

# A Daily Oat Based Skin Care Regimen for Atopic Skin

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## ABSTRACT

Intense moisturization and gentle cleansing is important to those with atopic dermatitis since dry skin can further exacerbate the disease. Patients with atopy have a compromised skin barrier that allows for high rates of water loss and an easy entry for inflammatory triggers, allergens and irritants. Exogenous factors can trigger a patient with atopy to flare, thus resulting in intense pruritus and further breakdown of the skin barrier.

The fundamentals of a daily skin care routine are essential for hydration and maintenance of a healthy skin barrier in atopic skin. Cleansers and moisturizing creams should be free of fragrances and other potential irritants and allergens, to prevent further insult to an already compromised skin barrier. Moisturizing creams need to contain occlusives, skin protectants and other key components that protect the barrier, provide soothing benefits, and help with the water binding capacity of the skin. Creams need to be applied frequently and liberally to the entire body.

Patients, between the ages of 12 – 60, with mild to moderate atopic dermatitis according to the criteria of Hanifin and Rajka were enrolled into this multi-center, blinded, clinical study. For 8-weeks patients used a daily skin care regimen consisting of twice a day application of an oatmeal based occlusive cream (with vitamins and ceramides) and an oatmeal glycerin cleanser for all moisturizing and body cleansing. Patients were allowed to use their normal topical medications for their atopic dermatitis. Independent dermatologist evaluations were performed at multiple time points during the study.

Significant improvements ( $p < 0.05$ ) in EASI (Eczema Area Severity Index) and IGA (Investigators Global Assessment) scoring were observed by the dermatologist after only 2 weeks of using the oat based daily skin care regimen. Improvements in perceived itch ( $p < 0.05$ ) were also noted at the 2-week time point. Patients provided positive feedback after using the regimen, they perceived multiple skin benefits including improved skin texture, decreased discomfort and an overall improved look and feel. In conclusion, this clinical study of a gentle oat based regimen demonstrates the importance of the fundamentals of basic daily skincare when it comes to managing and caring for atopic skin.

## STUDY DESIGN

This was an 8-week monadic, blinded, clinical study to evaluate the tolerance and efficacy of an oat based skin care regimen in subjects with mild to moderate atopic dermatitis.

### Population

Twenty-five subjects between 12 and 60 years old (approximate mean age 29.8 years) completed the 8-week treatment. To qualify, subjects had to have mild to moderate atopic dermatitis according to the criteria of Hanifin and Rajka and at least 5% Body Surface Area (BSA) involved. Subjects had to be on a stabilized treatment regimen (topical steroids or prescription topical eczema medications, including flare medications) but were required to stop any current body moisturizers. The study was approved by an IRB and informed consent was obtained from all subjects.

### Treatment

The 8-week treatment regimen consisted of: 1) an oat based body cream to be used twice daily, morning and night (or more often if needed); and 2) an oat based body wash, used once a day in the shower or bath.

Subjects were allowed to use their prescribed topical treatment as per their usual routine.

### Evaluations

Clinical and subjective evaluations were performed at Weeks 0 (Baseline), 2, 4, and 8. These included:

- Investigators' Global Assessment (IGA) using a 0-5 scale
- Investigator scoring of Eczema Area and Severity Index (EASI) was performed separately for head/neck, trunk, upper limbs and lower limbs. The overall EASI composite score was also calculated.

