Reduction of subcutaneous fat and improvement in cellulite appearance by dual-wavelength, low-level laser energy combined with vacuum and massage

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Abstract
Background: This study compares the efficacy and safety of low-level, dual-wavelength laser energy and massage with massage alone for the reduction of subcutaneous fat in the thighs of normal women. The device was an early prototype of the FDA-cleared SmoothShapes™ system (Eleme´ Medical, Merrimack, NH, USA). Methods: The thighs of each individual (n=102) were randomized to either laser light (dual wavelength of 650±20 nm and 915±10 nm) and massage or to massage alone (control). Individuals who completed the study (n=74) received a mean of 14.3 treatments over 4–6 weeks. Magnetic resonance imaging (MRI) scans quantified fat pad dimensions before and after the final treatment. Results: Fat thickness decreased for the leg treated with laser-massage by 1.19 cm² (mean) and increased by 3.82 cm² (mean) for the control leg over time. The difference was statistically significant (p<0.001). Among those who completed the study, 82.26% responded to treatment. Individuals reported looser-fitting clothing and satisfaction with the procedure and results. Adverse effects were limited to occasional increases in urinary frequency. Conclusion: Low-level, dual-beam laser energy with massage appears to be safe and more efficacious than massage alone for reducing subcutaneous fat in the thighs of normal women.

Key words: Cellulite, fat reduction, low-level laser, laser lipolysis, MRI

Introduction
Although not considered a specific disease, cellulite is of major cosmetic concern, especially to post-pubertal women. Patients typically present with dimpling of the skin in the thighs and buttocks (1), and their skin resembles cottage cheese or the external surface of orange peel. The appearance of cellulite is believed to be due to hormonally mediated fat deposition, compression of capillary vasculature by fat lobules, reduced venous return, development of clumped fat lobules, and deposition of proteins around clumped fat lobules (2). In addition to the thighs and buttocks, cellulite may occur in the breast, upper arms, lower abdomen, and other areas of subcutaneous adipose deposition. The condition is found in slim as well as obese individuals, can be accentuated by excess weight, and is very prevalent in adult women (3,4).

A variety of methods have been advocated for improving the appearance of cellulite. Modalities include subcision (5,6); liposuction (7–10); ultrasound- and laser-assisted liposuction (10,11); massage-suction and skin kneading by mechanical device using Endermologie (LPG Systems, Valence, France) (12); 810-nm diode laser energy with cooling and mechanical massage (13,14); infrared light (700–2000 nm) with radiofrequency (RF) and suction-based massage (13,15–17); RF (18); mesotherapy and injection lipolysis (19,20); topical aminophylline (21,22) and retinol (23); and botanical extracts (24). Numerous nutritional supplements are also touted as beneficial for the reduction or elimination (or both) of cellulite and fat.

Current light-based technologies are potentially destructive, use wavelengths not specific to lipids, deliver disappointing short-term improvements, and have not been shown to induce metabolic activity to restore affected tissue to its pre-cellulite state. Scientific support for their efficacies is anecdotal and based on subjective criteria for assessing response to treatment (4).
This study compares the efficacy and safety of low-level, dual-wavelength laser energy and massage with massage alone for the reduction of subcutaneous fat in the thighs of 102 individuals. This device is a prototype of the SmoothShapes™ system (Eleme Medical, Merrimack, NH, USA), cleared by the FDA for the temporary reduction in the appearance of cellulite.

