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REVIEW

Improvement in Atopic Dermatitis Using a Novel Topical 2% Cannabidiol (CBD) Application

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ABSTRACT

Background: Atopic dermatitis (AD) is a prevalent chronic inflammatory skin condition characterized by Th2-type inflammation, significantly impacting patients' quality of life. Patients often experience dryness, severe itching, and skin lesions, necessitating interventions to manage discomfort and flare-ups. Common treatments, such as topical corticosteroids and calcineurin inhibitors, are effective but have adverse effects, making them unsuitable for long-term use. Consequently, there is an ongoing effort to find sustainable and safe alternative treatments. Recently, cannabidiol (CBD), a non-psychoactive compound derived from the *Cannabis sativa* plant, has gained attention in dermatology for its anti-inflammatory properties.

Methods: This pilot study utilized a 4-week open-label observational prospective cohort design to evaluate the effects of a 2% CBD cream-based topical application in patients ($n = 19$) with moderate-to-severe atopic dermatitis. Participants were given the topical CBD product to apply daily to affected areas and were examined at baseline, week 1, week 2, week 4, and week 8. Primary outcomes measured included the appearance of eczema lesions and patient satisfaction with the treatment.

Results: Participants reported improvements in skin hydration, comfort, inflammation relief, and overall skin appearance. Various objective evaluations and clinical photography were consistent with patient reported improvement.

Conclusions: These results support the potential of CBD as a sustainable and effective treatment option for mild to moderate atopic dermatitis.

1 | Introduction

Atopic dermatitis (AD) is a prevalent chronic inflammatory skin condition characterized by Th2-type inflammation, which significantly impacts patients' quality of life [1]. Patients often suffer from dryness, severe pruritus, and skin lesions, necessitating interventions to manage discomfort and flare-ups. Post-diagnosis treatment typically focuses on moisturizing the skin, controlling itching, and improving skin appearance [2]. Common treatments, such as topical corticosteroids and calcineurin inhibitors, are effective but have adverse effects, making them unsuitable for long-term use [3]. Consequently, there is an ongoing effort to find sustainable and safe alternative treatments.

Recently, cannabidiol (CBD), a non-psychoactive compound derived from the *Cannabis sativa* plant, has gained attention in dermatology for its anti-inflammatory properties [4]. Preliminary research suggests that CBD may help modulate Th2 immune responses when applied topically [5]. However, further

research is needed to determine its clinical efficacy and potential role in dermatological practice.

Our pilot study aims to evaluate the therapeutic benefits of a 2% CBD cream-based topical application in individuals diagnosed with mild to moderate atopic dermatitis. We hypothesize that CBD will effectively alleviate common symptoms of AD, thereby enhancing patients' overall quality of life. If our findings validate the efficacy of CBD for treating atopic dermatitis, it could pave the way for a sustainable long-term treatment regimen, offering patients an alternative to prescription steroids.

2 | Methods

This pilot study utilized a 4-week open-label observational prospective cohort design to evaluate the effects of a 2% CBD cream-based topical application in patients with moderate-to-severe atopic dermatitis. Participants were given the topical CBD product to apply daily to affected areas and were examined at baseline, immediately after application, week 1, week 2, week 4, and week 8 to assess patient satisfaction and long-term effects. Primary outcomes measured included the appearance of eczema lesions and patient satisfaction with the treatment. Visual assessments were performed using baseline and post-study photo measurements, utilizing the VIGA-AD validated scale to quantify improvements and document changes in lesion appearance. Patient satisfaction was measured using a scale-based questionnaire.

Applications were restricted to areas of concern, and treatment of all body areas was permitted. Patients were instructed to apply one pump per affected area, wash hands before applying, apply twice daily (morning and evening), and apply on clean skin, preferably after showering. The CBD cream was applied to lesions characterized by erythema, vesicles, excoriations, crusts, and papules. It was advised that no more than 25 lesions covering an area greater than 50 cm^2 in total be treated during the study. The maximum dose was 240 mL of cream in 30 days, while the minimum dose was 0.5 mL (one pump) in 30 days.

Informed consent was obtained from participants through a form provided by the supervising physician. Inclusion criteria included being over 18 years old, being diagnosed with moderate-to-severe eczema, not currently using steroids or biologics, not using other topical products, not being pregnant, and having no allergies to any ingredients in the cream. The study included 19 individuals of mixed genders and all Fitzpatrick skin types. Participants were closely monitored for any adverse effects throughout the study at each time point. Data collection began following REB approval by Advarra on October 24, 2022, under Pro00066042. The study protocol was reviewed and approved by the institutional review board, and all participants provided written informed consent before participation. Confidentiality and privacy were maintained, with data securely stored. Collected information included legal names, dates of birth, clinical histories of skin conditions, allergies, past and current medications, and weekly photos at each time point. Participants were informed of their right to withdraw from the study at any time without consequence. The clinical trial was registered on ClinicalTrials.gov under ID: NCT06022874.

