Original Articles

Importance of texture and sensorial profile in cosmetic formulations development

Importância do perfil de textura e sensorial no desenvolvimento de formulações cosméticas

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ABSTRACT

Introduction: The evaluation of the clinical efficacy of cosmetic formulations in real conditions of use is indispensable and the correlation of these results with texture and sensory profile analyses is necessary because impacts directly in the continuity of cosmetic treatment.

Objective: The evaluation and correlation of the texture and sensorial profile, and clinical efficacy of cosmetic formulations containing alfafa oligosaccharides, cassava polysaccharides and sunscreens.

Methods: It was evaluated the texture and sensorial profile, and clinical efficacy of formulations through biophysical and imaging analysis techniques.

Results: The methods presented a good correlation, because formulation added with suncreens and active ingredients provided better spreadability and sensorial properties. The assessment of clinical efficacy was coherent with the sensory analysis once the "skin smoothness" parameter could be proven with the increase of hydration and improvement of skin microrelief.

Conclusions: The application and correlation of the used techniques enabled the definition and obtainment of a formulation with sensory acceptance and proven clinical efficacy in the improvement of texture and skin hydration. Thus, this study provides contribution in dermatological area, once an appropriate sensory favors the adhesion to the use of the product and the consequent treatment success.

Keywords: efficacy; cosmetics; biophysics; polysaccharides; oligosaccharides

RESUMO

Introdução: *Assim como a avaliação da eficácia clínica de formulações cosméticas nas reais condições de uso é imprescindível, a correlação destes resultados com análises do perfil de textura e sensorial faz-se necessária, pois impactam diretamente na continuidade do tratamento cosmético.*

Objetivo: *Avaliar e correlacionar o perfil de textura, características sensoriais e eficácia clínica de formulações cosméticas contendo oligossacarídeos da alfafa, polissacarídeos da mandioca e filtros solares.*

Métodos: *Foram avaliados o perfil de textura, características sensoriais e a eficácia clínica de formulações, por meio de técnicas de biofísica e análise de imagem.*

Resultados: *Os métodos empregados apresentaram correlação, pois, a formulação acrescida de filtros e ativos proporcionou melhores espalhabilidade e características sensoriais. A avaliação da eficácia clínica se mostrou coerente com a análise sensorial uma vez que o parâmetro "pele macia" pode ser comprovado com o aumento da hidratação e melhora do microrrelevo da pele.*

Conclusões: *A aplicação e correlação das técnicas empregadas possibilitaram a definição e obtenção de formulações com aceitação sensorial e eficácia clínica comprovadas na melhora da textura e hidratação da pele. Assim, este estudo apresenta contribuição na área dermatológica, uma vez que o sensorial adequado favorece a adesão ao uso do produto e o consequente sucesso do tratamento.*

Palavras-chave: *eficácia; cosméticos; biofísica; polissacarídeos; oligossacarídeos*

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INTRODUCTION

The aging process brings the loss of structural integrity to the skin, that occurs due to a decreased in cell renewal, vascularization, number of keratinocytes, fibroblasts, collagen and elastin fibers, in addition to the flattening of the dermal-epidermal junction, and a reduction in the immune response, which leads to change in functions such as cutaneous protection, absorption, thermoregulation and sensory perception. Moreover, exposure to exogenous factors – air humidity, ultraviolet radiation – as well as endogenous factors – hormones – possibly alters the balance between the stratum corneum and the lipid layer.[1-3]

Whereas there are still no means to prevent the occurrence of genetic aging processes, cosmetic products with anti-aging properties are only able to prevent, delay and alleviate the effects caused by extrinsic factors.[4] Furthermore, the cosmetic industry has been committed to developing formulations that meet current consumer needs, integrating many benefits to the skin in a single product.[5]

Among cosmetic active principles used for anti-aging and cutaneous health general improvement purposes, research on Alfalfa extract *(Medicago sativa)* evidenced a mechanism of action similar to that of Retinol ("retinol like"), which has the potential to stimulate cell activity, favoring the renewal of the epidermis and regulating the differentiation of keratinocytes. In addition, it promotes stimulation of type I collagen synthesis and reduction in the activity of the metalloproteinases, the latter responsible for the destruction of elastin fibers.[6,7]

