

Original Article

# A prospective, interventional, randomized, open-label, comparative, three-arm, parallel allocation, single-center clinical study to evaluate the effectiveness of Venusia CeraPlus cream and lotion as an adjuvant in the treatment of atopic dermatitis

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## ABSTRACT

**Objectives:** Atopic dermatitis (AD), often referred to as eczema, is a persistent inflammatory skin disorder that exhibits a remarkable prevalence worldwide. Adjuvant therapies, alongside prescribed treatment, have potential in effective management. The present clinical study aims to explore the safety and efficacy of two test formulations (cream and lotion) on the AD condition when used as an adjuvant alongside the prescribed treatment.

**Materials and Methods:** A prospective, interventional, randomized, open-label, comparative, three-arm, parallel allocation clinical study was conducted on 45 participants, diagnosed with AD based on the AD severity index (ADSI) score between 2 and 8 (mild-to-moderate eczema) with two independent lesions. They were equally distributed into three arms: Arm 1 – cream with standard of care (SoC), Arm 2 – lotion with SoC, and Arm 3 – SoC alone. They were randomized to receive either of the test products with SoC or SoC alone, for 28 days, and underwent dermatological, instrumental, and subjective assessments.

**Results:** The mean ADSI score in arm 1 was significantly reduced by 45.556% and 81.349%, and for arm 2 by 51.403% and 93.240% on day 14 and 28, respectively ( $P < 0.0001$ ). Arm 3 also exhibited a significant reduction of 32.355% and 63.946% ( $P < 0.0001$ ). After 24 h (Day 02), arms 1 and 2 demonstrated significant improvement in skin moisturization by 47.861% and 42.742%, whereas arm 3 exhibited 34.862% increase ( $P < 0.0001$ ); in contrast, the respective untreated control sites showed 0.121%, 0.848%, and 4.527% improvement in moisturization. Test sites of arms 1 and 2 showed greater improvement by 36.11% and 22.33% than arm 3. A reduction by 26.648%, 26.308%, and 21.371% for the skin barrier function for treated sites of arms 1, 2, and 3 was recorded on day 02, wherein 1.408%, 0.998%, and 1.451% change from baseline was examined in respective control sites. Clinically, the cream and lotion, when applied along with SoC, exhibited 22.39% and 23.04% greater results than the SoC alone. Both the test products were found effective in retaining/improving skin's moisture and in reducing the severity of eczema/AD, skin itchiness, and skin redness as assessed by subjective feedback.

**Conclusion:** The test products (cream and lotion), when used as an adjuvant, alongside the prescribed treatment, were found effective in reducing the severity of AD within 28 days, improved skin moisturization and skin barrier function within 24 h, and helped in reducing skin itching and redness, and were well tolerated.

**Keywords:** Atopic dermatitis, Ceramide, Eczema, Skin moisturization, Transepidermal water loss

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## INTRODUCTION

Atopic dermatitis (AD), commonly known as eczema, is a widespread and chronic inflammatory skin condition affecting millions worldwide, characterized by dry skin and intense itching due to a compromised skin barrier.<sup>[1]</sup> The disorder affects people of all ages and ethnicities. AD is ranked as the 15<sup>th</sup> most prevalent nonfatal disease and represents the highest burden among skin conditions, as indicated by disability-adjusted life-years (DALYs).<sup>[2]</sup> The global prevalence of AD is estimated to be 2.6%, affecting nearly 204.05 million people, which includes 101.27 million adults and 102.78 million children. The condition is more prevalent in females (2.8%) than in males (2.4%).<sup>[3]</sup> India significantly contributes to the global statistics, with an estimated prevalence between 3% and 5% across all age groups, translating to approximately 20–30 million cases. The prevalence is notably higher in urban areas, attributed to urbanization, lifestyle changes, pollution, western dietary influences, and improved access to diagnostics. Conversely, rural areas exhibit lower prevalence rates, which can be linked to traditional lifestyles, reduced exposure to environmental triggers, and underdiagnosis stemming from limited healthcare access and dependence on traditional remedies.

The condition is characterized by recurring eczematous lesions and intense pruritus. Severe scratching, red, dry, thickened, and cracked skin that reinforces the threat of skin infections might be experienced much more often. AD often affects specific areas of the body, with skin folds, the head, face, and neck, hands and wrists, and feet and ankles being commonly involved.<sup>[4]</sup> Recurrent eczematous lesions are characterized by severe pruritus. The condition is defined by indicative symptoms such as intense scratching, erythematous, dry, thickened, and fissured skin, which increases the risk of secondary infections. Acute lesions typically appear as ill-defined, red, scaly patches, often accompanied by swelling and blistering, while chronic lesions are usually distinguished by skin thickening and changes in pigmentation. It is associated with increased risk of multiple comorbidities, including food allergy, asthma, allergic rhinitis, and mental health disorders.<sup>[5]</sup>

The severity and distribution of AD can vary widely, from mild to severe manifestations. Mild eczema is identified by localized, occasionally dry, and slightly scaly patches. Moderate eczema is characterized by heightened erythema and edema, with little to no oozing or crusting. Conversely, severe eczema may involve the entire body, resulting in acute skin failure with extensive, red, oozing lesions that are susceptible to secondary infections. The primary symptom, intense itching, may significantly impact patients' daily activities, productivity, and sleep, leading to diminished quality of life.<sup>[6]</sup>

AD results from a multifaceted interaction of immune system dysregulation, genetic mutations in the epidermis, and environmental influences that compromise the integrity of the epidermal barrier.<sup>[7]</sup> While AD currently has no cure, treatments that manage inflammation and immune response can alleviate or eliminate symptoms. For mild-to-moderate AD, the primary treatment consists of topical anti-inflammatory agents such as corticosteroids in various strengths, along with alternatives such as calcineurin inhibitors, topical phosphodiesterase 4 inhibitors, and topical Janus kinase inhibitors.<sup>[8]</sup> Topical corticosteroids are the most effective and fastest way to soothe and manage skin inflammation in AD treatment. Topical adjuvant therapies serve a complementary role in the management of AD by improving the efficacy of conventional therapeutic treatments or by targeting specific pathophysiological mechanisms of the condition. These interventions contribute to the restoration of the skin barrier and modulation of the immune response that results in the overall improvement in disease management. These therapies are often advantageous in cases of mild-to-moderate AD and may reduce the reliance on systemic treatments and their associated risks. The use of moisturizers is recommended as the mainstay and should be continued in all lines of therapy as per the guidelines formulated by the Indian Dermatology Expert Board Members (DEBM).<sup>[9]</sup> Regular application of moisturizers and emollients is essential to maintain skin hydration, particularly after exposure to water. Moisturizers enriched with five essential ceramides – Ceramide 1, 2, 3, 4, and 6-II – are effective in improving skin barrier dysfunction (SBD) and managing conditions like AD. Incorporating oat extracts and hyaluronic acid into a ceramide moisturizer can enhance clinical outcomes in SBD-related disease.

