The 800-nm diode laser in the treatment of leg veins: Assessment at 6 months

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Background: The efficacy of the 800-nm diode laser system in clearing leg veins was analyzed subjectively and objectively in a variety of leg veins.

Methods: A total of 10 women (age 25-55 years, skin types II-IV) with a variety of leg vein types were treated with an 800-nm diode laser. A sequence of pulses (5-8 stacked pulses, pulse duration 50 milliseconds, delay 50 milliseconds) was applied on a 3-mm spot (210-336 J/cm² fluence, depending on vessel size). Treatment on the same vein was performed at intervals of 2 months until complete clearance was achieved (maximum: 3 treatments). The results were assessed at 6 months from the last treatment. Patients evaluated their subjective improvement by means of a questionnaire to elicit the satisfaction index. In an independent objective assessment, the clearance index was based on the pretreatment and posttreatment clinical photography, also analyzed by a computer program.

Results: All patients completed the trial with mild but transient side effects. The patient 6-month assessments for very good, good, fair, poor, and worse were 1, 5, 3, 1, and 0, respectively. For the clinician-assessed clearance index, the numbers for the same grades were 2, 6, 2, 0, and 0, and for the computer assessment they were 1, 6, 2, 1, and 0. No patient scored worse in any assessment. The overall satisfaction index and clinician and computer clearance indexes were 60%, 80%, and 70%, respectively.

Limitations: No control group could be obtained in this study.

Conclusions: The 800-nm diode laser as used in the study may well offer an effective treatment method for leg veins that is comparatively pain and side-effect free. Best results were obtained in vessels of 3 to 4 mm in diameter located on the thigh, and in patients with phototype III skin. No correlation was seen between results and patient age. (J Am Acad Dermatol 2006;54:282-9.)

Leg vein treatment is not a simple procedure, and no single treatment method has consistently shown satisfactory results. As an alternative to the conventional technique of sclerotherapy, numerous types of laser have been used at different wavelengths in the visible or infrared spectrum, in addition to intense pulsed light systems.1-5

This study was designed to assess, subjectively and objectively, the efficacy of the 800-nm diode laser at 6 months after the last treatment session in the elimination of leg veins of 1 to 4 mm in diameter. A comparative evaluation was carried out to identify any possible differences in treatment results by considering patients’ anatomic aspects and their

Abbreviations used:
CLI: clearance index
F: fair
G: good
P: poor
SI: satisfaction index
VG: very good
W: worse
different skin phototypes. The possible correlation that might exist between the efficacy in vein clearance and the patient’s age, skin phototype, vessel size, and location were examined. In addition to the objective clinical assessment of the results by an independent dermatologist based on clinical photography, a computerized automatic image extraction system was used to assess objectively the characteristics of the lesion before and at the end of treatment. These results were correlated with the satisfaction index (SI) rated subjectively by the patient.

**METHODS**

**Patients**

In all, 10 women with a variety of skin phototypes (1 type II, 5 type III, and 4 type IV) participated in the study, aged between 28 and 55 years (mean: 38.7 years). The study was approved by our ethics committee and, having been informed of the aim and all aspects of the study, all patients signed written informed consent for both their treatment and for the clinical photography. Sclerotherapy had not been performed in any patient. All patients were clinically examined before commencement of the study using Doppler ultrasound (180plus, Sonosite, Bothell, Wash) to confirm that saphenous veins and collaterals were competent with no reticular and no perforator veins.

The vessels selected for treatment were blue and red in color, ranging from 1 to 4 mm in diameter. In all, 7 patients had blue-colored vessels and 3 had red. One patient had vessels of 1 mm in diameter, two with 2 mm, 3 with 4 mm, and 4 with 3 mm. One lesion was located on the ankle, 4 on the calf, and the remaining 5 on the thigh (Table I).

Exclusion criteria included refusal to sign the informed consent, pregnancy, oral contraceptive treatment, a history of venous thrombosis of the legs, and skin phototype higher than IV.

