Outcome of different endovenous laser wavelengths for great saphenous vein ablation

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Objective: **The objective of this randomized, prospective, blinded study was to determine the relative effects of two laser wavelengths in the treatment of great saphenous vein (GSV) insufficiency.**

Methods: **Fifty-one male and female patients scheduled for routine laser treatment of GSV insufficiency provided signed informed consent for the procedure. Patients were randomized to receive endovenous laser treatment with a wavelength of 810 or 980 nm. The same surgeon, blinded to the wavelength, performed all procedures. Nonoperating study staff, blinded to the laser wavelengths, evaluated patients before and after the procedure regarding physical signs and symptoms. Patients were monitored within 72 hours after the procedure (via duplex ultrasonography), at 1 week (by procedural site photos scored for bruising, as well as a pain score), at 3 weeks, and at 4 months for bruising, physical and emotional effects of the procedure (scored by patients on a five-point visual analogue scale), and symptoms (scored by the physician), along with adverse events. Patients were followed up for a year to determine the long-term efficacy of the procedure.**

Results: **The 51 patients (38 women and 13 men; mean age, 52.4 ± 11.7 years) completed treatment and follow-up examination (30 legs for each wavelength). At 72 hours after the procedure, no significant differences were noted between patient outcomes, physical conditions, and symptoms and or possible adverse events. At 1 week after the procedure, bruising scores were significantly different ($P < .005$): patients in the 980-nm group showed less bruising of the procedure site than the patients in the 810-nm group. Only three physical or symptom parameters presented with significant differences ($P < .05$) over time—less itching was noted by 810 nm–treated patients at 3 weeks after the procedure, lower levels of pain intensity were seen in the 980 nm–treated patients at the 4-month follow-up visit, and lower varicose vein ratings were seen for the 980 nm–treated patients at the 4-month follow-up visit. Thirteen legs were phlebitic at 7 days after the procedure (10 in the 810-nm group and 3 in the 980-nm group). Two treatment failures occurred (one patient in each treatment group); both patients exhibited flow in the treated venous segment at the 4-month follow-up visit. Two other patients (one in each group) had treatment failure at the 1-year follow-up, demonstrating venous insufficiency in the treated segment.**

Conclusions: **Both laser wavelengths were effective in treating GSV insufficiency, with no major complications and a paucity of adverse outcomes. (J Vasc Surg 2006;43:88-93.)**

Traditional treatment for great saphenous venous (GSV) insufficiency and resulting varicosities has involved surgical ligation and stripping of the vessel segments. However, the associated morbidity and patient dissatisfaction with the procedural results have led to the development of alternative techniques for treating these vessels. Ambulatory phlebectomy and perforate invagination stripping evolved to minimize the problems seen with traditional surgical techniques.[1,2] Nonsurgical techniques such as ultrasound- and transcatheter-guided sclerotherapy, along with radiofrequency ablation, have been developed as options in the treatment of large-vessel varicosities.[3-5] Endovenous laser therapy is one of the newest methods for outpatient treatment, achieving ablation of the treated vein, better cosmetic results, and no reduction in patient mobility.[6-9]

Endovenous laser treatment involves placement of a bare-tipped optical laser fiber inserted through a needle puncture into an affected vein. The fiber is advanced through the vein and placed accurately within the vessel segment with the assistance of duplex ultrasound imaging. The laser is turned on, and the fiber is slowly pulled back through the vessel, thus allowing delivery of laser energy to the vessel lumen to produce endothelial and venous wall damage with subsequent fibrosis.

To date, there have been no published comparison studies of the various laser wavelengths and their efficacy in treating incompetent saphenous veins. Two wavelengths of lasers were selected for use in this investigation—810 and 980 nm—because of their differences in characteristic absorption and their utility in the treatment of saphenous venous insufficiency. The 810-nm wavelength is specific for hemoglobin absorption, whereas the 980-nm wavelength is specific for hemoglobin and water. This article presents the findings of a blinded, randomized investigation comparing the effects of 810- and 980-nm diode lasers in endovenous laser treatment of saphenous venous insufficiency.

