doi:10.36849/JDD.9437

 ORIGINAL ARTICLE

An Investigator-Developed Regimen for Treatment and Prevention of Post-Inflammatory Hyperpigmentation in Skin of Color

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ABSTRACT

Background: There is an unmet demand for a post-inflammatory hyperpigmentation (PIH) treatment and prevention that is not only effective and accessible, but also safe to use in darker skin tones.

Objective: To evaluate the safety and efficacy of a comprehensive investigator-developed skincare regimen in reducing post-inflammatory hyperpigmentation (PIH) and improving patient-reported satisfaction in skin of color patients.

Materials and Methods: In this single-center, prospective, non-blinded, non-randomized 12-week study, ten participants with a diagnosis of PIH and identified as skin of color received two SkinCeuticals Pigment Balancing Peel treatments at baseline and week 6, Discoloration Defense Serum, Hydrating B5 Gel, LHA Cleanser Gel, and Daily Brightening ultraviolet (UV) Defense Sunscreen. Assessments were conducted at baseline, week 6, and week 12. The primary endpoint was the change in satisfaction with overall facial appearance post-treatment. Secondary endpoints included changes in the Dermatology Life and Quality Index (DLQI), FACE-Q social and psychosocial functioning, erythema and melanin index, and expectations and satisfaction with treatment.

Results: Participants reported significantly greater satisfaction with overall facial appearance at 12 weeks post-treatment compared to baseline ($P<0.001$). Improvements were also observed in quality of life, with Dermatology Life Quality Index scores decreasing significantly ($P<0.001$). Patients reported enhancements in skin texture and tone, social confidence, and psychological functioning. High levels of satisfaction with the treatment regimen and minimal adverse effects were noted across participants.

Conclusion: This investigator developed a comprehensive skincare regimen that combines a series of chemical peels with a daily at-home treatment regimen is a safe and effective approach for improving post-inflammatory hyperpigmentation, enhancing satisfaction with facial appearance, and promoting psychosocial well-being in individuals with skin of color.

J Drugs Dermatol. 2026;25(4):330-336. doi:10.36849/JDD.9437

INTRODUCTION

Post-inflammatory hyperpigmentation (PIH) is a common acquired condition resulting from an overproduction of melanin or abnormal deposition of melanin in the epidermis or dermis following inflammation.[1] PIH can appear following several types of inciting inflammatory factors, such as acne, atopic dermatitis, burns, wounds, insect bites, allergic reactions, or psoriasis.[2] PIH can be difficult to treat and impact patients' self-esteem.[3] This condition can improve spontaneously, but usually takes months to years to fade, creating a need for long-term treatment.1 PIH is particularly prominent in the skin of color, greatly affecting quality of life and causing profound psychosocial distress.[1,3,4] One study found that 54% of patients felt embarrassment due to their hyperpigmentation with 22% experiencing a severe negative impact on their quality of life.[5] Another study found 51% of participants endorsing their PIH as more bothersome than the initial cause.[6]

The estimated prevalence of PIH among African Americans is reported to be as high as 9.99%.[7] PIH is one of the leading causes for cosmetic consultation, and accounts for the high demand for effective skin lightening therapies.[8] In 2022, the pigmentation disorders treatment market was estimated to be valued at 6.8 billion USD and is growing in demand.[9] The current treatments for PIH include topical lightening agents such as hydroquinone combined with a retinoid and steroid.[1] However, hydroquinone is associated with significant side effects such as skin lightening and permanent discoloration to the skin and ochronosis, limiting the ability to provide effective and well-tolerated treatment.[10] Steroids are also ineffective for long-term use due to the side effect of skin atrophy.[10] There is a lack of strong therapeutic options for treating PIH that are well tolerated, safe, effective, and accessible. In this study, we investigated the safety and efficacy of a comprehensive skincare regimen in the treatment of PIH among skin of color patients.

TABLE 1.

Eligibility Criteria	
Inclusion Criteria	**Exclusion Criteria**
• Men and women ages 18+ • Clinical diagnosis of post-inflammatory hyperpigmentation • Non-Caucasian • Fitzpatrick skin types IV-VI • Available and willing to comply with study instructions and attend all study visits • Able and willing to provide written and verbal informed consent	• Subject has any skin pathology or condition that could interfere with the evaluation of the test products or requires the use of interfering topical or systemic therapy. • Caucasian/ Non-Hispanic • Subject has any condition which, in the investigator's opinion, would make it unsafe for the subject to participate in this research study. • Pregnant, lactating, or is planning to become pregnant during the study. • Subject is currently enrolled in an investigational drug or device study. • Subject has received an investigational drug or has been treated with an investigational device within 30 days prior to the initiation of treatment (baseline). • Study participant has facial hair that could interfere with the study assessments in the opinion of the investigator. • Study participant is unable to communicate or cooperate with the investigator due to language problems, poor mental development, or impaired cerebral function. • Subject has known hypersensitivity or previous allergic reaction to any of the active or inactive components of the test articles. • Subject has the need or plans to be exposed to artificial tanning devices or excessive sunlight during the trial.

