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ORIGINAL CONTRIBUTION

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Efficacy of a shower cream and a lotion with skin-identical lipids in healthy subjects with atopic dry skin

Enzo Berardesca MD, PhD[1] | Susan Mortillo[2] | Norma Cameli MD, PhD[1] | Marco Ardigo MD[1] | Maria Mariano MD[1]

[1]San Gallicano Dermatological Institute, Rome, Italy

[2]Colgate-Palmolive Company, Piscataway, NJ, USA

Correspondence
Enzo Berardesca, San Gallicano Dermatological Institute, Rome, Italy.
Email: berardesca@berardesca.it

Funding information
Colgate-Palmolive Company (Piscataway, NJ, USA)

Summary

Background: Atopic dermatitis is a chronic, pruritic inflammatory skin disease that adversely affects quality of life.

Aims: The current study evaluates the efficacy of a shower cream and a lotion, each with skin-identical lipids and emollients, in the treatment of atopic dry skin of subjects with a history of atopic condition.

Methods: In all, 40 healthy females with clinically dry skin on the lower legs were enrolled in the study and underwent 4 weeks of daily use of the shower cream and 2 additional weeks of both the shower cream and the body lotion. Subjects were evaluated at day 0, week 4, and week 6. Skin barrier function was assessed by Tewameter®, skin hydration by Corneometer®, smoothness and desquamation by Visioscan®, and stratum corneum architecture by reflectance confocal microscopy (RCM). The investigator assessed the degree of dryness, roughness, redness, cracks, tingling and itch, and subjective self-assessment evaluated the perception of skin soothing, smoothness, and softness.

Results: Skin barrier function and skin moisture maintenance were significantly improved using the shower cream. The lotion with physiological lipids, together with the shower cream, also improved skin barrier function and moisture. Both the shower cream and the body lotion reduced clinical dryness, roughness, redness, cracks, tingling and itch, according to the dermatologist, and increased soothing, smoothness, and softness, according to the subjects of the study.

Conclusion: The combination of a shower cream and a lotion with physiological lipids efficiently restores skin barrier function and increases skin hydration, becoming an effective skin-care option for patients with atopic dry skin.

KEYWORDS
atopic, dermatology, emulsions, skin, skin physiology/structure

1 | INTRODUCTION

Atopic dermatitis is a chronic, pruritic inflammatory skin disease frequently affecting children, but that may occur at any age.[1] Its prevalence has been reported to be 4%-28% in children and 1%-7% in adults, depending on the country and diagnostic criteria applied.[2-7] Atopic dermatitis occurs because of the interaction of genetic factors, environmental elements, and infectious agents, which may result in defects in skin barrier and immune abnormalities.[7,8] Precise etiology is unknown although current theories center on a disordered immune response, especially on an imbalance of cytokines.[6] From time to time, most patients with atopic dermatitis have acute

flares [9] with inflamed, red, itchy patches, and in between flares, the skin may suffer from atopic dry skin, a state of chronic dry skin in patients prone to atopic dermatitis.

Dry skin is caused by a skin barrier defect that results in a loss of water from the stratum corneum.[10] Symptomatology includes itch, tightness, scaly and flaky appearance, as well as severe inflammation and cracks, with high risk of secondary infection.[11] Some environmental factors, frequent washing, use of harsh detergents, or exposure to low-humidity environments can aggravate dry skin, and when untreated, it can lead to a flare of underlying conditions, such as atopic dermatitis.[10] According to this, recommendations for the management of dry skin encompass the use of mild skin cleansers, the reduction of the frequency and duration of exposure to water, and topical application of lipophilic and humectant-containing skincare products.[12,13] Recommendations about non-pharmacologic interventions to patients prone to atopic dermatitis also comprise showering or bathing with warm water and the application of moisturizers.[8,14-16] Thus, moisturizers remain the mainstays of maintenance therapy for patients with atopic dry skin.[14]

Not all moisturizers and emollients are considered to be equally effective, mostly depending on their formulation.[10] The shower cream and lotion tested in this study are both formulated with a unique combination of skin-identical lipids and emollients. One ingredient, castoryl maleate, functions as a pseudo-ceramide and glycerine is a well-known moisturizing ingredient. Physiological lipids, such as ceramides, can help replenish and restore the intercellular lipid matrix,[10,17,18] while humectants, such as glycerine, attract and hold water in the stratum corneum.[10]

The main aim of the current study was to evaluate the efficacy of a shower cream and a lotion with skin-identical lipids and emollients in improving the dry skin of subjects with a history of atopic condition.

