



Original Research Article

Evaluating the use of an advance lotion for addressing skin hyperpigmentation

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ABSTRACT

Background: Localized hyperpigmented spots on the skin can cause concern due to their associated aesthetic implications. Skin types higher on the Fitzpatrick scale are particularly more susceptible to the development of hyperpigmentation. Several studies focusing on the pathophysiology of hyperpigmentation reveal that exposure to ultraviolet radiation can trigger or further exacerbate the condition. Many topical formulations are available in the market, consisting of either individual or a combination of agents. Of late, there has been an increased interest in botanical extracts as safer alternatives to traditional skin-brightening agents. However, there is a paucity of human trials evaluating the outcomes associated with such combination products.

Aim: This study examined the efficacy and safety aspects related to the use of Advance Lotion, which contains *Rumex occidentalis*, licorice, kojic acid, arbutin, and vitamin E as key ingredients, for addressing skin hyperpigmentation.

Materials and Methods: The outcomes were evaluated using instrumental variables that are well-established indicators of skin pigmentation and based on self-assessment by study participants.

Results: The results revealed a significant reduction in skin pigmentation and cumulative improvements upon the continued use of Advance Lotion. There were no associated cases of skin intolerance as observed in the clinical examination or reported by the study participants.

Conclusion: These promising results indicate the effectiveness of this product in visibly reducing pigmentation.

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1. Introduction

Although skin hyperpigmentation may be caused by inflammatory reactions, ultraviolet (UV) exposure, photoaging, increased estrogen levels, and phototoxic drugs, UV exposure has been identified as a common factor that aggravates most hyperpigmentation disorders.^{1,2} Localized hyperpigmentation, although prevalent among Fitzpatrick skin types IV and higher, is also observed in individuals with lower Fitzpatrick scores.³

The desire for aesthetically pleasing skin motivates those with hyperpigmentation disorders to seek measures to reduce skin irregularities, which may cause stress, anxiety, and psychological distress in such individuals, which, in turn, may negatively impact their quality of life.^{4,5} Often, such conditions go without appropriate corrective measures due to gaps in knowledge and circulating myths (e.g., individuals with skin of color do not need sunscreen or facial products).^{6,7} Individuals with hyperpigmentation disorders, such as melasma, have lower Dermatology Life Quality Index scores than those with vitiligo, lichen planus, bullous pemphigoid, acne scarring, and pityriasis rosea.⁸

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The treatment for localized hyperpigmentation includes eliminating causal factors and using photoprotection along with active pigment reduction with topical formulations.³ Most topical formulations target various steps of the melanogenesis pathway, including competitive inhibition of tyrosinase, targeting melanosome maturation or transfer, stimulation of keratinocyte turnover, and oxidation and breakdown of melanin.^{2,3} Combinations of agents targeting different stages of melanogenesis are known to provide better outcomes and reduce side effects marketed formulations may also contain sunscreens and stabilizers.³

Topical cosmetic products used to treat hyperpigmentation have varying levels of evidence supporting their efficacy and safety.² Although some studies have investigated individual components of cosmetic products, few trials examined the efficacy and safety profiles of commercially marketed combination products and botanical extracts.

This study examined the efficacy and safety profile of Advance Lotion, a combination product that includes botanical extracts. The formulation of Advance Lotion includes kojic acid; arbutin; and extracts of *Morus alba*, *Curcuma longa*, *Artocarpus lakoocha*, and *Glycyrrhiza glabra*, which have skin-brightening, UV-filtering, anti-inflammatory, and antioxidant properties. Studies have shown that each of these individual agents is efficacious in reducing skin pigmentation by inhibiting tyrosinase activity and melanin dispersal.^{9–14} In addition, Advance Lotion also contains a photoprotective and depigmenting agent, vitamin E acetate, which acts as a free radical scavenger, alters lipid peroxidation of the melanocyte membrane, increases intracellular glutathione content, and inhibits tyrosinase.^{15,16}

The effect of Advance Lotion in reducing pigmentation following its application on the face, neck, and upper trunk (back) regions was evaluated in this study. Clinical evaluations for the in-use skin tolerance of this product were also carried out.

