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Dermatology Research

Efficacy of Dual-Wavelength Coherent Low-Level Laser in Reducing Submental Fat

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ABSTRACT

Purpose: *Submental fat is a frequent aesthetic concern that can negatively affect quality of life. While low-level laser devices are FDA cleared for body circumference reduction, their use in the submental region has not been systematically studied. This study evaluated the safety and efficacy of a high-energy dual-wavelength low-level laser (405 nm violet, 520 nm green) for reducing visible submental fat.*

Patients and Methods: *This prospective, dual-center, open-label study incorporated blinded endpoint evaluation. Adults aged 18–65 years with measurable submental fat received eight non-contact treatments of 15 minutes each, delivered twice weekly over four weeks. The primary endpoint was the 12-week post-treatment responder rate, defined as correct identification of pre- versus post-treatment photographs by at least two of three independent board-certified cosmetic surgeons. Secondary endpoints included caliper-based submental skinfold thickness, participant satisfaction, and safety assessments.*

Results: *Thirty-one participants were enrolled; 30 were included in the intent-to-treat analysis and 24 in the per-protocol analysis. At 12 weeks post-treatment, the intent-to-treat responder rate was 86.7%, exceeding the predefined success threshold of 80%. In the per-protocol population, the responder rate was 95.8%. Mean submental skinfold thickness decreased by 5.45 mm. Participant satisfaction increased from 77% at week 4 to 92% at 12 weeks. No device-related adverse events occurred, and BMI remained stable.*

Conclusion: *A four-week regimen of eight non-contact treatments with a dual-wavelength low-level laser produced clinically meaningful and durable improvements in the appearance of submental fat with excellent safety and high patient satisfaction.*

Keywords

Noninvasive, LLLT, Green laser, Violet laser, Body Contouring.

Abbreviations

LLLT: low level laser therapy, mm: millimeters, ITT: Intent to treat, PP: Per-protocol, nm: nanometer, BMI: Body Mass Index.

Introduction

Submental fullness, informally referred to as a "double chin," is a prevalent cosmetic concern that increases in frequency with advancing age due to changes in adipose distribution, skin elasticity, and cervicomental angle. Surveys indicate that approximately one quarter to nearly one half of adults report being concerned by submental fat,[1] often describing behavioral modifications such as avoiding photographs or altering clothing to conceal the neck. Tens of thousands of submental liposuctions and neck lifts are performed annually,[2] reflecting the ongoing interest in corrective procedures. In recent years, however, patient demand

has shifted toward less invasive options that minimize discomfort and shorten recovery time. Reflecting this trend, plastic surgeons performed roughly 15.6 million cosmetic procedures in 2020, with nearly 90% consisting of minimally invasive approaches.[3] Industry analyses estimate that the global market for submental reduction procedures, encompassing both surgical and nonsurgical modalities, exceeded $1 billion USD in 2023 and is projected to surpass $2 billion by 2030.[4] This market trajectory highlights the importance of developing effective, well tolerated treatment alternatives.

Low level laser therapy (LLLT) has demonstrated reproducible efficacy in reducing body circumference across several anatomical sites, including the waist, hips, thighs, upper abdomen, and upper arms. The consistency of outcomes across trials has supported FDA market clearances for indications related to reduction of overall body circumference (K192544, K162578, K243811). The present study was designed to extend these findings to the submental region, with the specific aim of evaluating whether a dual wavelength LLLT (violet 405 nm, green 520 nm) could achieve responder rates above the predefined threshold of 80% at 12 Weeks post final treatment.

Material and Methods

Study Design

This was a prospective, dual center, open label study with blinded primary endpoint evaluation conducted by three independent board-certified cosmetic surgeons. The trial was registered at ClinicalTrials.gov (Identifier: NCT05954065). All participants provided written informed consent using an Institutional Review Board (IRB) approved consent form.

Eligible participants were men or women aged 18–65 years with visible submental fat and caliper measured submental skinfold thickness greater than 10 millimeters (mm). Key exclusion criteria included alternative causes of submental enlargement, recent aesthetic interventions in the region, dermatological conditions interfering with assessment, implanted electronic devices, pregnancy, or concurrent participation in other investigational studies. Participants were instructed to maintain body weight within ±5% and refrain from other body contouring treatments during the study.

Intervention

The handheld device (Erchonia Corp.) delivered dual coherent line generated beams at 405 nanometer (nm) violet and 520 nm green, each at an output power of 7.5 milliwatt. Treatments were performed in a noncontact mode, with the device positioned 3–4 inches from the skin and centered on the submental pad using a hands-free stand. Each session lasted 15 minutes, with participants receiving two sessions per week for four weeks (total of eight treatments). Eye protection was provided and worn at each session.

