A Randomized Controlled Clinical Study to Evaluate the Effectiveness of an Active Moisturizing Lotion With Colloidal Oatmeal Skin Protectant Versus Its Vehicle for the Relief of Xerosis

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*The use of brand names does not imply endorsement by Mayo Clinic.

**ABSTRACT**

Xerosis is a common skin condition, occurring most often in the winter and in low relative humidity, which results in loss of moisture, cracking, and desquamation. Many emollient creams and lotions are available for use as preventive moisturizers. However, few controlled experiments have been published comparing the efficacy of active moisturizing products versus the vehicle used to deliver the products to the skin. Therefore, we conducted this randomized, double-blind, controlled clinical study to objectively compare a commercially available moisturizing product against its own vehicle. The active colloidal oatmeal moisturizer used in this study showed significant benefits versus its vehicle control in several dermatological parameters used to measure skin dryness.

**INTRODUCTION**

Xerosis is a major cause of pruritus, particularly in climates with low humidity or cold temperatures and in older persons. When skin is extremely dry, excessive flaking of corneocytes can cause the formation of microfissures and an increase in mast cells and histamine levels, which results in chronic itch. Although many available topical products can provide patients with moisturizing benefits, few well-controlled clinical studies have been conducted that demonstrate significant benefits of specific active compounds. We performed a randomized, controlled clinical study to address this deficiency in the literature. We aimed to compare the moisturizing abilities of the active ingredient in a commercially available colloidal oatmeal skin protectant with its vehicle lotion.

**METHODS**

This study was approved by the Mayo Clinic Institutional Review Board. Patients seen in the Department of Dermatology, Mayo Clinic, Rochester, Minnesota, were recruited to participate in the study between December 2011 and April 2012. Thirty women aged 18 to 70 years with bilateral moderate to severe xerosis and bilateral mild to moderate pruritus on the lower legs were enrolled. All patients who agreed to participate provided informed consent. For all potential subjects, the skin on their lower legs was clinically graded at a preliminary visit. Eligible subjects needed to have bilateral moderate to severe dryness (scores of 2-4 on a 0-4 skin dryness scale) and bilateral mild to moderate itch (scores of 1-2 on a 0-3 subjective itching scale) on both lower legs. Subjects were excluded from the study if they had active dermatitis or other skin disease involved on their legs.

All enrolled subjects were instructed to refrain from using any leave-on products on their lower legs for the 5 days before the start of the study. During the first study visit (baseline, day 0), each subject was assigned to use both test products in a bilateral study design: one product labeled as “A,” to be used on the right leg, and the other labeled as “B,” to be used on the left leg. The 2 test products were a commercially available skin relief moisturizing lotion with colloidal oatmeal skin protectant (Aveeno Skin Relief Moisturizing Lotion, Johnson & Johnson CCI) and its matching vehicle lotion (provided by Johnson & Johnson CCI). Both the subjects and the clinical investigator were blinded as to the identity of products “A” and “B,” which was randomized for each patient. Subjects were instructed to apply the products to the lower legs twice daily and continue with this application regimen for 3 weeks, then discontinue all treatments for 1 more week.

**Clinical Evaluations**

Test sites on the lower legs of each of the subjects were graded clinically by the author (A.N.K.). Grading was done at baseline (day 0), after 21 days of treatment, and after a 1-week regression period without treatment (day 28). Scaling and cracking of the skin were graded on a scale of 0 (no scaling or cracking) to 9
grades reported for active moisturizing lotion and vehicle lotion at baseline and after 21 days of treatment are shown in Table 2, along with the change in grade and the percentage decrease. The active moisturizer was perceived as better at relieving itch than the vehicle alone.

**Instrumental Measurements**

The products’ effect on the skin surface at the test sites was measured by using 2 instruments: the Corneometer CM 825 (Courage + Khazaka electronic GmbH) and the Skicon 200EX (Acaderm). These instruments quantify moisture content in the stratum corneum by an electrical method. The Corneometer measures capacitance in Corneometer units, and the Skicon measurements are made in microsiemens, the SI unit for electrical conductance and the reciprocal of electrical resistance. Three replicate measurements were taken on each lower lateral leg at the midpoint between the knee and ankle. Measurements were made at each of the 3 visits.

A high-definition microscope (HI-Scope Advanced KH-3000 Video Microscope System, HiroxUSA) also was used to capture x100 magnification images of the skin in a dimension of approximately 2x3 mm at the designated sites. Test areas were marked by the study coordinator and marked again as needed to ensure that the same site was imaged during each session. HI-Scope images were obtained for several patients on each lower lateral leg, in an area with minimal hair, at baseline, day 21, and day 28.

