

The Efficacy of Emollient in Restoring Transepidermal Water, Skin pH and Hydration in African Patients with Atopic Dermatitis (EMTePHADerm) – A Randomized Double-blind Controlled Trial

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Abstract

Introduction: The skin biophysical parameters of atopic dermatitis (AD) patients show decreased hydration, elevated skin pH, and increased trans-epidermal water loss (TEWL). Emollients that improve these are not commonly tested in African climes. We aimed to compare the effects of two emollients used in moisturizing on AD clinical severity, skin hydration, pH, and TEWL in Nigeria.

Methods: Prospective cohort review of AD patients in two tertiary hospitals in Lagos, Nigeria, from June to December 2022, in a randomised double-blind trial of two emollients following ethical approval. The EASI scores, hydration, skin pH, and TEWL were measured before the intervention and re-evaluated after six weeks and three months of daily use of either the intervention or control emollient. Skin measurements were done on the chin and forearm using the Courage + Khazaka Electronic GmbH® system.

Results: Of 140 participants, 62.9% were females; the mean age was 24.5 ± 19.8 years. Baseline measurements were higher on the chin compared with the forearm, with mean hydration values of 56.7 ± 18.5 : 40.0 ± 20.7 , pH 6.5 ± 2.1 : 5.5 ± 0.4 , and TEWL 32.4 [CI: $24.5 - 52.2$]: 18.8 [CI: $13.7 - 34.8$]. Skin hydration increased, and TEWL and pH levels ($p < 0.042$) were reduced with the intervention emollient compared to the control (Vaseline Advanced Repair Intensive Lotion) at both six weeks and three months. The daily use of both emollients significantly reduced skin pH ($p < 0.001$). EASI scores significantly improved ($p < 0.001$) in patients from baseline, regardless of the emollient used; however, there was no significant difference in EASI scores between the emollients.

Conclusion: Daily moisturizing improves skin pH and hydration in AD patients residing in the southwestern part of Nigeria, resulting in a reduction in disease severity. TEWL is reduced with daily moisturization. Individuals with AD are encouraged to moisturize at least daily, regardless of the weather conditions.

Keywords: Atopic Dermatitis; Emollient; pH, TEWL, Nigeria

Efficacité des émollients capable de restaurer l'eau transépidermique, le pH cutané et l'hydratation chez les patients africains atteints de dermatite atopique (EMTePHADerm) : essai contrôlé randomisé en double aveugle

Introduction: Les paramètres biophysiques cutanés des patients atteints de dermatite atopique (DA) montrent une diminution de l'hydratation, une élévation du pH cutané et une augmentation de la perte en eau transépidermique (PIE). Les émollients améliorant ces paramètres ne sont pas couramment testés sous les

climats africains. Notre objectif était de comparer les effets de deux émollissants utilisés en hydratation sur la gravité clinique de la DA, l'hydratation cutanée, le pH et la PIE au Nigéria.

Méthodes: Revue de cohorte prospective de patients atteints de DA dans deux hôpitaux tertiaires de Lagos, au Nigéria, de juin à décembre 2022, dans le cadre d'un essai randomisé en double aveugle portant sur deux émollissants après approbation éthique. Les scores EASI, l'hydratation, le pH cutané et la PIE ont été mesurés avant l'intervention et réévalués après six semaines et trois mois d'utilisation quotidienne de l'émollient d'intervention ou de l'émollient témoin. Les mesures cutanées ont été effectuées sur le menton et l'avant-bras à l'aide du système Courage + Khazaka Electronic GmbH®.

Résultats: Sur 140 participants, 62,9 % étaient des femmes; l'âge moyen était de $24,5 \pm 19,8$ ans. Les mesures initiales étaient plus élevées sur le menton que sur l'avant-bras, avec des valeurs moyennes d'hydratation de $56,7 \pm 18,5$; $40,0 \pm 20,7$, un pH de $6,5 \pm 2,1$; $5,5 \pm 0,4$ et une PIE de $32,4$ [IC: $24,5 - 52,2$]; $18,8$ [IC: $13,7 - 34,8$]. L'hydratation cutanée a augmenté, et les niveaux de PIE et de pH ($p < 0,042$) ont été réduits avec l'émollient d'intervention par rapport au témoin (Vaseline Advanced Repair Intensive Lotion) à six semaines et à trois mois. L'utilisation quotidienne des deux émollissants a significativement réduit le pH cutané ($p < 0,001$). Les scores EASI se sont significativement améliorés ($p < 0,001$) chez les patients par rapport à l'inclusion, quel que soit l'émollient utilisé; cependant, aucune différence significative n'a été observée entre les scores EASI des deux émollissants.

