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Human Platelet Extract (Plated) Hair Serum for Hair Health Improvement: A Double-blind, Placebo-controlled Clinical Study

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Background: The primary aim of this study was to demonstrate the benefits of topical human platelet exosome extract (HPE) (plated) hair serum for improving hair and scalp health in participants with self-perceived thinning hair.

Methods: This single-center, placebo-controlled, double-blind study enrolled 39 healthy men and women 18–65 years of age with self-perceived thinning hair. Participants applied either HPE for 9 months or a topical placebo for 6 months with the option to cross over to HPE at 6 months for an additional 3 months. End points included improvements in the global aesthetic appearance of hair, as assessed by a blinded live evaluator; participant-reported outcomes; hair trichoscopy; and independent physician photograph evaluations. Safety data included monitoring for adverse events.

Results: Blinded live evaluator assessments demonstrated statistically significant improvements in the global aesthetic appearance of hair for volume/fullness, density, scalp coverage, and appearance, with all *P* values less than 0.0001 within the HPE group and statistical improvement over the control at months 3 and 6 for volume/fullness, density, and scalp coverage. Participant-reported outcomes for within-group changes for HPE were statistically significant for all hair health parameters, including density, volume fullness, scalp coverage, scalp health, thickness, amount, quality, color, dryness, strength, and overall health of the hair. Hair trichoscopy analyses were significantly improved from baseline within the HPE group. Independent physician photography review demonstrated greater improvements within the HPE group. No adverse effects were observed.

Conclusions: This study demonstrates that topical HPE (plated) hair serum with Renewosome technology significantly improves hair and scalp health and is safe and well tolerated. *(Plast Reconstr Surg Glob Open 2025;13:e6562; doi: 10.1097/GOX.0000000000006562; Published online 18 March 2025.)*

INTRODUCTION

Androgenic alopecia (AGA) is the most common cause of hair loss, affecting 30%–50% of men (male-pattern hair loss) and approximately 30% of middle-aged women (female-pattern hair loss).[1] The mechanisms of AGA are multiple, interwoven, and common to both male-pattern hair loss and female-pattern hair loss.[2] Among them is the hypothesis of genetically predisposed oxidative stress resulting from increased expression of proinflammatory cytokines attributable to chronic perifollicular microinflammation.[3]

AGA is characterized by hair follicle miniaturization caused by perturbation of the growth cycle via dihydrotestosterone accumulation.[4,5] Dihydrotestosterone accumulates because of the inhibition of testosterone metabolism by 5α-reductase. Additionally, exposure to high oxidative stress levels in the skin leads to the accumulation of reactive oxygen species in hair follicles. These reactive oxygen species, such as hydrogen peroxide and superoxide, overcome the follicular antioxidant defense capacity, which

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leads to premature and dysfunctional human dermal papilla cells.[6] With exacerbation and without intervention, AGA becomes irreversible.[2]

Alopecia is attributable to varied mechanisms and features a multifactorial predisposition. Conventional medical interventions, such as platelet-rich plasma (PRP), corticosteroids, minoxidil, and finasteride, have several limitations. Therefore, several therapeutic strategies for alopecia in regenerative medicine are currently being explored, including human platelet-derived exosome extract.[2]

Multiple modalities have been used to improve the appearance of thicker, fuller hair. Topical and oral supplements have been used by consumers for many years. Treatments such as laser therapy, PRP, and microneedling have also shown promise in increasing terminal hair density. The various therapies listed above have shown variable results in differing patient populations. Topical actives have gained attention for their local site of action, convenience, and fewer systemic side effects.[7,8] Advancements in topical delivery systems, such as emulsions, encapsulations, liposomal formations, and exosome therapies, offer promising avenues for enhancing the efficacy and safety of topical treatments for AGA.

New frontiers in exosome application have shown promise in preclinical studies[9]; however, topical cosmetic application for hair and scalp health has not been studied. This pilot study aimed to evaluate changes to scalp and hair health using a topical cosmetic formulation containing human platelet exosome extract (HPE) in healthy men and women 18–65 years of age with self-perceived thinning hair.

MATERIALS AND METHODS

This is a single-center, prospective, double-blind, placebo-controlled study to evaluate the topical use of (plated) hair serum for the improvement of self-perceived thinning hair. The study was conducted in accordance with the Code of Federal Regulations on the Protection of Human Participants (45 CFR Part 46) and institutional research policies and procedures for cosmetic studies. Sterling Institutional Review Board approved the study, and all participants signed informed consent before any study procedures were performed.

