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ORIGINAL ARTICLE

Clinical evaluation of the safety and efficacy of a 1060 nm diode laser for non-invasive fat reduction of the flanks

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Abstract

Background: Laser hyperthermia-induced lipolysis is a non-invasive method of localized fat treatment. Non-invasive approaches could be an option for a growing number of patients who are risk-averse and are seeking out non-invasive alternatives to surgical procedures such as liposuction. This study evaluated the safety and efficacy of a 1060 nm diode laser for the non-invasive fat reduction of the flanks.

Methods: A total of 30 subjects were enrolled in this prospective, single center study. Subjects received one 25-min treatment with a 1060 nm diode laser to both flanks. Follow-up visits were conducted at 6 and 12 weeks after the last treatment. Ultrasound adipose thickness, body weight, and circumference measurements were taken at baseline and at the 6- and 12-week follow-up visits. Subject satisfaction was assessed using a self-assessment of fat reduction, pain, and tolerability scales, and a subject satisfaction questionnaire. Safety was assessed via the presence or absence of any adverse events.

Results: The average age of subjects was 47.3 years. A total of 27 subjects completed the treatment and returned for both follow-up visits. An adipose reduction of $7.57 \pm 1.15\%$ at 6 weeks post-treatment ($p < 0.0001$) was measured using ultrasound. High subject satisfaction was seen, with 74% of subjects reporting being either "satisfied" or "very satisfied" with their results on a 5-point Likert Scale. Eighty-two percent of subjects stated they would recommend the treatment to their friends. All subjects had either mild or moderate pain, with 52% of subjects rating their pain as "mild" (1–3), while 48% rated their pain as moderate (4–7) on the Wong-Baker Scale.

Conclusions: A single treatment with a 1060 nm diode laser was both safe and effective in reducing unwanted fat in the flanks without any unanticipated adverse events. Subjects described their treatment pain as mild or moderate and were highly satisfied with their treatment outcomes.

KEYWORDS
fat reduction, flank contouring, laser therapy, non-invasive body contouring, thermal lipolysis

1 | INTRODUCTION

Liposuction is one of the top five cosmetic treatments requested by both men and women in the United States.[1] However, due to the risk of surgery-related problems, and the prevalence of more non-invasive methods, energy-based in-clinic treatment alternatives are becoming more popular for patients who want a contoured silhouette but do not want to undergo surgery or have limiting issues that prevent them from being surgical candidates. To address this rising need, a growing variety of non-surgical technologies have become widely available to provide alternative possibilities. Lasers, high-intensity focused ultrasound, high-intensity focused electromagnetic devices (HIFEM), radiofrequency devices, and cryolipolysis are all non-surgical energy-based fat removal options.[1]

Lasers cause an increase in tissue temperature in both the adipocyte and peri-adipocyte environments. This increases localized catabolic rates of the fat cells, resulting in the breakdown of triglycerides into free fatty acids and glycerol, which then exit the adipocyte via a free fatty acid transporter.[2] Specifically, a temperature of 42–47°C results in adipocyte injury, triggering an immune response.[3,4] The immune system eliminates the cellular debris from the apoptosis and necrosis of adipocytes over the course of 6–12 weeks post-treatment. Correlating with the removal of necrotic and apoptotic adipose cells, previous studies have shown that results after 1060 nm treatment were observed at 6 weeks post-treatment and peaked at 12 weeks post-treatment.[2,3,5,6]

Previous work has focused on the 1060 nm diode laser and safety and efficacy non-invasive fat reduction on the abdomen,[7] therefore the objective of this study was to evaluate the safety and efficacy of using the 1064-nm diode laser for non-invasive fat reduction of the flanks.

2 | METHODS

2.1 | Study design

This single-arm study consisted of two centers (Clinic 01 Sacramento CA USA and Clinic 02 Dallas TX USA) and identical study protocols at both centers were approved by Western Institutional Review Board, Inc. (WIRB) for Clinic 01 and the Institutional Review Board at the University of Texas Southwestern Medical Center for Clinic 02. The trial was conducted according to the Declaration of Helsinki and all its revisions. The study enrolled 30 subjects who received a 25-min diode treatment to their flanks using a 1060 nm laser diode.

2.2 | Subject recruitment

Male and female volunteers over the age of 18 with a body mass index (BMI) score of less than 30, who were interested in non-invasive lipolysis of the flanks were recruited. Subjects had to agree to refrain from making major changes in their diet or lifestyle during the study. Subjects were screened for exclusionary criteria, including but not limited to pregnancy in the last 3 months, prior liposuction in the last 12 months, trauma or tattoos in the treatment area, and disorders of the skin. Informed consent was obtained from all subjects.

