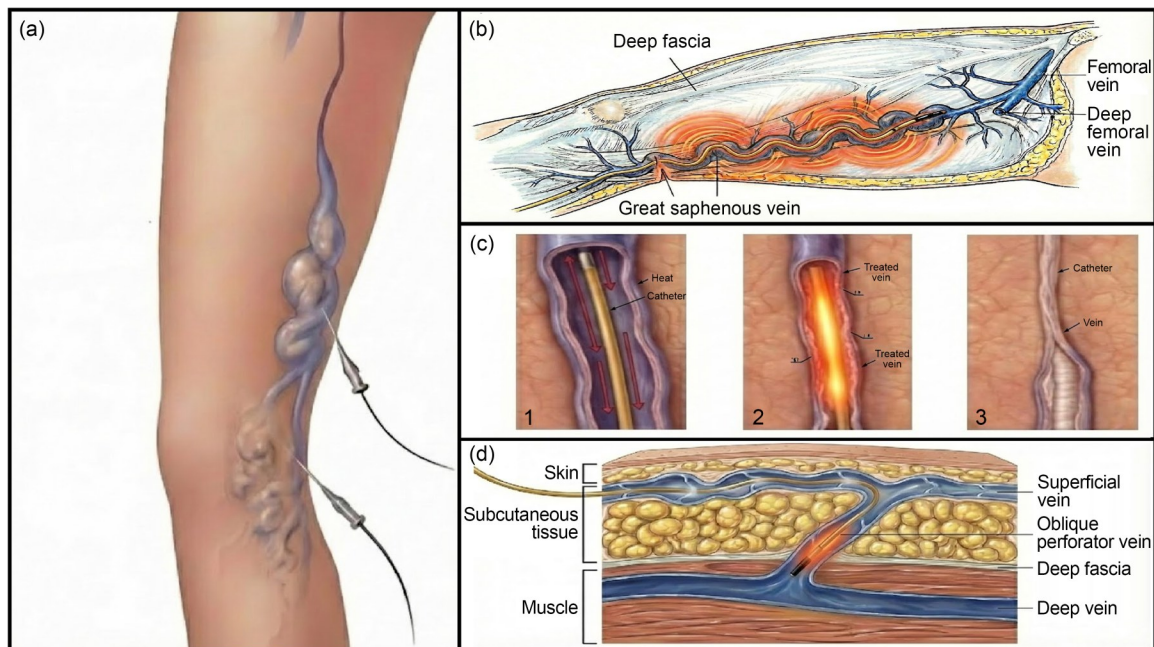


Fig. 1 The radiofrequency ablation (RFA) mechanism. (a) Macro view of the varicose lower limb. (b) Orange-highlighted great saphenous vein (GSV) path as the primary endovenous ablation target. (c) The RFA mechanism sequence: intraluminal catheter placement; thermal energy delivery inducing endothelial destruction and vessel wall contraction; final venous occlusion and fibrosis. (d) Treatment of perforating veins

