



Editor's Choice

A Prospective, Split-Face, Randomized Study Comparing a 755-nm Picosecond Laser With and Without Diffractive Lens Array in the Treatment of Melasma in Asians

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Background and Objectives: Treatment of melasma with lasers remains a challenge due to its limited clinical efficacy in addition to high rates of recurrence and side effects. Recently, picosecond lasers have shown favorable results in treatment of benign pigmented lesions. To compare the efficacy and safety of using a 755-nm picosecond laser for the treatment of melasma in a split-face manner, having one side treated with a fractionated beam (diffractive lens array [DLA] coupling) and with a full-beam (flat optics) on the other side.

Study Design/Materials and Methods: Eighteen subjects presenting with mixed-type melasma were enrolled. Each patient was randomly treated with a 755-nm picosecond laser coupled with DLA on one side of the face and without DLA (flat optics) on the other side. The laser was delivered through an 8-mm spot size with an average fluence of 0.4 J/cm^2 at 2.5 Hz for a total of two passes without pulse overlapping. All subjects received five monthly treatments. Subjective (clinical evaluation) and objective (color readings) assessments on the degree of pigment clearance and adverse effects were obtained at 1-, 3-, and 6-month after the final treatment.

Results: At 6 months after the last treatment, physician-rating scores were 1.50 ± 0.76 and 1.50 ± 0.65 of the DLA and flat-optics sides, respectively. Pigment clearance significantly improved from 1 to 6 months after the treatment on each side ($P = 0.019$ on DLA and $P = 0.023$ on flat-optics sides). No statistically significant differences in physician-rating scores between the two treatment techniques were observed at all follow-up visits. Objective assessments of melasma clearance corresponded to the clinical evaluation. However, the full-beam (flat optics) provided lower incidence of postinflammatory hyperpigmentation than the fractionated one.

Conclusions: A 755-nm picosecond laser is safe and effective for the treatment of melasma in dark-skinned individuals. The use of DLA does not provide additional benefit over the flat optics in clearing pigmentation. Lasers Surg. Med. © 2020 Wiley Periodicals LLC

Key words: Asians; diffractive lens array; melasma; picosecond laser treatment; 755 nm

INTRODUCTION

Melasma is a common and well-described dermatological condition that primarily affects females, especially those with darker-skinned phototypes [1]. The condition is otherwise asymptomatic and there are no clear associations with any systemic illnesses. Nevertheless, melasma can be psychosocially detrimental to affected patients. Traditional treatment approaches with topical medications and chemical peels are commonly used, but due to the refractory and recurrent nature of melasma, patients often seek alternative treatment modalities such as laser and light therapy. These devices have been used for the treatment of melasma with varying degrees of success, but are associated with a high level of recurrence over time and some with an increased risk for postinflammatory hyperpigmentation (PIH) or hypopigmentation [2–4].

Picosecond lasers are currently available with laser outputs of 532-, 670-, 755-, 785-, and 1064-nm. At present, there have been limited data published about their efficacy in the treatment of melasma [2,5–7]. More recently, fractionated picosecond handpieces have been developed for the purpose of resurfacing and rejuvenation. Little is known about the benefit of fractionated beams of picosecond-pulsed lasers for this indication. Due to the inherent characteristic of picosecond lasers to work via photoacoustic mechanisms, they potentially present a new treatment modality that may be suitable for patients with melasma.

The objective of the present study is to compare the efficacy and safety of a fractionated beam (diffractive lens array [DLA]) and a full-beam (flat optics) of a 755-nm picosecond laser for the treatment of melasma using subjective and objective clinical evaluation.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

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Fig. 1. (A) Fifty-five-year-old woman (FST V) with mixed-type melasma (A) at baseline on the left side, (B) at 1 month after five treatments with 755-nm picosecond laser without DLA (flat optics), (C) 3 months after treatment, and (D) 6 months after treatment; (E) at baseline on the right side, (F) at 1-month after five treatments with 755-nm picosecond laser coupled with DLA, (G) 3 months after treatment, and (H) 6 months after treatment. Note the continued improvement from 1 to 6 months after the final treatment. DLA, diffractive lens array; FST, Fitzpatrick skin types.