Primary study inclusion criteria included men and women 18–65 years of age (inclusive) with a body mass index of 18.5–35 kg/m^2 with self-perceived mild to moderate thinning hair. Exclusion criteria included, but were not limited to, pregnancy, breast-feeding, any new use of a product to prevent or promote hair growth, diagnosis of hair loss disorder (such as alopecia areata or scarring forms of alopecia), history of hair transplant or severe hair loss, history of active or chronic conditions that could affect study results (such as autoimmune thyroid disease), and active skin disease to the application area (eg, eczema and psoriasis).

The active ingredient group regimen included the use of 1 dropper full of topical HPE (plated) hair serum applied to the scalp in areas of thinning hair once daily for 9 months. Control group participants applied 1 dropper full of placebo serum (glycerin vehicle) product to the scalp once daily in areas of thinning hair for 6 months. After 6 months, they were unblinded and crossed over to the active group with topical HPE (plated) hair serum (1 dropper full) applied to the scalp in areas of thinning hair once daily for 3 months. As this was an initial pilot study, 80% of participants were randomized to the active ingredient to ensure efficacy and safety; 20% of the participants randomized to the control group were able to receive the active product after 6 months to assess efficacy further and encourage continued participation within the study.

Takeaways

Question: What are the benefits of hair and scalp health using a topical hair serum with human platelet exosome extract (plated)?

Findings: A double-blind, placebo-controlled study showed significant improvements in hair volume/fullness, density, scalp coverage, and appearance within the active group and statistical improvements over the control at months 3 and 6. Hair trichoscopy analyses were significantly improved from baseline within the active group.

Meaning: Topical (plated) hair serum with Renewosome technology has been demonstrated to be safe and effective as an avenue for thinning hair and scalp health.

Study end points included the following:

1. Improvement when compared with baseline in global aesthetic appearance of hair, as assessed by a blinded live evaluator at 1, 3, 6, and 9 months using a 7-point Likert scale (+3 greatly improved, +2 moderately improved, +1 slightly improved, 0 no change, −1 slightly worsened, −2 moderately worsened, and −3 greatly worsened) across 5 dimensions of hair health (hair density, scalp coverage, volume/fullness, breakage/damage, and overall hair appearance).
2. Participant Self-assessment and Hair Health Questionnaires at 1, 3, 6, and 9 months comparing outcomes to baseline, which included questions measured on a 7-point Likert scale (+3 greatly improved, +2moderately improved, +1 slightly improved, 0 no change, −1 slightly worsened, −2 moderately worsened, and −3 greatly worsened).

Other observed end points included hair trichoscopy assessments with the validated HairMetrix device (Canfield Scientific, Parsippany, NJ), including hairs per square centimeter, average hairs per follicular unit (FU), average hair width, and FUs per square centimeter.[10] Additionally, independent blinded physician evaluations of the changes from baseline at months 3 and 6 were performed using the photographs to assess hair density, scalp coverage, volume/fullness, and overall hair appearance.

Participants attended in-office visits, underwent clinical assessments, and completed self-assessments and hair health questionnaires at baseline and months 1, 3, 6, and

9. They were instructed to inform the clinical staff if they experienced any adverse events.

STATISTICAL METHODS

All study data were summarized with descriptive statistics. Continuous variables were summarized with means, SDs, medians, and ranges. Categorical variables were summarized with counts and percentages. Groups were compared on continuous baseline characteristics using *t* tests and on categorical baseline characteristics using chi-square tests or the Fisher exact tests, as appropriate. Repeated measures regression modeling methods were used to compare within and between groups while adjusting for age and ethnicity imbalances. Repeated measures mixed modeling methods were used to compare independent reviewers on photographic reviews. No adjustments for multiple comparisons were planned. All tests were 2-sided, and results with a *P* value less than or equal to 0.05 were considered statistically significant.

RESULTS

A total of 39 participants were consented. There were 31 participants enrolled in the active ingredient group, HPE (plated) hair serum, and 8 in the control group, placebo serum (glycerin vehicle). Participants were followed up for 9 months. At 6 months, the control group was unblinded and allowed to cross over to the active ingredient group. All control participants agreed to cross over to the active HPE for the duration of the study. Two active group participants discontinued after the 3-month visit for personal reasons, and an additional 4 participants were lost to follow-up after 6 months, for a total of 33 evaluable participants at month 9. No adverse events were reported or observed among the participants. The mean age was 35.13 ± 11.51 in the control group, including 5 women and 3 men, and 46.45 ± 12.35 in the active group, including 15 women and 16 men. The Fitzpatrick skin phototypes of the participants were as follows: active group (I = 1, II = 14, III = 11, IV = 5) and control group (I = 1, II = 1, III = 5, IV = 1).