The key points relating to skin hydration, skin comfort/relief from inflammation, itch/scratch-free duration, and texture of the product, such as greasiness, flare-up decline, and overall appearance, were investigated via patient questionnaires or quantifiable data. Data from the visual assessments and patient satisfaction questionnaires were analyzed using descriptive statistics such as a 7 point-Likert scale (1 – Never, 2 – Rarely, 3 – Occasionally, 4 – Sometimes, 5 – Frequently, 6 – Usually, and 7 – Every time), or Yes/Sometimes/Maybe/No responses. Neutral responses were split, with one-third attributed to the positive category and two-thirds to the negative category to better understand the inclination of respondents. Photographs that were of poor quality, missing at specific time points, or could not be assessed due to blurriness or incorrect orientation were excluded. The primary statistical method included paired *t*-tests to assess changes over time, with a *p*-value of < 0.05 considered statistically significant. Key measures included the slope and intercept of Viga-AD scores, standard deviations, *R*-squared value, *F*-statistic, and *t*-statistics for slope and intercept.

3 | Results

The study included 19 participants, of which 6 were males and 13 were females. The affected areas due to atopic dermatitis varied among the participants. The hands were the most commonly affected area, with 11 participants reporting involvement. This was followed by the arms, which were affected in 9 participants. Other areas included the legs in 6 participants, the neck and face each in 3 participants, the back in 2 participants, the armpits in 2 participants, the feet/ankles in 2 participants, and the scalp, full body, and torso each in 1 participant. Participants spanned across different age ranges, with 5 participants aged between 0 and 20 years, 6 participants aged between 21 and 30 years, 4 participants aged between 31 and 40 years, 2 participants aged between 41 and 50 years, and 2 participants aged between 51 and 60 years.

The duration of eczema among participants also varied. Eight participants had been experiencing eczema for 0–5 years, 4 participants for 6–10 years, 5 participants for 11–20 years, and 2 participants for 21–30 years. The average duration of eczema among the participants was approximately 9.68 years. Regarding past treatments, participants had tried various methods before joining the study. Prescription and non-prescription steroids were the most common, used by 12 participants. Natural moisturizers were used by 3 participants, prescription pills by 1 participant, and oils by 1 participant. In addition, lotions and creams were used by 7 participants, salt water by 1 participant, and red light therapy by 1 participant. Notably, 2 participants had not used any prior treatments (Table 1).

Approximately 67% of participants experienced an immediate increase in skin hydration at week 1. By weeks 2 and 4, this percentage increased to 78%, indicating a consistent improvement in skin hydration over the study period. Regarding a soothing or comforting feeling on the irritated skin, 74% of participants reported experiencing this sensation at week 1. This increased to 83% at week 2 and remained at 74% by week 4. When asked if they felt immediate relief from skin inflammation, 74% of participants agreed at week 1 and week 2, while

68% reported the same at week 4 (Figure 1). Participants were asked how long their skin felt itch-free. At week 1, approximately 63% reported being itch-free for more than 6 h, and 88% for more than 4 h. By week 2, 62% were itch-free for more than 6 h, and 93% were itch-free for more than 4 h. At week 4, 67% of participants were itch-free for more than 6 h, and 89% were itch-free for more than 4 h (Figure 2). The study evaluated the absorption and greasiness of the CBD cream. At week 1, 90% of participants reported that the cream was absorbed quickly without a greasy feeling. At week 2, 79% confirmed quick absorption, and at week 4, 84% continued to experience non-greasy absorption (Figure 3). Results regarding skin condition improvement were consistent across weeks 1, 2, and 4, with 74% of participants agreeing that their skin condition had improved (Figure 4).

Approximately 94% of participants preferred the natural alternative (CBD cream) over a prescription steroid. During the 8-week follow-up survey, approximately 74% of participants saw a decline in flare-ups. In addition, 100% of participants indicated they would use the product in the future, 95% stated they would recommend the product to a friend, and 94% preferred the CBD cream over a prescription steroid after trying the natural alternative (Figure 5).

During the study, some mild adverse effects were reported by a few subjects. They were not felt to be related to the studied product. In week 1, one subject reported experiencing anxiety and depression, while another described pruritis at the back of the neck. A 3rd subject reported a tingling sensation over the left arm. No adverse effects were observed during week 2. In week 4, further reports included dry and pruritic skin from one participant and a burning sensation/skin thickening from another. One individual reported breakthrough bleeding during day 5 of their menstrual cycle. Last, one participant experienced frequent panic attacks. These effects were carefully monitored by the physician overseeing the study and deemed unrelated to the study.

