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Original Research Article

Method development and process validation in dermatology: assessing methods of UV exposure for inducing skin tanning and efficacy evaluation of anti-tanning agents

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ABSTRACT

Background: Understanding the differential impacts of natural versus artificial UV exposure and validating a method to evaluate tanning prevention products are crucial for advancements in dermatological research and skincare. This study aimed to develop and validate a process for inducing skin tanning using natural sunlight and artificial UV-lamps, determining the optimal UV dosages to induce controlled tanning and erythema.
Methods: Six adults aged 18 to 55 were exposed to natural sunlight and a 365nm UV-lamp, with incremental exposure times and doses. Sunlight exposure was at 7600 μW/cm^2 for 20, 35, and 50 minutes, while the UV-lamp provided 78, 97.5, and 117 mJ/cm^2 doses. Skin tan and erythema were measured using Mexameter® MX-18-probe on days 1, 3, and 7. Test products A and B were applied to evaluate their protective efficacy, with untreated sites as controls. Safety assessments included dermatological evaluations for adverse effects.
Results: Sunlight exposure led to a mean erythema index (EI) increase of 40.22, 42.55-, and 47.12-units post-exposure, and mean melanin index (MI) increase of 37.78, 46.22, and 59.20 units by day 3. UV-lamp exposure resulted in less consistent increases, with maximum EI rise of 12.09 units and MI rise of 7.79 units. Test products significantly prevented tanning and erythema compared to untreated sites, with no adverse effects observed.
Conclusions: Direct sunlight exposure was more effective than artificial UV-light in reliably inducing tanning and erythema, establishing it as a method for such studies. The UV-lamp doses were insufficient for consistent results. The study validated a method for evaluating anti-tanning products, confirming their efficacy and safety. These findings support further research and optimization in UV exposure techniques, standardizing a method to induce tanning using direct sunlight exposure.

Keywords: Melanin index, Erythema index, Anti-tanning, Sunlight exposure, UV radiation, Dermatological assessment

INTRODUCTION

Skin tanning is a common skin issue resulting primarily from exposure to UV radiation from the sun. These skin responses, which include increased melanin production and erythema (skin redness), are not merely cosmetic concerns but also indicators of underlying skin damage. Prolonged or intense UV exposure can lead to severe dermatological conditions, including premature aging and skin cancers. Melanin production acts as a defence mechanism against UV radiation, leading to darker skin (tanning), while erythema is an acute response characterized by skin redness due to blood vessel dilation.[1-4]

To mitigate these adverse effects, various cosmetic products have been developed. Sunscreens, containing active ingredients that absorb, reflect, or scatter UV radiation, are among the most common preventive measures. Sun-protective clothing, hats, and sunglasses provide physical barriers against UV radiation. Post-exposure treatments, such as after-sun lotions and creams with soothing agents like aloe vera and antioxidants, aim to reduce inflammation and promote skin healing. Despite these measures, the effectiveness of anti-tanning products can vary significantly, necessitating reliable assessment methods to ensure their efficacy in protecting against UV-induced skin damage.[5,6]

Several techniques are employed to evaluate the efficacy of anti-tanning products. *In vivo* methods involve controlled human exposure studies where participants' skin responses to UV radiation are measured using instruments like the Mexameter® MX 18 probe, which quantifies the EI and MI. *In vitro* methods often use reconstructed human epidermis models exposed to UV radiation to assess the protective effects of sunscreen formulations. Spectrophotometry and photometry measure the absorbance and reflectance of UV radiation by sunscreens, providing estimates of their protective capabilities. These methods, though effective, can be complex and resource-intensive, underscoring the need for simpler yet reliable assessment techniques.[7,8]

In this study, two techniques were employed to induce tanning and erythema: direct sunlight exposure and UV lamp exposure. Direct sunlight exposure utilized natural sunlight in Ahmedabad, Gujarat, where high solar irradiance provided an effective source of UV radiation. This method mirrored real-life sun exposure conditions, offering a comprehensive assessment of skin responses to UV radiation. UV lamp exposure involved a controlled and precise artificial UV light source, using an EU RoHS compliant 365nm UV curing lamp by Edmund optics, with an irradiance of 1300 $\mu W/cm^2$. This method allowed for incremental and accurate dosages of UV radiation, facilitating standardized assessments.

