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Clinical Efficacy of A New Pigment Correcting Serum in Multiple Ethnicities



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One of the most striking and distinguishable characteristics in humans is skin color. Its variety is inherently tied to the multitude of human races and ethnicities. Race is a biological term that distinguishes human populations based on physical and genetically distinct characteristics. Ethnicity on the other hand is associated with culture and regional geography, and is often used to further distinguish sub-populations. Within race, minor biological variation can exist and correlate with specific ethnic populations resulting in the diverse color palette of human skin.

BIOLOGICAL DIFFERENCES IN MELANOGENESIS

Human skin color is determined by the amount and deposition of melanin in the skin. Studies have shown that there is no significant difference in the number of pigment-producing melanocytes among racial groups. Skin color variation is attributed to differences in melanocyte activity, melanin production, melanosome size, and melanin distribution within keratinocytes. Research has shown that melanocytes derived from dark skin types have up to 10x more tyrosinase activity than melanocytes from light skin types.[1] Ethnic populations with darker skin types (African, Indian) have greater melanin content compared to light-skinned populations (European, Chinese and Mexican).[2] Furthermore, the melanosomes, in which melanin is synthesized, stored, and transported, appear to play a significant role in human skin color variation. First, melanosomes in African skin are larger in size than those in Caucasian skin, with Asian skin having melanosomes of intermediate size. Additionally, melanosomes in darker skin are predominantly distributed individually throughout the cytosol, whereas lighter skin shows small clusters of four to eight melanosomes.[2,3] Finally, skin type also influences melanosome degradation within the keratinocyte. In darker skin types melanosomes can be found in all epidermal cell layers up to the stratum corneum, whereas in light skin the melanosomes are mostly confined to the basal layers of the epidermis. Studies have shown that light skin keratinocytes lose melanosomes more rapidly during terminal differentiation, as the clustered melanosomes supposedly are degraded more efficiently, resulting in an absence of melanosomes in the upper epidermal cell layers of Caucasian skin.[3-6]

ETHNIC SKIN

Currently, 80% of the world population has what is considered "ethnic skin," i.e. non-Caucasian skin, encompassing all intermediate and dark skin types (Fitzpatrick Skin Types III–VI). Regardless of origin, even skin tone is considered a mark of youth and beauty in many cultures around the world. Although several aesthetic treatments are available, hyperpigmentation is more challenging to address in ethnic skin due to differences in pigment biology. Furthermore, ongoing globalization is increasing the number of people of mixed heritage, which complicates treatment strategies as the risk of unexpected outcomes grows. SkinMedica developed a new pigment correcting serum, LYT2, that addresses many of the key pigmentation pathways in order to achieve maximum efficacy in all skin types. To that end, a clinical study was performed to determine the efficacy of LYT2 in multiple ethnicities.

EFFICACY OF A COMPREHENSIVE PRODUCT IN A VARIETY OF ETHNIC POPULATIONS

To establish efficacy in a variety of ethnicities, efficacy of LYT2 was assessed in a randomized, double-blind comparison study using prescription 4% hydroquinone cream (HQ) as the positive control. Forty-three female subjects with moderate to severe facial hyperpigmentation and aged 31-65 years completed the 12 week clinical study. Subjects were randomized to receive LYT2 on the left or right facial side, and HQ on the

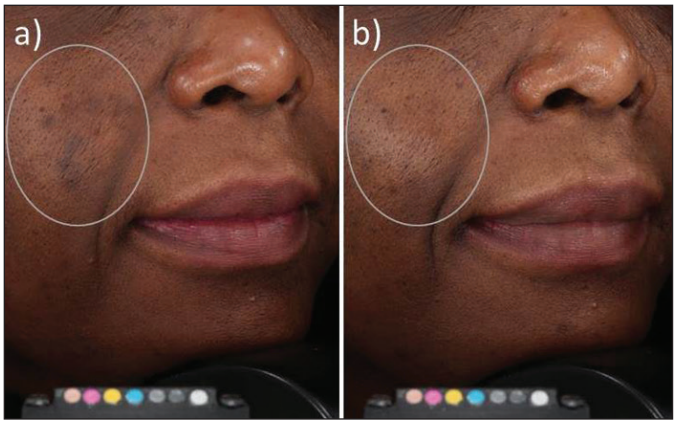

Figure 1: Improvements in the appearance of post-inflammatory hyperpigmentation at baseline (a) and eight weeks of twice-daily use of LYT2 (b) in a 40-year-old African American female with Fitzpatrick Skin Type V.

other facial side. Both treatment products were applied twice-daily, after cleansing. Subjects' left and right facial sides were assessed for Overall Hyperpigmentation at all visits (baseline, week 2, week 4, week 8, and week 12) by an expert grader blinded to the treatment assignment. Standardized digital photographs were also taken at all visits.