For the end point of the blinded live evaluator assessment, statistically significant improvements from baseline were identified at all time points within the active HPE group for hair density, scalp coverage, volume/fullness, and hair appearance. Hair breakage and damage were significantly improved at months 3, 6, and 9 within the active group. Furthermore, between-group analyses showed that the active HPE group had a statistical improvement over the control group at months 3 and 6 for hair density (0.95 HPE, $P = 0.05$ versus 0.5 control and 1.17 HPE, $P < 0.0001$ versus −0.13 control), scalp coverage (0.9 HPE, $P = 0.009$ versus 0.25 control and 1.17 HPE, $P < 0.0001$ versus −0.25 control), and volume fullness (0.77 HPE, $P = 0.029$ versus 0.25 control and 0.79 HPE, $P < 0.0001$ versus 0 control).

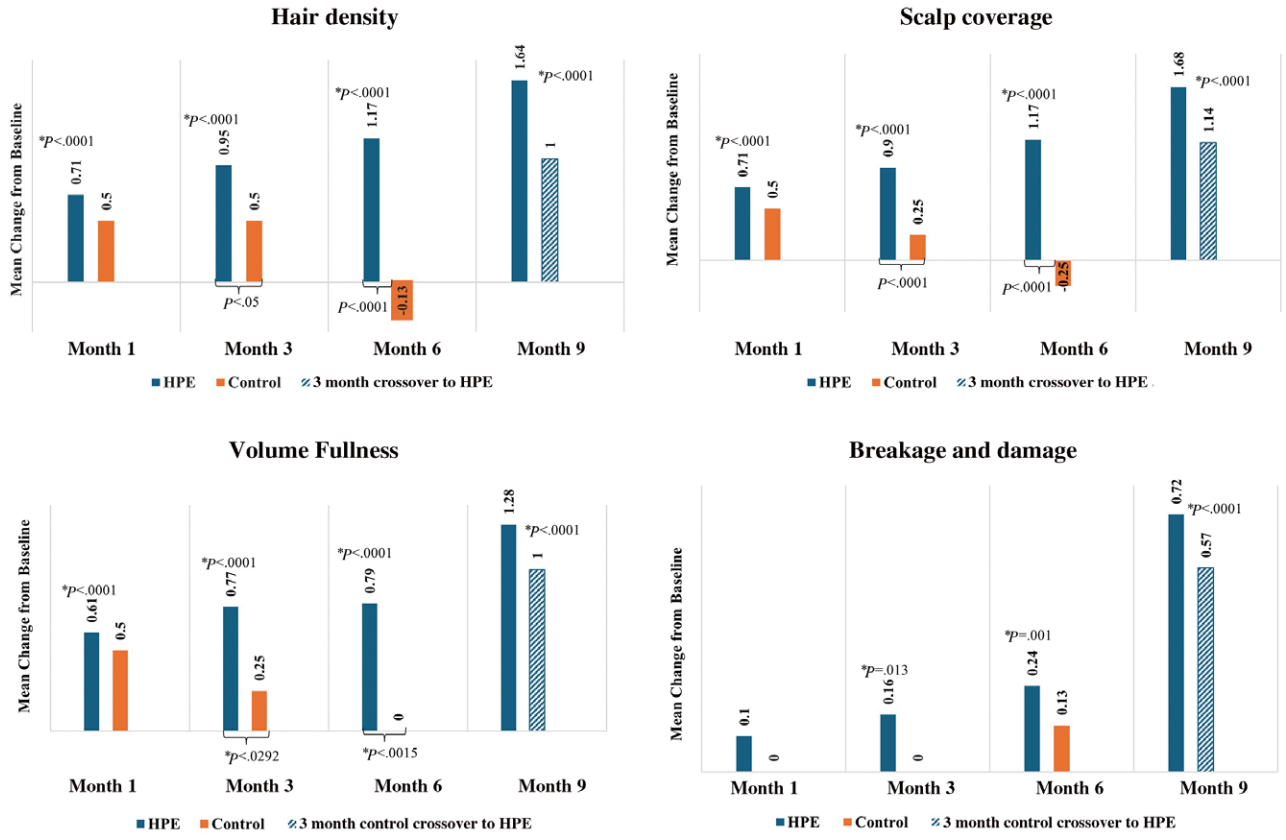

Fig. 1. Mean change from baseline as graded by the blinded evaluator.

