

Application of Low-Level Laser Therapy for Noninvasive Body Contouring

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Background: Low-level laser therapy (LLLT) is a noninvasive treatment for a wide-assortment of medical ailments. A recent application is for noninvasive body slimming. A Level 1 clinical study was completed and recorded a significant reduction in circumferential measurements across waist, hips, and thighs compared to placebo subjects. Questions remain unanswered to whether the result observed was based upon simple fluid redistribution. The purpose of this retrospective study was to evaluate the efficacy of LLLT for noninvasive body slimming and determine if the loss was attributable to fluid or fat relocation.

Methods: Data from 689 participants were obtained to evaluate the circumferential reduction demonstrated across the treatment site of the waist, hips, and thighs as well as nontreated systemic regions. Patient data were not pre-selected; all reports provided by clinics using LLLT for body contouring were used to evaluate the efficacy of this treatment. Participants received a total of six LLLT treatments across 2-weeks having baseline and post-procedure circumferential measurements recorded. Measurement sites included waist, hips, thighs, arms, knees, neck, and chest.

Results: The mean circumferential reduction reported for the waist, hips, and thighs 1 week after the treatment regimen was 3.27 in. ($P < 0.0001$). Furthermore, participants demonstrated an overall mean reduction of 5.17 in. across all measurement points 5.17 in. ($P < 0.0001$). Each anatomical region measured exhibited a significant circumferential reduction.

Conclusion: These data reveal that the circumferential reduction exhibited following LLLT is not attributable to fluid or fat relocation as all measurement points, including nontreated regions, reported an inch loss. *Lasers Surg. Med.* 44:211–217, 2012. © 2012 Wiley Periodicals, Inc.

Key words: noninvasive; body-contouring; adipocyte; emulsification; photobiomodulation

INTRODUCTION

Noninvasive body contouring has developed into a notable alternative to more invasive aesthetic procedures.

Limited downtime, shortened procedure duration, and decreased incidence of adverse event—all define the benefits of noninvasive body-contouring procedures. Numerous mechanisms including radiofrequency, cryolipolysis, ultrasound, and low-level laser therapy (LLLT) have emerged, and afford patients fundamentally different treatments: either designed to lyse the adipocyte, tighten the skin, or collapse and deflate the adipocyte [1–3]. Inexorably, the desired clinical outcome and the time required for manifestation are contingent on the modality applied. For instance, Dover et al. [4] have evaluated an ablative technology and reported a 1.8 mm reduction in the subcutaneous adipose layer after 16 weeks. Disparately, LLLT, a nonablative application proven to collapse the adipocyte, has exhibited a clinical result of 3.5 in. (91 mm) in 2 weeks [5]. Accordingly, aesthetic clinicians must substantiate marked differences between noninvasive devices to prevent cursorily adopting untried technologies. Resultantly, this article aims to corroborate the clinical utility of LLLT as a noninvasive body-contouring procedure.

Jackson et al. [5] reported that LLLT with defined parameters reduces circumferential measurements of the waist, hip and thigh evidenced by a cumulative loss of 3.54 in. in 2 weeks. This response—substantiated by numerous histological investigations—is secondary to the formation of a transitory pore within human adipocytes membranes. Degradation of the bilipid membrane has been reported to induce the release of intracellular constituents including accumulated fatty material [6–9]. However, the exact mechanism of action, including the removal and metabolism of liberated fatty material, remains enigmatic.

There is no debate that fat catabolism is a fundamental process of the body's endogenous metabolic network; nevertheless, how this process is specifically affected by laser light is evasive. The circumferential reduction reported by

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Jackson et al. [5] denotes material—presumably intracellular lipids—permeated from the treated area. It was postulated by the authors that the lipid material is degraded in the lymphatic system prior to entering the circulatory system; the newly formed nonesterified free fatty acids (NEFAs) are further catabolized during beta-oxidation. To corroborate this mechanism, a study evaluated patient serum chemistry following a body-contouring regimen with LLLT and reported no elevations in lipid content—in part, substantiating the theory [10]. However, it could be surmised that the liberated material and consequential slimming could arise inadvertently as a result of simple fluid redistribution.

