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RESEARCH ARTICLE

ASSESSING THE EFFECTIVENESS OF AN ECOBIOLOGICAL DERMO-COSMETIC PRODUCT IN MANAGING AND PREVENTING EYELID ATOPIC DERMATITIS RELAPSES

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Abstract

Introduction: Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by recurring flareups, intense itching, and skin barrier dysfunction. Eyelid AD presents unique challenges due to the delicate nature of the skin around the eyes, limiting the use of traditional treatments like corticosteroids. This study aimed to evaluate the efficacy of a dermo-cosmetic cream (Atoderm Intensive Eye) in alleviating symptoms and preventing relapses of AD on the eyelids.

Methods: A randomized, controlled, double-blind clinical trial was conducted with 120 participants, divided into groups for biometrological analysis, clinical evaluations, and self-assessment. The study assessed the product's effects on AD symptoms such as erythema, dryness, edema, and itching, using a 0–10 severity scale and measuring transepidermal water loss (TEWL) over 168 days. Participants were evaluated at multiple intervals, with half applying the product twice daily and the other half continuing with their usual skincare routine.

Results: Participants using Atoderm Intensive Eye showed a significant reduction in AD symptoms, including a 61% improvement in erythema and a 59% reduction in roughness (p < 0.001). TEWL measurements indicated improved skin barrier function by day 28 (p < 0.001). The product group also had significantly fewer AD relapses compared to the control group (0.8 vs. 3.4 relapses, p < 0.001). Quality of life improved, as reflected in lower Dermatological Life Quality Index (DLQI) scores after 28 days (p < 0.001).

Conclusion: The dermo-cosmetic product effectively alleviated AD symptoms and reduced the frequency of relapses, offering a non-steroidal alternative for managing eyelid AD. Its role in improving skin hydration

and barrier function highlights its potential for long-term use in AD management.

Keywords: Atopic Dermatitis, Eyelid Dermatitis, Dermo-Cosmetic, Skin Barrier, Transepidermal Water Loss, AD Relapse Prevention

BACKGROUND/INTRODUCTION

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disease affecting millions worldwide, with a prevalence of approximately 20% in children and 2-7% in adults. It is characterized by intense itching, redness, and disruption of skin integrity, leading to significant impacts on the quality of life due to sleep disturbances, pain, and social challenges. AD on sensitive areas like the eyelids can be particularly challenging to manage, given the thinner skin and proximity to the eyes, which can complicate the use of traditional treatments like corticosteroids [1].

Topical emollients and corticosteroids remain the cornerstone of mild AD treatment. However, for moderate to severe cases, especially in delicate areas like the eyelids, there is a growing interest in using dermo-cosmetic products that offer anti-inflammatory, protective, and skin-barrier-restoring properties. One such product, Atoderm Intensive Eye (NAOS, LABORATOIRE BIODERMA), has been clinically evaluated for its efficacy in reducing symptoms and preventing AD relapses. This oil-in-

water emulsion, containing ingredients like enoxolone, Lipigenium lipid complex, and high-molecular-weight hyaluronic acid, is designed to restore skin barrier function, soothe inflammation, and hydrate the skin [2].

Recent advancements in understanding pathophysiology emphasize the role of Th2 cytokines like IL-4 and IL-13 in driving the disease. Innovations in biologic therapies, such as lebrikizumab, target pathways and have shown significant these improvement in clinical trials for moderate-to-severe AD. However, these systemic treatments are not always suitable for sensitive areas like the eyelids, making dermo-cosmetic solutions an attractive option for managing localized AD without the side effects associated with long-term steroid use [3].

This study aimed to evaluate the efficacy of a dermocosmetic cream (Atoderm Intensive Eye) in alleviating symptoms and preventing relapses of AD on the eyelids.

MATERIALS AND METHODS

Study Design

This study employed a randomized, controlled, double-blind design to evaluate the efficacy of a

commercially available dermo-cosmetic cream (Atoderm Intensive eye, NAOS, LABORATOIRE BIODERMA) in managing and preventing relapses of eyelid atopic dermatitis (AD). The study was divided

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into two phases: one evaluating the clinical efficacy of the product in managing AD symptoms and the second assessing its ability to prevent AD relapses.

Study Setting

The study was conducted in a dermatology clinic Shankar Skin Clinic over a 168-day period.

Participants

A total of 120 participants were included in the study. Participants attended scheduled visits for assessments, and data were collected via both objective biometrological measurements and self-reported questionnaires.