Conclusion: L'hydratation quotidienne améliore le pH et l'hydratation de la peau chez les patients atteints de dermatite atopique résidant dans le sud-ouest du Nigéria, ce qui entraîne une réduction de la gravité de la maladie. La PIE est réduite grâce à une hydratation quotidienne. Les personnes atteintes de dermatite atopique sont encouragées à hydrater leur peau au moins une fois par jour, quelles que soient les conditions météorologiques.

Mots-clés: Dermatite atopique, Émollient, pH, PIE, Nigéria

Introduction

The characteristic features of different skin types are influenced by both genetic and environmental factors, which impact dermatoses across all skin phototypes.¹ Atopic dermatitis is a prototype inflammatory skin disorder with familial tendencies and an inherited inability to retain skin hydration, among many other features.² Atopic dermatitis is one of the most common dermatoses seen in dermatology clinics in Nigeria^{1,3,4} and Sub-Saharan Africa.¹ A major complaint and clinical feature of AD patients is dryness of the skin, which is a physical manifestation of the functional mutation of the filaggrin gene (FLG) responsible for stratum corneum cohesion and skin barrier integrity.⁵⁻⁸ This disruption of the skin barrier's integrity results in increased trans-epidermal water loss, elevated skin surface pH, and disruption of the skin microbiome in individuals with atopic dermatitis (AD).^{2,5} These are responsible for the dry, scaly, itchy and sometimes weepy skin of AD patients with increased susceptibility to skin infections.^{2,9,10} Important differences regarding the filaggrin gene for AD in Africans and also Afro-American

populations have been observed, and some other mutations such as for Claudin-1 may be more important in these patients.¹¹⁻¹³

Studies of skin biophysical properties in AD patients report typical lower skin hydration, elevated skin pH and increased trans-epidermal water loss (TEWL).^{9,10} Emollients are thus a major part of the treatment of AD, as adequately moisturized skin helps reduce the itching sensation and scratching in patients.^{2,14} This is a key step in breaking the itch-scratch-itch cycle in AD patients, ultimately reducing disease severity.

Certain environmental influences are known to worsen the clinical presentation of atopic dermatitis.^{15,16} The ambient weather conditions affect patients with AD, typically due to increased TEWL and reduced skin hydration.^{15,17} Extreme and abrupt changes in the weather can worsen AD.^{15,17} In temperate climates, AD tends to worsen during winter and spring.^{18,19}

In the tropics, AD is worse during the dry season.¹⁵ AD patients also tend to sweat frequently in tropical climates and thus find it challenging to adhere to

frequent moisturizing, citing increased sweating as a side effect of emollient use. The humid weather causes increased sweating and oiliness, making the skin feel sticky and uncomfortable, even with the use of emollients.^{14,20} However, moisturizing remains a priority for maintaining skin barrier integrity and function, even in humid weather. In patients with AD, moisturizing the skin is crucial, but the choice of emollient is key to ensuring adherence to dermatologists' skincare recommendations. For tropical climates, a lightweight emollient with efficient components that maintain skin hydration without generating excessive sweating is preferred.²⁰

Topicrem® DA Baume, one of the emollients available for use in the management of AD, is a relatively new product in the Nigerian market. The manufacturers promote it as a fluid and non-oily emulsion with high moisturizing and lipid-replenishing properties, featuring active ingredients such as allantoin, flax oil, and shea butter, among others. Allantoin is a heterocyclic organic compound and a derivative of urea, which explains its strong moisturizing properties. Urea is hygroscopic; thus, it causes the retention of water in the stratum corneum.²¹ It has also been shown to stimulate healthy cell proliferation, epithelization, and wound healing.^{22,23} The Topicrem DA Baume has been tested and used successfully in other regions; however, it has yet to undergo clinical testing in Nigeria. To assess the efficacy of emollients, an objective tool is needed to measure the impact on disease severity. The Eczema Area Severity Index (EASI) is one of the few validated objective tools for measuring disease severity in atopic dermatitis (AD).²⁴ A few other scoring tools include the Scoring Atopic Dermatitis (SCORAD), Objective Scoring Atopic Dermatitis (SCORAD), Patient-Oriented Scoring for Atopic Dermatitis (PO-SCORAD), and Patient-Oriented Eczema Measure (POEM),²⁴⁻²⁶ which are often used in various studies. EASI was the preferred tool in this study because of its focus on visible lesions, which is considered better for monitoring responses to treatment in clinical trials. The Dermatology Life Quality Index (DLQI) was used to measure the subjective impact of the disease and treatment on quality of life.²⁷

The study aimed to compare the efficacy of Topicrem® DA Baume emollient in improving skin hydration, trans-epidermal water loss and skin surface pH with that of an established skin emollient, Vaseline Advanced Repair Intensive lotion, already in use in Nigeria.

