Efficacy of diode laser (810 and 940 nm) for facial skin tightening

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Summary

Background Laser treatment has been introduced for facial skin tightening. However, no prior study has used a diode laser to treat facial skin laxity.

Aims To evaluate the efficacy and safety of a 810- and 940-nm diode laser (MeDioStarNeXT) for treating facial skin laxity.

Methods Thirty patients, with facial skin laxity grading scale II-IV, were enrolled in this study. Each patient underwent four sessions with a 810- and 940-nm diode laser (MeDioStarNeXT) treatment over 3-week intervals. Improvement in the laxity of facial skin was evaluated using a Cutometer MPA 580, spectrophotometer, and a grading scale.

Results Significant improvement was observed with the Cutometer F3 and R7 parameters at 1 and 3 months after complete treatment, respectively. Physician assessment showed significant improvement in the laxity scale at 1 and 6 months after treatment. Approximately 10% of the patients reported mild pain or minor adverse events. Ninety-eight percent of the patients were satisfied with the treatments.

Conclusion Treatment with a diode laser (810 and 940 nm) is safe and may be effective for facial skin tightening. Maintenance treatment is necessary to sustain the effect of treatment.

Keywords: diode laser, facial skin laxity, cutometer

Introduction

Skin aging includes two main categories. Intrinsic skin aging is an inevitable change due to telomere shortening and age-related changes in the skin's appearance. Extrinsic skin aging is commonly called photoaging and is due to ultraviolet damage, which is clinically characterized by dyschromia, elastosis, fine rhytides, erythema, telangiectasia, textural changes, and keratoses.¹ Skin laxity is a common cosmetic condition for middle-age patients, which is linked with chronological

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aging and exposure to solar radiation.² Skin elasticity is a property of the skin that allows it to amend and regain shape when stretched or deformed.³ Facial laxity results from a decrease in the skin elasticity, which is clinically characterized by cheek sagging and nasolabial fold formation. Nasolabial fold severity is related to diminished dermal elasticity and an increasing subcutaneous adipose tissue layer.⁴ These changes might induce sagging formation in the upper cheek area and, subsequently, a line or groove is formed. Skin aging may cause psychological problems and prompt patients to seek treatment assistance.

The current treatment options for nonsurgical skin tightening may be classified into 3 main groups based on their targets: (1) infrared (IR) lasers, which target the dermis and induce neocollagenesis, minimizing

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rhytides; (2) intense pulse light (IPL) sources, which target the melanin pigment and blood vessels, improving dyschromia and erythema-telangiectasia, and (3) radiofrequency (RF) devices, which stimulate the collagen contracture, targeting skin laxity.⁵ Studies have been conducted on combination treatments with IR, RF. and/or IPL and diode laser to treat facial skin laxity and rejuvenation, resulting in improvement in the clinical outcomes with minor side effects, such as temporary erythema and edema without scarring or dyspigmentation.^{5–7} A comprehensive grading scale of the severity of various aspects of skin aging, including rhytides, laxity, and multiple components of photoaging, has been used to assess the efficacy of treatment, providing a more quantitative analysis of each category as well as the overall improvement.⁵

The diode laser MeDioStar NeXT (Asclepion Laser Technologies GmbH, Jena, Germany) has a combination of two wavelengths, 810 and 940 nm, and the target chromophores are hemoglobin and water. In selective photothemolysis, water absorbs laser energy, causing a direct thermal effect on the deep dermis, stimulating fibroblasts to promote collagen remodeling. Hemoglobin absorbs the laser energy, which triggers the cutaneous vessels to generate cellular mediators and growth factors that are necessary to produce new collagen bundles.⁷ To the best of our knowledge, no previous studies used diode laser (810 and 940 nm) alone to treat facial skin laxity. Hence, the objective of this study was to evaluate the efficacy and safety of a diode laser with wavelengths of 810 and 940 nm (MeDioStar NeXT) for treating facial skin laxity. The primary outcome is improvement in the facial skin laxity, and the secondary outcome is decrease in skin pigmentation.

