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Original Research Article

Clinical and safety outcomes of a prospective, eight-week and monocentric study of a multi-active topical serum in facial hyperpigmentation in Indian skin

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ABSTRACT

Background: Facial hyperpigmentation is a common dermatological concern in individuals with Fitzpatrick skin phototypes III-IV. Current treatment options are often limited by tolerability issues and restrictions on long-term hydroquinone use. This study evaluated the efficacy and safety of SOLGLO-AZ Serum, a hydroquinone-free multi-active topical formulation, in Indian adults with facial hyperpigmentation.
Methods: In this prospective, open-label, monocentric study, 34 adults with facial hyperpigmentation were enrolled, of whom 32 completed the study. Participants applied SOLGLO-AZ serum once nightly for 8 weeks. Efficacy was assessed at baseline, day 30, and day 60 using clinical blemish scores and Antera 3D imaging-derived skin luminance (L*) and pigmentation indices. Safety and participant satisfaction were evaluated using clinical assessments and self-assessment questionnaires.
Results: By day 60, mean blemish scores decreased by 25% ($p<0.05$), skin luminance (L*) increased by 18.8% ($p<0.05$), and mean pigmentation values decreased by 9.2% ($p<0.05$) compared with baseline. More than 93% of participants reported improvement in pigmentation, skin tone evenness, overall appearance, and satisfaction with the product. No clinically significant adverse events, erythema, edema, or irritation were observed.
Conclusions: Once-nightly application of SOLGLO-AZ Serum for 8 weeks resulted in significant improvement in facial hyperpigmentation, high patient satisfaction, and excellent tolerability in Indian adults with Fitzpatrick skin phototypes III–IV. These findings support the use of hydroquinone-free multi-active topical formulations for the management of facial hyperpigmentation.

Keywords: Facial hyperpigmentation, Facial hyperpigmentation serum, Hyperpigmentation treatment

INTRODUCTION

Facial hyperpigmentation, including post-inflammatory hyperpigmentation (PIH), melasma, and solar lentigines, is a major dermatological concern in India, especially in individuals with Fitzpatrick skin phototypes III-IV individuals.[1-3] Approximately 20-40% of women and 10-20% of men attending dermatology clinics in India, present with some form of facial discoloration.[4,5] PIH occurs after inflammatory conditions like acne, eczema, or psoriasis and is clinically manifested as irregular, darkened skin patches that remain after the resolution of underlying inflammation.[6] PIH is more common among individuals with skin of color, as these individuals have a higher susceptibility to inflammation. Another form of hyperpigmentation is melasma, a chronic form of

photoaging-caused by excessive melanin production and characterized by uneven brown-gray macules. It is usually observed on and around the skin that is most exposed to direct sunlight. Enlarged melanocytes and dispersed melanosomes in keratinocytes, across all the layers of the skin are some of the pathophysiological hallmarks of melasma.[7] Solar lentigines, also referred to as 'age spots' are small and rounded, brown-black macules, pre-dominant in areas which are frequently exposed to sunlight (face, upper back, shoulders and hands).[8] While facial hyperpigmentation is primarily aesthetic in nature, it can significantly impact patient's psychosocial well-being and quality of life.[9]

The management of facial hyperpigmentation, particularly in individuals with darker skin is challenging. Conventional hyperpigmentation treatments involve combinations of tretinoin, hydroquinone, or topically applied corticosteroids, which have modest efficacy-but often face limitations regarding longer use, undesirable effects, and even relapses.[10]Although topical treatments containing hydroquinone remain the most effective, their long-term use is restricted in India under Schedule H2 due to the associated risks of skin discoloration and irritation in darker skin types.[11] This prompts a growing need for safer-and more effective hydroquinone-free alternatives that target various stages of melanin production. Few of the alternatives like kojic acid and cysteamine exist, but often pose challenges with irritation in Indian skin.[1,11,12]

