Evaluation of the Safety and Efficacy of the Picosecond Alexandrite Laser With Specialized Lens Array for Treatment of the Photoaging Décolletage

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Background: Fractionated lasers are routinely used to treat the characteristic cutaneous signs of photoaging. In this study, we evaluate the use of picosecond pulse duration combined with a diffractive lens array for treatment of photodamage of the décolletage.
Methods: Twenty subjects with Fitzpatrick skin types I–IV were enrolled in a prospective open-label trial evaluating the efficacy of the 755 nm picosecond pulsed alexandrite laser with diffractive lens array for treatment of photodamage to the décolletage. Each subject received a series of four laser treatments at 3 week intervals. Follow up evaluation was performed 1 and 3 months later by a masked investigator and consisted of assessment of dyspigmentation, erythema, keratosis, texture, and rhytides on a standardized 5 point scale; global aesthetic improvement 5 point scale; and investigator and subject satisfaction questionnaire. Adverse events and treatment discomfort was also assessed.
Results: Statistically significant improvement in dyspigmentation, keratosis, and skin texture were observed at both 1 and 3 month follow up intervals ($P < 0.05$). rhytides initially demonstrated significant improvement at the 1 month time point, but this significance was not maintained at 3 months ($P = 0.08$). There was no statistically significant improvement noted in erythema. The majority of subjects were satisfied, with a mean rating of 2.8/6 (one being extremely satisfied and six being extremely dissatisfied). Subject pain was 3.6/10.
Conclusion: The 755 nm picosecond pulsed alexandrite laser with diffractive lens array can be an effective option for rejuvenation of the photodamaged décolletage. Lasers Surg. Med. 48:188–192, 2016.

Key words: photodamge; rejuvenation; picosecond; alexandrite; chest; non-ablative; fractionated

INTRODUCTION

Cumulative ultraviolet radiation from the sun damages human skin, causing visible signs of photoaging consisting of changes in skin color, vascularity, texture, and wrinkling. Multiple treatment modalities have been employed to address this concern including lasers, intense pulsed light, radiofrequency, and ultrasound. Ablative skin resurfacing, while effective at treating signs of photoaging, requires extended patient recovery time. In order to help decrease recovery time, non-ablative and fractionated lasers have increased in popularity [1–3].

Q-switched non-ablative lasers (specifically the 1,064 nm), have demonstrated improvement in skin photoaging and rejuvenation [4–6]. The picosecond alexandrite laser, causes both photomechanical and photothermal effects on tissue and produces greater tensile strength than the previous generation of nanosecond lasers [7]. Apart from tattoos, the picosecond alexandrite laser has shown efficacy in treating benign pigmentary lesions such as Nevus of Ota [8] and other pigmented lesions (abstract from ASLMS meeting Chan). Utilizing a specialized diffractive lens array, focal increases in energy density can be delivered within a single spot while maintaining overall fluence at a low level. Via this fractionation, clinical effect can be increased while still maintaining an excellent safety profile. A recent study by Brauer et al. [9] demonstrated the effective use of this technology in the treatment of acne scarring. The aim of this study is to investigate the non-ablative picosecond alexandrite laser with a diffractive lens array for the treatment of the visual signs of photoaging of the décolletage.

MATERIALS AND METHODS

Study Design

This is a prospective, open-label, Institutional Review Board (IRB)-approved clinical trial that was conducted in accordance with the Declaration of Helsinki and the International Conference on Harmonization. The IRB used was New England IRB (NEIRB). Twenty subjects age 18–85 with Fitzpatrick skin type I–IV and a baseline décolletage photodamage composite score of at least moderate-to-severe as previously described [10] were

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enrolled after informed consent was obtained. Subjects were excluded from the trial if they had a history of resurfacing procedures such as laser, medium, or deep chemical peel to the décolletage within the previous 6 months; intense pulsed light or superficial chemical peel within the previous 1 month; or topical therapy with retinoids, imiquimod, 5-fluorouracil, ingenol mebutate, diclofenac, alpha-hydroxy acids, or salicylic acids to the décolletage within the previous 1 month.

