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Efficacy and Safety of a Botanical Topical Serum on Male and Female Androgenetic Alopecia

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Abstract

Androgenetic alopecia (AGA) is a common form of hair loss in both men and women, it affects up to 80% of men and 50% of women during their life. The current treatments approved for AGA are limited, inconstantly effective and might be associated with adverse events. The aim of this study was to evaluate the efficacy and safety of a botanical topical serum (SERUM THICKER) applied for 6 months in 14 males and 10 females with mild to moderate androgenetic alopecia. The hair parameters were assessed using trichoscopy images obtained with high resolution camera FotoFinder Leviacam® and analyzed with optimized software from TrichoLAB™ and Vitual tattoo™ technology. Hair loss was assessed using a wash-test procedure, and self-assessments were collected via questionnaires. Both at 28 days and 168 days, a significant increase of the hair density was observed, respectively +4.8% ($p = 0.038$); +11.7% ($p < 0.001$) for 1 application per day and +5.2% ($p = 0.032$); +9% ($p < 0.001$) for 2 applications/week. Reported to the whole scalp, this represents an estimation of hair gain of 7000 hair in 6 months for subjects applying SERUM THICKER once a day and 5000 hair for subjects applying SERUM THICKER twice then once a week. Although, the analysis of hair shedding during washing did not permit to show a time effect or any effect of the application frequency, the analysis showed a marginal time effect in the group treated once a day ($p = 0.0674$). Regarding efficacy on hair loss and regrowth, although no statistical analysis were performed, it seems that for all questions and for both groups the positive answers were higher after 6 months of treatment than after 1 month. SERUM THICKER represents an interesting, effective, well-tolerated and safe multitarget treatment to address mild to moderate AGA in male and female. Efficacy was observed from one application per week and seems greater once applied once daily.

Keywords

Hair Regrowth, Androgenic Alopecia, Botanical

1. Introduction

Androgenetic alopecia (AGA) is a common form of hair loss in both men and women, it affects up to 80% of men and 50% of women in the course of their life. The prerequisites for AGA are a genetic predisposition and sufficient circulating androgens. The dihydrotestosterone (DHT) (active form of testosterone) accelerates the hair cycle which results in a miniaturization of the follicle leading to an increase in the ratio of vellus hair, a decrease of total hair count, an increase in the ratio of telogen hair and subsequently an increase of hair shedding. Patients suffering from AGA, often complain about the excessive hair shedding visible during hair washing or combing.

In men, AGA is also known as male-pattern baldness. Hair is lost in a well-defined pattern, beginning above both temples. Over time, the hairline recedes to form a characteristic "M" shape.

Hair also thins at the vertex (near the top of the head), often progressing to partial or complete baldness. The pattern of hair loss in women differs from male-pattern baldness. In women, the hair becomes thinner all over the head, and the hairline does not recede. Androgenetic alopecia in women rarely leads to total baldness [1]. Despite being a non-life threatening condition, it has been reported that AGA has a high impact on the quality of life [2].

The current treatments approved for AGA are limited to Minoxidil for male and female and Finasteride only for male. These synthetic drugs are frequently associated with adverse events mainly local and mild but sometimes systemic and severe.

In addition, this treatment is inconstantly effective, it has been demonstrated that 38% to 46% of males with moderate to severe AGA would not respond to Minoxidil treatment [3].

The other limitations of topical Minoxidil are the frequency of application (once to twice per day), the local intolerance such as pruritus and erythema and also its tendency to grease the hair.

Thus, cosmetics products represent the alternative to the drugs. However, the lack of well-conducted clinical trials makes the objective comparison between products difficult.

The ideal alternatives would be a topical product to limit systemic passage, with pleasant organoleptic properties, safe, showing significant efficacy on both genders and with limited constraints of use.

Since thousands of years, the botanical ingredients have been used in traditional medicine and in skincare thanks to their convenience as well as the diversity and abundance related to the biological activity. Provided they are made

from plants known to be safe for human use, botanical products, either drug or cosmetic, are much safer and better suited for the long-term treatment of chronic conditions.

The aim of this study was to evaluate the anti-hair loss effect, the hair growth effect and the cutaneous acceptability of SERUM THICKER applied for 6 months in male and female with mild to moderate androgenetic alopecia.

2. Material and Method

The study consisted on an open label study performed in normal conditions of use under Dermatological control.

The study took place at DERMATEC, Tassin-La-Demi-Lune, France, from January 2020 to July 2020.

Caucasian males and females from 18 to 65 years old with mild to moderate androgenetic alopecia (Norwood-Hamilton scale grade II to III for males and Savin scale grade I-1 to I-3 for females) were enrolled (**Figure 1**).

The subjects were followed for 6 months during which 3 visits were performed: Day 0 (baseline), Day 28 and Day 168.

