

[ORIGINAL RESEARCH]

Effect of 635nm Low-level Laser Therapy on Upper Arm Circumference Reduction

A Double-blind, Randomized, Sham-controlled Trial

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ABSTRACT

Objective: To assess the safety and efficacy of low-level laser therapy as a noninvasive method for reducing upper arm circumference. **Design:** Randomized, double-blind study whereby healthy subjects (N=40) with a body mass index of 20 to 35kg/m² received three 20-minute low-level laser therapy (N=20) or sham treatments (N=20) each week for two weeks. **Measurements:** Upper arm circumference was measured after three and six treatments and two weeks post-treatment. Primary success criterion was the proportion of subjects achieving a combined reduction in arm circumference of ≥ 1.25 cm measured at three equally spaced points between the elbow and the shoulder. Secondary outcomes included total measurement change at each time point and subjective satisfaction ratings. **Results:** After six treatments, the low-level laser therapy group showed a combined reduction in arm circumference of 3.7cm versus 0.2cm in the sham treatment group ($p < 0.0001$). Significantly more subjects in the low-level laser therapy group (N=12; 60%) achieved ≥ 1.5 cm total decrease in upper arm circumference versus sham-treated subjects (N=0; 0%) ($p < 0.0005$). Low-level laser therapy treatment resulted in a combined reduction in arm circumference of 2.2cm after three treatments and 3.7cm after six treatments (for each, $p < 0.0001$) indicating a progressive and cumulative treatment effect. Body mass index remained unchanged for all subjects. A significantly greater number of subjects in the low-level laser therapy treatment group were satisfied with their results ($p < 0.05$), believed their upper arm appearance improved ($p < 0.0005$), and indicated the results exceeded expectations ($p < 0.05$). The treatments were painless and no adverse events were reported. **Conclusion:** Noninvasive low-level laser therapy is safe, painless, and effective in reducing upper arm circumference and is associated with a high degree of subject satisfaction. (*J Clin Aesthet Dermatol.* 2012;5(2):42-48.)

Noninvasive body contouring is one of the fastest growing segments of the cosmetic aesthetic industry.¹ Surgical options carry disadvantages, such as the use of anesthetics,² pain, swelling, and long recovery,³ and there is an increasing public demand for procedures with fewer side effects and shorter recovery times. Many new noninvasive body contouring technologies have been developed including suction-massage, radiofrequency energy, high-frequency focused ultrasound, cryolipolysis, and low-level laser therapy (LLLT).⁴⁻¹³

LLLT has been shown to be an efficacious adjunct therapy for numerous cosmetic procedures, including breast augmentation and lipoplasty.^{14,15} With regard to body contouring, a randomized, double-blind, sham-controlled study using a 635nm LLLT device (Zerona®, Erchonia Corporation, McKinney, Texas) showed circumferential reduction of the waist, hips, and thighs following six treatments administered over a two-week period.¹⁴⁻¹⁷ This device has been shown to provide other significant clinical benefits including reduction in cholesterol and leptin levels

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while remaining noninvasive and relatively risk free.¹⁸ This device has been cleared by the United States Food and Drug Administration (FDA) as a noninvasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. The biochemical mechanism of action of LLLT appears to increase cyclic adenosine monophosphate (cAMP) production via cytochrome C oxidase activation, which causes the breakdown of cell lipids in adipocytes and the formation of transitory pores in their cell membrane with subsequent cell collapse.¹⁹⁻²¹ Therefore, LLLT appears to provide a safe and effective alternative for the reduction of subcutaneous tissue volume.

The objective of the following double-blind, randomized, sham-controlled study was to assess the safety and efficacy of LLLT as a noninvasive method for reducing upper arm circumference.

METHODS

Study subjects. The study enrolled men and women (N=40) aged 18 to 65 years with a body mass index (BMI) of 20 to 35kg/m². Participating subjects were randomized in a double-blind fashion to receive LLLT (N=20) or sham treatment (N=20). Subjects were required to meet the American Academy of Cosmetic Surgery criteria for brachioplasty²² and indicate their ability and willingness to maintain their usual diet and exercise regimen for the duration of the study. Subjects agreed to refrain from participating in any other body contouring or weight loss procedures or programs during the course of the study including, but not limited to, over-the-counter and prescription appetite suppressants, diet plans, surgical procedures, and alternative therapies.

