Evaluation of the efficacy of Taurine in Seborrheic Dermatitis: pilot clinical study phase I and II

Érica Savassa Pinto Cacoci[1,2*], Cassiano Carlos Escudeiro[2,3], Celso Martins Junior[1,2], Matheus Henrique Vieira [1,2], Ursulandrea Sanches Abelan[1,2], Chung Man Chin[4,5]

1. School of Pharmaceutical Sciences, University of São Paulo State (UNESP), Brazil

2. Brazilian Academy of Tricology (ABT), Brazil

3. IPclin Laboratory Group, Brazil

4. Department of Drugs and Medicine, University of São Paulo State" (UNESP), Brazil

5. Advanced Research Center in Medicine, School of Medicine, Union of the Colleges of the Great Lakes (UNILAGO), Brazil

*Corresponding author: erica.cacoci@gmail.com

Introduction. Seborrheic dermatitis is a chronic, non-contagious and recurrent condition, in which skin inflammation occurs and appears in the form of erythematous and scaly plaques, located in more oily areas such as the scalp, face, neck and back. Conventional treatment can be carried out with the use of antifungal and anti-inflammatory medications, and in many cases on an ongoing basis. Taurine, which is a sulfur amino acid, has been studied due to its high antioxidant and anti-inflammatory power and in this unprecedented pilot study we investigated the effects of taurine solution on the scalp of patients with seborrheic

dermatitis. **Methods and Results**. A total of 30 patients were selected between September 2022 and February 2023 after approval from the CAAE ethics committee number 57093622.5.0000.5426. Phase I of the pilot study was carried out on ten (10) healthy volunteers to verify the occurrence of adverse effects. In phase II, thirty (30) patients with seborrheic dermatitis on the scalp were divided into two groups of 15 patients each. The first group was treated with the taurine solution and the control group with the solution without taurine, in homecare and subjected to evaluation for 4 consecutive weeks. Patients were evaluated by trichoscopy with polarized and non-polarized light, considering erythema, scaling and pruritus. The results showed that 100% of patients in the group treated with the taurine solution observed an improvement in itching from the first week of use, in addition to an improvement in erythema and scaling in the first weeks of treatment. All participants were satisfied with the results, while the control group had no significant improvement after the end of the treatment period. The study also demonstrated that there was no relationship between Phototype and seborrheic dermatitis in these patients. **Conclusion**. the results of the pilot study allow us to conclude that taurine reduces the signs of erythema, scaling and itching on the scalp of patients with seborrheic dermatitis, without adverse effects. The study provides opportunities for its continuation in more robust clinical trials.

Keywords: Seborrheic Dermatitis; taurine; scalp, skin inflammation.

Introduction

The scalp is an extension of the skin with a high number of hair follicles (around 100,000-150,000 in normal conditions), sebaceous glands and the arrector pili muscle (ABELAN, et al., 2021; RESTREPO, 2010). Scalp's microbiota located on the horny layer has several important functions that help maintaining its health, such as immunity increase, improvement of skin barrier function, pathogens proliferation regulation, among others. An imbalance in scalp microbiota may lead to alterations and dysfunctions in this area, possibly causing pathologies (MORGADO; SOARES, 2021). Among the factors that can interfere with natural microbiota we can mention environmental changes, geographic location, diet, use of medications and cosmetics and increased sebum production (ABELAN et al., 2021).

Regardless on cause, excess scalp sebum creates the ideal environment for microorganisms' proliferation, including *Malassezia* spp. – a resident fungi species whose excessive presence may result in itching, flaking, inflammation, reduced peripheral blood circulation and hair loss. This is the reason why it is important to control sebum and balance microbiota (ABELAN et al., 2021).

Seborrheic Dermatitis (SD) is a chronical, recurrent, and highly incident (5% world prevalence) inflammatory disease that causes signs and symptoms like seborrhea, pruritus, erythema and dysbiosis affecting many regions abundant in sebaceous glands including the scalp, face and chest (SAMPAIO *et al.*, 2011; RAMOS; SILVA *et al*., 2014; TUCKER; MASOOD, 2023; PEYRI; LLONART, 2007). Its precise physiopathology remains unclear, but current theories highlight the importance of microbiota, mainly *Malassezia* spp. (SAMPAIO *et al.*, 2011; ADALSTEINSSON, *et al.*, 2020; TAO, *et al.,* 2021).

