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Skin health promoting effects of a proprietary nutraceutical ingredient (SesZen-BioTM): a placebo controlled, double-blind, and randomized clinical study

Ratna Upadhyay*, Mihir C. Gadani, Sneha Badak

Department of Phytochemistry, Zenherbs Lab Pvt Ltd, Mumbai, Maharashtra, India

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*Correspondence: Dr. Ratna Upadhyay,

E-mail: ratna.upadhyay@fitcircle.in

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ABSTRACT

Background: This study evaluated the skin health benefits of SesZen-BioTM, a 0.5% natural biotin supplement derived from *Sesbania grandiflora*, previously linked to hair growth, in healthy adults aged 30-55 with mild skin ageing. **Methods:** In a single-center, double-blind, placebo-controlled trial, participants between ages 30-55 years with mild skin ageing received either SesZen-BioTM or a placebo, with assessments conducted on days 0, 28, and 56. Parameters measured included facial wrinkles, fine lines, skin elasticity, hydration, skin barrier function and overall skin health. **Results:** Significant reduction (p<0.01) in crow's feet area by 27.11% (day 28) and 48.14% (day 56) and 17.95% and 51.17% reduction in fines lines were observed in the treatment group as compared to 12.1% reduction for placebo group at day 56. Physician global assessment (PGA) scores showed improvement in skin condition by 14.07% (day 28) and 20.58% (day 56) for SesZen-BioTM treatment group. The facial skin tone assessment described by individual typology angle (ITA) showed lighter skin tone by 30.55% (day 28) and 58.23% (day 56) (p<0.01). Treatment group showed decrease in retraction time for skin elasticity on day 56, decreased skin roughness and increased skin hydration. Both groups showed decreased transepidermal water loss (TEWL) on both visits (days 28 and 56) as compared to baselines (p<0.01). The placebo group showed no improvement in PGA score, skin tone lightness (L*) and ITA score, skin hydration, or skin elasticity.

Conclusions: SesZen-BioTM appears to effectively promote skin health, reducing fine lines and improving skin tone, elasticity, and hydration, suggesting a viable strategy for combating skin aging and enhancing overall skin appearance.

Keywords: Claim substantiation, Skin barrier, Nutraceuticals, Moisturization, Skin health

INTRODUCTION

The physiology of skin is affected by internal factors such as age, genetic, and hormonal changes alongside external factors including ultraviolet (UV) rays, smoking, dietary changes, and pollution. The internal factors cause ageing due to formation of reactive oxygen species, declined metabolic function, reduced proliferation of basal layers of the skin leading to thinning and dryness. External factors have varied effects on the skin, for instance, UV rays cause overproduction of matrix metalloproteinases, reactive

oxygen species (ROS), thickening of stratum corneum leading to skin roughness, loss of elasticity, and appearance of wrinkles.¹

Beauty comes from within. There exists a strong connection between well-regulated lifestyle which involves caloric restriction, exercise, and stress reduction and deterioration of ROS in the body.² The ROS species have constructive as well as destructive roles in our body. The body needs to maintain a strong balance between ROS species and cell's intrinsic and dietary antioxidant levels. Pro-oxidants or ROS has major roles in inflammatory

response, cognitive response, fertility, and among others. However, inequality between ROS production and inability of cell to detox them causes oxidative stress that has severe effect on skin.³

Most people consume a healthy diet and obtain adequate nutrients that maintain the health of the skin throughout their lives. However, in absence of such nutrients the skin's appearance is affected and can be reversed by making alterations to dietary habits in case of the absence of underlying diseases.⁴ Nutraceuticals are dietary components perceived as food that can have medical and health benefits.⁵ Of the many options available natural phytocompounds including polyphenols, vitamins, dietary peptides, polysaccharides, polyunsaturated fatty acids, and antioxidants, can have significant effect on skin health.⁶ Thus, combined effect of new-age cosmetics with substantiated claims and mechanism of action with food supplements can help one achieve total wellness one might desire.⁷

Sesbania grandiflora, an underutilized legume, is now being explored for its nutritional, phytochemical, and health benefits. Although, ayurvedic texts of India mentions the use of legumes of *S. sesban*. Also, there are several phytochemicals such as fatty acids, saponins, galactomannan, and saponins, reported to be present in *Sesbania* seeds. The barks and leaves of *S. grandiflora* are reported for anti-inflammatory, anti-microbial, anti-diabetics, and anticancer activities. However, a detailed study redefining its importance as a nutraceutical active is lacking.