Materials and methods

Subjects

Healthy female volunteers (n=102) aged 18–50 years (40 ± 7.6) with identifiable trochanteric fat pads enrolled in an IRB-approved study conducted at the University of Massachusetts Medical School in Worcester, MA and at the Beth Israel Deaconess Medical Center, an affiliate hospital of Harvard Medical School in Boston, MA. The women were no more than 15% overweight as determined by body mass index (BMI), reported stable weight and clothing size measurements during the previous 6 months, and were required to maintain baseline food and activity patterns during the study period. They underwent a complete history and physical examination which included weight, height, smoking status, drug regimens (particularly diabetic and weight loss), heart rate, and blood pressure. Cardiovascular, abdominal, neurological and cutaneous findings were noted. Cellulite distribution and texture were estimated subjectively by clinical observation and objectively by photography and circumference measurements (hip, buttocks, and thigh) at sites referenced to anatomical landmarks. Magnetic resonance imaging (MRI) images were obtained for all patients in multiplanar planes using standardized techniques followed by cross-sectional pixel quantification of the respective structural constituents of the thigh.

Individuals undergoing treatment of hypertension or diabetes obtained clearance to participate from their primary physicians. Pregnancy, a tattoo or suntan in areas to be treated, undergoing steroid or immunosuppressant therapy, claustrophobia, MRI-sensitive implanted medical devices, and a history of deep vein thrombosis were grounds for exclusion. All the women signed an informed consent to participation in accordance with the IRB-approved study.

Treatment

Treatments were planned to avoid the premenstrual part of the cycle. Thighs of subjects were randomized to treatment with either a combination of scanning laser (concentric 650 ± 20 nm at 0.5 W and 915 ± 10 nm at 1 W) and massage, or with massage alone. The thigh treated with massage alone served as a control for each individual. For every treatment, thighs were divided into three circumferential segments, each of which received multiple transverse or longitudinal passes to ensure full coverage of the entire thigh and lower buttock. Each session lasted approximately 40 minutes. A trained, physician-supervised technician administered the treatments.

The individuals received a mean of 14.3 treatments, one to three per week, over 4–6 weeks. For those who failed to keep appointments, up to 20 treatments were given; this subgroup received an average of three treatments every 2 weeks. Individuals were blinded as to the treatment of each thigh. After laser light exposure, both thighs were manually massaged 10 times. The direction of the massage was always from distal to proximal in a longitudinal direction. A kneading motion and vigorous friction mechanical techniques (effleurage and petrissage) were alternated.

MRI scans quantified the dimensions of fat pads before the start of treatments and after the final treatment and were interpreted by a blinded independent radiologist. Scans were digitized and pixel counts of the respective fat, muscle, bone, and skin layers were separated and calculated in order to determine a relative density of fat as measured in each two-dimensional axial image. Clinical examples are shown in Figures 1–3.

Skin surfaces were analyzed by digital photography (Figure 4). Measurements of thigh circumference were made at biweekly visits while neurological and peripheral vascular exams were made at the midpoint and at the end of the study. All participant-reported adverse effects were documented at each session.

At an exit interview following all treatment sessions, each individual was asked to report on the presence or absence of pain or tingling during treatment, changes in urinary habits, and on skin turning red or otherwise.

Data analysis

Changes over time in thigh measurements were analyzed with the Wilcoxon signed-ranked tests. Changes with p-values less than 0.05 were considered significant.

Results

Efficacy

Among the 65 individuals who had both pre- and post-treatment MRI measurements (Table I), the fat thickness decreased over time by 1.19 cm² (mean) for the leg treated by laser-massage and increased by 3.82 cm² (mean) for the leg treated by massage alone. The corresponding median values for the laser-massage and massage-alone treated legs were
200 cm$^2$ and 4.10 cm$^2$, respectively. The difference in the change over time between the laser-massage treated leg and the massage-alone treated leg was statistically significant ($p < 0.001$). Among the individuals, changes in fat pad thickness of the laser-massage thighs ranged from no change to up to 36.79% compared with the massage-only (control) thighs.

Among the 71 individuals who had both pre- and post-treatment thigh circumference (tape) measurements, changes over time between the laser-massage and massage-alone treated legs ($0.09 \pm 1.819$ vs $0.11 \pm 1.628$, mean $\pm$ SD) did not differ significantly ($p = 0.968$). The inherent variability in manual tape measurements may have obscured differences (if present) in the actual thigh circumferences.