Reasons for exclusion from participation in the study included chronic illness, such as diabetes mellitus and cardiovascular disease; prior cardiac surgery or implanted pacemaker; active or recurrent cancer, ongoing chemotherapy, or radiation therapy; mastectomy or other surgery involving the axillary lymph nodes; medical conditions known to cause weight changes, bloating, or edema; prior surgical intervention for weight loss or sculpting of the arms; active infection, wounds, or external trauma to the areas to be treated; mental illness or developmental disability that in the professional judgment of the investigator may preclude the comprehension of informed consent or jeopardize the objectives of the study; photosensitivity disorder; participation in any type of research during the past 30 days; breast feeding, pregnancy, or planned pregnancy prior to the end of study.

Treatment device. The low-level laser energy device is a noninvasive dermatological aesthetic treatment cleared by the FDA for use as a noninvasive aesthetic dermatological treatment for reducing the circumference of hips, waist, and thighs. The LLLT device consists of four independent diodes that are positioned 120 degrees apart and tilted at a 30-degree angle. A fifth diode is positioned at the centerline. The 17mW of red 635nm of laser light emitted from each diode is collected and processed through a proprietary lens that redirects the beam with a line

refractor. The refracted light from each diode is bent into a random spiraling circle pattern that is independent of the other diodes. These overlapping patterns ensure total coverage of the target treatment area. The total amount of energy delivered to the skin during each treatment was 3.94J/cm².

Procedure. Each subject was randomized to receive six active or sham treatments 2 to 3 days apart with the low-level energy laser device over a two-week period. Both the test and sham devices have the same physical appearance and emit light when activated that is indistinguishable to both the subject and the administration investigator. The investigator and subjects were provided with eye protection during the laser procedure.

Study assessments. The circumference of each upper arm was measured using a flexible tape measure at three equally distributed points between the elbow (olecranon) and the shoulder (acromion) while the arm was in a relaxed state. For each arm, the distance from the tip of the elbow to each measurement point was recorded at baseline to ensure that subsequent measurements were obtained at the same location. All arm circumference measurements were performed by a member of the investigative team not involved in performing LLLT treatments.

The primary outcome measure was the number of subjects achieving a total decrease in arm circumference of ≥ 1.25 cm for the three combined measurement points after two weeks (6 LLLT treatments) and the mean difference between the combined arm circumference measurements for the active treatment and sham groups at all time points. Secondary outcomes assessed at the completion of the study included changes in BMI and several subjective ratings, which measured subject attitudes about overall satisfaction with their results, improvements in the appearance of their upper arms, and their treatment expectations using five-point rating scales.

All study assessments were performed at baseline, at the completion of treatment, and two weeks post-treatment. Following the baseline physical examination, a blinded investigator noted any changes in existing skin condition including scars, cellulite, stretch marks, discoloration, stria, dimpling, and skin quality and elasticity following treatment. Details about food and drink consumption, physical activity, and adverse events for each subject were recorded daily.

Statistical analysis. For the primary efficacy outcome, Fischer's exact test for two independent proportions was used to compare the proportion of successes between treatment groups. Analysis of variance (ANOVA) was used to compare changes in upper arm circumference measurements across four time points for each treatment group. The Tukey HSD test for *post-hoc* analysis was used to assess for significant changes between Baseline and Week 1, Week 1 and Week 2, Baseline and Week 2, Baseline and two weeks post-treatment, and Week 1 and 2 weeks post-treatment. Fischer's exact test was also used to compare the two positive responses for each subjective assessment question with the two negative responses, such

TABLE 1. Subject demographics

	LLLT GROUP (N=20)	SHAM GROUP (N=20)	ALL (N=40)
Gender	—	—	—
Mean age (SD), years	43.75 (10.37)	49.15 (12.65)	46.45 (11.74)
Race/ethnicity, N (%)			
Caucasian	8 (40)	12 (60)	20 (50)
African American	1 (5)	1 (5)	2 (5)
Hispanic	11 (55)	7 (35)	18 (45)
Body mass index (SD), kg/m ²	27.96 (5.00)	28.59 (4.86)	—

