Combined endovenous laser therapy and microphlebectomy in the treatment of varicose veins: Efficacy and complications of a large single-center experience

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Objective: **This study evaluated the safety and clinical and anatomic effectiveness of endovenous laser therapy (EVLT) and microphlebectomy in the treatment of varicose veins secondary to saphenous reflux.**

Methods: **From January 1, 2005, to December 31, 2007, 1985 EVLT procedures were performed in 1559 eligible patients (1263 women) with a mean age of 52.8 years (range, 18-89 years). A 810-nm diode laser and microphlebectomy were used. All sites of superficial axial reflux above and below the knee were ablated. Symptoms of venous insufficiency were present in 97%, and 102 patients (6.54%) had an open ulcer when they underwent operation. Patients had clinical follow-up visits, including duplex ultrasound examination, at 1 week, 1 month, 3 months, and yearly and were assessed for deep venous thrombosis (DVT), recanalization of the ablated vein, nerve injury, ulcer healing, and resolution of symptoms.**

Results: **A total of 1652 great saphenous veins (83.22%), 285 small saphenous veins (14.36%), 40 anterolateral tributaries (2.02%), and 8 posteromedial tributaries (0.40%) were ablated. An average of 19 phlebectomies were performed per case treated (range, 1-58). The primary ablation rate at 15 and 30 months was 91.26% and 78.25% by Kaplan-Meier analysis. Recanalization occurred in 35 veins (1.76%); in this group, 15 (42.9%) exhibited symptoms of venous insufficiency and were successfully closed with a second EVLT. Body mass index >30 kg/m^2 and a vein diameter ≥8.5 mm were the only factors predictive of recanalization. Postoperatively, the 102 ulcers showed healing at a mean of 5.2 weeks (range, 2-10 weeks), and only three reopened (2.94%). No major complications occurred. Two DVT (0.13%) occurred, but no pulmonary emboli or skin burns. Local transient paresthesia at the ankle and midcalf level occurred in 38 patients (2.43%).**

Conclusions: **EVLT of all sites of superficial axial reflux above and below the knee and microphlebectomy demonstrated that the combined approach is safe and effective at eliminating reflux, affording symptomatic relief, and healing ulcers. It offers the additional advantage of resolving varicose veins and its cause in just one visit, leading to immediate better cosmetic results. (J Vasc Surg 2008;■■:■■■.)**

Venous insufficiency is a genetically influenced, chronic, and progressive disorder. The ultimate goal of any treatment regimen is to eliminate sources of reflux in order to control symptoms and progression of disease, improve cosmesis, promote ulcer healing, and prevent recurrence or a combination of these. The best therapeutic results are based on two hemodynamic principles: the abolishment of the highest point of reflux and the elimination of the incompetent and dilated venous segments.

Endovenous laser treatment (EVLT) allows delivery of laser energy directly into the vein lumen. Published reports confirm that endovenous laser ablation of an incompetent great saphenous vein (GSV)[1-6] or small saphenous vein (SSV)[7,8] is safe[9] and can provide outcomes equal to or better than traditional surgical ligation and stripping.[10-13]

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Some practitioners advocate ablating the thigh segment of the GSV and treating the remaining visible varicosities with sclerotherapy during subsequent follow-up visits. Our chosen protocol is to perform EVLT of all refluxing truncal veins, above and below the knee, and to remove all varicose veins with microphlebectomies (MPs) at the same time. This approach mirrors past protocols in which the incompetent GSV was stripped in combination with stab avulsion of varicosities. Several large series have included GSV, SSV, anterolateral tributary (ALT) and posteromedial tributary (PMT) EVLT ablations, but studies specifically of the success rate and risks associated with EVLT combined with MP have included only a small number of patients.[14,15] The purpose of this study is to report the safety and clinical and anatomic effectiveness of the combined application of EVLT and MP in a large number of patients from a single center.

