

## General Review

# Update on Endovenous Radio-Frequency Closure Ablation of Varicose Veins

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Until recent years, the gold standard for treatment of truncal varicose veins has been high ligation and stripping of the saphenous vein. In the course of the last decade, new minimally invasive techniques based on endothermal ablation are progressively supplanting conventional surgery in the treatment of varicose veins. The endovenous treatment of varicose veins has been developed to reduce complications associated with conventional surgery and to improve quality of life. Radio frequency ablation (RFA) available since 1999 is now established as a safe and efficacious treatment for the ablation of refluxing saphenous veins. Among the emerging therapies, RFA with VNUS ClosureFAST is promising because it has eliminated almost all disadvantages associated with conventional surgery by “stripping” (bruises, scars, ecchymosis, inguinal recurrence, neovascularization, and mainly, prolonged incapacity) with an immediate occlusion rate close to 100%. When it is compared with endovenous laser ablation, RFA technology is associated with less post-procedural pain, less ecchymosis and tenderness, and better quality of life (QOL) measures. The aim of this article is to summarize the available evidence in the RFA treatment of varicose veins.

## INTRODUCTION

Chronic venous insufficiency affects a considerable part of the population. However, it is not considered an illness, but its a pathological process with a wide range of clinical manifestations, which are sometimes severe. Indeed, varicose veins in lower limbs and their symptoms are the most frequent vascular pathology that affects 20% to 25% of women and 10% to 15% of men.<sup>1,2</sup>

In most cases, varicose veins are caused by the truncal insufficiency of the greater saphenous vein (GSV) (70%) and less frequency for small saphenous vein and perforators.<sup>3,4</sup> Thus, for some years now, it has been clearly established that the eradication of the GSV reflux is the Achilles' heel of treating this

pathology and should, therefore, be the first therapeutic objective.<sup>5,6</sup> This eliminates hydrostatic pressure from the column of blood produced by the failing vein, this being the main hemodynamic mechanism implied in the development and progression of varicose veins.

For decades, the most efficient treatment for truncal varicose veins has been sapheno-femoral arch ligation and stripping the GSV. In recent years, technology has led to the development and application of new minimally invasive therapies based on endovenous laser ablation and radio-frequency ablation (RFA). The main objective of RFA is to improve patients' QOL and to minimize the problems associated with conventional stripping surgery (bruising, infected wounds, scarring, ecchymosis, relapsing inguinal neovascularization and, above all, prolonged incapacity for work).

## MECHANISM OF ACTION OF ENDOVENOUS RFA

Endovenous RFA is defined as the use of radio frequency (RF) signals to cause cell damage or to

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alter or destroy tissue structure by means of a hyperthermia process. RF waves represent electromagnetic energy within a frequency range of 300 kHz to 1 MHz. When waves come in contact with tissue, they cause a vibration and friction of atoms and transformation of their mechanical energy into thermal energy (ohmic or resistive heating).

The therapeutic objective of RFA is to generate a fibrotic occlusion of the pathologic vein and its subsequent disappearance through atrophy<sup>7,8</sup> (Fig. 1). RF waves act particularly well on connective tissue by breaking collagen triple-helix junctions. This phenomenon takes place at temperatures  $>60^{\circ}\text{C}$ . These molecular changes significantly increase the contractile force of collagen—which, at the macroscopic level, implies reduced venous light—and shortening and thickening of vessel walls. In short, the macro/microscopic changes taking place in venous walls after applying RF energy are as follows: (a) endothelial destruction; (b) collagen denaturalization and contraction; (c) shortening and thickening of venous walls; and (d) reduced vessel light.

The most characteristic fact of RFA is the low temperature of this treatment ( $90\text{--}120^{\circ}\text{C}$ ) if compared with other energy sources. Very high temperatures must be avoided because boiling, vaporizing, and carbonization of tissues can occur, alterations which other energy sources like endolaser may cause ( $700\text{--}1,500^{\circ}\text{C}$ ).<sup>9</sup>

## VNUS CLOSURE RF EQUIPMENT

RFA by means of the Closure system requires a generator and a bipolar catheter (VNUS Medical Technologies, San José, CA). During the last decade two types of catheters have been used.

### ClosurePLUS Catheter

The ClosurePLUS catheter, in use until 2007, came with a therapeutic end point with a collapsible bipolar electrode, and the surgeon opened and closed it using its handle. There were two catheters available, depending on the size of the veins to be treated: for veins with a diameter up to 8 mm (5F) and for those with a diameter up to 12 mm (8F) (Fig. 2). The generator had a control unit with a display to show temperature (treatment range of  $85\text{--}90^{\circ}\text{C}$ ), impedance (ohms), and power (watts). Heat was generated in the vein wall and not in the catheter tip (resistive heating). During ablation, the catheter had to be removed at a rate of 2.5 to 3 cm/min. The main disadvantages of ClosurePLUS were slowness, variability and, at times, the need to remove the catheter during treatment to clean

the clot, which formed at the electrode level. Because of these drawbacks, the company innovated and developed a new catheter: ClosureFAST.