In the current study, a standardized extract of S. grandiflora with 0.5% of biotin content, was evaluated for its skin health promoting ability as a nutraceutical product in healthy adult human volunteers. Our previous study highlights the hair-growth promoting efficiency in human volunteers of this extract, SesZen-BioTM which showed improved hair density and hair thickness and increased serum ferritin content. Mechanistically the improvement in hair health was attributed to the rich biotin content. Biotin is reported in the past for its ability to boost skin and hair health. Several reports exist on improved hair health due decrease in hair loss and shedding upon biotin supplementation. Another underlying mechanism of SesZen-BioTM could be by increasing ferritin content in the blood. In the same study, females with alopecias exhibited lower ferritin levels as compared to healthy adults. Thus, improvement in ferritin levels may have positive effects on hair health.9

The product SesZeb-BioTM was tested for its skin-health promoting activity including anti-ageing benefits in tandem. The health of the skin can be detected by monitoring skin firmness, skin roughness, pigmentation, loss of elasticity, and wrinkling.⁴ Hence in the current study, 51 subjects were divided into two groups viz., placebo and test group. Both groups received one capsule in the night and one in the morning of either placebo or

SesZen-BioTM. The skin health refinement effects of SesZen-BioTM were monitored for eight weeks for population with skin showing mild ageing appearance (Glogau skin age II and III). The aim of the study was to evaluate use of nutraceutical product of *Sesbania grandiflora* to reduce fine lines, wrinkles, and skin roughness as its primary objective. Skin tone evenness, transepidermal water loss (TEWL), skin hydration, skin elasticity, physician global assessment (PGA) scoring, Glogau skin age, an improvement in skin parameter were monitored under secondary evaluation objectives.

METHODS

All the subjects included in the study were fully aware of the procedures, signed an informed consent. The study protocol and informed consent document (ICD) were approved by ACEAS Independent Ethics Committee on 24 September 2022 before initiation of the study with ICMR ethical guidelines, and applicable federal government codes ICH-GCP, New drugs, and clinical trials rules, 2019 and Declaration of Helsinki.

Subjects and study design

This was a randomized, placebo-controlled, double-blind, two-arm, single-centre, proof-of-concept safety, and efficacy clinical study. A total of 54 subjects enrolled in the study from ages between 30-55 years and 51 subjects completed the study (07 males and 44 females). This clinical trial was registered with Clinical Trial Registry of India (CTRI) under the number CTRI/2022/10/046324 on 10/10/2022. The inclusion criteria for the study in mentioned in Table 1. Each subject was randomised to participate in the trial in either the control/placebo group (N=26) or test/SesZen-BioTM group (N=25). Both the groups took one capsule in the day and one capsule in the night for 56 days/8 weeks.

Product composition

Each test capsule contained 250 mg of 0.5% biotin standardized *Sesbania grandiflora* leaf extract, SesZen-BioTM capsules and placebo group received a control capsule made up of Tapioca based starch. Both the products were of Zywie Ventures Private Limited (Zenherb Labs Private Limited, India).

Primary efficacy evaluations

The product was tested for its ability to reduce facial wrinkles and fine lines. The crow's feet area and fine lines were monitored using Visioscan® VC 20 Plus from the baseline on day 01 before test treatment, week 4 (day 28) and week 8 (day 56) for both the groups.