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METHODS

Patients. Patients were consecutively selected individuals awaiting surgery to treat GSV insufficiency at the Vein Institute of New Jersey (Morristown, NJ) who had provided written informed consent before the procedure. Patients were informed that they would be randomized to one of the two wavelengths of laser for the procedure and that these were the typical wavelengths used for the treatment of saphenous venous insufficiency at the institution and in the USA. This study followed the principles as outlined in the Declaration of Helsinki. All subjects gave informed consent; the experimental protocol and informed consent were approved by the Institutional Review Board.

Patients were eligible for treatment if they were at least 21 years of age, had symptomatic varicose veins and duplex scan–determined GSV incompetence, and were willing to return for all follow-up visits after the procedure. The prestudy duplex examination evaluated the patient for superficial venous insufficiency, superficial venous thrombosis, deep venous insufficiency, deep venous thrombosis, and measurement of the superficial veins of the GSV and the small saphenous vein from groin to ankle. The duplex examination also evaluated any other vascular tributary that may have been insufficient (the anterior circumflex, for example). Patients were excluded from study participation if they had bleeding disorders, varicose veins without GSV incompetence, or any other medical condition that would not allow for safe completion of the surgical procedure. Deep venous insufficiency was not an exclusion from study participation, but deep venous thrombosis from popliteal proximal was an exclusion factor.

Patients underwent a complete physical examination before the procedure. All patients completed an evaluation of involved limb pain before treatment by using a five-point visual analogue scale on which 1 indicated no pain and 5 indicated intense pain. Patients completed a physical activity/emotional survey to define the effects of their leg problems on daily function (Fig 1, online only).

A staff nurse not associated with the study performed the patient randomization; the nurse selected a blinded randomization card (labeled for the intended wavelength device) for each patient before the procedure. The blind was broken, the patient was assigned to the specific treatment group, and the surgical staff prepared the treatment room with the appropriate laser. To blind the operating physician to the equipment, the surgical lasers to be used in the study were housed in identical cases, and all identifying markings were masked. AngioDynamics (Queensbury, NY) provided the 980-nm laser used in the study, and biolitec, Inc (East Longmeadow, MA) provided a Ceralas D 810-nm laser for study use. Throughout the surgical procedure and all patient follow-up examinations, the physician was blinded to the patient's treatment group. Once the study was completed, the blind was broken for the collected data, and the findings were analyzed.

Surgical technique. After providing written informed consent for the procedure, the patient was brought to the procedure room and placed supine on the surgical table. The patient was draped in the usual sterile fashion. Local anesthetic, consisting of approximately 150 to 200 mL of 0.25% lidocaine/epinephrine (buffered with 8.5% sodium bicarbonate), was used to anesthetize the skin and provide tumescent anesthesia localized to the saphenous compartment.

Under ultrasound guidance, the GSV was accessed at or below the knee area by using a 21-gauge micropuncture catheterization set (AngioDynamics). Once the 5F microsheath was inserted into the GSV, the distance from the puncture site to the saphenofemoral junction was measured. The inner cannula from the microsheath was then removed, and a 0.035-inch guidewire (AngioDynamics) was advanced beyond the saphenofemoral junction into the common femoral vein under direct ultrasound guidance (Logic Book; General Electric, Milwaukee, WI). After a 45- or 65-cm 5F sheath (AngioDynamics) was marked to indicate the depth of anticipated penetration, the sheath was backloaded onto the 0.035-inch wire and advanced through the GSV to 1.5 cm below the saphenofemoral junction or just distal to the epigastric vein. Once the sheath was stabilized, the introducer and access wire were removed, and a 600-μm bare-tipped fiber (AngioDynamics) was placed into the sheath. The aiming beam of the laser fiber was then observed to the end of the sheath by visual observation of the skin illumination and via ultrasonography (which had previously been placed in the desired position). The sheath was withdrawn to the fiber's locking mechanism, thus exposing the laser fiber tip approximately 2.5 cm outside the sheath.

