

# A Six-Month, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of a Nutraceutical Supplement for Promoting Hair Growth in Women With Self-Perceived Thinning Hair

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## ABSTRACT

Hair loss is a complex problem that generates significant concern for those who are affected. Patients seeking medical treatments have limited options, and are increasingly turning to natural therapies. A novel nutraceutical product containing a proprietary Synergen Complex<sup>®</sup> composed of standardized, active botanicals with potent anti-inflammatory, adaptogenic (anti-stress), antioxidant, and dihydrotestosterone-inhibiting properties has been developed to improve hair growth and hair quality.

The objective of this 6-month randomized, double-blind, placebo-controlled study was to assess the ability of this oral supplement (Nutrafol<sup>®</sup> Women's Capsules) to strengthen and promote the growth of hair in adult women with self-perceived thinning. Enrolled subjects were randomized to receive active treatment (n=26) or placebo (n=14). The primary endpoint in this study was a statistically significant increase in the number of terminal and vellus hairs based on phototrichograms obtained through macrophotography analysis.

Daily intake of the nutraceutical supplement resulted in a significant increase in the number of terminal and vellus hairs in the target area at day 90 and day 180 vs placebo ( $P < 0.009$ ). Blinded Investigator Global Hair Assessments revealed significant improvements in hair growth ( $P = 0.016$ ) and overall hair quality ( $P = 0.005$ ). A significant percentage of subjects receiving active treatment also reported improvement in hair growth, volume, thickness, and hair growth rate, as well as decreased anxiety and other wellness parameters. There were no reported adverse events.

**Conclusion:** This nutraceutical supplement safely and effectively promoted hair growth in women with self-perceived thinning. It provides a multi-targeted therapeutic approach to hair loss by addressing micro-inflammation, stress, and oxidative damage with clinically tested, standardized, and bio-optimized phytoactive ingredients. ClinicalTrials.gov: NCT03206567

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## INTRODUCTION

Hair loss is a chronic and progressive condition affecting at least 50% of women by age 50.<sup>1-4</sup> The most common cause of hair loss, androgenetic alopecia (female pattern hair loss), affects at least 40% of women, and will progress without treatment.<sup>2,5</sup> Effectively treating it is important because hair loss can have a significant psychological impact resulting in symptoms of depression<sup>3</sup> and diminished quality of life, especially in women.<sup>6-8</sup> Women of all ages can be affected and the presentation of thinning in women usually differs from men in that it is diffuse. Even sub-clinical hair thinning and increase in shedding may be an early stage in the gradual process of female pattern hair loss.<sup>9</sup> Despite much research on the subject, the complex pathophysiology of hair loss in women is still not fully understood, which is reflected in the currently limited therapeutic options.

Traditionally, alopecia has been sub-classified to reflect morphology and etiology, scarring vs non-scarring, hereditary vs acquired,

and inflammatory vs non-inflammatory. As a result, the only available therapeutics were developed to address singular targets and mechanisms, such as the case with anti-androgen therapies (finasteride, spironolactone, etc) and vasodilator minoxidil.

Unfortunately, many of these medications represent potential reproductive dangers<sup>10</sup> and the quality of evidence supporting their use in women is generally poor.<sup>11</sup> The application of topical minoxidil, which is the only US Food and Drug Administration (FDA)-approved drug for treatment of hair loss in women, is found to be difficult to incorporate into daily hair-care routines. It may also cause growth of facial hair, as well as irritant or allergic dermatitis to vehicles in topical minoxidil preparations.<sup>12,13</sup>

New research indicates however that hair loss is not the result of one singular pathway. Androgens are not the sole player in this much larger picture, and neither is simple nutritional

deficiency, especially when it comes to women. As the complexity of follicle biology comes to light, so does the understanding that hair loss in women is the result of an accumulation of multiple factors caused by intrinsic and extrinsic triggers including hormonal fluctuations, genetics, diet, oxidative damage and aging, and environmental aggressors (eg, ultraviolet light and pollutants), as well as mediators of psycho-emotional stress (eg, cortisol).<sup>4,14-20</sup>

