Safety and Efficacy of a Novel, Variable-Sequenced, Long-Pulsed, 532-nm and 1,064-nm Laser With Cryogen Spray Cooling for Pigmented and Vascular Lesions

Jordan V. Wang, MD, MBE, MBA,* Shirin Bajaj, MD,* Robert Murgia, DO,† Sean Z. Wu, MD,† Robert Weiss, MD,† Roy G. Geronemus, MD,* Omar A. Ibrahimi, MD, PhD,‡ and Suzanne Kilmer, MD§

BACKGROUND Patients frequently seek treatment for vascular and pigmented lesions. More recently, a novel, variable-sequenced, long-pulsed, 532-nm and 1,064-nm laser with cryogen spray cooling was developed to offer greater flexibility in treatments.

OBJECTIVE A prospective clinical trial evaluated the safety and efficacy of a novel, variable-sequenced, long-pulsed, 532-nm and 1,064-nm laser with cryogen spray cooling (DermaV, Lutronic, South Korea).

MATERIALS AND METHODS Subjects with vascular and/or pigmented lesions were enrolled and underwent laser treatments.

RESULTS Twenty-three subjects were enrolled with vascular lesions (39.1%), pigmented lesions (17.4%), and both (43.5%). Mean age was 53.1 years, and 91.3% were women. Fitzpatrick skin types II–IV were included. All subjects were treated with 532 nm, and 4 were also treated with 1,064 nm. According to 4 blinded physician reviewers, correct before and after photographs were selected in 94.7%, 92.1%, 84.2%, and 76.3% of cases. Overall, 86.8% were responders, meaning that at least 3 of 4 reviewers agreed. For Global Aesthetic Improvement Scale, improvement occurred in 81.6%, 81.6%, 81.6%, and 76.3% of cases. No serious adverse events occurred. Overall, 87.0% of subjects reported being very satisfied or satisfied.

CONCLUSION A novel, variable-sequenced, long-pulsed, 532-nm and 1,064-nm laser with cryogen spray cooling can safely and effectively improve vascular and pigmented lesions.

Patients frequently seek treatment for the aesthetic improvement of vascular and pigmented lesions. More traditional treatment modalities have included cryosurgery, electrocautery, surgery, chemical peels, and topicals that can constrict blood vessels or lighten pigmentation. In recent decades, laser treatment has become increasingly more common, especially as discrete targets could be selected using distinct wavelengths with selective photothermolysis.[1–6] For vascular conditions, the lasers selectively target hemoglobin to heat the blood vessels and thermally damage them. In contrast, lasers can effectively target melanin for the treatment of pigmented lesions.

For vascular lesions especially, the 585-nm and 595-nm pulsed dye laser (PDL) with cryogen spray cooling has represented the gold standard for many years.[7–14] It has been used to treat a variety of vascular conditions, including rosacea, telangiectasias, and port-wine birthmarks. The introduction of the long-pulsed 532-nm potassium titanyl phosphate (KTP) laser and 1,064-nm neodymium-doped yttrium aluminum garnet (Nd:YAG) laser allowed for additional flexibility in the treatment of vascular and pigmented lesions.[15–19] However, these devices have typically used contact cooling methods to protect the epidermis from thermal damage. This type of cooling modality can limit the amount of energy that can be safely delivered due to limitations in the depth and temperature of the cooling gradient. The cold contact method may also increase risks of postinflammatory hyperpigmentation in certain patient populations who may be prone to develop this.

More recently, a novel, variable-sequenced, long-pulsed, 532-nm and 1,064-nm laser with cryogen spray cooling was developed to combine both wavelengths into a single device and offer flexibility in treatments. It allows for large spot sizes up to 16 mm for increased treatment speed and greater depth of laser penetration, the selection of various pulse structures to treat diverse vessel morphologies, effective epidermal and dermal cooling, and real-time temperature monitoring with smart rolling technology. In this multicenter, prospective study, we evaluated the safety and efficacy

*From the *Laser and Skin Surgery Center of New York, New York, New York; †Maryland Dermatology Laser Skin and Vein, Hunt Valley, Maryland; ‡Connecticut Skin Institute, Stamford, Connecticut; §Laser and Skin Surgery Center of Northern California, Sacramento, California*

R. Weiss, R. Geronemus, O. Ibrahimi, and S. Kilmer are on the advisory board for Lutronic. O. Ibrahimi is the medical director for Lutronic.