Intervention

The 755 nm picosecond alexandrite laser with diffractive lens array (Picosure, Cynosure, MA) was utilized for all treatment sessions. Up to four treatment sessions were delivered at 3 week intervals. Prior to treatment, subject chests were cleansed with 4% chlorhexidine gluconate solution and a thin layer of topical anesthetic ointment consisting of compounded 7% lidocaine and 23% tetracaine was applied for 30 minutes. The anesthetic was then fastidiously removed. Laser energy was applied over the entire treatment area at a fixed spot size of 6 mm, with a fluence of 0.71 J/cm^2 and 10 Hz until a minimum of 3,500 pulses were delivered or a clinical endpoint of moderate erythema was achieved. This was typically achieved in 2–4 passes. There was a 0–10% overlap between each pulse. Discrete pigmentary lesions or rhytides were treated with focused passes to a clinical endpoint of mild greying or frosting. Cold air cooling was applied for comfort as necessary. Following laser treatment, a petrolatum ointment was applied.

Evaluation of Efficacy and Satisfaction

Assessment of photodamage to the décolletage by a blinded, non-treating investigator was performed at baseline, 1 month follow-up and 3 month follow-up time points. At each of these time points, scores between 0–4 were rendered for dyspigmentation, erythema, keratosis, texture, and rhytides as previously described [10]. All investigator evaluations were performed via digital photography except texture evaluation which was performed at each visit. Additionally, a five point global aesthetic improvement scale was assessed at 1 month and 3 month follow-up time points. Subject and investigator satisfaction with treatment was assessed on a six point scale at 1 and 3 month time points.

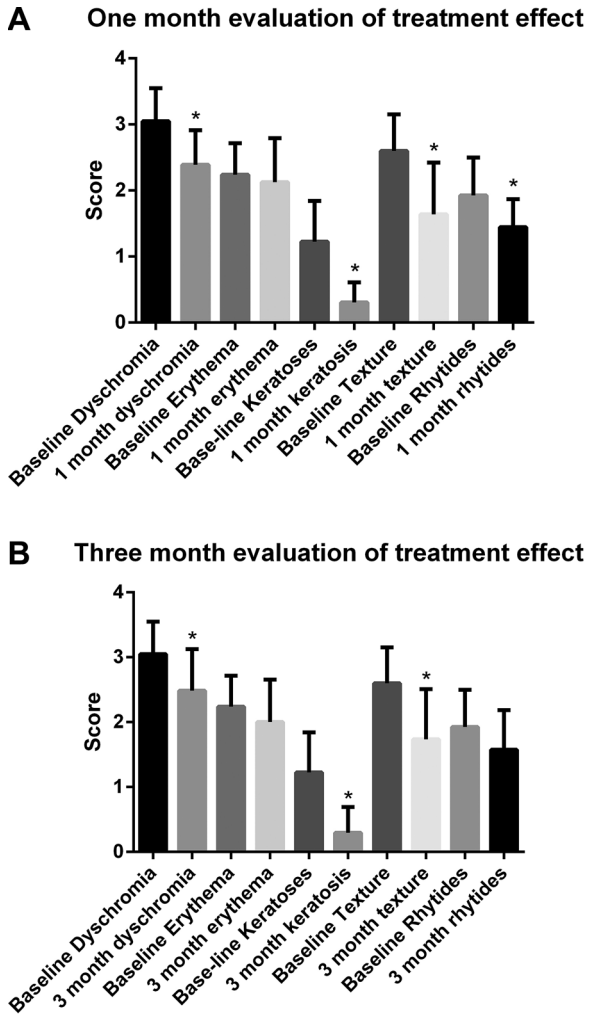

Fig. 1. Rejuvenation of the photodamaged décolletage. **A**: At 1 month post-laser treatment, significant improvements were noted in dyspigmentation, keratosis, texture and rhytides on a standardized 5 point scale ($^*P < 0.05$, $n = 18$, mean ± SD). No significant improvement was seen in erythema. **B**: At 3 month post-laser treatment, significant improvements persisted for dyspigmentation, keratosis, and texture. However, rhytides and erythema were not significantly improved from baseline ($^*P < 0.05$, $n = 17$, mean ± SD).

