

Interest in an Emollient Containing Pentyl Rhamnoside in the Management of Xerosis and Atopic Skin

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Xerosis is frequently associated with atopic dermatitis. Emollients are the first line of treatment for the management of atopic and non-atopic xerosis. Thus, an emollient containing lipids to restore the skin barrier, thermal spring water to soothe the skin, and pentyl rhamnoside, which provides anti-inflammatory activity, could be of interest in treating xerosis and atopic skin.

The aim of this study was to assess the interest and tolerability of an emollient containing pentyl rhamnoside, a fatty acid, ceramide, cholesterol, and thermal spring water in treating atopic and non-atopic xerosis.

Xerosis has many etiologies, including external aggression, senescence, drugs, infection, and atopic dermatitis, which is the most frequent cause. The stratum corneum of patients with atopic xerosis reveals not only decreased hydration, but also mildly impaired barrier function, including an increase in transepidermal water loss, elevated pH values, and an increased turnover rate of the stratum corneum consisting of thick layers of smaller-sized corneocytes.^{1,2} Mutations in the filaggrin gene are extremely common in patients with atopic xerosis and are present in up to 10% of the population.³

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Emollients are commonly used by patients with dry skin conditions to restore the defective barrier function and to repair dry skin and its consequences, pruritus in particular.^{4,5} The importance of using emollients in the treatment of atopic xerosis has been recognized through practice and validated by numerous clinical trials.^{4,6} Emollients restore the defective barrier function, but should also make flares of atopic dermatitis less frequent. Finally, emollients improve the quality of life of children and their parents.

Emollients mainly contain lipids.⁴ A combination of essential fatty acids, ceramides, and phytosterols is optimal for restoring the cutaneous barrier by filling in the skin cracks, thereby targeting xerosis.⁷ Topical applications of a fatty acid, ceramide, and cholesterol have been shown to restructure the skin barrier, improve desquamation, and restrict the evaporation of water contained in the epidermis.⁸

Pentyl rhamnoside is a carbohydrate compound that belongs to the rhamnose family. It is characterized by a 5-carbon radical with amphiphilic properties. Indeed, it significantly increases its bioavailability in comparison with rhamnose, which is only hydrophilic, suggesting a rapid cutaneous penetration.⁹ Recent data have

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demonstrated that pentyl rhamnoside exhibits a potential anti-inflammatory activity targeted to the keratinocytes at the primary stage of epidermal inflammation.¹⁰

Thus, the combination of pentyl rhamnoside, a fatty acid, ceramide, cholesterol, and thermal spring water could be of interest in the management of atopic xerosis.

The purpose of this study is to assess the interest and tolerability of a topical skin care regimen with an emollient containing pentyl rhamnoside, a fatty acid, ceramide, and cholesterol for the treatment of atopic and non-atopic xerosis.

METHODS

Study Design

Individuals suffering from atopic xerosis, non-atopic xerosis, or both were included in this open-label, multicentric trial. This study was conducted in France from September 2007 to March 2008. Most of the investigators were private practitioners who consisted of pediatricians and dermatologists.

The participants were aged 3 years and older, had no intolerance to any of the ingredients, no other dermatological conditions that could interfere with the trial, and were not pregnant or nursing. An informed consent was given. The participants all had xerosis, either adult atopic or non-atopic xerosis, infantile atopic dermatitis, or senile xerosis, with inflammatory lesions covering less than 10% of their total body surface on the first day of the trial visit. None of the participants were using topical steroids or immunosuppressants on the areas under evaluation and 7 cm around these areas in the week preceding the trial. None of the participants were using oral steroids or immunosuppressants, either continuously or intermittently, for less than one month, or receiving phototherapy in the week preceding the trial. Lastly, none of the participants had iatrogenic xerosis or atopic dermatitis complicated by superinfection.

During the trial, participants had to apply the emollient that contained pentyl rhamnoside, a fatty acid, ceramide, and cholesterol twice daily to areas with xerosis (apart from areas undergoing inflammatory flares) for 3 months. They used a standardized cleansing gel prior to applying the emollient.

EVALUATION CRITERIA

The evaluation of xerosis was based on a 4-point scale, where 0 indicated absent; 1, mild; 2, moderate; and 3, severe. The evaluations were determined by the investigator at day 90.

