Radiofrequency Endovenous ClosureFAST versus Laser Ablation for the Treatment of Great Saphenous Reflux: A Multicenter, Single-blinded, Randomized Study (RECOVERY Study)

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PURPOSE: The present study was designed to address the hypothesis that radiofrequency (RF) thermal ablation, as represented by the ClosureFAST system, is associated with improved recovery and quality-of-life (QOL) parameters compared with 980-nm endovenous laser (EVL) thermal ablation of the great saphenous vein (GSV).

MATERIALS AND METHODS: Eighty-seven veins in 69 patients were randomized to ClosureFAST or 980-nm EVL treatment of the GSV. The study was prospective, randomized, single-blinded, and carried out at five American sites and one European site. Primary endpoints (postoperative pain, ecchymosis, tenderness, and adverse procedural sequelae) and secondary endpoints (venous clinical severity scores and QOL issues) were measured at 48 hours, 1 week, 2 weeks, and 1 month after treatment.

RESULTS: All scores referable to pain, ecchymosis, and tenderness were statistically lower in the ClosureFAST group at 48 hours, 1 week, and 2 weeks. Minor complications were more prevalent in the EVL group ($P = .0210$); there were no major complications. Venous clinical severity scores and QOL measures were statistically lower in the ClosureFAST group at 48 hours, 1 week, and 2 weeks.

CONCLUSIONS: RF thermal ablation was significantly superior to EVL as measured by a comprehensive array of postprocedural recovery and QOL parameters in a randomized prospective comparison between these two thermal ablation modalities for closure of the GSV.

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Abbreviations: EVL = endovenous laser, GSV = great saphenous vein, QOL = quality of life, RF = radiofrequency, SFJ = saphenofemoral junction, VCSS = Venous Clinical Severity Score

THE treatment of superficial venous disease has undergone dramatic changes during the past decade. Before this period, elimination of saphenous vein reflux was accomplished surgically (ie, with ligation and stripping) or chemically (ie, with sclerotherapy). Surgical ligation and stripping is associated with complications including hematoma and paresthesia, and has not been well accepted by patients in the United States, who perceive the procedure as risky, disfiguring, and requiring hospitalization with a lengthy convalescence. Additionally, stripping is known to be fraught with recurrences in approximately 50% of treated patients who are followed on a long-term basis (1–3). Sclerotherapy of the saphenous vein, to the contrary, is performed commonly throughout the

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world with minimal risk, but, with high failure rates (4). Catheter-based thermal ablation with electromagnetic energy delivery to the endoluminal space (either radiofrequency [RF] or laser), has arguably become the gold-standard treatment for symptomatic great saphenous vein (GSV) incompetence. Endovenous thermal ablation of the GSV was designed to hasten patient recovery; however, since the earliest published experiences with these devices approximately a decade ago, reports in the literature have concentrated on safety and efficacy (5).

RF catheters were the first devices to become available to venous interventionists for GSV ablation. Relatively early follow-up after RF ablation demonstrated only 87% occlusion of the GSV at 5 years, with a 21% varicose vein recurrence rate in a multicenter registry completed by Merchant and Pichot (11). Studies followed comparing this new technique versus traditional surgery. Four randomized controlled trials (6–10) have compared endovenous RF ablation versus surgical vein stripping, and all reported superior results with RF ablation.

Findings included faster recovery, less postoperative pain, fewer adverse events, and superior quality-of-life (QOL) scores (6–10). The earlier-generation RF ablation system operating at 85°C had two distinct disadvantages compared with endovenous laser (EVL) treatment. These were slow pullback speed and the occasional need to remove the catheter to clear coagulum from the bipolar electrodes. The introduction of the ClosureFAST RF catheter (VNUS Medical Technologies, San Jose, California) has led to dramatic improvement in the procedure. These improvements include elimination of the laborious pullback, short energy cycle, and rapid treatment as a result of a constant temperature level of 120°C.