2 | MATERIALS AND METHODS

2.1 | Study subjects

A total of 40 healthy subjects were enrolled in the study. Subjects were females, between 18 and 50 years old, who had a history of atopic condition, but no evidence of current active atopic dermatitis when enrolled. Subjects had clinically dry skin on the lower legs (score of 5 or higher using a visual analogue scale (VAS) from 0 to 10). No concurrent topical therapy or moisturizers were permitted for 2 weeks prior to the study. No oral corticosteroids or other medication potentially influencing skin conditions were permitted during the study. Medication for chronic treatment, such as hypertension, diabetes, cardiovascular disease, was allowed as long as the dose was not modified during the study. Subjects with active symptoms of allergy, atopic dermatitis, irritation, allergy to any type of skin-care product or conditions of the skin in the test area were considered inappropriate for participation; uncontrolled diseases, pregnancy or nursing were also considered exclusion criteria. All subjects were fully informed and understood all the procedures, risks and benefits of the study, and they read and signed the informed consent form provided.

2.2 | Shower cream and lotion formulation

The shower cream was formulated as a mild liquid cleanser and the body lotion as an oil-in-water emulsion. Both were made according to good manufacturing practice (GMP). Castoryl maleate was used in the formulation of both the shower cream and lotion. The total skin-identical lipids accounted for approximately 0.5%-2% of the formulation. The quality of the formulation was checked in relation to key release specifications including stability.

2.3 | Study design

The study was conducted in San Gallicano Dermatological Institute (Rome, Italy), after approval by its Institutional Review Board. A 2-week wash-out period was carried out from March 24th to April 6th, 2014. After this, the test period was conducted in two parts: the first part consisted of 4 weeks of daily use of the shower cream; the second part consisted of 2 additional weeks of continuing to use the shower cream and also using a body lotion, at least once daily (Figure 1). Subjects recorded their usage of test products in a written diary. The test period took place from April 7th to May 23rd, 2014.

2.4 | Interventions

Subjects were instructed to apply the shower cream to the entire body, including the lower legs from knee to ankle, wetting the skin, lathering into skin for 10 seconds, waiting 90 seconds, and finally rinsing for 15 seconds more. The body lotion had to be spread over the entire body, including the lower legs from knee to ankle. During both the wash-out and test periods, subjects had to avoid any other topical treatment and/or moisturizer.

Three visits were carried out: baseline visit at day 0, from when subjects started using the shower cream, a second visit at week 4, from when subjects added the use of the body lotion, and a third visit at week 6.

2.5 | Outcomes

All specified outcomes were assessed in all of the subjects enrolled (n = 40), which presented a dryness score of 5 or higher at baseline visit (measured by VAS from 0 to 10). A subset analysis was performed in subjects with severe skin dryness, defined as subjects with a dryness score of 7 or higher (n = 19), to determine skin hydration, barrier function, and dermatologist- and subject-reported outcomes.

2.5.1 | Instrumental assessment

Instrumental evaluation was performed on the anterior surface of either right or left lower leg. Measurements were performed at baseline (Day 0), week 4, and week 6.

