

# Cellulite Control Cream Firms, Smooths and Reduces Cellulite

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## INTRODUCTION

Approximately 90% of adult women suffer from cellulite<sup>1</sup>—the bumpy, “orange peel” appearance of skin, typically affecting the hips, buttocks and thighs. The causes of cellulite remain poorly understood. But the emerging pathophysiological picture suggests that disorganization, proliferation and hardening of fibrous septae over time lead to the appearance of bulging fat lobules under the skin.<sup>2</sup> These changes may be associated with peripheral circulatory failure and metabolic failure.<sup>2</sup> Edema, inflammation, oxidative stress, hormones and localized adipocyte hypertrophy also may be involved.<sup>3</sup>

What is clear is that virtually all adult women – 98% in one study<sup>4</sup> – worry and feel self-conscious about cellulite.<sup>5</sup> And while many energy-based and minimally invasive devices target cellulite, their effects are generally mild to moderate.<sup>6</sup> The multifactorial nature of cellulite requires a multifaceted approach that addresses the problem at as many levels as possible.

A new cream combining natural cosmeceutical ingredients that boost cellular metabolism and battle cellulite at the cellular level has shown the ability to provide statistically significant improvements in objective measurements including thigh circumference, buttock firmness, skin temperature (a reflection of cellular activity) and skin relief/depressions after either 4 or 8 weeks’ use. The cream also improved how most subjects felt about their cellulite at these time points.

## METHODS

The investigator enrolled 32 Caucasian female patients between 34 and 46 years old with stage 2 or 3 cellulite according to the Nurnberger-Muller rating scale:<sup>7</sup>

- **Stage 2** Spontaneous dimpling when standing but not when lying down, with orange-peel appearance visible to the naked eye.
- **Stage 3** Dimpling present without manipulation when standing or lying, plus orange-peel surface with raised areas and nodules.

The investigator instructed patients to use the anti-cellulite cream twice daily, morning and night, on clean, dry skin, applying homogenously over the right or left buttock and thigh (based on a randomization scheme) for 56 consecutive days.

Patients had to be in generally good health and willing to maintain their current eating, exercise and cosmetic habits throughout the study, because changes in these areas could alter results. The investigator excluded patients who had used anti-cellulite products or treatments in the previous 30 days, and those with skin diseases and/or alterations such as tattoos that would impair evaluation of treated areas.

At a recruitment visit, the investigator verified volunteers’ answers to a telephone survey, explained the study protocol (on a written handout given to patients) and signed informed consent documents with those who met all inclusion criteria. Additionally, patients received detailed instructions geared toward eliminating bias in study measurements. For example, the protocol prohibited participants from eating, drinking alcoholic or caffeinated beverages or smoking at least 2 hours before any study visit. Patients also could not use any topical drugs or cosmetics on the legs and buttocks within 12 hours before each visit.

At each study visit (baseline, week 28 and week with 56), the investigator recorded the temperature and relative humidity of the room in which patients sat for 15 minutes to get acclimatized before undergoing the following measurements, with each patient standing over a grid to assure consistent positioning at all visits:

- Photographs of the thighs and buttocks (anterior and lateral views) with standardized lighting.
- Circumference measurements of the thighs (in triplicate) using a circumference scale (Seca GmbH & Co.), placing the measuring tape at a standard height with patients in a standing position.
- Clinical cellulite scores of the thigh and buttocks with and without pinching using a 5-point visual scale (0 = no cellulite; 4 = significant cellulite with deep depressions).
- Skin firmness using a Cutometer SEM 575 (Courage-Khazaka Electronic GmbH). Placed in 3 standardized positions on the anterior thigh at least 10 cm from the knee and at least 2 cm apart, this negative pressure device gauged the viscoelastic properties of the skin. The investigator took 3 measurements at each spot and averaged them out to plot a distance-versus-time curve that allowed calculation of the elastic recuperation index.

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- Skin temperature and thermal imaging, both done with an E60 thermal camera (FLIR).
- Skin relief/surface contour of the upper thigh using the Antera 3D (Miravex Ltd.) in depressions mode, using a stadiometer (Seca) to position patients consistently.