Secondary efficacy evaluation

Three measurements similar to primary efficacy evaluation were taken for every parameter on day 0

(baseline), day 28, and day 56. The test subjects were evaluated for skin dryness, fine wrinkles/line, coarse wrinkling/lines, laxity, roughness, and sallowness after 8 weeks from baseline by a dermatologist or dermatologist-trained evaluator with respect to PGA scoring using Griffiths scale. The effect of SesZen-BioTM on the test subjects receiving it versus placebo was monitored by assessing their Glogau skin age by a dermatologist or dermatologist-trained evaluator. Both the groups were

tested for change in skin colour i.e. L* a* b* and ITA angle using skin-colorimeter CL 400 and effect of test product on skin versus placebo was evaluated. Assessment of the effect of test treatment on skin elasticity using DermaLab®Combo was performed. Effect on skin moisturization due to the test product was monitored using the instrument MoistureMeterEPiD. The transepidermal water loss was measured with Vapometer. Noticeable improvement using facial photographs were monitored.

Table 1: Inclusion criteria for the clinical study.

S. no.	Inclusion criteria
1	Fitzpatrick skin type III to VI, mild skin ageing, Glogau skin age II and III
2	Follow routine skincare and avoid using any new skin care products
3	Would agree to not undergo cosmetic procedure before 3 months and during the course of the study
4	Not use any new skin, hair, and home care products (laundry detergents)
5	Women not pregnant, not breastfeeding, and ensured no pregnancy during the duration of study
6	Signed informed consent and ensure will adhere to study procedures
7	Did not have thyroid problems, anaemia, or active dermatological conditions
8	Ensured were not on retinoid or steroids supplements 4 weeks prior to the start
9	Ensured were not on antibiotic treatment
10	Had no addictions or chronic illness
11	Were not on or not had any plans on starting on weight loss programs
12	Or any reason of being excluded from the study at dermatologist's discretion
13	Have not participated in other similar cosmetics, devices or therapeutic trials within the last four weeks

Safety evaluations

Dermatologist evaluated the safety of the product by monitoring adverse events such as unbearable irritation, tingling, skin redness and dryness, and burning sensation.

Statistical analysis

All the data points were recorded as mean±SD. Student's T-test was applied to test statistical difference between baseline and products. One-way analysis of variance (ANOVA) and post hoc analysis was conducted to measure the difference between samples and time points. A p value below 0.05 was considered to be statistically significant.

RESULTS

Demographic data

A total number of 51 volunteers completed the trial. The demographic data of the volunteers is mentioned in Table 2

Primary evaluations

There was a statistically significant reduction observed in the crow feet area wrinkles by 27.11% at day 28 and 48.14% at day 56 with p value <0.01 in subjects who received SesZen-BioTM as their treatment as compared to no significant difference observed in subjects who

received placebo (Figure 1). The fine lines were reduced by 17.95% and 51.17% at day 28 and day 56 and the difference was statistically significant with p value <0.01, the placebo group showed on 12.1% reduction in fine lines at day 56 (Figure 2). As per one-way ANOVA, there was a statistically significant difference between the treatment group and placebo on day 56 indicating the effective of SesZen-BioTM in the reduction of fine lines and wrinkles (Table 3). There was a statistically significant decrease in roughness of the skin in subjects by 356.48 and 902.85 at day 28 and day 56 who received test treatment as compared to no statistically significant change in roughness of skin in subjects who received placebo (Figure 3).

Table 2: Demographics of the total population (n=51) who participated in the clinical trial.

Particulars	Data (%)
No of male volunteers	7
No of female volunteers	44
Average age in years (SD)	39.4 (5.80)
Average weight in kg (SD)	62.4 (13.9)
Average height in cm (SD)	159 (6.90)
No of volunteers with combination skin	10 (19.6)
No of volunteers with dry skin	18 (35.3)
No of volunteers with normal skin	11 (21.6)
No of volunteers with oily skin	11 (21.6)
No of volunteers with sensitive skin	1 (2.0)

Table 3: Skin parametric evaluation for SesZen-Bio[™] and placebo for 28 days and 56 days.