Developing a straightforward yet effective method for inducing tanning and erythema using direct sunlight has significant advantages. Unlike artificial UV lamps, which emit a narrow spectrum of UV radiation, natural sunlight provides a full range, offering a more realistic assessment of everyday sun exposure. This approach simplifies the process, reducing the need for specialized equipment and controlled environments, and enhances the evaluation of anti-tanning products in preventing erythema and tanning. It simulates real-life scenarios, providing valuable insights into effectiveness of various products in protecting against UV-induced skin damage.

The objective of this study was to develop and validate the process of skin tanning induced via various methods, that can be utilised for future clinical studies related to testing anti-tanning products or tanning prevention. The study focused on developing generating skin tanning using two different methods and determining a more suitable and accurate method considering the Indian weather. This study determined the optimal dosages of UV exposure from both natural sunlight and artificial UV lamps to induce controlled tanning and erythema, measured using the Mexameter® MX 18 probe. Additionally, the study aimed to standardise a method for the evaluation of effectiveness of test products in preventing UV-induced tanning and erythema, and to validate the safety of the UV exposure methodology. The instrumental evaluation was accompanied by dermatological assessments utilising the Draize scale for the assessment of tanning and erythema. The ultimate goal was to establish a reliable and controlled methodology for inducing tanning and erythema, providing a robust framework for future research and the development of effective tanning prevention strategies.

METHODS

Ethical conduct of the study

This study was conducted in accordance with the principles outlined in the declaration of Helsinki and the ICH Good Clinical Practice (GCP), and Indian Council of Medical Research (ICMR) guidelines. Ethical approval for the study protocol was obtained from the ethics committee [registered with the central drugs standard control organization (CDSCO) (registration# ECR/281/Indt/GJ/2017/RR-21) and the office for human research protections (OHRP) US department of health and human services (DHHS) (registration# IRB00011046)], prior to the commencement of any study-related activities. All participants provided a signed informed consent before enrolment in the study. The consent process included a detailed explanation of the study objectives, procedures, confidentiality measures, and the voluntary nature of participation.

The study was registered at ClinicalTrials.gov with the identifier NCT06384092, ensuring transparency and adherence to ethical standards in clinical research. Throughout the study, participant safety and well-being were prioritized, with continuous monitoring for any adverse events and prompt reporting procedures to the ethics committee as required. The ethical conduct of this study ensured the integrity of the research and the protection of participant rights and safety.

Study design

This open-label, two-arm methodology validation study was conducted to evaluate the induction of skin tan using distinct UV light sources and to assess the safety and efficacy of test products in preventing skin tanning and erythema in healthy adult human participants. A total of 6 adult male and female subjects aged between 18 to 45 years were enrolled as per the inclusion and exclusion criteria.

Only healthy adult males and non-pregnant, non-lactating females were eligible for inclusion. Additionally, subjects with Fitzpatrick skin types III to V or a Skin colorimetric ITA° value ranging from 20° to 41° at the application site (forearms) were included to ensure a diverse representation of skin tones. Lastly, subjects needed to exhibit a willingness to comply with the study plan, including follow-up visits and product applications, and provide written informed consent. Subjects were excluded if they had active skin diseases such as eczema or psoriasis, or if they were using photosensitizing medications that could interfere with UV-induced skin responses. A history of severe adverse reactions to skincare or cosmetic products, and the presence of open wounds, infections, or cuts at the application sites were grounds for exclusion. Additionally, individuals with a history of significant sunburns in the past three months were excluded to minimize potential confounding effects on the study outcomes. These criteria were implemented to ensure the integrity of the study results and the safety of the participants throughout the research process.

