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Original Research Article

Efficacy of skin care regime in improving biophysical parameters of skin: a split face clinical study

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ABSTRACT

Background: Background: Healthy and glowing skin is an aspired skin benefit among consumers and is linked to well-groomed appearance and self-esteem. Face cleansing is the first line of grooming practice as a part of hygiene among consumers. While these facial cleansers help to keep skin clean, skin also needs additional care as it is exposed to environmental pollution or solar radiation or other aggressors like dry or cold weather that can damage or strip of skin's moisture, making it dry, rough and dull impacting the overall skin health.
Methods: The present clinical study is a randomized, mono centric, split face trial conducted in 40 healthy Indian female volunteers in the age group of 20-45 years. The objective of the study was to evaluate the efficacy of a face cleanser vs regime (face cleanser + face moisturiser) formulated with glycerol, niacinamide, 12-hydroxystearic acid and hexylresorcinol in improving skin hydration, brightness, glow and reducing the severity of dark spots.
Results: Both regime and face cleanser demonstrated improvement in glow, hydration and reduction in dark spot intensity on 2 weeks of regular use. Regime is significantly superior in all the biophysical parameters of skin. Both cleanser and regime are well accepted among the subjects without any adverse events like redness, itching or irritation.
Conclusions: While both face cleanser and regime demonstrated improvement in skin biophysical parameters, regime was significantly superior and accepted by participants for sustained skin benefits. Hence, it is recommended to adopt regime-based skin care treatments for sustained skin benefits.

Keywords: Niacinamide, Hexylresorcinol, Glow

INTRODUCTION

Human skin color is determined by the levels of pigment, the melanin located in the epidermis of skin, inherently by genetics. This natural pigment in skin is an adaptation to protect skin from the harmful effects of UV radiation in population evolved closer to equator.[1] However, hyper-pigmented conditions like acne marks, melasma, solar lentigines and uneven skin tone are consequence of various external and internal factors like exposure to UV radiation, pollution, hormonal imbalances or post inflammatory conditions followed by acne or physical injury or trauma to skin like wounds or burns.[2] Occasionally exposure to harsh chemicals like glycolic peels or high pH products also induce pigmentation in susceptible people.[3]

While hyperpigmented spots or uneven skin tone is not life threatening, they can cause significant social impact on self-confidence and perceived appearance in people

suffering from persistent pigment issues like acne marks and pigment patches.[4] It is estimated that prevalence of hyper-pigmentation disorders is up to 50% and commonly seen in melanin rich skin (like type IV and V). According to a study conducted on Indian population, majority of dark spots, are presented as post inflammatory hyper-pigmentation marks due to acne in people under 35 years, while only 10% constitute other skin pigmentation problems.[5] Several therapeutic interventions are available to achieve faster clinical outcomes, such as leave on creams with melanin inhibiting or de-pigmentation actives like hydroquinone and kojic acid, epidermal exfoliators like glycolic acid peels, or procedures like CO_2 laser resurfacing for severe hyperpigmentation conditions. Such treatments are proven to have perceivable clinical outcomes.[6,7] However, they are associated with side effects including skin irritation, erythema, dyschromia or pigmentary rebound in susceptible people.[8] These treatments may also increase skin sensitivity in such susceptible population and need to be used under the supervision of dermatologists.

India is a tropical country, with most of the people have melanin-rich skin and are highly susceptible pigmentation issues at some or other point of time in life. Hence the burden of hyper-pigmentation issue is far more high among Indian population. The Indian beauty and personal care market is expanding rapidly, reaching a value of US$10.5 billion in 2021.[9] There has been a substantial shift in consumer behaviour and expectations in skincare category, moving away from basic skin brightening solutions to science driven, dermatologically tested approaches for managing day to day skin care problems like dullness, dryness and pigmentation concerns. Consumers are increasingly looking for science-based ingredients, clinical proof and adopting regimen-based skincare treatments, involving the use of multiple complementary products designed to cleanse, treat, protect, and maintain skin health. The present clinical study was designed to evaluate the efficacy of a facial cleanser formulated with skin brightening and barrier enhancing technologies, compared with a comprehensive skincare regimen comprising the same facial cleanser with face moisturiser made with hydration and depigmentation technologies like, glycerol, hexylresorcinol, niacinamide respectively. In the present study we evaluate and compare the improvement in biophysical parameters associated with skin health and appearance in Indian women presenting with dull skin and dark spots upon treating with only face cleanser vs regime.

