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Clinical Outcome of the Topical Application of a Novel Hair Growth Ingredient, USPlus DERM, in Men and Women

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Abstract

Background: USPlus® DERM Topical is a proprietary lipidosterolic extract of saw palmetto concentrated in key bioactive free fatty acids important for hair structure and hair characteristics, and with potent activity against 5α-reductase 1, to support hair follicle growth and hair regrowth.

Methods: Adults aged 25-65 years experiencing unresolved hair loss for ≥6 months participated in a 12-week blinded clinical study evaluating the daily application of a 2% serum of USPlus DERM on the scalp. Dermatologic assessments were made at baseline and after 12 weeks of use, while participants reported their impressions at baseline and after 4, 8, and 12 weeks of use.

Results: Twenty-two participants (15 male, 7 female) completed the study. At 12 weeks, dermatologic assessment found significant improvements in hair loss for men (8.7%, *P*=0.009) and women (25.2%, *P*=0.004), with dandruff also less visible (31.7% decrease; *P*=0.047). Within the first 4 weeks of use, 59.1% of participants agreed that the product appeared to stimulate hair growth. After 8 weeks, participant assessment of general hair loss and density improved by 18.4% and 10.2% (*P*=0.129 and *P*=0.007, respectively), and hair loss when styling decreased by 28.9% (*P*=0.013).At study end (12 weeks),the majority of participants (90.9%; *P*=0.0001) noticed an improvement in hair loss/density. General hair loss and density improved by 22.4% and 19.5% (*P*=0.067 and *P*=0.001, respectively) and hair loss when styling decreased by 34.2% (*P*=0.005). Participant-rated product satisfaction was a mean 7.7/10, compliance with use was high, and the product was well tolerated.

Conclusions: Over 12 weeks, participants with a range of hair and skin types experienced a significant improvement in hair loss and hair density with the use of USPlus DERM Topical serum over 12 weeks. The proprietary USPlus DERM extract shows promise in supporting healthy hair growth and characteristics.

List of abbreviations

5αR = 5α-reductase; DHT = dihydrotestosterone; FFA = free fatty acid; HRQoL = health-related quality of life; LSESr = lipidosterolic extracts of *Serenoa repens* (saw palmetto); PHL = pattern hair loss; SD = standard deviation.

Introduction

The hair loss treatment market was valued at USD $20.5 billion in 2023 and is projected to grow at a compound annual growth rate of 7% to $32.9 billion by the end of 2030 [1]. Hair loss is typically related to one or more of the following factors: genetics, hormonal changes, underlying health issues or medication use, stress, or due to hair follicle damage, such as from chemical treatments [2]. Androgenetic alopecia, or pattern hair loss (PHL), is the most common form of hair loss [3].By age 50, PHL affects one-half of men and one in five women [4, 5]. Androgens are involved in normal hair growth, but can lead to PHL when excess conversion of testosterone to the more potent metabolite, dihydrotestosterone (DHT) occurs at androgen-sensitive areas of the scalp via the 5α-reductase (5αR) enzyme [5]. Increased DHT production and elevated levels of androgen receptor sites on hair follicles affect the hair growth cycle and lead to follicular miniaturization and thinning [6].

Hair loss can be addressed with short-term medical treatment or the withdrawal of a causative medication, but PHL is a progressive condition that overlaps both medical and aesthetic considerations [2, 7]. A number of effective treatments are available for PHL, including pharmacologic and natural therapeutics [2, 4]. For example, the 5αR inhibitor drugs have been shown to reverse hair loss; finasteride targets the type 2 5αR isoenzyme, while dutasteride targets both type 1 and type 2 5αR isoenzymes [2, 8]. But some patients avoid or discontinue pharmacologic agents due to concerns regarding long-term treatment and/or side effects [6, 9]. Drug costs can also be a barrier [6]. These patients may prefer natural treatment options, including plant-based topical oils (ie, pumpkin and tea tree); proprietary nutraceutical mixtures and marine complexes; and lipidosterolic extracts of *Serenoa repens* (LSESr), also known as saw palmetto [1, 4, 6].