MATERIALS AND METHODS

Patient selection and criteria. This prospective cohort observational study included 1559 patients with venous insufficiency who presented for routine evaluation at the vein clinic and underwent 1985 EVLT ablations. Directed history and physical examination was performed to

document varicosities and symptoms according to the CEAP classification. All patients had preoperative documentation of axial venous reflux using a Sonosite (Sonosite Inc, Bothell, Wash) duplex ultrasound (DUS) unit.

Inclusion criteria included varicose veins caused by saphenous reflux (GSV and SSV) and their tributaries in patients aged >18 years. Exclusion criteria included nonpalpable pedal pulses, inability to ambulate, deep vein thrombosis (DVT), general poor health; pregnancy, breastfeeding, or plan to become pregnant immediately after treatment; and extremely tortuous veins that would not allow endovenous catheterization. After an initial examination and consultation, patients who met the selection criteria were offered the choice of surgery or EVLT. Nearly all patients chose EVLT rather than surgical ligation and stripping. All patients gave informed consent before treatment.

Technique. All patients were treated as an ambulatory procedure in the angiography suite under local anesthesia and conscious sedation using intravenous benzodiazepine. DUS imaging was done with the patient standing. All refluxing truncal veins were identified and marked in the skin, and a percutaneous entry point was chosen where reflux was no longer seen or where the vein became too small to access for ablation. Patients were placed in the supine position and turned to the prone position if the SSV needed to be ablated.

With the use of local anesthesia and sonographic guidance, the vein was punctured using the Seldinger technique. If we were unable to gain access percutaneously, the vein was pulled out with a crochet needle at the marked entry point through a 2-mm skin incision. A 5F introducer sheath was placed into the vein over a guidewire and advanced past the saphenofemoral junction (SFJ) into the common femoral vein in the GSV, ALT, and PMT cases (Fig 1), and past the saphenopopliteal junction (SPJ) into the popliteal vein in the SSV cases, accessing at the ankle level if needed to ablate the entire length of a refluxing vein.

The intraluminal position within the vein was confirmed by aspiration of nonpulsatile venous blood and visualization with ultrasound. A 600-μm laser fiber was introduced into the sheath and advanced to the first site mark. The sheath was then withdrawn to the second site mark, exposing the distal 3 cm of the bare-tipped laser fiber. The sheath and fiber were pulled back together and positioned at the superficial venous system under ultrasound guidance. Position was confirmed by direct visualization of the red aiming beam of the laser fiber through the skin.

Tumescent local anesthesia, consisting of 200 to 400 mL of 0.1% lidocaine neutralized with sodium bicarbonate, was administered along the perivenous space under ultrasound guidance. In addition to its role as an anesthetic, delivery of diluted lidocaine in the surrounding perivenous space will (1) compress even the largest diameter veins to ensure circumferential contact between the laser fiber and vein walls, maximizing energy transfer, and (2) provide a fluid barrier protecting adjacent nontarget structures from heat-related damage.

Fig 1. Simultaneous access of refluxing veins. Introducer sheath in the anterolateral tributary (*white arrow*) and in the great saphenous vein (*black arrow*).

The tip of the laser fiber was repositioned within the GSV or SSV, 5 to 10 mm distal to the SFJ or SPJ, respectively. Tip position was checked again by ultrasound and direct visualization of the red aiming beam through the skin. Laser energy was delivered using an 810-nm diode laser (Diomed Holdings Inc, Andover, Mass) at 14 W in continuous mode. The vein was treated from 5 to 10 mm below the SFJ or SPJ to approximately 1 cm above the skin entry site. The laser fiber was withdrawn at an average rate of 1 mm/s for the proximal third of the GSV, the ALT, and PMT, and 2 mm/s for the rest of the GSV and for EVLT applied for the SSV and the GSV below the knee. These rates of withdrawal represent about 140 J/cm and 70 J/cm of energy delivered, respectively. These steps were repeated as needed to treat all refluxing truncal veins.

All patients underwent concomitant MP according to Muller principles described elsewhere.[16] An ophthalmic scalpel was used to make a 2-mm skin incision, and a crochet device was used to remove the refluxing tributaries immediately after the laser ablation.