For control purposes, the investigator measured each subject's ankle circumference (cm) in triplicate at each visit using the Seca measuring tape to assess liquid retention. Also at each visit, the investigator weighed patients using a Vulcano digital scale (Taurus). The investigator excluded from statistical analysis any subjects with fluctuations of 5% or higher in weight and/or ankle perimeter.

## STUDY MATERIALS

The study cream (Oraser® Cellulite Control) contains a breakthrough blend of ingredients that reduce the contour and appearance of cellulite quickly and effectively:

- **Plankton extract** Provides a slimming and toning effect by increasing cellular and tissue metabolism, which in turn improves muscle tone.
- **Saccharide isomerase** Minimizes new "nightly" fat deposits by interrupting the body's natural circadian rhythm and stimulates new collagen for added firming.
- **Caffeine, coenzyme A and carnitine** Accelerate the breakdown of fat tissue by enhancing metabolism.
- **Carrageenan extract** Provides instant firming and tightening effects.
- **Phosphatidylcholine** Stimulates fat-destroying lipase enzymes.

## STATISTICAL ANALYSIS

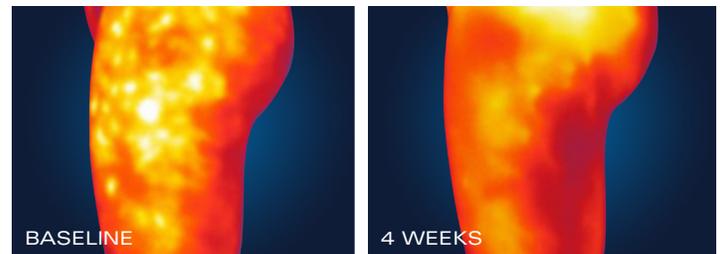
Data entry, analysis and advanced statistical analysis were performed by the investigator and validated by an independent investigator. The investigator performed a detailed statistical analysis using SPSS Statistics 20.0 software (IBM). The investigator used the Shapiro-Wilk test to assure a normal data distribution was obtained. If normal data distribution was verified, Student's t-test was applied to compare pre- and post-treatment values at each time point. For abnormal data distributions, the investigator used the nonparametric Wilcoxon test. Two significance values (0.05 and 0.10) were established.

## RESULTS

Of the 32 patients enrolled, the investigator included 22 in final results. A total of 10 dropped out for unknown reasons unrelated to the cream, had erroneous measurements or did not meet control specifications. Routine measurements of weight and ankle circumference showed that on average,

both parameters changed less than 1% throughout the study. The mean amount of product patients used per application was  $2.05 \pm 0.50$  g during the first month, and  $1.08 \pm 0.37$  g during the second month.

Objective measurements revealed statistically significant changes at one or more time points in the superior thigh, buttocks, skin temperature and skin contour. In the superior thigh, patients experienced a transient, statistically significant mean increase of 0.52% at day 28, followed by a statistically significant mean decrease of 0.82% ( $p = 0.04$  versus baseline) at day 56. At this time point, superior thigh perimeter decreased for 54.5% of patients, with a maximum decrease of 5.43%. At day 28, a statistically nonsignificant 45.45% of patients experienced superior thigh decreases, with a maximum of 1.50%.



**Infrared Thermography** Uneven fat build-up can cause varied distribution of temperature. An increase in uniformity of skin temperature demonstrates an increase in microcirculation and the reduction of uneven fat build-up.