METHODS

Ethics and informed consent

The study was conducted at Mascot Spin Control, Mumbai, India, in December 2025, under the supervision of a qualified dermatologist serving as the Principal Investigator. All study-related documents were reviewed, and the study protocol received approval from Institutional Ethics Committee, on 6th December 2025. The study was performed in accordance with the approved protocol, the ICMR National Ethical Guidelines (2017), ICH E6(R3) Good Clinical Practice (GCP), Good Clinical Laboratory Practice (GCLP) guidelines, the Declaration of Helsinki (2013), and all other applicable regulatory and ethical requirements.

Clinical design

The study was a split face, randomized, blinded and monocentric with a treatment period of 2 weeks. Female volunteers in the age group of 20-45 years with dark spots and dull skin were recruited as per inclusion and exclusion criteria. Demographics of the study volunteers are shown presented in Table 1. Participants used face cleanser and regime on the split face as per randomization. Pregnant and lactating women were excluded from the study. Volunteers with any skin related problems or allergies that can potentially interfere in the study results were also excluded from the study as per the dermatologist's discretion. Subjects have undergone wash-out period of 3 days with a neutral cleanser. Volunteers were restricted from using any skincare products during the study period. Post wash out, total of 40 participants qualified for treatment phase, all of them completed the study.

On the baseline visit, subjects were acclimatized for 15 minutes at 22° C±5 and relative humidity of 50±5% followed by instrumental assessment: brightness by L* using Spectrophotometer CM-26d (Konica Minolta), hydration with Corneometer CM 825 and trans-epidermal water loss (TEWL) by Tewameter® TM 300 (Courage + Khazaka Electronic GmbH). Skin smoothness was assessed using Antera 3D® (Miravex Limited) imaging.

Skin dullness, evenness of skin tone and skin clarity were assessed by a dermatologist using a 10-point visual assessment scale. For skin dullness, a score of 0 indicated highly radiant/glowing skin and 9 indicated very dull skin. For skin tone evenness, 1 represented a high unevenness and 10 is even-toned skin. For skin clarity, 0 indicated clear skin, whereas 9 indicated skin with visible blemishes and imperfections.

To assess skin hydration and TEWL measurements were taken on cheekbones, skin brightness and smoothness were assessed on forehead. The following are assessment time points: after 1st application (T instant), 1 week and 2 weeks. Both face cleanser and regime were used twice a day on half face as per randomization. Consumer assessment on efficacy of cleanser and regime was recorded. Feedback on product's sensory attributes like overall satisfaction, post usage sensory on skin like hydration, roughness, smoothness etc., were also collected.

Statistical analysis

All statistical tests for clinical data were performed at two-sided 5% level of significance and 95% confidence interval and Statistical software PAST 4.03 and SigmaStat 3.5 were used for the analysis of the data. Paired t-test was used to evaluate the efficacy vs baseline, and 2 sample t-test was used to compare between the face cleanser and face cleanser+moisturiser regime.

RESULTS

Demographics of the study volunteers

Table 1: Demographics and volunteers characteristics at baseline.

Age range	20-45 years
Gender category and number of participants	Female and 40
Ethnicity	Asian (Indians)
Skin condition	With dull skin and dark spots

Skin brightness

Skin brightness was assessed by L* (luminescence) using spectrophotometer. There is significant improvement in skin brightness upon using face cleanser or regime at all assessment time points T instant, 1 week and 2 weeks vs respective baselines. All the study participants (100%) showed improvement in brightness by the end of 2 weeks treatment period. Face cleanser showed an improvement of 1.7% and regime demonstrated an improvement of 2.7% (vs baseline) by the end of two-week treatment period. Regime delivered significantly higher brightness at week 2 compared to face cleanser alone (Figure 1).