Apart from active principles that act in the long term, the use of principles with immediate tightening effect, such as the cassava's bio polymerized sugar *(Manihot esculenta),* can contribute to the perceived efficacy of cosmetic formulations, since after application of the product on the skin, this active is capable of forming a three-dimensional mesh composed of high molecular weight polysaccharides, lending resistance and cohesiveness, allowing a significantly rapid tightening effect.[8,9]

Nonetheless, for the verification of the potential effects described, it is necessary to conduct clinical effectiveness studies under actual use conditions. For this end, *in vivo* non-invasive methods are employed, including biophysical and skin imaging analysis techniques using multiple devices with different physical and/or physicochemical principles that facilitate the interpretation of the outcomes regarding the performance of a particular cosmetic product on the skin.[10]

In this manner, it is possible to evaluate parameters linked to the stratum corneum's water content, transepidermal water loss and cutaneous microrelief, among others, using the Tewameter®, Corneometer® and Visioscan® devices.[10,11]

It is important to note that in order for the cosmetic formulations to be in fact effective, choosing good active principles and showing evidence of clinical effectiveness are only two of a series of important steps to be considered during the development of these formulations. For example, it is also imperative that the formulation offers enjoyable sensory characteristics and good spreadability on the skin, aimed at providing consumers' wellbeing and conditions for continuity of the cosmetic treatment.[12,13]

For that end, conducting texture and spreadability trials using the TA.XT plus texturometer device are crucial because they allow analyzing the influence of the components' mechanical properties, and comparing these results with sensory analyses. This supports the development of formulations with different sensory characteristics, which in turn promote the continuity of their use.[13,14]

In this context, innovative methods such as texture analysis combined with clinical effectiveness can mean a great contribution to the development of cosmetic products with proven efficacy and differentiated sensory characteristics.

OBJECTIVE

The present study was aimed at evaluating and correlating the texture, sensory characteristics and clinical effectiveness profiles of cosmetic formulations containing alfalfa's oligosaccharides, cassava's polysaccharides and sunscreens.

MATERIALS AND METHODS

Assessed formulations

A multifunctional cream gel formulation was developed based on Polyacrylamide (and) C13-14 Isoparaffin (and) Laureth-7 (Sepic), Ethylhexyl Palmitate (Croda), Bis-ethylhexyloxyphenol methoxyphenyl triazine (Basf), Octocrylene (Symrise), Methylene bis-benzotriazolyl tetramethylbutylphenol (Basf), Glycerin (Mapric), Propylene glycol (Mapric), Cyclomethicone (Dow Corning), Cyclopentasiloxane (and) Dimethicone crosspolymer (Dow Corning), Polyglyceryl-10 myristate, Triethylhexanoin, Glycerin, Water (Nikko Chemicals), Phenoxyethanol, Methylparaben, Ethylparaben, Propylparaben, Butylparaben, Isobutylparaben (Mapric), BHT (Mapric), Disodium EDTA (Mapric), aqua.

Was also analyzed a commercial gel-cream based on: aqua, Octocrylene, glycerin, Dodecane, Homosalate, Ethylhexyl salicylate, Butyl methoxydibenzoylmethane, Cyclopentasiloxane, Dimethicone reticulate copolymer, Hydroxyethyl acrylate copolymer / Sodium acryloyldimethyl taurate, Squalene, Polysorbate-60, Dicaprylyl ether, Castanea sativa seed extract, Phenylbenzimidazole sulfonic Acid, C12-15 Alkyl benzoate, Caprylic/Capric triglyceride, Diethylamino hydroxybenzoyl hexyl benzoate, Glyceryl Stearate (and) PEG-100 Stearate, Soybean (Glycine soja) extract, Biosaccharide gum-2, Biosaccharide gum-3, Xanthan gum, Sodium hydroxide, Phenoxyethanol, Acrylates/C10-30 Alkyl acrylate crosspolymer, Tocopheryl acetate, fragance, BHT, Biosaccharide gum-5, Disodium EDTA, Methylchloroisothiazolinone, Coffea robusta seed oil extract, Lycopene.