Recent research has transformed AD treatment methodologies. The present clinical study was designed to explore the potential of the test formulations (cream and lotion) formulated with active ingredients, namely Ceramide I (EOP), II, III (NP), IV, VI (AP), *Avena sativa* (Oat), kernel oil, *Avena sativa* (Oat) bran extract, and sodium hyaluronate for the effective management of disease condition as an adjuvant along with the prescribed treatment.

## MATERIALS AND METHODS

### Study design and participants

This was a prospective, interventional, randomized, open-label, comparative, three-arm, parallel allocation, single-center clinical study to evaluate the effectiveness of test products (Venusia CeraPlus Cream and Venusia CeraPlus Lotion) as an adjuvant in the treatment of AD. A total of 45 participants (15 participants in each arm) were enrolled in this study. The treatment arms were equally randomized for

screening-passed participants. Each trial participant in arm 1 and arm 2 received one test product (Venusia CeraPlus Cream and Venusia CeraPlus Lotion, respectively) along with the prescribed treatment, i.e., standard of care (SoC), twice daily, whereas participants from Arm 3 applied only SoC twice daily during the study duration. The study duration was 28 days and consisted of 4 visits, which included one screening and enrolment visit (day 01), followed by three evaluation visits on day 02, day 14, and day 28 [Figure 1]. All eligible participants underwent dermatological and instrumental assessments. Subjective feedback was also obtained regarding the perception of the product and participants' satisfaction after product usage. Safety was assessed throughout the study by monitoring adverse events.

The sample size was based on the available literature and past study experience on a similar indication. Considering 20% drop out criteria, 45 participants (15 participants in each arm) were enrolled to get at least 36 completers

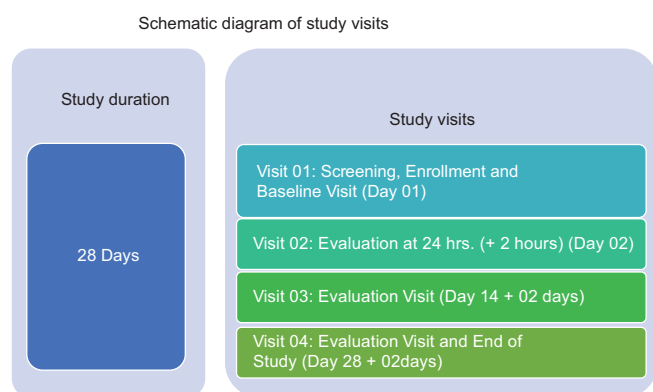
(12 in each arm) at the end of the study. The safety population included all randomized participants who received at least 1 application of test products. The intent-to-treat population included all randomized participants who received 1 or more applications of test products and returned at least one post-baseline efficacy visit data. Per protocol population included all randomized participants who had completed the study without any major protocol deviation. 43 participants completed the study, whereas participant R031 in arm 2 and R021 in arm 3 had voluntarily withdrawn their consent and were discontinued from the study [Table 1].

## Ethics

The clinical study was conducted in accordance with "The Code of Ethics of the World Medical Association" (Declaration of Helsinki), ICMR ethical guidelines, and ICH (Step 5) "Guidance on Good Clinical Practice." The Institutional Ethics Committee registered with the Central Drugs Standard Control Organization (CDSCO) had reviewed and approved the study protocol (Version 01) and study documents on August 23, 2024. The trial was prospectively registered with the Clinical Trial Registry of India on September 04, 2024, before study initiation. An informed consent form was explained to the volunteers, and was signed by the participants. The participant's identity was kept confidential, and the data were handled as per in-house standard operating procedures and applicable regulations.

## Inclusion criteria

The present study was conducted on male and non-pregnant, non-lactating females, aged between 18 and 55 years. The



**Figure 1:** Schematic diagram of study visits.

**Table 1:** Summary of participant disposition.

Disposition	ARM 1 (N=15) n (%)	ARM 2 (N=15) n (%)	ARM 3 (N=15) n (%)	Overall (N=45) n (%)
All screened participants	-	-	-	45 (100)
Screen failure participants	-	-	-	0 (0)
Participants' screening passed but not randomized	-	-	-	0 (0)
Number of participants randomized but not taken any treatment	-	-	-	0 (0)
All randomized participants	15 (100)	15 (100)	15 (100)	45 (100)
Participants completed the study	15 (100)	14 (93.33)	14 (93.33)	43 (95.56)
Safety population	15 (100)	15 (100)	15 (100)	45 (100)
ITT population	15 (100)	14 (93.33)	14 (93.33)	43 (95.56)
PP population	15 (100)	14 (93.33)	14 (93.33)	43 (95.56)
Participants discontinued the study	0 (0)	1 (6.67)	1 (6.67)	2 (4.44)
Reason for discontinuation:				
Withdrawal by participants	0 (0)	1 (6.67)	1 (6.67)	2 (4.44)

ITT: Intent to treat, N: Number of randomized participants in the specified treatment, n: Number of participants in specified category, PP: Per protocol.  
 Arm 1= Test product (Cream) as add-on to SoC (Clobetasone Butyrate IP [0.05% w/w] cream), Arm 2= Test product (Lotion) as add-on to SoC (Clobetasone Butyrate IP [0.05% w/w] cream), Arm 3= prescribed treatment (Clobetasone Butyrate IP [0.05% w/w] cream).

participants diagnosed with AD based on the AD severity index (ADSI) score between 2 and 8 (mild-to-moderate eczema), with two independent lesions, were included. Participants, with good health, devoid of any illness or condition that could interfere with study assessments or pose unacceptable risk, were the other key inclusion criteria. Participants needed to be willing and able to adhere to the study protocol, apply the test product as directed, and follow all provided study guidelines.

### Exclusion criteria

Participants with dry skin and chronic illness, psoriasis (psoriatic lesions), any clinically significant systemic disease, any cutaneous condition on the test site that could have interfered with the study, or known allergy to the active ingredient/raw material of the test product, were excluded. Participants who had used any investigational product in any form or participated in any clinical trial within 30 days before first application, or participants with any other condition that could have warranted exclusion from the study as per the investigator's discretion, were also excluded from the study.