Table 1. Mean Improvement From Baseline as Graded by the Blinded Participants (Control Group Was Blinded Until the Month 6 Visit)

Blinded Participant—Mean Improvement From Baseline*	Month 1 HPE	Month 1 Control	Month 3 HPE	Month 3 Control	Month 6 HPE	Month 6 Control	Month 9 HPE	Control Crossover—3 mo Post-HPE $P \leq 0.05$
Overall hair health	0.47 $P = 0.015$	0.38	0.94 $P < 0.0001$	0.63	1.0 $P < 0.0001$	0.75	1.52 $P < 0.0001$	1.43
Scalp health	0.45 $P = 0.023$	0.38	0.74 $P < 0.0001$	0.63	1.18 $P < 0.0001$	0.63	0.92 $P < 0.0001$	0.67
Scalp coverage	0.48 $P = 0.002$	0.13	0.77 $P < 0.0001$	0.75 $P = 0.017$	1.18 $P < 0.0001$	0.88 $P = 0.006$	1.19 $P < 0.0001$	0.67
Color	0.1	0.13	0.48 $P < 0.0001$	0	0.45 $P = 0.001$	0	0.72 $P < 0.0001$	0.50
Strength	0.52 $P = 0.003$	0.25	0.68 $P < 0.0001$	0.63	0.93 $P < 0.0001$	0.25	1.04 $P < 0.0001$	0.67
Amount	0.52 $P = 0.002$	0.38	0.97 $P < 0.0001$	0.75 $P = 0.025$	1.07 $P < 0.0001$	0.50	1.31 $P < 0.0001$	0.50
Thickness	0.58 $P = 0.003$	0.13	0.81 $P < 0.0001$	0.88 $P = 0.015$	1.21 p<.0001	0.88 $P = 0.015$	1.23 $P < 0.0001$	0.83
Volume fullness	0.71 $P = 0.0003$	0.25	0.97 $P < 0.0001$	0.88 $P = 0.019$	1.21 $P < 0.0001$	1.13 $P = 0.003$	1.35 $P < 0.0001$	1.0
Hair density	0.74 $P < 0.0001$	0.25	1.1 $P < 0.0001$	0.75 $P = 0.032$	1.14 $P < 0.0001$	1.0 $P = 0.004$	1.23 $P < 0.0001$	1.0
Dryness	0.26 $P = 0.026$	0.13	0.32 $P < 0.002$	0.25	0.52 $P = 0.0002$	0.13	0.76 $P < 0.0001$	0.67
Quality	0.65 $P = 0.002$	0.63	0.97 $P < 0.0001$	0.75 $P = 0.046$	1.24 $P < 0.0001$	1.0 $P = 0.008$	1.19 $P < 0.0001$	1.0

*All statistically significant *P* values are listed.