Under ultrasound guidance, dilute local anesthesia was infused around the GSV along the entire segment to be treated, by using 22- or 25-gauge needles. Approximately 150 to 200 mL of this solution was administered, thus creating a 10-mm gap between the skin and the vein as well as a 10-mm diameter around the vein (as verified by ultrasound examination). After modified tumescent anesthesia was completed, the laser fiber final position was verified with ultrasonography to confirm that the fiber tip had not moved during anesthesia administration. Laser energy (10 W) was delivered in a continuous fashion through the vein walls of the segment being treated, and the pullback speed on the fiber was calculated to achieve a standard energy rate of 50 J/cm. External manual compression was used only at the level of the saphenofemoral junction, thus enabling the physician to block heat transmission into this area. Manual compression was performed by using the ultrasound probe that had been placed in proper position. Once the entire vessel segment had been treated with laser energy and was confirmed to be closed (by duplex ultrasonography), the catheter and laser fiber were removed, because no sclerotherapy or phlebectomy procedures were performed with the saphenous vein treatment. A ½–inch Steri-Strip (3M, St Paul, MN) cut into thirds was placed over the previous entry puncture site and covered with a sterile 2 × 2-inch gauze pad. A full-thigh class 2 compression stocking (30-40 mm Hg) was then placed on the treated limb. The patient was instructed to wear this stocking continuously until bedtime the following evening. For the next 6 to 10 days, the patient was instructed to wear the stocking during nonsleep hours only. No activity limitations were placed on the patient except for restrictions against participation in high-impact aerobics. All patients were also instructed to take a nonsteroidal anti-inflammatory medication (celecoxib 200 mg/d) once daily for the first 10 days after the procedure.

Clinical data collection. All patients were to return to the clinic within 72 hours of the procedure, where they each underwent a duplex ultrasound procedure to evaluate flow in the treated vein, whether the treated vein was closed and opened, and whether a thrombus was present. If a thrombus was found, the duplex procedure would clarify where it was located in relation to the saphenofemoral junction. The patients returned to the office at the end of a week for photographic documentation of the procedure site and to determine a pain score. Photographs of the procedure site were scored according to a bruising scale from 0 (no visible bruising) to 5 (extreme bruising). The patients were also scheduled to return to the clinic at 3 weeks and 4 months after the procedure for physical and symptom evaluations.

At 72 hours, 3 weeks, and 4 months after the procedure, all patients were to complete a survey of physical activity (Fig 1, online only), and the physician documented the patients' current symptom status. Patient-measured pain was documented with a visual analogue scale on which 1 indicated no pain and 5 indicated the worst pain ever felt. Symptoms and physical signs evaluated by the physician included pain, venous edema, inflammation, ulceration, varicose veins, skin pigmentation, induration, the need for compression therapy, fatigue, venous claudication, itching, dermal sclerosis, and congestion (Fig 2, online only). Any complications or adverse events that occurred from the day of the procedure were documented. At 1 year after the procedure, all patients were to return for a duplex examination of the vessel to determine whether the treated vessel remained closed.

Statistical analysis. All demographic data were analyzed to determine the mean values for each laser group. An analysis of variance was performed to evaluate all physical activity and symptom survey parameters. Statistical significance was defined as $P \leq .05$.

RESULTS

The patient groups were similar in age (51.1 ± 11.3 years for the 810-nm group and 53.6 ± 12.2 years for the 980-nm group) and sex distribution. Patients in each group were similar in regard to their pretreatment symptoms and physical signs at baseline. Patient CEAP scores for the leg to be treated were very similar for these two populations (2.03 ± 0.62 for the 810-nm group and 2.23 ± 0.63 for the 980-nm group).

Nine of the 51 patients involved in the study had 2 legs treated; of these patients, 9 legs were treated with the 810-nm laser, and 9 were treated with the 980-nm laser. Because of the randomization process, some of these patients had both legs treated with the same wavelength laser, whereas others had one leg treated with the 810-nm laser and one leg treated with the 980-nm laser. Because so few study patients were treated bilaterally, statistical analysis of this subset was not performed.