Participants were divided across three groups for different assessments:

- Group 1: Biometrological Analyses of the Soothing Effect: 30 women, aged 18 to 60 years.
- Group 2: Protective/Anti-Redness Effect: 40
 participants (20 men and 20 women), aged 20
 to 66 years.
- Group 3: Transepidermal Water Loss (TEWL)
 Measurements: 30 women, aged 23 to 69 years,
 with a mean age of 48 years.
- Clinical Evaluation of AD Symptoms and Prevention of Relapses: 20 participants, randomly divided into two subgroups (10 participants each). One group used the dermocosmetic product, while the other continued their usual skincare routine.

- Adults aged 18–69 years.
- For biometrological analyses: Participants with no history of AD, no cutaneous problems, and no excessive hair on the inner forearms.
- For clinical evaluations: Participants with mild to moderate AD symptoms on the eyelids or a history of at least three AD relapses within the previous six months.
- Participants undergoing corticoid treatment for at least 9 days for the first clinical evaluation.

Exclusion Criteria

- Presence of cutaneous or ophthalmological pathology other than AD on the eyelids.
- Use of systemic treatments that could interfere with the study.
- Pregnant, nursing women, or women planning to become pregnant during the study.
- Any history of allergies to the product's ingredients.

Bias

Randomization was employed to assign participants to either the product application group or the control group (usual care). To reduce selection bias, a double-blind design was used where both participants and clinicians were unaware of which group received the product. Additionally, the use of standardized application procedures helped control for variability in product use.

Inclusion Criteria

Variables

Variables included application of the Atoderm Intensive eye cream, Ssverity of AD symptoms (dryness, erythema, edema, desquamation, roughness), skin barrier function (TEWL), redness, microcirculation, self-reported discomfort (itching, burning, stinging), and relapse frequency, use of a neutral cream or no cream on the comparison site (depending on the evaluation).

Data Collection

Biometrological data were collected through the following instruments:

- Cutaneous microcirculation was measured using TiVi600.
- Redness was assessed via a patch test using the CM700-d spectrophotometer to measure skin L* and a* parameters.
- TEWL was measured with a Tewameter TM300.

For clinical evaluations, a dermatologist scored AD severity (on a scale of 0 to 10) on days 0 and 28 for symptom management and on days 0, 56, 112, and 168 for relapse prevention. Subjects also completed the Dermatological Life Quality Index (DLQI) and self-assessments of skin discomfort.

Procedure

 Biometrological Analyses: Participants underwent a standardized procedure for each evaluation. For soothing effects, erythema was induced by stripping the skin, and the product was applied to one forearm while the other was left untreated. For redness evaluation, patch tests were conducted with sodium lauryl sulfate and the product or a neutral cream applied to the forearm. TEWL was measured at baseline and after 28 days, with the product applied twice daily to one forearm.

- Clinical Evaluation for AD Management:
 Participants applied the product to their eyelids twice daily for 28 days. Dermatological assessments and participant-reported data were collected on days 0 and 28.
- 3. <u>Clinical Evaluation for Relapse Prevention</u>:

 Participants were divided into two groups, with one group applying the product twice daily while the control group followed their usual skincare routine. Assessments were conducted on days 0, 56, 112, and 168.

Statistical Analysis

Data are presented as mean \pm standard error of the mean (SEM). The normality of data distributions was evaluated using the Shapiro–Wilk test (α =0.01). Depending on the distribution, paired Student's ttests were used for normally distributed data, while the Wilcoxon signed-rank test was applied for nonnormal data. A significance level of p<0.05 was considered statistically significant.

Ethical considerations

The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

RESULTS

Biometrological Analyses

Soothing Effect on Cutaneous Microcirculation

A total of 30 women, aged 18 to 60 years, participated in the evaluation of the soothing effect of the product on cutaneous microcirculation. Erythema was induced by stripping on both forearms, with the product applied on one arm and the other left untreated (Table 1).

Microcirculation was measured at three time points: before stripping, immediately after, and 30 minutes post-application. The forearm treated with the dermo-cosmetic product showed a significant reduction in erythema compared to the untreated arm.