2. Materials and Methods

2.1. Study design

In this monocentric study, individuals were followed up for 45 days, and their status was compared to their initial state. Following an initial screening to establish the baseline, study visits were planned on Day 21 and Day 45. Data on instrumental and self-assessment variables were collected and analyzed to determine the test product's efficacy and skin tolerance. Patients' demographics, medical and surgical history, and medication use were recorded during the first visit.

This trial was approved by the Ethics Committee (Approval form no. CL/083/1 119/STU) and carried out in compliance with the protocol, Declaration of Helsinki,

Good Clinical Practice (GCP), and Indian Council for Medical Research (ICMR) guidelines concerning medical research in human subjects. Written informed consent was obtained from all subjects before the study initiation. The identity of the subjects was kept confidential, and no identifying features were shown in the photographs.

2.2. Subjects

Women aged 18–55 years with hyperpigmentation on the face, neck, or upper trunk (back) were enrolled in this study. The study subjects were informed orally and in writing of all study procedures and objectives. Eligibility criteria included subjects voluntarily agreeing to provide informed consent and compliance with the study protocol. The protocol criteria included avoiding sun exposure to the extent possible and not using any products with the same end benefit during the entire study duration. Subjects receiving topical treatment for any face condition 2 weeks before the first visit were excluded. The inclusion criteria were women in the age group of 18 to 55 years with hyperpigmented spots on the face or neck or upper trunk (back) areas and willing to avoid unusual sun exposure as far as possible for the entire study duration. Exclusion criteria also included pregnant or lactating women and those under treatment for a dermatologic condition (such as eczema, psoriasis, severe sun damage, or dermatitis) that may have interfered with the evaluation of the study product. Those using skin-whitening medication 2 months before the trial or any systemic medical treatment with potential for interference with study treatment within the past month were also excluded. Subjects in an exclusion period or participating in any clinical trial within 30 days before screening were also part of the exclusion criteria. The discontinuation criteria included the unexpected occurrence of parameters mentioned in the exclusion criteria during the observation period, product intolerance (fully recorded by the investigator), noncompliance by the subject, or the participant's request.

2.3. Study treatment

The trial subjects were provided with the test product (Biluma® Advance Lotion) marketed by Galderma India Pvt. Ltd. and sunscreen (Sunscreen with SPF 50) for twice-daily use (morning and night before bedtime). This study focused on the face, neck, and upper trunk (back) as regions of interest (ROIs) to assess efficacy and safety variables. Before applying the test product, the subjects were instructed to wash the ROI and dab dry with a towel. Following the wash, a thin layer of the lotion (approximately 5 g) was applied on the face, neck, and upper trunk (back) areas by gentle rubbing. Instructions were provided to avoid product contact with the eyes and to rinse immediately with ample water in case it happened.

2.4. Efficacy endpoints

The primary efficacy parameters were skin radiance, skin color, skin gloss, and skin hydration measurements. Skin radiance and skin color were based on spectrophotometer readings for attaining L*values and individual typology angle (ITA), respectively. The spectrophotometer (Konica Minolta) illuminates the skin with white light emitted by two pulsed xenon lamps, and a system of photoelectric cells measures the difference between the emitted light and the light reflected by the skin. Skin gloss was measured using the SkinGlossMeter (Delfin Technologies, Kuopio, Finland). The SkinGlossMeter measures specularly reflecting light from the skin and other nonplanar surfaces. The gloss values are measured using a photodetector, and the total intensity of the reflected beam is then calculated. Skin hydration was determined using MoistureMeterSC (MMS) readings. The MMS (Delfin Technologies, Kuopio, Finland) measures the hydration of the skin surface, the stratum corneum. The skin is an electrically layered structure. The electrical properties of its layers are related to their water content. The subjects were acclimatized under controlled conditions of temperature (22°C–24°C) and humidity (40%–60%) for 30 minutes before recording instrumental variables. Before and after photographs were taken for representative purposes.

2.5. Safety endpoints

The safety parameters were based on clinical evaluation for in-use tolerance using a scale from 0 to 3—0 being ‘none’ and 3 being ‘severe.’ The evaluation parameters included erythema, edema, cutaneous dryness, roughness, and others (as specified in the clinical protocol).

