

SMOOTHSHAPES® CELLULITE TREATMENT PRODUCES CIRCUMFERENTIAL THIGH REDUCTION
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Background and Objective:

Early studies with the SmoothShapes® 11w system demonstrated the effectiveness in improving the appearance of cellulite by altering dermal and subcutaneous structures as well as decreasing superficial subcutaneous fat. However, these early studies did not focus on circumferential fat reduction. This IRB approved study was undertaken to evaluate the efficacy of SmoothShapes treatments for the thigh circumferential reduction.

Design/Materials and Methods:

SmoothShapes combines dual-band light at 650 and 915nm wavelengths with massage and vacuum. 26 female volunteers between the ages of 21 and 45 with visible cellulite were selected for the study. Subjects had one leg randomly assigned for treatment while the other served as control. The treated leg received 30 minute treatments twice a week for a total of 8 treatments. A novel measuring tool and technique was developed to insure constancy and consistency of measurements. Measurements were obtained by blinded personnel at the upper, mid and lower thigh levels before the initial treatment, before the 5th and 8th treatments and one and three months post treatment.

Results:

22 subjects completed 1 month follow up. Of those, 91 % had a decrease in circumference of the treated thigh at all three levels with a respective mean decrease of 1.5, 0.92 and 0.66 cm ($p < 0.0001$; $p < 0.0002$; $p < 0.0005$). 22 subjects completed 3 month follow up. Of those, 72 % maintained a decrease in circumference of the treated thigh at all three levels with a respective mean decrease of 0.9, 0.7 and 0.6 cm ($p < 0.0057$; $p < 0.001$; $p < 0.183$). Subjects experienced no pain and anticipated side effects were limited to transient erythema and rarely occurring mild bruising.

Conclusions:

Thigh circumference reduction can be obtained with non-invasive, pain free treatments. SmoothShapes is effective in reducing thigh circumference for a minimum of 3 months. Further evaluation of long term reduction is pending based on the findings of six month post treatment measurements.

Background and Objective:

Cellulite is a skin condition afflicting predominantly women. Cellulite is caused in part by fat cells residing in the superficial layer of the subcutaneous fat layer. This fat is not affected by diet or exercise and cannot be burned as fuel. Hormones regulate its deposition. Cellulite affects 85-98% of post-pubertal females of all races. Little agreement exists between experts on the origin of cellulite except that hormones and skin architecture play an important role. There are four leading hypotheses that attempt to explain the physiology of cellulite which include:

- sexually dimorphic skin architecture
- altered connective tissue septae
- vascular changes
- inflammatory factors

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Figure 1: Internal Components of the Photomology Module

The SmoothShapes™ system utilizes simultaneously delivered 915nm infrared and 650 nm visible light, controlled suction (vacuum) and mechanical massage and is intended for non-invasive and selective heating of cutaneous and subcutaneous tissues.

The 650 nm wavelength was selected for its action in modifying permeability of the adipocyte membranes and enhancement of fat emulsification. This wavelength falls into the so called optical window where there is relatively minimal absorption in the skin components which allows for good penetration to the subcutaneous fat level.

The choice of 915 nm wavelength was based on its preferential absorption in lipids. This wavelength penetrates well into the tissue with even less scattering than 650nm but gets absorbed by the lipids in fat. Temperature inside the adipocytes become slightly elevated causing fat liquefaction. Evacuation of liquefied fat from the inside of adipocytes into intracellular space is facilitated by continuous vacuum massage.

The light sources operate in continuous wave (CW) mode and total power output from the system is ~11 watts. This system is capable of heating the subcutaneous fat up to a maximum temperature of <40°C. The maximum temperature achieved at the fat layer may increase the rate of lipolysis in the adipose tissue (thus reducing regional fat accumulation) and thermally stimulate the development of the hypodermal fibrous strands. Multiple passes are required to achieve a desired temperature rise in the subcutis. At the same time, the heat is not accumulated in the epidermis and upper dermis due to significantly higher thermal drain rate from these areas. This combination eliminates risks while providing desired efficacy.



Figure 2: Photomology Module In Use On Thigh

Design/Materials and Methods:

This open-label multi-center study was designed to evaluate the effect of thigh circumference reduction with the SmoothShapes™ system. The results being presented in this poster are from 22 subjects from one study site.

Healthy pre-menopausal females between the ages of 21 and 45, with mild to moderate visible cellulite, a Body Mass Index (BMI) no greater than 26, who reported stable weight over the prior six months and who were free of any systemic or dermatological conditions were eligible to participate. Subjects were required to maintain their baseline food and activity patterns during the course of the study and to wear consistent undergarments at each visit.