When EVL ablation entered the arena, 3-year follow-up on 499 limbs treated in a single center demonstrated successful ablation in 93% of 121 limbs seen at 2 years, with no recurrences in 40 limbs followed to 3 years (12). Reasons for more effective ablation with EVL versus RF were not clear until articles on the dose–response relationship between laser energy and durability of vein occlusion were published in 2004 by Proebstle et al (13). Bruising, transient pain, and induration of the thigh are common adverse events after EVL, which are most likely caused by laser-induced perforation of the vein wall and extravasation of blood into surrounding tissue (14–16). After EVL, one can generally expect 70% of limbs to experience some degree of pain, and 50% to require analgesics for pain management (8). Kabnick reported an average pain score of 2.6 on a scale of 0–5 after EVL (17).

The present study is a multicenter, prospective, randomized trial to compare recovery and QOL factors between RF and EVL ablation. As will be detailed in the next section, the ClosureFAST device was compared with a 980-nm EVL at comparable energy delivery to close incompetent GSVs.

The presence and intensity of postoperative pain, ecchymosis, and tenderness; adverse procedural sequelae such as deep vein thrombosis, paresthesia, phlebitis, hyperpigmentation, and infection; and periprocedural analgesic agent use and QOL were measured at 48 hours, 1 week, 2 weeks, and 1 month after treatment.

MATERIALS AND METHODS

From March through December 2007, 87 veins in 69 patients were randomized to undergo treatment with the ClosureFAST RF catheter or 980-nm laser (Biolitec, East Longmeadow, Massachusetts) of the GSV. The study was prospective, randomized, single-blinded, and conducted at five American sites and one European site. A private, independent external review board (Essex Institutional Review Board, Lebanon, New Jersey) was used for oversight and approval by all centers.

Investigators were required to have documented clinical experience with RF and EVL devices. Patients between the ages of 18 and 80 years with incompetent GSVs documented on duplex ultrasound (US; B-mode and color Doppler imaging) were eligible. Reflux was considered significant if reversal of flow was present for more than 0.5 seconds after distal compression in the standing position. Exclusion criteria consisted of: thrombus in the vein of interest, previous GSV treatment, pregnancy, known malignancy, and use of anticoagulant medication with the exception of low-dose aspirin. To maintain the single-blind nature of the study, the actual treatment procedure was not discussed with the participants.

US-guided percutaneous access followed by perivenous tumescent anesthesia with 0.1% lidocaine with epinephrine was performed before thermal ablation. RF ablation was performed with an intraluminally placed ClosureFAST device with a 7-cm heating element. After positioning the catheter tip 2 cm from the saphenofemoral junction (SFJ), segmental energy delivery at 120°C was delivered in 20-second cycles. Two cycles were applied to the proximal vein, followed by one cycle to the remaining venous segments. The EVL group was treated with a 980-nm wavelength in the continuous mode at 12 W of power with a linear endovenous energy density of 80 J/cm.

After treatment, the limbs were wrapped with compression bandages and class II compression stockings; subjects were instructed to ambulate frequently. After 24–72 hours, bandages were removed and subjects were instructed to continue to use the compression stockings for 2 weeks. At 24–72 hours, postprocedural duplex US was performed to assess the status of vein occlusion and thrombosis. Patients were asked to complete a questionnaire at each visit that focused on pain assessment and QOL issues.

Visits at 1 and 2 weeks were limited to clinical assessment and patient questionnaires. The final visit at 1 month included duplex US. Phlebectomy was not permitted until at least 30 days had elapsed after the procedure.

Primary Endpoints

The presence and intensity of postoperative pain was measured by the subject on a validated visual analog scale ranging from 0 (no pain) to 10 (most severe pain). Ecchymosis was measured by the clinic staff on a scale ranging from 0 (no ecchymosis) to 5 (ecchymosis over the entire segment and extension above or below the treatment segment). All ranges are described in **Table 1**. The incidence of adverse procedural sequelae such as deep vein thrombosis, paresthesia, phlebitis, hyperpigmentation, and infection were also recorded. Phlebitis was defined as induration and erythema along the course of the target vein. Other sequelae were defined by standard clinical criteria.