### ClosureFAST Catheter and RFGPlus Generator, Model RFG2

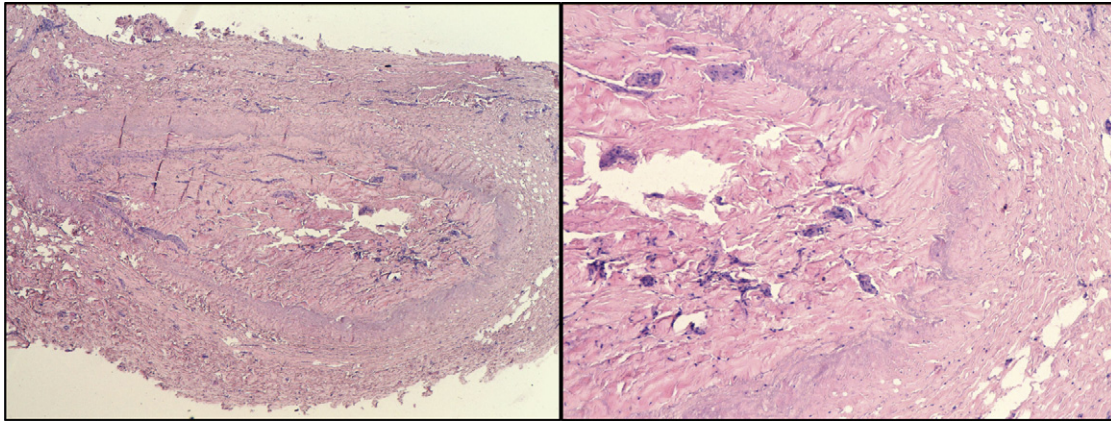
Several research studies at both the experimental and clinical levels<sup>9,10</sup> were conducted prior to the development of this new RF platform. In August 2006, VNUS Medical Technologies, Inc. (San Jose, CA) notified the Food and Drug Administration's approval to commercialize the new ablation catheter ClosureFAST, which was available in the United States in the first quarter of 2007. ClosureFAST has implied major change, as it improves efficacy and also substantially reduces ablation times.<sup>11,12</sup>

It is based on a very accurate RFA system controlled by a feedback mechanism by means of which the RFG2 generator uses the minimum power required (in the range of 15–40 watts) to reach the preestablished treatment temperature ( $120^{\circ}\text{C}$ ) during 20-second cycles. The ClosureFAST catheter (Fig. 3) has the therapeutic element at its tip of 7F in diameter and 7 cm long with a thermocouple: during ablation, removal of the catheter (pullback) is segmentary, in intervals of 7 cm; thus the total treatment time is reduced to 2 to 3 minutes, unlike ClosurePLUS, which required between 15 and 20 minutes.

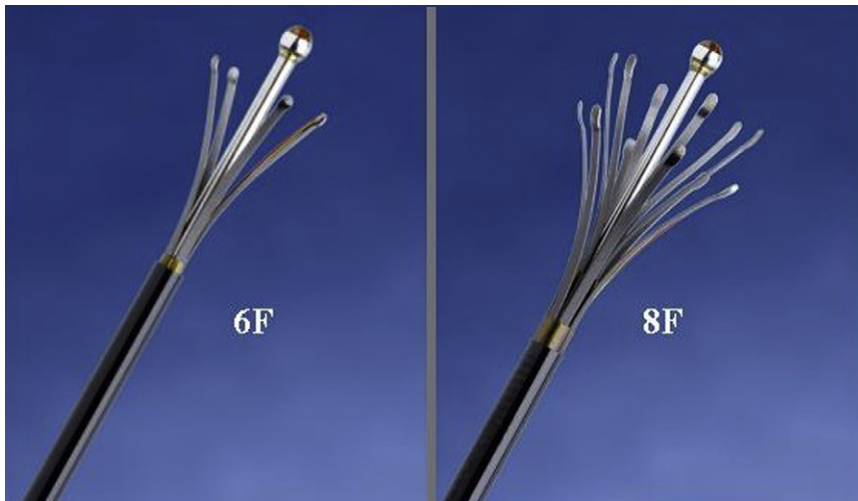
## PROCEDURE

Before surgery, accurate mapping (cartography) should be done using the duplex-scanning method from the groin to the ankle to highlight tortuous vein stretches, ectasia areas, and incompetent, perforator, and varicose veins. For the vast majority of patients, this procedure may be done with local tumescent anesthesia. The purpose of tumescence is threefold: analgesia, protecting skin and neighboring structures against heat, and favoring the contact made between the electrode and the vein. It is a totally echo-assisted procedure. Access to the GSV is variable: it can be surgical via mini incision, or percutaneous following the Seldinger technique. Those vein segments with ectasia can benefit from a second 20-second cycle, and this is mandatory in the proximal segment to the saphenofemoral junction. In the case that more than one vein needs to be treated using the same catheter in a given patient, it is advisable to place a 0.025" guidewire in the catheter light to maintain the catheter's light permeability after heating.

To avoid recurrences, occluding the onset of collateral veins with retrograde flow is essential. To perform



**Fig. 1.** Hematoxylin–eosin stain. Human saphenous vein occluded by lumen fibrosis (*Archive Dr García-Madrid*).



**Fig. 2.** VNUS ClosurePLUS catheter.

this, the catheter tip must be placed no further than 2 cm away from the saphenofemoral junction (Fig. 4). At the end of the procedure, it is absolutely necessary to conduct an ultrasonography check control to assess that the treated segment is efficacious and that common femoral vein permeability is correct (Fig. 5). To rule out any thrombotic-type complication, specifically heat-induced thrombosis (EHIT), a duplex-scanning control study is recommended in the first four days after performing the procedure.<sup>13</sup>

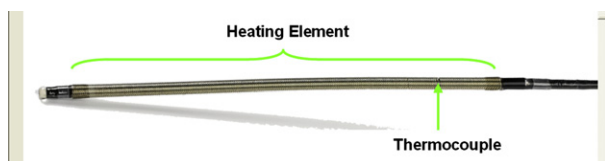
#### **CLINICAL EXPERIENCE AND SCIENTIFIC EVIDENCE WITH RFA**

In recent years, minimally invasive treatment of varicose veins by means of RFA has progressively

extended to developed countries, with more than 500,000 procedures performed to date. Apart from the GSV, this treatment has been extended and indicated to treat other venous segments such as the anterior saphenous vein, the lesser saphenous vein, and perforating veins.<sup>14</sup>

VNUS Medical Technologies (San José, CA) developed the VNUS Closure RF system. It was used for the first time in 1998 and was approved by the Food and Drug Administration in March 1999. Another RFA device, the Celon RFITT (Olympus Medical Systems, Hamburg, Germany), appeared later, which operates at a lower temperature (60–85°C). However, there is much less experience and scarce bibliography available regarding this system.