Multiple factors contribute to the pathogenesis of facial hyperpigmentation. Various pathways involving tyrosinase, increased melanosome synthesis and melanocyte transfer, and persistent inflammatory signaling are potential targets for hyperpigmentation treatment. Therapies targeting only one of these pathways or monotherapies with suboptimal dosages often yield slow results, whereas agents that simultaneously target several steps of melanogenesis have shown better outcomes.[13-16] Liposomal delivery systems further improve the cutaneous bioavailability and tolerability of active ingredients such as azelaic acid.[17,18]Although individual ingredients and some dual/triple combinations have been studied in Indian patients, few published data exist on single formulation that simultaneously combines mechanistically complementary agents.[19-21]

Despite the increasing use of such multi-active cosmetic serums in practice, there are limited published clinical data on hydroquinone-free formulations that combine several mechanistically distinct agents into a single, once-daily product and evaluate them systematically with both clinical grading and instrumental imaging in Indian populations. To address this gap, the present study was designed as a prospective clinical trial on this multi-active cosmetic formulation involving Indian adults with facial hyperpigmentation. The primary objective of this study was to evaluate the efficacy of once-nightly SOLGLO-AZ Serum in reducing facial hyperpigmentation over eight weeks, as measured by changes in clinical blemish intensity score and Antera 3D-derived skin luminance and pigmentation indices compared with baseline. The secondary objective was to assess patient-reported improvement in pigmentation and skin tone, overall satisfaction, and safety and tolerability outcomes of the serum in Fitzpatrick III-IV phototypes.

METHODS

Study design

This was a single-center, prospective, open-label, and single-arm clinical study conducted at C.L.A.I.M.S. Pvt. Ltd., a Clinical Research Organization (CRO), Mumbai, Maharashtra, India, between 19 May 2025 and 21 July 2025. The study evaluated the efficacy and safety of a test product for treating facial hyperpigmentation. The study was approved by the Independent Ethics Committee (Re-Registration number: ECR/245/Indt/MH/2015/RR-22) on May 5, 2025, and registered with the Clinical Trials Registry-India (CTRI/2025/05/086559). The study was designed and conducted in compliance with the protocol, ICMR guidelines (2017), ICH (The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use) E6 (R3) guidelines for good clinical practice (2016), good clinical laboratory practices (GCLP), Declaration of Helsinki (Brazil, October 2013), and other applicable Regulatory Requirements.The study spanned eight weeks and involved visits at baseline (day 0), day 30, and day 60-per participant. All participants provided voluntary written informed consent before participation and were thoroughly informed about the study procedures, expected outcomes, and possible side effects prior to and during the study period.

Study population

34 participants, including both men and women, with Fitzpatrick skin phototypes III-IV, of age between 18 to 60 years and diagnosed with facial hyperpigmentation (age spots, sun burn/tanning, PIH, acne spots, and melasma specks/spots), were enrolled in the study. Of these, 32 participants completed the study, leading to a 10% dropout rate. The enrolled participants had healthy skin on the test area and were willing to refrain from using any other cosmetic products that could have significantly confounded the study results. The participants were instructed to avoid excessive sun exposure and refrain from using products with the same clinical benefits throughout the study.

Pregnant or breastfeeding women, subjects working outdoors with exposure to intense sunlight, those with high sensitivity to any ingredient in the test product, those using topical retinoids or skin lightening treatments, those undergoing systemic medical treatment within the past 1 month, and those undergoing procedures such as laser

treatments or chemical peels for hyperpigmentation - were excluded from the study.

Study procedure

The test product, SOLGLO-AZ Serum ((batch no. FV/2025/006/007; manufacturing date April 2025; expiry March 2027), was supplied by Fovero Healthcare LLP, 130, 1st Floor, Shanta Industrial Estate, I. B. Patel Road, Goregaon (East), Mumbai 400063, Maharashtra, India. The participants were screened for baseline assessments, during which they discontinued previous depigmenting treatments. The participants were administered the designated treatment for the entire study period (May 19, 2025, to July 21, 2025). After gentle cleansing and drying, they were instructed to apply a sufficient quantity (approximately 0.5 mL) of this product once nightly to the affected facial areas with a gentle massage for 60 consecutive days. No other depigmenting agents, exfoliants, or anti-acne topical agents were permitted during the study period, and all participants were encouraged to use a broad-spectrum sunscreen.