Skin	SesZen-Bio TM							Placebo							Λ				
param-	T28			T56			T28			T56			One-way ANOVA						
etric tests	Mean	SD	Mean	SD	P1	P2	Mean	SD	Mean	SD	P3	P4	P5	P6	P7	P8	P9	P10	
Crow's feet	-27.11	18.49	-48.14	16.04	< 0.01	< 0.01	3.59	31.71	-11.21	29.1	0.623	0.129	0.0250	0.8809	0.0000	0.0000	0.0000	0.98 28	
Fine lines	-17.95	11.64	-51.17	10.55	< 0.01	< 0.01	-1.55	18.01	-12.1	20.91	0.315	0.0134	0.0000	0.9935	0.0350	0.0000	0.0000	0.06 79	
Rough- ness	356.48	524.17	902.85	1891.85	< 0.01	< 0.01	103.18	213.41	154.16	349.89	0.324	0.0953	0.2317	0.8129	0.8943	0.0316	0.0501	0.99 79	
PGA	-14.07	9.92	-20.58	10.97	< 0.01	< 0.01	-3.34	6.38	-4.11	9	0.0355	0.0244	0.9995	0.2023	0.0276	0.1635	0.0203	0.82 46	
L*	1.32	1.34	1.36	7.62	< 0.01	< 0.01	-0.39	1.62	0.21	1.72	0.259	0.585	0.9999	0.4516	0.7688	0.4345	0.7525	0.95 49	
A*	0.21	7.71	-4.05	22.5	0.841	0.6	2.27	7.62	4.45	8.72	0.179	0.0254	0.6730	0.9472	0.6755	0.3425	0.1167	0.93 85	
B*	-4.23	5.99	0.01	11.18	<0.01	0.525	-3.33	4.98	0.04	10.59	< 0.01	0.431	0.3216	0.9835	0.3166	0.5324	0.0000	0.52 63	
ITA	30.55	38.4	58.23	62.04	< 0.01	< 0.01	1.73	41.08	9.76	32.9	0.345	0.635	0.1408	0.1166	0.3695	0.0015	0.0015	0.92 29	
Retraction	-7.69	27.91	-13.98	23.71	0.104	< 0.01	21.48	24.39	10.33	39.61	<0.01	0.703	0.8792	0.0047	0.1324	0.0003	0.0256	0.55 50	
Young's Modulus	2.68	21.39	-2.76	17.98	0.948	0.321	-4.94	20.97	-8.33	18.01	0.0876	0.0109	0.7636	0.5231	0.2046	0.9795	0.7499	0.92 92	
Viscoelas- ticity	18.44	42.8	19.03	44.01	0.322	0.219	-18.76	20.23	-11.15	27.23	<0.01	0.0222	0.9999	0.0018	0.0194	0.0015	0.0164	0.87 07	
Moisture- Meter	3.84	6.43	6.79	10.08	< 0.01	< 0.01	2.29	5.75	2.41	9.14	0.0652	0.199	0.5761	0.9073	0.9264	0.2125	0.2350	0.99 99	
Vapometer	-13.77	12.13	-26.49	16.94	< 0.01	<0.01	-14.59	16.87	-20.57	15.25	<0.01	<0.01	0.0238	0.9772	0.4127	0.0391	0.5350	0.52 32	

Student's t-test: P1 –between baseline and 28 days for SesZen-BioTM, P2 –between baseline and 56 days for SesZen-BioTM, P3 –between baseline and 28 days for placebo, P4 –between baseline and 56 days for SesZen-BioTM one-way ANOVA: P5 –T28 and T56 for SesZen-BioTM, P6 –T28 for SesZen-BioTM and placebo, P7 – T28 for SesZen-BioTM and T56 placebo, P8 – T56 for SesZen-BioTM and T56 for placebo, P9 – T28 for plac

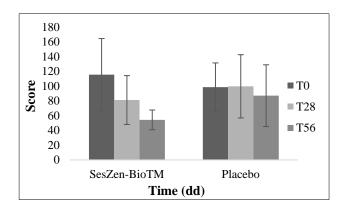


Figure 1: Crow's feet wrinkle score for SesZen-BioTM and placebo on day 0, 28, and 56. Decrease in score indicates reduction in wrinkles.