Table I. Procedural details

Variable	*810-nm-wavelength laser (30 limbs)*	*980-nm-wavelength laser (30 limbs)*
No. limbs treated	30	30
Phlebitis	10	3
No phlebitis	20	27
CEAP score		
Mean (SD)	2.03 (0.62)	2.23 (0.63)
Range	0-4	1-4
Treated vein diameter		
No phlebitis (mm)	9.39	8.72
Phlebitis (mm)	10.59	11.96
Energy used		
All vessels (J/cm)	49.25	45.92
No phlebitis (J/cm)	49.99	44.73
Phlebitis (J/cm)	50.00	56.66
Pullback speed		
All vessels (cm/min)	16.03	17.51
No phlebitis (cm/min)	15.96	17.54
Phlebitis (cm/min)	16.10	12.61

Thirteen patients presented with phlebitis at 1 week after the procedure (10 patients in the 810-nm group and 3 in the 980-nm group): phlebitis was defined as induration, erythema, pain to palpation, and a palpable cord. The differences in the amount of laser energy used and the specifics of the treatment of these patients vs the patients who did not develop phlebitis are presented in Table I. A subset analysis (performed at 1 week after the procedure) of postprocedural symptoms and physical condition parameters for patients who presented with clinical superficial phlebitis indicated that patient-graded pain scores were significantly increased compared with patients who did not have phlebitis after the procedure. When questioned by using a visual analogue pain score of 0 to 10 (0, no effect; 10, worst pain ever), these patients on average graded their pain at 5.0, whereas patients without phlebitis graded their pain at 2.5. At 72 hours after the procedure, no significant differences between the study groups were noted for any of the patient symptoms or physical condition parameters (as shown in Figs 1 and 2, online only) or for procedural outcomes. By 7 days after the procedure, bruising scores (Table II) were significantly different between treatment groups (P = .0047), with less bruising noted for the 980-nm group compared with the 810-nm group. After surgery, only three physical or symptom parameters had significant differences over time when the groups were compared (Table III). Itching was significantly lessened at 3 weeks after the procedure for the 810-nm group compared with the 980-nm group (P = .031), but this difference was not maintained at the 4-month visit. Postprocedural pain inten-

Table II. Patient bruising scores* at 1 week after the procedure

Variable	*810-nm-wavelength laser*	*980-nm-wavelength laser*
All patients	2.40 (30)	1.55 (30)†
No phlebitis	2.40 (20)	1.39 (27)
Phlebitis	2.40 (10)	3.00 (3)

Data are mean (number of patients).
*Bruising scores were based on a five-point grading system where 0 indicates no visible bruising and 5 indicates extreme bruising, as shown below.
†P =.0047. Patient subsets were not analyzed for statistical significance.

Score = 0 Score = 2 Score = 5

Table III. Postprocedural differences in symptoms and physical condition

Variable	*810-nm-wavelength laser*	*980-nm-wavelength laser*	P *value*
Itching			
72 h	0.467 (30)	0.433 (30)	.872
3 wk	0.167 (30)	0.500 (30)	.031*
4 mo	0.033 (30)	0.034 (29)	.981
Pain intensity			
72 h	2.63 (30)	2.20 (30)	.081
3 wk	2.10 (30)	2.07 (30)	.891
4 mo	1.50 (30)	1.21 (30)	.028*
Varicose vein rating			
72 h	1.60 (30)	1.43 (30)	.325
3 wk	1.50 (30)	1.27 (30)	.194
4 mo	0.97 (30)	0.31 (29)	.00*

Data are mean (number of patients).
*P values determined with analysis of variance, where $P \leq .05$ was defined as statistically significant.

sity was significantly lessened in the 980-nm group compared with the 810-nm group at the 4-month follow-up visit (P =.028). The varicose vein rating was significantly lower (thus indicating a decrease in visible varicosities) in the 980-nm group vs the 810-nm group at the 4-month follow-up visit (P = .004). The remaining parameters (defined in Figs 1 and 2, online only) did not show significant differences between groups (Table IV).

There was an overall lack of postprocedural complications in both patient populations. However, there were four treatment failures in this study population (two patients in each treatment group); all patients with treatment failure exhibited a return of flow in the treated segment of the GSV by their 1-year follow-up visits, and reflux was noted after limb compression and release. The remaining 56 treated legs remained flow free at 1 year after the procedure and were defined according to the protocol as treatment successes.