Study outcome parameters

Efficacy evaluation

The primary efficacy endpoints included clinical blemish scores, skin luminance (L*) values, and pigmentation average index from baseline to days 30 and 60. The blemish intensity was scored on a 0-4 scale, where 0 indicated no visible pigmentation, 1 minimal pigmentation, 2 mild pigmentation, 3 moderate/pronounced pigmentation, and 4 severe/intense pigmentation. Skin luminance and pigmentation indices were quantified using Antera 3D imaging of the target lesion, with higher L* values indicating lighter skin and lower pigmentation values indicating reduced melanin content. Secondary efficacy endpoints included patient self-assessment of perceived reduction in pigmentation marks, improvement in skin tone evenness, facial appearance, overall product satisfaction, and willingness to recommend the product, as assessed using structured questionnaires. Top-2-box scores (agree + strongly agree) were used to summarize positive responses.

Safety assessment

Safety and tolerability were assessed at each visit of the study. Any adverse events that occurred during the study were recorded. A modified Draize scale was used to clinically grade erythema, edema, dryness, and subjective irritation such as stinging, burning, or itching, after the application of the test product, with grades ranging from 0 (none) to 4 (severe).

Statistical analyses

The analysis was conducted using SPSS 10.0. Continuous data were summarized as mean and standard deviation, and categorical data were represented as numbers and percentages. Changes in blemish scores, L* and pigmentation indices from baseline to day 30 and day 60 were evaluated using two-tailed paired t-test, and the non-normal data were analyzed using the Wilcoxon signed-rank test. A two-sided $p<0.05$ was considered statistically significant for all comparisons.

RESULTS

Of the thirty-four subjects enrolled, thirty-two subjects completed the study (84.4% women, 15.6% men, mean age 34.9±9.40 years, all Fitzpatrick skin types III-IV). There was a 10% dropout rate, as two subjects were lost to follow-up (Table 1).

Table 1: Demographics and clinical parameters of the participants, (n=32).

Characteristics	Value
Age (in years)	34.9±9.40
Age range (in years)	19-54
Gender	Female, 27 (84.4%); male, 5 (15.6%)

Efficacy evaluation

Clinical improvement in blemish score

As shown in Figure 1, there was a significant reduction in blemish scores on days 30 and 60 compared to the baseline. From 3.0 at baseline, the mean clinical blemish score decreased to 2.84 on day 30 and 2.25 at day 60, corresponding to an approximate 25% reduction by the end of the study, which was statistically significant. The most substantial change occurred between weeks 4 and 8, resulting in visible lightening of blemish in most participants by final visit. Thus, the mean blemish score improved progressively over 8-week treatment period.

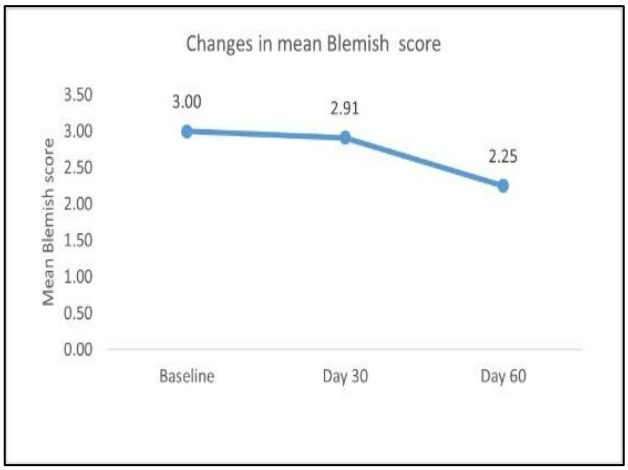

Figure 1: Changes in the mean clinical blemish score over 8 weeks.