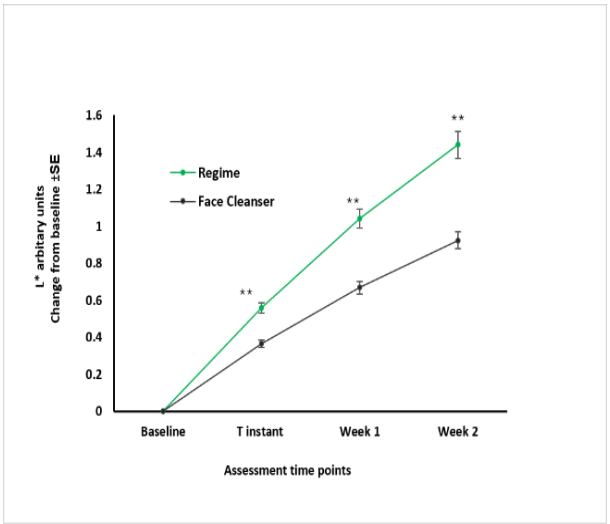


Figure 1: Skin brightness measured by L*.

Data expressed as change from baseline±SE (**p<0.05 Face cleanser vs regime).

Skin dullness

Dullness was assessed by dermatological visual assessment on a scale of 0-9 as dullness score. There is significant reduction in skin dullness (improvement in skin glow) upon using face cleanser or regime at all assessment time points vs respective baselines. Face cleanser showed reduction in skin dullness by 6.8% while regime 12.9% vs respective baseline. Regime delivered significantly higher glow (as dullness reduced) at week 2 compared to face cleanser alone and was superior at all assessment time points (Figure 2).

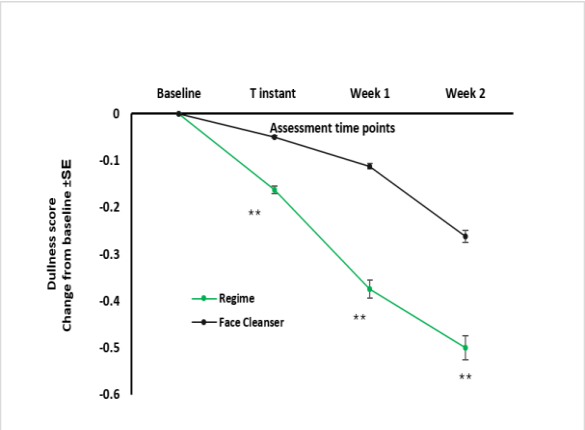


Figure 2: Skin dullness.

(data expressed as change from baseline±SE **p<0.05, Face cleanser vs regime.

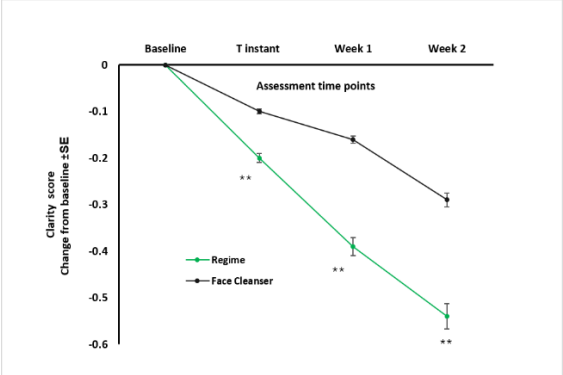


Figure 3: Skin clarity.

Data expressed as change from baseline±SE. **p<0.05, Face cleanser vs regime.

Skin clarity

Skin clarity was assessed using dermatological visual assessment on a scale of 0-9. There is significant improvement in skin clarity upon using face cleanser or regime at all assessment time points vs respective baselines. Face cleansers showed an improvement of skin clarity by 7.5% and regime by 13.9% vs respective baselines by the end of 2-week treatment (Figure 3).

Regime delivered significantly higher skin clarity at Week 2 compared to face cleanser alone.

Skin even tone

Skin even tone was assessed by dermatological visual assessment on a scale of 1-10. There is significant improvement in skin tone upon using only face cleanser or regime by the end of 2 weeks treatment. Face cleanser showed an improvement of skin even tone by 8.4% and regime by 13.7% the end of 2-week treatment period vs respective baseline. Regime delivered significantly superior skin clarity at Week 2 compared to face cleanser alone (Figure 4).