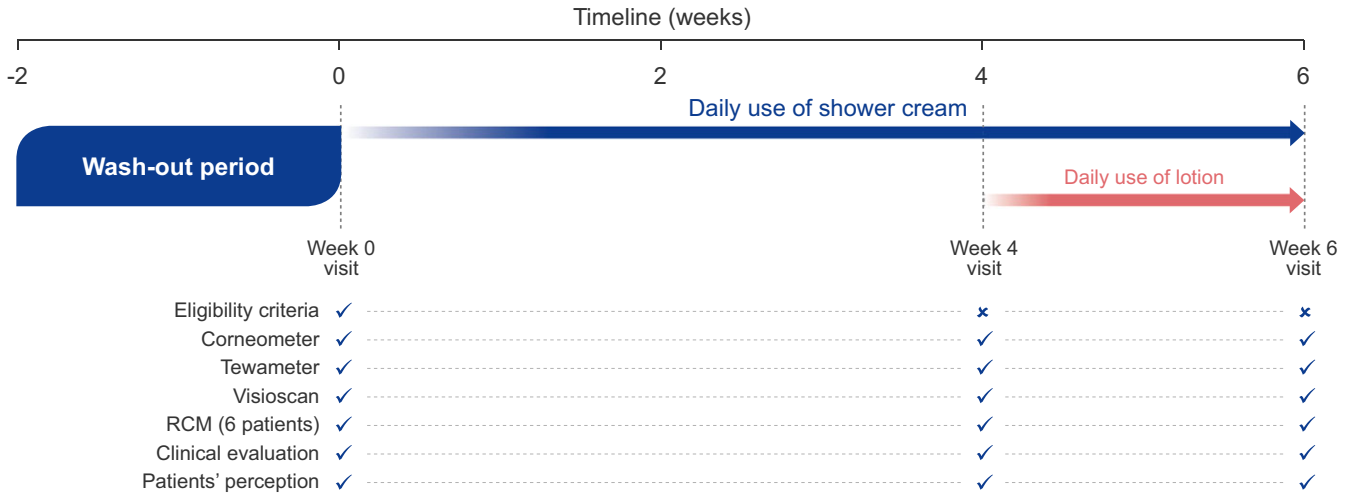

FIGURE 1 Study design and evaluations done at baseline, week 4, and week 6 visits. RCM: Reflectance Confocal Microscopy

- Barrier function was assessed by measuring transepidermal water loss (TEWL) with a Tewameter® (Courage and Khazaka, Koln, Germany). Each TEWL measurement was averaged over the last 20 seconds of a 30-second or 1-minute measurement period (or until the level was stabilized).
- Skin hydration was measured by an electrical capacitance method, using the Corneometer® CM 825 (Courage and Khazaka, Koln, Germany). The mean value of 5 readings was calculated in corneometer units (CU).
- Skin smoothness and desquamation were determined by ultraviolet macrophotography with a Visioscan® VC 98 camera (Courage and Khazaka, Koln, Germany).
- Stratum corneum architecture was assessed on a subset of 6 subjects using in vivo reflectance confocal microscopy (RCM) with a VivaScope® 3000 (Lucid Technologies, Henrietta, NY, USA) operating with a diode Class 3A laser (European version), at a wavelength of 830 nm, with power lower than 35 mW at tissue level.

2.5.2 | Dermatologist-reported outcomes

Clinical assessment was performed on the anterior surface of both right and left lower leg at baseline, week 4, and week 6. The degree of dryness, roughness, redness, cracks, tingling, and itch were assessed by the dermatologist, using a VAS score from 0 ("not at all" or "absent") to 10 ("extreme"). Dryness, redness, and cracks were determined visually, roughness was assessed by tactile evaluation, and itching and tingling by subject evaluation (reported by subjects to the dermatologist).

2.5.3 | Subject-reported outcomes

Subjective self-assessment was performed to evaluate the perception of skin soothing, smoothness, and softness, using a VAS score from 0 to 10 on both legs, at baseline, week 4, and week 6.

2.5.4 | Safety

Any unanticipated adverse event (other than minor skin irritation, possible allergic reaction, erythema, dryness, itching, burning, stinging, or blistering) had to be reported, documented, and followed to resolution by the Investigator.

2.6 | Statistical analysis

Mean values (M) were described for quantitative continuous variables. Standard deviation (SD), standard error (SE), and 95% Confidence interval (95% CI) were computed. Paired Student's *t* test and Wilcoxon's test were used to determine *P* value for instrumental and clinical data, respectively. Values of $P \leq .05$ were considered statistically significant. The statistical analysis was conducted using International Business Machines Corporation (IBM) SPSS Statistics software, version 22.0.

