Efficacy and Tolerability of a Comprehensive Brightening Serum Plus a Dual Antioxidant System in Skin of Color Patients with Moderate to Severe Facial Hyperpigmentation

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OBJECTIVE

To evaluate the safety and efficacy of a cosmetic topical brightener (LYT2) in combination with a dual serum antioxidant system (LVS) in in skin of color patients with moderate to severe facial hyperpigmentation.

CONCLUSIONS

The LYT2 + LVS regimen was well tolerated, and produced significant improvements in hyperpigmentation, skin-tone evenness, and radiance

The LYT2 + LVS regimen produced high patient-perceived efficacy and overall satisfaction

LYT2 + LVS may be a novel, non-prescription regimen for skin of color patients seeking to improve hyperpigmentation and overall skin quality

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INTRODUCTION

Background

- Hyperpigmentation disorders disproportionately affect individuals with skin of color
  - These can be by several different biological or environmental factors
  - These conditions are challenging to treat in patients with skin of color
- These disorders are often recalcitrant or relapsing and require continuous treatment
  - The gold-standard therapies containing Hydroquinone (HQ) cannot be used for extended periods of time because of adverse effects
  - Cosmetic topical therapies are in demand, but current options lack efficacy
- Comprehensive treatment regimens are needed to adequately address hyperpigmentation in skin of color
  - Agents that reduce melanogenesis or neutralize extrinsic stressors show efficacy as single agents but may synergize when used together
  - A comprehensive HQ-free, retinol-free cosmetic topical brightener (LYT2) was previously shown to be effective at improving hyperpigmentation in skin of color[1,2]
  - A dual serum providing broad antioxidant protection and skin repair support (LVS) was shown to protect from multiple extrinsic stressors and improved overall skin appearance
  - A complete regimen using these agents in combination has not formally been evaluated

METHODS

Study Design

- Open-label, single center study
- Individuals must have had investigator-assessed moderate to severe overall facial hyperpigmentation (score of 4-9 on the modified Griffiths' scale).
- Key exclusion criteria
  - a pre-existing dermatologic condition that could interfere with study assessments
  - known allergies or sensitivities to the ingredients in the study products
  - women who were pregnant or nursing

Treatment Regimen

- LVS Day and Night serum (Lumivive System, SkinMedica, Allergan Aesthetics, an AbbVie Company) – used each once daily
- LYT2 (Lytera 2.0, SkinMedica) - used twice daily
- Facial Cleanser (SkinMedica) – used twice daily
- Broad-spectrum SPF 35 sunscreen (SkinMedica) – used once daily, reapplied as needed
- Ultra Sheer Moisturizer (SkinMedica) - used twice daily

Study Assesments

- Study visits occurred at baseline, week 2, week 4, week 8 and week 12
- Standardized Digital Photography(Canfield VISIA-CR), and investigator assessments for the following parameters were conducted at all visits:
  - Overall Hyperpigmentation, Skin Tone Evenness, Radiance
    - 0-9 scale (0=none, 1-3=mild, 4-6=moderate, 7-9=severe)
- Subject self-assessment questionnaires were completed at all follow-up visits
- Tolerability of treatment was assessed via capture of adverse events at each follow-up visit

RESULTS

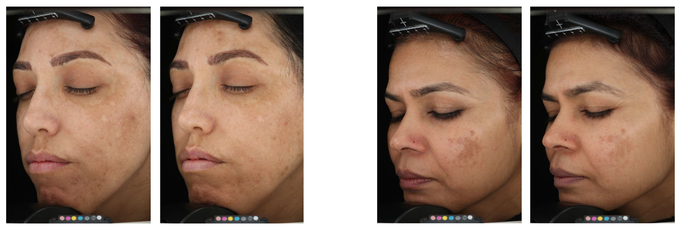
- Thirteen patients enrolled in the study (Table 1)
  - The demographic was exclusively Asian, Hispanic or African American
- Of the 13 patients enrolled, 10 completed the study
  - The dropouts were due to withdrawn consent
- Study regimen provided significant improvements versus baseline for all investigator efficacy assessment parameters by week 12 (Figures 1&2)
- Significant changes in skin-tone evenness and radiance were observed starting at week 4, which progressed until the end of the study (Figure 2)
- At week 12, almost all patents responded "agree" or "strongly agree" to all attributes of self-percieved efficacy
- All subjects noted at least some improvement in skin condition by week 8 (Figure 4)
- Most patients reported good or excellent overall satisfaction with the regimen by week 12
- One treatment related adverse event was reported
  - Patient experienced irritation and stinging that resolved once the regimen was discontinued, and the patient withdrew from the study