The study comprised three visits: Visit 01 for screening, enrolment, and pre- and post-UVA dose assessment; visit 02 for post-exposure assessment on day 3±1; and Visit 03 for post-exposure assessment on day 7±1. Prior to enrolment visit, subjects were instructed not to apply any lotions/creams on test sites and to cover their arms completely with clothing throughout the study period. Before initiating the exposure, efficacy parameters were assessed, including EI and MI, using Mexameter® MX 18 probe. Dermatological assessment conducted by dermatologist-trained evaluator and a dermatologist using Draize scale to provide qualitative measure of skin reactions (Table 1). Ahmedabad in Gujarat, hot semi-arid climate region (Köppen climate classification: BSh), was chosen as location for solar radiation exposure, starting at noon when solar irradiance is highest. Solar irradiance was measured using validated solar irradiance meter, and average irradiance of sunlight recorded as 7600 µW/cm^2. This irradiance was administered incrementally over durations of 20, 35, and 50 min to test sites, allowing for controlled exposure to varying intensities of solar radiation.

Table 1: Draize scale for evaluation of skin lesions.

Score for erythema/ dryness/ wrinkles	Reaction	Score for edema	Reaction
0	No reaction	0	No reaction
1	Very slight erythema/dryness with shiny appearance	1	Very slight edema
2	Slight erythema/dryness/ wrinkles	2	Slight oedema
3	Moderate erythema/dryness/ wrinkle	3	Moderate edema
4	Severe erythema/wrinkle/ scale	4	Severe edema

For UV light exposure, an EU RoHS (2011/65/EU) compliant 365 nm UV curing lamp by Edmund optics was utilized. The lamp had an irradiance of 1300 µW/cm^2 at a distance of 76.2 mm. The dosage of UV radiation emitted was managed by controlling the time of exposure to the site. Three incremental doses of UV were administered, with exposure times of 60, 75, and 90 seconds, corresponding to energy doses of 78 mJ/cm², 97.5 mJ/cm^2, and 117 mJ/cm^2 respectively.

The study focused on the 365 nm wavelength that falls under the UV-A spectrum, known for its effectiveness in inducing tanning and erythema. Other wavelengths were not explored in this study but could be considered in future research to identify optimal conditions. Various intensities were tested in preliminary trials to determine the most effective dosage for inducing tanning and erythema.

The subjects were evenly distributed to either receive the exposure form sunlight or the UV lamp. During Visit 01, subjects underwent site marking on their forearms, with three test sites on the left arm (treated with product A, B, and one untreated site) and three untreated test sites on the right arm (Figure 1). The UVA dosages administered to the test sites were consistent for sites T1, T2, U1 on right arm-with doses of 97.5 mJ/cm^2 via UV lamp and constant exposure of 35 mins via direct sunlight. Varied doses altered using exposure time for sites U2, U3, U4 on the left arm. For solar radiation exposure, the duration of exposure to direct sunlight was determined based on the atmospheric conditions of Ahmedabad (Figure 2).

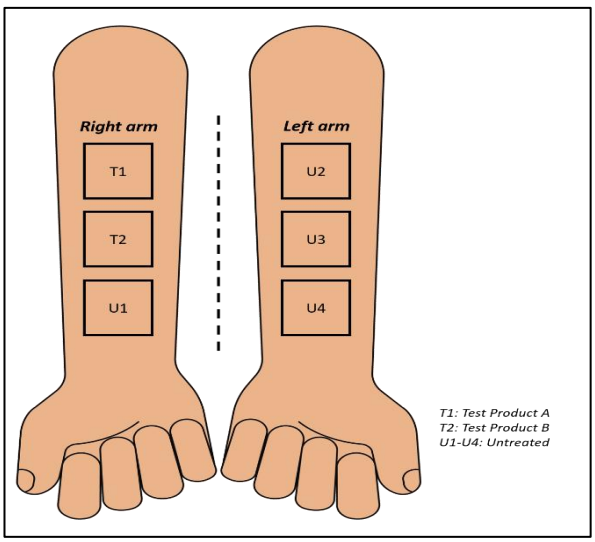

Figure 1: Site marking on both the arms.

