







Research Article

A Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Assess the Efficacy of a Nutritional Supplement in Female Androgenic Alopecia

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Introduction. Androgenetic alopecia (AGA), the most common form of hair loss in women, is characterized by progressive hair thinning and loss of terminal hairs over frontal and parietal regions of the scalp. This study aimed to evaluate the efficacy of the nutritional supplement Pilopectan® WOMAN 5αR (PPT5α) composed of specific plant extracts, vitamins, and minerals in women with initial to moderate AGA. **Methods.** This was a prospective, randomized, double-blind, placebo-controlled clinical trial study. Forty-seven women (aged 25–59 years) with AGA grade I/II were randomized to daily receive PPT5α ($n = 24$) or placebo ($n = 23$), and the treatment safety, as well as the percentages of terminal hair in frontal and parietal areas from trichoscopic images, was assessed at 0, 3, and 6 months. Secondary outcomes included self-assessed hair parameters and overall treatment satisfaction. **Results.** A total of 44 women completed the study. At 6 months, patients who received the nutritional supplement showed high percentages of terminal hair both in the frontal (77.6% vs 69.8%, $p = 0.02$) and parietal (77% vs 64.3%, $p = 0.02$) areas compared to the placebo group. Self-assessed evaluation of hair parameters showed an improvement in the reduction of hair loss and hair thickness both at the 3-month ($p = 0.004$ and $p = 0.012$) and 6-month ($p = 0.009$ and $p = 0.004$) visits. At the 3 month visit, the intervention group also showed higher treatment satisfaction ($p = 0.01$). No significant adverse events were reported. **Conclusion.** These results evidence that the nutritional supplement PPT5α may be beneficial in preventing progression or even improving the condition of AGA in the early stages.

1. Introduction

Androgenetic alopecia (AGA) is the most common cause of hair loss in both males and females and is the combined result of an androgen-dependent process and genetic factors [1, 2]. It is characterized by progressive follicular miniaturization and an increased telogen phase, with the subsequent reduction in the number of hairs [3]. The onset of hair thinning in women may occur at any age after puberty, with the incidence increasing with age [2], but in recent years, its appearance has also been observed at early ages

[4, 5]. In females, it is presented as a diffuse hair loss over the central scalp, and the frontal hairline is usually spared (rarely leading to total baldness), while in males, hair loss is most prominent in the vertex and frontotemporal regions. While alopecia is considered a mild skin disease, hair loss has a negative effect on self-image and self-esteem, leading to anxiety and depression, with women reporting a high impact on quality of life [6]. At present, topical minoxidil and oral finasteride are the only treatments approved by the Food and Drug Administration (FDA) for AGA treatment [7]. Minoxidil is a potassium channel opener with vasodilatory

effects that promotes hair growth by increasing the duration of the anagen phase and promoting angiogenesis in the surrounding hair follicles [8]. On the other hand, finasteride acts as a competitive and specific inhibitor of type II 5 α -reductase, thereby preventing the conversion of testosterone to dihydrotestosterone (DHT) [9]. Despite their effectiveness, both treatments have associated adverse events (AEs) [7, 9, 10]. Topical minoxidil AEs include irritant and allergic contact dermatitis, pruritus, scalp irritation, and facial hypertrichosis [7], while those of oral finasteride include anxiety, depression, memory disturbance, headache, impotence, erectile dysfunction, and loss of libido [9]. Consequently, there is an unmet need for effective treatments and alternative therapies that improve patients' hair loss.

