dermamelan® method:
safety and efficacy of an innovative topical depigmentation treatment that acts in different signalling pathways of the melanogenesis process for an integral treatment of severe hyperpigmentations such as melasma

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INTRODUCTION

Depending on the genetic predisposition of the individual and the environmental factors, such as ultraviolet radiation, melanocytes can cause abnormal melanin accumulation that results in different types of **skin hyperpigmentation (melasma, PIH, ephelides and lentigo). Melasma is the hyperpigmentation with the highest therapeutic complexity.** It is clinically characterised by the appearance of pigmentation spots, generally symmetrical, on the face, in particular on the cheeks, the dorsum of the nose, forehead and upper lip.[1,2,3] In the cells, the most recent **scientific evidences have shown that there are several pigmentation signalling pathways**[4] whereby different cell types are involved in the regulation of melanogenesis. The inflammatory pathway and the vascular pathway are the most relevant in melasma, since microscopic data have evidenced that skin with melasma shows infiltrated mast cells and an increase in blood vessels.[5]

Many current treatment methods are based only on the removal of superficial melanin accumulation, such as laser, intense pulsed light (IPL), chemical peelings and creams with acids. Other medical topical medical treatments, such as those containing hydroquinone, can regulate melanocyte activity, but have a very limited therapeutic time due to their safety profile.

dermamelan® exerts a **corrective action**, stimulating epidermal renewal, and **regulating** action, controlling melanin synthesis, both **intracellularly inside the melanocyte** and **intercelullarly through the main signalling pathways of melanogenesis**. The regulation of key pigment targets is essential to maintain a therapeutic control of the disease, in particular in the case of the most severe and chronic hyperpigmentations, such as melasma.

OBJECTIVE

To evaluate the efficacy and safety of the dermemlan® method for the treatment of hyperpigmentation with a topical formula containing specific active ingredients producing a dual **mechanism of action, corrective and regulating**, both intercellularly and intracellularly.

MATERIALS AND METHODS

Between October 2018 and February 2021 **a prospective study was performed in 54 volunteers** from both sexes and a mean age of 34 years. The inclusion criteria were phototypes II-IV with melasma, lentigo, PIH and/or ephelides. The assessment methods used were VISIA, Mexameter, Janus, MASI index, photographic records, safety and efficacy questionnaires and Likert type surveys. The control visits were scheduled for days 0, 7, 15, 30, 60, 90 and 120. The changes in the variables were analysed at each control visit from the baseline control and the data were managed statistically (Student's T test with 95% confidence interval). Furthermore, the Cohen's d statistical method was used to calculate the effect size.

The **treatment protocol** consists of one clinical session (phase 1) and a protocol at the clinic of 4 months in duration (phase 2):

Phase 1: application at the clinic of depigmenting **dermamelan® mask** and iontophoresis **dermamelan® ion mask**. Removal of both masks after 4 hours at home with warm water.

Phase 2: after 48 h/72 h, start of 4-month home treatment with **dermamelan® treatment** twice a day, and the coadjuvants **melan recovery** and **mesoprotech® melan 130 pigment control** to moisturise and protect the skin from sun radiation, respectively.

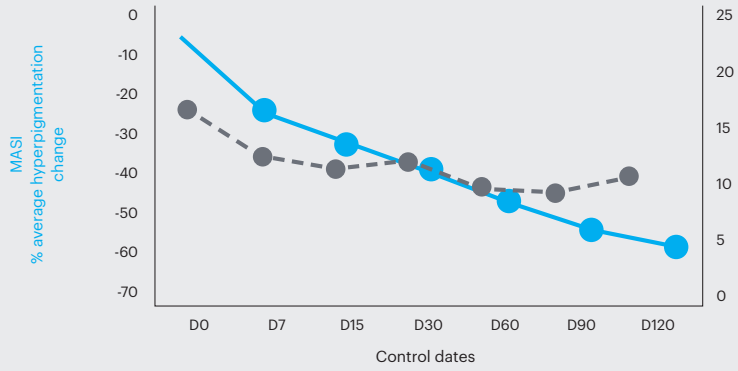
AT THE CLINIC 4 h

AT HOME 4 months

RESULTS

Dermamelan® method has been shown to be a depigmenting method with **clinical and cellular efficacy,** that inhibits specifically tyrosinase and acts in the different cell processes involved in melanogenesis. Studies *in vitro* have shown that the cultures of melanocytes treated with dermamelan® show a reduction of dendricity and a reduction of total melanin of 89%.

Significant reduction of JANUS and MASI, the latter with a Cohen's d of 2.84, that shows a very large effect size.



-57%
reduction of hyperpigmentation (Cohen's d 2.84)

-32%
reduction of wrinkles

Results *in vivo*

Some of the most illustrative case reports are given below. Only 20% of the patients reported mild local skin reactions derived from the treatment.

CASE 1:

CASE 2:

CASE 3:

CASE 4:

CONCLUSIONS

- Depigmenting method with unique active ingredients such as **[syn]pigmenTarget®** and **melaphenone®** that offer a corrective and regulating action, both intracellularly (unique tyrosinase inhibitor) and intercellularly (acting in the main signalling routes of the melanogenesis process).
- dermamelan® is an innovative depigmentation treatment that has been shown to be effective and safe for the treatment of **melasma, PIH, ephelides and lentigo**.

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Scan the QR code to view the protocol of application of **dermamelan®** over the area to be treated.

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