

An Evaluation of the Moisturizing and Anti-Itch Effects of a Lactic Acid and Pramoxine Hydrochloride Cream

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An open-label, single-center, observer-blinded, controlled trial was conducted during the winter months to evaluate the moisturizing and antipruritic effects of a unique formulation of lactic acid 12% neutralized with ammonium hydroxide and pramoxine hydrochloride (HC1) 1% in 24 women with a history of dry itchy skin. Baseline assessments for appearance of dryness of both lower legs of each patient were conducted by a blinded expert grader; skin surface hydration was measured by the IBS Co, Ltd, Skicon-200 (Hamamatsu, Japan) conductivity meter; and dryness and itch were measured through self-assessment surveys. The women stopped the use of all moisturizing agents 7 days prior to and throughout the study and were allowed to use only a nonmoisturizing soap for bathing and shaving. Patients were randomized as to which leg to apply the test cream; the opposite leg was used as a nontreated control. Patients applied the test product liberally to the assigned leg twice daily for 7 days and had repeat assessments for appearance and hydration on the morning of days 3 and 7; self-assessments of itch and dryness were completed on days 1, 2, 3, 6, and 7.

Expert grader assessment of skin dryness showed significant improvement with the test

cream compared with no treatment on day 3 (P=.0004) and on day 7 (P<.0001). Patients had statistically significant improvement in skin surface hydration by day 3 (P<.0001), with further improvement by day 7 (P<.0001). Patients also reported significant improvements in skin dryness and itch by day 1 (P<.0001 and (P<.0001, respectively), which continued to improve through day 7 (P<.0001 and P<.0001, respectively). In conclusion, the test cream was shown to be an effective moisturizer and antipruritic agent in treating dry itchy skin.

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Xerotic eczema is a mildly inflammatory variant of eczematous dermatitis that commonly develops on the lower legs of adults and elderly individuals during dry times of the year.¹ In addition to other symptoms associated with dry skin, these individuals frequently present with symptoms of pruritus.¹ α -Hydroxy acids, lactic acid in particular, have been shown to be effective moisturizing agents for the treatment of xerotic eczema and other forms of dry skin.¹⁻⁶ Pramoxine hydrochloride (HCl) is known to have antipruritic properties.⁷⁻⁸ The test cream used in this investigation is a special formulation containing a moisturizing agent, lactic acid 12% neutralized with ammonium hydroxide, and an antipruritic, pramoxine HCl 1%.

The primary objective of this study was to assess the skin-moisturizing effectiveness of the test cream using the IBS Co, Ltd, Skicon-200 (Hamamatsu, Japan) conductivity meter in conjunction with an expert grader assessment, with secondary objectives of assessing the itch-relief and moisturizing effectiveness of the test cream through self-assessments.

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Table 1.

Dryness Grading Scale*

0	Normal skin	No signs of dryness
2	Mild dryness	Slight, but definite roughness; fine scaling present; may have a powdery or ashy appearance
4	Moderate dryness	Moderate roughness; somewhat coarser; perceptible thickening may be present
6	Marked dryness	Marked roughness, coarse scaling; cracking evident; definite thickening may be present
8	Severe dryness	Very marked roughness; very coarse scaling; cracking progressing to fissuring; marked thickening may be present

*Intermediate grades of 1, 3, 5, and 7 were allowed for finer distinctions.

Methods

This was an open-label, single-center, observer-blinded, controlled trial conducted during the winter months at the Skin Study Center in Broomall, Pennsylvania.

Patients—Patients eligible for recruitment were healthy, nonpregnant, nonlactating women with intact, dry, itchy skin (atopic background). All women had a skin moisture content value less than 150 μ siemens for conductance, an itch rating on a visual assessment scale, and a dry skin score of 4 or higher determined by an expert grader at baseline. An expert grader scale of 0 to 8 was used where 0 was normal skin and 8 was severe dryness (Table 1).

Patients were excluded if they had a history of any significant skin disorder, had open sores or fissures on their legs, had any unstable medical condition, or, in the opinion of the investigator, would be unable to complete the study as written. Approval of the Allendale Investigational Review Board was obtained for the investigation, and all participants signed an informed written consent.