Nutrition has a profound impact on the quantity and quality of hair, as evidenced by cases of hair loss caused by severe malnutrition [11, 12]. Normal supply, uptake, and transport of proteins, calories, trace elements, and vitamins are crucial in tissues with high biosynthetic activity such as the hair follicle [11]. For instance, protein is essential for the production of healthy hair considering that the hair shaft is made up almost completely of keratin protein. Pilopectan® Woman 5 α R (PPT5 α) is a nutritional supplement specially formulated to treat hair loss caused by androgenic alopecia in women. PPT5 α components include plant extracts *Serenoa Repens* L. (saw palmetto berry extract) and *Cucurbita Pepo* L. (pumpkin seed oil), which have demonstrated inhibitory effects on 5 α -reductase [13, 14]; collagen, which strengthens the attachment of hair to the follicle [15] and plays a role in hair follicle aging [16]; vitamin E and B and zinc, which provide nutrition and antioxidant benefits; and sulfur-containing amino acids, L-cystine and L-methionine, which are involved in the formation of keratin, the hair's structural protein. The effects of vitamins, minerals, and plant extracts from nutritional supplements on hair loss are still barely understood, and therefore, more scientific evidence is needed. Accordingly, the aim of the present study was to evaluate the efficacy of the nutritional supplement PPT5 α in the treatment of female AGA grade I/II using a randomized, double-blind, placebo-controlled clinical trial. In addition, we assessed the patient's satisfaction with the treatment as well as the effect of the treatment on the patient's self-perception of hair parameters.

2. Materials and Methods

2.1. Study Design. This is a randomized, double-blind, placebo-controlled clinical trial to assess the degree of efficacy and safety of the nutritional supplement Pilopectan® WOMAN 5 α R (PPT5 α) over a period of 6 months in women with androgenic alopecia grades I and II, according to Sinclair's scale, a 5-point visual analogue midscalp clinical grading scale [17]. Secondary objectives were to evaluate hair cosmetics, treatment satisfaction, perception, and time to improve. The included patients were assessed in one control visit at baseline (T0) and another control visit at the end of the study (6 months, T6). In addition, one scheduled telephone call at 3 months (T3) was performed. The study was conducted at the Dermatology Department of the Ramón y

Cajal University Hospital (Madrid, Spain) between December 2021 and August 2022. The study was in compliance with the Declaration of Helsinki and was evaluated and approved by the local Ethics Committee of Hospital Universitario Ramón y Cajal in Madrid (approval code number: ALOPILOP 06-2020). The sample size was calculated using an online calculator, considering a confidence level of 95% and a margin error of 5%.

2.2. Study Population. Patients who fulfilled all the inclusion criteria and none of the exclusion criteria were included in the study. The inclusion criteria were as follows: women with grade I and II androgenic alopecia as defined by dermatologists of the Dermatology Department of the Ramón y Cajal University Hospital and according to Sinclair's scale, being aged between 25 and 60 years, and who signed informed consent. The exclusion criteria were as follows: patients with any other type of alopecia, hyperandrogenism, patients under systemic hormonal treatment including contraceptives, patients with gestational desire, patients with telogen effluvium, acute or chronic, and patients diagnosed with thyroid disorders or hypersensitivity to any ingredient.

2.3. Intervention. The enrolled participants were randomized using simple randomization and allocated in a 1:1 ratio to receive for a 6-month time period either a daily oral tablet of Pilopectan® WOMAN 5 α R as the intervention group or a placebo as the control group. To maintain allocation concealment, randomization was based on the codes created by the sponsor to prevent investigators and patients from predicting the treatment arms. These codes were the only information to identify whether the product belonged to the active or placebo groups. The nutritional supplement and placebo were packaged in anonymous blisters and white boxes and subsequently labeled. When participants attended their scheduled follow-up appointments at the clinic, it was required for them to bring along the blister packs. This procedure aimed to evaluate their nutritional supplement consumption and ascertain whether any tablets were left unused. The composition of PPT5 α is listed in Table 1. Patients were evaluated at baseline and at three and six months.

2.4. Outcome Measures. The primary outcome of the clinical trial was the safety and efficacy of PPT5 α improving female androgenic alopecia. To evaluate efficacy objectively, clinical and trichoscopic photographs were taken at standardized scalp points at baseline and at 6 months visits by using a FotoFinder® image system, and images were evaluated by an independent, blinded investigator using systematized analysis software (Trichoscale®). Variables analyzed were the percentage of terminal and vellus hair. Evaluation of the safety and tolerance of PPT5 α was assessed by the collection of undesired side effects by the investigator and the patients by means of a data collection logbook in each control visit and scored on a 3-point scale (1 = mild, 2 = moderate, and 3 = intense side effects). Secondary

TABLE 1: Composition of Pilopectan® Woman 5αR (PPT5α).