Using a visual analogue scale, the participants underwent an evaluation at baseline and on days 30 and 90 for clinical signs and symptoms, such as xerosis, erythema, pruritus, skin tightness, and skin discomfort. Their quality

of life was determined by using the Dermatology Life Quality Index (DLQI) or Children's Dermatology Life Quality Index at baseline and on days 30 and 90.^{11,12} Questionnaires to determine quality of life consisted of 10 questions, with possible responses ranging from 0 to 3. Therefore, the total score could vary between 0 and 30. The higher the score, the greater the impact on the patient's quality of life. The tolerance and cosmetic appraisal of the product was rated highly satisfactory, satisfactory, not very satisfactory, and not at all satisfactory by the total population. The subpopulation with atopic dermatitis had a subset of criteria, including scoring atopic dermatitis (SCORAD),¹³ the number and duration of inflammatory flares, and the consumption of steroids.

STATISTICAL ANALYSIS

This study was a noncomparative, prospective, open-label study. Comparisons were performed using the χ^2 test, Fisher exact test, or Wilcoxon signed rank test when the data were arranged by rank with a type I error of 5%.

RESULTS

Population

There were 397 participants with dry skin who were enrolled in this study, with an average age of 25.6 years (minimum age, 6 months; maximum age, 89 years). They claimed dry skin had been present for an average of 12 years. Of the 397 participants, 211 (53%) had infantile atopic dermatitis (Figure 1). The majority of patients were female (60%).

The treatment was carried out for an average period of 96 days. The participants were divided into 2 groups.

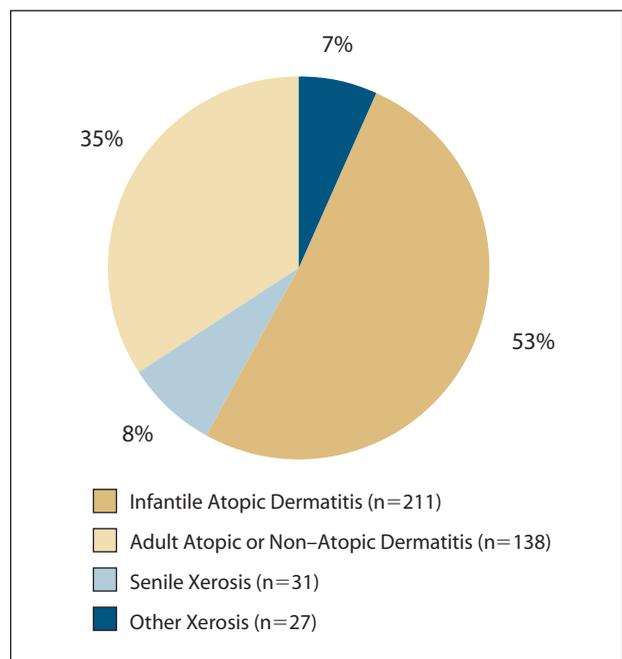


Figure 1. Breakdown of patients by indication.

