Marketing Report

Anti-Cellulite Study

Products under Test

Code/proDERM	Product/Code/Sponsor
A	Untreated area
B	Massage device (Cellulite-ReleaZer + concomitant oil)
C	Untreated area, until assessment Day 168
D	Massage device (Cellulite-ReleaZer + concomitant oil) applied until Day 85, untreated between Day 85 and assessment Day 168
E	Untreated until Day 85, massage device (Cellulite-ReleaZer + concomitant oil) applied between Day 85 and Day 168
F	Massage device (Cellulite-ReleaZer + concomitant oil), assessment Day 168

Sponsor
Beurer GmbH, Ulm / Donau, Germany

Study Site
proDERM Institute for Applied Dermatological Research, Schenefeld/Hamburg, Germany

Director Operations/ Principal Investigator
Dipl.-Phys. Marianne Brandt

Study Schedule
Start of the Study: February 27, 2018
End of the Study: August 21, 2018

Aim of the Study
The objective of the study was to assess the anti-cellulite efficacy of a massage device used on the thighs of female subjects after 12 weeks of usage in comparison to an untreated area. Investigations of volume (by AEVA measurements) and grading of cellulite (by rating of macrophotos) were performed. Furthermore, product traits as well as sensitivity and sensation of the test area were judged by means of self-assessment questionnaires.

The study was reviewed by an independent institutional review board (IRB) for ethical approval.

Subjects
40 enrolled subjects, 37 valid subjects with an age of 47.0 ± 5.8 years (mean ± standard deviation)

Mode of Use of the Product(s) under Test
The application was performed every second day on the assigned thigh for 15 minutes.

Main Inclusion Criteria
Female subjects (between 30 and 55 years of age) with a cellulite-score according to proDERM-Score of 4 to 6 (corresponding to moderate degree of cellulite) at the test areas according to visual assessment during recruitment and a BMI (Body mass index) between 18 and 30.

Summary of Test Procedure
Screening: The subjects came to the Study Site. They were informed about the study and gave their written consent. The subjects were weighed without shoes and asked about their height to determine the BMI. The suitability of each subject was evaluated according to the inclusion/exclusion criteria.

Summary of Test Procedure (continued)

Day 1: The subjects returned to the Study Site. They stayed in a climatized room for at least 30 minutes with uncovered thighs. During acclimatization the subjects answered a questionnaire. Afterwards, macrophotos were taken (Baseline) under standardized illumination on the back side and on the outer side of the thighs. Following this, AEVA volume measurements were performed, also at the back side and on the outer side of the thigh. The test product(s) were issued to the subjects with instructions how to use them on the assigned test areas. The assignment of test product(s) was done according to a randomization scheme provided by proDERM. The first product application was performed under the guidance of a technician. The subjects documented the use of the test product in a diary provided by the Study Site. After the first use of the test product the subjects answered a second questionnaire.

Day 2 to 28: Subjects used the test product as described above (see 'Application Mode'). They documented the usage in the diary.

Day 29: Subjects returned to the Study Site for a compliance check of application. The subjects were asked to use the product as they did in the past days and were corrected, if necessary. Furthermore, the subjects answered a questionnaire.

Day 30 to 56: Subjects used the test product as described above (see 'Application Mode'). They documented the usage in the diary.

Day 57: Subjects returned to the Study Site for a compliance check of application (see Day 29).

Day 58 to 84: Subjects used the test product as described above (see 'Application Mode'). They documented the usage in the diary.

Day 85: Subjects returned to the Study Site. They were weighed again and stayed in a climatized room for at least 30 minutes with uncovered thighs. Then, capturing of images and instrumental measurements on the test areas was repeated. The subjects filled out a questionnaire concerning test material traits as well as questionnaires regarding sensitivity and sensation of the test area.

Day 85 to 167: Subjects decided whether they continued to use the test product, as described above (see 'Application Mode'), and additionally on the other thigh (continuous application group), or if they stopped the usage of the test product altogether (regression group). If they continued the usage, they documented it in a diary. The subjects continued to adhere to all other study conditions. Day 168: All subjects returned to the Study Site. They were weighed again and stayed in a climatized room for at least 30 minutes with uncovered thighs. Then, capturing of images and instrumental measurements on the test areas were repeated. The subjects filled out a questionnaire concerning test material traits as well as questionnaires regarding sensitivity and sensation of the test area. The subjects were allowed to keep the test products.

Additionally, 6 trained graders evaluated the macrophotos concerning the parameter 'degree of cellulite' after Day 85 and after Day 168.

Evaluation Criteria

- Volume by AEVA
- Macrophotos (Cellulite Photography Stand)
- Image Evaluation
- Questionnaires

Results and Discussion

The objective of the study was to assess the anti-cellulite efficacy of a massage device used on the thighs of female subjects after using it for 12 weeks as well as for 24 weeks of usage in comparison to an untreated area.

The following can be concluded according to the results of this study:

- After 12 weeks treatment with the **massage device** (Day 85), AEVA measurements showed that the skin of the outer thighs was smoother than untreated skin.
- After 12 weeks treatment with the **massage device** (Day 85), grading of images by trained graders showed that the skin of the outer thighs was visually smoother.
- After this formerly smoothened skin on the outer thighs was not treated with the **massage device** any more for 12 further weeks (Day 168), AEVA measurements and visual grading showed a regression of the effect.
- According to the participating subjects, the skin felt more *stable*, *stronger* and *lighter* directly after the first use of the **massage device** than before.
- The **massage device** and the feeling and appearance of the massaged skin were evaluated positively by the majority of the participating subjects.
- Most of those subjects who continued to use the massage device for another 12 weeks after 12 weeks usage, evaluated their skin feelings to be even more positive, while most of those subjects who did not continue the massage during the last 12 weeks evaluated their skin feelings to be worse.

As a result of this study, a measurable and visible improvement of the appearance of cellulite on thighs of female subjects was documented after 12 weeks usage of the massage device cellulite-ReleaZer with oil. This improvement of cellulite reverted after 12 further weeks without massage.

Signature

Dipl.-Phys. Marianne Brandt
- Director Operations/ Principal Investigator -

15.4.2019
Date / Signature