Safety of a picosecond laser with diffractive lens array (DLA) in the treatment of Fitzpatrick skin types IV to VI: A retrospective review

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Background: Laser therapy in patients with skin of color is associated with an increased rate of complications. The 755-nm picosecond laser with the diffractive lens array (DLA) has been used for the treatment of scars, striae, and rejuvenation. By delivering high energy to focused areas, the DLA minimizes complications.

Objective: This study explores the adverse events associated with treatment with the 755-nm picosecond laser with DLA in individuals with Fitzpatrick skin type IV to VI.

Method: A retrospective chart review of patients treated with the 755-nm picosecond laser with DLA with a standardized spot size of 6 mm, fluence of 0.71 J/cm^2, and pulse width of 750 to 850 picoseconds was performed. Standard clinical photographs were obtained before treatment and at follow-up. Treatment sites were assessed for dyspigmentation, erythema, edema, and herpetic lesions.

Results: A total of 56 patients with Fitzpatrick skin type IV to VI, atrophic and hypertrophic scars, and pigmented lesions or striae were included. Ten patients (17.9%) were lost to follow-up. Transient adverse events, most commonly erythema and hyperpigmentation, were reported after therapy; these resolved in all cases.

Limitations: Retrospective design is a limitation.

Conclusion: The 755-nm picosecond laser with the DLA device may be a safe therapeutic alternative for unwanted scars, pigmented lesions, and striae in patients with skin of color. (J Am Acad Dermatol 2016;74:931-6.)

Key words: cutaneous laser; diffractive lens array; picosecond laser; postinflammatory hyperpigmentation; safety; skin of color.

Laser therapy in patients with skin of color is challenging because of a high risk for unwanted side effects. Darker-skinned patients have increased epidermal melanin content[1] and the melanosomes tend to be larger and nonaggregated

Abbreviations used:

DLA: diffractive lens array
LIOB: laser-induced optical breakdown
PIH: postinflammatory hyperpigmentation

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compared with lighter-skinned patients.[2,3] The increased melanin can absorb the laser energy, increasing thermal injury to surrounding tissue and result in dyspigmentation, textural changes, and scarring.

In addition to causing unwanted side effects, the higher pigment content competitively absorbs the laser energy decreasing treatment efficacy.[4] Therefore, when treating individuals with Fitzpatrick skin type IV to VI proper selection of a laser and treatment parameters that minimize epidermal and dermal injury is crucial. Longer wavelengths, cooling devices, and lower treatment fluences have been shown to minimize complications.[1,5,6]

CAPSULE SUMMARY

- Laser therapy in patients with skin of color can be associated with adverse events.
- Treatment with the 755-nm picosecond laser and diffractive lens array in patients with Fitzpatrick skin type IV to VI resulted in no permanent complications.
- This device may offer a safe treatment modality for scars, pigmented lesions, and striae in darker skin types.

Currently, there is no consensus on the standard of care for the treatment of scars, photoaging, striae, and pigmented lesions with lasers. The literature on the efficacy and safety of laser therapy in patients with skin of color remains limited. Fractional nonablative laser resurfacing and fractional ablative lasers have been shown to be effective for the treatment of acne scars,[7-9] photorejuvenation,[10] striae,[11-13] and melasma.[14,15] There is, however, still a substantial risk for postinflammatory hyperpigmentation (PIH) with fractional lasers, especially with ablative lasers.[16,17] Recent studies have reported a low occurrence of PIH with the use of nonablative fractional lasers for acne scars when conservative treatment parameters are used.[17,18] Q-switched lasers have shown some efficacy for the treatment of pigmented lesions such as freckles,[19] nevus of ota,[20] and Hori macules[21] in patients with dark skin.[22] Studies using the Q-switched neodymium:yttrium-aluminum-garnet, Q-switched alexandrite, and Q-switched ruby lasers in patients with skin of color have demonstrated an approximately 10% to 25% risk of PIH.[19,23-25]

