Efficacy and Tolerability of a Double-Conjugated Retinoid/Alpha Hydroxy Acid Cream and a Complementary Skincare Regimen in a Series of Subjects of Varying Skin Types with Mild to Moderate Blemish-Prone Skin

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INTRODUCTION

- Blemishes are one of the most common skin conditions treated by dermatologists.[1,2]
- Retinoids, alpha hydroxy acids (AHAs) and beta hydroxy acids (BHAs; salicylic acid) are often used first-line and in combination with other products to improve skin clarity.[1,3,4]
- A balance must exist in reducing sebum and improving skin clarity, while minimizing irritation and disruption of the skin barrier. Further, darker skin tones are prone to Post-inflammatory Hyperpigmentation (PIH).[2,3]
- A formulation leveraging double-conjugated retinoid technology with additional lactic acid, salicylic acid and other key ingredients to support the skin barrier (AHARet-SA) demonstrated early improvements in the appearance of skin clarity and pores in a study population that included subjects with predominantly lighter skin tones.[5]
- Herein, we describe the evaluation of AHARet-SA Serum and a complementary skincare regimen that included exfoliating peel pads comprised of a double-conjugated retinoid/AHA and a triple-acid blend (glycolic, lactic and salicylic acids), a cleansing gel, moisturizer and sunscreen in a series of subjects with varying skin types and mild to moderate blemish-prone skin.

OBJECTIVES

- Evaluate the efficacy, tolerability and subject satisfaction of AHARet-SA and a complementary skincare regimen in a series of subjects with varying skin types and mild to moderate blemish-prone skin.

METHODS

- This single-center, open-label clinical trial evaluated the efficacy, tolerability and subject satisfaction of a skincare regimen in subjects 30-55 years of age with mild to moderate blemish-prone skin according to the Investigator Global Assessment 5-point scale (0 [Clear skin; no inflammatory or noninflammatory lesions] to 4 [Severe; up to many noninflammatory and inflammatory lesions/no more than a few nodular lesions]).
- This 12-week regimen included:
  - AM: Cleansing Gel and a Mineral-based Sunscreen Stick (SPF 56)
  - PM: Cleansing Gel, Exfoliating Peel Pads 3x/week (M-W-F) for the first 8 weeks; 2x/week (M & F); AHARet-SA Serum
  - AM/PM (Optional): Lightweight Moisturizer
- Exclusion criteria included dermatological disorders (e.g., severe acne vulgaris), autoimmune diseases, acute illness, open wound/lesion or irritated skin in the area to be treated; and, subjects who were pregnant, lactating or planning a pregnancy during the study period.
- Subjects were deemed eligible for inclusion in the study following a 2-week wash out period of any cosmetic product containing AHAs, BHAs, peptides, growth factors, skin lightening/brightening agents, non-prescription vitamin A derivatives, plant stem cell extracts, vitamin C-based topical antioxidants, other antioxidants or like products; and following a 4-week wash out period of products containing prescription retinoids or hydroquinone.
- Subjects who had taken Isotretinoin within the prior 6 months or had undergone chemical peels, microdermabrasion, microneedling, or a like procedure within the prior 3 months, were also excluded from study participation.
- Improvements from baseline in Skin Clarity were based on the use of the 5-point Investigator Global Assessment Scale (0 [Clear] to 4 [Severe]) at 4, 8, and 12 weeks.
- Changes in the appearance of Skin Tone, Pore Size, Fine lines and Wrinkles, Erythema, and Dryness/Flaking were assessed from baseline at 4, 8, and 12 weeks using a 6-point categorical scale (0 [None] to 5 [Severe]).
- Digital images were obtained at baseline, 4, 8, and 12-weeks using Canfield VISIA Imaging Systems (Canfield Scientific Inc., Parsippany, NJ).
- Subjects completed self-assessment questionnaires through week 12.
- Adverse Events (AEs) were captured throughout the study period.

RESULTS

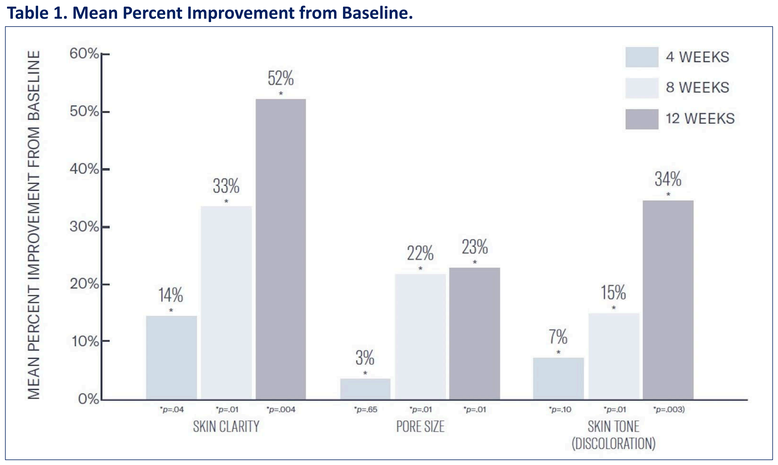
DEMOGRAPHICS

- Eleven (11) subjects were enrolled, and 8 subjects completed the study.
- All subjects were female with a mean age of 38 years.
- Fifty-five percent (55%) of subjects were FST IV, 27% were FST V, and 1 subject each was FST I and FST III.
- 82% of enrolled subjects were African American.

