

A single center, prospective, randomized trial to assess the efficacy of a skin lightening formulation containing ellagic acid, hydroxyphenoxy propionic acid, yeast extract, and salicylic acid in Brazilian subjects with melasma

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Introduction: _____

Melasma is a pigmentary skin disorder primarily related to facial hyperchromia and a chronic disease characterized by symmetrical dark spots in photo-exposed areas. Treatment principles include protection against UV radiation and the inhibition of melanin synthesis inside melanocytes. Historically, therapeutic treatment of melasma has been challenging. The gold standard of melasma treatment is hydroquinone; however, this highly cytotoxic substance has been banned in multiple countries, increasing the demand for non-hydroquinone alternative treatments.¹

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Objective: _____

To determine the efficacy of a non-hydroquinone, cosmeceutical, skin lightening formulation in improving facial melasma in Brazilian subjects.

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Methods: _____

34 subjects with Fitzpatrick skin type II to V exhibiting mild to moderate melasma applied a formulation containing hydroxyphenoxy propionic acid, ellagic acid, yeast extract, and salicylic acid twice daily for 90 days in this prospective IRB-approved study. Pigmentation was measured objectively using a colorimetric assessment together with Visia[®] image analysis. Subjective analysis was performed using melasma area and severity index (MASI), investigator grading on a four-point scale (severe, mild, moderate, none) and subject self-assessment at baseline, D30, D60, and D90 visits as well as MELASQoL questionnaire at baseline and D90. The mean decrease in pigmentation was calculated using objective and MASI measurements and validated with ANOVA statistical analysis.

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Results: _____

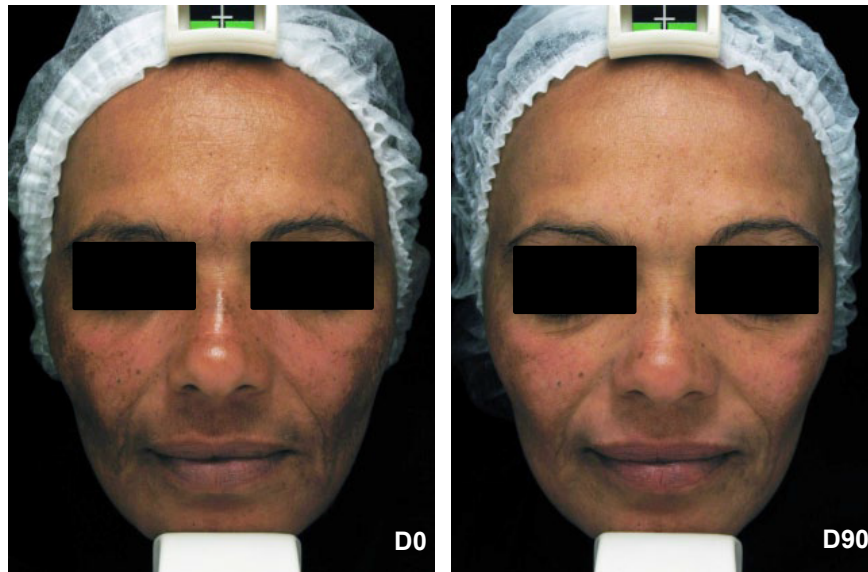
MASI Score decreased from 15,5 to 8,82 ($p < 0,0001$). As a result of skin lightening, visual typological angle increased by 2-fold from 14,08 to 27,75 ($p < 0,0001$). Both subject and physician assessments showed statistically significant improvement in clinical grading after 90 days of treatment. Subjects also reported statistical significance improvement in quality of life attributes at the end of the study. No adverse events were observed during the study

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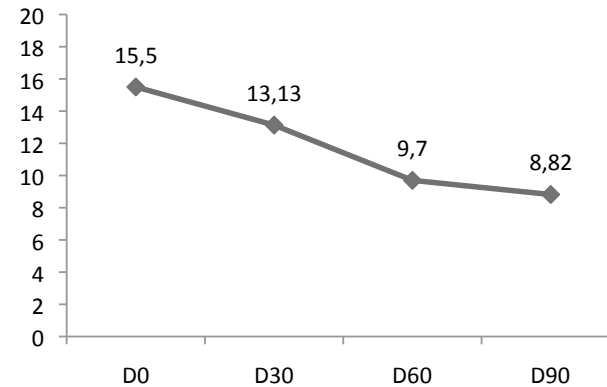


Results:

Visia® image analysis



Average MASI Score values



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Conclusion: _____

This new formulation containing hydroxyphenoxy propionic acid, ellagic acid, yeast extract and salicylic acid significantly improved subject facial pigmentation utilizing an alternative to hydroquinone for the treatment of melasma. These results suggest a promising safe cosmeceutical treatment option for melasma, either alone, or in conjunction with other therapeutic treatments.

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