Fig. 1. Continued

MATERIALS AND METHODS

This randomized, controlled, split-face, prospective study was conducted at a tertiary academic skin laser center of a university hospital. The study protocol was approved by the Institutional Review Board of the Faculty of Medicine Siriraj

Hospital, Mahidol University, Bangkok, Thailand (Si 392/2019). Written informed consent was obtained from all study participants prior to the treatment. A total of 18 females with Fitzpatrick skin types (FST) IV and V presenting with mixed-type melasma were enrolled. Mixed-type melasma is defined

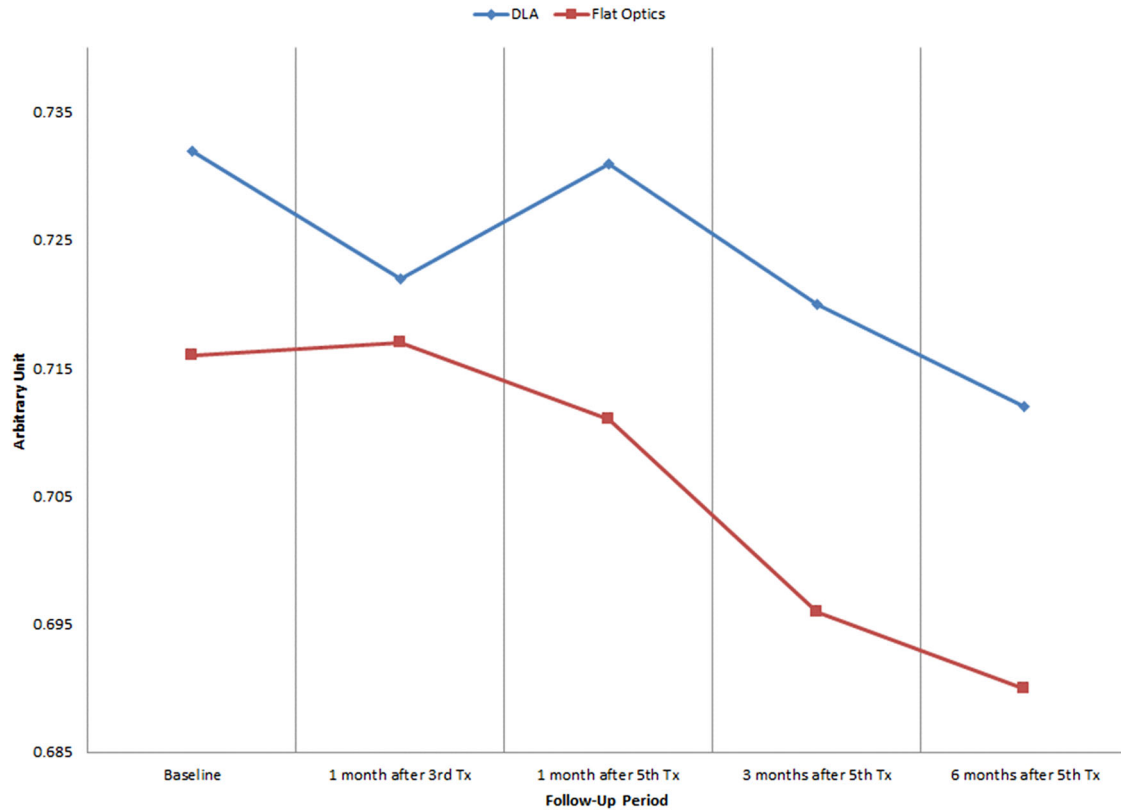


Fig. 2. Average melanin content measured using Antera® 3D CS at baseline and 1, 3, and 6 months after five treatments with 755-nm picosecond laser. No statistically significant differences in melanin content measurements between treatment sides were observed at all follow-up visits. The gradual improvement was noted at 1–6 months after the final treatment.

as that presenting with deposition of melanin in both the epidermis and dermis, which under Wood's lamp examination shows increased fluorescence in some skin regions, but not in all [8]. All patients did not receive any other treatment during the period of the study. Exclusion criteria included subjects under the age of 18 or over the age of 65, those who had used bleaching creams, chemical peels, or laser treatments within the past 6 months prior to enrollment, those who were pregnant or breastfeeding, and those who were on oral contraceptive pills. All subjects were prohibited to use any topical or systemic corticosteroids, vitamin A derivatives, bleaching creams or undergo any facial procedures throughout the duration of the study. They were likewise advised to maintain the same facial skincare products, and daily use of a broad-spectrum sunscreen with SPF 50 on the face. Birth control measures other than oral contraceptives were required for women in the reproductive age.

