A double-blind, randomized placebo controlled clinical study demonstrates Cellulight® activity on cellulite.

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KEYWORDS
Melon concentrate;
Cellulite;
Adipocytes;
Superoxide dismutase.

Abstract
Cellulite could be defined as a combination of several factors including enlargement of fat lobules and a fibrosis state induced by alterations of the network of connective tissue strands. In this work, we evaluated the anti-cellulite effect of a melon juice concentrate rich in SOD (Cellulight®) on women. Cellulight® was supplemented orally at 40 mg per day during 56 consecutive days. Results show a 11.3% significant reduction of cellulite in the supplemented group, compared to the placebo. According to already documented effects of SOD, it is suggested that Cellulight® could act both on adipose tissue metabolism and on the connective tissue strands network. Further investigation are necessary to document these proposed mechanism of action of Cellulight®.

Introduction
Cellulite is a common term used to describe a localized metabolic disorder of subcutaneous tissue that provokes an alteration in the female body shape. It presents as a modification of skin topography evident by skin dimpling and nodularity¹. It appears in 85-98% of post-pubertal women and is rarely seen in men. Common but not exclusive areas where cellulite is found are the thighs, buttocks, and to a lesser extent the abdomen. Contrary to popular belief, cellulite is not related to obesity, since it occurs in overweight, normal, and thin women. While not a pathologic condition, it remains an issue of cosmetic concern to a great number of individuals².

The primary objective of the present study was to evaluate and compare the anti-fat nodes effect of Cellulight® versus a placebo after 28 and 56 days of use.
Material and Methods

**Study design and treatment**
The study was performed in the private Clinical Experimentation Center, DERMSCAN Laboratory on 41 healthy women with cellulite aged between 31 and 50 years old.

Main inclusion criteria were as follows: healthy nonsmoker women between 30 and 50 years old, subject with visible fat nodes on stomach and/or thighs.

Main non-inclusion criteria were: cutaneous pathology on the studied zone; subject suffering from a cardiovascular disease; treatment acting on the subcutaneous lipids (thinners…) or stop of this type of treatment for less than one month; any topical or systemic treatment during the previous weeks liable to interfere with the assessment of the tolerance and of the efficacy of the studied products; any drugs taken continuously the 7 days before the inclusion; any drugs taken during more than two weeks in the month before the inclusion; subject having taken a food supplement in the two months before the inclusion; known allergy to one of the components.

Women were divided into two groups: CL group supplemented with 40 mg per day of Cellulight® (n=21), PL group with a placebo (n=20), during 56 days. The subjects could not modify their diet or sport habits during all the study.

**Tested product**
Cellulight® (CL, Bionov, Avignon, France) is a proprietary superoxide dismutase (SOD)-rich and encapsulated melon concentrate (GMO free).

**Global tolerance**
On D0, the global health state of the subject and their medical history were evaluated by clinical examination by the physician in charge of the study on purpose to check the compatibility of their health with taking the studied product (risk of decrease in blood pressure).

On D56, the possible felt and/or observed effects were reported to allow the evaluation of global tolerance. This evaluation takes into account the relevant elements reported by the subject (functional and physical signs) as well as those noted during the examination (clinical signs). The comparison of these signs was used to conclude the final tolerance of the studied product. The global tolerance of the studied product was defined as the least favorable result.

**Scoring of fat-nodes**
Fat nodes were assessed on thighs and stomach at D0, D28 and D56. The practitioner assessed the aspect of the skin, in terms of cellulite, by scoring fat-nodes, without pinching, according to the linear non-structured scale ranging from 0 to 10, presented below:

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>0</td>
<td>few pronounced</td>
</tr>
<tr>
<td>10</td>
<td>very pronounced</td>
</tr>
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The evaluation by the practitioner of the skin aspect regarding cellulite gives a good indication of the visual efficacy of the product.

**Statistical analysis**
The effect over time for each product (CL, PL) was carried out using repeated measures ANOVA, followed by the pairwise comparison of three times (D0,D28,D56) using the Fisher’s test.

The comparison between CL and PL was performed using a factorial ANOVA on each change (D28-D0 and D56-D0). A value of p<0.05 is considered as statistically significant.

Results and discussion

**Study Population**
Forty one women aged between 30 and 51 years (mean 44) with a BMI from 23 to 30 participated to the study. There was no statistical difference between the two groups at baseline in scores for fat nodes confirming the homogeneity of groups at D0.