Photographs

Standardized frontal and bilateral lateral photographs were captured at each study visit using a fixed camera setup and light illumination. Images were anonymized and randomized for review. Three independent board-certified cosmetic surgeons served as blind evaluators, working independently without communication or collaboration. The presentation order of images was randomized by computer algorithm.

Efficacy Endpoints and Statistical Analysis

The primary efficacy endpoint was the responder rate at 12 Weeks post treatment, defined as correct identification of pre- versus post-treatment images by at least two of three independent blinded evaluators. Study success was defined as ≥80% responders. Secondary endpoints included caliper-based skinfold measurements (total fold and single-layer), participant satisfaction assessed by a 5-point Likert scale, and body mass index (BMI) as a control variable. Safety assessments included monitoring of adverse events.

Per the clinical study protocol, the principal analysis population for the primary efficacy outcome was the intent-to-treat (ITT) cohort. The ITT population was predefined as all consented and enrolled subjects who had a photograph of the submental region captured at the end of the 4-week treatment assessment, thereby ensuring that at least one post-baseline image was available for endpoint evaluation. Accordingly, the ITT efficacy analysis comprised 30 of the 31 initially enrolled subjects. Of these, 24 participants (80%) completed the study per-protocol (PP) through the 12 Weeks post-treatment, and their baseline and 12 Week post treatment images were used for the primary endpoint assessment. The remaining six participants (20%) completed the Week 4 assessment but did not return for the 12 Week post treatment endpoint visit. For these individuals, the Week 4 submental image was carried forward as the 12 Week post treatment image for the ITT analysis using a last observation carried forward (LOCF) approach.

Results

Thirty-one (31) women were enrolled. The ITT population comprised 30 participants; one subject discontinued after three treatments and was excluded because no post-treatment image was available for baseline comparison. In the ITT cohort (n=30), the mean age was 45.6 ± 9.2 years (range 26–61). All participants were female and Caucasian. The mean baseline BMI was 32.7 ± 6.4 kg/m².

Primary Outcome

In the ITT population analysis, the three independent blinded evaluators correctly identified the pre-treatment and post-treatment submental images in 26 of 30 subjects (86.7%), thereby surpassing the predefined primary efficacy success criterion of 80% by 6.7%. The full blinded evaluators' identification scores are presented in Table 1.

Table 1 Primary Efficacy Outcome Responder Rate: ITT Population.

# Blinded Evaluators Correct (N=30)	N	%
TOTAL CORRECT	**26**	**86.67%**
3 of 3 Correct	23	76.67%
2 of 3 Correct	3	10.00%
< 2 of 3 Correct	*4*	*13.33%*

Within the per-protocol analysis population, the three independent blinded evaluators correctly distinguished baseline and post-treatment (12 Weeks post-final treatment) submental images in 23 of 24 participants (95.8%). This result exceeded the predefined primary efficacy success criterion of 80% by 15.8%, demonstrating a strong and consistent treatment effect. The full blinded evaluators' identification scores are presented in Table 2.

Table 2: Primary Efficacy Outcome Responder Rate: PP Population.

# Blinded Evaluators Correct (N=24)	N	%
TOTAL CORRECT	**23**	**95.83%**
3 of 3 Correct	20	83.33%
2 of 3 Correct	3	12.50%
< 2 of 3 Correct	*1*	*4.17%*

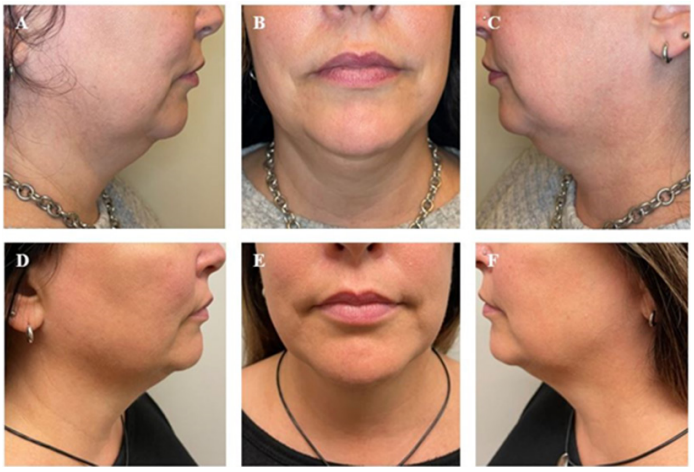

Figure 1: Baseline submental region photographs (A–C) and corresponding images obtained at 12 Weeks post-treatment (D–F).