Once the procedure was completed, compression pads were applied over the treated area, and a low-stretch elastic compression bandage using Comprilan (BSN Jobst, Inc, Charlotte, NC) was placed on the treated limb. In the open ulcer cases, an Unna boot using Flexidress (Convatec,

Princeton, NJ) was used and changed weekly until complete healing was achieved.

All patients were encouraged to ambulate the day of the procedure, to resume their normal daily activities in 2 to 3 days, and to wear the elastic bandage 24 hours a day for 2 days and then to replace it with a 15 to 20 mm Hg, full-thigh or pantyhose graduated support stocking for at least 1 month at all times, except to sleep or shower. Nonsteroidal anti-inflammatory drugs and an oral second-generation cephalosporin were ordered for the first week after therapy.

Follow-up protocol. Patients had clinical follow-up visits, including DUS examination at 1 week, 1 month, 3 months, and yearly thereafter. At the time of the visit, patients were asked about the severity of immediate post-procedural pain; timing to resume daily normal activities, work and exercise; complaints of nerve injury, and about changes in their extremity symptoms compared with those before the procedure. The presence of residual varicosities, edema, skin changes, and ulceration was recorded. The DUS scans assessed for the presence of DVT and for saphenous ablation or recanalization, defined as the absence or presence of flow, respectively, in a previously ablated vein. At the 3-month visit, patients were asked to complete a patient satisfaction questionnaire, a nonvalidated instrument that we created, asking about relief of symptoms of chronic venous insufficiency, cosmetic results, and overall satisfaction.

Statistical analysis. Means and standard deviation were calculated for continuous variables, *t* tests were used to compare continuous variables with normal distribution, and the Kaplan-Meier survival estimate was used to report the primary ablation rate. We used this method to link ablation with mean follow-up, a measure of the strength of the series, and time after the procedure. Univariate and multivariate logistic regression was used to quantify the association of selected risk factors with the incidence of recanalization of the ablated vein. The risk factors used were age, gender, preoperative presence of ulcer, weight, height, body mass index (BMI) >30 kg/m^2, diameter and length of the treated vein, and linear endovenous energy density. The estimated effect of the risk factors is presented in terms of the odds ratio (OR) and *P* value. Statistical significance was set at $P = .05$, and the significant variables in the univariate model were included in a forward stepwise fashion for the final multivariate analysis. All calculations were done with Stata 6.0 software (StataCorp, Collage Station, Tex).

RESULTS

Three operators performed 1985 endovenous laser ablations in 1559 patients who also underwent MP for treatment of varicose veins during a 36-month period at a single medical facility. Symptoms were present in 97% of patients, who had a median CEAP clinical class of C 3.6 (range, 2-6). Open ulcers were present in 102 patients (6.54%) at operation. Demographics and CEAP clinical classification of the studied population are summarized in Table I.

Table I. Patient characteristics and disease severity scores by C category of the CEAP classification

Characteristics	*No. (%)*	*Means (SD)*
Patients	1559	
Procedures	1985	
Age, years		52.8 (12.6)
Weight, kg		72.4 (15.2)
Height, cm		164 (8.7)
Body mass index		26.5 (4.6)
Sex		
Female	1263 (81.01)	
Male	296 (18.99)	
CEAP		
C2	518 (33.2)	
C3	263 (16.9)	
C4	550 (35.3)	
C5	126 (8.1)	
C6	102 (6.5)	

SD, Standard deviation.

Ablation was performed in 1652 GSVs (83.22%), 285 SSVs (14.36%), 40 ALTs (2.02%) and 8 PMTs (0.4%). Of the GSVs treated, 49.2% were ablated to the above the knee level, 28.1% to the knee, 10.8% below the knee, and 1.8% to the ankle level. Pretreatment vein diameter, measured in the upright position 1 to 2 cm below the SFJ and SPJ, was a mean of 9.2 mm (range, 4-26 mm), and a mean of 6.8 mm (range, 4-15 mm) for the GSV and SSV cases, respectively. Vein characteristics of the entire series are reported in Table II. Patients underwent an average of 19 MPs (range, 1-58).

