

A Prospective, Multi-Center Study to Evaluate the Safety and Efficacy of a Vegan Nutraceutical to Improve Hair Growth and Quality in Females Following a Plant-Based Diet

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ABSTRACT

Hair thinning affects upwards of 50% of women by age 50, impacting their social-emotional wellbeing. It is a condition now thought to be driven by a multi-factorial etiology, including diet and nutrition. Women following vegan, vegetarian, or other plant-based diets have specific needs for nutrients traditionally sourced from animals, which could affect hair health.

To support hair growth and quality in women following a plant-based diet, a novel vegan nutraceutical (Nutrafol® Women's Vegan Capsules, Nutraceutical Wellness, Inc., New York, NY) was evaluated for its ability to support hair health. The objectives of this 6-month, multi-site, single-blind prospective clinical study was to evaluate the safety and efficacy of the nutraceutical to improve hair growth and quality in women consuming a plant-based diet. The primary endpoint in this study was an increase in terminal hair count at day 180 compared with baseline, as assessed through phototrichogram analysis. Ninety-five subjects completed the study.

Daily intake of the nutraceutical resulted in a significant increase in the number of terminal hairs at day 90 ($P < 0.01$) and day 180 ($P < 0.01$). There was also an increase in total hair counts ($P < 0.01$), the terminal-to-vellus ratio ($P < 0.01$), and a decrease in shedding ($P < 0.01$). Global Investigator Ratings revealed improved hair growth ($P < 0.00001$) and overall quality ($P < 0.00001$). In-person hair strength and brittleness assessments significantly improved as well ($P < 0.01$ for both). A significant proportion of subjects reported improved hair quality, appearance, texture, and volume. Hair problems affecting the quality of life of the subjects were also reported as improved. This study demonstrated significant improvements in hair growth and quality in a plant-based population with a vegan nutraceutical.

ClinicalTrials.gov Identifier: NCT05332743.

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INTRODUCTION

Hair loss and thinning are common conditions affecting both men and women that are more recently recognized to be the result of multiple causes.¹ Hair loss can have a significant, detrimental impact on self-esteem, psychosocial functioning, and the overall quality of life of affected individuals.^{2,3} It can also present a substantial financial burden on individuals seeking treatment.⁴

There are few United States Food and Drug Administration (FDA)-approved medical treatment options for women.⁴ Conventional options include FDA-approved topical minoxidil,

but most women are treated with off-label medications including spironolactone, 5- α reductase inhibitors such as finasteride or dutasteride, and, more recently, low dose oral minoxidil.⁴ While these medications are effective for thinning hair, they may either have low adherence rates due to effects on hair texture and styling or be associated with side effects.^{4,5} In-office procedures including Platelet-Rich Plasma (PRP) therapy and devices like Low-Level Laser therapy are also common practice, though patients are increasingly turning to more accessible, over-the-counter solutions for thinning hair, including natural therapies and dietary supplements.^{4,5}

Nutrition influences hair growth and quality, as illustrated by hair conditions seen in malnutrition or specific restrictive diets.⁶ For example, individuals who follow a vegan or vegetarian diet have unique dietary challenges given their limited food patterns.⁷ This can lead to a risk of increased nutritional deficiencies that will impact overall hair health.^{7,8} For example, collagen and keratin, both key structural proteins for hair, are typically derived from protein-rich sources, which the general population tends to source from animal-based foods.^{9,10} Iron and zinc deficiencies may develop more easily on a plant-based diet and affect hair growth.^{11,12} Pesticides used in plants for human consumption may alter the gut microbiome.¹³ Overall, while a plant-based diet may have beneficial influences on health, they increase the chance of nutritional deficiencies that can affect hair health.