2.3 | Investigational device

The device (Venus Bliss™, Toronto, Canada) used has four 1060 nm diode laser applicators connected to the main console which contains a power supply, a water-based cooling system, laser driver and laser controller, along with a graphical user interface, allowing the operator to control the device settings. A belt is used to secure the laser applicators on the treatment area, allowing hands-free operation and to ensure the laser always remains in contact with the skin during treatment. Each applicator contains a water-cooled window for contact tissue cooling to prevent the skin from overheating and four touch sensors to ensure proper placement and contact during laser emission; the treatment window covers an area of 60 mm × 60 mm (Figure 1). Anesthesia is not required for this treatment in general and was not used in this study.

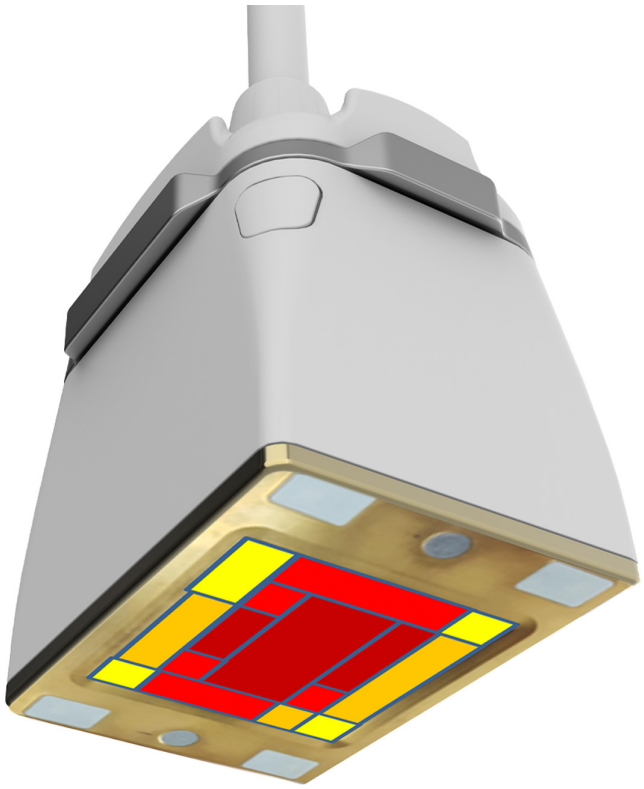


FIGURE 1 Diode energy distribution over the treatment window. Diagram presenting the bottom of an applicator. The colored box in the middle represents the treatment window. Colors represent the energy density, with most of the energy density delivered to the areas in dark red, lighter red and orange zones. The yellow zone has the least amount of energy density.

2.4 | Treatment protocol

Each subject received a single treatment with the investigational device. Subjects were placed in the prone position on a treatment lounger or seated in a chair, with their flank area exposed. A belt with frames which hold the diodes in place during treatment, was affixed to their midsection with straps and clips. The belt has the capability of holding four diodes in place during treatment, two on each flank, which was typical for each subject (Figure 2). In smaller subjects, only two diodes were used, one per flank. Treatment time was 25 min, with each applicator delivering 1.4 W/cm^2 and being reduced to as low as 1.1 W/cm^2, if necessary, for comfort based on subject feedback.

Ultrasound measurements, body weight, and circumference at the mid-flank (approximately an inch above the iliac crest, depending on the area of visible protrusion) were obtained during the treatment visit prior to the treatment session. Subjects presented for follow-up visits at 6 and 12 weeks post-treatment to repeat body weight and circumference measurements and ultrasound imaging. At baseline and at the final 12-week follow-up visit, subjects completed the modified Simple Lifestyle Indicator Questionnaire (SLIQ) to ensure they maintained consistency in their lifestyle for the study duration.[8] Lifestyle questions assessed diet, alcohol consumption, smoking, stress, and activity levels. Subject satisfaction was evaluated at the 12-week visit using the five-point Likert Subject Satisfaction Scale from 0 to 4, with 0 being "very unsatisfied" and 4 being "very satisfied" as well as a brief questionnaire requesting feedback about their treatment experience.[8]

2.5 | Clinical measurements

The study's endpoints included subject satisfaction surveys, assessment of adverse effects, circumference measurements, weight, and empirical measurements of adipose thickness at the treated areas using ultrasound.