Clinical studies have shown that saw palmetto extract, used as a combination or single-ingredient product for oral or topical application, can address hair loss [9-17].Additionally, this treatment has been associated with only minor side effects, and patients have reported high rates of satisfaction [9, 12-17]. LSESr have been shown to be potent inhibitors of 5αR 1 and 2 [18-20] and address PHL via a mechanism that is similar to 5αR therapeutics [21]. LSESr extracts have a unique fatty acid profile [22], and the quality, quantity, and distribution of free fatty acids (FFA) in LSESr drives their ability to inhibit 5αR enzymes [19, 20]. As the most common lipids in hair [23, 24], FFAs are highly bioactive and are taken up rapidly at androgen receptor sites, including the skin and scalp [24, 25]. FFAs coat and protect the hair shaft [23], are essential to follicle structure [26], and

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help regulate hair health and the hair cycle [24, 27].Animal models have shown that, after oral administration, available bioactive FFAs such as those found in LSESr quickly localize to androgen receptor sites, such as the skin and scalp [25]. where hair follicles are located. The potency of LSESr products, however, varies substantially due to differences in FFA profiles; specifically, the levels of bioactive FFAs [18-20].

USPlus® DERM (Valensa International; Eustis, FL) is a novel, proprietary LSESr extracted to naturally enrich the level of FFAs and deliver a highly concentrated ratio of the four most bioactive FFAs shown to help address hair loss and support hair regrowth [25, 28-30]. Extracted using a proprietary ultra-high pressure carbon dioxide process, this standardized quality ingredient meets the United States Pharmacopeia Monograph for potency, purity and authenticity. USPlus DERM has established biological activity to strongly inhibit 5αR enzymes 1 and 2 [18] and has been shown to promote hair growth ex-vivo in healthy human hair follicles [31].

Study Objective

This quantitative, blinded observational consumer-use pilot study evaluated the efficacy (hair loss and regrowth), tolerability, and acceptance of USPlus DERM Topical, applied as a 2% serum to the scalp in adult men and women over three months of use (March 18-June 9, 2024).

Materials and Methods

Participants and Study Design

Participants were from the Paris, France region, identified from a database of panelists participating in consumer use tests (SYRES Sensory & Consumer Research; Chavenay and Paris, France). Participants were initially pre-selected based on being in the target age group of 25 to 65 years. The 210 pre-selected participants were screened by phone during February and early March 2024 with a 33-item questionnaire to assess eligibility, hair care product use history, hair characteristics, and hair and scalp condition. For this pilot study, a minimum enrollment of 22 men and 10 women was needed to achieve the study criteria for a minimum of 15 male and 5 female completers, with balanced representation across the age ranges of 25-35, 36-45, 46-55, and 56-65 years. All eligible participants were referred for a baseline dermatologist evaluation, conducted on 18 March 2024 at SYRES Sensory & Consumer Research in Paris. A study timeline is shown in (Figure S1).

The clinical study protocol allowed for the inclusion of participants with all hair types and hair and scalp conditions, including dandruff. To be included, participants were required to have experienced hair loss for at least 6 months, ranging from slight to significant or chronic. Participants agreed to use the hair growth serum at home for the next 12 weeks according to instructions, and to commit to being available for the full study period, with regular access to email. Participants could not have been involved in another consumer use study in the previous 2 months; if they were using other anti-hair loss products, they agreed to stop using the products one month prior to the start of this study. Participants also agreed to complete study questionnaires on Week 4 (ending 14 April 2024), Week 8, (12 May 2024), and Week 12 (9 June 2024).

Participants who were using treatment for severe conditions such as cancer, diabetes, or Parkinson's disease, or who were on morphine or had hair transplants were excluded. Additional exclusion criteria were lack of participant availability on study dates due to holidays, illness, or travel; planned vacations during the study period; pregnancy, likelihood of pregnancy, or breastfeeding; known scalp sensitivities; issues with taste or smell; ongoing medical or dermatologic treatment; history of allergies to cosmetic products; simultaneous participation in another clinical study; and/or employment in a profession related to cosmetics, hygiene, or hair care, including close household or family ties to these industries. Figure 1 shows the flowchart for study participants screened, enrolled, and completing the USPlus DERM Topical consumer use study.

At the first study visit (Week 0/baseline), participants underwent dermatologic assessment to evaluate their stage of hair loss, using established classification systems for male and female pattern baldness. Hair loss scoring was done using the Hamilton-Norwood scale for men (Stage I [minimal or no hair loss] to Stage VII [only thin band of hair remaining], with each stage corresponding respectively to 1-7 points) and the Ludwig-Savin scale for women (Stage I-1 to I-4 [minimal thinning], II-1 to II-2 [moderate thinning], and Stage III [severe thinning], with each stage corresponding respectively to 1-7 points) [32]. Dermatologic evaluations of dandruff visibility, skin phototype (Fitzpatrick scale, Types I [maximum sun sensitivity] to VI [lowest sun sensitivity]), and scalp health were also made at baseline.

