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 ORIGINAL ARTICLE

Efficacy and Tolerability of a Topical Pigment-Correcting Serum in Melasma and Postinflammatory Hyperpigmentation

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ABSTRACT

Background: Melasma and postinflammatory hyperpigmentation (PIH) are common disorders of hyperpigmentation of key aesthetic concern. This study assessed the efficacy and tolerability of a serum formulated with lotus sprout extract, tranexamic acid, and niacinamide (LTN serum) for the treatment of melasma and PIH secondary to acne.

Methods: A 16-week, single-center, open-label study enrolled women (≥20 years of age) with mild to severe melasma or PIH. Participants applied LTN serum twice daily on the full face. Endpoints included assessments of overall hyperpigmentation, skin tone unevenness, and tactile roughness, modified Melasma Area Severity Index (mMASI), Mexameter measurements of melanin content in target lesions, Melasma Quality of Life Questionnaire (MelasQoL), participant self-assessment questionnaires, and tolerability.

Results: Of 30 female participants (n=15 per group), 57% self-identified as Black or African American, and 70% had Fitzpatrick skin types (FST) IV–VI. At week 16, significant decreases versus baseline were observed in both groups for overall hyperpigmentation (37% and 31% for the melasma and PIH groups, respectively; $P<0.009$ for both groups), skin tone unevenness (38% and 33%; $P<0.008$), and tactile roughness (67% and 52%; $P\leq0.005$). mMASI and MelasQoL scores were significantly improved starting at week 4, with continuing significant improvement through week 16 ($P\leq0.05$ and $P>0.005$, respectively). Mean change in melanin content was –36.5 at week 16 (melasma and PIH groups combined; $P<0.0003$). All tolerability parameters remained below mild.

Conclusions: The LTN serum is an effective treatment for improving melasma and PIH, particularly among participants with FST IV–VI.

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INTRODUCTION

Hyperpigmentation is characterized by uneven skin tone, commonly due to excess melanin production.[1] Hyperpigmentation is one of the most common dyschromias and is more prevalent in individuals with higher concentrations of melanin in the skin.[1-3] Two common types of hyperpigmentation are melasma and postinflammatory hyperpigmentation (PIH).[1,4] Melasma is characterized by tan-brown patches of pigmentation across the cheeks, nose, forehead, and other areas of the face.[2] The development of melasma is caused by several factors, including genetics, UV and visible light radiation, and hormonal influences, including oral contraception, hormone replacement therapies, and pregnancy.[5-7] PIH is an inflammatory hypermelanosis caused by a cutaneous inflammatory response, such as to acne, burns, picking of the skin, or certain cosmetic procedures.[1,4] Melasma and PIH can have negative psychosocial impacts on individuals with either condition, including low self-esteem and emotional well-being.[8,9]

Both melasma and PIH are difficult to treat and often require a combination approach using topical agents and in-office procedures, including chemical peels, laser/light therapy, microneedling, and microdermabrasion.[10,11] Despite the availability of treatments, achieving complete clearance in patients with melasma or PIH is challenging, particularly in individuals with skin of color, who naturally have higher concentrations of melanin in the skin. Thus, topical agents that are effective across a range of skin tones and capable of addressing multiple pigmentation conditions are warranted. To further these efforts, a serum formulated with lotus sprout extract, tranexamic acid, and niacinamide (LTN serum; Allergan Aesthetics, an AbbVie company, Irvine, CA) is now available for pigment correction.[12] This study evaluated the safety and efficacy of the LTN serum over 16 weeks for the treatment of mild to severe melasma and acne-associated PIH.

MATERIALS AND METHODS

Study Design

A 16-week, single-center, open-label clinical study was conducted from February 2023 to September 2023. The study adhered to the Declaration of Helsinki and International Council for Harmonization Good Clinical Practice guidelines. An institutional review board reviewed and approved the study protocol at the center (Advarra IRB, Columbia, MD), and all participants provided informed consent prior to enrollment in the study.