Adipose layer thickness was measured using a MicroMaxx (SonoSite Inc., Bothell, WA) with an L38 10 MHz transducer at Clinic 01 and a GE Venue 40 diagnostic ultrasound device (General Electric Healthcare, Wautwatosa, WI) with a 12-MHz transducer at Clinic 02. The measurements were taken in the treatment areas at each follow-up visit based on photographs with the applicators in place and markings of the applicator locations. The same technician performed each of the ultrasound recordings at each clinical center, with the same minimum required compression force per acceptable standard for ultrasound imaging.[9] Hip circumference was measured at the same anatomical area using the same tape measure at each visit. Clinic 01 used landmarks on the body and distance from the umbilicus to accurately place the measuring tape around the subject. At Clinic 02, the subject was placed against a measuring tool (Seca 206, Seca, CA, USA) that allowed the investigator to locate the same area to be measured at each visit.

2.6 | Safety evaluations

At regular intervals during the treatment, subjects were asked to rate their pain using the Wong Baker™ scoring system. The Wong Baker™ pain assessment scale goes from 0 (no pain) to 10 (worst pain).[10] Immediately after treatment, the subjects were asked to rate their overall pain perception of the treatment. After removing the belt, the investigator examined the treated areas for hemorrhage, burn, erythema, edema, and purpura using a 5-point scale: 1 = none, 2 = trace, 3 = moderate, 4 = marked, 5 = severe. Subjects were asked to report any other self-observed adverse events at follow-up visits.

2.7 | Statistical analyses

Changes in clinical measurements from baseline to the 6- and 12-week follow-up visits, including weight, body circumference, and adipose thickness were tested using Student's paired *t*-test. For the subject satisfaction surveys analyses, the Wilcoxon signed-rank test was used. Descriptive statistics were also used. Unless otherwise indicated, mean ± standard error (SE) is shown.

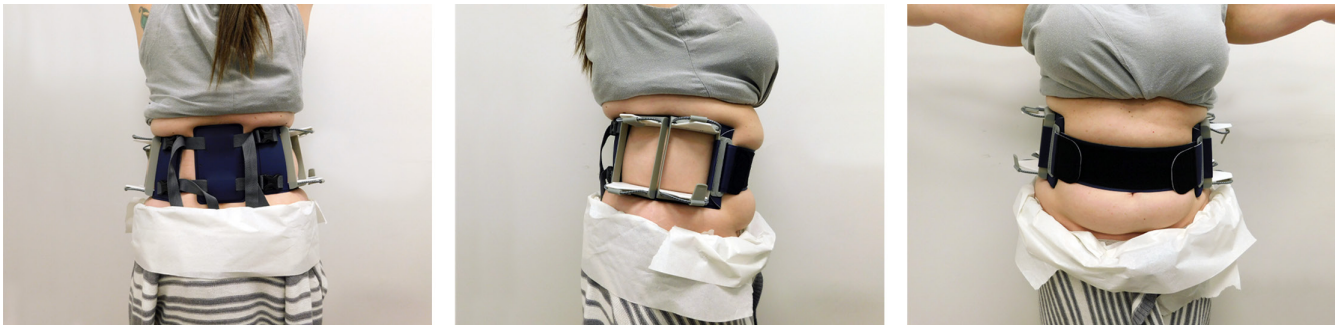


FIGURE 2 Belt position for flanks. This example shows how the belt was positioned and where the applicators were placed. The belt has four sites where applicators are placed. In the case of smaller subjects, the belt was placed in the same position but using only one diode on each side instead of two per side.

3 | RESULTS

3.1 | Subject demographics

Thirty male and female subjects (15 at each clinical center) were enrolled in the study, of whom 27 completed screening, treatment, and both the 6- and 12-week follow-up visits. Three[3] female subjects dropped out, one prior to treatment and two were lost to follow-up. Of those who completed all visits, 24 were female (89%), and 3 were male (11%). The majority of subjects (92.6%) were Caucasian. Most subjects had Fitzpatrick skin type II (55.6%), but a considerable number were type III (29.6%) and type IV (14.8%). The mean BMI was 25.5 ± 3.1 (mean ± SD). The mean age of subjects in the study at the time of enrollment was 47.3 years, with a range of 22–69 years old (Table 1). All subjects completed a lifestyle survey pre-treatment and at the 12-week follow-up. The results of the lifestyle questionnaire confirmed that all subjects remained consistent with their diet, activity levels, smoking, and consumption of alcohol habits.

3.2 | Body measurements

Body weight remained stable between baseline (156.5 ± 4.1 lbs), and the 6-week (156.0 ± 4.0 lbs) and 12-week (155.7 ± 4.1 lbs) post-treatment follow-up visits. Likewise, body circumference remained unchanged from baseline (36.23 ± 0.59 in) to both the 6- or 12-week follow-up measurements of 36.14 ± 0.59 in and 35.89 ± 0.61 in, respectively. Although there was a very subtle downward trend in both body weight and circumference, this was not statistically significant.

TABLE 1 Demographic data of participants.