Materials and methods

Study design

The Ethics Committee and Review Board of The Institute of Dermatology, Bangkok, Thailand, approved this study protocol. Thirty healthy 35- to 60-year-old male and female Thai patients with Fitzpatrick skin phototypes III to IV and moderate-to-severe facial skin laxity were enrolled in the study. Exclusion criteria consisted of patients with a history of keloids or hypertrophic scarring, skin malignancy, open wound on the face, facial herpes simplex infection, bleeding disorder, photosensitive disorder, heritable disorders of connective tissue, pregnancy and lactation, the use of oral and topical retinoids within the preceding 6 months, a history of facial laser treatment within 6 months of the treatment and a history of injection with filler, botulinum toxin, within the preceding 6 months. Only subjects consenting to longitudinal follow-up during the study were enrolled. Patients were allowed to continue their use of moisturizers and sunscreen during the study.

Treatment parameters

The patients were treated with four sessions, over 3week intervals, using the 810- and 940-nm diode laser (MedioStaNeXT) device. Two treatment processes were used to treat patients in each session. The first process was the painting technique with a smooth pulse mode. During the first process, eight passes were performed at the malar, nose, and chin areas; the settings were 8-10 J/cm², 16-20 ms pulse duration, and 6 Hz. At the forehead area, four passes were performed, and the settings were $4-6 \text{ J/cm}^2$. 10-12 ms pulse duration, and 6 Hz. An infrared thermometer device was used to maintain the temperature at close to 40–42 °C during this painting technique for stimulate the collagen remodeling that can make skin tightening. The second process included two passes of a staged pulse technique, with a skin rejuvenation mode, contact cooling, and cooling gel; the settings were 200-250 ms, 1 Hz, and a single pulse. The energy setting was allowed to adjust according to the patient's skin type and specific susceptible areas. Basically, in patients with Fitzpatrick skin phototype type III, on the malar, nose, and chin area, 25-30 J/cm² was used, which was reduced to 15-20 J/cm² at the forehead area. In patients with Fitzpatrick skin phototype type IV, this value was reduced to 20-25 J/cm² and 10-15 J/cm², respectively. A single physician (N.V.) performed all of the treatment sessions. Digital photographs were taken using the Canfield Visia CR System (Canfield, Fairfield, NJ, USA) in the standard manner prior to each treatment session and at 1, 3, and 6 months after the last treatment. Sunscreen (SPF 60) was prescribed to all patients after laser treatment, and the patients were advised to avoid the sun.

Assessments

Clinical outcomes were evaluated using a Cutometer[®] MPA 580 (Courage+Khazaka electronic GmbH, Cologne, Germany), spectrophotometer, and grading scale for assessing rhytides, laxity, and photodamage² before and after each treatment session. A patient sat-

isfaction questionnaire and serial photography were evaluated at every visit. A five-point scale (0–4 points for no improvement, <25%, 25–50%, 51–75%, and >75% improvement) was assessed by patients and non-treating dermatologists using serial photography at baseline and every visit at 1, 3, and 6 months after last laser treatment. Adverse effects, such as erythema and postinflammatory hyperpigmentation, were evaluated. Pain during treatment was assessed with a pain score using a standard 0–10 visual analog scale. Follow-up was conducted at 1, 3, and 6 months after laser treatment.

Skin elasticity was determined using a noninvasive, in vivo suction skin elasticity meter, Cutometer MPA $580^{\textcircled{(0)}}$ (suction skin elasticity meter), with a 2-mm-diameter probe at a negative pressure of 400-m bar applied to the skin in the perpendicular direction for a period of 2 s of suction, which was followed by 2 s of

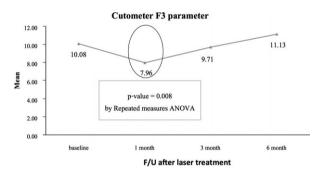


Figure 1 Mean of the Cutometer F3 parameter.

