

A Cooling Gel Cream With Oat Provides Improvement to Quality of Life for Everyday Lifestyle Impact, and Itch Frequency & Bother, in Atopic Dermatitis Patients

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Introduction

Atopic dermatitis is a chronic inflammatory skin condition mainly thought of in children, but there is increasing evidence that it is highly prevalent in adults as well. In the US, the estimated prevalence in adults has been reported to be between 3.2% to 10.2%, depending on the criteria used to define AD.¹ AD can have a significant impact on overall quality of life, including lifestyle impacts as well as frequent and bothersome itching. A topical cooling gel cream with oat was evaluated in a 2-week clinical study on patients with AD. Demonstrated benefits of the gel cream for improvements to AD through Atopic Dermatitis Severity Index (ADSI) grading as well as improvements in itch severity have been shown previously.² This poster presents the corresponding benefits to quality of life along with visualization of the cooling characteristics of the gel cream.

Methodology to Determine Quality of Life for Lifestyle Impact and Itch

Methods

- **Design:** 2-week, Institutional Review Board approved, single center, prospective clinical study with direct comparison to baseline condition
- **Population:** 35 Males or Females, 18 to 65 years old, Fitzpatrick skin type I-VI with
 - mild to moderate atopic dermatitis (AD) severity rating (3-7.5 on Rajka and Langel and Severity Index)
 - At least 1 lesion area on face or body with 5-12 on Atopic Dermatitis Severity Index (ADSI) score, ADSI pruritis sub-score 1-2 (mild-moderate), and ADSI erythema sub-score ≥ 2 (moderate)
 - Target lesion Itch score ≥ 4 (Visual Analog Scale)
- **Evaluation tools:** baseline, week 1 and week 2
 - Dermatology Life Quality Index (DLQI) questionnaire³ (Table 1)
 - Itch Quality of Life (QoL) questionnaire rating both frequency and bother using a 5 point scale
 - Self-assessment of product benefit using a 5 point scale
- **Statistical Analysis:** Comparison to baseline scores for each patient at each visit were assessed using a Wilcoxon signed-rank test for DLQI and Itch QoL, $p \leq 0.05$. Self-assessment scores of product benefits were tabulated.

Test Product was a gel cream applied at least twice daily, containing 2% Colloidal Oatmeal with an evaporative emollient for cooling, in a moisturizing vehicle

Thermal imaging was captured with a FLIR Systems, ThermoCAM S60 thermal camera to provide a visualization of the cooling properties of the gel cream versus a water control on normal skin. The small sample size did not allow for statistical or further analysis.

Table 1. Dermatology Life Quality Index (DLQI) with sub-scales for Lifestyle Impact

