Clinical Efficacy and Tolerability of a Topical HQ-Free Serum on Females with Self-Reported Pregnancy-Induced Facial Melasma

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BACKGROUND

Melasma, a progressive form of hyperpigmentation, occurs more often in healthy women than men. The actual etiology is indefinite; however, pregnancy, hormonal changes, UV/sun exposure, photosensitizing medications, and genetic predisposition have all been considered as contributing factors. This dysfunction of the pigmentary system results in symmetric brown or gray-brown patches on sun-exposed areas of the face, particularly on the forehead, cheeks, upper lip, and chin. Often the psychosocial impact of melasma leads to a negative effect on quality of life and emotional well-being.

OBJECTIVE

To assess the cosmetic efficacy and tolerability of a HQ-free and retinol-free serum (LYT2), in non-pregnant women with mild to severe melasma which was self-perceived as being induced by a previous pregnancy.

STUDY DESIGN

- Twelve-week, single-center clinical usage study with visits at baseline, weeks 4, 8 and 12.

Subject Demographics

- Thirty female subjects aged 30-50 years with Fitzpatrick Skin Types (FST) II to IV presenting with mild to severe overall hyperpigmentation on the face due to melasma which is self-perceived to be induced by a previous pregnancy completed the study.
- Caucasian (73%), Asian (20%) and African American (7%)

Treatment

All subjects received LYT2, cleanser, moisturizer and sunscreen. Subjects applied LYT2 twice-daily after cleansing. All subjects used cleanser and moisturizer twice-daily, and a physical sunscreen once in the morning (and as needed throughout the day).

Clinical Assessments

At all visits, the investigator assessed for:

- Overall Hyperpigmentation (0-9 scale; 0=None, 1-3=Mild, 4-6=Moderate, 7-9=Severe)
- Global Improvement in Overall Hyperpigmentation (0-5 scale)
- Melasma Area and Severity Index (MASI)
  - Each subject's face was divided into 4 areas to be evaluated separately: forehead (F), right malar region (MR), left malar region (ML), and chin (C).
  - For each area, the pigment intensity (PI), lesion size (A) and homogeneity (H) was assessed.
  - MASI score for the whole face was calculated using the following equation: MASI = 0.3 (PIF + HF) AF + 0.3 (PIMR + HMR) AMR + 0.3 (PIML+ HML) AML + 0.1 (PIC + HC) AC
  - The values 0.3, 0.3, 0.3, and 0.1 represent the respective percentages of total facial area. The maximum score for MASI is 48 and the minimum score is 0.

Tolerability assessments for erythema, scaling, edema, burning, stinging, and itching were graded on a 4-point scale at all visits.

Subject Self-Assessment Questionnaires

At all follow-up visits, subjects completed a self-assessment questionnaire on self-perceived efficacy, product texture and product attributes.

At baseline and Week 12, subjects completed a Melasma Quality of Life (MelasQol) Questionnaire (Likert Scale: 1=Not bothered at all to 7=Bothered all the time).

Standardized Digital Photography

Standardized digital photographs were taken using the VISIA-CR Imaging System (Canfield Imaging Systems) at all visits. Image analysis on a target dark spot for skin brightness (L*) was conducted for each time point.

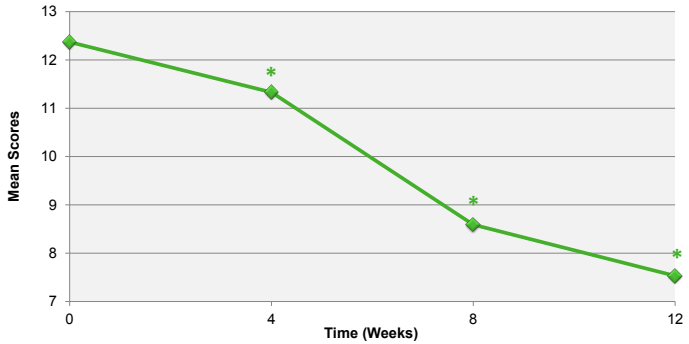
Bioinstrumentation

Corneometer and tewameter measurements were conducted for all visits.