Demographic data	Results ($N = 27$)
Age, mean (SD) (years)	47.3 (13.1)
Age, range (years)	22–69
Weights (lbs)	156.5 (21.1)
BMI	25.5 (3.1)
Gender, *n* (%)	
Female	24 (88.9%)
Male	3 (11.1%)
Race	
Caucasian	25 (92.6%)
Asian	1 (3.7%)
Black or African Descent	1 (3.7%)
Fitzpatrick skin type	
II	15 (55.6%)
III	8 (29.6%)
IV	4 (14.8%)

3.3 | Adipose thickness

Subjects had a statistically significant mean reduction from baseline in adipose thickness in the treated area as measured using ultrasound in both percent reduction and absolute reduction at 6 weeks (−7.57 ± 1.15%, −1.2 ± 0.2 mm, $p < 0.00001$) and at 12 weeks (−6.91 ± 1.43%, −1.1 ± 0.2 mm, $p < 0.0001$) with a maximal reduction of 27% in one subject following treatment (Table 2). An example of ultrasound before and after images is shown in Figure 3.

3.4 | Treatment pain

Subjects reported a mean (± SE) pain level of 3.1 ± 0.40 (median 3.0) both during and immediately post treatment, on the 11-point Wong-Baker™ Faces Pain Rating Scale. This score translates to "mild pain". The highest recorded pain reported was a 7; however, this was seen in only one subject.

3.5 | Subject evaluation of treatment and satisfaction with outcome

Subjects rated their satisfaction with the treatment and the outcome at an average of 3.3 ± 0.18 on a scale from 0 to 4. No subjects gave a final satisfaction rating of 0 (very unsatisfied), whereas 20 out of 27 (74%) of the subjects listed their final satisfaction as either 3 "satisfied" or 4 "very satisfied". Of these, 15 out of 27 (56%) were "very satisfied" (Figure 4).

Subjects were asked to assess when they noticed changes in the treated areas. By 12 weeks after treatment, 74% of subjects reported that they saw a change in the treated area of focal fat. The largest proportion of subjects began noticing changes as early as 1 month after treatment (44%), while the remainder noticed changes 2 to 3 months post treatment (30%) (Figure 5); while 26% saw no visible change, 74% of subjects reported a mild to significant level of positive change (Figure 6).

Heat, stinging, tingling, and burning following treatment were limited. Fifty-six percent of subjects reported no sensitivity post treatment. 41% of subjects had sensitivity that lasted fewer than 3 days, while only one subject experienced sensitivity lasting longer than 3 days. During the treatment, most subjects reported feeling heat (59%), while 37% reported feeling burning and 26% reported feeling tingling. Eighty-one percent of subjects stated that they would recommend this treatment to a friend.

3.6 | Immediate effects and adverse events

Immediately post-treatment, the investigators visually examined each subject for observed hemorrhage, burn, purpura, erythema, edema and other visual signs of skin trauma. Erythema was reported

TABLE 2 Adipose reduction measured via ultrasound at 6 weeks and 12 weeks post treatment.

Time point	Adipose thickness (mm)	Adipose thickness compared to baseline ± SE (mm)	Reduction compared to baseline ± SE%
Baseline	15.2	–	–
6-Week follow-up	14.0	−1.2 ± 0.2	−7.57 ± 1.15%
12-Week follow-up	14.1	−1.1 ± 0.2	−6.91 ± 1.43%