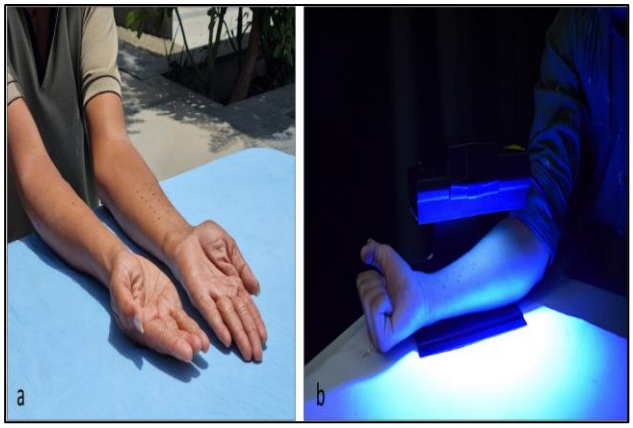

Figure 2: (a) Direct sun exposure to the test sites (b) UV radiation exposure using a UV curing lamp.

The study focused on finding the optimum UVA dose causing erythema and tan without adverse effects, with EI and MI serving as primary parameters-evaluated based on the sites U2, U3, and U4. Evaluation of test products involved detailed assessments of skin responses, including EI, MI, and dermatological evaluations using the Draize scale for qualitative assessment - based on the sites T1, T2, and U1. This comprehensive study design aimed to standardize a method for inducing controlled tan and erythema on the skin, facilitating accurate evaluation of test products' effectiveness in preventing skin tanning and erythema. Details about the test products utilised in this study are mentioned in the Table 2.

Table 2: Details about the test products.

Test product	Test product A	Test product B
Active ingredient	Green tea extract	Avobenzone (Butyl methoxydibenzoylmethane)
Formulation type	Cream	Cream
Mode of application	Topical	Topical
Dose	0.2 ml/site	0.2 ml/site
Manufacturer	S H Kelkar and company limited, India	S H Kelkar and company limited, India

Subject disposition

This open-label, two-arm methodology validation study was conducted to evaluate the induction of skin tan using distinct UV light sources and to assess the safety and efficacy of test products in preventing skin tanning and erythema in healthy adult human participants. A total of 6 adult male and female subjects aged between 18 to 45 years were enrolled as per the inclusion and exclusion criteria.

Sample size calculation

Given the investigational nature of the study, we opted to use convenience sampling for sample size determination. The in-vivo determination of SPF as per the FDA guidance for industry: labelling and effectiveness testing, and the BIS (Bureau of Indian standards) IS 17494:2021; ISO 24444:2019 guidelines require an observation on 10 subjects to be studied. Considering the fact that this study was a pilot for method standardisation, a sample size of six subjects was chosen to evaluate the feasibility and initial efficacy of the UV exposure methods.[9,10]

The age range of 18 to 55 years was selected to capture a broad spectrum of adult skin responses to UV exposure and anti-tanning agents, reflecting real-world variability. However, future studies with larger and more stratified sample sizes are necessary to validate these findings across different age groups and skin types.

Statistical analysis

The statistical analysis aimed to comprehensively assess the safety and efficacy of the test products in preventing skin tanning and erythema induced by UV exposure. Descriptive statistics were used to characterize continuous variables, including the number of subjects (N), mean, standard deviation (SD), median, minimum, and maximum values for the test products. Categorical variables were presented as frequency and percentage, with graphical representation when deemed necessary to provide a clear understanding of the data.

Both the EI and MI of each test site were measured three times repeatedly, and the mean value of the three measurements was considered for analysis. The changes in EI and MI before and after UV exposure were calculated to quantify the extent of erythema and tanning responses, respectively. Specifically, ΔE represented the difference in EI after UV exposure compared to before exposure, while ΔM represented the difference in MI after UV exposure compared to before exposure. Higher values of ΔE and ΔM indicated greater redness and tanning, respectively. Statistical analysis was conducted using SPSS software, Version 29.0.1.0 (171), with a significance level set at 5%.

RESULTS

Six adult participants aged between 18 and 45 years were recruited for this study, and there were no instances of dropouts or withdrawals, ensuring comprehensive data collection throughout the study period. The study exhibited strong adherence to both the intervention and assessment schedules. In our examination of tanning and erythema induction upon exposure to two distinct light sources, natural and artificial, using the Mexameter® MX 18 probe, we observed notable alterations in both the MI and EI.