The dermatologist examined participants' scalps for any discomfort or physical signs, and baseline photographs were taken. Also at this visit, participants were provided with blinded 2% USPlus DERM Topical serum in plain glass bottles labeled "growth serum" and with product lot number information.

Participants were instructed to maintain their usual shampoo and hair care regimen without modification throughout the study, and to apply the product 4 times weekly (3 applications on clean, wet hair, and 1 application on dry hair) over the next 12 weeks. Prior to product application, participants were directed to shake the bottle. Next, they were instructed to apply two pipettes of serum to the roots and scalp, massage it in for several minutes, and leave the product on without rinsing. A 3-item questionnaire, administered at Weeks 4, 8, and 12, asked participants to confirm whether they were adherent to the use of the product and the frequency of use as directed, and to document any reasons for treatment non-adherence over the preceding 4 weeks.

A final dermatological assessment occurred at Week 12, and study-end photographs were taken. The primary outcome was in hair loss and overall scalp condition following use of USPlus DERM Topical 2% serum for 12 weeks. Secondary outcomes were assessed using participant-reported data obtained at Weeks 4, 8, and 12 from a 15-question, 4-point semantic scale (1=agree, 2=somewhat agree, 3=somewhat disagree, and 4=disagree) that evaluated overall improvements in hair loss and hair density, and hair characteristics such as body, health, suppleness, softness, strength, shine, and thickness. Participants also appraised the product's impact on hair loss, density, regrowth, scalp stimulation, and the visibility of affected areas, and provided their opinion regarding the impact of the product on daily hair loss and hair loss when styling. In addition to the semantic scale questionnaire, study participants completed 3

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numeric rank questions evaluating general hair loss (0=no hair loss at all to 10=severe hair loss), hair loss when styling (0=no hair loss at all to 10=severe hair loss), and hair density (0=very low hair density to 10=very high hair density) after 4, 8 and 12 weeks of USPlus DERM Topical use. Participants were also asked a yes/no question regarding whether they noticed an improvement in hair loss or density, and, if applicable, at which study Week they observed this change. Last, at Week 12, participants completed a product satisfaction questionnaire.

Statistical Analysis

Descriptive statistics were used to summarize data, including means, standard deviations (SD), counts, and percentages. For dermatologist-assessed hair loss and appearance of dandruff, and for participant assessments using numeric ranking (0-10), the Student's t-test was applied, comparing responses at Week 4, 8, and 12 vs baseline. For participant assessments using the 4-point semantic scale, a Z-test was applied, comparing the proportion of participants who "agreed" or "somewhat agreed" to participants who "disagreed" or "somewhat disagreed" at each discrete time point (Weeks 4, 8, and 12). The Z-test was also applied to compare the proportion of participants who did vs did not notice an improvement in hair loss or density each week. The threshold for statistical significance was set at 0.05. Analyses were performed using Microsoft Excel (Redwood, WA, USA) and Modalisa (Paris, France).

Results

Participant Characteristics

Of the pre-selected consumers, 30 (22 men, 8 women) met eligibility criteria and were subsequently recruited; of these, 27 attended the baseline visit and consented to be in the study. A total of 22 (73.3%) participants completed the study and were included in the analysis (n=5 lost to follow-up; Figure 1). Treatment compliance was high; all participants reported using the LSESr serum as directed through the end of the study, with the exception of 3 participants (2 ran out of serum a few days before study end; 1 forgot to use the serum during Week 11).

(Table 1) and (Table S2) show baseline participant demographic and hair/scalp characteristics. The study population consisted of 15 [68.2%] males and 7 [31.8%] females, with mean (SD) age at study entry of 49.3 (11.0) years (range, 25-65). All participants reported hair loss of a mild (5 [22.7%]), moderate (14 [63.3%]), or significant (3 [13.6%]) level, with 77.3% of participants (17) experiencing hair loss for longer than 2 years. With respect to hair characteristics, participants had normal (8 [36.4%]) or normal to dry hair (6 [27.3%]) that was straight (12 [54.5%]) or wavy (7 [31.8%]) and very short (5 [22.7%]) or short (8 [36.4%]), with normal/average density (19 [86.4%]). Most participants had either skin phototype III (7 [31.8%]) or IV (9 [40.9%]) and a dry (8 [36.4%]) or normal (10 [45.4%]) scalp; 7 (31.8%) reported scalp sensitivity. In addition to hair loss, some participants reported hair problems such as dandruff (9 [40.9%]) and damaged, brittle, or fragile hair (7 [31.8%]).