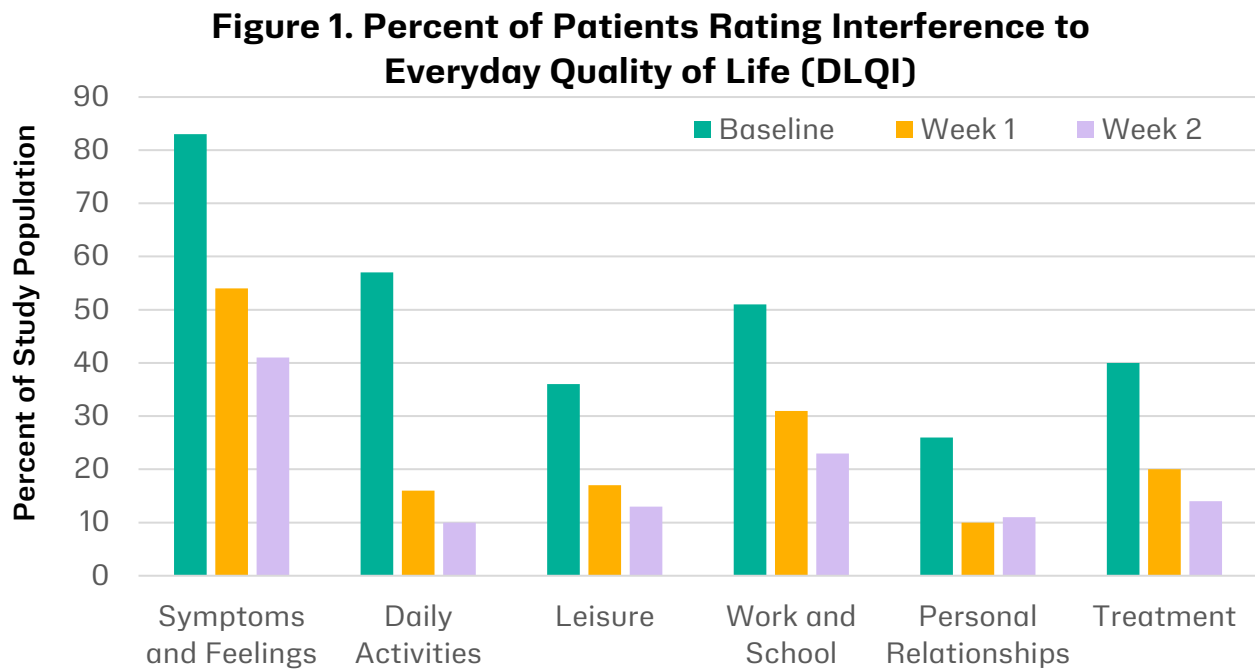
Sub-Categories for Analysis	DLQI Questions ³
Symptoms and feelings	How itchy, sore, painful, or stinging has your skin been? How embarrassed or self-conscious have you been because of your skin?
Daily activities	How much has your skin interfered with you going shopping or looking after your home or yard? How much has your skin influenced the clothes you wear?
Leisure	How much has your skin affected any social or leisure activities? How much has your skin made it difficult for you to do any sport?
Work and school	Has your skin prevented you from working or studying? If "No", over the last week how much has your skin been a problem at work or studying?
Personal relationships	How much has your skin created problems with your partner or any of your close friends or relatives? Over the last week, how much has your skin caused any sexual difficulties?
Treatment	How much of a problem has the treatment for your-skin been, for example by making your home messy, or by taking up time?

- Adverse Events Summary:** There were two non-serious adverse events
- mild facial acne possibly related to product use, patient continued on study
 - moderate irritant contact dermatitis on face and eyes, probable relatedness, patient discontinued from study

Everyday Quality of Life Improved for Atopic Patients in All DLQI Sub-Categories

Results

- 35 patients completed the study; the diverse population consisted of females (81%) and males (19%) with Black (44%) and Caucasian (56%) patients and a range of Fitzpatrick skin types



- Incidence of interference with everyday quality of life for AD patients in six sub-categories, showing reduced impact through use of gel cream after 1 week and continuing through 2 weeks (Figure 1)

Table 2. Mean Change and Impact of Gel Cream Use to Resolve Interference in Everyday Life (% of Population)

DLQI Sub-Categories and Total	Maximum Score	Mean Change/Improvement from Baseline after week 2	% Patients that improved to 'no impact' after week 2
Symptoms and Feelings	6	2.4	41
Daily Activities	6	1.5	47
Leisure	6	0.6	23
Work and School	3	0.5	29
Personal Relationships	6	0.6	14
Treatment	3	0.5	26
DLQI Total*	30	6.0*	31

- Each DLQI sub-scale and DLQI Total showed significant improvement after 1 and 2 weeks of product use, $p < 0.05$
- Of those noting interference with lifestyle parameters at baseline, 41% had no interference from Symptoms and Feelings after 2 weeks and 47% had no interference for Daily Activities. Other lifestyle influences were also resolved within the population with product use (Table 2)

*For DLQI Total, a change of ≥ 4 points represents a clinically meaningful difference; DLQI total improved from moderate to slight life impact.