Table 1: Reduction in erythema on treated and untreated forearms

Time Point (mean ± SEM)	Treated Forearm	Untreated Forearm	p-value
Baseline (before strip)	20.5 ± 1.2	21.0 ± 1.3	0.54
Immediately after strip	50.2 ± 2.5	50.5 ± 2.3	0.83
30 min post-application	25.3 ± 1.6	41.8 ± 2.1	< 0.001

A paired Student's t-test revealed a significant reduction in erythema on the treated forearm compared to the untreated forearm (p < 0.001), indicating a strong soothing effect of the product.

Protective/Anti-Redness Effect

A total of 40 participants (20 men and 20 women, aged 20 to 66) underwent patch testing with sodium

lauryl sulfate. After 18 hours, patches were removed, and skin color parameters were measured 6 hours post-removal.

The product demonstrated a significant protective effect by reducing redness compared to the neutral cream (Table 2).

Table 2: Comparison of lightness (L*) and redness (a*) between product and neutral cream

Treatment	L* (Lightness)	a* (Redness)
Neutral Cream	68.5 ± 1.1	16.3 ± 1.2
Atoderm Intensive Eye Cream	70.8 ± 1.0	12.1 ± 1.1

p-value	0.003	<0.001

The product led to a statistically significant increase in skin lightness (L*) and a significant decrease in

redness (a*) compared to the neutral cream (p < 0.001).

Transepidermal Water Loss (TEWL)

In the TEWL study, 30 women, aged 23 to 69 years (mean: 48 years), with dry to very dry skin, were assessed for barrier function over a 28-day period.

One forearm received the product twice daily, while the other was left untreated. TEWL values were measured at baseline and after 28 days (Table 3).

Table 3: TEWL in treated and untreated forearms over 28 days

Time Point (mean ± SEM)	Treated Forearm	Untreated Forearm	p-value
Day 0	10.1 ± 0.5	10.0 ± 0.6	0.82
Day 28	6.5 ± 0.4	9.8 ± 0.5	< 0.001

A significant reduction in TEWL was observed in the treated forearm by day 28 (p < 0.001), suggesting the product improved skin barrier function and hydration.

Clinical Evaluation of Subjects Presenting AD Symptoms on Eyelids

A total of 20 participants with mild to moderate AD symptoms on the eyelids were assessed for product performance. AD severity was evaluated using a 0 to 10 scale across various symptoms. Dermatologist assessments on day 0 and day 28 showed a significant reduction in symptom severity (Table 4).

Table 4: Reduction in AD symptom severity on eyelids after product application

Symptom (mean ± SEM)	Day 0	Day 28	% Improvement	p-value
Dryness	6.8 ± 0.5	3.2 ± 0.4	53%	< 0.001
Erythema	5.4 ± 0.6	2.1 ± 0.5	61%	< 0.001
Edema	4.7 ± 0.4	1.8 ± 0.3	62%	< 0.001
Desquamation	4.9 ± 0.3	2.0 ± 0.3	59%	< 0.001
Roughness	5.6 ± 0.4	2.3 ± 0.3	59%	< 0.001

Dermatological assessments indicated a statistically significant improvement in all AD symptoms (p < 0.001).

Participants self-evaluated their skin discomfort (tightness, stinging, burning, itching) on days 0 and 28 (Table 5).

Self-Reported Symptoms

Table 5: Self-reported improvement in discomfort (tightness, stinging, burning, itching)

Symptom (mean ± SEM)	Day 0	Day 28	% Improvement	p-value
Tightness	6.3 ± 0.6	2.8 ± 0.4	56%	< 0.001
Stinging	5.5 ± 0.5	1.7 ± 0.3	69%	< 0.001
Burning	4.2 ± 0.4	1.2 ± 0.2	71%	< 0.001
Itching	6.1 ± 0.5	2.5 ± 0.3	59%	< 0.001

Self-reported discomfort significantly decreased across all symptoms after 28 days of product application (p < 0.001).

Clinical Evaluation of the Anti-Relapsing Effect of the Product

In the second phase of the study, participants were evaluated for relapse prevention. The 20 participants

were divided into two groups: one applying the product twice daily and the other following their usual skincare routine (Table 6). Participants in the product group experienced significantly fewer relapses during the study period (168 days).

Table 6: Comparison of relapses between product group and control group

Group	Relapses (mean ± SEM)	p-value
Product Group (n=10)	0.8 ± 0.3	< 0.001
Control Group (n=10)	3.4 ± 0.6	

The product group had significantly fewer relapses compared to the control group (p < 0.001).

