A Clinical Comparison of Pure Omental Lipid Versus a Typical Moisturizers for the Treatment of Dry Skin

Abstract

A clinical evaluation (Dry Skin Leg Regression Assay) of the effects of a product containing Pure Omental Lipids (POL Cream) verses a typical moisturizer (Cetaphil Moisturizing Lotion) was conducted in 21 subjects with moderate to severe dry skin of the lower legs. Product treatment consisted of a one week washout period followed by four days of product applications twice a day (BID) with a three day regression period (no product applications). Clinical evaluations for dryness/roughness (via an expert grader), moisturization (via electrical conductance) and trans epidermal water loss (TEWL) were made at baseline, day 4 (12 hours after the last application), and at day 7 (3 days post product use). The POL Cream decrease skin surface dryness/roughness by 94% versus 55% for the Cetaphil Moisturizer, increased skin hydration by 167% versus 32%, respectively and improved barrier function (TEWL) by 13% versus 7% when compared to the typical moisturizer. Additionally, after both products had not been used for three days, the test sites for the POL formula still demonstrated a 36% improvement in the overall condition and appearance of dry/rough skin, a 58% increase over the baseline moisture content of the skin and a 16% improvement in barrier function (TEWL) compared to 14%, 10% and 9% for the same categories measured for typical moisturizer, respectively. Both products tested demonstrated significant improvement in the overall condition of dry/rough skin, skin hydration and barrier function. However, the overall appearance of dry/rough skin as well as the amount of moisture content measured in the skin and barrier function demonstrates that the POL Cream has a higher affinity for binding moisture and strengthening barrier function in the skin and maintains a better appearance of healthy looking skin that is well moisturized even after product use is discontinued.

Methodology

The experimental design used was based on the leg regression test first described by Kligman with some refinements. Suitable candidates were placed on a one week pretrial conditioning program during which time they were not allowed to treat their legs with any moisturizers, sunscreen, or other topically applied products. Additional restrictions on cleansing and removal of leg hair were also imposed and maintained throughout the study. At the end of the pretrial conditioning period, individuals with moderate to severe dryness on the lower legs were chosen as panelist for the actual trial. Test products were topically applied to mapped sites twice a day (BID) for 4 days. At the end of the treatment period, the panelists were monitored for an additional 3 days to see how quick these sites regressed to a non treated condition. A total of 21 female panelists between the ages of 40 and 65 were involved in these trials. Various expert grader and instrumental readings were made in a blinded fashion as described below:

1. Expert Grader Evaluation Expert grader evaluations were made of dryness at the test sites at baseline and at day 4. An evaluation was also made 3 days after treatments were completed (day 7). Subjects were evaluated using a 1 to 8 scale, whereby, 1 was minimal dryness and 8 severe dryness.

2. Electrical Conductance Testing Electrical conductance measurements were taken with a Skicon200 Skin Surface Hygrometer, at baseline and at day 4 (12 hours after the last application) as well as after 3 days without treatment (regression period). The ability of an alternating current to flow through the stratum corneum is an indirect measure of its water content. The value recorded represents the AC conductance 5 seconds after placing a spring loaded probe tip to the test site. This timing interval is sufficiently long enough for the electronic circuits to stabilize in response to this change in electrical conductance but short enough not to be influenced by an increased hydration at the probe tip due to its being occlusive and acting as a hindrance to the normal water loss at the test site.

3. Water Loss Measurements (TEWL) - Measurements were made using a recently calibrated cyberDERM RG1 Evaporimeter System (Broomall, PA) with TEWL Probes (Unit P5 and Probes 715 and 716) that were manufactured by Cortex Technology (Hadsund, Denmark) and available in the US through cyberDERM, inc. (Broomall, PA). Duplicate water loss measurements were taken from each leg site on Day 0 as well as on Day 4 and Day 7 (Regression Days 0 & 3 respectively). The measurements were taken from each site and electronically recorded using a spreadsheet format based on Excel software that computed the average value for each test site. Such measures provided a noninvasive method for determining the barrier function of the stratum corneum. Damage leads to a disruption of the barrier that is accompanied by elevated water loss rates.

Results

Conclusion

Based on the data obtained from the this study, it appears that the product formulated with Pure Omental Lipids compared to a typical moisturizing product has significant benefits with respect to the treatment of subjects with moderate to severe dry skin.

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