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 4-9 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 or 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

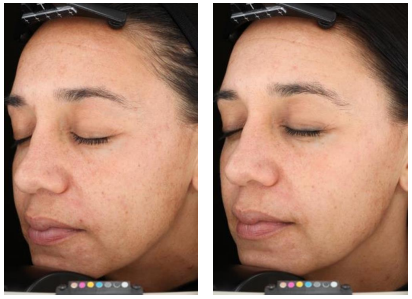
- Fourteen male and female subjects (FST III, IV and VI) presenting with moderate to severe hyperpigmentation completed the twelve week study. Three subjects discontinued the study, due to treatment-related adverse events which were skin-related.
- At week 8, significant improvements in all efficacy parameters including overall hyperpigmentation, overall photodamage, and skin tone unevenness ($p<0.03$; n=16; student's paired t-test)
- At week 12, all efficacy parameters continued to show significant improvements ($p<0.01$; n=14; student'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.

Figure 1: Visible Improvements at Week 8

Female subject, Age 44, Fitz III

Left to Right: Baseline & Week 8 after 2 VP treatments, and 6 weeks of twice daily use of LYT2

Figure 2: Visible Improvements at Week 12



Female subject, Age 36, Fitz III

Left to Right: Baseline & Week 12 after 3 VP treatments, and 9 weeks of twice daily use of LYT2

Figure 3a: Dermoscopy Image Baseline vs. Week 12

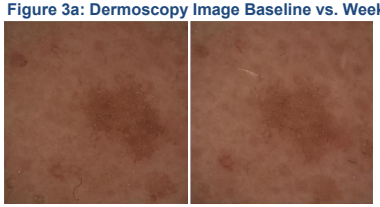
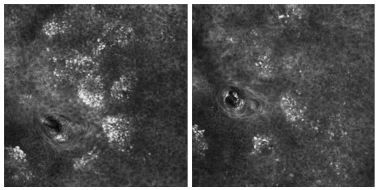


Figure 3b: RCM Image Baseline vs. Week 12

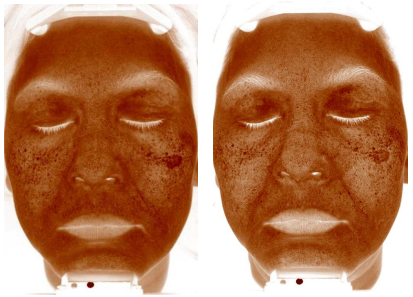


Female subject, Age 56, Fitz IV

3a) Dermoscopy of pigmented lesion showing improvements in skin tone at Baseline (Left) versus Week 12 (right)

3b) RCM single frame (0.5 x 0.5mm) at Baseline,(left) versus Week 12 (right) showing a decrease in pigmented keratinocytes (bright white round cells)

Figure 4: Visible Improvements at Week 12



Female subject, Age 45, Fitz III

Left to Right: Baseline, & Week 12 after 3 VP treatments, and 12 weeks of twice daily use of LYT2

Figure 5: Subject Self-Assessment Questionnaire at Week 12

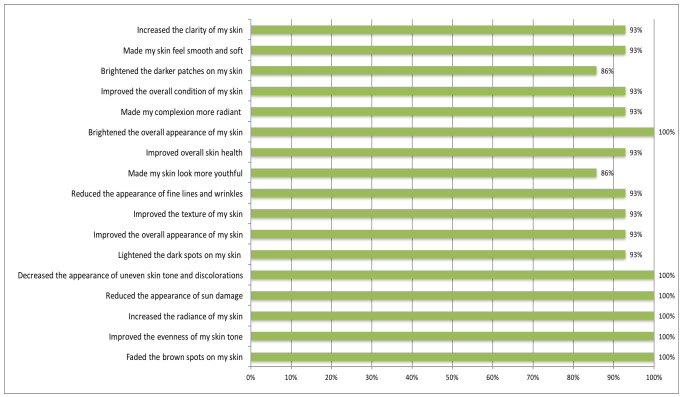
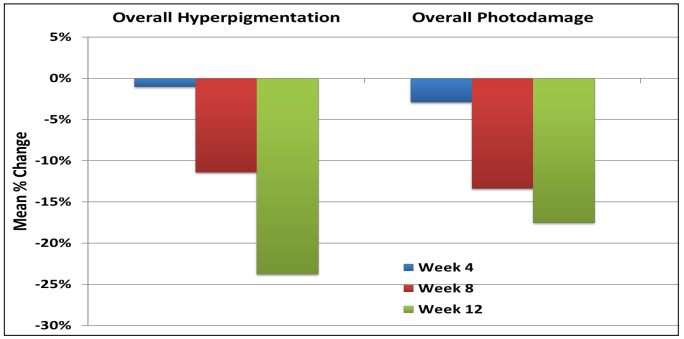


Figure 6: Investigator Efficacy Assessments of the Face



Improvements observed in overall hyperpigmentation and overall photodamage at week 4 through week 12 with statistically significant improvements observed at weeks 8 and 12 ($p<0.03$; student's paired t-test).

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.

DISCLOSURES

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

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