Combining in-office chemical peel procedures with topical therapy of a comprehensive pigmentation control product for multi-ethnic subjects with moderate to severe facial hyperpigmentation

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BACKGROUND
Skin discoloration is a common concern with limited treatment options for multi-ethnic patients due to the increased risk of Post Inflammatory Hyperpigmentation (PIH). The use of superficial chemical peels is an effective and well-tolerated treatment for patients of various ethnic origins. Combination therapy such as brightening topicals paired with chemical peels has been shown to be more effective in addressing hyperpigmentation.

OBJECTIVE
To assess the efficacy and tolerability of a daily topical regimen (HQ free) in combination with a series of three superficial chemical peels in patients with moderate to severe facial hyperpigmentation.

STUDY DESIGN
- Open-label, single-center clinical usage study
- Twelve week study duration with visits at baseline, week 4, week 8 and week 12

Subject Demographics
- Male and Female subjects (n=17) aged 36-69 years, with Fitzpatrick Skin Types (FST) III, IV and VI, who identified as Asian, Hispanic, African American, or Caucasian ethnicities presenting with moderate to severe hyperpigmentation (as determined by a grade of 4-8 on the overall hyperpigmentation scale) were enrolled in the study.

Test Products
- Comprehensive HQ-free Pigmentation Control Product (LYT2)
- Superficial Chemical Peel (VP)

Treatment
Subjects received a series of three VP treatments every four weeks during the twelve week study. A basic skincare regimen of cleanser, moisturizer, and physical sunscreen was provided to subjects. In addition to LYT2 which was applied post peel approximately 5-7 days on once facial peeling was complete. After cleansing, subjects were instructed to apply a thin layer of LYT2 to the entire face morning and evening.

Clinical Assessments
- At all visits, the investigator graded the subjects’ skin on the following facial parameters (0-9 scale)
  - Overall Hyperpigmentation
  - Overall Photodamage
  - Skin Tone Unevenness
  - Global Improvement in Hyperpigmentation (0-4 scale; at follow-up visits only)

Subject Self-Assessment Questionnaires
- Subjects also completed a self-assessment questionnaire at all follow-up visits (weeks 4, 8 and 12) regarding the appearance of the facial skin.

Instrumentation
Standardized digital photographs of the face were taken at all visits using the VISIA-CR Imaging System (Canfield Scientific, Inc.) Reflectance Confocal Microscopy (RCM) images (VivaScope® 1500, Caliber Imaging and Diagnostics) were captured at baseline and week 12 visits on three subjects.

RESULTS
- Fourteen male and female subjects (FST III, IV and VI) presenting with moderate to severe hyperpigmentation completed the twelve week study. Three subjects discontinued the study, due to treatment-related adverse events which were skin-related.
- At week 8, significant improvements in all efficacy parameters including overall hyperpigmentation, overall photodamage, and skin tone unevenness (p<0.03; n=16; subject’s paired t-test)
- At week 12, all efficacy parameters continued to show significant improvements (p<0.01; n=14; subject’s paired t-test)
- The combination treatment of VP and LYT2 was highly-rated at Week 12 by subjects in self-perceived efficacy and patient satisfaction (Figure 5)
- At study completion, 100% of subjects felt moderately and very satisfied with the combination regimen.

DISCLOSURES
This study was sponsored by Allergan. All authors met the ICMJE authorship criteria. All authors are employees of Allergan.

CONCLUSIONS
These results demonstrate the aesthetic benefits to multi-ethnic patients with use of a daily non-HQ regimen combined with a series of 3 superficial chemical peels.