Compounded, these factors lead to dysregulation of complex follicle immunology and biology, affecting the follicle through increased expression of pro-apoptotic and pro-inflammatory cytokines, perifollicular micro-inflammation, and release of reactive oxygen species.<sup>14,18,19</sup> The acceptance of this multi-factorial nature driving hair loss requires that any effective therapeutic approach should be multi-targeted against not only the intrinsic and extrinsic factors, but also

downstream mediators of inflammation and oxidative damage.<sup>4</sup>

A novel nutraceutical supplement has been developed to provide a multi-modal approach to thinning in women (Nutrafol® Women's Capsules). It features the Synergen Complex®, a composition of standardized phytoactives with clinically tested anti-inflammatory, stress-adaptogenic, antioxidant, and dihydrotestosterone (DHT)-inhibiting properties. The featured phyto-compounds include curcumin, ashwagandha, saw palmetto, and tocotrienols – all bio-optimized for increased bioavailability.<sup>21</sup>

The objective of this 6-month randomized, double-blind, placebo-controlled study was to evaluate safety and determine whether the daily use of this novel nutraceutical supplement will strengthen and promote the growth of hairs (terminal and vellus) in adult women with self-perceived thinning hair.

**TABLE 1.****Subject Self-Assessment Questionnaire**

*Instructions: Please complete the following questions by circling the number in the column which best describes your opinion of the change you have seen throughout the duration of the study (compared to baseline) for each characteristic.*

	Greatly Improved	Moderately Improved	Slightly Improved	No Change	Slightly Worsened	Moderately Worsened	Greatly Worsened
Overall hair growth	+3	+2	+1	0	1	2	3
Overall hair volume	+3	+2	+1	0	1	2	3
Scalp coverage	+3	+2	+1	0	1	2	3
Thickness of hair body	+3	+2	+1	0	1	2	3
Hair amount	+3	+2	+1	0	1	2	3
Hair quality	+3	+2	+1	0	1	2	3
Hair color	+3	+2	+1	0	1	2	3
Hair dryness	+3	+2	+1	0	1	2	3
Hair shine	+3	+2	+1	0	1	2	3
Hair strength	+3	+2	+1	0	1	2	3
Hair breakage	+3	+2	+1	0	1	2	3
Softness of hair body	+3	+2	+1	0	1	2	3
Hair shedding/loss	+3	+2	+1	0	1	2	3
Amount of noticeable new hair	+3	+2	+1	0	1	2	3
Hair growth rate	+3	+2	+1	0	1	2	3
Hair length (ability to grow longer than usual)	+3	+2	+1	0	1	2	3
Ease of styling	+3	+2	+1	0	1	2	3
Overall hair appearance (does hair sit better on head)	+3	+2	+1	0	1	2	3
Sleep Quality	+3	+2	+1	0	1	2	3
Stress Levels	+3	+2	+1	0	1	2	3
Anxiety Level	+3	+2	+1	0	1	2	3
Overall Well-Being	+3	+2	+1	0	1	2	3
Nail strength	+3	+2	+1	0	1	2	3
Nail Growth rate	+3	+2	+1	0	1	2	3
Growth of Eyebrow hair	+3	+2	+1	0	1	2	3
Growth of eyelashes	+3	+2	+1	0	1	2	3
Skin smoothness	+3	+2	+1	0	1	2	3
Overall skin health	+3	+2	+1	0	1	2	3

TABLE 2.

**Subject Ease of Use Questionnaire**

*Instructions: Please check the box which most accurately describes your response to the usage questions related to the investigational products taken during the course of your participation in the study*

	Yes	No
Was it easy/convenient to add the capsules to your daily routine?		
Was it more convenient to take the capsules once a day than to apply a topical product to your scalp once or twice a day?		
Do you feel more comfortable taking a natural supplement over a drug for your hair loss?		
Would you recommend this solution to any of your friends who suffer from hair loss?		