Table 1
Grading Criteria for Ecchymosis

Grade	Treated Area with Ecchymosis (%)
0	None
1	<25
2	25–50
3	50–75
4	75–100
5	Extension above or below treated segment

Secondary Endpoints

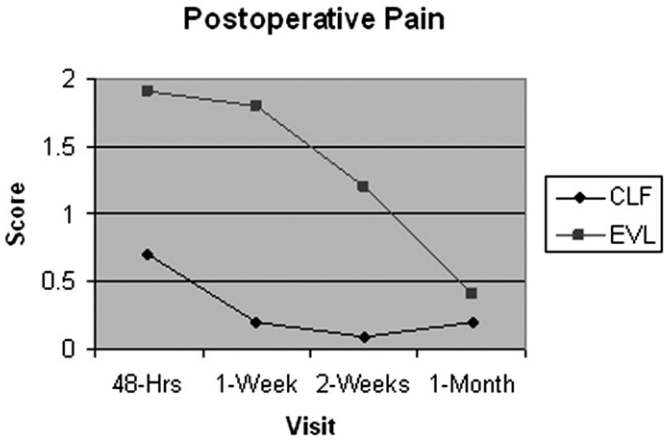
Duplex US was used to determine which veins were closed within 3 cm of the SFJ at 48 hours and 1 month. Reflux was considered present if reversal of flow lasted more than 0.5 seconds after distal compression in the standing position. A Venous Clinical Severity Score (VCSS) was recorded during each follow-up visit (18). Limb tenderness was measured on a scale ranging from 0 (no tenderness) to 10 (acutely severe tenderness) at each follow-up visit. The use of periprocedural analgesic agents was limited to ibuprofen with a maximum dose of 800 mg twice daily. Subjects were instructed to take the medication only if required for pain control. Pill counts were recorded at all visits. QOL issues were measured by the second version of the Chronic Venous Insufficiency Quality of Life Questionnaire (19).

Randomization was performed within 24 hours before the procedure and was accomplished by the investigators accessing a Web site and downloading the procedure to be performed. SAS software (version 9.1; SAS, Cary, North Carolina) was used to calculate sample size. All analyses assumed two-sided tests with an α level of 0.05, desired power of 80%, and 20% loss to follow-up. The Student t test was used for quantitative value analysis such as pain and tenderness scores, and the Fisher exact test was used for proportions. QOL including general pain and associated physical, social, and psychological parameters was measured with the Chronic Venous Insufficiency Quality of Life Questionnaire, version 2. VNUS Medical Technologies provided financial support for data collection and clinical monitoring and participated in the protocol design.

Table 2
Demographic Characteristics of Study Patients

Demographics	ClosureFAST	EVL	*P* Value*
Limbs	46	41	
Age (y)	51.6 ± 12.8 (35)	52.4 ± 15.3 (41)	.8215
Female sex	29 (82.9%)	31 (75.6%)	.5748
Height (inches)	69.4 ± 13.5 (35)	66.6 ± 3.6 (41)	.1986
Weight (lbs.)	157.6 ± 19.6 (35)	165.0 ± 28.4 (41)	.1960
VCSS	4.7 ± 3.1 (46)	4.9 ± 2.8 (41)	.6907
CEAP (class 2)	43 (93.5%)	36 (87.8%)	.4671
Mean length of treated segment (cm)	35.6 ± 13.4 (45)	42.2 ± 14.0 (41)	.3785
Diameter 3 cm from SFJ (mm)	5.1 ± 2.3 (46)	6.0 ± 2.8 (41)	.1154

Note.—Values expressed as means ± SD. Values in parentheses are the numbers of patients in which measurements were available unless otherwise indicated. CEAP = Clinical/Etiology/Anatomy/Pathophysiology.
* Fisher exact test.



Visit	Postoperative Pain CLF mean ± SD (m)	EVL mean ± SD (m)	*t* test *P* value
48 Hour	0.7 ± 0.9 (46)	1.9 ± 1.6 (41)	<.0001
1 Week	0.2 ± 0.6 (40)	1.8 ± 1.8 (36)	<.0001
2 Weeks	0.1 ± 0.4 (43)	1.2 ± 1.7 (39)	<.0001
1 Month	0.2 ± 0.8 (46)	0.4 ± 1.2 (41)	.2962

