Volume 31, Number 1, 2014

AMERICAN ACADEMY
OF COSMETIC SURGERY

The American Journal of Cosmetic Surgery

TO ADVANCE THE SPECIALTY
OF COSMETIC SURGERY AND
QUALITY PATIENT CARE

ORIGINAL ARTICLE

A Double-Blind, Sham-Controlled Study Demonstrating the Effectiveness of Low-Level Laser Therapy Using a 532-nm Green Diode for Contouring the Waist, Hips, and Thighs

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Introduction: *A low-level laser therapy (LLLT) device emitting 635 nm of red light is an effective, noninvasive method of reducing the circumference of the waist, hips, thighs, and upper arms. This randomized, double-blind, sham-controlled study assessed the effectiveness of an LLLT device emitting 532 nm of green light for body contouring using the same treatment protocol as the red 635-nm LLLT device.*

Materials and Methods: *Enrolled subjects were 18–65 years of age with a body mass index (BMI) < 30 kg/m². The LLLT device consists of 5 independent diodes, each emitting 17 mW of green laser light with a frequency of 532 nm (Erchonia ML Scanner, Erchonia Corporation, McKinney, Tex). Subjects were randomized to receive active (n = 35) or sham LLLT treatments (n = 32) over a 2-week period. Three treatments were administered each week, 2–3 days apart. Efficacy assessments included waist, hip, and thigh circumference measurements; body weight; and BMI following 3 LLLT treatments (week 1), 6 LLLT treatments (week 2), and 2 weeks following the final procedure. A treatment satisfaction survey was completed at week 2. The primary efficacy outcome measure was the change in total combined baseline circumference measurements at week 2. The criterion for individual treatment success was ≥3.0-inch reduction in combined circumference measurements, and overall study success was ≥35% difference in the proportion of subjects in each treatment group achieving individual treatment success. Secondary efficacy outcomes included the change in total combined baseline circumference measurements at each subject evaluation as well as satisfaction survey results.*

Results: *At week 2, the LLLT-treated subjects demonstrated a mean (SD) decrease in total combined circumference measurements of 3.9 (3.0) inches (P < .0001) compared with 1.1 (2.3) inches for sham-treated subjects. Among LLLT-treated subjects, 24 (68.6%) achieved a ≥3-inch mean decrease in total combined circumference measurements compared with 6 (18.8%) in the sham group (P < .0001). The effects of LLLT treatment were independent of baseline body weight, BMI, and total baseline circumference measurement. Compared to baseline measures, the LLLT-treated subjects demonstrated significant decreases in circumference measures for each individual treatment area at the week 1, week 2, and 2 weeks posttreatment evaluations. Among subjects responding to the satisfaction survey, an overall satisfaction response was obtained from 65% of LLLT subjects versus 19% of sham-treated subjects.*

Conclusions: *The use of LLLT device equipped with 532-nm green diodes is a safe and effective means for noninvasive body contouring of the waist, hips, and thighs.*

Received for publication October 4, 2012.

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DOI: 10.5992/AJCS-D-12-00048.1

The use of low-level laser light is an effective, noninvasive method of body sculpting. Several double-blind, sham-controlled studies have reported significant reductions in the circumference of hips, waist and thighs,[1] and upper arms,[2,3] following the application of 6 treatments of low-level laser energy 2–3 days apart over a 2-week period. The laser device used in these studies emits 17 mW of red 635-nm laser light from each of 5 independent diodes, delivering a total of 3.94 J/cm² of energy to the skin per treatment. This device has been cleared by the US Food and Drug Administration as a noninvasive dermatological esthetic treatment for the reduction of the circumference of hips, waist, and thighs (Erchonia ML Scanner, Erchonia Corporation, McKinney, Tex).

Lasers using other frequencies of light have also been used in dermatology. Green laser light has been used to treat medical conditions such as superficial vascular lesions[4,5] and acne vulgaris.[6,7] Esthetic applications of green lasers include the removal of unwanted blemishes, including freckles,[8,9] port wine stains,[10–14] hypertrophic scars,[15] and tattoos.[16,17]

Green lasers have also been used as a noninvasive method to improve skin tone and remove mild rhytides.[18,19] In one study, 3–6 applications of a 532-nm green laser with an energy output of 7–15 J/cm^2 for 7–20 milliseconds at monthly intervals were associated with mild-to-moderate improvement in the appearance of rhytides, moderate improvement in skin tone and texture, and great improvement in the reduction of redness and pigmentation, which persisted for up to 18 months after the last treatment.[20]

