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ORIGINAL RESEARCH

The Efficacy of Noninvasive 1060-Nm Diode Lasers for Submental Lipolysis: A Pilot Study

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Background: Submental fat is a noticeable fat in the submental region that is of great concern aesthetically, especially to female patients. A 1060-nm diode laser is a clinically proven device for the laser lipolysis of subcutaneous fat cells. This study aimed to evaluate the safety and efficacy of a 1060-nm diode laser for submental fat reduction.

Methods: Twenty subjects with unwanted localized submental fat were treated with a single session of a 1060-nm diode laser with an energy setting between 0.95 and 1.40 W/cm^2, depending on each patient's tolerance. Submental fat thickness measurements were documented at baseline, and 1, 3, and 6 months after treatment. Clinical photographs, ultrasound images, and adverse events were evaluated at each follow-up visit. Subjects responded to a satisfaction questionnaire at the end of the study.

Results: The subjects had a mean age of 34.55 ± 6.19 years, a mean body weight of 70.66 ± 10.55 kilograms, and most (95%) were women. The average energy setting was 0.95–1.40 W/cm^2, with a pain score of 3.90 ± 1.30 on a 0-to-10 scale. A significant reduction in submental fat thickness measured by ultrasound was noted at post-treatment month 3 (falling to 0.46 ± 0.13; $P = 0.013$). However, there was a slight increase in the submental fat thickness at the 6-month follow-up (to 0.48 ± 0.12); the change in the thickness relative to the baseline was nonsignificant ($P = 0.121$). Most subjects reported an improvement 6 months after the treatment. No severe adverse events were observed throughout the study period.

Conclusion: Our study demonstrated the potential role of 1060-nm Diode laser for the treatment of localized submental subcutaneous adiposities. It is a promising alternative treatment modality for patients seeking an in-office, nonsurgical procedure for fat reduction without severe complications.

Keywords: 1060-nm, diode laser, lipolysis, submental fat

Introduction

Currently, people seek consultations to improve their facial appearance. Maintaining a good body physique increases individuals' self-esteem and improves their emotional and social well-being.[1] Facial features are considered indicators of the attractiveness of a person.[1] The appearance of the chin and jawline or the submental area is a common facial concern that can profoundly impact a person's feelings.[1]

According to the 2019 American Society for Dermatologic Surgery consumer survey, 73% of 3645 respondents were concerned about excess fat in their chin and neck.[2] Excessive submental fat is either due to genetics or lifestyle factors, such as an unhealthy diet or a sedentary lifestyle.[1] This excessive fat can be corrected through surgical procedures, including submental liposuction and submentoplasty.[3,4] However, the procedures have pitfalls that can be frustrating to patients. They include nerve injury, bleeding, hematoma, seroma, postinflammatory hyperpigmentation, infection, and scarring.[4,5]

More and more people are actively seeking noninvasive fat reduction and rejuvenation procedures.[5] Noninvasive treatment modalities have emerged that address unwanted fat in the submental area with less downtime and complications

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than surgical procedures. Among them are injection adipolysis,[5–8] cryolipolysis,[9–11,20–22] radiofrequency,[12] high-intensity focus ultrasound,[13,14] laser lipolysis[15–18] and microwave technology.[23]

A recent study done by Salsi et al used microwaves technology for unwanted fat reduction and submental skin tightening.[23] The technology utilizes selective microwave frequency producing localized heat and is absorbed by that fat through a biophysical process called "dielectric heating".[23] A total of 48 subjects underwent submental treatment for 6 sessions and showed significant decrease in submental fat and laxity at 12 weeks follow-up.[23] No significant adverse effects were noted among the subjects.[23]

Studies have demonstrated the efficacy of a 1060-nm diode laser for fat reduction in some areas of the body.[15–18] The laser has a high affinity for adipose tissue due to its long wavelength. It raises the temperature of adipose cells to between 42 °C and 47 °C, damaging their structural integrity. Inflammatory responses are stimulated. The body naturally eliminates disrupted fat cells and cellular debris by attracting macrophages and removing the cells and debris through phagocytosis. Several investigations have established the safety of the laser in patients with skin of color.[15–18]