Several clinical and experimental works were published from the year 2000, demonstrating that



**Fig. 3.** ClosureFAST catheter.

RFA is a safe, effective method to abolish saphenous vein reflux.<sup>15-18</sup> One of the most relevant was the multicentre study published by Merchant et al.<sup>19,20</sup> with 1,222 treated limbs and a 5-year follow-up. This study presented an occlusion and reflux absence rate of 85%, and a very high patient satisfaction rate.

### RFA VERSUS STRIPPING

The publication of four prospective, randomized, comparative studies which opposed the conventional gold standard surgery technique of saphenofemoral junction ligation and stripping of the GSV had a great impact on the diffusion of RFA.<sup>18,21-25</sup> The results of these four studies were coincident RFA not only equaled the efficacy of conventional surgery, but was also clearly much better, as it offered less postsurgery pain, better QOL, and a much quicker recovery.

The study of Rautio et al.<sup>24</sup> demonstrated less pain (using the visual analog scale [VAS]) at rest ( $P = 0.017$ ), when standing up ( $P = 0.026$ ), and when walking ( $P = 0.036$ ). The most important differences found even remained up to day 14 postsurgery, and the need for painkillers for the RFA group was three times lower ( $0.4 \pm 0.49$  ibuprofen pills/day vs.  $1.3 \pm 1.09$  pills/day) if compared with stripping ( $P < 0.004$ ). The time it took to return to work was also clearly shorter for RFA ( $6.5 \pm 3.3$  days) if compared with stripping ( $15.6 \pm 6.0$  days) ( $P < 0.001$ ), and physical recovery was also much quicker (RAND-36 quality of life survey). In the midterm (3 years), the presence of varicose veins was slightly higher for RFA than for stripping (33% vs. 23%, respectively).<sup>23</sup>

The Endovenous Obliteration versus Ligation and Vein Stripping<sup>22</sup> study is a multicentre, prospective, randomized study that opposes conventional surgery, which analyzed several procedural variables and long-term efficacy. It included 45 RFA limb procedures and 36 stripping procedures. After 4 months, the first publication compared recovery time, complications, and QOL-related variables. The most striking differences between both groups were postsurgery recovery time when patients

returned to their normal activities after 1.15 days (RFA) versus 3.89 days (stripping) ( $P = 0.02$ ), and they went back to work after 4.7 days (RFA) versus 12.4 days (stripping) ( $P < 0.05$ ). The stripping group presented a higher morbidity rate after 3 weeks, especially in relation to the presence of bruising, ecchymosis, and pain. The postsurgery venous clinical severity score (VCSS) scale was also seen to favor the RFA group at 72 hours and 1 week; logically, these differences caught up with each other with time. The QOL assessment (Chronic Venous Insufficiency Questionnaire [CIVIQ]-2) was seen to give clearer better results for RFA, mainly for the global score and the pain scale. Impact on the clinical and hemodynamic results was compared again after 2 years.<sup>22</sup> Both procedures were found to be equally efficient, and no differences were found at either the clinical (symptoms and signs of, and recurrences) or the hemodynamic level, as assessed by the duplex-scanning method (lack of reflux: 91.7% RFA vs. 89.7% stripping). Of all the treated saphenous veins, 41% were undetectable after the 2-year follow-up. The recurrence rate obtained in this study was lower for the RFA group (14% vs. 21%), but was not statistically significant. Similar results were found for neovascularization, which was also lower for RFA (2.8%) when compared with stripping (13.8%). RFA also obtained a better QOL score after 1 and 2 years ( $P < 0.001$ ).

In 2006, another prospective, randomized study was published that compared three techniques: closure RF ( $n = 20$ ), stripping ( $n = 20$ ), and cryostripping ( $n = 20$ ).<sup>25</sup> During the 6-week follow-up, the QOL test (CIVIQ-2) ( $P = 0.012$ ) was seen to favor the RFA group, reporting less discomfort than the other two techniques (2.6 vs. 7.9 vs. 17.1, respectively). RFA was also the least painful ( $P = 0.014$ ) and favored a quicker return to work (7 days) if compared with stripping (14 days) and cryostripping (12 days) ( $P = 0.021$ ).

Hinchliffe et al.<sup>21</sup> compared RFA ( $n = 16$ ) with conventional surgery ( $n = 16$ ) in treating bilateral relapsing varicose veins of the GSV. The results favored RFA for most study variables: shorter surgical time (25.5 vs. 40 minutes,  $P = 0.02$ ), less pain according to VAS (1.7 vs. 3.8,  $P = 0.02$ ), and less ecchymosis according to the digital image analysis technique (11.9 vs. 21.8,  $P = 0.02$ ).