3 | RESULTS

3.1 | Description of subjects

Median age of enrolled subjects was 44.5. Distribution by age was the following: 2.5% of subjects between 18 and 30 years old, 10% between 31 and 40, and 87.5% between 41 and 50. 85% of subjects had a past history of atopic dermatitis, 5% of subjects suffered from rhinitis, 7.5% had a history of atopic dermatitis and rhinitis, and 2.5% had a history of atopic dermatitis, rhinitis, and asthma.

3.2 | Barrier function

Analysis of TEWL showed a significant decrease in the mean level of water loss, expressed as g/h/m^2 (SD), from 15.50 (3.86) g/h/m^2 at baseline to 11.11 (3.22) g/h/m^2 at week 4 ($P \leq .05$), to 8.24 (3.33) g/h/m^2 at week 6 ($P \leq .05$; Figure 2). Very similar results were

obtained in the sub-analysis of subjects with severely dry skin (Figure S1A).

3.3 | Skin hydration

No significant differences were detected in the levels of hydration, by Corneometer® evaluation, at baseline 24.46 (4.67) CU and at week 4 24.54 (5.52) CU at week 4 ($P > .05$). However, significant changes were observed from week 4-24.54 (5.52) CU -, to week 6-39.49 (10.17) -, ($P \leq .05$; Figure 3). These results were consistent in patients with severely dry skin (Figure S1B).

3.4 | Roughness and scaliness

Figure 4 shows the typical effect of shower cream at week 4, and of shower cream plus lotion at week 6 in skin roughness and scaliness, by Visioscan® images, showing a more regular structure of the skin and a higher level of skin hydration.

3.5 | Stratum corneum architecture

Images from stratum corneum and epidermis were taken using RCM to evaluate the structure and state of intercellular lipids. No major structural changes in the stratum corneum and epidermis were detected at week 4, while at week 6 a more organized structure and a normally packed stratum corneum were observed (Figure 5).

3.6 | Dermatologist-reported outcomes

The dermatologist-reported outcomes were scored using the 0-10 VAS (0 = "not at all" or "absent," 10 = "extreme"). The evaluation of dryness by the dermatologist significantly changed from baseline to week 4 (6.61 [1.15] vs 5.89 [1.23]; $P \leq .05$) and from week 4 to 6 (5.89 [1.23] vs 2.16 [1.30]; $P \leq .05$). Likewise, the evaluation of roughness decreased from baseline to week 4 (5.10 [1.70] vs 3.23 [1.58]; $P \leq .05$) and from week 4 to week 6 (3.23 [1.58] vs 0.83 [1.00]; $P \leq .05$). The evaluation of redness also showed significant differences from baseline to week 4 (0.81 [1.38] vs 0.27 [0.75]; $P \leq .05$) and from week 4 to 6 (0.27 [0.75] vs 0.01 [0.08], $P \leq .05$). Subjective evaluation of itch, according to subjects' opinions, significantly improved from baseline to week 4 (5.33 [2.04] vs 2.91 [2.24]; $P \leq .05$) and from week 4 to 6 (2.91 [2.24] vs 0.32 [0.73]; $P \leq .05$). The evaluations by dermatologist of other parameters, such as cracks and tingling, also significantly improved after the first 4 weeks and after the last 2 weeks (Figure 6). Similar results were obtained in the sub-analysis of subjects with severely dry skin (see supplementary data, Figures S2 and S3).

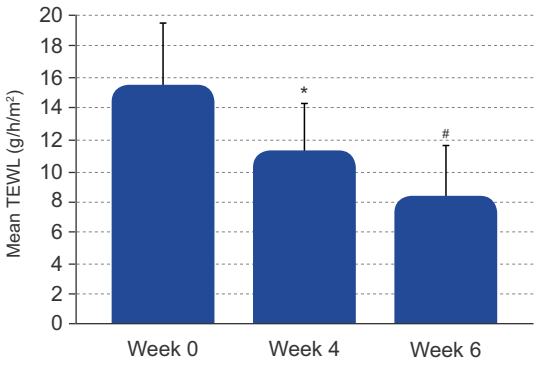

FIGURE 2 Tewameter results at day 0, week 4 (shower cream), and week 6 (shower cream and lotion). Error bars represent SD; * Statistically significant from baseline at 95% CI; # Statistically significant from baseline and week 4 at 95% CI; CI: Confidence Interval; SD: Standard Deviation; TEWL: Transepidermal water loss