Other factors such as stress, hormonal triggers, inflammation, oxidative stress, and biological aging have compounding influence on the hair follicle.^{1,14} The multifactorial nature of hair health requires a solution that, in addition to targeting these factors, also addresses the bio-specific needs of consumers following a plant-based diet.¹⁵ Oftentimes, supplements for vegan or vegetarian consumers are formulated by simply removing animal-based ingredients, potentially leaving a gap in nutrient consumption. Current evidence suggests that there may be alternative vegan ingredients that support mechanisms traditionally targeted with animal-derived ingredients. For example, collagen consumption has been linked to improvements in skin, hair, and nail health, but is traditionally sourced from bovine, porcine, or fish.¹⁶⁻¹⁸ Recent research has shown that the plant the Moldavian Dragonhead may increase the expression of type I collagen in *C. elegans*.¹⁹ In vitro studies also suggest that it activates FOXO-1 and Phosphorylation of AMPK-1, both linked to stem cell longevity and aging.¹⁹ When tested as an oral supplement, female subjects with sun-damaged skin exhibited improved skin hydration, elasticity, and skin density.¹⁹ Another key structural component of collagen and elastin synthesis is the amino acid hydroxyproline, which is generally consumed from meat. Bamboo is reported to be up to 70% silica, which may increase tissue levels of hydroxyproline, making this a useful vegan source to combat the natural loss of collagen.²⁰ Silica may also be involved in GAGs (compounds that make up connective tissues) synthesis and acts as a cross-linking agent in strengthening keratin.²¹

Taken together, these data indicate that some vegan-sourced botanicals and phyto-extracts may support nutrient gaps traditionally associated with a plant-based diet, and in doing so could improve hair growth. The objective of this 6-month, multi-site, single-blind study was to evaluate the safety and efficacy of a novel nutraceutical formulated with vegan ingredients to promote hair growth in adult women consuming a plant-based diet.

MATERIALS AND METHODS

Study Design and Subjects

This was a multi-center, single-blind, single-arm study of a vegan nutraceutical in women leading a plant-based diet (ClinicalTrials.gov Identifier: NCT05332743.) Eligible subjects were healthy women aged 18 to 50 with self-perceived hair thinning confirmed by a dermatologist investigator. Selection criteria are listed in Table 1. All subjects were self-described as following a plant-based diet for at least the 3 months prior to enrollment. Plant-based was inclusive of vegetarian, lacto-vegetarian, ovo-vegetarian, lacto-ovo-vegetarian, vegan, raw vegan, pescatarian, pollotarian, or flexitarian/semi-vegetarian (defined for this study as eating red meat no more than 3X/week). Participants agreed to maintain their current diet for the duration of the study. The study was approved by an Institutional Review Board (Advarra, Columbia, MD) and conducted in compliance with good clinical practice. All participants provided written, informed consent prior to participating in the study.

Study Procedures

After subject eligibility was confirmed, subjects were instructed to take 4 capsules a day of the vegan nutraceutical (Nutrafol® Women's Vegan Capsules, Nutraceutical Wellness, Inc., New York, NY) with a meal for the 6-month duration of the study. The study consisted of clinic visits at baseline, day 90, and day 180, in addition to compliance calls on days 30, 60, and 135. Each clinic visit included a physical examination (blood pressure, heart rate, weight, and height) and a hair examination.

On the first visit during the hair exam, a region of interest (ROI) of 1 cm² considered to be a transitional zone between an area of thinning and healthy hair was selected along the frontalis bone where the frontal hairline and lateral hairline meet. This ROI was recorded based on a 3-point triangulation measurement between the medial canthus, lateral canthus, and preauricular skin pit. This point was identified, and the center was marked at each subsequent visit based on the recorded measurements. This ROI was used for analysis using phototrichograms (Canfield HairMetrix®) digital photography, with identified vellus and terminal hair counts based on the width of the hair. These counts were also verified by the dermatologist. The extrapolated measurements collected based on these phototrichograms included: the sum of hair widths (total scalp coverage), hair diameter (mean hair width), terminal to vellus ratio, average number of hairs per follicular unit, follicle count per 1 cm², and mean inter-follicular distance.

Hair shed counts were assessed by a hair pull test in 4 different regions of the scalp: the vertex area, both parietal areas, and the occipital area. Gentle traction was applied on a group of approximately 60 hairs. A hair pull test was considered positive if more than 10% or 6 hairs came out with the pull, indicating active hair shedding.²² Subjects were instructed not to wash or

TABLE 1.