The Food and Drug Administration approved the use of a 755-nm alexandrite picosecond laser (Cynosure, Westford, MA) for the treatment of unwanted tattoos and pigmented lesions in all skin types in 2012. In 2014 the 755-nm picosecond laser with the diffractive lens array (DLA) received clearance for the treatment of acne scars and wrinkles in skin types I to IV. The picosecond laser delivers short pulse bursts of energy to the skin in the picosecond range. Picosecond pulses effectively confine the energy delivered to the target producing photothermal effects in addition to significant photomechanical effects.[26-28] The intense photomechanical impact successfully fragments ink and pigment particles. By delivering picosecond pulses, lower fluences of energy are needed for effective treatment.[27,29] Treatment with lower fluences is thought to decrease epidermal injury and risk of dyspigmentation.[1,6]

The DLA is an optical hand attachment for the 755-nm picosecond laser that allows for the delivery of focal zones of highly concentrated energy (Fig 1). The array is composed of approximately 120 tightly packed diffractive lenses that are evenly separated 500 μm from each other. Each microbeam releases high levels of energy to focused areas that are evenly dispersed over a set spot size. The fluence of 0.71 J/cm^2 is the average fluence over the entire treated area. In the high-energy zones the fluence is approximately 14 to 15 J/cm^2 for the 6-mm spot size DLA. With the DLA, less than 10% of the skin is exposed to high fluence while the surrounding skin is treated with lower fluence, thus minimizing collateral damage.

By delivering high-powered pulses in the picosecond range to concentrated areas, the 755-nm picosecond laser with DLA is thought to decrease the amount of unwanted side effects. This retrospective chart review examines the rate of and characterizes the adverse events in patients with Fitzpatrick skin type IV to VI treated with the 755-nm picosecond laser with DLA.

METHODS

The Essex Institutional Review Board approved this study (PICOSAFETY2014). This was a retrospective nonrandomized study of patients with Fitzpatrick skin type IV to VI who received treatment with the 755-nm picosecond laser with DLA. Patients were recruited from a single private practice by chart review from November 2011 to September 2014. Inclusion criteria included age greater than 18 years, Fitzpatrick skin type IV to VI, and treatment with the 755-nm picosecond laser with DLA. The Fitzpatrick skin type was assigned by the study investigator. The Fitzpatrick skin type was based on answers to a sun-exposure reaction questionnaire and the investigator's objective determination, or on photographic review. Photographs were taken before initial laser treatment and at follow-up visits. The spot size and

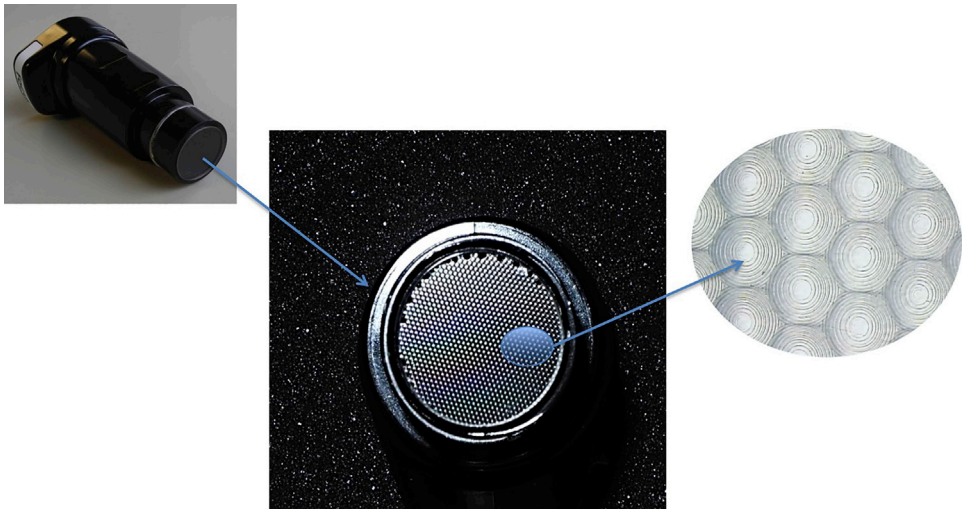

Fig 1. Specialized optic attachment delivers pulses that are evenly distributed 500 μm apart.

fluence are fixed treatment parameters for this handpiece and cannot be adjusted. All patients were treated with a spot size of 6 mm, fluence of 0.71/cm^2, repetition rate of 5 Hz, and pulse width of 750 to 850 ps. For facial cases 3000 to 7000 pulses were delivered to the entire face, for an average of 2 to 4 passes. The clinical end point was epidermal whitening, erythema, or edema.