DISCUSSION

The primary aim in the treatment of saphenous vein insufficiency should be directed toward identification of the highest level of reflux and ablation of the incompetent venous segment. Although surgical ligation and stripping have been used successfully in the past, the current trend toward the endovenous laser technique has shown that patients respond well to the procedure and that the incompetent venous sections can be treated readily.

Gerard et al[10] and Oh et al[9] detailed their findings with the 980-nm diode laser. They found complete occlusion and retraction of the GSV over the postoperative period (4 and 12 weeks, respectively). Proebstle et al[11] have shown

Table IV. Study findings

Variable	*Laser wavelength (nm)*	*Before the procedure*	*After the procedure (at 4 mo)*	P *value**
Physical and emotional parameters (patient generated)				
Intensity of pain	810	2.37	1.50	≤.005
	980	1.90	1.21	≤.005
Limitations because of leg	810	2.23	1.47	≤.005
	980	2.13	1.38	≤.005
Sleep lost	810	1.77	1.20	≤.005
	980	1.63	1.24	.037
Limits of standing	810	2.60	1.83	≤.005
	980	2.73	1.48	≤.005
Limits of stairs	810	1.93	1.53	.072
	980	1.60	1.38	.215
Crouching/kneeling	810	2.47	1.57	≤.005
	980	1.90	1.38	.014
Walking briskly	810	2.10	1.40	≤.005
	980	1.80	1.34	.055
Travel	810	2.10	1.20	≤.005
	980	2.13	1.10	≤.005
Housework	810	1.97	1.40	≤.005
	980	1.67	1.24	.011
Social functions	810	2.00	1.33	.011
	980	1.97	1.10	≤.005
Sporting activities	810	2.20	1.67	.023
	980	2.23	1.62	.023
Feel on edge	810	1.87	1.37	.050
	980	2.67	1.41	≤.005
Tired quickly	810	2.43	1.67	.009
	980	2.30	1.52	.009
Burden	810	1.23	1.23	—
	980	1.47	1.07	.057
Precautions	810	2.40	1.87	.063
	980	2.67	1.59	≤.005
Embarrassed	810	3.30	2.47	.024
	980	3.80	2.48	≤.005
Irritated	810	1.70	1.30	.122
	980	2.20	1.48	.024
Handicapped	810	1.43	1.17	.296
	980	1.83	1.14	.006
Difficulty in the morning	810	1.73	1.33	.141
	980	1.77	1.17	.019
Don't feel like going out	810	1.40	1.20	.408
	980	1.77	1.14	.009
Physical symptoms (physician generated)				
Pain	810	1.33	0.37	≤.005
	980	1.13	0.17	≤.005
Venous edema	810	0.97	0.03	≤.005
	980	0.80	0.10	≤.005
Inflammation	810	0.50	0.03	.005
	980	0.23	0.00	.049
Varicose veins	810	2.03	0.97	≤.005
	980	2.03	0.31	≤.005
Pigmentation	810	0.20	0.13	.339
	980	0.47	0.07	.038
Induration	810	0.20	0.00	.105
	980	0.40	0.00	.011
Compression	810	0.80	1.17	.157
	980	0.67	1.45	≤.005
Fatigue	810	1.10	0.13	≤.005
	980	0.73	0.17	≤.005
Venous claudication	810	0.03	0.00	.321
	980	0.27	0.00	.008
Itching	810	0.23	0.03	.046
	980	0.50	0.03	≤.005
Dermal sclerosis	810	0.03	0.00	.321
	980	0.00	0.00	—
Congestion	810	0.67	0.07	≤.005
	980	0.67	0.03	≤.005