Dermatological Life Quality Index (DLQI)

Participants filled out the Dermatological Life Quality Index (DLQI) questionnaire, which measured the impact of AD on their quality of life. A significant improvement in DLQI scores was observed for both product performance (day 28) and relapse prevention (day 168) (Table 7).

Table 7: Dermatological Life Quality Index (DLQI) scores at different time points

Assessment (mean ± SEM)	Day 0	Day 28	Day 168	p-value	p-value
				(Day 28)	(Day 168)
DLQI Score	14.5 ± 2.2	6.5 ± 1.8	4.8 ± 1.6	< 0.001	< 0.001

The DLQI scores improved significantly after 28 days of treatment (p < 0.001), and the impact on quality of

life continued to improve during the relapse prevention phase (p < 0.001).

DISCUSSION

The biometrological analyses demonstrated that the investigated dermo-cosmetic product significantly erythema reduced and improved skin microcirculation. In the soothing effect study, 30 women showed a marked reduction in erythema 30 minutes after application compared to the untreated forearm (p < 0.001). This suggests that the product has a rapid soothing effect, effectively reducing skin redness after irritation. The protective/anti-redness study with 40 participants revealed that the product significantly increased skin lightness (L*) and reduced redness (a*) compared to a neutral cream (p < 0.001), demonstrating its ability to protect the skin from irritation and redness caused by sodium lauryl sulfate.

The TEWL study involving 30 women with dry to very dry skin indicated a significant improvement in skin barrier function. After 28 days, the treated forearm exhibited significantly lower TEWL compared to the untreated forearm (p < 0.001), indicating better hydration and a stronger skin barrier. This underscores the product's moisturizing benefits and its ability to enhance skin barrier integrity.

In the clinical evaluation of subjects with AD symptoms, 20 participants with mild to moderate AD on the eyelids experienced significant improvements in all measured symptoms, including dryness, erythema, edema, desquamation, and roughness. Dermatologist assessments revealed symptom severity reductions of over 50% across all categories (p < 0.001). Self-reported symptoms such as tightness, stinging, burning, and itching also improved significantly (p < 0.001), indicating the product's efficacy in reducing AD-related discomfort.

The anti-relapsing effect study demonstrated that participants using the product had significantly fewer relapses compared to the control group (p < 0.001). Those in the product group experienced an average of 0.8 relapses over the study period, compared to 3.4 relapses in the control group, showing that the product effectively prevents flare-ups of AD.

Finally, the DLQI results showed that participants' quality of life improved significantly during both phases of the study. After 28 days of product use, DLQI scores decreased by more than 50% (p < 0.001), reflecting a reduction in the negative impact

of AD on daily activities and psychological well-being. These improvements continued into the relapse prevention phase, with further significant reductions in DLQI scores at day 168 (p < 0.001).

These results indicate that the Atoderm Intensive Eye cream provides substantial benefits for individuals with eyelid atopic dermatitis. Its ability to soothe irritation, protect against redness, improve skin barrier function, and prevent relapses makes it an effective treatment option for managing both active symptoms and long-term prevention of AD flare-ups. Furthermore, the significant improvement in participants' quality of life highlights the broader positive impact the product can have on overall well-being for those suffering from AD. Overall, the product was well-tolerated, with no significant adverse effects reported.

A clinical and hardware evaluation was conducted of an emollient cream containing filagrinol in pediatric patients with atopic dermatitis. The study demonstrated that the filagrinol cream significantly improved skin moisturization, reduced transepidermal water loss, and was well-tolerated by the children. The use of the cream was associated with a reduction in dermatitis relapses during the remission phase, supporting its role in managing atopic dermatitis effectively [4].

A study assessed the use of a cream with 5% filagrinol for children with atopic dermatitis. This study highlighted that the filagrinol-based emollient, when used consistently, helped in maintaining skin

hydration and preventing disease flares. The product proved to be beneficial in reducing the severity of atopic dermatitis symptoms and contributed to longer periods of remission [5].

Similarly, a study focused on the philosophy of ecobiology in skincare products. Their work emphasized the benefits of developing skincare products using eco-friendly and biologically compatible ingredients. These ecobiological products not only showed efficacy in improving skin conditions but also reduced environmental impact. This study provided insights into the potential advantages of ecobiological products in managing chronic skin conditions like atopic dermatitis [6].

The efficacy of an ecobiological dermo-cosmetic product was evaluated specifically designed for managing eyelid atopic dermatitis. Their clinical trial showed that the product helped reduce inflammation at the eyelid level following the use of topical corticosteroids. More importantly, it was effective in preventing the recurrence of dermatitis symptoms, indicating that this product could be a viable option for long-term management of eyelid atopic dermatitis [7].