Intervention

Each of the 18 subjects was randomly treated with a 755-nm picosecond laser (PicoSure®; Cynosure, Westford, MA) coupled with a DLA on one side of the face and without DLA on the other side (flat optics). The randomization was done by using a block randomization plan generated from the website www.randomization.com. The laser with a pulse-

duration of 750 picoseconds was delivered through an 8-mm spot size with average fluence of 0.40 J/cm^2 at 2.5 Hz for a total of two passes without pulse overlapping under cold air-cooling device (Cryo 6; Zimmer Aesthetics, Neu-Ulm, Germany). All subjects received five treatments at 1-month intervals.

Evaluation

Objective and subjective evaluations on the degree of pigment clearance and adverse effects were obtained at baseline, 1-month after the third treatment and 1-, 3-, and 6-month after the final (fifth) treatment. Objective evaluation included measurement of melanin content, melanin index (M.I.) and area of melasma using a skin imaging device (Antera® 3D CS; Miravex Limited, Dublin, Ireland), melanin reflectance spectrometry (Mexameter® MX18; Courage-Khazaka, Koln, Germany), and an image analysis program (ImageJ; National Institutes of Health, Bethesda, MD and the Laboratory for Optical and Computational Instrumentation, Madison, WI), respectively.

Blinded observers evaluated the degree of pigment clearance by comparing baseline photographs with post-treatment photographs. Standardized photographs were taken from the front and sides of both cheeks using a clinical imaging system (VISIA®-CR; Canfield Scientific,

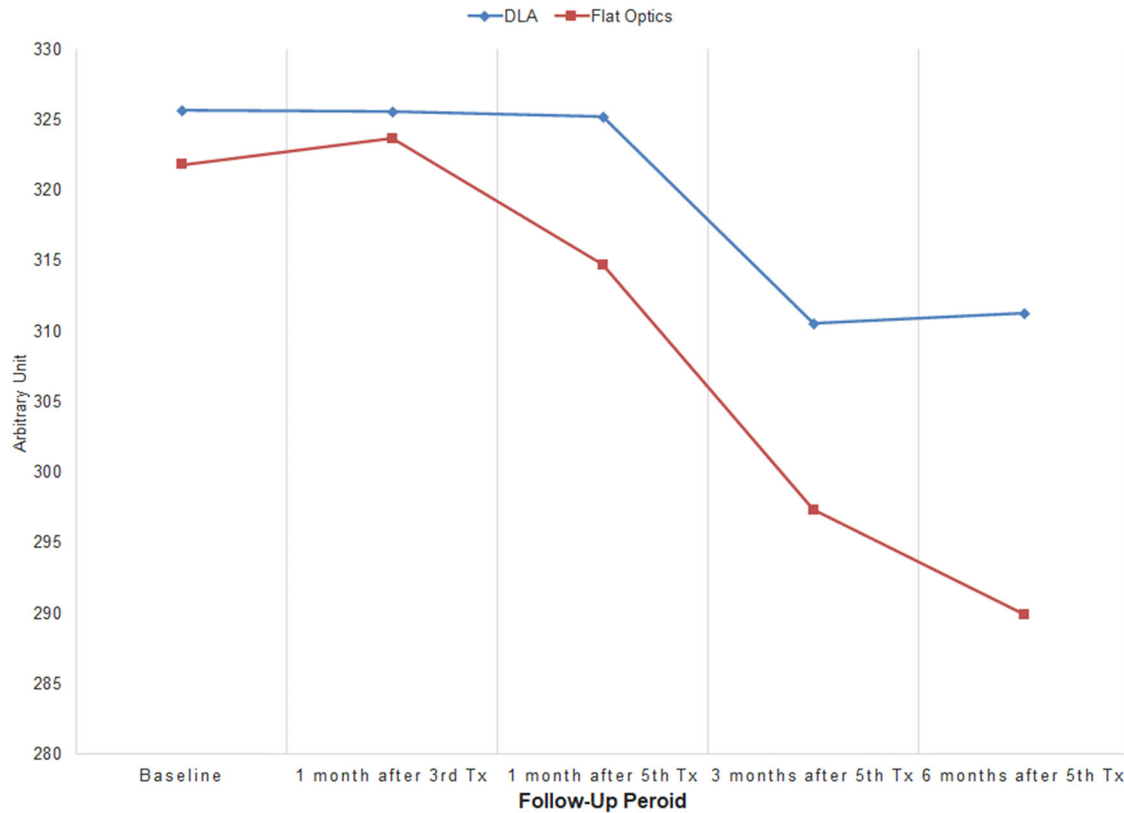


Fig. 3. Average Melanin Index (M.I.) measured by Mexameter® at baseline and 1, 3, and 6 months after five treatments with 755-nm picosecond laser treatment. No statistically significant differences in M.I. between treatment sides were observed at all follow-up visits. There is a notable trend toward improvement at 1–6 months after the final treatment.