The study was conducted in the spirit of the French and European Guidelines for Good Clinical Practice, the recommendations of the ICH (International Conference on Harmonization, EMA/CHMP/ICH/135/1995 adopted in November 2016 and according with the Helsinki Declaration in its latest version (Seoul 2008) and the laws and regulations in force. All subjects provided a signed informed consent form.

The primary endpoint was the hair density (hair/cm^2) also called target area hair count (TAHC). The secondary efficacy endpoints were other hair parameters (such as the number of new hair, number of lost hair, hair thickness), the quantification of hair loss with the wash test procedure, a self-assessment questionnaire and a clinical examination. Safety was assessed by the collection of adverse event by the investigator and by self-assessment questionnaires filled in by subjects.

The hair parameters were assessed using trichoscopy images obtained with high resolution camera FotoFinder Leviacam® and analyzed with optimized software from TrichoLAB™ led to reach objective, quantitative, precise and reproducible measurements (**Figure 2**). Virtual Tattoo™ is a painless and non-invasive technology developed in order to help ensuring that the same examination spot was used in all examinations following the baseline. It allowed immediate confirmation of correct location selection with no risk of fading. As for Hair-To-Hair Matching™ (H2H) technology based on the Follicular Map concept, it allowed to increase measurement sensitivity and precision. Investigational product effect may thus be confirmed with a lower number of subjects compared to a traditional hair count study [4].

The wash test allowed to quantify the hair loss with a standardized, noninvasive and simple method before and during treatment application period [5]. After 3 days of abstention from shampooing, subjects soaped and rinsed their hair

in the sink or bathtub with the draining hole covered by a piece of gauze in order to collect all hairs caught in the gauze. The hairs were then gathered in an identified paper envelope or sachet and brought to the evaluator to be counted and weighed. This test was performed at D0 and D28. The analyzed parameter was the number of shed hair.