MATERIALS AND METHODS

Study Design

This single-center, prospective, non-blinded, non-randomized 12-week clinical study was conducted at the New York Harbor Veterans Affairs Brooklyn Campus between March and July 2025. The study protocol was approved by the New York Harbor Veterans Affairs Institutional Review Board, and all participants provided written informed consent prior to participating in this study.

Patients

Eligible participants were adults over the age of 18 years old with a clinical diagnosis of PIH and identified as skin of color and are Fitzpatrick skin types IV-VI. Detailed inclusion and exclusion criteria are listed in Table 1.

Study Products and Treatment Regimen

Participants received a comprehensive skincare regimen consisting of SkinCeuticals products (L'Oréal USA), including two in-office Pigment Balancing Peel treatments administered by a board-certified dermatologist, once at the initial study visit and again at week 6. This chemical peel contains 40% unbuffered glycolic acid, 10% citric acid, 27% vitamin C, and 4% emblica. One week following the baseline peel, participants began a twice-daily at-home regimen for 12 weeks, including the products detailed in Table 2.

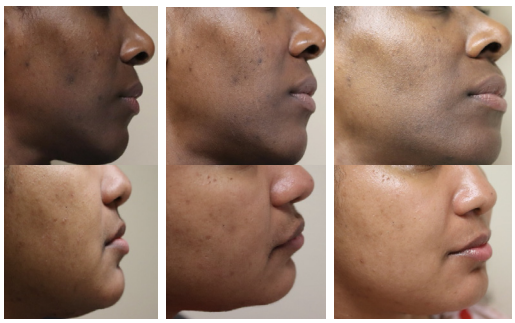
Efficacy Assessments

To evaluate the efficacy of the comprehensive skincare regimen, assessments were performed at baseline, week 6, and week 12. The primary outcome was the change in patient satisfaction with facial appearance from baseline to week 12, measured using the FACE-Q Satisfaction with Facial Appearance Overall Scale. Raw scores were converted to a 0–100 scale using the Rasch transformation, with higher scores indicating greater satisfaction. Secondary outcome measures included changes in quality of life as assessed by the Dermatology Life Quality Index (DLQI), which ranges from 0 to 30, with lower scores indicating better quality of life. Additional FACE-Q Aesthetic Scales were used to evaluate patient-reported satisfaction with treatment, psychological and social functioning, and overall outcome satisfaction.

TABLE 2.

Key Ingredients of the Skinceuticals Products Used in the Treatment Regimen	
Product	**Key Ingredients**
Discoloration Defense Serum	Tranexamic acid, niacinamide, kojic acid, hydroxyethylpi-perazine ethane sulfonic acid
LHA Cleansing Gel	Lipo-hydroxy acid, glycolic acid, salicylic acid, glycerin, sorbitol
Hydrating B5 Gel	Hyaluronic acid, panthenol (provitamin B5)
Daily Brightening UV Defense Sunscreen SPF 30	Broad-spectrum UV filters, tranexamic acid, niacinamide, phenylethyl resorcinol

FIGURE 1. Clinical improvement in PIH over 12 weeks of treatment. Standardized photographs of a participant at baseline (left), week 6 (middle), and week 12 (right) demonstrate progressive reduction in hyperpigmented lesions and improved skin tone uniformity.



At each study visit, skin measurements were performed using the Mexameter® (Courage + Khazaka, Cologne, Germany), a narrow-band reflectance spectrophotometer. Values for melanin and erythema index were recorded at predetermined facial regions where the patient had the most PIH. Three readings per site were averaged for accuracy. These measurements provided quantitative data on pigmentary changes and skin tone evenness throughout the treatment period. The Mexameter outputs unitless values: melanin index values typically range from 0 to 1,000+, with higher scores indicating increased pigmentation, while erythema index values range from 0 to 999, reflecting the degree of skin redness or inflammation. Standardized digital photography using the TwinFlash RL Clinical Camera (CanfieldSci, Parsippany, NJ) was captured at each visit. Consistent lighting, camera settings, and patient positioning were maintained to ensure comparability over time (Figure 1).