Extracted information included: patient age; patient gender; Fitzpatrick skin type; medical history; treatment indication; treatment site; previous treatment for same indication; previous adverse events; concomitant treatments such as intralesional triamcinolone acetonide with or without 5-fluorouracil injections, chemical peels, or laser treatments for the same indication; number of treatments with the 755-nm picosecond laser with DLA; anesthesia requirements; adverse events; length of adverse events; and valacyclovir administration.

RESULTS

Patient population

Fifty-six patients with Fitzpatrick skin type IV to VI were identified as having undergone treatment with the 755-nm picosecond laser with DLA during the period of November 2011 to September 2014. Of these, 47 were women and 9 were men. The average age was 33.5 years. Of those treated, 35 (62.5%) were categorized as having type IV skin, 12 (21.4%) had type V skin, and 9 (16.1%) had type VI skin. Treatment indications included acne scars (54.5%) (Figs 2 and 3) and other scars (5.20%), specifically 1 atrophic and 2 hypertrophic scars. Striae accounted for 29.8% of the treatments. Pigmented lesions accounted for 10.5% of the treatments: 4 patients with dyschromia, 1 café-au-lait macule, and 1 nevus of Ota. Eighteen patients (32.1%) received previous laser treatments or chemical peels for the same indications; none reported dyspigmentation from prior treatments. Four patients (7.14%), all being treated for acne scars, received concomitant treatments for their scars. One patient was treated with intralesional triamcinolone acetonide. Another patient received intralesional triamcinolone and 5-fluorouracil injections, in addition to treatments with the pulsed dye laser. The third patient was treated with the pulsed dye laser. The fourth patient who received concomitant treatments had chemical peels and a nonablative fractional laser treatment. The 4 patients with concurrent treatments did not report any adverse events after treatment with the 755-nm picosecond alexandrite laser with DLA. The average number of treatments was 3.05 (range 1-13 treatments). In all, 25 patients (44.6%) requested anesthesia. A total of 22 received topical anesthesia with lidocaine 2.5% and prilocaine 2.5% cream, 4% lidocaine cream or 20% benzocaine, 6% lidocaine, or 4% tetracaine cream. Three patients received local anesthesia with 1% lidocaine with epinephrine a few minutes before the procedure. Pain score was not recorded for most patients, however no treatments were discontinued for excessive discomfort. Ten patients (17.9%) were lost to follow-up after the first treatment.

Adverse events

Transient side effects included hyperpigmentation, erythema, edema, crusting, or scabbing. Seven patients reported erythema, 6 patients reported hyperpigmentation, 1 patient reported scabbing, and 3 patients reported edema after treatment with the 755-nm picosecond laser with DLA. These temporary adverse events resolved within 2 weeks, usually within a few days. The transient side effects were