Selection Criteria	
Inclusion Criteria	
1.	Females aged 18-50, leading a plant-based lifestyle for at least 3 months and for the duration of the study.
2.	All Fitzpatrick skin types with self-perceived thinning, confirmed by a dermatologist.
3.	General good health, as determined by the Investigator.
4.	Willing to maintain the same hair length, hairstyle, and coloring practices for the duration of the study.
Exclusion Criteria	
1.	Pregnant, planning a pregnancy, or nursing.
2.	Serious complications due to COVID-19 previously or during the study as determined by the investigator.
3.	Clinical diagnosis of hair loss disorder such as alopecia areata, telogen effluvium or scarring forms of alopecia.
4.	History of acute or chronic disease that could interfere with study participation or affect study results.
5.	Current hair loss or skin disease (eg, psoriasis, atopic dermatitis, skin cancer, eczema, sun damage, seborrheic dermatitis), infections, cuts, and/ or abrasions on the scalp or condition (eg, sunburn, tattoos) on the treatment area that, in the opinion of the Investigator, might put the subject at risk or interfere with the study conduct or evaluations.
6.	History of surgical correction of hair loss on the scalp.
7.	Use of any products or devices purported to promote scalp hair growth within the 6 months prior to study start.
8.	Utilization of low-level lasers for hair growth in the last three months.
9.	Females who have started the use of hormones for birth control or hormone replacement therapy within the last 6 months.
10.	History of burning, flaking, itching, and stinging of the scalp.
11.	History of malignancy or currently undergoing chemotherapy or radiation treatments.
12.	Known allergy to any of the ingredients in the investigational product.
13.	Known history or recent blood work indicating iron deficiency, bleeding disorders or platelet dysfunction syndrome, subjects receiving anticoagulant therapy or smokers with usage >20 cigarettes/day.
14.	Use of any medications or medicated shampoos that are known to potentially cause hair loss or affect hair growth, as determined by the Investigator.

shampoo their hair for 24 hours prior to the clinic visit to ensure accurate results.

Global Investigator Assessments of change in hair growth and quality at days 90 and 180 were done via Standardized Global photography taken with Canfield IntelliStudio System[®]. Global ratings were done using a 7-point Likert scale, in which 0 indicated no change, negative values (-1 to -3) indicated worsened, and positive values (+1 to +3) indicated improvement. Hair quality was defined as the composite of hair brittleness, dryness, texture, strength, scalp coverage, and overall appearance. Hair strength and brittleness were further assessed in person by the site investigator. Strength and brittleness were rated on a 10-point Visual Analog Scale (VAS) with a rating of ten being the highest rating (very strong or not brittle).

Self-assessment questionnaires including perception of treatment benefit and a Quality of Life (QoL) questionnaire were administered at all timepoints, including during the compliance calls.

Study Endpoints

The primary endpoint was the increase in mean terminal hair count at day 180 relative to baseline (day 0), as measured by

phototrichograms. The secondary endpoints were the change in all hair counts (total, terminal, and vellus) across all timepoints, change in terminal to vellus ratio, follicle count, and mean inter-follicular distance compared with baseline measured by phototrichograms; improvement in hair quality and growth assessed by physician ratings of global photographs; decreased hair shedding pull test compared with baseline; and perceived improvement in subject's assessment of change in hair growth and appearance measured with Subject QoL assessment and consumer perception questionnaires. Safety analyses were done, and adverse events were compiled.

Statistical Analysis

Descriptive statistics were used to compile the study population baseline demographics, distributions, and variables. The primary outcome measurement was evaluated using a one-sample t-test comparing the means for the 2 correlated samples. Continuous measurements across 3 timepoints (days 0, 90, and 180) were evaluated through analysis of variance (ANOVA) with subsequent Tukey HSD analysis. Responder rates or other assessments of proportions were evaluated using a one-sample t-test for proportions, Fisher's exact test, or Chi-Square analysis when the data were presented in contingency table format. The overall change in paired categorical contingency table greater

than 2x2 was analyzed using the McNemar-Bowker test for symmetry. Categorical data were also further categorized into groups related to the degree of change across time and analyzed using a one-sample t-test. A $P < 0.05$ was considered statistically significant for clinically meaningful change.

RESULTS

Demographics and Baseline Characteristics

One hundred and ten subjects were enrolled in the study and 95 subjects completed the study per the protocol. The average age was 34.9 ± 9.7 y (range: 18 - 52). Fifty-two percent of these subjects considered themselves semi-vegetarian, 11% vegetarian, and 7% vegan. The rest of the population classified themselves as pollotarian, pescatarian, or lacto-vegetarian. The per-protocol population was diverse – see table of demographics for details (Table 2).