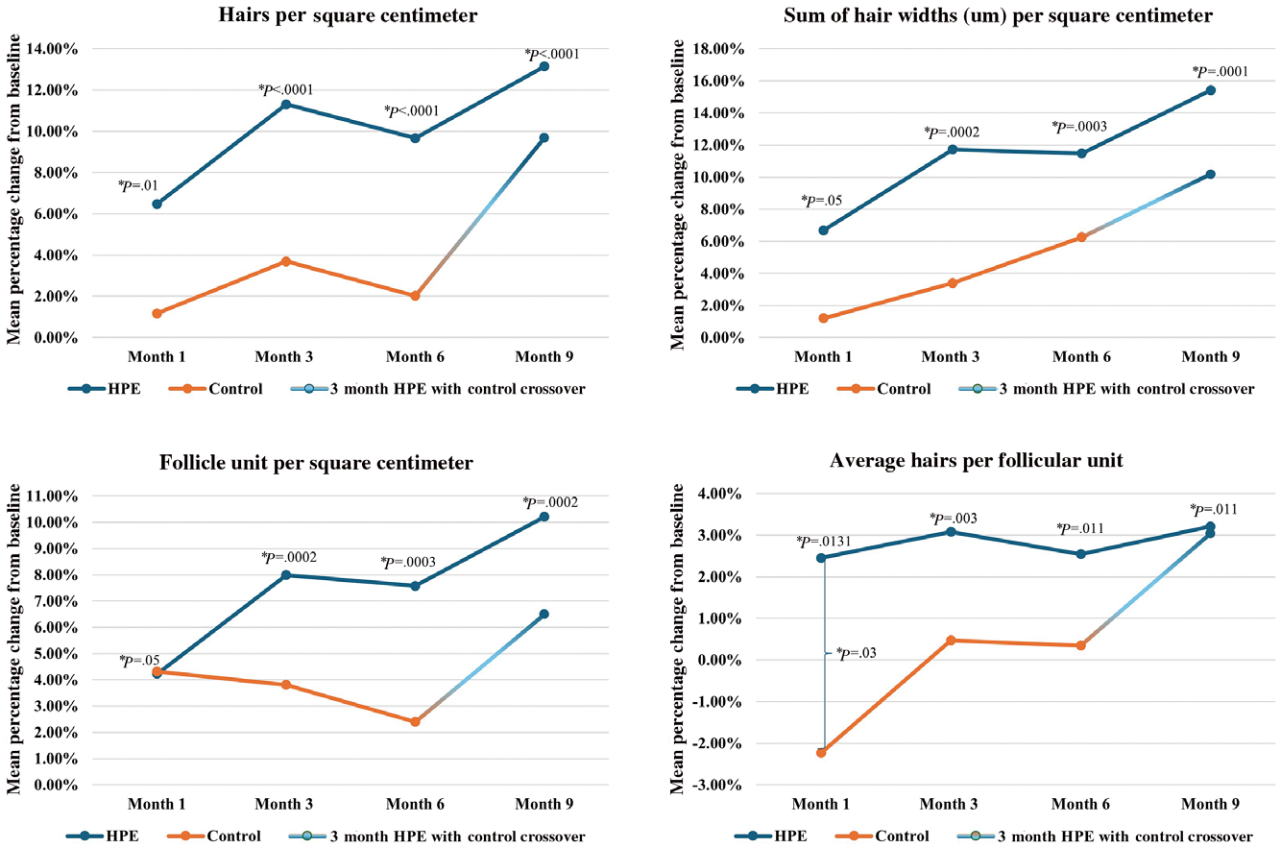

Fig. 2. Mean percentage change from baseline in the hair trichoscopy measures.

Within the control group, hair appearance improved at months 3 and 6. There were no other significant changes in the control group before the crossover to the active HPE. At 3 months postcrossover from control to HPE, all the hair parameters assessed—density, scalp coverage, volume/fullness, hair appearance, and breakage/damage—were statistically improved. Figure 1 displays the mean change from baseline as graded by the blinded evaluator.

For the blinded participant self-assessment and hair health questionnaires, blinded participants graded changes from baseline for the following hair assessments: density, volume fullness, scalp coverage, scalp health, thickness, amount, quality, color, dryness, strength, and overall health of the hair. The HPE group had significant improvements from baseline in all 11 hair assessments at all follow-up time points at months 1, 3, 6, and 9, except color at month 1. The control group graded improvements at month 3 for 6 assessments of density, volume fullness, scalp coverage, thickness, amount, and quality, and at month 6 for 5 assessments of density, volume fullness, scalp coverage, thickness, and quality. After the control group crossed over to active HPE, all graded hair assessments at post 3 months improved. Table 1 displays the mean improvement from baseline as graded by the blinded participants (the control group was blinded until the month 6 visit).

Hair trichoscopy measures included output from the HairMetrix (Canfield Scientific, Parsippany, NJ) device, which provides artificial intelligence-driven real-time hair measurements without clipping. At months 1,3, 6, and 9, there were statistically significant mean percentage changes from baseline within the active HPE group in the following measures: hairs per square centimeter (HPE: 6.48%, $P = 0.0095$; 11.30%, $P < 0.0001$; 9.66%, $P < 0.0001$; 13.14%, $P < 0.0001$ versus control: 1.71%, $P = 0.3759$; 3.69%, $P = 0.1772$; 2.02%, $P = 0.3325$ and crossover: 9.68%, $P < 0.0001$), sum of hair widths (μm) per square centimeter (HPE: 6.69%, $P = 0.05$; 11.72%, $P = 0.0002$; 11.48%, $P = 0.0003$; 15.42%, $P = 0.0001$ versus control: 1.20%, $P = 0.4688$; 3.40%, $P = 0.2491$; 6.25%, $P = 0.0887$ and crossover: 10.19%, $P = 0.0004$), FU per square centimeter (HPE: 4.23%, $P = 0.05$; 7.99%, $P = 0.0002$; 7.58%, $P = 0.0003$; 10.21%, $P = 0.0002$ versus control: 4.32%, $P = 0.0722$; 3.81%, $P = 0.0978$; 2.40%, $P = 0.2081$ and crossover 6.49%, $P = 0.0006$), and average hairs per FU (HPE: 2.45%, $P = 0.0131$; 3.08%, $P = 0.0026$; 2.54%, $P = 0.0110$;