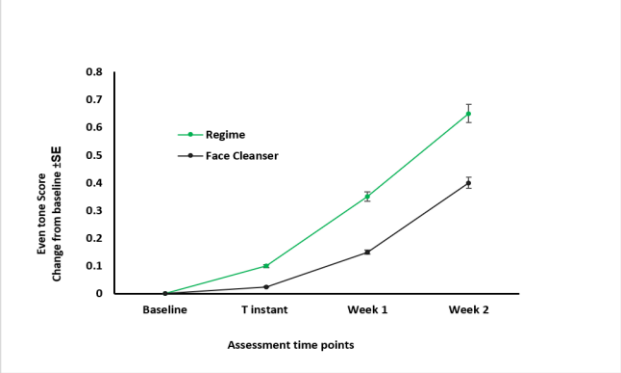


Figure 4: Skin even tone.

Data expressed as change from baseline±SE. **p<0.05, Face cleanser vs regime.

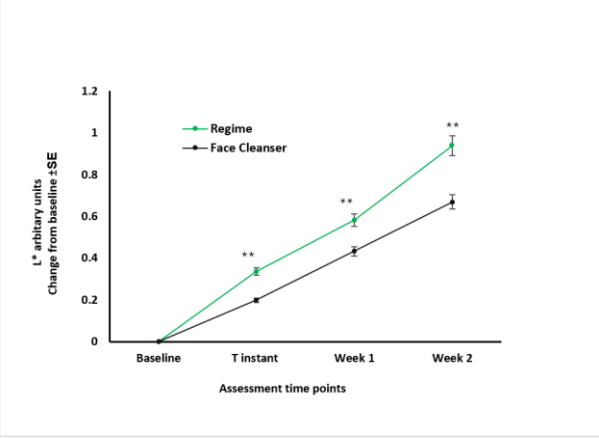


Figure 5: Dark spot lightning- spot L*.

Data expressed as change from baseline±SE (**p<0.05, Face cleanser vs regime).

Dark spot lightening

Dark spot pigment intensity was assessed by measuring L* on dark spot. There is significant reduction in spot pigment upon using face cleanser or regime at all assessment time points vs respective baselines. Face cleanser showed an improvement in spot lightning by 1.3% and regime demonstrated an improvement of 1.8% vs respective baselines by the end of 2-week treatment period. Regime delivered significantly better spot lightning at week 2 compared to face cleanser alone (Figure 5).

Skin hydration

Skin hydration was measured using Corneometer. There is significant improvement in skin hydration upon using face cleanser or regime at all assessment time points vs respective baselines. Face cleanser showed an improvement in hydration by 23.7% face regime by 61.6 % (vs baseline) by the end of 2-week treatment period. Regime delivered 2.5 times higher hydration compared to face cleanser alone (Figure 6).

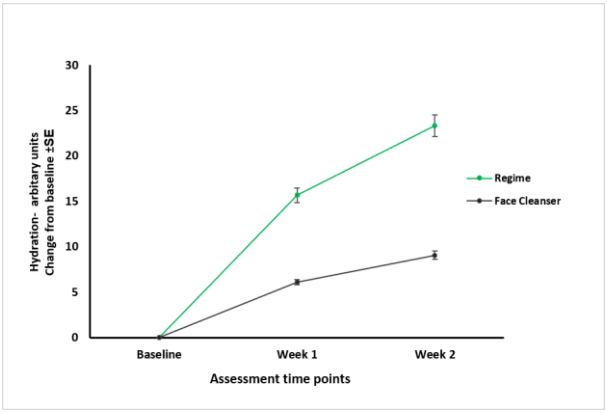


Figure 6: Hydration.

Data expressed as change from baseline±SE (**p<0.05, Face cleanser vs regime).