Viga-AD scores showed a significant decrease over the study period, with a slope of -0.1709 ($p < 0.0001$) and an intercept of 1.6316 ($p < 0.0001$). The R-squared value was 0.1931. The primary measure of effectiveness was the Viga-AD scores recorded at different time points, specifically at Week 0, Week 1, Week 2, and Week 4. The average Viga-AD scores showed a consistent decline throughout the study. At the beginning of the study (Week 0), the average Viga-AD score was 1.64. This score decreased to 1.37 by Week 1, slightly increased to 1.40 by Week 2, and further dropped to 0.91 by Week 4. Similarly, the median Viga-AD scores followed this trend, starting at 1.71 at Week 0 and decreasing to 1.00 by Week 4. The standard deviation of the scores ranged from 0.43 to 0.57, indicating consistent variability among the participants' responses. The minimum and maximum scores recorded during the study ranged from 0.00 to 3.00, highlighting the range of severity among the participants.

To determine the statistical significance of the changes in Viga-AD scores over time, paired t-tests were conducted between different time points. The mean difference in Viga-AD scores between Week 0 and Week 1 was 0.27, with a standard deviation of 0.56. The t-statistic for this comparison was 2.15, resulting in a p-value of 0.05, indicating statistical significance. Between Week 0 and Week 2, the mean difference was 0.24, with a standard deviation of 0.82. The t-statistic for this comparison was 1.27, with a p-value of 0.22, suggesting no statistical significance. The comparison between Week 0 and Week 4 showed a mean difference of 0.78, with a standard deviation of

TABLE 1 | Demographic and Clinical Characteristics of Patients with Atopic Dermatitis.

Category	Value
Sex	
Number of males	6
Number of females	13
Affected areas	
Hands	11
Feet	1
Legs	6
Arms	9
Neck	3
Face	3
Back	2
Scalp	1
Full body	1
Armpit	2
Torso	1
Feet/Ankles	2
Age range	
Age range (0–20)	5
Age range (21–30)	6
Age range (31–40)	4
Age range (41–50)	2
Age range (51–60)	2
Duration of Eczema	
Duration range (0–5 years)	8
Duration range (6–10 years)	4
Duration range (11–20 years)	5
Duration range (21–30 years)	2
Average duration (years)	9.68
Past treatments	
Prescription and non-prescription steroids	12
Natural moisturizers	3
Prescription pills	1
Oils	1
Lotion and creams	7
Salt water	1
Red light therapy	1
None (prior treatments)	2

Note: Data collected and reported for participants that met the inclusion criteria included sex, affected areas, age range, duration of eczema, and past treatments.