Nutritional information	Per tablet
Vitamin B3	16 mg
Vitamin B5	6 mg
Vitamin B6	1.4 mg
Vitamin B7 (biotin)	50 μg
Vitamin E	12 mg
Zinc	10 mg
L-Cystine	50 mg
L-Methionine	50 mg
Extract of <i>Serenoa repens</i>	160 mg
Extract of <i>Cucurbita pepo</i> L.	100 mg
Extract of <i>Punica granatum</i> L.	50 mg
Extract of <i>Solidago virgaurea</i> L.	5 mg
Hydrolyzed collagen	250 mg
Hyaluronic acid	25 mg

Note: Active ingredients of PPT5α and the amount of each component per tablet.

outcomes were an improvement in self-perceived hair attributes, which were self-assessed by a questionnaire in terms of thickness, amount of hair, hair shedding, and hair strength. Each parameter was scored on a 5-point Likert scale (1 = very little, 2 = little, 3 = neutral, 4 = much, and 5 = very much). In addition, cosmetic-related parameters were subjectively evaluated in terms of brightness and softness. Finally, the level of patient's satisfaction with the treatment and the time to positive response (visit in which an improvement is observed) were also recorded and scored on a 4-point scale (0 = not at all, 4 = very satisfied, 0 = no improvement, and 4 = much improvement, respectively).

2.5. Statistical Analysis. All the statistical analyses were performed using SPSS (Statistical Package for SPSS, version 23.0, Inc., Chicago, IL, USA). The Shapiro–Wilk test was used to examine the normality of continuous variables. Normally distributed numerical variables (age) were expressed as the mean ± standard deviation, and the independent sample *t*-test was used for comparison between groups. Variables having a nonnormal distribution (percentage of terminal and vellus hair) were expressed as the median (Q1 and Q3), and group comparison was performed using the Mann–Whitney *U* test. Ordinal variables (self-assessment hair parameters and patients' satisfaction and improvement perception) were expressed as the median (Q1 and Q3), and the comparison was made using the Mann–Whitney *U* test. Finally, dichotomous variables (adhesion to treatment) were expressed as percentages and analyzed using the chi-square test. Differences were considered statistically significant when $p < 0.05$.

3. Results

3.1. Study Participants. Figure 1 shows the study flowchart describing patient allocation and follow-up. A total of 47 women participated in the study. Twenty-four of them were randomly assigned to receive the nutritional supplement and 23 to receive the placebo. The minimum age of the volunteers was 25 years, and the maximum was 59 years. All of

the patients completed baseline and 3 months visit; however, three women dropped out because of undesired side effects, two of them from the placebo group and one from the intervention group. Only those patients who completed the study were included for the data analysis.

At baseline, the groups were homogeneous in terms of mean age, percentage of terminal and vellus hair in the frontal and parietal areas, self-assessed hair parameters hair thickness, amount of hair, hair loss and hair strength, and hair cosmetic parameters such as shine and softness (Table 2).

3.2. Primary Outcome. A comparison of the trichoscopic images at six months (T6) vs. baseline (T0) showed that, although not in a significant way, the percentage of terminal hair in the frontal area appreciably decreased in the placebo group (71.1 [63.7, 78.3] T0 vs. 69.8 [61.8, 75.3] T6; $p = 0.35$) while slightly increased in the PPT5α group (73.2 [69.1, 79.6] T0 vs. 77.6 [72.4, 79.4] at T6; $p = 0.54$) (Figure 2(a)). In the parietal area, both the placebo group and the intervention group presented a diminution in the percentage of terminal hair, but this reduction was more pronounced in the placebo group (71.6 [61.5, 76.9] T0 vs. 64.3 [57, 75.2] T6; $p = 0.12$) than in the PPT5α group (77.2 [71.1, 82.3] T0 vs. 77 [71.7, 79.9] T6; $p = 0.66$). Macroscopic and microscopic images of representative placebo and PPT5α patients are shown in Figure 2(b).