TABLE 2.

Per-Protocol Demographics	
Ethnicity	Percentage
Non Hispanic/Latino	80%
Hispanic/Latino	20%
Race (n=95)	Percentage
Caucasian	54%
Asian	20%
Hispanic	3%
African American	3%
Middle Eastern	2%
American Indian	1%
Hawaiian/Pacific Islander	1%
White/Asian	3%
White/African American	3%
White/American Indian	1%
Other (not specified)	9%

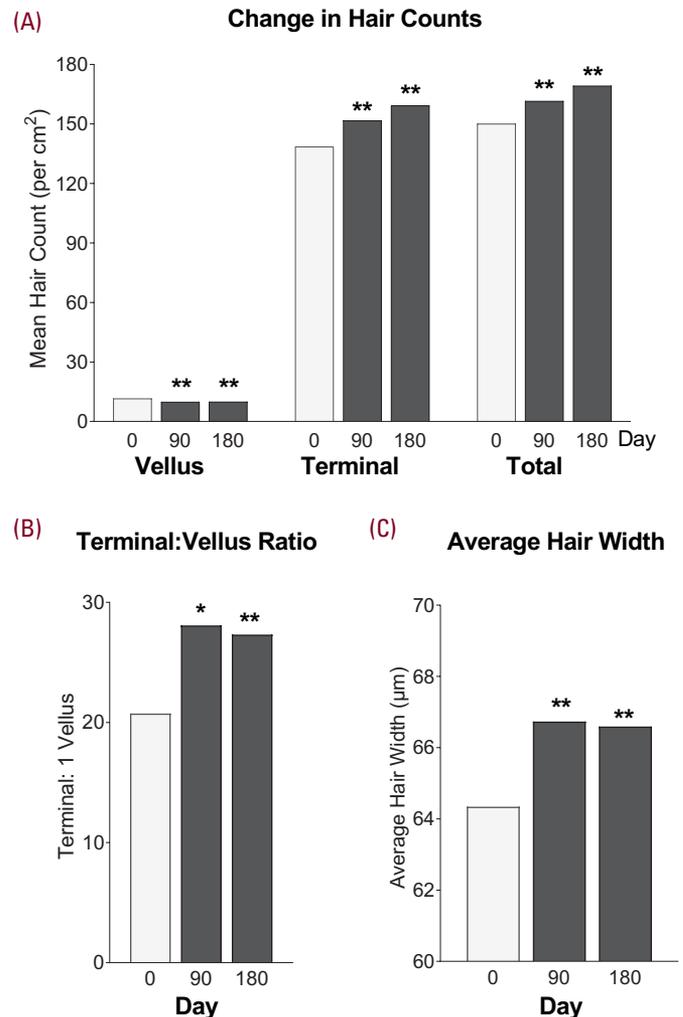
Primary Endpoint

There was a significant and progressive increase in terminal hair count from baseline (138.6 ± 37.2 hairs per cm^2) to day 180 (159.3 ± 43.9 hairs per cm^2 , $P < 0.0001$) meeting the primary endpoint for efficacy (Figure 1). These changes translated into a 15% increase in terminal hairs between day 0 and day 180. Test site analysis for the per-protocol population confirmed that the primary endpoint was met independently at both test sites.

Secondary Endpoints

Total hair counts also progressively and significantly increased throughout the study (150.1 ± 35.8 at baseline to 161.6 ± 38.8 at day 90 to 169.2 ± 42.8 per cm^2 at day 180, $P < 0.01$, Figure 1), translating into an increase of 12.8% by day 180 compared with baseline. The number of vellus hairs significantly decreased over time (11.5 at baseline to 9.9 at day 180, $P < 0.01$), though there was