### Test product(s)

The test products in the present study were Venusia CeraPlus Cream and Venusia CeraPlus Lotion (marketed by Dr. Reddy's Laboratories Ltd., India). Both the test products are formulated with the ingredients, namely ceramide I (EOP), II, III (NP), IV, VI (AP), *Avena sativa* (Oat), kernel oil, *Avena sativa* (Oat) bran extract, and sodium hyaluronate. The prescribed treatment, i.e., SoC, was topical steroid clobetasone butyrate IP (0.05% w/w) cream. Participants applied approximately 1–2 g (1–2 fingertip units) of SoC directly on each affected area of skin. The SoC was then spread uniformly in a circular motion and was allowed to get absorbed in the skin. Post this, approximately 1–2 g (1–2 fingertip units) of test product was applied directly to each affected area of participants in arm 1 and arm 2 as per randomization. The test product was spread uniformly in a circular motion and was allowed to be absorbed into the skin. Both SoC and test products were used twice daily (morning and evening). For a 24-h assessment, the test product was applied to all the lesions except one lesion, which was considered a control for assessment of hydration and transepidermal water loss (TEWL). Post 24-h assessments, the product and SoC were applied as instructed. The test product was applied once at the facility on visit 01 (day 01). Post 24-h assessment (i.e., on day 02), the SoC and test products were applied before leaving the facility, and at home, the 2<sup>nd</sup> application was done. From day 03 onward, the SoC and test products were applied twice daily by the participants themselves.

### Efficacy endpoint(s)

The primary endpoint was to assess the effect of test products on eczema by dermatologist assessment using ADSI.<sup>[10]</sup> Signs and symptoms, namely pruritus, erythema, excoriation, exudation, and lichenification, were scored in a four-point grading scale (being 0= none, 1= mild, 2= moderate, and 3= severe). A sum of the scores of all five signs represented the ADSI severity score (wherein, 0–<2= clear/almost clear, 2–<6= mild, 6–<9= moderate, and 9–<15= severe).

The secondary endpoints included assessment of skin moisturization using Corneometer<sup>®</sup> CM 825 (Courage-Khazaka Electronic, Köln, Germany), the skin barrier function by measuring TEWL using the TEWAmeter<sup>®</sup> TM 300 (Courage-Khazaka Electronic, Köln, Germany), participant satisfaction questionnaire after product usage, and product response index (participant perception about the product) on scheduled visits.

Safety was assessed throughout the study by recording the incidence of adverse events (AEs) or serious during the scheduled study visits by the investigator and self-reporting by the participants throughout the study conduction.

### Statistical analysis

Detailed analysis was presented in the statistical analysis plan, and a statistical analysis report was prepared. The statistical analysis was done using SAS<sup>®</sup> statistical software (Version: 9.4 or higher; SAS Institute Inc., USA). Demographic characteristics and results of the study were summarized with descriptive statistics (N, Mean, SD, Median, Minimum, and Maximum) for continuous variables and frequency and percentages for categorical variables. For ADSI, analysis was performed versus baseline (i.e., within group) and versus the comparator arm. For instrument analysis, analysis was performed versus baseline (i.e., within group) and versus the comparator arm. In addition, the test site was also compared with the control site. Safety endpoints were listed only. All statistical tests used a significance level of  $\alpha \leq 0.05$ . Two-tailed tests were performed for all analyses that used statistical testing.

## RESULTS

### Participant demography

In this study, a total of 45 participants were enrolled, of whom 29 were males and 16 were females. The age of enrolled participants ranged between 25 and 54 years, with an average of 44.1 years [Table 2].

**Table 2:** Summary of demographic characteristics – safety population.

Category/Statistics	ARM 1 (N=15)	ARM 2 (N=15)	ARM 3 (N=15)	Overall (N=45)
Age (Completed Years)				
<i>n</i>	15	15	15	45
Mean±SD	43.4±5.97	45.8±7.54	43.1±8.29	44.1±7.27
Median	43.0	49.0	44.0	45.0
Min, Max	33, 54	32, 54	25, 54	25, 54
Gender ( <i>n</i> [%])				
Male	11 (73.33)	9 (60.00)	9 (60.00)	29 (64.44)
Female	4 (26.67)	6 (40.00)	6 (40.00)	16 (35.56)
Predominant race ( <i>n</i> [%])				
Asian	15 (100)	15 (100)	15 (100)	45 (100)
Other	0 (0)	0 (0)	0 (0)	0 (0)

Max: Maximum, Min: Minimum, N: Number of participants in respective treatment group, n: Number of participants in specified category, SD: Standard deviation. Arm 1= Test product (Cream) as add-on to SoC (Clobetasone Butyrate IP [0.05% w/w] cream), Arm 2= Test product (Lotion) as add-on to SoC (Clobetasone Butyrate IP [0.05% w/w] cream), Arm 3= prescribed treatment (Clobetasone Butyrate IP [0.05% w/w] cream).

## Efficacy assessments

### Assessment of eczema by a dermatologist using ADSI

The mean ADSI score in arm 1 was 7.3 at baseline, which was decreased to 3.9 and 1.3 on day 14 and day 28, respectively, indicating a statistically significant reduction by 45.556% and 81.349% (all  $P < 0.0001$ ). In arm 2, the score was reduced from 7.4 to 3.6 on day 14 (51.403%) and 0.5 on day 28 (93.240%), showing a statistically significant reduction from baseline (all  $P < 0.0001$ ). For arm 3, the mean score recorded was 7.3 at baseline, while the score was decreased to 4.9 on day 14 and 2.6 on day 28, exhibiting statistically significant reduction by 32.355% and 63.946%, respectively (all  $P < 0.0001$ ). Between-group analysis for arm 1 versus arm 3 demonstrated a statistically significant difference at day 14 ( $P < 0.0003$ ) and day 28 ( $P < 0.0001$ ), where arm 1 was, respectively, 41.41% (1.4 times) and 27.79% (1.3 times) greater than arm 3 on day 14 and day 28 in terms of reduction in the severity of ADSI. For arm 2 versus arm 3, there was a statistically significant difference on day 14 and day 28 (all  $P < 0.0001$ ). Arm 2 was found to be 60.61% (1.6 times) and 47.69% (1.5 times) greater than arm 3 in terms of reduction in the severity of ADSI on day 14 and day 28, respectively [Table 3 and 4, Figures 2-4].

### Assessment of skin moisturization using Corneometer® CM 825

For the test site in arm 1, the mean score of skin moisturization was 30.628 at baseline, which was improved to 45.186 on day 02, indicating statistically significant improvement of 47.861% ( $P < 0.0001$ ). On the other hand, the control site exhibited only 0.121% improvement at Visit 2, i.e., evaluation after 24 h. on day 02. There was a statistically significant difference observed between the

Test site and Control site at day 02 ( $P < 0.0001$ ). Skin moisturization was found to be 299.14 times greater in the test site, as compared to the control site. For the test site in arm 2, the mean was observed to be 30.535 at baseline, which was increased to 43.619 on day 02, showing statistically significant improvement by 42.742% on day 02 ( $P < 0.0001$ ). The control site exhibited only 0.848% improvement. There was a statistically significant difference ( $P < 0.0001$ ) between the test and control sites, wherein the test site was found to be 50.18 times greater than the control site. For the test site of arm 3, the mean was recorded as 30.548 at baseline. The value was increased to 41.244 on day 02, demonstrating statistically significant improvement by 34.862% on day 02 ( $P < 0.0001$ ). The control site showed a reduction by 4.527% after 24 h. There was a statistically significant difference between test and control sites ( $P < 0.0001$ ). The test site was 7.21 times greater than the control site in terms of improvement in skin moisturization on day 02.