Participants

Adult women (20–69 years of age) with Fitzpatrick skin types (FST) II–VI were included if they had mild to severe (grade 1–3) melasma on the Melasma Severity Rating Scale or mild to severe (grade 3–9) PIH secondary to acne on the Overall Hyperpigmentation Scale. Key exclusion criteria included a preexisting or dormant dermatologic condition (eg, psoriasis, atopic dermatitis, rosacea, skin cancer, etc), active symptoms of allergy, cold sore or warts, sunburn, open wounds, neurotic excoriations, excessive scarring, tattoos, or other skin conditions in the treated area that would interfere with the assessments of the study; use of chemical peels, microdermabrasion, microneedling, or dermaplaning within the last month prior to the study; and any use of retinoid-containing products in the prior 3 months.

Treatment

On day 1, participants were instructed to use the following skincare regimen on the full face in the morning for 16 weeks: 1) cleanse the face using the provided facial cleanser (SkinMedica Facial Cleanser; Allergan Aesthetics, an AbbVie company), 2) apply a thin layer of the LTN serum and allow to dry for 30 seconds to 1 minute, 3) apply a thin layer of moisturizer (SkinMedica Ultra Sheer Moisturizer), and 4) apply a thin layer of sunscreen (SkinMedica Essential Defense Mineral Shield Sunscreen). In the evening, participants repeated the application procedures, with the exclusion of the sunscreen application. Study visits occurred at baseline and weeks 2, 4, 8, 12, and 16.

Assessments

Hyperpigmentation, Skin Tone Unevenness, and Tactile Roughness

Investigator-assessed clinical grading of overall hyperpigmentation, skin tone unevenness, and tactile roughness was performed on the full face using a modified Griffith scale, where 0=none (best possible condition), 1–3=mild, 4–6=moderate, and 7–9=severe.

Modified Melasma Area Severity Index

The severity of melasma was assessed for the whole face using the modified Melasma Area Severity Index (mMASI) for the melasma group only. mMASI is a composite score combining the severity (darkness of pigment in the affected area compared with adjacent normally pigmented skin) and the extent of the facial area involved, measured across 4 facial units: forehead, left and right malar cheek, and chin. The maximum total score is 24, with lower scores representing less pigmentation.

Mexameter Measurements

A Mexameter MX18 instrument (Courage+Khazaka electronic GmbH, Cologne, Germany) was used to objectively measure the melanin content of a targeted pigmented lesion on the face and an adjacent area with normal pigmentation at each study visit among participants in both groups. All measurements were taken in triplicate and averaged. The same targeted lesion and adjacent areas were assessed at each visit to ensure consistency.

Melasma Quality of Life Questionnaire

A validated Melasma Quality of Life Questionnaire (MelasQoL) was utilized to assess the emotional and psychological impact of melasma in the melasma group at each study visit. Higher scores were indicative of worse melasma-related quality of life.

Self-assessment Questionnaires

Participants completed a self-assessment questionnaire at each study visit (weeks 2, 4, 8, 12, and 16) to evaluate their self-perceived efficacy and experience with the LTN serum.

Standardized Digital Photography

Participants were photographed using the Canfield VISIA-CR system (Canfield Scientific, Parsippany, NJ) at each study visit to capture visual changes in the treated areas of the face. The same position was utilized at each visit to ensure consistency in imaging and assessment.

Tolerability Parameters

Tolerability of the LTN serum was evaluated by the investigator and participants using a 4-point scale (0=none, 1=mild, 2=moderate, and 3=severe) to assess irritation parameters (erythema, dryness/scaling, burning/stinging, and itching) at each study visit.

Statistical Analysis

The intent-to-treat population was utilized for all statistical analyses and included all participants who received treatment and completed at least 1 postbaseline evaluation. The Wilcoxon signed rank test was utilized to compare differences in baseline assessments and assessments at weeks 2, 4, 8, 12, and 16. All statistical tests were 2-sided and conducted at the 5% significance level.

RESULTS

Participants

A total of 30 participants were enrolled and included in the study analyses (Table 1). Overall, 29 (97%) participants completed the study. One participant in the PIH group was lost to follow-up.

Demographic and baseline characteristics were similar between the melasma and PIH groups (Table 1). The mean age of participants was 45.8 years. Over half of all participants were FST III–V (83.3%). In the melasma group, 33.3% of participants were Asian, and 86.7% of participants in the PIH group were Black or African American.