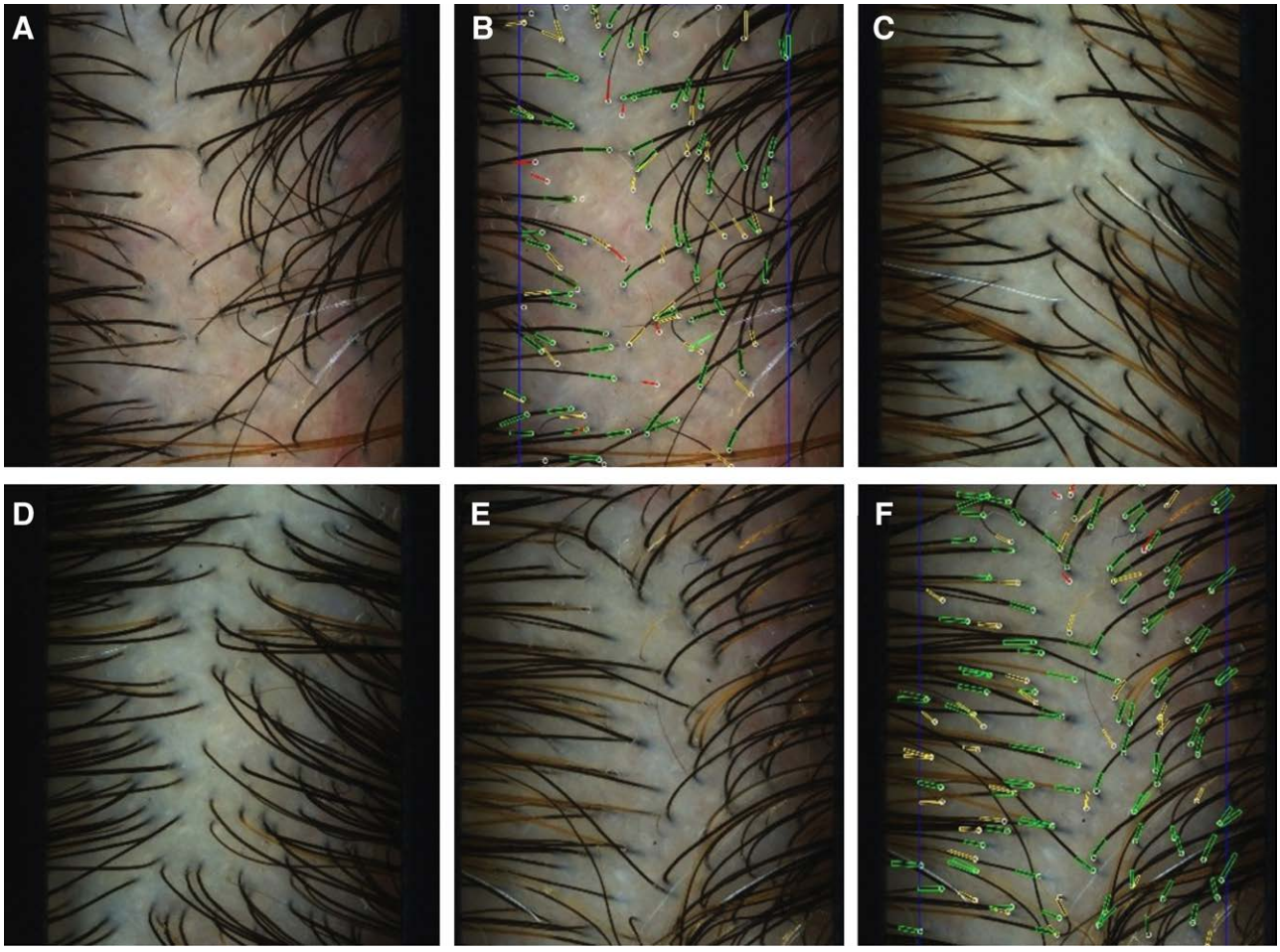

Fig. 3. HPE participant—HairMetrix trichoscopy images. A, Baseline. B, Baseline assessment. C, Month 3. D, Month 6. E, Month 9. F, Month 9 assessment