*Line graph showing mean±SD blemish scores (0-4 scale) at baseline, day 30, and day 60, (n=32).

Instrumental evaluation using 3D imaging

As shown in Figure 2 and 3 respectively, a significant improvement in the mean skin luminance (L*) value and average pigmentation value was noted on days 30 and 60 as compared to the baseline. From a mean of approximately 44.5 at baseline, the skin luminance (L*) as measured by Antera 3D, increased to 46.3 at day 30 and 52.8 at day 60, with an 18.8% increase by the end of the study (day 60) relative to baseline, which was statistically significant. The average pigmentation, as measured by Antera 3D, decreased from 69.3 at baseline to 66.5 at day 30 and 62.9 at day 60, representing a 9.2% reduction that was also statistically significant. Clinical improvement in pigmentation was observed at day 30 and day 60, as compared to baseline, as shown in Figure 4 and 5 using Antera 3D photographs and Figure 6 using digital photographs.

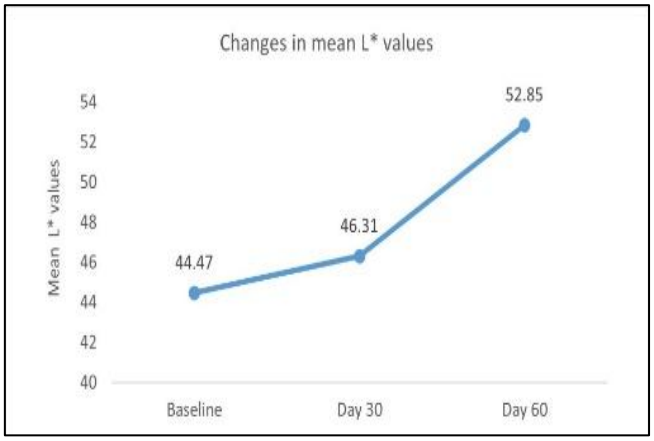

Figure 2: Changes in the mean skin luminance (L*) values over 8 weeks.

Line graph showing mean±SD skin luminance at baseline, day 30, and day 60 (n=32). Higher L values indicate lighter skin tone.

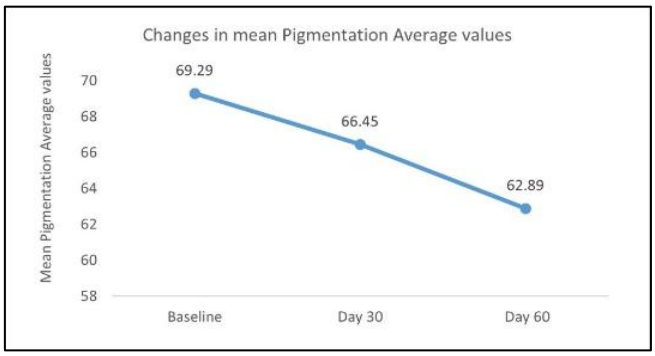

Figure 3: Changes in the mean pigmentation average values over 8 weeks.

*Line graph of mean±SD pigmentation average at baseline, day 30, and day 60 (n=32). Lower values indicate reduced pigmentation.