At the six-month visit, the nutritional supplement group presented a high percentage of terminal hair compared to the placebo group both in the frontal area (69.8 [61.8, 75.3] Plcb vs. 77.6 [72.4, 79.4] PPT5α; $p = 0.02$) and parietal area (64.3 [57, 75.2] Plcb vs. 77 [71.7, 79.9] PPT5α; $p = 0.02$). Accordingly, a lower percentage of vellus hair was also detected for the intervention group in the frontal area (30.2 [24.7, 38.2] Plcb vs. 22.4 [20.6, 28.1] PPT5α; $p = 0.02$) and parietal area (35.7 [24.8, 43] Plcb vs. 23 [20.1, 28.3] PPT5α; $p = 0.02$) (Figure 2). These differences were not present at baseline visit.

3.3. Secondary Outcomes. The analysis of the self-assessed hair parameters between baseline and follow-up visits showed a significant improvement in “reduction of hair shedding” (Figure 3(a)) and “hair thickness” (Figure 3(c)) scores at 3 and 6 months vs. baseline in PPT5α patients, but not in the placebo group. By contrast, differences between control visits and baseline were not observed for “hair strength” (Figure 3(b)) or “amount of hair” (Figure 3(d)) parameters in neither the placebo nor the intervention group. Similarly, we did not detect significant differences in the cosmetic parameters “hair brightness” or “softness” (Suppl. Figures 1A and 1B, respectively).

Treatment satisfaction was higher in the PPT5α group than in the placebo group at 3 and 6 months, but these differences were only statistically significant at the 3-month visit ($p = 0.01$) (Figure 4(a)). Moreover, the PPT5α group also showed a trend towards better self-perceived improvement at 3 months and at 6 months, although without statistical significance (Figure 4(b)). Finally, there were no differences between the placebo and PPT5α groups in the percentage of patients who reported they never missed

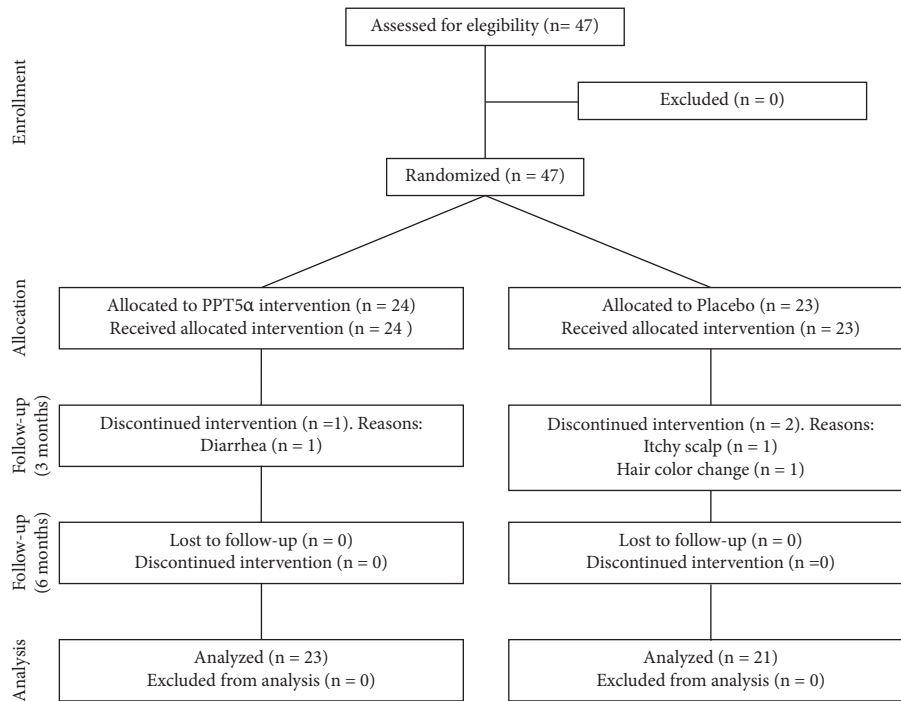


FIGURE 1: Flow diagram of subject progress through the phases of the randomized trial.

