

# A Novel Approach to Enhancing the Quality and Appearance of Photoaged Skin

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## ABSTRACT

**Background:** Moisturizers create the illusion of smooth, soft skin by placing a temporary film over the skin surface or by imparting a transient hydration benefit that does not clinically improve the quality or appearance of skin.

**Objective:** The objective of this 8-week study was to assess the clinically relevant effects of a 3-step facial treatment program to improve the multiple qualities of photoaged skin.

**Methods:** Thirty-five female subjects were evaluated at baseline and after 2, 4, and 8 weeks. Measures included investigator and subject assessments and noninvasive measures of skin hydration, elasticity, sebum, and exfoliation.

**Results:** This novel approach resulted in significant objective, subjective, and bio-instrumental improvements in the appearance and quality of photoaged skin. At the end of the study, the investigator efficacy assessments demonstrated significant reduction in roughness, sebum, redness, and dirt with improvement in skin dryness, moisturization, clarity, smoothness, softness, radiance, and overall appearance without use of a moisturizer. The treatment products were well-tolerated.

**Conclusion:** Use of this novel approach safely and effectively improved multiple clinical endpoints of photoaged skin through cleansing, aggressive exfoliation, and sebum reduction in the absence of a traditional moisturizer.

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## INTRODUCTION

Well-moisturized, hydrated, healthy skin is typically described as smooth and soft. Low transepidermal water loss (TEWL) is an instrumental indication the skin is well-hydrated with an intact barrier;<sup>1</sup> however, unexfoliated skin can exhibit low TEWL while possessing poor tactile and visual properties. Retained rough skin scale can camouflage underlying smooth soft skin. Moisturizers are the basis for most anti-aging skin regimens, although many moisturizers create temporary smooth, soft skin by placing a film over the skin surface, creating greater adhesion between the desquamating corneocytes.<sup>2,3</sup> These qualities are beneficial from a cosmetic standpoint, but are temporary, lasting only until the film is disrupted or removed by washing.<sup>1</sup> This explains why traditional anti-aging moisturizers must be used daily because the moisturizer does not address the cause of the rough skin.

The following research evaluated a novel facial treatment system comprised of 3 steps: cleansing with lauryl oat amino acids and a blend of botanical extracts to remove surface debris; skin resurfacing with magnesium oxide crystals, *Melaleuca alternifolia* (tea tree) leaf oil, and glycerin to restore smoother skin texture; and oil control pads containing 2% salicylic acid and glycolic acid to provide exfoliation and remove surface sebum.

## METHODS

### Study Subjects

Thirty-five female subjects with Fitzpatrick skin types I–III and approximately 50 years of age were enrolled. The subjects denied receiving regular facial treatments or visiting skincare

professionals or dermatologists. Subjects had skin dullness, redness not related to rosacea, oiliness, rough or uneven skin texture, and dyspigmentation.

Exclusion criteria included the presence of skin disease, use of systemic or topical medications that could influence the study outcome, hypersensitivity to any of the ingredients of the study products, pregnancy or planned pregnancy, breastfeeding, clinically significant unstable medical disorders, or any other illness or condition that could jeopardize the objectives of the study.

Subjects of childbearing potential expressed their willingness to use an acceptable form of birth control during the study and to use only the assigned study products during the study, except for their normal non-medicated facial cosmetics. Each subject provided signed informed consent and a photography consent (Concordia Clinical Research's Institutional Review Board, Cedar Knolls, NJ) prior to participation.

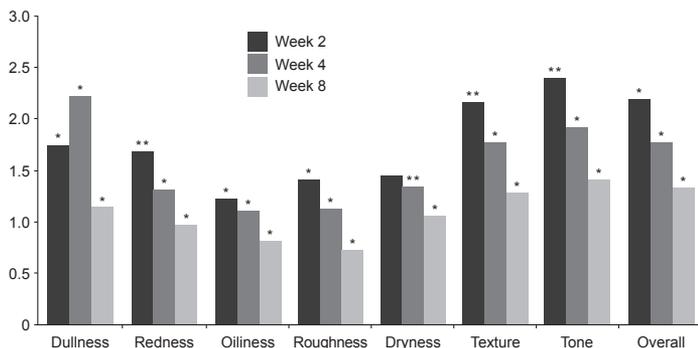
### Study Materials

Components of the Treatment Program (ZO<sup>®</sup> Getting Skin Ready™ [GSR™] Treatment Program; ZO Skin Health, Inc., Irvine, CA) included a mild foaming facial cleanser, an exfoliating scrub, and oil control pads.

