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Evaluation of selected parameters of a soothing emollient cream for atopic and sensitive skin

Ocena wybranych parametrów łagodzącego kremu emoliencyjnego do skóry atopowej i wrażliwej

ABSTRACT

Introduction: Atopic dermatitis is a chronic skin disease characterized by impaired barrier function and itching, often accompanied by inflammation. Emollients play a key role in therapy.

Aim: This study aimed to evaluate an emollient cream specifically designed for individuals with atopic, sensitive, and dry skin.

Materials and methods: The safety and efficacy of an oil-in-water emulsion, which is a class I medical device, were evaluated using *in vitro* and *in vivo* studies. *In vitro* tests involved the determination of cytotoxicity and irritation potential in cell models and reconstructed human epidermis, while *in vivo* studies included patch testing, clinical evaluation of efficacy, and instrumental measurements of skin parameters. In addition, an observational use study was conducted in people with atopic dermatitis to evaluate the effects of the product and user satisfaction.

Results: An *in vitro* evaluation, including cytotoxicity and irritation potential tests in an epidermal model, confirmed that the tested preparation had no irritating effect. *In vivo* studies showed improved skin hydration, support for the lipid barrier, and a smoothing effect, with the level of hydration persisting for at least five hours after application. An observational study revealed that over 70% of participants reported improved hydration and experienced relief from skin tightness. The reduction in itching was less pronounced. The product was well tolerated, and patch tests showed no allergic reactions.

Conclusions: Emollients are an essential and effective component in the treatment of skin with a disturbed hydrolipid barrier. However, the study's results emphasise the need for a variety of preparations tailored to individual preferences and the range of symptoms.

Keywords: atopic dermatitis (AD), emollients, sensitive skin, moisturizing medical device, barrier cream.

STRESZCZENIE

Wstęp: Atopowe zapalenie skóry jest przewlekłą chorobą skóry charakteryzującą się zaburzoną funkcją barierową i świądem, często przebiegającą ze stanem zapalnym. Kluczową rolę w terapii odgrywają emolienty.

Cel: Celem badania była ocena kremu emolientowego przeznaczonego do skóry atopowej, wrażliwej i suchej.

Materiały i metody: Ocenę bezpieczeństwa i skuteczności emulsji typu olej w wodzie, będącej wyrobem medycznym klasy I, przeprowadzono z wykorzystaniem badań *in vitro* i *in vivo*. Testy *in vitro* obejmowały ocenę cytotoksyczności oraz potencjału drażniącego w modelach komórkowych i zrekonstruowanym ludzkim naskórku, natomiast badania *in vivo* obejmowały test płatkowy, ocenę kliniczną skuteczności oraz instrumentalne pomiary parametrów skóry. Dodatkowo przeprowadzono obserwacyjne badanie użytkowe u osób z atopowym zapaleniem skóry w celu oceny efektów stosowania preparatu i satysfakcji użytkowników.

Wyniki: Ocena *in vitro*, obejmująca badania cytotoksyczności oraz potencjału drażniącego w modelu naskórka, potwierdziła brak działania drażniącego badanego preparatu. Badania *in vivo* wykazały poprawę nawilżenia skóry, wsparcie bariery lipidowej oraz efekt wygładzenia, a poziom nawilżenia utrzymywał się przez co najmniej pięć godzin po aplikacji. Badanie obserwacyjne wykazało, że ponad 70% uczestników zgłosiło poprawę nawilżenia i doświadczyło ulgi w napięciu skóry. Redukcja świądu była mniej wyraźna. Wyrób był dobrze tolerowany, testy płatkowe nie wykazały reakcji alergicznych.

Wnioski: Emolienty stanowią niezbędny i skuteczny element terapii skóry z zaburzoną barierą hydrolipidową. Wyniki badań podkreślają jednak potrzebę dostępności różnych preparatów, dostosowanych do indywidualnych preferencji oraz nasilenia objawów.

Słowa kluczowe: atopowe zapalenie skóry (AZS), emolienty, skóra wrażliwa, nawilżenie wyrób medyczny, krem barierowy.