2.6. Participant-reported outcomes

A subjective self-assessment questionnaire was administered to the participants to understand their perception of the effects of the product. There were separate questionnaires for efficacy and in-use tolerance, with recorded responses ranging from ‘strongly disagree’ to ‘strongly agree.’ The efficacy parameters included in the questionnaire were (1) skin moisture status, (2) visible reduction in pigmentation, (3) skin glow, and (4) overall feeling (if better than before). The tolerance questionnaire included pricking, tingling, itching, and burning sensations.

2.7. Statistical analysis

The continuous variables were summarized using summary statistics, such as the number of observations, mean, standard deviation (SD), or median with a range of minimum and maximum. Tests of significance were based on the Student’s t-test. The reported p-values were obtained using two-sided tests with a 5% significance level. All

statistical analyses were performed using SPSS 10.0.

3. Results

3.1. Baseline characteristics

In this study, 31 female participants aged 18–55 years (mean=41.61, SD=5.75, range 27–53 years) were recruited. Baseline characteristics on instrumental variables for skin radiance, color, hydration, and gloss were recorded. These measurements were obtained from the face, neck, and upper trunk (back) regions and are summarized in Table 1.

3.2. Effect on skin radiance

Significant improvements in skin radiance (L*values) from the baseline were observed as a result of the application of the test product on ROI by Day 21 and Day 45 (Table 1 and Figure 2a). The differences on Day 21 accounted for an improvement of 2.8%, 4.4%, and 2.6% for the face, neck, and upper trunk (back), respectively. The improvements from baseline at Day 45 were 4.7%, 5.5%, and 4.6% for the face, neck, and upper trunk (back), respectively.

3.2.1. Effect on Skin Color



Figure 1: Representative digital photograph of the face, neck, and back.

Figure 1: Representative digital photographs of the face, neck, and upper trunk (back).

The application of the test product on ROI resulted in significant improvements in mean skin color from the baseline as measured by ITA values (Table 1 and Figure 2b). On Day 21, the improvements accounted for 89.1%, 117%, and 28% for the face, neck, and upper trunk (back), respectively. The improvements by Day 45 accounted for 148%, 138%, and 46.9% for the face, neck, and upper trunk (back), respectively.

Table 1: Summary of measurement records for instrumental variables on Day 21 and Day 45

	Baseline	Day 21	% Improvement by Day 21	Day 45	% Improvement by Day 45
Skin radiance (spectrophotometer readings)					
Face	48.58±4.18	49.96±3.94	2.8*	50.86±4.04	4.7*
Neck	48.31±5.23	50.45±4.14	4.4*	50.97±3.99	5.5*
Upper trunk (back)	45.66±3.88	46.85±3.77	2.6*	47.76±3.90	4.6*
Skin color (spectrophotometer readings)					
Face	-4.58±13.02	-0.50±12.68	89.1*	2.22±12.63	148*
Neck	-5.67±16.30	0.97±11.69	117*	2.17±11.59	138*
Upper trunk (back)	-13.48±12.30	-9.70±11.91	28*	-7.15±12.21	46.9*
Skin hydration (Moisture Meter SC readings)					
Face	21.48±11.10	21.97±11.25	NSI	24.75±13.41	NSI
Neck	47.57±18.70	46.60±15.04	NSI	56.42±17.71	18.6*
Upper trunk (back)	27.93±10.38	26.67±9.52	NSI	32.91±12.44	17.8*
Skin gloss (skin gloss meter readings)					
Face	48.35±06.35	49.22±6.31	NSI	49.95±5.50	NSI
Neck	42.89±04.36	43.46±4.25	NSI	43.98±4.66	NSI
Upper trunk (back)	43.01±04.06	43.72±3.96	NSI	45.31±4.62	5.3*

*Significant (p<0.05).

NSI: No significant improvement.

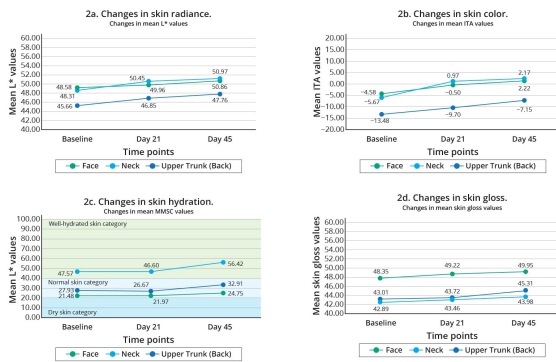


Figure 2: Changes in instrumental measurements from baseline to Day 21 and Day 45. ITA: Individual typology angle; L: Luminosity; MMSC: Moisture Meter stratum corneum.