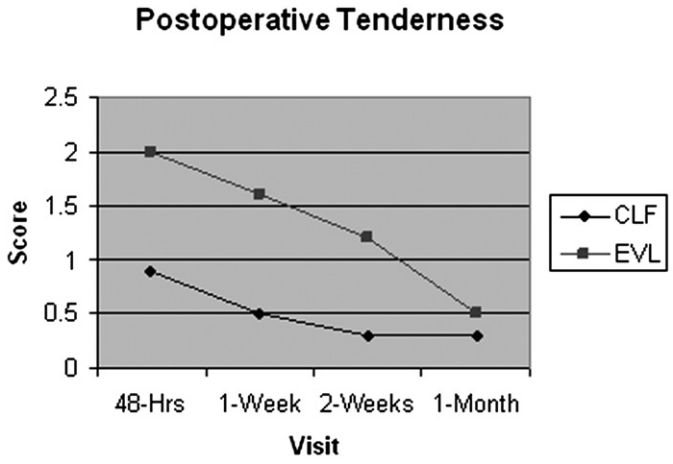
Figure 1. Postoperative pain measured at each follow-up visit.

RESULTS

Forty-six limbs were randomized to undergo RF treatment and 41 to undergo EVL. As depicted in **Table 2**, there were no significant differences between the groups regarding age, sex, height, weight, presenting VCSS, Clinical/Etiology/Anatomy/Pathophysiology class, mean length of treated segment, or target vein diameter. Approximately 90% of subjects fell into Clinical/Etiology/Anatomy/Pathophysiology class C2 (ie, varicose veins); however, classes C3–C6 were also represented in the study. Approximately 80% of subjects were treated for symptom relief. Prevention of disease progression, venous ulceration, and cosmetic concerns were other indications for therapy.

Primary Objectives

Postoperative pain.—As illustrated in **Figure 1**, the ClosureFAST group reported significantly lower pain levels than the EVL group during visits at 48 hours (0.7 vs 1.9), 1 week (0.2 vs 1.8),



Visit	Current Tenderness CLF mean ± SD (m)	EVL mean ± SD (m)	*t* test *P* value
48 Hour	0.9 ± 1.3 (46)	2.0 ± 2.3 (41)	.0048
1 Week	0.5 ± 1.2 (40)	1.6 ± 1.8 (36)	.0036
2 Weeks	0.3 ± 0.7 (43)	1.2 ± 1.5 (39)	.0005
1 Month	0.3 ± 1.0 (46)	0.5 ± 1.2 (41)	.5761

Figure 2. Current postoperative tenderness measured at each follow-up visit.

Table 3
Postoperative Ecchymosis as Measured at Each Visit

Visit	Response (%)	ClosureFAST	EVL	*P* Value*
48 Hours	None	30 (66.7)	8 (19.5)	<.0001
	0–25	15 (33.3)	13 (31.7)	
	25–50	0	14 (34.1)	
	50–75	0	5 (12.2)	
	75–100	0	1 (2.4)	
1 Week	None	26 (65.0)	9 (25.7)	<.0001
	0–25	13 (32.5)	12 (34.3)	
	25–50	0	10 (28.6)	
	50–75	1 (2.5)	4 (11.4)	
2 Weeks	None	35 (81.4)	13 (33.3)	<.0001
	0–25	7 (16.3)	18 (46.2)	
	25–50	1 (2.3)	6 (15.4)	
	50–75	0	2 (5.1)	
1 Month	None	45 (97.8)	31 (77.5)	.0050
	0–25	1 (2.2)	9 (22.5)	

* Fisher exact test.

and 2 weeks (0.1 vs 1.2). The *P* values for these visits were all less than .0001. Differences in pain levels did not reach statistical significance at the 1-month visit (0.2 vs 0.4; $P = .2962$).

Postoperative tenderness.—As illustrated in **Figure 2**, the RF ablation group reported significantly lower tenderness than the EVL group during visits at 48 hours (0.9 vs 2.0; $P = .0048$), 1 week (0.5 vs 1.6; $P = .0036$), and 2 weeks (0.3 vs 1.2; $P = .0005$). Differences in tenderness did not reach statistical significance at the 1-month visit (0.3 vs 0.5; $P = .5761$).