Recently, in 2010, Subramonia and Lees published another randomized study that compared the short-term results between RFA and stripping.<sup>26</sup> The RFA procedure required more time than conventional surgery: 76 versus 48 minutes ( $P < 0.001$ ). Nevertheless, the PLUS catheter was

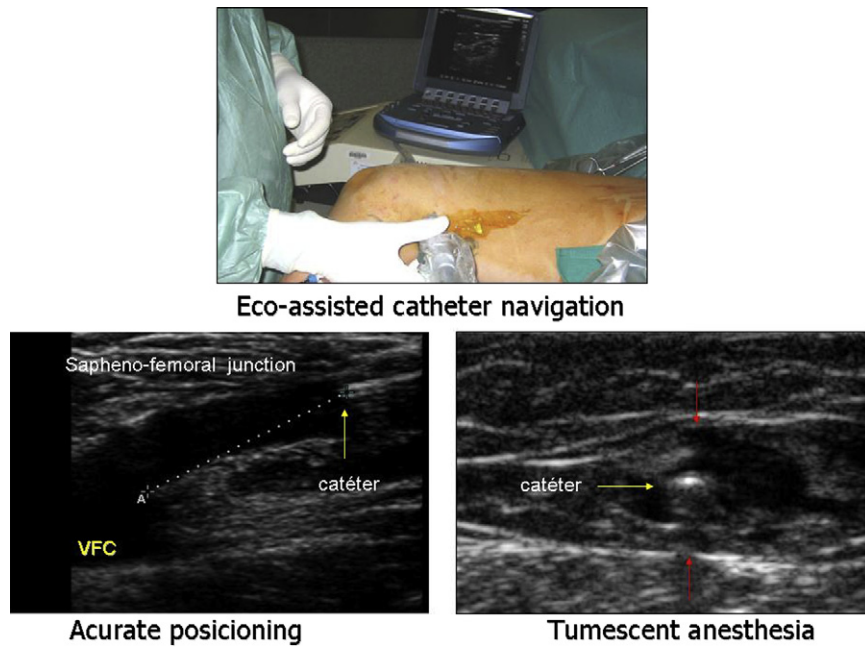


Fig. 4. Echo-assisted steps of radio-frequency Closure ablation.

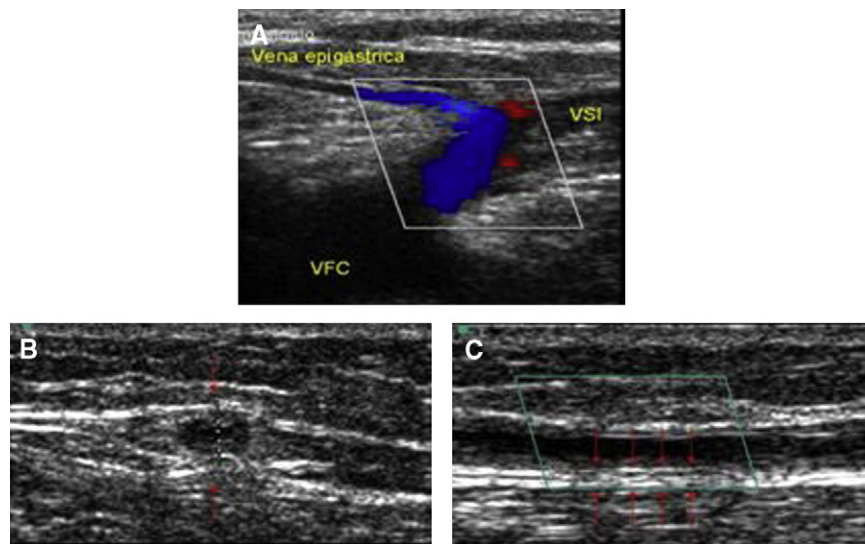


Fig. 5. Ultrasonography pattern after endovenous radio-frequency ablation: (A) Patent epigastric vein without flow in the great saphenous vein, (B) Echogenic pattern showing occlusion of the great saphenous vein, and (C) Increase of wall thickness.

used in this study, which required between 15 and 20 minutes to complete correct ablation; this catheter is no longer in use. Patients returned to their normal activities considerably sooner after RFA (a median of 3 [2–5] vs. 12.5 [4–21] days [ $P < 0.001$ ]). VAS-measured postsurgery pain was substantially less after RFA (a median of 1.70 [0.50–4.30] vs. 4.0 [2.35–6.05] [ $P = 0.001$ ]).

Patient satisfaction (VAS score), QOL (Aberdeen Varicose Vein Questionnaire), and need for painkillers also considerably favored RFA. This study concludes that RF ClosurePLUS treatment for saphenous varicose veins requires a slightly longer time, but offers overall better short-term results.

In short, after reviewing all these works, one conclusion may be drawn: the former RFA

**Table I.** Summary of the most relevant literature in endovenous radiofrequency ablation VNUS Closure (radiofrequency ablation [RFA])

Author	Publication	Tipo estudio Type of study	Conclusions	RF	CIR	Follow-up	Occlusion/lack of reflux	Varicose relapse
Manfrini et al. (comparison closure versus restore)	J Vasc Surg 2000;32:330–42	PNA	Closure system more effective than restore	151		6 months	94%	4%
Rautio et al.	J Vasc Surg 2002;35:958–65	PAC	Less pain. Faster return to work. Lower social cost	15	13	8 weeks		
Merchant et al.	J Vasc Surg 2002;35:1190–6	Multicentre registry	Efficacy comparable to stripping to 1 and 2 years. High satisfaction of patient	319		2 years	90%	10%
Lurie et al. (EVOLVEs)	J Vasc Surg 2003;38:207–14	PAC	Return to activity 1.15 vs. 3.89 ( $P = 0.02$ ) Return to activity 4.7 versus 12.4 ( $P < 0.05$ ) Better quality of life to 1 and 2 years	45	36	2 years		
Perälä J, et al.	Ann Vasc Surg 2005;19:669–72	PAC	No recanalization in occluded segment	15	13	3 years		33% vs. 23%
Merchant et al.	J Vasc Surg 2005;42:502–9	Multicentre registry	Durable abolition of reflux after RF. Higher body mass index implies worst anatomical results	1,222		5 years	84%	13%
Nicolini	Eur J Vasc Endovasc Surg 2005;29:443–9	PNA (Multicentre)	Important clinical improvement. Absence of reflux remains constant 3 years. Patent segment longer than 5 cm correlated with recurrence	330		3 years	88%	12%
Lurie et al.	Eur J Vasc Endovasc Surg 2005;29:67–73	PAC	Results at 2 years at least comparable in efficacy to stripping. RF better score in quality of life	44	36	5 years		RF (14%) versus CIR (21%)
Hinchliffe et al. (relapsed varicose veins)	Eur J Vasc Endovasc 2006;31:212–18	PAC (double-blind)	Faster (25.5 vs. 40 min stripping) ( $P = 0.02$ ). Less pain (1.7 vs. 3.8) ( $P = 0.02$ ). Less bruises (1.7 vs. 5.2)	16	16	1 year		
Dunn et al.	Ann Vasc Surg 2006;20:625–9	Case series	Closure system 90°C vs. 85°C. Reduces treatment time to a half with the same efficacy	85		6 months	90%	