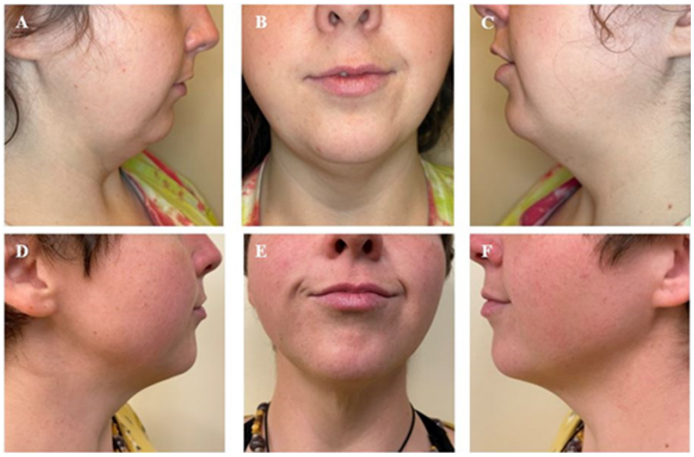

Figure 2: Baseline submental region photographs (A–C) and corresponding images obtained at 12 Weeks post-treatment (D–F).

Secondary Outcome

Submental Skinfold

Submental skinfold thickness demonstrated progressive reductions over the study period. The mean total skinfold decreased from 28.71 mm at baseline to 24.97 mm at Week 4 (end of treatment) and further to 23.26 mm at 12 Weeks post, representing a cumulative reduction of −5.45 mm. Corresponding single layer thickness values decreased from 14.35 mm at baseline to 12.50 mm at Week 4 and 11.64 mm at 12 Weeks post, for a net reduction of −2.71 mm, illustrate in Figure 4. These findings indicate that measurable improvement was evident immediately after treatment completion and continued to progress during follow up.

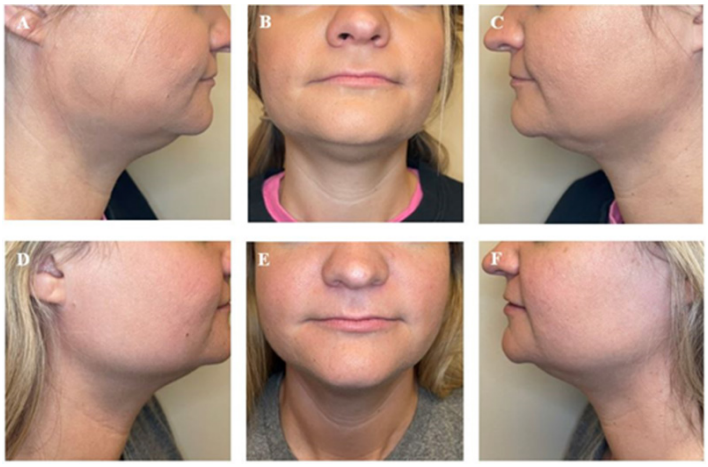

Figure 3: Baseline submental region photographs (A–C) and corresponding images obtained at 12 Weeks post-treatment (D–F).

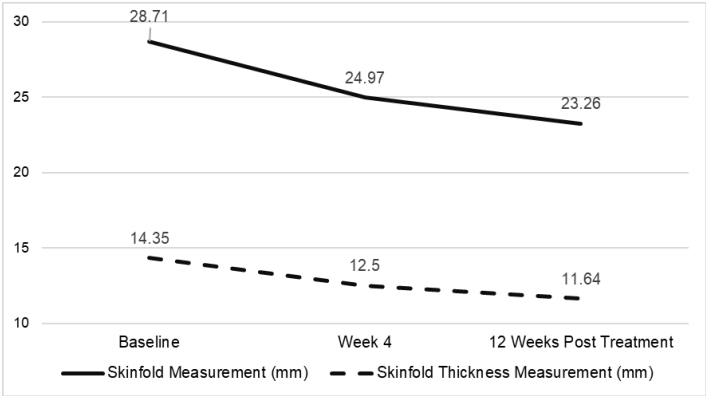

Figure 4: Skinfold and Submental Skinfold Thickness Measurements (mm) Across Study Assessments: ITT Population.