Address correspondence and reprint requests to: Jordan V. Wang, MD, MBE, MBA, Laser and Skin Surgery Center of New York, 317 E 34th Street, 6th Floor Research Department, New York, NY 10016, or e-mail: drjordanwang@gmail.com

Dermatol Surg 2023;00:1–4
http://dx.doi.org/10.1097/DSS.0000000000003831

of this laser in the treatment of pigmented and vascular lesions.

Materials and Methods

Healthy subjects with vascular and/or pigmented lesions were enrolled at physician discretion at 3 clinical sites. This study was approved by an independent IRB. Informed consent was obtained. Subjects underwent treatment with a novel, variable-sequenced, long-pulsed, 532-nm and 1,064-nm laser with cryogen spray cooling (DermaV, Lutronic, South Korea). Treatment parameters were selected at physician discretion and were based on early clinical results, physician experience, and live clinical endpoints during the treatment. Settings were recorded at each treatment visit. Subjects were allowed to receive up to 9 treatments with treatment intervals ranging from 2 to 8 weeks. Subjects did not receive other treatments for the lesions during the study, and treatment was limited to the affected areas of the lesions.

At all treatment and follow-up visits, standardized photographs were taken of the condition and area being treated. For larger lesions, multiple photographs were taken to capture different body areas if needed. Follow-up visits occurred at 1 and 3 months after the last treatment. Four blinded physicians were instructed to select the correct before and after photograph and grade randomized sets of photographs using the 5-point Global Aesthetic Improvement Scale (GAIS) (1: very much improved, 2: much improved, 3: improved, 4: no change, and 5: worsened). Different lighting modes of the images were shown to evaluators, which were chosen based on whichever ones best highlighted the targeted lesion or condition. Safety data and adverse events were recorded throughout the study.

Results

A total of 23 subjects underwent treatment with the novel, variable-sequenced, long-pulsed, 532-nm and 1,064-nm laser with cryogen spray cooling. This included treatment for vascular lesions (39.1%; $n = 9$), pigmented lesions (17.4%; $n = 4$), and vascular and pigmented lesions (43.5%; $n = 10$). At the time of first treatment, the mean age was 53.1 years (R: 25–75 years). Of all subjects, 91.3% ($n = 21$) were women and 8.7% ($n = 2$) were men. For Fitzpatrick skin type, 65.2% ($n = 15$) of subjects were Type II, 30.4% ($n = 7$) were Type III, and 4.3% ($n = 1$) were Type IV.

Subjects had a mean of 3.5 treatments (R: 1–9 treatments). Median treatment interval was 4 weeks (R: 2–8 weeks), whereas follow-up interval was 4 weeks (R: 3–12 weeks). Locations included the face for 56.5% ($n = 13$); neck for 8.7% ($n = 2$); neck and chest for 8.7% ($n = 2$); face and décolleté for 8.7% ($n = 2$); lower extremities, face, and hands for 8.7% ($n = 2$); décolleté and face for 4.3% ($n = 1$); and face, décolleté, and lower extremities for 4.3% ($n = 1$).

All subjects ($n = 23$) were treated using the 532-nm wavelength, and 4 subjects were also treated using the 1,064-nm wavelength during the same session. The mean spot size was 10.5 mm (R: 3–16 mm). Mean fluence was 9.8 J/cm^2 (R: 0.9–51 J/cm^2) for the 532-nm wavelength and 54.9 J/cm^2 (R: 4.8–200 J/cm^2) for the 1,064-nm wavelength. For the 532-nm wavelength, 30.4% ($n = 7$) were treated using the single pulse mode, 8.7% ($n = 2$) with the submillisecond mode, 47.8% ($n = 11$) with the submicrosecond mode, and 13.0% ($n = 3$) with the submillisecond and submicrosecond mode. All treatments were performed with the single pulse mode for the 1,064-nm wavelength.

A total of 38 photographic sets were available for review. According to 4 independent, blinded, physician reviewers, the correct before and after photograph was selected in 94.7%, 92.1%, 84.2%, and 76.3% of cases. Overall, 86.8% were considered to be responders, meaning that at least 3 of the 4 reviewers selected the correct photographs. When assessing GAIS, improvement occurred in 81.6%, 81.6%, 81.6%, and 76.3% of cases. The mean GAIS scores were 2.6, 2.7, 2.8, and 3.0 by the reviewers. The overall mean GAIS was 2.8.

During the study, only expected treatment effects were observed, which included transient erythema and transient edema. All were mild and resolved without any medical intervention. No serious adverse events occurred. The mean pain score during treatment was 2.6 of 10 without any additional pain management strategies, including topical or local anesthesia. All subjects believed the temporary discomfort was tolerable. Overall, 87.0% of subjects reported being very satisfied or satisfied with their treatment and would recommend this treatment to someone else.

