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 ORIGINAL ARTICLE

An Over-the-Counter Healing Ointment: Benefits in Dry Skin and Wound Healing

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ABSTRACT

Background: The use of ointments can be beneficial for dry, chapped, or cracked skin and also for supporting wound healing. We describe the results of 2 studies with an over-the-counter healing ointment (HO) to evaluate the effects on skin hydration and in the setting of wound healing after dermatologic procedures.

Methods: Study 1 was a single-center, in-use study using HO on qualified areas at least once daily for 4 weeks in subjects with dry, cracked body skin and self-perceived sensitive skin. Study 2 was a multi-center study of wound healing in subjects using HO on a daily basis after having dermatologic surgical procedures.

Results: In Study 1, there was a significant reduction in skin dryness after 1 and 4 weeks of HO use ($P<0.05$). Image analysis of the skin revealed a significant increase in skin smoothness after the first application of HO in 100% of subjects ($P<0.05$). Tolerability and safety were excellent, and HO was well-perceived by subjects throughout the study. In Study 2, HO improved clinical assessments at all time points compared with baseline with a decrease in erythema, edema, scabbing/crusting, and an improvement in overall wound appearance ($P<0.05$). There was no worsening or significant increase in measures for tolerability parameters at any study visits. Additionally, HO achieved a favorable perception by study subjects.

Conclusions: HO has a well-established safety profile and has been shown to improve both skin hydration and the overall wound healing process after dermatologic surgical procedures.

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INTRODUCTION

Dry skin – leading to a scaly and flaky appearance – is not only common but is also frequently exacerbated by factors such as frequent cleansing and/or use of harsh cleansers and low relative environmental humidity that can have an additive effect on loss of skin hydration.[1] It can be a symptom of skin or systemic diseases but can also occur de novo, particularly in elderly individuals.[1] Dry skin often drives pruritus, which can lead to the itch-scratch cycle that can increase infection risk and worsen other skin diseases.[1] Both dry skin and pruritus are also associated with a negative impact on patients' quality of life.[2] When present in more severe degrees, dry skin can lead to erythema, fissuring, or cracking of the skin.[1] Moisturizers and ointments, often over-the-counter (OTC) products, have long been a mainstay for the treatment of dry, cracked skin and have been shown to have therapeutic benefits.[3-6] When recommending an OTC product for patients, it is important for clinicians to understand the ability of the product to support skin hydration.

Appropriate post-surgical wound care is critical to rapid skin healing without complications. The foundation of wound management is creating an occlusive, clean, and moist environment to reduce the possibility of infection and support the phases of wound healing.[7] To achieve a good condition for wound healing, topical antibiotics, and OTC petrolatum-based ointments are frequently used. Both methods have comparable wound-healing properties, but topical antibiotics can induce drug resistance or cause allergic contact dermatitis.[8-10] Thus, ointments are commonly selected as first-line skin protection after dermatologic procedures.

Cetaphil® Healing Ointment (HO, Galderma Laboratories, LP, Dallas, TX) is an ideal, multi-functional OTC skin protectant containing petrolatum, shea butter, and vitamin E that can address both dry skin and pruritus. Petrolatum provides occlusion, while shea butter softens, smooths, and hydrates the skin, and vitamin E provides support for moisture levels in the skin. Two studies were conducted with HO, the first to

identify the impact on skin dryness and smoothness as well as the subject perception of the product. The second evaluated the efficacy and safety of HO in facilitating wound healing after dermatologic procedures.

MATERIALS AND METHODS

Study 1: Dry Skin

This was a single-center, 4-week clinical study to assess the efficacy and tolerability of HO (Cetaphil® Healing Ointment, Galderma Laboratories, LP, Dallas, TX) on dry, cracked skin.

Subjects applied the test product to the qualified areas daily for 4 weeks and were instructed to reapply throughout the day as needed. Eligible patients were aged 18 to 60 years, had any Fitzpatrick skin phototype, with dry, cracked skin on the body and self-perceived sensitive skin. Subjects were excluded if they had allergies to skin care products, chronic dermatologic diseases, severely dry skin that was bleeding or peeling, or dermal conditions on the test sites that interfered with study assessments. All subjects provided written informed consent to participate in the study.