**METHODS****Study Subjects**

Eligible subjects were healthy women 21 to 65 years old with Fitzpatrick skin types I to IV and self-perceived thinning hair, as confirmed by the investigator. Subjects agreed to follow study procedures, provide a negative pregnancy test, and use a sound method of contraception (if within childbearing years), as well as maintain their current diet, medications, exercise routines, hair shampooing, and color treatment frequency for the duration of the study. The study was approved by an institutional review board and conducted in compliance with good clinical practice. All participants provided written informed consents prior to participating.

Reasons for exclusion from study participation included: participation in other clinical research; pregnancy or nursing; recent (<6 months) initiation of hormones for birth control or hormone replacement therapy; current use of treatments for thinning hair including minoxidil or light therapy within the last 3 months; or other medications that are known to cause hair loss or affect hair growth (eg, cyproterone acetate, aldactone/spironolactone, 5-alpha-reductase inhibitors) within the last 6 months. Also excluded were subjects with a self-reported history of uncontrolled diseases (eg, diabetes, hyperthyroidism, hypothyroidism); with bleeding/platelet disorders or on anticoagulant therapy; or with the presence of other hair loss disorders and active dermatologic

or other health conditions that, in the opinion of the investigator, might place the subject at risk or interfere with the study treatment and clinical evaluations.

**Test Material**

Subjects were randomized in a double-blinded fashion 2:1 to receive a novel oral nutraceutical supplement (Nutrafol Women's Capsules; Nutraceutical Wellness, Inc., New York, NY) or placebo. The investigational product contains a patent-pending Synergen Complex, a proprietary blend of standardized clinically-tested and bio-optimized phytoactive extracts, and additional vitamins, minerals, and botanicals. Some of the key ingredients in the supplement include standardized extracts of ashwagandha, curcumin, saw palmetto, tocotrienol-rich tocotrienol/tocopherol complex, piperine, and capsaicin, as well as hydrolyzed marine collagen, hyaluronic acid, and organic kelp. Placebo treatment consisted of inert capsules with same appearance. Subjects were instructed to take 4 capsules of their assigned treatment once daily with a meal or immediately following a meal at approximately the same time each day.

**Study Procedures**

The study consisted of 3 clinic visits at baseline, day 90, and day 180. The investigator performed a physical examination at each visit, which included a basic body systems overview, vital signs, and scalp examination to rule out possible confounding scalp conditions. A urine pregnancy test was obtained from women of childbearing years. Subjects were also queried on general lifestyle practices, including exercise, smoking, alcohol, diet, and stress.

During the baseline visit, a 1 cm<sup>2</sup> target area was selected on the anterior lateral triangle of the scalp along the frontalis bone where the frontal and lateral hairlines meet. This area was recorded for further assessments using a 3-point location based on measurements taken from the medial canthus, lateral canthus, and preauricular skin pit to the hairline junction. The target area was marked with the center indicating the 3-point triangulation point.

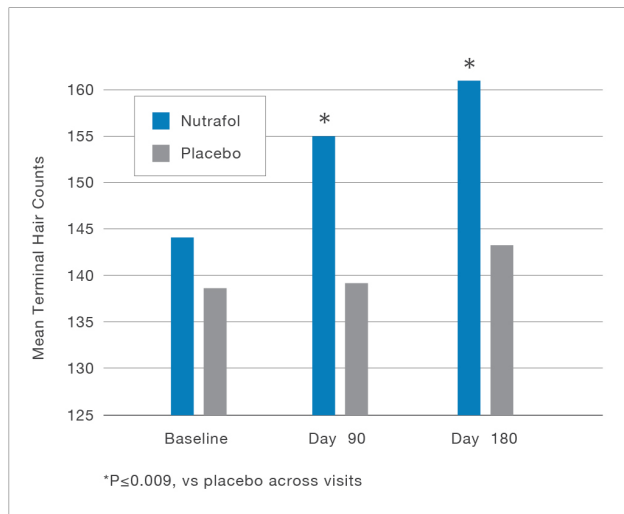
TABLE 3.