RESULTS

- The HQ-free and retinol-free serum demonstrated a statistically significant decrease in clinical grading scores at weeks 4, 8 and 12 when compared with baseline for the following parameters (all p<0.001; Wilcoxon Signed-Rank Test):
  - Overall Hyperpigmentation
  - Melasma Area and Severity Index (MASI)
- Statistically significant increase in mean scores for Global Improvement in Overall Hyperpigmentation at all visits (all p<0.001; Wilcoxon Signed-Rank Test)
- MelasQol Combined Score showed a statistically significant improvement at Week 12 compared to baseline indicating an increased perception of quality of life (p<0.03; Wilcoxon signed-rank test).
- Corneometer and tewameter measurements continuously improved from baseline at all follow-up visits, indicating an improvement in skin hydration and skin barrier function, respectively.
- Image analysis for brightness (L*) showed statistically significant improvements from baseline at all follow-up visits (all p≤0.025; paired t-test).
- LYT2 was well-tolerated with tolerability scores remaining similar to baseline scores.
- Highly rated by subjects for self-perceived efficacy and product texture/attributes with a significant proportion of subjects agreeing to favorable responses by week 12.
  - 97% of subjects were satisfied with LYT2 by week 12
  - 77% of subjects saw moderate or marked improvement by week 12
  - 83% of subjects agreed it performed better than past facial treatments

Figure 1: Melasma Area and Severity Index (MASI)



*Statistically significant improvements vs. baseline (all p<0.001; Wilcoxon Signed-Rank Test).

Figure 2: 41 y/o Caucasian (FST IV) at baseline (Left) and after 12 weeks of treatment (Right)

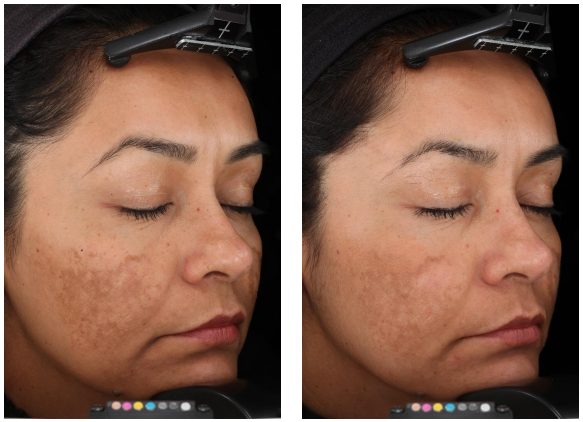
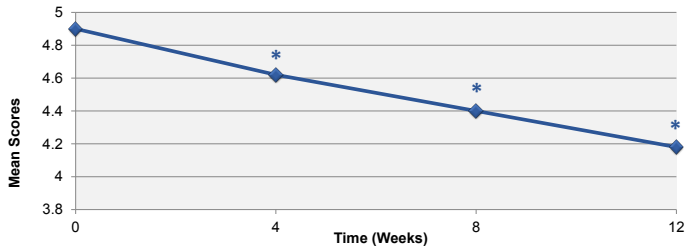
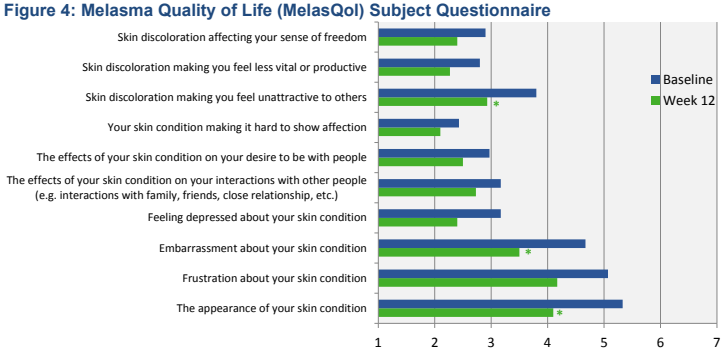


Figure 3: Overall Hyperpigmentation



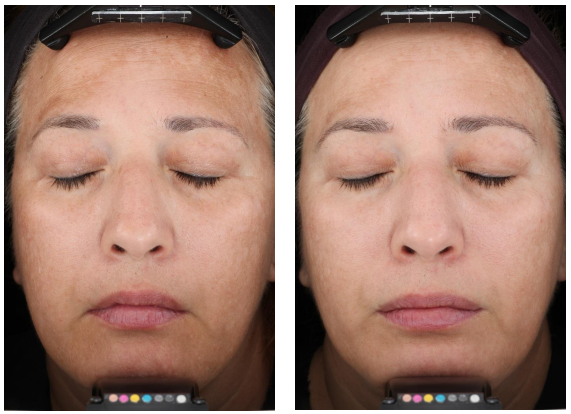
*Statistically significant improvements vs. baseline (all p<0.001; Wilcoxon Signed-Rank Test).

Figure 4: Melasma Quality of Life (MelasQol) Subject Questionnaire



*Statistically significant improvements vs. baseline (all p≤0.049; Wilcoxon signed-rank test).

Figure 5: 44 y/o Caucasian (FST IV) at baseline (Left) and after 12 weeks of treatment (Right)



CONCLUSIONS

Results from this study support the efficacy and tolerability of this HQ-free and retinol-free serum in improving the appearance of mild to severe facial melasma in subjects with self-perceived pregnancy-induced melasma.

DISCLOSURES

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

Presented at the Fall Clinical Dermatology Conference Series, October 12-15, 2017, Las Vegas, NV, USA