Table 1: Participant Demographic, Scalp, and Hair Characteristics at Baseline (Week 0)

Characteristic	Participants, N=22
Age, mean (SD)	49.3 (11.0)
Age group, n (%)	
25-35	3 (13.6)
36-45	7 (31.8)
46-55	5 (22.7)
56-65	7 (31.8)
Sex, n (%)	
Male	15 (68.2)
Female	7 (31.8)
Scalp and hair characteristics	
Scalp sensitivity, n (%)	
Yes	7 (31.8)
No	15 (68.2)
Hair density, n (%)	
Thin	3 (13.6)
Normal/average	19 (86.4)
Hair problems, n (%)	
Hair loss	22 (100.0)
Mild hair loss	5 (22.7)
Moderate hair loss	14 (63.3)
Significant hair loss	3 (13.6)
Light dandruff	9 (40.9)
Damaged, brittle, fragile hair	7 (31.8)
Flat hair, lack of volume	3 (13.6)
Dull hair	1 (4.5)
Duration of hair loss, n (%)	
6-11 months	2 (9.1)
1-2 years	3 (13.6)
Over 2 years	17 (77.3)

SD = standard deviation.

Outcomes

In this pilot clinical trial, mean change in participanthair loss and overall scalp condition following USPlus DERM Topical treatment are shown in (Table 2) (Table S3) shows individual scores). From Week 0 to Week 12, dermatologist-assessed mean (SD) hair loss for men using improved significantly, decreasing by 8.7%, from 3.8 (1.4) to 3.5 (1.4), according to Hamilton-Norwood scale (P=0.009). Similarly, for women, dermatologist-assessed mean (SD) hair loss improved significantly, decreasing by 25.2%, from 2.9 (1.2) to 2.1 (1.1), according to the Ludwig-Savin scale (P=0.004). Dandruff visibility also improved significantly, decreasing by 31.7% from 1.9 (2.5) to 1.3 (1.6) (P=0.047). Photographic evidence confirming hair loss improvements is shown in (Figure S2).

(Figure 2) and (Table S4) show responses to the 15-item questionnaire administered at Weeks 4, 8, and 12 to evaluate participants' perceptions of how treatment affected their hair and scalp. By 4 weeks of serum use, 13 (59.1%) of participants agreed/somewhat agreed that the product seemed to stimulate hair growth/regrowth, and 14 (63.6%) agreed/somewhat agreed that the product helped maintain better hair density, but the difference between these proportions and the proportion of participants who disagreed/somewhat disagreed was not significant. By Weeks 8 and 12, this proportional difference was significant, with 17 (77.3%) (P<0.05) and 20 (90.9%) (P<0.001) agreeing/somewhat agreeing, respectively. By Weeks 8 and 12, participant-reported findings that the product reduced hair loss were significant, with 16 (72.7%) (P<0.05) agreeing/somewhat agreeing at Week 8 and 19 (86.4%) (P<0.01) agreeing/

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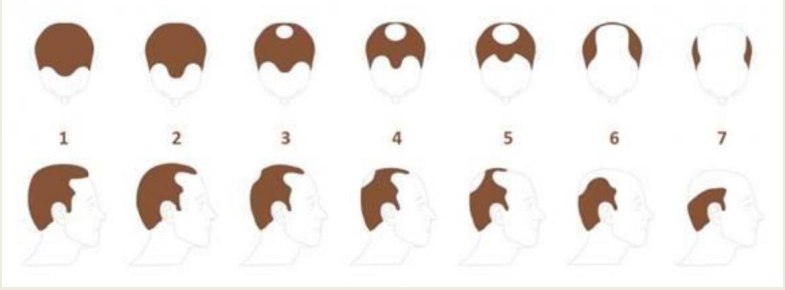
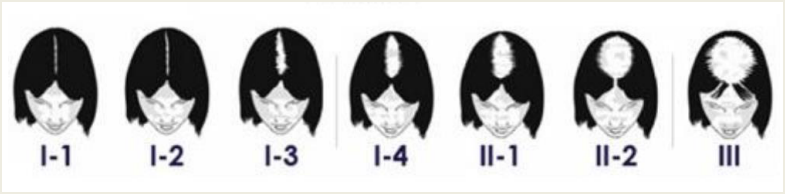
Evaluation of hair loss according to the Hamilton-Norwood scale for men (Stage 1-7), N=15