Postoperative ecchymosis.—Statistically significant differences in the presence and degree of ecchymosis between treatment groups were identified at all visits (**Table 3**). The differences were most marked at the 48-hour, 1-week, and 2-week visits ($P < .0001$). Sixty-seven percent of limbs in the ClosureFAST group had no bruising at the 48-hour visit, versus only 20% with no bruising in the EVL group. One limb in the ClosureFAST group (2.2%) showed ecchymosis covering more than 25% of the treated area across all visits, compared with 21 of the EVL-treated limbs (51.3%).

Complications/adverse sequelae.—Complications, as demonstrated in **Table 4**, were statistically more prevalent in the EVL group than the ClosureFAST group (22.0% vs 4.4%; $P = .0210$). There were two patients in the RF ablation group with at least one related complication reported, compared with 15 patients in the EVL group.

The development of superficial phlebitis ($P = .0200$) was the only complication in which a statistical difference could be demonstrated at 48 hours; however, when complications were present, the numbers were greater in the patients treated with EVL.

Secondary Objectives

VCSS.—VCSS evaluations were recorded on all patients at the initial evaluation, and subsequently at all visits (**Fig 3**). There were no significant differences ($P = .6907$) in VCSSs between treatment groups (ie, RF vs EVL) at screening (4.7 vs 4.9). However, at the 48-hour (4.7 vs 6.2; $P = .0009$), 1-week (4.2 vs 5.9; $P = .0002$), and 2-week visits (4.0 vs 5.3; $P = .0035$), subjects in the RF group had significantly reduced scores compared with the EVL group. This statistical difference was not sustained at the 1-month visit (2.7 vs 3.2; $P = .2825$). In reviewing the components of the VCSS, the reason the ClosureFAST group showed an advantage can be traced to reduced postoperative pain and edema.

QOL scores.—QOL measures were an important consideration in this study; measurements in five categories were obtained before the surgical procedure and at all follow-up visits. As illustrated in **Table 5**, there were no significant differences in QOL between treatment groups at

Table 4
Complications Identified at Follow-up Visits

Visit	Variable	ClosureFAST	EVL	*P* Value*
48 Hours	Hyperpigmentation	0	0	
	Phlebitis	0	5 (12.2)	.020
	Paresthesia	0	1 (2.4)	.471
	Erythema	0	3 (7.3)	.101
	Infection	0	0	
	TE/DVT	0	1 (2.4)	.471
1 Week	Hyperpigmentation	0	0	
	Phlebitis	0	1 (2.4)	.471
	Paresthesia	1 (2.2)	0	1.000
	Erythema	0	0	
	Infection	0	0	
	TE/DVT	0	1 (2.4)	.471
2 Weeks	Hyperpigmentation	0	0	
	Phlebitis	0	2 (4.9)	.219
	Paresthesia	1 (2.2)	2 (4.9)	.600
	Erythema	0	3 (7.3)	.101
	Infection	0	0	
	TE/DVT	0	1 (2.4)	.471
1 Month	Hyperpigmentation	1 (2.2)	0	1.000
	Phlebitis	0	0	
	Paresthesia	0	0	
	Erythema	0	0	
	Infection	0	0	
	TE/DVT	0	0	
Sequelae at any follow-up	Hyperpigmentation	1 (2.2)	0	>.999
	Phlebitis	0	6 (14.6)	.009
	Paresthesia	1 (2.2)	2 (4.9)	.0600
	Erythema	0	4 (9.8)	.045
	Infection	0	0	
	TE/DVT	0	1 (2.4)	.471
	Total limbs	2 (4.4)	9 (22.0)	.021

Note.—Values in parentheses are percentages. DVT = deep vein thrombosis; TE = thromboembolism.
* Fisher exact test.

screening ($P > .0500$). Pain and physical scores were statistically lower in the RF group at 48 hours and 1 week. By the 2-week visit, all QOL parameters were statistically different in favor of the ClosureFAST group. These statistical differences disappeared at 1 month.

Change in QOL scores.—Changes in global QOL scores were better with ClosureFAST treatment at 7 and 14 days after treatment (**Table 6**). Single-dimension QOL measures for physical symptoms and pain were also statistically better with RF treatment at 1-week and 2-week visits. Improvement in psychologic scores was better for RF than EVL at 7-day follow-up.

Vein occlusion and elimination of truncal reflux were achieved in 100% of limbs irrespective of treatment modality.