Decorato et al demonstrated that the optimal time for a 1060-nm diode laser to cause significant adipocyte injury is 20 to 25 minutes. Use for longer than 25 minutes can create palpable nodules in the subcutaneous fat.[15,17] Work by Bass and associates and by Katz et al demonstrated a significant fat reduction in the abdomen and flanks, respectively, 12 weeks after treatment, measured by ultrasound.[15,18] Neither study documented any severe complications.[15,18]

There was also an increasing demand for leg contouring among Asian patients. A recent study done in Thailand by Yan et al showed efficacy of 1060 nm Diode laser in reducing medial knee fat thickness.[24] A total of 19 subjects with localized unwanted fat on the medial knees were enrolled into this study. Significant reduction in knee circumferences at 1-, 3-, and 6-month follow-up visits compared with baseline, and knee fat thickness measured by ultrasound in both axial and sagittal plane at 1 and 6 months after treatment were recorded.[24] Minimal and transient side effects were noted among patients.[24]

In view of these scientific findings, our investigation aimed to evaluate the safety and efficacy of a 1060-nm diode laser for submental fat reduction.

Methods

This single-site, prospective, clinical pilot study was conducted at the Skin Laser Center of Siriraj Hospital, Mahidol University in Bangkok, Thailand. We enrolled 20 healthy women and men aged between 20 and 65 and weighing 60 to 80 kilograms. Written informed consent was obtained from all subjects before prior the start of the study. The study was approved by the Human Research Ethics Committee of Siriraj Hospital (approval reference: Si420/2018). The procedures used in the research study adhered to the tenets of the 1975 Declaration of Helsinki.

The investigators gathered all demographic data, clinical histories, and physical examination findings related to the submental area prior to its treatment with a 1060-nm Diode laser.

The inclusion criteria consisted of healthy adult volunteers of both sexes. All subjects agreed to neither receive any kind of dermatologic/surgical procedures nor other body treatments aiming at reducing body fat during the entire study period. Subjects were excluded from the study if any of the following were met: pregnant or lactating women; a history of liposuction, surgical procedures, laser procedures, gold therapy, neuropathic disorders, skin malignancies, hypertrophic scar or keloid formation, skin infections, skin hypersensitivity, photosensitivity reactions, or herpes virus infection; evidence of compromised healing; an immunodeficiency disorder (including HIV infection or AIDS); the use of immunosuppressive medications; impaired skin sensation; diabetic neuropathy; or underlying psychological conditions.

The investigators evaluated each subject's unwanted localized fat in the submental area. The baseline fat thickness was measured in a supine position using an ultrasound imaging device (iU 22 xMatrix, Philips Healthcare, Eindhoven, the Netherlands). The primary endpoint of the study was a statistically significant reduction in submental fat layer thickness compared with the baseline at follow-up visits held 1, 3, and 6 months after treatment. The secondary endpoint was a subject satisfaction score of 3 or higher after the treatment, measured by improvement scale surveys conducted at the follow-ups.

A 1060-nm Diode laser device, Sculpsure (Cynosure, Westford, MA, USA), was used in the study. The investigator and all the subjects wore protective eyewear goggles specific to protect against the 1060-nm wavelength during the laser treatment. The submental treatment was performed using one applicator with head gear. The flat non-suction applicator

was placed on the subject's submental area. The applicator was inserted into the appropriate frame and was placed in contact with the skin.

The subject was treated with a single laser session of 1060-nm Diode laser. For each patient, the optimal power setting was identified to maximize treatment efficacy and at the same time, guarantee safety and patient comfort. The power setting was in the range between 0.95 and 1.40 W/cm^2, depending on an individual subject's pain tolerance. The spot size was 14.2cm^2. The exposure time for all subjects was 25 minutes,[15,18]. The treatment of fat in the submental area started from 1.5 cm below the lower border of the mandible up to the hyoid bone. This is to avoid treating the area of the arteries, veins and marginal mandibular nerve. The Diode laser at 1060 nm delivers heat below the surface of the skin to safely and permanently destroy fat cells. It also uses a constant cooling technology to keep subjects comfortable and safe without the risks of any burns. After the treatment, the subjects rated their pain using a 0-to-10 scale (0 = none; 10 = worst possible).[18]

Clinical photographs and ultrasound images were taken at all follow-ups to assess the efficacy of the laser. All subjects answered an improvement scale survey, and adverse events were monitored at each follow-up visits. Submental fat thickness was also measured using ultrasound images, and the subjects' body weights (in kilograms) were documented. The submental fat thickness of subjects showing weight gain and no weight gain at 1, 3, and 6 months after their treatment were compared with baseline values.