INTRODUCTION

Atopic dermatitis (AD) is a chronic skin disease that, according to estimates, affects up to 20% of children and 10% of adults [1]. The disease is characterised by frequent lesion recurrence and persistent pruritus [2]. Topical non-pharmacological treatment with emollients is the baseline therapy for the management of AD symptoms and maintenance treatment for remission periods [3]. The mode of action of emollients is based on the content of humectants (e.g., glycerol or hyaluronate) and occlusive agents (petrolatum, natural oils). These ingredients act as a moisturising barrier, promoting hydration in the stratum corneum (humectants) and inhibiting water loss from the skin (occlusives). High lipid content contributes to the moisturising properties of emollient-based products [4], which are effective in reducing disease severity [5]. Emollients exhibit beneficial effects not only by lowering AD symptoms, but also by prolonging the no-flare periods and limiting the amount of topical corticosteroid used [6]. There is no conclusive evidence for the superiority of any emollient product or ingredient [7]. The choice of emollient products should be made by the patient and the physician and based on individual preferences [8-10]. The most crucial features to consider when choosing the right emollient are application properties and efficacy. Formulations of emollients should correspond to the season (more lipophilic in winter, more hydrophilic in warmer months), as well as the site afflicted by lesions [8, 11].

AIM OF THE STUDY

The study aimed to investigate the safety, efficacy, and overall satisfaction with an emollient body cream (hereinafter marked as 16915) in individuals with AD and those with dry, sensitive, or allergic skin. *In vivo* assessments included analyses of skin parameters after treatment and self-evaluation questionnaires for participants.

MATERIALS AND METHODS

Tested formulation

The tested formulation is a class I medical device (MD) topical oil-in-water emulsion based on emollients: canola oil, hemp seed oil, avocado oil, glycerol, and mineral oil, designed to alleviate AD symptoms, as well as soothe and soften the epidermis. The composition has been designed for body moisturising and was appropriate for patients of all ages (from birth). Detailed list of ingredients was as follows: Aqua (Water), Canola (Canola) Oil, Paraffinum Liquidum (Mineral Oil), Petrolatum, Glycerin, Cannabis Sativa (Hemp) Seed Oil, Cetearyl Alcohol, Persea Gratissima (Avocado) Oil, Potassium Cetyl Phosphate, Sodium Polyacrylate, Lonicera Caprifolium (Honeysuckle) Flower Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Lanolin, Pentaerythrityl Distearate, Hydroxyacetophenone, Tocopherol.

Study design

To comprehensively evaluate the product's safety and efficacy, *in vitro* and *in vivo* studies were conducted. In *in vitro* assays, the influence on cell viability and irritation potential in the human reconstructed epidermis (RHE) model was evaluated. Additionally, two independent *in vivo* studies were performed to assess the safety of the formulation, as well as its efficacy in reducing the symptoms of AD and skin sensitivity.

In vitro studies

A preliminary safety assessment of 16915 was performed using an MTT cytotoxicity assay in the L929 murine fibroblast cell line, according to ISO 10993-5:2009 [12]. Cells were seeded in 96-well plates, cultured overnight, and treated with seven concentrations of the evaluated product (20%, 10%, 2%, 1%, 0.1%, 0.01%, 0.001%). Positive control (PC) used in the study was 0.5% sodium dodecyl sulfate (SDS; MatTek, Ashland, MA, USA). Phosphate-buffered saline (PBS; Biowest, Bradenton, FL, USA) was used as a negative control (NC). Cells were incubated for 24h with the tested concentrations. After that time, cells were washed with PBS, and 50 µL of MTT solution (1 mg/mL; Sigma-Aldrich, Burlington, MA, USA) was added to each well. After 2 hours incubation (37°C; 5% CO_2), MTT was removed from the wells and the formed formazan crystals were dissolved in 100 µL of isopropanol (POCH, Gliwice, Poland). Absorbance was measured at 570 nm immediately after formazan was dissolved (BioTek Epoch Microplate Spectrophotometer, Agilent Technologies, Santa Clara, CA, USA). Cell viability was expressed as a percentage of optical density in negative control cells and calculated using the following equation (1) [13]:

$$Cell\ viability\ (\%) = \frac{OD_{sample} - OD_{blank}}{OD_{control} - OD_{blank}} \times 100\%. \quad (1)$$

The sample was considered noncytotoxic if the mean viability was >70% of untreated control cells.

For the skin irritation assay, EpiDerm™ Human Reconstructed Epidermis (RHE) Model (MatTek, Ashland, MA, USA) was used. The assay was performed in accordance with ISO 10993-10:2013 [14]. Tissues were exposed for 1 hour to 30 µL of the tested substances: undiluted tested cream (16915), sterile PBS (NC; Biowest, Bradenton, FL, USA), and 5% SDS (PC; MatTek, Ashland, MA, USA). Reference samples were naphthalene acetic acid (Ref1; Sigma-Aldrich, Burlington, MA, USA) and cyclamen aldehyde (Ref2, Sigma-Aldrich, Burlington, MA, USA). Subsequently, cells were rinsed with PBS and transferred to fresh culture medium. After a 42-hour incubation, the MTT tissue viability assay was performed. Tissues were transferred to 24-well plates and incubated with 1 mg/mL MTT for 3 hours. After that time, tissues and formazan crystals were dissolved in 2 mL of isopropanol. The optical density of the samples was then measured at 570 nm. Relative cell viability was expressed

as a percentage of optical density in NC and calculated using the following equation (2) [13]:

$$Tissue\ viability\,(\%) = \frac{OD_{sample} - OD_{blank}}{OD_{control} - OD_{blank}} \times 100\%. \quad (2)$$

The skin irritation potential of the test samples was predicted if the relative cell viability was below 50% of NC.