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**Table I. Patient and vessel characteristics**

<table>
<thead>
<tr>
<th>Patient No</th>
<th>Age, y</th>
<th>Phototype</th>
<th>Vein color</th>
<th>Vein diameter, mm</th>
<th>Vessel location</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>55</td>
<td>III</td>
<td>Blue</td>
<td>4</td>
<td>Thigh</td>
</tr>
<tr>
<td>2</td>
<td>28</td>
<td>IV</td>
<td>Red</td>
<td>1</td>
<td>Ankle</td>
</tr>
<tr>
<td>3</td>
<td>42</td>
<td>II</td>
<td>Blue</td>
<td>3</td>
<td>Calf</td>
</tr>
<tr>
<td>4</td>
<td>28</td>
<td>III</td>
<td>Red</td>
<td>2</td>
<td>Calf</td>
</tr>
<tr>
<td>5</td>
<td>38</td>
<td>III</td>
<td>Blue</td>
<td>3</td>
<td>Thigh</td>
</tr>
<tr>
<td>6</td>
<td>39</td>
<td>IV</td>
<td>Blue</td>
<td>3</td>
<td>Thigh</td>
</tr>
<tr>
<td>7</td>
<td>37</td>
<td>III</td>
<td>Blue</td>
<td>3</td>
<td>Thigh</td>
</tr>
<tr>
<td>8</td>
<td>44</td>
<td>III</td>
<td>Blue</td>
<td>4</td>
<td>Calf</td>
</tr>
<tr>
<td>9</td>
<td>41</td>
<td>IV</td>
<td>Blue</td>
<td>4</td>
<td>Calf</td>
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<tr>
<td>10</td>
<td>35</td>
<td>IV</td>
<td>Red</td>
<td>2</td>
<td>Thigh</td>
</tr>
</tbody>
</table>

**Laser and treatment**

An 800-nm diode laser was used (DS66, Nidek Co Ltd, Aichi, Japan). The hand piece delivered an output power of 60 W by a 3-mm beam. Vessels were treated with contiguous spots. Each spot consisted of a sequence of 5 to 8 overlapping pulses (50-millisecond duration, 50-millisecond interval) depending on the vessel size. The fluence of each pulse was 42 J/cm². Consequently, the cumulated fluence for each spot varied between 210 and 336 J/cm². Cooling was applied during laser irradiation.

The cooling system consisted of a continuous jet of chilled air on the target area from a nozzle built into the hand piece (Cryo 5, Zimmer Medizin Systems GmbH, Neu-Ulm, Germany). Patients had areas selected for the study and received between 1 and 3 treatments depending on the response of the target vessels. Although treatments were done at intervals of 2 weeks on veins in a variety of locations on each patient, a treated vein of the area selected for the study was not treated again until 2 months had elapsed. The fact that patients came for treatment on other areas permitted the precise, frequent follow-up of vein evolution after treatment.

Treatment was stopped when the results were considered satisfactory as far as the clearing of the vessel was concerned, or if treatment was highly painful. The treatment of a vein ended when both the patient and the clinician considered that the result achieved was sufficient and better results could not be achieved.

After the treatment was complete, a cream containing 0.25% prednicarbate (a synthetic corticosteroid, 11β, 17, 21-trihydroxypregna-1,4-diene-3,
20-dione 17-[ethyl carbonate 21]-propionate) was applied gently on the treated area. No compression dressing was applied. Patients were advised to avoid exposure to sunlight until after the last treatment. The use of a UVA/UVB sunscreen with a solar protection factor of 60 was recommended to help avoid UV exposure-related dyschromic changes. Patients returned 6 months after the last session on the area selected for the study to evaluate the result and for the final clinical photography session.

**Clinical photography**

Digital macrophotographs were taken (Mavica MVC-FD91 2 MPx, Sony Corporation, Tokyo, Japan) (high-resolution setting) of the target vessels before and 6 months after treatment for the documentation of the treatment and to assess its progression. Self-adhesive white labels were placed as near as possible in the same position each time, using the previous photograph as a guide, to frame the treated area for the use of the computer program as described below. The digital photography for each patient was stored on an individual diskette and kept in her personal file. All photography was performed by the same person under conditions that were as identical as possible.

**Subjective evaluation**

At 6 months after treatment, patients were questioned as to the degree of satisfaction with the result obtained using a 5-grade scale: very good (VG), good (G), fair (F), poor (P), and worse (W). The results were tabulated as percentages of the total number of patients treated. The VG and G scores were combined to obtain the overall SI.

**Evaluation of the clinical photography**

The clinical photography before and after treatment was assessed by an independent experienced clinician. Treatment efficacy was scored on a 5-point scale based on the clearance rate expressed as a percentage, with 0% as the original condition: VG, clearing of the veins from 100% to 75%; G, clearing from 50% to 74%; F, clearing from 25% to 49%; P, clearing from 0% to 24%; and W if the condition of the vessel was W at the final assessment than at the pretreatment stage. The overall clearance index (CLI) was obtained from sum of the top two scores.

