

Efficacy of a cosmetic formulation containing a blend of nanoencapsulated antioxidants by in vitro, ex-vivo and in vivo studies

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Introduction:

Application of antioxidants in cosmetic products contributes to collagen preservation and synthesis, acting in melanogenesis and overall skin health and appearance improving [1,2].

Therefore, the objective of this study was to evaluate the efficacy and safety of a cosmetic formulation containing a blend of ingredients, by ex-vivo and clinical evaluations.

Materials & Methods:

The in vitro tests were performed through the measurement of Mitochondrial reactive oxygen species (mROS) in human fibroblasts cell culture after IR-A radiation and after IR-A plus treatment with the investigational cosmetic product. After the approval of Ethics Commi ee measurements of melanin, type 1 procollagen were performed in ex-vivo human issue from elective plastic surgery after UV radiation and after radiation plus the cosmetic treatment.

In addition, filaggrin was also measured in ex-vivo human issue, but this time after skin barrier rupture with SLS 5% and after this rupture plus investigational product treatment.

Finally, a clinical study was performed by instrumental measurements in order to evaluate the skin hydration (Corneometer®), skin oiliness (Sebumeter®), collagen synthesis with diffuse reflection spectroscopy (DRS) and swelling around the eyes using Vectra XT imaging system. For this, after the approval of Ethics Commi ee 20 healthy females aged 40 to 50 years old, Fitzpatrick phototype II, III and IV were recruited. In addition, a self-assessment questionnaire was applied for evaluation of perceived efficacy by study subjects. Safety and tolerance studies were also carried out with the product under use as well as acne lesions count on skin by an investigator dermatologist.

Results & Discussion:

The in vitro study showed the investigational product (IP) statistically ($p < 0.001$) decreased mROS by -73.13% at 10.01mg/ml; -64.58% at 3.17mg/ml and -59.88% at 1mg/ml.

The ex-vivo study showed that the product statistically ($p < 0.001$) decreased melanin pigmentation by 81.53% in the irradiated and treated group, when compared to the irradiated and non-treated. Furthermore, the product statistically ($p < 0.001$) increased type 1 procollagen by 260.40%, when compared to only irradiated group. Also, a significant ($p < 0.05$) increase in filaggrin production was observed when compared to the SLS ruptured and not treated group.

The clinical study results showed a significant ($p < 0.001$) decrease on skin superficial oiliness after 1 and 4 hours of IP application, when compared to the control area (non-treated) and a significant ($p < 0.001$) increase in the dielectric constant after 1, 4, 8, 12 and 24h of product application when compared to non-treated area, suggesting an increase in the stratum corneum water content. There was no adverse event, physical sign nor reported sign, showing that the studied cosmetic product presents a high tolerance profile on normal skin. The acne lesions count presented a significant decrease in non-inflammatory lesions ($p = 0.0135$) and non-significant reduction in inflammatory lesions ($p = 0.6641$). DRS results analysis showed a significant increase ($p < 0.05$) in the values of I340/I295 (collagen/tryptophan) after 56 and 84-day period of treatment, which suggests an increase in collagen synthesis on facial skin. The Vectra XT imaging analysis showed that the cosmetic product promoted a significant ($p < 0.05$) reduction in the swelling around the eyes in 95% of subjects after 1h of application and after 14 and 28 days of daily use in 100% of subjects ($p < 0.05$). Finally, 120 subjects answered the self-assessment questionnaire, and the product was well appreciated by them: 91% reported their skin softer, 83% noticed an improvement in the skin overall appearance and 93% in skin hydration.

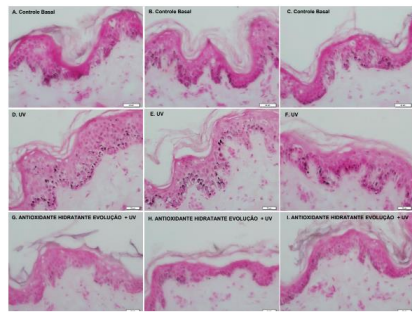


Figure 1. Histological evaluation of melanin pigmentation in ex vivo skin fragments treated with the evaluated product and subjected to UV radiation. (B,C), Basal Control. (D-F), UV. (G-I), Ex vivo skin fragments treated with the investigational product and subjected to UV radiation. Reference bar corresponds to 50 µm.