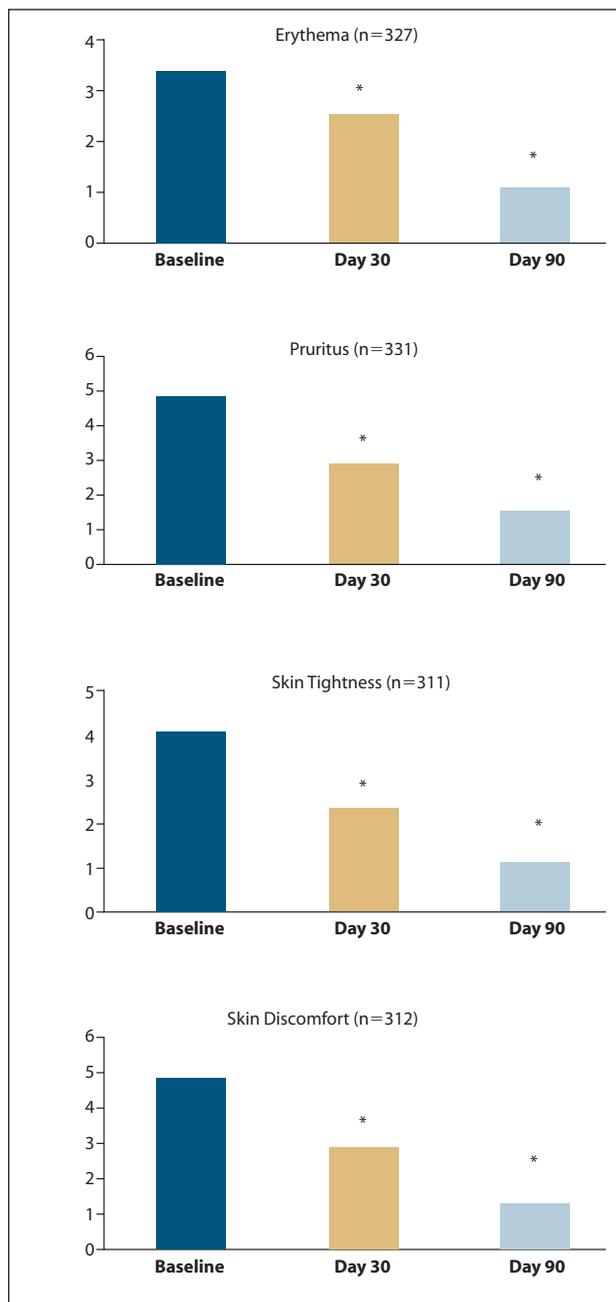


Figure 2. A visual analogue scale of changes in the clinical signs and symptoms of xerosis. Asterisk indicates $P < .0001$ versus baseline.

One group of 178 (45%) participants used the emollient in monotherapy without any associated drug treatment, and the second group of 219 (55%) participants used the emollient in combination with one or several medical therapies. Local therapies and steroids were the most frequently used by 99 (25%) participants, and 123 (31%) participants used systemic antihistamines.

PRIMARY CRITERION

The intensity of xerosis was evaluated by investigators on day 90. Three months of applying the emollient led to a

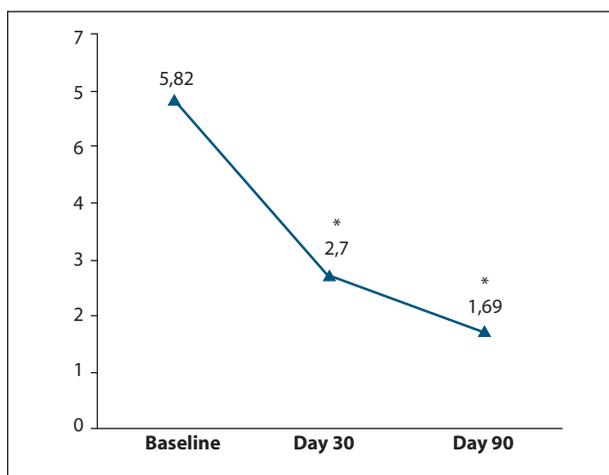


Figure 3. Changes in the quality of life of participants with xerosis during a 90-day study. Asterisk indicates $P < .0001$ versus baseline.

significant reduction ($P < .0001$) of the intensity of xerosis by 54.2% as compared with baseline, according to the investigators.

SECONDARY CRITERIA

The intensity of xerosis was evaluated by patients on day 90. Xerosis was significantly reduced ($P < .0001$) after 3 months of use of the emollient by 68% as compared with baseline, according to the patients.

Change in Clinical Signs and Symptoms

All clinical signs (ie, erythema, pruritus, skin tightness, skin discomfort) improved significantly ($P < .0001$) after 3-month use of the emollient (Figure 2).

Impact on Quality of Life

At the end of the clinical study, a significant improvement ($P < .0001$) of 71% was observed in the quality of life of the participants, according to the DLQI questionnaire (Figure 3).

Tolerability

The investigators judged that the tolerability of the emollient and cleansing gel were satisfactory or highly satisfactory for 96% and 94% of the participants, respectively.

Cosmetic Appraisal

The overall agreement of the emollient was rated as satisfactory or highly satisfactory by 369 (93%) of the participants. The product texture and ease of application were judged satisfactory or highly satisfactory by 361 (91%) and 353 (89%) of the participants, respectively. After use of the emollient, the skin was nourished, soothed, and comfortable for 393 (99%), 385 (97%), and 389 (98%) of the participants, respectively.