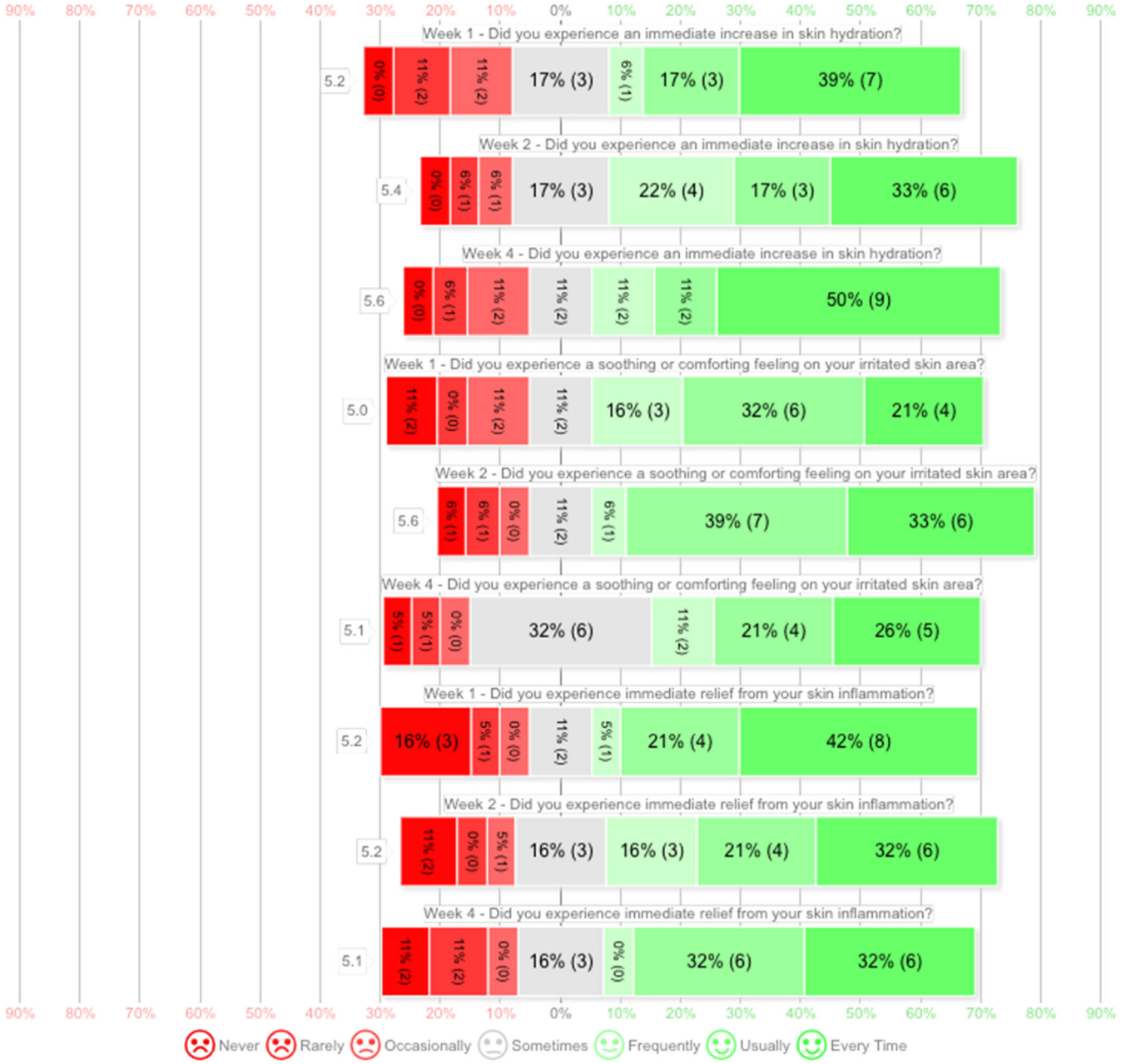


FIGURE 1 | Patient Responses to Skin Hydration, Comfort, and Inflammation Relief Over 4 Weeks. Patients were given a Likert scale to rate their responses based to certain questions such as: Did you experience an immediate increase in skin hydration?, Did you experience a soothing or comforting feeling on your irritated skin area?, and Did you experience immediate relief from your skin inflammation?.

0.54. The *t*-statistic for this comparison was 4.39, resulting in a highly significant *p*-value of 0.0004.

Further comparisons included Week 1 versus Week 2, with a mean difference of −0.04 and a standard deviation of 0.75. The *t*-statistic for this comparison was −0.29, with a *p*-value of 0.78, indicating no significant change. The comparison between Week 1 and Week 4 showed a mean difference of 0.51, with a standard deviation of 0.57. The *t*-statistic for this comparison was 3.79, with a *p*-value of 0.001, indicating a significant reduction. Finally, the comparison between Week 2 and Week 4 demonstrated a mean difference of 0.54, with a standard deviation of 0.47. The *t*-statistic for this comparison was 4.85, resulting in a highly significant *p*-value of 0.0002 (Figure 6).

The observed clinical response was consistent with all the Viga-AD scores (Figures 7–12).

4 | Discussion

The findings from this study suggest that a 2% CBD topical application may offer significant therapeutic benefits for individuals with moderate-to-severe atopic dermatitis (AD). Over the 8-week study period, participants reported improvements in several key areas, including skin hydration, comfort, inflammation relief, and overall skin appearance. These results align with the growing body of evidence supporting the potential anti-inflammatory and skin-soothing properties of cannabidiol

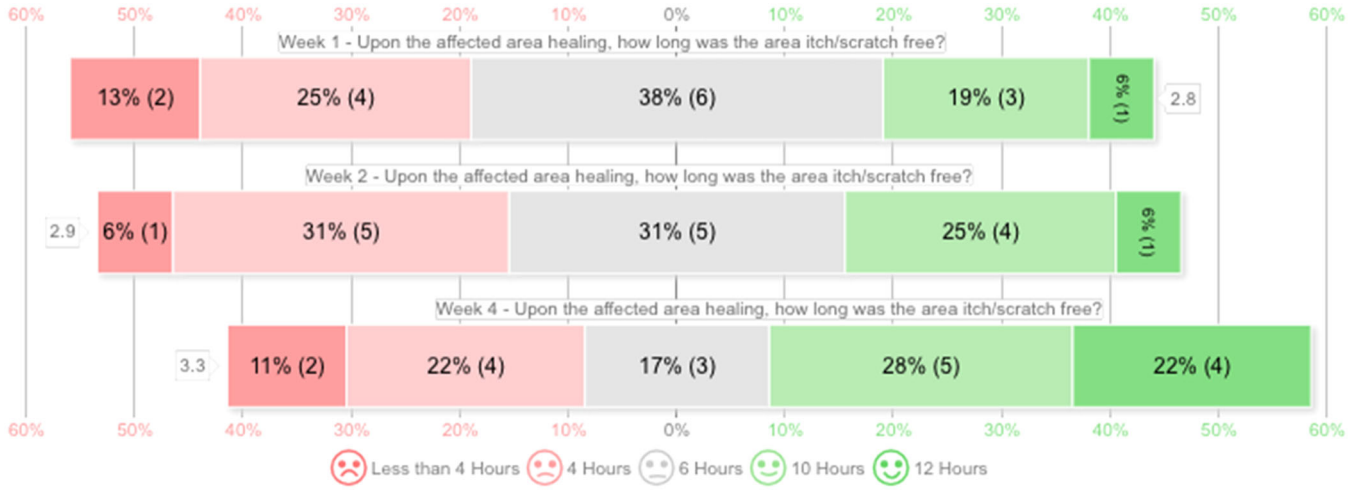


FIGURE 2 | Duration of Itch/Scratch-Free Periods After Healing Over Four Weeks. Patients were given a Likert scale to rate their responses based on itch/scratch-free time.