There were four treatment failures (0.2%). The procedure was a technical failure in two patients because the cannulation failed in one and the guidewire could not be passed in the other. The treatment could not be completed in the two other patients because of a tortuous vein in one and the laser unit did not function properly in the other.

The primary ablation rate for the 1985 veins treated during the study period was 91.26% at 15 months and 78.25% at 30 months, as shown by Kaplan-Meier analysis (Fig 2, Table III). During the study period, 35 veins recanalized (1.76%) in 35 patients. Of these, symptoms of venous insufficiency (anatomic and clinical failure) developed in 15 (42.9%), and they were successfully treated with a second EVLT. The other 20 patients that showed an open vein during follow-up were asymptomatic (anatomic failure), and DUS imaging showed no significant reflux within a smaller vein; therefore, they did not receive a second EVLT.

A statistical analysis was performed to ascertain factors that would increase the risk for recanalization (Table IV). Patients with a BMI >30 kg/m^2 and a vein diameter of ≥8.5 mm had a statistically significantly greater risk of recanalization. In the analysis, if <70 J of energy was delivered per centimeter of ablated vein, the risk of recanalization was higher. Among the 15 patients who represented an anatomic and clinical failure and who underwent

Table II. Vein details and laser energy density

Characteristics[a]	*GSV*	*SSV*	*ALT*	*PMT*
Veins, No.	1652	285	40	8
Diameter, mm	9.2 (3.5)	6.8 (1.8)	7.9 (2.1)	7.7 (1.6)
Treated length, cm	33.04 (13.7)	15.8 (6.7)	11.9 (6.5)	9.3 (3.2)
Total energy, J	2478 (1043)	1224 (515.6)	1105 (634)	947.8 (308)
Laser energy, J/cm	79.4 (35.4)	81.2 (34.3)	95.1 (29.5)	104.2 (38.8)

GSV, Great saphenous vein; *SSV,* small saphenous vein; *AMT,* anterolateral tributary; *PMT,* posteromedial tributary.
[a]Continuous data are presented as means (standard deviation).

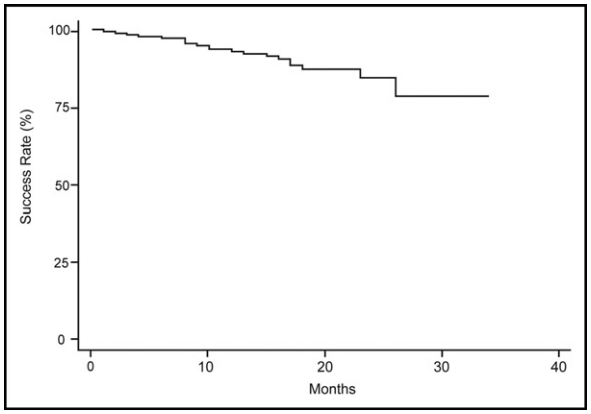

Fig 2. Kaplan-Meier analysis shows primary closure rate.

a second EVLT, recanalization occurred in only one, who had a BMI of 31 kg/m^2.

The 102 limbs with an open ulcer that were operated on showed healing at a mean of 5.2 weeks (range, 2-10 weeks) after the procedure, and only three reopened during the study period (2.94%). Of the 102 ulcerated limbs, EVLT of both the GSV and SSV was performed in 38 (37%), and EVLT of the SSV only was performed in 19 (18.6%).