3.3. Effect on skin hydration

No significant improvements in skin hydration values were noted on Day 21 for the ROI. However, the measurement for the neck and upper trunk (back) showed an improvement following the test product application on Day 45 (Table 1). These changes accounted for an increase in MMSC values by 18.6% and 17.8% for the neck and upper trunk (back), respectively (Table 1 and Figure 2c). There was no significant change in these values for the face at any time point.

3.4. Effect on skin gloss

There were no significant changes in skin gloss after 21 days of applying the test product for any of the ROIs. Similarly, on Day 45, no significant improvement was noted for the face and neck regions. However, an improvement of 5.3% in mean skin gloss measurements for the upper trunk (back) was observed on Day 45 (Table 1 and Figure 2d).

3.5. Participant-reported outcomes

The responses to the self-assessment questionnaire were gathered for facial skin variables, which included moisturization status, pigmentation, glow, and overall appearance. Moisturization status, pigmentation, glow, and overall feel were perceived to have improved by Day 21. Further self-perceived improvements were recorded on the continued application of the test product till Day 45. The results showed a cumulative improvement in skin variables as observed from a change in self-assessed responses from ‘agree’ on Day 21 to ‘strongly agree’ by Day 45. Such a change was more prominent in the reduction in pigmentation compared to other parameters (Figure 3). A summary of responses from the self-assessment is provided in Figure 4.

3.6. Safety

The clinical examination did not reveal any skin intolerance such as pricking, tingling, itching, or burning sensation in response to the test product among study subjects. Participants’ self-assessments also showed no reports of

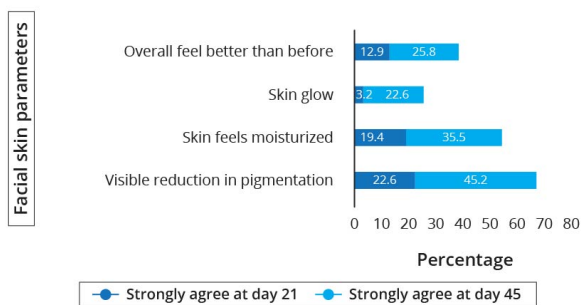


Figure 3: Cumulative improvements in self-assessment parameters were observed by an increase in the number of respondents selecting strongly agree (comparison of responses on Day 21 and Day 45).

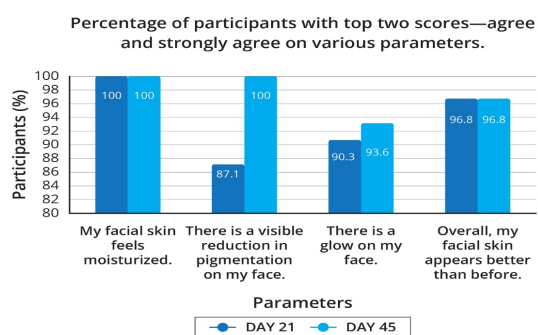


Figure 4: Summary of responses from the self-assessment questionnaire for efficacy reflecting cumulative improvement in the perception of respondents after the use of Advance Lotion.

skin intolerance. There were no test product-related adverse events. One participant developed pityriasis rosea, which was unrelated to the test product.

4. Discussion

Although widely marketed, there is a shortage of studies that systematically evaluate the proposed claims of the efficacy and safety of topical skin-brightening products. Recently, there has been an increased interest in exploring the use of botanical extracts on account of safety concerns associated with traditional depigmentation agents. Experimental studies have tested the proposed benefits of several botanicals, but controlled clinical trials are lacking.¹⁷ This study evaluated the efficacy and safety of Advance Lotion, a formulation with combinations of agents, including plant-derived, skin-brightening components. Additional ingredients with UV filter, moisturizing, antioxidant, and anti-inflammatory activities are also part of this formulation.