**Tolerance**
Only one subject in the CL group and two subjects in the PL group, reported transitory discomfort sensations that could be related to the product or placebo respectively intake. No noticeable variation in blood pressure and pulse was observed whatever the group.

Under the conditions of this study, conducted under clinical control, product “Cellulight® 40 mg” and “Placebo” were globally very well-tolerated.
**Fat nodes score**

Groups were significantly similar at D0. No statistically significant evolution of fat nodes on stomach was observed in the CL group, compared to the PL group at D28 or D56.

Results obtained for fat nodes scoring on thighs are presented in Table 1.

<table>
<thead>
<tr>
<th></th>
<th>Visual cellulite score on thighs</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>D0</td>
<td>D28</td>
<td>D56</td>
</tr>
<tr>
<td>Placebo</td>
<td>6.1 ± 0.3</td>
<td>6.3 ± 0.3</td>
<td>6.2 ± 0.3</td>
</tr>
<tr>
<td>Cellulight®</td>
<td>5.9 ± 0.4</td>
<td>5.7 ± 0.4</td>
<td>5.5 ± 0.4</td>
</tr>
<tr>
<td>*p value</td>
<td>NS</td>
<td>&lt;0.05</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

*Table 1: Visual cellulite score on thighs at D0, D28 and D56 for CL and PL groups. Values are mean ± SD.*

No statistically difference was observed in the PL group between different visits. When compared with the basal value (D0), Cellulight® tends to reduce fat nodes on thighs at D28 (*p*=0.0701). At D56, Cellulight® significantly reduces fat nodes on thighs by 6.8%, compared to D0 (*p*=0.0012).

When compared together, groups are statistically different at D28 and D56. Cellulight® significantly reduces fat nodes on thighs by 9.5% (*p*=0.0152) and 11.3% (*p*=0.0217), respectively at D28 and D56 (Figure 1).

A complementary analysis have been realized on women with a pooled (thighs + stomach) fat nodes scores superior to 4.8 at D0 (n=34), meaning excluding women with low levels of cellulite. Results are presented in Figure 2.

![Figure 1: Effect of Cellulight® on fat nodes on thighs compared to placebo. Values are mean of scores ± SD. n=41; NS: non-significant; *, p<0.05.](image)

![Figure 2: Effect of Cellulight® on fat nodes on thighs and stomach, compared to placebo. Scores are the pool of scores measured on thighs and on stomach. Values are mean of scores ± SD. n=34; NS: non-significant; *, p<0.05.](image)

**Discussion & conclusion**

The statistical analysis showed a regular and continuous decrease of fat nodes on thighs with Cellulight® versus placebo on D28 and D56. These results are interesting because it is the first time that a 100% natural ingredient, supplemented orally, is demonstrated to significantly reduce cellulite compared to a placebo. They also bring evidence of Cellulight®’s quick action – from 28 days of supplementation – as well as a durable efficacy – until 56 days.

The absence of effect of Cellulight® on stomach compared to placebo could be due to the fact that fat nodes on this area are far less pronounced than the one on thighs. This phenomenon is observed in our study with a mean fat nodes score of 5.6 on stomach vs 6.0 on thighs at D0. This conduces to a most sensitive and difficult determination of possible changes on stomach.

The complementary results obtained on the pooled and stratified population – considering fat nodes scores on stomach + thighs > 4.8; n=34 – confirm the pervious analysis. When
taking into account only subjects with pronounced fat nodes (score > 4.8), cellulite reduction is statistically significant in the Cellulight® group compared to placebo.

Despite the lack of fundamental knowledge regarding its physiology, cellulite has been suggested to result from adipose tissue protrusions to the dermis, enlargement of fat lobules and alterations of the network of connective tissue strands that connect the dermis to deeper tissue layers. This last condition could be associated as a fibrosis state of concerned tissues. All these phenomena lead to the well-known padded or orange peel-like appearance\(^1\), \(^3\), \(^4\).

SOD reducing effects on fibrosis states are already largely documented due to its use as a medicine in order to fight cancers radiotherapy induced fibrosis\(^5\)-\(^9\).

However, there is no available data on possible action of SOD on fat lobules size regulation. This could be an innovative and interesting working hypothesis to investigate Cellulight® mechanism of action on cellulite.

Complementary study on Cellulight® mechanism of action could help to argue its demonstrated clinical efficacy on cellulite.

References