

A Cooling Gel Cream With Oatmeal Provides Fast Relief of Atopic Dermatitis Flare

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Introduction

- Atopic dermatitis (AD), an incurable inflammatory skin disease, manifests as flares of dry skin, itch, and a weakened skin barrier
- Patients commonly experience AD/eczema flares characterized by localized areas of erythema and intense pruritus¹
- Since chronic courses of AD appear in many patients, treatment aims to prevent occurrences and reduce the duration and degree of flares if they occur²
- Prevention is best achieved by reducing skin dryness and the desire to scratch, lessening the risk of infection
 - When prevention is unattainable, treatment of the flare to reduce and manage symptoms is warranted¹
- Itching, the leading symptom of AD, is also the most impactful on quality of life³: 91% of patients³ experience itch daily and 36% identify itch reduction as their primary treatment goal⁴
 - Persistent irritation and scratching advances barrier damage, can prolong the flare, and can cause area skin discoloration over time

Objective

- This study evaluated the benefits, including therapeutic skin and quality-of-life benefits, of using a gel cream formulation containing colloidal oat and ingredients that provide quick cooling and itch relief over a 2-week period in the treatment of AD/eczema flare symptoms

Clinical study methodology

Design	2-week, Institutional Review Board–approved, single-center, prospective clinical study with direct comparison to baseline condition
Population	Inclusion criteria <ul style="list-style-type: none">Male or female, 18-65 years of age, Fitzpatrick skin type I-VI with a mild to moderate AD severity rating (3-7.5 on Rajka and Langeland Severity Index)≥1 lesion area on face or body and a 5-12 on the ADASI, a 1-2 ADSI pruritus subscore (mild to moderate), and a ≥2 ADSI erythema subscore (moderate)Target lesion with a VAS score of ≥4 for itch
Evaluation tools	Clinical measures <ul style="list-style-type: none">ADSI assessment of target lesion and clinical evaluation of dryness, tactile roughness, and lesion skin tone vs normal overall skin toneVAS for itch assessment of the target lesion Tolerability <ul style="list-style-type: none">Tolerability evaluations of target lesion; facial skin evaluated separately for overall irritation and combined for subjective burning/stinging Self-assessment questionnaires <ul style="list-style-type: none">Self-assessment questionnaires included DLQI and self-perception of product’s impact on soothing and/or cooling (<2 min, Hours 2 and 4) after the first application on Day 1 Digital photography before and after treatment
Statistical analysis	Each postbaseline score was compared with baseline using a Wilcoxon signed rank test (individual clinical scores, VAS, DLQI), paired t-test (ADSI composite), or binomial test (self-perception), p≤0.05

AD, atopic dermatitis; ADASI, Atopic Dermatitis Severity Index; DLQI, Dermatology Life Quality Index; VAS, visual analog scale.

Investigational product

- Topical leave-on gel cream contained 2% colloidal oatmeal, which is an approved skin protectant drug for over-the-counter use to temporarily protect and help relieve minor skin irritation and itching due to eczema
 - Other ingredients: an evaporative emollient to aid in cooling and a robust emollient package to aid in moisturization
- The gel cream was intended for treatment of eczema flare and to provide itch, irritation, and dry skin relief
- Application to the target lesion was scheduled at least twice daily, AM and PM, and to the entire face once daily; additional applications to the target lesion were allowed as needed