Table 1 Mean difference of the Cutometer's parameters comparedwith baseline and follow-up at 1, 3, and 6 months after the finaltreatment

	Mean difference	SD	<i>P</i> -value
F3 parameter			
Baseline—1 month after	2.12	4.08	0.008
the final treatment			
Baseline—3 months after	0.37	3.18	0.528
the final treatment			
Baseline—6 months after	-1.05	3.58	0.118
the final treatment			
R7 parameter			
Baseline—1 month after	0.01	0.09	0.746
the final treatment			
Baseline—3 months after	-0.06	0.07	<0.001
the final treatment			
Baseline—6 months after	-0.02	0.09	0.206
the final treatment			

release. Ten repetitions of the measurement cycle were performed. A strain-time curve was derived from the measurement of cheek skin.^{4,5,8} The measurement point was 2 cm below the crossline between the midpupillary line and the angle of the alar nasi. We used the cutometer parameters F3 and R7 because they were previously reported as significant in evaluating the age-related changes in the skin elasticity of the cheek.⁸

Statistical analysis

The paired *t*-test was employed to statistically analyze clinical efficacies by comparing the clinical result at 1 and 3 months post-treatment with baseline. Measurements of the cutometer and spectrophotometer were analyzed using repeated-measures ANOVA. The Spearman rank correlation coefficient was used to analyze the correlation of the laxity scale of photography graded by two nontreating dermatologists. Patient selfassessment of the clinical outcome using a global improvement score was analyzed using Friedman twoway ANOVA. All computations were performed with

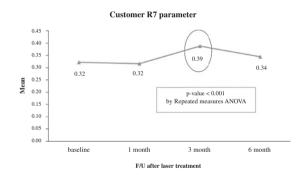
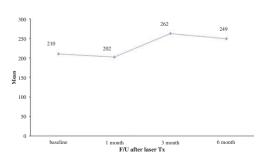


Figure 2 Mean of the Cutometer R7 parameter.



Spectrophotometer : Melanin

Figure 3 Mean spectrophotometer value for evaluating skin pigmentation.

SPSS software (IBM Corporation, Armonk, NY, USA). All the *P*-values were two-sided, and statistical significance was defined as P < 0.05. The percentage of adverse effects was recorded on the basis of a patient interview.

Results

Demographics

Thirty Thai subjects completed four treatment sessions and were included in the data. The mean age was 51.7 years with a range of 38–59 years. Ten of thirty patients (33%) were Fitzpatrick skin type III, and the remaining patients (67%) were type IV.

Efficacy evaluation

Cutometer

Significant improvement in facial laxity at 1 month after last treatment (P = 0.008) was observed with the F3 parameter (Fig. 1, Table 1). Significant improvement in facial laxity at 3 months (P < 0.05) after the last treatment was also observed with the R7 parameter. At 6 months after treatment, the tightening of the

skin seemed to persist with no statistical significance (P = 0.464) (Fig. 2, Table 1).

Spectrophotometer

After complete treatment, skin pigmentation trended to reduce, and there was no statistical significance (P = 0.21) on the spectrophotometer at 1 month (Fig. 3).

Patient self-assessment

Patient self-assessment of the clinical outcome showed moderate-to-marked improvement at the 2nd, 3rd, and 4th treatment sessions with percentages of 56.7%, 66.7%, and 83%, respectively. During the follow-up periods, 90% of the patients had significantly moder-ate-to-marked facial skin tightening (Fig. 4). Almost all of the patients were satisfied, would like to continue the treatment and may advise others to undergo the treatment as well.

Physician assessment

Evaluation of the clinical efficacy by two nontreating dermatologists using photography evaluation of the laxity scale and global improvement scale (GIS). There was a positive moderate correlation coefficient

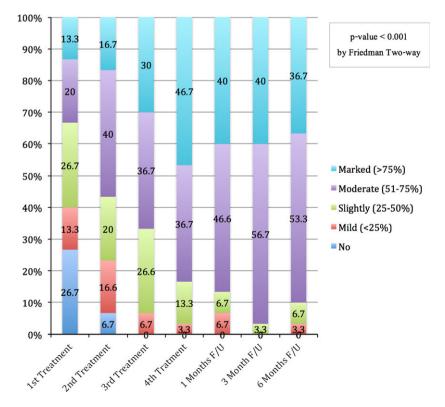


Figure 4 Patient self-assessment of the skin laxity improvement.