Patient Satisfaction

At Week 4, 77% of participants reported being somewhat or very satisfied, increasing to 92% at 12 weeks post-treatment. This progressive rise in both overall satisfaction and its intensity paralleled the objective reductions in submental skinfold thickness observed over the same interval, providing convergent evidence for a durable and clinically meaningful treatment effect. The breakdown of satisfaction ratings is presented in Table 3.

Body Mass Index

BMI remained stable throughout the study period, indicating that reductions in submental fat appearance were not attributable to weight change. Mean BMI was 32.09 ± 6.01 kg/m² at baseline, 31.98 ± 6.02 kg/m² at Week 4, and 31.84 ± 5.94 kg/m² at 12 weeks post-treatment.

Table 3: Participant Satisfaction by Study Visit.

Satisfaction Rating Category:	4 Weeks (N=30)	12 Weeks Post (N=24)
Very Satisfied	18 (60%)	16 (67%)
Somewhat Satisfied	5 (17%)	6 (25%)
Neither	6 (20%)	2 (8%)
Not Very Satisfied	1 (3%)	-
Not at All Satisfied	-	-

Safety

No treatment or device related adverse events occurred.

Discussion

This study demonstrates that combined violet (405 nm) and green (520 nm) LLLT wavelengths achieve clinically meaningful reductions in submental fat. The endpoint methodology mirrored that of pivotal trials supporting FDA clearance of cryolipolysis (K151179) and hyperthermic 1,060 nm laser (K171992), employing a 12-week post-treatment follow-up and the same predefined primary outcome of blinded correct identification of baseline versus post-treatment photographs by at least two of three independent reviewers, with a prespecified success criterion of ≥80% responders. In this study, the PP responder rate of 95.8% exceeded the correct-identification rates reported for other FDA-cleared technologies, including 91% for cryolipolysis (K151179) and 93% for hyperthermic 1,060 nm laser (K171992). Importantly, the tolerability profile of the LLLT was notably superior. Treatments with the dual-wavelength low-level laser were administered in a non-contact, non-thermal fashion and were not accompanied by procedure-related pain, swelling, or numbness; no device-related adverse events were observed. In contrast, cryolipolysis and hyperthermic laser procedures are often associated with post-treatment discomfort, erythema, and edema [5,6], with nodularity reported as an occasional side effect of hyperthermic laser lipolysis [7] and paradoxical adipose hyperplasia recognized as a rare but documented complication of cryolipolysis [8].

Violet (405 nm, ~3.06 eV) and green (520 nm, ~2.38 eV) wavelengths were selected for their comparatively high photon energies and correspondence with critical absorption sites within the mitochondrial electron transport chain. High-energy visible photons are capable of initiating photochemical interactions with intracellular chromophores, including flavins, porphyrins, and opsin-like proteins. These primary absorption events propagate downstream signaling cascades characterized by transient generation of reactive oxygen species and mobilization of intracellular calcium, processes known to influence mitochondrial respiration and cytoskeletal organization within adipocytes [9].

Evidence indicates that these wavelengths correspond to absorption peaks of distinct complexes within the mitochondrial electron transport chain: violet light interacts primarily with Complex I (NADH:ubiquinone oxidoreductase) and Complex II (succinate dehydrogenase) [10-12], while green light corresponds to Complex III (cytochrome bc1 complex) [13,14]. Impairments in these complexes have been documented in individuals with adiposity and are exacerbated by aging [15], obesity [16,17], and metabolic syndrome [18]. Targeted stimulation at these absorption sites may enhance electron flux, restore mitochondrial efficiency, and promote metabolic activity in otherwise dysfunctional adipocytes. At the cellular level, this bioenergetic modulation is consistent with structural changes observed in prior electron microscopy studies, including the transient formation of nanoscale pores in the plasma membrane and subsequent lipid efflux into the interstitial compartment [19]. Clinically, such effects manifest as progressive reductions in submental fat thickness. Furthermore, the relatively high photon energy of violet and green light enables faster initiation of photochemical events compared with longer, lower-energy wavelengths, thereby permitting shorter treatment durations without compromising efficacy. Collectively, these mechanistic considerations provide a robust scientific framework supporting the dual-wavelength low-level laser as a safe, effective, and mechanistically plausible modality for submental contouring, integrating principles of adipocyte biology and mitochondrial bioenergetics.

Conclusion

A four-week course of eight non-contact treatments with a dual-wavelength handheld low-level laser produced significant reductions in submental fat. Improvements were confirmed by blinded image assessments, measurable decreases in submental skinfold thickness, and high participant satisfaction. These findings support LLLT as a safe, painless alternative to invasive or minimally invasive procedures for submental fat reduction.

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