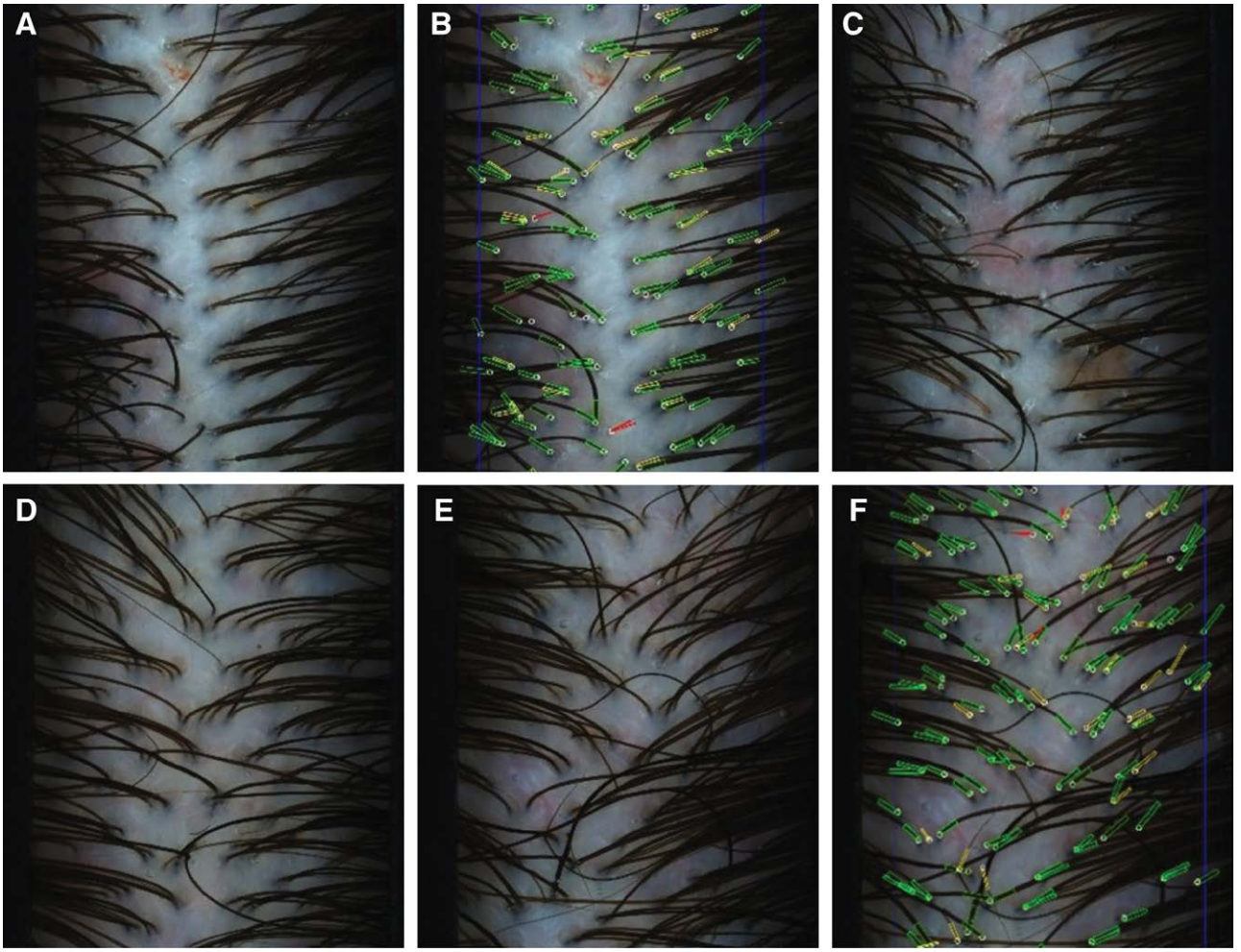

Fig. 4. Control participant—HairMetrix trichoscopy images. A, Baseline. B, Baseline assessment. C, Month 3. D, Month 6. E, 3 months post crossover to HPE. F, 3 months post crossover to HPE assessment.

3.21%, $P = 0.0113$ versus control: −2.23, $P = 0.2430$; 47%, $P = 0.8593$; 35%, $P = 0.9073$ and crossover: 3.04%, $P = 0.0015$). The active HPE group had a statistical improvement over control at month 1 for average hairs per FU (HPE 2.45%, control −0.03%, $P = 0.0299$). The control group did not have a statistically significant mean percentage change improvement in measurements until crossing over to HPE. Figure 2 displays the mean percentage change from baseline in the hair trichoscopy measures, and Figures 3 and 4 display the images.