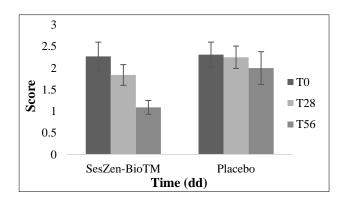


Figure 2: Fine lines score for SesZen-BioTM and placebo on day 0, 28, and 56. Decrease in score indicates reduction in fine lines.

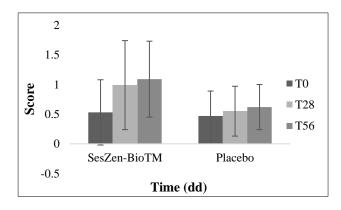


Figure 3: SeR score for SesZen-BioTM and placebo on day 0, 28, and 56. Increase in SeR score indicates increase in skin smoothness.

Secondary efficacy evaluations

The PGA score for wrinkles, lentigines, elastosis, skin roughness, pore size, telangiectasia, sallowness and skin laxity as assessed by dermatologist trained evaluator was improved by 14.07% and 20.58% at day 28 and day 56 respectively in subjects who received SesZen-BioTM as compared to less change of PGA score in subjects who received placebo (p<0.01) (Figure 4). But for both these

groups the change was statistically significant from the baseline. However, on week 8, there was a statistically significant difference observed between the PGA scores for treatment and placebo indicating the effectiveness of SesZen-BioTM (p=0.0203, one-way ANOVA) (Table 3).

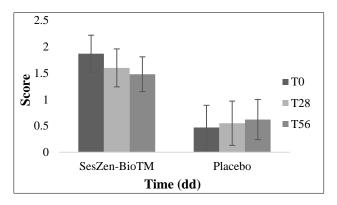


Figure 4: PGA score for SesZen-BioTM and placebo on day 0, 28, and 56. Decrease in PGA score indicates improved skin parameters.

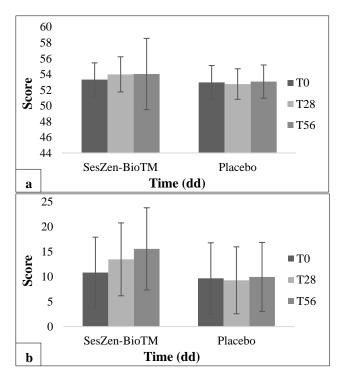


Figure 5: (a) L* and (b) ITA score for SesZen-BioTM and placebo on day 0, 28, and 56. Increase in L* and ITA scores indicate lighter skin tone.

There was no change observed in the Glogau skin type in subjects who received SesZen-Bio TM or placebo. Both the groups were tested for change in skin colour i.e. L* a* b* and ITA angle using skin-colorimeter CL 400 and effect of test product on skin versus placebo was evaluated. Facial skin tone was described by L* using Colorimeter CL-400. Results showed that the skin tone became significantly lighter with p value <0.01 in subjects who received SesZen-Bio TM as compared to no significant

difference observed in the subjects who received placebo. No significant difference was observed in a* and b* values in both the arms (Figure 5a).

Facial skin tone was described by ITA using colorimeter CL-400. Results showed that the skin tone became significantly lighter with 30.55% and 58.23% at day 28 and day 56 with p value <0.01 in subjects who received SesZen-BioTM as compared to no significant difference observed in the subjects who received placebo (Figure 5b). There was a statistically significant difference observed between treatment and placebo groups (p<0.01, one-way ANOVA) on 8th weeks proving the positive effects of SesZen-BioTM on the skin tone of the volunteers in 8 weeks.

There was a decrease in retraction time from baseline with p<0.01 observed at day 56 of test treatment usage as compared to no reduction in retraction time observed in subjects who received placebo as the treatment. On the contrary, in 4 weeks, the retraction time increase for subjects receiving placebo (p<0.01), thus making SesZen-BioTM treatment even more effective for maintaining elasticity of skin (Figure 6a). The was marked decrease in retraction time seen for volunteers receiving SesZen-BioTM by the end of 8 weeks and was statistically significant as compared to the placebo (Table 3).