Methods

This was a prospective, double-blind, randomized, non-inferiority clinical trial on 150 consecutive consenting AD patients who attended the dermatology outpatient clinics of the Lagos University Teaching Hospital (LUTH) and the Lagos State University Teaching Hospital (LASUTH). Both are tertiary hospitals in Lagos, Southwest Nigeria, the commercial centre of Nigeria and the most populous city in Africa.²⁸ The clinical trial was registered under the Pan African Clinical Trial Registry (www.pactr.org) with trial registration number PACTR202209711529835.

Topicrem® DA Baume and Vaseline Advanced Repair Intensive Lotion were used for the study. The lotions (400ml) were pre-filled into identical 500ml capacity containers with pumps. Then, numbers were generated systematically using the alphabet A-Z and numbers 1-50 manually. Three numbers were assigned randomly to bottles containing the sample (Topicrem DA Baume) and the control (Vaseline Repair) as a set for a patient's 3-visit treatment and documented. The creams were labelled correctly, arranged accordingly and stored for dispensing. This was done by an independent scientist who did not participate in the research.

The study participants consisted of newly diagnosed and established patients with AD attending Dermatology clinics at two tertiary hospitals. Seventy-five patients were recruited from each of the teaching hospitals. The study was conducted over six months, from June to December 2022, and each participant was followed up for an additional three months. Consultant dermatologists assessed all study participants, and the diagnosis of AD was made using the UK working group criteria, taking into account local differences in the African population, such as visual flexural eczema, which is a key feature.^{29,30}

The questionnaire was administered to participants, and the following data were captured: socio-demographics, relevant AD history, current emollients and AD clinical features. Atopic dermatitis disease severity was measured at each visit using the EASI® score. The EASI assessment tool, which targets four specific anatomic regions, multiplies the percentage of the affected areas on the head, trunk plus genitals, upper limbs and lower limbs plus buttocks and then adds this number to the severity scores of the four specific symptoms, which are erythema, redness, thickness, scratching and lichenification. Erythema was assessed by the presence of purplish hues, greyish or darker brown colour than the surrounding skin. The total EASI score ranges from 0 to 72 points, with the highest score indicating a more severe form of AD. Disease severity is subsequently graded from Clear (0), Almost Clear (0.1-1.0), Mild (1.1-7.0), Moderate (7.1-21.0), Severe (21.1-50.0), and Very Severe (50.1-72.0), depending on the total score obtained.

The Multi Probe Adapter (MPA CT Plus) Courage + Khazaka Electronic GmbH were the instruments used for the measurement of test parameters. The attached probes were the Corneometer CM 825, the Skin-pH-Meter PH 905, and the Tewameter TMHex, which were used to measure hydration status, pH, and TEWL, respectively. Examination and testing were conducted between 8:00 a.m. and 12:00 noon each day in an air-conditioned room maintained at an average temperature of 27 °C. Each participant was allowed to acclimatize to the room temperature for approximately 15 minutes. Afterward, the selected skin site was cleansed with a swab soaked in distilled water and left to air dry for 3 minutes before the skin assessment.

Three measurements were taken at week 0 using the corneometer and pH metre from a selected area on the chin and the volar aspect of the forearm near the elbow, and the mean values were recorded. One measurement of the highly sensitive Tewameter TMHex was taken from the same areas for trans-epidermal water loss, as per the manufacturer's instruction manual.

The participants were then given an anonymous emollient and instructed to apply it daily to their entire body, including the test areas, while following their regular dermatitis care plan as prescribed by their dermatologist. Skin hydration, trans-epidermal water loss and skin surface pH were measured again at weeks 6 and 12 at the exact locations.

Half of the patients were given the test emollient from Topicrem® DA Baume (Test group), while the other half received the established emollient, Vaseline Advanced Repair Intensive Lotion (Control group). An independent scientist, a pharmacist not involved in the research, blinded the emollients, which were packaged in identical, plain bottles with computer-generated serial numbers, as previously stated. Neither the investigators nor the participants were aware of the content of the packaged bottles given to them. The emollients were provided to the patients at no cost. The identity of the blinded bottles was revealed after analysis of the collated data.

Statistical analysis was performed using the IBM Statistical Package for the Social Sciences (SPSS), version 28. Mean and standard deviations were used as measures of central tendency, and the median and interquartile range (IQR) were used when the data were not normally distributed. Pairwise comparisons (or post-hoc analysis) were conducted when there was a statistically significant difference in the means of two or more groups. The ANOVA test was used to compare means, while the Kruskal-Wallis test was used to compare medians. When comparing two groups of means, the independent t-test was used. Bonferroni corrections were applied to minimize type I error from multiple comparisons.