Investigator Assessments

In the melasma group, significant improvements compared

TABLE 1.

Participant Demographics and Baseline Characteristics			
	Study Population		
Parameter	PIH (n=15)	Melasma (n=15)	Total (n=30)
Age, mean, years	39.6	52.0	45.8
Female, n (%)	15 (100)	15 (100)	30 (100)
Race/Ethnicity, n (%)			
Asian	0 (0.0)	5 (33.3)	5 (16.7)
Black or African American	13 (86.7)	4 (26.7)	17 (56.7)
Hispanic or Latino	1 (6.7)	1 (6.7)	2 (6.7)
Multiple	0 (0.0)	2 (13.3)	2 (6.7)
White	1 (6.7)	3 (20.0)	4 (13.3)
Fitzpatrick skin type, n (%)			
II	1 (6.7)	2 (13.3)	3 (10.0)
III	1 (6.7)	5 (33.3)	6 (20.0)
IV	5 (33.3)	5 (33.3)	10 (33.3)
V	7 (46.7)	2 (13.3)	9 (30.0)
VI	1 (6.7)	1 (6.7)	2 (6.7)

with baseline were observed as early as week 2 in overall hyperpigmentation ($P \leq 0.04$) and tactile roughness ($P \leq 0.04$) and at week 4 for skin tone unevenness ($P \leq 0.002$), with continuing significant improvements at each follow-up visit through week 16 (Figure 1). In the PIH group, significant improvements vs baseline in overall hyperpigmentation ($P \leq 0.04$) occurred by week 2 and in skin tone unevenness ($P \leq 0.007$) and tactile roughness ($P \leq 0.005$) by week 4, with continued significant improvements through week 16 for all 3 skin quality parameters. Compared with baseline, the LTN serum significantly improved facial melasma severity from week 4 onward, with up to a 32% reduction in mMASI continuing throughout the 16-week study duration ($P \leq 0.05$; Figure 2A). Melanin content in target lesions decreased from –6.8 at week 2 to –36.5 at week 16 (both groups combined, $P<0.04$; Figure 3).

Participant Assessments

Participant assessment of the emotional and psychological effects of melasma following LTN treatment was significantly improved versus baseline from weeks 4 through 16, based on the MelasQoL ($P<0.005$; Figure 2B). Results of the participant self-assessment questionnaires showed that participants strongly agreed with statements that were indicative of satisfaction with the LTN treatment and regimen. The strongest satisfaction ratings (≥60%) at week 2 were for "helped prevent new discoloration and maintain even skin tone" and "works well on my skin type/tone" for both the melasma and PIH groups (Figure 4A). With continued use, at least 80% of participants in the melasma group and 70% in the PIH group agreed that the LTN serum "improved the overall tone and clarity of my skin" and "reduced the area of uneven skin tone"; in addition, a majority of participants in both groups agreed that the LTN serum was convenient to use as part of a daily skincare regimen, it fit into their current regimen, and they would recommend the serum to a friend (Figure 5). Figure 6 and Figure 7 show representative photos of improvement in skin quality over the course of the study in participants with melasma or PIH, respectively.