Clinical evaluation of skin dryness was conducted at visit 1 (baseline) as well as weeks 1 and 4 using a 10-point scale of 0=no dryness to 9=severe scaling/fissuring. The area of dry skin and tolerability was evaluated at all visits. Objective tolerability (erythema, edema, scaling) and subjective tolerability (burning, stinging, itching, dryness) were rated at baseline, week 2, and week 4 using a 4-point scale of 0=none to 3=severe. Safety was monitored for all subjects throughout the study via the collection and evaluation of adverse events (AEs). Macroscopic imaging was performed (VisioScan VC 98, Courage + Khazaka electronic GmbH, Koln, Germany) at baseline, post-1st application, week 3, and week 4; these images were analyzed for smoothness. Subjects also completed a self-assessment questionnaire at all visits.

Descriptive statistics were summarized for all applicable evaluation parameters. All statistical tests were 2-sided at a confidence level of 95% ($P \leq 0.05$). Mean change from baseline for clinical grading and tolerability were performed using Wilcoxon signed rank test, while mean change from baseline for imaging analysis was performed using paired t test.

Study 2: Wound Healing After Dermatologic Procedures

This was a 28-day study with subjects instructed to liberally apply HO to the surgical site twice daily and reapplication and bandaging as needed after dermatologic procedures (Mohs surgery, skin biopsy, or excision on the head/neck or body). To participate, subjects were aged 18 to 85 years, had a clinical diagnosis requiring any of the aforementioned procedures, had no history of allergy or hypersensitivity to cosmetic or skincare products, and had no other factors that would interfere with study assessments. The study was approved by the Institutional Review Boards. All subjects provided written informed consent and the study was conducted in accordance with good clinical practice.

Study evaluations included clinical grading by the investigator of erythema and edema (0=none to 3=severe); overall wound appearance (0=excellent, 1=good, 2=fair, 3=poor); and scabbing/crusting (0=none, 1=slight or up to 30%, 2=moderate or 31% to 60%, 3=extensive or 61% to 90%, and 4=almost complete/complete or 91% to 100%). Half-point scoring was allowed in clinical grading as necessary to better describe the condition. Subjects completed tolerability assessments for burning, itching, and pain (0=none to 3=severe) at the surgical site and completed a self-assessment questionnaire at days 7, 14, and 28 to record the subject's perception of the study product's effect on their wound and overall satisfaction. Standardized photography was performed at all study visits. Safety was monitored for all subjects throughout the study via collection and evaluation of AEs.

A descriptive statistical summary was provided for clinical grading and tolerability assessments and included mean, median, standard deviations, and range of values at all applicable time points. Mean change from baseline (pre-procedure) was estimated for applicable post-baseline time points. Percent mean change from baseline and percent of subjects improved or worsened were also calculated. Questionnaires were tabulated. Two-sided statistical testing was interpreted based on a 5% significance level ($P \leq 0.05$). Mean change from baseline for clinical grading and tolerability were performed using Wilcoxon signed rank test, while favorable response from self-assessment questionnaire was performed using binomial test.

RESULTS

Study 1: Improvement of Dry Skin

A total of 39 subjects were enrolled in the study, with 35 subjects completing the study; the mean age of subjects was 48 years (range 30 to 60 years). The majority (57.1%) were White/Caucasian, 37.1% were Black/African American, and 5.6% were mixed racial background or American Indian/Alaskan native. All Fitzpatrick skin types were included as follows: 8.6% phototype I, 42.9% phototype II, 5.7% phototype III, 5.7% phototype IV, 28.6% phototype V, and 8.6% phototype VI.

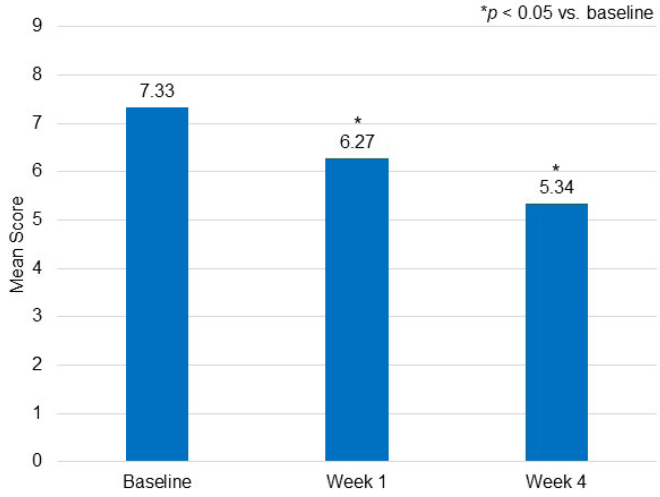
Effectiveness

As shown in Figure 1, there was a significant improvement in skin dryness after use of HO ($P<0.05$ vs baseline for all visits). At baseline, the mean dryness score was 7.3; by week 4, the mean score had decreased to 5.3.