Results

Patient characteristics

A total of 140 participants completed the study, comprising 62.9% (88) females and 37.1% males. Patients ranged in age from 1 to 95 years, with a mean age of 24.5 ± 19.8 years, as shown in Table I. The majority were unemployed and unmarried, and 37.9% were students. More details on employment categories are presented in Table 1.

Disease Severity

At baseline, 49.3% of participants had mild disease, with 30% and 7.1% presenting with moderate and severe disease, respectively, using the EASI score. The extremities were more affected than the trunk and the head. There was significant improvement with both emollients as the EASI score reduced by > 80% at the end of 3 months ($p < 0.001$)—Table II.

After six weeks and three months of the study, there was no statistically significant difference in disease severity between participants in the intervention and control arms. However, participants in the intervention arm had a higher number of clear and almost clear diseases and fewer participants with moderate disease. There were no participants with severe disease in either group at six weeks and three months.

Biophysical Parameters

Skin Hydration

At baseline, the mean hydration value in participants was 56.7 ± 18.5 on the chin compared to 46.0 ± 20.7 on the forearm. The hydration status decreased slightly to 56.4 ± 18.2 on the chin and 43.9 ± 18.3 on the forearm after three months of moisturizing, regardless of the emollient used. Figure 1. However, a pairwise comparison of the hydration status of participants in the two groups revealed improved hydration in the skin of participants in the intervention arm compared to the control group after six weeks, and this improvement persisted at the third-month review. The difference, however, was not statistically significant. (Tables III)

Skin pH

The mean pH of the skin of the chin was higher than that of the forearm at baseline (6.5 ± 2.1 and 5.5 ± 0.4 , respectively). The range of pH was 4.6–13.11 on the chin compared to 4.19–7.30 on the forearm. The pH level decreased significantly to 5.6 ± 0.5 on the chin ($p < 0.001$) but remained almost unchanged at 5.5 ± 0.3 on the forearm at the third month of skin moisturization, regardless of the product used. (Figure 2)

A pairwise comparison of skin pH between the intervention and control groups across time points revealed a significant reduction in skin pH on the chin over six weeks and three months, with values of 6.2 ± 1.7 and 5.6 ± 0.6 , respectively, using the test emollient. (Table IV)

Trans Epidermal Water Loss (TEWL)

At baseline, the median TEWL was 32.4 [24.5 – 52.2] on the chin and 18.8 [13.7 – 34.8] on the forearm. With the application of emollient, there was an increase in TEWL on both the chin and forearm, irrespective of the product used. However, a pairwise comparison of the test and control products across time points shows a lower TEWL in the intervention group compared with the control at six weeks and three months on the chin, and vice versa on the forearm, although this difference was not statistically significant. Figure 3 & Table III

Discussion

This study found that moisturizing the skin of patients with atopic dermatitis in a humid climate in Nigeria improved the biophysical parameters of skin hydration and pH and reduced clinical severity (as measured by EASI).

Patients with AD were seen across a wide age range, though most were young, with a mean age of 24.5 ± 19.8 years and a female preponderance. Atopic dermatitis typically starts in early childhood, and most people with AD have remission of symptoms by early adolescence, but some patients continue to be symptomatic throughout their lives.^{26,31} This explains the demographic characteristics of the study participants, who are predominantly young. There has been no clear gender prevalence of AD, but it appears females present more to the clinics,³² especially in skin-related diseases, and this may account for the higher frequency in this cohort.^{33,34}

Baseline measurements revealed that approximately half of the participants had mild disease (49.3%) based on the EASI score, while moderate disease was observed in 30% of patients. The EASI score has been criticized for its reduced sensitivity in detecting mild AD compared to moderate or severe disease when compared with other validated scoring tools.²⁵

This can be inferred from the high probability that patients in this study had used topical steroid creams before visiting the skin clinic [SO62], as there is a frequent practice of self-medication in society, which may result in a reduction in disease severity.³⁵ Triple-action tube creams containing potent steroids are easily purchased online and as over-the-counter (OTC) medications in Nigeria. However, in most climates, mild AD is more common than moderate to severe AD, and our study is no different.³⁶

The skin of the chin was better hydrated than the forearm at baseline, and this may have to do with the fact that the chin is less constrained and free of clothing. The chin also has more sebum due to the relatively higher frequency of sebaceous glands in that region,³⁷ which may help retain hydration on the skin. Studies have shown higher hydration in the head compared with the forearm.^{33,36} At six weeks of follow-up, the skin in the test group was better hydrated than in the control group, and this improvement was further evident at the three-month review, lending credence to the hydration claim of the test emollient. The study took place between June (near the peak of the rainy season, with higher humidity) and December (during the dry “harmattan” season, characterized by lower humidity).¹⁵ The harmattan winds are calm, dust-laden breeze from the Sahara which blows over West Africa from December to February. Studies show that the skin is less hydrated in more humid weather conditions, which may explain the overall reduction in skin hydration status during the study period. Skin hydration is a function of epidermal integrity and intact stratum corneum.