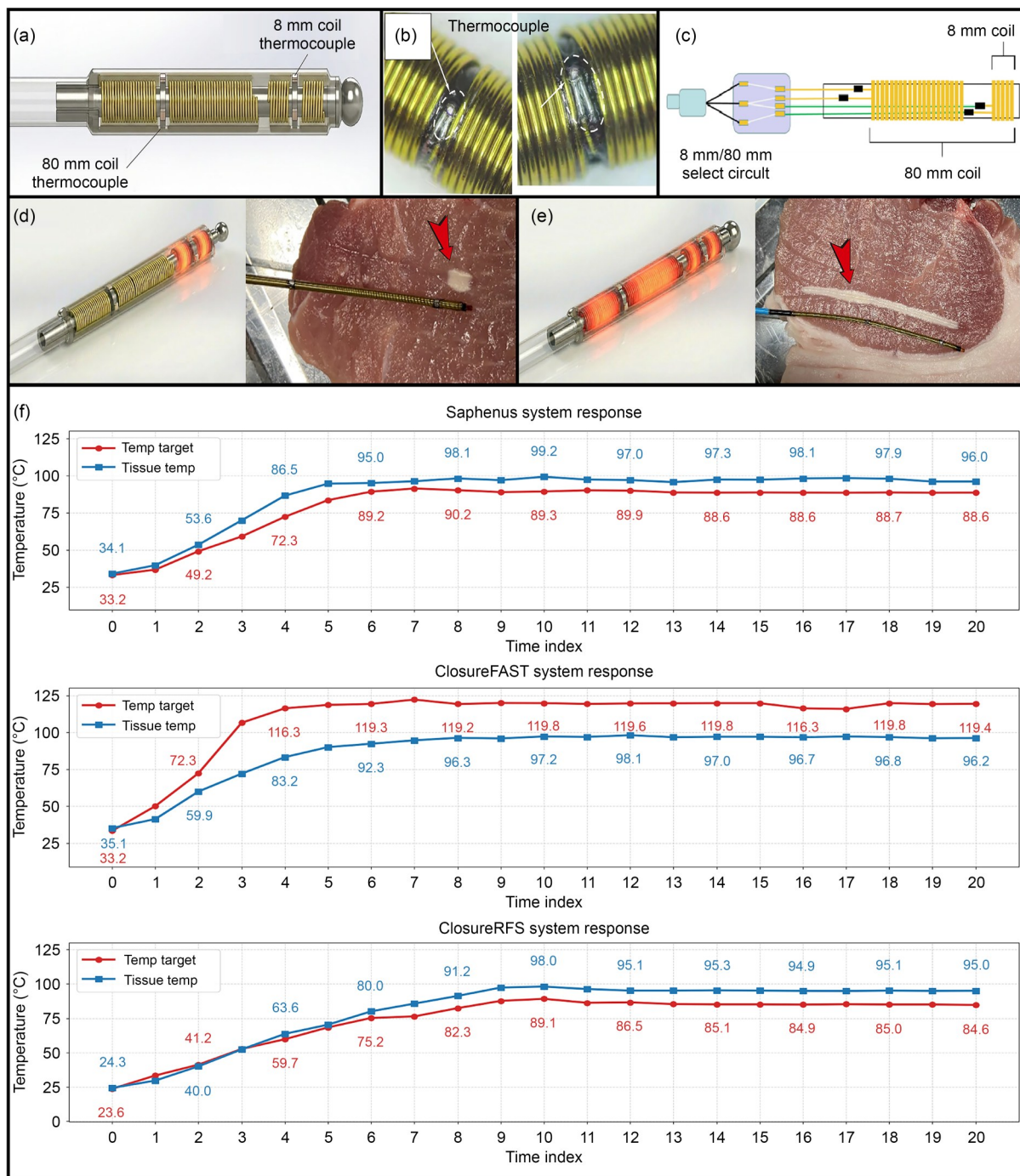


Fig. 2 Design, working mechanism, and thermal response of the dual-mode radiofrequency ablation catheter. (a) Schematic illustration of the catheter tip design. (b) The ClosureFAST thermocouple loading position. (c) Schematic of the selection circuit. (d) Activation of the 8 mm ablation mode. (e) Activation of the 80 mm ablation mode. (f) Comparative temperature response curves

between them is achieved via the gating circuit in the handle and the relay switch in the console (operated through the interface), as depicted in Fig. 2c. The 8 mm segment targets PVs, while the 80 mm segment treats the GSV, as illustrated in Figs. 2d and 2e. In this way, the radiofrequency closure catheter adapts to both lesion sites without the need for instrument exchange.

2.2 Temperature sensing validation and temporal response testing

To validate the performance of the proposed temperature sensing mechanism, temporal response testing was performed on the Saphenus catheter and compared with the Medtronic ClosureFAST and ClosureRFS systems.

Temperature data were acquired using calibrated T-type thermocouples (National Institute of Standards and Technology (NIST)-traceable reference, accuracy of ± 0.1 °C). The sensors measure the catheter surface temperature at the catheter–tissue interface, rather than the coil temperature or lumen temperature. The target temperatures were set to 90 °C for the Saphenus system, 120 °C for the ClosureFAST system, and 85 °C for the ClosureRFS system. The measured tissue temperature response curves were recorded in real time to evaluate the stability, feedback efficiency, and time-to-target characteristics of each system. These results are presented in Fig. 2f.

2.3 In vitro experiment

Specimen preparation Freshly harvested saphenous veins (SVs) from goat hindlimbs were obtained immediately post-euthanasia.

Experimental design Control group—Medtronic ClosureFAST catheter (7 Fr, 80 mm heating length), standard protocol (120 °C for 20 and 40 s). Experimental groups—Saphenus catheter (6 Fr, dual-mode, 80 mm segment for SVs), tested at 90, 80, 70, and 60 °C, separately, with both 20-s and 40-s duty cycles.

Assessment scope Circumferential wall necrosis, collagen denaturation depth, and endothelial disruption were analyzed by using hematoxylin and eosin (H&E) and Masson's trichrome staining.

The primary goal was to confirm and select the optimal working parameters for vessel occlusion before proceeding to in vivo animal models.

2.4 Establishing an animal experimental model

This study was designed as a preliminary preclinical investigation. Given that vessel occlusion is the primary biological endpoint of RFA, and is a highly consistent and robust effect,

a sample size of six animals per group was considered sufficient in goat models to demonstrate descriptive and pathological equivalence.