TABLE 1. Demographic Characteristics

Mean age (min–max, N = 20)	60.5 ± 10.2 (39–80)
Gender N (%)	
Male	1 (5%)
Female	19 (95%)
Baseline photodamage (mean ± SD out of 4)	
Dyspigmentation	3.4 ± 0.4
Erythema	3.0 ± 0.3
Keratosis	1.2 ± 0.6
Texture	2.6 ± 0.6
Rhytides	2.9 ± 0.7
Pulses delivered per treatment (mean ± SD)	6,631 ± 1,915

TABLE 2. Global Aesthetic Improvement Scale

Follow up time point	Global aesthetic improvement evaluation (mean ± SD, out of 5)
1 month	2.6 ± 0.9
3 month	2.3 ± 1.3

1 = very much improved, 2 = much improved, 3 = improved, 4 = no change, 5 = worse.

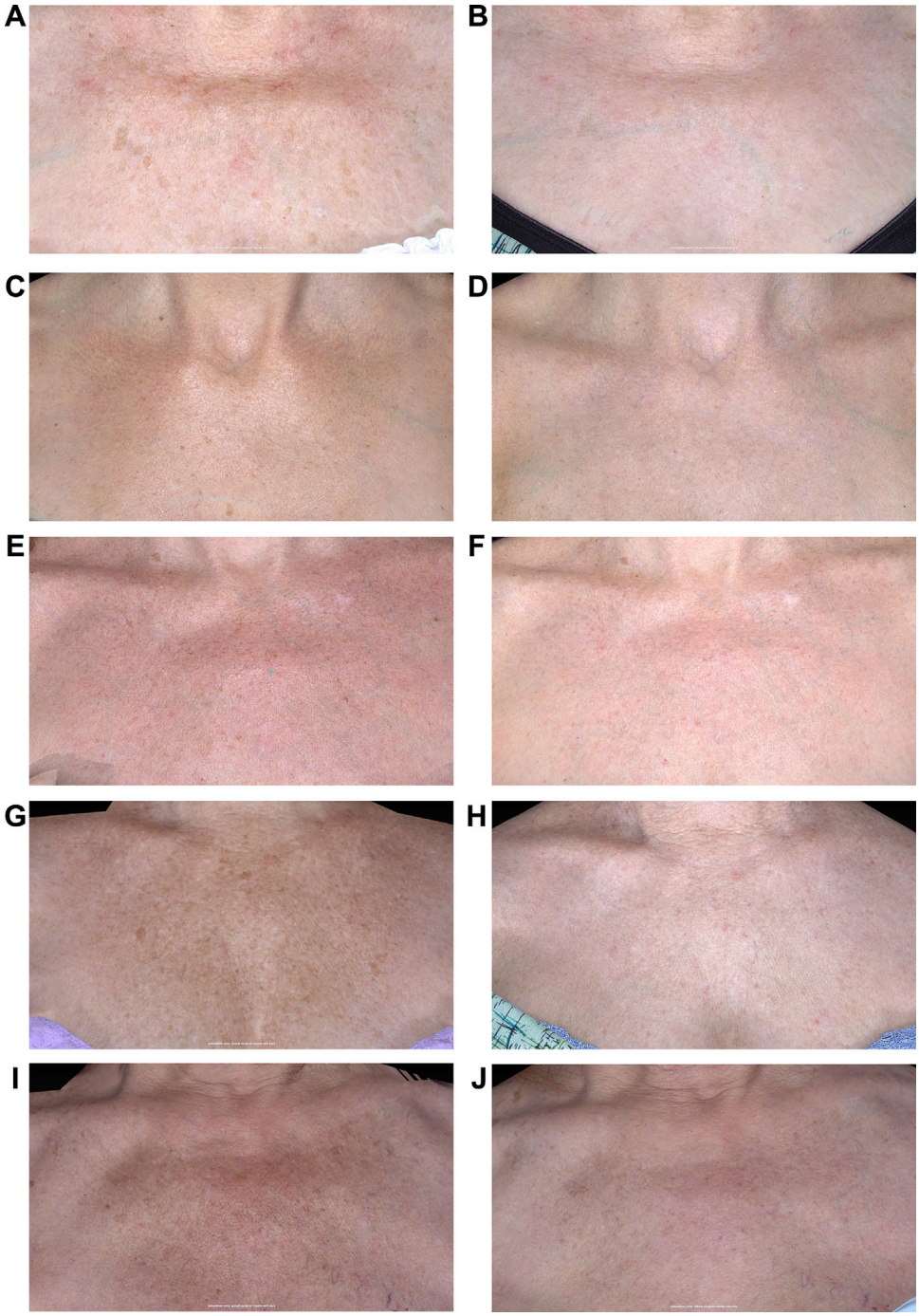

Fig. 2. Before and after laser treatment of the photodamaged décolletage. All photographs were acquired via the stationary Canfield Vectra 3D imaging system and were therefore taken under identical circumstances of lighting, body position, and camera angle. **A**: Eighty-year-old female, skin type I, pre-treatment. **B**: Post-treatment. **C**: Fifty-two-year-old female, skin type II, pre-treatment. **D**: Post-treatment. **E**: Fifty-four-year-old female, skin type II, pre-treatment. **F**: Post-treatment. **G**: Sixty-four-year-old female, skin type III, pre-treatment. **H**: Post-treatment. **I**: Seventy-five-year-old woman, skin type IV, pre-treatment. **J**: Post-treatment.

Evaluation of Safety

Visual analog scales were used to assess burning, stinging, itching, and pain immediately post treatment.

Photographic Documentation

All digital images were taken under identical settings using the stationary Canfield Vectra 3D imaging system to ensure comparability and to eliminate slight variations in lighting, position, and camera angle that are unavoidable with standard 2D photography.

Statistical Analysis

Statistical evaluation was performed with GraphPad Prism 6. The unpaired, two-tailed Student's t test was utilized to determine the difference in means between groups. All data is represented as mean ± SD.

RESULTS

Among the 20 subjects enrolled in the study, 18 completed the 1 month follow up visit and 17 completed the 3 month follow-up visit. The mean age was 60.5 ± 10.2 with 95% of subjects being female. Sixteen subjects underwent the full four treatment sessions, one subject received three treatment sessions, and three subjects received two treatment sessions. A mean of 6,631 ± 1,915 pulses were delivered per treatment. These data, as well as baseline photodamage scores, are represented in Table 1.