The mean pH of the skin of the chin was alkaline at baseline compared to that of the forearm. Several studies have shown that the skin on the chin has higher pH values than the skin on the forehead,²² while a few others have cited no differences. The chin is a sebum-rich area and is slightly covered by the lower lip and, thus, not as sun-exposed as the forehead or the forearm. In AD, the closer the pH is to the normal range of 4.5-5.2, the better it is for the skin microbiome and defensive activity, with reduced disease flares. Moisturizing with the Topicrem DA Baume test product significantly

reduced the pH of the skin of the chin compared to the control product and the skin of the forearm. This translated to a reduction in disease severity as well.

Transepidermal water loss (TEWL) refers to the effectiveness of the skin in providing a barrier against water loss from within. An increase in TEWL leads to dryness, and xerosis is a major feature of AD. At baseline, the median TEWL was higher on the chin than on the forearm. This may be because clothing can reduce TEWL on the forearm, which is often covered, unlike the face and chin, which are constantly exposed. There was a reduction in TEWL on the chin at six weeks from baseline, and a further reduction was observed at three months using Topicrem® DA Baume compared to control (Vaseline). This reduction, however, was not significant and was not observed in forearm measurements. Factors affecting TEWL levels include skin blood flow, skin temperature, the lipid content of the stratum corneum, and the degree of corneocyte formation.³⁸ Reduced transepidermal water loss is associated with improved skin barrier function, which emollients could influence. Again, the lack of change on the forearm could be due to clothing, which is protective against the ambient air and ultraviolet rays from the sun, both of which can influence TEWL. There were similar findings in a study by Seghers et al. in Singapore.²⁰

Limitations

The skin biophysical properties were measured in a room with a controlled ambient temperature of 27°C, which may not always accurately represent the actual situation of the participants. Higher temperatures are reached in Lagos, Nigeria, and measurements taken at different times of the day may give a more realistic picture. It is also worth noting that this study was conducted on an outpatient basis; therefore, patient care practices between visits may not be uniform.

Conclusion

The tropical climate of Lagos, Nigeria, may exacerbate trans-epidermal water loss in the skin of patients with atopic dermatitis; however, effective moisturization can reduce this loss, restore skin

hydration, and lower the skin's pH. This correlates with a reduction in the severity of the disease, thereby improving the quality of life for individuals suffering from this chronic condition. Patients are encouraged to apply the emollient at least once a day, although twice a day may further reduce TEWL in the country's humid prevailing weather. Emollients should, therefore, become widely available and affordable as basic care for AD, also in Sub-Saharan Africa, as recently postulated.³⁹

Competing interests

The authors declare no competing interest.

Authors' contributions

All authors made substantial contributions to the article

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Figure 2. Comparison of Average Skin pH Status in Participants on Topicrem vs. Vaseline

Figure 3. Comparison of Average TEWL in Participants on Topicrem (blue) vs. Vaseline(orange)

Table I: Sociodemographic characteristics of study participants

Variable	(n =140)
Age at last birthday, years	
Mean \pm SD	24.5 \pm 19.8
Range	1 – 95
Sex	
Female	88 (62.9)
Male	52 (37.1)
Ethnicity	
Yoruba	89 (63.6)
Igbo	25 (17.9)
Other*	26 (18.6)
Employment status	
Employed	42 (30.0)
Unemployed	98 (70.0)
Occupation	
Student	53 (37.9)
Unemployed	35 (25.0)
Technical services	12 (8.6)
Retired	10 (7.1)
Trader	6 (4.3)
Administrative services	5 (3.6)
Fashion and beauty	4 (2.9)
Educational services	4 (2.9)
Financial services	3 (2.1)
Health services	3 (2.1)
Information technology	3 (2.1)
Real estate	2 (1.4)
Marital status	
Single	102 (72.9)
Married	37 (26.4)
Widowed	1 (0.7)
Educational status	
No formal education	13 (9.3)
Primary	27 (19.3)
Secondary	44 (31.4)
Tertiary	56 (40.0)

Other: Hausa, Anang, Bini, Egbira, Egun, Engenni, Esan, Ibibio, Idoma, Igala, Ijaw, Ika, Ishan, Isoko, Ogba, Okrika, Okun, Ora, Urhobo*

Table II: Severity of Atopic Dermatitis in Study Participants (Comparison of Time Points)