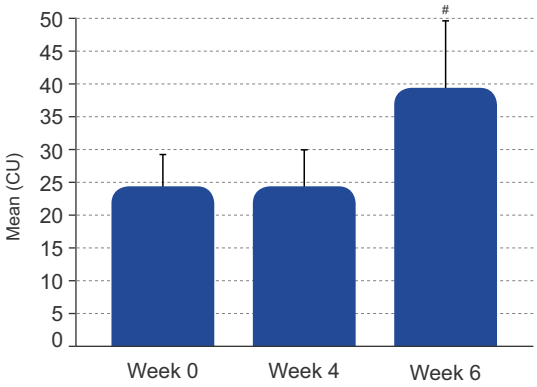

FIGURE 3 Corneometer results at day 0, week 4 (shower cream), and week 6 (shower cream and lotion). Error bars represent SD; # Statistically significant from baseline and week 4 at 95% CI; CI: Confidence Interval; CU: Corneometer Units; SD: Standard Deviation

3.7 | Subject-reported outcomes

The subject-reported outcomes were scored using the 0-10 VAS. The mean perception of smoothness significantly improved from 2.43 (1.79) at baseline to 4.42 (2.03) at week 4 ($P \leq .05$), and to 8.16 (1.44) at week 6 ($P \leq .05$). The mean perception of soothing and softness also increased from baseline visit to week 4, and from week 4 to week 6 (Figure 7). Similar results were obtained in the sub-analysis of subjects with severely dry skin (data not shown).

3.8 | Safety

No adverse events were observed or reported either in the subjects exclusively using the shower cream or in those combining it with the lotion.

4 | DISCUSSION

Recommendations addressing skin care and xerosis prevention advise the cleansing and application of skin-care products to moisturize and repair the skin.[12,13] In patients with a history of atopic dermatitis and atopic-prone skin, prevention measures are far more important.[14,15] A balance between hydration and barrier repair needs

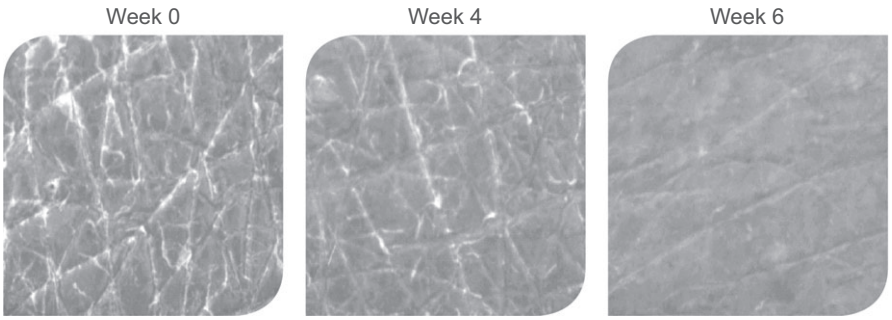

FIGURE 4 Visioscan results at day 0, week 4 (shower cream), and week 6 (shower cream and lotion). An example of skin surface images at baseline, week 4, and week 6

