Treatment of Spider Veins of the Lower Extremity With a Novel 532 nm KTP Laser

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Background and Objectives: This study investigated a novel, high-power, 532 nm frequency-doubled Nd:YAG, KTP laser with contact cooling for the treatment of spider veins of the lower extremities.
Study: Twenty female subjects with Fitzpatrick skin types I–III, were treated to 79 sites using the 532 nm wavelength of a dual-wavelength 532/1,064 nm laser (Excel V, Cutera, Brisbane, CA) with a 5 mm-diameter spot, fluences ranging from 13 to 15 J/cm^2, and a pulse-duration of 40 milliseconds. Two treatments were performed 12 weeks apart. Photographs were taken at baseline and 12 weeks following the final treatment. Improvement was assessed by two independent physicians reviewing photographs in a blinded fashion using a 5-point improvement scale.
Results: All subjects demonstrated improvement resulting in a median improvement of 2.5 (one-sample Wilcoxon signed rank test, 95% CI: 1.9–2.9, $P = 0.000$). The reviewers were highly consistent (kappa of 0.85), and highly accurate (kappa of 0.85) in identification of "after photograph" and they were highly consistent in grading improvement. Subjects and the treating physician reported "significant" to "very significant" (~51 to 100%) improvement in 75% and 69% of subjects, respectively. Post-inflammatory hyper-pigmentation was seen in 2% of sites (1/64). No serious adverse effects reported. All subjects tolerated the treatments well (mean pain score of 2.9/10).
Conclusion: Treatment of spider veins of the leg with a novel 532 nm KTP laser was found to be safe and effective, with minimal discomfort and adverse effects in Fitzpatrick skin types I–III. Lasers Surg. Med. 46:81–88, 2014.

Key words: KTP; laser; leg; spider vein

INTRODUCTION

Spider veins of the lower extremities are a common condition affecting 29–41% of women and 6–15% of men in the United States [1]. Sclerotherapy is the mainstay treatment of spider veins smaller than 4 mm in diameter [2–5]. Sclerotherapy is particularly well suited for spider veins greater than 0.5 mm in diameter. However, small vessels (<0.5 mm) are often resistant or technically challenging for sclerotherapy treatment, especially matt telangiectasias which can result from sclerotherapy or vein stripping and may worsen after further sclerotherapy [4,5]. Therefore, lasers have been used as a non-invasive modality for the treatment of spider veins, especially when vessels are small in diameter, when treating telangiectatic matting resulting from sclerotherapy or vein stripping, or in patients who are needle phobic [6–16].

A variety of lasers have been developed to treat vascular lesions based on the principle of selective photothermolysis, including the long, pulse-duration alexandrite and neodymium-doped, yttrium-aluminum-garnet (Nd:YAG) lasers, the pulsed-dye laser (PDL), and the Nd:YAG laser incorporating a potassium-titanyl-phosphate (KTP) frequency-doubling crystal. Both the PDL and KTP laser emit wavelengths of 595 and 532 nm, respectively, which are strongly absorbed by hemoglobin and are quite effective at removing red, lower extremity telangiectasias [9–14]. Pulsed dye lasers (PDL) have been widely used for the treatment of various vascular lesions including facial telangiectasias, port-wine stains, and hemagiomas. Treatment of lower-extremity spider veins with PDL has been shown to be effective, especially with the introduction of latest generation 595 nm PDL which offers longer pulse durations by delivering eight micropulses in a pulse envelope of up to 40 milliseconds in duration [11]. The 532 nm KTP laser can deliver even longer pulse durations than the PDL and has also been shown to be highly safe and effective for the treatment of lower extremity spider veins [10,12–14]. New technologic advances enabled development of KTP lasers with more power and improved contact cooling, as compared to previously available KTP lasers, and we investigate the efficacy of such a laser here.

The 532 nm wavelength, which is produced by frequency doubling an Nd:YAG laser at 1,064 nm via placing a KTP

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crystal in the laser beam's path, is well absorbed by oxyhemoglobin. Compared to the 595 nm PDL wavelength, 532 nm has a significantly higher coefficient of absorption for hemoglobin and a slightly higher coefficient of absorption for melanin [11]. Due to the significant melanin absorption of both wavelengths, post-inflammatory hyperpigmentation as a result of leg vein treatment is a significant risk in darker skin types or tanned skin.