Treatment Regimen—Patients were randomized to apply the test cream liberally to one leg twice daily for 7 days with the opposite leg serving as a control (no treatment). The women stopped the use of all moisturizing agents 7 days prior to and throughout the study and were allowed to use only a nonmoisturizing soap for bathing and shaving. Daily high and low air temperatures and humidity were recorded during the study.

Outcome Measures—Evaluation of skin condition was completed by a blinded expert grader using the 0 to 8 assessment scale described in Table 1.

Table 2.

Weather Information

Study Day	Temperature, °F			Humidity, %
	High	Low	Noon	
0	50	39	46	60
1	48	41	45	100
2	57	40	51	51
3	35	23	30	30
4	48	28	43	30
5	58	35	52	29
6	50	40	44	57
7	46	39	43	100

Evaluations were conducted at the baseline visit (day 0) and on days 3 and 7, before application of the test cream. Assessment of skin surface hydration of the lateral aspects of the right and left calves of each patient was conducted using the Skicon-200 conductivity meter at baseline (day 0) and on days 3 and 7. As has been previously

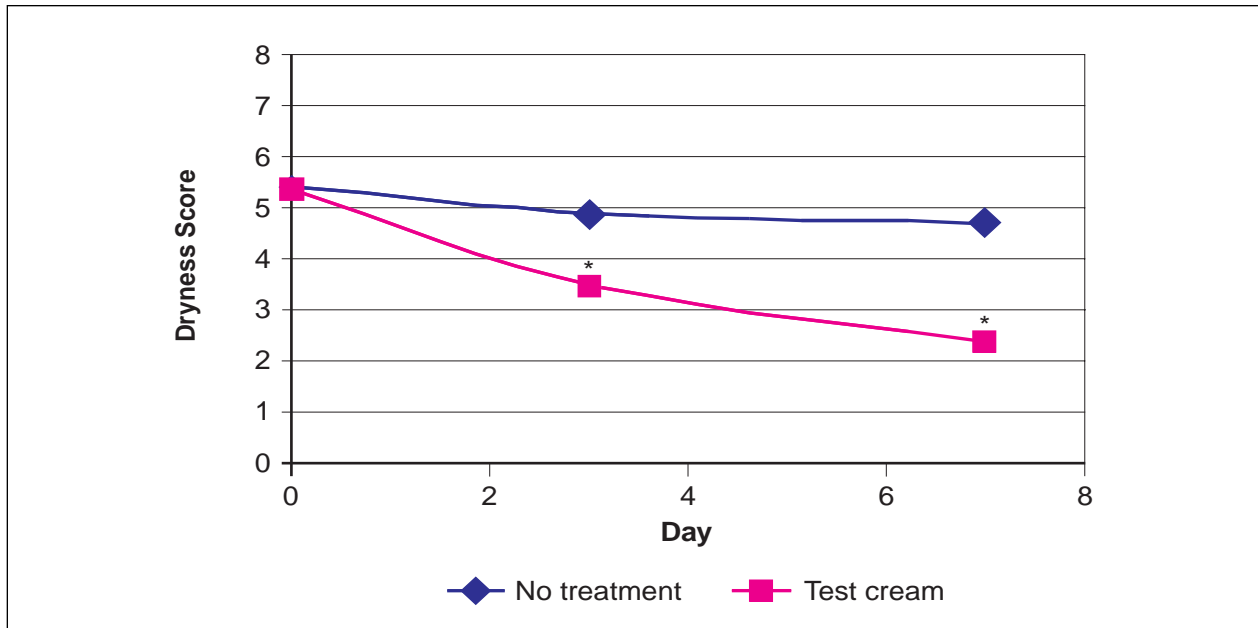


Figure 1. Expert grader-rated appearance of skin dryness on a scale of 0 to 8 (0=no dryness, 8=severe dryness). Asterisk indicates $P<.001$ vs control.

