



Alleviating Itchy, Extra-Dry Skin with an Oatmeal Skin Protectant Lotion

Judith Nebus, Warren Wallo, Glen Nystrand, Melissa Chu, Ellen S. Kurtz, PhD;
Johnson & Johnson Consumer Inc. Skillman, NJ, USA

ABSTRACT

- Maintaining stratum corneum function is important for proper skin hydration and for providing a protective environment against external aggressors. Colloidal Oatmeal (oat flour), humectants and skin protectants are well known ingredients used for proper skin care maintenance. These ingredients maintain the stratum corneum by acting as occlusive agents, attracting water to the skin or forming a protective barrier on the skin.
- Dry skin is more prevalent during the winter months but can persist all year, especially in areas of low humidity. When skin is extremely dry and irritated, there is excessive flaking of corneocytes, and micro fissures can occur in the stratum corneum resulting in a high transepidermal water loss rate. At times, skin can become so dry and irritated that there is an increase in mast cells and histamine levels causing itch among patients.
- A controlled clinical study was conducted to evaluate the effectiveness of a body lotion containing Colloidal Oatmeal (oat flour), oat extract, oat oil and a skin protectant in alleviating extra-dry, itchy skin. Healthy female subjects with itch and extra-dry skin on their lower legs were enrolled in the 2-week study. Subjects applied the lotion to the lower leg area twice a day. Benefits of the lotion were assessed by clinical evaluations, instrumental measures and self-assessments. Itch intensity was monitored daily through patient diaries.
- Clinical evaluations demonstrated significant improvements ($p < 0.05$) in dryness, scaling and skin roughness as early as 1 day after use of the triple oat skin protectant lotion. In addition, adhesive skin samples showed a significant decrease ($p < 0.05$) in fine and coarse flaking. Transepidermal water loss values decreased over time. Most important, patients perceived significant mean improvements in itch intensity levels after only 1 day of use of the oatmeal skin protectant lotion.
- This clinical study clearly demonstrated that this topical preparation containing oatmeal (oat flour), oat extract, oat oil and a skin protectant was effective in both relieving itch and dry skin while improving stratum corneum function in patients with itchy, extra-dry skin. Efficacy was demonstrated by clinical evaluations, instrumental methods and subject itch diaries. This triple oat skin protectant lotion also was effective in restoring moisturization and textural benefits to the skin.

INTRODUCTION

- Dry skin and its associated discomforts can be ameliorated through hydration and proper daily skin care. A daily moisturizing regimen utilizing skin protectants, humectants and oatmeal can be beneficial in restoring skin barrier function and alleviating itch in those with xerosis.
- Colloidal Oatmeal (oat flour) is a natural ingredient and is recognized by the U.S. Food and Drug Administration (FDA) as a skin protectant. Colloidal Oatmeal (oat flour) is rich in nutrients including proteins, polysaccharides and lipids and is well known for its ability to soothe and relieve a variety of minor skin irritations including itch. The proteins of Colloidal Oatmeal (oat flour) carry water to skin and act as a buffering agent to help maintain barrier integrity. The polysaccharides serve a dual function by attracting atmospheric moisture to the skin and leaving a protective film. Other key components present in oats, such as avenanthramides, have a soothing and anti-irritant effect on the skin. Oatmeal (oat flour), when combined with humectants in a body lotion can provide numerous moisturization benefits to the skin as well as help alleviate the itchiness associated with extra dry, uncomfortable skin.

STUDY DESIGN

- **Population** - Twenty-eight healthy female subjects between 18 and 60 years of age completed the study. Upon enrollment, all subjects exhibited chronic mild to moderate itch with moderate to severe dry skin on their lower legs. Exclusion criteria included those with acute inflammatory lesions on the lower leg area, individuals on medications that could interfere with the outcome of the study and those with known allergies/sensitivities to the test product. Informed consent was obtained from all subjects.
- **Treatments** - This was an investigator-blinded, randomized study. Subjects applied the triple oat skin protectant lotion to the lower leg area twice a day for the two-week study period.
- Benefits of the triple oat skin protectant lotion were determined by:
 - Clinical Evaluations: Performed on Day 0, 1, 7 and 14
 - Itch Diaries: Completed daily prior to product application, 2 and 30 minutes post-application
 - Self-Assessments: Performed on Day 0, 1, 7 and 14
 - Adhesive Skin Sampling/Desquamation Measurements: Day 0, 1, 7 and 14
 - Transepidermal Water Loss Measurements: Day 0, 1, 7 and 14
 - Imaging: Day 0 and 14

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RESULTS

Figure 1. Clinical Evaluations: Improvements in Itchy, Extra-Dry Skin

- Clinical evaluations of the subjects' lower legs showed significant improvements ($p < 0.05$) in skin dryness, scaling and roughness after 1 day of use of the triple oat skin protectant lotion when compared to baseline mean values. In addition, subjects perceived a significant ($p < 0.05$) mean reduction in itch intensity as soon as the Day 1 time point. Improvements in skin dryness, textural parameters and itch were maintained throughout the remainder of the study.