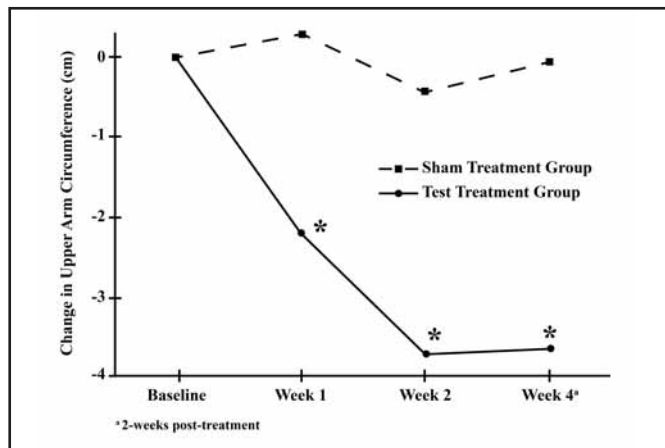


Figure 1. Among subjects treated with low-level laser therapy, the mean decrease in upper arm circumference was significantly greater than sham-treated subjects at Week 1 (3 treatments), Week 2 (6 treatments), and Week 4 (2 weeks post-treatment). *= $p < 0.0001$, Fischer's exact test.

as “Improved a lot” and “Improved a little” versus “Worsened a little” and “Worsened a lot.” For each analysis, significance was established at $p < 0.05$.

Ethics. The protocol used in this study adhered to the Good Clinical Practice guidelines of the International Conference on Harmonization and was approved by an independent Institutional Review Board (U.S. IRB, Miami, Florida, #2011 CCCR/01). Informed written consent was obtained from each subject prior to participation in any study-related activities.

RESULTS

Demographics. The entire study protocol was

completed by all enrolled subjects. Thirty nine subjects were female and one subject was male. Subject ages ranged from 22 to 65 years with no significant age difference between the two treatment groups (Table 1).

Upper arm circumference. Among the subjects undergoing LLLT treatment, 12 (60%) achieved a ≥ 1.5 cm decrease in upper arm circumference versus 0 (0%) of the sham-treated subjects ($p < 0.0005$). The LLLT treatment group showed a 3.7cm combined reduction in arm circumference versus a 0.2cm reduction in the sham treatment group after the six treatments and at the two-week post-treatment assessment (for each, $p < 0.0001$). A 2.2cm reduction in total circumference measurement occurred following the first week of three laser procedures ($p < 0.0001$) and a 3.7cm reduction following the second week of three laser procedures ($p < 0.0001$), indicating a progressive and cumulative treatment effect of the laser (Figure 1). For the right arm, there was a significant decrease in circumference between Baseline and Week 1 ($p < 0.01$) and between Week 1 and Week 2 ($p < 0.01$), which remained stable between Week 2 and Week 4. Similarly for the left arm, there was a significant decrease in circumference between Baseline and Week 1 ($p < 0.01$) and between Week 1 and Week 2 ($p < 0.05$), which remained stable between Week 2 and Week 4. For sham-treated subjects, there were no statistically significant changes detected between any time points for either arm.

Subject satisfaction assessments. With respect to subjective measures, a significantly greater number of subjects in the LLLT group was satisfied with its results (N=16 vs. N=6; $p < 0.05$) (Table 2, Figure 2). A significantly higher number of LLLT-treated subjects also indicated the appearance of their upper arms improved (N=18 vs. N=7; $p < 0.005$) (Table 3, Figure 3) and believed that the

TABLE 2. Overall satisfaction with treatment

	LLLT GROUP (N=20)	SHAM GROUP (N=20)
<i>"Overall, how satisfied are you with any change in the appearance of your arms after you finished all of the laser procedures?"*</i>		
Very satisfied	8 (40)	2 (10)
Somewhat satisfied	8 (40)	4 (20)
Neither satisfied nor dissatisfied	4 (20)	10 (50)
Not very satisfied	—	3 (15)
Not at all satisfied	—	1 (5)

*Significantly more subjects in the test group were satisfied with their results, N=16 vs. N=6; $p < 0.05$, Fischer's exact test; LLLT=low-level laser therapy

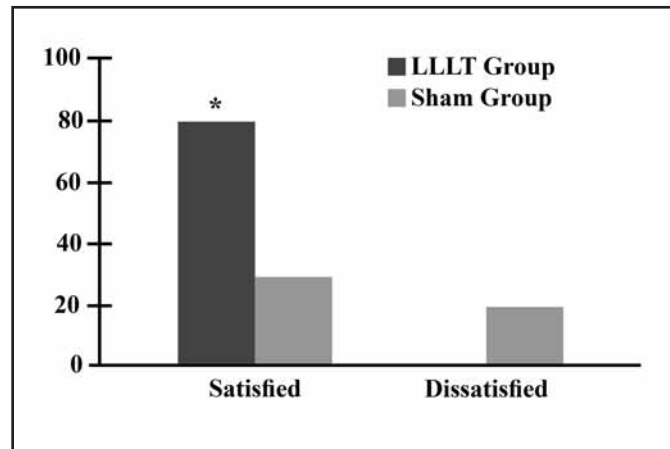


Figure 2. Significantly more subjects in the low-level laser therapy group (LLLT) were satisfied with their results. None of the LLLT-treated subjects indicated any level of dissatisfaction. *= $p < 0.05$, Fischer's exact test.