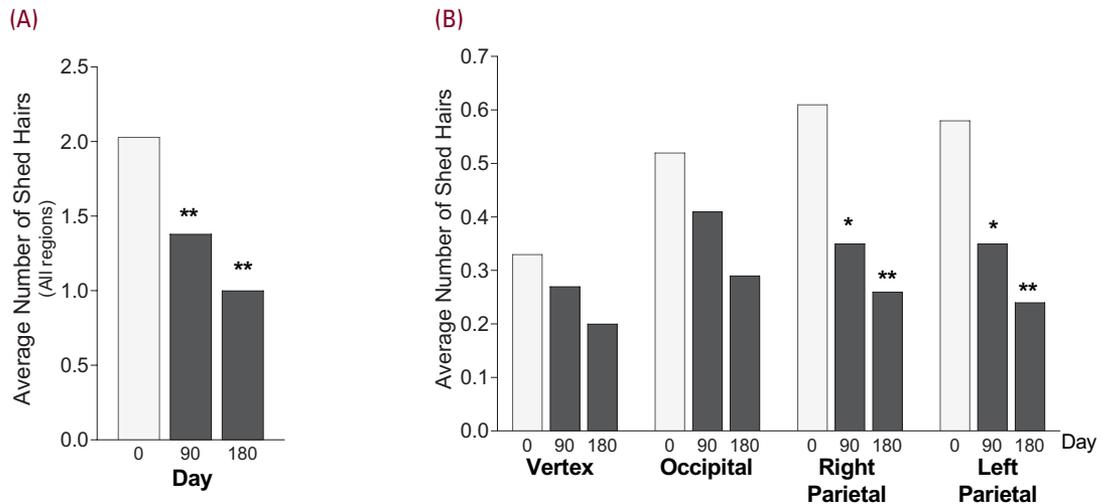
FIGURE 1. Changes in hair parameters from baseline to day 180. (A) Terminal and total hair counts significantly increased throughout the duration of the study. Vellus hair count decreased. (B) This resulted in a significant increase in terminal-to-vellus hair ratio. (C) There was also a significant increase in the average hair width.



* $P < 0.05$ in Tukey HSD Test compared with day 0.
** $P < 0.01$ in Tukey HSD Test compared with day 0.
HSD, honest significant difference

an increase in the terminal-to-vellus hair ratio at day 90 ($P < 0.05$) and 180 ($P < 0.01$, Figure 1). There was also a significant increase in average hair width, increasing from $64.3 \mu\text{m}$ at baseline to $66.6 \mu\text{m}$ by day 180 ($P < 0.01$). Finally, the average number of hairs per follicular unit increased from baseline to day 180 (1.2 ± 0.1 to 1.3 ± 0.2 , $P < 0.01$) and the inter-follicular distance decreased from 1.14 to 1.09 mm ($P < 0.01$). Taken together, an increased number of hairs and smaller inter-follicular distance indicates an increase in scalp coverage.

FIGURE 2. Hair shedding decreases over time. (A) Average total hair shed per subject from all combined regions significantly decreased. (B) This was driven by a significantly decreased shed count in the right and left parietal regions.



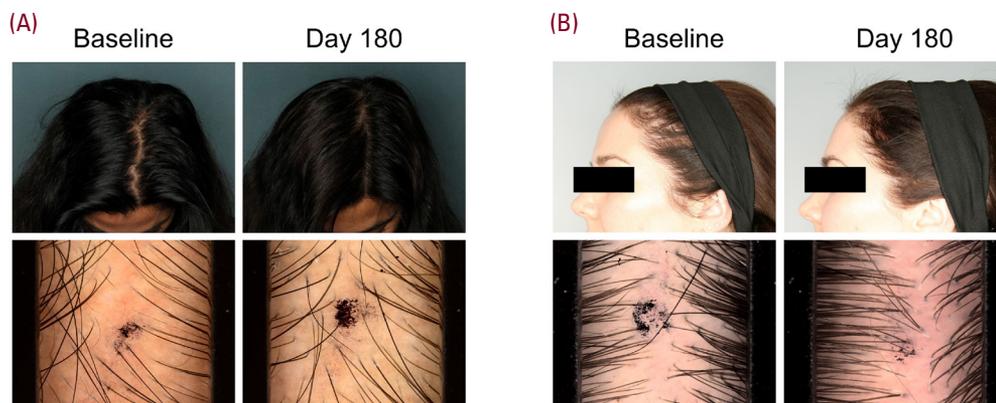
* $P < 0.05$ in Tukey HSD Test compared with day 0.
** $P < 0.01$ in Tukey HSD Test compared with day 0.
HSD, honest significant difference

For hair shedding counts, there were no positive hair pull tests recorded, confirming that none of the subjects was experiencing active hair shedding at any timepoint. Total hair shed combined from all regions significantly and progressively decreased throughout the study (2.0 ± 2.3 at baseline, 1.4 ± 1.5 by day 90, and to 1.0 ± 1.3 by day 180; $P < 0.01$ at both timepoints, Figure 2). When assessed by region, the right parietal and left parietal areas of the scalp both decreased significantly compared with baseline ($P < 0.01$ for both), while the vertex and the occipital regions did not ($P = 0.27$ and 0.09 , respectively) (Figure 2).

