

Evaluation of the Safety and Efficacy of a Low Fluence, Picopulsed, Alexandrite Laser in a Pico-Toning Technique With a Diffractive Lens Optic for the Treatment of Photodamage and Textural Improvement in “Off the Face” Applications

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ABSTRACT

Background: The diffractive optic coupled with a picosecond pulsed alexandrite laser has been shown to effectively minimize pigmentation while improving the appearance of textural irregularities and rhytides. We evaluated the safety and efficacy of the diffractive optic laser treatment for off of the face applications including the hands and décolletage in a pico-toning technique.

Study: 20 healthy female patients (40-70 years of age) were treated with a picosecond pulsed alexandrite laser with a diffractive lens. 10 of the patients were enrolled in a prospective hand assessment study (20 hands) while the remaining 10 subjects were enrolled in an IRB approved study treating photodamage of the décolletage. Protocol for both groups included 4 treatments to the designated area with a picopulsed alexandrite laser with a diffractive lens on a 6mm handpiece delivering 0.71 J/cm² with 10 Hz repetition at 3 week intervals (+/- 7 days) with follow up at 1 month and 3 months post fourth treatment using standardized digital photography.

Results: Statistically significant improvement in the overall appearance of pigmentation, texture and rhytides were recorded at each subsequent visit and at 1 and 3 months post the final laser treatment. Clinical photographs were evaluated from baseline to the final photo at 3 months post last laser treatment by the treating physician, patient, and an independent evaluator. All hand subjects and chest subjects showed improvement in all 3 areas which were found to be statistically significant. No adverse events occurred in either study group.

Conclusion: These study results show significant improvement in not only pigmentation, but in texture and rhytides in all subjects receiving pico-toning laser treatments to off of the face areas. The laser was well tolerated by all patients with no adverse effects. The use of a diffractive lens optic on a 6 mm fixed spot size handpiece with a picopulsed alexandrite laser, in a pico-toning technique, provides a safe, low fluence, yet effective treatment for not only pigment dyschromia but also textural irregularities and rhytides when treating the hands and décolletage.

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INTRODUCTION

The first picosecond laser was FDA approved in 2012 for the treatment of tattoos and benign pigmentation. Over the next year, adaptations to the laser included the development of a novel diffractive lens array which redistributes light into a multitude of high fluence, focused spots embedded in a low fluence background. These high fluence spots deliver 20 x greater fluence than the low powered background, thus enabling a robust treatment for photorejuvenation while minimizing subsequent adverse effects. This is thought to be partially achieved through the creation of a photoacoustic wave, and the subsequent production of LIOBs (laser induced optical breakdown), which constitutes one of the multiple entities occurring in the skin which research physicians are just beginning to unravel and understand. The link between the presence of the LIOB and the improvement in not only pigmentation, but also dermal collagen, may be a leading factor associated with the benefit of pico-toning in skin revitalization.

The concept of laser toning is not new. In the past, the use of Q-switched neodymium-doped yttrium aluminum garnet laser (QS:YAG) has gained popularity for facial rejuvenation, especially in the Asian population.^{1,2} Laser toning has been primarily focused on the face, due in part to the fact that while off the face applications with low fluence QS:YAG modalities could diminish pigmentation, they could not match the visual improvement of rhytid reduction and textural improvement as seen on facial applications. A recent published article established the safety and efficacy with the use of a picosecond pulsed laser for the décolletage.³ The purpose of our study was to evaluate the efficacy and safety profile for the improvement of pigmentation, skin texture, and rhytid reduction for off of the face applications with a low fluence, pico-toning technique utilizing a diffractive lens optic.

MATERIALS AND METHODS

Twenty healthy female patients aged 40-70 (mean age 55.25) with Fitzpatrick skin type II to IV were treated. Ten of the patients

FIGURE 1. Baseline and 3 months post 4 laser treatments to décolletage with 6mm Focus lens delivering 0.71 j/cm².

were enrolled in a prospective hand assessment study (20 hands) while the remaining ten subjects were enrolled in an IRB approved study for the treatment of photodamage of the décolletage. We combined the data from both studies for “off the face” results for this study.

Exclusionary criteria for both groups included pregnancy, collagen vascular diseases, immunodeficiency, or a suntan in the area of treatment.