In vivo tests

Hypoallergenic properties of 16915 were evaluated using the Jadassohn-Bloch technique with Rudzki modifications [15]. The assessment was performed in accordance with the Declaration of Helsinki of 1964 (with further amendments) [16]. For the semi-open patch test, 50 healthy individuals (age 18-70) with sensitive skin and no history of allergy to any of the ingredients were included. In the group, 34% of subjects (n=17) had a positive medical history of AD or eczema, confirmed by a physician. Patch readings were performed at 48 and 72 hours after application.

An efficacy study was performed in a group of 24 individuals (age 2-76 yrs, mean age 26.46 yrs) from Jun 1st to Jul 5th, 2023. The participants provided written consent to participate in the study. In the group, 88% of participants (n=21) were characterized by dry skin, and 29% (n=7) reported symptoms of AD. The tested formulation was applied for 14 days, with subjects being instructed to use the product at least once daily, or more frequently if needed. Additionally, an instrumental evaluation of the emollient and skin conditioning properties of the tested cream after a single application was performed. In a subgroup of participants (n=5), skin condition measurements were obtained using Multi Probe Adapter (MPA) Systems (Courage & Khazaka Electronics GmbH, Köln, Germany). The following parameters: hydration (Corneometer), lipid content – referred to as a protective layer on the surface (Sebumeter), and transepidermal water loss (TEWL; Tewameter) were measured before applying the cream on the volar side of the forearm (baseline) and for five consecutive hours after a single application. For the evaluation of skin smoothness, the following parameters were assessed at baseline and 3 hours after application: V-value (depth, volume, and number of creases and skin irregularities), and S-value (unit indicating the ratio of folded to smooth skin in the analysed area).

An observational study to evaluate efficacy and satisfaction among a group of AD-affected individuals was conducted in collaboration with the Polish Society for Atopic Diseases (PTCA). Participant inclusion was based on online submissions and verification of PTCA membership. The study investigators did not establish a diagnosis of atopic dermatitis; however, all participants were registered members of the PTCA, suggesting a prior clinical diagnosis of AD. The study was carried out from Nov 5th to Dec 4th, 2020. Product samples (n=100) were delivered to subjects in original packaging. Participants were requested to apply the product liberally on cleansed, dry skin. After two weeks, they were asked to complete an online questionnaire about their opinions on the product. The questionnaire included questions about changes in skin condition after the treatment (e.g., hydration, dryness prevention, irritation, and erythema relief), as well as perceptions of the cream's characteristics: texture, packaging type, and general satisfaction. The online questionnaire was anonymous and did not contain any questions that could collect personally identifiable information. This study was based on descriptive statistics obtained from participants who consented to complete the survey. The study was not a post-market clinical follow-up investigation under the European Union Medical Device Regulation (MDR Annex XIV, Part B, Section 6.2). Instead, it was a non-interventional study to assess patients' experiences with the medical device emollient cream.

RESULTS

In vitro assays

The tested formulation was observed to be non-cytotoxic at concentrations equal to or below 0.1%. The concentration-dependent relative cell viability is presented in fig. 1.

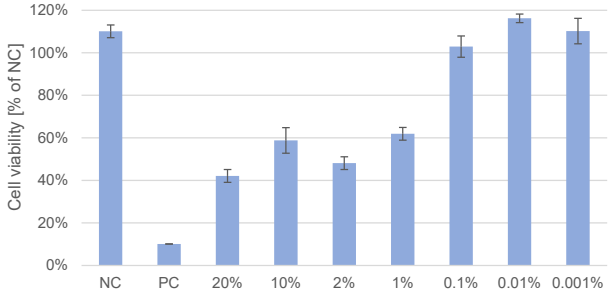

Fig. 1. Influence of 16915 in concentration 0.001–20% on L929 murine fibroblast cell viability. Values are presented as mean viability ± SD from 3 independent experiments performed in duplicate (n=6) NC – negative control (PBS); PC – positive control (0.5% SDS). **Source:** Own elaboration.