Discussion

This novel, variable-sequenced, long-pulsed, 532-nm and 1,064-nm laser with cryogen spray cooling was demonstrated to be effective and safe in the treatment of pigmented (Figure 1) and vascular (Figure 2) lesions. The 532-nm wavelength can treat superficial dermal vessels, whereas the 1,064-nm wavelength can penetrate deeper. The latter wavelength can also target darker hued vessels, such as reticular veins and thicker vascular blebs. The 532-nm

Figure 1. Female subject at baseline (left) and at follow-up (right) after 4 treatments.

Figure 2. Female subject at baseline (left) and at follow-up (right) after 5 treatments.

wavelength can additionally offer improvement in the appearance of pigmented lesions. This device offers clinical versatility with its 2 available wavelengths. It has a relatively high peak power, which can potentially allow for improved destruction of lesions. The integration of cryogen spray cooling to this platform is a safety feature of this solid-state laser. With the adjustable cryogen spray cooling, various parameters can be adjusted, including the duration of cooling pre- and post-pulse and the time period of cooling delay, which can offer increased flexibility. With the avoidance of contact cooling, there is no undesirable medium effect from surface pressure and hair. The surrounding skin can be protected from undesired thermal damage for patient safety.

Unique to this device is the variable sequential pulse technology. Three different pulse structures are available to select from, including the single pulse mode, submillisecond mode, and submicrosecond mode (Figure 3). The single pulse mode delivers even and level energy throughout the duration of the pulse, which can range 0.3 to 40 ms. The submillisecond mode delivers a set of 1.5-ms pulses in succession, and the submicrosecond mode delivers a set of 0.3-ms pulses in succession, both for as long as 5 to 40 ms in total duration. The vast range of sizes of blood vessels and densities of vascular lesions may respond differently to the various pulse structures. Based on thermal relaxation time, larger vessels generally require longer pulse durations, whereas smaller vessels require those that are shorter. For the submillisecond and submicrosecond modes, as the total pulse duration is lengthened, the number of the sequential pulses being delivered is increased, and the total energy is delivered. Early findings suggest that some lesions can respond better to the different pulse modes. However, additional studies are needed to best optimize the selection of pulse mode and treatment parameters based on lesion morphology. Often, the fluence can be decreased with the sequential pulsing modes, which may offer improved versatility and safety.

This novel laser offers several features to increase the speed of treatment and reduce total treatment time. This is especially important when treating large body surface areas or large vascular lesions, such as port-wine birthmarks. The laser spot size is capable of being increased up to 16 mm with a flat-top beam profile, allowing for even energy delivery throughout the treatment area with each pulse and deeper penetration. There is also a rolling tip that can be attached to allow for increased speed and convenience (IntelliTrak Technology). Using this smart tip, physicians can set a predetermined percentage of overlap of the pulses, and the timing of the pulses are automatically adjusted based on the rolling speed of the handpiece to deliver the preset overlap amount. A real-time temperature sensor is also integrated to help monitor skin surface temperatures with each pulse, which can help to avoid inadvertent and undesired bulk heating. In this study, there were no unexpected treatment effects or serious adverse events.

Although limited by the number of subjects treated with various vascular and pigmented lesions, this study demonstrates the early results that can be achieved with this variable-sequenced, long-pulsed, 532-nm and 1,064-nm laser. As the study progressed, the growing clinical data and increased experience using this laser helped to better optimize the laser parameters used with each successive treatment allowing for improved clinical outcomes. A larger

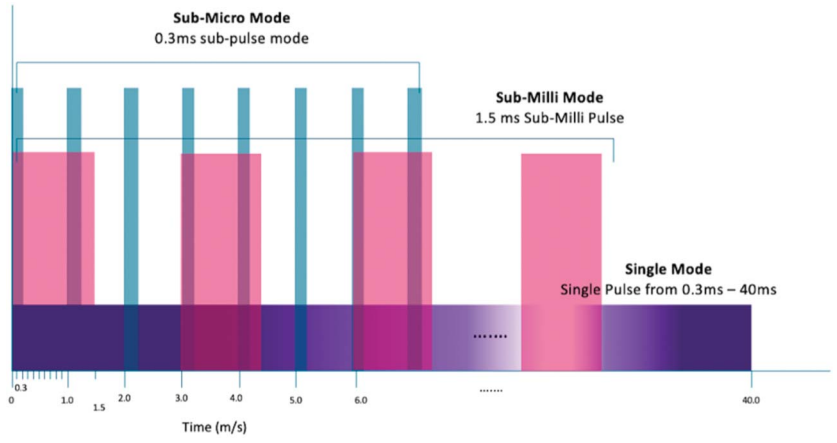

Figure 3. The three pulse structures available with this long-pulsed, 532-nm and 1,064-nm laser depicting single pulse mode, submillisecond pulse mode, and submicrosecond pulse mode.

prospective study is needed to further validate our findings, which should demonstrate improved results using even greater optimized settings.