Mild to moderate pain along the course of the treated vein during the first week and ecchymoses along the area of tumescent anesthesia administration and at phlebectomy sites were noted in most patients, as well as indurations. Superficial phlebitis of associated tributary varicose veins was noted in 58 patients (2.9%) and resolved with compression therapy and over-the-counter nonsteroidal anti-inflammatory medication in all cases. Local transient paresthesia at the ankle and midcalf level occurred in 38 patients (2.43%) and resolved spontaneously after 2 weeks. Most of these patients underwent extensive MP below the knee. Hyperpigmentation occurred in 62 patients (4%) and cellulitis in 16 (1%). Only two cases (0.13%) of DVT were found, and both were in the GSV group. One of these patients, who had May-Thurner syndrome, required endovenous thrombolysis and stent placement at the left common iliac vein. The second patient had ileofemoral involvement and was successfully treated after a 6-month course of oral anticoagulation, with the GSV remaining occluded. No patients presented with pulmonary embolism or skin burns. Lidocaine toxicity developed in a patient (0.06%) who required 52 phlebectomies, and this resolved uneventfully.

Of the 500 patients who completed the patient satisfaction questionnaire, 93% claimed their symptoms had diminished to none, 87% were highly satisfied with the cosmetic results, and 91.4% were willing to undergo the procedure again.

DISCUSSION

Although GSV reflux is the most common underlying cause of varicose veins, other sources of superficial reflux often contribute to or are the sole cause of significant lower extremity varicosities. For instance, the SSV incompetence has been associated with the entire spectrum of signs and symptoms of chronic venous disease, including ulceration.[17] SSV reflux is found in 10% to 20% of patients with varicose veins, as we did in 14.36% of our studied population, and nontrunkal superficial reflux—ALT and PMT—is identified in 10% to 15% of patients with varicose veins.[18] Furthermore, our early experience demonstrated that EVLT of residual reflux below the knee was required to control symptoms in a few patients.

The clinical significance of persistent below the knee (BK) GSV (BK-GSV) reflux after EVLT has been studied by other investigators. Theivacumar et al[19] evaluated 69 limbs after EVLT of the thigh GSV and found BK-GSV reflux of >1 second duration in 28 (41%). Although the Aberdeen Varicose Vein Symptom Severity scores improved in this latter group of patients, the change was significantly less compared with the patients in whom no reflux was found in the untreated BK-GSV. Those 28 patients also needed more sclerotherapy to complete treatment.[19] Similar results have been observed by Timperman,[20] who also reported that symptomatic relief is obtained safely and effectively with additional EVLT of the BK-GSV.

Improved understanding of the mechanism of action of EVLT and its high degree of safety and effectiveness in the treatment of GSV reflux has led to the exploration of treatment of non-GSV sources of superficial reflux, with excellent results.[5] Therefore, by targeting all the sources and length of axial reflux, above and below the knee, we can provide patients with a safe and superior alternative to ablating just the proximal portion of a refluxing saphenous vein, and this is the rationale behind our approach.

Table III. Anatomic results during 34 months of follow-up

Follow-up, months	*Veins at risk, No.*	*Failures, No.*	*LFU, No.*	*Successful treatment, %*	*SE (95% CI)*
1	1985	5	84	99.40	0.0027 (0.9857-0.9975)
5	333	10	432	97.62	0.0063 (0.9601-0.9859)
10	214	10	92	93.72	0.0136 (0.9045-0.9590)
15	110	4	95	91.26	0.0182 (0.8693-0.9421)
20	53	4	52	87.07	0.0261 (0.8071-0.9145)
25	18	1	30	84.26	0.0380 (0.7507-0.9028)
30	4	1	11	78.25	0.0679 (0.6123-0.8846)
34	1	0	2	78.25	0.0679 (0.6123-0.8846)

LFU, Lost to follow-up; *CI,* confidence interval; *SE,* standard error.

Table IV. Risk factors for recanalization by univariate and multivariate analysis

Variable	*Univariate OR (95% CI)*	*P*	*Multivariate OR (95% CI)*	*P*
Female sex	2.70	.04	1.80	.22
Open ulcer	1.37	.05	1.30	.13
Weight	0.90	.14		
Height	1.00	.72		
BMI >30 kg/m^2	2.37	.05	2.97	.02
Vein diameter ≥8.5 mm	1.07	.05	1.08	.04
Length of vein	1.00	.90		
LEED <70 J/cm	2.32	.05	1.70	.18

BMI, Body mass index; *CI,* confidence interval; *LEED,* linear endovenous energy density; *OR,* odds ratio.