Primary endpoint results

The primary objective of this study was to determine the optimal dosage of UV exposure from sunlight and a UV lamp in terms of changes in EI and MI, without causing adverse effects. The Mexameter® MX 18 probe was used to measure these indices on day 01 (before and after 6 hours of exposure), day 03, and day 07.

When exposed to direct sunlight, the EI showed a significant increase from baseline. At site U2, the EI increased by a mean of 40.22 units at 15 minutes post-exposure, while at U3 and U4, the mean increases were 42.55 and 47.12 units, respectively. These results indicate an incremental rise in erythema with increasing exposure durations to sunlight (20 minutes, 35 minutes, and 50 minutes, respectively). The peak erythema indices for all three sites were observed at 15 minutes post-exposure. This suggests that 20 minutes of exposure is sufficient to induce substantial erythema, as it produced similar trends in the EI as the longer exposure durations of 35 and 50 minutes.

In terms of the MI, the results showed a mean increase from baseline by 21.67 units at U2, 13.22 units at U3, and 20.77 units at U4 at 15 minutes post-exposure. On day 03, the MI continued to rise, showing mean increases of 37.78, 46.22 and 59.20 units at U2, U3 and U4 respectively. This indicates a progressive increase in tanning with longer exposure durations. The peak melanin indices were observed on day 03 across all doses, suggesting that 20 minutes of exposure is sufficient to induce significant tan, similar to the trends observed for longer exposure durations.

Exposure to an artificial UV light source produced varied results. The EI showed a mean increase from baseline by 5.22, 12.09 and 6.68 units at U2, U3 and U4 respectively at 15 minutes post-exposure. Unlike the sunlight exposure, the erythema did not consistently increase with higher dosages of UV radiation (78 mJ/cm^2, 97.5 mJ/cm^2, and 117 mJ/cm^2). The peak erythema indices for U2 and U3 were observed on day 03, while U4 peaked at 15 minutes post-exposure, indicating inconsistent erythema induction by the artificial UV light. The MI showed a mean increase from baseline by 3.56, 7.79 and 7.67 units at U2, U3 and U4 respectively at 15 minutes post-exposure.

Similar to the erythema results, the MI did not show a consistent rise with increasing UV dosages. On day 03, the MI increases were 4.91 units at U2, 4.05 units at U3, and 12.10 units at U4, again indicating inconsistent tanning trends with increasing dose of UV light (Figure 3).

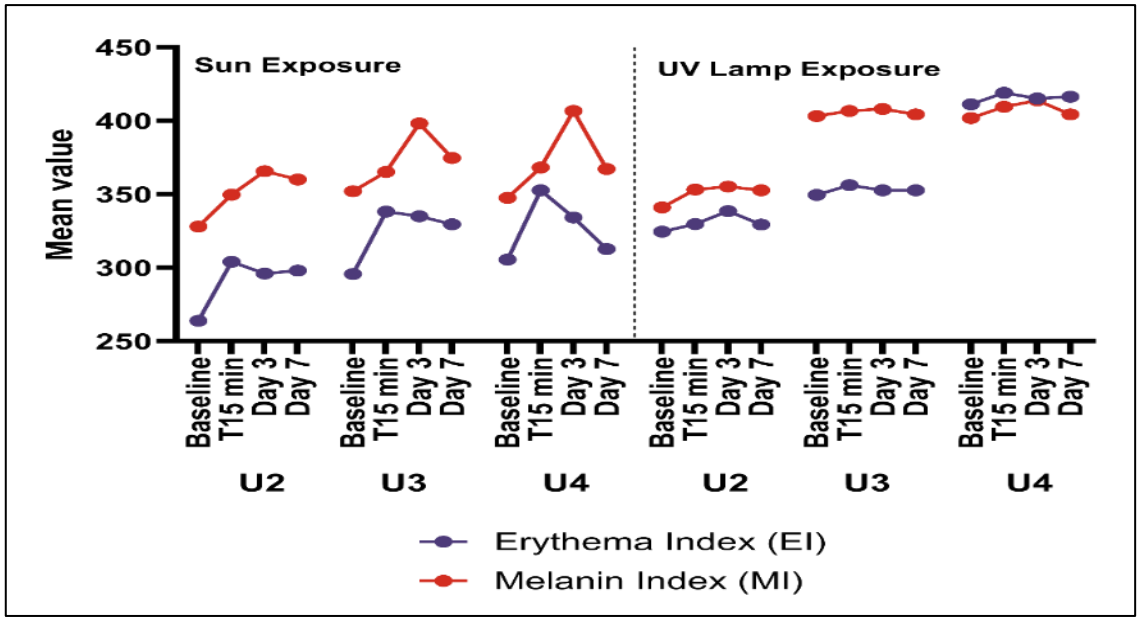

Figure 3: Comparison between solar and UV lamp exposure-dosage comparison.