Data of between-group analysis (arm 1 vs. arm 3) reflected a statistically significant difference ( $P = 0.0084$ ), wherein arm 1 was 36.11% (1.36 times) greater than arm 3 in terms of improvement in skin moisturization on day 02. For arm 2 versus arm 3, on the other hand, reflected no statistically significant difference on day 2 ( $P = 0.0966$ ), though arm 2 was clinically 22.33% (1.22 times) greater than arm 3 [Table 5 and Figure 4].

### Assessment of skin barrier function by measuring TEWL using TEWA meter® TM300

For the test site of arm 1, the mean score of 13.37 was recorded at baseline. The mean value was decreased to 9.81 on day 02, indicating a statistically significant reduction by 26.648% for the skin barrier function ( $P < 0.0001$ ). For the control site, the reduction was 1.408%. However, there was a

**Table 3:** ADSI assessment by dermatologist.

Visit	Parameters	ARM 1 (N=15)	ARM 2 (N=14)	ARM 3 (N=14)
Visit 01	Mean±SD	7.3±0.59	7.4±0.63	7.3±0.61
Visit 03	Mean±SD	3.9±0.70	3.6±0.76	4.9±0.62
	Mean CFB ( <i>P</i> -value)	-3.3±0.90 (<0.0001)	-3.8±0.80 (<0.0001)	-2.4±0.50 (<0.0001)
	% Difference	-41.41 <sup>#</sup>	-60.61 <sup>§</sup>	-
	X time improvement	1.4 <sup>#</sup>	1.6 <sup>§</sup>	-
	% CFB	-45.556	-51.403	-32.355
	( <i>P</i> -value) between groups	0.0003 <sup>#</sup>	<0.0001 <sup>§</sup>	-
Visit 04	Mean±SD	1.3±0.49	0.5±0.52	2.6±0.63
	Mean CFB ( <i>P</i> -value)	-5.9±0.88 (<0.0001)	-6.9±0.77 (<0.0001)	-4.6±0.50 (<0.0001)
	% Difference	-27.79 <sup>#</sup>	-47.69 <sup>§</sup>	-
	X time improvement	1.3 <sup>#</sup>	1.5 <sup>§</sup>	-
	% CFB	-81.349	-93.240	-63.946
	( <i>P</i> -value) between groups	<0.0001 <sup>#</sup>	<.0001 <sup>§</sup>	-

Arm 1: Test product (Cream) as an add-on to SoC (Clobetasone Butyrate IP [0.05% w/w] cream). Arm 2: Test product (Lotion) as add-on to SoC (Clobetasone Butyrate IP [0.05% w/w] cream). Arm 3: prescribed treatment (Clobetasone Butyrate IP [0.05% w/w] cream). # Indicates % Difference and X time improvement for arm 1 versus arm 3, § Indicates % difference and X time improvement for arm 2 versus arm 3. Here *P* Value is for between group analysis, i.e. Arm 1 vs. Arm 3 and Arm 2 vs. Arm 3, hence for Arm 3, *p* value is NA. ADSI: Atopic dermatitis severity index, CFB: Change from baseline, ITT: Intent to treat, Max: Maximum, Min: Minimum, N: Number of participants in respective treatment group, n: Number of participants in specified category, SD: Standard deviation

**Table 4:** ADSI severity bands.

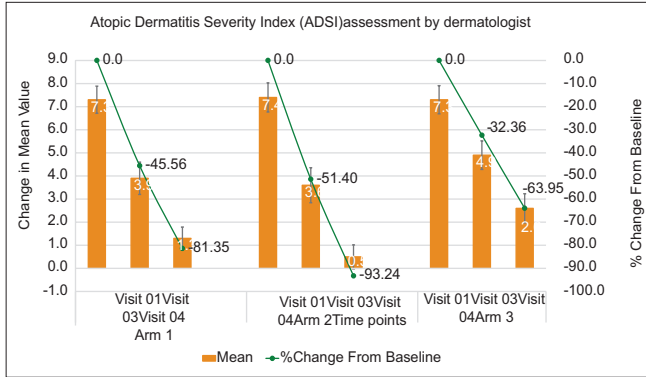
Visit	ADSI severity bands	ARM 1 (N=15) n (%)	ARM 2 (N=14) n (%)	ARM 3 (N=14) n (%)
Visit 01	Clear/almost clear (0-<2)	0 (00)	0 (00)	0 (00)
	Mild (2-<6)	0 (00)	0 (00)	0 (00)
	Moderate (6-<9)	15 (100)	14 (100)	14 (100)
	Severe (9-<15)	0 (00)	0 (00)	0 (00)
Visit 03	Clear/almost clear (0-<2)	0 (00)	0 (00)	0 (00)
	Mild (2-<6)	15 (100)	14 (100)	12 (85.71)
	Moderate (6-<9)	0 (00)	0 (00)	2 (14.29)
	Severe (9-<15)	0 (00)	0 (00)	0 (00)
Visit 04	Clear/almost clear (0-<2)	10 (66.67)	14 (100)	0 (00)
	Mild (2-<6)	5 (33.33)	0 (00)	14 (100)
	Moderate (6-<9)	0 (00)	0 (00)	0 (00)
	Severe (9-<15)	0 (00)	0 (00)	0 (00)

Arm 1: Test product (Cream) as add-on to SoC (Clobetasone Butyrate IP [0.05% w/w] cream). Arm 2: Test product (Lotion) as add-on to SoC (Clobetasone Butyrate IP [0.05% w/w] cream). Arm 3: Prescribed treatment (Clobetasone Butyrate IP [0.05% w/w] cream). ADSI: Atopic dermatitis severity index, N: Number of participants in respective treatment group, n: Number of participants in specified category, PP: Per-protocol

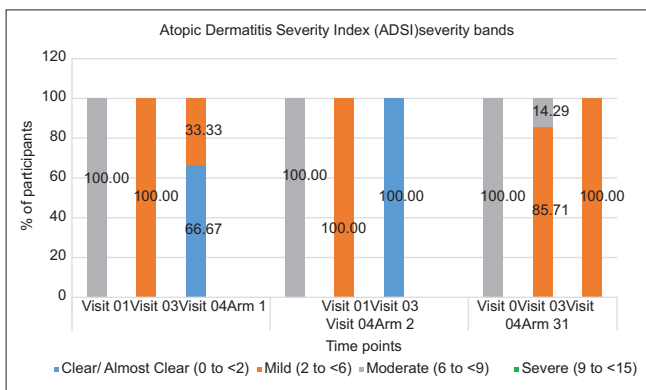
statistically significant difference between the test site and the control site, wherein the test site was found to be 18.45 times greater than the control site. For the test site of arm 2, the baseline value was 13.66, which was decreased to 10.07 on day 02. There was a statistically significant reduction by 26.308% ( $P < 0.0001$ ). In the control site, the reduction of 0.998% was recorded, which is negligible. For the test versus control site, there was a statistically significant difference. The test site was 26.42 times greater than the control site in terms of improvement in Skin Barrier Function on day 02. For the test

site of arm 3, the baseline score was 13.63, which was reduced to 10.71 on visit 02. There was a reduction by 21.371%, which is statistically significant ( $P < 0.0001$ ). In the control site, the reduction was 1.451% on day 02. However, the difference was statistically significant between both sites, where the test site was 14.57 times greater than the control site in terms of improvement in skin barrier function on day 02.