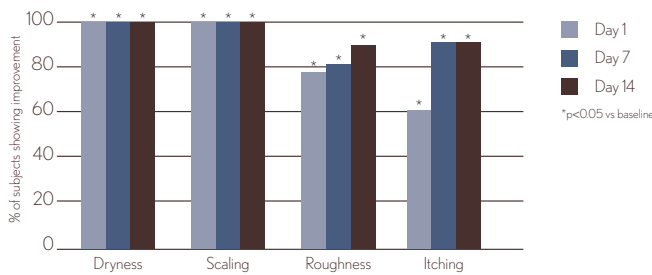


Figure 3. Self Assessments: Improvements in the Appearance and Discomforts Associated with Itchy, Extra-Dry Skin

- Subjects noticed significant visible improvements ($p < 0.05$) in the roughness, dryness and scaling of their skin as early as the Day 1 time point. In addition, itching due to excessive dryness was alleviated after 1 day of use of the triple oat skin protectant lotion. These improvements were all maintained throughout the course of the study.

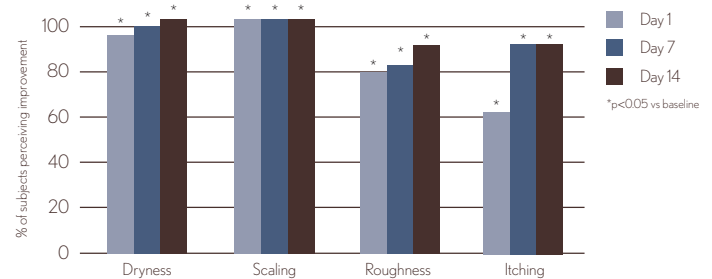


Figure 2. Self Assessments: Reduction of Itch, First 3 Days of the Clinical Study

- Subjects evaluated itch each day prior to the morning application of the triple oat skin protectant lotion and again at 2 and 30 minutes post-application. Starting as early as 2 minutes, and including 30 minutes, after the first application (Day 0) there was a significant improvement in mean itch perception scores when compared to the pre-application score. In addition, itch perception scores significantly improved ($p < 0.05$) after application of the triple oat skin protectant lotion on Days 1-3.

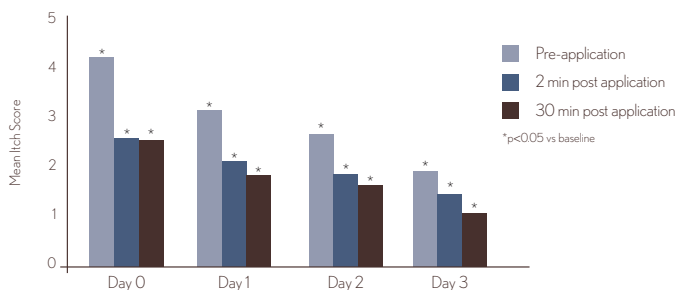
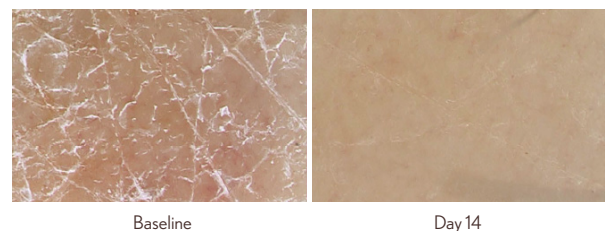


Figure 4. High Resolution Digital Images Before and After Use of the Triple Oat Skin Protectant Lotion

- High resolution digital imaging shows dramatic visible improvements in skin textural properties including dryness and flaking after two weeks of using the triple oat skin protectant lotion.



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CONCLUSIONS

This clinical study demonstrates that this triple oat skin protectant lotion was shown to significantly alleviate the itch ($p < 0.05$) and improve the condition of moderate to severely dry skin. This lotion was well tolerated in subjects with compromised itchy, dry skin and there were no serious treatment related adverse events reported during the study period. Efficacy of this triple oat skin protectant lotion was demonstrated by:

- Clinical evaluations showed that the triple oat skin protectant lotion significantly improved ($p < 0.05$) dryness, scaling and roughness as early as 1 day after use. Improvements were maintained over the duration of the study with continued use of the lotion.
- Subjects perceived a significant mean reduction in itch intensity ($p < 0.05$) after 1 day of use of the triple oat skin protectant lotion. Daily itch diaries showed that the pre-application itch scores at each time point (Days 1–14) all showed a significant mean improvement ($p < 0.05$) when compared to the baseline (Day 0) pre-application of the triple oat skin protectant lotion as demonstrated by the 2- and 30-minute post-application mean itch values when compared to the pre-application value on Days 0 through 3.
- Adhesive skin sampling demonstrated a significant decrease ($p < 0.05$) in both fine and coarse flaking starting after 1 day of application of the triple oat skin protectant lotion. Transepidermal water loss rates at Days 7 and 14 also showed a significant improvement ($p < 0.05$) in the skin barrier when compared to baseline values.
- Separate clinical studies demonstrated that this triple oat skin protectant lotion did not induce dermal sensitization, was non-comedogenic and provided 24-hour moisturization to the skin.

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