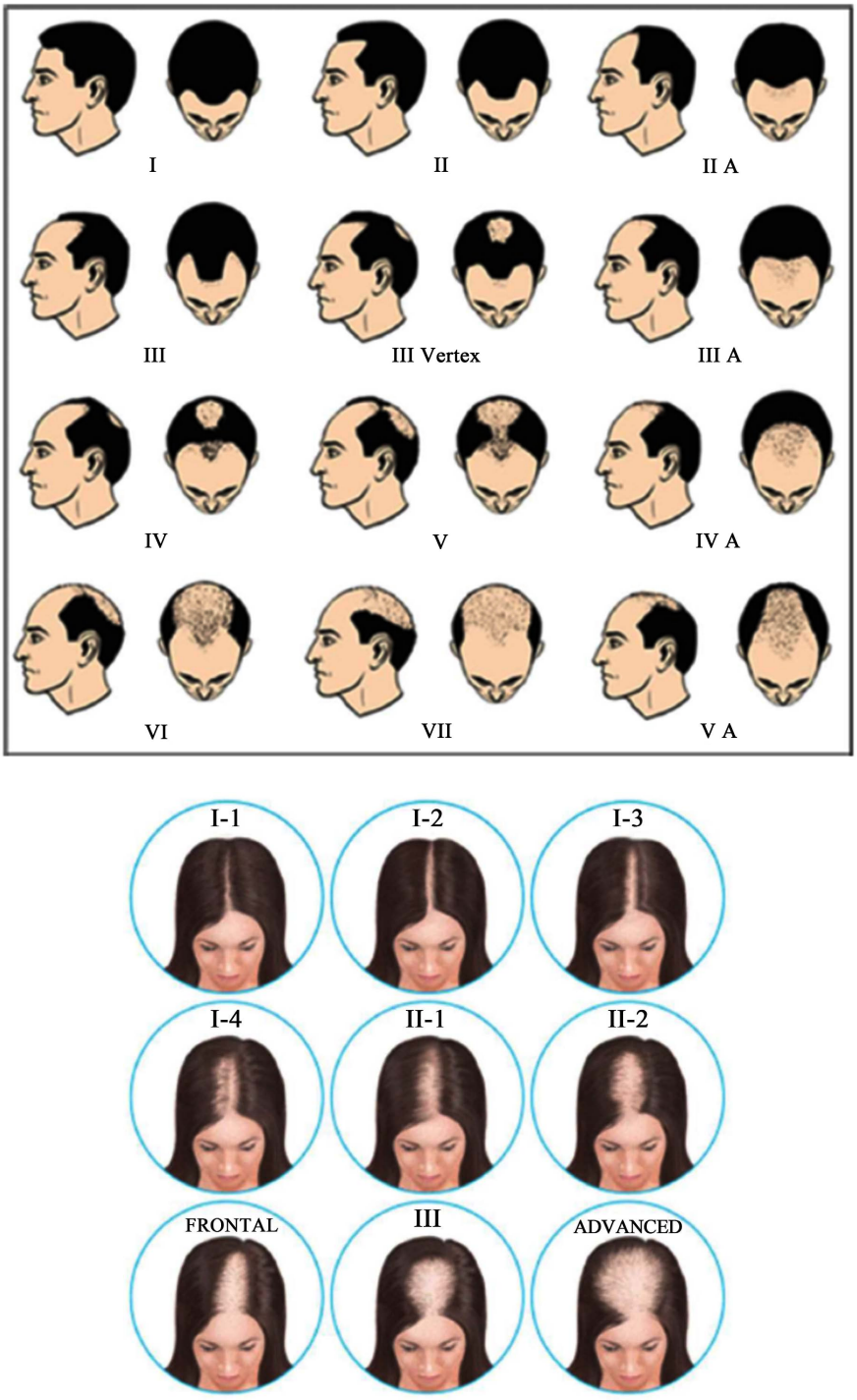

Figure 1. Alopecia grades. Top: Norwood-Hamilton scale for male-pattern baldness. Bottom: Savin scale for female-pattern baldness.

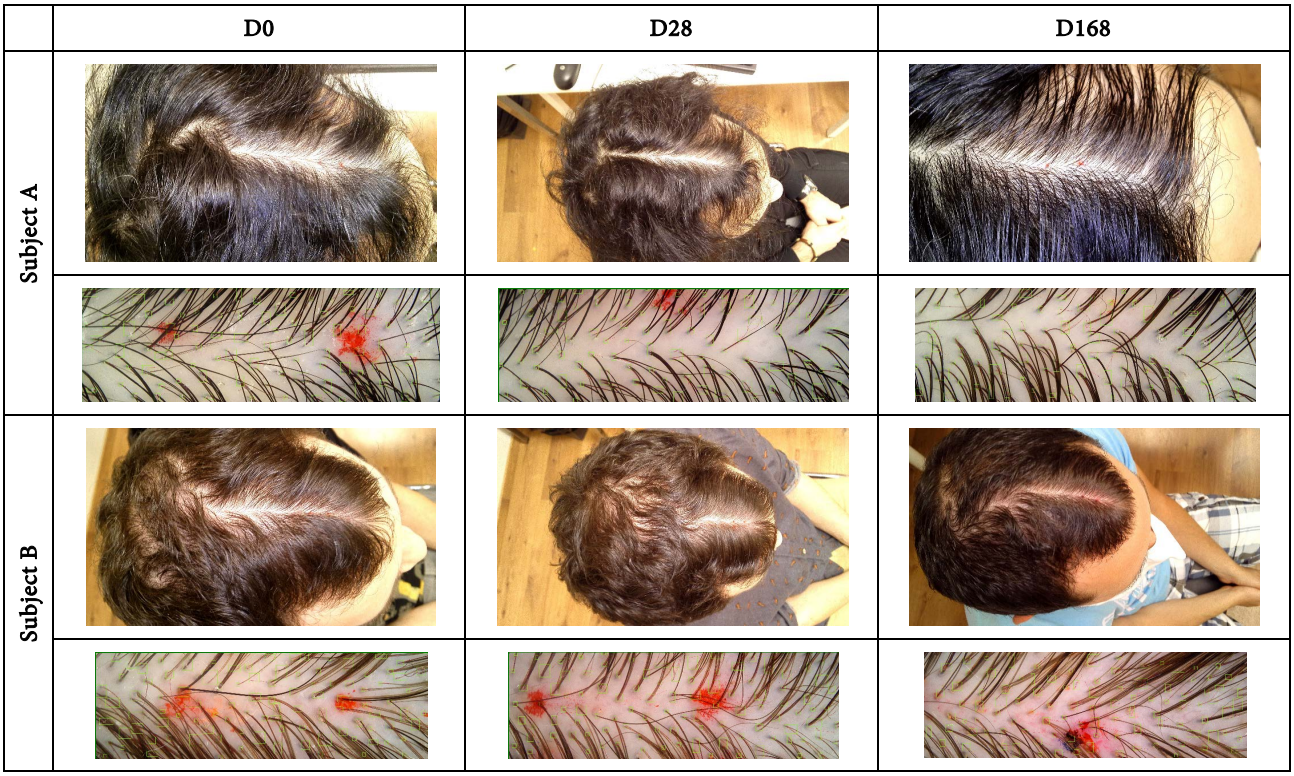

Figure 2. Example of subjects who applied THICKER SERUM once a day (subject A) or twice a week during the first month and once a week then (subject B). Global photography and corresponding macrophotography (FotoFinder Leviacam®).

Self-assessment questionnaire consisted on 22 questions on the product usage, organoleptic properties and the self-perception of efficacy. The subjects were asked to fill the questionnaires at D28 and D168. The response options were completely agree, agree, slightly disagree or disagree.

Clinical examination of the entire scalp was performed at D0 and D168 by a dermatologist.