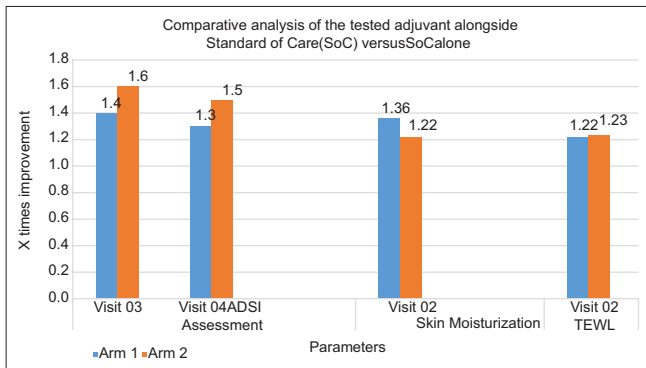
For arm 1 versus arm 3, there was no statistically significant difference ( $P = 0.1120$ ); however, clinically arm 1 is



**Figure 2:** ADSI assessment by dermatologist. ADSI: Atopic dermatitis severity index.



**Figure 3:** ADSI severity bands. ADSI: Atopic dermatitis severity index.



**Figure 4:** Comparative analysis of the tested adjuvant alongside SoC versus SoC alone. SoC: Standard of care.

22.39% (1.22 times) greater than arm 3. The difference was statistically not significant ( $P = 0.1365$ ) for arm 2 versus arm 3 as well. However, clinically arm 2 was 23.04% (1.23 times) greater than arm 3 in terms of improvement in skin barrier function [Table 6 and Figure 4].

### Assessment of participant satisfaction questionnaire

In every study visit, all the participants had a positive response (agree/strongly agree) on retention/improvement in skin's moisture by retaining/improving skin barrier function; reduction in the severity of eczema/AD; reduction in the itchiness of the skin; and reduction in skin redness. The agreement had shown a trend of response shifted from "agree" to "strongly agree" at the end of the study for all 3 study arms. None of the participants reported any feeling of hypersensitivity reactions, namely redness, swelling, dryness, burning, rash, or irritation throughout the study visits for all treatment groups. The results clinically indicate that Venusia CeraPlus Cream and Venusia CeraPlus Lotion are effective as an adjuvant, along with prescribed treatment, in retaining/improving skin's moisture and in reducing the severity of eczema/AD, skin itchiness, and skin redness. Both the test products, when used along with prescribed treatment, were well tolerated [Table 7, Figure 5a and b].

### Assessment of product response index (perception about product)

All study participants (100%) reported that the test products, namely cream and lotion, were easy to use/apply and absorbed quickly after application. Moreover, the products were found to be non-greasy and had an appealing fragrance [Figure 6].

### Safety assessments

The test products were purported to be safe as no local intolerance was observed in any of the study participants during the study conduction.

### DISCUSSION

The origins of AD are intricate and multifactorial.<sup>[5]</sup> AD leads to skin inflammation, an imbalance in the immune system characterized by a predominance of T-helper 2 cell responses, and a compromised epidermal barrier. The itching is driven by interactions among keratinocytes, the immune system, and non-histaminic nerve endings.<sup>[6]</sup> Modern research on AD pathogenesis indicates that it may involve a dysfunction of the epidermal barrier, immune response disruption, skin microorganism colonization, heightened infection risk, and various psychological factors, among other contributors.<sup>[11,12]</sup> A growing array of innovative and targeted therapies offers potential for effective disease management, particularly in patients with resistant conditions.<sup>[5]</sup>

Recent advancements in the treatment of AD have led to the development of personalized and targeted therapeutic

**Table 5:** Skin moisturization.

Visit	Parameter	Arm 1 (N=15)		Arm 2 (N=14)		Arm 3 (N=14)	
		Test	Control	Test	Control	Test	Control
Visit 01 (Day 1)	Mean±SD	30.628±2.2651	32.417±1.4271	30.535±2.1275	32.375±1.7361	30.548±2.3129	32.269±1.6801
Visit 02 (Day 2)	Mean±SD	45.186±3.0969	32.466±1.8957	43.619±5.0842	32.636±1.6183	41.244±5.7381	30.785±6.1005
	Mean CFB (P-value)	14.558±2.6224 (<0.0001)	0.049±0.9240	13.084±3.9327 (<0.0001)	0.261±0.7514	10.696±4.5126 (<0.000)	-1.484±5.9963
	% CFB	47.861	0.121	42.742	0.848	34.862	-4.527
	X times improvement	299.14**	-	50.18**	-	7.21**	-
	% Difference	36.11 <sup>#</sup>	-	22.33 <sup>\$</sup>	-	-	-
	Between-group analysis						
	P-value	0.0084 <sup>#</sup>	-	0.0966 <sup>\$</sup>	-	-	-
	X times improvement	1.36 <sup>#</sup>	-	1.22 <sup>\$</sup>	-	-	-

Arm 1: Test product (Cream) as add-on to SoC (Clobetasone Butyrate IP [0.05% w/w] cream). Arm 2: Test product (Lotion) as add-on to SoC (Clobetasone Butyrate IP [0.05% w/w] cream). Arm 3: Prescribed treatment (Clobetasone Butyrate IP [0.05% w/w] cream). The P value has been calculated using two sample t-test. \*\* Indicates X time improvement for Test site vs. Control site. # Indicates X time improvement for Arm 1 versus Arm 3, \$ indicates X time improvement for Arm 2 versus Arm 3. CFB: Change from baseline, ITT: Intent to treat, Max: Maximum, Min: Minimum, N: Number of participants in respective treatment group, n: Number of participants in specified category, SD: Standard deviation

