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Original Research Article

A prospective, randomized double-blind, placebo-controlled study for safety and efficacy of SesZen-Bio™: a proprietary *Sesbania grandiflora* extract in managing hair and scalp health in healthy adults

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ABSTRACT

Background: Hair loss, a common multifactorial condition affecting both genders, results from causes like extrinsic factors (pollution, sun, humidity, and temperature), nutritional variation, or intrinsic factors such as ageing, heredity, hormonal and medical conditions. Some of the damages caused by these factors can be effectively managed with multivitamins, minerals, antioxidant natural products. Present study assessed use of standardised herbal *Sesbania grandiflora* extract for improving hair density, hair thickness and scalp health along with a serum biomarker to establish the probable mechanism of action.
Methods: The study was approved by the ethics committee and was conducted as per standard national regulations. 51 randomized subjects (mean age: 39.40±5.80 years) received either test-treatment or placebo for consecutive 56 days. Instrumental assessments included a phototrichogram to assess hair density, thickness, and scalp condition.
Results: SesZen-Bio™ which is derived from *Sesbania grandiflora* extracts showed an improvement in hair density, hair thickness and ferritin in 8 weeks of usage suggesting it stimulates the keratin production which resulted in improved follicle growth. By day 56 of usage, hair density and thickness improved by 58.92±28.69 cm^2 and 3.68±2.69 µm respectively from baseline (both $p<0.0001$) in the treatment group. This indicates towards 25% improvement in hair density, 16.94% in hair thickness and almost 72% volunteers indicated an improvement in hair health along with 27% increase in serum ferritin.
Conclusions: *Sesbania grandiflora* extract -SesZen-Bio® showed beneficial nutritional effects on research subjects, proving its usefulness as a well-tolerated and efficient daily supplement to improve hair health.

Keywords: Biotin, *Sesbania grandiflora*, Hair loss, Hair thinning, Alopecia

INTRODUCTION

Patterned hair loss including androgenetic alopecia (AGA) is the most common form of hair loss affecting both the genders. It is marked by a receding frontal hairline in males and diffuse hair thinning in females. Notably, in females, the preservation of the frontal hairline is frequently observed.[1-4] The term "Female Pattern Hair Loss" (FPHL) has gained preference over AGA in females and stands as the most prevalent hair loss disorder among females.[5-7] About 50% of males experience hair loss by the age of 50

years while 25% of females experience hair loss by the age of 49 years, and >50% by the age of 79 years.[5-9]

To address problems associated with hair loss, most of the synthetic drugs being used have shown several side effects associated with them. Various herbal extracts are known for their therapeutic effect related to hair growth promotion. The ability of these extracts to improve hair health can be majorly attributed to the presence of secondary metabolites, vitamins, and minerals.10 According to the World Health Organization (WHO), over 2 billion people globally suffer from deficiencies of essential vitamins and minerals. Remarkably, the prevalence of adults worldwide utilising daily vitamin supplements, whether for therapeutic purposes or chronic disease prevention, has escalated very rapidly in recent years.[11] Deficiencies in essential vitamin supplementation can cause poor hair and skin health, leading to various disorders.[12,13]

Evidences highlights the role of supplementation with multivitamins and minerals in the management of hair and skin disorders, leading to notable enhancements in skin and hair health.[13] While supplementation is readily available and cost-effective, it is crucial to discern which specific vitamins and minerals hold promise in addressing hair loss.[12] Hair loss can significantly diminish overall quality of life of adult males and females with association of symptoms of clinical depression, particularly more severe in females than in males.[14,15]

The test treatment used in the present study contains *Sesbania grandiflora* extract (commonly known as Agati) [(SesZen-Bio®, Zywie Ventures Private Limited), Zenherb Labs Private Limited, India] which is standardised for 0.5% biotin and contains various cofactors which are used for their antioxidant, astringent, antihistaminic, anxiolytic, anticonvulsive and febrifugal activities.[16-18] The leaves and flowers of Agati are abundant in vitamins (biotin, A, C, B2, etc) and minerals (zinc and selenium), whereas the bark and flowers are rich in polyphenols.[19]