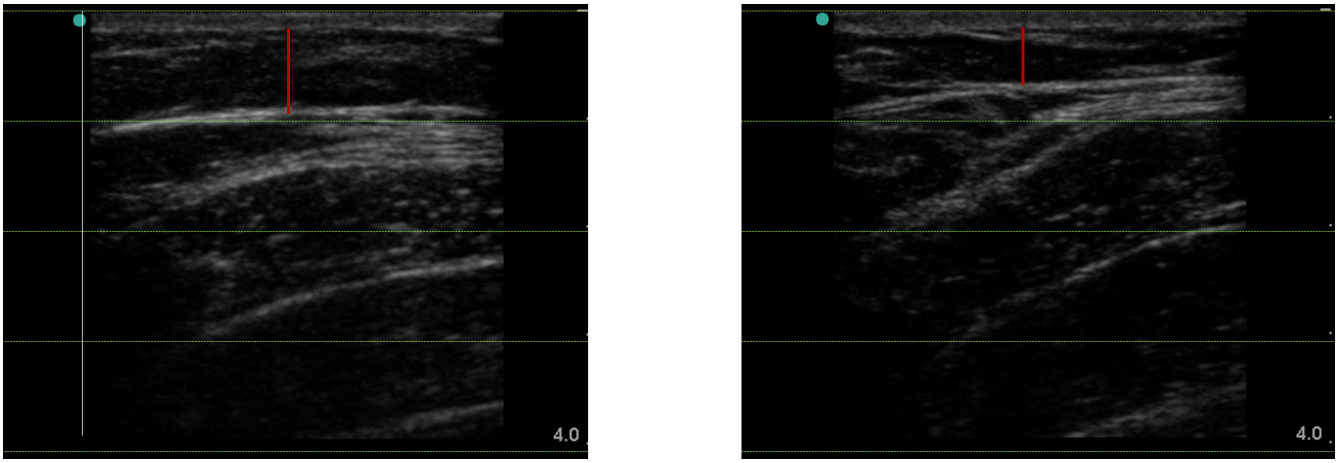
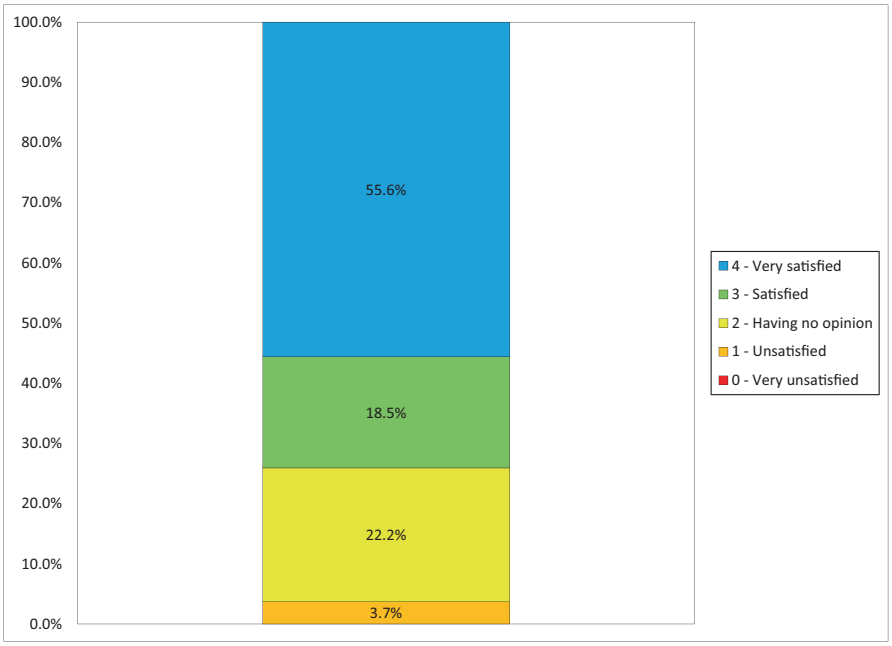


FIGURE 3 Ultrasound images showing a 31% decrease (from 8 to 5.5 mm) between baseline (left) and 12 weeks post-treatment (right). Red lines indicate the adipose layer thickness in each photograph.

FIGURE 4 Average satisfaction with treatment results at follow-up using the Subject Satisfaction Scale (SSS).



in all 27 subjects, while 14 (52%) were observed to have edema. Purpura was observed in 2 (7%) subjects and was rated as trace in one and moderate in the other case. The investigator noted that pinching of the skin by the belt could have been the reason for these instances of purpura. Hemorrhage, burn or other signs of skin trauma were not noted. No unanticipated adverse events were reported throughout the course of the study.

4 | DISCUSSION

Surgical methods remain the most effective in reducing body fat and giving patients a more desired figure. Several non-surgical technologies have been developed that are non-invasive and require little to no downtime. These include radiofrequency, cryolipolysis, high intensity focused ultrasound (HIFU), high intensity focused