Elucidation of the exact mechanism requires extensive histological examination; however, determining whether the reduction in the circumferential measurements of treated areas occurs via simple fluid redistribution can be substantiated in the clinic. If abated measurements are secondary to fluid or fat relocation, then remote non-treated regions would exhibit an increase in their circumferential measurements during and following LLLT. Here, we performed a nonrandomized, noncontrolled retrospective study to surmise whether redistribution of fluid is the inherent cause of the reported body contouring subsequent to LLLT.

METHODS

Participants

Participants who presented with voluminous fat deposits positioned within the subcutaneous fat layer of the waist, hips, and thighs received treatment with a low-level laser device. No minimal layer of fat thickness was required for individuals to participate. A total of 689 participants agreed to share their clinical outcomes for publication purposes. All participants were deemed eligible to participate in the study based on their individual history and the physical criteria set-up by all participating clinics. The mean age of participants was 48.67 years with a range of 20–84 years. The mean weight for subjects was 159.75 lbs. Females were the predominant gender with a reported 92.3% of the total enrolled population. Fifty independent private practice clinics throughout the USA provided their clinical data for assessment. Due to the retrospective nature of the study, some variables including measurement sites, age, or weight were provided for all subjects. As a result, the total number of subjects assessed for an anatomical region(s) will vary.

Prior to administering LLLT, all participants were provided with a detailed explanation of the treatment procedure and understood that their outcomes, absent of any protected health information, could only be used for peer-reviewed publication purposes. Participants were excluded from the study based on the following criteria: active illness, severe cardiovascular disease, terminal disease (i.e., cancer), liver or kidney disease, pregnancy, breastfeeding, disease of the thyroid gland, uncontrolled diabetes, drastic weight fluctuations, and other ailments impacting their overall quality of health.

The clinical data obtained for this study were obtained from participants who actively sought the services of a clinician providing LLLT for slimming purposes, that is, participants were not openly recruited. Participants were not offered any form of compensation. Furthermore, all participants were financially responsible for the procedure or related evaluations. Treating clinicians were financially responsible for the device. Participants were not asked to abstain from receiving any other treatment to promote body contouring and/or weight loss while receiving LLLT; moreover, patients were not advised to abstain from dietary changes and no standard diet was recommended. A standard supplement regimen was outlined for clinics considering the use of nutritional support which included tablets containing 100 mg of niacin, 100 mg of niacinamide, 200 mg of green tea extract, 100 mg of L-carnitine, 60 mg of Ginkgo Biloba, and 300 mg of omega-3 fatty acids. It was not mandatory for patients to consume the supplement. The use of a supplement was introduced to fortify fat-catabolism of the liberated lipids only. It was suggested that two tablets were consumed twice daily during the treatment administration phase; however, it remains unclear which clinics and how many patients embraced supplementation. The study was an assessment of real-world patients, with suggestions concerning hydration and supplementation, but without strict parameters regarding adherence. Restriction of adjunctive modalities to assess the efficacy of LLLT was performed in the level 1 clinical trial conducted by Dr. Jackson et al. whereas the purpose of this retrospective investigation was to evaluate the average circumferential reduction demonstrated within the medical community.

Randomization and Blinding

The clinical data presented in this study were obtained in a noncontrolled, nonrandomized manner. Data for 689 patients were reported. Patient data were not pre-selected; all data provided by clinics was random using LLLT for body contouring were required to properly evaluate the efficacy of the treatment.

Intervention

Participants received treatment with a multiple head low-level diode laser consisting of five independent diode laser heads each with a scanner emitting 635 nm (red) laser light, and each diode generating a 17-mW output (Zerona™, Erchonia Medical Inc., McKinney, TX).