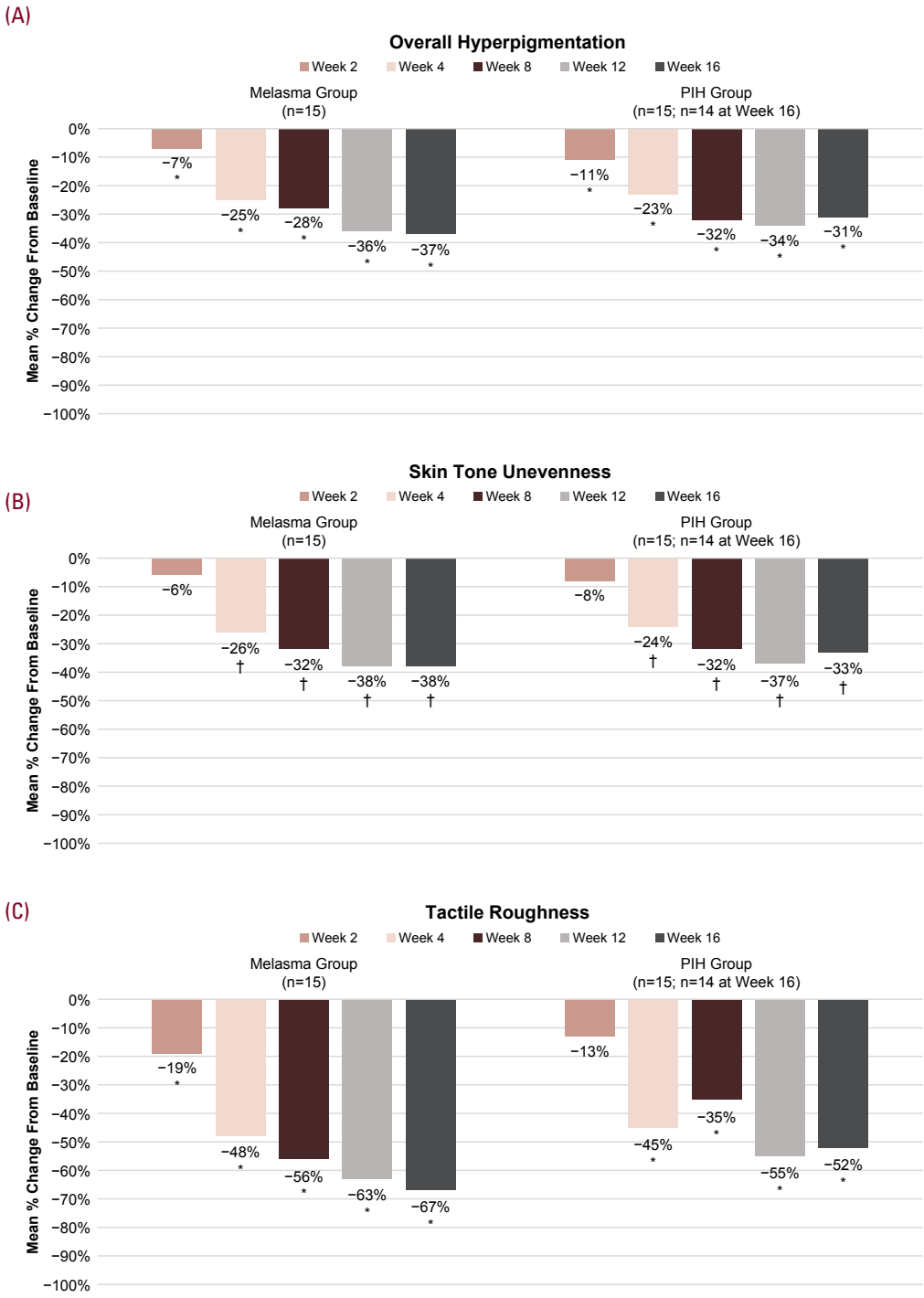
Tolerability and Safety

Overall, LTN serum was well tolerated, with mean scores for erythema, itching, dryness/scaling, and burning/stinging remaining below mild in both groups from weeks 2 through 16. No participant reported a serious adverse event or discontinued due to an adverse event.