TABLE 3. Change in appearance following treatment

	LLLT GROUP (N=20)	SHAM GROUP (N=20)
<i>"Overall, how much do you think the appearance of your arms has improved?"*</i>		
Improved a lot	2 (10)	3 (15)
Improved a little	16 (80)	4 (20)
No change	2 (10)	13 (65)
Worsened a little	—	—
Worsened a lot	—	—

*Significantly more subjects in the LLLT group believe their appearance improved, N=18 vs. N=7; $p < 0.005$, Fischer's exact test LLLT=low-level laser therapy

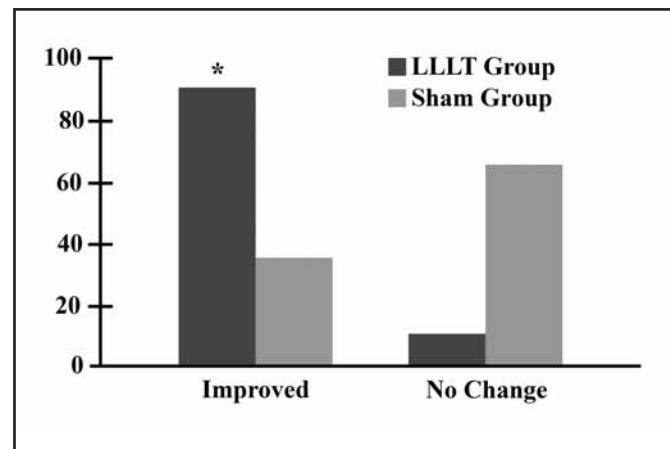


Figure 3. Significantly more subjects in the low-level laser therapy group perceived an improvement in the appearance of their upper arms. *= $p < 0.005$, Fischer's exact test.

beneficial effects of the laser procedure exceeded their expectations (N=10 vs. N=5; $p < 0.05$) (Table 4, Figure 4).

Body mass index. BMI measurements did not change significantly across or between any of the three measurement points for either LLLT- or sham-treated subject groups. For subjects in the LLLT group, the mean (standard deviation, SD) BMI was 27.96 (5.00), 28.12 (5.09), and 27.97 (5.07) at Baseline, end of treatment, and two weeks post-treatment, respectively, while the mean

BMI for the sham-treated subjects was 28.59 (4.86), 28.69 (4.95), and 28.69 (4.93) at the same time points. Further, there were no deviations from baseline diet and exercise patterns or concomitant medication use that might impact study outcome measures.

Safety. No treatment associated pain or discomfort of any kind was reported by the subjects. No changes in baseline physical examination of the treatment areas were observed and there were no reports of adverse events.

TABLE 4. Treatment expectations

	LLLT GROUP (N=20)	SHAM GROUP (N=20)
<i>"How do you think your arms look after the procedures compared with what you had expected before the procedures?"*</i>		
Much better than expected	3 (15)	2 (10)
A little better than expected	7 (35)	3 (15)
About the same as expected	9 (45)	8 (40)
A little worse than expected	1 (5)	6 (30)
Much worse than expected	—	1 (5)

*Significantly more subjects in the LLLT group believe their results were better than expected, N=10 vs. N=5; $p < 0.05$, Fischer's exact test; LLLT=low-level laser therapy

DISCUSSION

Low-level light therapy has been shown to provide a safe and effective therapeutic option for several clinical applications including acute pain associated with rheumatoid arthritis,²³ osteoarthritis,²⁴ and neck pain.²⁵ It has also been shown to increase the speed of wound healing^{26,27} and curing infections around dental implants.²⁸ More recently, it has been shown that LLLT can be used as a method for performing noninvasive body contouring.²⁹