Responders to treatment comprised 80.26% of individuals. Responders were those in whom (i) a reduction in fat thickness on the laser-massage thigh was greater than the corresponding change in fat thickness on the massage thigh or (ii) an increase in fat thickness in the laser-massage thigh was less than a corresponding increase in the massage thigh. All other individuals were considered unresponsive to treatment. A Student’s $t$-test showed that among responders, the mean incremental increase in fat thickness of the laser-massage thighs compared to the massage thighs was significantly greater ($p < 0.001$) than the corresponding mean increase among non-responders.

Among the 74 individuals who completed the study, 56.2% definitely exercised, 26% may have exercised somewhat, and 17.8% did not exercise during the study period. The effects of exercise are controlled for by treating one thigh with laser and massage and the contralateral thigh with massage alone.
Safety

Of the 92 individuals who received at least one treatment, 71% experienced pain or tingling during treatment, changes in urinary habits, or redness on their skin. Among these 71%, 53% reported their skin turning red, 24% reported tingling during treatment, and 21% reported pain during treatment. In the 21% group, 84.6% said that pain was related to the massage and 11% reported changes in urinary habits. Any experience of pain was not side-specific. Adverse reactions to treatment were not observed.

Satisfaction

Individuals completed a questionnaire at the end of the study. Among the 74 individuals who completed the study, 31.9% were definitely pleased with the results, 57.0% were somewhat pleased, and 11.1% were not satisfied; 26.4% reported a subjective definite difference in the laser-massage treated versus the massage treated thighs, whereas 19.2% noticed a definite difference in how their clothes fit them; 91.8% reported that the treatment was relaxing and 72.6% would participate in the program again; 72.6% would definitely recommend the treatment program to a

Figure 3. Participant before treatment (A) with a corresponding horizontal MRI image of the right and left thighs (B); after 14 treatments (C) with a corresponding horizontal MRI image (D). The skin is noticeably smoother in the post-treatment image (C).
friend; and 80.3% would continue maintenance treatments if available. One individual noted transient sacroiliac tingling during treatment.

Discussion

This study confirms that the combination of low-level, dual-wavelength laser with massage safely provides significantly greater reduction in subcutaneous fat than massage alone and that participant satisfaction with the treatment and results is generally high.

Fat pad thicknesses in the treated thighs were objectively measured by (i) scanning MRI images at 3000 and 5000 Hz to arrive at pixel counts for the entire thigh and each anatomic constituent, and then (ii) subtracting the pixel count of the entire thigh exclusive of the fat layer from the pixel counts of the entire thigh. MRI scans yield a more objective value than a tape measure or ultrasound transducer because they are very reproducible and free of operator bias (25). Such measurements can also be randomized to the treated side to eliminate bias of the image interpreter.

Table II summarizes the physical modalities for improving the appearance of cellulite, including the present device.

Subcision is associated with high patient satisfaction (6), but it is also invasive; has adverse effects such as pain, bruising, hyperpigmentation, and skin puckering (4,32); and the duration of clinical effects are not known (17). Liposuction, though potentially effective for body contouring (7), is not recommended for cellulite because treatment may result in increased skin dimpling (26). The relatively new minimally invasive operative procedure of laser-assisted lipolysis requires surgical anesthesia and may have some benefit for cellulite-afflicted skin but there are no controlled studies to confirm that.

Endermologie LPG has been suggested as a method to rapidly reduce edema and ecchymosis after liposuction (33). The device is designed to disorganize adipose tissue and smooth it out over a series of treatments by sucking up the skin and rolling the soft tissues between two rotating rollers (12,33). The technique is based on the assumption that cellulite is partly due to impaired circulation and lymphatic drainage (32). Endermologie is an FDA-approved device for a temporary reduction in the appearance of cellulite.