DISCUSSION

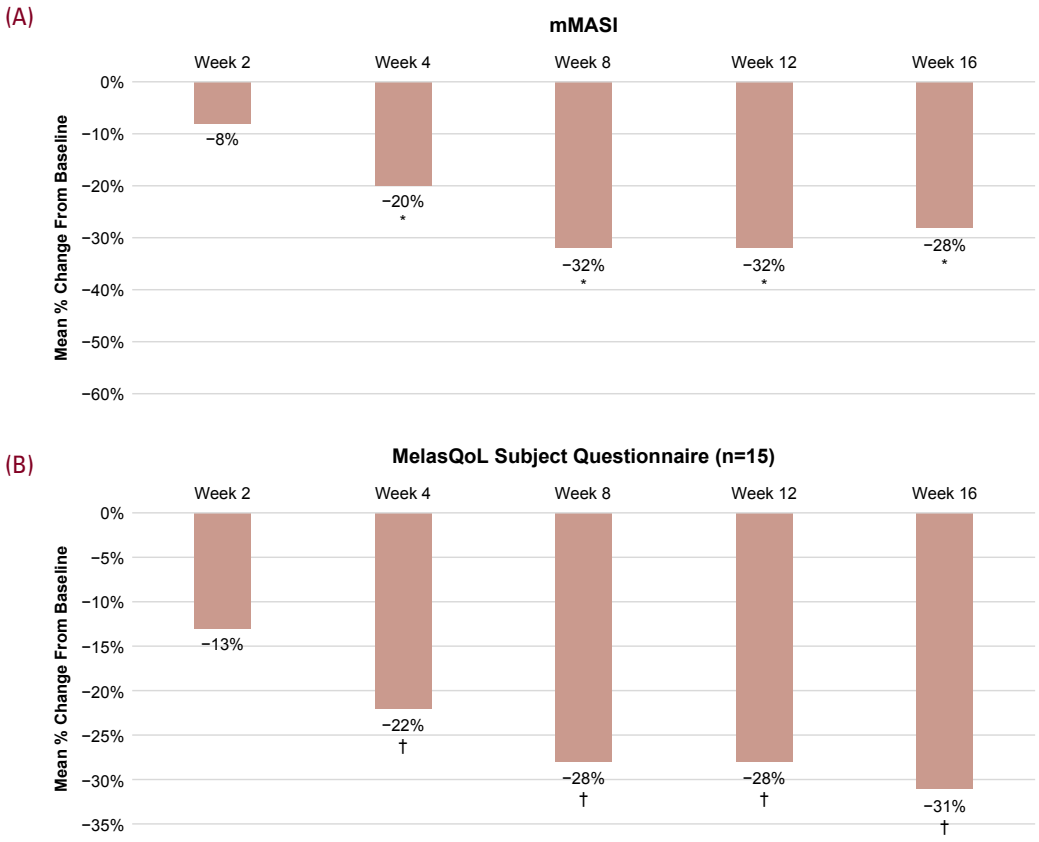
In this study, participants with mild to severe melasma or PIH were treated with the LTN serum over the whole face for 16 weeks. Significant improvements were demonstrated in overall hyperpigmentation, skin tone unevenness, tactile roughness, and melasma severity (mMASI) in participants from diverse backgrounds with FST II–VI. From week 2 onward, hyperpigmentation in both groups significantly decreased. Skin tone unevenness significantly improved as early as week 4 and onward for each group. Improvements in tactile roughness were observed starting at weeks 2 and 4 for the

FIGURE 1. Mean percentage change from baseline in (A) overall hyperpigmentation, (B) skin tone unevenness, and (C) tactile roughness after 2, 4, 6, 8, 12, and 16 weeks of treatment with the LTN serum.



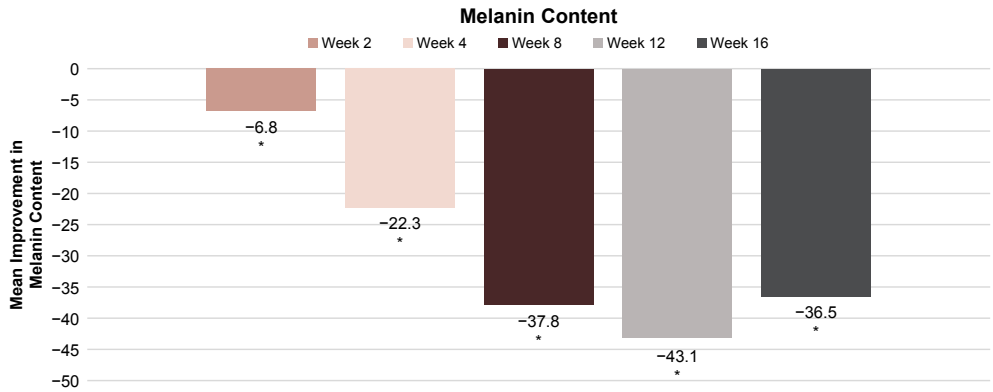
LTN, lotus sprout extract, tranexamic acid, and niacinamide; PIH, postinflammatory hyperpigmentation. *$P \leq 0.04$ vs baseline; †$P \leq 0.007$ vs baseline.

FIGURE 2. (A) Mean percentage improvement from baseline for mMASI in the melasma group. (B) Mean percent change for the MelasQoL throughout the study in the melasma subgroup.