Variable	Baseline (n = 140)	Six weeks (*n = 134)	Three months (*n = 118)	Test statistic	P-value
	Median (IQR) [Min, Max]	Median (IQR) [Min, Max]	Median (IQR) [Min, Max]		
Site					
Head and Neck	0.0 (0.0 – 0.6) [0.0 – 3.0]	0.0 (0.0 – 2.0) [0.0 – 1.5]	0.0 (0.0 – 0.0) [0.0 – 1.2]	14.724	< 0.001
Trunk	0.6 (0.0 – 2.7) [0.0 – 12.6]	0.0 (0.0 – 0.8) [0.0 – 8.4]	0.0 (0.0 – 0.3) [0.0 – 7.3]	24.544	< 0.001
Upper extremities	0.8 (0.2 – 2.4) [0.0 – 9.6]	0.4 (0.0 – 0.8) [0.0 – 9.0]	0.0 (0.0 – 6.0) [0.0 – 6.0]	42.997	< 0.001
Lower extremities	2.4 (0.4 – 5.9) [0.0 – 19.2]	0.0 (0.0 – 2.4) [0.0 – 8.4]	0.0 (0.0 – 1.6) [0.0 – 16.0]	45.445	< 0.001
Total score	4.8 (2.0 – 10.4) [0.0 – 43.5]	1.6 (0.6 – 4.7) [0.0 – 17.4]	0.8 (0.0 – 3.0) [0.0 – 29.9]	70.519	< 0.001
EASI score interpretation	n (%)	n (%)	n (%)		
Clear	4 (2.9)	19 (14.2)	33 (28.0)	110.190	< 0.001
Almost clear	15 (10.7)	31 (23.1)	34 (28.8)		
Mild disease	69 (49.3)	67 (50.0)	40 (33.9)		
Moderate disease	42 (30.0)	17 (12.7)	11 (9.3)		
Severe disease	10 (7.1)	0 (0.0)	0 (0.0)		

SD: Standard Deviation; Min: Minimum; Max: Maximum; Test Statistic: Kruskal-Wallis Test.

Difference in EASI score from baseline of > 66.7% and >80% at 6 weeks and 3 months, respectively.

Table III: Comparison of hydration status, skin pH and TEWL of participants in the Test vs control group (6 weeks and 3 months)

Variable		6 weeks				3 months			
		<i>Mean ± SD</i>		Test Statistic	p-value	<i>Mean ± SD</i>		Test Statistic	p-value
		Test group	Control group			Test group	Control group		
Skin Hydration Status	Chin average	54.8 ± 16.0	51.9 ± 15.7	1.032	0.304	59.5 ±20.9	53.9 ± 15.6	1.202	0.117
	Forearm average	43.4 ± 20.9	42.3 ± 17.7	0.309	0.758	47.9 ±18.4	40.7± 17.9	1.509	0.137
Skin pH	Chin average	6.2 ± 1.7	6.3 ± 1.7	0.448	0.655	5.6 ± 0.6	5.7 ± 0.5	0.557	0.578
	Forearm average	5.5 ± 0.4	5.5 ± 0.5	0.095	0.924	5.4 ± 0.3	5.5 ± 0.3	2.056	0.042
TEWL	Chin average	40.2 ± 18.5	41.7 ± 18.6	0.496	0.621	41.7 ±20.2	43.1 ± 23.1	0.343	0.732
	Forearm average	29.5 ± 20.3	29.1 ± 19.3	0.123	0.738	30.1 ±17.5	28.9 ± 18.6	0.336	0.738

Comment: There was improved hydration in the skin of test moisturizer users compared with control-moisturizer users after six weeks, and this continued at the 3-month review.

Table IV: Pairwise comparison of the skin pH of participants across time points.

Skin pH	Mean difference	Standard Error	P-value	Lower bound	Upper bound
Chin Average					
Baseline vs Week 6	0.31	0.19	0.249	-0.14	0.77
Week 6 vs 3 months	0.59	0.20	0.011	0.11	1.07
Baseline vs 3 months	0.90	0.20	< 0.001	0.42	1.37

Comment: Improved skin pH after 3 months of use.

Comment: The skin pH was significantly reduced on the forearm in users of Topicrem compared with those using Vaseline.