The biochemical effects of low-level energy laser on adipose tissue appears to be mediated through an effect on cytochrome C oxidase, a large mitochondrial membrane enzyme that facilitates the transfer of electrons from cytochrome C to oxygen. In this manner, LLLT stimulates the mitochondria in adipocytes to increase adenosine triphosphate (ATP) synthesis with subsequent upregulation of cAMP. The increased cAMP stimulates cytoplasmic lipase, which converts triglycerides into fatty acids and glycerol, which can pass through pores formed in the cell membrane.^{20,21} In a study conducted by Neira et al,³⁰ high magnification scanning and transmission electron microscope images of adipose tissue revealed this transitory pore formation. Following the application of low-level laser energy, fatty acids, glycerol, and triglycerides pass across the membrane through these transitory pores and into extracellular space resulting in complete adipocytes deflation.³⁰ It is presumed that triglyceride and fatty acid oxidation occurs within the extracellular space.^{18,21,31-40}

Although significant clinical and histological effects of LLLT on adipocytes have been demonstrated, some skepticism regarding the clinical effectiveness of LLLT as well as potential confounding variables persist. A recent study conducted by Elm et al⁴¹ showed no significant

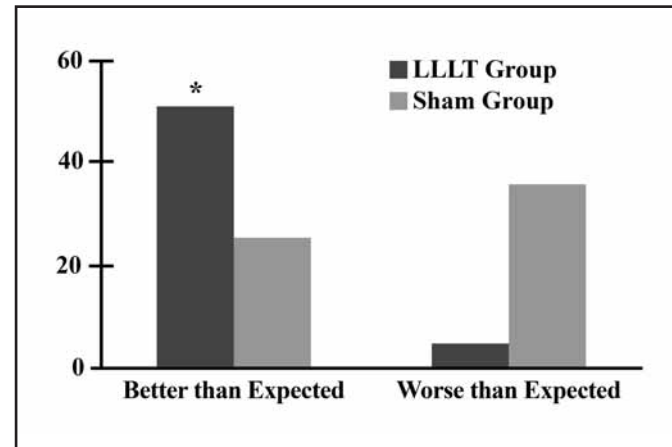


Figure 4. Significantly more subjects in the low-level laser therapy (LLLT) group believed the results they achieved following the LLLT procedure exceeded their expectations. *= $p < 0.05$, Fischer's exact test.

reduction in waist circumference at either seven days or one month following LLLT treatment; however, this study was flawed in three important ways: first, the number of subjects was extremely small (N=5); second, only partial body sites were treated; and finally, one of the authors failed to disclose a significant conflict of interest.⁴¹

Conversely, the double-blind, placebo-controlled trial conducted by Jackson et al¹⁶ randomized 67 subjects to undergo six laser treatments over a two-week period (three treatments weekly spaced two days apart) with a multiple diode head, low-level laser (635nm, 17mW; N=35), or sham treatment with a multiple-head non-laser light emitting diode (635nm, 2.5mW; N=32). Following treatment, the decrease in total circumference measurements was significantly greater for the LLLT subjects at all time points. No adverse events were reported.^{16,42}

Although it had been hypothesized that fat released following LLLT treatment may appear in the bloodstream where it might adversely affect the lipid profile, a nonrandomized, uncontrolled study that assessed serum triglyceride and cholesterol levels subsequent to LLLT showed an actual reduction in both serum cholesterol and leptin levels.¹⁸

In summary, the results of this double-blind, controlled, randomized study designed to assess the efficacy of 635nm LLLT in reducing upper arm circumference demonstrated a significant progressive and cumulative treatment effect among treated subjects. Any potential confounding variables from a prior body contouring study including diet, supplements, and measuring errors were satisfactorily addressed. Since all study participants were blinded as to whether or not they were in the treatment group, and no study participants in either group experienced a change in

BMI or deviated from baseline diet and exercise patterns, the authors conclude that the decrease in arm circumference is the result of LLLT treatments. Subjective evaluations confirmed the effectiveness of the treatments. Further studies will optimize the results of 635nm LLLT, investigate other possible indications for treatment, and assess the overall metabolic effect of treatment.

CONCLUSION

Noninvasive LLLT was significantly more effective at reduction of arm circumference than sham treatments at every tested time point. This study showed significant results without any apparent confounding variables. Subjective assessments were significantly positive for the treatment group. No pain or discomfort of any kind was associated with treatment and no adverse events were reported by any subject throughout the study. Together, these results indicate low-level energy laser treatment appears to be a safe and effective method for noninvasively reducing upper arm circumference.

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