Improved Quality of Life for Itch Frequency and Bother Across 23 Parameters

Figure 2. Impact of Gel Cream Use to Resolve Itch Frequency and Itch Bother (Change in Population that Resolved After 2 weeks)

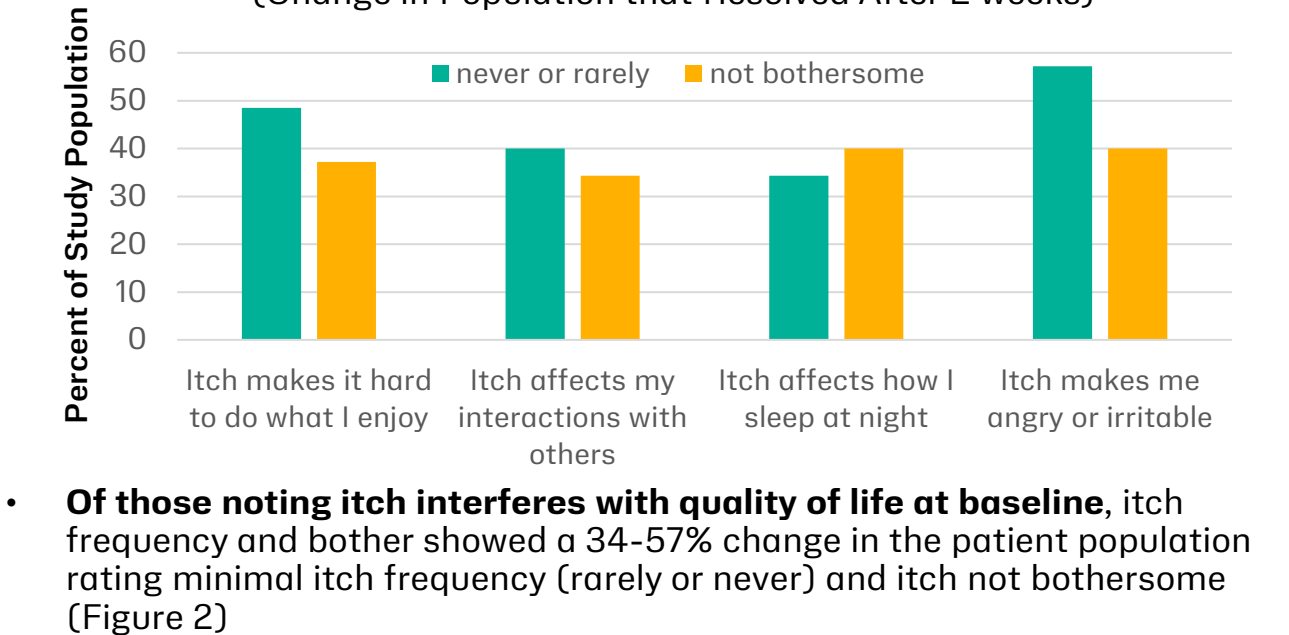


Table 3. Percent of Population Experiencing Frequent & Bothersome Itch

Itch....	...makes it hard to do what I enjoy		...affects my inter-actions with others		...affects how I sleep at night		...makes me angry or irritable	
	Freq	Bother	Freq	Bother	Freq	Bother	Freq	Bother
Baseline	57%	63%	49%	60%	66%	71%	63%	63%
Week 2	9%	26%	9%	26%	31%	31%	6%	23%

Freq (frequency) = Itch frequency sometimes + often + all the time; Bother = somewhat + very + severely bothered