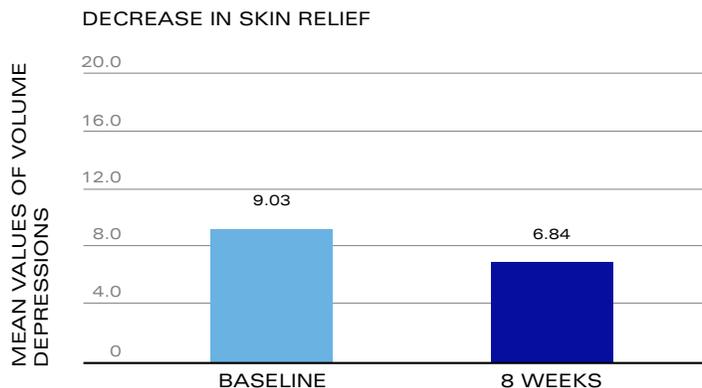
Patients' inferior thighs experienced mean decreases of 0.01% (maximum 3.29%) at day 28 and 0.96% at day 56, but neither change reached statistical significance. At day 56, 72.73% of patients experienced inferior thigh decreases, with a maximum reduction of 5.56%.

Patients' buttocks showed statistically significant reductions at day 56 with and without pinching. At this juncture, patients had achieved mean reductions of 0.64 ( $p = 0.00$  versus baseline) and 0.32 ( $p = 0.02$ ), respectively, on a 5-point scale. The corresponding figures at 28 days – 0/no change and 0.05, respectively – failed to reach statistical significance.

To account for ambient temperature changes between the various measurement points for skin temperature, the investigator subtracted the differences between the temperature of the measurement room at days zero, 28 and 56 from the differences between skin temperature measurements taken at those points. These calculations revealed a statistically significant mean increase at day 28 of  $0.49^{\circ}\text{C}$  ( $p = 0.001$  versus baseline), with 86.36% of

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**Volume Depressions** Skin relief measurements were assessed with a stadiometer and images were obtained with Antera 3D® on depressions mode. Statistically significant decrease in skin relief with 59% of patients occurred after 8 weeks, with a maximum decrease of 97%.

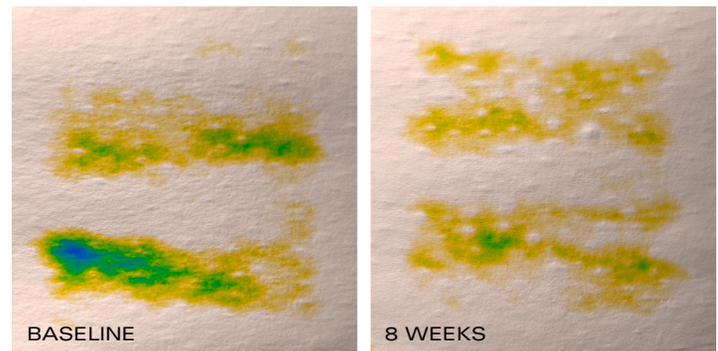
patients having increased skin temperature, with a maximum increase of 1.93°C. At day 56, the investigator observed a statistically nonsignificant mean decrease of 0.24°C.

Skin relief measurements showed a statistically significant mean reduction of 24.28% (90% confidence interval;  $p = 0.072$ ) in volume of depressions at day 56. At this time point, 59.09% of patients exhibited decreased skin relief, with a maximum reduction of 97.15%. At day 28, relief measurements showed a statistically nonsignificant mean decrease of 24.36%.

Patients also completed subjective questionnaires regarding the cream and their experiences with it. At day 28, 81.8% said their skin was smoother after applying the cream; 68.2% said it was moister; and 50% said it was firmer. Also at day 28, 31.8% of participants said their clothing felt looser.

When rating product efficacy at day 56, 77.3% of patients said the cream led to slight or moderate global improvement in the appearance and condition of their skin. In a separate question, 72.7%, 68.2% and 63.6% said that the treatment had improved the smoothness, moisturization and tone of their skin, respectively. At no point did the treatment cause any discomfort or unpleasant sensations.

The proportion of patients who said they felt either slight or moderate improvements in cellulite, irregularity and thinning and sculpting of the thighs or buttocks at the



Lighter colored measurement represents less depression depth.

study's conclusion ranged between 59.1% and 72.8%, with responses roughly split equally between "moderate" and "slight." And a large majority of patients – 77.3%, 72.7%, and 63.6%, respectively – said they would like to continue using the product, would recommend it to friends and would purchase it themselves.

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