Spreadability analysis

In order to assess the contribution of the studied sunscreens and active principles (alfalfa oligosaccharides and cassava polysaccharides) on the developed formulation's physical and mechanical properties, a TA.XT plus texturometer device and a TCC spreadability Rig probe were used in the present study. The trials' results were provided by the device's software. The parameter *work of shear* was evaluated (Area F-T 1:2).[15]

To this end, the developed multifunctional formulation was subdivided into 3 portions. Accordingly, the F1 (vehicle formulation), F2 (F1 plus sunscreens) and F3 (F2 plus active principles) formulations were compared, the latter being the object of analysis. It worth to note that these formulations had their stability proven by a stability test.[16]

METHODS

This stage was previously approved by the Research Involving Human Subjects Ethics Committee of the Faculdade de Ciências Farmacêuticas de Ribeirão Preto – USP (SP, Brazil) (Protocol: 1.0420228 04/2015).

Sensory analysis

The sensory analysis was performed in 2 stages. The first was aimed at evaluating the contribution of sunscreens and active principles in the sensory characteristics of the developed formulation. The second was aimed at evaluating the sensory characteristics of the studied formulation as compared to a commercial formulation.

Both analyzes were performed in the anterior region of the forearm in all 20 volunteers in the first stage, and in 10 volunteers in the second stage.

In the first step, the forearms were divided into 3 quadrants, with each volunteer applying one of the formulations (F1, F2 and F3) in one of the quadrants, performing 10 clockwise rotations. After the application, the volunteers answered a sensory evaluation questionnaire containing the following parameters: *touch sensation*, *spreadability*, *skin smoothness*, *absorption*, *oiliness*, *brightness*, *absorption*, and *white residue*. The parameters were scored according to the following criteria: 1 - Very poor, 2 - Poor; 3 - Fair, 4 - Good, 5 - Excellent.

In the second step, a random application of 20 μL of the formulations FA (commercial formulation) and FC (multifunctional formulation F3) was performed in 3 regions (one of them being the control region) of the forearms of 10 volunteers. Before starting the study, the volunteers were instructed to spread the formulation performing 10 clockwise rotations. The questionnaire "check-all-that-apply" (CATA) was used, with questions on the sensory characteristics related to the parameters perceived immediately after the application (*oily/greasy*, *sticky*, *smooth*, *easily absorbed* and *easy to spread*) and those related to the effects on the skin perceived 5 minutes after the application (*oily residue*, *hydrated skin*, *smooth skin*, *whitish residue* and *intention to buy*).[18]

Clinical effectiveness evaluation

Ethical aspects

The volunteers were informed and advised on the study's goals and methods, having agreed to participate, signing a Term of Free and Informed Consent approved by the Research Ethics Committee (Resolution 466, 12/12/2012, Brazilian National Health Council).

Population and sample / Selection of volunteers

For the assessment of the immediate effects of the studied formulations, 10 female volunteers were selected (Fitzpatrick phototypes II to IV, aged from 20 to 50 years). The following exclusion criteria were used in the selection of volunteers: pregnancy or lactation; previous history of adverse reactions to the use of cosmetic products; use of drugs likely to produce abnormal cutaneous response; localized or generalized dermatological diseases; and excessive hair in the study regions.

Evaluation of immediate effects

This stage of the study comprised the assessment of the immediate effects of the studied formulation (F3, which in this stage was renamed with the acronym FC) as compared to a commercially available formulation (FA) containing polysaccharides and sunscreens for improving hydration, transepidermal water loss and the skin's microrelief. In this way, the formulations were applied on 10 volunteers, in 3 previously randomly defined regions in the forearms, with 1 of these regions being established as the control region. The measurements were taken before the application of the formulations and 2 hours after. The outcomes were compared among them and to their respective baseline values. All measurements were performed after 15 minutes of acclimatization in controlled temperature and air humidity (20-22°C and 45-55%, respectively).[10]

Biophysical techniques and skin imaging analysis: Transepidermal water loss (TEWL)

The Tewameter® TM 300 (Courage-Khazaka, Germany) device was used in this study. It measures the water evaporation on the skin's surface based on the diffusion principle described by Adolf Fick in 1885. The probe remained on the skin for 20 seconds, obtaining an average value for the TEWL.[19,20]