Descriptive analysis was used for the demographic data. The data were analyzed using a paired *t*-test (normality) for parametric distribution. The statistical analysis was performed using the statistical software PASW Statistics for Windows, version 18.0 (SPSS Inc, Chicago, IL, USA), with a P value < 0.05 indicating statistical significance.

Results

Twenty healthy subjects completed the study. Their demographic data are detailed in Table 1. The subjects' mean age was 34.55 ± 6.19 years, their mean body weight was 70.61 ± 10.56 kilograms, and 95% (19/20) were women. They received a single treatment with a 1060-nm diode laser, with an average energy setting of 0.95 to 1.40 W/cm^2 (Table 1). The documented body weight changes of the subjects at the follow-ups were nonsignificant (Table 2).

The average submental fat thickness at baseline was 0.51 ± 0.09 cm (Table 2). There was a significant reduction in the fat thickness at post-treatment month 3 compared with the baseline, with a decrease to 0.46 ± 0.13 cm (P = 0.013). However, 6 months after the treatment, the submental thickness had increased (to 0.48 ± 0.12 cm). The change in the thickness relative to the baseline was nonsignificant (P = 0.121; Table 2).

Based on the dynamic subgroup analysis, the subjects who did not gain body weight responded better to treatment (Table 3). The mean baseline fat thickness was 0.52 ± 0.11 (Table 3). The fat thickness of the nonweight-gain group showed a significant reduction at post-treatment months 1 (0.46 ± 0.12 cm; P = 0.014) and 3 (0.46 ± 0.15; P = 0.042) compared with the baseline (Table 3). On the other hand, the mean fat thickness of the weight-gain group did not show a significant reduction at either post-treatment months 1 or 3 (P = 0.106 and 0.197, respectively; Table 3).

Table 1 Demographic Data of Patients Enrolled in the Study

Characteristics	Mean ± SD*
Age (years)	34.55 ± 6.19
Sex (%)	Female 19 (95%) Male 1 (5%)
Weight (kg)	70.61 ± 10.56
Energy setting (W/cm^2)	0.95–1.40
Pain score	3.90 ± 1.30

Abbreviation: *SD, standard deviation.

Table 2 Evaluation Parameters of Whole Study

Parameters	Baseline	1 Month After Treatment	3 Months After Treatment	6 Months After Treatment
Body weight (kg)				
Mean ± SD	70.61 ± 10.56	70.60 ± 10.58	69.90 ± 10.81	69.89 ± 10.66
Max–Min	53–91	53–91	53–91	53–91
***P* value**		0.990	0.464	0.417
Fat thickness (cm)				
Mean ± SD	0.51 ± 0.09	0.50 ± 0.13	0.46 ± 0.13	0.48 ± 0.12
Mean difference		↓ 0.01	↓ 0.05	↓ 0.03
***P* value**		0.539	0.013*	0.121

Note: *Statistically significant at $P < 0.05$.

Table 3 Comparison of Evaluation Parameters of Weight-Gain and Nonweight-Gain Groups

Parameters	Weight-Gain Group (n = 7)		Nonweight-Gain Group (n = 13)		Comparison Between the 2 Groups
	Mean ± SD	*P* value	Mean ± SD	*P* value	*P* value
Body weight (kg)					
Baseline	69.53 ± 7.34		71.27 ± 12.17		0.715
1 month after treatment	71.14 ± 7.43	0.307	70.31 ± 12.22	0.197	0.872
3 months after treatment	71.74 ± 8.36	0.178	68.85 ± 12.13	0.014*	0.563
6 months after treatment	71.69 ± 7.77	0.105	68.85 ± 12.13	0.014*	0.565
Fat thickness (cm)					
Baseline	0.49 ± 0.05		0.52 ± 0.11		0.477
1 month after treatment	0.56 ± 0.11	0.106	0.46 ± 0.12	0.014*	0.097
3 months after treatment	0.45 ± 0.09	0.197	0.46 ± 0.15	0.042*	0.881
6 months after treatment	0.50 ± 0.8	0.840	0.47 ± 0.14	0.051	0.658

Note: *Statistically significant at $P < 0.05$.