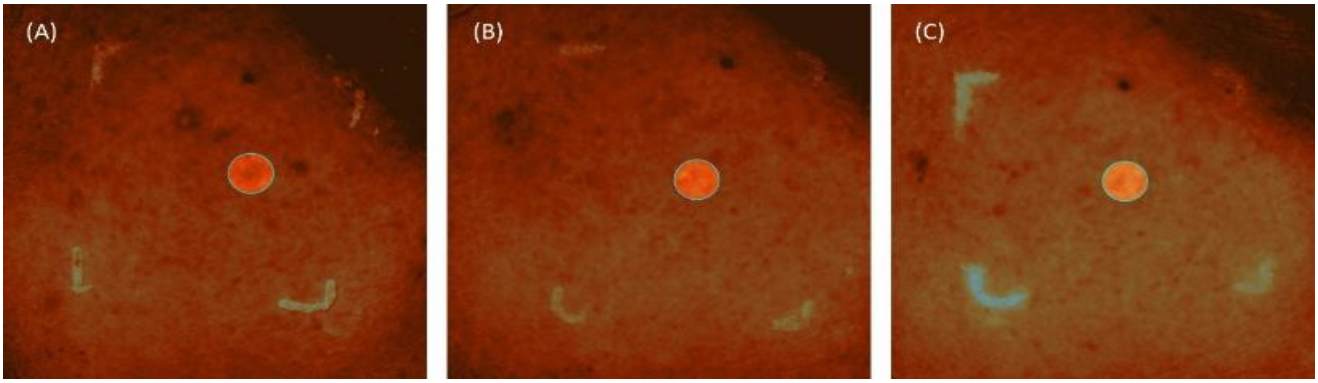

Figure 4: Representative images showing average pigmentation using Antera 3D imaging for a 22-year-old female patient, over 8 weeks.

*A-C: Representative Antera 3D images of pigmentation average in a 22-year-old female volunteer (right cheek) at baseline (A), day 30 (B), and day 60 (C) showing reduction in the dark-coded pigmented area and lower mean pigmentation average.

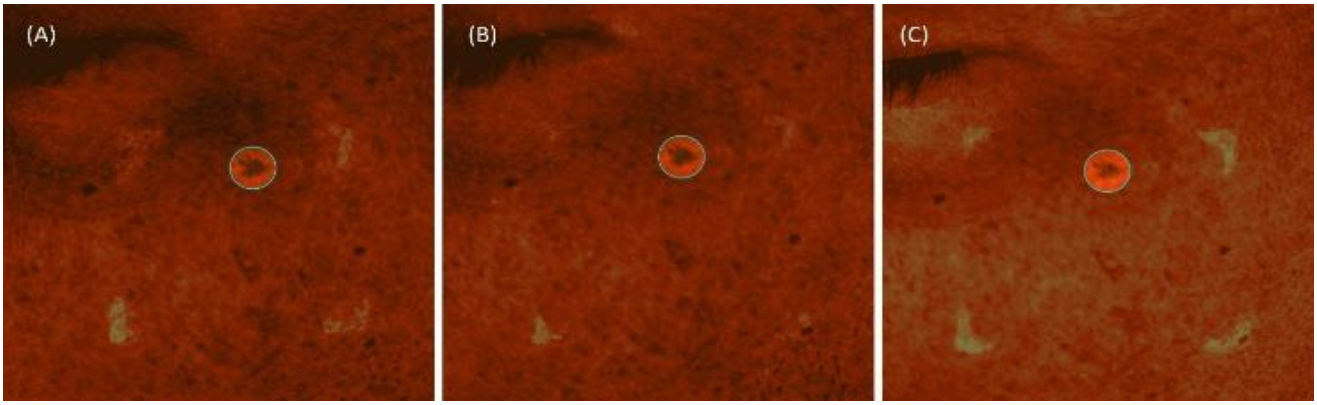

Figure 5: Representative images showing average pigmentation using Antera 3D imaging for a 40-year-old male patient, over 8 weeks.

*A-C: Representative Antera 3D images of pigmentation average a 40-year-old male volunteer (left cheek) at baseline (A), day 30 (B), and day 60 (C) showing reduction in the dark-coded pigmented area and lower mean pigmentation average.