Statistical Analysis

All statistical analyses were conducted using Microsoft Excel (Microsoft Corporation, Redmond, WA). Descriptive statistics, including means and standard deviations (SD), were calculated for all continuous variables. To evaluate treatment efficacy, paired t-tests were performed to compare values between time points (baseline vs. week 6, and week 6 vs. week 12) for the following outcomes: FACE-Q Satisfaction with Facial Appearance scores, DLQI scores, and Mexameter® indices (melanin and erythema index). A two-tailed P-value < 0.05 was considered statistically significant. The raw scores of the primary outcome measure (FACE-Q Satisfaction with Facial Appearance Scale) were converted into a standardized 0–100 scale using the Rasch transformation method before analysis. Only participants who completed both baseline and follow-up assessments were included in the final analysis.

Adverse Events

Participants were closely monitored for the occurrence of adverse events (AEs) throughout the study period. They were instructed to record any treatment-related symptoms or concerns in a study diary and to promptly report any emergent issues to the research team.

RESULTS

Participants

Ten participants were enrolled and received the study treatment regimen. The majority were female (90%), and most identified as Black or African American (80%), with the remaining identifying as Hispanic or Latino (20%). The mean age was 47.1 years (range:

TABLE 3.

Baseline Demographics of Participants	
Characteristic	**Total (n = 10)**
Age in years, mean ± SD	47.1 ± 13.23
Sex, n (%)	
Female	9 (90%)
Male	1 (10%)
Race and ethnicity, n (%)	
Black or African American	8 (80%)
Hispanic or Latino	2 (20%)
Fitzpatrick Skin Types, n (%)	
Type IV	2 (20%)
Type V	5 (50%)
Type VI	3 (30%)

TABLE 4.

Patient Testimonials on Efficacy and Tolerability of the Skinceuticals Chemical Peels and Product Regimen	
Patient Number	**Patient Reviews**
1	I love the overall end result my face is even tone and smooth.
2	My face is glowing.
3	No comment.
4	No side effects. I enjoyed using the products.
5	Products were good. Didn't like the after effects of the peel.
6	I love my outcome! When starting the regimen my skin was very dry and had to adjust to the moisturizer but my skin did within a week.
7	Overall good experience, products were very hydrating especially discoloration defense serum and sunscreen.
8	I love the outcome. I feel my face is glowing.
9	I definitely noticed a difference in the dark spots lightening or appearing lighter instead of darker.
10	No comment.

30 to 70 years). Fitzpatrick skin types included Type IV (20%), Type V (50%), and Type VI (30%) (Table 3). All participants completed the study per protocol, with no participants lost to follow-up.

Safety and Tolerability

No severe AEs were reported during the study. Mild, treatment-related AEs were observed in 3 participants (30%) following administration of the Pigment Balancing Peel. Reported symptoms included transient redness, peeling, and burning. All events resolved spontaneously without the need for medical intervention and resulted in no long-term effects. No adverse events were reported with the use of the at-home products, including the Discoloration Defense Serum, Hydrating B5 Gel, LHA Cleansing Gel, or Daily Brightening UV Defense Sunscreen.

Efficacy

Patient Reported Outcomes

At the final study visit, all 10 participants completed a patient-reported outcomes (PRO) questionnaire assessing their experience with the treatment regimen. On a 0–4 scale, where 4 indicated "very noticeable improvement" and 0 indicated "no improvement," participants reported a high level of improvement in PIH (mean: 3.5 ± 0.71, 87.5%), overall facial appearance (mean: 3.4 ± 0.52, 85%), and the way their skin feels (mean: 3.4 ± 0.52, 85%). Satisfaction with the regimen was similarly high, with a mean overall satisfaction score of 3.5 ± 0.53, or 87.5%. When asked about their likelihood of recommending the treatment to others, the mean score was 3.4 ± 0.70 (85%). The skincare regimen was rated as very easy to use, with a mean difficulty score of 0.2 ± 0.42, where 0 indicated "very easy." Reported side effects were minimal, with a mean score of 0.9 ± 1.29 (22.5%), indicating that most participants experienced few or no adverse symptoms. Table 4 summarizes patient testimonials regarding their overall experience with the investigator-designed chemical peels and PIH regimen.