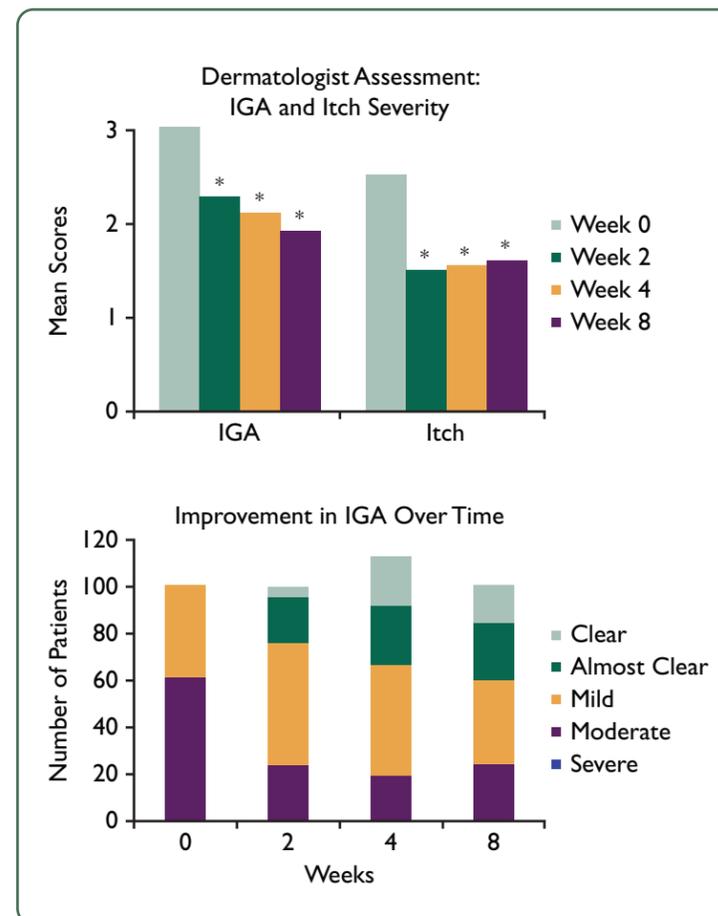
- Moisturization was measured instrumentally on an uninvolved site on the mid-lower leg (Weeks 0, and 8)
- Dermatology Life Quality Index (DLQI) (Weeks 0, 4 and 8) consisted of responses to 10 questions based on skin problems the patient encountered during the previous week. Separate questionnaires were provided for adults (>17 years) and children (12-16 years)
- Subject safety assessments (0-4 scale): itching, burning and stinging
- Final Subject Assessments based on the efficacy and acceptability of the regimen were completed at the Week 8 visit.

## RESULTS

The skin care regimen consisting of an oatmeal based occlusive cream and an oatmeal based cleanser was well tolerated in patients with mild to moderate atopic dermatitis. Efficacy results showed a statistically significant improvement in many parameters, including IGA, EASI, itch and moisturization. Burning and stinging, which were mostly absent at baseline, did not change during the study.

The regimen was found also to be compatible with various topical eczema medications used by several subjects. These included: triamcinolone (9 subjects), hydrocortisone (4), desonide (2), halobetasol propionate (1), desoximetasone (1), tacrolimus (1), and pimecrolimus (1).

**Figure 1. Dermatologist Assessment: IGA and Itch Severity**



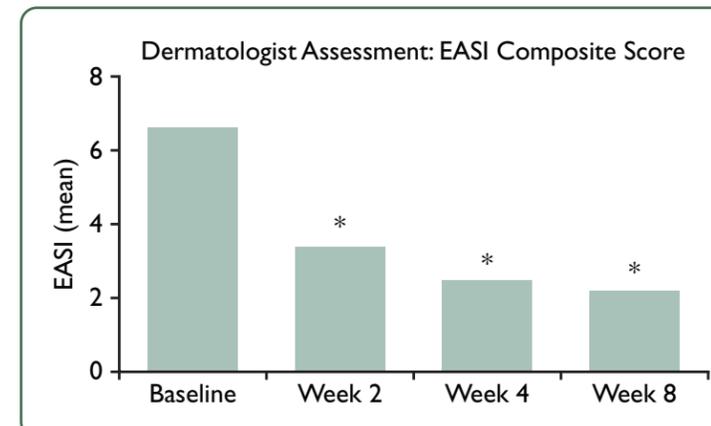
\*Significant improvement ( $p < 0.01$ )  
 Dermatologist evaluations showed a statistically significant improvement ( $p < 0.01$ ) in the IGA scores and in itch severity after 2, 4 and 8 weeks of regimen use.