**Mean Target Area Hair Counts**

	Study Medication [Nutrafol]			Placebo		
	Day 0	Day 90	Day 180	Day 0	Day 90	Day 180
<b>Terminal Hairs</b>	141.7 (11.5)	151.4 (16.3) <sup>a</sup>	156.4 (16.4) <sup>b</sup>	136.5 (12.7)	137.5 (9.6)	141.3 (14.5)
<b>Vellus Hairs</b>	13.3 (2.4)	14.6 (1.9) <sup>c</sup>	15.4 (1.9) <sup>d</sup>	13.5 (2.1)	13.1 (2.0)	13.2 (1.5)
<b>Total Hair Count</b>	155.0 (13)	166.0 (17.4) <sup>e</sup>	171.8 (17.9) <sup>f</sup>	150.0 (14.3)	150.6 (11.2)	154.5 (15.5)

<sup>a</sup>p=.009, <sup>b</sup>p=.006, <sup>c</sup>p=.000, <sup>d</sup>p=.000, <sup>e</sup>p=.003, <sup>f</sup>p=.002, each vs. placebo across visits

**FIGURE 1.** Active treatment resulted in significant improvement in the growth of terminal hairs, as indicated by mean target area terminal hair counts increasing from 141.7 at baseline to 151.4 at day 90 and 156.4 at day 180.

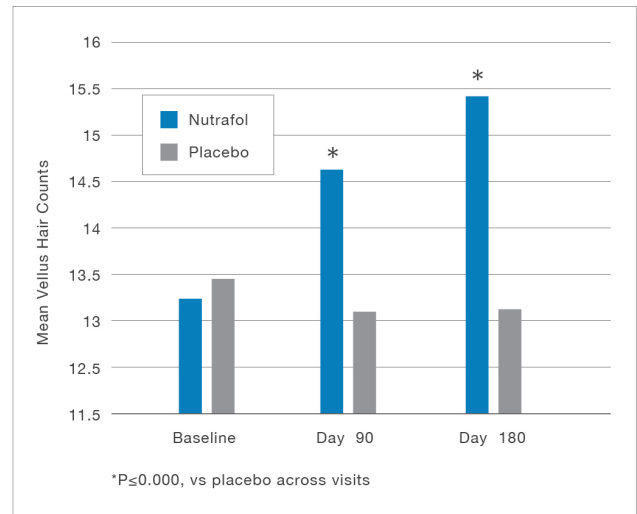


Phototrichograms were taken of the target area at each visit using macrophotographs (Canon PowerShot® G16 digital camera and 3GEN DermLite® FOTO Pro dermoscopy lens). A 2cm<sup>2</sup> marking template placed around the triangulation point and target area was used for creating the bundle of hair to be measured for hair mass index (HMI) (HairCheck™, Divi International Co.) at each visit. Ten terminal hairs were randomly selected at the border of the area and cut at the base of the scalp, and the mean diameter of the hairs was measured at each visit using microscopic digital images (Dino-Lite Digital Microscope; AnMo Electronics Corporation). At each study visit, 2-D standardized global photographs (6 views) were obtained of the entire head, scalp, and target area using standardized lighting and set-up (IntelliStudio® System; Canfield Scientific, Inc.) All 2-D images were used to assist in grading overall general hair growth, hair quality, coverage, and fullness assessments.

At visits 2 and 3, with the assistance of global photographs, the blinded investigator assessed Global Hair Growth and Global Hair Quality Improvement (hair brittleness, dryness, texture, shine, scalp coverage, and overall appearance) compared with baseline. Scoring was based on a 7-point scale where -3=greatly decreased/worsened, -2=moderately decreased/worsened, -1=slightly decreased/worsened, 0=no change, +1=slightly increased/improved, +2=moderately increased/improved, and +3=significantly increased/improved.

Subjects completed the Women's Hair Loss Quality of Life (QOL)<sup>22</sup> on all visits, and the Self-Assessment questionnaire (SAQ) (Table 1) and Ease of Use questionnaire (Table 2) at day 90 and day 180.