Most subjects were satisfied with their treatment outcomes 1 and 6 months after their treatment (Figure 1). The mean pain score was 3.90 ± 1.30 on a 0-to-10 scale (Table 1). All subjects reported mild erythema and mild tenderness immediately after treatment, but the side effects were transient. No severe side effects (hypopigmentation, hyperpigmentation, scarring, fat dystrophy, or infection) were found throughout the study period.

Clinical photographs and ultrasound images of a representative subject are presented in Figures 2 and 3. They illustrate improvements 3 and 6 months after the treatment.

Discussion

Excessive submental fat can substantially impact people's feelings of attractiveness.[1] Work by Bauman et al validated that submental fat can negatively affect the psychological well-being of individuals. In their study analysis, the researchers documented that excessive submental fat can affect the emotional well-being of people. The data revealed

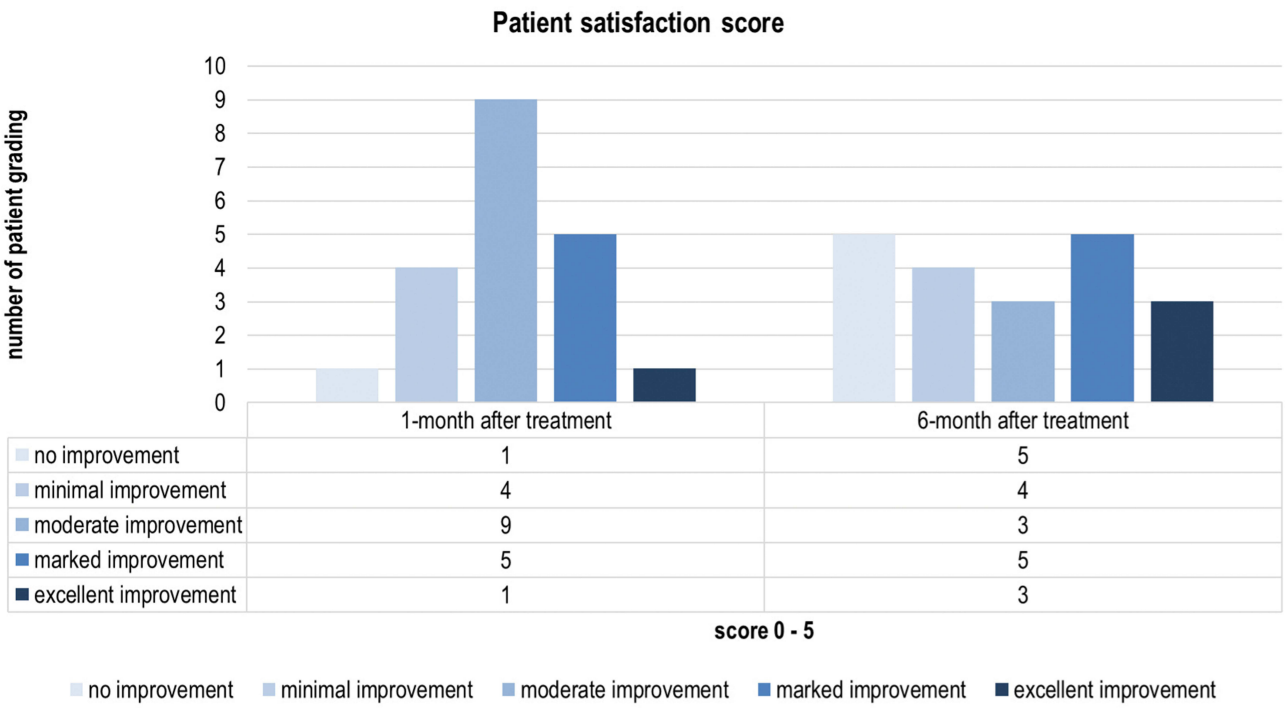

Figure 1 Subjects' self-improvement scores for both groups at all follow-ups.

