Cellulite, found in most post-pubertal women and located on many body areas, is perceived as uneven, lumpy textured skin best visualized with side lighting of the affected area. It has been described as an “orange peel” or “cottage cheese” skin appearance made more prominent by subcutaneous fat. The etiology of cellulite is unknown, yet modern theories include genetic predisposition (1,2), vascular insufficiency (3,4,5), changes in lipid metabolism, and structural changes in the extracellular matrix (ECM) (6,7). Products containing retinol have been promoted for use in improving the appearance of cellulite by primarily supporting the structure of the ECM. Reported in literature and used commonly in aesthetic spas, microcurrent treatment of the skin using an electrolytic-conductive primary gel with retinol cream products (Product B) is seen as an alternative for improving cellular appearance. This double blind study compared a retinol-containing topical cream to commercially-available microcurrent spa-equivalent skin care regimens for cellular appearance improvement.

OBJECTIVE

To understand the ability of non-cellular targeted microcurrent skin care regimens to improve the appearance of cellulite as compared to a market leader retinol cream.

STUDY DESIGN:

In a double blind clinical study, one retinol-containing cream and two microcurrent regimens (Table 1), employing different topical formulations, were tested over 12 weeks with 20 subjects in each of these study arms. Four common areas of cellulite involvement (posterior upper thigh, abdomen, ventral upper arm, and neck) were gradated by clinician, subject self-assessment, and girth measurements. Cellulite was defined as visible dimpling of the skin without the presence of shadows from deep-cut indurations. No manipulation of the skin appearance through pinching was allowed to create a defined appearance. Lack of body fatiness and lack of firming were defined as sagging skin over the anatomic area. Following study entry, subjects were asked to complete an entry questionnaire. At the baseline visit, subjects were weighed and photographed. Both the subject and the dermatologist primary investigator completed a questionnaire detailing the appearance of the cellulite at weeks one, four, eight, and 12 weeks. Thigh circumference and weight were measured at baseline and at weeks four, eight, and 12.

TARGET SITES FOR EVALUATION:

Digital photography and evaluations were conducted of the following target sites: Abdominal—lower overall appearance, overall appearance Abdomen—lower Upper Arm—underside, lifting, smoothing, overall appearance Neck—front, lifting, smoothing, overall appearance Overall Cellulite—lifting, smoothing, overall appearance Overall Cellulite—lifting, smoothing, overall appearance

STUDY REGIMENS:

RETINOL: TCF67. Topically, cosmetic formulations contain a retinol concentration of 0.1 – 0.5% w/w with an ideal concentration of 0.1% w/w when resistance and safety become a concern. A market leading clinically-based cosmetic product was selected as a benchmark control for this study. To reduce initial irritation, the retinol cream was used once daily every other day for the first week and once daily for the second week. Thereafter, the retinol treatment was used twice daily. RETINOIDS: TCF67. Topically, cosmetic formulations contain a retinol concentration of 0.1 – 0.5% w/w with an ideal concentration of 0.1% w/w when resistance and safety become a concern. A market leading clinically-based cosmetic product was selected as a benchmark control for this study. To reduce initial irritation, the retinol cream was used once daily every other day for the first week and once daily for the second week. Thereafter, the retinol treatment was used twice daily. RETINOIDS: TCF67. Topically, cosmetic formulations contain a retinol concentration of 0.1 – 0.5% w/w with an ideal concentration of 0.1% w/w when resistance and safety become a concern. A market leading clinically-based cosmetic product was selected as a benchmark control for this study. To reduce initial irritation, the retinol cream was used once daily every other day for the first week and once daily for the second week. Thereafter, the retinol treatment was used twice daily. RETINOIDS: TCF67. Topically, cosmetic formulations contain a retinol concentration of 0.1 – 0.5% w/w with an ideal concentration of 0.1% w/w when resistance and safety become a concern. A market leading clinically-based cosmetic product was selected as a benchmark control for this study. To reduce initial irritation, the retinol cream was used once daily every other day for the first week and once daily for the second week. Thereafter, the retinol treatment was used twice daily. RETINOIDS: TCF67. Topically, cosmetic formulations contain a retinol concentration of 0.1 – 0.5% w/w with an ideal concentration of 0.1% w/w when resistance and safety become a concern. A market leading clinically-based cosmetic product was selected as a benchmark control for this study. To reduce initial irritation, the retinol cream was used once daily every other day for the first week and once daily for the second week. Thereafter, the retinol treatment was used twice daily. RETINOIDS: TCF67. Topically, cosmetic formulations contain a retinol concentration of 0.1 – 0.5% w/w with an ideal concentration of 0.1% w/w when resistance and safety become a concern. A market leading clinically-based cosmetic product was selected as a benchmark control for this study. To reduce initial irritation, the retinol cream was used once daily every other day for the first week and once daily for the second week. Thereafter, the retinol treatment was used twice daily.