(r = 0.5-0.7) for the laxity scale of photography graded by the two nontreating dermatologists (Table 2). The physician assessment of the clinical outcome showed significant improvement in the laxity scale at 1, 3, and 6 months after treatment (P < 0.001). Figures 5 and 6 showed the serial photographs of 48-year-old participant. The facial skin laxity in this case was improved particularly at 1-month follow-up and still noticeable at 6-month follow-up.

 Table 2 Physician assessments of the laxity scale by two non-treating dermatologists

Mean	Correlation coefficient (r)	P-value	SD
2.067 1.767 2.167 2.167 1.933 2.200	0.663 0.490 0.580 0.439 0.633 0.492	<0.001 0.006 0.001 0.015 <0.001 0.006	0.58 0.50 0.59 0.53 0.52 0.48
	1.767 2.167 2.167 1.933	1.767 0.490 2.167 0.580 2.167 0.439 1.933 0.633 2.200 0.492	1.767 0.490 0.006 2.167 0.580 0.001 2.167 0.439 0.015 1.933 0.633 <0.001

The result of the GIS assessment showed that 53.3% of the patients had mild improvement in their skin laxity (<25%) at 1 and 3 months and 66.7% at 6 months after treatment (Table 3).

Safety evaluation

Approximately 10% of the patients reported only mild pain (pain score 1–3) or minor adverse events, such as mild hyperpigmentation and transient erythema. During all treatment sessions, approximately 81% of the treatment sessions were reported as erythema free, 19% were reported as involving mostly mild erythema, and only one session was reported as involving moderate erythema, which diminish spontaneously within a few days. The majority of the patients reported no hyperpigmentation and few cases reported a mild degree of hyperpigmentation. During the 3rd and 4th laser treatments, erythema seems to be more tolerable than in the earlier sessions. There were also no reports of hypopigmentation, infection, dermatitis, or scarring



Figure 5 Photographs of 48-year-old patient. The serial photographs compared those of baseline and those of follow-up period after completed treatment sessions. The facial skin laxity was improved particularly at 1-month follow-up.



At Baseline

At 6th month follow-up after completed 4 treatment sessions

Figure 6 Photographs of the same patient as Figure 5. The compared photographs between pretreatment and the last follow-up. The facial skin laxity improvement was still noticeable.

$\label{eq:condition} \textbf{Table 3} \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ $
two nontreating dermatologists

	Comparing GIS at baseline and at the follow-up after last laser treatment Number of patients (%)		
GIS	Follow-up	Follow-up	Follow-up
	1 month	3 months	6 months
No improvement	14 (46.67)	14 (46.67)	10 (33.33)
Mild improvement	16 (53.33)	16 (53.33)	20 (66.67)

up to 6 months after treatment. Details of the adverse events are shown in Table 4.

Discussion

We evaluated the efficacy and safety of a diode laser (810 and 940 nm) for treating facial skin laxity. The outcome of the study showed good results according to both objective and subjective assessments. Our objective assessment involved the use of cutometer R7 and F3 parameters, which are the best parameters for evaluating skin elasticity. To the best of our knowledge, few studies have used a cutometer to evaluate the skin-tight-ening effect, which is most likely due to the difficult measurement technique. A significant improvement in facial laxity at 1 month after the final treatment was observed

with the F3 parameter (P < 0.05), and at 3 months, significant improvement was observed with the R7 parameter (P < 0.05). From the results of the cutometer, as an objective parameter, the best treatment responses were achieved at approximately 1–3 months after the completed treatment sessions. Therefore, in clinical practice, maintenance treatment may be necessary every 2–3 months to maintain the treatment result. Interestingly, the patient's self-assessment showed moderatemarked significant improvement in skin laxity over the course of laser treatment and in the follow-up periods up to 6 months.