A cohort study evaluated the effects of witch hazel extract cream in treating eyelid dermatitis. The results showed significant improvements in both the acute and chronic manifestations of eyelid dermatitis. Patients using the cream experienced relief from symptoms and had fewer relapses, suggesting the

product's efficacy in managing and preventing dermatitis in the sensitive eyelid region [8].

A systematic review and meta-analysis of patients with atopic eyelid dermatitis who underwent patch testing. The study revealed that approximately 26.3% of the patients experienced a relapse during follow-up, indicating the chronic nature of the condition. However, the study underscored the importance of targeted treatments, such as specific dermo-cosmetic products, in improving outcomes and preventing long-term sequelae in patients with eyelid atopic dermatitis [9].

CONCLUSION

In conclusion, the dermo-cosmetic product Atoderm Intensive Eye demonstrated significant efficacy in managing symptoms of atopic dermatitis on the eyelids, such as dryness, erythema, and itching, while also preventing relapses. It proved to be a safe and effective non-steroidal alternative for both treatment and long-term care, particularly in sensitive areas. These findings suggest that incorporating dermo-cosmetic products into AD management can enhance skin barrier function and reduce the frequency of flare-ups, improving patients' overall quality of life.

LIMITATION

The limitations of this study include a small sample population who were included in this study. Furthermore, the lack of comparison group also poses a limitation for this study's findings.

RECOMMENDATION

Based on these findings, dermo-cosmetic products should be considered as part of a comprehensive treatment plan for patients with eyelid AD, particularly for those seeking steroid-free options.

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CONFLICT OF INTEREST

The authors have no conflicting interests to declare.

LIST OF ABBREVIATION

AD – Atopic Dermatitis

TEWL - Transepidermal Water Loss

DLQI – Dermatological Life Quality Index

SEM – Standard Error of the Mean

IL – Interleukin

Th2 – T-helper cell type 2

REFERENCES

- Efficacy and Safety of Lebrikizumab in Combination With Topical Corticosteroids in Adolescents and Adults With Moderate-to-Severe Atopic Dermatitis: A Randomized Clinical Trial (ADhere). JAMA Dermatol. 2023; Available from: https://jamanetwork.com/journals/jamadermat ology/fullarticle/2801416
- Atopic dermatitis: New therapeutic options and long-term management strategies. American Academy of Dermatology. Available from: https://www.aad.org

- Lebrikizumab: A novel IL-13 inhibitor for the treatment of atopic dermatitis. ClinicalTrials.gov.
 NCT04250337. Available from: https://clinicaltrials.gov
- 4. Masalskiy SS, Smolkin YS, Smolkina OY. Clinical and hardware evaluation of moisturizing properties and tolerability of an emollient cream with filagrinol in atopic dermatitis in children. Adair. 2023. Available from: https://adair.elpub.ru/jour/issue/download/9/ 9#page=18
- 5. Smolkin YS. Evaluation of a cream with 5% filagrinol in preventing disease flares in children with atopic dermatitis. Adair. 2023. Available from:

https://adair.elpub.ru/jour/issue/download/9/8#page=18

- Mcewen L, Déchelette C, Fauverghe S. Ecobiology: More than just a word, a philosophy emerging from skincare. Ethics, Medicine and Public Health. 2023. Available from: https://www.sciencedirect.com/science/article/pii/S2352552523000853
- 7. Bergera-Virassamynaïk S, Ardiet N. Evaluation of the efficacy of an ecobiological dermo-cosmetic product to help manage and prevent relapses of eyelid atopic dermatitis. Clinical, Cosmetic and Investigational Dermatology. 2023. Available from:

https://www.tandfonline.com/doi/abs/10.2147 /CCID.S401576

- 8. Veronese F, Esposto E, Airoldi C, Di Cristo N. Cohort study on the efficacy of a witch hazel extract cream for the eyelids and eye contour area and a cleansing face cream in dermatitis of the eyelids. Cosmetics. 2024. Available from: https://www.mdpi.com/2079-9284/11/3/83
- Borzova E, Snarskaya E, Bratkovskaya A. Eyelid dermatitis in patch-tested adult patients: a systematic review with a meta-analysis. Scientific Reports. 2024. Available from: https://www.nature.com/articles/s41598-024-69612-z