Secondary endpoint results

The secondary endpoint aimed to evaluate the effectiveness of the test treatments in terms of changes in EI and MI using the Mexameter® MX 18 probe on day 01 (before and after 6 hours of exposure), day 03, and day 07. Test product A was applied to Site T1, test product B to site T2, and Site U1 was left untreated.

Under direct sunlight exposure, the erythema peaked at 15 minutes post-exposure across all sites. The mean increase from baseline in the EI was 22.11, 14.62 and 36.00 at T1, T2 and U1 respectively at 15 minutes post-exposure. This indicates that both test products were effective in reducing skin erythema compared to the untreated site, with test product B being more effective. Specifically, test product A prevented erythema by

38.58% and test product B by 59.39% at 15 minutes post-exposure in comparison to the untreated site. By day 7, these readings were 114.11% for test product A and 216.05% for test product B, demonstrating substantial long-term effectiveness. For tanning, the peak was observed on day 3 post-exposure across all sites. The mean increase from baseline in the MI was 23.60 units at T1, 19.52 units at T2, and 37.73 units at U1 on day 3. Both test products effectively reduced skin tan compared to the untreated site, with test product B again proving more effective. The reduction in the MI was 37.45% for test product A and 48.26% for test product B on day 3. By day 7, the rises in the MI were 46.00% less for test product A and 185.37% less for test product B in comparison to the untreated site, indicating their efficacy in preventing skin tanning over time.

When exposed to an artificial UV light source, the erythema peaked at 15 minutes post-exposure for sites T1 and T2, but on day 3 for site U1. The mean increase from baseline in the EI was 7.44, 7.78 and 9.52 units at T1, T2 and U1 respectively at 15 minutes post-exposure. At day 3, the EI decreased by 1.30 units at T1 and 2.56 units at T2, but increased by 21.23 units at U1. This suggests that both test products were effective in reducing erythema compared to the untreated site, with test product A being slightly more effective. However, the inconsistent induction of erythema using the 97.5 mJ/cm^2 dose makes these results less reliable. For tanning induced by the artificial UV light source, the results were also inconsistent. The MI peaked on day 3 for sites T1 and T2, but at 15 minutes post-exposure for site U1. Due to the inconsistent melanin induction at the 97.5 mJ/cm^2 exposure dose, UV lamp exposure did not provide reliable results for assessing the effectiveness of the test products (Figure 4).