In the current study reported here, we investigate the effect of two consecutive 532 nm laser treatments on clearance of spider veins of the lower extremity, as assessed by blinded review of digital images. Additionally, the treating physician's assessment and the subjects' self-assessment of improvement were recorded, as were the incidence of adverse effects and the tolerability of laser treatments.

MATERIALS AND METHODS

This was a single center, prospective, uncontrolled study which investigated the safety and efficacy of treatments with the 532 nm KTP laser (Excel V, Cutera, Brisbane, CA) for the treatment of lower extremity spider veins. The Excel V laser was cleared by the Food and Drug Administration for treatment of vascular lesions. This research study was approved by the Allendale Institutional Review Board (AIRB, Old Lyme, CT), and informed consent was obtained prior to subject participation.

Subjects

Twenty subjects were enrolled in the study, and were recruited as they presented for various treatments to a dermatologic laser center. Subjects were included if they had lower extremity spider veins less than 0.75 mm in size, were over 18 years of age, and had Fitzpatrick skin type I–III. All subjects presenting for treatment were female and ranged in age from 32 to 66 with a mean age of 48. Subjects ranged in Fitzpatrick skin type from I to III, with 1 subject having type I skin (5%), 15 subjects having type II skin (75%), and 4 (20%) having Fitzpatrick type III skin. All subjects, except one who had 3 sites, had 4 separate sites of lower extremity spider veins, each measuring at least 5 cm × 5 cm in area, for a total of 79 treatment sites. Exclusion criteria included evidence of a suntan in the area to be treated, scarring or infection in the area to be treated, a history of any previous spider vein treatment, isotretinoin administration within 6 months of presentation, anticoagulant administration, a history thromboembolism or a history of hypercoagulability, active pregnancy, or a history of keloid formation.

Laser Device

The study device was a high-power, dual-wavelength 532/1,064 nm laser (Excel V, Cutera). The laser utilizes contact cooling via a chilled sapphire window, and adjustable spot-sizes from 2 to 12 mm in 1 mm increments, pulse-widths from 1.5 to 40 millisecond at 532 nm, and a broad range of fluences. In this study, only the 532 nm KTP laser was used to target superficial leg telangiectasias. Cooling is achieved with a very efficient chilled sapphire window integrated into the treatment handpiece, which is placed in contact with the skin surface, enabling excellent visualization of target telangiectasias during treatment, with temperatures adjustable to 5, 10, 15, or 20°C. The treatment beam is highly uniform with a top-hat distribution, thus minimizing hot spots within the treatment beam. This laser is capable of high power output delivering up to 850 W at 532 nm out of the handpiece.

Laser Treatment

Leg veins that were less than 0.75 mm in diameter and linear or branching were selected for treatment. Subjects were treated with a 532 nm KTP laser (Excel V, Cutera). Laser pulses were administered using a 5 mm-diameter spot through a chilled sapphire window which provided contact cooling at 5°C. To facilitate smooth movement of the chilled sapphire window across the skin surface, a thin layer of water-based gel was applied to the skin surface prior to treatment (Spectra 360 electrode gel, Parker Laboratories, Inc., Orange, NJ). Anti-fog drops were applied to the side of the sapphire window not adjacent to the skin to prevent fogging of the window during treatment (Sea Drops, McNett, Corporation, Bellingham, WA). Subjects were treated using a cross-polarizing headlamp (v600, Syris Scientific, Gray, ME) to ensure visualization of all veins within a given treatment site. Treatment fluences ranged from 13 to 15 J/cm^2 using a 40 millisecond pulse-duration and were administered using a 5 mm-diameter treatment beam. Each vessel was treated with 1–2 passes until vessel clearance or slight purpura was achieved. A total of 79 treatment areas, 5 cm × 5 cm in size were treated. Treatment sites were identified at each subsequent visit using global photographs to identify local landmarks. Subjects returned for a second treatment and photographs 12 weeks after the first treatment, and then again for final photographs 12 weeks after the second treatment.