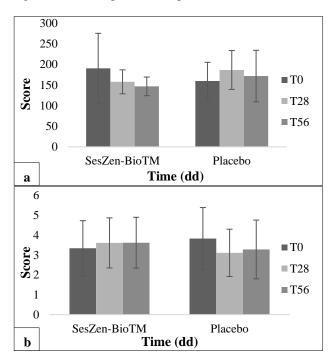


Figure 6: (a) Retraction time score, and (b) visco elasticity measurement for SesZen-BioTM and placebo on day 0, 28, and 56. Decrease in the retraction time and an increase in the viscoelasticity score indicates increase improved skin elasticity.

There was no statistically significant decrease observed in the Youngs modulus values in both the arms. The viscoelasticity parameter was measured for both the arms. In the placebo, as compared to the baseline there was a statistically significant difference in viscoelasticity in the 4th week and increased at the 8th week but remained below the baseline indicating no positive effect on viscoelasticity (Figure 6b). The SesZen-BioTM showed increase in the elasticity in both the weeks, although not significant. The one-way ANOVA statistics indicated a statistically significant difference between treatment and placebo confirming positive effect of SesZen-BioTM on skin elasticity (Table 3).

Additionally, there was an improvement in skin hydration as measured with Moisturemeter EpiD with p value <0.01 observed in subjects who received the SesZen-BioTM (Figure 7a). The authors anticipate that the test treatment was effective in increasing the skin hydration which in turn showed an improvement in viscoelasticity. As per the Figure 7b subjects who received SesZen-BioTM as the treatment showed a statistically significant decrease in TEWL. Vapometer measurements shows highly statistically significant change with p value <0.01 and on visit 02 (day 28) and visit 03 (day 56) and placebo showed improved TEWL as well.

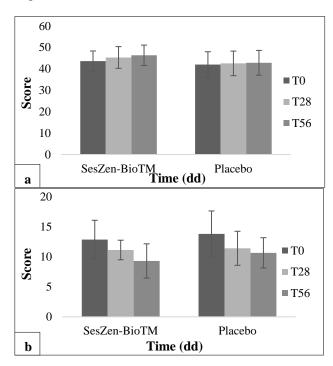


Figure 7: (a) MoistureMeter Epi D, and (b)
Vapometer score for SesZen-BioTM and Placebo on
day 0, 28, and 56. Increase in score for Moisturemeter
Epi D indicates increased moisturization whereas a
decrease in the score for Vapometer indicates better
barrier function.

DISCUSSION

A plenty of natural ingredients are essentially promoted to counteract skin-ageing such as green tea, known for its rich polyphenol profile, can fight signs of UV-induced DNA damage and inflammation with reported positive effects on

skin parameter. 10,11 On the contrary several studies have reported no significant data when compared to placebo controls. 12 Pomegranate extract, resveratrol- rich grape skin extract, carotenoids, fatty acids, and collagen, though effective *in vitro* has only few studies reported for their positive outcomes in clinical trials. 12-15 In the Europe, nutritional supplements used for skin health benefits are considered as "nutraceuticals" thereby necessitating European food safety authority (EFSA) to track and substantiate their claims from a regulatory perspective. 12

A recent article on evidences to support the application of nutraceuticals on skin health reported several studies conducted in vitro or human trials. 12 The article specifically mentions limitations of literature present on positive outcomes of orally consumed nutraceuticals in human volunteers or availability of fool-proof well designed trials to highlight effects of such products. Also, despite robust studies and positive outcomes from in vitro and animal trials, this data does not seem to correlate with human studies. While some studies show positive outcomes, either the volunteer numbers are minimal or comparison with placebo is missing or only data versus baseline is evaluated. Thereby it is necessary to establish the correct route from lab to market that will ensure the consumers that the nutraceutical companies design products with highest efficacy, effective and safe dosages with confidence. 12

Amidst the beauty brands and upcoming nutricosmetics, while majority of these natural ingredients and nutritional supplements are supported for their applications in the skincare sector, more extensive and rigorous studies are warranted. Keeping this view in mind, SesZen-BioTM a proprietary ingredient with 0.5% biotin was formulated as capsules. The dosage was determined as per dissolution studies. ¹⁶ The formulated capsules were tested for its skinhealth promoting ability in human volunteers with crow's feet skin.