The purpose of this randomized, double-blind, sham-controlled study was to assess the effectiveness of a 532-nm green-diode low-level laser therapy (LLLT) device for noninvasive body contouring of the waist, hips, and thighs using the same treatment protocol that has proven to be effective for the red 635-nm LLLT device.[1–3]

Materials and Methods

Subjects

The study enrolled male and female subjects 18–65 years of age with a body mass index (BMI) <30 kg/m^2. Enrolled subjects satisfied the guidelines for liposuction or the use of liposuction techniques for the removal of localized deposits of adipose tissues that do not respond to diet and exercise, and specifically for body contouring in the areas of the waist, hips, and bilateral thighs.[21] All subjects expressed their willingness and ability to maintain their normal diet and exercise regimen throughout the duration of the study and to abstain from any other body contouring treatment, weight loss programs, surgical procedures, alternative therapies, over-the-counter and prescription medications, and dietary, herbal, and mineral supplements.

Exclusion criteria included prior surgical intervention for body sculpting or weight loss such as liposuction, abdominoplasty, stomach stapling, or lap band surgery; cardiovascular disease or prior cardiac surgery; presence of an implanted device such as a pacemaker; diabetes mellitus requiring treatment with insulin or oral hypoglycemic medications; current cancer; a medical condition or current use of medications known to affect weight or cause bloating or swelling; irritable bowel syndrome; photosensitivity disorder; medical or other contraindication for body sculpting or weight loss; active infection, wound, or other external trauma to the areas to be treated; serious mental health illness such as dementia or schizophrenia, psychiatric hospitalization in the past 2 years, or developmental disability or cognitive impairment that might preclude adequate comprehension of the informed consent or jeopardize the study objectives; participation in a clinical study or other type of research in the past 30 days; and pregnancy, breast feeding, or planning pregnancy prior to the end of study participation.

Experimental Device

The LLLT device used in this study is a Class IIIb laser consisting of 4 independent mounted diodes positioned 120° from one another and tilted at a 30° angle (Erchonia MLS, Erchonia Corporation). A fifth diode is positioned at the centerline. Each scanner emits 17 mW of green laser light with a frequency of 532 nm. The 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 then bent into a random, spiraling circle pattern that is independent of the other diodes. The target area is approximately 8 × 10 inches (80 in^2 or approximately 516 cm^2) and the overlapping light patterns ensure total coverage of the target area. Protective eyewear was provided for the investigator and subject (NoIR LaserShields, NoIR Laser Co, South Lyon, Mich).

Procedure

Subjects were randomized to undergo 6 active or sham LLLT treatments over a 2-week period. Three treatments were administered each week, 2–3 days apart. During each procedure, the LLLT exposure time was 15 minutes across the frontal region and 15 minutes across the lateral region of each treated area.

Outcome Measures

Subjects were evaluated at the end of week 1 following the first 3 LLLT treatments, at the end of week 2 following all 6 LLLT treatments, and again 2 weeks following the final LLLT procedure. Outcome measures at each evaluation include circumference measurements of the waist, hips, and both thighs, as well as body weight and BMI. In addition, subjects

Table 1. Primary Outcome: Treatment Success

	LLLT Subjects ($n = 35$)	Sham Subjects ($n = 32$)
Change in total circumference, mean (SD)	−3.9 (3.0)*	−1.1 (2.3)
Subjects achieving success, *n* (%)	26 (68.6)†	6 (18.8)

*$P < .0001$ vs baseline; *t* test for independent samples.
†$P < .0001$ vs sham treatment, Fischer exact test.

completed a treatment satisfaction survey during the week 2 evaluation. There were no significant differences in the baseline physical characteristics of subjects in the 2 treatment groups except for the mean (SD) left thigh circumference, which was 23.5 (1.6) inches in the LLLT group and 22.3 (1.7) inches in the sham group ($P < .05$).

Study Endpoints

The primary efficacy outcome measure was the change in total combined baseline circumference measurements at the end of the 2-week treatment phase. The criterion for individual treatment success was predefined as a ≥3.0-inch reduction in combined circumference measurements for the waist, hips, and thighs. The criterion for overall study success was predefined as ≥35% difference in the proportion of subjects reaching the individual treatment success between treatment groups. Secondary efficacy outcomes included the change in total combined baseline circumference measurements at each subject evaluation, change in body weight and BMI, and the results of the subject satisfaction survey.