Biotin, alternatively recognized as Vitamin B7 or H (with H derived from "Haar und Haut," German for "hair and skin"), is a water-soluble B vitamin serving as a crucial cofactor for numerous carboxylases which play pivotal role in the cellular metabolism of fatty acids, amino acids, and gluconeogenesis.[20]

Due to its affordability and widespread availability, biotin has emerged as an effective solution for hair health, promoting longer and healthier growth.[21] With biotin and other co-factors, test treatment is anticipated to enhance hair growth and improve hair health and skin health. *In silico* studies suggest that it is twice as effective as synthetic biotin in hair care.[19,22] This study was conducted to gain deeper insights into the safety, efficacy, and utilization of test treatment (SesZen-Bio®) vs placebo in healthy subjects with poor hair (thin, dry and brittle) and alopecia.

METHODS

Ethical conduct of the study

This study was conducted according to the Declaration of Helsinki (Brazil, October 2013), Good Clinical Practices (GCP) for clinical research in India 2005, new drugs and clinical trials rules 2019, Food Safety and Standards Authority of India (FSSAI) guidelines, ICH GCP E6 (R2) guidance on good clinical practice, and with ICMR's National ethical guidelines for biomedical and health research involving human participants, 2017. The study protocol [version#02 (Final)], informed consent form [version#01 (Final)], case report form [version#01 (Final)], and all other required documents were approved by ACEAS independent ethics committee prior to the commencement of the study procedures. This clinical study was registered with the Clinical Trial Registry of India (CTRI) with CTRI number CTRI/2022/10/046324 and in ClinicalTrials.gov with identification number: NCT05800496.

Research design and plan

This was a randomized, placebo-controlled, double-blind, two-arm, proof-of-concept clinical study designed to evaluate the safety and efficacy of test treatment in healthy human subjects with poor hair as well as alopecia conducted at NovoBliss Research Private Limited, Ahmedabad, Gujarat, India from October 2022 to January 2023. A total of 54 subjects (27 subjects per arm) aged 30 to 55 years, were enrolled in order to get 50 evaluable subjects. The decision to enrol 50 subjects (25 subjects per arm) was made in consideration with proof-of-science/concepts, clinical safety, and efficacy study objectives. From 54 enrolled subjects, 51 (25 subjects in test treatment group and 26 in placebo group) completed the study and 3 subjects were lost to follow-up. Test treatment group included 20 females and 5 males while placebo group included 24 females and 2 males. All the subjects provided written informed consent before getting enrolled in the study. The 56-day study had evaluations at Day 01 (baseline), Day 28 (visit 2), and Day 56 (visit 3). Baseline assessments, including age, weight, height, gender, medical history, vital signs, and physical examination were done on Day 01.

The primary efficacy evaluations done in the study included, measuring hair density, thickness and scalp condition using CASLite-Nova (Catseye Systems & Solutions Pvt Ltd, India) and visual appearance of hair and scalp before and after treatment. Secondary efficacy evaluations include analyzing test treatment and placebo for increase in serum ferritin and the subjective perception of subjects.

Inclusion criteria

Eligible subjects were healthy adults aged 30 to 55 years, including males and non-pregnant and non-lactating females with a negative pregnancy test, had thin, dry, and

brittle hair and experienced hair loss and refrained from using cosmetic procedures for three months before and during the study period. Subjects who were willing to provide written consent and had used hair care products before, but not medicated shampoos containing Minoxidil or hair growth treatments, except the test treatment or placebo, during the study period were included. The subjects continued to follow their regular hair regime throughout the study.

Exclusion criteria

Subjects with hair issues like thinning, hair fall or hair loss due to clinical conditions like anemia, thyroid problems, allergies, or sensitivity to test treatment or placebo ingredients, including *Sesbania grandiflora*, and those with scalp conditions apart from hair loss and dandruff were excluded from the study. Individuals with active dermatological conditions like eczema, psoriasis, acne; those on systemic therapies in the past four weeks; users of topical retinoids in the last two weeks or had planned to use during the study period were also excluded. Subjects who had undergone recent hair growth treatments (within three months), hair procedures (e.g., hair-transplant or laser treatment), drug or alcohol addiction, chronic skin illnesses, planned scalp shaving, irritated, or visibly inflamed scalp or severe scalp disease, or any other condition deemed suitable for exclusion at the dermatologist's or investigator's discretion and participation in similar clinical studies within the last four weeks were also excluded from the study.