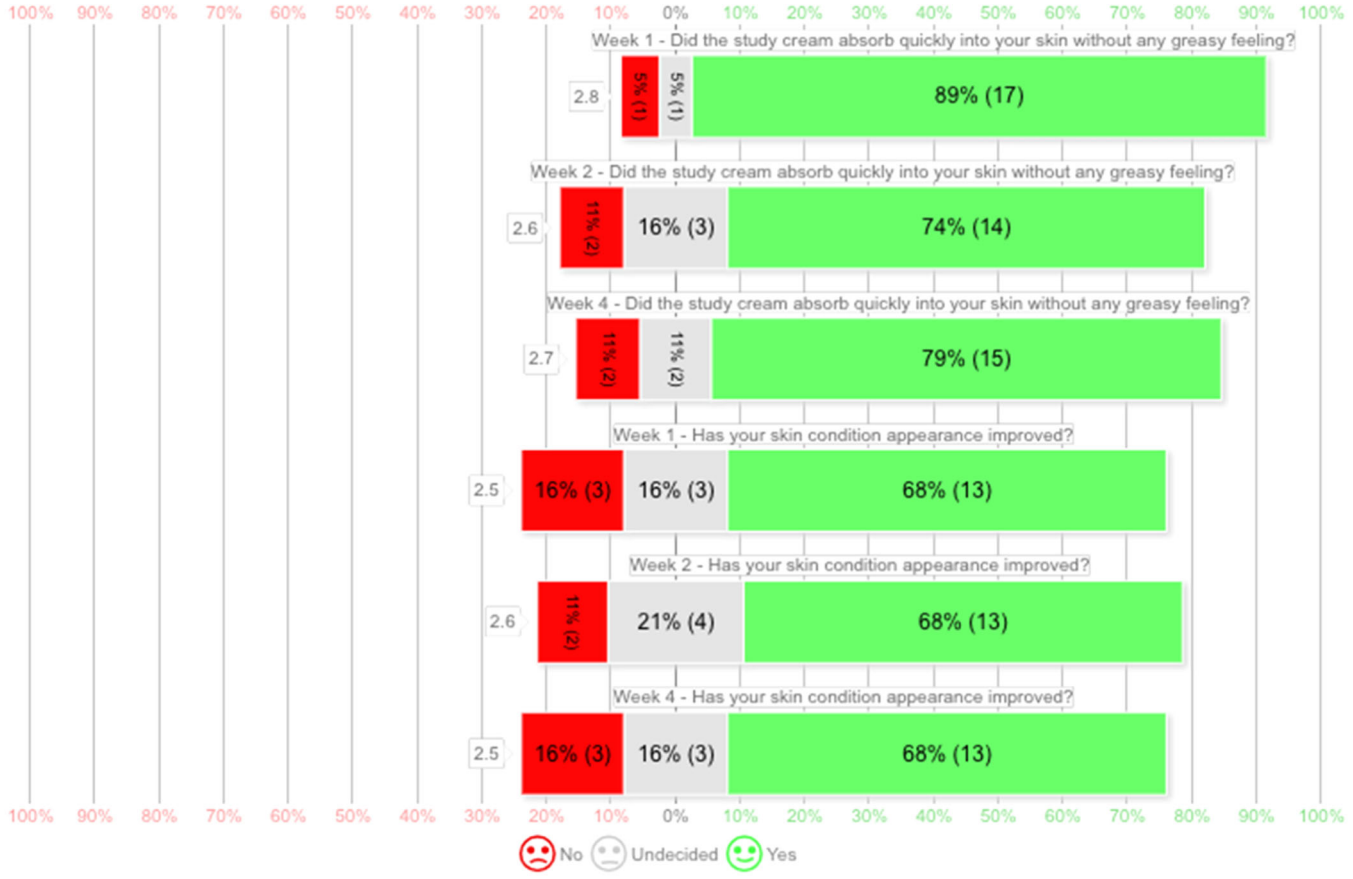


FIGURE 3 | Patient Responses to Skin Condition Improvement and Satisfaction Over Four Weeks. Patients were asked questions about the 2% CBD cream and its application to affected areas as well as if their appearance of the area had improved.