Stötter et al.	Phlebology 2006;21:60–4	PAC	Significant advantages versus stripping regarding pain and return to activity	20	20	6 weeks		
Kianifard et al.	Surgeon 2006;4:71–4	PMNA	RF absence of neovascularization	55	55	1 year		RF (0%) versus CIR (11%)
Proebstle et al. Subramonia and Lees	J Vasc Surg 2008;47:151–6 Br J Surg 2010;97:328–36	PMNA PAC	ClosureFAST RF ClosurePLUS requires more surgical time versus CC, better early results in patients with saphenous varicose veins	252 47	41	6 months 5 weeks	99.6% 100%	
Creton et al.	Ann Vasc Surg 2010;24:360–6	Multicentre registry	Sustained high efficacy at 1 year	295		1 year	97%	
Author	Publication	Type of study	Conclusions	RFA	EVL	Follow-up	Occlusion/lack of reflux	Varicose relapse
Puggioni et al.	J Vasc Surg 2005;42:488–93	PCNA	Occlusion of VSI >90% for both techniques. Three cases of thrombus protrusion in VFC with EVL	53	77	1 month	90.9% vs. 94.4%	
Morrison et al.	Semin Vasc Surg 2005;18:15–18	PAC	ClosurePLUS versus EVL	50	50	1 year	80% vs. 66%	
Almeida et al.	Ann Vasc Surg 2006;20:547–52	Retrospective	ClosurePLUS versus EVL	128	819		94.5% vs. 98.3%	
Gale SS et al.	J Vasc Surg 2010;52:645–50	PAC	ClosurePLUS versus EVL. Both effective in symptom reduction. EVL more bruising and discomforting although more effective	59	70	1 year	72% vs. 95%	
Almeida et al.	J Vasc Interv Radiol 2009;20:752–9 RECOVERY	PAC	Comparative versus endolaser. ClosureFAST significantly better in postsurgery pain, VCSS, and quality of life	46	41	2 weeks		
Shepherd et al.	Br J Surg 2010;97:810–18	PAC	FAST versus EVL. RFA: less pain. Same quality of life at 6 weeks	64	67	6 weeks		

PNA, multicenter prospective nonrandomized; PAC, comparative prospective randomized clinical trial; EVL, endovenous laser ablation; RF, radio frequency; PMNA, prospective multicenter not randomized; VCSS, venous clinical severity score.

ClosurePLUS (now a discontinued catheter) offers definitive advantages over stripping in the short/midterm: less pain, bruising, and ecchymosis, better aesthetic results and, above all, patients return to work sooner. It also offers efficacy for 3 to 5 years, which is the equivalent to stripping. It is likely that state-of-the-art ClosureFAST segmentary ablation, introduced into the clinical practice in 2007, is much quicker and more efficient than PLUS, and also overcomes stripping in midterm efficacy terms (Table I).

## RF VERSUS ENDOLASER

There are two interesting studies that compared the thermal endovenous ablation methods, RFA and EVL.<sup>7,8</sup> It is essential to point out that RFA causes a circular, homogeneous lesion without perforating the venous wall and without carbonization. Therefore, although both procedures are thermal ablation methods, there are important differences between them from the technical perspective, which have been clearly evidenced at the experimental level in the works of Schmedt et al. and of Weiss.<sup>27</sup>

To date, there have been five clinical comparative studies conducted to compare RFA and RVL. Two used ClosurePLUS, two others worked with ClosureFAST, and one used Celon RFITT.

In the first of these, published by Puggioni et al. in 2005,<sup>28</sup> 77 patients were consecutively treated with EVL and 53 with RFA PLUS. The technical success at 1 month was 93.9% (100% for EVL and 96% for RFA). These authors reported a larger number of complications for EVL: 20.8%, and 7.6% for RFA ( $P = 0.049$ ). Of all the EVL-treated patients, 2.3% (3 of 77) developed a protruding thrombus in the common femoral vein. Here, we should bear in mind a design bias, as a duplex-scanning was done as a follow-up with only 50% of the patients.

In 2006, Almeida and Raines<sup>29</sup> published a larger case load (819 EVL and 128 RFA PLUS) with a longer follow-up time (1.5 years). The rechanneling rate was somewhat higher for RF (5.5%) versus EVL (1.7%). The extension rate of the thrombus in the common femoral vein was 0.2% for EVL, and it was absent for RFA.