Test treatment and randomization

Subjects were randomly assigned to receive either test treatment [SesZen-Bio® capsules, Zywie Ventures Private Limited (Zenherb Labs Private Limited, India)] or placebo (capsules made up of Tapioca based starch, Zywie Ventures Private Limited, India) as per the generated randomization code. The active ingredient in the test treatment comprises 250 mg *Sesbania grandiflora* extract which is standardised for 0.5% biotin. The capsules were designed for oral administration, with a specified dosage of one capsule in the morning and one capsule at night. Randomization list was generated using R software (The R foundation, Vienna, Austria. version: 4.1.2, 64 bit). Complete double-blinding was maintained wherein neither the subjects nor the investigator was aware of the test treatment/placebo allocation.

Statistical analysis

Statistical analyses were performed using R software (version 4.2.2). Continuous variables including change from baseline readings were presented as descriptive statistics employing paired t-test and presented as mean, standard deviation (SD), and 95% confidence interval (CI). Efficacy comparison between test treatment and placebo was done using two-samples t-test. Level of significance of $p<0.05$ was considered statistically significant. Data of discontinued or lost follow-up subjects was excluded from the analyses.

RESUTS

Subject demographics

Out of the 54 subjects initially enrolled, 51 successfully completed the study (3 were lost to follow-up), with 25 individuals (mean age: 38.9±5.97 years) receiving test treatment and 26 individuals (39.8±5.72 years) receiving placebo. Further baseline demographics of both groups are detailed in Table 2.

Primary efficacy evaluations

Assessment with CASLite-Nova showed that hair density significantly improved by 58.92±28.69 square cm (mean±SD) (95% CI: 29.79 to 50.46, $p<0.0001$) in test treatment group and by 8.92±24.64 square cm (95% CI: -1.03 to 18.87, $p=0.07$) in placebo group on Day 56 of treatment. Overall, test treatment showed greater improvements compared to placebo ($p<0.0001$) (Figure 1 and 2). Similarly, hair thickness significantly improved in treatment arm by 3.68±2.69 µm (95% CI: 2.57 to 4.79, $p<0.0001$) and by 1.42±2.97 µm (95% CI: 0.22 to 2.62, $p=0.0219$) in placebo arm on Day 56. Test treatment was superior over placebo ($p=0.0064$) (Table 3) (Figure 2). Visual assessment revealed greater improvement in general appearance of hair (in terms of improved hair volume, density, plasticity, shininess and smoothness) as well as scalp (in terms of reduction in itchiness, redness, roughness, and scaliness) in treatment arm compared to placebo arm. No improvements in scalp dryness and keratin were observed after 56 days in either group.

Secondary efficacy evaluations

Serum ferritin levels which are associated with hair loss conditions, increased by 27% in subjects who consumed test treatment compared to placebo consuming subjects, signifying the role of biotin supplementation in hair loss. Based on general perception questionnaire, overall, up to 72% of subjects who had used test treatment were extremely satisfied with the usage of the treatment as compared to 3.85% of subjects who had used placebo. 60% subjects liked test treatment very much in terms of increase in hair strength compared to 15.38% subjects in placebo group. 64% subjects agreed that their hair got very much thicker after using test treatment as compared to 11.54% subjects who used placebo.

Safety evaluation

No treatment induced adverse events were reported by either subjects or investigator throughout the entire study duration.

Table 1: Primary and secondary evaluations.

S. no.	Primary efficacy objectives	Secondary efficacy objectives
1.	Change in hair density after 56 days of treatment from baseline and also between the treatment and placebo group.	Evaluate the effect of the test treatment and placebo group in terms of change in serum ferritin after 56 days of treatment from baseline and between the groups.
2.	Change in hair thickness after 56 days of treatment from baseline and also between the treatment and placebo group.	Evaluation of test treatment and placebo per subjective perception.
3.	Change in visual hair and scalp appearance after 56 days of treatment from baseline and also between the treatment and placebo groups.	