Post laser treatment care consisted of applying a petrolatum-based ointment to treatment sites following a treatment session (Aquaphor Healing Ointment, Beiersdorf, Inc., Wilton, CT), and then twice daily for 2 weeks. Subjects were instructed to avoid sun-exposure to treatment sites throughout the study period.

Photographs

Global photographs for identifying treatment sites at follow-up visits and cross-polarized close-up photographs for evaluation of laser treatment effect were taken at baseline, and at 12 weeks following each of 2 laser treatments using a 12.3 megapixel D90 Pro-SLR digital camera with a 60 mm f/2.8 D Micro-Nikkor lens (Nikon, Inc., Tokyo, Japan). The same professional medical photographer took all study photographs (Canfield Scientific, Inc., Fairfield, NJ). Photography was performed in the same room, with the same camera using identical magnification, exposure, and lighting.

Blinded Evaluation of Cross-Polarized Photographs

Cross-polarized photographs taken at baseline, 12 weeks following the first laser treatment and 12 weeks following the second and final laser treatment were used for blinded photographic assessments. Two paired, 4×6 inch, high-resolution (400 dpi) photographs were placed adjacent to one another, professionally printed in landscape orientation on 8×12 inch glossy premium quality photograph paper (Fujifilm, Tokyo, Japan). A data collection form was printed on the lower portion of each page to collect the reviewer's assessment. An online tool (Research Randomizer, Version 3.0) was used to randomize the positions of the pre- and post-treatment photographs on each page and the order of each page in the presentation binder. Two independent physician reviewers who were blinded to the chronological order of photographs, photograph time point, and laser treatment parameters rated the photographs for the degree of improvement. The blinded reviewers first determined the chronological order of the pre- and post-treatment photographs, then rated the percentage improvement. The percentage improvement scale (0–4) was used for the assessments: 0 = no improvement (0%), 1 = mild improvement (<25%), 2 = moderate improvement (26–50%), 3 = significant improvement (51–75%), 4 = very significant improvement (76–100%). If the pre-treatment photograph was selected as improved, a negative score would be recorded in the final analysis.

Subjective analyses were performed by the treating physician and the subjects themselves. The treating physician evaluated improvement 12 weeks following the final treatment as compared to pre-treatment photographs using the 1–4 scale described above. Subjects rated their improvement subjectively 12 weeks after the final treatment using a 5-point scale: 1 = very much not satisfied, 2 = not satisfied, 3 = somewhat satisfied, 4 = satisfied, 5 = very much satisfied).

Statistical Analysis

Statistical analysis was performed using Minitab statistical package, version 16.2.2.0 (Minitab Inc., State College, PA). Since an ordinal scale was used to assess improvement, the one-sample Wilcoxon rank test, a non-parametric method, was performed for statistical testing. P values less than 0.05 were considered statistically significant and all tests were two sided. Additionally, 95% confidence intervals were calculated for the estimates of improvement. The median improvement scores and their variability (spread) by time point and reviewer were displayed in a box plot graph. During the analysis of blinded assessments, if the reviewer was unable to distinguish pre- and post-treatment photographs from one another, a score of zero (no improvement) was given, and if the pre- and post-treatment photographs were incorrectly identified, a negative value was assigned to the improvement score. In addition to the presentation of the median improvement scores, the frequency distribution (percentages) of sites and subjects with improvement were displayed in bar charts by time point and reviewer.

Pairwise matching of scores was performed for all sites to determine the magnitude of agreement between the two physician reviewers. Matching of improvement scores was reported as percentages of perfect matches and matches with a score difference. Simple percentage agreement was used instead of kappa statistics because the precision of kappa coefficient decreases as the number of categories in the scale increases [17,18]. The magnitude of agreement between two reviewers in identification of pre- and post-treatment photographs was measured by using the kappa statistic since there were only two categories (before and after). Inter-reviewer reliability, or consistency, indicated agreement when pre- and post-treatment photographs were identified either correctly or incorrectly by both reviewers. Inter-reviewer validity or accuracy occurred only when the pre- and post-treatment photographs were labeled correctly by both reviewers. Kappa agreement analysis was used because, unlike simple percentage agreement, kappa coefficient takes into account that reviewers will sometimes agree simply by chance and calculates agreement above and beyond that expected by chance alone.