(CBD) in dermatological applications. Participants reported an average increase in skin hydration of 74%, with the highest percentage observed at week 2 and sustained through week 4. This improvement may be attributed to CBD's ability to enhance skin barrier function, thereby alleviating dryness and discomfort [4, 6]. Enhanced skin hydration is crucial for AD patients, as it helps in maintaining the skin's integrity and reduces the likelihood of flare-ups [7]. Inflammation relief and itch-free duration are critical outcomes for AD patients [8]. In this study, 72% of participants experienced immediate relief from inflammation, while 90% reported being itch-free for an average of 4 h. These results are consistent with previous studies that have indicated CBD can modulate immune responses and reduce the production of pro-inflammatory cytokines involved in the pathophysiology of atopic dermatitis [9, 10]. One common issue with topical therapies in

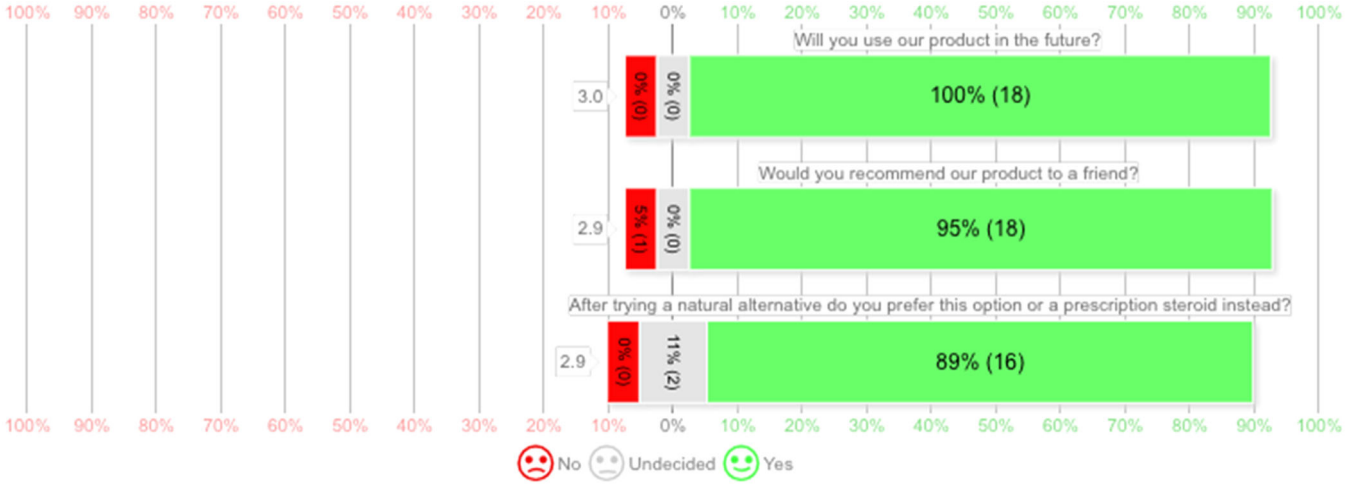


FIGURE 4 | Patient Responses Pertaining to Flare Up Frequency obtained at 8 week Follow Up Appointment. Patients were asked if the amount of flare-ups they experienced before using the 2% CBD cream had declined upon its use.

FIGURE 5 | Patient Feedback on Product Usage and Preferences. Patients were asked questions about the 2% CBD cream regarding its utility and future use for their atopic dermatitis when compared to a steroid product.

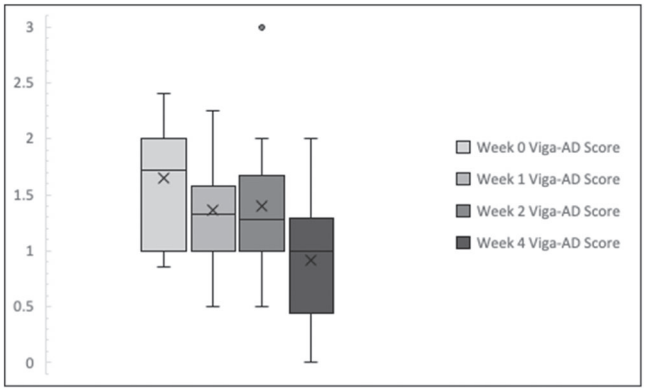
dermatology is patient convenience, particularly concerning greasiness and absorption rates [11]. In this study, 84% of participants reported that the CBD cream was absorbed quickly without leaving a greasy residue. This fast onset of absorption likely contributed to higher patient satisfaction and compliance, which are essential for the effectiveness of any topical treatment.

Consistent improvement in skin condition was noted throughout the study, with 74% of participants reporting a decline in flare-ups over the study period of 8 weeks. These results suggest that CBD may have a role in the long-term management of AD by reducing the frequency of flare-ups. The follow-up survey further underscored the positive impact experienced by patients, with 100% indicating they would use CBD in the future, 95% willing to recommend it to a friend, and 94% preferring it over prescription steroids. These levels of preference suggest that CBD could be a viable alternative to traditional pharmacotherapy, which often has adverse effects and can lead to steroid withdrawal [12, 13].