Safety Measures

Prior to treatment, the investigator recorded the presence of hernias, scars, asymmetries, cellulite, stretch marks, or discoloration; the presence of stria and dimpling; the condition of the underlying abdominal musculofascial system and the presence or absence of flaccidity and diastasis recti; and skin quality and elasticity. These skin markers were reevaluated at the end of the 2-week treatment phase of the study and at the 2-week posttreatment evaluation. Spontaneous and elicited reports of adverse events were recorded throughout the study.

Statistical Analysis

The intent-to-treat population included all subjects who underwent randomization and provided baseline

Table 2. Change in Total Circumference Measurements, Mean (SD)

	LLLT Subjects ($n = 35$)	Sham Subjects ($n = 32$)
Baseline	119.9 (8.5)	117.0 (11.3)
Week 1	117.0 (9.0)†	116.4 (11.8)
Week 2	116.1 (8.1)†	115.9 (11.5)*
2 Weeks post	115.9 (8.9)†	115.7 (11.2)

*$P < .05$ vs baseline.
†$P < .01$ vs baseline, Tukey HSD test.

circumference measurements. All enrolled subjects completed the 2-week treatment phase of the study. One-way analysis of covariance for 2 independent samples were performed on the combined change in circumference measurements to adjust for the covariates of baseline body weight, BMI, and combined body circumference. Thirteen subjects did not provide circumference measurements at the 2-week posttreatment evaluation, and the last observation carried forward procedure was used for missing data. Student *t* test for independent samples was used to assess between-group differences in baseline body circumference measurements.

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

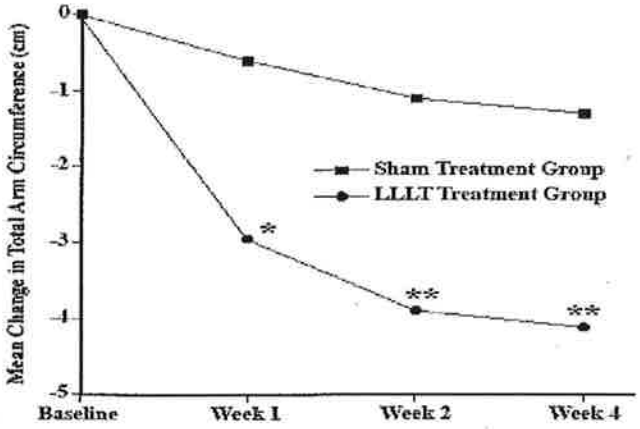

Figure 1. *Mean change in total circumference measurements in the intent-to-treat population. Compared to baseline measures, subjects who received low-level laser therapy (LLLT) demonstrated significant decreases in circumference measures for each individual treatment area at the week 1, week 2, and 2-week posttreatment evaluations.*
*$P < .05$; **$P < .01$.

Table 3. Change in Circumference for Each Treated Area, Mean (SD)

	LLLT Group ($n = 35$)	Sham Group ($n = 26$)
Waist		
Baseline	33.5 (3.9)	32.6 (5.0)
Week 1	32.8 (3.8)*	32.5 (5.1)
Week 2	32.5 (3.6)†	32.6 (5.2)
2 Weeks post	32.4 (3.6)†	32.5 (5.2)
Hip		
Baseline	39.8 (3.3)	39.3 (3.9)
Week 1	38.9 (3.0)†	39.0 (3.9)
Week 2	38.6 (2.9)†	38.8 (3.8)
2 Weeks post	38.6 (3.2)†	38.7 (3.8)
Right thigh		
Baseline	23.4 (1.8)	22.7 (2.3)
Week 1	22.7 (2.0)†	22.6 (2.4)
Week 2	22.6 (1.9)†	22.3 (2.1)
2 Weeks post	22.6 (2.0)†	22.4 (2.1)
Left thigh		
Baseline	23.4 (1.6)	22.5 (2.1)
Week 1	22.7 (1.9)†	22.4 (2.3)
Week 2	22.4 (1.8)†	22.2 (2.1)
2 Weeks post	22.3 (1.9)†	22.2 (2.0)

*$P < .05$.

†$P < .01$ vs baseline; 1-way ANOVA for correlated samples.

independent institutional review board (Western Institutional Review Board, Olympia, Wash). Each subject provided signed informed consent prior to participating in any study-related activities.

Results

Sixty-seven subjects were enrolled in the study and were randomized to the LLLT ($n = 35$) and sham ($n = 32$) treatment groups. Each subject completed the study through the 2-week evaluation visit; however, 16 subjects did not return for the 2-week postprocedure follow-up evaluation.