Adverse Effects

Pain levels were assessed immediately post-treatment using the 0–10 numeric pain rating scale (0 = no pain to 10 = worst possible pain). Adverse effects including erythema, edema, purpura, and pain were assessed immediately following each treatment by the treating physician, and evaluated using a 4-point scale (0 = none, 1 = mild, 2 = moderate, 3 = severe). Post-inflammatory hyperpigmentation, hypo-pigmentation, telangiectatic matting, and scarring were also evaluated by the treating physician 12 weeks following each treatment using the above scale.

RESULTS

Twenty subjects were initially treated for their lower-extremity spider veins, and two of those subjects failed to return for the second treatment because they left the area during the study period. An additional three subjects were excluded from the second treatment because they were tan during the follow-up visit, all of whom subsequently avoided sun-exposure and were photographed at the final study visit. Two subjects were lost to follow-up and 16 subjects with 64 treatment sites completed their final study visit at 12 weeks after the second and final laser treatment.

Blinded Photographic Assessment of Improvement

Blinded photographic assessments by two independent physician reviewers demonstrated a statistically significant resolution of spider veins. An improvement of 2.5 points (~60 to 65% clearance), using a 5-point scale, was measured in the appearance of spider veins of the leg at 12 weeks following the second and final laser treatment (Table 1). Spider vein resolution 12 weeks following the first treatment was also statistically significant, with

TABLE 1. Improvement in Spider Leg Veins by Time Point

Time point	*n*	Median	95% Confidence interval	*P*
12 Weeks post-1st treatment	15	1.8	(1.0, 2.4)	0.001[a]
12 Weeks post-2nd treatment	16	2.5	(1.9, 2.9)	0.000[a]

[a]Significant (one-sample Wilcoxon signed test).

photographs demonstrating a 1.8-point (~45 to 50% clearance) improvement.

Descriptive data displayed in Figure 1 indicate an increase in median scores following the second and final treatment. Discrepancy in reporting of medians following the second treatment, 2.5 points (Table 2) versus 2.4 points (Fig. 1), is a result of ranking of scores done for the one-sample Wilcoxon rank test.

The strength of agreement between reviewers in identification of the post-treatment photograph is shown in Table 2. The consistency (inter-reviewer reliability) and accuracy (inter-reviewer validity) between blinded reviewers were "very good" at 12 weeks post-second (final) treatment improving from "good" at 12 weeks post-first treatment (Table 2). Of the 60 photographic pairs assessed at 12 weeks post-first treatment, there were five pairs where at least one of the reviewers was not able to determine the post-treatment photograph and were labeled as "undecided." This dropped to two pairs of 64 at 12 weeks following the second treatment. Three of five pairs which were labeled as undecided at 12 weeks following the first treatment were taken from the same subject.

Reviewers were highly consistent in rating of improvement where scores had "perfect match" to "match with one score difference" in 90 to 94% of sites (Table 3).

Figure 2 shows the percentage of sites by level of improvement and time point. The improvement score of each site was calculated by averaging scores from two blinded reviewers. Data indicated that all subjects had improvement following the second treatment, and "significant" to "very significant" (~51 to 100%) improvement was seen in 50% of sites.

Comparison of subjects self-assessment of improvement and clinical assessments by the treating physician are shown in Figure 3 as a percentage of subjects. Both subject assessments and treating physician assessments indicated that all subjects had "moderate" to "very significant" (~26 to100%) improvement 12 weeks following the final treatment. Subjects and the treating physician reported "significant" to "very significant" (~51 to 100%) improvement in 75% and 69% of subjects, respectively.

All 16 subjects who completed the final follow-up visit were satisfied with the improvement and would recommend the laser treatment to others.

Figure 4 shows examples of digital images, before (a), 12 weeks after 1 (b), and 12 weeks after the second and final (c) treatment.