Study Design

Prior to administering the treatment, participants were evaluated and received physician consultation. The week prior to the first treatment, participants were advised to hydrate, consuming the recommended 2 L of water per day. All patients participated in the hydration protocol. If participants decided to include supplementation, the supplement would be implemented during this pre-procedure week. Consumption of supplements was not mandatory; therefore, patients may or may not have consumed

supplements during the trial. The circumference in inches of the participants' waist, hips, bilateral thighs, bilateral arms (across the bicep muscle), bilateral knees, chest, and neck were recorded at four time-points. All circumferential measurements were made by encircling the greatest area of subcutaneous fat volume and were identified based on anatomical landmarks in order to maintain proper repositioning at subsequent time-points. Furthermore, the same clinician at each independent clinic was responsible for all the circumferential measurement recordings for a given participant to maintain consistency. Although the waist, hips, and thighs were treated with the device, systemic, nontreated regions were measured to determine if fluid redistribution was the cause of slimming. These areas were measured to determine if they experienced any circumferential changes after a treatment regimen with LLLT. Finally, to reduce measurement bias, the tape measurement device was a self-adhering, pressure sensitive device, which possesses a mechanism that encircles the participant without the need for the clinician to apply pressure to record the circumferential measurement. The device allowed the tape measure to attach to a self-adhering mechanism that required the technician to simply press a button to initiate tape contraction. Tape measure contraction would continue until no further contraction was possible. During the time of contraction, the technicians hand was not to make any contact with the tape measuring device. This device ensured that a similar degree of pressure was applied at all time-points, minimizing the potential for human error. Furthermore, participants were required to assume a consistent anatomical position with their back placed flush against a firm surface, abdomen extended, arms up and out at shoulder height, all while holding their breath. This procedure was utilized at all time-points. No patient weight was recorded as previous trials indicated an insignificant reduction in weight subsequent LLLT has been reported.

The circumferential measurements for each anatomical region were recorded at two time points: pre-procedure and 1 week post-procedure. However, data are reported as the mean change in the total combined circumference (total number of inches) from the pre-procedure to 1-week post-procedure time-points for the waist, hips, thighs, arms, knees, neck, and chest individually.

The treatment was immediately initiated following the pre-procedure time-point. The treatment phase lasted for two consecutive weeks, with each participant receiving three treatments per week for a total of six treatments. LLLT was applied every other day for a total of 40 minutes. The procedure required that participants

receive treatment on their waist, hips, and thighs for 20 minutes in both the supine and prone position. The center diode was positioned 4–12 in. above the abdomen, centered along the body's midline, with the four remaining diodes positioned above the lateral abdomen and thigh regions. After 20 minutes, participants would enter a prone position where the diodes were repositioned in a similar fashion to the anterior stimulation for another 20 minutes. Treatments were only targeted to the waist, hips, and thighs.

Statistical Analysis

The primary outcome measure was the change in the total combined inches of the circumferential measurements (bilateral arms and knees, neck, and chest) from the pre-procedure measurement to the 1 week post-procedure time-point. In addition, the change in total combined inches of the circumferential measurement for the waist, hips, and thighs from the pre-procedure to the 1 week post-procedure time-point was also evaluated.

Paired *t*-tests and repeated-measure analysis of variances (ANOVA) for the sample was applied to evaluate the mean change in circumference measurements from the pre-procedure to the 1 week post-procedure time-point.

RESULTS

Six-hundred and sixty subjects reported data for the waist, hips, and thighs. The mean baseline circumferential measurement for each anatomical area was 121.41 in. Following the six treatment regimen with LLLT, the mean reduction for the 660 participants was -3.27 in., which was statistically significantly different compared with the baseline measurement ($P < 0.0001$). Across the individual regions for the waist, hips, and thighs, a significant difference was observed (Table 1).

The mean percent change of the circumferential reduction from baseline to after study treatment for the individual anatomical areas and collectively for the waist, hips, and thighs was calculated (Table 2).

Circumferential measurements of the systemic, nontreated regions displayed a circumferential reduction with each anatomical area reporting a significant difference when compared with baseline (Table 3).