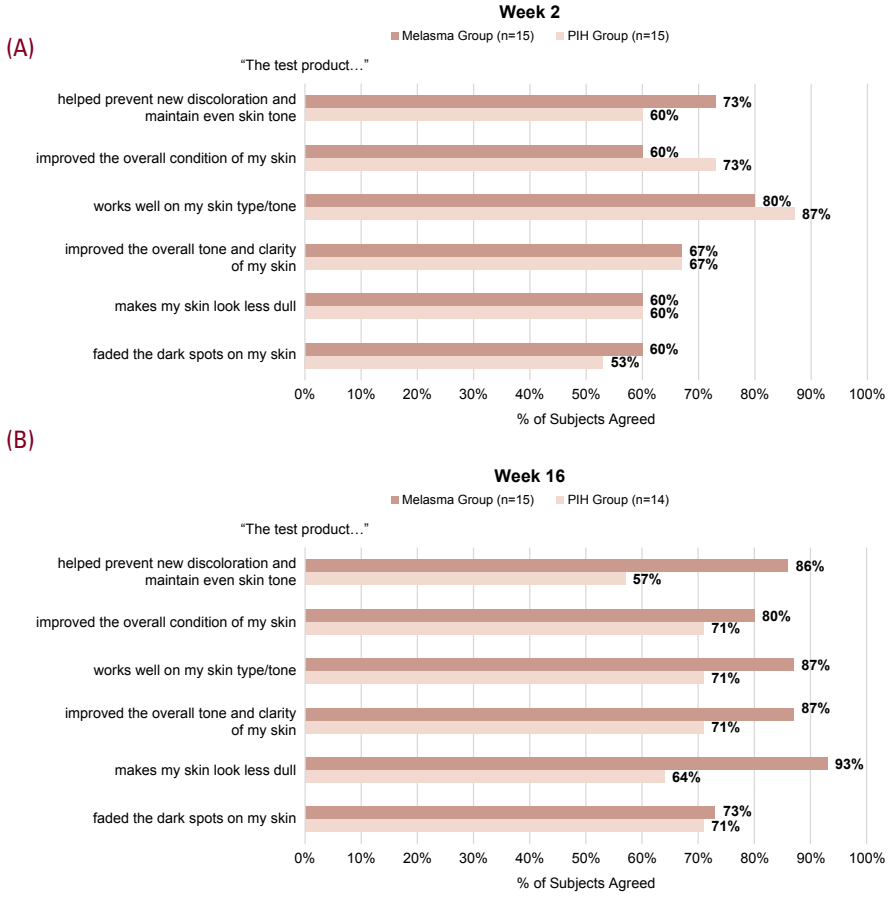
MelasQoL, Melasma Quality of Life Questionnaire; mMASI, modified Melasma Area and Severity Index. *$P \leq 0.05$ vs baseline; †$P \leq 0.004$ vs baseline.

FIGURE 3. Mean change in melanin content via Mexameter measurement of a targeted pigmented lesion for both groups combined.



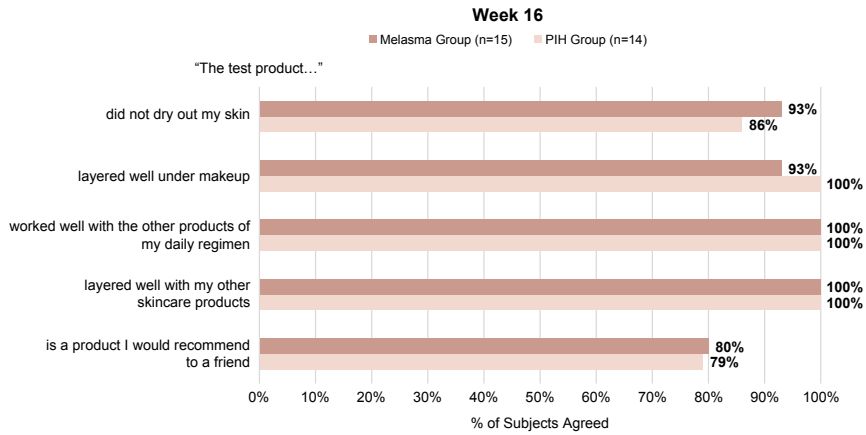
*$P \leq 0.05$ vs baseline.