In the RHE assay, 16915 did not exhibit irritant potential. The mean tissue viability was 112.8 ± 10.5%, and the viability of PC was 4.4 ± 0.8%. Results of the evaluation of irritant potential are presented in fig. 2.

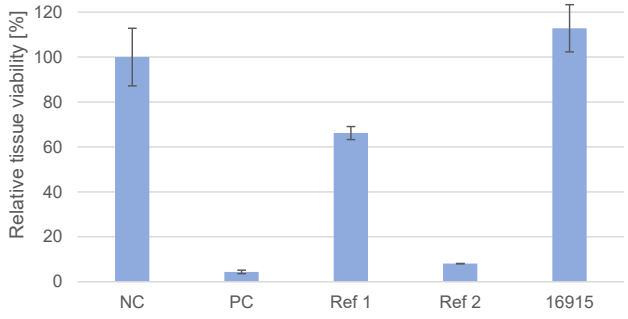

Fig. 2. Influence of 16915 on RHE model tissue viability. Values are presented as mean viability ± SD from two experiments performed in triplicate (n=6). NC – negative control (PBS); PC – positive control (0.5% SDS). **Source**: Own elaboration.

In vivo assays

Patch tests in all subjects were negative at 48 and 72 hours, indicating hypoallergenicity in the test subjects.

In the 5-hour assay, the elevated hydration level was maintained throughout the test. After 5 hours, the mean hydration level in the group was 125 ± 8%. For skin lipid levels, the reference point used in the calculations was values measured after 1 hour (93-267 µg/cm^2) to evaluate the time required for the lipid-replenishing effect to be observed. The level of skin lipids decreased gradually to 35% of the reference point at the endpoint (5 h). Decreased TEWL values were observed up to 3 h after cream application (88.5% of baseline TEWL value). Detailed changes observed in the assay are demonstrated in fig. 3.

In the skin smoothness assay, a 9.3% reduction of V-value (skin crease depth and volume) was observed in the tested group. Additionally, a 6.1% reduction in folded surface area (S-value) was observed (Fig. 4).

Efficacy study in individuals with AD

A total of 107 participants completed the questionnaire. It results from the fact that in several cases, both AD-affected child and their parent/guardian evaluated the cream and shared their experience. What is worth noting, majority of subjects were under 18 years of age. In the group, 41.1% volunteers (n=44) were undergoing/had undergone steroidal treatment of AD. Baseline characteristics of the group are summarized in tab. 1.

Although the participants were instructed to apply the product liberally for 14 days, treatment duration varied from 1-3 days (n=11) to over 14 days (n=10). Regarding application frequency, the majority of subjects (62.6%; n=67) used the product twice daily. Tab. 2 summarizes treatment duration and frequency of product application among participants.

In over half of the participants (57.9%; n=62), a noticeable effect of formulation on overall skin condition was observed within 2 days of the first application. For 15.8% of subjects (n=17), the improvement in skin condition was observed immediately. For 7.5% of participants (n=8), treatment results were not observed (Fig. 5).

The participants observed changes in their skin condition. The most frequently observed change was an increase in skin smoothness, hydration, and softness (41.1, 39.3, and 37.4% of participants, respectively). Study participants also noticed a reduction in erythema, irritation, and pruritus. Changes in skin condition observed by test subjects are presented in fig. 6.

The user satisfaction survey revealed that the tested emollient formulation was well-received by the majority of participants in terms of application properties. Most of the users found the product easy to apply (76.6%) and spread (75.7%), with over half agreeing that it absorbed quickly (75.7%) and left a non-greasy protective layer (77.6%). Notably, while 74.8% of participants expressed willingness to recommend

