

A Twelve Week Monadic Clinical Study Evaluating the Efficacy and Tolerance of a products Regimen in subjects with Hyperpigmentation

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Objectives:

Assess the efficacy and the tolerance of a topical products regimen intended to reduce hyperpigmentation, signs of aging and improve photo damaged skin condition

Materials and Methods:

27 females' volunteers aged from 40 to 59 years old were enrolled to apply during 12 weeks a topical regimen of 6 products:

- Mild Gel (oily skin) or Cream Wash (dry skin),
- Enhance Brightening Complex,
- SunVanish Broad Spectrum SPF 25 containing hydroquinone 4%,
- Sunscreen Broad Spectrum Lotion SPF 40,
- Clarifying Gel or Cream (for oily or dry skin) with 4% hydroquinone
- Night Renewal Cream

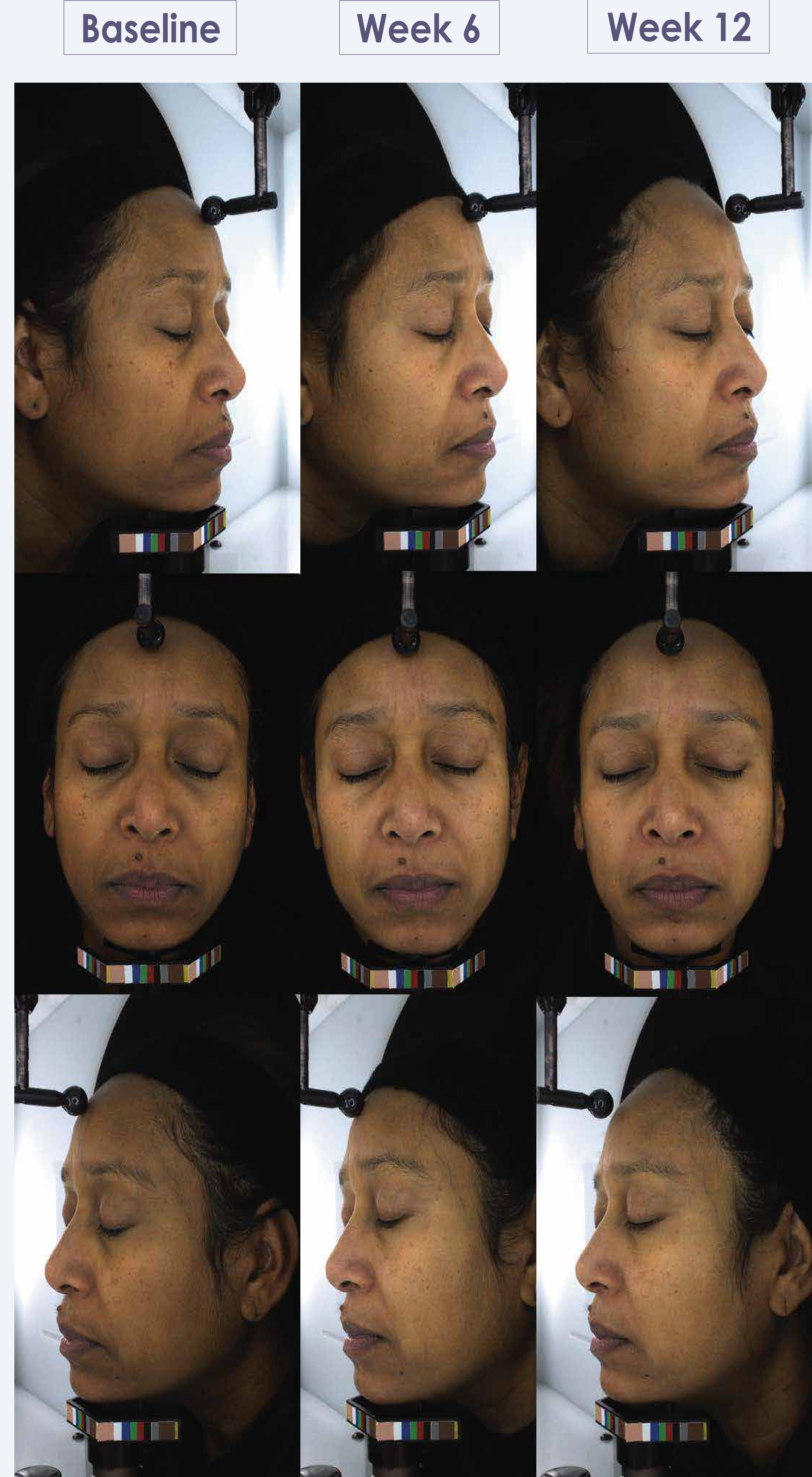
Efficacy assessments included an expert clinical grading for skin tone (evenness and clarity), skin texture/smoothness, brightness, radiance/luminosity, complexion health, and overall appearance using Visual Analog Scales (VAS).

Intensity of dark spots / PIH was evaluated by the expert grader using a five-point ordinal scale and pigmentation using the MASI scale.

Instrumental evaluation was performed with Cosmetics™ SIAscope (Astron Clinica, Toft, UK) for epidermal melanin evolution and image analysis with Clarity™ 2D Research System Ti (Clarity BTBP, CA, USA) for MASI, Spots, Radiance, Homogeneity and Sub-Surface Spots.

Objective tolerance was assessed by a board certified dermatologist and subjective tolerance by inquiring with subjects about the incidence and severity of subjective irritation sensation.

Study visits occurred at Baseline (BL), Week 6 (W6) and Week 12 (W12).