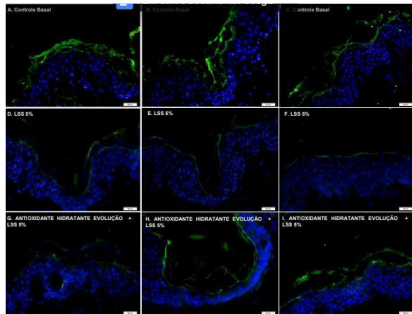


Figure 5 shows immunofluorescence images of filaggrin protein synthesis. As we can see, through the semi-quantification of the images obtained (Figure 3), breaking the barrier with SLS 5% decreased the production of filaggrin by 28.28% in relation to the basal control ($P < 0.001$).

Conclusions:

The proposed cosmetic product was safe and effective in the improvement of skin conditions and appearance by increasing collagen synthesis, resulting in firmer, less rough, softer and smoother skin. The reduction of melanin and increased of filaggrin suggest a blemishes reduction and a more hydrated skin, which was shown by Corneometer® measurements. In addition, the product was effective for application on the oily skin since it reduced the superficial sebum amount and can act in the control of skin hydrophilic balance. In the clinical evaluation the study participants also perceived the improvement of skin hydration and smoothness observed in the instrumental measurements. Finally, the present study has an important contribution since it showed the benefits of a cosmetic product based on nanoencapsulated antioxidants using different and innovative evaluation methods.

References:

1 - Shih BB, Farrar MD, Vail A, Allan D, Chao MR, Hu CW, Jones GDD, Cooke MS, Rhodes LE. Influence of skin melanisation and ultraviolet radiation on biomarkers of systemic oxidative stress. *Free Radic Biol Med*. 2020 Nov 20;160:40-46.
2 - Boo YC. Human Skin Lightening Efficacy of Resveratrol and Its Analogs: From In Vitro Studies to Cosmetic Applications. *Antioxidants (Basel)*. 2019 Aug 22;8(9):332

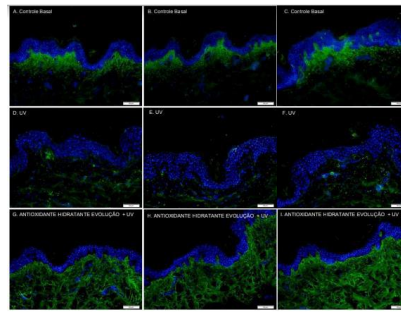


Figure 2 presents the immunofluorescence images of the protein synthesis of type I procollagen. As we can see, through the semi-quantification of the images obtained (Figure 3), the exposure to UV radiation decreased by 49.64% to type I procollagen concentration compared to baseline control ($P < 0.001$). On the other hand, treatment with the evaluated product was able to significantly increase the production of type I procollagen by 260.40% ($P < 0.001$), when compared to the UV group.



Figure 3 represents the VECTRA XT image results: the investigational product promoted a significant reduction in swelling under the eyes after 28 days of daily use ($p < 0.05$) in 100% of participants.

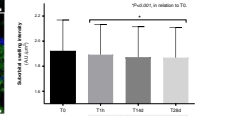


Figure 4 - Mean values obtained in the suborbital swelling intensity (SI) before (T0), after 1-hour (T1h), 14 (T14d) and 28 (T28d) days of home use of the investigational product. Data represent the mean ± standard deviation (n=19; Student t-test, *significant compared to T0) ($p < 0.001$)

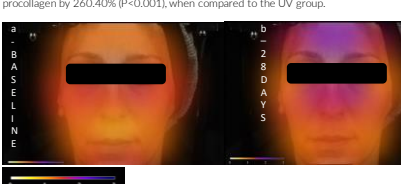


Figure 6 - the collagen map is generated by an algorithm that creates a color map based on collagen rate values, which corresponds to the ratio between collagen intensity (340nm) and tryptophan intensity (295nm). The collagen map is visually represented by a color palette applied to the image. The scale ranges from 0.0 (very low collagen content - white) to 3.0 (very high collagen content - dark blue). According to the DRS results, there was a significant increase ($p < 0.05$) in the values of I340/295 after 56 and 84 days of treatment, indicating that there was a significant increase in collagen synthesis in the facial skin, as seen in the graph 2.



Figure 7. Mean values of I340 / I295 (collagen). Mean ± SD. (n=14).