DISCUSSION

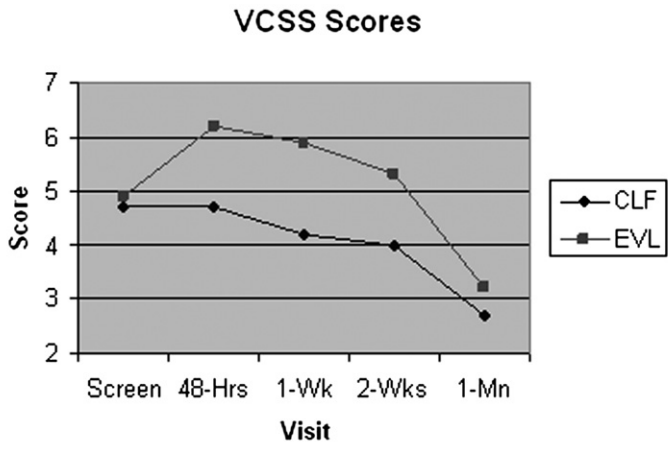
Robust clinical data are available comparing RF ablation versus EVL, but these data mostly focus on the safety and efficacy of either endoluminal technique (20). Morrison (21) published a retrospective comparison of RF and laser vein ablation with 1-year follow-up in which 50 patients were randomized to undergo treatment with bipolar RF or 810-nm pulsed laser vein ablation. Postprocedural bruising and pain were greater with laser treatment, and primary GSV occlusion rates were better with RF (80%) than with laser (66%; $P < .0500$) (21). The current study focused on postoperative recovery differences between RF and EVL in a prospective, randomized manner, with a maximum of 1 month follow-up. The primary clinical intent of the procedure did not differ between randomization groups; 80% of the patients in both treatment groups were enrolled for symptom relief.

Postprocedural pain, tenderness, ecchymosis, and phlebitis were more prevalent in the laser-treated limbs, likely resulting from high treatment temperatures and vein wall perforation by laser energy with subsequent extravasation of boiled blood from the treated vein. All scores referable to pain, ecchymosis, and tenderness were statistically lower in the RF group at 48 hours, 1 week, and 2 weeks. Minor complications were more prevalent in the EVL group ($P = .0210$); there were no major complications. All QOL measures were statistically better in the RF group at 48 hours, 1 week, and 2 weeks.

We also looked at VCSSs that have been previously reported with endovenous RF ablation. In the trial of RF versus vein stripping reported by Lurie et al (8), mean VCSSs were reduced from a pretreatment score of 4.8 to 2.5 at 3 weeks after treatment. This is similar to the extent of VCSS reduction seen in the present trial, in which the VCSS of 4.7 at baseline decreased at each follow-up visit, ending at 2.7 at 30 days after treatment. Patients treated with EVL also experienced a mean reduction of VCSS from baseline to 30 days after treatment (4.9 to 3.2). However, for the follow-up periods of 2, 7, and 14 days, the average VCSS of patients treated with EVL were 6.2, 5.9, and 5.3, all of which were higher than pretreatment levels. This suggests that patients treated with EVL, on average, take longer to show improvement beyond pretreatment levels.

In the present trial comparing ClosureFAST catheter treatment versus 980-nm EVL, we observed excellent correction of parameters linked to venous reflux and, presumably, the expected venous hypertension secondary to GSV incompetence irrespective of the device used for treatment.

All indices measuring postinflammatory sequelae demonstrated a statistically significant difference favoring RF ablation versus EVL, and the differences did not result from differences in energy delivery. The linear endovenous energy density delivered to the vein was comparable between groups. Parameters describing the



Visit	VCSS Scores CLF mean ± SD (m)	EVL mean ± SD (m)	*t* test *P* value
Screening	4.7 ± 3.1 (46)	4.9 ± 2.8 (41)	.6907
48 Hours	4.7 ± 1.6 (46)	6.2 ± 2.5 (41)	.0009
1 Week	4.2 ± 1.5 (40)	5.9 ± 2.3 (35)	.0002
2 Weeks	4.0 ± 1.8 (43)	5.3 ± 1.9 (39)	.0035
1 Month	2.7 ± 2.2 (46)	3.2 ± 1.8 (41)	.2825

Figure 3. VCSSs measured at each follow-up visit.