Parameter	Baseline	Week 12	Percent change	*P* value
Mean (SD)	3.8 (1.4)	3.5 (1.4)	−8.7%	0.009
Min, max	2, 7	2, 7	_	

Evaluation of hair loss according to the Ludwig-Savin scale for women (Stage 1-7), N=7



Parameter	Baseline	Week 12	Percent change	*P* value
Mean (SD)	2.9 (1.2)	2.1 (1.1)	−25.2%	0.004
Min, max	2, 5	1, 4	_	
Dandruff visibility (scale of 0-10, 10 = most visibility), N=22				
Parameter	**Baseline**	**Week 12**	**Percent change**	***P* value**
Mean (SD)	1.9 (2.5)	1.3 (1.6)	−31.7%	0.047
Min, max	0, 9	0, 5	–	

Table 2: Dermatologist-Assessed Hair Loss and Dandruff Visibility at Baseline and Week 12

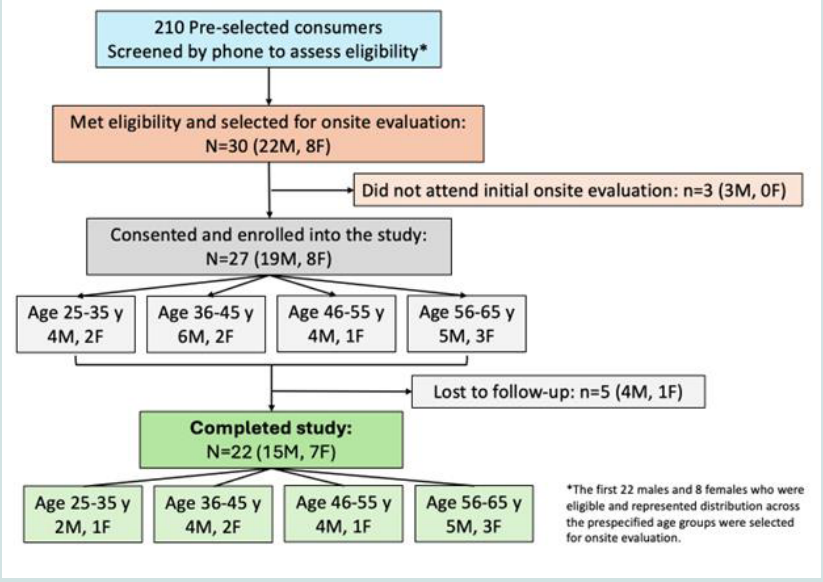


Figure 1: Enrollment Flow Chart

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Figure 2: Radar Chart of Participant-Reported Efficacy at Weeks 4, 8, and 12 of USPlus DERM Use.
Percentages reflect the frequency of participants (N=22) who "agree" or "somewhat agree" with the given statements at each timepoint.

somewhat agreeing at Week 12. Also, by Week 12, 16 (72.7%) (P<0.05) of participants agreed/somewhat agreed that the areas affected by hair loss seemed less visible, and that the product seemed to stimulate hair growth/regrowth. Last, 17 (77.3%) of participants agreed/somewhat agreed that the product seemed to stimulate their scalp (P<0.05) and indicated that they felt they were losing less hair when styling (P<0.05) and every day (P<0.05).

(Figure 3) shows participant rankings (ranging from 0 to 10) of general hair loss, hair loss with styling, and hair density at Week 0 and after Weeks 4, 8, and 12 of using USPlus DERM Topical. At baseline, participants rated their hair loss in general as a mean 4.9 (2.3) out of 10; at Week 12, hair loss in general was reduced by 22.4%, to 3.8 (2.3) (P=0.067). Participants rated their baseline hair loss while styling as a mean (SD) 5.2 (2.2) out of 10; the rating was reduced significantly by 34.2% (to 3.4 [2.2]) at Week 12 (P=0.005). Likewise, at baseline, participants ranked their hair density as a mean (SD) 5.3 (1.4) out of 10; at Week 12, this score improved significantly, by 19.5%, to 6.4 (1.8) (P=0.001).

(Figure 4) and (Table S5) show the study timeline, by week; this illustrates if and when participants observed benefits in hair loss and density. Progress was rapid, with 14 (63.6%) noticing improvement by the end of Week 4 of USPlus DERM Topical use. The difference in the proportion of patients who did vs did not notice improvement was statistically significant by the end of Week 7 (16 [72.7%]; P<0.05), and increased to 18 (81.8%; P<0.01) by the end of Week 8, and 20 (90.9%; P<0.001) by the end of the study. Only 2 (9.1%) participants reported noticing no improvements over the study period.