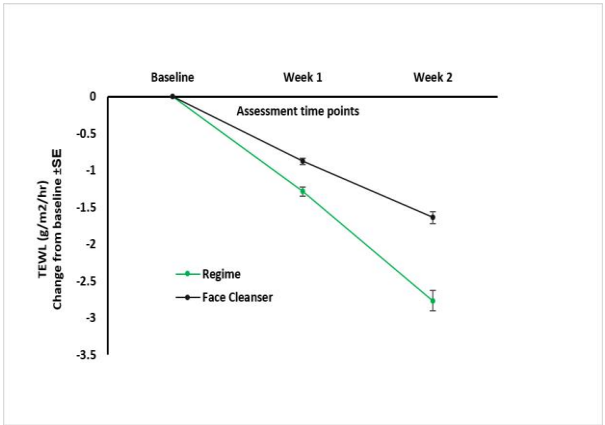


Figure 7: Transepidermal water loss.

Data expressed as change from baseline±SE (**p<0.05 Face cleanser vs regime).

Skin barrier integrity (measured by TEWL)

Skin barrier integrity was measured using Tewameter. There is significant improvement in skin barrier integrity

(reduction in the TEWL) upon using face cleanser or regime at all assessment time points vs respective baselines. Face cleansers showed an improvement of barrier integrity by 11.8% and regime showed an improvement of 19.7 % (vs respective baselines) after 2 weeks. Face regime demonstrated significantly higher barrier integrity compared to only face cleanser (Figure 7).

Skin roughness

Skin roughness was assessed based on Antera 3D image analysis. There is significant reduction in roughness of skin upon using face cleanser or regime at all assessment time points vs respective baselines. Face cleanser showed a reduction in roughness by 7.2% and regime by 10.7 % (vs baseline) by the end of 2-week treatment period. Regime showed significantly higher reduction, making skin smoother compared to only cleanser (Figure 8).

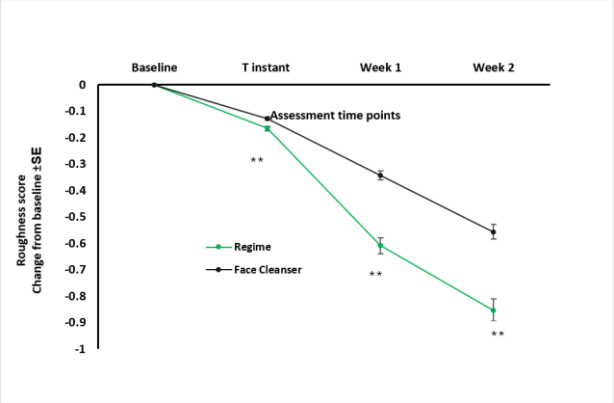


Figure 8: Skin roughness.

Data expressed as change from baseline±SE (**p<0.05 Face cleanser vs regime).

DISCUSSION

In the present 2-week clinical study conducted on Indian women suffering from dark spots and dull skin, both face cleanser and regime demonstrated significant improvement in skin brightness, even tone, dark spot reduction, contributing to improved skin clarity and glow, along with enhanced skin hydration and barrier integrity. Both the face cleanser and face regime was well accepted, with regime demonstrating significantly superior performance across studied biophysical parameters compared to skin cleanser alone. Moreover, 100% of the participants reported improvement in skin condition like glow, brightness, dark spot fading, hydration, soft and supple skin feel and healthier skin post using the regime and rated that regime is more efficacious than face cleanser alone.

Face cleansers in general are formulated for a primary purpose of skin hygiene by cleaning dirt, grime, pollutants deposited on skin and to remove skin's natural secretions like sebum and sweat. With the evolving consumer expectations on the benefit spaces, face cleansing category has transformed from simple cleansing format to advanced science -driven skin care benefit providing technologies to deliver brightness, hydration, barrier protection etc. In the present clinical study face cleanser is designed with technologies like niacinamide, 12-hydroxystearic acid and glycerol to deliver brightness with even tone, barrier protection and hydration respectively. Niacinamide is a multi-functional ingredient, demonstrated based on invitro studies to improve skin barrier health by upregulating the synthesis of ceramides, barrier proteins and proven to inhibit melanin transfer up to 68% basis melanocyte-keratinocyte co-culture and pigment reconstructed epidermis model.[10,11] Studies conducted on living skin equivalent model with cleansers made with 12-hydroxystearic acid has significantly upregulated the makers of barrier and hydration - aquaporin 3, keratin 14, heat shock proteins.[12] In concurrence with the above mechanistic explanation of the technologies used and depositions studies, the face cleanser in the present clinical demonstrated improvement in skin benefits like brightness, hydration and barrier integrity.