**FIGURE 2.** Active treatment resulted in a significant improvement in the growth of vellus hairs, as indicated by mean target area vellus hair counts increasing from 13.3 at baseline to 14.6 at day 90 and 15.4 at day 180. Placebo resulted in a decrease in hair counts.



## Study Endpoints

The primary endpoints were increase in terminal, vellus, and total hair counts at 3 and 6 months, as analyzed through phototrichograms. The secondary endpoints were improved grading on the blinded Investigator Global Hair Assessments for hair growth and hair quality, changes in terminal hair diameter and bundle measurements, and responses on the subject SAQ, Ease of Use, and QOL. Safety endpoints were changes in physical exam and queries on potential adverse events (AEs).

## Method of Data Analysis

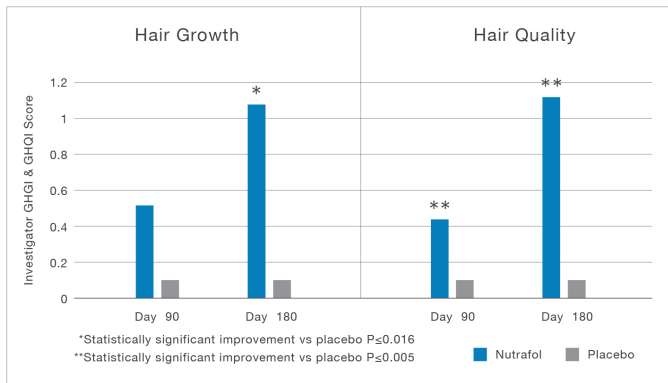
Statistical analysis: Descriptive statistics were obtained for all variables. Tests of normality of continuous measures and homogeneity of variance were performed. Changes from baseline hair growth, hair diameter, hair counts, total score for QOL responses, and SAQ responses were tested using analyses of variance with repeated measurements. Changes in QOL and SAQ items were also tested using Chi-square. All statistical tests were two-tailed. Differences were considered statistically significant at the level of a *P* value of *P*≤0.05.

## RESULTS

### Demographics and Baseline Characteristics

Subjects in the active treatment group (n=26) and placebo group (n=14) had mean (SD) ages of 48.3 (10.5) years and 53.14 (5.7) years, respectively, which were not significantly different. Two subjects identified themselves as Asian, 32 as Caucasian, and 6 as Hispanic. The 2 groups were not significantly different with respect to race/ethnicity or skin types, and were not different with respect to main study outcomes including the number of terminal hairs in the target area, the number of vellus hairs

**FIGURE 3.** Investigator Global Hair Growth Improvement (GHGI) and Global Hair Quality Improvement (GHQI) Scale scores significantly improved for subjects treated with active product vs placebo at day 90 and day 180.



in the target area, HMI, or mean hair diameter measurements. The 2 groups did not demonstrate any significant differences in lifestyle attributes or baseline mental attitude qualities except for a higher level of stress among subjects in the placebo group (42.3% vs 78.6%;  $P=0.028$ ). All the significant findings reported below were unchanged even after controlling for their initial level of stress using repeated measures (RM)-ANOVA.

### Primary Endpoints

There was a significant difference between groups for the number of terminal ( $f_{2,74}=6.61$ ,  $P=0.004$ ), vellus ( $f_{2,74}=12.29$ ,  $P<0.0001$ ), and total hair counts ( $f_{2,74}=9.11$ ,  $P<0.001$ ) in the target area across all visits. The mean target area hair counts for these endpoints are summarized in Table 3. There were significant improvements at both day 90 and day 180 over baseline for the active group compared with placebo group for these 3 measurements (all  $P$  values  $P<0.009$ ).

