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Effect of Skin Barrier Emulsion Cream vs a Conventional Moisturizer on Transepidermal Water Loss and Corneometry in Atopic Dermatitis: A Pilot Study

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ABSTRACT

The repair and maintenance of the epidermal barrier is of the utmost importance in the treatment of atopic dermatitis (AD). While barrier creams and emollients are considered to be a foundation of AD therapy, there is little comparative data between various product options. This was a pilot study with a small sample size to investigate the use of skin barrier emulsion cream vs a commonly used moisturizing lotion to improve the epidermal barrier in subjects with atopic dermatitis.

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INTRODUCTION

It is now well recognized that the epidermal barrier serves not only to prevent the entry of exogenous factors such as irritants or allergens, but also to mediate disease. Although it was long known that dysfunction of the barrier may directly contribute to atopic dermatitis (AD), most of the evidence now suggests that there is a significant relationship between epidermal barrier dysfunction and cutaneous inflammation.

One of the primary functions of the stratum corneum (SC) is to maintain homeostasis by the regulation of water content with regulation of water flux, and thus the modification of transepidermal water loss (TEWL).[1-3] The now outdated bricks and mortar model of the SC provided a reasonable basis for conceptualizing its components. The bricks are the corneocytes, comprised primarily of keratin macrofibrils protected externally by a cornified cell envelope cohesively held together by corneodesmosomes.[4] The cornified cell envelope is composed predominantly of proteins (eg, loricin, involucrin) and a covalently bound outer lipid monolayer that is made up primarily of long chain ceramides.[1,4,5,6] The mortar is a bilayered intercellular membrane comprised of 3 major classes of lipid components present in a relative ratio of approximately 3:1:1—ceramides, cholesterol, and fatty acids. These major physiological SC lipids are produced enzymatically within the SC from specific precursor lipids.[1,2,4,7,8,9]

We now know that the physiological properties of these lipids, in this specific composition, permit the SC to perform its primary functions.[1,2,3]

Each component of the intercellular lamellar lipid membrane influences proper SC function. When the epidermal barrier in normal skin is disrupted, this results in upregulation of cholesterol, ceramides, and free fatty acids.[10]

A specific ceramide-dominant, physiologic lipid-based barrier repair emulsion cream (EpiCeram® Skin Barrier Emulsion, Puracap Pharmaceutical, LLC, South Plainfield, New Jersey) is a Food and Drug Administration—cleared 510K prescription medical device product indicated for the treatment of dry skin conditions and to manage and relieve the burning and itching associated with various types of dermatological conditions including AD, irritant contact dermatitis, and radiation dermatitis. This formulation has a 3:1:1 molar ratio of ceramides, cholesterol, and free fatty acids that simulates the relative amount of these same 3 lipid components in the endogenous intercellular lipid membrane of the SC.

Specifically, the formulation contains ceramide (pseudo-ceramide-104 or PC-104), conjugated linoleic acid (CLA), and cholesterol in an emollient base. The base consists of a patented controlled release system (MultiSal™ Encapsulation Technology, Salvona, Hamilton, New Jersey) that facilitates the slow release of PC-104, CLA, and cholesterol (Figure 1).

The advantages of this skin barrier emulsion are that it is steroid free, with no restriction on application site or duration, and also no age restriction.

A pilot study was undertaken to determine the effects of this barrier repair emulsion cream (EpiCeram) on skin hydration and TEWL, and to compare it with the effects of a commonly used petrolatum-based moisturizing lotion (Eucerin®, Beiersdorf AG, Hamburg, Germany).

STUDY DESIGN

This was a single-center, randomized, investigator-blind study. Subjects were randomized at a 1:1 ratio for the application of the study treatment to the left side and the moisturizing lotion (Eu-

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FIGURE 1. MultiSal™ technology delivery.

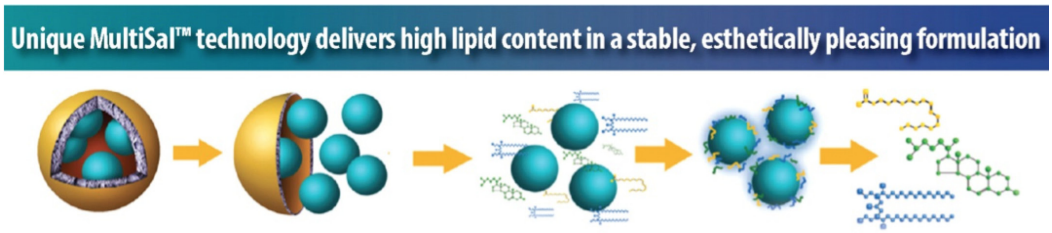

TABLE 1.

Investigator's Global Assessment Score	
Score	**Description**
0 = Clear	No inflammatory signs of atopic dermatitis
1 = Almost Clear	Just perceptible erythema and Just perceptible population/infiltration
2 = Mild Disease	Mild Erythema and Mild population/infiltration
3 = Moderate Disease	Moderate Erythema and Moderate population/infiltration
4 = Severe Disease	Severe Erythema and Severe population/infiltration
5 = Very Severe Disease	Severe Erythema and Severe population/infiltration with oozing/crusting

cerin) to the contralateral side, or for the application of EpiCeram to the right side and control product to the contralateral side.