**Computer-based processing**

The recorded digital images corresponded to a whole treated area from which image samples could be extracted. Samples were automatically normalized by removing noise, standardizing brightness and scaling using the fiducial markers, and adjusting contrast and luminosity parameters. All these procedures were performed by the computer program. This software was developed together with the Computer Architecture Department, the University of Malaga (Spain).

A Canny operator was next used as an optimal edge detector, working in a multistage process that resulted in an image made up of 1 pixel—thick connected segments that closely followed the faint margins of the feathering of the veins. In this way, the pretreatment and posttreatment areas of the affected zone in each image were computed. This could, thus, be used as a sensitive and objective comparative measurement not only for diagnostic reports on the pretreatment condition of veins, but also for demonstrating objectively the improvement and efficacy of the prescribed treatment. The digital data for each set of before and after images were analyzed as described above, and a clearance grade was assigned by the computer to each patient. This followed the same scoring system as the clinician’s assessment scale. The CLI was calculated from the top two scores.

**Histologic assessment**

A cross section of 5 patients consented to having biopsy specimens taken before and immediately after the first treatment, with biopsy specimens being taken from the same vein for both the pretreatment and posttreatment specimens. Some specimens were routinely processed and stained with the Masson trichromic method, and others were immunostained with an anti-CD34 antibody to assess the state of the blood vessels posttreatment.

**RESULTS**

All 10 patients completed the study including the assessment of the degree of satisfaction with the result at the 6-month assessment. In all, 5 patients needed 3 sessions, 4 needed 2, and 1 needed a single session.
All patients experienced some discomfort during treatment, but there was no relationship between patient phototype and the level of discomfort.

As for side effects, erythema was seen in all patients, but was transient, clearing significantly by 2 weeks after treatment, and disappearing completely after 8 weeks (Fig 1). Matting was seen in two patients, but was not related to the patient phototype. Hyperpigmentation was seen in 2 of 4 patients with skin phototype IV, but resolved spontaneously in both cases by 6 months after the last treatment. Blistering and slight pruritus were seen in two patients each, and all had resolved spontaneously by 4 weeks after treatment.

Laser parameters were not changed for the following treatment session in those patients who developed hyperpigmentation or blistering. Attention was, however, paid to move the laser hand piece more rapidly over the vein silhouette at the time of pulse stacking during treatment. Air cooling was also used more consistently on the skin. In all cases, no further complication or worsening of pigmentation or blisters was seen.

### Subjective assessment using SI

In the patient SI scores at 6 months after the final treatment, 1, 5, 3, and 1 patients scored VG, G, F, and P, respectively; no patient scored W. The overall

<table>
<thead>
<tr>
<th>Samples</th>
<th>c</th>
<th>d</th>
</tr>
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<tbody>
<tr>
<td>Sample area (pixels)</td>
<td>267800</td>
<td>267800</td>
</tr>
<tr>
<td>Number of spots</td>
<td>30457</td>
<td>19510</td>
</tr>
<tr>
<td>Percentages</td>
<td>100 %</td>
<td>64 %</td>
</tr>
</tbody>
</table>

Fig 2. Example of computer assessment of clearance index. Assessment before (A) and after (B) 6 months of treatment in typical venous lesion. Edge detector—based markings for same images are seen in C and D. Inset table shows pixel-based areas and number of discrete spots for same time points, allowing percentage calculation of improvement.
SI of 60% was calculated by adding the VG and G scores, expressed as a percentage of the patient population.

**Objective clinician assessment**

The numbers of patients placed by the independent clinician in the VG (75%-100%), G (50%-74%), F (25%-49%), and P (0%-24%) grades at the 6-month assessment were 2, 6, 2, and 0, respectively. No patient was rated W. The overall CLI of 80% was calculated by combining the top two values.

**Objective computer assessment**

The computer, using the same grading as for the clinician assessment, assessed the clearance rate as VG, G, F, and P in 1, 6, 2, and 1 patient, respectively. No patient was rated W. The computer assessed the overall CLI as 70%.