A total of 24 goats were randomly assigned to four groups ($n=6$ each) using a computer-generated sequence to compare the novel Saphenus RFA catheter against commercial controls: (1) the Saphenus 80 mm segment vs. Medtronic ClosureFAST; (2) the Saphenus 8 mm segment vs. ClosureRFS. After a two-week acclimation period, and after fasting and weighing, outcomes were assessed using a single-blind method via blood biochemistry, hematology, coagulation tests, vascular ultrasound, and histopathology (H&E/Masson's trichrome staining), as detailed in Table 1.

To minimize assessment bias, two specialists independently evaluated the vascular ultrasound and histopathological results for the SVs and PVs. These specialists had no knowledge of the group allocations or which devices were being used.

Due to the shorter length and smaller diameter of PVs compared to SVs, it was anticipated that complete closure would occur more rapidly. Therefore, we omitted the 14-d intermediate endpoint for PVs and only evaluated their closure status at the final 30-d endpoint.

2.5 Ultrasound vascular examination

For the goat SV group, vascular ultrasound was performed postoperatively at 14 d and 30 d to assess post-ablation recanalization, stenosis, or closure. For the PV group, scans were conducted preoperatively, immediately following the procedure, and at 30 d. The degree of closure was defined by incompressibility, absence of colored Doppler flow, and luminal filling with echogenic material; stenosis involved reduced diameter, partial thrombosis, and residual flow; recanalization required the reappearance of continuous flow. All evaluations were independently performed by an experienced blinded sonographer.

Table 1 The experimental design

Group	Cohort	Number	Radiofrequency closure system			
			Saphenous veins		Perforating veins	
			Left	Right	Left	Right
Saphenus 80 mm	14 d	6	yes	yes	–	–
	1-Month	6	yes	yes	–	–
ClosureFAST	14 d	6	yes	yes	–	–
	1-Month	6	yes	yes	–	–
Saphenus 8 mm	Immediate	6	–	–	yes	yes
	1-Month	6	–	–	yes	yes
ClosureRFS	Immediate	6	–	–	yes	yes
	1-Month	6	–	–	yes	yes

2.6 Gross observations and pathological histological observations

During the trial, animals were monitored for their mental state, behavior, diet, excretion, skin changes at the puncture site, and survival. Body weight and anal temperature were recorded preoperatively and at 14 and 30 d postoperatively. Hematological, biochemical, and coagulation parameters were assessed preoperatively and at Day 30 postoperatively.

Gross observations included inspection of hindlimb skin for hematomas or burns, evaluation of tissue damage around the SVs and PVs (e.g., thrombosis and ulcers), and assessments of vein closure, recanalization, or perforation. Major organs (heart, liver, spleen, lungs, kidneys, brain, and pituitary gland) were examined and weighed, and corresponding organ coefficients (organ weight/fasting body weight) were calculated.

The goat SVs and PVs were fixed in 10% formalin, processed for paraffin embedding, sectioned, and stained with H&E and Masson's trichrome. Pathological analysis covered the intima, media, and adventitia; thrombus formation; recanalization or perforation; inflammatory responses; and granulation tissue/intimal hyperplasia.

3 Results and discussion

3.1 Temperature testing results

Table 2 presents a comparative analysis of heating performance between the Saphenus series catheters and the standard control groups (ClosureFAST and ClosureRFS) across two clinical applications: SVs and PVs. The evaluation focuses on three key metrics: heating speed, temperature stability, and total thermal dose.

Heating efficiency (time to reach the target temperature) The Saphenus catheters demonstrated superior heating speed. In SVs, the Saphenus 80 mm reached the target temperature in (5.1 ± 0.2) s, which is faster than the ClosureFAST $((6.3 \pm 0.3)$ s). A more significant difference was observed in PVs, where the Saphenus 8 mm took only (5.0 ± 0.2) s, compared to (8.5 ± 0.4) s for the ClosureRFS.

Temperature stability The stability was measured by the standard deviation of the temperature after reaching the target.

The Saphenus series showed lower variance (smaller standard deviations) in both groups. For instance, the Saphenus 8 mm maintained a stability of ± 1.17 °C, while the ClosureRFS had a value of ± 1.41 °C, indicating that the Saphenus catheters provide more consistent and controlled thermal output.

Thermal dose delivery The thermal dose, calculated as the area under the temperature–time curve, as shown in Fig. 2f, was consistently higher in the Saphenus groups.

3.2 Results of the in vitro experiments

Regarding the extent of vascular tissue degeneration and necrosis, treatment at 90 °C for 20 s in the experimental group achieved an equivalent effect to a 40-s treatment in the control group. Similarly, an 80 °C treatment for 40 s in the experimental group produced a comparable effect to the 20-s treatment in the control group. The specific results are presented in Table S1 and Fig. S1 (supplementary information).