Evaluation of Efficacy

Following 2–4 laser treatment sessions, subjects were evaluated at 1 month and 3 month follow-up time points. At 1 month significant improvements were noted in dyspigmentation, texture, keratosis, and rhytides ($P < 0.05$) (Fig 1A). At the 3 month time point, improvement was persistent in all categories except rhytides which demonstrated a trend toward improvement which was not statistically significant ($P = 0.08$, Fig. 1B). Erythema was not consistently improved at any follow up time point evaluation. Global aesthetic improvement was assessed at a mean ± SD of 2.6 ± 0.9 at 1 month and 2.3 ± 1.3 at 3 months indicating that most subjects demonstrated an "improved" to "much improved" result (Table 2). Representative images of before and after treatment are shown in Figure 2A–J.

Evaluation of Satisfaction

Both subject and investigator rated their satisfaction with the treatment regimen at the 1 and 3 month follow-up time points. These evaluations were performed separately so as to avoid one party influencing the other. The reported satisfaction levels demonstrated a high degree of parity and typically were reported in the "slightly satisfied" to "satisfied" range (Table 3).

Evaluation of Safety

Tolerability of the treatment was quantified immediately post-procedure. Burning and stinging was rated at 1.6/3 with zero being none and three being severe. Itching was rated at 0.35/3. On a 10 point visual analog scale, pain was given an average rating of 3.7/10. Adverse events included transient erythema that typically lasted 1–3 days. One case developed an urticarial reaction to the treated areas immediately posttreatment. This resolved acutely with no lasting sequelae. There were no cases of scarring.

TABLE 3. Satisfaction Rating

Follow up time point	Investigator satisfaction (mean ± SD, out of 6)	Subject satisfaction (mean ± SD, out of 6)
1 month	2.5 ± 1.1	2.8 ± 1.4
3 month	2.4 ± 1.4	2.6 ± 1.2

1 = extremely satisfied, 2 = satisfied, 3 = slight satisfied, 4 = slight dissatisfied, 5 = dissatisfied, 6 = extremely dissatisfied.