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**Fig 3.** Typical example of histologic assessment. A, In pretreatment findings, dilated varicose vein is clearly visible. B, In immediate posttreatment findings, vessel has closed with fibrosclerotic changes in vessel lumen, surrounded by coagulated collagen fibers. C, Higher magnification permits detailed observation of changes to vessel wall morphology, with apparent damage to intima coupled with sclerotic reaction. D, Immunostaining with anti-CD34 antibody at higher magnification shows positive staining, demonstrating destructive fibrotic changes to vessel wall and hyalinization phenomenon in collagen fibers. (A, B, and C, Masson trichromic stain; original magnifications: A and B, ×125; C and D, ×250.)
The above data are shown side by side for comparison in Table II. The overall SI was lower than the clinician-assessed SI, as has been seen in previous reports, but with the computer CLI interestingly positioned between these values.

As an example, Fig 2 shows examples of the computer-generated data based on the clinical photography before treatment. Fig 2, A and B, shows the findings before and 2 months after one treatment, respectively, with clearly visible improvement in the color, caliber, and size of the veins. The computer images in Fig 2, C and D, show F clearing, and the differences in both the sample area (in pixels) and the number of spots representing the veins themselves were calculated, giving an improvement rate of 36%. This could be expected to improve with the second and third treatments.

**Histologic assessment**

Fig 3, A, gives the pretreatment findings showing an obviously dilated varicose vessel with prominent endothelium. Fig 3, B, shows the condition immediately after treatment with the 800-nm system at the parameters given above. The vessel has been completely closed and shows fibrosclerotic changes to its structure, with coagulated collagen fibers visible in the perivascular area, all under an intact and normal-looking epidermis. In Fig 3, C, at higher magnification, immediately after treatment, the normal condition of the intima has been lost. The phlebosclerosis phenomenon and prominent endothelium were detected with immunostaining using an anti-CD34 antibody technique (Fig 3, D). This technique permits the observation of vessel characteristics, which show evident, prominent endothelium, and fibrosclerotic changes. The perivascular collagen fibers show degenerative changes and hyalinization.

**Representative clinical case**

Patient 1, a 55-year-old woman, skin type III, is seen in Fig 4, A, before treatment, with veins on the upper aspect of her left thigh. She required 3 treatments. Six months after the third treatment the final result was VG as seen in Fig 4, B.

**DISCUSSION**

The anatomic features of leg veins define the requirements for a laser to effectively target these vessels. Specifically, the following parameters are critical: penetration depth of laser radiation into the skin and blood, pulse duration, fluence, and the proportion of laser energy absorbed by epidermal chromophores, mainly melanin. In this study, leg vein treatment was performed with an 800-nm diode laser. Diode laser development is in the ability of near-infrared wavelengths to penetrate deeper into tissue with reduced melanin absorption and absorption in the tertiary hemoglobin peak within dilated vessels. The effective penetration depth in blood for laser light at a wavelength of 800 nm, according to the diffusion theory, depends on the oxygen concentration. Using data reported by Roggan et al, the effective penetration depth in blood for laser light at a wavelength of 800 nm is approximately 0.8 mm. Oxyhemoglobin and deoxyhemoglobin display similar values because 800 nm is an isobestic point for these two components, possibly as the target chromophore is shifting from the pigment to the highly proteinaceous structure of hemoglobin. To effectively coagulate the vessel without damaging the surrounding tissue, heating should remain within the thermal relaxation time. For vessel sizes varying between 1 and 3 mm, calculations show that the thermal relaxation time must be equal or superior to 500 milliseconds. Pulse stacking (5-8 pulses) as used in this study aimed to reach this specific requirement. The fluences used in this study (210-336 J/cm²) are similar to those reported by Kaudewitz et al using
a 940-nm diode laser, namely 250 to 400 J/cm². Similarly, Passeron et al.¹⁰ using a similar system, demonstrated that an effective treatment for leg veins was obtained at fluences equal to 300 J/cm². Eremia et al.⁵ evaluating an 800-nm diode laser, reported fluences ranging from 180 to 700 J/cm².

The high level of patient satisfaction without any anesthesia being required and with minimal discomfort tends to prove that the choice of the parameters was appropriate. As with other studies, the subjective patient assessments of their satisfaction with the result were lower than the clinician-assessed clearance rate, with the computer program—assessed rate between the two. This study examined efficacy from a number of other parameters, however, including the age of the patient, phototype, vessel diameter, and vessel location (Table III). The main conclusions were that the best results were seen in vessels of 3 to 4 mm in diameter, usually appearing blue, which is borne out by previous studies on laser treatment of leg veins at 755 and 810 nm.²,³,⁵ In addition, blood vessels located on the thigh responded better compared with those on the calf and ankle. As for phototypes, the best results were seen in phototype III. There was no correlation between patient age and the treatment result. These findings should be borne in mind during patient selection, and also when ensuring patients have a realistic expectation of the treatment results.