Figures 1 and 2 demonstrate improvements in terminal and vellus hair growth. The increase in terminal hair counts translated into a significant improvement of 6.8% by day 90 and 10.4% by day 180 from baseline for the active treatment group vs a negligible improvement of 0.07% and 3.5% for the placebo group. For vellus hair counts, the improvement from baseline for the active treatment group was 10.1% by day 90, increasing to 15.7% by day 180. The placebo group resulted in a decrease of vellus hair counts by -2.9% at day 90 and -2.2% at day 180. Similarly, the increase in total hair counts for the active treatment group represented a change of 7.1% at day 90 and 10.8% at day 180 from baseline, while placebo group improvement was negligible at 0.4% and 3% respectively.

### Secondary Endpoints

#### Blinded Investigator Global Hair Assessments

There was a significant and progressive improvement for the active group compared with the placebo group across visits on both

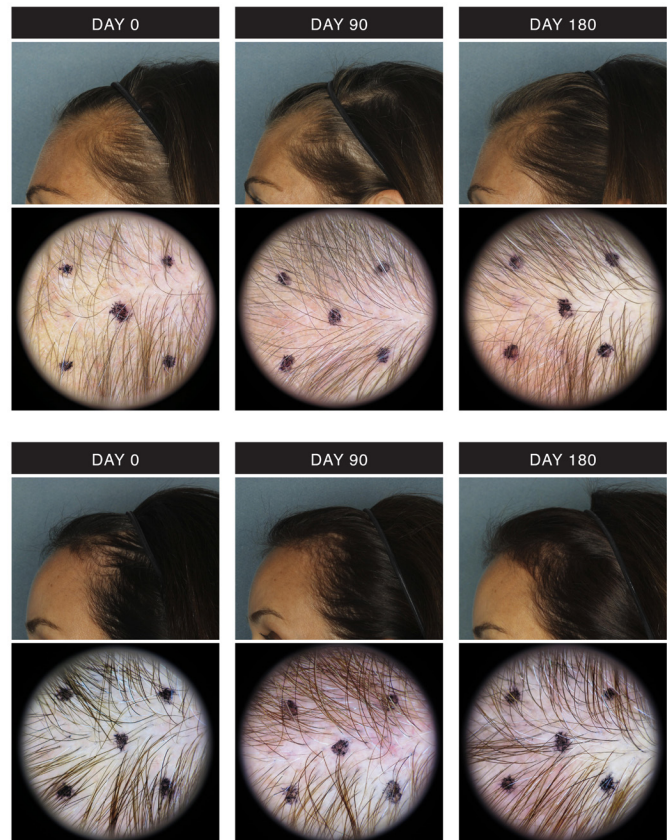
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**FIGURE 4.** Improvement in hair growth for 2 representative subjects treated with the active product. **Top Row:** Global photographs of target area showing visible clinical improvement from baseline (left), to day 90 (center) to day 180 (right). **Bottom Row:** Macro photographs of selected target area at baseline (left), day 90 (center), day 180 (right).



Hair Growth and Quality scales. At day 180, the mean (SD) hair growth improvement score was 1.08 (1.1) for the active treatment group vs 0.08 (0.76) for the placebo group ( $f_{1,37}=6.43$ ,  $P=0.016$ ) and the mean hair quality improvement scores were 1.12 (0.87) for the active treatment group vs 0.08 (0.76) for the placebo group ( $f_{1,37}=8.76$ ,  $P=0.005$ ). These results are shown in Figure 3. There was a strong trend for HMI improvement for the active group compared with the placebo group ( $f_{1,27}=3.51$ ,  $P=0.069$ ). There were no significant changes in mean hair diameter.

#### Self-Assessment Questionnaire

For subjects in the active group compared with placebo there were significant improvements in hair breakage (active: day 90=.31; day 180=.69; placebo: day 90=.85; day 180=.15;  $f_{1,37}=11.3$ ,  $P=0.002$ ) and anxiety levels (active: day 90=.42; day 180=.15; placebo: day 90=-.23; day 180=.08;  $f_{1,37}=5.37$ ,  $P=0.026$ ).

In order to examine the improvement at the end of study, the percentage of subjects who rated themselves as *improved* (slightly improved to greatly improved) were compared with

TABLE 4.