The 4-week trial period consisted of 2 clinical visits—the first a screening/baseline visit, and the second a follow-up visit at week 4. Male or female subjects of any race, aged 7 years and older, were eligible for inclusion. Subjects were required to have a definitive diagnosis of AD as per Rajka-Hanifin criteria, rated as mild to moderate in disease severity (score of 2 or 3) based on the Investigator's Global Assessment Score at baseline (Table 1). Eligible subjects were required to have a minimum body surface area involvement of 5%.

"The SBEC may contribute to epidermal barrier maintenance through its physiologically balanced 3:1:1 ratio of essential lipid delivery."

The investigator identified bilateral target areas on the body for assessments. There were 2 types of assessment performed: TEWL and corneometery for hydration.

Assessment of barrier function was performed via standard TEWL measurements taken with a Tewameter 300 meter (Courage + Khazaka [C + K] GmbH Electronic, Koln, Germany). Three sequential readings were taken from each target area. A minimum of 1 minute elapsed between the completion of one reading and the initiation of the next.

Using the same target areas as for TEWL, the investigator assessed skin hydration using a Corneometer 825 meter (C + K Electronic GmbH, Koln, Germany). Five timed readings were taken from each target area (0 mins, 15 mins, 30 mins, 45 mins, and 60 mins). Each timed reading was comprised of 3 sequential readings (a minimum of 1 minute elapsed between the completion of one reading and the initiation of the next).

RESULTS

A total of 10 subjects were enrolled in the study (Table 2). Corneometry readings show that both interventions positively impacted skin hydration. For example, the average percentage improvement from baseline to week 4 at time 0 was 108% for the skin barrier emulsion cream (SBEC). There was no statistical significance in scores between the SBEC and the moisturizing lotion at week 4.

Although there was no statistically significant difference between the 2 groups, there was a trend in favor of the SBEC for overall median percentage hydration improvement. Skin barrier emulsion cream improved overall median percentage hydration by 55% at week 4 compared with baseline vs 37% for the moisturizing lotion.

Transepidermal water loss readings were decreased by both the SBEC and the moisturizing lotion applications at week 4. There was no statistically significant difference between the 2 groups. However, there was a trend in favor of the SBEC in reduction of TEWL at week 4 compared with baseline. Average TEWL value decreased by 2.2 units with the SBEC application at week 4 compared with 1.4 units with the

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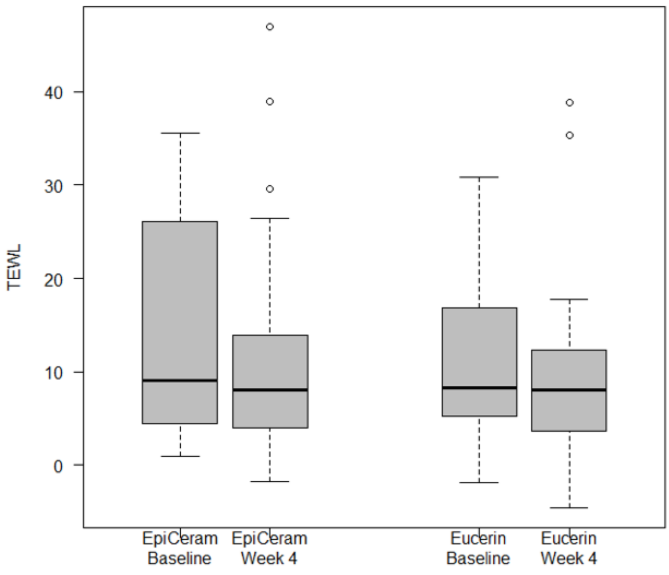
TABLE 2.

Patient Demographic With Baseline Characteristics	
Variable	**n = 10**
Age	31 (22); 17 [12, 68]
Sex	
Male	4 (40%)
Female	6 (60%)
Race	
White	3 (30%)
Black	3 (30%)
Hispanic	2 (20%)
Asian	2 (20%)
Baseline IGA	
2	5 (50%)
3	5 (50%)
Baseline BSA	9 (2); 9 [6, 13]

IGA, Investigator's Global Assessment; BSA, body surface area.

FIGURE 2. Boxplot of transepidermal water loss readings under treatment with EpiCeram® and Eucerin®, at baseline and at week 4.



TEWL, transepidermal water loss.

moisturizing lotion. Median percentage change in TEWL was 15.9% reduction with the SBEC at week 4 vs 14.5% increase with the moisturizing lotion (Figure 2).

DISCUSSION AND CONCLUSION

Petrolatum has a long history of use in the treatment of AD and is recognized for its occlusive properties. On the other hand, the SBEC may contribute to epidermal barrier maintenance through its physiologically balanced 3:1:1 ratio of essential lipid delivery. This ceramide-dominant, physiologic lipid-based barrier formulation with its 3:1:1 molar ratio of ceramides, cholesterol, and free fatty acids simulates the relative amount of these same 3 lipid components in the SC and may provide important benefits to AD patients. Additionally, another study showed that the effects of the SBEC on scoring atopic dermatitis (SCORAD), pruritus, and sleep habits are comparable to those for fluticasone propionate cream.[11]

Taken together, the available data suggest that the SBEC is a suitable option to manage epidermal barrier dysfunction, to improve skin hydration, and to reduce TEWL. However, this is a small sample size pilot study that does not have the statistical power to detect any significant differences in performance of the 2 products, even though a trend is signaled in favor of the SBEC. Additionally, we also have clinical studies of the SBEC that show efficacy in AD patients.

DISCLOSURES

This study is funded by Puracap Pharmaceutical, LLC. Dr. Kircik has served as an advisor, investigator, and consultant for Puracap Pharmaceutical, LLC.

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