Primary Outcome

At the 2-week evaluation, the subjects treated with LLLT demonstrated a mean (SD) decrease in total combined circumference measurements of 3.9 (3.0) inches ($P < .0001$) compared to a 1.1 (2.3) inch decrease for the subjects in the sham treatment group (Table 1). Among the subjects in the LLLT group, 24 (68.6%) achieved a ≥3-inch mean decrease in total

Table 4. Body Weight Measurements, Mean (SD)

	LLLT Group ($n = 35$)	Sham Group ($n = 26$)
Weight		
Baseline	154.3 (28.8)	154.2 (26.2)
Week 1	154.2 (29.3)	154.3 (26.4)
Week 2	153.4 (29.0)*‡	154.1 (26.1)
2 Weeks post	153.7 (28.9)†	154.1 (25.9)
BMI		
Baseline	25.8 (2.9)	24.8 (3.3)
Week 1	25.9 (2.9)	24.8 (3.3)
Week 2	25.7 (2.9)‡	24.8 (3.3)
2 Weeks post	25.8 (2.9)	24.7 (3.2)

*$P < .01$.

†$P < .05$ vs baseline.

‡$P < .05$ vs week 1; 1-way ANOVA for correlated samples.

combined circumference measurements compared with 6 (18.8%) in the sham group ($P < .0001$). A covariate analysis revealed that the LLLT treatment is more effective than sham treatment ($P < .0001$) and is independent of baseline body weight, BMI, and total baseline circumference measurement.

Secondary Outcome

The changes in total body circumference measurements for subjects in each treatment group at each evaluation time are summarized in Table 2 and shown graphically in Figure 1. Compared to baseline measures, the LLLT-treated subjects demonstrated significant decreases in waist circumference at the week 1 evaluation ($P < .05$) and all treated areas at the week 2 ($P < .01$) and 2-week posttreatment evaluations ($P < .01$). Among the sham-treated subjects, a significant mean decrease in total body circumference was observed at

Table 5. Subject Satisfaction*

	LLLT Group ($n = 31$)	Sham Group ($n = 31$)
Very satisfied	13 (42)	2 (6)
Somewhat satisfied	7 (23)	4 (13)
Neither satisfied nor dissatisfied	5 (16)	20 (65)
Not very satisfied	4 (13)	5 (16)
Not at all satisfied	2 (6)	...

*Values represent number of responses (%). Responses were not received from 4 subjects in the LLLT group and 1 subject in the sham group.

Figure 2. *Proportion of subjects expressing overall treatment satisfaction. Responses to questions regarding subject satisfaction with the overall change in body shape were obtained from subjects who received low-level laser therapy (LLLT) (n = 31) and sham-treated subjects (n = 31) following the procedure. An overall satisfied response was obtained from 20 LLLT subjects (65%) compared with 6 from sham-treated subjects (19%).*

the 2-week evaluation ($P < .05$). The mean changes in individual treatment areas are summarized in Table 3. Table 4 demonstrates the findings of the independence of both weight and BMI.

Responses to questions regarding subject satisfaction with the overall change in body shape following the procedure administration were obtained from 31 LLLT-treated subjects (87%) and 31 sham-treated subjects (95%) and are summarized in Table 5. An overall satisfied response was obtained from 20 LLLT subjects (65%) versus 6 sham-treated subjects (19%) (Figure 2).

Safety

No changes in baseline skin condition or skin markers were observed for any subject. No subject reported

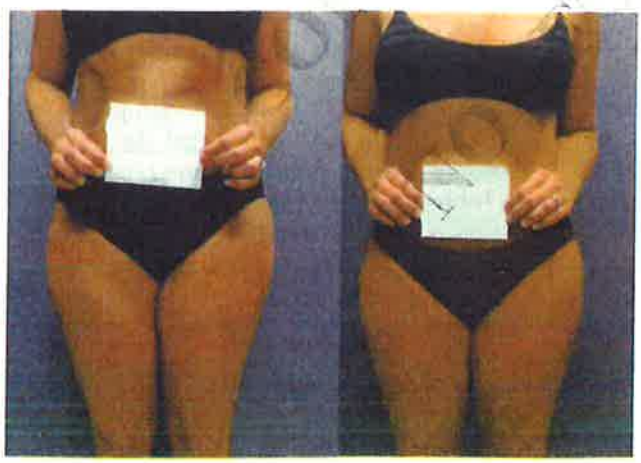

Figure 3. *Before and after images of patient 1, front views. Note decrease in abdominal fat pad, and notice the decrease in the left thigh appearance. Patient is thinner overall. Submitted by Dr Jackson.*