**Table 1. Investigator Global Assessment**

% Patients in Each IGA Category Over Time	Week			
	0	2	4	8
Severe	–	–	–	–
Moderate	61	24	19	24
Mild	39	52	48	36
Almost Clear	–	19	24	24
Clear	–	5	21	16

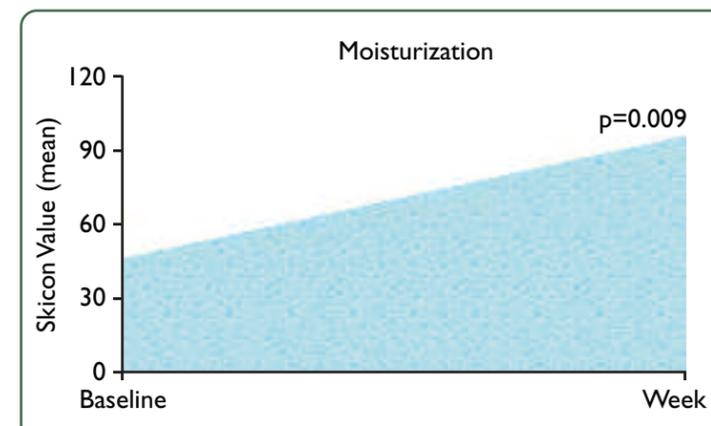
Improvement in IGA scores was apparent throughout the study, but especially within the first 2 weeks of treatment.

**Figure 2. Dermatologist Assessment: EASI Composite Score**



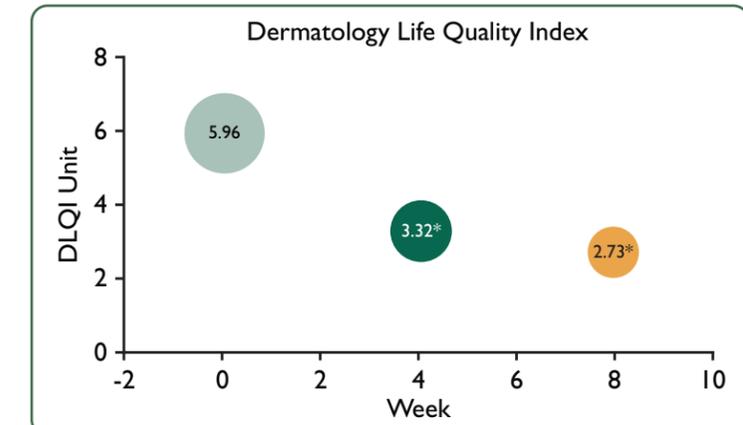
Dermatologist evaluations showed a statistically significant improvement ( $p < 0.001$ ) in the EASI composite scores after 2, 4 and 8 weeks of regimen use.  
 \*Significant improvement ( $p < 0.001$ )

**Figure 3. Skin Moisturization Measured by Skicon**



Skin moisturization, tested on an uninvolved site of the lower legs, was significantly increased ( $p = 0.009$ ) after 8 weeks of using the oatmeal based skin care regimen.

**Figure 4. Dermatology Life Quality Index (DLQI)**



A decrease in DLQI score indicates improvement in the quality of life (QOL). The significant improvement in QOL attributes observed here at 4 and 8 weeks of regimen use, matches the significant improvement in the skin condition of patients as observed by the dermatologist (IGA and EASI).  
 \*Significant improvement ( $p < 0.05$ )

**Table 2. Final Product Subject Assessment**

Final Self-Assessment	% of Patients Agreeing
Effective in hydrating the skin	83
Gentle and mild to skin	79
Softening and soothing irritated skin	79
Alleviating signs and symptoms of eczema	71
Alleviating itch and skin discomfort	70
Soothing and calming the discomfort of eczema through the night	70

Final self assessments showed that patients liked the regimen finding it soothing, moisturizing and effective in alleviating skin discomfort.

## CONCLUSIONS

- The study showed that:
- The oat based skin care regimen was beneficial and well tolerated in subjects with atopic dermatitis.
  - The regimen was compatible with the concomitant topical eczema medications used.
  - IGA, EASI and itch severity were all significantly improved as early as week-2 of use.
  - Dermatology Life Quality Index was significantly improved at 4 and 8 weeks.
  - Instrumental evaluation demonstrated that the oat based regimen provided significant skin moisturization.

## REFERENCES

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