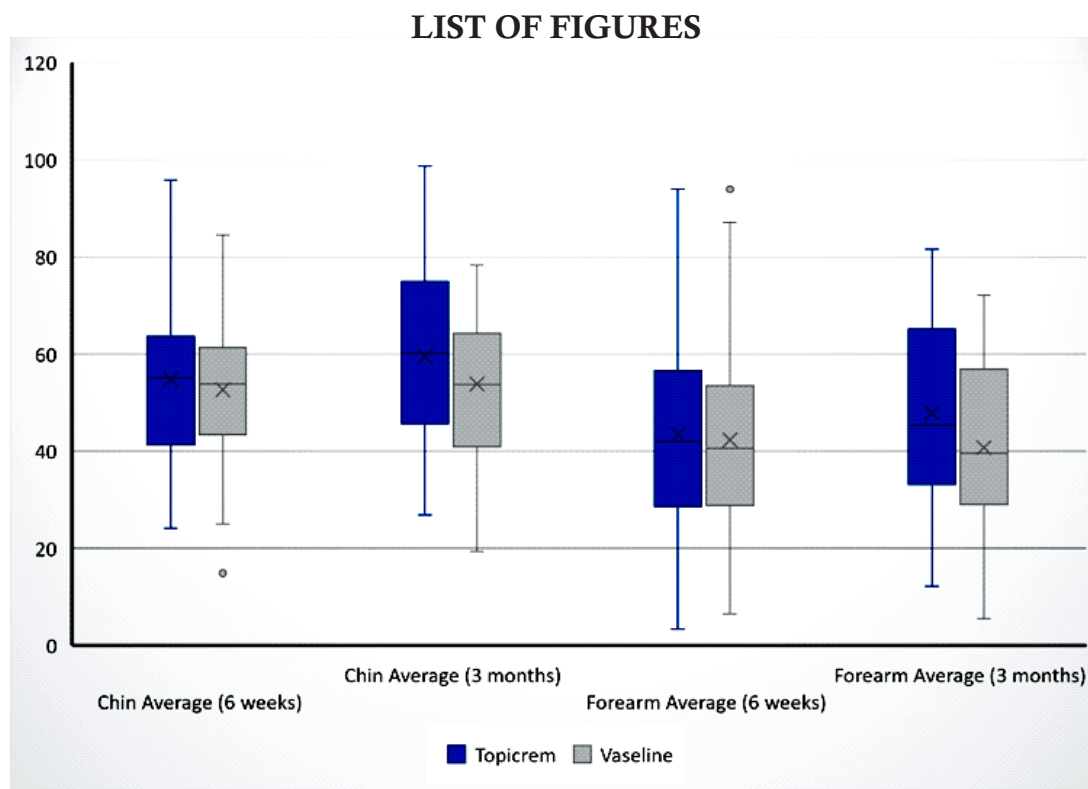


Figure 1: Comparison of Average Skin Hydration Status in Participants on Topicrem vs. Vaseline