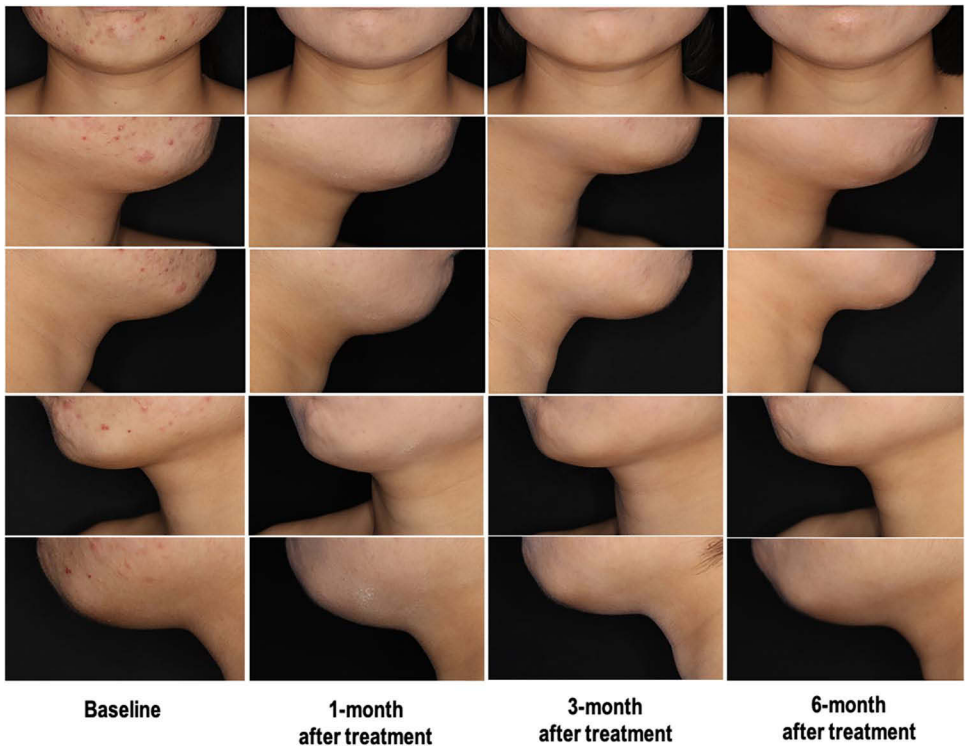

Figure 2 Clinical photographs of a representative patient.

that concerns about chin and neck appearance negatively impacted women's feelings and emotional well-being more than men's.[1] In the present study, majority of subjects included were women. Behavioral changes occurred in as many as 75% of people with a considerable amount of chin fat.[1] More female than male respondents avoided taking photographs (40%