Results

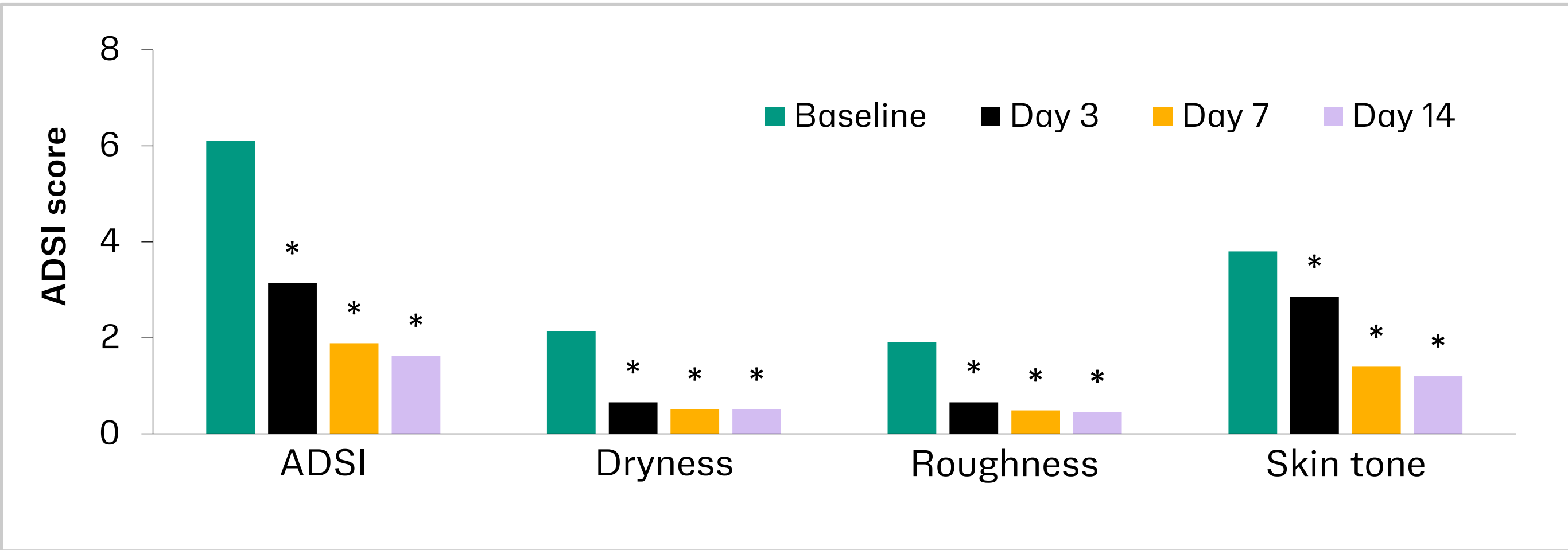
- Of 36 participants enrolled in the intent-to-treat group, 35 completed the study
- Participants’ ages ranged from 20 to 65 years (mean 50.7 years) and 80.6% were female; Fitzpatrick skin type and natural skin tone/color are described in **Table 1**

Table 1. Diverse skin tones/skin color included in the intent-to-treat population

Fitzpatrick skin type	Natural skin tone/skin color	N	(%)
I	Pale/fair to light white	6	(16.7)
II	White to light beige	14	(38.9)
III	Beige to light tan/light olive	0	(0)
IV	Medium tan/medium olive to light brown	1	(2.8)
V	Medium brown to dark brown	4	(11.1)
VI	Darkest brown to darkest black	11	(30.6)

Dermatologist clinical grading

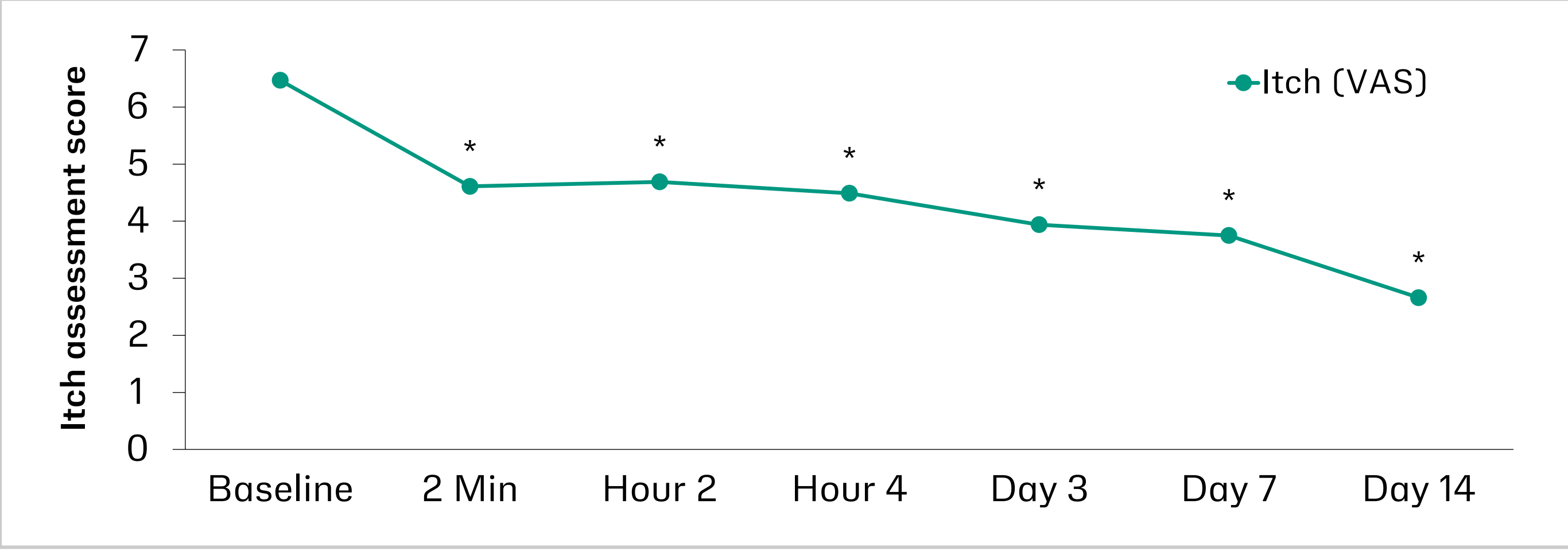
Figure 1. Dermatologist-assessed mean scores