3.3 Results of the animal experiments

Endovenous RFA was performed on SVs and PVs that met the diameter criteria in the hind limbs of the goats. These results are shown in Table 3. All target vessels were occluded, with no recanalization events occurring. Moreover, post-ablation ultrasound examination revealed the absence of blood flow in some veins or only the presence of discontinuous low-velocity blood flow.

3.4 Vascular ultrasound assessments

We next compare the Saphenus 80 mm and the control group using ClosureFAST for treating the SVs. In particular, quantitative venous vascular ultrasound examinations were performed on goats at 14 d and 30 d. Ultrasound images showed that the target vessels following ablation exhibited vessel wall thickening, abundant thrombus formation within the lumen (as indicated by the red arrows in Fig. 3), no significant blood flow signal, and no evidence of vascular recanalization, perforation, or injury to adjacent organs. The results are presented in Fig. 3.

During the ablation procedure on the lower-limb PVs for the Saphenus 8 mm experimental group and the ClosureRFS control group, high-echo spots were observed within the PVs

Table 2 Measuring the surface temperature of the radiofrequency catheter

Metric	Saphenous veins		Perforating veins	
	Saphenus 80 mm	ClosureFAST	Saphenus 8 mm	ClosureRFS
Time to reach the target temperature (s)	5.1 ± 0.2	6.3 ± 0.3	5.0 ± 0.2	8.5 ± 0.4
Temperature stability (°C)	± 1.22	± 1.34	± 1.17	± 1.41
Thermal dose	1776.45 ± 0.63	1765.87 ± 0.33	1776.70 ± 0.39	1626.77 ± 0.33

Temperature stability: standard deviation of the temperature after reaching the target. Thermal dose: calculation of area under the temperature–time curve

Table 3 Vessel diameter per group and temperature changes during ablation

Metric	Saphenous veins		Perforating veins	
	Saphenus 80 mm	ClosureFAST	Saphenus 8 mm	ClosureRFS
Ablation length (cm)	8	7	1.7	1.7
Initial ablation temperature (°C)	33.07±1.62	35.38±3.16	27.07±3.15	26.00±1.51
Ablation temperature (°C)	90	120	90	85
Ablation time per site (s)	20	20	20	60
Ablation method	Multipoints	Multipoints	Two points	Two points
Preoperative vessel diameter (cm)	0.56±0.14	0.47±0.06	0.52±0.08	0.49±0.07
30-d Average vessel diameter (cm)	0.30±0.13	0.28±0.09	0.31±0.11	0.30±0.10
Average reduction	0.26±0.06	0.16±0.06	0.21±0.07	0.18±0.04
Average reduction <i>P</i> value	0.072		0.089	

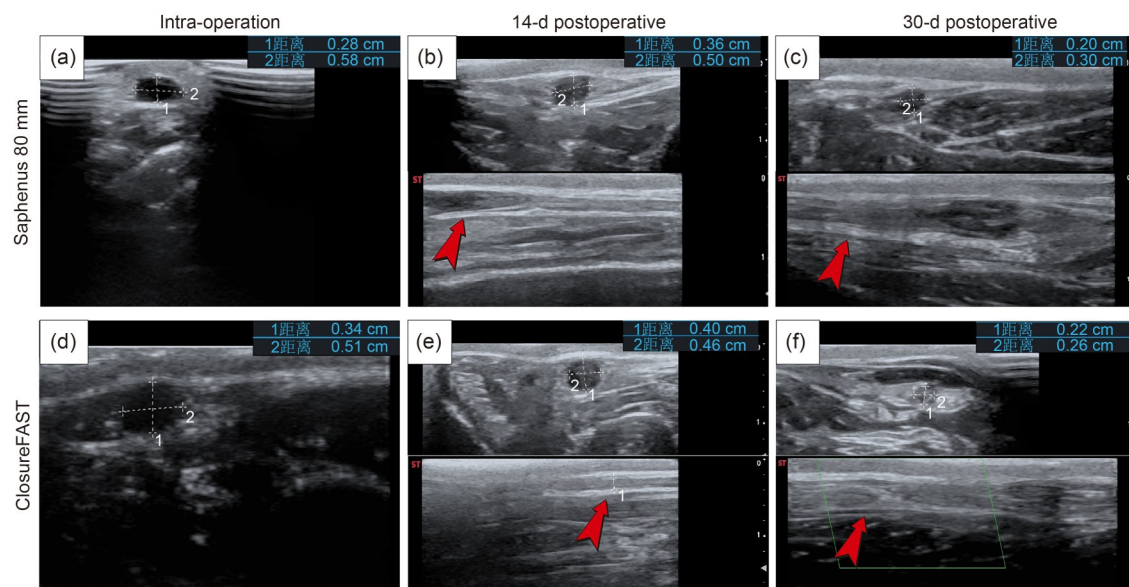


Fig. 3 Comparative ultrasound assessment of the goat saphenous veins (SVs) following radiofrequency ablation. (a–c) Representative ultrasound images from the Saphenus 80 mm experimental group taken intraoperatively (a), at 14 d post-operation (b), and at 30 d post-operation (c). (d–f) Representative ultrasound images from the ClosureFAST control group taken intraoperatively (d), at 14 d post-operation (e), and at 30 d post-operation (f). Red arrows indicate the treated vein segments, showing vessel wall thickening and complete luminal occlusion (thrombus formation) with no evidence of recanalization in either group. Blue text in the figures shows the distance value