Table 5
QOL Measures during Follow-up

Visit	Measure	ClosureFAST	EVL	*P* Value*
Screening	Pain	7.1 ± 3.2 (45)	7.3 ± 2.4 (40)	.7337
	Physical	11.6 ± 4.9 (45)	11.2 ± 4.9 (40)	.7217
	Social	5.7 ± 3.1 (45)	6.1 ± 3.0 (40)	.5892
	Psychologic	16.3 ± 7.7 (45)	15.5 ± 6.0 (40)	.5897
	Global	40.6 ± 17.2 (45)	40.0 ± 14.5 (40)	.8584
48 Hours	Pain	4.6 ± 2.0 (46)	6.2 ± 2.8 (41)	.0022
	Physical	7.6 ± 3.5 (46)	9.8 ± 4.6 (41)	.0131
	Social	4.3 ± 2.6 (46)	4.9 ± 2.7 (41)	.2776
	Psychologic	11.2 ± 4.4 (45)	12.8 ± 5.1 (41)	.1311
	Global	27.7 ± 11.5 (45)	33.7 ± 13.7 (41)	.0302
1 Week	Pain	3.6 ± 1.2 (35)	5.4 ± 2.0 (35)	.0000
	Physical	5.9 ± 1.6 (35)	8.1 ± 3.0 (35)	.0002
	Social	3.6 ± 1.2 (34)	4.3 ± 1.8 (35)	.0402
	Psychologic	10.0 ± 2.5 (35)	11.5 ± 2.9 (35)	.0207
	Global	23.0 ± 6.1 (34)	29.5 ± 8.5 (35)	.0006
2 Weeks	Pain	3.7 ± 1.3 (42)	5.1 ± 1.9 (38)	.0003
	Physical	6.0 ± 2.0 (42)	7.9 ± 3.3 (38)	.0023
	Social	3.4 ± 0.9 (41)	4.4 ± 2.1 (38)	.0044
	Psychologic	9.7 ± 2.0 (42)	10.7 ± 2.5 (37)	.0404
	Global	22.9 ± 5.4 (41)	27.6 ± 8.3 (37)	.0034
1 Month	Pain	3.6 ± 1.2 (45)	3.5 ± 0.8 (39)	.5347
	Physical	6.0 ± 1.9 (44)	5.6 ± 1.0 (39)	.2279
	Social	3.2 ± 0.7 (45)	3.3 ± 0.8 (39)	.4822
	Psychologic	9.8 ± 1.9 (45)	9.8 ± 1.5 (39)	.9893
	Global	22.7 ± 5.0 (44)	22.2 ± 3.3 (39)	.6135

Note.—Values expressed as means ± SD. Values in parentheses are the numbers of patients in which measurements were available unless otherwise indicated.
* Student *t* test.

amount of delivered energy along the vein—referred to as linear endovenous energy density (in J/cm) and endovenous fluence equivalent (ie, cylindrical approximation of the inner vein volume to expressed energy distribution, in J/cm^2)—have been shown to correlate with saphenous vein recanalization (22–25).

The RF procedure is better tolerated by patients because controlled heating avoids the vein perforations often seen with EVL; this is the case even with high dosing of thermal energy. The linear endovenous energy density, as explained earlier, is frequently used to compare energy dosing in endovenous procedures. With the first-generation (ie, bipolar) RF device, the catheter pullback velocity had to be slow enough to allow resistive heating of the vein wall to a target temperature of 85°C. With the ClosureFAST catheter, the temperature is kept stable at 120°C during a 20-second treatment cycle. At the SFJ, a second cycle of energy is delivered, averaging a linear endovenous energy density of 116.2 J/cm ± 11.6 for the first 7 cm of vein juxtaposed to the SFJ to ensure good vein closure at this critical site (26). Distal to the SFJ, 68.2 J/cm ± 17.5 is delivered to each 7-cm treatment site. This aggressive "double energy cycle" at the zone of the SFJ is supported by a study performed by Almeida and Raines (20) in which most recanalizations occurred in the first 12 months and developed in the GSV proximal to the posterior thigh circumflex vein at the SFJ. The posterior thigh circumflex vein, when large, drains cooler blood (37°C) into the treatment segment, and does not allow proper heat-induced closure of the SFJ; therefore, the SFJ requires more energy to close.