Parsippany, NJ). Global percentage of pigment clearance was evaluated over the entire treatment area. Two blinded physicians subjectively assessed the degree of pigment clearance using a quartile grading scale (0 = no improvement, 1 = 1–25% improvement, 2 = 26–50% improvement, 3 = 51–75% improvement, and 4 = 76–100% improvement).

Patient satisfaction was likewise assessed using a quartile grading scale (0 = no improvement, 1 = 1–25% improvement, 2 = 26–50% improvement, 3 = 51–75% improvement, and 4 = 76–100% improvement). Patients were also asked to evaluate pain levels during the treatment for each side using a Visual Analogue Scale (VAS). The scale ranged from 0 (no pain) to 10 (severe pain). Duration of erythematous appearance and adverse effects including the occurrence of any infections, erosions, blistering, scarring, hypopigmentation, and hyperpigmentation of each intervention were recorded. The study subjects were asked to pay an extra office visit if they noticed any signs of adverse effects including discoloration, textural change, and infections.

Statistical Analysis

All continuous variables were expressed as mean (M) \pm standard deviation. Comparison of the same treatment group over two-time points was performed using the

repeated measure analysis of variance. Between-group differences were computed using the paired *t* test at a confidence interval of 95%. Statistical analysis was done using SPSS 24.0 (IBM, Armonk, NY). All probability values were two-tailed and a $P < 0.05$ was considered statistically significant.

RESULTS

Patient Characteristics

The average age of subjects enrolled was 45.5 years (range, 38–63) with FST IV and V. The average duration of presence of melasma was 5.46 ± 3.36 years. Fourteen of the 18 subjects enrolled completed the treatment protocol and were followed up through the end of the study. Four subjects were withdrawn from the study because two had scheduling conflicts and the others were unable to be contacted during follow-up.

Objective Evaluation

There were no statistically significant differences in the baseline values of melanin content ($P = 0.158$), MI ($P = 0.730$), and melasma area ($P = 0.195$) between treatment sides. At 1 to 6 months after the last treatment, measurements of melanin concentration ($P = 0.280$