SERUM THICKER is a lotion containing 97% of botanical ingredients including 5% Capixyl®. Capixyl® is a biomimetic signal peptide with red clover extract rich in Biochanin A. It preserves hair follicle stem cells activity, modulates DHT via 5-α reductase activity inhibition, stimulates extracellular matrix renewal and anchoring proteins synthesis and decreases pro-inflammatory cytokines such as IL-8 (internal data). Four to 6 pipettes (1 mL per pipettes) of SERUM THICKER, depending on the hair density, were applied in the evening over the whole scalp, followed by a massage. The subjects were divided in 2 groups, group A received SERUM THICKER once daily; group B received SERUM THICKER twice a week during the first month and once a week then.

The evaluation of product and time effects were analysed using a mixed effects linear model taking into account time, application frequency (once a day vs. twice a week then once a week) and their interaction as fixed effects, and subject as a random effect. Pairwise comparisons were assessed without any adjustment of p-value. In addition, comparison between the two application frequency

groups (once a day vs. twice a week then once a week) was evaluated using Student's test. If normality and homoscedasticity were not verified (respectively tested by Shapiro and Bartlett tests), a Wilcoxon test was done. Statistical analysis was done using the R software (version 3.6.3). The significance level was set at 5%.

3. Results

3.1. Demographic

Twenty-four subjects completed the trial, 14 males and 10 females aged from 23 to 53 years old (36.1 years old in average) presenting mild to moderate AGA (Table 1).

3.2. Hair Parameters

After 28 days and 168 days of treatment applied once a day, a significant increase of the TAHC was observed compared to baseline, respectively +4.8% (or 9.1 hair/cm^2, $p = 0.038$) and +11.7% (or 22.4 hair/cm^2, $p < 0.001$) (Table 2, Figure 3).

After 28 days and 168 days of treatment applied twice a week then once a week, a significant increase of the TAHC was observed compared to baseline, respectively +5.2% (or 9.4 hair/cm^2, $p = 0.032$) and +9% (or 16.2 hair/cm^2, $p < 0.001$) (Table 2, Figure 3). However, no significant difference between the application frequencies was observed after 28 days or 168 days of treatment.

Reported to the whole scalp and considering an average of 56% of hair loss in mild to moderate AGA, this represents an estimation of hair gain of:

- 7000 hair in 6 months for subjects applying SERUM THICKER once a day.
- 5000 hair in 6 months for subjects applying SERUM THICKER twice then once a week.

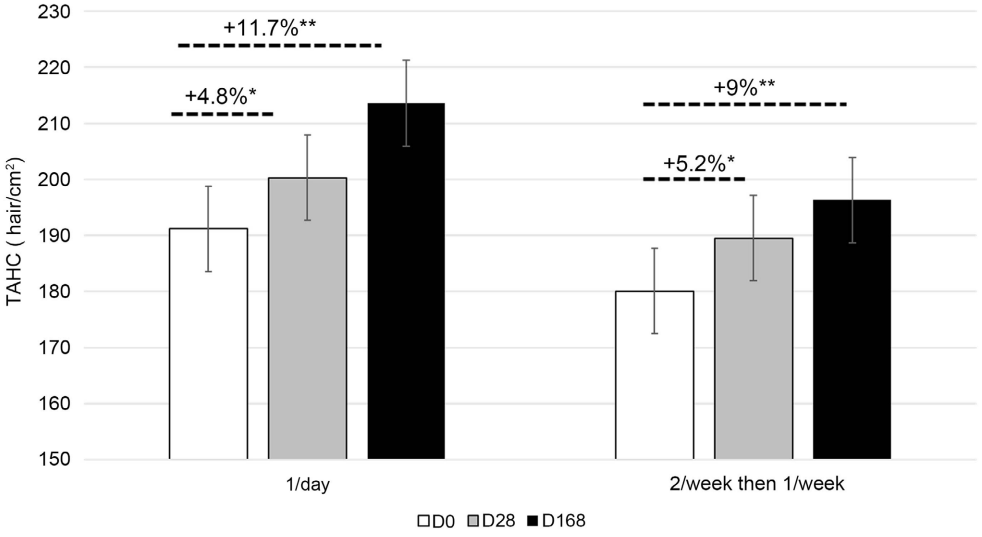

Figure 3. Target area hair count (hair/cm^2) after 28 and 168 days of treatment one application per day or two applications a week then once a week. * $p < 0.05$, **$p < 0.001$.

Table 1. Demographic data. Group A: subjects received SERUM THICKER once daily. Group B: subjects received SERUM THICKER twice a week during the first month and once a week then.