## Subject Self-Assessment Results

% of Nutrafol Subjects Improved at Day 180	Quality
80.8%*	Overall hair growth
73.1%*	Overall hair volume
80.8%*	Thickness of hair body
23.1%*	Hair color
76.9%*	Amount of noticeable new hair
73.1%*	Hair growth rate
15.4%*	Stress level
15.4%*	Anxiety level
15.4%*	Sleep quality
19.2%*	Overall well-being
23.1%*	Skin smoothness
26.9%*	Overall skin health

\*Statistically significant improvement  $P \leq 0.05$ 

Percentage of subjects reporting improvement with active treatment at 6 months.

those rated as *no improvement* (no change to greatly worsened) for each question. Among those randomized to active treatment, 21 (80.8%) reported significant improvement in thickness of hair body compared with 6 (46.2%) of placebo-treated subjects ( $\chi^2=4.88$ ,  $df=1$ ,  $P=.027$ ). Furthermore, among those randomized to active treatment, a significant number of subjects improved in overall hair growth, overall hair volume, hair color, amount of noticeable new hair, hair growth rate, stress levels, anxiety levels, sleep quality, overall well-being, skin smoothness, and overall skin health (all  $P < .05$ ). Percentage improvement in the active group is summarized in Table 4.

*Subject Ease of Use Questionnaire*

At the end of study, 84.6% of the active subjects found it easy to add the capsules to their daily routine and found it more convenient to take capsules vs using a topical application. 88.5% preferred taking a natural supplement. 73.1% would recommend it to their friends suffering from hair loss.

*Women's Hair Loss Quality of Life Questionnaire*

There were no significant differences between the 2 groups for the total score. In order to examine the improvement, the percentage of subjects who rated themselves as *improved* (a lot to very much) and those who rated *no improvement* (not at all to a little) was computed for each item. At the end of

TABLE 5.

## Quality of Life Results

% of Nutrafol Subjects Improved at Day 180	Quality
47%* (P=0.014)	My condition impacts my self esteem
33%* (P=0.007)	My condition makes me feel self conscious about my thinning hair
50%* (P=0.008)	Because of my thinning hair, I fear being the center of attention
73%* (P=0.032)	Because of my thinning hair, I am less outgoing than I would like to be
47%* (P=0.007)	Because of my thinning hair, I feel unattractive
53% (P=0.067)	I am embarrassed by my thinning hair
67% (P=0.076)	Because of my thinning hair, I avoid social gatherings
67% (P=0.065)	I feel my thinning hair is affecting my personal relationships

\*Statistically significant improvement within the Nutrafol group vs baseline  $P \leq 0.03$ 

Percentage of subjects reporting improvement with active treatment at 6 months.

the study (day 180) there were significant improvements compared with baseline for the active group subjects on 5 out of 15 items, including how the condition impacts self-esteem, self-consciousness, and feelings of unattractiveness. There were strong trends for 3 more items. None of these changes were significant for the placebo group. These results are summarized in Table 5.

*Safety*

No treatment-related AEs were reported during the study.

**DISCUSSION**

The results of this study showed that the administration of a novel supplement with Synergen Complex to women with thinning hair was safe and effective. The results showed a significant increase in the number of terminal, vellus and total hair counts at 3 months, with further improvement by 6 months of use vs placebo, which did not result in significant growth. These measurements were accompanied by significant and progressive visible clinical improvement in hair growth and hair quality for the treatment group, as determined by a blinded investigator. These outcomes demonstrated a steady improvement from baseline to day 90 to day 180, suggesting that improvement may progress with continued treatment. There was also a strong trend in the HMI, and while the mean diameter measurements did not reach statistical significance, the trends indicate that it would likely be significant with a larger sample size.

