A Six-Month Open-label Prospective Clinical Study to Evaluate Improvements in Hair Strength and Growth in Men and Women using Standardized Nutraceuticals

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INTRODUCTION/OBJECTIVES

Hair thinning is a prevalent concern influenced by multiple factors including stress, hormonal changes, diet, and lifestyle, with varying impacts across demographic groups. Oral supplements addressing these key root causes through a multi-targeting, patented, botanical-based Synergen Complex have been developed to combat hair thinning across different populations. Numerous clinical studies have confirmed the benefits of these oral hair growth nutraceuticals (HGN) for improving hair, including growth and quality. This study sought to expand on existing evidence by further evaluating the effectiveness of these HGN in enhancing hair strength and length in adults with thinning hair.

MATERIALS & METHODS

- This was a six-month, prospective, open-label study targeted enrollment of 250 participants (50 per group):
  - Women's HGN (W): Women aged 18–44 M
  - Menopause HGN (MW): peri-, post-, and Menopausal women aged 45–70
  - Vegan HGN (V): Plant-based women aged 18–44
  - Postpartum HGN (PP): Parous women aged 18–44
  - Men's HGN (M): Men aged 25–50
- All had thinning hair confirmed by the study dermatologist.
- Assessments occurred at baseline, day 90, and day 180.
- Quantitative measurements included hair shaft diameter via light microscopy (investigator blinded to the timepoint) and hair breakage/shedding via a four-region hair pull test.
- Hair qualities were assessed via dermatologist evaluation using a 5-point scale (0=excellent, 4=very poor).
- Subject self-perception was assessed post-baseline via a 4-point questionnaire. Results were divided among participants who disagreed (1,2) or agreed (3,4) with the statement.

SAFETY

Two subjects assigned to the V group discontinued due to possibly related AEs - one of nausea and vomiting and one reported increased acne. Both were considered moderate in nature and resolved when the supplement was discontinued.

CONCLUSION

This study demonstrates that these targeted hair growth nutraceuticals significantly enhance hair shaft diameter and reduce shedding, resulting in longer, stronger hair across their intended populations. These findings support the efficacy of hair growth nutraceuticals for hair thinning, offering promising options throughout various life stages and lifestyles for improved hair health.

RESULTS

A total of 252 subjects were enrolled in the study, with 244 completing per protocol. Average ages for each demographic were (years): W 34.0; V 34.7; MW 59.4; PP 38.5; M 40.8. Two participants (V group) discontinued from possibly related AEs, with all others discontinuing for reasons unrelated to the study supplement.

Hair Fiber Diameter
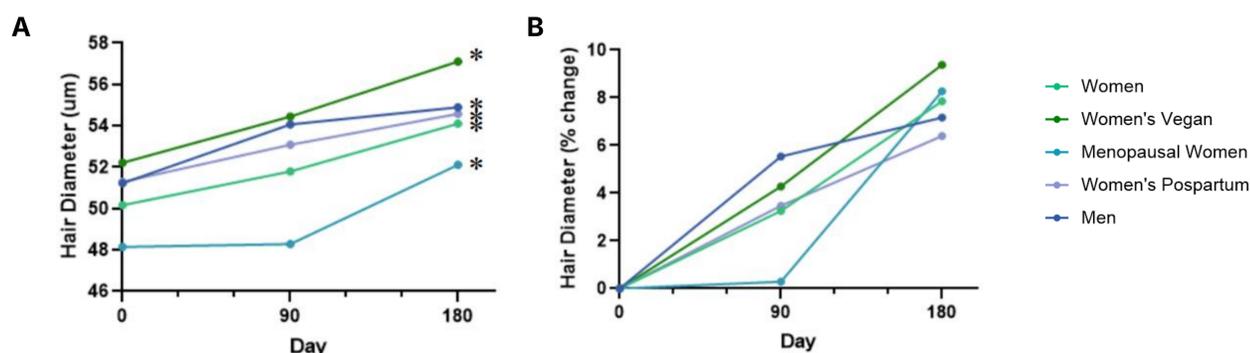
Figure 1. All formulas produced a statistically significant increase in hair diameter at day 180 compared to baseline (figure 1A). Subjects in the W group increased by 8% (4 ± 10 μm), V by 9% (+5 ± 7 μm), MW by 8% (4 ± 9 μm), PP by 6% (3 ± 7 μm), and M by 7% (+4 ± 1 μm), (figure 1B).