### Efficacy and Tolerability Measures

Digital images were obtained of the frontal face and 45° right and left angles, using six standardized lighting modes to ana-

**FIGURE 1.** Subject self-assessment questionnaire. The subject self-assessment questionnaire revealed significant improvement in each of the eight measures of skin quality. \*denotes  $P<0.001$ ; \*\*denotes  $P<0.05$ .



lyze the skin for roughness/texture, pigmentation, pore count/size reduction, and redness (Visia-CR™ Facial Imaging System; Canfield Scientific, Parsippany, NJ). The investigator assessed treatment efficacy by using the following parameters: skin roughness/texture, pigmentation, pores, hydration, elasticity, redness, sebum, dirt removal, moisturization, clarity, smoothness, softness, firmness, texture, radiance, suppleness, and overall skin quality.

Subjects rated treatment efficacy by using the following parameters: dullness, redness, oiliness, roughness, dryness, texture, tone, and overall skin quality. Each parameter was rated on a 5-point scale ranging from 0 (none) to 4 (severe) at baseline and weeks 2, 4, and 8. Using a second Subject Self-Assessment Questionnaire, subjects were asked to rate other aspects of skin quality at weeks 4 and 8, including appearance, smoothness, oiliness, pores, texture, color, and health, using the 5-point scale of 1 (strongly disagree/worse) to 5 (strongly agree/much improvement).

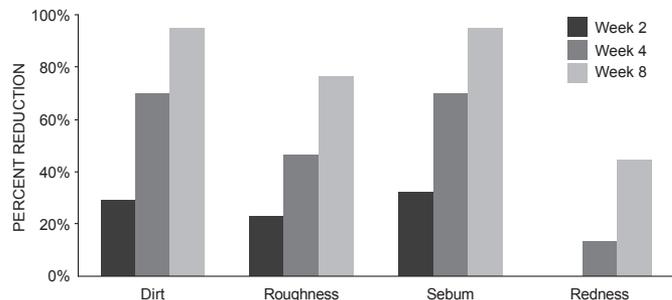
Objective skin assessments were pin probe hydration (DermaLab Corneometer®; Hadsund, Denmark), elasticity (DermaLab Elasticity®; Hadsund, Denmark), sebum (Courage + Khazaka Sebumeter®; Cologne, Germany), and dirt removal (CuDerm D-Square®; Dallas, TX).

The investigator and subjects rated tolerability by using the following parameters: stinging, burning, itching, tightness, redness, flaking, roughness, irritation, dryness, and overall sensitivity. Efficacy and tolerability parameters were rated on a 5-point ordinal scale 0 (none) to 4 (severe) at baseline and weeks 2, 4, and 8.

#### Study Procedures

During the baseline study visit, the investigator completed a skin condition and tolerability assessment and obtained a med-

**FIGURE 2.** Investigator assessments. Improvements remained significant at week 8 ( $P<0.001$ ).



ical history. Noninvasive skin assessments performed at that time included skin hydration, elasticity, sebum, and cleanliness. Subjects were dispensed the study products and instructed on how to apply the cleanser each morning, followed by a scrub with the exfoliating polish and then an application of the oil control pads. Each evening, subjects were to cleanse the skin again and reapply the oil control pads. Subjects were permitted to use their own self-selected SPF 30+ sunscreen as needed. A daily diary was used to confirm compliance with study procedures.

#### Study Endpoints

The primary efficacy endpoint was the change in skin assessment following treatment with the study products. The safety endpoint was the overall incidence of all adverse events reported during the study, with tolerability based on investigator assessments of skin irritation.