Laser wavelengths based on the affinity of hemoglobin for infrared light have been effective in destroying incompetent veins at the expense of causing robust perivenous inflammation. To overcome the problem of venous perforation, EVL technology continues moving further toward the development of longer wavelengths targeting the last peak of water absorption; the idea being that hemoglobin absorption is totally bypassed, allowing more robust absorption of laser photons by interstitial water in the vein wall.

By targeting the vein wall, EVL

Table 6
Changes in QOL at Follow-up versus Screening

Visit	Measure	ClosureFAST	EVL	*P* Value*
48 Hours	Pain	−2.5 ± 3.1 (45)	−1.2 ± 3.3 (40)	.0677
	Physical	−4.2 ± 4.1 (45)	−1.6 ± 6.5 (40)	.0325
	Social	−1.6 ± 3.1 (45)	−1.4 ± 3.6 (40)	.7798
	Psychologic	−5.2 ± 6.6 (44)	−2.9 ± 7.4 (40)	.1393
	Global	−13.5 ± 14.6 (44)	−7.1 ± 19.0 (40)	.0854
1 Week	Pain	−3.9 ± 2.8 (34)	−1.8 ± 2.5 (35)	.0013
	Physical	−6.0 ± 4.0 (34)	−2.8 ± 4.7 (35)	.0029
	Social	−2.2 ± 2.8 (33)	−1.7 ± 3.2 (35)	.4725
	Psychologic	−6.8 ± 6.5 (34)	−3.1 ± 4.9 (35)	.0110
	Global	−19.1 ± 13.9 (33)	−9.4 ± 13.3 (35)	.0044
2 Week	Pain	−3.8 ± 3.1 (41)	−2.3 ± 3.0 (37)	.0327
	Physical	−6.0 ± 4.3 (41)	−3.4 ± 6.3 (37)	.0332
	Social	−2.7 ± 2.9 (40)	−1.5 ± 3.5 (37)	.0979
	Psychologic	−7.0 ± 6.8 (41)	−4.8 ± 6.9 (36)	.1580
	Global	−19.9 ± 14.7 (40)	−12.4 ± 17.6 (36)	.0457
1 Month	Pain	−3.5 ± 3.2 (44)	−3.8 ± 2.5 (39)	.6990
	Physical	−5.4 ± 4.5 (43)	−5.4 ± 5.1 (39)	.9937
	Social	−2.5 ± 2.9 (44)	−2.7 ± 3.2 (39)	.8279
	Psychologic	−6.5 ± 6.8 (44)	−5.7 ± 6.3 (39)	.5765
	Global	−17.8 ± 15.4 (43)	−17.5 ± 15.2 (39)	.9463

Note.—Values expressed as means ± SD. Values in parentheses are the numbers of patients in which measurements were available unless otherwise indicated.
* Student *t* test.

may improve its postoperative recovery profile. Interestingly, targeting of the vein wall exclusively has always been the goal of RF ablation. This has been true from the first device operating at 85°C to the contemporary ClosureFAST catheter operating at 120°C. In the original bipolar RF ablation procedure, the vein wall served as a resistive element for transfer of energy from anode to cathode; in the contemporary ClosureFAST device, the vein wall is the direct recipient of conducted heat from a 7-cm-long heating element.

Limitations of this study were the small sample size and 1-month follow-up. However, the investigators believed most postprocedural effects resolve after 1 month. The authors do not believe there are major cost considerations that might influence choice of device; however, a formal cost–benefit analysis was not performed.

In this prospective randomized study to compare an RF vein ablation catheter and EVL, RF treatment showed better results than EVL treatment in all primary endpoints and many secondary endpoints. RF treatment produced significantly less pain, bruising, and tenderness, as well as fewer adverse sequelae than laser treatment. Also, RF vein ablation resulted in more significant improvements in VCSS, global QOL scores, and pain and physical QOL for a period lasting 2 weeks after treatment. It is remarkable to note the consistent convergent improvement in both study arms in regard to QOL and VCSS. The data were statistically significant favoring RF ablation postoperatively at the 2-week assessment, however, equalization in most recovery parameters was observed between groups at 1 month.

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