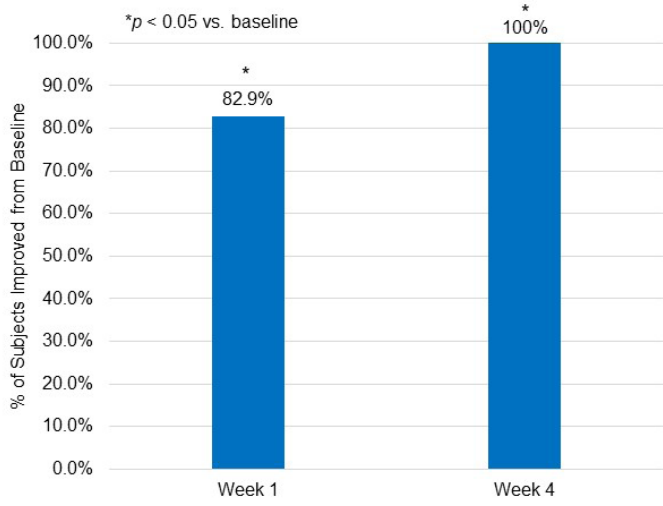
Image Analysis: Increase in Skin Smoothness

Clinical image analysis showed a marked increase in skin

FIGURE 1. Clinical assessment of skin dryness. (A) Improvement in mean score, (B) proportion of subjects experiencing less skin dryness.