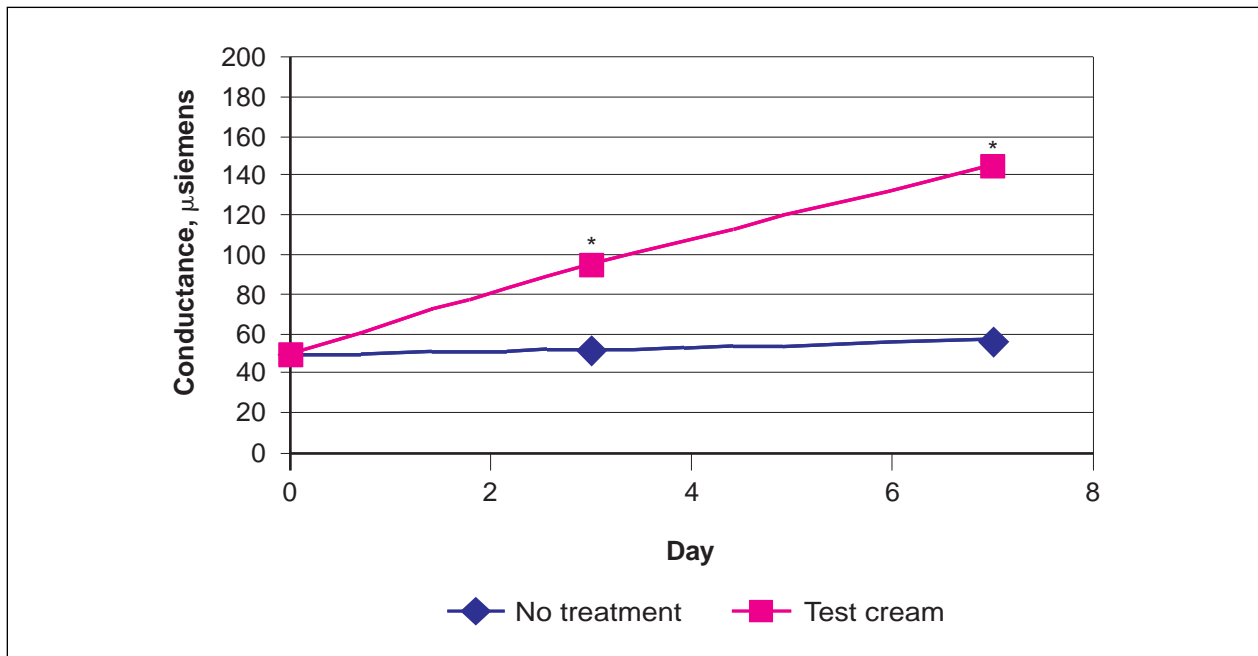


Figure 2. Skin surface hydration assessed by the IBS Co, Ltd, Skicon-200 conductivity meter. Asterisk indicates $P<.0001$ vs control.

demonstrated, the Skicon-200 conductivity meter provides an objective assessment of the water content of the skin through the use of an alternating current flow through the stratum corneum.⁹⁻¹¹ A higher value is an indication that the skin surface is more hydrated. Self-assessments of itch and dry-

ness were conducted on each leg on separate scales at baseline (day 0) and on days 1, 2, 3, 6, and 7 using a 10-point scale where 0 indicated no itching or dryness and 10 indicated severe itching or dryness. Daily high and low air temperatures and humidity are reported in Table 2.

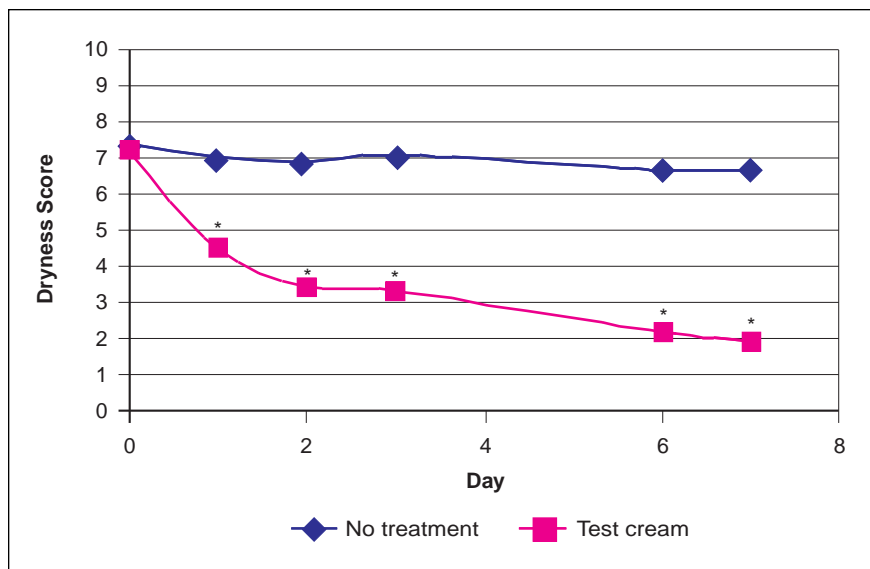


Figure 3. Patient self-assessment of skin dryness (0=no dryness; 10=severe dryness). Asterisk indicates $P < .0001$ vs control.