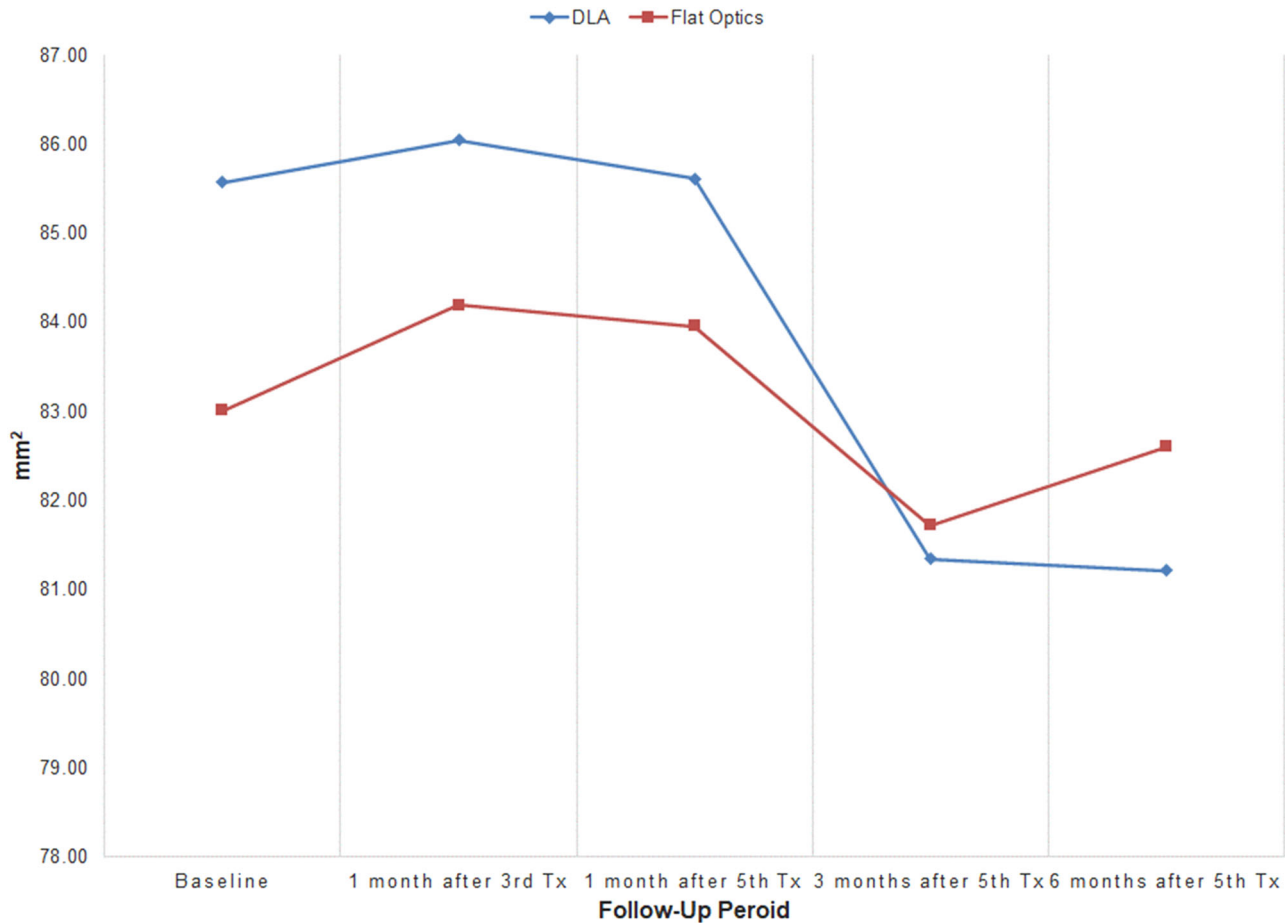


Fig. 4. Average of melasma area analyzed by ImageJ at baseline and 1, 3, and 6 months after five treatments with 755-nm picosecond laser. No statistically significant differences in average melasma area between treatment sides were observed at all follow-up visits. Similar to Figures 2 and 3, there is a notable trend toward improvement at 1–6 months after the final treatment.

on DLA and 0.397 on flat-optic sides), M.I. ($P = 0.758$ on DLA and 0.110 on flat-optics sides), and melasma area ($P = 0.231$ on DLA and 0.057 on flat-optics sides) remained unchanged and showed a trend toward improvement. No statistically significant differences in melanin concentration, M.I., and melasma area measurements between treatment sides were observed at all follow-up visits. However, the clearance of melanin concentration on the flat optics side was statistically better than the DLA side at 3 months after the last treatment ($P = 0.022$). Figures 2–4 demonstrate melanin content, M.I., and melasma area measurements.

Subjective Evaluation

The means of pain scores were 4.36 ± 1.38 and 3.56 ± 1.60 on the DLA and flat-optics sides, respectively. The DLA side was significantly more painful than the flat-optics side ($P = 0.006$). The erythematous appearance after treatment lasted an average of 1.85 ± 0.69 and 0.85 ± 0.55 days on the DLA and flat-optics sides, respectively. The erythematous appearance cleared significantly faster on the flat-optics

side than the DLA side ($P < 0.001$). Mild PIH was observed in 28.6% and 14.3% of the subjects on the DLA and flat-optics sides, respectively. All PIH were transient and resolved spontaneously after 1 month. The development of PIH occurred sporadically and did not correlate with the number of treatments. There were no reports of infection, scarring, or hypopigmentation recorded in this study.

Physician Assessment

After one month of fifth treatment, 7% and 14% of the subjects were rated as nonresponders on the DLA and flat optic sides, respectively. At the 1-month follow-up visit, physician-rating scores were 1.14 ± 0.53 and 1.07 ± 0.61 on the DLA and flat-optics sides, respectively. At 6 months after the last treatment, physician-rating scores were 1.50 ± 0.76 and 1.50 ± 0.65 on the DLA and flat-optics sides, respectively (Table 1). Pigment clearance significantly improved from 1 to 6 months after treatment on both sides ($P = 0.019$ on DLA and $P = 0.023$ on flat-optic sides; Fig. 1). There was no statistically significant difference in physician-rating scores between the two treatment techniques at all follow-up visits.