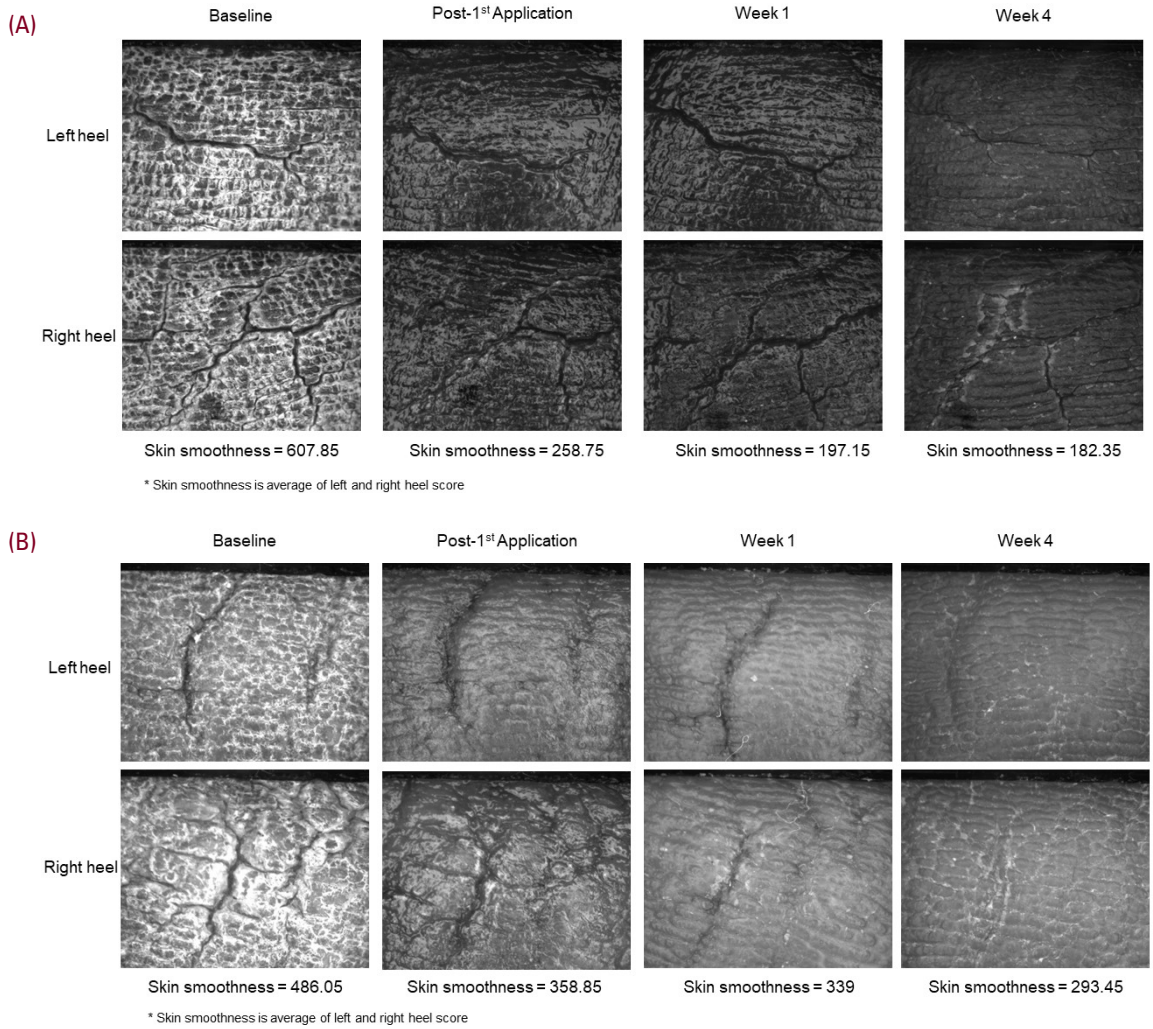


→ Significant improvement in skin dryness after 1 week and 4 weeks of usage.



→ All subjects achieved improvement in skin dryness at the end of the study.

FIGURE 2. Macroscopic images of cracked skin and imaging analysis of skin smoothness in 2 representative subjects.



smoothness after the first application, at week 1 and week 4, with 100% of subjects showing improvement after one application. Mean skin smoothness scores decreased from 520.2 at baseline to 269.4 at week 4 (P<0.05); and there was significant improvement in skin smoothness compared with baseline at all study visits including at the immediate post-application evaluation (P<0.05 for all). Two representative images are shown in Figure 2.

Questionnaire: Favorable Subject Perception

Self-assessment questionnaires revealed a positive perception of HO at each timepoint post-baseline. Immediately after the first application, the majority of subjects reported their skin was nourished (80.0%), felt pleasant (85.7%), and was soothed (82.9%). At week 1, subjects felt their skin texture had improved (88.6%), their skin was relieved (85.7%), and felt softer (85.7%). By week 4, more than 90% reported a noticeable decrease in dryness and fissuring, increased softness, and noticeable increase in hydration and smoothness. HO was perceived to be soothing to dry, cracked skin by 91.4% of subjects. More than 80% of subjects also reported feeling more confident and that their skin quality had improved.

Safety

There were no AEs that were considered related or possibly related to HO. There was no worsening or increase in score for tolerability parameters assessed by the clinical grader (edema, erythema, scaling) and subjects (burning, stinging, itching, dryness) compared with baseline. Therefore, HO was well-tolerated by study subjects.

Study 2: Improved Wound Healing After Dermatologic Procedures

A total of 15 subjects were enrolled in the study with 12 subjects completing the study, with a mean age of 56.3 years and a slight majority of females (53%). The majority of subjects had Fitzpatrick skin phototypes I or II (73%). Surgical procedures included: excision (40%), Mohs surgery (33%), and skin biopsy (27%), which were spread almost equally between the body (53%) and the head/neck (47%).