Treatments were conducted at the office of Saluja Cosmetic and Laser Center, Huntersville, North Carolina and all subjects were treated by the lead physician. Subjects were informed of treatment protocol and post treatment care and were provided with written consent before participation. All participants consented to sun protection for the duration of the study with the use of physical block sunscreen with an SPF of at least 30.

Subjects were photographed at baseline (prior to treatment), at each subsequent appointment prior to treatment, and at 1 and 3 months post 4th treatment.

Study Protocol

Treatment protocol for both groups were for subjects to receive 4 treatments to the designated area at 3 week intervals (+/-7 days) with follow up visits at 1 month and 3 months post fourth treatment using standardized digital photography. No anesthetic was utilized for the hand subject group. For the décolletage patients, a mixture of lidocaine 7%/prilocaine 7% (Pliaglis, Galderma) was applied for 30 min prior to laser treatment. The laser used in the study was the Picosure Laser, (Cynosure, Westford, MA), a 755 nm picosecond laser using the 6 mm fixed spot size handpiece with the diffractive lens array (FOCUS lens)

FIGURE 2. Baseline and 3 months post 4 laser treatments to décolletage with 6mm Focus lens delivering 0.71 j/cm².

delivering a fluence of 0.71 j/cm² at 10 hz repetition rate. Cold air was administered during the treatment at a low setting of 2-3 (Smartcool, Cynosure, Westford, MA). The average number of pulses per treatment delivered to the hand group was 2425 and the average number of pulses for the décolletage group was 5683. Treatment consisted of 4-6 passes until a clinical endpoint of erythema of the skin and a mild white ash coloration to lentigenes or darkening of dyschromia was observed.

Treatment Evaluation

Each patient treated for the décolletage completed an evaluation form prior to treatment and at 1 and 3 month follow up visits which included subject and investigator satisfaction

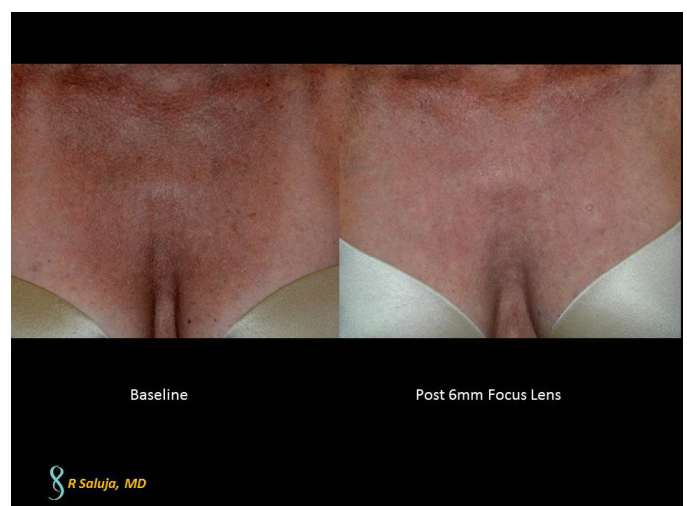
FIGURE 3. Baseline and 3 months post 4 laser treatments to décolletage with 6mm Focus lens delivering 0.71 j/cm².

FIGURE 4. Baseline and 3 months post 4 laser treatments to the dorsum of the hand with a 6mm Focus lens delivering 0.71 j/cm².

questionnaires. At the initial screening evaluation, investigator assessment was tabulated based on a modified Alexiades-Armenakas Comprehensive Grading Scale of Skin Aging with a numerical value assigned to baseline dyschromia, erythema/telangiectasia, keratosis, texture, and rhytides of the areas to be treated and evaluations were again performed at the exit visit. The same photographer took photographs at baseline, prior to each visit, and finally at 1 and 3 month follow up visits. All photos were taken with a Nikon D5100 digital camera.

RESULTS

Throughout this study, patients experienced improvements to the laser treated tissue. Alexiades-Armenakas grading for the

décolleté showed an average improvement of 1.05 at 1 month (down from a baseline of 3.10) and 1.40 at 3 month follow up visits. Investigator satisfaction scores for the décolleté at 3 month follow up was 50% for extremely satisfied and 50% for satisfied. Investigator satisfaction for the hands at 3 months was 30% slightly satisfied and 70% satisfied. There were no ratings lower than “slightly satisfied” in either treatment group. Subject satisfaction was the same for décolleté and hands at 50% very satisfied and 50% satisfied. Investigator Global Aesthetic Improvement Scale ratings at 3 months for décolleté patients showed 40% of patients to be “very much improved,” 30% to be “much improved,” and 30% were “improved.” At the 3 month follow up visit, GAIS on the hands revealed 40% of patients being “much improved” and 60% of the patients being “improved.” All results were found to be statistically significant using a student t-test. No adverse events were recorded.