**Self-Assessment**

Subjects completed a self-assessment questionnaire at baseline, day 21, and day 28. Subjects rated the condition of the skin on each of their lower legs and expressed their preferences about which product, A or B, was more effective for several parameters.

**Statistical Analysis**

All data were collected in a blinded fashion by the clinical investigator and given to the nonclinical investigator for transmission to an independent statistician for unblinding and data analysis. Mean differences in values between products were compared using paired t tests. Changes from baseline for each product were also tested using paired t tests. Proportions were compared using the McNemar test. Preferences were tested using the binomial test. P<.05 was considered statistically significant.

**RESULTS**

**Clinical Evaluations**

After 21 days of treatment, the changes from baseline value for the parameters of scaling and overall dryness were significantly greater for the active moisturizer than its vehicle (P=.03 and P=.004, respectively; Table 1). The subjects were asked to grade the intensity, duration, and frequency of their itch at both test sites, using a 0 to 3 scale for each parameter. The average
After 21 days of treatment, all 30 patients stated which lotion, A or B, they preferred for different parameters. After the data were unblinded, indicating which leg had which lotion for each patient, it became evident that considerably more patients expressed a preference for the active moisturizing lotion over the vehicle for all parameters (Table 3).

**DISCUSSION**

Xerosis and pruritus are together a major field of study within dermatology, and many products have been researched and manufactured in an attempt to bring relief to the millions of patients affected by these conditions. In particular, many topical products are designed to both moisturize the skin and relieve itching. However, despite many studies that aimed to prove the efficacy of these products, few have demonstrated that the active ingredients of these products have any significant benefits when compared with their own vehicle. This study was conducted in an attempt to amend this oversight.
During this study, the active moisturizing lotion with colloidal oatmeal skin protectant showed significant benefits over its vehicle lotion control in several key dermatological parameters. Double-blinded, clinical grading by a dermatologist demonstrated that the active moisturizing lotion had significantly greater improvements from baseline than the vehicle for the parameters of scaling, overall dryness, and intensity, duration, and frequency of itch. In addition, the active moisturizing lotion demonstrated significantly better hydration as measured by the Corneometer and Skicon at 21 and again at 28 days (after the 1-week regression). Furthermore, the self-assessments also demonstrated that patients favored the active moisturizing lotion on almost all tested attributes.

These results support that the active ingredient in this particular moisturizing product is, in fact, beneficial to the skin and assists in maintaining proper hydration of the skin and in the prevention of pruritus. It is valuable for the practicing dermatologist to have clear evidence-based results showing that the active ingredients in a skin care product have the actual effect promised and are more effective than the vehicle. These results are especially important for dermatologists to make informed product recommendations to their patients. Further examination of the active ingredients in skin care products to ensure their efficacy should be an area of focused research in the future.

ACKNOWLEDGMENTS

The authors thank Michael Suero (Johnson & Johnson CCI) for technical contributions, David Lewin (Statistically Speaking, LLC) for statistical analysis, and Kristopher De Young (Kaztronix, LLC) for his assistance in manuscript preparation.

DISCLOSURES

The article was funded by Johnson & Johnson CCI. The authors have no relevant conflicts of interest to declare.

REFERENCES


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TABLE 3.

Self-Assessment of Patient Preferences

<table>
<thead>
<tr>
<th>Preference on Day 21</th>
<th>Preferred Lotion*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Active Moisturizing Lotion</td>
</tr>
<tr>
<td>Better overall appearance</td>
<td>26 (87)</td>
</tr>
<tr>
<td>Less itchy</td>
<td>25 (83)</td>
</tr>
<tr>
<td>Less dry</td>
<td>26 (87)</td>
</tr>
<tr>
<td>Softer and smoother</td>
<td>26 (87)</td>
</tr>
<tr>
<td>Less irritated/more comfortable</td>
<td>26 (87)</td>
</tr>
<tr>
<td>Feels more moisturized</td>
<td>26 (87)</td>
</tr>
</tbody>
</table>

*Number (%) of patients who preferred each lotion.

FIGURE 3. HI-Scope Images of a Small Area on the Lower Lateral Legs of One of the Test Subjects. (Original magnification, ×100.) One leg was treated with the active moisturizing lotion (left images) and the other was treated with only the vehicle (right images). a) Baseline. b) After 21 days of treatment. c) After the 1-week regression period (day 28).