

Clinical Evaluation of a 4% Hydroquinone plus 1% Retinol Treatment Regimen for Improving Melasma and Photodamage in Fitzpatrick Skin Types III-VI

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Abstract

The benefits of monotherapy with hydroquinone for melasma and retinoids for photodamaged skin is well established. Here we report results of a hydroquinone skincare regimen designed for melasma treatment combined with a cosmetic retinol cream on subjects presenting with both melasma and facial photodamage in a 24-week study. Improvement in melasma and photodamage efficacy parameters of melasma pigmentation intensity and melasma area and severity index (MASI), as well as overall photodamage and mottled hyperpigmentation were found by week 4, the first post-baseline time point. By week 8 significant improvements were also found in melasma disease severity assessment, tactile roughness, fine wrinkles, crepiness, actinic lentigines, and laxity. By week 18 significant reduction in coarse wrinkles was evident. Benefits persisted through the study end with over ¾ of participants demonstrating improvements in 10 of the 11 graded attributes. For the remaining attribute, coarse wrinkling, approximately 50% of the panel showed improvement. The regimen produced an average of “marked improvement” in melasma severity (51-75% improvement). Results of tolerance evaluations documented overall treatment mildness for a majority of the study participants. Subject questionnaires concur with high ratings of the study regimen for tolerability, efficacy perception, product aesthetics and overall treatment satisfaction in subjects of Fitzpatrick Skin Type III-VI classification with melasma and photodamage in mild-to-moderate severity.

Methods

- **Study:** Single-center, investigator-blinded study in adult females with mild-to-moderate epidermal melasma and photodamage
- **Treatment:** 4% hydroquinone skin care system plus retinol 1% cream for 24 weeks
- **Efficacy assessments:** improvements in melasma severity, pigmentation intensity, photodamage, patient satisfaction
- **Tolerability assessments:** erythema, dryness, peeling, burning and stinging. Adverse events (AEs) were assessed throughout

Results

- Improvements relative to baseline were significant from week 4 onwards for pigmentation intensity (P<.001), MASI (P=.003) and integrated photodamage (P=.044), and from week 8 for melasma severity (P<.001). By week 24, significant reductions in melasma severity (37.1%), pigmentation intensity (47.7%), MASI (64.1%) and integrated photodamage (42.4%) scores were reported (all P<.001, **Figure 1**). Overall improvement in melasma was adjudged to be ‘marked’ (51%-75%) by week 24. The majority of patients reported favorable responses to treatment efficacy and general skin condition. Representative patient examples are showing benefits in melasma and photodamage are shown in **Figure 2**.
- Individual photodamage parameters improved significantly from week 4 onwards for mottled hyperpigmentation (P<.001), and from week 8 for lentigines, tactile roughness, laxity, fine wrinkling (all P<.001), and crepiness (P=.006). Improvement in coarse wrinkling was significant from week 18 (P=.002). By week 24, significant reductions in lentigines (56.1%), tactile roughness (48.8%), laxity (40.5%) mottled hyperpigmentation (46.2%), fine wrinkling (43.7%), coarse wrinkling (20.0%) and crepiness (54.1%) scores were reported (all P<.001, **Figure 3**)
- No patient discontinued due to lack of efficacy or treatment-related AEs. One patient (2.8%) reported severe cutaneous intolerance (dryness and peeling from week 4)

Figure 1: Mean Percent Change in Efficacy Parameters from Baseline (ITT population Week 4-24, N=33)