Gale et al.<sup>30</sup> recently published another prospective, randomized, comparative study that compared EVL (810 nm) ( $n = 48$ ) and RFA PLUS ( $n = 46$ ), and reported results after 1 month and 1 year. This work shows that both methods were highly effective for reducing symptoms (VCSS, CEAP, CIVIQ-2). RFA PLUS provided a better later rechanneling rate (11 RFA and 2 EVL,  $P = 0.002$ ). In conclusion, EVL proved more efficient than RFA PLUS, but was

associated with a higher rate of ecchymosis and discomfort during the perioperative period.

The RECOVERY study published by Almeida et al.<sup>11</sup> in 2009 is a multicentre, comparative study. In 69 patients, 87 veins were randomized, and the study groups were EVL (980 nm) ( $n = 41$ ) and RFA. It used the new ClosureFAST ( $n = 46$ ). The main objectives of the 1-month follow-up were post-operative pain, ecchymosis, swelling, and complications in the procedure. The secondary objectives of this study were the clinical scale of venous severity and QOL (VCSS and QOL scores). These authors concluded that RFA FAST was significantly superior to EVL in postprocedural recovery and QOL parameters. Complications were more prevalent in the EVL group (22.0% vs. 4.4%,  $P = 0.02$ ).

The other comparative study carried out also with the state-of-the-art ClosureFAST catheter has been recently published in 2010 by Shepherd et al.<sup>31</sup> A total of 131 patients were compared (EVL: 980 nm,  $n = 64$ ) and RFA:  $n = 67$ ), analyzing pain 3 days after surgery and QOL after 6 weeks (AVVQ, VCSS, and SF12). The study showed less pain in patients who underwent RFA during the first 10 days ( $P = 0.001$ ). The periods for return to both work and daily activities were similar for both groups, with 70% of the patients returning to work within the first week. Moreover, both groups improved QOL (AVVQ, VCSS, and SF12) after surgery, and there were no statistically significant differences between them. In another work from the same author,<sup>32</sup> patients treated with RFA returned to work before those treated with EVL (5 vs. 9 days,  $P = 0.022$ ).

The laser and RF ablation study,<sup>33</sup> which compared Celon RFITT and EVL (810 nm) (87 treated limbs), was designed to assess pain and swelling in the short term. This study revealed results similar to those of previous works, although it distinguished between unilateral and bilateral procedures.

In summary, with the information available to date regarding these two techniques of endovenous thermal ablation, we can say that RFA achieves results similar to those of EVL and that it is also less painful, causes less bruising, and ecchymosis and confers a better short-term QOL (Table I). In relation to the steam ablation, the information available is still scarce.

## META-ANALYSIS

In recent years, two interesting meta-analyses have been published on the treatment of varicose veins.<sup>34,35</sup> However, results regarding RF have become outdated, as the studies reviewed are



the ones published before 2007 and therefore the system ClosurePLUS is outdated. Cutting-edge RF ClosureFAST is demonstrating to be faster and much more efficient than the previous one (96.9% at 1 year).<sup>36</sup>

## NEOVASCULARIZATION

Groin neovascularization is defined as the presence of serpiginous veins that are of 2 to 4 mm in diameter from the femoral vein and are caused by an angiogenesis procedure. The groin incision and surgical section of the saphenofemoral junction (SPJ) triggers a process of response to the injury in this area with hematoma formation, exposure of the endothelium, and release of angiogenic factors that will motivate the neovascularization of the area.<sup>37,38</sup> Duplex ultrasonography studies demonstrate that it is present in half of the patients after 2 years of surgery.<sup>39,40</sup> It is one of the causes of postsurgical recurrence after SPJ ligation of the arch of the saphenous vein. Even several studies show that despite being a correct surgical technique, neovascularization constitutes the leading cause of recurrences, ranging from 52% to 85%.<sup>5,6,40,41</sup>

Kianifard et al.<sup>42</sup> did not observe neovascularization in those patients who had undergone RFA versus 11% in those who underwent stripping. Other authors also report that inguinal neovascularization is almost absent after endovenous procedure.<sup>43</sup> RFA maintains permeable the epigastric vein, which at first could constitute a cause of recurrence in accordance with the canons of conventional surgery. However, it seems that it could protect against neovascularization by preserving physiological drainage of the abdominal wall.<sup>42,44</sup> Another cause of recurrence prevented with RFA is the absence of revascularization of the saphenectomy tract that happens between 6% and 17% of stripping after one year.<sup>45</sup>

Several studies have clearly shown that the ligation of the SPJ is not necessary during endovenous ablation procedures.<sup>43,46</sup> It does not provide any benefit and also adds the drawbacks associated to inguinal surgical approach.

## COMPLICATIONS

Early complications (skin burns and neuritis) have been clearly overcome with the routine use of tumescent anesthesia. The incidence of deep vein thrombosis in most of the studies is below 1%, except for the series of Hingorani et al.<sup>47</sup> where 16% deep vein thrombosis is achieved. However,

there is an entity related to the techniques of endovenous thermal ablation, named in 2007 by Kabnick and colleagues "endovenous heat-induced thrombosis" (EHIT). Detection of its presence is usual in these techniques, although only its proximity or extent within the common femoral vein is an indication for anticoagulant treatment. Although there is very scarce information on this matter, it seems that it behaves differently from classical superficial venous thrombosis, as in endovenous heat-induced thrombosis, the thrombus is more attached and, as a general rule, it will experience a spontaneous retraction in 7 to 10 days.

## SUMMARY

The introduction of minimally invasive endovenous thermal ablation procedures during the first decade of the 21st century has greatly stimulated interest in venous pathology. We can say that the treatment of varicose veins by endovenous RFA VNUS ClosureFAST is nowadays a safe, mid-term, and highly effective technique. Its main advantages are the early return to work activity, the lack of pain, and the optimal medical and aesthetic results, thus improving significantly quality of life and satisfaction of the patient.