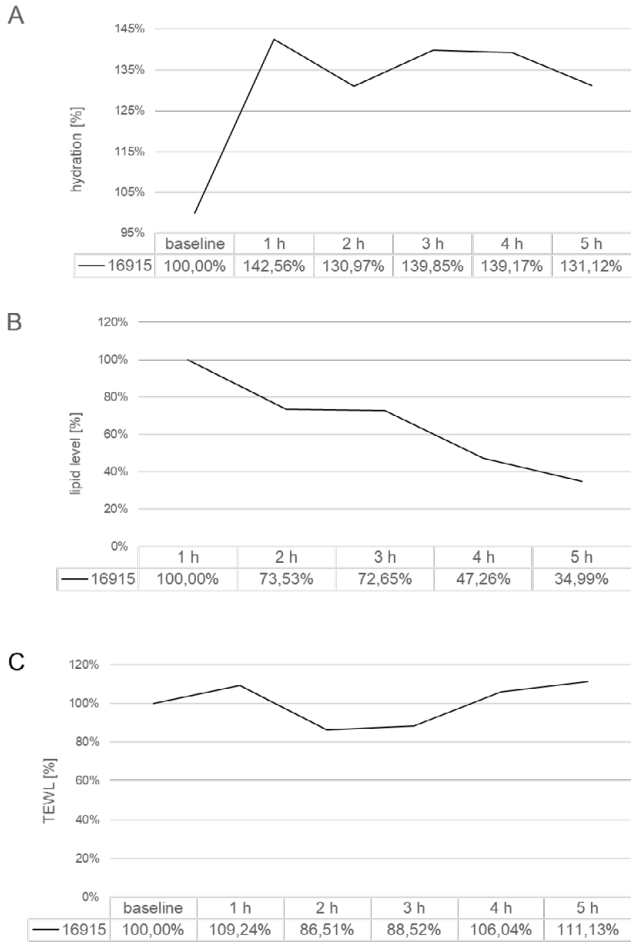

Fig. 3. The influence of 16915 on skin hydration (A), lipid content (B), and TEWL (C) after a single application. For hydration and TEWL, values are presented as mean percent of baseline and after 5 consecutive hours post-application. For lipid content, values are expressed as the mean change of lipid level from baseline (1 h after application). **Source**: Own elaboration.

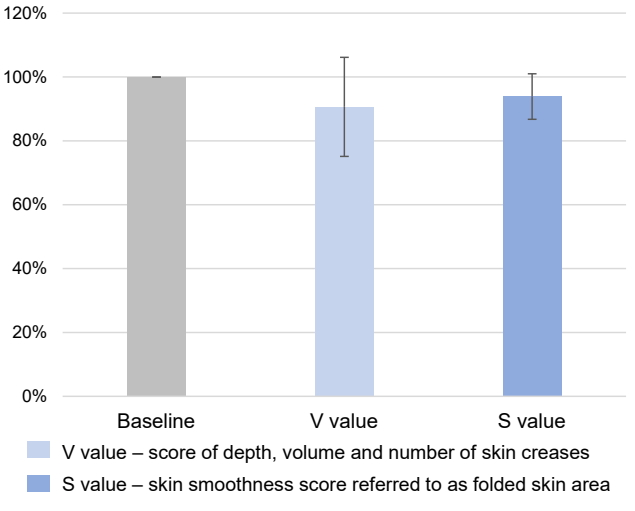

Fig. 4. Changes in skin smoothness parameters 3 hours after a single application of 16915. V-value is a unit which represents depth, volume, and the number of skin creases. S-value is a unit referring to the degree of skin smoothness, expressed as mean change from baseline values (100%) ± SD (n=5). **Source:** Own elaboration.

Tab. 1. Baseline characteristics of the study group. **Source**: Own elaboration.

Age		
	n	%
0-6 months	1	0.9%
6-12 monts	3	2.8%
1-3 yrs	24	22.4%
4-6 yrs	20	18.7%
7-12 yrs	13	12.2%
13-17 yrs	2	1.9%
18-25 yrs	6	5.6%
26-35 yrs	21	19.6%
36-45 yrs	15	14.0%
46-55 yrs	1	0.9%
56+	1	0.9%
Gender		
Females	77	72.0%
Males	30	28.0%
Skin conditions reported before the test		
Atopic dermatitis	77	72.0%
Eczema	13	12.2%
Psoriasis	6	5.6%
Erythema	41	38.3%
Irritation, burning sensation	37	34.6%
Skin roughness	45	42.1%
Skin dryness	40	37.4%
Excessive scaling	13	12.2%
Atopic skin	36	33.6%
Pruritus	38	35.5%
Have you been undergoing any systemic or topical steroidal therapy?		
No	63	58.9%
Yes, after treatment	20	18.7%
Yes, in the treatment	24	22.4%

Tab. 2. Treatment duration and application frequency in the study group. **Source**: Own elaboration.

		Frequency of application				
		Less than once daily	Once daily	2 times daily	3 times daily	Total
Treatment duration	1-3 days	-	2	7	2	11
	4-7 days	-	7	29	5	41
	8-14 days	-	5	25	15	45
	>14 days	1	1	6	2	10
	Total	1	15	67	24	107

the product, fewer users (59.8%) indicated that it would replace their current skincare routine (Fig. 7). In terms of efficacy, 71.9% of participants reported that the cream effectively hydrated the skin, while 74.5% agreed that it softened and smoothed the epidermis. Additionally, a significant number of users observed improvements in specific AD symptoms, including reduced skin roughness (78.5%), scaling (72.9%), and discomfort from taut skin (77.6%). However, the effectiveness of the cream in alleviating erythema (65.4%), irritation (63.6%), burning (67.3%), and pruritus (62.6%) was rated slightly lower, indicating potential variability in individual responses. Notably, while 74.8% of participants expressed willingness to recommend the product, fewer users (59.8%) stated that it would replace their current skincare routine. These findings highlight the formulation's favorable user acceptance, particularly for hydration and barrier restoration (Tab. 3).