of both groups immediately after the procedure; additionally, low-echo areas were visible around the vessels where tumescent solution was injected. In some cases, no significant blood flow was detected, while in others, only discontinuous low-velocity blood flow was observed. As shown in Fig. 4, at 30 d post-operation, irregular medium-echo areas were identified within the lumens of the goat PVs in both the experimental and control groups, and no significant blood flow was detected in any of them (as indicated by the red arrows in Fig. 4).

3.5 Comparative analysis of postoperative outcomes

Within three days of the operation, no skin redness, ecchymosis, or ulceration was observed in the surgical area. The

wounds healed well, with no signs of restricted activity or unwillingness to bear weight on the hind limbs. During the intraoperative and postoperative observation periods, no abnormal deaths occurred, with the survival rate of both the experimental group and the control group being 100%.

3.6 Vascular histomorphology

In the SV experimental and control groups at 14 d post-operation, intravascular thrombosis formation, intimal degeneration, collagen degeneration of smooth muscle bundles in the medial layer, and small fissures and delamination between smooth muscle bundles were observed.

In the goat SV experimental group and control group at 30 d post-operation, in some goat SVs, thrombus organization occurred within the vascular lumen, with thrombi obstructing

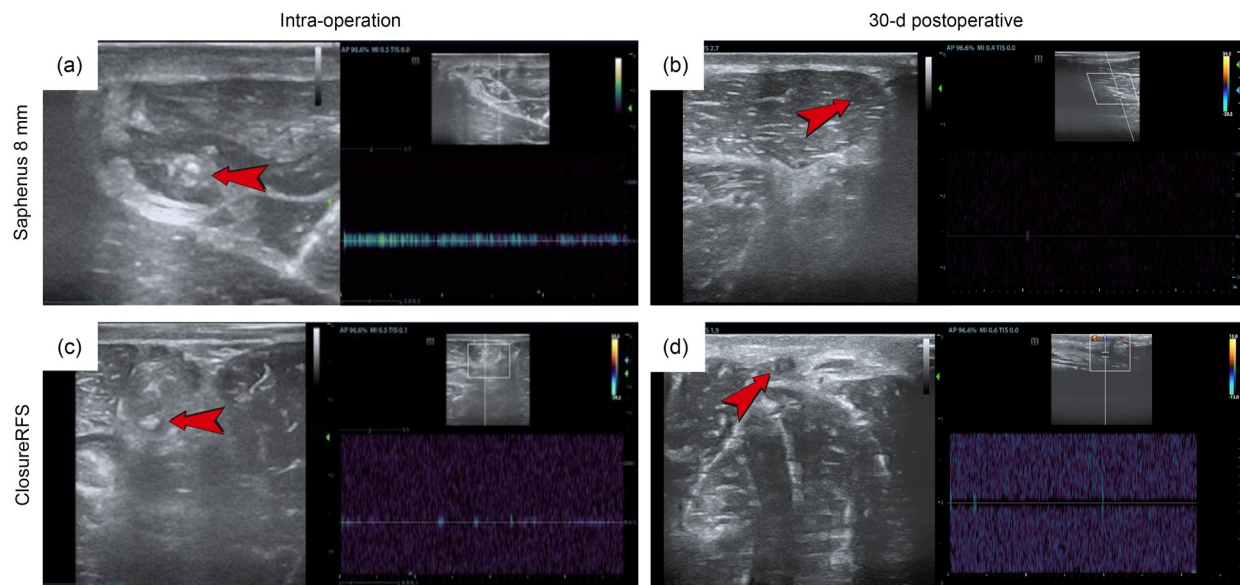


Fig. 4 Comparative ultrasound assessment of perforating vein occlusion between the Saphenus 8 mm and ClosureRFS systems. (a) Experimental group treated with the Saphenus 8 mm catheter. There is immediate vessel occlusion with high-echo spots within the lumen and no detectable blood flow signals on Doppler. (b) 30-d Postoperative ultrasound of the Saphenus 8 mm group. The target vein remains successfully occluded, appearing as an irregular medium-echo area with no signs of recanalization. (c) The control group treated with the ClosureRFS system, showing similar immediate occlusion and absence of blood flow. (d) 30-d Postoperative ultrasound of the ClosureRFS group, confirming persistent occlusion with no blood flow signal

80% of the lumen. Microscopic capillary neovascularization, which is indicative of normal thrombus organization and tissue remodeling, was observed within the occluded lumen, along with multinucleated giant cell reactions and microcalcification. Furthermore, collagen fiber hyperplasia was present among the smooth muscles of the vascular media, and small vessel dilation, along with fibrous tissue hyperplasia, was seen within the adventitial adipose tissue (Fig. 5).