(Figure S3) shows participant-reported product satisfaction, evaluated at the end of the study. Participants ranked their satisfaction with the product as a mean 7.7 out of 10, with over one-half (13 [59.1%]) ranking their satisfaction as ≥8 out of 10. Nearly all participants (20 [90.9%]) indicated they would like to continue using the product, and the majority indicated they would "certainly" or "probably" purchase the product (16 [72.7%]) and recommend the product to someone experiencing hair loss problems (17 [77.3%]). (Table S6) shows participant evaluation of product characteristics and sensation. At Week 12, all participants (22 [100.0%]) "agreed" or "somewhat agreed" that the product was easy to apply and pleasant to apply on wet or dry hair, and nearly all (20 [90.9%]) "agreed" or "somewhat agreed" that the texture and fragrance of the product was pleasant, and that the product was suitable for their hair type. The differences in the proportions of patients who agreed/somewhat agreed with these statements was statistically significant compared to the proportion of patients who disagreed/somewhat disagreed.

Overall, per dermatologist-assessment at Week 12, the product was well tolerated. One moderate case of erythema was reported (unrelated to product use). In addition, there was 1 case of severe burning/itching that occurred just after product application, but spontaneously regressed and did not recur with subsequent applications; and 1 case of moderate itching that was determined to be unrelated to the product.

Discussion

USPlus DERM Topical 2% hair growth serum was formulated with a new, proprietary LSESr ingredient containing concentrated amounts of the most bioactive FFAs [25, 28, 30] found to be important for hair structure and hair characteristics [23, 24, 26] and to play an important role in regulation of the hair growth cycle [24, 27]. The ingredient used in the hair growth serum, USPlus DERM, is a standardized quality saw palmetto extract that meets the United States Pharmacopeia Monograph for potency, purity, and authenticity. This 3-month, observational, consumer-use pilot study of USPlus DERM Topical 2% serum found significant improvements in hair loss reduction and hair density based on both dermatologist-assessed and participant-reported outcomes. Study participants were age-distributed (25-65 years), had a range of hair and skin types, and largely had a duration of hair loss ≥2 years. At study end (12 weeks),

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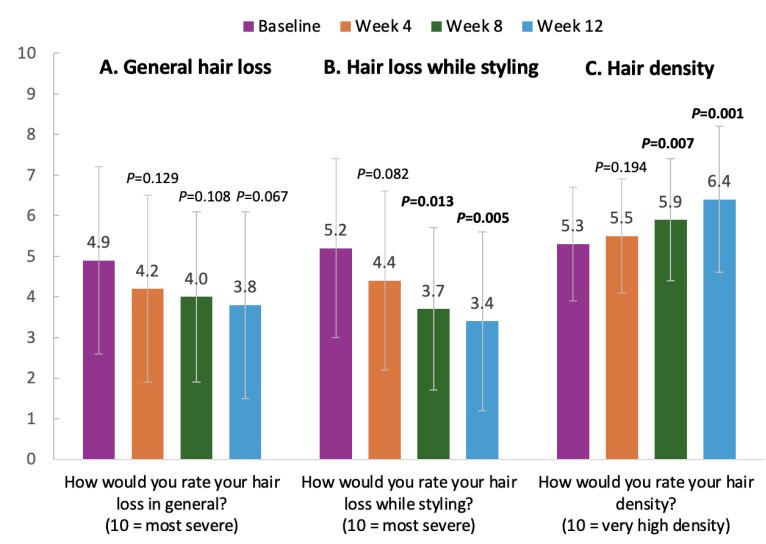

Figure 3: Participant-Reported (N=22) Ranking of A) General Hair Loss, B) Hair Loss with Styling, and C) Hair Density from Baseline to Week 12. Participants were asked to rank these items on a numeric scale of 0 to 10. For 3A, numeric ranking of hair loss, less hair loss is indicated by a decrease in score. For 3B, numeric ranking of hair loss when styling, less hair loss is indicated by a decrease in score. For 3C, numeric ranking of hair density, an increase in score indicates improvement for hair density. All P values are vs baseline.