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TARGET SITES FOR EVALUATION:

Digital photography and evaluations were conducted of the following target sites:

- Abdominal—lower overall appearance
- Overall Cellulite—lifting, smoothing, overall appearance
- Overall Cellulite—lifting, smoothing, overall appearance

STUDY REGIMENS:

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TABLE 1

<table>
<thead>
<tr>
<th>Test Matrix</th>
<th>Study Area</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retinol Containing Product</td>
<td>Abdominal—lower overall appearance</td>
<td>2.20 ± 0.009</td>
<td>2.13 ± 0.001</td>
<td>1.83 ± 0.001</td>
</tr>
<tr>
<td>Microcurrent Treatment of Topical Regimen A</td>
<td>Abdominal—lower overall appearance</td>
<td>2.55 ± 0.016</td>
<td>2.40 ± 0.011</td>
<td>2.40 ± 0.011</td>
</tr>
<tr>
<td>Microcurrent Treatment of Topical Regimen B</td>
<td>Abdominal—lower overall appearance</td>
<td>2.55 ± 0.016</td>
<td>2.40 ± 0.011</td>
<td>2.40 ± 0.011</td>
</tr>
<tr>
<td>Nitrogen Code</td>
<td>Overall Cellulite—lifting, smoothing, overall appearance</td>
<td>X</td>
<td>100% (10/10)</td>
<td>X</td>
</tr>
</tbody>
</table>

RESULTS

Data from clinical grading and subject self-assessment was analyzed by comparing change from baseline between treatment groups and longitudinally for each treatment, allowing each subject to serve as their own historical control. For simplicity, only the comparisons that were statistically significant are presented in Table 2. Photos representative of the study results are shown.

Overall, both microcurrent spa-equivalent treatments Product A and Product B outperformed the retinol cream. Additionally, although one microcurrent spa-equivalent treatment employed elevated levels of highly skin-targeted active ingredients (Product A), both microcurrent treatments were statistically equivalent, suggesting that a significant proportion of the improvement in the appearance of cellulite was derived independent of the topical treatment formulation used. No statistically significant changes in subjects’ overall body weight were detected during the course of the study, eliminating weight loss as a cause of cellulite reduction.

DISCUSSION

Cellulite is widely thought to be a skin appearance created by the structural organization of the subcutaneous compartment underlying the dermis. Ultrasound has convincingly shown herniations of subcutaneous tissue into the dermis in persons afflicted with cellulite. Retinoids are thought to improve the amount and structure of collagen, thereby improving the appearance of cellulite (Figure 5).

It has been shown that there is approximately a 35% decrease in blood flow in areas affected by cellulite compared with unaffected areas (9). Microcurrent treatment may enhance vascular, lymphatic, and intercellular fluid movement, allowing for reduced fluid retention and increased nutrient supply supporting remodeling. Further, the transmission of the microcurrent into the skin is enhanced by the conductive gel that also moisturizes the skin, improving texture and feel. This may explain the statistically significant improvement in cellulite appearance even with the microcurrent treatment arms as compared to the retinol cream alone.

CONCLUSION

This pilot study demonstrated the statistically significant ability of a microcurrent spa-equivalent and conductive gel to improve the appearance of cellulite more than a retinol cream. Further work will need to be done to better characterize the effects of microcurrent on skin structure and adipose tissue.

REFERENCES