The diagnosis of SD is mainly clinical and based on the typical clinical morphology of desquamation and erythema on sebum rich areas. If required, the diagnoses can be supported by trichoscopy, which shows atypical red vessels, arborized vessels, and red areas (KIBAR *et al*., 2015). If still uncertain, biopsy may be needed (CLARK *et al*., 2015).

Trichoscopy (or dermatoscopy) is a clinically important non-invasive technique to amplify scalp allowing to observe morphological characteristics invisible to naked eye (GOLYNSKA *et al*., 2022). It allows to differentiate desquamation caused by SD compared to psoriasis, tinea capitis, etc. based on specific characteristics (LACARRUBBA *et al*., 2015). In polarized light we can observe color, vascular pattern, pigmentary net, and skin atrophy. In non-polarized light we observe skin relief, oiliness, presence or absence of follicular ostia and desquamation.

SD treatment normally aims to eliminate clinical signs, improve associated symptoms (itching and desquamation) and avoid remission using long term therapies with topical antifungals and anti-inflammatories, as well as other therapies (BORDA *et al*., 2019; BERK; SCHEINFIELD, 2010; CASALS *et al*. 2019). Shampoos with different active ingredients such as zinc pyrithione, ketoconazole, selenium sulfide, tar, salicylic acid have also been successfully used (SCHWARTZ *et al.* 2013). Also, alternatives for SD treatment are welcome, to complement or reduce the use of conventional active ingredients that have some unwanted effects, or that are not well accepted because they leave hair with a sticky or hardened appearance. In this research work we suggest taurine as an alternative for SD.

Taurine, a sulfur amino acid, has been studied for its highly antioxidant and anti-inflammatory effects (WU, 1992; KIM et al., 2021). However, few studies have

compared the effects of taurine on inflammatory skin diseases. Therefore, this unprecedented study aimed to investigate the efficacy of topically applied taurine solution on scalp on patients with SD by perceived effectiveness and trichoscopy.

Materials and Methods

Formulation preparation:

Fragrance-free formulations with and without 1% taurine (treated and control group respectively) were prepared as aqueous solutions composed of: aqua as vehicle, 0.15% disodium EDTA, 2% glycerin, 1% PEG-40 hydrogenated castor oil, and 0.5% phenoxyethanol. The final pH was set with citric acid to 4.5 – 5.0. Stability was determined according to ANVISA guideline for 90 days (ANVISA, 2004).

Ethics:

Study was previously submitted to ethical assessment by UNESP Ethics Committee and was approved under the opinion number 5.830.072. All subjects had given their informed consent before participating in the safety and efficacy research.

Study site:

Study was conducted at Renov Clínica Capilar, located in Rua do Comércio, 291 – Tietê, Brazil.

Safety assessment:

10 healthy participants from both genders aged between 25 and 65 years were included in the safety assessment trial to verify the absence of adverse effects

with taurine solution usage before efficacy study was carried out. Exclusion criteria were ongoing inflammatory process, chronic or acute hair diseases, pregnant or lactating women. Patients were instructed to use product as follows: application of 20 drops (approximately 1 mL) once daily at night on scalp, distributed evenly through a light massage. The first application was performed at the study center by the Investigator for orientation purposes.

Study was accompanied by a Dermatologist to verify the appearance of clinical signs and report of discomfort sensations by the participants along use for 28 days (ANVISA, 2012; CIPRIANI & THIBES, 2009). Safety questionnaire to assess adverse effects was applied to participants on D28 with questions described on **Table I**.

Table I. Safety questionnaire applied to the participants (CIPRIANI & THIBES, 2009).

Question	Possible answers
Have you felt any discomfort?	No / Yes - describe
After how many days have the symptoms begin?	Describe if applicable
Have you followed instructions of use correctly?	Yes / No
Was product suspended right after problem perception?	Yes / No
Have you ever had any problem or allergic reaction to any similar product?	Yes / No
Do you use any products together?	Yes / No

Efficacy assessment:

Clinical randomized placebo-controlled double-blind trial was conducted to assess the effectiveness of 1% taurine aqueous solution compared to control in patients diagnosed with SD.

30 patients with diagnosed SD on scalp aged between 25 and 65 years from both genders were included in the trial. Exclusion criteria were patients unable to understand the method used, pregnant and lactating women, neurological, psychiatric, and photosensitizing diseases, collagenosis, patients using photosensitizing or immunosuppressive medications or with clinical suspicion of skin cancer.