	Group A	Group B
Gender		
Male	7 (58%)	7 (58%)
Female	5 (42%)	5 (42%)
Total	12 (100%)	12 (100%)
Age (years)		
Mean (sd)	41.1 (7.4)	36.1 (9.9)
Median	40.5	36
Min-Max	30 - 53	23 - 53
Type of scalp		
Dry	4 (33%)	3 (25%)
Normal	5 (42%)	4 (33%)
Oily	3 (25%)	5 (42%)
Sensitive	5 (42%)	3 (25%)
Not sensitive	7 (58%)	9 (75%)
Alopecia grade Male (Norwood-Hamilton scale)		
II	1 (14%)	5 (71%)
IIa	1 (14%)	0
III	5 (71%)	2 (29%)
Alopecia grade Female (Savin scale)		
I-1	3 (60%)	0
I-2	0	3 (60%)
I-3	2 (40%)	2 (40%)

Table 2. Hair parameters at D0 (baseline), D28 and D 168 in both groups A (one application per day) and B (two applications a week then once a week). Estimated marginal mean and standard error (under brackets) are given. Intragroup pairwise comparisons between Dx and baseline (D0) were performed for "target area hair count" and "average terminal hair thickness" (hair/cm^2). *p* values are given if significant, otherwise ns is given for not significant.

		Group A (once a day)	Group B (twice a week)	Difference between groups
Target area hair count (hair/cm^2)	D0	191.2 (7.6)	180.1 (7.6)	*ns*
	D28	200.3 (7.6)	189.5 (7.6)	*ns*
		9.1 (4.3)	9.4 (4.3)	
	D0 - D28	+4.8%	+5.2%	-
		p = 0.038	*p = 0.032*	
	D168	213.6 (7.7)	196.3 (7.6)	*ns*
		22.4 (4.6)	16.2 (4.4)	
	D0 - D168	+11.7%	+9%	-
		p < 0.001	*p < 0.001*	

Continued

Average terminal hair thickness (µm)	D0	65 (2)	66 (2)	*ns*
	D28	66 (2)	64 (2)	*ns*
	D0 - D28	1 (1) +1.5% *ns*	−2 (1) −2.9% *ns*	-
	D168	61 (2)	60 (2)	*ns*
	D0 - D168	−4 (2) −6.8% *p = 0.006*	−6 (1) −9.2% *p < 0.001*	-
Number of lost hair (/cm²)	D28	12 (1.5)	15.1 (2.1)	*ns*
	D168	12.8 (1.6)	13.1 (1.8)	*ns*
Average thickness of lost terminal hair (µm)	D28	59 (3)	60 (3)	*ns*
	D168	61 (2)	64 (4)	*ns*
Number of new hair (/cm²)	D28	17.7 (2.8)	20.3 (3.1)	*ns*
	D168	25.4 (3.9)	28.3 (0.8)	*ns*
Average thickness of new terminal hair (µm)	D28	59 (3)	56 (2)	*ns*
	D168	56 (2)	51 (2)	*ns*

A significant decrease of average terminal hair thickness at D168 for both application frequencies was observed, respectively −6.8% for 1 application per day and −9.2% for 2 applications per week (Table 2, Figure 4). No significant difference between the application frequencies was observed.

Regarding the number of lost hair per cm², the average thickness of lost terminal hair, the number of new hair per cm² and the average thickness of new terminal hair, no significant difference between D28 and D128 or between application frequencies was observed (Table 2).

3.3. Wash Test

Overall, the analysis of hair shedding during washing did not permit to show a time effect or any effect of the application frequency (Table 3). However, the analysis showed a marginal time effect in the group treated once a day (p = 0.0674).

3.4. Questionnaires

Regarding efficacy on hair loss and regrowth, although no statistical analysis was performed, it seems that for all questions and for both groups the positive answers were higher after 6 months of treatment than after 1 month (Table 4 and Figure 5, Figure 6). It seems that either after 1 month or 6 months of treatment, positive answers were higher in subjects applying the product every day (group A) than in subjects applying the product twice a week during the first month and

then once a week (group B) (Figure 5, Figure 6). The higher difference between the number of positive answers between D168 and D28 was for the statements "*In sight as in touch, you seem to have more hair*" and "*The hair grows faster*" respectively for groups A and B (Figure 5). The higher difference between the number of positive answers between group A and B was for the statements "*This product has an anti-hair loss action*" at D28 and "*The product slows down progressive hairloss*" *and* "*This product has an anti-hair loss action*" at D168.