#### Statistical Analysis

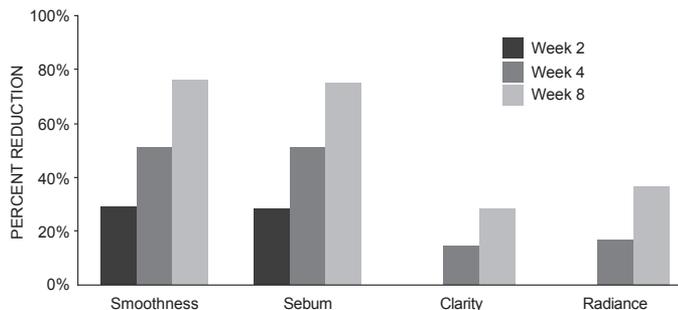
A Wilcoxon signed-rank two-tailed paired test was used for longitudinal analysis of all ordinal data as compared to baseline. A Student's t-test was used for all numerical instrumental data. Statistical significance was defined as  $P<0.05$ .

## RESULTS

Among the 35 enrolled subjects, two withdrew from the study. The remaining 33 subjects were Caucasian with a mean age of 51.1 years. No compliance issues were noted, and all collected data were included in the final analysis.

#### Subject Assessments

The results of the subject self-assessment questionnaires revealed significant improvement in each of the eight measures of skin quality (Figure 1). There were also consistent improvements in subject-assessed measures of skin quality, including appearance, smoothness, oiliness, pores, texture, color and

**FIGURE 3.** Investigator assessments. Improvements remained significant at week 8 ( $P<0.001$ ).

overall health. There were significant improvements in hydration ( $P=0.058$ ) and sebum ( $P<0.001$ ) at week 4 with significant improvements in sebum ( $P<0.001$ ) and cleanliness ( $P=0.009$ ) at week 8.

### Investigator Assessments

Subjects returned for their first investigator evaluation at week 2. The efficacy assessments revealed significant reductions in baseline skin roughness (23%) and sebum (33%), along with improvements in skin cleanliness (29%), skin dryness (17%), smoothness (28%), softness (29%), and overall appearance (13%).

By week 4, the investigator efficacy assessment demonstrated continued reduction in roughness (45%), sebum (69%), redness (15%), and dirt (68%; Figure 2) with improvement in skin dryness (37%), moisturization (44%), clarity (16%), smoothness (52%), softness (51%), radiance (17%), and overall appearance (24%). These improvements continued to remain significant at week 8 ( $P<0.001$ ; Figure 3).

### Instrumental

The noninvasive instrumental assessments parallel the investigator and subject evaluations. Cleanliness measurements, which were sticky tapes pressed against the skin and designed to assess retained scale, demonstrated a 24% reduction ( $P=0.009$ ) in facial skin scale after 8 weeks of use of the regimen. Facial sebum was reduced by 33% ( $P<0.001$ ) at 8 weeks. No statistically significant changes were seen in elasticity or corneometry, both measures of skin moisturization. Facial imaging revealed improvements in pore size/pore count and skin roughness (Figure 4). These findings confirmed that the improvement seen in skin smoothness and softness was not related to enhanced moisturization, but rather to improved skin exfoliation.

### Tolerability

Two subjects withdrew from the study due to facial stinging and burning. These subjects used the exfoliant scrub too aggressively, as determined by the dermatologist investigator.

**FIGURE 4.** Facial imaging. Facial imaging revealed improvements in pore size/pore count and skin roughness.

While the magnesium oxide particles produced superior exfoliation, excessive pressure while rubbing the product over the face can damage the skin barrier, resulting in undesirable skin sensitivity. Careful counseling by the dermatologist is required before embarking on this skincare exfoliation regimen to prevent skin barrier damage.