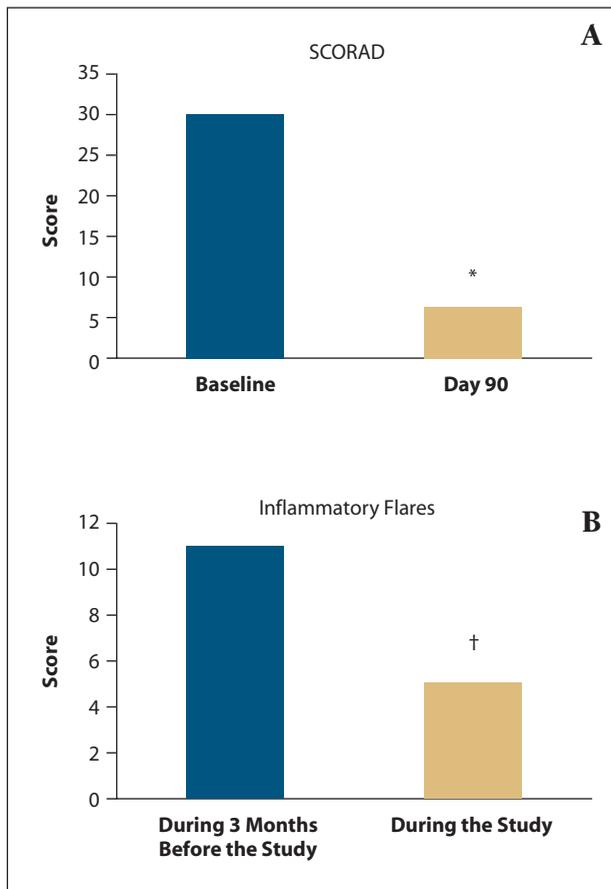


Figure 4. Results on atopic population, with scoring atopic dermatitis (SCORAD) values (A) and the duration of inflammatory flares recorded (B). Asterisk indicates versus baseline; dagger, versus 3 months prior to the study. $P < .0001$ versus baseline; $P < .0001$ versus 3 months before.

The level of satisfaction was also very high. The investigators and the participants were satisfied or highly satisfied in 385 (97%) and 389 (98%) of the cases, respectively.

PARTICIPANTS WITH ATOPIC DERMATITIS

Of the 397 participants, 211 (53%) were children suffering from atopic dermatitis, with an average age of 8 years old. A significant decrease ($P < .0001$) of the SCORAD index was observed after a 3-month application of the emollient as compared with baseline value (−80%) (Figure 4). Moreover, on day 90, the number and the duration of inflammatory flares was reduced significantly ($P < .0001$) by 31% and 54%, respectively, as compared with the 3-month period before the start of the study (Figure 4).

The percentage of participants applying topical steroids during the 3 months prior to the start of the study significantly decreased ($P < .001$) during the study period from 58% to 42%.

DISCUSSION

Results of this trial demonstrated the clinical interest of an emollient containing pentyl rhamnoside, a fatty acid, ceramide, cholesterol, and thermal spring water in a large population of individuals with dry skin. Topical applications of the product significantly improved atopic xerosis, non-atopic xerosis, or both and its associated clinical signs (ie, erythema, pruritus, skin tightness, skin discomfort), with excellent tolerability.

In order to establish if the treatment with the emollient made the participants feel better, their quality of life was assessed by using the DLQI or Children's Dermatology Life Quality Index questionnaires.^{11,12} Only a few studies measure the impact of atopic dermatitis on quality of life by calculating the DLQI score.¹⁴ In the present study, we showed a strong improvement of the participants' quality of life after 30 days of using the emollient. This result could be explained by the improvement of the participants' general skin conditions.

A particular attention to children with atopic dermatitis was given. The use of an emollient is recommended in the guidelines for atopic dermatitis management because emollients improve the appearance and symptoms of dry skin (xerosis) associated with this skin condition.¹⁵ The severity of atopic dermatitis was evaluated by the SCORAD index, the most frequently used validated tool in dermatology trials.^{13,14} A 3-month application of the emollient led to a significant decrease of the SCORAD index, which was accompanied by a reduction of the number and the duration of inflammatory flares.

Moreover, the percentage of participants using topical steroids was lowered during the study, suggesting a sparing effect of the emollient. Thus, by improving the skin barrier function, it would limit the penetration of environmental irritants and allergens that trigger cutaneous inflammatory mechanisms.¹⁶ This emollient contains the adequate lipid trio of a fatty acid, ceramide, and cholesterol combined with pentyl rhamnoside, providing potential anti-inflammatory properties.

In conclusion, this clinical trial showed that the specific combination of an emollient containing pentyl rhamnoside, a fatty acid, ceramide, cholesterol, and thermal spring water is useful in the management of atopic and non-atopic xerosis.

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