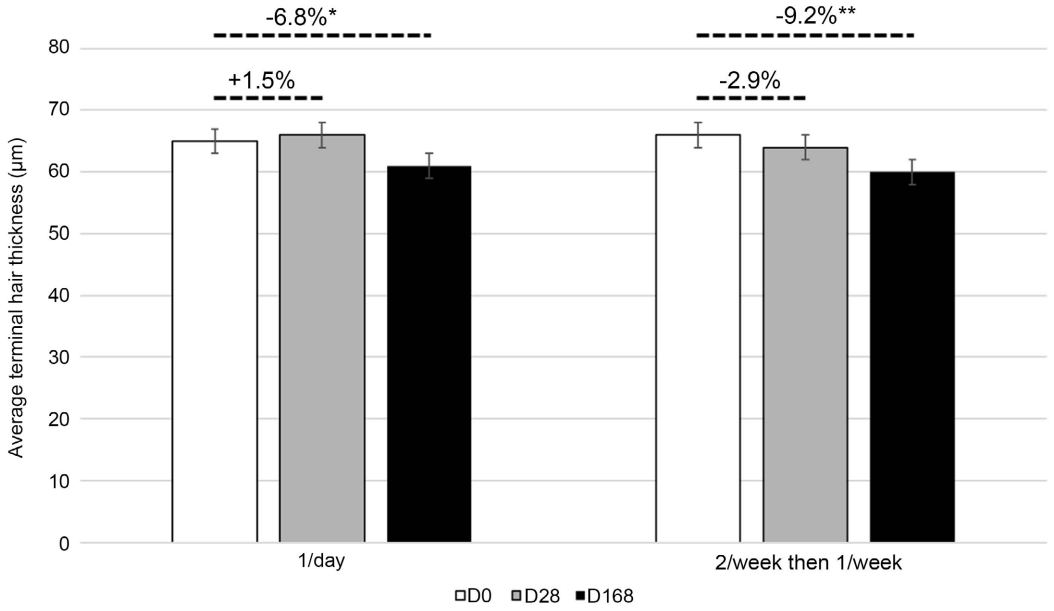

Figure 4. Average terminal hair thickness (µm) after 28 and 168 days of treatment one application per day or two applications a week then once a week. *p < 0.05, **p < 0.001.

Figure 5. Self-assessment of efficacy of SERUM THICKER on hair loss and regrowth. Green = Group A at D28, Striped green = Group A at D168, Blue = Group B at D28, Striped blue = Group B at D168. Group A: one application per day. Group B: two applications a week then once a week.

Table 3. Number of shed hair according to time and to frequency of application (wash test). Group A: one application per day. Group B: two applications a week then once a week.

Number of shed hair	Group A (once a day)	Group B (twice a week)	Difference between groups
D0	31.5 (53.4)	25.4 (24.8)	*ns*
D28	19.0 (22.6)	22.3 (19.7)	*ns*
	−12.5 (32.1)	−3.1 (16.7)	
D0 - D28	−39.6%	−12.1%	
	ns	*ns*	

Table 4. Self-assessment questionnaire on the product efficacy. Percentage of positive answers (=completely agree and agree). Group A: one application per day. Group B: two applications a week then once a week.

	Group A (once a day)		Group B (twice a week)	
	D28	D168	D28	D168
The product combats thinning hair.	75	90	33	82
The product reduces loss of density	50	80	42	64
The product slows down progressive hair loss.	58	90	42	55
Hair grows thicker than before.	58	80	25	36
The balance of the scalp is preserved.	100	100	75	91
The hair seems denser, as if you had more hair.	58	80	50	64
The scalp is toned.	75	100	42	82
The hair is thicker.	50	70	25	45
This product promotes healthy hair growth rise.	67	90	42	64
The hair is stronger.	50	80	33	73
In sight as in touch, you seem to have more hair.	42	90	42	64
The hair grows faster.	58	70	25	55
This product has an anti-hair loss action.	83	90	33	55
This product is suitable for my type of hair.	92	100	92	91
Your impression about this product is good.	92	100	83	82
Would you buy this product? (Yes).	83	100	42	73

Regarding efficacy on hair thickness, although no statistical analysis were performed, it seems that for all questions and for both groups the positive answers were higher after 6 months of treatment than after 1 month (Table 4 and Figure 6). It seems that either after 1 month or 6 months of treatment, positive answers were higher in subjects applying the product every day (group A) than in subjects applying the product twice a week during the first month and then once a week (group B). The higher difference between the number of positive answers between D168 and D28 was for the statements "*The hair is stronger*" and "*The product combats thinning hair*" respectively for groups A and B

(Figure 6). The higher difference between the number of positive answers between group A and B was for the statements "*The product combats thinning hair*" at D28 and "*Hair grows thicker than before*" at D168.

The product usage and organoleptic properties (texture, odour, easy application) were well appreciated by subjects of both groups as of the first month of use (Table 5). However, subjects applying the serum every day (group A) found the product leaves hair oily over the time. Subjects applying the serum twice a week (group B) found the product had a wet effect. After 6 months of use 100% of subjects of panel A and 73% of subjects of panel B wanted to buy the product (Table 6). Besides, 100% of subjects of group A and 82% of subjects of group B had a good impression about the serum.

Table 5. Self-assessment questionnaire on the product usage and organoleptic properties. Percentage of positive answers (=completely agree and agree). Group A: one application per day. Group B: two applications a week then once a week.