## DISCUSSION

This research demonstrated that multiple progressive and sustained improvements in the appearance and quality of skin can be achieved with a comprehensive cleansing, exfoliating, and oil controlling regimen. No changes in skin water content were observed with either corneometry or elasticity measurements, indicating the absence of a moisturization effect, yet the investigator and subject assessments perceived an improvement in skin softness and smoothness. Cleanliness measurements demonstrated a 24% reduction in facial skin scale, accounting for the smoother, softer skin appearance of the photoaged skin from the 3-step regimen. The initial cleansing step wetted the skin and removed excess sebum through the use of the synthetic detergents, sodium laureth sulfate, and cocamidopropyl betaine. This wetting was necessary to soften the corneocytes for desquamation by the exfoliating skin polish. Mechanical exfoliation was induced by sodium bicarbonate and magnesium oxide particles within the scrub. Finally, chemical exfoliation and oil control are achieved with pads containing salicylic acid, mandelic acid, urea, witch hazel, and *Rosa canina* (dog rose) fruit extract. The oil control pads also incorporated botanical anti-inflammatory agents *Rosa canina* fruit (dog rose), *Phellodendron amurense* bark (amur cork tree), *Hordeum distichon* (barley), and *Camellia sinensis* leaf (green tea). The pads also contained *Spiraea ulmaria* leaf, a natural source of salicylates.

Moisturizers are the basis of most anti-aging regimens because they place a film over the skin surface, or deliver transient hy-

gration effects that create the illusion of immediately improved skin roughness. The tactile smoothness created by the moisturizer is the result of friction reduction between the finger and the skin created by ingredients that induce skin slip, such as dimethicone, cyclomethicone, and cyclopentasiloxane. Anti-aging moisturizers also function as emollients by temporarily smoothing down desquamating skin scale to make the skin feel soft. Dimethicone, cyclomethicone, and cyclopentasiloxane also function as emollients, in addition to ingredients such as cetyl alcohol, propylene glycol, octyl palmitate, isopropyl stearate, and isopropyl palmitate. Placing a film over the skin surface and smoothing down desquamating corneocytes are temporary cosmetic improvements that are only realized while the film is continuous over the skin surface. Rubbing and water contact will immediately destroy the film or remove transient emollients and the cosmetic effect will also immediately disappear. Thus, the skin is not actually smooth and soft; it only appears smooth and soft.

The goal of this research was to comprehensively address the overall quality and appearance of photoaged skin without moisturization in a more meaningful and functional manner. Wetting the skin with water/cleanser, followed by mechanical exfoliation and an oil control pad achieved smoother, softer skin without a moisturizer. Instead of smoothing the skin scale repeatedly with daily applications of a moisturizer, the skin scale was permanently removed to initiate cellular renewal. The improvement was observed as early as week 2, with continued cumulative improvement noted until the study terminated at week 8. Continued use of the 3-step regimen would be required, however, as the skin scale is continually produced and accumulating.

Excess sebum output can accentuate the appearance of pores and retained skin scale. Sebum also acts as a wetting agent, similar to the exogenous emollients previously discussed, extending the retention time of skin scale. Removal of sebum from the skin surface is therefore essential to optimize exfoliation. These were the roles of the oil control pad containing astringent ingredients.

The efficacy of the 3-step regimen created an opportunity to evaluate the difference between the appearance of moisturized photoaged skin, when a product film or transient emollient moisturizers is covering the skin surface, and unadorned, smooth, soft, photoaged skin. Well-moisturized skin, through the use of a moisturizer, does not yield permanence of effect, and is not functionally relevant. The 3-step regimen created functionally smooth, soft skin that was a reality rather than a cosmetic illusion.

## CONCLUSION

The 3-step treatment resulted in multiple statistically significant

improvements in photoaged skin that a common moisturizer alone cannot deliver. At week 4, subjects demonstrated reductions in skin roughness, sebum, redness, with improvement in skin dryness, the appearance of moisturization, clarity, smoothness, softness, radiance, and overall appearance. These improvements progressively continued throughout the study, maintaining significance at week 8 with minimal tolerability issues. This research demonstrated that multiple improvements in skin quality and appearance can be achieved through a cleansing, exfoliating, and oil control regimen rather than temporary wetting of skin scale through the use of traditional moisturizers.

## DISCLOSURE

Zoe Diana Draelos MD received funding from ZO Skin Health to conduct the research.

## ACKNOWLEDGMENT

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