Our study result was consistent with the efficacy of a study report on Polaris WR, which combines the radiofrequency and diode laser energies (Electrooptical synergy or ELOS).⁶ The improvement in the facial rhytides was observed in the majority of patients with clinical improvement scores of 25-50%, and patient satisfaction surveys reflected the clinical improvements observed at the 9-week, 3-month, and 6-month follow-up visits, which were rated as 93%, 86%, and 81%, respectively. However, some adverse events in the ELOS system, such as mild-to-moderate pain, post-treatment erythema, and transient edema, were reported for most of the patients. Another study reported on the effectiveness of combination treatment using bipolar radio frequency-based intense pulsed light (470–980 nm), infrared light

Adverse event	Laser treatment Number of patients (%)				
	1	2	3	4	Friedman test
Adverse event					
None	24 (80)	24 (80)	27 (90)	24 (80)	<i>P</i> < 0.001
Mild	5 (16.7)	6 (20)	3 (10)	2 (6.7)	
Moderate	1 (3.3)	0	0	0	
Severe	0	0	0	0	
Pain (Pain score)					
None (0)	17 (56.7)	22 (73.3)	25 (83.3)	27 (90)	<i>P</i> = 0.002
Mild (1–3)	13 (43.3)	8 (26.7)	5 (16.7)	3 (10)	
Moderate (4–6)	0	0	0	0	
Severe (7–9)	0	0	0	0	
Severe intolerable (10)	0	0	0	0	
Erythema					
None	21 (70)	24 (80)	25 (83.3)	27 (90)	<i>P</i> = 0.161
Mild	9 (30)	5 (16.7)	5 (16.7)	3 (10)	
Moderate	0	1 (3.3)	0	0	
Severe	0	0	0	0	
Hyperpigmentation					
None	30 (100)	28 (93.3)	30 (100)	29 (96.7)	P = 0.300
Mild	0	2 (6.7)	0	1 (3.3)	
Moderate	0	0	0	0	
Severe	0	0	0	0	
Dry skin	0	2 (6.7)	1 (3.3)	1 (3.3)	

Table 4 Adverse events of laser treatment

(700–2000 nm), and a diode laser (915 nm) in a split-face trial.⁷ All patients showed statistically significant reduction in the photoaging global score. Objective measurements showed significant improvements in the melanin index and elasticity (R5 and R7) as well as increases in the levels of procollagen types I and III and elastin. This study efficacy is consistent with our study. However, the treatment protocol of the other study required the application of topical anesthetic cream, and all of the patients still reported mild pain during the procedures.

Our treatment protocol was safe. There were no serious or permanent adverse effects. The most common adverse effects found in our study were only temporally pain and erythema, demonstrating this technique is well tolerated. Additionally, the patient population in our study included Asians with Fitzpatrick skin types III to IV, which are prone to having more side effects, especially postinflammatory hyperpigmentation. The protocol settings were adjusted to minimize complications in our study. Nevertheless, the majority of the patients reported a lack of hyperpigmentation and few cases reported only transient and mild hyperpigmentation, which did not need any treatment. Therefore, regarding the efficacy and safety, diode laser (810 and 940 nm) may be considered a suitable choice for facial skin tightening in higher Fitzpatrick skin types, such as in Asians. In a white population, the treatment settings may have to be adjusted to obtain optimal results without excessive risk of dyspigmentation.

The limitation of our study is the relatively short follow-up period of 6 months after the final treatment session because optimal improvement may be evident after 6-12 months of follow-up. The histological studies showed increases in the collagen laver thickness that persisted for 1 year following 980 nm diode laser use to treat solar elastosis.9 The clinical benefit from the dermal remodeling process normally starts several months after treatment and continues for years after the initiation of the cutaneous wound-healing cascade.8 Our study was also limited by the small sample size and lack of a sham control group. We attempted to control for observer bias by using two nontreating dermatologists, who were blinded to the results, to evaluate the outcome of skin elasticity.

In conclusion, our study suggests that a diode laser (810 and 940 nm) is safe and may be an effective treatment for facial skin tightening. Maintenance treatment every 2–3 months may be the optimum interval for maintaining the results.

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