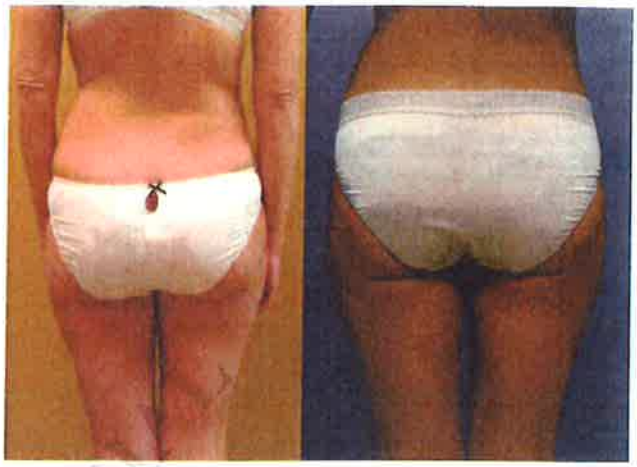

Figure 4. *Before and after images of patient 2, back views. The after photo was taken closer than the before to demonstrate the space between the thighs following treatment. Submitted by Dr Jackson.*

any deviation from baseline diet, exercise, or concomitant use of medication that was likely to affect the outcome of the study.

Discussion

Two weeks following the last treatment, subjects treated with the 532-nm green-diode LLLT demonstrated significant decreases in the circumference of each treated body area. The total mean combined circumference measurements for LLLT-treated subjects decreased by 3.9 inches versus 1.1 inches for sham-treated subjects. The effects of LLLT were significantly greater than sham treatment and were independent of baseline body weight, BMI, and total circumference measurements. These results compare favorably with the results of a previous study using the red 635-nm LLLT device. In that study, the total mean combined circumference measurements for LLLT-treated subjects decreased by 3.52 inches versus 0.68 inches for sham-treated subjects.[1]

A decrease in total combined circumference measurements of 3 or more inches was achieved by 68.6% of LLLT-treated subjects versus 18.8% of sham-treated subjects. These results are also similar to the results with the red 635-nm LLLT device in which the mean decrease in total combined circumference measurements of 3 or more inches was achieved by 62.9% of LLLT-treated subjects versus 6.25% sham-treated subjects.[1]

There were no reports of adverse events at any time during the study. No adverse events were reported in the studies employing a red 635-nm LLLT device for

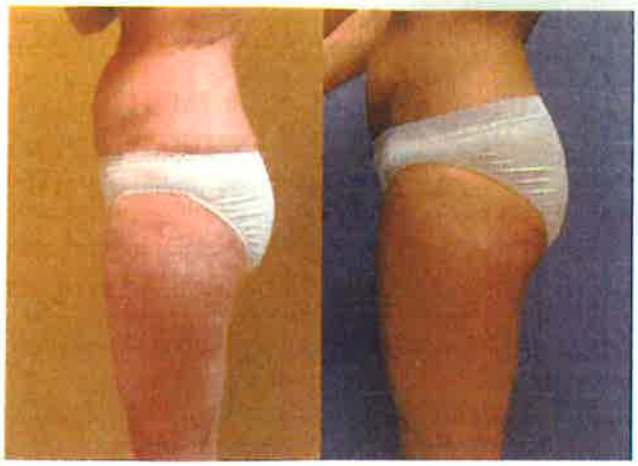

Figure 5. *Before and after images of patient 2, side views. Notice the decrease in abdomen and smoother appearance of the outer thigh. There is a lack of bulge on the outer thigh in the post-procedure photo. Submitted by Dr Jackson.*

the treatment of the waist, hips and thighs,[1] and upper arms.[2] Clinical laboratory parameters were not measured; however, previous work demonstrated no change in serum levels of cholesterol and triglycerides following the treatment of the abdomen with LLLT using the same protocol used in the present study.[22] Although the mechanism remains unclear, serum triglycerides in that study actually decreased in 16 of 19 treated subjects (84%) and serum cholesterol decreased by an average of 18.8 mg/dL.