TABLE 1. Physician Evaluation on the Degree of Melasma Clearance in 14 Subjects Using a Quartile Grading Scale

Follow-up time	Mean \pm SD		<i>P</i> value between group
	DLA	Flat optics	
1 month after 5th treatment	1.14 \pm 0.53	1.07 \pm 0.61	0.336
3 months after 5th treatment	1.50 \pm 0.759	1.50 \pm 0.85	1.000
6 months after 5th treatment	1.50 \pm 0.759	1.50 \pm 0.65	1.000
<i>P</i> value between visit	0.019	0.023	

Assessments were conducted using photographs taken before and 1, 3, and 6 months after fifth treatment by two blinded independent dermatologists.

DLA, diffractive lens array; Quartile Grading Scale (0 = no improvement, 1 = 1–25% improvement, 2 = 26–50% improvement, 3 = 51–75% improvement, and 4 = 76–100% improvement); SD, standard deviation.

Patient Assessment

Patient rating scores at the 1-month follow-up visit were 1.43 ± 1.09 and 1.29 ± 0.91 at the DLA and flat-optics sides, respectively versus 1.57 ± 1.28 and 1.43 ± 1.09 at the end of the follow-up (6 months after five treatments). A trend toward better pigment clearance from 1 to 6 months after the final treatment session on the DLA side was observed ($P = 0.071$ on DLA and $P = 0.397$ on flat-optics sides). There was no statistically significant difference in patient rating scores between the two treatment techniques at all follow-up visits. Table 2 demonstrates the improvement in pigment clearance using a quartile grading scale assessed by the patients at 1, 3, and 6 months after the final treatment comparing DLA and flat-optic techniques.

DISCUSSION

The pathogenesis of melasma remains inconclusive, but the current research suggests that it is a multifactorial condition where pathways of pigment homeostasis are disrupted in the epidermis, extracellular matrix, and dermis [9]. Recent innovations in laser design have introduced a new class of lasers that generate picosecond-domain pulses. Shorter laser pulse durations result in pigment fragmentation that is more a result of photoacoustic than photothermal effects. Therefore, it is hypothesized to be more efficient at pigment removal without inducing excessive thermal damage to the surrounding normal tissue. Thermal damage seems to be the greatest drawback of conventional Q-switched laser

treatment for patients with melasma, and likely the cause of the high incidence of PIH after treatment. A recent systematic review by Wu et al. [10] reported the use of picosecond lasers for melasma in one case series, one prospective open-label trial, four prospective, randomized split-face trials, and one randomized controlled trial and concluded that this modality may be offered as an adjunctive treatment in patients with moderate to severe melasma. However, it was also mentioned that the safety and efficacy of fractionated versus nonfractionated delivery is yet to be confirmed.

The use of low-fluence 1064-nm Q-switched neodymium-doped:yttrium aluminum garnet (Nd:YAG) laser is recognized as an effective and safe treatment for moderate to severe dermal and mixed-type melasma. There is, however, a high likelihood of recurrence when the long-term results are considered, and side effects such as rebound hyperpigmentation and mottled hypopigmentation have been seen particularly in dark-skinned Asian patients [11,12]. Moreover, a split-face trial in 12 Taiwanese patients demonstrated that by using an endpoint of mild erythema and swelling without petechiae, a 755-nm alexandrite picosecond laser provided a faster and better clearance rate for melasma as compared with a 1064-nm QS-Nd:YAG laser [13].

Our study confirms the observation of a recent study investigating the efficacy of a 755-nm picosecond laser with a DLA for treatment of melasma in 20 Taiwanese patients with FST IV using similar treatment parameters to ours but with a repetition rate of 10 Hz.

TABLE 2. Patient-Reported Improvement Using a Quartile Grading Scale at 1, 3, and 6 Months After Fifth Treatment

Follow-up time	Mean \pm SD		<i>P</i> value between group
	DLA	Flat optics	
1 month after 5th treatment	1.43 \pm 1.09	1.29 \pm 0.91	0.336
3 months after 5th treatment	1.21 \pm 1.12	1.36 \pm 1.15	0.165
6 months after 5th treatment	1.57 \pm 1.28	1.43 \pm 1.09	0.165
<i>P</i> value between visit	0.071	0.397	

DLA, diffractive lens array; Quartile Grading Scale (0 = no improvement, 1 = 1–25% improvement, 2 = 26–50% improvement, 3 = 51–75% improvement, and 4 = 76–100% improvement); SD, standard deviation.