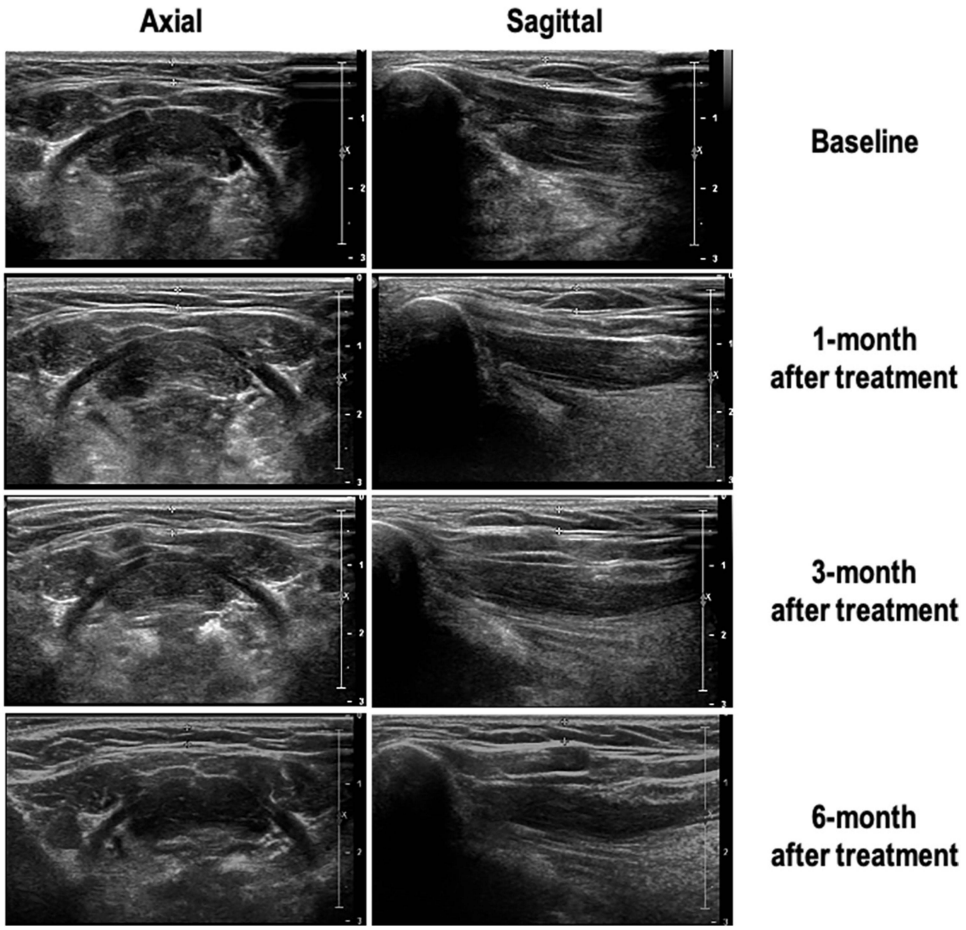

Figure 3 Ultrasound images (2 dimensions) of the representative patient.

vs 31%). Additionally, more women than men (44% vs 34%) said posting photographs of themselves on social media sites was stressful due to their perception that their chin and neck area appeared unattractive.[1] Because of these emotional sequelae, physicians must evaluate the submental area during aesthetic consultations.

Laser lipolysis generates controlled hyperthermia using a specific wavelength and optimal energy in the subcutaneous layer. Hyperthermia then causes photomechanical and photothermal reactions that destroy adipocytes and stimulate an inflammatory response.[17,18]

1060-nm Diode laser wavelength technology has a high affinity for adipose tissue. The laser raises the temperature of adipose cells between 42°C and 47°C, damaging their structural integrity.[24] After the treatment session, the body naturally eliminates the disrupted cells over the next few months.[24] Disrupted fat cells are permanently eliminated from the body and will not regenerate. Previous studies on 1060-nm diode lasers showed significant reductions in localized subcutaneous fat on the abdomen[15] and flanks.[18]

In the study by Bass et al, significant mean reductions in the fat layer thickness of the abdomen from baseline were observed 6 and 12 weeks after treatment.[15] At 12 weeks, 91% (31/34) of the subjects were satisfied with the treatment.[15] Using the same laser device, an earlier pilot investigation on the flanks by Katz et al demonstrated a significant mean fat reduction based on ultrasound images.[18] Twelve weeks after the treatment, 96% (41/43) of the subjects reported being satisfied with their treatment outcomes.[18]

A recent study done in Thailand by Yan et al, used the same device, 1060 nm Diode laser, to evaluate its efficacy for medial knee fat reduction. This showed significant reduction in knee circumferences ($p< 0.001$) at 1-, 3-, and 6-month follow-up visits compared with baseline, and knee fat thickness measured by ultrasound in both axial and sagittal plane at 1 and 6 months after treatment ($p = 0.036$ and $p <0.001$, respectively) were recorded.[24]

In the present study on the submental area, we found a similar significant reduction in fat thickness at post-treatment month 3 (0.46 ± 0.13 cm) compared with the baseline ($P = 0.013$). However, at the 6-month follow-up, there was a slight increase in the submental thickness (to 0.48 ± 0.12 cm). The change in the thickness relative to the baseline was nonsignificant ($P = 0.121$; Table 2). Most of our subjects expressed satisfaction with their treatment outcomes 1 and 6 months after the treatments (Figure 1). This study shows that the 1060-nm diode laser is helpful for subcutaneous fat reduction in the submental area for at least a short period after treatment. The authors believe additional treatment sessions must be undertaken to maintain the fat reduction in the submental area.