The 30 participants were then randomly divided into two groups of 15 after anamnesis on the first day of the study. Group 1 was treated with taurine solution (taurine group), and group 2 was treated with the control solution without taurine (control group). Products were topically applied on scalp for 28 consecutive days as homecare therapy. Patients were instructed to use product as follows: application of 20 drops (approximately 1 mL) once daily at night on scalp, distributed evenly through a light massage. The first application was performed at the study center by the Investigator for orientation purposes.

Trichoscopy assessments were performed at frontal, vertex, occipital, right parietal and left parietal regions by capturing optical trichoscopy images (Model AM4113T, Dinolite®) with polarized and non-polarized lights at visits D0 and D28 (respectively first and 28th day of the study). Images were compared per time and treatment to verify erythema and desquamation.

Perceived effectiveness was assessed by the application of a questionnaire based on the work of Faneli and co-workers (2019). The questionnaire applied to the participants is described in **Table II**. The qualitative variables were presented by frequency analysis.

Table II. Perceived effectiveness questionnaire applied to the participants.

Question	Possible answers
Would you recommend the treatment to a friend or relative?	Yes / No
Have you noticed improvement in erythema (redness)?	Yes / No
Have you noticed improvement in itching?	Yes / No
Were you satisfied with the treatment?	Yes / No
Phototype classification according with Fitzpatrick	I to VI*
Would you continue the treatment?	Yes / No

*Legend:

I: white skin, always burns, never tans, very sensitive to the sun.

II: white skin, always burns, tans slightly, sensitive to the sun.

III: light brown skin, burns moderately, tans moderately, normal sun sensitivity.

IV: moderately brown skin, burns slightly, always tans, normal sun sensitivity.

V: dark brown skin, rarely burns, always tans, little sun sensitivity.

VI: black skin, never burns, totally pigmented, insensitive to sun.

Results and Discussion

Hair topical aqueous solutions were developed with 1% taurine based on previous studies. Anderheggen and co-workers (2006) proved cutaneous anti-inflammatory and lipid synthesis results with this concentration of taurine, Degim and co-workers (2002) proved its would healing efficacy, and Kyriakopoulos and co-workers (2022) its psoriasis healing effect. In this research we focused on SD. The obtained preparation proved to be easy to apply on scalp and did not leave oily aspect on hair. It remained stable in all conditions during the stability assay except for indirect sunlight exposure, thus showing a requirement for opaque packaging to condition test product for the following assays.

The developed formulation proved to be safe for topical human use on scalp during safety test, as none of the 10 healthy participants assessed reported having felt any discomfort sensations nor presented any clinical signs on the test regions after 28 consecutive days of use. All participants answered the applied questionnaire denying any discomfort sensations and symptoms, affirming to have followed usage instructions properly, denying having had problems with similar products as well as denying having used other products together with the investigational one.

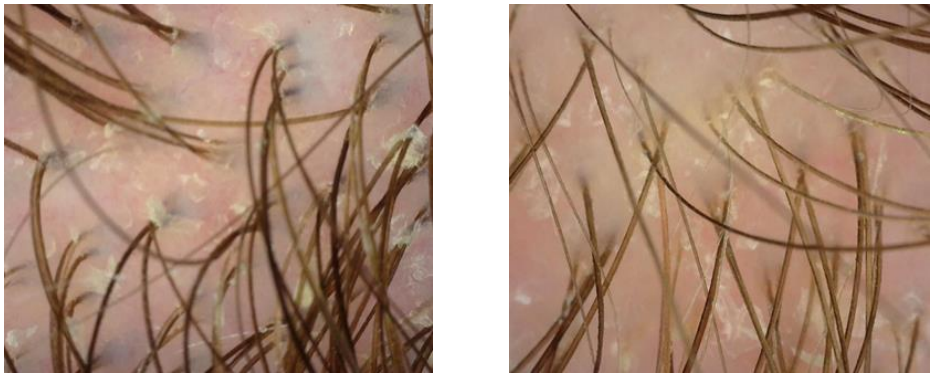
For efficacy assessment, patients were randomized into groups, and randomization allowed an equally divided distribution among groups concerning age and gender variation. Both groups had the same number of male and female participants, avoiding possible bias related to gender differences in treatment response.