Table 2: Demographic details.

Parameters	Variables	Test treatment (n=25)	Placebo (n=26)	Total (n=51)
Gender N (%)	Females	20 (80.0)	24 (92.30)	44 (86.30)
	Males	5 (20.0)	2 (7.70)	7 (13.70)
Age (years)	Mean (standard deviation)	38.9 (5.97)	39.8 (5.72)	39.4 (5.80)
	Median (minimum, maximum)	39.0 (30.0, 53.0)	39.0 (30.0, 50.0)	39.0 (30.0, 53.0)
Weight (cm)	Mean (standard deviation)	61.5 (14.2)	63.2 (13.9)	62.4 (13.9)
Height (kg)	Mean (standard deviation)	160 (6.93)	157 (6.77)	159 (6.90)

Table 3: Improvement across various hair parameters.

Efficacy para-meters	Visits (days)	Test treatment group				Placebo group				Comparison between groups
		Mean (SD)	Indivi-dual Mean %CFB	95% confidence interval		Mean (SD)	Indivi-dual Mean %CFB	95% confidence interval		P value*
				Lower limit	Upper limit			Lower limit	Upper limit	
Hair density	Day 28	287.75 (31.18)	17.74%↑	29.79	50.46	242.25 (30.17)	4.80%↑	0.83	19.42	<0.0001
	Day 56	304.16 (41.12)	25.29%↑	47.08	70.76	242.42 (27.50)	4.45%↑	-1.03	18.87	<0.0001
Hair thick-ness	Day 28	16.12 (1.54)	16.90%↑	0.96	3.04	15.00 (1.53)	7.24%↑	-0.20	1.78	0.0884
	Day 56	17.80 (2.45)	28.42%↑	2.57	4.79	15.58 (2.61)	11.48% ↑	0.22	2.62	0.0064

Note: CFB: change from baseline, ↑: shows improvement, ↓: shows reduction, *p value determined employing two-sample t-test.

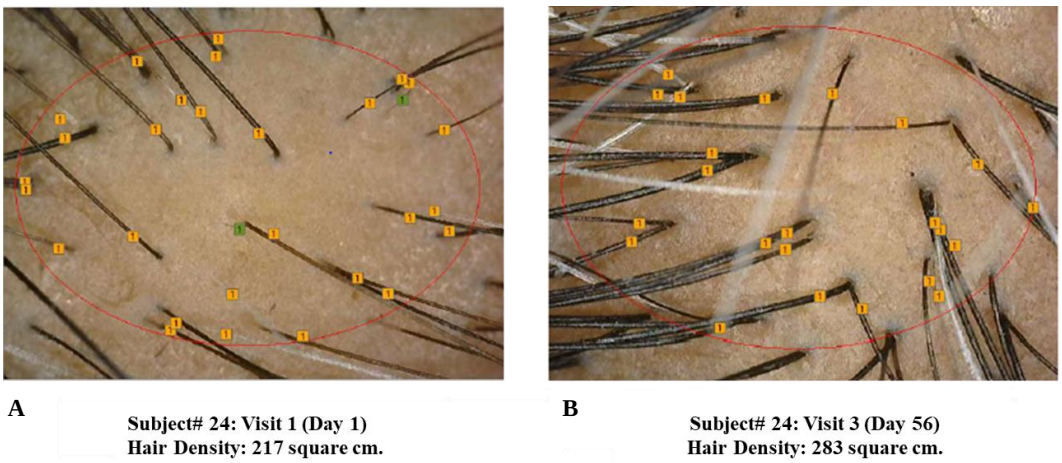

Figure 1 (A and B): Change in hair density in treatment group as measured by CASLite-Nova.