DISCUSSION

This is the first study to demonstrate the safety and efficacy of the 755 nm picosecond alexandrite laser with diffractive lens array for rejuvenation of the photodamaged décolletage. Because of the decreased density of pilosebaceous units on the chest as opposed to the face, aggressive ablative resurfacing options in this area are often suboptimal with increased risk profile. Therefore, safe, non-ablative treatment modalities are of unique importance when addressing the décolletage.

Three main mechanisms of action are hypothesized to promote the ability of the picosecond pulsed 755 nm alexandrite laser for cutaneous rejuvenation: the short pulse duration enables the delivery of both photothermal and photomechanical effect to treated tissue, the 755 nm wavelength efficiently targets cutaneous pigmentation via selective photothermolysis, and fractionation via the diffractive lens array allows higher focal peak energy to be delivered while maintaining a low overall fluence and therefore excellent safety profile. The micro columns of concentrated laser energy through the diffractive lens have increased fluence whereas the overall fluence delivered in the 6 mm spot remains low at 0.71 J/cm^2. Histologically, these mechanisms translate into increased dermal elastin, collagen, and mucin thus potentially having a positive effect on skin texture and wrinkling. Indeed, alleviation of acne scarring has recently been demonstrated using this technology [9].

This study is limited by its small sample size and open-label nature. Further exploration of this technology should involve prospective controlled comparative trials with other proven treatment modalities such as intense pulsed light and fractionated thulium fiber laser [11]. Comparisons between fractionated and non-fractionated picosecond and Q-switched lasers would also be of interest.

REFERENCES

1. Alexiades-Armenakas M. Rhytides, laxity, and photoaging treated with a combination of radiofrequency, diode laser, and pulsed light and assessed with a comprehensive grading scale. J Drugs Dermatol 2006;5(8):731–738.

2. Alexiades-Armenakas MR, Dover JS, Arndt KA. Fractional laser skin resurfacing. J Drugs Dermatol 2012;11(11):1274–1287.
3. Rabe JH, Mamelak AJ, McElgunn PJ, Morison WL, Sauder DN. Photoaging: Mechanisms and repair. J Am Acad Dermatol 2006;55(1):1–19.
4. Gold MH, Sensing W, Biron J. Fractional Q-switched 1,064-nm laser for the treatment of photoaged-photodamaged skin. J Cosmet Laser Ther 2014;16(2):69–76.
5. Huo MH, Wang YQ, Yang X. Split-face comparison of intense pulsed light and nonablative 1,064-nm Q-switched laser in skin rejuvenation. Dermatol Surg 2011;37(1):52–57.
6. Luebberding S, Alexiades-Armenakas MR. Fractional, non-ablative Q-switched 1, 064-nm neodymium YAG laser to rejuvenate photoaged skin: A pilot case series. J Drugs Dermatol 2012;11(11):1300–1304.
7. Saedi N, Metelitsa A, Petrell K, Arndt KA, Dover JS. Treatment of tattoos with a picosecond alexandrite laser: A prospective trial. Arch Dermatol 2012;148(12):1360–1363.
8. Chesnut C, Diehl J, Lask G. Treatment of Nevus of Ota with a Picosecond 755-nm Alexandrite laser. Dermatol Surg 2015;41(4):508–510.
9. Brauer JA, Kazlouskaya V, Alabdulrazzaq H, Bae YS, Bernstein LJ, Anolik R, Heller PA, Geronemus RG. Use of a picosecond pulse duration laser with specialized optic for treatment of facial acne scarring. JAMA Dermatol 2015;151(3):278–284.
10. Alexiades-Armenakas M. A quantitative and comprehensive grading scale for rhytides, laxity, and photoaging. J Drugs Dermatol 2006;5(8):808–809.
11. Wu DC, Friedmann DP, Fabi SG, Goldman MP, Fitzpatrick RE. Comparison of intense pulsed light with 1,927-nm fractionated thulium fiber laser for the rejuvenation of the chest. Dermatol Surg 2014;40(2):129–133.