Stratum corneum's water content

The stratum corneum's water content was determined using the Corneometer® CM 825 device (Courage-Khazaka, Germany), coupled to a software that measures the stratum corneum's hydration level. This technique's principle is based on measuring the electrical capacitance of the skin, according to the amount of water present in it. Ten measurements were performed in the studied region, with the results expressed in arbitrary units (A.U.) by the device itself, depending on the stratum corneum's water content.[11]

Cutaneous microrelief

The Visioscan® VC 98 device (Khazaka, Germany) was used to determine the skin's cutaneous microrelief. The device provides qualitative and quantitative information about the skin's surface in physiological conditions using optical profilometry techniques, which are based on the digitalization process of images obtained by a video camera. With this method, the following parameters related to the skin's surface were evaluated (SELS - Surface Evaluation of Living Skin): *roughness* (SEr) -

portion of dark spots representing the skin's roughness; *wrinkles* (SEw) - number and width of wrinkles, the greater the number of wrinkles the greater is Sew; *smoothness* (SEsm) - shape and width of wrinkles, the higher the value of this variable, the better the texture and softness of the skin.[21]

Statistical analysis

The data were tested for normality by the Shapiro-Wilk test for each evaluation performed, using the statistical software Origin 8.

To evaluate the correlation among all studied parameters in each of the regions, the Pearson correlation was used with the assistance of the software GraphPad Prism 5. The ANOVA (Bonferroni test) for comparison of means was performed for all parameters ($p < 0.05$).

RESULTS

Spreadability analysis

According to the spreadability test results (Graph 1), a significantly greater value for *work of shear* was gauged for the formulation F1 than for F2 and F3 ($P < 0.05$), suggesting that the addition of sunscreens and active principles to the formulations have improved their spreadability. Moreover, the comparison of F2 with F3 did not evidence significant differences in spreadability values, indicating that the decrease in the *work of shear* value is exclusively due to the addition of sunscreens to the formulations (F2 and F3).

Sensory analysis

Based on the analysis of these results (Graph 2) it was possible to notice that the formulations in general fared well in the volunteers' percentage of acceptance, while the formulation containing sunscreens and active principles (F3) had the highest percentages of maximum ratings in most of the evaluated parameters, regarding the other formulations.

In the second stage of the sensory analysis, it was possible to observe that the formulations in general have obtained the same percentage of characterization for each of the parameters evaluated.

It is important to note that, immediately after the application (Graph 3) the commercial formulation (FA) received a higher percentage of characterization regarding the parameter *easily absorbed* and a lower percentage regarding the parameter *sticky*. On the other hand, regarding the effects 5 minutes after the application of the formulations (Graph 4) the FC formulation stood out regarding the parameters *smooth skin* and *intention to buy*.

Clinical effectiveness evaluation

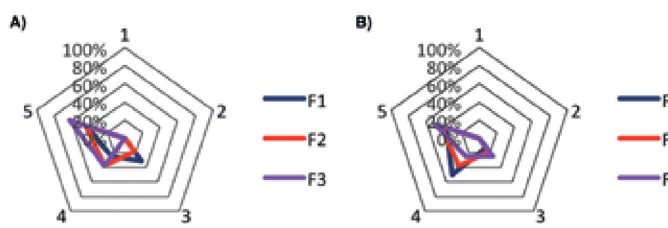
Transepidermal water loss (TEWL)

Based on the analysis of the results (Graph 5) it was observed that 2 hours after the application, a reduction trend could be observed in TEWL for both formulations.

Stratum corneum'a water content

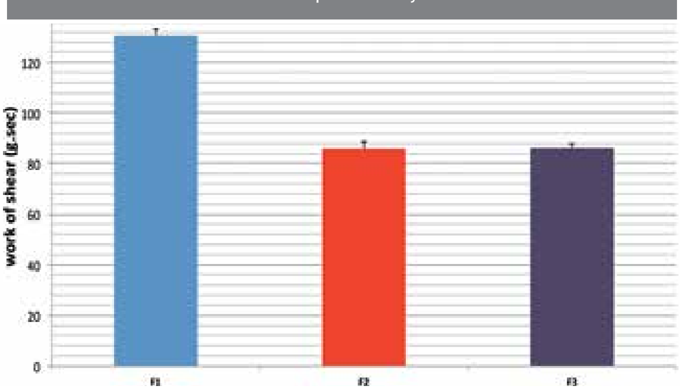
Based on the analysis of the results (Graph 6), it was possible to observe a significant increase ($p < 0.05$) in hydration