Adverse Effects

Immediately post-treatment, the majority of sites demonstrated mild erythema (Table 4). Edema was

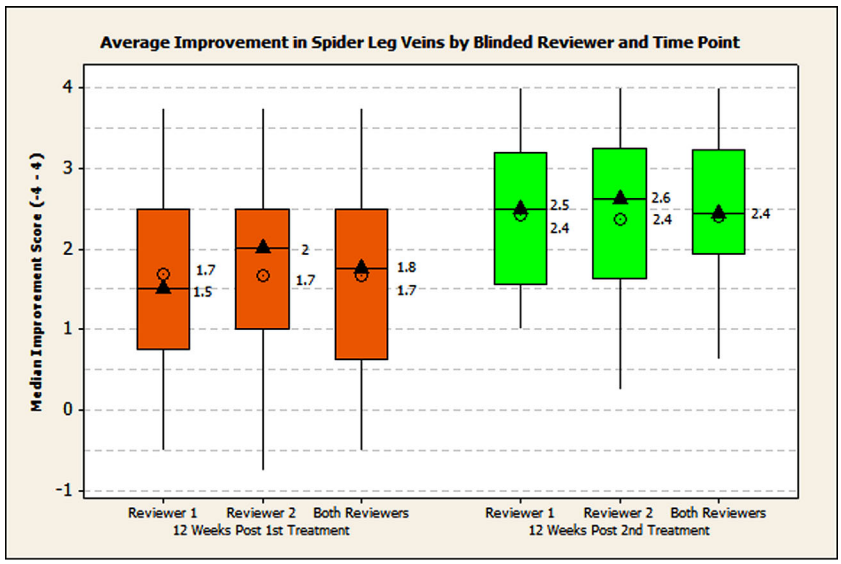

Fig. 1. Median improvement in spider veins of the leg by blinded reviewer and time point. (The box illustrates the interquartile range (IQR) extending from the 25th percentile to the 75th percentile with a line placed at the median (50th percentile). The bottom and top end of whiskers show the minimum and maximum data points, respectively. The triangle symbol indicates the median and the circle symbol indicates the mean).

TABLE 2. Kappa Analysis of Agreement between Two Independent Reviewers in Identification of the "After Photograph"

Time point	Total number of subjects	Total number of sites	Kappa coefficient[a]	
			Inter-reviewer reliability	Inter-reviewer validity
12 Weeks post-1st treatment	15	60	0.78	0.62
12 Weeks post-2nd treatment	16	64	0.85	0.85

[a]Kappa coefficient (strength of agreement): poor <0.20, fair 0.21–0.40, moderate 0.41–0.60, good 0.61–0.80, and very good 0.81–1.00.

observed immediately in 24% of treatment sites after the first treatment, and 62% of sites following the second. Transient post-inflammatory hyper-pigmentation was seen in one site (2%) 12 weeks following the second treatment. No purpura, blistering, hypo-pigmentation, telangiectatic matting, scarring, or other adverse effects were reported. Treatments were well tolerated with a mean pain score of 2.9 (SD 0.8) on a scale of 0 (none) −10 (worst).

DISCUSSION

This study demonstrates that a novel, high-power, long pulse-duration, contact cooled, KTP laser is safe and effective for removing spider veins of the lower extremity less than 0.75 mm in diameter. Based on blinded review of photographs by independent physician raters, 86% of treatment sites improved following one treatment increasing to 100% of sites following the second treatment. Blinded reviewers were highly consistent and accurate in identifying the chronological order of pre- and post-treatment photographs and were highly consistent in grading improvement. Subjective evaluations of improvement by the treating physician and the subjects themselves were quite similar, with 50% of subjects rating improvement 12 weeks after the final treatment as very significant, and 25% as significant; while the treating physician rated 31% as very significant and 38% as significant.

Adverse effects in the current study were quite minimal, and treatments were extremely well tolerated. Post-inflammatory hyperpigmentation was seen in one of 64 sites (2%) 12 weeks after a single treatment, as assessed by the treating physician. It was observed in a subject with skin type II following her second treatment. This adverse effect is common following laser treatment and sclerotherapy injections for removal of leg veins. The low incidence of hyperpigmentation in the current study may have been due to the exclusion of subjects with Fitzpatrick skin types IV–VI, the extremely efficient contact cooling, and the exclusion of tanned subjects. In the current study, contact cooling was provided via a chilled sapphire window kept at a temperature of 5°C. Evidence for the high efficiency of the contact cooling were the uncharacteristically low scores for pain recorded among subjects in the current study of 2.9/10.0. A previous study using a 532 nm laser to treat leg veins recorded a pain score of 1.9 on a 5-point scale, corresponding to a 3.8 score on a 10-point scale [5]. However, that study used a laser with a shorter (10 millisecond) pulse-duration, which could have accounted for the higher pain score [10]. No blisters, scarring, or hypo-pigmentation were noted in any treatment site.