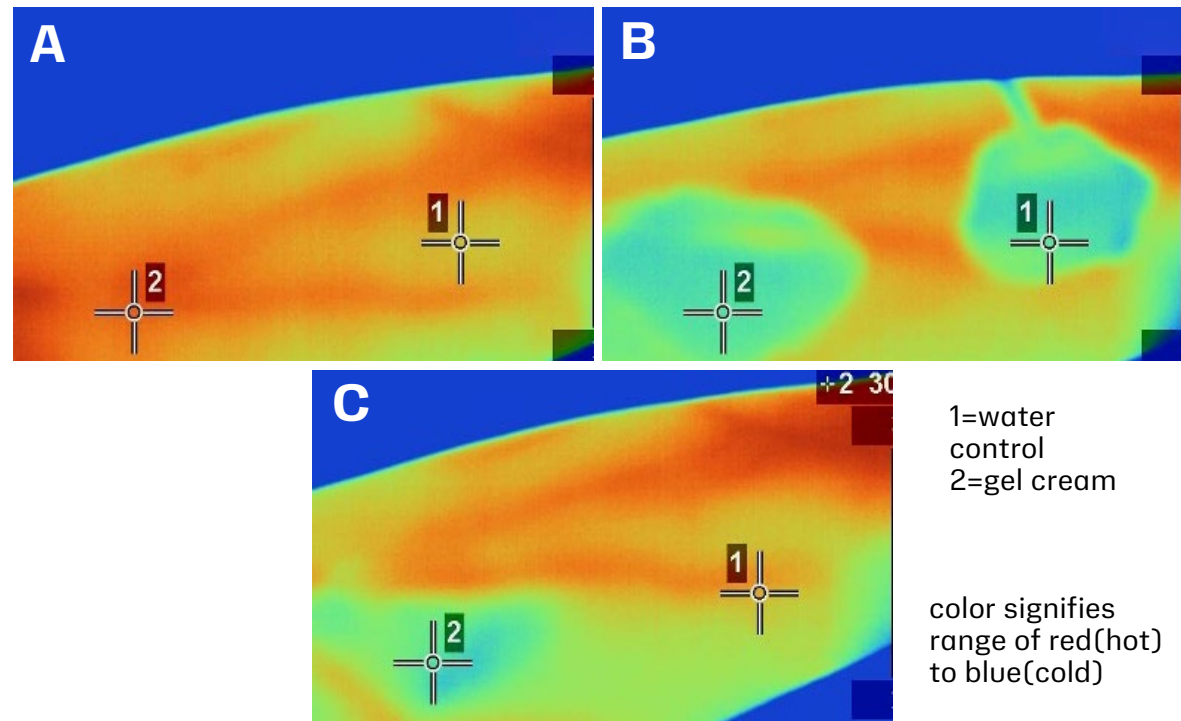
Table 4. Significantly Reduced Frequency and Less Bothersome Itch was noted for 23 Quality of Life parameters after 2 weeks

Itch Quality of Life Parameters After 2 Weeks, p<0.05
My itchy skin condition bleeds; hurts; burns or stings; or scars
I spend a lot of money treating my itchy skin condition; it forces me to buy special soaps, detergents, and lotions
My itchy skin condition makes it hard to work or do what I enjoy; limits the types of foods I can eat; limits the types of clothes I can wear
My itchy skin condition affects my interaction with others; affects how I sleep at night; interferes with my sex life
I need to scratch my itchy skin; it often makes it difficult to concentrate
I am frustrated; embarrassed by my itchy skin condition; it drives me crazy/nuts; it makes me feel angry or irritable; and makes me feel depressed or sad
I worry about what other people think about me because of my itchy skin condition; it makes me feel self-conscious; my self-esteem has changed because of my itchy skin condition
I worry that the itching will last forever

- Self-assessment of product benefits further supported the QoL data with patients agreeing that
 - irritated, itchy dry skin was less bothersome (86%)
 - they were better prepared to manage itchy dry skin flare ups (91%)
 - provides cooling relief to itchy dry skin (91%)

Visualization of Cooling Effect and Summary of the QoL Benefits for Oat Gel Cream

Figure 3. Thermal Imaging Visualization of the Cooling Properties of the Gel Cream on Normal Skin at (A) Baseline, (B) Immediately post-application, (C) After 10 minutes



- Cooling of skin, lasting through 10 minutes post-application, provides additional benefit to the soothing oat-containing formula

Conclusions

- Quality of Life for Atopic Dermatitis patients goes beyond measurement of clinical symptoms** and is an important consideration when treating patients
- The DLQI Total Sum of Scores** is most often reported without looking further to the sub-categories
 - Sub-categories showed the most impact from the gel cream was in Symptoms and Feelings and Daily Activities**, followed by Leisure, Work and School, and Treatment impacts, while Personal Relationships were impacted the least by treatment
- Frequency and bother of itch can be profoundly affected by topical treatment** and go beyond measures of itch severity alone
 - Treatment with gel cream helped with enjoyment in life, interactions with others, sleep and mood**
- Self-assessment of product benefits additionally supports the QoL data with **cooling further visualized through thermal imaging**
- The oat-containing, cooling gel cream delivers QoL benefits for itch and everyday life impact, with consumer perceivable benefits across a diverse population**

References

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