FIGURE 4. Participant self-assessment questionnaire for product efficacy parameters at (A) week 2 and (B) week 16 in all participants in the PIH and melasma treatment groups.



PIH, postinflammatory hyperpigmentation.

FIGURE 5. Participant self-assessment questionnaire for product attributes and ease of use at week 16 in all participants in the PIH and melasma treatment groups.



PIH, postinflammatory hyperpigmentation.

FIGURE 6. (A) Representative images of a 58-year-old Asian female with Fitzpatrick skin type III and melasma at baseline and week 16 under standard 1 lighting conditions. Note improvements in skin tone evenness in the malar area after treatment with LTN serum. (B) Representative images of a 47-year-old Asian female with Fitzpatrick skin type V and melasma at baseline and week 8 under cross-polarizing lighting conditions.

Note improvements in skin tone evenness in the forehead, malar, and cheek areas after treatment with LTN serum. LTN, lotus sprout extract, tranexamic acid, and niacinamide.

melasma and PIH groups, respectively. In the melasma group, significant improvements were observed from week 4 onward on the mMASI and MelasQoL. Overall, participants were highly satisfied (>80%) with the LTN serum and believed it fit into their current skincare regimen. Lastly, the LTN serum was well tolerated in both groups throughout the study, with only mild symptoms reported by participants.

The results of this study align with a previous study, which compared the change in hyperpigmentation and melasma severity after treatment with a pigment-correcting, hydroquinone-free serum (LTN serum) versus 4% hydroquinone alone. In that 12-week study, which enrolled equal proportions of individuals from 4 major ethnic backgrounds, participants who incorporated the pigment-correcting serum achieved similar results to hydroquinone in overall hyperpigmentation, skin tone evenness, and mMASI scores.[12] However, participants achieved higher satisfaction ratings after using the pigment-correcting serum compared with hydroquinone.[12] This is likely due to side effects associated with hydroquinone use, including irritation and contact dermatitis.[1] In the current study, participants across a range of skin types, including strong African American

FIGURE 7. Representative images of a 26-year-old Black female with Fitzpatrick skin type V and PIH at baseline and week 8 under standard 1 lighting conditions.

Note improvements in skin tone evenness in the cheek area and reduction in intensity of PIH spots on the forehead after treatment with LTN serum. LTN, lotus sprout extract, tranexamic acid, and niacinamide; PIH, postinflammatory hyperpigmentation.

representation, also achieved similar satisfaction results in both the melasma and PIH groups after treatment with the LTN serum, indicating its efficacy in reducing the psychosocial impacts of both types of hyperpigmentation.

Epidemiological studies have shown that the occurrence of melasma and PIH, particularly PIH secondary to acne, is more common in skin of color (FST IV–VI) compared with lighter skin.[3,7,10] In addition, dyschromias are often more challenging to treat, and treatments are less effective in skin of color.[7,13,14] To complicate matters further, certain treatment modalities, such as laser therapies and chemical peels, may have a higher propensity to cause or exacerbate hyperpigmentation in individuals with darker skin types.[3,11,14] A growing body of research has shown there are innate differences in the process of melanogenesis and skin architecture among individuals from different ethnic and racial origins; thus, certain conditions, such as melasma, tend to occur more frequently in some groups than others.[10,11,15,16] Skin of color differs from lighter skin types in that darker skin normally has larger, more uniform, and more mature (stage IV) melanosomes containing higher levels of melanin that are dispersed more widely throughout the skin.[3,13,17] In addition, melanosomes are more rapidly degraded during keratinocyte terminal differentiation in light skin (FST I–II) than in darker skin (FST V–VI).[18] In individuals with melasma, the melanocytes of hyperpigmented skin are larger, with higher numbers of melanosomes and overall greater quantities of dermal and epidermal melanin compared with normal skin.[19,20]