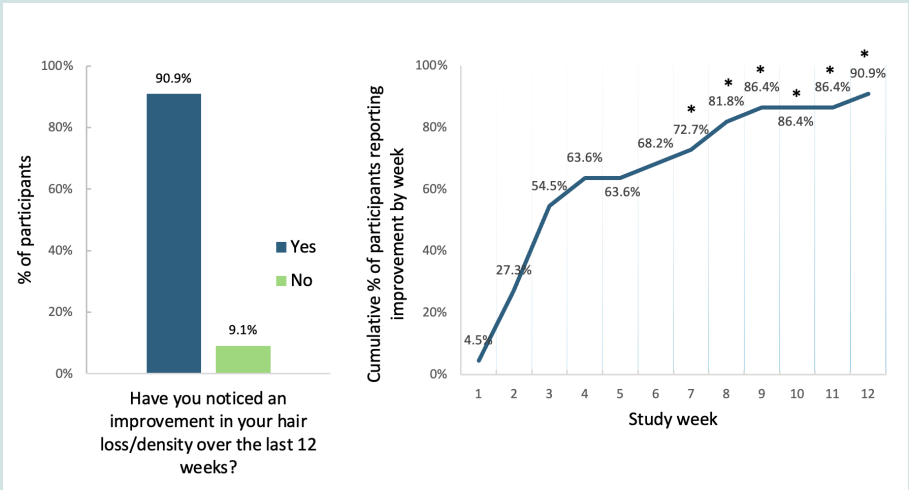

Figure 4: Participant-Reported (N=22) Improvement in Hair Loss/Density from Baseline to Week 12. An asterisk indicates a statistically significant difference in the proportion of participants who did vs did not notice improvement

dermatologist-assessed male PHL decreased by 8.7%, and female PHL by 25.2%, and a 31.7% reduction in visible dandruff was also seen. The majority of participants (90.9%) noticed less hair loss and improved hair density, with over one-fifth (27.2%) observing changes within 2 weeks of product use, and two-thirds (63.6%) within 4 weeks of use. By 8 weeks, participant assessment of general hair loss and hair density improved by 18.4% and 11.3% (P=0.129 and P=0.007, respectively), and hair loss when styling decreased by 28.9% (P=0.013). At study end, participant-assessed hair loss reduction in general compared to baseline decreased by 22.4%, hair density improved by 19.5%, and participants reported a 34.2% reduction in hair loss when styling hair. Additionally, three-quarters of participants reported that the areas affected by hair loss seemed less visible (72.7%), that they felt they were losing less hair every day (77.3%), and that the product seemed to stimulate hair growth/regrowth (72.7%).

Furthermore, product satisfaction was high (7.7 out of 10), with 90.9% of participants indicating interest in continued use of the product after the study end, and 72.7% indicating interest in purchasing the product, regardless of the cost. Compliance with serum application/use was also high, and the product was well-tolerated, with no side effects attributable to its use. Given these results from this pilot clinical trial, the combined efficacy, tolerability,

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and acceptability of USPlus DERM Topical makes this product a feasible option for addressing hair loss and hair regrowth [4].

Hair loss, including pattern hair loss, can negatively affect an individual's self-image, with research confirming that PHL can cause emotional and psychological distress due to worry, embarrassment, shame, frustration, and/or depression. In turn, this can negatively affect health-related quality of life (HRQoL). Likewise, having access to PHL treatment improves HRQoL [33]. Many individuals with PHL are seeking natural treatment options that offer effective results with a lower risk of side effects (adverse events associated with PHL prescription therapy includes dry scalp, skin irritations and reddening, headache, and sexual and ejaculatory dysfunction) [6].