Hair Pull Test

The total number of hairs removed was lower at day 180 than baseline in all groups, with significance compared to baseline seen in the W, V, and MW categories. There were also decreases in all groups in broken hairs, with significance compared to baseline found among the W and MW participants.

Investigator Rated Hair Parameters
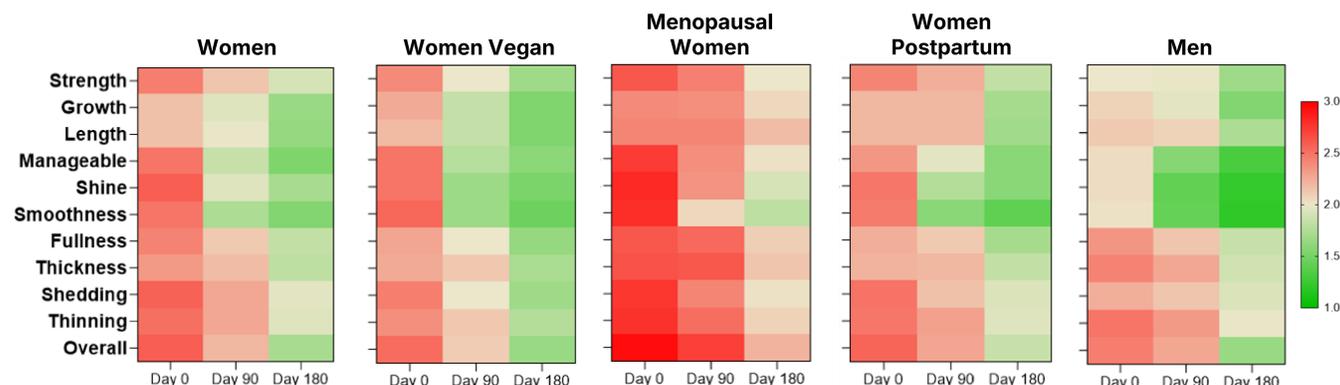
Figure 2. Heat maps showing average investigator ratings over the course of the study for each parameter. Ratings in all groups and all parameters progressively improved throughout the duration of the study, and all evaluated parameters were significantly improved at day 180 compared to baseline (p<0.01 for all).

Participant Self-Perception Questionnaire

Statement	Percent Agreeing with the Statement, Day 180				
	W	V	MW	PP	M
My hair is less dry/brittle.	92%	93%	94%	94%	96%
My hair quality improved.	96%	96%	94%	94%	98%
The appearance of my hair improved.	96%	98%	92%	94%	94%
My hair looks healthier.	94%	98%	96%	98%	92%
My hair volume improved.	84%	87%	90%	82%	73%
My hair is shedding less.	82%	98%	88%	88%	80%
My baby hairs are growing out.	92%	96%	90%	92%	80%
My hair strength improved.	96%	96%	92%	92%	86%
My hair is growing longer.	94%	91%	80%	88%	73%
My hair thickness/fullness improved.	88%	93%	90%	86%	88%
My scalp coverage improved.	90%	85%	88%	86%	67%
My part line looks thicker/fuller.	88%	89%	92%	84%	65%
My hairline looks thicker/fuller.	90%	85%	88%	86%	67%
My hair thinning is slowing down.	94%	96%	92%	90%	88%

Table 1. Percent of subjects reporting agreement with the question. A significant proportion of subjects in each group agreed with each of the statements at day 180 (p<0.001 for all).