These data suggest that melasma may develop, at least in part, through increased melanosome synthesis in melanocytes and subsequent transfer to keratinocytes.[20] PIH is caused by localized inflammation, which damages the epidermis and causes increased synthesis of melanin and stimulates melanin-containing melanosomes to be released from melanocytes into the surrounding tissue.[11,15] Individuals with more darkly pigmented skin frequently exhibit increased levels and

activity of inflammatory markers both in the skin and in the circulation, creating a pro-inflammatory environment that may predispose them to the development of PIH.[11] LTN serum contains a proprietary formulation that targets all 6 key stages of the melanin life cycle, which includes melanocyte activation, melanosome development, melanin production, melanosome transfer, melanosome degradation, and melanin removal. LTN serum contains lotus sprout extract, which has been shown to specifically decrease skin pigmentation by inducing autophagy-mediated melanosome degradation as well as inhibition of melanosome synthesis and maturation.[17,21,22] This multipronged approach to depigmentation may contribute to the efficacy and tolerability of LTN serum in melasma and PIH, especially in people with skin of color, as observed in this and in an earlier study.[12]

A key strength of this study was the evaluation of LTN serum in individuals from multiple racial and ethnic groups, thereby demonstrating the effectiveness of LTN serum in treating melasma and PIH across a range of skin types. Few topical HP products are tested in a diverse and/or majority darker skin type study population, as these individuals tend to be more refractory to treatment, due to higher levels and broader distribution of melanin in these skin types.[3,13] In contrast, this study showed the benefit of LTN serum in treating hyperpigmentation, including melasma, in a diverse population with darker skin types, a subpopulation that is especially difficult to treat.[7,13,14]

Limitations of the study included a small sample size, which may limit the generalizability of the results, and the single-center, open-label, uncontrolled study design. Although comparison with the baseline condition of each participant serves as an internal control on an individual basis, the study design complicates making distinctions between improvements that would have arisen naturally and improvements that might have occurred through product intervention. Indeed, without intervention, it is possible for there to have been a worsening of the dyschromic condition, which may have increased any differences in effect between LTN serum and a control product. In addition, the study overlapped with a seasonal change from midwinter (February) through the end of summer (September). Therefore, it is possible that during the middle 4 months of the clinical study (ie, April to July), as daytimes lengthened and subjects spent more time outside, they were exposed to more heat and higher UV index levels for longer periods of time, which can lead to worsening melasma if no intervention is made. The study data support a potential effect of the summer season on melasma severity, showing a leveling off of LTN serum effect on mMASI and MelasQoL scores at week 12. However, despite the possible influence of unfavorable environmental conditions, LTN serum overall led to significant improvements in melasma and PIH severity throughout the study to week 16.

Treatment with the LTN serum was well tolerated and led to a significant and clinically meaningful improvement in melasma and PIH severity across a range of skin types. These results support the use of the LTN serum for aesthetic purposes, in which a pigment-correcting product can treat multiple hyperpigmentation conditions.

DISCLOSURES

The conflict of interest disclosures reveal varying degrees of industry involvement among the authors, with a significant concentration of ties to AbbVie and Allergan Aesthetics. Specifically, P Huang, T Cheng, and E Makino are all employees of Allergan Aesthetics (an AbbVie company) and may hold AbbVie stock. P Grimes maintains extensive relationships across the pharmaceutical and skincare sectors, serving as a clinical investigator and/or consultant for numerous companies—including AbbVie, Allergan Aesthetics, Clinuvel, Galderma, Incyte, Johnson & Johnson, L'Oreal, Merck, and Pfizer, among others—while also holding a position as a board member for Clinuvel. S Dias has no conflicts of interest to disclose.

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Data Sharing Statement

AbbVie is committed to responsible data sharing regarding the clinical trials we sponsor. This includes access to anonymized, individual, and trial-level data (analysis data sets), as well as other information (eg, protocols, clinical study reports, synopses, or statistical analysis plans), as long as the trials are not part of an ongoing or planned regulatory submission.

These clinical trial data can be requested by any qualified researchers who engage in rigorous, independent, scientific research, and will be provided following review and approval

of a research proposal, Statistical Analysis Plan (SAP), and execution of a Data Use Agreement (DUA). Data requests can be submitted at any time after approval in the US and Europe and after acceptance of this manuscript for publication. The data will be accessible for 12 months, with possible extensions considered. For more information on the process or to submit a request, visit the following link: https://vivli.org/ourmember/abbvie, then select "Home".

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