Immediately following the operation, transmural injury occurred in one specimen from the PV test group and in five specimens from the control group. The injured areas were filled with thrombi formed by abundant fibrin aggregation, and were accompanied by necrosis and exfoliation of intimal endothelial cells, atrophy of medial smooth muscle cells, and swelling of fibers in the media and adventitia. In addition, all specimens in both the test and control groups exhibited luminal thrombotic occlusion or stenosis. The perivascular connective tissue in the specimens of both groups showed edema, with vascular congestion or exudation, as well as minimal inflammatory cell infiltration. No necrosis or severe thermal damage was observed. These results are illustrated in Fig. 6.

At 30 d after the operation, all specimens in the PV experimental group exhibited luminal occlusion or obstruction, with visible thrombotic tissue, granulation tissue hyperplasia, and abundant capillaries. The vascular structure was unclear, being complicated by fibrosis and inflammatory infiltration. In the control group, all PVs displayed luminal obstruction or stenosis, local intimal hyperplasia, medial fibrosis, and a

relatively intact adventitial structure. The perivascular connective tissue showed no edema, congestion, hemorrhage, or necrosis in any of the groups.

3.7 Discussion

In this study, we presented and validated a novel radiofrequency ablation catheter system—the Saphenus—which enables single-device treatment of the GSV and PVs. Its core innovation lies in relocating the temperature sensor to a sensing ring between ablation coils, allowing direct monitoring of the tissue interface temperature instead of coil heat. Combined with a thinner PET insulation layer, this optimizes heat transfer to tissue, yielding precise correspondence between the preset 90 °C and the actual coil temperature. Consequently, the system achieves equivalent biological effects with a lower temperature than conventional 120 °C systems.

The Saphenus system offers a “low temperature, high efficiency” advantage, achieving 100% venous occlusion at 90 °C. Biothermodynamically, its optimized thermal response pathway reduces energy waste from conduction loss. This efficiency enhances safety: it prevents blood boiling, gas formation, and tissue carbonization [11, 12], while also narrowing the lateral thermal diffusion radius. Moreover, histological analysis showed significantly fewer transmural injuries versus controls (one versus five cases), confirming better confinement of thermal energy within the venous wall. This minimizes collateral damage to adjacent nerves and