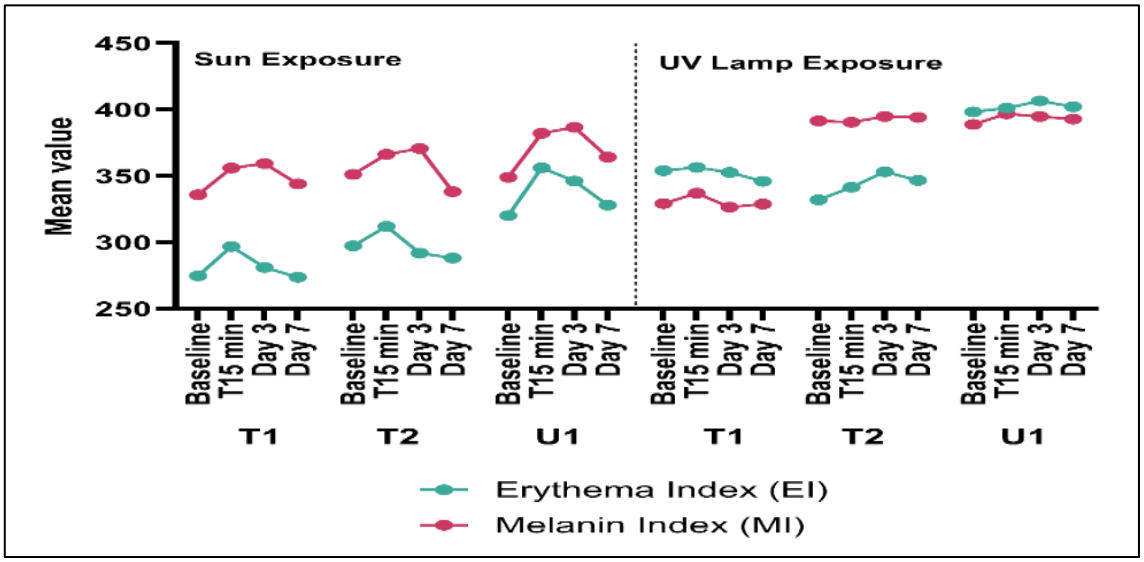

Figure 4: Comparison between solar and UV lamp exposure-product comparison.

Comparison between solar and UV lamp exposure

A comparison of the results from solar and UV lamp exposure revealed that both the EI and MI showed more consistent incremental trends with increasing radiation dosage when exposed to direct sunlight compared to the UV lamp. The erythema indices observed at 15 minutes post-exposure and the melanin indices on day 03 suggest that direct sunlight exposure is more effective in inducing reliable erythema and tanning responses.

In comparing the effectiveness of the test products under direct sun exposure, both products resulted in lower increases in the erythema and melanin indices compared to the untreated site. All sites exposed to direct natural sunlight achieved peak erythema at 15 minutes post-exposure and peak melanin levels on day 3 post-exposure. This consistent pattern among treated and untreated sites indicates that minimal exposure to natural sunlight can reliably induce tanning and erythema. In contrast, exposure to the UV lamp resulted in inconsistent peaks in both the erythema and melanin indices, highlighting the unreliability of the artificial UV light source at energy the administered doses in this context.

Dermatological assessment using draize scale and safety endpoint results

The dermatological assessment using the Draize scale showed that 100% of subjects exposed to direct sunlight scored a 3 for erythema 15 minutes post-exposure. This indicates a highly effective induction of redness compared to the UV lamp exposure, which did not achieve the same level of erythema. However, no significant changes were observed in skin dryness or wrinkles, suggesting that the exposures did not cause substantial skin hydration loss/wrinkling. This confirms that both natural and artificial UV light sources, at doses administered, effectively induced erythema without causing adverse effects such as skin dryness or wrinkling.

The test methods employed for inducing tanning and erythema on the skin-both artificial and natural-were found to be effective and safe. Throughout the study, there were no instances of blistering, burns, or inflammation observed in any of the subjects. Additionally, the dermatological assessments revealed no occurrences of oedema in any subject, further confirming the safety of the exposure methods used. The test products demonstrated significant effectiveness in preventing tanning and erythema compared to the untreated sites. Importantly, there were no test product-emergent side effects observed on the skin of any subject. This indicates that the sun protection creams used in the study are safe for application on the skin, offering both protective benefits against tanning and erythema without causing adverse effects.

DISCUSSION

This study aimed to determine the optimal dosage of UV exposure from sunlight and a UV lamp in terms of changes in erythema and melanin indices, and to evaluate the effectiveness of test products in preventing these changes. The study also assessed the safety of the methods and products used. The results obtained offer significant insights into the effectiveness of controlled sunlight exposure versus artificial UV light exposure in inducing tanning and erythema, as well as the protective efficacy of anti-tanning creams.