TABLE 2: Baseline characteristics of randomized subjects.

	Placebo (<i>n</i> = 21)	PPT5α (<i>n</i> = 23)	Comparison between groups
Age, years (mean ± SD)	42.95 ± 11.03	39.78 ± 8.74	<i>p</i> = 0.3
<i>Trichoscopic parameters (median (Q1, Q3))</i>			
Frontal	% terminal hair	71.1 (63.7, 78.3)	<i>p</i> = 0.59
	% fuzzy hair	28.9 (21.7, 36.3)	<i>p</i> = 0.57
Parietal	% terminal hair	71.6 (61.5, 76.9)	<i>p</i> = 0.08
	% fuzzy hair	28.4 (23.5, 38.5)	<i>p</i> = 0.09
<i>Self-assessed hair parameters (median (Q1, Q3))</i>			
Hair thickness	2 (1, 3)	2 (1, 3)	<i>p</i> = 0.33
Amount of hair	2 (2, 3)	3 (2, 3.5)	<i>p</i> = 0.29
Reduction of hair loss	2 (1, 3)	2 (2, 3)	<i>p</i> = 0.19
Hair strength	3 (1, 3)	3 (1.5, 3.5)	<i>p</i> = 0.78
<i>Self-assessed cosmetic parameters (median (Q1, Q3))</i>			
Hair shine	3 (2, 3)	3 (2, 3)	<i>p</i> = 0.71
Hair softness	3 (2, 3)	3 (2, 4)	<i>p</i> = 0.65

a dose either at the 3-month visit (71.4% Plcb vs. 65.2% PPT5α; *p* = 0.66) or at the 6-month visit (71.4% Plcb vs. 69.6% PPT5α; *p* = 0.89), indicating that PPT5α was easily incorporated into daily routines.

3.4. Undesired Side Effects. In the placebo group, at the 3-month visit, two patients reported itchy scalp and hair color change. Both patients discontinued the study. In the PPT5α group, at the 3-month visit, 3 patients reported abdominal pain, increased hair loss, and diarrhea, and the latter discontinued the study. At the 6-month visit, three patients from the PPT5α group reported abdominal pain and an increase in hair shedding. None of the patients at the six-month visit discontinued the study.

4. Discussion

Hair loss is a complex problem that has a negative effect on self-image and self-esteem in those who are affected [6]. AGA is a chronic type of alopecia in which finding an adequate treatment that provides good results and avoids adverse effects is challenging. In this context, the potential of nutritional supplements as safe and natural alternative treatments for female AGA has been gaining recognition in recent years [7, 18]. In this study, we evaluated the efficacy of Pilopectan® WOMAN 5αR (PPT5α), a nutritional supplement containing natural ingredients with anti-5α-reductase, antioxidant, and keratin formation activities in women with AGA grades I and II. Our results showed that after six months of treatment, the intervention group showed higher