Graph 2: Sensory analysis of F1, F2 and F3 formulations



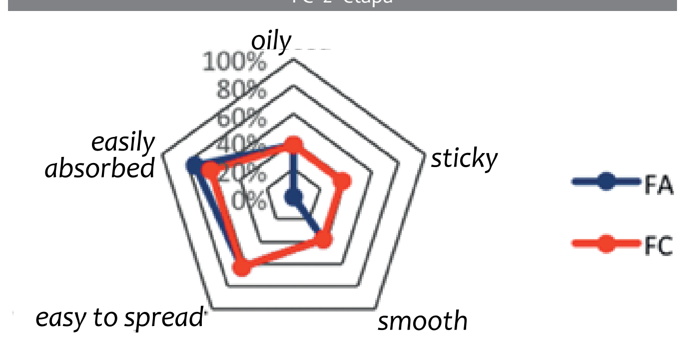
Evaluation of the formulations regarding the parameters spreadability **(A)**, touch sensation **(B)**; ratings: 1 - Very poor, 2 - Poor; 3 - Fair, 4 - Good, 5 - Excellent

Graph 1: Spreadability test



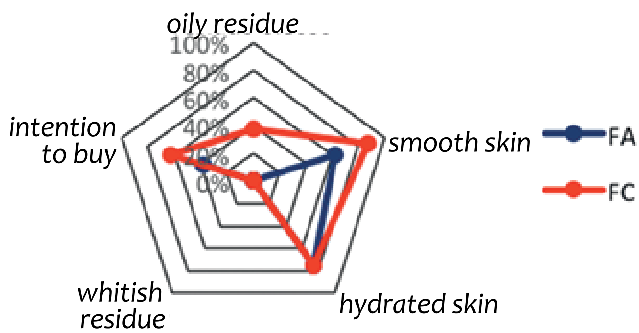
Spreadability test based on the evaluation of the parameter work of shear. Comparison between F1 (vehicle formulation), F2 (vehicle + sunscreen) and F3 (F2 + active principles). *Statistically significant values in the comparison with other formulations' results

Graph 3: Análise sensorial comparativa entre as formulações FA e FC- 2ª etapa



Comparative sensory analysis between FA and FC formulations – 2nd stage. Comparative sensory analysis between FA (commercial formulation) and FC (study formulation). The following parameters were evaluated immediately after the application: *oily/greasy, sticky, smooth, easily absorbed and easy to spread*

Graph 4: Comparative sensory analysis between FA and FC formulations – 2nd stage



Comparative sensory analysis between FA (commercial formulation) and FC (study formulation). The following parameters were evaluated 5 minutes after the application: *oily residue, hydrated skin, smooth skin, whitish residue and intention to buy*

linked to the application of both formulations, with the comparison results indicating superiority of the FA regarding FC formulation.

Cutaneous microrelief

Based on the analysis of the data related to the parameter SEr – which evaluates the skin's roughness – it was possible to observe that the FC formulation showed a higher tendency of decrease for this parameter 2 hours after the application (Graph 7).

DISCUSSION

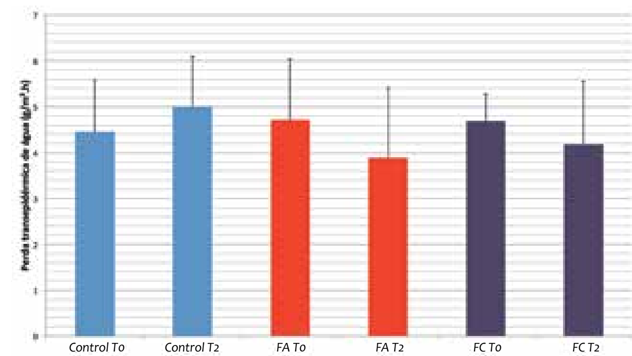
Despite being crucial, evidence of clinical effectiveness alone is not sufficient to ensure the success of a new cosmetic product, since these products must have sensory features that meet consumers' expectations, thus assisting in the adherence to the prescribed treatment. As a result, the analysis of texture and sensory characteristics of cosmetic products are instrumental for securing that formulations meet expectations.[12,18]