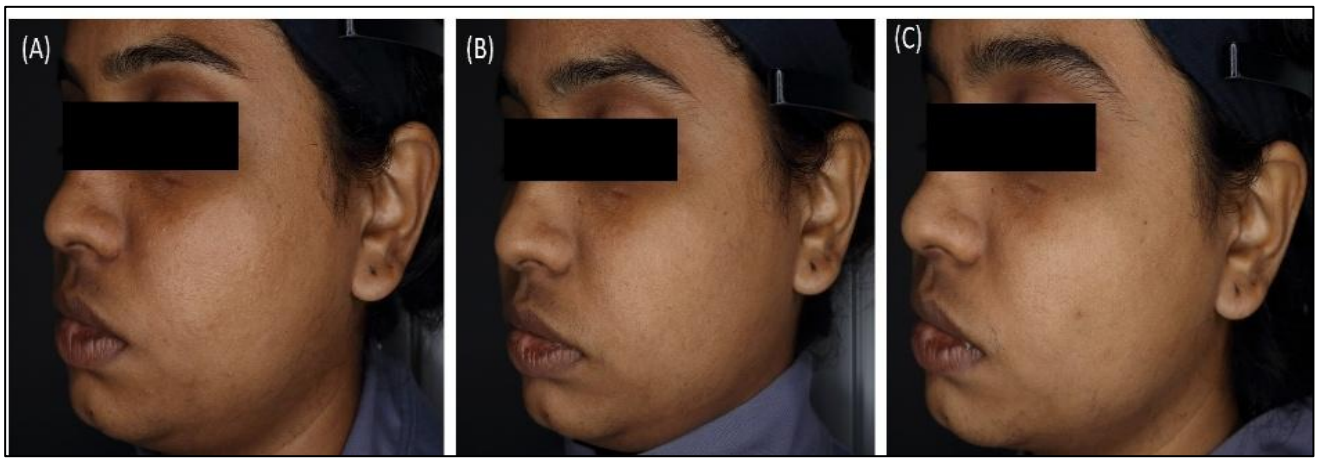

Figure 6: Clinical photographs (standard digital images), female, 22 years, left cheek.

*Serial clinical photographs of a 22-year-old female participant (left cheek) at baseline (A), day 30 (B), and day 60 (C). Progressive lightening of hyperpigmented macules and more homogeneous skin tone are visible after 8 weeks of once-nightly serum application.

Subjective efficacy assessments using self- assessment questionnaires

In addition to objective measures, subjective assessments aligned with these findings. As shown in Table 2 and Figure 7, at week 4, approximately 75% or more of the total participants reported a reduction in pigmentation marks, which increased to approximately 97% by week 8. The perceived evenness of skin tone, overall facial appearance, product satisfaction, and willingness to recommend the serum-all followed the same strong positive trend. The serum was well tolerated during the study period. A small number of participants experienced mild, transient local reactions, such as slight erythema or dryness, during the early days of use, which resolved spontaneously without the need for discontinuation or additional treatment. No moderate or severe erythema, edema, burning, or pruritus was observed on clinical examination, and most visits were graded as having no local reaction on the modified Draize scale.

Table 2: Subjective self-assessment on day 30 and day 60 (% of participants agreeing or strongly agreeing-top-2-box scores, (n=32).

Statements	Day 30 (%)	Day 60 (%)
Pigmentation marks on my face have been reduced.	78.1	96.9
My facial skin tone has become even.	62.5	93.7
The appearance of my facial skin improved significantly.	68.8	96.9
I am satisfied with this product.	62.5	93.7
I would recommend this product to others.	59.4	93.7