The current study gives insights into the onset of action of topical application of a LSESr serum on hair loss, as well as its impact on hair characteristics and other important conditions such as dandruff. These clinical results are supported by prior research, spanning more than two decades, showing that saw palmetto extracts, administered as oral therapy [10, 11, 14-16]or in topical formulations [9, 12, 13, 17] can play a key mechanistic role in preventing hair loss and promoting hair regrowth. Specific to oral therapy, Rossi et al (2012) studied 100 men with androgenetic alopecia to determine the 2-year comparative effectiveness of LSESr monotherapy and the 5αR therapeutic finasteride. LSESr monotherapy use resulted in a 38% improvement in hair regrowth, compared to a 68% improvement in the finasteride group [16]. Ablon and Kogan (2018) conducted a 6-month randomized clinical study of women with self-perceived hair thinning, receiving either an oral LSESr combination hair growth supplement (n=24) or a placebo (n=12). By day 180, participants using the LSESr combination product had significantly improved hair growth and overall hair quality as assessed by an investigator, as well as enhanced self-perception of hair growth, volume, thickness, and overall hair health [10]. A subsequent 6-month randomized trial conducted by Ablon and Kogan (2021) to evaluate the same oral LSESr combination product randomized menopausal women with thinning hair to receive active treatment (n=40) or placebo (n=30). Compared to placebo, participants using the LSESr product showed progressive and significant decreases in hair shedding by day 180 (mean reduction, 32%), as well as significant increases in terminal, vellus, and total hair counts [11]. As part of a randomized, controlled 4-arm study of adult men and women with androgenetic alopecia (N=80), Sudeep et al (2023) evaluated a nonconventional saw palmetto ingredient, delivered as both an oral and topical product and evaluated for 16 weeks. By study end, the oral product was shown to reduce hair shedding by up to 29% and to increase hair density by 5.2%. Additionally, participants taking the oral saw palmetto product showed significant reductions in DHT levels compared to placebo (P<0.007) [17]. Across these studies, the oral LSESr products were well-tolerated, with no [10, 16, 17] or only minor [11] adverse events

In addition to saw palmetto oral supplements, research evaluating LSESr for topical application has included the use of lotions and serums, in combination with other active ingredients [9, 12, 13] or as a single active ingredient [17]. LSESr topical combination products have shown improvements in hair density and hair mass [9, 12-14]. Morganti et al (1998) evaluated the topical application of a combination LSESr lotion over 50 weeks in men and women with androgenetic alopecia (n=24 in each group). The LSESr combination lotion increased hair mass and hair number starting at week 10; by study end, the LSESr combination lotion increased hair mass by 30% and increased hair number by 27%[13]. Wessagowit et al (2015) conducted an open-label study of 50 men with androgenetic alopecia using a LSESr topical combination serum applied for 4 weeks, followed by a LSESr combination lotion for 20 weeks. This regimen increased terminal hair count compared to baseline at 12 and 24 weeks, decreased medium-sized and vellus counts at 24 weeks, and changed median androgenetic alopecia stage from 4 to 3 at 24 weeks [9].In a double-blind randomized study, Masoud et al (2020) evaluated a topical LSESr combination product with rosemary oil plus 5% minoxidil (n=12) versus 5% minoxidil (n=12) in men with mild to moderate androgenetic alopecia and found that use of the LSESr-containing product significantly improved hair diameter compared to minoxidil alone, and significantly improved hair density compared to baseline. Study participants who added this LSESr combination to minoxidil noted increased hair growth, hair loss reduction, and improved hair appearance [12].As noted previously, Sudeep et al (2023) conducted a 4-arm randomized controlled study in participants with androgenetic alopecia to evaluate a nonconventional saw palmetto ingredient; in this analysis, the topical product was formulated in a concentrated 20% lotion, applied for 16 weeks in adult men and women. By study end, the lotion was shown to reduce hair shedding by up to 22.2% and to increase hair density by 7.6% [17]. All of these LSESr-containing topical products and the nonconventional saw palmetto topical lotion had a positive effect on hair regrowth and scalp appearance and were associated with only minor side effects. Treated individuals report high rates of satisfaction [9, 12, 13, 17].

Over 12 weeks, the use of a 2% serum of USPlus DERM led to dermatologically assessed improvement in hair loss in both men and women. Topical application of the LSESr had a significant impact on hair density and led to a significant reductions in hair loss with styling. The use of this proprietary LSESr with concentrated bioactive FFAs also improved hair characteristics and led to reduction in dandruff, as reported by the study participants and on dermatologic assessment, respectively.

Conclusion

This blinded pilot consumer use trial showed that USPlus DERM, applied topically as a 2% serum (USPlus DERM Topical), improved hair characteristics, supported hair structure and hair density, and addressed hair loss and hair regrowth in participants with a range of skin and hair types, including many individuals who had been experiencing hair loss for 2 years or longer. At 12 weeks, 90.9% of study participants indicated an improvement in hair density and less hair loss. The product was well-tolerated, and its sensory characteristics were well-accepted. These results indicate that USPlus DERM with concentrated bioactive FFAs is an effective LSESr for men and women looking for a natural solution to address hair loss, improve hair density, and support healthy hair growth and characteristics.

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Conflicts of Interest

W. Stephen Hill and Margaret H. Dohnalek are employees of Valensa International. Catherine Carletto is a consultant to VENDEIS, which distributes the active ingredient for the USPlus DERM Topical formulation.

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