Conclusion

A novel, variable-sequenced, long-pulsed, 532-nm and 1,064-nm laser with cryogen spray cooling was demonstrated to effectively improve the appearance of vascular and pigmented lesions. This laser was demonstrated to be safe, well-tolerated, and well-liked by subjects.

References

1. Goldberg DJ. Laser removal of pigmented and vascular lesions. *J Cosmet Dermatol* 2006;5:204–9.
2. Hamilton MM. Laser treatment of pigmented and vascular lesions in the office. *Facial Plast Surg* 2004;20:63–9.
3. Geiges ML. History of lasers in dermatology. *Curr Probl Dermatol* 2011;42:1–6.
4. Astner S, Anderson RR. Treating vascular lesions. *Dermatol Ther* 2005;18:267–81.
5. Altshuler GB, Anderson RR, Manstein D, Zenzie HH, et al. Extended theory of selective photothermolysis. *Lasers Surg Med* 2001;29: 416–32.
6. Anderson RR, Parrish JA. Selective photothermolysis: precise microsurgery by selective absorption of pulsed radiation. *Science* 1983;220: 524–7.
7. Jeon H, Bernstein LJ, Belkin DA, Ghalili S, et al. Pulsed dye laser treatment of port-wine stains in infancy without the need for general anesthesia. *JAMA Dermatol* 2019;155:435–41.
8. Geronemus RG. Pulsed dye laser treatment of vascular lesions in children. *J Dermatol Surg Oncol* 1993;19:303–11.
9. Brauer JA, Farhadian JA, Bernstein LJ, Bae YS, et al. Pulsed dye laser at subpurpuric settings for the treatment of pulsed dye laser-induced ecchymoses in patients with port-wine stains. *Dermatol Surg* 2018;44: 220–6.
10. Brightman LA, Geronemus RG, Reddy KK. Laser treatment of port-wine stains. *Clin Cosmet Investig Dermatol* 2015;8:27–33.
11. Geronemus RG, Kauvar AN. The pulsed-dye laser for infantile hemangiomas. *Plast Reconstr Surg* 1996;97:1302–3.
12. Bernstein EF, Lee J, Lowery J, Brown DB, et al. Treatment of spider veins with the 595 nm pulsed-dye laser. *J Am Acad Dermatol* 1998;39: 746–50.
13. Richards KA, Garden JM. The pulsed dye laser for cutaneous vascular and nonvascular lesions. *Semin Cutan Med Surg* 2000;19:276–86.
14. Liu A, Moy RL, Ross EV, Hamzavi I, et al. Pulsed dye laser and pulsed dye laser-mediated photodynamic therapy in the treatment of dermatologic disorders. *Dermatol Surg* 2012;38:351–66.
15. Kelly KM, Choi B, McFarlane S, Motosue A, et al. Description and analysis of treatments for port-wine stain birthmarks. *Arch Facial Plast Surg* 2005;7:287–94.
16. Eichenfield DZ, Ortiz AE. Efficacy and safety of the 532-nm KTP and long-pulsed 1064-nm neodymium-doped yttrium aluminum garnet laser for treatment of vascular malformations. *Dermatol Surg* 2020; 46:1535–9.
17. Becher GL, Cameron H, Moseley H. Treatment of superficial vascular lesions with the KTP 532-nm laser: experience with 647 patients. *Lasers Med Sci* 2014;29:267–71.
18. Clark C, Cameron H, Moseley H, Ferguson J, et al. Treatment of superficial cutaneous vascular lesions: experience with the KTP 532 nm laser. *Lasers Med Sci* 2004;19:1–5.
19. Zawodny P, Stój E, Kulig P, Skonieczna-Żydecka K, et al. VISIA skin analysis system as a tool to evaluate the reduction of pigmented skin and vascular lesions using the 532 nm laser. *Clin Cosmet Investig Dermatol* 2022;15:2187–95.