Our findings indicate that controlled direct sunlight exposure yielded more consistent and reliable results in inducing both tanning and erythema of the skin compared to artificial UV light. Specifically, sunlight exposure resulted in a mean increase in EI of 40.22 at U2, 42.55 at U3, and 47.12 at U4 at 15 minutes post-exposure, demonstrating a clear incremental rise with increasing exposure durations. Similarly, the MI increased by 21.67 at U2, 13.22 at U3, and 20.77 at U4 at 15 minutes post-exposure, with a more pronounced rise observed on day 3. These findings align with previous research suggesting that natural sunlight, with its broader spectrum of UV radiation, is effective in inducing skin changes.[11,12]

In contrast, the artificial UV light source, administered in incremental doses of 78 mJ/cm², 97.5 mJ/cm^2, and 117 mJ/cm^2, showed inconsistent results. The EI increased by 5.22 at U2, 12.09 at U3, and 6.68 at U4 at 15 minutes post-exposure, indicating variability in response to different dosages. The MI also showed an inconsistent rise with values of 3.56 at U2, 7.79 at U3, and 7.67 at U4 at 15 minutes post-exposure. These results suggest that the doses used were insufficient to induce reliable and reproducible changes in skin indices, highlighting the limitations of using artificial UV light for such purposes. These findings contrast with those reported by Ma et al.[8] Accessed on 20 June 2024, where significant erythema was observed in subjects exposed to 45 mJ/cm^2, indicating that this dosage is relatively safe yet capable of inducing notable skin reactions in the Han Chinese population. This disparity may be attributed to demographic differences. Nevertheless, additional research is needed to investigate the induction of erythema and tanning using artificial UV light sources in the Indian population.[8]

When evaluating the effectiveness of the test products, both demonstrated significant protective effects against sunlight-induced tanning and erythema. Test product A, which contains green tea extract, resulted in a 38.58% reduction in erythema and a 37.45% reduction in the MI at 15 minutes post-exposure and day 3, respectively, compared to the untreated site. Green tea extract is known for its antioxidant properties and ability to protect the skin from UV damage, which is consistent with these findings.[13-15] Test product B, containing avobenzone, showed even greater efficacy, with reductions of 59.39% in erythema and 48.26% in the MI, in comparison to the untreated site. Avobenzone is a well-established chemical sunscreen agent that provides broad-spectrum UVA protection, explaining its superior performance in preventing UV-induced skin damage. These findings align with existing literature on the effectiveness of these ingredients in sun protection products.[16,17] The study's results on the effectiveness of the test products under artificial UV light exposure were less reliable due to the inconsistent induction of erythema and melanin. Nonetheless, both test products still showed some degree of protective effect, albeit less pronounced than under natural sunlight exposure.

Our study validated a process for inducing tanning to evaluate anti-tanning products. This process involved measuring changes in erythema and melanin indices using the Mexameter® MX 18 probe, a method that proved effective and consistent. The study's findings support the use of this method in future research and product testing. In terms of safety, no adverse effects such as blistering, burns, inflammation, or oedema were observed, underscoring the safety of the exposure methods and test products used. This is consistent with other studies that have reported minimal side effects from controlled UV exposure and use of anti-tanning products.

The doses of UV radiation from the UV lamp used in this study were insufficient to produce reliable results. Furthermore, the study validated an effective process for inducing tanning to evaluate anti-tanning products. The study encountered challenges with the consistency and reliability of the UV lamp in inducing tanning and erythema. Future research should explore different wavelengths and intensities to identify the most effective conditions for controlled UV exposure, and focus on refining UV lamp dosages and further exploring the protective mechanisms of anti-tanning products catered to the Indian demographic. Limitations of this study include the small sample size, which may affect generalizability of the results. Larger, long-term studies are needed to confirm these findings and to explore the long-term effects of repeated UV exposure on skin health.

CONCLUSION

This study demonstrates that controlled direct sunlight exposure is more effective than artificial UV light in inducing tanning and erythema of the skin. The consistent and reliable results observed with natural sunlight exposure underscore its potential as a standard method for inducing these skin changes in clinical and research settings. The UV doses administered via the UV lamp-up to 117 mJ/cm² were found to be insufficient for reliable induction of tanning and erythema, highlighting the need for further refinement in artificial UV exposure protocols.

Furthermore, the study validated a method for evaluating the effectiveness of anti-tanning products. The safety of the exposure methods was also confirmed, with no adverse effects observed. This methodology can be utilized to evaluate the efficacy of anti-tanning products, providing a controlled and reliable means to induce tanning and erythema. Further research should focus on refining this methodology and expanding its application to diverse populations and varying environmental conditions to enhance its reliability and relevance.

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