In the physicians' evaluation at one month after three treatments, 40% of patients showed good improvement, whereas 40% and 20% of patients showed moderate and mild improvement, respectively [5]. MASI score before and after laser therapy showed significant improvement from 9.0 ± 4.8 to 6.5 ± 3.7 . There were 5% of the study subjects developing mild PIH, which resolved within 3 weeks.

One unifying concept in all the laser and light therapies that have been tested so far is the synergism between topical anti-tyrosinase preparations and the laser and light procedures. In general, pre- and post-treatment topical regimens in conjunction with laser and light procedures help reduce the risk for rebound hyperpigmentation, PIH, and increases the longevity of the lightening effect on melasma [1,3,14]. Controlling risk factors that could aggravate melasma by regular use of sun protection and avoidance of hormonal triggers are also important to maintain the benefits from laser treatment [3,15].

A significant number of patients (~50%) experience recurrence to some degree within 3–6 months of their laser- and light-based procedure regardless of the type of device used [2,14]. However, limitations in interpreting these disparate clinical studies include varied FSTs and patient populations, nonstandardized grading systems used to assess improvement or recurrence and more importantly, very few of these studies are randomized with controls.

In the present study, the maintenance of the clinical outcome was as long as 6 months after the treatment was discontinued without the use of any topical bleaching preparations as post-treatment maintenance. On the basis of the authors' long-term experience in using laser and light therapy for melasma, 755-nm picosecond laser treatment seems to provide longer remission intervals compared with other laser and light options.

In practice, laser procedures are rarely used as a monotherapy for melasma treatment. The beneficial effect of using topical bleaching agents in conjunction with picosecond laser treatments is still inconclusive. A previous prospective, randomized, split-face trial observed a statistically significant difference of modified melasma area severity index scores but no significant difference of melanin index measurements between the side treated with fractional picosecond 1064-nm laser combined with topical hydroquinone 4% cream and the side treated with topical hydroquinone alone [2]. Another randomized, split-face, controlled trial by Choi et al. [6] showed that a picosecond laser with dual wavelengths (1064 and 595-nm) combined with hydroquinone 2% cream had superior efficacy to hydroquinone 2% cream monotherapy (77% of the patients in the combination treatment group showed more than 50% lightening compared with 3% of the hydroquinone monotherapy group). Further randomized controlled trials are necessary to confirm whether the combined use of topical and laser treatments could offer any synergistic outcomes, slow the recurrence of melasma, or decrease the number of treatments necessary to see improvements.

It has been shown that the high energy delivered by the 755-nm picosecond laser equipped with the DLA is absorbed by intraepidermal melanin within the epidermal focal zone. Within these localized zones, an electron avalanche breakdown alternatively termed "laser-induced optical breakdown" produces focal vacuoles in the epidermis [16]. This closed injury is associated with the production of dermal collagen, elastic tissue, and mucin with minimal post-treatment downtime and has been proven effective for the treatment of atrophic acne scars [17,18], pigmented lesions [2], striae [19], and photo-damaged skin [2,20]. In the present study, we did not observe any changes in terms of textural improvement or rejuvenation effects on the DLA (fractionated beam) side. One possible reason for this may be because of the difference of treatment techniques used. We intended to use a conservative technique by performing only two passes of treatment without pulse overlapping in our study while treatment for rejuvenation and atrophic scar purposes is normally done with a more aggressive technique (over 2 passes with 15–20% of pulse overlapping) [20,21]. The benefit of fractional picosecond laser over the full-beam for the treatment of melasma has yet to be confirmed since most of the previous studies were not designed to compare this efficacy [5–7,19]. To the best of our knowledge, the present study is the first study to demonstrate that the full-beam (flat optics) 755-nm picosecond laser provides less downtime and treatment discomfort and offers a comparable clinical outcome and lower incidence of PIH than the fractionated one.

Despite these significant findings, the present study has several limitations. The population size was small because of the difficulties in compliance regarding long-term follow-ups. The total period that each study subject stayed in the study was approximately 1 year. Thailand has 4–5 months of summer a year with a sunny environment that can interfere with the therapeutic outcomes because of the risk of continuous exposure to ultraviolet light.

In summary, the 755-nm picosecond laser is a safe and effective treatment for melasma in dark-skinned individuals, and it can be a good alternative for patients who are refractory to the conventional therapy.

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