In this context, the spreadability analysis can be considered a very important pre-requisite in the development of formulations, for it enables developers to understand the influence of certain components in the product's final physical properties in an objective manner.[13]

Based on the results obtained, it was possible to observe that the formulations containing sunscreen had a lower value for *work of shear* than that of the vehicle formulation, which suggests that it will have better spreadability on the skin. This phenomenon may be related to the fact that the emulsifying polymer used in the formulations forms polymeric networks with water, in a way that when there is addition of oily sunscreens, the formulation's viscosity decreases, consequently decreasing the *work of shear*.[22]

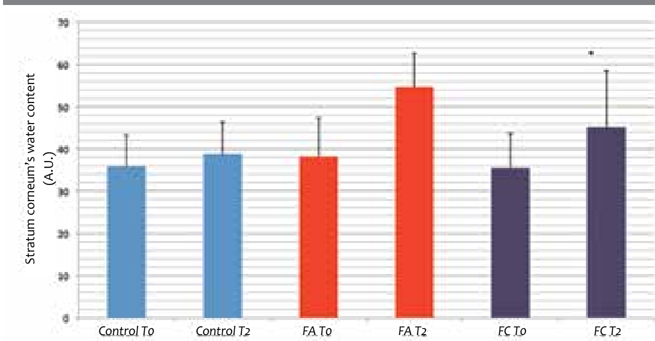
The application of sensory analysis in the development of cosmetic formulations is key to developing formulations that are well accepted by consumes. In addition, a formulation's sensory

Graph: Transepidermal Water Loss (TEWL) analysis



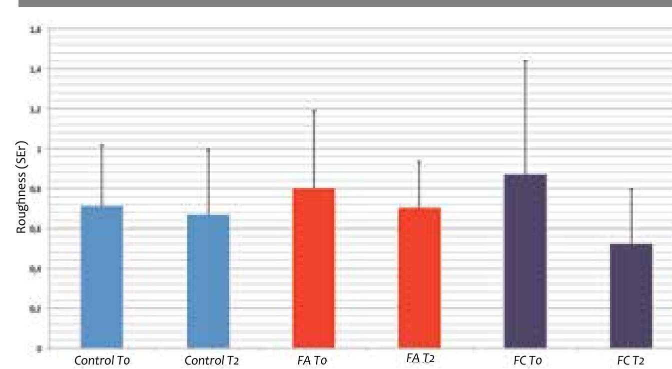
Transepidermal water loss analysis (Tewameter®) before and after the application of FA (commercial formulation) and FC (study formulation), compared to a control area

Graph 6: Stratum corneum's water content analysis



Stratum corneum's water content before and 2 hours after the application of FA (commercial formulation) and FC (study formulation), compared to a control area. * Different statistical means as compared to their baseline values. FA (p = 0.0005), FC (p = 0.0311) and FAt45 compared to FCt45 (p = 0.0232)

Graph 7: Spreadability test



Evaluation of the skin's roughness based on the parameter SEr (portion of black dots representing the degree of skin roughness) before and 2 hours after the application of FA (commercial formulation) and FC (study formulation), as compared to a control area characteristics is as important as its clinical effectiveness since it is known consumers stop using formulations that have unpleasant sensory characteristics even knowing they can bring benefits for the skin.[18, 23]

In this manner, the first sensory analysis was aimed at characterizing the formulations as well as evaluating its acceptance by consumers, which can be measured based on the rating attributed to each assessed characteristic.[24,25] The results obtained with this analysis showed that the formulations had good acceptance percentages attributed by the study patients. Furthermore, it was demonstrated that the formulation containing sunscreens and active principles (F3) had higher percentages for the maximum rating for most of the parameters evaluated as compared to the other formulations. This outcome suggests that the presence of the active principles, which are the object of analysis of the present paper, when present in the formulations containing sunscreen, improved their sensory characteristics due to the cassava's extract filmogenic properties,[9] for instance.

Moreover, the outcomes demonstrated that adding sunscreens to the cosmetic formulations has contributed to their sensorial improvement, which was also demonstrated in the objective assessment of spreadability. Therefore, these results are satisfactory, for the presence of sunscreens in cosmetic formulations for daily use is very important for the protection of the skin against solar radiation.[26]

In the second analysis of the sensory characteristics, the *benchmark* concept, already used in a number of scientific studies and methodologies for comparing outcomes, was employed.[27,28] In the present study, this concept was used to compare the multifunctional formulation F3 with a commercially established formulation that was chosen based on the expectations regarding clinical effects to be derived from the developed formulation (gel cream formulation with immediate tightening effect and capable of increasing cell regeneration and photoprotection) as well as the intended target consumers.