**Table 6:** TEWL assessment using TEWAmeter<sup>®</sup> TM300.

Visit	Parameter	Arm 1 (N=15)		Arm 2 (N=14)		Arm 3 (N=14)	
		Test	Control	Test	Control	Test	Control
Visit 01 (Day 1)	Mean±SD	13.37±0.689	13.82±0.463	13.66±0.616	14.04±0.641	13.63±0.524	14.05±0.559
Visit 02 (Day 2)	Mean±SD	9.81±0.789	14.01±0.538	10.07±1.503	14.18±0.560	10.71±1.337	14.25±0.500
	Mean CFB (P-value)	-3.57±0.686 (<0.0001)	0.19±0.331	-3.59±1.373 (<0.0001)	0.14±0.174	-2.91±1.29 (<0.0001)	0.20±0.211
	% CFB	-26.648	1.408	-26.308	0.998	-21.371	1.451
	X times improvement	-18.45**	-	-26.42**	-	-14.57**	-
	% Difference	-22.39 <sup>#</sup>	-	-23.04 <sup>\$</sup>	-	-	-
	Between-group analysis						
	P-value	0.1120 <sup>#</sup>	-	0.1365 <sup>\$</sup>	-	-	-
	X times improvement	1.22 <sup>#</sup>	-	1.23 <sup>\$</sup>	-	-	-

Arm 1: Test product (Cream) as add-on to SoC (Clobetasone Butyrate IP [0.05% w/w] cream). Arm 2: Test product (Lotion) as add-on to SoC (Clobetasone Butyrate IP [0.05% w/w] cream). Arm 3: prescribed treatment (Clobetasone Butyrate IP [0.05% w/w] cream). The P value has been calculated using two sample t-test. \*\* Indicates X time improvement for test site versus control site. # indicates X time improvement for Arm 1 versus Arm 3. \$ indicates X time improvement for Arm 2 versus Arm 3. Here p Value is for Control vs. Test Arms, hence for Control, p value is NA. CFB: Change from baseline, ITT: Intent to treat, Max: Maximum, Min: Minimum, N: Number of participants in respective treatment group, n: Number of participants in specified category, SD: Standard deviation

approaches that address the intricate pathophysiology of the condition. For mild-to-moderate AD, topical therapies continue to be fundamental, focusing on diminishing inflammation, repairing the skin barrier, and relieving itching. Topical corticosteroids are considered the primary treatment for AD exacerbations,<sup>[12]</sup> though they are associated with various adverse effects, including skin atrophy, telangiectasia, striae, purpura, increased susceptibility to bruising, and ulceration. Additional potential side effects encompass

infections, acne-like eruptions, tachyphylaxis, excessive hair growth, changes in skin pigmentation, or allergic contact dermatitis.<sup>[13]</sup> Consistent use of moisturizers as adjunct therapy in AD has demonstrated substantial benefits in enhancing skin barrier integrity, alleviating symptoms, and improving overall patient well-being.<sup>[14]</sup> Clinical guidelines advocate for the use of moisturizers across all stages of the condition, highlighting their role in preventing flare-ups and reducing dependence on pharmacologic treatments.

**Table 7:** Participant satisfaction questionnaire.

Question	Response	Visit 02			Visit 03			Visit 04		
		Arm 1 (N=15) n (%)	Arm 2 (N=14) n (%)	Arm 3 (N=14) n (%)	Arm 1 (N=15) n (%)	Arm 2 (N=14) n (%)	Arm 3 (N=14) n (%)	Arm 1 (N=15) n (%)	Arm 2 (N=14) n (%)	Arm 3 (N=14) n (%)
Retention/improvement in skin's moisture	Agree	15 (100)	14 (100)	14 (100)	15 (100)	14 (100)	14 (100)	2 (13.33)	3 (21.43)	8 (57.14)
	Strongly agree	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	13 (86.67)	11 (78.57)	6 (42.86)
Feeling of any hypersensitivity reactions (redness, swelling, dryness, burning, rash, irritation)	Yes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	No	15 (100)	14 (100)	14 (100)	15 (100)	14 (100)	14 (100)	15 (100)	14 (100)	14 (100)
Reduction in the severity of eczema/atopic dermatitis	Agree	NA	NA	NA	15 (100)	14 (100)	14 (100)	2 (13.33)	4 (28.57)	8 (57.14)
	Strongly agree	NA	NA	NA	0 (0)	0 (0)	0 (0)	13 (86.67)	10 (71.43)	6 (42.86)
Reduction in the itchiness of the skin	Agree	NA	NA	NA	15 (100)	14 (100)	14 (100)	1 (6.67)	3 (21.43)	8 (57.14)
	Strongly agree	NA	NA	NA	0 (0)	0 (0)	0 (0)	14 (93.33)	11 (78.57)	6 (42.86)
Reduction in skin redness	Agree	NA	NA	NA	15 (100)	14 (100)	14 (100)	2 (13.33)	3 (21.43)	7 (50.00)
	Strongly agree	NA	NA	NA	0 (0)	0 (0)	0 (0)	13 (86.67)	11 (78.57)	7 (50.00)

Scale: 1: Strongly disagree, 2: Disagree, 3: Neither agree nor disagree, 4: Agree, 5: Strongly agree, NA: Not applicable. Arm 1= Test product (Cream) as add-on to SoC (Clobetasone Butyrate IP [0.05% w/w] cream), Arm 2= Test product (Lotion) as add-on to SoC (Clobetasone Butyrate IP [0.05% w/w] cream), Arm 3= prescribed treatment (Clobetasone Butyrate IP [0.05% w/w] cream).