Given that RFA is safe and effective with level 1A scientific evidence (American Venous Forum 4.9.0 recommendation) can be offered as a primary choice for the treatment of truncal varicose veins.<sup>21,22,24-26,42</sup>

It is important to remember that despite the benefits of RFA, like any medical procedure, may have complications. It is necessarily an adequate learning curve, as for its proper execution, it requires a set of perfect skills such as the infiltration technique of tumescent anesthesia, percutaneous venous approach, and catheterization. Moreover, it requires a familiarity with the use of duplex ultrasonography, which is essential in the planning of the strategy and correct control of all steps of the procedure and to monitor these patients.

We should consider the fact that the optimal treatment of varicose veins is not easy, given that there are different treatment options and different anatomical patterns. To achieve excellent results, an individual approach strategy is required—and in most of the cases, a combination of several techniques.

## REFERENCES

1. Evans CJ, Allan PL, Lee AJ, et al. Prevalence of venous reflux in the general population on duplex scanning: the Edinburgh vein study. *J Vasc Surg* 1998;28:767–76.

2. Yamaki T, Nozaki M, Iwasaka S. Comparative study of duplex-guided foam sclerotherapy and duplex-guided liquid sclerotherapy for the treatment of superficial venous insufficiency. *Dermatol Surg* 2004;30:718–22.
3. Labropoulos N, Leon M, Nicolaides AN, et al. Superficial venous insufficiency: correlation of anatomic extent of reflux with clinical symptoms and signs. *J Vasc Surg* 1994;20:953–8.
4. Labropoulos N, Delis K, Nicolaides AN, et al. The role of the distribution and anatomic extent of reflux in the development of signs and symptoms in chronic venous insufficiency. *J Vasc Surg* 1996;23:504–10.
5. Dwerryhouse S, Davies B, Harradine K, Earnshaw JJ. Stripping the long saphenous vein reduces the rate of reoperation for recurrent varicose veins: five-year results of a randomized trial. *J Vasc Surg* 1999;29:589–92.
6. Winterborn RJ, Foy C, Earnshaw JJ. Causes of varicose vein recurrence: late results of a randomized controlled trial of stripping the long saphenous vein. *J Vasc Surg* 2004;40:634–9.
7. Schmedt CG, Sroka R, Steckmeier S, et al. Investigation on radiofrequency and laser (980 nm) effects after endoluminal treatment of saphenous vein insufficiency in an ex-vivo model. *Eur J Vasc Endovasc Surg* 2006;32:318–25.
8. Schmedt CG, Meissner OA, Hunger K, et al. Evaluation of endovenous radiofrequency ablation and laser therapy with endoluminal optical coherence tomography in an ex vivo model. *J Vasc Surg* 2007;45:1047–58.
9. Dunn CW, Kabnick LS, Merchant RF, et al. Endovascular radiofrequency obliteration using 90 degrees C for treatment of great saphenous vein. *Ann Vasc Surg* 2006;20:625–9.
10. Zikorus AW, Mirizzi MS. Evaluation of setpoint temperature and pullback speed on vein adventitial temperature during endovenous radiofrequency energy delivery in an in-vitro model. *Vasc Endovascular Surg* 2004;38:167–74.
11. Almeida JI, Kaufman J, Gockeritz O, et al. Radiofrequency endovenous ClosureFAST versus laser ablation for the treatment of great saphenous reflux: a multicenter, single-blinded, randomized study (RECOVERY study). *J Vasc Interv Radiol* 2009;20:752–9.
12. Proebstle TM, Vago B, Alm J, et al. Treatment of the incompetent great saphenous vein by endovenous radiofrequency powered segmental thermal ablation: first clinical experience. *J Vasc Surg* 2008;47:151–6.
13. Frasier K, Latessa V. Minimally invasive vein therapy and treatment options for endovenous heat-induced thrombus. *J Vasc Nurs* 2008;26:53–7.
14. Bacon JL, Dinneen AJ, Marsh P, et al. Five-year results of incompetent perforator vein closure using TRans-Luminal Occlusion of Perforator. *Phlebology* 2009;24:74–8.
15. Weiss RA, Weiss MA. Controlled radiofrequency endovenous occlusion using a unique radiofrequency catheter under duplex guidance to eliminate saphenous varicose vein reflux: a 2-year follow-up. *Dermatol Surg* 2002;28:38–42.
16. Chandler JG, Pichot O, Sessa C, et al. Defining the role of extended saphenofemoral junction ligation: a prospective comparative study. *J Vasc Surg* 2000;32:941–53.
17. Manfrini S, Gasbarro V, Danielsson G, et al., Endovenous Reflux Management Study Group. Endovenous management of saphenous vein reflux. *J Vasc Surg* 2000;32:330–42.
18. Rautio TT, Perala JM, Wiik HT, et al. Endovenous obliteration with radiofrequency-resistive heating for greater saphenous vein insufficiency: a feasibility study. *J Vasc Interv Radiol* 2002;13:569–75.
19. Merchant RF, DePalma RG, Kabnick LS. Endovascular obliteration of saphenous reflux: a multicenter study. *J Vasc Surg* 2002;35:1190–6.
20. Merchant RF, Pichot O. Long-term outcomes of endovenous radiofrequency obliteration of saphenous reflux as a treatment for superficial venous insufficiency. *J Vasc Surg* 2005;42:502–9.
21. Hinchliffe RJ, Ubhi J, Beech A, et al. A prospective randomised controlled trial of VNUS closure versus surgery for the treatment of recurrent long saphenous varicose veins. *Eur J Vasc Endovasc Surg* 2006;31:212–8.
22. Lurie F, Creton D, Eklof B, et al. Prospective randomised study of endovenous radiofrequency obliteration (closure) versus ligation and vein stripping (EVOLVEs): two-year follow-up. *Eur J Vasc Endovasc Surg* 2005;29:67–73.
23. Perala J, Rautio T, Biancari F, et al. Radiofrequency endovenous obliteration versus stripping of the long saphenous vein in the management of primary varicose veins: 3-year outcome of a randomized study. *Ann Vasc Surg* 2005;19:669–72.
24. Rautio T, Ohinmaa A, Perala J, et al. Endovenous obliteration versus conventional stripping operation in the treatment of primary varicose veins: a randomized controlled trial with comparison of the costs. *J Vasc Surg* 2002;35:958–65.
25. Stötter L, Schaaf I, Bockelbrink A. Comparative outcomes of radiofrequency endoluminal ablation, invagination stripping, and cryostripping in the treatment of great saphenous vein insufficiency. *Phlebology* 2006;21:60–4.
26. Subramonia S, Lees T. Randomized clinical trial of radiofrequency ablation or conventional high ligation and stripping for great saphenous varicose veins. *Br J Surg* 2010;97:328–36.
27. Weiss RA. Comparison of endovenous radiofrequency versus 810 nm diode laser occlusion of large veins in an animal model. *Dermatol Surg* 2002;28:56–61.
28. Puggioni A, Kalra M, Carmo M, et al. Endovenous laser therapy and radiofrequency ablation of the great saphenous vein: analysis of early efficacy and complications. *J Vasc Surg* 2005;42:488–93.
29. Almeida JI, Raines JK. Radiofrequency ablation and laser ablation in the treatment of varicose veins. *Ann Vasc Surg* 2006;20:547–52.
30. Gale SS, Lee JN, Walsh ME, et al. A randomized, controlled trial of endovenous thermal ablation using the 810-nm wavelength laser and the ClosurePLUS radiofrequency ablation methods for superficial venous insufficiency of the great saphenous vein. *J Vasc Surg* 2010;52:645–50.
31. Shepherd AC, Gohel MS, Brown LC, et al. Randomized clinical trial of VNUS ClosureFAST radiofrequency ablation versus laser for varicose veins. *Br J Surg* 2010;97:810–8.
32. Shepherd AC, Gohel MS, Lim CS, et al. Pain following 980-nm endovenous laser ablation and segmental radiofrequency ablation for varicose veins: a prospective observational study. *Vasc Endovascular Surg* 2010;44:212–6.
33. Goode SD, Chowdhury A, Crockett M, et al. Laser and radiofrequency ablation study (LARA study): a randomised study comparing radiofrequency ablation and endovenous laser ablation (810 nm). *Eur J Vasc Endovasc Surg* 2010;40:246–53.
34. Luebke T, Gawenda M, Heckenkamp J, Brunkwall J. Meta-analysis of endovenous radiofrequency obliteration of the great saphenous vein in primary varicosis. *J Endovasc Ther* 2008;15:213–23.