There were significant and progressive improvements in the Global Investigator Ratings of hair quality and growth throughout the study. The proportion of subjects rated as improved compared with neutral or negative was analyzed and found to be

statistically significant for both hair quality and growth ($P < 0.05$ and $P < 0.00001$ respectively). For hair quality, 79% of subjects were rated as improved, and only 21% of subjects were rated as having no change at day 180. No subjects received ratings of "worsened" at either timepoint. In considering hair growth, 87% of subjects were considered improved, and only 11% were considered "no change" from baseline by day 180. Two subjects were considered "worsened." Figure 3 shows improvements in a representative subject seen through global photographs, as well as phototrichogram images of the target area for that subject. In person investigator-rated hair strength and brittleness improved during the study. Hair strength ratings increased from 7.3 ± 1.5 to 8.7 ± 1.0 ($P < 0.01$), and hair brittleness ratings improved from 6.8 ± 1.6 to 8.2 ± 1.0 ($P < 0.01$).

FIGURE 3. Improvement in hair growth in 2 representative subjects. (A) Thirty-five-year-old, vegetarian, mixed race/other Pacific Islander. (B) Thirty-six-year-old vegan Caucasian.



Top row: Global photographs showing visible clinical improvements.
Bottom row: Phototrichogram images of selected target area.

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TABLE 3.

Subject Assessment Results	
Since the start of the study ...	Percentage of Subjects Reporting Improvement at Day 180
My hair feels more nourished and less dry/brittle.	78%*
I have noticed an improvement in overall hair quality.	85%*
I have noticed an improvement in the appearance of hair health.	87%*
I have noticed an improvement in hair texture.	69%*
I have noticed an improvement in hair volume.	69%*
I have noticed reduced hair shedding.	67%*
I have noticed baby hairs growing out.	79%*
I have noticed an improvement in hair strength.	82%*
I have noticed an improvement in speed of hair growth.	69%*
My hair feels longer	80%*
I have noticed an improvement in fullness/thickness of hair.	72%*
I have noticed more new hairs.	76%*
I have noticed an improvement in scalp coverage.	65%*

*Indicates a significant proportion of subjects reporting a favorable response compared with the proportion of subjects reporting an unfavorable response ($P < 0.01$).

Subjective assessment of changes in hair parameters and quality of life as measured by questionnaires also reflected the improvements in hair counts and ratings seen in this study (Table 3). Notably, a significant proportion of subjects reported perceiving their hair as more nourished and less dry/brittle, improved overall hair quality, and improved appearance of hair health. Quality of life parameters pertaining to hair showed that hair thinning affected day-to-day life for all subjects, and feelings of attractiveness, comfort socializing, and self-consciousness improved. Notably, at baseline, 70% of subjects reported spending much time making their hair look thicker/fuller. By day 180, this trend reversed, and 68% of subjects reported 'none' or 'just a little bit' of time making their hair look thicker/fuller. Likewise, at the beginning of the study, a majority (64%) of subjects reported that 'problems with their hair made them feel as though they appear older', but by day 180 the proportion of subjects decreased to only 32% reporting this.

Safety

In general, the product was well tolerated. No serious adverse events (AEs) were reported. A total of 10 incidences of potentially related AEs were reported by 7 subjects. Eight AEs were determined to be of mild severity and 2 of moderate severity. Most pertained to minor gastrointestinal issues (constipation 40%, abdominal pain 10%, and gastroesophageal reflux disease 10%) or to symptoms of 'head feels hot' and headache (30%). All resolved with no medical interventions.