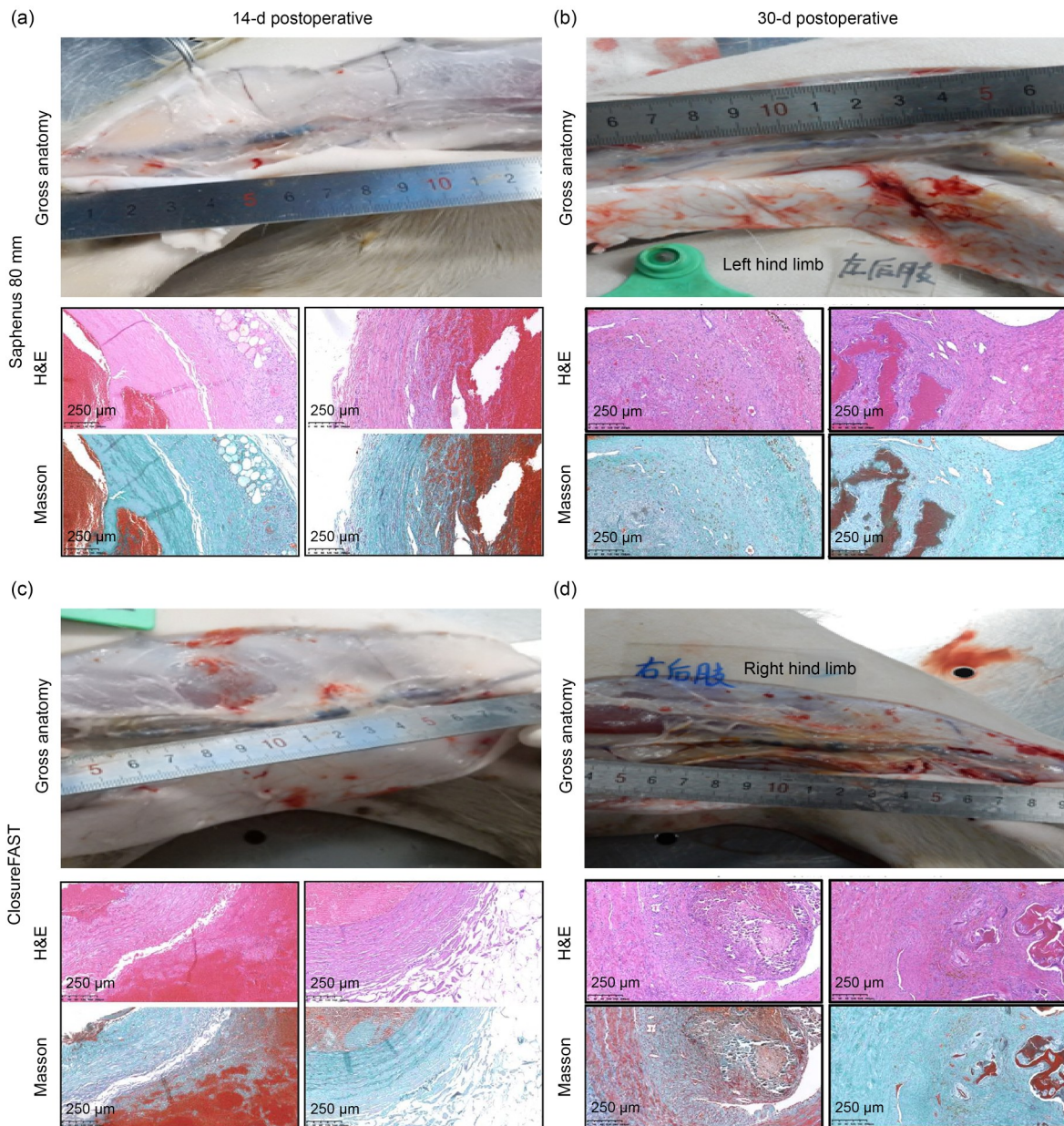


Fig. 5 Gross anatomical and histopathological evaluation of the saphenous veins (SVs) following radiofrequency ablation. (a) Intima: thrombosis, luminal thrombosis, and intimal degeneration; Media: approximately 90% smooth muscle collagen degeneration, large fissures, and delamination; Adventitia: capillary proliferation in adipose tissue, fibrous hyperplasia. (b) Intima: vascular formation; Media: collagen hyperplasia between smooth muscle bundles. (c) Intima: thrombosis, local fibrosis, and degeneration; Media: approximately 40% collagen degeneration, fissures. (d) Intima: vascular formation with calcification; Media: collagen hyperplasia

tissues, offering a wider safety margin—especially for small or superficial veins.

Goat models, which exhibit relatively human-like vascular anatomy and physiology [13, 14] (in particular, veins with diameters >3.5 mm [15, 16] and similar wall composition), were selected for radiofrequency closure trials [17]. The Saphenus catheter demonstrated short-term (30-d) efficacy comparable to controls, achieving complete occlusion via thrombus formation and fibrosis without recanalization (Figs. 3 and 4). This indicates sufficient thermal

energy delivery for collagen denaturation, consistent with RFA mechanisms.

Although the follow-up time was relatively short, advanced histopathological findings (thrombus organization and collagen hyperplasia) strongly predict permanent occlusion and low long-term recanalization risk [18, 19]. No significant intergroup differences were observed in vital signs or hematology, and there was an absence of device-related adverse events (e.g., skin burns and deep vein thrombosis), thus validating the system's safety profile [20].