Based on the analysis of the results, it was possible to observe that the formulations had similar sensory characteristics: the parameter *sticky* was attributed to the FC formulation (but not to the FA formulation), however the parameters *smooth skin* and *intention to buy* were more pronounced in FC. This indicates that, in general, the formulations had similar performances; nevertheless regarding the decisive factor *intention to buy*, the study formulation outstripped the commercial formulation. Conclusively, the developed formulation showed desirable sensory characteristics, comparable to those of a well-established commercial formulation.

Clinical effectiveness analyzes are of great importance for evaluating the effects of formulations under actual conditions of use, so that they meet the expectations regarding the improvement of both the visible general conditions of the skin and the damage caused to it by the aging process.

In line with this, the TEWL analysis plays a key role in the clinical efficacy evaluation, since the skin's hydration is directly related to the integrity of the skin barrier function and a low level of transepidermal water loss. This implies that it is possible to evaluate, for example, whether certain cosmetic formulations contribute to reducing TEWL using the Tewameter® device.[29]

Based on the analysis of the results, it was possible to observe a decrease trend in the TEWL values. A plausible explanation for this reduction is the fact that both formulations have various components, such as silicones, polysaccharides and emollients that aid in the formation of a hydrophobic film on the skin's surface, preventing the transepidermal loss of water.[30]

The evaluation of the stratum corneum's water content is instrumental in the assessment of the cosmetic formulation's ability to moisturize the skin. For that end, the Corneometer® device was used in the present study to analyze whether the formulation in question would be able to significantly increase the skin's hydration 2 hours after application, compare outcomes with those of the commercial formulation and the baseline.[11]

Based on the analysis of the results, it was possible to verify that there was improvement 2 hours after the application of both formulations. It is important to note that the statistical comparison of the results of the two formulations suggested that the commercial formulation FA provided greater hydration. This increase can be attributed to the fact that FA has a greater number of hydrating ingredients than FC.

In addition, the results were consistent with the sensory evaluation's outcomes, for most patients attributed the rating *hydrated skin* to both FA and FC.

Finally, analyzing the cutaneous microrelief also has great importance in the clinical effectiveness evaluation of cosmetics, since it allows obtaining an indirect measure of hydration through the evaluation of images – turgid cells provide a more uniform and less rough skin surface. Furthermore, the film-forming active principles' effectiveness of both formulations could be tested and compared regarding the formation of a film on the skin, thus decreasing its roughness.[21]

Based on the results, it was verified that the FC formulation was more prone to decrease the skin's roughness, thus indicating that the cassava's polysaccharides were effective in forming a film on the skin, which contributed to improve its microrelief.

These results were in line with the stratum corneum's water content analysis, as well as with the sensory analysis, where it was evidenced that the patients perceived increased softness of the skin 5 minutes after applying the FC formulation. Therefore, the improvement in the skin's microrelief resulting from decreased roughness and the formation of film was more pronounced in FC as compared to FA, especially according to the patients' perception of effectiveness.

The immediate tightening effect attributed to the cassava's polysaccharides confirms the outcomes previously observe by the authors' research group,[31] which had already used the same device to verify the cassava extract's immediate tightening effect in a gel formulation.

In summary, according to the analysis of the obtained results, it was possible to demonstrate the importance of the set of techniques employed in the present study for the development of an effective formulation with good sensory acceptance. Thus, knowledge of the interaction between the formulation and the skin is critical, for the adherence to the treatment and the proven clinical effectiveness of a cosmetic formulation are strongly correlated to the success of a medical prescription.

CONCLUSION

The application and correlation analysis of the techniques employed allowed specifying and obtaining a formulation with proven sensorial acceptance and clinical effectiveness for the improvement of the skin's texture and hydration. In this manner, the present study contributes for the dermatologic field, given that appropriate sensory characteristics helps the patient to adhere to the use of the product, therefore favoring the treatment's success. ●

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