EFFICACY

- As early as week 4, significant mean percent improvement from baseline in Skin Clarity occurred (14%; *p*=.04) with continued, progressive improvement through week 12 (52%; *p*=.004) (Table 1).
- There were significant improvements in the appearance of Skin Tone (15%; *p*=.01) and Pore Size (22%; *p*=.01) by week 8 with continued improvements through week 12 (34%, *p*=.003; 23%, *p*=.01, respectively; Figures 1-3).
- Visible improvements in the appearance of PIH were observed.
- For Dryness/Flaking, the mean score at baseline was 0 (none), and only minor increases were observed over time.
- Mean improvement in Erythema and Fine Lines and Wrinkles was minimal throughout the study; however, this may be due to low mean scores at baseline in both categories, and a younger subject demographic.
- By week 12, 75% of subjects demonstrated a ≥1-grade improvement in Skin Clarity, with 63% demonstrating ≥2-grade improvement from baseline.

Table 1. Mean Percent Improvement from Baseline.



SUBJECT SATISFACTION

- Subjects reported high levels of satisfaction throughout the study period.
- After only 4 weeks, 80% of subjects reported their skin felt less oily or greasy, and healthier looking with less visible pores.
- After 12 weeks, 88% of subjects reported the overall appearance and texture of their skin improved, noting their skin appeared less blotchy, more even looking, with fewer blemishes or breakouts, and less shiny.
- All subjects reported they would continue to use the products at the conclusion of the study.

TOLERABILITY

- All AEs were mild and transient, and possibly related to study products.
- AEs included mild dryness, stinging/burning (with initial application), breakouts, and itching.
- No subject discontinued the study owing to an AE.

Figure 1: Improvement from baseline to week 4.

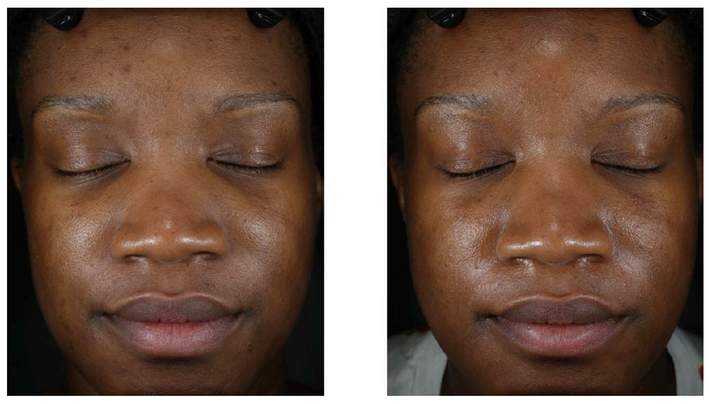


Figure 2: Improvement from baseline to week 8.

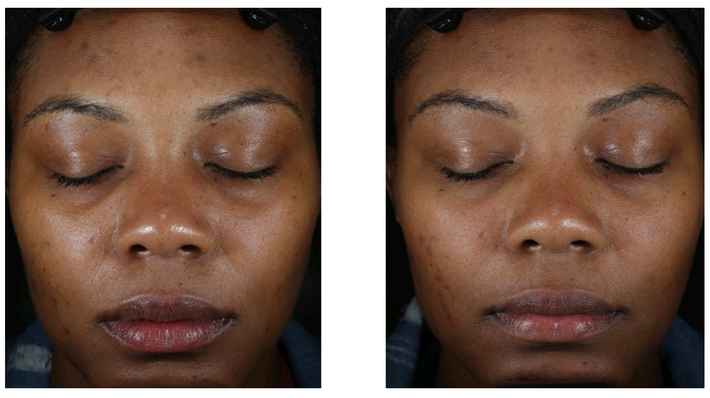
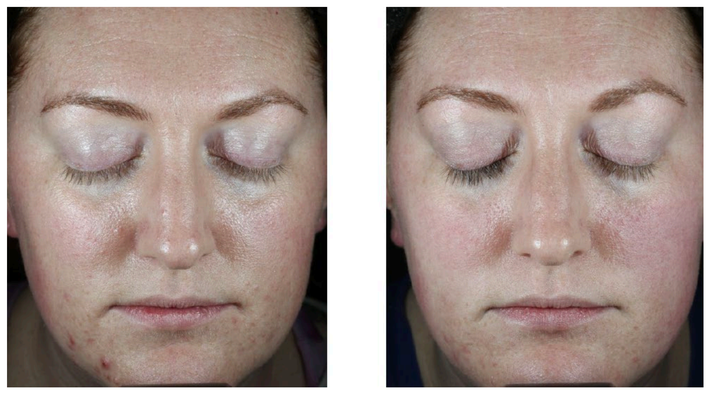


Figure 3: Improvement from baseline to week 12.



CONCLUSIONS

- A skincare regimen comprised of products formulated with a double-conjugated retinoid/AHA, lactic, glycolic and salicylic acids and additional ingredients to support the skin barrier demonstrated visible improvements in Skin Clarity in subjects with predominantly FST IV and V and mild to moderate blemish-prone skin.
- Early significant improvements from baseline in Skin Clarity were demonstrated with continued, progressive improvement through week 12.
- Significant improvements in Skin Tone and Pore Size occurred by week 8 with continued improvements through week 12.
  - Visible improvements in the appearance of PIH were observed.
- Subjects reported high levels of satisfaction with the study products throughout the study period.
- The regimen was well tolerated and no subject discontinued use of study products due to an AE.

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Dr. Hartman and Dr. Dyck served as study investigators.
Ms. Nelson is an employee of skinbetter science.

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