*Highly significant improvement in all parameters, at all timepoints (p<0.001) vs baseline.

- Over the 14-day period, dermatologist grading of the target lesion showed significant improvements (p<0.001) in Atopic Dermatitis Severity Index cumulative score (**Figure 1**), inclusive of individual parameters of erythema, pruritus, and lichenification each on a 0-3 scale (none to severe)
- Exudation and excoriation showed improvement but were minimal at baseline and therefore did not reach statistical significance
- Dryness and tactile roughness (0-3 scale) and skin tone of lesion compared with normal overall skin tone (0-9 scale) showed significant improvement at all timepoints (p<0.05; **Figure 1**)

Figure 2. Itch assessment (VAS) mean scores



*Highly significant improvement at all timepoints (p<0.001) vs baseline.

VAS, visual analog scale.

- Subjective itch assessment results indicated immediate improvement in itch within 2 minutes of application and sustained improvements through Hour 2 and Hour 4 and continuing through Day 14 with continued use (**Figure 2**)

Tolerability

- The gel cream was well tolerated in this sensitive population; overall irritation of target lesion and facial skin, as well as burning/stinging showed improvement from baseline at each visit (p≤0.05)
- Two nonserious adverse events were reported: 1 participant had mild facial acne, possibly related to product use, and continued the study; 1 participant had moderate irritant contact dermatitis on the face and eyes, with probable relationship to product use, and discontinued from the study