While cleansers are proven to provide skin benefits, the contact time of 30 to 60 seconds limits the levels of deposition of functional actives, with most of the actives in the formula being washed off during rinsing and hence the outcomes; which is clearly demonstrated in the present clinical study, with regime (face cleanser+moisturiser) being significantly superior in all benefit spaces compared to only face cleanser.

Leave on treatment in the present clinical study is developed with functional levels of hydrating and brightening technologies (glycerol, hexylresorcinol, niacinamide) that can deliver effective hydration, dark spot reduction, glow, brightness, and other benefits. Pigmentation disorders like dark spots, acne marks, freckles, melasma and age spots are the top 5 dermatological problems with least 50% of population suffers from the same, at some point of time in life. Dark spots are the localized hyperpigmented spots, due to excessive deposition of melanin like post inflammatory hyperpigmentation spots in acne- the acne marks, age spots or solar lentigines due to chronological aging, or freckles due exposure to sun light in type I and type II skin, whereas tanning response which is a diffused uneven pigmentation of skin in higher skin types like III, IV.[13-15]

One of the objectives of the present clinical study was to evaluate the efficacy of the regime (face cleanser+moisturiser) in lightening dark spots and improving skin clarity, with visible outcomes, that are perceivable to consumers. While the cleanser evaluated in the study demonstrated improvement in skin conditions like brightness and glow, addition of a leave on treatment delivered faster and more sustained visible benefits with

60% more brighter skin vs only face cleanser and faster reduction in dark spot intensity by the end of 2-weeks treatment. This faster reduction could be attributed to the mechanisms of action of hexylresorcinol and niacinamide (at optimum levels in the present moisturiser) proven to inhibit melanin synthesis by 35% in melanocytes based in in vitro cell-based studies or melanin transfer respectively.[16]

Human skin is endowed with basal levels of melanin which gives the natural skin colour, the constitutive pigmentation and is determined by genetics, whereas facultative pigmentation is the consequence of exposure to external factors like exposure to UV, pollution, grooming habits and internal factors like susceptibility to acne prone skin or hormonal imbalances. Uneven skin tone in general is not the clear well defined dark spot with borders, but a diffuse borderless uneven pigmentation across the face due to tanning response or exposure to harsher environmental stressors like pollution, leading dull skin, often accompanied by loss of hydration and barrier integrity in pollution exposed skin.[17] Multiple clinical studies demonstrated the role of niacinamide both as single ingredient or in combination with other functional actives like vitamin c, retinyl propionate in improving the skin conditions like brightness, barrier integrity, even tone, resolution of symptoms of atopic dermatitis and regulating sebum production.[18-21] In concurrence to the above-mentioned studies, the face regime with functional levels glycerol, hexylresorcinol, niacinamide has shown superior and faster improvement in hydration, fading dark spots, glow, skin clarity and even tone with smoother skin by the end of two weeks treatment.

Limitations

The present clinical study is the split face comparative design (face cleanser vs regime), with only female participants. Inclusion of men with higher number of participants can add more scientific value to the study.

CONCLUSION

In the present clinical study dermatological, instrumental and imaging assessments are in agreement with enhanced biophysical parameters of the skin up on 2 weeks of treatment of cleanser and regime. Supporting the above assessments, 100% of the users strongly agreed that skin condition is far more superior (brightness, hydration, smooth and supple feel on skin, dark spot reduction) in the regime treatment compared to only face cleanser treated site, with no reported side effects like itching, burning , redness or dryness both for face cleanser or regime treated sites, indicating the both the cleanser and regime are safe to use on skin and well tolerated by 100% of the study volunteers. Hence to achieve the goal of sustained, faster and long-lasting skin benefits it is recommended to adopt regime-based skin care treatments.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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