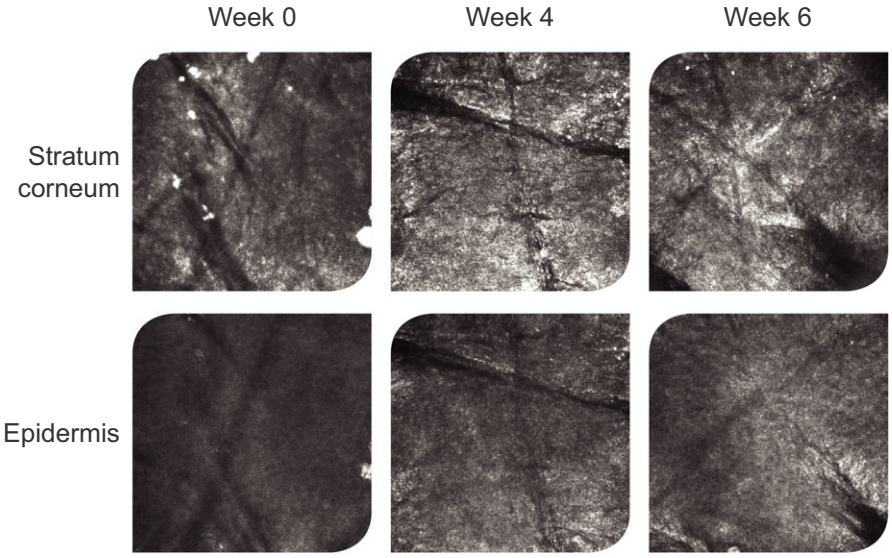

FIGURE 5 Reflectance confocal microscopy at day 0, week 4 (shower cream), and week 6 (shower cream and lotion)

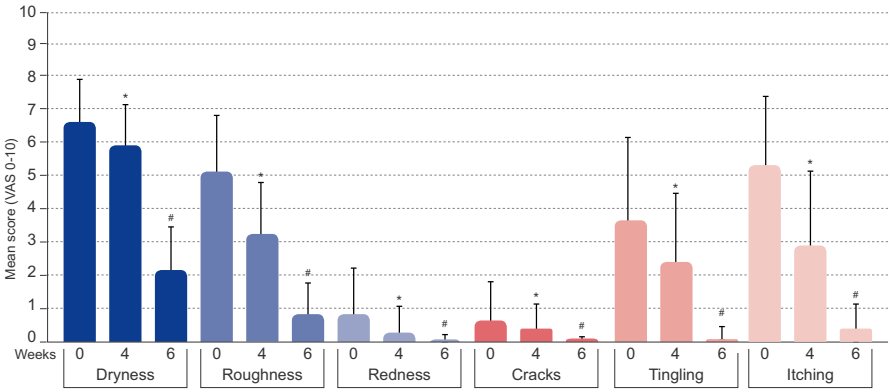

FIGURE 6 Dermatologist clinical evaluation by VAS score 0-10, at day 0, week 4 (shower cream), and week 6 (shower cream and lotion). Error bars represent SD; * Statistically significant from baseline at 95% CI; # Statistically significant from baseline and week 4 at 95% CI; CI: Confidence interval; SD: Standard Deviation; VAS: Visual Analogue Scale

to be found, as moisturizing and barrier repair properties are not always correlated and present in the same products, and the best hydrating lipid composition is often different from the optimal barrier repair formulation and vice versa.[19]

The use of natural soap is not recommended for preventing dry skin, as it may damage skin barrier due to its alkaline pH.[13] The use of soap with harsh detergents has been shown to remove skin lipids and natural moisture, as well as increase the stratum corneum pH.[10,20]

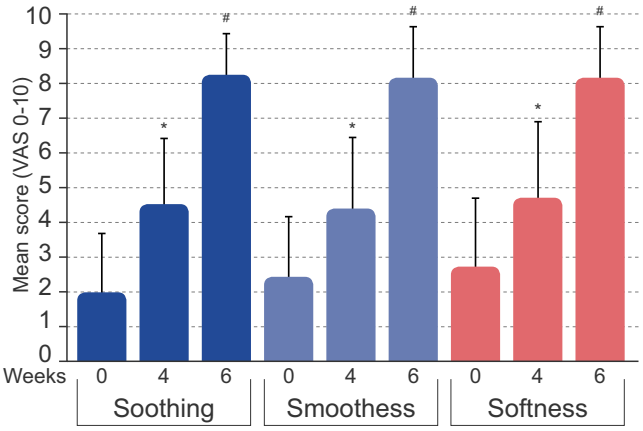

FIGURE 7 Subjects self-evaluation of soothing, smoothness, and softness, by VAS score 0-10, at day 0, week 4 (shower cream), and week 6 (shower cream and lotion). Error bars represent SD; * Statistically significant from baseline at 95% CI; # Statistically significant from baseline and week 4 at 95% CI; CI: Confidence interval; SD: Standard Deviation; VAS: Visual Analogue Scale

According to the results obtained by TEWL evaluation, the shower cream improved skin barrier function after 4 weeks of usage, even in subjects with severely dry skin. During these 4 weeks, the isolated use of the shower cream neither negatively affected the hydration of skin evaluated by Corneometer®, nor increased the roughness and scaliness of skin, as shown by Visioscan® images. No major structural changes in the stratum corneum and epidermis were seen after use of the shower cream. An improvement in skin condition was evidenced by significant reduction in visual dryness, roughness, redness, and itch after 4 weeks of using the shower cream. Subjects also reported improvements in the feeling of soothing, smoothness, and softness on their skin.