The study included a broad variety of ethnicities with subjects identifying as African American (44.4%), Hispanic (26.7%), Asian (6.7%), or Caucasian (22.2%) ethnicities. LYT2 provided statistically significant improvements in the appearance of facial hyperpigmentation at as early as week 2, with continuing significant improvements through week 12, as shown by mean Overall Hyperpigmentation scores (all $p<0.001$; Wilcoxon signed-rank test). The HQ treated group did not show significant improvements until week 4, with continued improvements through week 12 (all $p<0.001$; Wilcoxon signed-rank test). Overall, LYT2 provided comparable improvements to prescription 4% hydroquinone in the appearance of facial hyperpigmentation, trending towards significantly greater reductions at week 8 ($p\leq0.07$; mixed model on ranks). Analysis within each ethnicity sub-group (African American, Hispanic, and Caucasian) further support these results. Representative standardized digital photography of an African American subject, Hispanic subject, and Caucasian subject are shown in figures 1, 2, and 3, respectively.

CONCLUSIONS

The majority of clinical studies on hyperpigmentation are conducted in Caucasian and/or Fitzpatrick Skin Types I-III, creating a need to better understand effects on patients with various ethnic backgrounds and with Fitzpatrick Skin Types IV and higher. Considering the innate differences in melanin biology between different ethnicities, this clinical study shows the benefits of LYT2 in African, Hispanic and Caucasian ethnic origins. Further studies are in progress to assess efficacy in both light- and dark-skinned Asian populations as well as in different hyperpigmentation conditions (PIH, melasma, etc.). ■

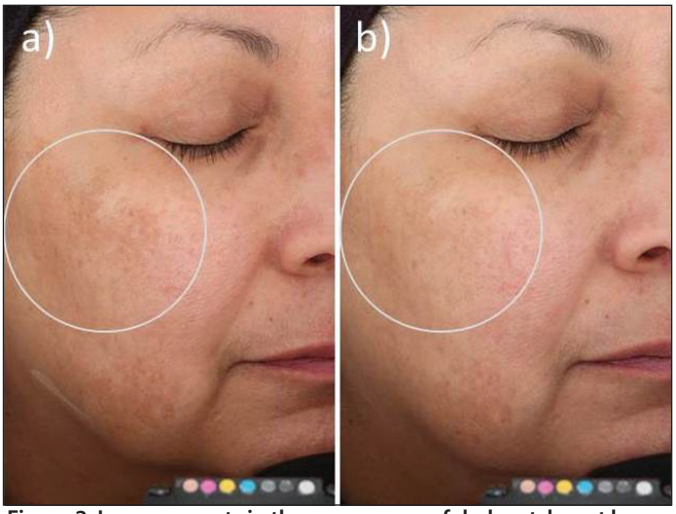

Figure 2: Improvements in the appearance of dark patches at baseline (a) and after twelve weeks of twice-daily use of LYT2 (b) in a 51-year-old Hispanic female with Fitzpatrick Skin Type IV.

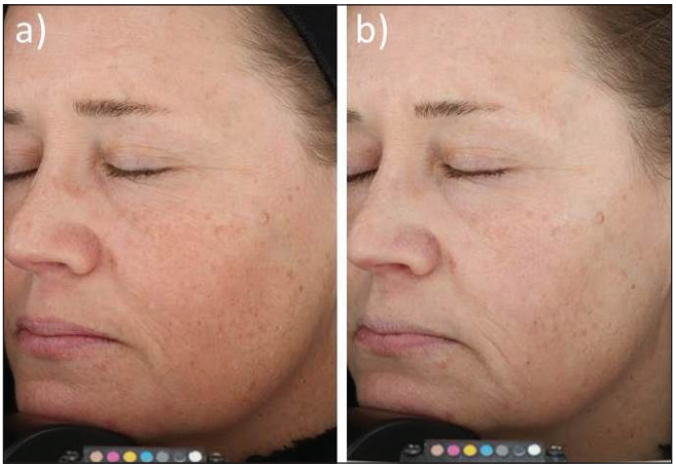

Figure 3: Improvements in the appearance of mottled pigmentation and visible redness at baseline (a) and after twelve weeks of twice-daily use of LYT2 (b) in a 48-year-old Caucasian female with Fitzpatrick Skin Type III.

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