As to skin phototype classification and distribution, patients from both groups belonged to phototypes II to IV, with the majority being II and III. Kirsten and co-workers (2021) had proven that SD incidence is significantly higher on phototype IV skin compared to phototype III after assessing 48,630 participants, what differed from the incidence in our assessed groups. Our prevalence was III>II>IV for both groups. However, our ‘n’ value was small and insufficient for a phototype SD prevalence frequency analysis. No patients with skin phototype I, V and VI were included in the research.

Patients’ trichoscopy images were visually compared between experimental times (D0 and D28) for each treatment to verify improvement regarding aspect of erythema and desquamation. The images from patients with same SD degrees of intensity were similar between groups on D0 (before treatment), and a significant difference was noticed between groups after 28 days treatment, as exemplified in **Figures 1 to 3**. While patients from control group did not present apparent reduction in erythema and desquamation along treatment, patients from taurine group improved those conditions thoroughly for different SD degrees of severity, being effective even on more severe cases (**Figure 3**).

Control Group

Before (D0) After (D28)



Taurine Grupo

Before (D0) After (D28)

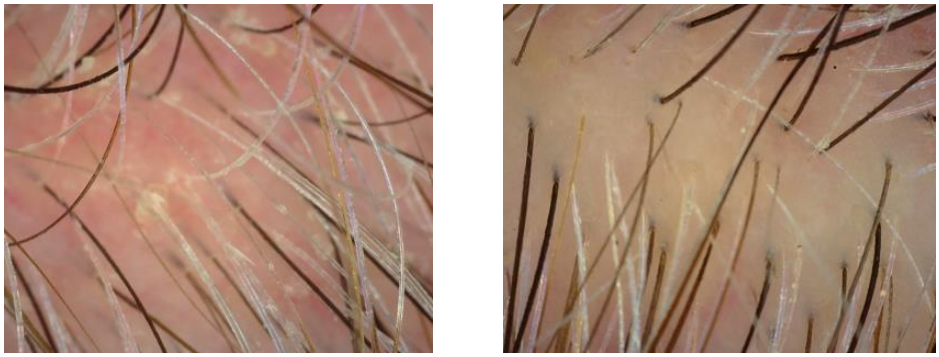
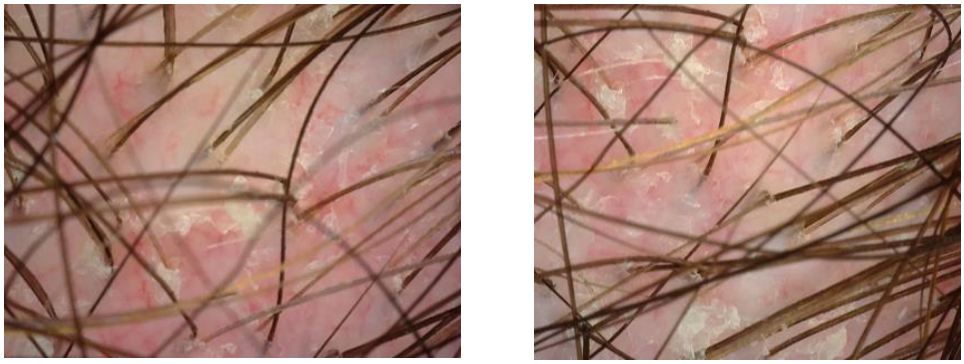


Figure 1. Trichoscopy images of patients before and after treatment (taurine versus control) – lower degree SD

Control Group

Before (D0) After (D28)



Taurine Grupo

Before (D0) After (D28)

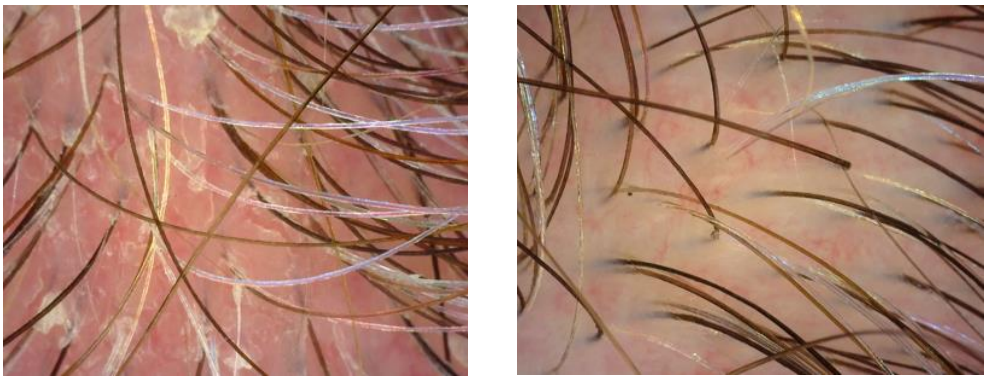


Figure 2. Trichoscopy images of patients before and after treatment (taurine versus control) – intermediate degree SD