DISCUSSION

The present study shows that daily intake of vegan nutraceuticals was safe and effective in improving hair growth and quality in women leading a plant-based lifestyle. Results showed a progressive increase in terminal and total hair counts throughout the study. Additional extrapolated measurements

collected based on these hair counts, such as mean hair width, follicle count per cm^2 , and the mean inter-follicular distance, all improved as well. Dermatologist ratings of global photographs for hair growth and quality, as well as in-person ratings of strength and brittleness also significantly improved. Hair shedding, along with improvements in hair appearance, volume, and growth, were also noted by the subjects and reflected in a better quality of life as it pertains to their hair.

The increase in terminal and total hair counts was coupled with a decrease in the number of vellus hairs over time. This, together with an increase in average hair diameter, may suggest that terminal hair growth is promoted compared with vellus hairs with ingestion of the supplement. Previous research suggests that thicker hair strands are associated with an increased linear hair growth rate.²³ It has also been noted that reduced hair growth rates observed in both male and female patterned hair loss are also tightly correlated to a reduction in hair diameter.²³ Thus, an increase in the number of terminal hairs seen in this study and a decrease in thin, vellus hairs could be improving hair growth by promoting the presence of thicker hair strands and providing more visible coverage.

The number of hair fibers per follicular unit and hair density are all affected by factors such as age and ethnic and/or racial background. In general, the number of hairs per follicular unit decreases with age.²⁴ But different ethnic or racial backgrounds have been linked to different densities.²⁴ Asian and Caucasian populations have been characterized as having a higher hair density than those of African descent.²⁴ In this study, the average number of hairs per follicular unit significantly increased from baseline to day 180 and the inter-follicular distance also decreased. Considering the diverse population of Asian, Caucasian, Hispanic, and African American subjects in this

study, an increased number of hairs and smaller inter-follicular distance may indicate an overall increase in scalp coverage irrespective of different racial or ethnic groups. Our results warrant further expanded studies in ethnic sub-populations for further characterization.

Both the investigator ratings of global photographs for hair quality and in-person dermatologist assessments of hair strength and brittleness significantly improved throughout the study. In addition, subjects reported improvements in overall hair quality, appearance of hair health, hair strength, and hair feeling less dry/brittle. Hair growth and quality have long been linked to the dietary and nutrient intake of an individual.²⁵ Including ingredients that support the nutritional gaps in subjects following a plant-based diet may have contributed not only to the hair growth seen in these results, but also the improvements in hair quality such as strength.

Hair growth and quality have documented impacts on the quality of life, especially in women.²⁶ Women are also about twice as likely than men to describe themselves as vegetarians.²⁷ The data presented in this study show that the subjects reported improvements in hair quality, volume, growth, and coverage. It also decreased the impact of 'problems with their hair on feelings of self-consciousness, attractiveness, and socializing'. The nutraceutical was also reported to be well tolerated and easy to incorporate into a daily routine, making this an important tool given the current landscape of hair growth solutions for women following a plant-based diet.

Current hair growth treatment options for women are limited. Considering that veganism, vegetarianism, and other animal-restrictive diets are more popular among women, this population may benefit from tailored therapies for hair thinning.^{7,8} It is important to take into account the inherent differences in sources for required vitamins, minerals, and nutrients essential for healthy hair. The approach in many plant-based diets is to remove animal-based sources without providing vegan alternatives for important nutrients. By leveraging plant-based ingredients with clinical support for hair growth, the vegan nutraceutical studied here aims to fill the nutrient gaps from removing animal-sourced nutrients.¹⁹ In doing so, the results support improved hair growth, quality, and satisfaction of the subjects' hair in a population that is plant-based. To our knowledge, this is the first study to demonstrate significant improvements in hair growth and quality in a plant-based population with these ingredients.

LIMITATIONS

This study was conducted in a large and diverse population of women leading a plant-based lifestyle. A placebo arm would have provided a control, arguably decreasing bias in the subjective assessments of the study. The results of this study warrant the development of future studies in an expanded

population with a placebo-controlled design.

DISCLOSURES

Dr Sivamani has served as a scientific advisor for Nutraceutical Wellness LLC. Dr Ablon has previously received research grants from Nutraceutical Wellness LLC. Drs Maloh and Nong have no disclosures to report. Drs Hazan and Raymond are employees of Nutraceutical Wellness LLC. Funding for this study was provided by Nutraceutical Wellness LLC.

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