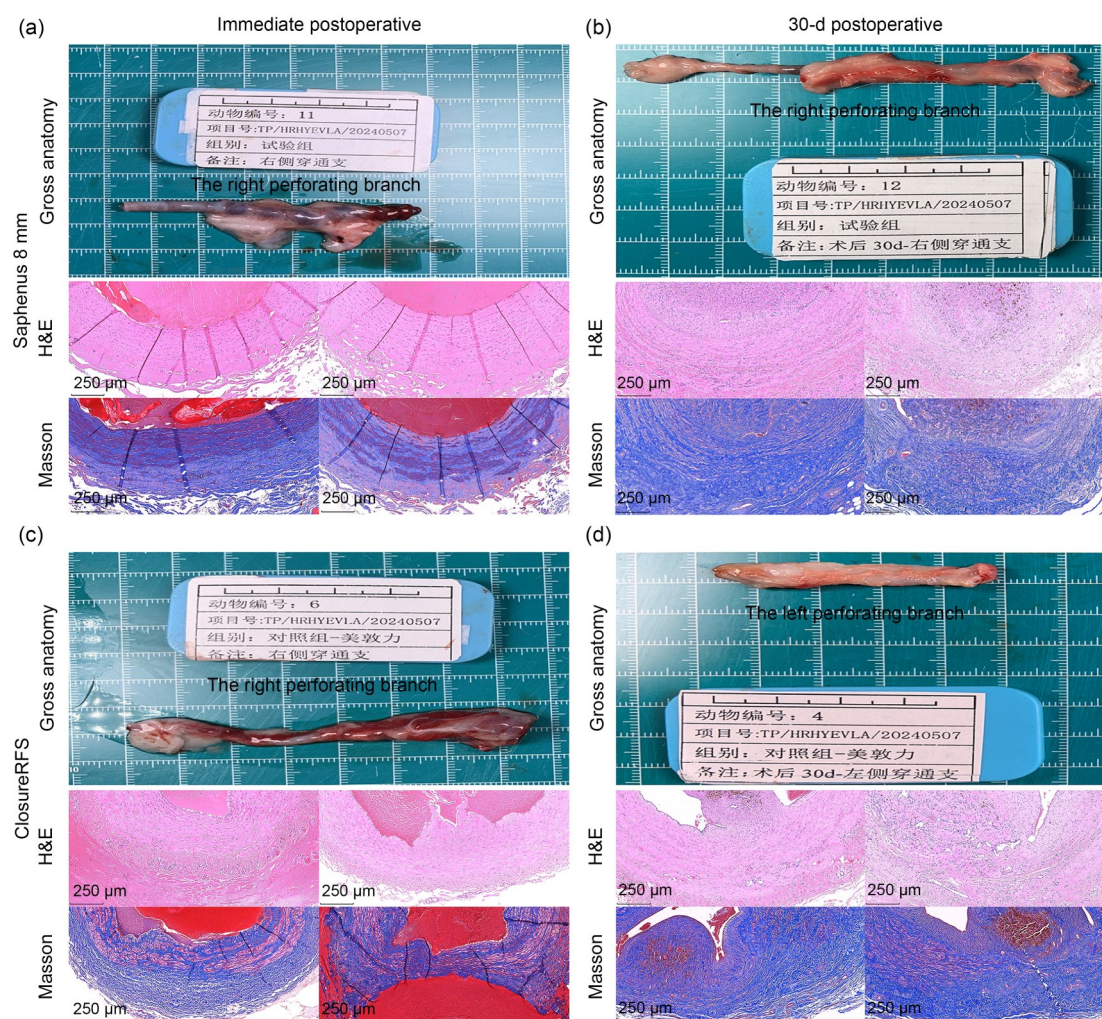


Fig. 6 Gross examination and histopathological evaluation of perforating veins (PVs) following radiofrequency ablation with the Saphenus system versus the ClosureRFS system. (a) Intimal necrosis/desquamation, medial smooth muscle atrophy, and fiber swelling in media/adventitia; thrombosis with luminal occlusion; substantial blue-stained fiber thickening in media/adventitia. (b) Vascular occlusion with thrombus organization/granulation tissue hyperplasia (abundant capillaries); unclear structure, fibrosis, and mixed inflammation (neutrophils/lymphocytes/macrophages); organized thrombus shows collagen proliferation in media/adventitia. (c) All segments: intimal endothelial necrosis/desquamation with focal media/adventitia fiber swelling. (d) Stenosis with thrombus organization/granulation replacement; mild focal intimal hyperplasia, medial/adventitial fibrosis, and mixed inflammation; macrophage deposits; Masson's trichrome: collagen hyperplasia (slender/disorganized). Representative specimens were selected from either side; laterality was not a grouping variable

4 Conclusions

A novel radiofrequency ablation system (Saphenus) for varicose veins was proposed, featuring a 6 Fr diameter for Chinese clinical settings, dual-mode heating segments (8 mm for PVs and 80 mm for the GSV), and an optimized temperature sensor for direct tissue interface monitoring. Compared to Medtronic ClosureFAST/RFS systems, the Saphenus system achieved faster heating, better temperature stability, and equivalent or superior venous occlusion at a lower target temperature (90 °C versus 120 °C) in goat models. The results showed 100% occlusion at 30 d, no recanalization or device-related adverse events, and a reduced incidence of transmural injury (one versus five cases). These findings demonstrate that

the Saphenus system is a safe, effective, and economically favorable alternative for clinical practice in China, with a wider safety margin against endovenous heat-induced thrombosis.

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Author contributions Conceptualization: ZG, XMZ, ZYG, and ZJL. Methodology: ZG, ZYG, and ZJL. Writing—original draft: ZG and XMZ. Writing—review & editing: ZJL. Project administration: ZJL. All authors contributed to the study conception and design. All authors read and approved the final manuscript. All authors have read and agreed to the published version of the manuscript.

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval The study was approved by the Animal Ethics and Welfare Committee of Lifutai Bio Co., Ltd. (Approval No. IACUC-20240513-01).

Data availability The raw data supporting the conclusions of this article are not publicly available due to privacy restrictions/commercial confidentiality/third-party intellectual property rights. However, the derived analytical data and de-identified datasets are available from the corresponding author upon reasonable request.

Use of generative AI tools No generative AI tools were used in the preparation of this manuscript.

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