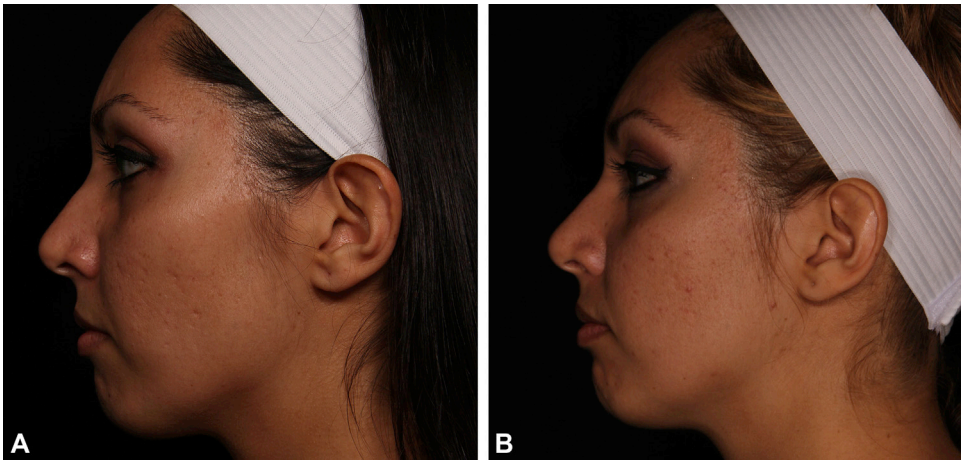

Fig 2. Patient with Fitzpatrick skin type IV treated with the 755-nm picosecond laser with diffractive lens array for acne scars before (**A**) and 3 months after (**B**) the sixth treatment.

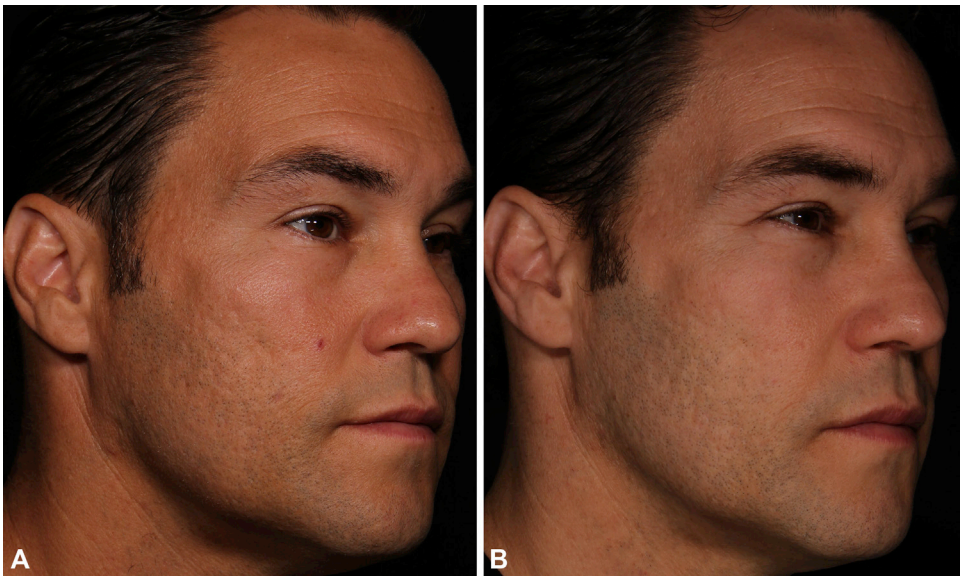

Fig 3. Patient with Fitzpatrick skin type IV treated with the 755-nm picosecond laser with diffractive lens array for acne scars before (**A**) and 1 month after (**B**) the sixth treatment.

either self-reported by the patient and documented in the medical record or in a few select cases described by the health care provider at follow-up. Two patients (4.35%), each treated 1 time with the 755-nm picosecond laser and DLA, reported hyperpigmentation that took 1 month to resolve. One of these patients was Fitzpatrick skin type V and received treatment for a hyperpigmented and hypertrophic lesion on her leg. The other patient had Fitzpatrick skin type IV and received treatment for striae on her thigh. Another patient with Fitzpatrick skin type IV received 6 treatments to her right buttock and right thigh and 5 treatments to the back of her right leg with the 755-nm picosecond laser with DLA for unwanted striae. Hyperpigmentation was observed on the back of her leg after her fifth treatment but resolved 2 to 3 months after the fifth and final treatment on the back of her leg.

A subset of patients were instructed to apply a topical mid-potency steroid 2 times a day for 3 days after treatment. Prophylactic valacyclovir was reserved for patients who received laser treatments on their face. Eleven of the 33 patients who received laser treatment on their face were given prophylactic valacyclovir after the procedure. No patient reported a herpetic outbreak.