Exclusion criteria included pregnancy or lactation, BMI greater than 26, serious concomitant systemic disease (cancer or history of cancer, heart condition, uncontrolled diabetes, pain syndrome), dermatological conditions in the treatment area requiring systemic or topical therapy, severe cellulite with referred pain and/or tenderness in area of cellulite, neuropathy, inability or unwillingness to comply with the study requirements, coagulation disorders, use of anticoagulants or tendency for bruising, daily use of aspirin or systemic corticosteroids, vascular disorders (phlebitis or varicose veins) or tattoos in the area to be treated, any prior aesthetic surgery affecting the area to be treated (liposuction, Subcision®) 6 months prior to the study, any other anti-cellulite treatment 3 months prior to the study, inflammation or active infection in the area to be treated, cutaneous or vascular alterations that make it difficult to visualize and document cellulite, or any other condition that, in the opinion of the investigator, can compromise the evaluation of the study.



Figure 3: Laser Measure

The following evaluations were performed pre-treatment, before treatments 5 and 8 and at 1, 3 and 6 months after the last treatment:

- Photographs using 35mm digital camera
- Body composition analysis with InBody 520 (Biospace, Beverly Hills, CA),
- Height, body weight and BMI measurements
- Thigh circumference measurements
- Investigator classification of cellulite using the Nürnberger-Müller scale,
- Subjective rating of cellulite severity

A novel measuring tool (Figure 3) and technique was developed to ensure constancy and consistency of measurements. Subjects were positioned on a standardized photography mat (Figure 4) that eliminated variation in foot width distance and leg position. A laser beam was then projected onto the thigh at 3 different levels, upper, mid and lower. A marker was used to mark the anterior, medial and posterior aspects of each thigh directly over the projected laser beam. Measurements were then obtained by blinded personnel using a pressure sensitive tape measure (Figure 5) that eliminated tightness variables.



Figure 4: Standardized Photography mat

One leg was randomly assigned for treatment while the other served as control.

The entire thigh was treated and received 30 minutes of light exposure twice a week for a total of 8 treatments. The energy levels administered were as follows: 10 watts of 915nm diode laser, 1 watt of 650nm LED light, suction level did not exceed 500 millibars (375 mmHg). SmoothShapes specifications are shown in Table 1.

The treatment consisted of applying the Photomology module to the skin, setting vacuum so that it maintained a consistent seal on the skin. The Photomology module was then moved in a distal to proximal stroke that began at the knee area and commenced at the gluteal fold. The orientation of the strokes was either longitudinal or horizontal in nature. The areas that displayed the worst cellulite were treated for a minimum of 4 minutes to ensure adequate tissue temperature elevation. Other areas that were not affected by cellulite were treated for ~2 minutes.

Subjects completed a survey before and after each treatment and reordered their daily food intake throughout the treatment and follow up course.



Figure 5: Pressure Sensitive Measuring Tape

Results:

22 subjects completed 1 month follow up. Of those, 91% had a decrease in circumference of the treated thigh at all three levels, upper, mid, lower thigh, with a respective mean decrease of 1.5, 0.92 and 0.66 cm ($p < 0.0001$; $p < 0.0002$; $p < 0.0005$). 22 subjects completed 3 month follow up. Of those, 72% maintained a decrease in circumference of the treated thigh at all three levels with a respective mean decrease of 0.9, 0.7 and 0.6 cm ($p < 0.0057$; $p < 0.001$; $p < 0.183$). Subjects experienced no pain and anticipated side effects were limited to transient erythema and rarely occurring mild bruising.

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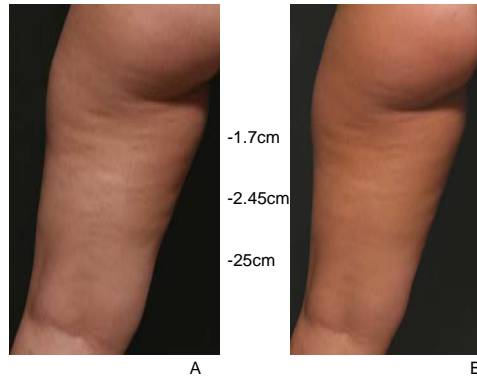


Figure 6: Pre and Post treatment photographs.
Photographs taken at baseline and 3 months after treatment 8.

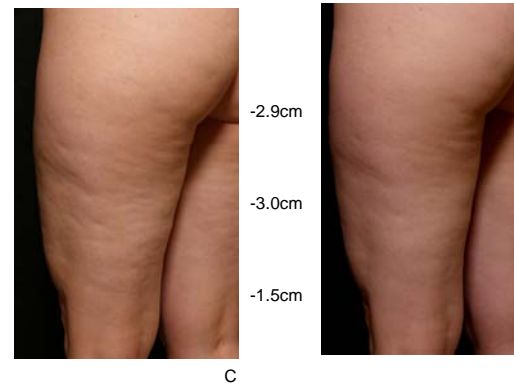


Figure 7: Pre and Post treatment photographs.
Photographs taken at baseline and 3 months after treatment 8.