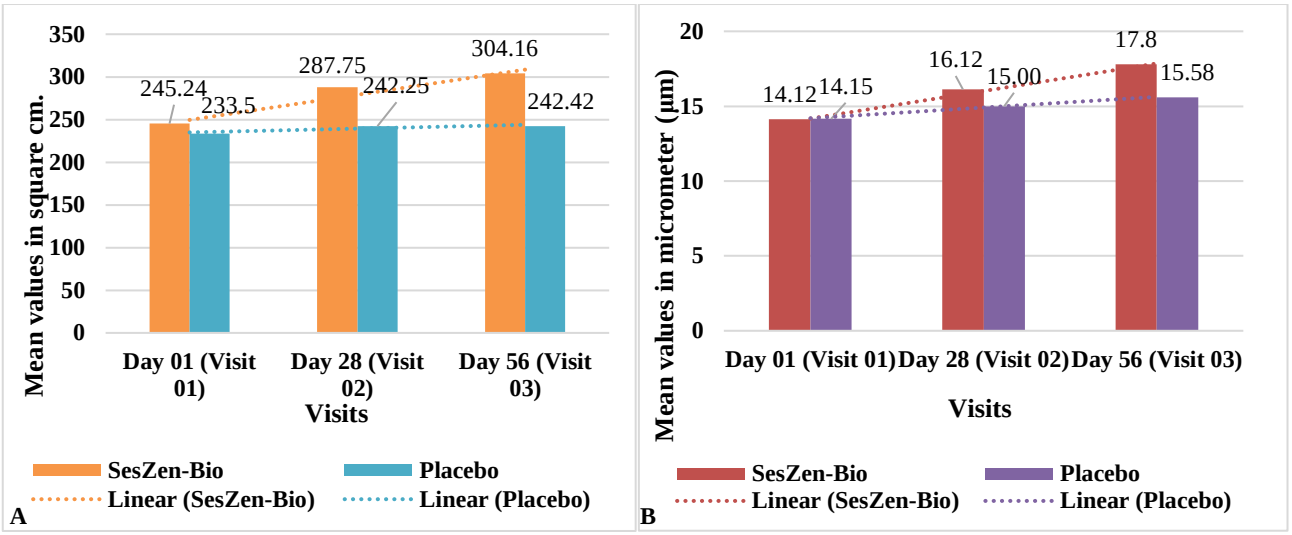

Figure 2: Evaluation of (A) hair density and (B) hair thickness for treatment and placebo group.

DISCUSSION

This clinical study compared and evaluated the safety and efficacy of capsules of test treatment containing *Sesbania agati* (rich in multivitamins and antioxidants like biotin, vitamins A, C, B2 and other phytomarkers like polyphenols and triterpenoids) with placebo. The evaluations revealed that the test treatment was well tolerated and efficacious as compared to baseline readings and placebo group with substantial improvement in hair density, thickness, and scalp condition.

In silico testing suggested that test treatment enhances hair follicle growth and improve hair health.[19] In a survey of 900 physicians, including 300 dermatologists, 66% of dermatologists stated recommending dietary supplements to their patients to improve their skin and hair health.[23]

Hair loss conditions are multifactorial, ranging from improper nutrition, environmental factors causing stress to hormonal imbalances, inflammation, drug use and many more.[24] External factors such as exposure to certain pollutants and ultraviolet-B radiations can cause loss of hair proteins, resulting into poor hair follicle health and damaged hair.[25] Research has provided evidence of a link between oxidative stress and occurrence of hair loss. Individuals with hair loss typically display reduced antioxidant levels in their scalp region alongside an elevated lipid peroxidation index.[26] *Sesbania grandiflora* leaves are rich in antioxidants. Arthanari et al conducted a comprehensive investigation to assess the antioxidant potential of *Sesbania grandiflora* leaves and flowers. Their research unveiled the remarkable antioxidant capacity of *Sesbania grandiflora* leaves. The study assessed free radical scavenging effects, specifically focusing on activities against 2,2-diphenyl-1-picrylhydrazyl (DPPH•), O_2•, NO•, H_2O_2, and OH• radicals. Notably, the DPPH assay demonstrated that *Sesbania grandiflora* exhibited significant radical scavenging effects that intensified with increasing concentration.[18] The results of our study show similar effect in terms of increased hair density and thickness.