DISCUSSION

There is a significant demand for cosmetic laser treatments in general, and in patients with skin of color specifically. The number of dark-skinned patients requesting cosmetic procedures in the

United States continues to increase. In 1999, 14% of the 4.6 million surgical and nonsurgical aesthetic procedures were performed on non-Caucasians.[30] The percentage of aesthetic procedures performed on ethnic minorities increased to 22% in 2013.[31]

The 755-nm picosecond laser has been shown to be an effective treatment for unwanted tattoos, specifically those with green and blue pigment.[28] Although the side-effect profile of the picosecond laser is believed to be low, there is still a risk of hypopigmentation in patients with tattoo, especially in those with darker skin. In part the development of DLA was intended to allow practitioners to safely treat patients with skin of color.

Our group reported the efficacy of the 755-nm picosecond laser and DLA for facial acne scarring.[32] Improvement in the pigmentation and texture of uninvolved skin was also observed, suggesting other potential uses for the 755-nm picosecond laser and DLA.[32]

It is believed that the high energy delivered by the 755-nm picosecond laser with the DLA targets melanin and is absorbed by intraepidermal melanocytes within the epidermal focal zone.[33] Within these localized zones, an electron avalanche breakdown alternatively termed "laser-induced optical breakdown" (LIOB) forms. These LIOBs are confined to the intraepidermis and have been demonstrated on histology.[34] The high fluence in these concentrated zones is designed to excite an electron that in turn leads to a cascade activation of nearby electrons. This phenomenon is referred to as "electron avalanche breakdown." Once LIOB is formed it absorbs most of the subsequent incoming laser irradiation. Normally 755-nm irradiation propagates into the dermoepidermal junction and dermis. However, when LIOB is present it causes a very localized and superficial absorption of the applied laser irradiation. Therefore, excessive radiation does not reach the dermoepidermal junction, protecting pigment, and minimizing collateral damage.

It has been hypothesized that the energy absorbed by the LIOBs is efficiently converted into pressure waves that propagate into the dermis. This barotrauma may lead to changes in the dermis that result in dermal improvement.[34] It has also been suggested that pressure waves cause a temporary period of enhanced cellular membrane permeability, which may or may not enhance cell signaling and result in a cytokine cascade. Which of these effects predominate—pressure injury or cell signaling—needs further investigation.

Our results demonstrate that the 755-nm picosecond laser with DLA may be a safe way to treat scars, pigmented lesions, and striae in darker skin types. Patients reported minimal to no downtime and in all cases the side effects were transient. Hyperpigmentation was the only adverse event that did not resolve within a few days. Three patients (6.52%) demonstrated PIH that cleared within 3 months without any intervention. Importantly, there were no reports of prolonged facial dyschromia even though over 50% of the treatments involved the face. Of note, the 3 patients with prolonged hyperpigmentation received treatment on their lower extremities. PIH on the lower extremities is thought to take longer to heal compared with other locations on the body.[35]

A subset of our patients was instructed to apply a topical mid-potency steroid twice daily for 3 days posttreatment. Treatment with the 755-nm picosecond laser with DLA can lead to transient erythema, edema, crusting, and scabbing. The inflammatory mediators and reactive oxygen species that are released after epidermal injury or a reactive skin response is believed to trigger the production of melanin.[36,37] Topical steroids may help reduce the inflammatory response after laser treatment and therefore prevent melanin overproduction and lower the risk for pigmentary alterations.[37]

There are limitations to this study. It is a retrospective chart review and therefore a reporting bias may exist. Several patients were treated with the 755-nm picosecond laser and DLA and then did not return for a follow-up examination or additional treatments; therefore there is a potential for adverse events of which we were never aware. In addition, the severity and exact time course of transient side effects were difficult to grade as they were often reported by the patient but resolved before physician evaluation. Concomitant treatments are a confounding variable that may confuse the clinical picture when evaluating both efficacy and safety. Any adverse events that were present at follow-up were evaluated and documented by a health care provider.

Conclusion

This retrospective analysis demonstrates the safety of the 755-nm picosecond alexandrite laser with DLA in patients with Fitzpatrick skin type IV to VI. No serious adverse events were reported. Hyperpigmentation, the most common side effect, was transient in all cases. This device offers a new and potentially safe therapeutic modality for scars, pigmented lesions, and striae in patients with Fitzpatrick skin type IV to VI.

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