As with other investigations, no severe adverse events were reported by the subjects in our study.[9,15,17,18] In a Korean cryolipolysis study on the submental area, no serious adverse effects (eg, prolonged erythema and permanent hyperpigmentation) were reported.[9,10] In a laser lipolysis study by Katz and associates, the majority of reported events (83%) were mild and temporary. For instance, edema resolved within 4 to 6 days, pain and bruising within 9 to 11 days, and subcutaneous nodules within 32 to 78 days.[18] Bass et al documented posttreatment tenderness as the most frequent adverse event.[15] Seventy-four percent (74%) of the events were reported as mild, 26% as moderate, and none as severe.[15] In addition, Yan et al, all subjects reported mild tenderness and erythema immediately after the treatment for medial knee reduction. No hypopigmentation, hyperpigmentation, scarring, fat dystrophy, infection, or paradoxical adipose hyperplasia were documented.[24]

The subjects in the current investigation reported an average pain score of 3.90 ± 1.30 on a 0-to-10 scale (Table 1). Although all subjects reported mild erythema and mild tenderness immediately after treatment, these side effects were transient. No severe side effects (hypopigmentation, hyperpigmentation, scarring, fat dystrophy, or infection) were found throughout the study period. The patient satisfaction done in the present study is due to their observation of minimal complications. 1060-nm Diode laser has far fewer adverse effects than other treatment modalities, such as surgery, microneedling devices, and injections. Regarding the safety profile, submental laser lipolysis is comparable to submental cryolipolysis and has higher patient tolerability than the ATX-101 procedure, which is a form of injection adipolysis.[10] Considering that the submental area is a visible facial region, it is prudent to avoid any side effects that could cause emotional burden among patients, such as scarring or permanent dyspigmentation.

The fat thickness of the nonweight-gain group at baseline was 0.52 ± 0.11 (Table 3). The fat thickness of this group showed significant reductions at post-treatment month 1 (0.46 ± 0.12 cm) and post-treatment month 3 (0.46 ± 0.15) compared with the baseline ($P = 0.014$ and 0.042, respectively; Table 3). On the other hand, the average fat thickness of the weight-gain group did not show a significant reduction at 1 or 3 months after treatment ($P = 0.106$ and 0.197, respectively; Table 3). Consequently, the authors believe that diet control and regular exercise must be undertaken by subjects to achieve and maintain satisfactory treatment results and patient satisfaction.

In conclusion, this study validated that using a 1060-nm diode laser safely and effectively reduces submental fat. This is the first study to report the clinical efficacy and safety of 1060-nm diode lasers for treating excessive subcutaneous fat in the submental areas of Asian subjects. The study's limitations are a single treatment administration, a small sample size, the absence of a comparative group, and a short follow-up period. Further studies are encouraged to determine whether additional treatment sessions would yield more fat reduction and to identify if long-term complications arise from this treatment modality.

Conclusion

Our study demonstrated the potential role of 1060-nm Diode laser for the treatment of localized submental subcutaneous adiposities. 1060 nm Diode Lasers is a promising alternative treatment modality for patients seeking an in-office, nonsurgical procedure for fat reduction without severe complications.

Data Sharing Statement

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Compliance with Ethics Guidelines

The study was approved by the ethics committee of the Siriraj Institutional Review Board. Written informed consent was obtained for the publication and use of all patients' images prior to their enrollment in the study. This study was performed in accordance with the Helsinki Declaration of 1964 and its subsequent amendments.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work. All authors read and approved the final manuscript.

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Disclosure

All authors declare that they have no conflicts of interest in this work.

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