	Group A (once a day)		Group B (twice a week)	
	D28	D168	D28	D168
The texture is pleasant	83	90	92	100
The odour is pleasant	83	90	92	91
The product is easy to apply	92	100	83	82
The product does not leave hair oily	92	50	75	82
The texture has no wet effect	67	60	42	45
The product is quickly absorbed	91	80	83	82

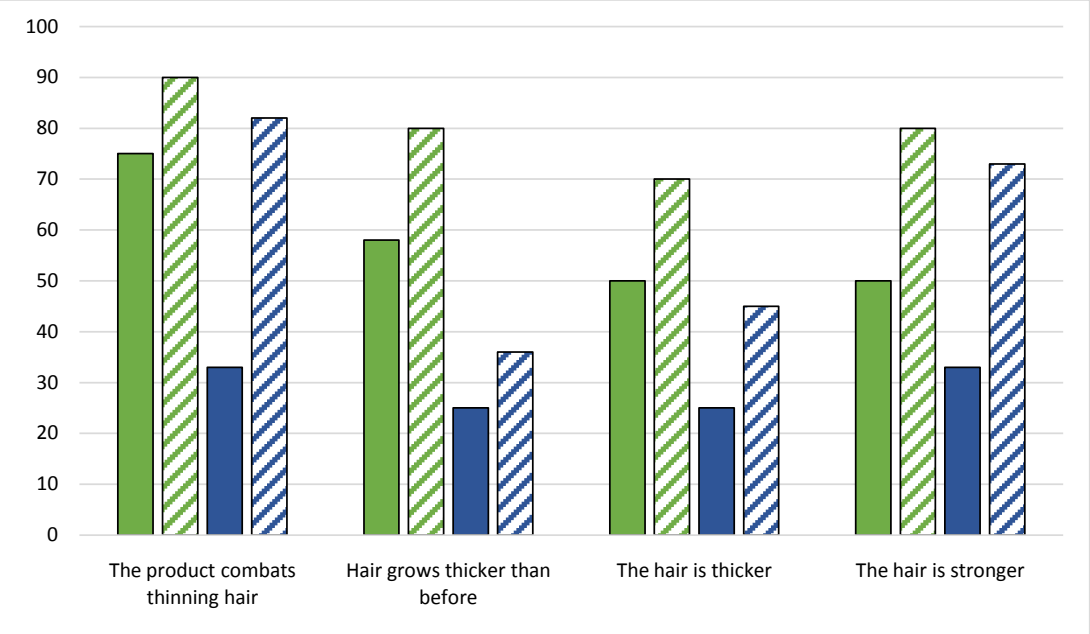

Figure 6. Self-assessment of efficacy of SERUM THICKER on hair thickness. Green = Group A at D28, Striped green = Group A at D168, Blue = Group B at D28, Striped blue = Group B at D168. Group A: one application per day. Group B: two applications a week then once a week.

Table 6. Clinical examination of subjects' scalps at baseline (D0) and after 6 months of treatment with SERUM THICKER with both application frequencies. Group A: one application per day. Group B: two applications a week then once a week.

	Group A (once a day)		Group B (twice a week)	
	D0	D168	D0	D168
Dandruff	9	5	5	4
Erythema	3	1	3	2
Itching	2	1	1	0
Papule	1	0	2	1

3.5. Clinical Examination

The main clinical symptoms observed during the trial were dandruff, erythema, itching and the presence of papules. Although no statistical analysis was performed, it seems that in both groups the frequency of all the symptoms decreased after 6 months of treatment (Table 6).

3.6. Safety

In both groups, all clinical signs present at D0 such as itching, dandruff, erythema, or papules were mild to very mild intensity. None worsened at D168 (Table 6). It seems that all symptoms present at D0 were even less frequent at D168. The Investigator judged the global cutaneous acceptability of SERUM THICKER as very good. There Self-assessment of safety revealed that symptoms were mild, local and mainly related to the process of application (Table 7).

4. Discussion

Androgenetic alopecia is the most common hair loss an affects both genders, however, up to date only two drug treatments are approved. In addition, they are inconstantly effective and may induce side effects.

Table 7. Self-assessment of safety based on spontaneous declaration during the trial. Group A: one application per day. Group B: two applications a week then once a week.