When combining the total circumferential reduction of the waist, hips, and thighs with the circumferential reduction for each systemic, nontreated region, the mean total circumferential loss for 556 subjects was 5.17 in., which was statistically significant ($P < 0.0001$).

Often, changes observed objectively may not correspond to subjective changes; therefore, objective analysis must

TABLE 1. Independent Mean Circumferential Change for Waist, Hips, and Thighs

| Anatomical region | <i>n</i> | Baseline (in.) | Post-procedure (in.) | Difference (in.) | <i>P</i> value |
|-------------------|----------|----------------|----------------------|------------------|----------------|
| Waist | 689 | 35.87 | 34.73 | -1.14 | <0.0001 |
| Hip | 677 | 39.68 | 38.73 | -0.95 | <0.0001 |
| Right thigh | 678 | 23.8 | 22.51 | -0.57 | <0.0001 |
| Left thigh | 679 | 22.96 | 22.35 | -0.61 | <0.0001 |

TABLE 2. Independent Mean Percent Change for Waist, Hips, and Thighs

| Body area | <i>n</i> | Mean percent change | Standard deviation of the percentage change |
|-------------|----------|---------------------|---|
| Waist | 660 | -3.16% | 3.62 |
| Hips | 660 | -2.34% | 2.64 |
| Right thigh | 660 | -2.33% | 3.55 |
| Left thigh | 660 | -2.53% | 3.37 |
| Combined | 660 | -2.64% | 2.30 |

be coupled with subjective before and after images. The first patient, who was 54 years, demonstrated a circumferential reduction across her waist, hips, and thighs of 5.875 in., which places her slightly above the calculated average for this study population (Fig. 1).

The next participant, who was 23 years old, experienced an 8.8-in. reduction across her waist, hips, and thighs. Her reduction falls above the average for the study population (Fig. 2).

The next participant, who was 44 years old, experienced a reduction of 6.875 in. across the waist, hips, and thighs, which was a statistically significant reduction that was also visually apparent (Fig. 3).

The next participant, who was 49 years old, experienced a reduction exceeding the average of the study population; she experienced a total inch reduction across all waist, hip and thighs of 7.0 in. (Fig. 4).

Lastly, it is important to illustrate the potential reduction for male participants. Although a 93.0% of the study population was comprised of females, some male participants exhibited significant reductions in their circumferential measurements. Figure 5 depicts a 30 years old

male who experienced a total circumferential reduction of 8.74 in. in 2 weeks.

DISCUSSION

These data corroborate the findings initially reported by Jackson et al. [5]. Furthermore, analysis of anatomical regions remote of the targeted treatment areas confirmed that fluid redistribution is not a likely cause for the reduction in the waist, hips, and thigh circumferential measurements. Our findings demonstrated an average reduction in the circumferential measurement of 3.27 in. in 2 weeks for the target treated regions of the waist, hips and thighs. In addition to this quantification, we used high-quality photography to illustrate that the outcomes were visually apparent to both trained clinicians and untrained individuals. Although further corroboration is warranted—including subjective analysis—the slimming observed ostensibly is secondary to lipid mobilization and subsequent metabolism, rather than, redistribution of fluid. Furthermore, the purview of laser-treated adipocytes requires further elucidation concerning the causal changes in adipocyte size may have on the synthesis of adipocyte-derived hormones—referred to as adipokines.