While the majority of participants in this study reported positive outcomes, including a preference for the CBD cream over prescription steroids and a reduction in flare-ups, some mild adverse effects were noted during the study period. These included symptoms such as anxiety, depression, itchiness, tingling sensations, stinging, dry and pruritic skin, a burning sensation, skin thickening, breakthrough bleeding, and frequent panic attacks. It is important to consider that these adverse effects may not be directly related to the topical CBD cream. The physician overseeing the study carefully monitored these symptoms throughout the trial and did not attribute them to the CBD treatment. Some of the reported effects, such as anxiety, depression, and panic attacks, are common psychological conditions and may have been influenced by factors unrelated to the treatment. In addition, some physical symptoms, such as pruritic and stinging, could be due to factors like irritation, existing wounds, or other external factors rather than the CBD cream itself. Overall, while these adverse effects warrant further investigation, the physician's assessment suggests that they were not directly linked to the application of CBD.

With respect to the statistical analysis of Viga-AD scores revealed a significant decrease over the study period, with a slope of -0.1709 ($p < 0.0001$) and an intercept of 1.6316 ($p < 0.0001$). The significant p-values for both the slope and intercept indicate a meaningful reduction in AD severity, supporting the effectiveness of the topical CBD treatment. However, the R-squared value of 0.1931 suggests that while there is a notable effect, other factors may also influence the outcomes observed.

Moreover, despite the promising results, this study has several limitations. The relatively small sample size and observational design may limit the generalizability of the findings. In addition, the absence of a control group makes it challenging to attribute the observed effects solely to the CBD treatment. The topical CBD formulation supplied by the study sponsor



	Week 0	Week 1	Week 2	Week 4
Average	1.64	1.37	1.40	0.91
Median	1.71	1.33	1.29	1.00
Standard deviation	0.52	0.43	0.56	0.57
Minimum	0.86	0.50	0.50	0.00
Maximum	2.40	2.25	3.00	2.00

	Week 0 - Week 1	Week 0 - Week 2	Week 0 - Week 4	Week 1 - Week 2	Week 1 - Week 4	Week 2 - Week 4
Mean	0.27	0.24	0.78	-0.04	0.51	0.54
Std Dev	0.56	0.82	0.75	0.54	0.57	0.47
t - statistic	2.15	1.27	4.39	-0.29	3.79	4.85
p - value	0.05	0.22	0.00040	0.78	0.001	0.0002

FIGURE 6 | Summary of Viga-AD Scoring over Four Weeks. Box plot of Viga-AD scores over study period. Descriptive statistics of measurements taken over four week period. Statistical analysis of the differences between time points over four week period.

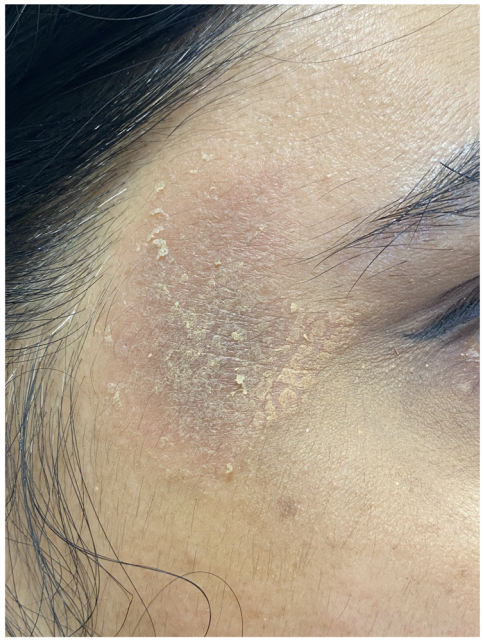


FIGURE 7 | Atopic dermatitis before application of 2% CBD cream.

FIGURE 8 | Improvement in atopic dermatitis after application of 2% CBD cream.

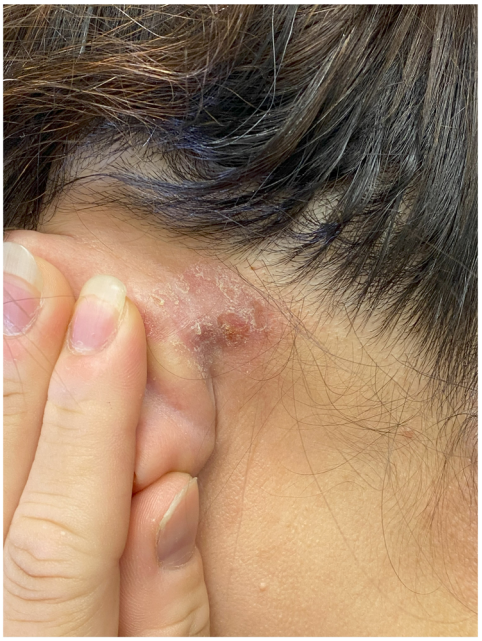


FIGURE 9 | Atopic dermatitis before application of 2% CBD cream.