Primary Outcome

Satisfaction with Overall Facial Appearance: At 12 weeks post-treatment, participants reported significantly greater satisfaction with their overall facial appearance compared to baseline. The mean satisfaction score increased from 41.8 ± 17.4 at baseline to 79.2 ± 16.1 post-treatment, reflecting an average 89.5%

TABLE 5.

Erythema Index Measurementsa at Baseline, Week 6, and Week 12, Assessed Using the Mexameter®			
Mexameter Erythema Measurement 1			
Participant	**Erythema Baseline**	**Erythema Week 6**	**Erythema Week 12**
1	471.0	464.3	464.4
2	463.0	454.3	476.0
3	386.0	393.0	420.0
4	396.0	413.0	420.0
5	454.0	463.0	461.0
6	451.0	441.0	430.6
7	423.0	445.3	453.6
8	412.0	441.6	445.0
9	461.0	459.3	470.6
10	436.6	446.3	448.0
Mexameter Erythema Measurement 2			
Participant	**Erythema Baseline**	**Erythema Week 6**	**Erythema Week 12**
1	460.3	462.3	468.3
2	461.6	462.6	461.3
3	421.6	416.3	430.0
4	379.3	387.6	411.0
5	435.6	456.0	452.0
6	445.6	433.0	433.0
7	420.6	424.0	438.0
8	369.3	431.6	437.6
9	456.6	463.3	445.6
10	472.3	450.3	479.6

TABLE 6.

Melanin Index Measurements at Baseline, Week 6, and Week 12, Assessed Using the Mexameter®			
Mexameter Melanin Measurement 1			
Participant	**Melanin Baseline**	**Melanin Week 6**	**Melanin Week 12**
1	736.0	711.0	679.6
2	830.0	846.0	822.0
3	908.3	904.0	877.0
4	898.0	873.0	865.0
5	847.3	830.0	793.6
6	627.0	623.3	599.0
7	883.0	852.3	842.0
8	895.0	862.3	838.0
9	744.0	749.3	687.6
10	870.3	841.6	839.3
Mexameter Melanin Measurement 2			
Participant	**Melanin Baseline**	**Melanin Week 6**	**Melanin Week 12**
1	711.3	703.3	683.3
2	804.3	798.6	757.3
3	881.0	889.0	877.0
4	907.0	900.7	882.3
5	858.6	826.0	789.6
6	608.3	603.0	599.0
7	878.3	877.0	866.3
8	906.6	873.0	855.0
9	744.0	776.3	730.6
10	836.6	820.3	815.6

improvement in satisfaction scores (P<0.001). Refer to Figure 1 for clinical photographs highlighting the improvements in PIH observed.

Secondary Outcomes

Erythema and Melanin Index: Mexameter® measurements were used to quantify erythema and melanin levels at two facial sites affected by PIH. Data were collected at baseline, week 6, and week 12. A progressive decrease in melanin index was observed across most participants, indicating improvement in hyperpigmentation. Erythema index remained stable or slightly decreased over the course of treatment. Full individual values are presented in Tables 5 and 6.

Dermatology Life Quality Index: Significant improvements in quality of life were observed following treatment, as measured by the DLQI. The mean DLQI score decreased from 6.5 ± 6.6 at baseline to 0.7 ± 1.3 post-treatment, indicating a substantial reduction in the impact of skin disease on daily functioning (P<0.01). Notably, 70% of participants reported a final DLQI score of 0, reflecting no negative impact of their skin condition on quality of life after completing the regimen.

Patient Expectations: Patient expectations regarding the impact of treatment were evaluated at baseline using the FACE-Q Expectations Scale. The mean expectation score was 84.8 ± 20.1 out of 100, indicating that participants generally anticipated a substantial positive effect from the treatment regimen. Notably, 60% of participants reported a perfect score of 100.

Patient Satisfaction with Outcome: Patient satisfaction with treatment outcome was assessed using the FACE-Q Outcome Satisfaction Scale. The average satisfaction score was 82.5 ± 17.9 out of 100. High satisfaction was observed across participants, with 90% of patients reporting scores above 68, and 50% scoring 87 or higher.

Psychosocial Functioning: Participants completed the FACE-Q Psychological Function Scale at baseline and week 12. At baseline, the mean psychological function score was 64.6

(SD = 19.1), which increased to 94.6 (SD = 15.1) at week 12. This reflects a significant improvement of 46.4% in psychological well-being following treatment. Notably, 80% of participants achieved the maximum score of 100 at week 12, compared to only 20% at baseline.