Subjective assessments of cooling and soothing

Table 2. Immediate and continued cooling and soothing of eczema flares on Day 1

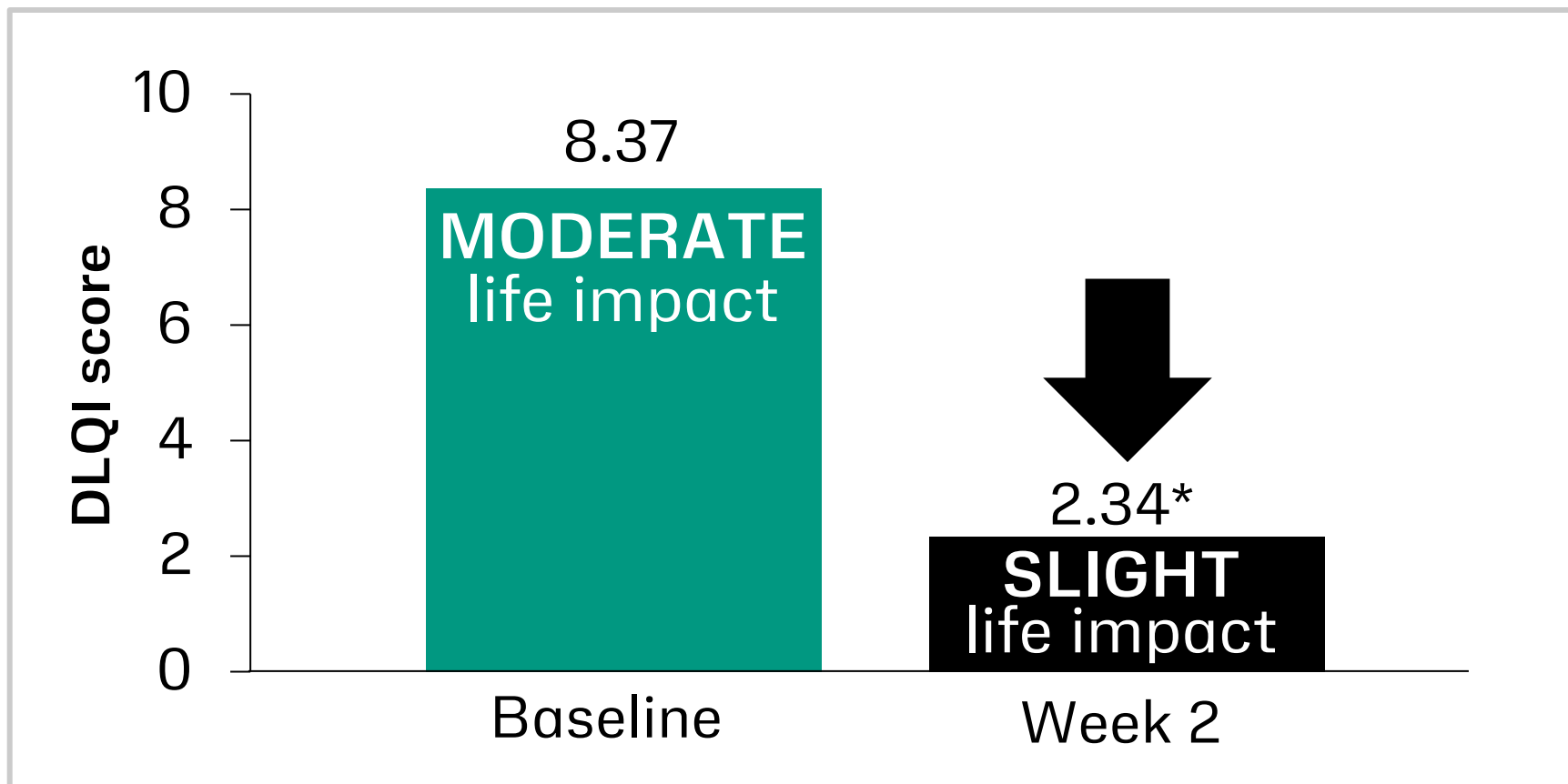
Participant self-assessed efficacy	Top 2 ratings - % agreement	
	Product cooled my eczema area	Product soothed/calmed my eczema area
<2 minutes after first application	89%	80%
2 hours after first application	80%	80%

- ≥80% of participants agreed that cooling/soothing was immediate and continued for 2 hours (**Table 2**)
- 4 hours post-first application on Day 1, 83% of participants agreed the product soothed/calmed their AD area
- At 2 weeks, participants agreed the gel cream provided cooling (91%) and soothing/calming relief (97%)

Quality of life

Figure 3. Global quality-of-life sum mean scores (DLQI)

- Dermatology Life Quality Index showed statistically significant improvement after 2 weeks’ use of the gel cream (**Figure 3**)
 - This represents a minimal clinically important difference as defined by a change in Dermatology Life Quality Index score of ≥4 points



* p<0.05 when compared with baseline mean score.

DLQI, Dermatology Life Quality Index.

Clinical photography

- Clinical photography further supports clinical grading and subjective measures (**Figure 4**)

Figure 4. Improvement in eczema flares from baseline to after 2 weeks



Conclusions

- This study demonstrated the benefits of using the 2% colloidal oatmeal over-the-counter gel cream with cooling and hydrating ingredients when used over 2 weeks by participants with mild to moderate AD; the benefits included
 - Highly efficacious management of the symptoms of AD/eczema flares
 - Instant and sustained itch relief
 - Instant cooling and soothing/calming sensations that last for hours after a single application
 - A clinically meaningful improvement in quality of life
- Routine application of a 2% colloidal oatmeal gel cream with an evaporative emollient for cooling and additional emollients for moisturization provides effective instant and long-lasting relief and treatment of mild to moderate AD/eczema flares

References

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