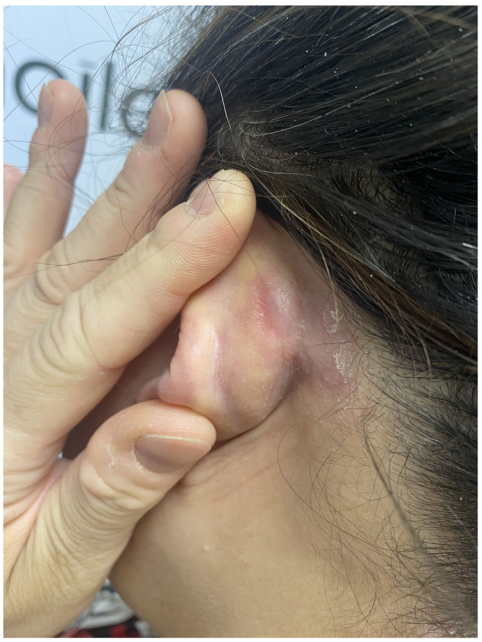


FIGURE 10 | Improvement in atopic dermatitis after application of 2% CBD cream.

contained other potentially beneficial ingredients, such as colloidal oatmeal and Vitamin D, which may have contributed to the observed improvements. Future studies with larger sample sizes, randomized controlled designs, and longer follow-up periods are essential to confirm these findings and establish more robust evidence for the therapeutic use of CBD in atopic dermatitis. Further research is warranted to determine if the observed data trends continue with expanded sample sizes. Longer study durations and the inclusion of a control group would enhance the reliability and validity of the conclusions, providing a clearer understanding of CBD's efficacy and role in the management of atopic dermatitis.

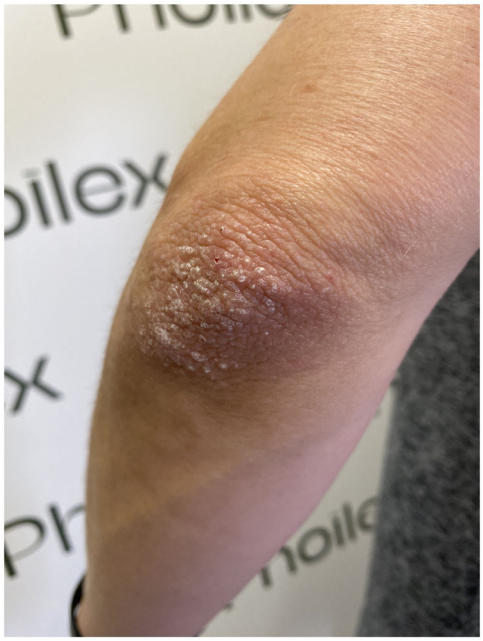


FIGURE 11 | Atopic dermatitis before application of 2% CBD cream.

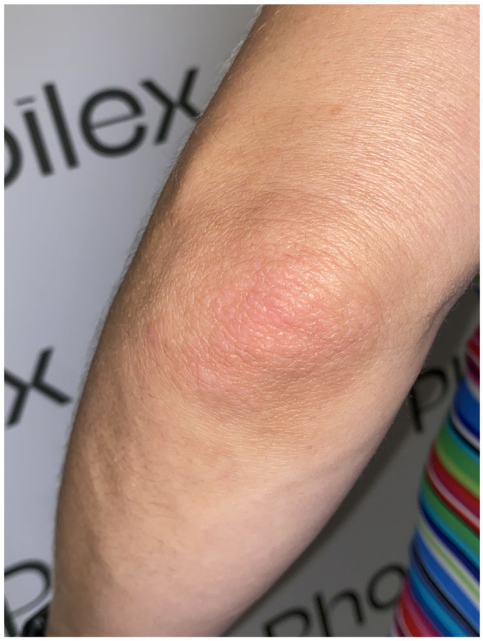


FIGURE 12 | Improvement in atopic dermatitis after application of 2% CBD cream.

5 | Conclusion

The application of 2% topical application has shown potential in alleviating common hallmark characteristics of mild to moderate atopic dermatitis by providing increased skin hydration, improved skin appearance, and reduced itching. There is merit to this line of query, and as such, future studies that further build upon this framework shall focus on other dermatologic conditions that align with atopic dermatitis similarities, such as psoriasis and rash prone skin.

Acknowledgments

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Conflicts of Interest

Financial support was provided to Sarah Hakim for her contributions to the study and responsibilities in overseeing the clinical trial by Phoilex Ltd. the study sponsor.

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