TABLE 3. Percentage of "Perfect Match" and "Match with One Score Difference" in Improvement Scores between Independent Reviewers by Time Point

Time point	Total number of sites	Perfect match (%)	Match with one score difference (%)
12 Week post-1st treatment	60	57	37
12 Week post-2nd treatment	64	58	32

The 532 nm KTP laser has been shown to treat facial telangiectasias safely and successfully, without purpura [19,20]. Similarly, treatment of superficial leg veins with the long pulse-duration KTP laser has also been shown to be safe and effective [10,12–14]. The thermal relaxation time of spider veins 0.2 to 0.8 mm in diameter ranges from 20 to 300 millisecond [15]. Lasers designed for treating vessels of many sizes should be capable of emitting variable pulse-durations while delivering sufficient fluences to enable larger spot sizes for adequate, even penetration of laser energy. Utilizing a laser emitting dual-wavelengths, such as the current system which is capable of delivering both 532 nm and 1,064 nm laser energy, enables successful removal of smaller red and larger blue vessels. In addition, the ability to deliver 532 nm, laser energy at clinically relevant fluences using shorter pulse-durations, in the 3–6 millisecond range, enables treatment of diffuse erythema as seen in patients with rosacea or port-wine stain birthmarks. The device used in the current study provides both 532 and 1,064 nm laser energy with a variable pulse-duration from 1.5 to 40 milliseconds at 532 nm and from 5 to 60 milliseconds at 1,064 nm, which is generated as a continuous single pulse. Spider veins of the leg differ considerably from facial telangiectasias. They are larger in diameter with thicker walls, are located deeper in the skin, their hemoglobin is less fully oxygen saturated, and they have high hydrostatic pressures relative to facial telangiectasias [7,16]. Additionally, leg veins are composed of a heterogeneous mix of vessels of different sizes and

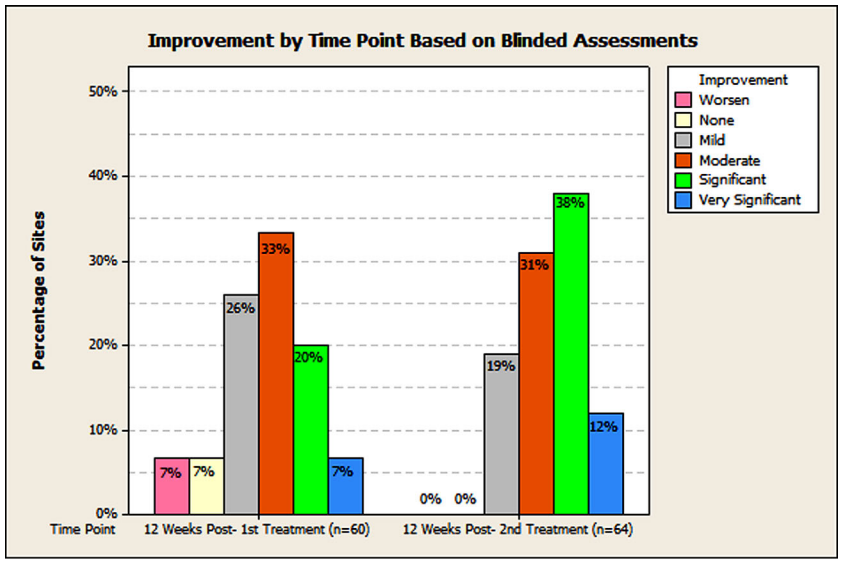

Fig. 2. Percentage of sites with improvement at two time points based on photographic assessments by two independent reviewers.

different flow rates. Therefore, more than one wavelength or one treatment modality may be necessary for treating the large variety of vessels seen in many patients presenting for removal of lower extremity spider veins [21].