35. van den BR, Arends L, Kockaert M, et al. Endovenous therapies of lower extremity varicosities: a meta-analysis. *J Vasc Surg* 2009;49:230–9.
36. Creton D, Pichot O, Sessa C, Proebstle TM. Radiofrequency-powered segmental thermal obliteration carried out with the ClosureFast procedure: results at 1 year. *Ann Vasc Surg* 2010;24:360–6.
37. De Maeseneer MG. Neovascularisation an adverse response to proper groin dissection. In: Bergan J ed. *The vein book*. Elsevier, 2007. pp 239–46.
38. Glass GM. Neovascularization in recurrence of varices of the great saphenous vein in the groin: phlebography. *Angiology* 1988;39(7 Pt. 1):577–82.
39. Kaspar S, Hadzi ND, Danek T, et al. Neovascularisation as a cause of recurrence after varicose veins operation [in Czech]. *Rozhl Chir* 2006;85:399–403.
40. Jones L, Braithwaite BD, Selwyn D, et al. Neovascularisation is the principal cause of varicose vein recurrence: results of a randomised trial of stripping the long saphenous vein. *Eur J Vasc Endovasc Surg* 1996;12:442–5.
41. Nyamekye I, Shephard NA, Davies B, et al. Clinicopathological evidence that neovascularisation is a cause of recurrent varicose veins. *Eur J Vasc Endovasc Surg* 1998;15:412–5.
42. Kianifard B, Holdstock JM, Whiteley MS. Radiofrequency ablation (VNUS closure) does not cause neovascularisation at the groin at 1 year: results of a case controlled study. *Surgeon* 2006;4:71–4.
43. Pichot O, Kabnick LS, Creton D, et al. Duplex ultrasound scan findings two years after great saphenous vein radiofrequency endovenous obliteration. *J Vasc Surg* 2004;39:189–95.
44. Fassiadis N, Kianifard B, Holdstock JM, Whiteley MS. Ultrasound changes at the saphenofemoral junction and in the long saphenous vein during the first year after VNUS closure. *Int Angiol* 2002;21:272–4.
45. Munasinghe A, Smith C, Kianifard B, Price BA, Holdstock JM, Whiteley MS. Strip-track revascularization after stripping of the great saphenous vein. *Br J Surg* 2007;94:840–3.
46. Gradman WS. Adjunctive proximal vein ligation with endovenous obliteration of great saphenous vein reflux: does it have clinical value? *Ann Vasc Surg* 2007;21:155–8.
47. Hingorani AP, Ascher E, Markevich N, et al. Deep venous thrombosis after radiofrequency ablation of greater saphenous vein: a word of caution. *J Vasc Surg* 2004;40:500–4.