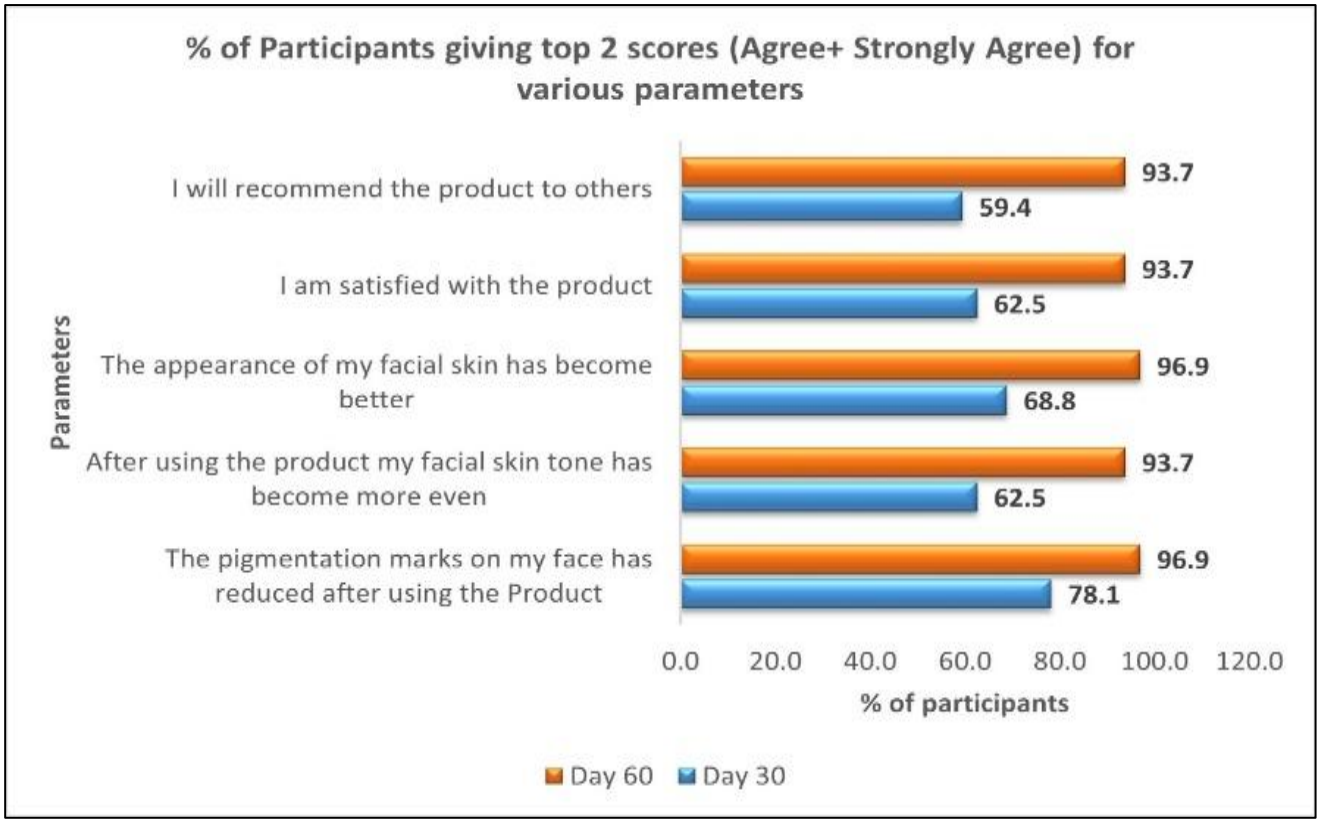

Figure 7: Percentage of subjects reporting agree to strongly agree for all the parameters, (n=32).
*Bar chart of percentage of participants agreeing/strongly agreeing (top-2-box) with each self-assessment statement at day 30 and 60.

DISCUSSION

This 8-week study demonstrated that once-nightly application of SOLGLO-AZ Serum reduced blemish scores by 25%, increased skin luminance (L*) by 18.8%, and decreased average pigmentation by 9.2% in Indian adults with Fitzpatrick skin types III-IV, as assessed by clinical grading of blemish scores and Antera 3D imaging. Significant objective improvements were matched by high patient satisfaction rates (>93%), and no irritation or adverse events were observed. The degree of lightening observed at week 8 surpassed that usually reported for most treatments that use only one active ingredient alone. For instance, a typical 20% azelaic acid cream achieves an 8-12% improvement in L* over a period of 12-24 weeks, while a 5% tranexamic acid is associated with a 10-14% improvement over 12 weeks.[18,19,21-24] Recent comparative analyses in Asian cohorts, including network meta-analyses of over 14 therapies have affirmed that combination regimens outperform single agents in melasma management, with multi-ingredient serums showing superior pigment reduction and fewer side effects.