The use of supplementation in this study attempted to address the striking nutritional deficiencies of U.S. citizens: with an estimated 76% of adults failing to consume the daily recommended serving of fruit and vegetables [11]. Accordingly, these deficiencies may abate key enzymes integral in lipid metabolism, and, as a result, extenuate the efficacy of noninvasive body contouring devices. It was the hope—through nutritional support—to mitigate limiting factors that may permeate a broader, cursory patient base, which, in turn, would yield results tantamount to the level 1 trial. Jackson et al. [5]—utilizing no supplements—have reported a mean 3.51 in. reduction

TABLE 3. Independent Mean Circumferential Change for Systemic Non-treated Anatomical Regions

| Body area | <i>n</i> | Baseline | Post-procedure | Difference | <i>P</i> -value |
|----------------|----------|----------|----------------|------------|-----------------|
| Neck | | | | | |
| Mean | 592 | 13.62 | 13.36 | -0.26 | <0.0001 |
| Std. deviation | 592 | 1.516 | 1.463 | 0.403 | |
| Right arm | | | | | |
| Mean | 631 | 12.30 | 11.98 | -0.32 | <0.0001 |
| Std. deviation | 631 | 2.65 | 2.56 | 0.47 | |
| Left arm | | | | | |
| Mean | 632 | 12.29 | 11.97 | -0.32 | <0.0001 |
| Std. deviation | 632 | 2.43 | 2.34 | 0.50 | |
| Chest | | | | | |
| Mean | 630 | 34.99 | 34.25 | -0.74 | <0.0001 |
| Std. deviation | 630 | 4.66 | 4.49 | 0.97 | |
| Right knee | | | | | |
| Mean | 614 | 15.29 | 15.00 | -0.29 | <0.0001 |
| Std. deviation | 614 | 1.81 | 1.73 | 0.53 | |
| Left knee | | | | | |
| Mean | 611 | 15.63 | 15.34 | -0.29 | <0.0001 |
| Std. deviation | 611 | 9.41 | 9.37 | 0.53 | |



Fig. 1. Fifty-four-year-old female following 2 weeks of laser therapy.

under stringent clinical guidelines: constrained to overweight BMI, no substantial comorbidities, and completion of a daily dietary journal. Herein we reported a 3.27 in. loss within a manifold cohort that presented with variable BMI, apathetic comorbidity restrictions, and no dietary journals. Nevertheless, our result of 3.27 in. is markedly close to the initial reporting by Jackson et al. [5]. Future studies with a more discernible dietary protocol will have substantiated or obviated the utility of supplementation and whether they ostensibly equate multifarious populations or nullifies the effect of the device. However, a daily journal was not implemented to glean subject supplement use throughout the study, and, as a consequence, hampered the ability to corroborate supplements' utility. Further investigations are warranted to substantiate the specific role supplements may play when coupled with noninvasive body-contouring devices.

LLLT is a recondite technology, and, accordingly, it has been unable to infiltrate the general medical community. However, photomedicine—a relatively new discipline—has innumerable peer-reviewed publications that substantiate its clinical utility for the treatment of numerous



Fig. 2. Twenty-three-year-old female following 2 weeks of laser therapy.



Fig. 3. Forty-four-year-old female following 2 weeks of laser therapy.

diseases and conditions [12–34]. Nevertheless, the difficulty lies in understanding how light, the most abundant energy source on Earth, can influence nonphotosynthetic cells and traverse the skin barrier without marked attenuation. A replete array of studies has proven coherent light is capable of bulk tissue stimulation—substantiating that laser energy can reach subdermal tissue [12,35,36]. Nevertheless, the significant difference between the study groups reported by Jackson et al. [5] verified, cogently, the clinical slimming is attributable to LLLT and no ancillary variables.

We corroborated that the results reported by Jackson et al. did not fortuitously arise due to simple fluid displacement. Although salient mechanistic questions remain, we know that the abated circumferential measurements following LLLT ostensibly results from an inexplicable mechanism. It has been postulated that lysosomal acid lipase—an enzyme synthesized by macrophage in lymph nodes—catalyzes the degradation of lipids, which produces nonesterified free fatty acids. Regardless of the fact the mechanism remains enigmatic, the slimming event subsequent to LLLT has been substantiated



Fig. 4. Forty-nine-year-old female following 2 weeks of laser therapy.



Fig. 5. Thirty-year-old male following 2 weeks of laser therapy.

by several studies, and, more importantly, occurs without producing a single adverse event. Accordingly, this therapeutic modality appears to be an effective and safe method for body slimming.

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