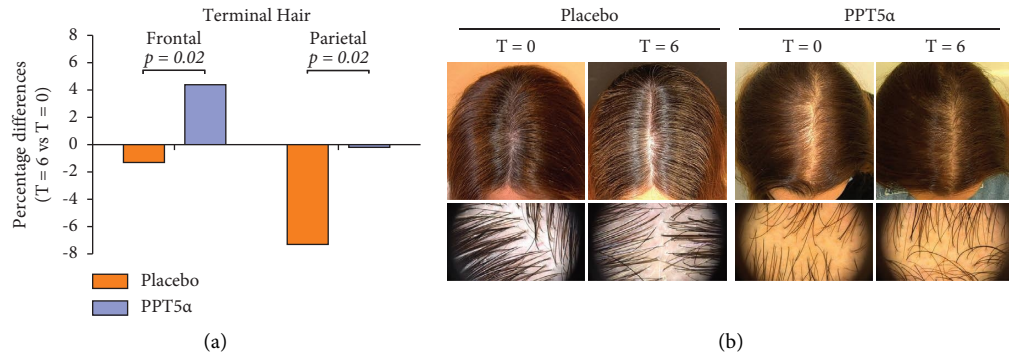


FIGURE 2: Patients treated with the nutritional supplement PPT5α presented a higher percentage of terminal hair than those in the placebo group both in the frontal and parietal areas at a six-month visit. (a) Differences in the median percentages of terminal hair from the baseline visit ($T=0$) to the end of the study ($T=6$) in the frontal and the parietal areas for the placebo and the intervention group obtained from trichoscopic photographs. A p value < 0.05 was considered statistically significant. (b) Macroscopic and microscopic images at the baseline ($T=0$) visit and at the end ($T=6$) of the study, for both the intervention and control groups.