Melanin overproduction in skin of color is driven by multiple pathways, including tyrosinase activity, melanosome transfer to keratinocytes, and paracrine stimulation via the plasminogen-plasmin system.[1,25,26]

The enhanced efficacy in the current trial can be attributed to the serum's multi-targeted approach, synergistically inhibiting multiple key melanogenic pathways, including tyrosinase inhibitors (azelaic acid, and alpha-arbutin), melanosome transfer blockers (niacinamide), plasminogen-activator inhibitors (tranexamic acid), fermentation-derived agents (Saccharomyces ferment), polyphenol-rich extracts with tyrosinase inhibitory effects (Vitis vinifera grape fruit extract), and amino acid, arginine collectively contributing to the improvement in pigmentation and epidermal barrier integrity, mitigating trans-epidermal water loss in humid environments.[17-29,31-38] Liposomal delivery strategically enhances penetration and minimizes irritancy usually observed with azelaic acid and exfoliating acids.[18] This is particularly advantageous for Indian skin phototypes III-IV, which are prone to PIH under tropical UV exposure and humidity.[26] Inclusion of Saccharomyces ferment with Vitis vinifera fruit extract and arginine adds novel benefits, such as microbiome normalization, antioxidant protection against UV-induced damage, and enhanced brightening, which are especially relevant for Indian skin facing environmental stressors that exacerbate uneven tone and PIH.[26,30,31-36]

These findings are consistent with the clinical and instrumental improvements observed in the present study. The absence of erythema, stinging, or burning sensations even with exfoliating acids like salicylic and

glycolic acids indicated better tolerability of liposomal encapsulation in tropical conditions, where conventional azelaic acid often leads to irritation in Indian skin.[17,18] This study addresses gaps in the existing literature, where many studies focus on melasma alone, whereas our cohort included diverse etiologies (melasma, PIH, and solar lentigines), reflecting Indian dermatological presentations. The limitations of this study include its open-label, single-arm design and relatively small sample size. The study duration of eight weeks was sufficient to demonstrate the rapid onset of benefit but not to determine longer-term durability or the effect of continued use or maintenance dosing. Future randomized controlled studies with longer follow-up, larger and more diverse Indian cohorts, and active comparators would be valuable for confirming and extending these results.

Despite these limitations, the findings of the present study have practical implications. To our knowledge, no prior clinical cosmetic trials in India have evaluated the clinical efficacy and safety of a once-nightly serum combining liposomal azelaic acid, tranexamic acid, niacinamide, Saccharomyces Ferment, Vitis Vinifera (grape) Fruit Extract, and arginine into a single formulation delivering rapid, objective, and clinically significant lightening of facial hyperpigmentation with remarkable tolerability. The ability to produce noticeable lightening within one to two months improved adherence and satisfaction. These results affirm the clinical benefits of multi-targeted, liposome-augmented combinations for Indian patients, thereby endorsing their use as safe, effective first-line treatments amidst increasing regulatory limitations on hydroquinones.[11] Further, this novelty represents a significant advancement, as the integration of these ingredients in a single, hydroquinone-free serum optimizes efficacy through complementary mechanisms-tyrosinase inhibition, anti-inflammatory effects, barrier reinforcement, and antioxidant defense-tailored to the unique needs of Indian skin, which often experiences amplified hyperpigmentation owing to genetic predisposition, intense sun exposure, and pollution.

CONCLUSION

In conclusion, SOLGLO-AZ Serum, a hydroquinone-free formulation featuring liposomal azelaic acid, tranexamic acid, niacinamide, alpha-arbutin, and the innovative Saccharomyces ferment with Vitis vinifera fruit extract and arginine, resulted in statistically significant and clinically relevant lightening of facial hyperpigmented spots within 8 weeks in Indian patients with Fitzpatrick skin types III-IV. The treatment led to a notable increase in skin luminance (+18.8%) and a decrease in pigmentation index (9.2%), as demonstrated through 3D imaging, along with over 93% patient satisfaction and an excellent safety profile of the treatment. This positions this serum as a highly appealing first-line or adjunctive treatment in the form of current regulatory context, which emphasizes the use of safe, multi-target depigmenting agents. These findings advocate the integration of advanced liposomal combinations into standard dermatological practices to address this condition.

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