Table 1. Patient Demographic Enrolled at Baseline

	# of subjects (N=13)
Age (years)	
Mean (SD)	44
Min, Max	34-54
Gender, n (%)	
Female	12 (92%)
Male	1 (8%)
Ethnicity, n (%)	
African American	5 (38.5%)
Asian	3 (23.0%)
Other	5 (38.5%)
Fitzpatrick Skin Type, n (%)	
III	3 (23%)
IV	5 (39%)
V	3 (23%)
VI	2 (15%)

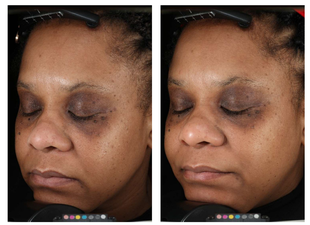
Figure 1A-C. VISIA-CR Images (Standard Lighting 2) Showing Improvements from baseline in Overall Hyperpigmentation, Skin-Tone Evenness, and Radiance

(**A**) Female, Age 38, Hispanic, Fitzpatrick type III (**B**) Female, Age 43, Asian, Fitzpatrick type IV



Baseline Week 12 Baseline Week 12

(**C**) Female, Age 42, African American, Fitzpatrick type V



Baseline Week 12

Figure 2. Improvements in Overall Hyperpigmentation, Skin Tone Evenness, and Radiance as Assessed by Investigator

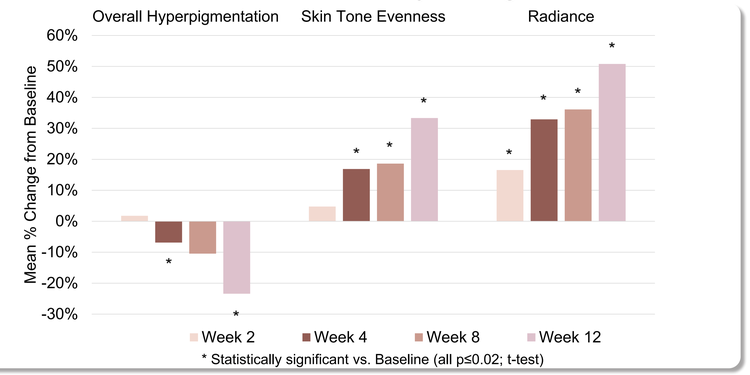


Figure 3. Subject Questionaire Results for Self-Assessed Efficacy at Week 12

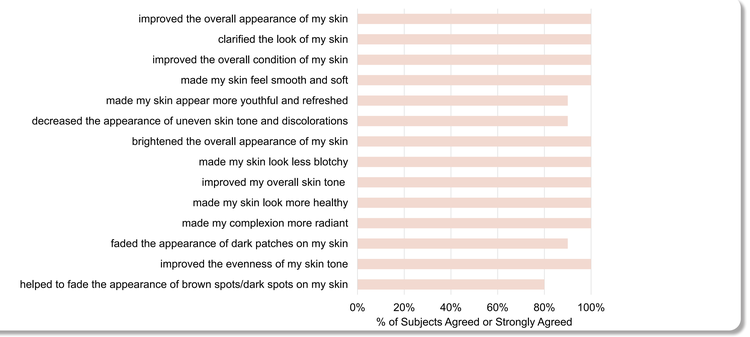


Figure 4. Subject Graded Overall Improvements

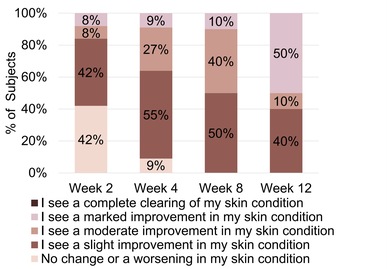


Figure 5. Subject Overall Satisfaction