Other devices for cellulite have combined light and/or RF with mechanical massage, but still have drawbacks. The TriActive device (Cynosure, Chelmsford, MA, USA) delivering 810-nm diode laser light (13) requires a multitude of treatments to achieve clinical effects (29,34). The 700–2000-nm infrared light with bi-polar RF and suction-based massage combination can initiate collagen remodeling (17), but the 700–2000-nm wavelength produces non-specific heating and RF energy provides non-selective and potentially destructive bulk tissue heating. Clinical effects persist for a few months, but long-term improvements are not documented. Monopolar RF devices such as Thermacool (Thermage, Hayward, CA, USA) and the Accent RF system (Alma Lasers, Inc., Israel) claim to have longer-lasting results (18). The latter may be

Table I. Changes in fat thickness (cm²) of thighs before and after treatment.

<table>
<thead>
<tr>
<th>Laser-massage</th>
<th>Massage</th>
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<tbody>
<tr>
<td></td>
<td>Pre-Tx</td>
</tr>
<tr>
<td>Mean</td>
<td>136.57</td>
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<tr>
<td>SD</td>
<td>34.718</td>
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Tx=treatment; SD=standard deviation.
attributed to a contribution from the collagen shrinking and skin tightening effects of radiofrequency (35). Topical therapies produce only a transient and superficial benefit due to their limited penetration into skin (17).

To overcome the drawbacks of these light- and radiofrequency-based modalities and how their results have been evaluated, investigators have explored the potential of dual-beam laser energy combined with massage and the use of ultrasound and MRI scans to quantify reduction in subcutaneous fat.

For example, Dr Coleman Levin achieved an 18% reduction in the thickness of subcutaneous fat of the buttocks and thighs with minimal adverse effects after treatment with low-intensity 623-nm and 904-nm laser energy (personal communication). Individuals received 20–30 treatments and changes in fat thickness were objectively quantified by ultrasound (1,36). In a similar study, Lach and Pap showed a 5–35% reduction in fat thickness and improvement in the appearance of cellulite in the thighs of 14 of 25 individuals who underwent a series of treatments with an infrared gallium arsenide/visible helium-neon laser followed by massage (30). In each individual, one thigh was treated with the dual-beam laser and massage while the other thigh was treated with massage alone. Fat reduction after the combined laser and massage treatments was greater and longer-lasting than that achieved by massage alone. Reductions were objectively quantified by MRI scans before and after the final treatment, as suggested by Querleux et al. (37), while massage-induced contour smoothing was documented by clinical photography. Thigh circumference measurements corroborated the MRI fat reduction data. The authors attributed the smoother skin and fat reduction to improved lymphatic drainage.

The low-level, dual-beam device in the present study is a prototype of the SmoothShapes™ system. The current SmoothShapes™ device emits 10 W of 915-nm laser light, which through interaction with lipids as a primary chromophore selectively heats fat (38) and promotes wound healing (39). The SmoothShapes™ device also includes vacuum-assisted mechanical massage capability because numerous studies show that massage promotes lymphatic and subcutaneous blood flow, new collagen deposition, firming and toning of the skin, and subjective clinical benefits (12).

The proprietary combination of 915-nm laser and 650-nm light energy with vacuum and contoured rollers for massage is called Photomology™ (31,40). The low-level visible (650-nm) light improves cell membrane permeability, increases collagen production, reduces edema, and relieves pain inflammation, all without destroying adipocytes (41–43). The infrared 915-nm laser light is preferentially absorbed in lipids liquefying fat, allowing it to mobilize into interstitial space (43) where massage physically assists in moving the fat towards and into the lymphatic system. The contoured rollers and vacuum move liquids from the interstitial fluid and promote lymphatic drainage.

**Conclusion**

Low-level, dual-beam laser energy with massage appears to be safe and more efficacious than massage.
alone for the reduction of subcutaneous fat in the thighs of normal women.

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References