Results:

21 females' volunteers with mean age of 51.4 years and II-IV Fitzpatrick skin type completed the study. 47.6% of subjects had dry facial skin and 52.4% oily facial skin.

Mean results at Baseline compared to those at Weeks 6 and 12 revealed statistically significant improvement for skin tone (evenness and clarity), texture/smoothness (visual), lightening / brightness, radiance / luminosity, complexion health, overall appearance and intensity of dark spots / age spots and for MASI Index score.

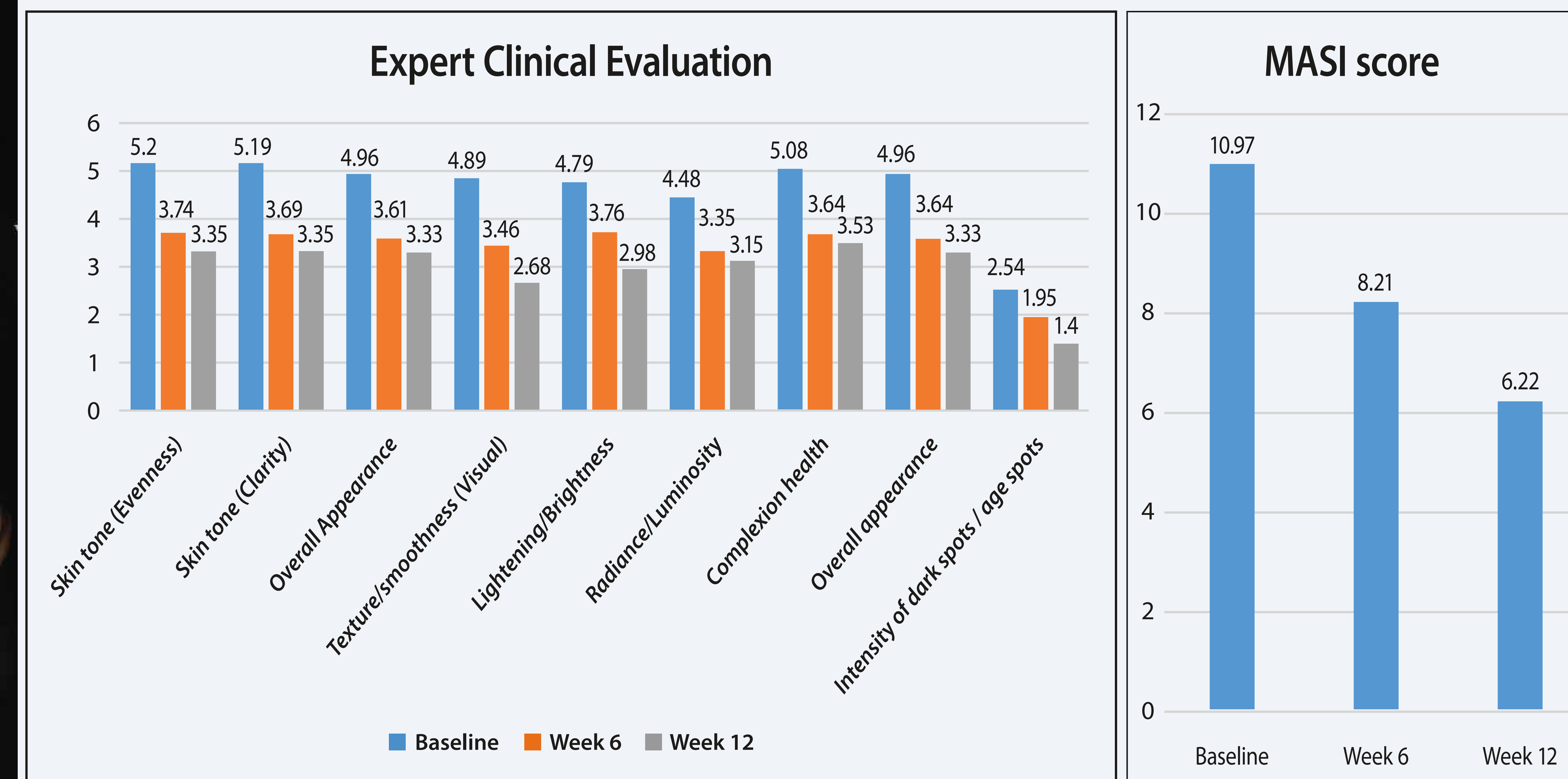
Images analysis comparing the mean scores from Baseline to subsequent visits revealed statistically significant improvements in pigment intensity, spots count, Homogeneity and MASI.

Objective tolerance evaluation showed a significant decrease of erythema at 12 weeks after regimen application ($p < 0.001$).

Subjective tolerance revealed that at Week 6, 100% of subjects did not feel any skin discomfort when using the test regimen and more than 90.0% found that the regimen gave their skin a more flawless look without any irritation.

More than 85% of subjects had an overall improvement of their skin without irritation or discomfort at week 12.

Majority of the subjects did not feel any skin irritation or discomfort after stopping the test regimen.



Conclusion:

The regimen led to significant improvements in facial skin appearance with evenness, clarity, smoothness, brightness, radiance, complexion health, overall appearance and intensity of dark spots and with MASI Index scores decrease after six and twelve weeks of use. The image analysis also revealed the test regimen to be effective at improving skin surface and sub-surface spots and skin radiance at the same periods. The regimen was well-tolerated in this study panel and consumer perception revealed significantly positive perception of its effects through 12 weeks of use as well as after one week of regression.