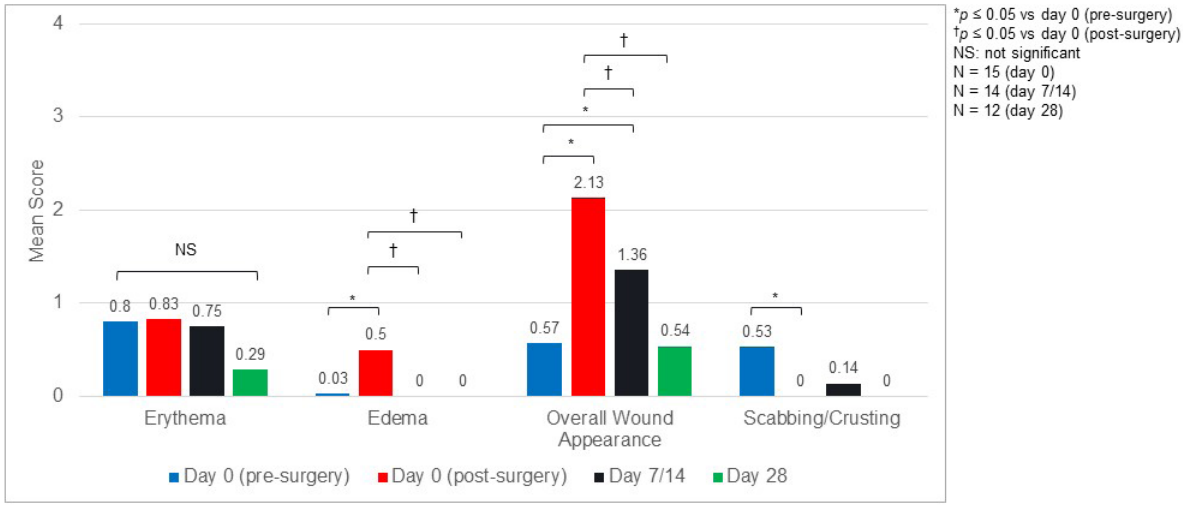
Effectiveness

Wound severity parameters based on mean scores were highest (worst) at the pre- and immediately post-procedure assessments at baseline and decreased (improved) over time (Figure 3). The pre- and post-procedure assessment mean scores for erythema were reduced from 0.8 (pre) and 0.83 (post) at baseline to 0.29 (nearly none/absent) by day 28. Mean edema scores were reduced from 0.5 at immediately post-procedure baseline to 0 at day 7/14, and edema continued to be absent through day 28 (P<0.05). For overall wound appearance, the mean pre-procedure score was 0.57 (excellent/good), which changed to 2.13 post-procedure (slightly greater than fair, P<0.05). Wound appearance improved over time, and by day 28 the score was 0.54 (P<0.05 vs post-procedure baseline). Clinical results are presented in Figure 4.

Questionnaire: Favorable Subject Perceptions

Subjects had very favorable perceptions of HO in the post-surgical setting. At day 7/14, 92.9% of subjects reported the wound felt moisturized, that HO soothed the wound and surrounding skin, and that HO improved the status of the

FIGURE 3. Clinical grading of wound parameters by investigator.



Erythema/edema grading scale: 0=none, 1-mild, 2=moderate, 3=severe; overall wound appearance grading scale: 0=excellent, 1=good, 2=fair, 3=poor; scabbing/crusting grading scale: 0=none, 1=slight, 2=moderate, 3=extensive, 4=almost complete/complete.

FIGURE 4. Standardized photography showing overall wound healing with healing ointment usage for 28 days.