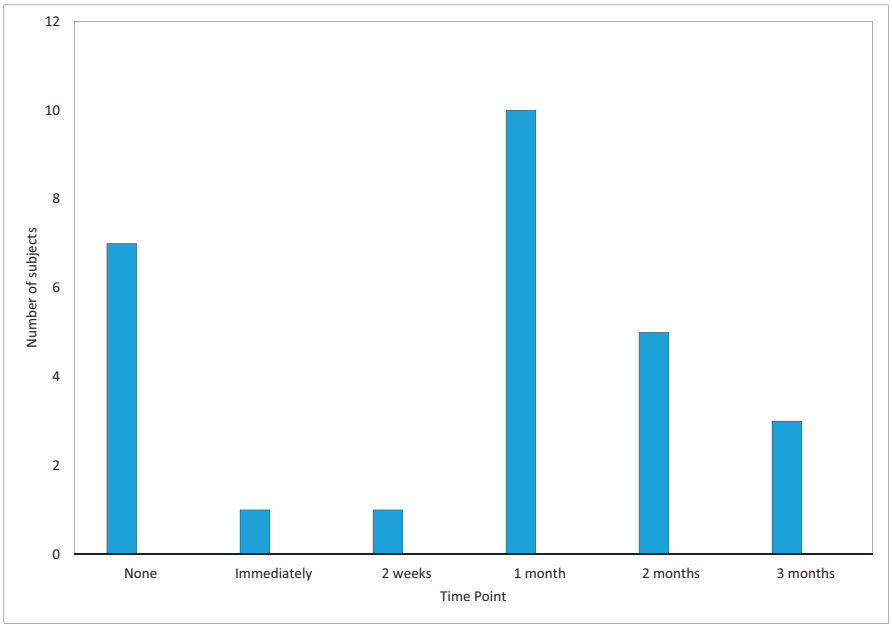


FIGURE 5 Subject evaluation questionnaire, question: "When did the subject notice changes in their skin?".

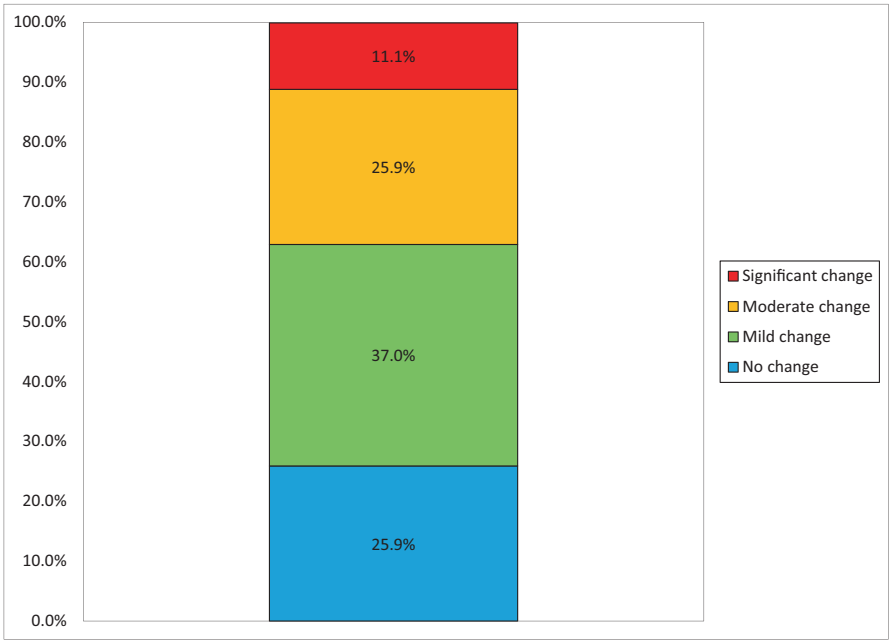


FIGURE 6 The level of positive change as observed by subjects 12 weeks post one treatment with a 1060 nm laser.

electromagnetic technology, non-thermal pulsed focused ultrasound (pFUS) and lasers.[5,11,12] This two-center study investigated the safety and efficacy of a single 1060 nm diode laser treatment for the non-invasive reduction of flank fat.

Ultrasound was used in this study to measure changes in adipose thickness between baseline and post treatment. Barton et al. proposed that ultrasound should be the standard for clinical subcutaneous fat measurements due to its reproducibility and low error.[9,13] Ultrasound can be a reliable and accurate method of assessing uncompressed subcutaneous adipose tissue thickness and is widely applied in sports medicine.[14–16] To enhance reproducibility, the same clinician performed all ultrasound measurements at each center in our study. The ultrasound measurements showed that subjects had significant fat reduction after just one 25-min treatment, resulting in a mean 7.6% (1.2 mm) reduction in the flank fat layer at 6 weeks post-treatment. This reduction did not disappear by 12 weeks and remained at 6.9% (1.1 mm). The maximal reduction seen was 27%, which is comparable to another 1060 nm diode laser study.[5] A further reduction is expected in a series of two or three monthly treatments. Katz and Doherty observed a similar (8%) reduction in fat at 6 weeks, but their subjects showed further improvement at 12 weeks.[5] The continuing decrease in fat between 6 and 12 weeks in the Katz and Doherty study may be attributed to combination of factors. Study population's BMI was different (BMI <30 in current study versus BMI <35 for Katz and Doherty, with subjects of BMI 30–35 showing the largest reduction), study skin type demography was different (with darker-skinned individuals in the Katz and Doherty study), and lastly, the treatment procedure was different

(two sided flanks treatment in our study versus one flank treatment under Katz and Doherty). Fat reduction in the flanks is an elective procedure, with aesthetic goals driving patients to undergo both invasive and/or non-invasive treatments. Therefore, patient satisfaction, efficacy, a good safety profile is key for physicians. In this study, 74% of subjects reported they were "satisfied" or "very satisfied" with their results and 81% reported they would recommend the treatment to a friend. Subject's recognition of the chronology of visible treatment results is an important component of satisfaction. Furthermore, definition of the oblique muscles could be more noticeable, or the skin appear "tighter" so the overall impact may be even more visible. Photographic demonstration of clinical results is presented in Figures 7 (Clinic 01), and 8 (Clinic 02). Figure 9 is an overlay image of photographs taken at baseline and at 12 weeks post-treatment.