Nutritional factors affecting hair health have been attributed to deficiencies in various vitamins and minerals, such as biotin and iron.[27] Biotin present in the test treatment maintains normal skin, hair and normal immune function and helps facilitating healthy growth and strengthening of hairs and nails.[28-33] Patel et al conducted a comprehensive review on the use of biotin for hair loss and identified 18 reports (including 10 with diagnosis of alopecia) in the literature that consistently reported improvements in hair growth upon biotin supplementation.[21] A randomized, double-blind, placebo-controlled study was conducted to evaluate the impact of oral supplement containing biotin and zinc (as some of the main ingredients) on hair growth and shedding in women with self-perceived thinning hair. After a 90-day supplementation period, the study revealed a reduction in hair shedding, enhancements in hair growth, strength, and overall hair health.[34]

Iron, an important mineral, helps your body to produce haemoglobin, a protein found in red blood cells that carries oxygen to cells, supporting their growth and repair, including cells that help with normal hair growth.[24,35] Iron deficiency is recognized as a significant factor contributing to hair loss in women. Serum ferritin levels serve as early indicators of iron deficiency. About 25% of the body's iron is stored in serum ferritin, and fluctuations in these levels may impact the process of hair growth.[36] The test treatment used here restores iron levels in blood and helps in managing hair loss caused by iron deficiency. This is attributed to improved serum ferritin content by 27% post consumption of test treatment. In a meta-analysis involving 36 studies, it was found that females experiencing non-cicatricial alopecias exhibited lower serum levels of ferritin compared to the healthy population. Additionally, the analysis concluded that supplementing with biotin could be beneficial in

addressing hair loss.[37] The present study introduced a unique element by incorporating *Sesbania grandiflora* and formulating capsules rich in biotin and other co-factors, which resulted in a remarkable enhancement of hair health. All of the above studies are consistent with the findings of this research, encouraging the efficacy of test treatment in individuals with poor hair health.

Minoxidil which is a widely used preparation for managing hair loss in both men and women, is often associated with several side effects including itching, scaling, facial hypertrichosis, edema and many more.[38-41] In the realm of limited treatment options, nutraceuticals are emerging as a safe and effective supplement options to promote hair growth and address certain forms of hair thinning. A prospective study assessing the effectiveness of a nutraceutical supplement in enhancing hair growth and quality for individuals with self-perceived hair thinning found that, after 12 and 24 weeks of test treatment supplementation, 83.70% of men and 79.50% of women experienced significant improvements in hair growth, density, thickness, volume, and overall appearance. Furthermore, the treatment was well-tolerated among the study population.[42]

In-vitro dissolution study on 0.8% biotin treated *Sesbania grandiflora* extract revealed similarity in dissolution rate between 0.8% and 0.5% biotin concentration, stating that significant dose reduction of 0.8% biotin capsules can achieve similar efficacy as 0.5% biotin (Gadani et al, unpublished).[43] This suggests that a dose reduction can also be considered.

Limitations

It is important to recognize certain limitations to this study. Study included a small sample size, necessitating further research with larger samples, to assess other hair parameters like hair growth rate, anagen to telogen ratio to measure number of anagen hairs, in diverse population and ethnicity which may provide more precise safety and efficacy effects of treatment in such population. Additionally, missing biomarkers may impact the accuracy of study results.

CONCLUSION

This study makes a substantial contribution to the growing body of evidence regarding the efficacy of plant-based solutions in enhancing hair. SesZen-Bio® is a proprietary extract obtained from *Sesbania grandiflora*. It demonstrated tolerability and efficacy owing to the presence of these natural active ingredients including *Sesbania grandiflora* and other co-factors. These ingredients effectively combat hair problems like hair loss, hair dryness, brittleness, while promoting hair thickness and density. Positive impact of SesZen-Bio® on hair makes it a suitable daily regimen for enhancing overall hair wellness. It caters to the hair loss caused through any of the reasons like hormonal imbalance, nutritional deficiency or inflammatory responses. Hence, this is a holistic solution for hair and scalp health.

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