With respect to body contouring, the mechanism of action of red LLLT appears to be due to its ability to

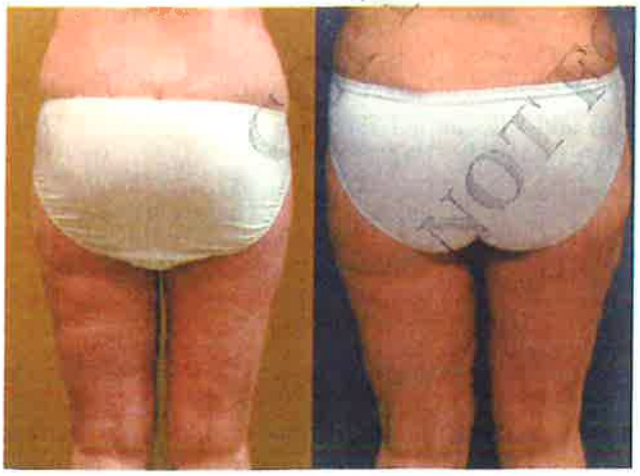

Figure 6. *Before and after images of patient 3, back views. These images demonstrate improvement in cellulite appearance in addition to better body contouring. The after picture is taken from a somewhat closer view to demonstrate that improvement. Submitted by Dr Jackson.*

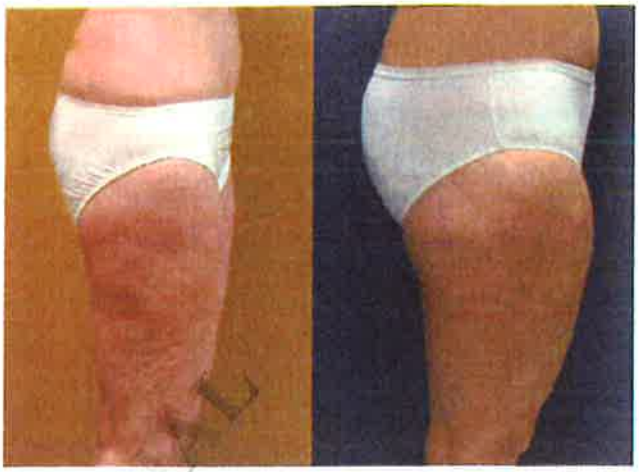

Figure 7. *Before and after images of patient 3, side views. These images demonstrate improvement in cellulite appearance in addition to better body contouring. The after picture is taken from a somewhat closer view to demonstrate that improvement. Submitted by Dr Jackson.*

increase cAMP production via cytochrome C oxidase activation, which results in the transient formation of pores in the cell membrane of adipocytes. This allows intracellular lipids to leave the cell and become oxidized within the extracellular space.[23,24] The net effect is the collapse of adipocytes[25–27] and a corresponding decrease in circumference of the treated body area.[1,2] Based on the safety and efficacy demonstrated by the use of green laser light in this study, we hypothesize that the green LLLT and red LLLT share this same mechanism of action.

In summary, a 532-nm green-diode LLLT device is safe and effective for noninvasive body contouring of the waist, hips, and thighs, using the same treatment protocol that has been shown to be effective for a red 635-nm LLLT device. The effects of LLLT were significantly greater than sham treatment and were independent of baseline body weight, BMI, and

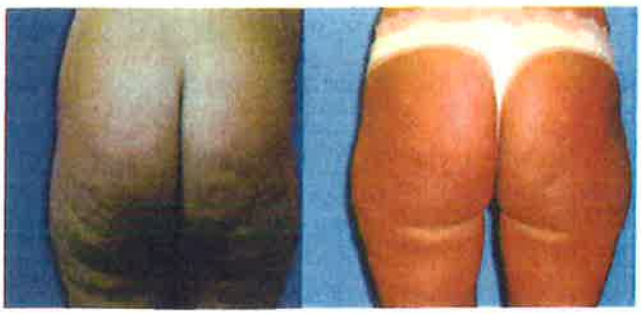

Figure 8. *Before and after images of patient 4, back views of buttocks and posterior thighs. Submitted by Dr Roche.*

total circumference measurements. (See Figures 3 through 8 for before and after images.)

Conclusion

The use of an LLLT device equipped with 532-nm green diodes is a safe and effective means for noninvasive body contouring of the waist, hips, and thighs. The results achieved with this device compare favorably with a device employing red 635-nm diodes and are independent of baseline body weight, BMI, and total circumference measurements.

Acknowledgments

The authors acknowledge the assistance of Elvira Walls, Regulatory Insight Inc and Dr Carl Hornfeldt, Apothekon Inc during the preparation of this manuscript. This study was sponsored by Erchonia Corporation, McKinney, Tex.

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