The near-infrared, 1,064 nm, Nd:YAG laser has been shown to be safe and effective for the treatment of larger diameter and deeper spider veins than were treated in the current study with the 532 nm KTP laser [22–26]. Compared to shorter wavelengths, the 1,064 nm Nd:YAG laser has a greater depth of penetration, is less well absorbed by melanin, and better absorbed by methemoglobin; therefore, it is capable of removing larger veins and doing so in darker skin types. However, since, 1,064 nm laser energy is more poorly absorbed by hemoglobin than 532 nm laser light, much higher fluences are required for vein removal with the former wavelength, and this is especially true for smaller, red telangiectasias. Thus, the therapeutic window is narrow for treating small red vessels with 1,064 nm laser energy, a reduction of the high margin of safety that exists with 532 nm KTP lasers [15]. The device used in this study is a high energy, variable pulse-duration, dual-wavelength 532/1,064 nm laser that can be potentially used to target leg veins of various sizes, colors from blue to red, and of various depths within the skin. Future studies should consider investigating the safety and efficacy of the 532 nm KTP

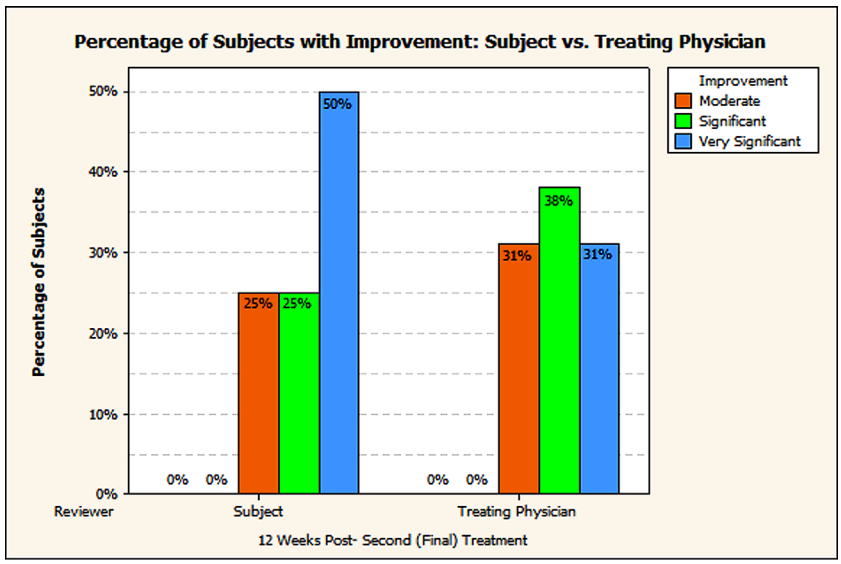

Fig. 3. Percentage of subjects with "moderate" to "very significant" improvement as assessed by the subject and the treating physician at 12 weeks post-second (final) treatment.