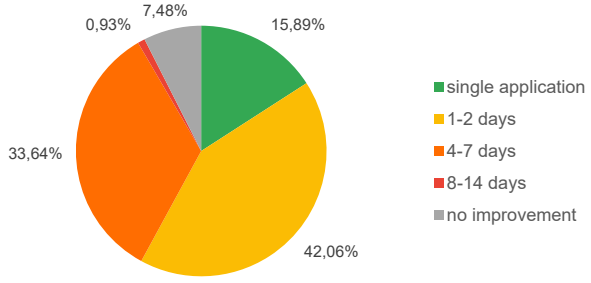

Fig. 5. The time from the first application to observed improvement in skin condition (n=107). **Source**: Own elaboration.

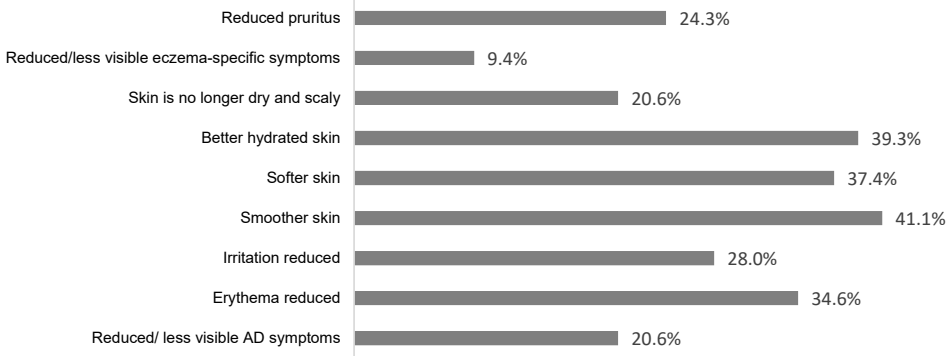

Fig. 6. Changes in skin condition observed by the participants (n=107). The values represent the percentage of participants who selected a given parameter in the multiple-choice question: 'How did your skin condition change after using the product? **Source**: Own elaboration.