No long-term complications were noted in this study, probably because of the means of delivering the sequence of stacked pulses and the efficient epidermal cooling, both of which also contributed to the minimal pain levels. The theoretic basics proposed by Mordon et al.¹¹ whereby methemoglobin formation in the target vein after the first pulse alters the optical characteristics of the vein to give more efficient absorption of subsequent pulses, seem to be confirmed by this study. The sequence of comparatively low-energy pulses (42 J/cm² each) used in the current study probably acted to induce a progressive buildup of heat in the target vein and in the immediately adjacent dermal tissue, thereby achieving efficient coagulation and lasting vein closure while minimizing pain and keeping collateral thermal damage in the surrounding dermis to a minimum. The CD34 immunostaining seen in Fig 3, D, showing closure of the vessel with the sclerosis phenomenon and changes in the vessel wall architecture, would appear to corroborate successful results in the target vessels.

The chilled air cooling, continuously applied before, during, and after each sequence of pulses, efficiently cooled the epidermis and protected it from any primary photothermal damage in addition to the wave of secondary heat propagating through the tissue toward the epidermis from the target vessel, while also minimizing patient discomfort. This allowed the necessary progressive increase in heat buildup to occur in the target area, and permitted the subsequent wound-healing processes to take place under the protection of an intact epidermis.

The wound-healing process takes well over 2 months, particularly when considering the long-term effects associated with the third remodeling phase. This dictated the 6-month assessment point used in the current study rather than a shorter one. Induction of a strong but quick first inflammatory stage is, however, a prerequisite to recruit the main and support cells necessary for this and the second

<table>
<thead>
<tr>
<th>Table III. Patient satisfaction index compared by patient age, phototypes, vessel diameter, and vessel location</th>
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<tbody>
<tr>
<td>Patient age, y</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>VG</td>
</tr>
<tr>
<td>G</td>
</tr>
<tr>
<td>F</td>
</tr>
<tr>
<td>P</td>
</tr>
<tr>
<td>W</td>
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<table>
<thead>
<tr>
<th>Diameter of veins</th>
<th>Location of veins</th>
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</thead>
<tbody>
<tr>
<td>SI</td>
<td>1-2 mm</td>
</tr>
<tr>
<td>-----------------</td>
<td>---------</td>
</tr>
<tr>
<td>VG</td>
<td>0</td>
</tr>
<tr>
<td>G</td>
<td>0</td>
</tr>
<tr>
<td>F</td>
<td>2</td>
</tr>
<tr>
<td>P</td>
<td>1</td>
</tr>
<tr>
<td>W</td>
<td>0</td>
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</tbody>
</table>

F, Fair; G, good; P, poor; SI, satisfaction index; VG, very good; W, worse.
proliferative phase. Creating in the target area a strong, progressive, but controlled zone of delivered thermal damage under an intact epidermis goes a very long way to achieving that goal. The macrophage cells recruited into the healing wound during the inflammatory stage were probably responsible for the positive changes in the appearance of the coagulated veins over time, giving the final VG clearance rates.

The results compare favorably with those obtained with the 1064-nm neodymium:yttrium-aluminum-garnet laser. The application of pulse stacking with low-energy pulses may achieve the energy required for vessel damage and closure without excessive heat propagation to the surrounding tissue. The use of a laser with pulse stacking seems to play a major role in the efficacy of leg vein treatment.

We believe that leg vein treatment with an 800-nm diode laser using appropriate parameters (sequence of several pulses to bring enough energy inside the vessel, leading to vessel heating equivalent to the thermal relaxation time in association with efficient epidermal cooling) may well offer an effective treatment method that is comparatively pain and side-effect free. This is very important when considering the pain, side effects, and increased risk of epidermal damage associated with the application of a high-energy sequence of pulses and other treatment modalities in laser leg vein treatment. An additional advantage of the cooling method used is the environmentally friendly use of continuously renewable chilled air, rather than using a cryogenic gas, which requires constant replenishing with its associated expense.

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REFERENCES