The primary efficacy endpoints showed a notable reduction in crow's feet area wrinkles and fine lines in the treatment group. SesZen-BioTM showed a statistically significant improvement in skin elasticity, as evidenced by decreased retraction time and increased viscoelasticity. PGA scores indicated a 14.07% improvement at day 28 and a 20.58% improvement at day 56 in the treatment group. This comprehensive improvement in skin condition, encompassing wrinkles, roughness, and sallowness, further supports the effectiveness of SesZen-BioTM. The product also improved skin hydration, as measured by the MoistureMeter EpiD, and reduced TEWL, indicating enhanced skin barrier function. The study reports no significant adverse effects or intolerances associated with SesZen-BioTM, highlighting its safety for long-term use. The placebo group did not show improvements in majority of the parameters, reinforcing that the observed benefits are attributable to the active ingredient rather than external factors. When compared to the placebo, SesZen-Bio™ demonstrated clear advantages

in all primary and secondary efficacy evaluations. The placebo group showed minimal changes in skin parameters, underscoring the active role of SesZen-BioTM in achieving the reported benefits. This contrast emphasizes the product's effectiveness and the robustness of the clinical trial results.

SesZen-BioTM is a standardized, natural, biotin-containing, nutraceutical product. The authors have previously studied SesZen-BioTM to validate presence of 100% natural carbon content in the product, evaluated its dissolution profile at different concentrations to achieve its dosage. 16,17 The proprietary SesZen-BioTM nutraceutical product was also tested on human volunteers for its hair growth promoting benefits and it was found to promote hair density, thickness, and serum ferritin in 56 days of its use. The study has effectively described efficacy and safety of a daily nutraceutical supplement, SesZen-BioTM, as a hair health promoting material.9 The effect of a similar nutraceutical blend Evelle® tablets was tested in 62 women for its skin-health benefiting potential. The product Evelle® also contained biotin apart from vitamins, zinc, and natural extracts. The data supported the hypothesis of improved skin elasticity, skin roughness, reduced melasma, and pigmentation.6 Thus, SesZen-BioTM, a standardized biotin containing phytochemical rich Sesbania grandiflora leaf extract has both skin and hair health promoting effects.

As mentioned earlier very few studies are available on the efficacy and safety of nutraceuticals. In this scenario, SesZen-BioTM stands out as a well-proposed, extensively studied, safe, and efficacious active for human hair and skin health.

Limitations

Includes potentially small sample size that affects generalizability and a duration of only 56 days, which may not capture long-term effects. Additionally, the focus on mild skin ageing limits applicability to more severe conditions. It was conducted at a single center, which may restrict the broader applicability of the findings. Addressing these limitations in future research is crucial for strengthening the results.

CONCLUSION

In the ever-evolving landscape of skincare and nutraceuticals, SesZen-BioTM emerges as a ground-breaking innovation that redefines the intersection of science and beauty. This proprietary ingredient, harnessing the power of *Sesbania grandiflora* with 0.5% biotin, not only stands out for its robust formulation but also for its compelling clinical performance. Our extensive research, including previous studies on hair health, establishes SesZen-BioTM as a versatile and potent nutraceutical, setting new standards for product efficacy in both hair and skin health. Compared to placebo, SesZen-BioTM consistently demonstrates superior performance and

benefits, reinforcing its status as a cutting-edge solution in the nutraceutical market. For consumers and industry professionals alike, SesZen-BioTM represents not just a product, but a promise of quality, efficacy, and safety. With proven results, scientific backup and a commitment to safety and efficacy, SesZen-BioTM is poised to lead the charge in the next generation of skincare and wellness furthering the future of nutraceutical excellence.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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