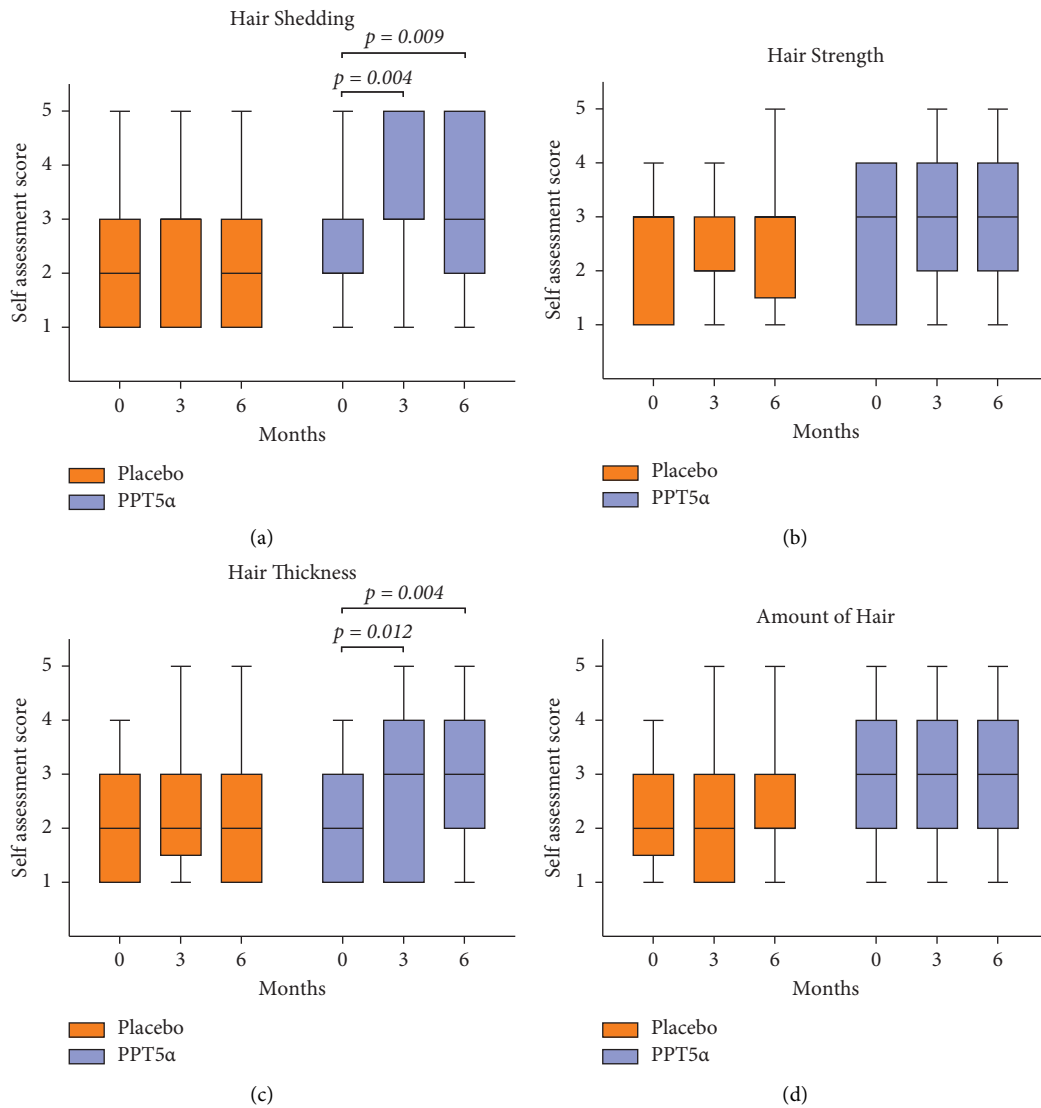


FIGURE 3: Self-assessed hair parameters “hair shedding” and “hair thickness” improved in PPT5α-treated patients. Self-perceived hair attributes were self-assessed by a questionnaire in terms of hair shedding (a), strength of hair (b), hair thickness (c), and amount of hair (d). Each parameter was scored on a 5-point Likert scale (1 = very little, 2 = little, 3 = neutral, 4 = much, and 5 = very much). Results were expressed by means of Box-Whisker plots depicting medians, first and third quartiles, and minimum and maximum values. A p value < 0.05 was considered statistically significant.

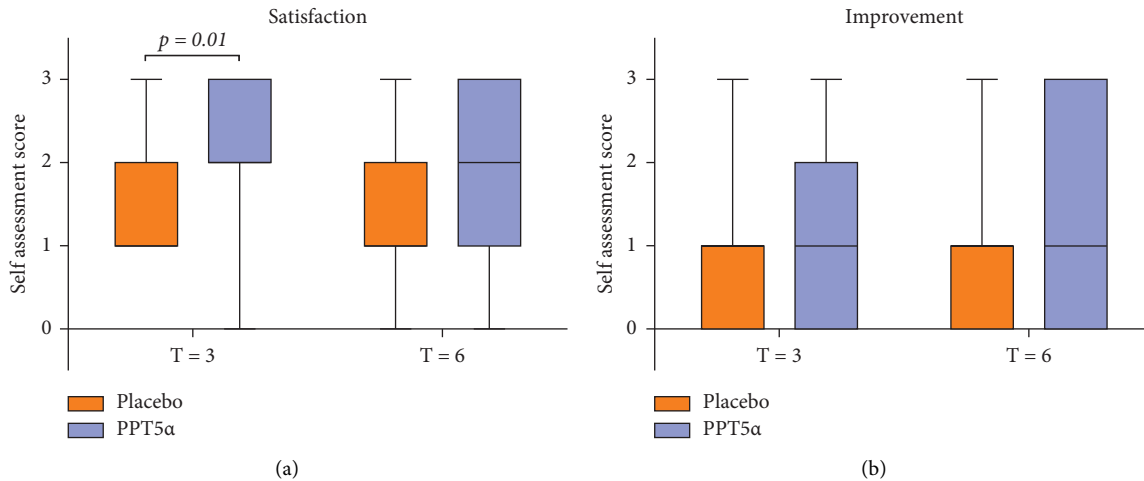


FIGURE 4: Treatment satisfaction was higher in the PPT5 α group than in the placebo group at a 3-month visit. The level of patient's satisfaction with the treatment (a) and the time to positive response (visit in which an improvement is observed) (b) were self-assessed by a questionnaire and scored on a 4-point scale (0 = not at all, 4 = very satisfied, 0 = no improvement, and 4 = much improvement, respectively). Results were expressed by means of Box-Whisker plots depicting medians, first and third quartiles, and minimum and maximum values. A p value < 0.05 was considered statistically significant.

percentages of terminal hair and lower percentages of vellus hair in both the frontal and parietal areas, compared to those who received a placebo. Moreover, the intervention group showed greater satisfactory grades and improved self-assessed scores related to hair thickness and reduction in hair shedding than did the control group.