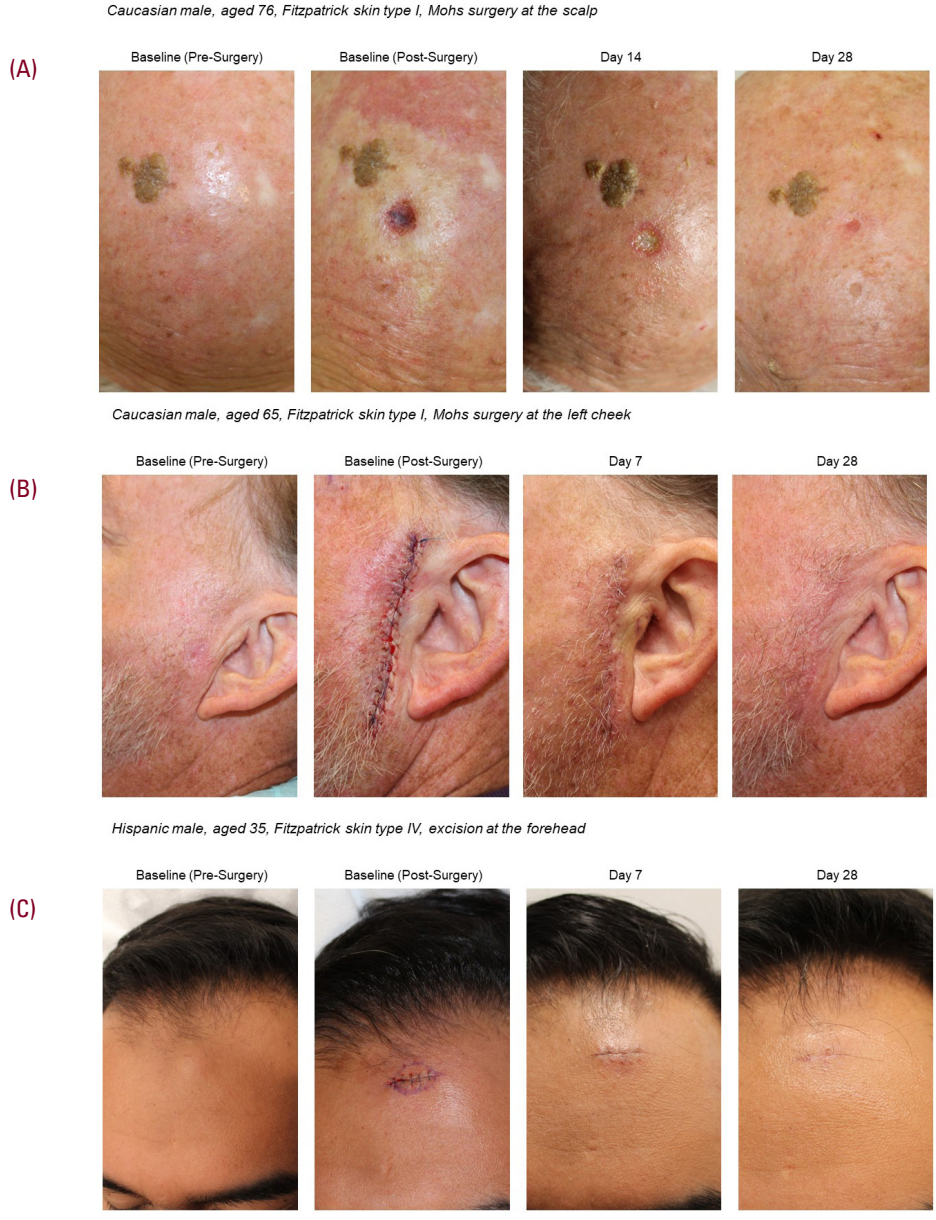
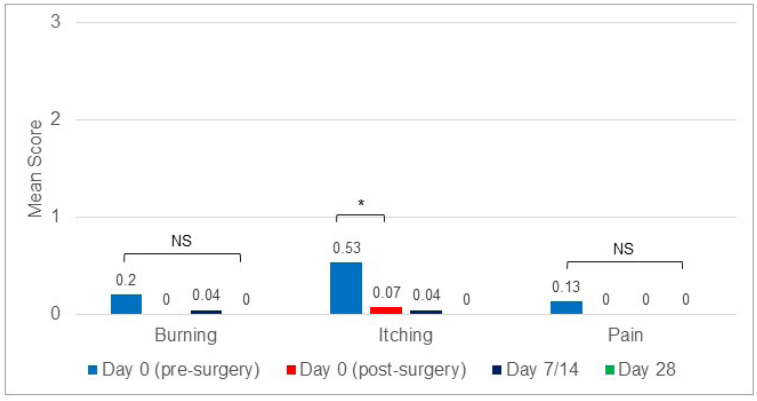


FIGURE 5. Tolerability scoring for subjects using healing ointment.



No worsening or significant increase in score for tolerability parameters by day 28.

wound; while 100% stated that HO did not irritate the wound area and 85.7% felt that HO left the wound feeling pleasant. At day 28, 100% of subjects believed that HO helped the wound heal effectively and provided a protective layer for the wound, and 91.7% said that HO kept the wound surface clean and moisturized. The majority (83.3%) reported that HO did not feel greasy on their skin.

Safety

No adverse events were reported during the study period. HO was well-tolerated by the subjects, with no worsening or significant increase in scoring for tolerability parameters by day 28 (Figure 5).

DISCUSSION

This healing ointment was formulated to heal and soothe extremely dry skin, cracked hands and heels, and other minor skin irritations. HO includes a high concentration of the active ingredient petrolatum (71.5%) to quickly protect/heal dry irritated skin. It also includes shea butter and vitamin E which help to soften, smooth, and hydrate skin as well as improve skin's resilience. Subjects have reported that they like that HO absorbs quickly without leaving behind a greasy residue. HO is formulated to be well-suited for sensitive skin, as it contains no preservatives, lanolin, or fragrances, and is hypoallergenic.[11]

In these studies, HO improved skin dryness and texture, with image analyses showing marked improvements on skin fissuring. The product was safe and well tolerated, and subjects perceived that the product was associated with rapid and lasting benefits for skin smoothness as well as relief of uncomfortable symptoms associated with dry skin and cracking. The properties of HO also make it a good candidate for post-surgical wound care and indeed, as shown by Study 2, HO was well tolerated and demonstrated effectiveness at promoting protection and wound healing following surgical procedures.

Based on the product's attributes and results from these studies, HO was shown to be effective and safe in those with sensitive skin.

DISCLOSURES

Dr Farberg and Ms Palomares have served as consultants for Galderma. Dr Meckfessel, Dr Emesiani, and Dr Nguyen are employees of Galderma Laboratories, LP, Dallas, TX.

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