Timing of visible changes was documented by having subjects' complete questionnaires at the end of the study. The largest group of subjects (44%) noticed changes 1-month post treatment. Within 2 months of treatment, more than 63% of subjects reported that they saw a change in the treatment area. By 3 months, 74% of subjects reported noticing a visible reduction of fat in the treatment area. The 1-month timeline of visible changes correlates with visible

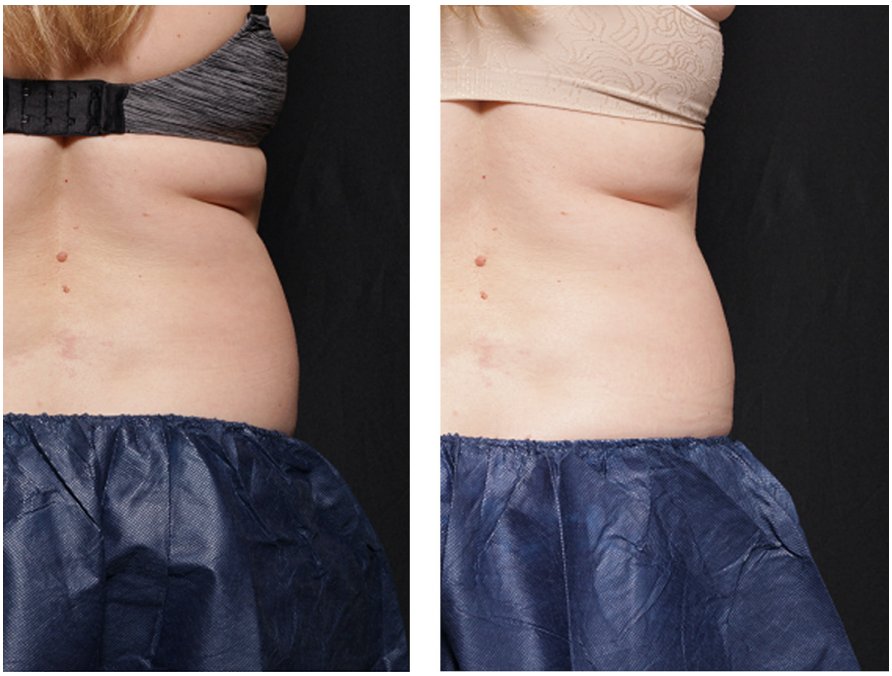


FIGURE 7 Subject pre- (left) and post-treatment (right) photographs. Post-treatment photographs were taken at the final follow-up visit, 12 weeks after receiving treatment.