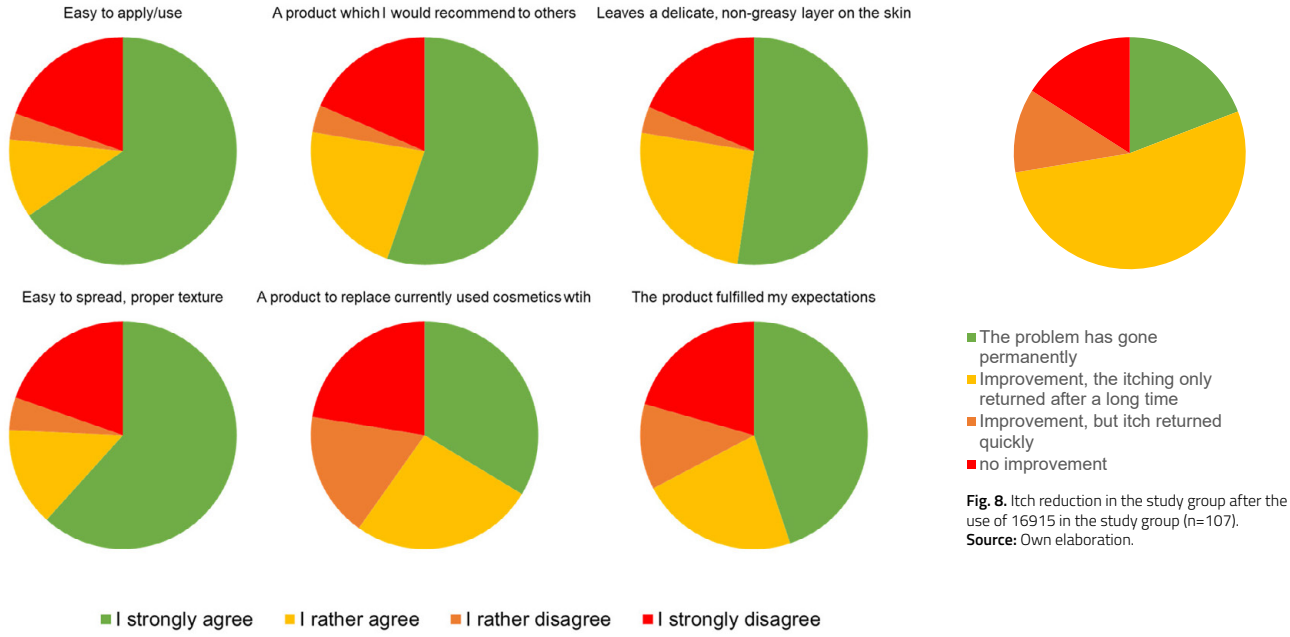

Fig. 7. Assessment of application properties of 16915 by study participants (n=107). **Source:** Own elaboration.

Fig. 8. Itch reduction in the study group after the use of 16915 in the study group (n=107). **Source:** Own elaboration.

Tab. 3. Assessment of efficacy 16915 in terms of reducing AD symptoms (n=107). **Source:** Own elaboration.

	I strongly agree	I rather agree	I rather disagree	I strongly disagree
Effectively replenishes lipids	43.9%	30.8%	7.5%	17.8%
Softens and smoothens the epidermis	56.1%	22.4%	6.5%	14.9%
Prevents the occurrence and worsening of dryness	45.8%	28.0%	11.2%	14.9%
Reduces erythema	36.5%	28.9%	14.9%	19.6%
Soothes irritation	34.6%	28.9%	16.8%	19.6%
Soothes burning	41.1%	26.2%	15.9%	16.8%
Reduces skin roughness	48.6%	29.9%	7.5%	14.0%
Reduces pruritus	33.6%	28.9%	19.6%	17.8%
Reduces skin scaling	35.5%	37.4%	12.2%	14.9%
Eliminates discomfort of taut skin	48.6%	28.9%	7.5%	14.9%

Immediate and long-term reduction of pruritus is a crucial feature for individuals affected by AD. In the tested population, 87.9% (n=94) reported experiencing itching. Among subjects experiencing pruritus, 84.0% agreed that the tested formulation reduced itch. In 19.2% of participants (n=18), the cream led to complete elimination of pruritus. Relapse of itch was observed by 64.9% of participants (n=61), however, only in 11.7% of subjects (n=11) the itch return was observed soon after product application. Itch reduction in volunteers is presented in fig. 8.

DISCUSSION

The presented study contributes to the growing body of evidence supporting the role of emollient therapy in managing AD and dry, sensitive skin. Emollients are widely recognized as the cornerstone of non-pharmacological treatment in AD, improving skin hydration, reducing barrier dysfunction, and alleviating symptoms such as pruritus and erythema. It might also be a valuable tool in the evaluation of AD-affected individuals in terms of their habits in emollient use. Most participants (85.1%; n=91) applied the emollient product at least twice daily. This is in accordance with the latest European recommendations, which state that frequent and liberal topical use of emollients is a basis for barrier-enhancement-oriented nonsteroidal treatment [11]. The obtained findings align with previous studies indicating that consistent and liberal application of emollients is associated with improved skin condition and prolonged remission periods [17]. Moreover, the study provided insight into patient preferences and adherence patterns, emphasizing the importance of tailored treatment strategies based on individual needs. In previous

work, a well-formulated, convenient-to-use, fragrance-free emollient was shown to improve patient satisfaction and treatment adherence, both of which are crucial parts of AD management [18]. This is in accordance with the work by Kunkiel et al. [19], which presented data collected in the population of AD patients in Poland. AD-affected patients participating in the study reported valuing emollients free of preservatives and allergens, as well as those with hydrating activity. Although a bottle with a pump was the preferred form of application in the study by Kunkiel et al., the previous work also showed that an emollient in a tube was well received (76.8% of volunteers agreed that the product was easy to use).

Ensuring the safety and tolerability of MD emollient formulations is crucial, particularly for individuals with AD and sensitive skin, who often have a compromised epidermal barrier and an increased risk of irritation or allergic reactions. The safety assessment of the tested cream (16915) demonstrated a favorable biocompatibility profile, as evidenced by the *in vitro* and *in vivo* assays. The MTT cytotoxicity assay confirmed the absence of cytotoxic effects at concentrations equal to or below 0.1%. Furthermore, the reconstructed human epidermis (RHE) model revealed no irritant potential, with tissue viability well above the 50% cutoff defined by international standards. These results support the safety of the formulation, aligning with prior research emphasizing the importance of biocompatibility in dermatological preparations [20]. The semi-open patch test further confirmed the cream's hypoallergenic properties, as no adverse reactions were observed among the 50 participants. This is particularly relevant given the increasing concern regarding potential sensitization associated with topical formulations designed to aid symptoms of skin inflammatory reactions, often associated with AD [21]. The formulation under investigation, composed of plant-derived oils and occlusive agents, appeared to provide a well-tolerated alternative for individuals with AD-prone skin. The instrumental assessments demonstrated a significant improvement in skin hydration following a single application of the tested formulation. Corneometric measurements indicated sustained increases in hydration for at least 5 hours, consistent with previous findings showing that emollients containing humectants, such as glycerol, effectively enhance stratum corneum hydration [17]. Moreover, a reduction in TEWL was observed, further supporting the formulation's role in reinforcing the skin barrier. Similar effects have been reported in studies evaluating lipid-based emollients, which help restore barrier integrity in AD [22].