The perception of hair loss for an individual can be distinct from clinical diagnosis and the observations of the treating physician.<sup>20,23</sup> While not life-threatening, it can have severe

consequences on a woman's self-esteem and quality of life, and may even lead to depression.<sup>3</sup> In this study, a significant percentage of subjects taking the supplement reported improvements in hair parameters, such as hair growth, thickness, and overall hair volume. Additionally, there was a significant improvement in wellness measures, such as anxiety levels, stress, and overall well-being. A significant percentage also reported improvements on 5 out of 15 QOL items, indicating improvement in feelings of self-consciousness, attractiveness, and self-esteem.

The stress of hair loss is further compounded by a lack of available treatment options. Many women find using minoxidil, the only FDA-approved treatment, to be difficult for daily application. In this study, the overwhelming majority of subjects taking the active product not only found it to be more convenient to incorporate into their daily routine over using a topical application, but also preferred taking a natural alternative – underscoring the increasing interest of patients turning to nutritional vitamins. This further emphasizes the importance of both physicians and patients to be cautious, selective, and knowledgeable about using supplements that have clinical data on phytoactive activity, bioavailability, standardized dosing, and potency.

While the full etiology of many types of hair loss remains unknown, it is clear that it is multi-factorial and addressing only nutrition or singular molecular pathways is not enough.<sup>4</sup> Increasingly studies show that, especially in women, multiple molecular pathways and factors including inflammation, dihydrotestosterone, aging, oxidative damage, and mediators of chronic stress play a significant role in compromising follicle activity.<sup>14-17,20</sup>

Botanicals in the Synergen Complex provide a unique therapeutic value because of their multi-modal clinical biological activity against these multiple molecular and environmental causative factors of hair loss. Their advanced patented extraction technology is improved for bio-optimization, standardization and bioavailability.<sup>21,24-26</sup> Standardized ingredients like curcumin and ashwagandha have been shown to lower inflammatory biomarkers such as C-reactive protein (CRP).<sup>27,28</sup> Curcumin inhibits factor NF- $\kappa$ B, decreasing the inflammatory pro-apoptotic cytokines TNF- $\alpha$  and interleukin 1 that induce catagen and follicular regression.<sup>29,30</sup> It has also been shown to have effect against androgens and androgen-induced downstream TGF- $\beta$  signaling that is implicated in follicular miniaturization and fibrosis.<sup>29,31,32</sup> This complements the documented anti-androgenic effects of another ingredient, saw palmetto, in hair loss.<sup>24</sup> Curcumin up-regulates transcription factor nuclear factor erythroid-like-2 (Nrf-2), which increases synthesis of endogenous antioxidants like glutathione and hemoxygenase 1, improving cellular defenses against oxidative stress.<sup>33</sup>

Ashwagandha, used in Ayurvedic medicine to build resistance to stress, contains steroidal lactones (withanolides) and other alkaloids that can mimic certain corticosteroids, interact with steroid receptors, and modulate cortisol levels, thereby improving the stress response.<sup>34</sup> Daily administration of the standardized ashwagandha in the Synergen Complex was shown to significantly reduce cortisol levels in chronically stressed adults<sup>35</sup> – providing the only available potential option for addressing the impact of psycho-emotional stress in hair loss. Accordingly, in the current study, subjects taking the investigational product reported significantly less anxiety.

These results support the results of other studies demonstrating the efficacy of oral administration of several ingredients found in the active treatment (*Serenoa repens*, tocotrienols) to improve the growth and hair quality in men and women.<sup>24,25</sup> The biological and clinical activity of these ingredients was discussed in detail in a recent article published in the *Journal of Drugs in Dermatology* by PK Farris et al.<sup>21</sup>

## CONCLUSION

The results of this study demonstrate the ability of a novel standardized nutraceutical supplement to significantly increase the number of terminal and vellus hairs based on macrophotography analysis, and significantly increase hair growth and hair quality based on Blinded Investigator Global Hair Assessments. No AEs or side effects were reported and the supplement was found to be well tolerated and easily incorporated into daily routines. It was additionally found to enhance subjects' QOL and self-perceived hair parameters.

## DISCLOSURES

Dr. Glynis Ablon received a research grant for the study. Dr. Sophia Kogan is a researcher at Nutraceutical Wellness, Inc.

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