Combining MP with EVLT offers the additional advantage of resolving the varicose veins in just one visit, leading to immediate better cosmetic results. Both procedures can be done simultaneously, under local anesthesia and conscious sedation, without a significant increase of complications. Our rate of postoperative pain, cellulitis, or paresthesias is not very different from series where EVLT was the only procedure performed. None of our patients found the paresthesias or numbness to be a significant concern. We did have a smaller number of patients with postoperative phlebitis compared with those series. This was not surprising, because leaving bulging saphenous tributaries without an outflow path will likely increase the blood stasis, with the subsequently increased risk of thrombosis.

Ulcer healing occurred at a mean of 5.2 weeks after treatment in the 102 patients who underwent the procedure with an open ulcer. Caution must be used, however, in the interpretation of the outcomes of ulcer healing. All patients underwent concomitant compression therapy (Unna boot), and this study does not isolate which benefits came from the EVLT vs the compression therapy. The ulcer reopened in only three patients, and one of them underwent a second EVLT due to recanalization of the ablated vein; the other two patients underwent subfascial endoscopic perforator surgery because perforator incompetence was judged to be the principal reason of ulcer recurrence.

The primary ablation rate for the 1985 veins treated during the years 2005 to 2007 of 91.26% at 15 months and 78.25% at 30 months is very similar to published reports. We only found two studies[5,21] reporting the primary ablation rate, by Kaplan-Meier analysis, after EVLT. Almeida and Raines[5] observed a primary closure rate of 92% at 500 days in 819 saphenous veins treated with EVLT, and Desmyttere et al[21] reported a primary ablation rate of 97% at 4 years in 511 GSVs treated with a 980-nm endovenous laser. During the study period, 35 veins recanalized (1.76%), representing an anatomic failure; however, these veins were noticeably smaller, and 57% of patients were symptom-free, without recurrent varicose veins. As a possible explanation, it is likely that shrinking a refluxing vein to a smaller diameter allowed the valves to completely or partially close, thus decreasing or eliminating reflux. Only 15 patients (42.9%) in this group presented with symptoms of venous insufficiency, indicating anatomic and clinical failure, and they were successfully treated with a second EVLT. Only one patient, with BMI of 31 kg/m^2, presented with an anatomic failure after his second EVLT, reflecting the importance of obesity as an independent risk factor for recanalization.

We observed that a BMI >30 kg/m^2 and a vein diameter ≥8.5 mm were independent risk factors for recanalization. Timperman[22] has also found that obesity was common among patients in whom recanalization occurred. It is known that obese patients have increased abdominal and femoral venous pressure.[23] In this latter group of failures, it is possible that the fibrosis caused by the EVLT was overcome by increased femoral venous pressure, with the saphenous vein reopening in a proximal to distal fashion, sometimes into a varicose tributary close to the SFJ that functions similarly to a relief valve. MP of these varicose tributary at the time of EVLT and ligation of the SFJ to isolate the GSV from increased venous pressure may improve the success of the endovenous ablation. These findings have relevance in counseling patients before the procedure about their risk of recanalization and also may suggest which patients should have a prophylactic ligation of the saphenous vein to reduce this undesired outcome.

CONCLUSION

The combined approach of EVLT of all sites of superficial axial reflux, above and below the knee, with microphlebectomy was demonstrated to be safe and effective at eliminating reflux, affording symptomatic relief, and heal-

ing ulcers. It offers the additional advantage of resolving varicose veins and their cause in just one visit, leading to immediate better cosmetic results. Further investigations may ascertain whether ligating the saphenous vein at the SFJ or SPJ in patients with vein diameters >8.5 mm or with BMIs >30 kg/m^2, will reduce the rate of recanalization, thus improving the long-term results of EVLT.

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AUTHOR CONTRIBUTIONS

Conception and design: CF, MR
Analysis and interpretation: CF, MR
Data collection: CF, MR, JC
Writing the article: CF, MR
Critical revision of the article: CF, MR, JC
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