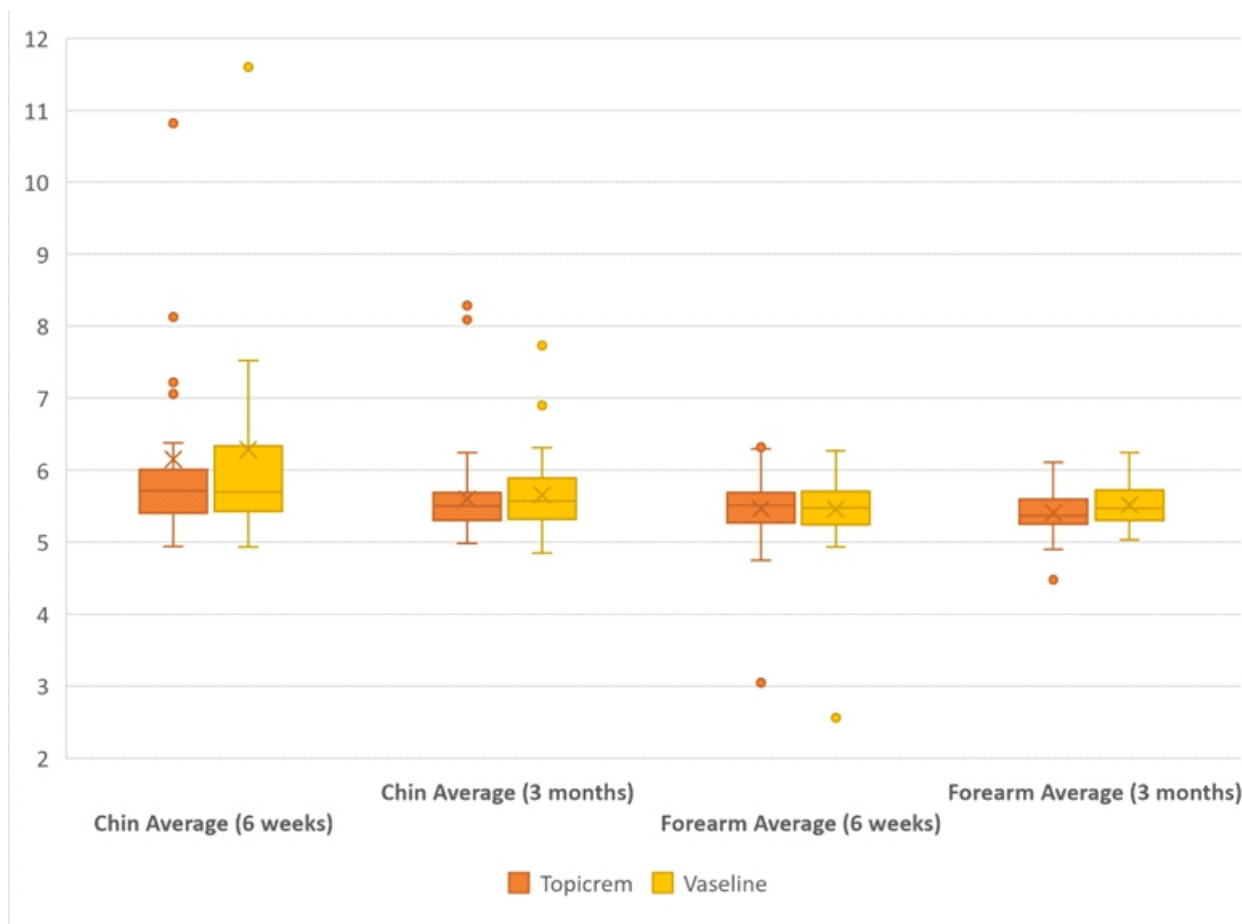


Figure 2: Comparison of Average Skin pH Status in Participants on Topicrem vs. Vaseline

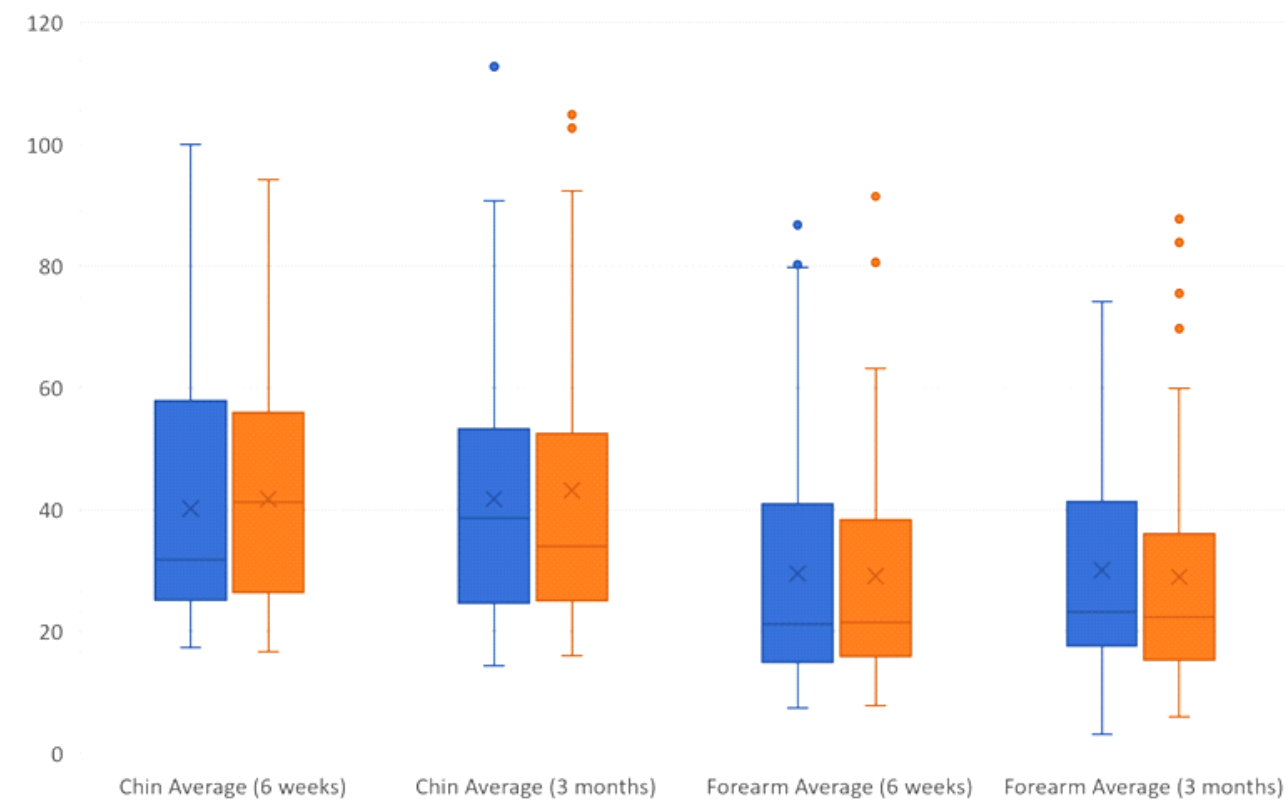


Figure 3. Comparison of Average TEWL in Participants on Topicrem (blue) vs. Vaseline(orange)