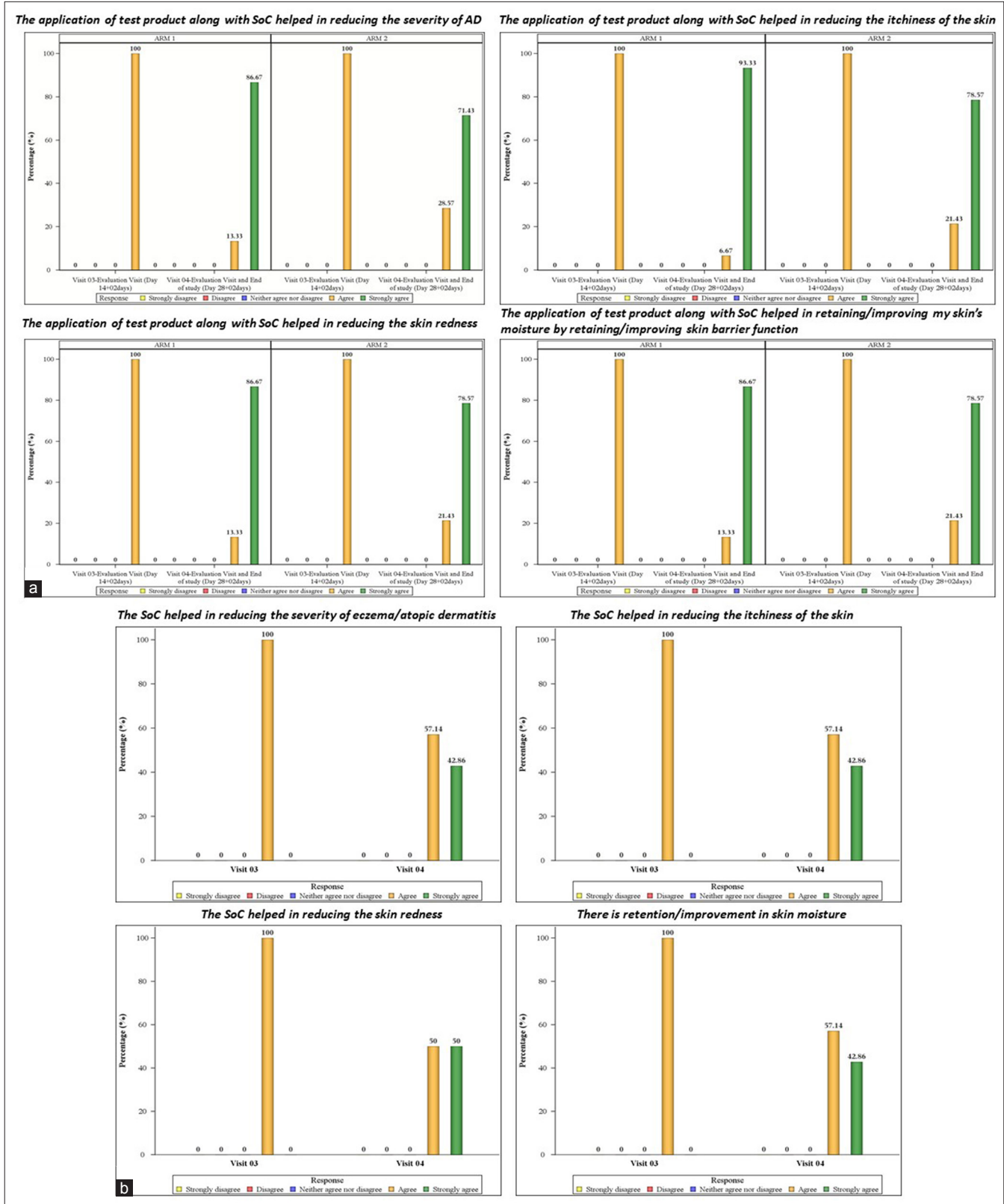
A randomized trial involving children aged  $\leq 15$  years demonstrated that consistent application led to symptom improvement (time to flare, risk of relapse, remission likelihood, physician-assessed disease severity, and quality of life), underscoring the importance of adherence over product selection.<sup>[15]</sup>

The ADSI serves as a measurement instrument for evaluating the severity of AD by examining the clinical manifestations of the disorder. This index employs a scoring framework that rates erythema, pruritus, exudation, excoriation, and lichenification on a scale ranging from 0 to 3, culminating in a total potential score of 15. The ADSI is instrumental in assessing the severity of AD and is frequently utilized to measure the efficacy of treatments. The data of the present study demonstrated that Venusia CeraPlus cream and Venusia CeraPlus lotion effectively changed the severity of AD from moderate at baseline to clear/almost clear at the end of the study, with a reduction of 81.349% and 93.240%, respectively, for cream and lotion. The results clinically indicate that both the test products are 1.3 times and 1.5 times more effective in reducing the severity of AD as an adjuvant when compared to standard treatment alone. In a double-blind, randomized clinical trial on mild-to-moderate AD patients, clinical severity was reduced by applying anti-inflammatory moisturizers by the second week, with a significant difference ( $P < 0.05$ ) of 24.50% compared with the

baseline.<sup>[16]</sup> In another double-blind, randomized, controlled clinical trial conducted on 60 participants with mild-to-moderate AD, the test product significantly ( $P \leq 0.05$ ) reduced the symptomatic clinical parameters at 12 weeks.<sup>[17]</sup> A randomized clinical trial involving 550 children with AD compared four types of emollients, i.e., lotion, cream, gel, and ointment, used twice daily over 16 weeks. The study found that all formulations led to symptom improvement, with no significant differences between them, highlighting the effectiveness of regular moisturizer use regardless of product type. These findings reinforce the role of moisturizers in better disease control and improved quality of life.<sup>[14]</sup>

Ceramide-based moisturizers provide numerous benefits for managing SBD. They offer prolonged action, effectively alleviate pruritus and erythema, reduce flare-ups, shorten recovery time, and minimize inflammation and steroid dependency. In addition, they restore barrier function, mimic natural moisturizing factors, maintain skin hydration, enhance quality of life, and lower the risk of complications.

Numerous studies have demonstrated significant long- and short-term benefits of moisturizers in reducing the need for steroids in cases of mild-to-moderate eczema.<sup>[18]</sup> Results of Corneometer exhibited 47.861% and 42.742% improvement in skin moisturization after 24 h of product application, respectively. The cream and lotion, when applied with SoC, demonstrated 1.36 times and 1.22 times greater results



**Figure 5:** Subjective assessment. (a) Response on the subjective questionnaire for test arms, (b) Response on the subjective questionnaire for Standard of Care (SoC) arm.