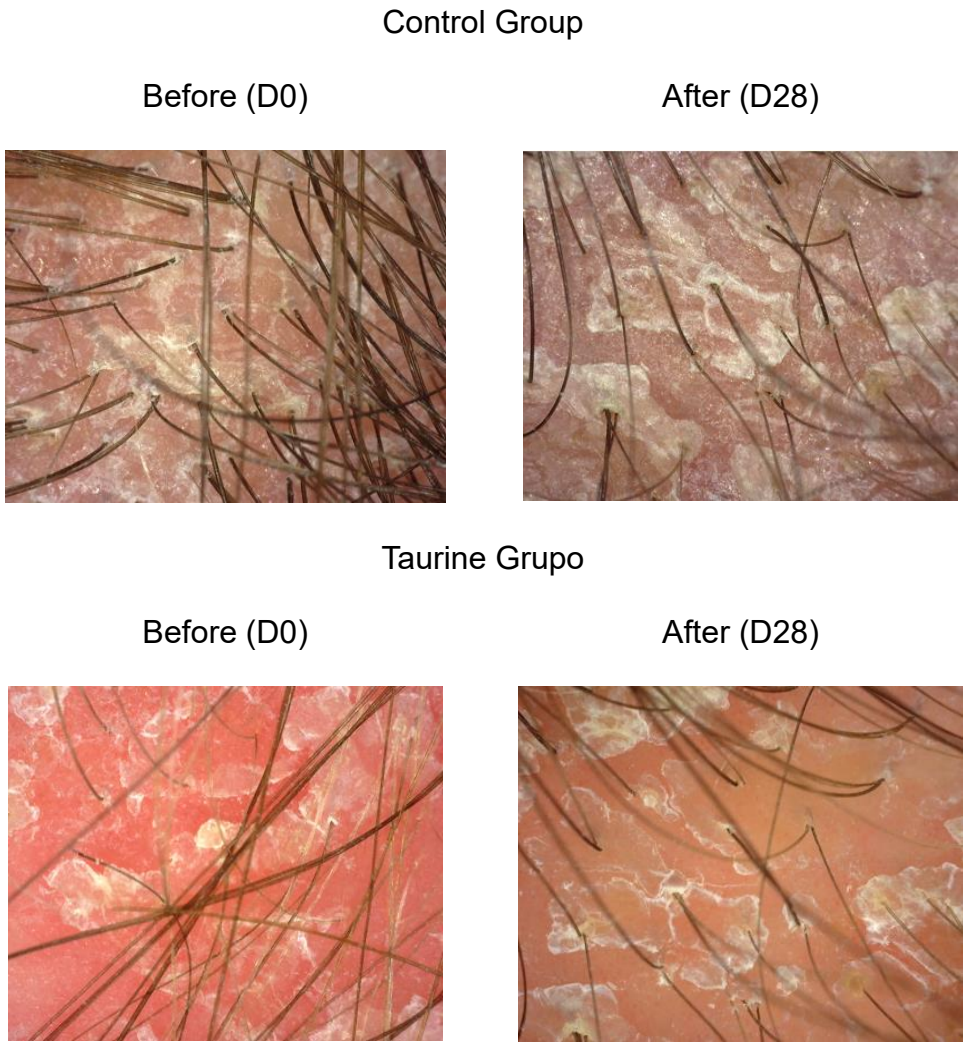


Figure 3. Trichoscopy images of patients before and after treatment (taurine versus control) – higher degree SD

Perceived effectiveness assessment questionnaires comparing treatment groups also revealed differences in treatment performance perception among patients, with significantly higher satisfaction levels obtained for taurine group for most assessed attributes. All patients (100%) submitted to taurine treatment gave positive responses to all assessed parameters. The only parameter with no difference between group was the intention to continue with the treatment, to

which 100% from both groups would agree to continue. The detailed results per group for each assessed attribute are described in **Table III**.

