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.

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
were published in 2004 by Proebstle et al. 

RF catheters were the first devices to become available to venous interventionalists for GSV ablation. Relatively early follow-up after RF ablation demonstrated only 87% occlusion of the GSV at 5 years, with 21% recurrences in 40 limbs followed to 3 years (12). Reasons for more effective ablation with EVL versus RF were not apparent 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 peri-procedural analgesic 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. Each site was independent of oversight and approval by all centers.

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.

US-guided percutaneous access followed by perivenuous 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, post-procedural 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.

Table 1. The...
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 a 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 (19).

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 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), 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.
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).

Table 3. Current postoperative tenderness measured at each follow-up visit.

<table>
<thead>
<tr>
<th>Visit</th>
<th>ClosureFAST (mean ± SD)</th>
<th>EVL (mean ± SD)</th>
<th>t test P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>48 Hour</td>
<td>0.9 ± 1.3 (46)</td>
<td>2.0 ± 2.3 (41)</td>
<td>.0048</td>
</tr>
<tr>
<td>1 Week</td>
<td>0.5 ± 1.2 (40)</td>
<td>1.6 ± 1.8 (36)</td>
<td>.0036</td>
</tr>
<tr>
<td>2 Weeks</td>
<td>0.3 ± 0.7 (43)</td>
<td>1.2 ± 1.5 (39)</td>
<td>.0005</td>
</tr>
<tr>
<td>1 Month</td>
<td>0.3 ± 1.0 (46)</td>
<td>0.5 ± 1.2 (41)</td>
<td>.5761</td>
</tr>
</tbody>
</table>

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 ablation 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
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 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 5.5, 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
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

\[ \text{J/cm} \]

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

\[ \text{J/cm} \]

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
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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References


15. Proebstle TM, Gul D, Lehr HA, Kargl A, Knop J. Infrequent early recanalization...