**P* value for analysis of variance of preprocedure vs 4-month findings, where significance was defined as $P \leq .05$.

that a 940-nm diode laser is effective in treating insufficiency of the lesser saphenous vein, with a 6-month follow-up showing no recanalization of the vessel. Min and associates'[12] long-term follow-up study showed that 93.4% of the limbs treated with the 810-nm endovenous laser remained closed at 2 years after the procedure, and this rate is similar to the 93.3% (28/30 limbs) success seen in our study at 1 year. Fifty percent (two of four) of our treatment failures were noted by the 4-month follow-up visit, the remaining two cases were seen at the 1-year follow-up visit. Gerard and colleagues'[10] short-term follow-up of patients treated with the 980-nm endovenous laser showed a 90% success rate at 1 month after the procedure, compared with the 93.3% (26/30 limbs) success seen in our study at 1 year after treatment. The results from our blinded comparison of these two wavelengths of endovenous laser seem consistent with, if not slightly better than, the success rates shown in previous studies.

The overall physical and symptom findings after treatment seemed very similar for our two device groups, with significant findings seen at the short-term (more bruising at 1 week after surgery for the 810-nm group) that did not seem to affect patient recovery over the longer term. This level of bruising may be related to one of two factors: anesthesia administration or perforation caused by the laser energy. Administration of anesthesia by intravenous injection could lead to some escape of blood into the surrounding soft tissue, with subsequent bruising. Laser energy applied in a pulsing mode has been shown to lead rarely to perforation of the vein wall, as discussed by Weiss.[13] In our institutional experience, laser energy delivered in a continuous mode is less disruptive of the vessel wall.

When comparing physical findings, only itching, postprocedural pain, and varicose vein ratings were significantly different between groups; however, these differences were seen only at single time points during follow-up and did not lead to complications or the need for further treatment. It is possible that these differences may be due to unexamined concomitant disease (for example, deep venous insufficiency), but further investigation into the effects on postoperative pain intensity needs to be pursued.

Overall, the results of this study showed that both the 810- and 980-nm laser wavelengths were effective in closing the GSV with a reflux-free saphenofemoral junction. Few untoward results were found with either treatment; no deep venous thrombosis (confirmed by ultrasound examination), pulmonary embolism, skin burns, or paresthesias were reported. Some ecchymosis was seen, and superficial phlebitis was more often present when the 810-nm laser was used. However, the pain noted after the procedure was most likely related to superficial phlebitis and not to the ecchymosis.[14]

CONCLUSION

The results of this study reveal some positive trending differences in favor of the 980-nm wavelength laser; there were more untoward results with the 810-nm wavelength. Both lasers seemed safe and effective for the treatment of GSV insufficiency.

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Physical parameters:

1. What was the intensity of pain in the ankles or legs?
2. To what extent did you feel bothered/limited in your work or other daily activities because of your leg problems?
3. Did you sleep badly because of your leg problems?
4. To what extent did your leg problems bother/limit you while doing the following movements or activities:
   - Standing for a long time
   - Climbing stairs
   - Crouching, kneeling
   - Walking briskly
   - Travel by car, bus, plane
   - Housework such as working in the kitchen, carrying a child, ironing, cleaning floors or furniture, doing handy work
   - Social functions, such as weddings, parties, restaurants, night clubs
   - Sporting activities, making physically strenuous efforts

Emotional parameters:

1. I feel on edge
2. I become tired quickly
3. I feel I am a burden to people
4. I must always take precautions
5. I am embarrassed to show my legs
6. I get irritated easily
7. I feel handicapped
8. I have difficulty getting going in the morning
9. I do not feel like going out

[Patients used a 5-point visual analog scale, where 1 = absence of condition, annoyance, or limitation and 5 = greatest intensity.]

Fig 1. Patient survey.

Venous Clinical Severity Score*:

1. Pain
2. Venous edema
3. Inflammation
4. Number of active ulcers
5. Active ulcers, size
6. Active ulcers, duration
7. Varicose veins
8. Skin pigmentation
9. Induration
10. Compressive therapy

Other Symptoms:

1. Fatigue
2. Venous claudication
3. Itching
4. Dermal sclerosis
5. Congestion sensation

[Physician used a 4-point scale, ranging: absent – mild – moderate – severe.]
* Based on the scoring system presented by Rutherford et al [14].

Fig 2. Physician's symptom assessment.