Female AGA is characterized by chronic and progressive miniaturization of the hair follicle with the conversion of terminal hair follicles in vellus-like hair, an increased telogen/anagen ratio, and a shortened hair cycle [3]. In this 6-month study, AGA progression was evidenced as a trend towards a decrease in the percentages of terminal hair and a consequent increase in those of vellus hair in both the frontal and parietal areas of the scalp of placebo-treated patients. Notably, the parietal area showed a greater percentage reduction in terminal hair than the frontal area. This differential behavior between the frontal and parietal areas may be related to the different rates of hair loss progression between both areas, as it appears earlier in the frontal area [4]. Moreover, a study measuring different areas of the scalp revealed that the parietal area had the lowest hair density, even in normal subjects [19]. Interestingly, this trend was not observed in the intervention group, in which the percentage of terminal hair increased in the frontal area of the scalp and remained stable in the parietal area. These results suggest that PPT5 α could not only be preventing AGA progression in the parietal area but also promoting terminal hair recovery in the frontal area.

An individual's perception of hair loss and other hair characteristics can differ from the clinical diagnosis and observations of the physician. In this study, patients treated with PPT5 α showed an improvement in self-assessed parameters related to the reduction of hair shedding and hair thickness; however, parameters such as hair strength or the amount of hair did not show any improvement. In contrast, the placebo-treated patients showed no improvement. As

progressive hair thinning and abnormal hair shedding are both hallmarks of AGA, these results are consistent with those observed in trichoscopic analysis and support the protective effect of this nutritional supplement in the progression of AGA. In this sense, the intervention group also showed higher overall satisfaction scores and, although not significantly, self-perceived improvement than participants in the placebo group. These results are especially relevant considering that this is a double-blinded study and support the evidence that the specific combination of the natural ingredients studied (plant extracts, hydrolyzed collagen, vitamins, and minerals) may be helpful in improving the overall appearance of hair and the self-image of female participants, which is the ultimate goal of any treatment addressing androgenic alopecia.

Although the etiology and pathogenesis of female AGA have not yet been completely elucidated, its multifactorial nature is evident and includes factors and molecular pathways, such as hormones, inflammation, oxidative damage, aging, and environmental factors [20–22]. Therefore, this condition cannot be addressed by targeting a single molecular pathway, and a multimodal approach is required. In this context, the combination of bioactive components present in PPT5 α provides a multitargeting approach to mitigate triggers for hair loss while restoring balance to the hair follicle. The standardized *Saw palmetto* extract and *Cucurbita pepo* extract have been shown to have an anti-androgenic effect [14, 20, 21]; vitamins provide nutrition and antioxidant benefits; amino acids, L-cystine and L-methionine, provide the raw components for keratin formation, and hydrolyzed collagen strengthens the attachment of the hair to the hair follicle. Taken together, these results support previous studies demonstrating the efficacy of the oral administration of several active ingredients found in this nutritional supplement to improve growth and hair quality in women with AGA.

5. Study Limitations

The main limitations of this study were the limited sample size and a relatively short follow-up period. Despite these limitations, we have been able to detect statistically significant differences between groups by using a randomized, double-blind, placebo-controlled study. Another inherent limitation of efficacy studies is the obtention of results under ideal conditions. In this sense, previous studies in the literature analyzing the use of nutricosmetics in real clinical practice for the treatment of other types of alopecia, such as telogen effluvium, have demonstrated the suitability of this type of study.

6. Conclusion

In conclusion, this study demonstrates that PPT5 α 's bioactive components effectively slow female AGA progression while improving patients' perception of hair thickness and shedding reduction. The supplement is safe and well tolerated, patients reported treatment satisfaction, and the results are clinically relevant, suggesting that this nutritional supplement could be included as an adjuvant treatment in routine clinical practice. Future research should explore the long-term effects of this nutritional supplement.

Data Availability

The trichoscopic data and data from the self-assessment questionnaires used to support the findings of this study are available from the corresponding author upon request.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

Acknowledgments

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Supplementary Materials

Supplementary data contain the results of the analysis of the self-assessed cosmetic parameters "hair brightness" and "softness" (Suppl. Figures 1A and 1B, respectively). (*Supplementary Materials*)

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