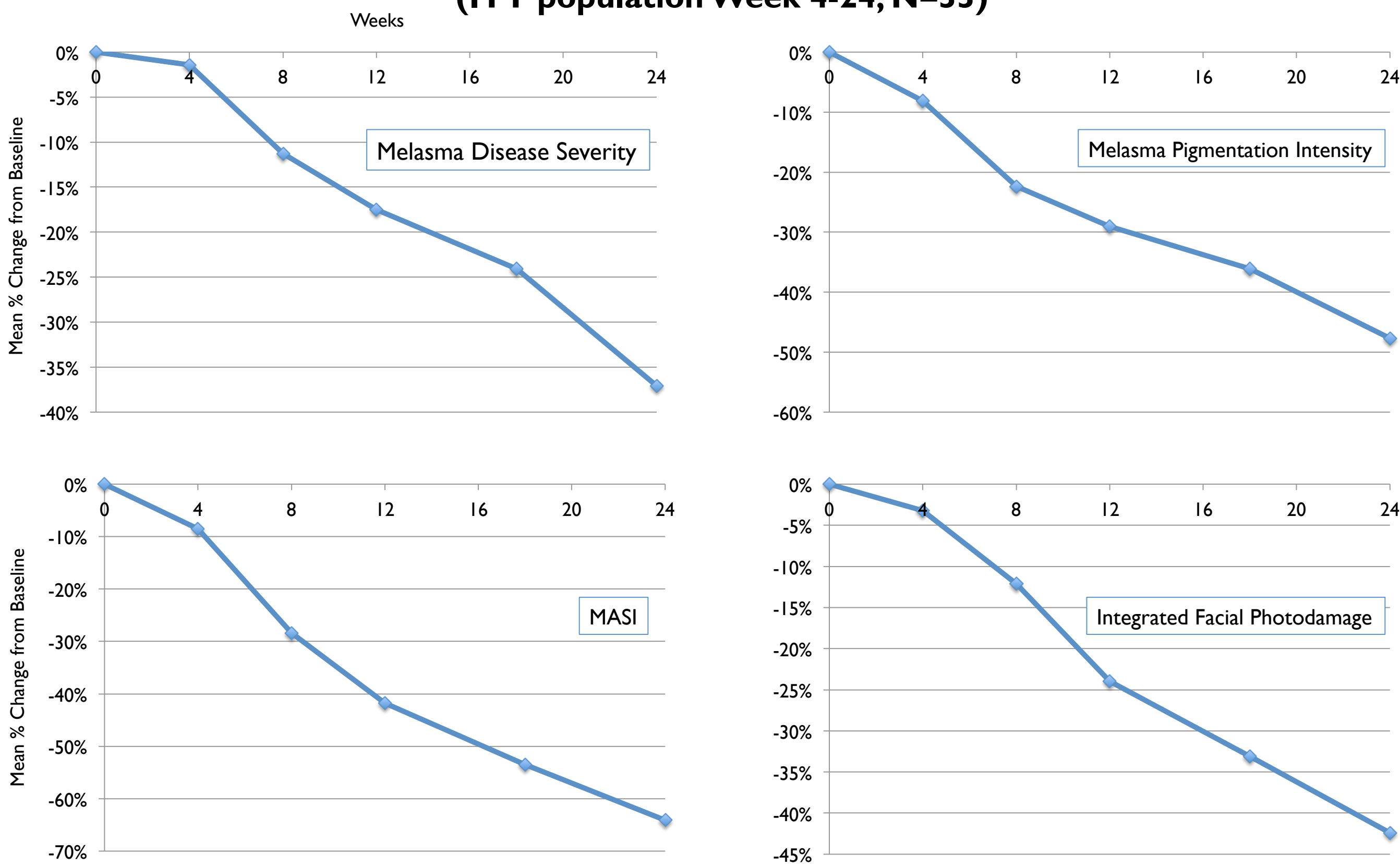
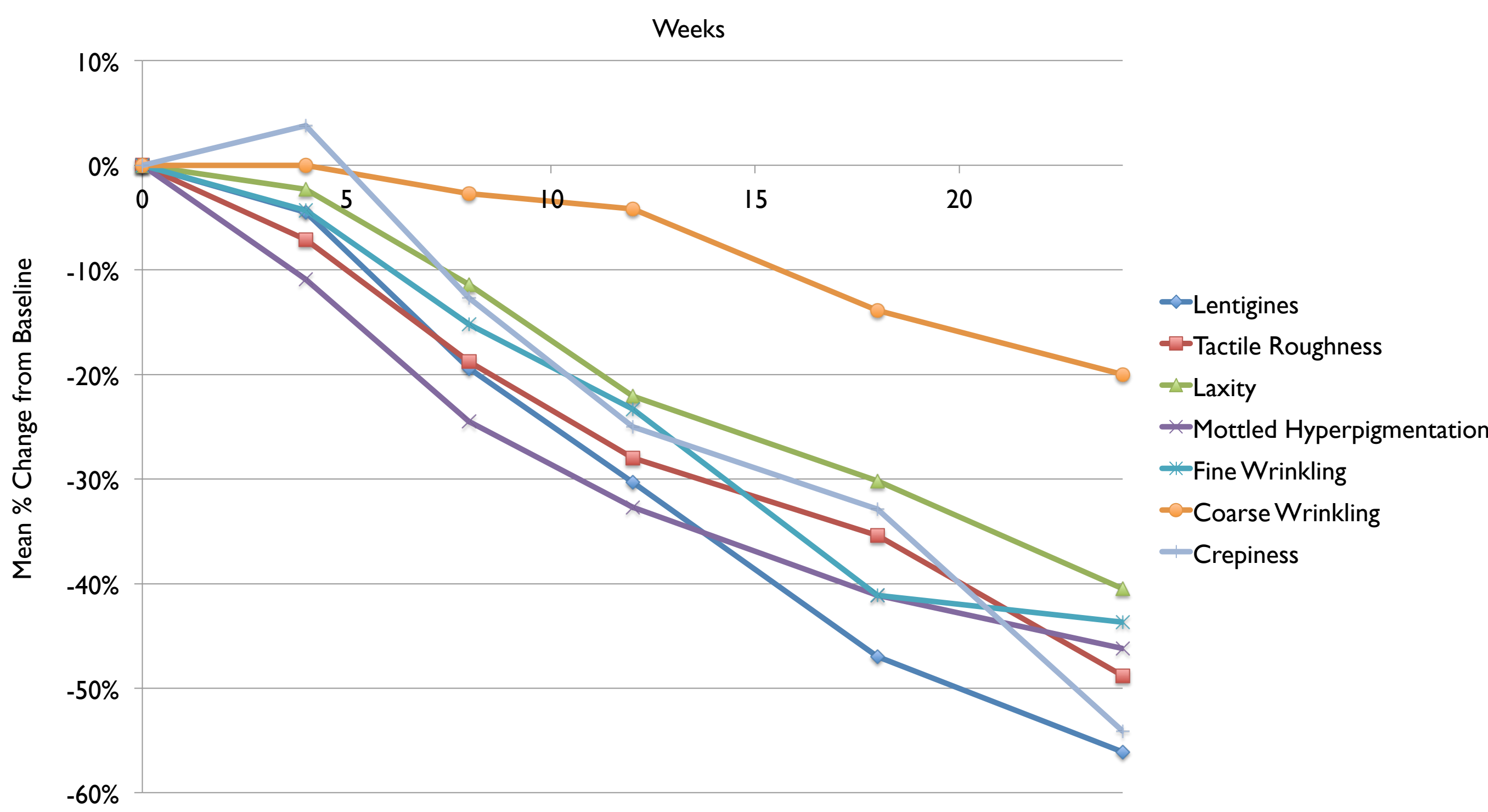


Figure 2: Representative Patient Examples Showing Improvements in Melasma Severity and Photodamage from Baseline to Week 18 and 24



Figure 3: Mean Percent Change in Individual Photodamage Parameters from Baseline (ITT population Week 4-24, N=33)



Conclusion

- **4% hydroquinone skin care system plus 1% retinol cream achieves significant reductions in melasma severity and pigmentation intensity**
- **There was also significant improvement in photodamage, with all individual parameters including coarse wrinkling significantly improved by week 24**
- **The treatment was generally well tolerated**