In the observational study, the tested formulation was well-received by individuals with AD and sensitive skin, with most participants reporting improvements in skin hydration, smoothness, and softness. Notably, 84% of participants experiencing pruritus observed itch relief after product application, an effect that has been previously documented with occlusive and humectant-based emollients [9]. Reduction in pruritus is a crucial outcome for AD management, as persistent itching exacerbates disease severity and impairs quality of life [2, 23].

The high satisfaction rates observed in this study underscore the importance of formulation properties in patient adherence to emollient therapy. The ease of application and non-greasy feeling were particularly valued, which is consistent with previous findings indicating that sensory attributes significantly influence long-term use of skincare products [24]. Adequate hydration and epidermal smoothing were among the most positively rated benefits, reinforcing the role of water-binding and occlusive agents in improving skin condition [25]. However, the slightly lower effectiveness scores for erythema, irritation, and pruritus suggest that while the formulation provides general skin barrier support, an additional anti-inflammatory therapeutic strategy may enhance the therapeutic potential for the treatment of AD-related symptoms. What is worth noting, the product itself did not contain any substances which would be able to actively reduce inflammation or pruritus, as its main mode of action was barrier enhancement by restoring the integrity of skin's hydrolipid protective layer. Furthermore, while over half of participants indicated they would recommend the product, fewer considered it as a complete replacement for their current regimen, highlighting the variability in individual skin needs and treatment preferences. These findings emphasize the need for personalized skincare approaches, as well as continued research into optimizing emollient formulations to better address both hydration and inflammatory symptoms in AD [26].

While the study provides valuable insights into the safety and efficacy of the tested formulation, several limitations should be pointed out. First, the observational nature of the research and reliance on self-reported outcomes introduce potential biases. Although patient-reported assessments are valuable in evaluating subjective symptoms such as pruritus and skin comfort, future studies should incorporate clinician-reported outcomes and objective skin assessments to corroborate these findings.

Second, while the study demonstrated short-term hydration and barrier protection benefits, longer-term studies are necessary to assess the cumulative effects of regular emollient use. Previous research proposed that sustained use of lipid-based emollients could lead to gradual improvements in skin barrier function over time.

Finally, although no conclusive evidence exists regarding the superiority of specific emollient formulations [7], the above study suggests that emollients based on plant and mineral oils may provide effective hydration and skin barrier protection with lower irritation risk. Furthermore, the results highlight the importance of patient adherence and application frequency. In the study, 85% of participants applied the product at least

twice daily, which is in accordance with European guidelines recommending frequent and liberal use of emollients to maintain skin barrier function and reduce flare-ups [11]. This underscores the necessity of patient education regarding the correct use of emollients, as inconsistent application has been associated with suboptimal clinical outcomes [8].

CONCLUSIONS

The present study supports the safety and efficacy of the tested emollient medical device in individuals with AD and sensitive skin.

The formulation demonstrated a favorable biocompatibility profile, improved skin hydration, and effectively reduced symptoms such as pruritus and erythema. These findings align with current knowledge on emollient therapy, emphasizing the role of regular application in maintaining skin barrier function and reducing AD exacerbation.

Further research is needed to explore long-term outcomes and compare the effectiveness of different emollient compositions.

SUMMARY

Atopic dermatitis is a widespread condition, therefore continuous development of emollients, which are considered the cornerstone of AD care, remains a crucial direction of research and practice. The results of the above study showed that the tested topical formulation was well tolerated, as confirmed in both laboratory models and patch testing. Instrumental measurements demonstrated sustained increases in hydration, reductions in TEWL, and improvements in skin smoothness post-application. Study participants reported enhanced softness, smoothness, and overall skin comfort, while individuals with AD also noted reduced itch intensity. The presented findings are consistent with previously published work, indicating that regular use of well-designed emollients supports the skin barrier and improves the well-being of individuals with atopic dermatitis.

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