The results of the satisfaction survey highlight the favorable perceptions of participants in the taurine group regarding the treatment recommendation, reporting a significant improvement in symptoms and higher levels of satisfaction. This analysis provides important insights into participants' experience and feedback regarding the effects of the proposed treatment.

Table III. Perceived effectiveness assessment results – patients' satisfaction levels per treatment group on D28.

	Taurine Group		Control Group		General		
Attribute	n=15	%	n=15	%	n=30	%	p-value
Would you recommend the treatment							*0.0063**
Yes	15	100	8	53.3	23	76.7	
No	0	0.0	7	46.7	7	23.3	
Have you noticed improvement in erythema (redness)							*0.0001**
Yes	15	100	4	26.7	19	63.3	
No	0	0.0	11	73.3	11	36.7	
Have you noticed improvement in itching?							*0.0001**
Yes	15	100	4	26.7	19	63.3	
No	0	0.0	11	73.3	11	36.7	
Were you satisfied with the treatment?							*0.0001**
Yes	15	100	4	26.7	19	63.3	
No	0	0.0	11	73.3	11	36.7	
Would you continue the treatment?							0.9999
Yes	15	100	15	100	30	100	
No	0	0.0	0	0.0	0	0.0	

Taurine is a sulfur amino acid present in high concentrations in organs such as the liver, heart, kidneys, and brain, in skeletal muscle and blood cells, with important physiological functions (PARK et al., 2014, BKAILY et al., 2020). It is one of the main osmolytes on skin and is highly concentrated in the keratinocytes of the epidermal stratum granulosum and spinosum (LOBO et al., 2001, COLLIN

et al., 2006). Besides regulating cell volume, it stabilizes the cell membrane (ARAKAWA; TIMASHE, 1985), stabilizes proteins (PASANTES-MORALES et al., 1985), protects against apoptosis induced by UV radiation (JANEKE et al., 2003), regulates the balance of electrolytes and minerals in cells, and supports the immune system by having antioxidant and anti-inflammatory functions (KIM et al., 2021). On skin, taurine stimulates lipid synthesis in the stratum corneum, prevents surfactant-induced transepidermal water loss (ANDERHEGGEN et al., 2006) and acts as an osmoregulator in human keratinocytes (WARSKULAT et al., 2004).

Very few studies involve the assessment of taurine effects on skin, and neither literature was found concerning application of taurine on scalp, nor its efficacy on SD. Hence the importance of this research work. Despite scarce literature, we could verify the potential of taurine for hair therapy applications.

Regarding applications on skin, studies demonstrated that taurine prevented dry skin after induction with surfactants by modulating the pro-inflammatory response and stimulating epidermal lipid synthesis (ANDERHEGGEN et al., 2006); improved wound healing in mice after 7-day applications (DEGIM et al., 2002); reduced cutaneous irritation by the production reduction in pro-inflammatory cytokines after topical applications in vitro and in vivo (SEO *et al.*, 2018); and inhibited the cytotoxic and pro-inflammatory effects induced by sodium dodecyl sulfate, including a decrease in the release of interleukin-1 alpha and prostaglandin E2, stabilization of keratinocyte membrane integrity and improvement of keratinocyte viability, which may partly explain its anti-inflammatory power on the skin (ANDERHEGGEN et al., 2006).

These findings about taurine efficacy on skin corroborate our findings, as the inflammatory symptoms of SD as erythema assessed in this study decreased considerably along treatment. Still, further research should be conducted with a larger number of patients to better understand therapeutic possibilities and mechanisms of action on inflammatory scalp pathologies.

Conclusion

After assessing the obtained results, the aqueous solution with 1% taurine was considered safe and did not cause adverse effects on the assessed participants. When compared to control group, trichoscopy images have shown that taurine was effective to significantly reduce erythema and desquamation on SD patients after 28 days' treatment with 1mL daily dose when compared to control group. These results proved taurine to be an alternative treatment for SD management for cosmetology, dermatology, trichology, and hair therapy fields.

Acknowledgments

The authors acknowledge Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – Brazil (CAPES) for funding this research (finance code 001). We also thank IPclin Group for partially assisting in the conduction of clinical trials in this research.

Conflict of Interest Statement

The authors declare no conflict of interest.

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