The use of emollients may help prevent water loss from skin although not all are equally convenient. For instance, Aqueous Cream BP is not recommended, as sodium lauryl sulfate is an anionic surfactant known to be an irritant, favoring transepidermal water loss.[21] Quite the opposite, the formulation of emollients together with humectant molecules, such as glycerine or urea, attracts and holds water in the skin[9,18] and physiological lipids, such as ceramides, help replenish and restore the intercellular lipid matrix.[17,18]

The use of the lotion with physiological lipids provided a significant, additional improvement in skin barrier function to that obtained with the shower cream alone. Skin hydration and Visioscan® evaluation of roughness and scaliness considerably improved. The application of the lotion resulted in better results in barrier function and skin hydration, even in subjects with severely dry skin. In addition, dermatologists' evaluation of dryness, roughness, redness, and cracks significantly improved, and subjects reported fewer feelings of itch and tingling, and greater skin smoothness, soothing, and softness than before using the lotion.

The non-pharmacologic intervention tested in this study has been demonstrated to restore the stratum corneum barrier, consequently improving the cosmetic appearance of the skin and outcomes such as roughness, itching, smoothness, and erythema. Available evidence states that restoring skin barrier function helps to reduce transcutaneous penetration of sensitizers or chemicals, which in turn can increase the release of proinflammatory mediators and trigger eczematous lesions or atopic dermatitis.[13,19] Consequently, both the shower cream and the body lotion can be used as a skin care and maintenance tool in subjects with atopic dry skin.

Atopic dermatitis has a clear effect on patients' quality of life, affecting domains such as sleep, mood, or depression,[22,23] so non-pharmacologic interventions, as the one described, may help increase patients' satisfaction and welfare. Besides, non-pharmacologic interventions have also been shown to decrease the amount of prescription agents needed to control atopic dermatitis,[15] thus being another potential benefit of the shower cream and body lotion.

When interpreting the results of the current study, some limitations need to be considered. First of all, the study has only been carried out in women. This decision was made to avoid the potential interference of the presence of hair on the legs for the instrumental evaluation, and assuming that results in men would be similar. Subjects within a broad range of age were enrolled to cover any possible difference in skin structure and function across the course of life. In the present study, no control analysis without product application in half of the body was performed. The main reason was that both the shower practices and the length of the study would have made it hardly feasible to keep half of the body as a control for the subjects participating. In this sense, a comparison with their own skin state at weeks 4 and 6 in an uncontrolled before-after study was considered the best control to observe significant changes in subjects receiving the same treatment. Uncontrolled before-after studies have some advantages such as lower variability and the requirement of fewer subjects although there is less control over confounding factors. Furthermore, controlled before-after studies usually have a high risk of bias because of the differences between groups that are also being compared. This study was therefore designed to measure the differences in skin state of the same subjects, which was deemed the most robust control to measure effects, as finding suitable controls with comparable baseline levels was not possible. A last consideration is that tested products were applied by the subjects in their homes, with no medical verification of proper usage. However, subjects were provided with clear instructions and recorded their daily practice in a diary, with no major incidents registered. This pragmatic approach may be taken as a strength as obtaining statistically significant effects under daily conditions could mean getting even greater results in a highly controlled study.

In conclusion, the current study demonstrates the efficacy of the combination of a shower cream and a body lotion with physiological lipids in the barrier function and the hydration of the skin of subjects with atopic dry skin, even in those with severely dry skin. An improvement was also shown in the evaluation of dryness and roughness by dermatologists, as well as in the patients' perception of itch and smoothness. The results obtained indicate that this is an effective skin-care option for patients with atopic dry skin.

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ORCID

Enzo Berardesca http://orcid.org/0000-0003-3423-5038
Norma Cameli http://orcid.org/0000-0002-6535-6935

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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