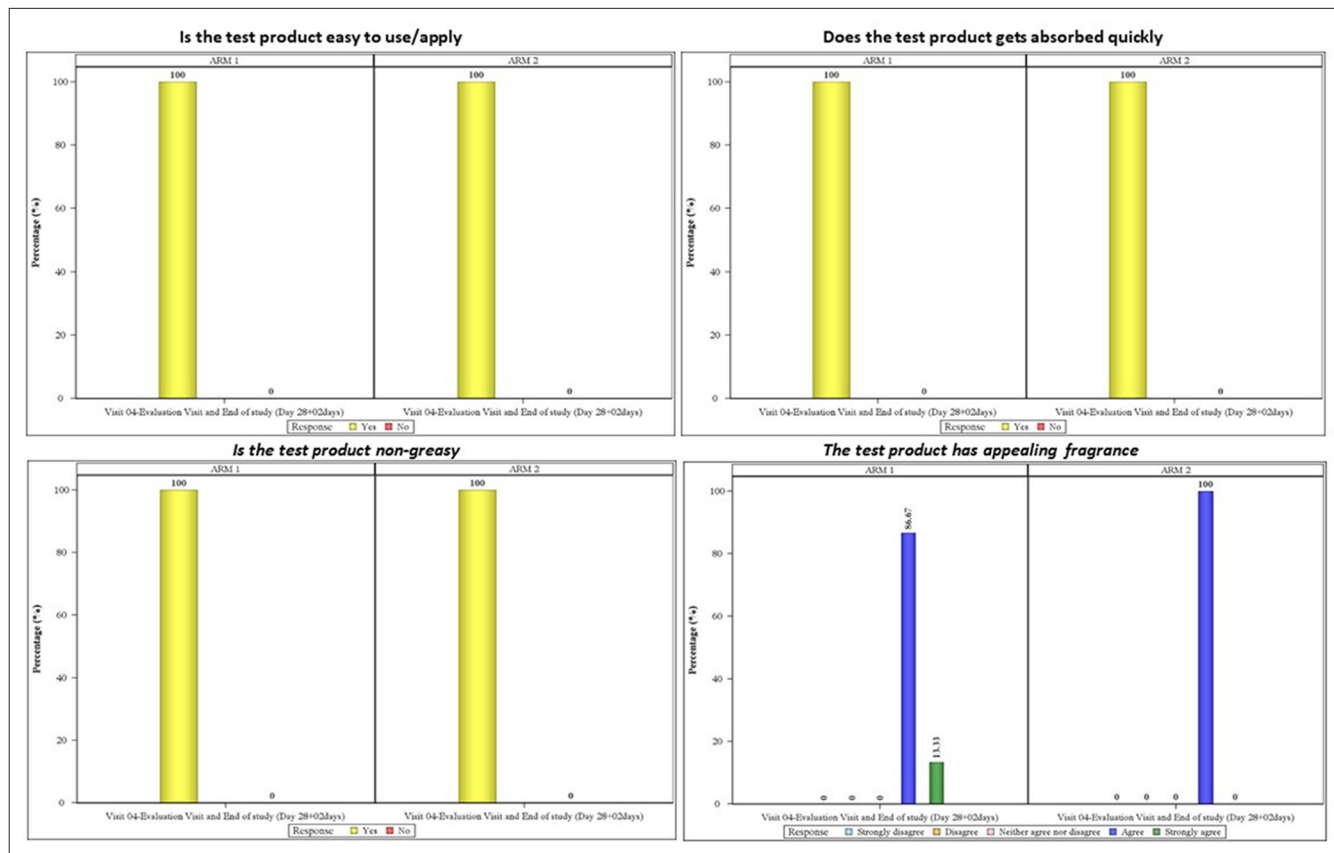


Figure 6: Product response index.

for improvement in surface skin hydration as compared to prescribed treatment only. In an open-label pilot study, an emollient formulation was tested for 14 days on eczema-prone individuals, wherein a significant increase ( $P < 0.01$ ) from  $36.45 \pm 10.51$  AU at baseline to  $42.55 \pm 12.70$  AU on day 14 was observed for skin hydration.<sup>[19]</sup> In a double-blind, randomized trial on 32 patients with mild-to-moderate AD, the test moisturizer containing occlusive, humectants, emollients, and anti-inflammatory ingredients was applied twice a day for 14 days. A significant increase ( $P < 0.05$ ) was observed between the baseline hydration and day 14 in the experiment group, wherein the skin hydration was increased from  $35.97 \pm 6.04$  AU to  $66.06 \pm 15.84$  AU.<sup>[16]</sup> In a similar clinical study, skin hydration was significantly increased from  $20.86 \pm 2.53$  AU to  $29.10 \pm 3.97$  AU on day 7 ( $P < 0.05$ ) in the moisturizer group without anti-inflammatory agents.<sup>[20]</sup> Ceramides constitute the primary lipid component of the lamellar structures found in the intercellular regions of the stratum corneum. Conditions such as AD can impair barrier function, resulting in a reduction of overall ceramide levels and alterations in ceramide composition. Moisturizers containing ceramides are crucial for supporting barrier integrity and preserving the skin's water permeability. The test products (cream and lotion) revealed a remarkable

moisturizing effect when applied as an adjuvant, along with the prescribed treatment.

The barrier defect in AD patients may partially result from reduced ceramide levels, which are sphingolipids found in the stratum corneum that contribute to the skin's barrier function and help prevent TEWL. Daily use of high-lipid emollients is essential for barrier restoration and flare prevention.<sup>[21]</sup> In the present study, the tested cream and lotion formulations were applied as an adjuvant, along with the prescribed treatment, in improving skin barrier function, wherein 26.648% and 26.308% reduction was recorded after 24 h of product application. The test formulations were found to be 1.22 times and 1.23 times more effective when compared to stand-alone SoC treatment for skin barrier repair function by measuring transepidermal water loss by TEWAmeter. The test products also effectively helped in reducing the itchiness and redness of the skin. In a double-blind, randomized, controlled clinical trial conducted on 60 participants with mild-to-moderate AD, significant ( $P \leq 0.05$ ) reduction for TEWL was recorded at week 4, 8, and 12 for test product, i.e., emollient "plus," though the comparator product, i.e., urea 10% also improved skin barrier by attracting water from the dermis or from the environment, thereby helped in preventing the moisture loss.<sup>[17]</sup> In another comparative

clinical study evaluating ceramide and aloe vera creams as barrier treatments for AD, TEWL values were measured at baseline and after 2 weeks of application. TEWL levels decreased progressively from baseline through weeks 0, 1, and 2 in both groups.<sup>[22]</sup>

In the present clinical study, the findings demonstrate that both test formulations, when used as an adjunct to the SoC, significantly enhanced skin hydration and reduced TEWL. These improvements are critical for restoring and maintaining the skin barrier in conditions such as eczema and AD. Furthermore, the test products were effective in alleviating erythema and soothing itchiness and irritation, indicating their potential role in reducing inflammatory symptoms. Given their barrier-repair and moisturizing properties, these formulations may also serve as suitable adjuncts in post-procedure care for patients with compromised skin integrity. By providing sustained moisturization, they are particularly appropriate for individuals undergoing dermatological treatments associated with skin dryness.

From a patient-centered perspective, the daily application of these moisturizers offers substantial real-world benefits for individuals with AD. Regular use helps maintain optimal skin hydration and reinforces the barrier function, thereby reducing the frequency and severity of flare-ups. This improvement in skin integrity alleviates common symptoms such as dryness, pruritus, and irritation, which often disrupt daily activities. By supporting barrier repair, these formulations may also decrease reliance on pharmacological interventions, providing a safer and more sustainable approach to long-term disease management.

### Limitations

The authors acknowledge a few limitations of the study. This clinical study was single-centric and required to be replicated in different biogeographic regions to further establish the efficacy of test formulations. The trial on a larger population and for a longer duration may be conducted to further establish the effect of test products.

### CONCLUSION

Venusia CeraPlus cream and Venusia CeraPlus lotion were found effective in reducing the severity of AD within 28 days when used as an adjuvant with the prescribed treatment. Both the test products were also found to be efficacious in improving skin moisturization and skin barrier function within 24 h. The test products effectively reduced skin itchiness and redness and were found to be effective in reducing symptoms of eczema severity. Both the test products were demonstrated to be safe based on no apparent or experienced discomfort or adverse events evidenced in the trial.

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**Ethical approval:** The research/study was approved by the Institutional Review Board at OM Institutional Ethics Committee, number DRL-IND-GGI-064-VEU/2024, dated August 23, 2024. CTRI/2024/09/073414.

**Declaration of patient consent:** The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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**Conflict of interest:** MG, SM, GD, AS, and BK are employees of Dr Reddy's Laboratories Ltd. The other authors declare no conflict of interest. The authors are also agreed with the content of this research article.

**Use of artificial intelligence (AI)-assisted technology for manuscript preparation:** The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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