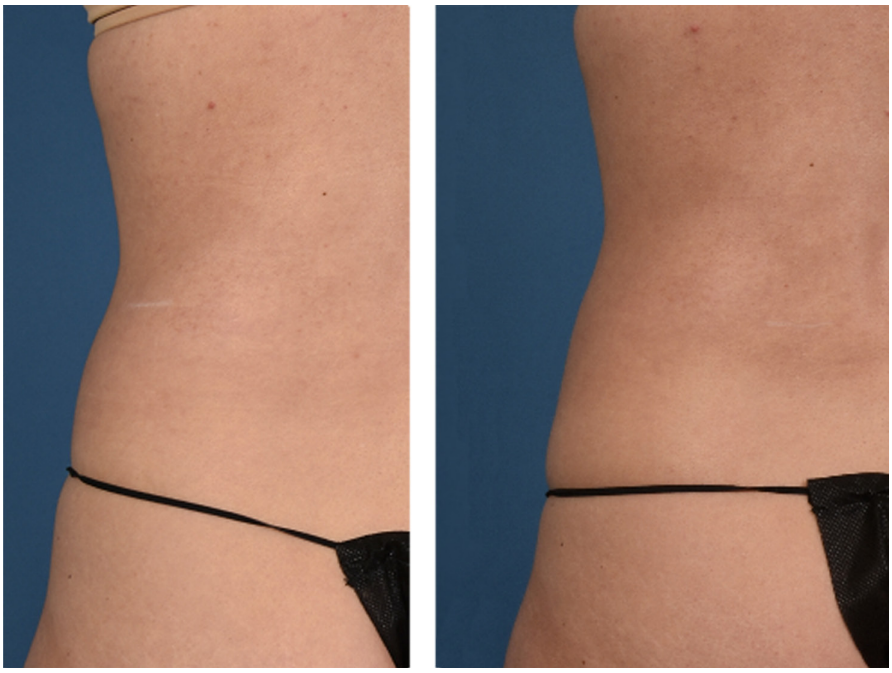


FIGURE 8 Subject pre- (left) and post-treatment (right) photographs. Post-treatment photographs were taken at the final follow-up visit, 12 weeks after receiving treatment.

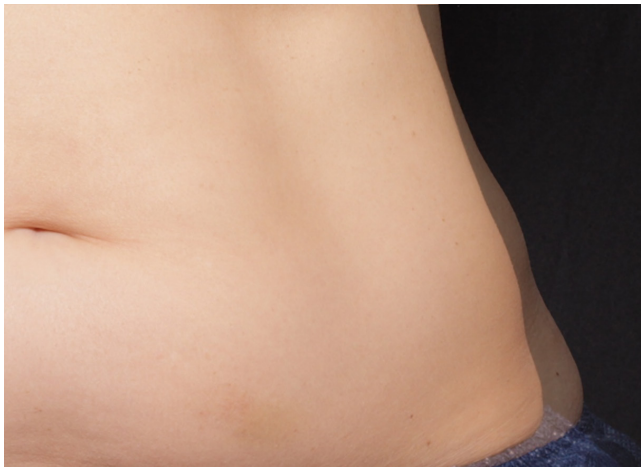


FIGURE 9 An overlay of pre- and 12-weeks post-treatment photographs of the flank area demonstrating a reduction.

signs of adipocyte injury by Day 14, followed by macrophage infiltration into the area and removal of apoptotic/necrotic cells, as previously demonstrated histologically.[17] This process of apoptotic cell clearance continues for 2–3 months, resulting in a diminished fat layer.[8] Given the timing of macrophage infiltration and apoptotic cell clearance, we believe that treatments should be given monthly if given in series, rather than just one as was done in this study.

Subject comfort during and after treatments as well as safety were demonstrated in this study. No incidence of burns or blisters occurred. Most subjects experienced transient erythema and edema. This is a common immediate anticipated side effect of diode treatments and has been shown to dissipate within a few days.[5] Treatment pain was limited and well tolerated by subjects with an average of 3.1 out of 10 on the Wong-Baker Faces Pain Rating Scale. This compares favorably to a study with a different 1060 nm diode device, where subjects scored their pain a 4 out of 10 on the Wong-Baker Faces Pain Rating Scale.[5]

Although subject weight decreased from baseline to 6-weeks (0.5 lbs) and 12-weeks (0.8 lbs) following treatment, this change was not statistically significant. A person's weight may change daily or even throughout the day depending on hydration, diet and the timing of measurements which increases variance, necessitating large changes for statistical significance. Similarly, although slightly reduced, there was no significant change in the subjects' body circumference. Given that subjects received only one treatment and, on their flanks, only, while the abdomen, bearing bulk of fat for circumferential effect was not treated, it is perhaps not surprising that there was no statistically significant change in circumference. More treatments and/or treatment of larger anatomical zones and/or having more subjects in the study might have resulted in a statistically significant difference given the trend towards significance at 12 weeks compared to baseline.

A limitation of this study was that it included a relatively small number of subjects. A greater number of subjects might show significant changes in body weight and circumference. In addition, only one treatment was performed, hence, it is unclear if multiple treatments would be additive or if each subsequent treatment would be less effective. Finally, obese individuals (>30 BMI) were excluded from the study; hence, it is unclear how effective the 1060 nm laser treatment would be on fat reduction in this population.

5 | CONCLUSION

The 1060 nm diode laser is a safe, effective and non-invasive option to reduce fat on the flanks with significant results after just one treatment. A high level of subject satisfaction, which correlated with good results, low treatment pain, and no unexpected adverse events, makes this a suitable option for physicians aiming to provide their patients with a non-invasive method of flank fat reduction.

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CONFLICT OF INTEREST STATEMENT

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

The authors confirm that the ethical policies of the journal, as noted on the journal's author guidelines page, have been adhered to and the appropriate ethical review committee approval has been received. The study protocols were approved by Western Institutional Review Board, Inc. (WIRB) for Clinic 01 and the Institutional Review Board at the University of Texas Southwestern Medical Center for Clinic 02. All included patients gave full informed consent for their participation in the study.

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