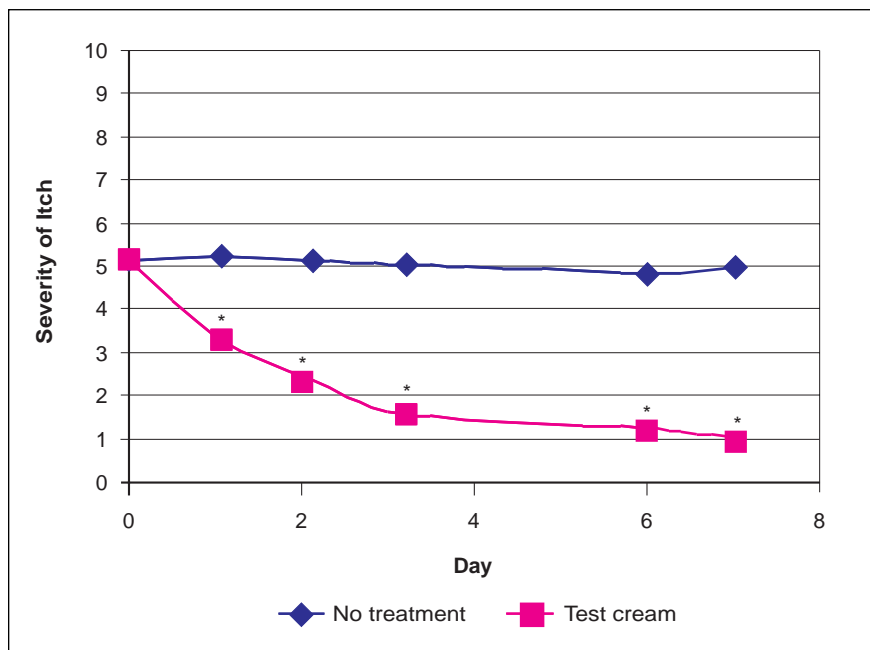


Figure 4. Patient self-assessment of itch (0=no itching; 10=severe itching). Asterisk indicates $P < .0001$ vs control.

A paired t test was used to compare treated versus untreated legs at each time point. For all analyses, a 2-tailed P value of less than 0.05 was used as the level of significance.

Results

Patient Demographics—A total of 24 women aged 18 to 55 years completed the study.

Efficacy—The test cream was statistically and clinically significantly better than the control for all measurable outcomes. An expert grader assessment of dryness showed significant improvement with the test cream compared with the control on day 3 (3.42 vs 4.88, respectively; $P = .0004$)

and on day 7 (2.29 vs 4.71, respectively; $P < .0001$) (Figure 1). Patients had statistically significant improvement in skin surface hydration on the treated side than on the control side by day 3 (94.23 vs 50.90, respectively; $P < .0001$), with further improvement by day 7 (144.51 vs 56.58, respectively; $P < .0001$) (Figure 2).

Through self-assessment surveys, patients also reported significant improvement by day 1 in both dry skin grades and severity of itch ($P < .0001$ vs control in both cases). Dry skin and itch continued to improve in the treated group through day 7 (dry skin, 1.88 vs 6.63, $P < .0001$ vs control; itch, 0.96 vs 5.00, $P < .0001$ vs control) (Figures 3 and 4).

Tolerability—There were no clinically significant adverse events reported during the course of this study.

Conclusion

Pruritus is a common complaint of patients with dry skin, particularly those patients with xerotic eczema. The results of this study show the effectiveness of a unique combination of lactic acid 12% neutralized with ammonium hydroxide and pramoxine HCl 1% in moisturizing and relieving the itch associated with dry skin. Significant improvements in both skin surface hydration and expert grader assessment of skin dryness were noted by day 3 and continued to improve throughout the treatment period.

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