Social Functioning: Participants completed the FACE-Q Social Function Scale at baseline and week 12. The mean baseline score was 66.3 (SD ± 23.58), which increased to a mean of 77.9 (SD ± 15.24) at week 12. This represents a 17.5% increase in social functioning scores post-treatment. Notably, 90% of participants either maintained or improved their social functioning scores, with 60% of participants scoring ≥ 90 on the final assessment.

DISCUSSION

This prospective, single-center investigator-developed clinical trial found that combining the SkinCeuticals Pigment Balancing Peel with a targeted skincare regimen significantly improved PIH, patient-reported satisfaction, and quality of life in patients with skin of color. The primary outcome of this study was improvement in patient satisfaction with facial appearance, assessed by the FACE-Q Satisfaction with Facial Appearance Overall Scale. At week 12, participants reported a significant 89.5% increase in satisfaction with facial appearance, with mean scores increasing from 41.8 ± 17.4 at baseline to 79.2 ± 16.1 post-treatment (P<0.001). This significant improvement underscores the regimen's ability to enhance patients' perception of their skin, which is a key concern among individuals with PIH, especially in skin of color populations.

This aligns with findings from previous studies that have highlighted the psychosocial burden of PIH and the limitations of traditional treatments. While hydroquinone-based therapies may be effective, they have been associated with AEs such as exogenous ochronosis and irritant dermatitis, particularly with prolonged use.[11] In contrast, studies exploring alternative depigmenting agents such as tranexamic acid, niacinamide, and chemical peels (eg, glycolic acid) have demonstrated moderate efficacy with improved safety profiles.[12,13] However, few trials have combined these agents into a comprehensive regimen evaluated prospectively in skin of color patients. Our results expand upon this emerging evidence, showing that a multi-agent, hydroquinone-free treatment can offer significant improvement in both objective and subjective outcomes.

In addition to the primary outcome, multiple patient-reported outcomes improved significantly. Quality of life, as assessed by the DLQI, decreased from 6.5 ± 6.6 at baseline to 0.7 ± 1.3 at week 12 (P=0.018), indicating a marked reduction in the burden of PIH on daily functioning. The FACE-Q Psychological Function scale increased from 64.6 ± 19.1 to 94.6 ± 15.1 (P=0.0008), reflecting improved self-confidence and overall mental well-being. Similarly, FACE-Q Social Function scores increased from 66.3 ± 23.6 to 77.9 ± 15.2 (P=0.048), suggesting enhanced confidence in social interactions. These PRO results are particularly meaningful given that previous studies on PIH have often focused on clinician-assessed outcomes rather than patient perspectives.[14] The use of patient-reported outcome measures such as the FACE-Q allows for a more comprehensive evaluation of treatment effectiveness, highlighting the patient experience.[15] Patients also reported high levels of treatment satisfaction, with a mean FACE-Q Outcome Satisfaction score of 82.5 ± 17.9. Additionally, 90% of participants felt their skin had improved, and 85% found the regimen easy to use, an important factor in treatment adherence. These findings reflect the growing demand for non-invasive, accessible solutions to pigmentary disorders that are safe and tolerable.

Despite these encouraging findings, our study has several limitations, including a small sample size of 10 participants, a lack of randomization, and the absence of a control group. These factors limit generalizability and introduce potential sources of bias. Additionally, the study was conducted during the late spring and summer months, when increased sun exposure may have influenced pigmentation outcomes despite the use of sunscreen, potentially confounding results. Larger, randomized controlled trials with longer follow-up periods are needed to confirm these results and determine the durability of treatment effects. This study contributes valuable evidence supporting a safe and efficacious treatment strategy for PIH in skin of color patients. The regimen significantly improved patient-reported satisfaction, psychological well-being, and quality of life over 12 weeks. These findings offer a foundation for further research into comprehensive, patient-centered therapies for pigmentary disorders.

CONCLUSION

This prospective clinical trial found that an investigator-designed skincare regimen combining a chemical peel with daily at-home products significantly improved PIH and patient satisfaction in patients with skin of color. Patients reported greater satisfaction with facial appearance, glowing skin, improved quality of life, and reduced melanin index levels by spectrophotometer assessment. The regimen was well tolerated with minimal adverse effects. While the small sample size and lack of a control group are limitations, these findings support the potential of safe, accessible treatments for PIH in skin of color populations.

DISCLOSURES

Kayla Zafar BA, Margaret Kabakova BS, and Lucie Joerg BA do not have any relevant conflicts of interest. Jared Jagdeo MD MS is the investigator for this investigator-initiated study. The New York Harbor VA Brooklyn Campus was the recipient of the grant funding.

Funding Sources: L'Oréal

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