The assessment included both instrumental and self-evaluation components. Standardized evaluation parameters for skin radiance, color, hydration, and gloss were used to gather measurements. The skin radiance was measured using spectrophotometer readings for L* values (luminosity index), representing the scale of 0 to 100 with darker shades closer to zero. This method allows the capturing of skin pigmentation.¹⁸ Statistically significant improvements in mean values from the baseline were observed after 21 days of application of the test product.

Further favorable change was noted on continued use of the test product till Day 45 (Figure 1). Significant enhancements in skin radiance were detected in all three ROIs (face, neck, and upper trunk [back]). The skin color was measured using the ITA metrics; ITA values expressed in degrees are calculated based on the L*a*b* system and are defined as the vector direction on the L*-b* plane. The reflected light from two pulsed xenon lamps of the spectrometer is analyzed using a microcomputer according to three axes of color: black to white = L*, green to red = a*, and blue to yellow = b*. These values are inversely related to skin pigmentation.¹⁹ The mean ITA values of the study group improved significantly by Day 21 and showed a cumulative improvement when final measurements were recorded on Day 45 (Figure 1). The total change from baseline by Day 45 was 148%, 138%, and 46.9% for the face, neck, and upper trunk (back), respectively. Self-assessment by the study participants corroborated the evidence observed from instrumental parameters for reducing skin pigmentation.

These observations suggest that continued use of the test product can result in cumulative improvements in skin depigmentation-related outcomes. However, it requires further investigation to establish the need for continued use to maintain the remission status. Such might be the case, especially for skin pigmentation resulting from underlying physiological changes, such as an imbalance in hormones or aging. Alterations in pigmentation due to UV exposure and photoaging are widely accepted. There may be benefits in using this product as a preventative measure for photoprotection and in those with skin tones which are more susceptible to pigmentation disorders.

The improvements observed in this trial are positively supported by the existing literature on the effectiveness of the individual formulation ingredients of the test product. Active components, such as kojic acid, arbutin, and glabridin (from licorice extract), inhibit tyrosinase. Similarly, compounds from the extracts of *Artocarpus lakoocha*, *Curcuma longa*, and *Morus alba* have been observed to elicit tyrosinase inhibitory activity in *in vitro* studies.^{9–14} Corresponding skin-whitening properties with the reduction in melanin formation have also been observed in human trials. Although kojic acid can potentially cause skin irritation, no such effect was noted in clinical

safety assessment and self-assessment by the subjects.²⁰ In addition to altering the production of melanin, the skin-brightening property of licorice extract can also be attributed to the melanin-dispersing potential of liquiritin.²¹

No significant improvements in skin hydration in the facial skin were observed. However, some improvement in hydration in the neck and upper trunk (back) region (18.6% and 17.8%, respectively) was noted by Day 45. These results suggest the possibility of a more noticeable outcome with continued use of the test product for a longer period beyond Day 45. Similar results were noted for skin gloss measurements, with significant effects observed in the upper trunk (back) region by Day 45. Interestingly, the responses from self-assessment reflect perceived improvement in skin hydration and gloss by the study participants. The addition of a wash to the care regimen with components that can alter the skin barrier function could potentially improve such aspects of the test product.^{22,23}

Despite these clear results, one of the limitations of the study is its monocentric design and small sample size, which would make it difficult to extrapolate these results to a larger population. Multicentric studies with larger sample sizes will be needed to confirm the results reported here.

5. Conclusion

Skin hyperpigmentation can result from a variety of reasons in individuals with certain skin tones, which are more susceptible than others. Skin photoaging and prolonged exposure to the sun can trigger or worsen this condition. Several topical formulations are available in the market; however, systematic studies to support their claims are lacking. This study demonstrates the efficacy and safety of the use of Advance Lotion for addressing hyperpigmentation. Both instrumental and self-assessment parameters reflected significant visible reductions in pigmentation. These promising results suggest that the product provides additional benefits on continued use and can serve as a preventive measure for those vulnerable to pigmentation disorders. This study shows the improvement in overall skin radiance and color without raising any tolerance concerns upon the application of the test product.

6. Author Contribution

All authors have contributed equally to the conception, design, drafting, review, and finalization of the manuscript.

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