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.