Groups	Timepoints	Description of the symptoms
Group A	Few seconds after each application	Very light itching during few minutes
Group B	Day 2	Heating feeling during few seconds very light intensity
Group B	Day 15	Scalp crust behind head for several days
Group B	Day 0	Very light tingling during few seconds
Group B	Days 6, 8, 12, 17, 20, 23, 26	Very light redness during few minutes after application

The objective of this study was to evaluate the anti-hair loss effect, the hair growth effect and the acceptability of SERUM THICKER applied for a 6-month period, by 24 subjects (male and female), from 23 to 53 years old, with mild to moderate androgenetic alopecia. SERUM THICKER showed a significant increase of hair density either after one application per day or twice then once per week. Indeed, taking into account a surface of 325 cm^2 for area affected by AGA (about 56% of total hair scalp according SALT score [6]), the estimated hair gain is about 7000 hair in 6 months for subjects applying serum once a day and about 5000 hair in 6 months for subjects applying serum twice then once a week. The absence of difference between dosages tends to mean that the serum has a remnant effect. Since it's a topical product, the skin may play the role of a reservoir releasing the product progressively. The formulation of SERUM THICKER ensures an efficacy on hair regrowth even with a weekly dosage which represents advantages, first, for patients' comfort and thus the observance, and second, regarding the competition for which the dosage generally recommended is one application daily. This increase of hair density is rapid and noticeable after the first month of application for both dosages (+4.8% for subjects applying serum once a day and +5.2% for subjects applying serum twice then one a week). As a comparison Minoxidil® 2%, the only topical drug approved in AGA, increased the hair density by 14% in 12 months compared to placebo 7% (relative change of 7%) [7]. Minoxidil® 5% foam, increased the hair density by 11% in 6 months compared to placebo 6% (relative change of 5%) (Clinicaltrials.gov NCT01226459 [8]).

Although no difference between application frequencies was observed probably due to the small sample size, according to self-assessment it seems that the serum is more effective once applied every day during 6 months. Interestingly, it seems that the duration of treatment impacts the hair density and regrowth, whereas the frequency of application impacts the hair loss.

Surprisingly, this increase of density is accompanied by a significant decrease of the density (data not shown) and the thickness of terminal hair. Thus, the new hair observed might be either miniaturized vellus hair or growing terminal hair but too "young" to have reached their final thickness. The only way to make the difference between these two populations is an additional measurement at Month-6 or Month-9. Indeed, by tracking these hair thanks to hair-to-hair matched method, it is possible to differentiate vellus from terminal hair, the latter having a diameter superior to 0.04 mm. From another point of view, the serum might have generated some new hair by re-activating inactive follicles or by reducing the kenogen phase for example, but hasn't stopped miniaturization which explains why the new hair are thin. The descriptive data may help to draw assumptions. Indeed, the thickness of new hair is >0.05 mm overall, whatever the dosages or timepoint, meaning that, in average, they correspond to thin terminal hair rather than vellus (assuming that vellus hair is defined by a diameter inferior to 0.04 mm and normal thick terminal hair defined by a diameter of 0.1

mm). In addition to the increase of density, the serum seems to reduce the hair shedding during washing after 1 month of application as showed by the Wash test (−39.6%; p = 0.0674).

Beside the anti-hair loss effect, it seems that the application of SERUM THICKER helps to reduce the dandruff, itching, erythema and the number of papules. Its specific formulation enhances efficacy of the active ingredients such as Capixyl®. This active complex has an anti-hair loss effect by acting on the hair follicular stem cells and on the cellular activity of the hair. It increases the size of the hair follicle for better anchoring fiber and better vitality of the hair. It also improves the cycle of growth and reverses the conditions responsible for alopecia.

These multiple effect might be explained by the botanical composition of the serum. Indeed, plant extracts are multi-component agents, enabling to address multi-therapeutic targets simultaneously. The global botanicals market was valued at USD 93.6 billion in 2020, registering a Compound Annual Growth Rate of 6.63%, during the period, 2021-2026 [9].

It's important to keep in mind that the hair were already dead three months before their shedding (telogen phase). So the effect of a serum may take time to counteract this normal cycle life. Despite the small sample size which limits the statistical power, this trial demonstrated that two applications per week followed by one application per week of SERUM THICKER may represent an interesting and safe treatment of hair loss or androgenic alopecia. Subjective assessment of serum tolerability and efficacy is key in the development of cosmetics and to create customer loyalty. A relevant method to do so is the completion of self-assessment questionnaire after immediate and repeated applications. Here, we demonstrated that SERUM THICKER is well accepted and tolerated either by the subject or by the investigators who judged the global cutaneous acceptability of SERUM THICKER as very good. This might be explained the well-made formulation and the absence of alcohol which distinguished SERUM THICKER to its competitor.

The serum usage and organoleptic properties were well appreciated by the subjects. After 6 months of use 100% of subjects who used the product every day had a good impression about the serum declared that they wanted to buy the serum.

5. Conclusion

This study supports the clinical effects of a topical hair solution containing 97% of botanical ingredients including 5% Capixyl® on the hair density (TAHC) after 28 and 168 days of application, either after daily application or twice a week. These results were confirmed by the subjects based on the self-assessment questionnaire. No significant effect was observed neither for the hair thickness nor for the hair shedding during wash test. This result might be achieved in more prolonged studies.

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Disclosure

PM is the employee of JF Lazartigue Laboratories as Clinical Research Manager. All of the authors participated in conducting the study from the protocol to the writing of the article.

Conflicts of Interest

There is no conflict of interest regarding this article.

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