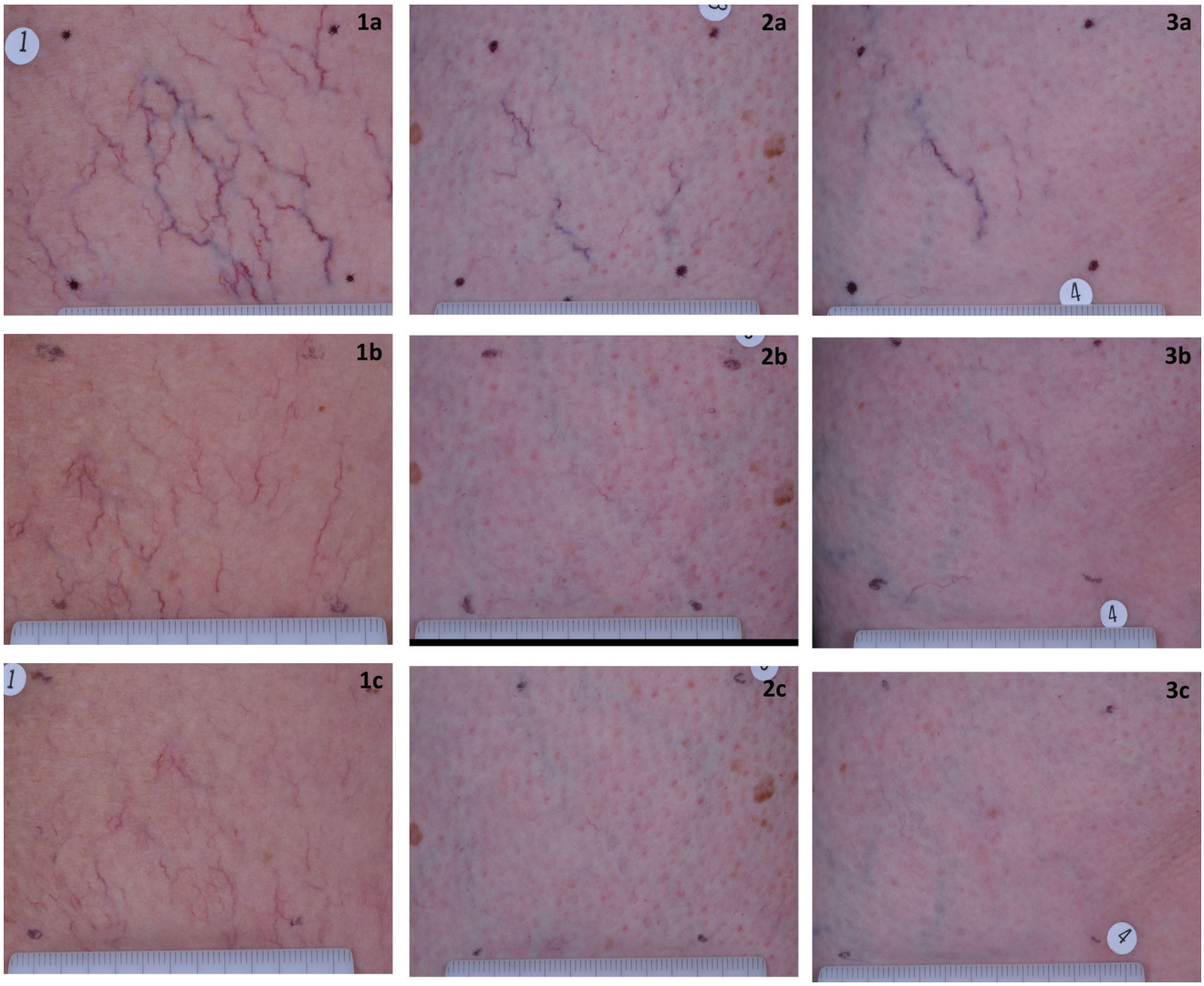

Fig. 4. Pre-treatment (1a, 2a, and 3a), 12 weeks post-first treatment (1b, 2b, and 3b) and 12 weeks post-second (final) treatment (1c, 2c, and 3c).

TABLE 4. Adverse Effects As Assessed by the Treating Physician by Number of Sites Treated (%)

		Immediately post-treatment			12 Weeks post-treatment			
Treatment #	Severity score	Erythema	Edema	Purpura	Hyper-pigmentation	Hypo-pigmentation	Telangiectatic matting	Scarring
1[a]	Absent	4 (5)	60 (76)	0	0	0	0	0
	Mild	58 (73)	19 (24)	0	0	0	0	0
	Moderate	17 (22)	0	0	0	0	0	0
	Severe	0	0	0	0	0	0	0
2[b]	Absent	0	21 (38)	0	0	0	0	0
	Mild	52 (93)	31 (55)	0	1 (2)	0	0	0
	Moderate	4 (7)	4 (7)	0	0	0	0	0
	Severe	0	0	0	0	0	0	0

[a]15 J/cm^2 with cooling at 5°C.
[b]13 J/cm^2 with cooling at 5°C.

wavelength in combination with the 1,064 nm Nd:YAG wavelength for the treatment of both small and large, and superficial and deeper leg veins in a single patient.

CONCLUSIONS

Treatment of lower extremity spider veins less than 0.75 mm in diameter with a novel, high powered, variable pulse-duration, 532 nm KTP laser is safe and effective, with minimal discomfort or side-effects in subjects with Fitzpatrick skin types I–III and non-sun tanned skin.

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