DISCUSSION

Laser toning has been described in the literature with various non-ablative devices. Perhaps the most popular laser modality utilized for this purpose has been the QS:YAG laser which utilizes low fluence settings in multiple passes to treat both pigmentary issues as well as remodeling the dermis primarily through a combined thermal and photoacoustic response.⁴ The exact mechanism of laser toning on the improvement of pigmentation is yet unknown, however, it has been proposed that melanin granules are fragmented and dispersed into the cytoplasm without cellular destruction by repetitive laser energy with a subphotothermolytic fluence (<5 j/cm²) over large spot sizes.⁵ While subphotothermolytic fluence can aid in minimizing pigmentation, the lower levels of energy may not be high enough to induce thermal or acoustic dermal remodeling to effect textural irregularities on or off of the face. The challenge lies in

FIGURE 5. Baseline and 3 months post 4 laser treatments to the dorsum of the hand with a 6mm Focus lens delivering 0.71 j/cm².**FIGURE 6.** Baseline and 3 months post 4 laser treatments to the dorsum of the hand with a 6mm Focus lens delivering 0.71 j/cm².

trying to balance pigment reduction with the use of low fluence, subphotothermolytic energy as to not induce post inflammatory hyperpigmentation or leucoderma, while still inducing enough thermal elevation in the dermis for neocollagenesis. Extrapolating the benefits of low fluence to the picosecond laser with a diffractive lens, may provide an answer.

In this study, fluences of 0.71 J/cm² were delivered with a diffractive lens optic so that effectively, the 130 microbeams within the lens would deliver 20 x the available energy as compared to the low fluence background. Less than 10% of the tissue is exposed to the higher fluence microbeams, thus allowing practitioners to create dermal collagen remodeling while minimizing risks to the epithelium.

Through histological analysis, Dr. Tanghetti has described the formation of a unique histological lesion termed LIOB (laser induced optical breakdown) which occurs in the epidermis with the use of the diffractive lens but spares epidermal cells around the basal layer and cornified layer of the skin.⁶ He further describes how high energy picosecond pulsed laser light targets melanin where a “lucky” electron is ejected from an absorber causing the number of free electrons to grow in an avalanche process which increasingly absorbs energy while shielding the underlying region, leaving an epidermal vacuole with cellular debris and thus minimizing visual pigmentation.

While these lesions are confined to the epidermal layer, there appears to be alteration of dermal collagen, elastin, and mucin and it is hypothesized that the photoacoustic wave created by the picosecond pulsation causes a cascade, releasing growth factors and inducing up regulation of genes which have a direct effect on fibroblasts.⁷ This unexpected finding begins to explain the revitalization effect and improvement of acne scarring which the device is FDA cleared to treat. In a recent study by Brauer et al, the diffractive lens showed a 24.3% volumetric scar analysis improvement post 6 treatments.⁸ These studies were primarily targeted to the face which has increased adnexal structures when compared to other body areas.

By studying the diffractive optic with a 6 mm handpiece, we found similar clinical findings of pigmentation clearance with improvement of textural irregularities and rhytides on the dorsum of the hand and décolletage. Further studies are warranted on lower limb areas and if indeed collagen stimulation occurs, may provide an important modality for total body rejuvenation.

CONCLUSION

The picosecond pulsed alexandrite laser system with the 6 mm diffractive lens array is a safe and effective method of treatment for skin rejuvenation (rhytides, pigmentation, texture) on body areas off of the face which inherently have fewer pilosebaceous

units. The nature of the pulse duration combined with the diffractive optic allows for the treatment of challenging areas with very little downtime or risk of complications. Further optimization of parameters may be necessary, however all patients treated in this study saw improvements with no issues of adverse events, indicating that the current protocol is sufficient for these types of treatments.

DISCLOSURES

Dr. Saluja received financial support for the décolletage component which was part of an IRB study. The support was the cost of the patient treatment which was given to the patient at no charge. Dr. Saluja did the hands component on her own with no financial support, but did receive technical support for statistical analysis for décolletage and hands. While a different study décolletage has recently been published by another group, (*Lasers Surg Med*, December, 2015) there has not been a hand/décolletage study to date.

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