The blinded independent physician hair assessments, based on the clinical photographs at months 3 and 6 compared with baseline, exhibited greater mean scores of improvements within the active HPE group compared with the control for the assessments of overall hair density, scalp coverage, hair volume/fullness, and overall hair appearance. At month 6, the scores remained similar to those at month 3, except for an increase in hair volume and fullness improvement within the HPE group. Before and after photographs of 2 men and 1 woman are shown in Figures 5–7.

The safety profile was excellent. There were no adverse events, and the product was well tolerated.

DISCUSSION

Topical (HPE) (plated) hair serum is an innovative topical cosmetic demonstrated to improve the appearance of hair and scalp health, including significant improvements in hair density, scalp coverage, and volume fullness. This evidence-based topical for hair loss harnesses the regenerative potential of exosomes, small vesicles that contain proteins, and nucleic acids that play key roles in cell-to-cell communication and tissue repair.[11] In hair loss, topical exosome therapy is postulated to stimulate hair follicle regeneration, prolong the growth cycle, and promote hair growth. Platelet-derived exosomes are proposed to encourage the proliferation and activation of dormant hair follicle stem cells, producing new hair shafts and increasing hair density. By delivering a concentrated source of topical HPE directly to the scalp, exosomes may rejuvenate aging or damaged hair follicles and restore normal hair growth cycles. Exosomes also have anti-inflammatory properties that can modulate the immune response, potentially reducing scalp inflammation and creating a more favorable environment for hair follicle regeneration.

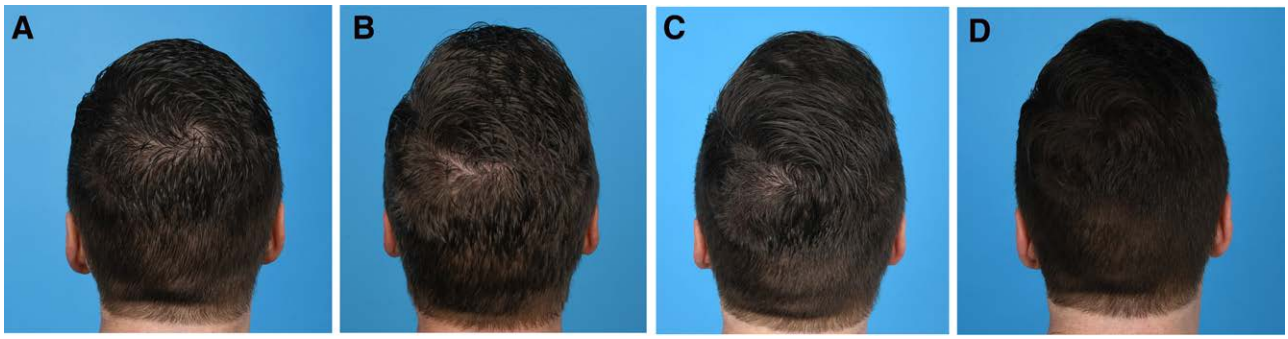

Fig. 5. Before and after photographs of a 55-year-old male HPE group participant with self-perceived thinning hair showed an improvement over time in hair density: baseline (A), month 3 (B), month 6 (C) and month 9 (D).

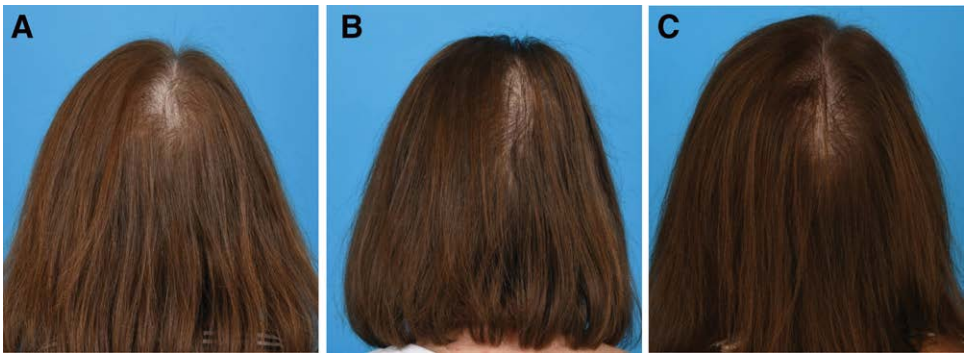

Fig. 6. Before and after photographs of a 68-year-old female HPE group participant with self-perceived thinning hair: baseline (A), month 3 (B) and month 6 (C). She reported at least a 1-grade improvement in hair thickness at all time points, and a 2-grade improvement in thickness at month 6.

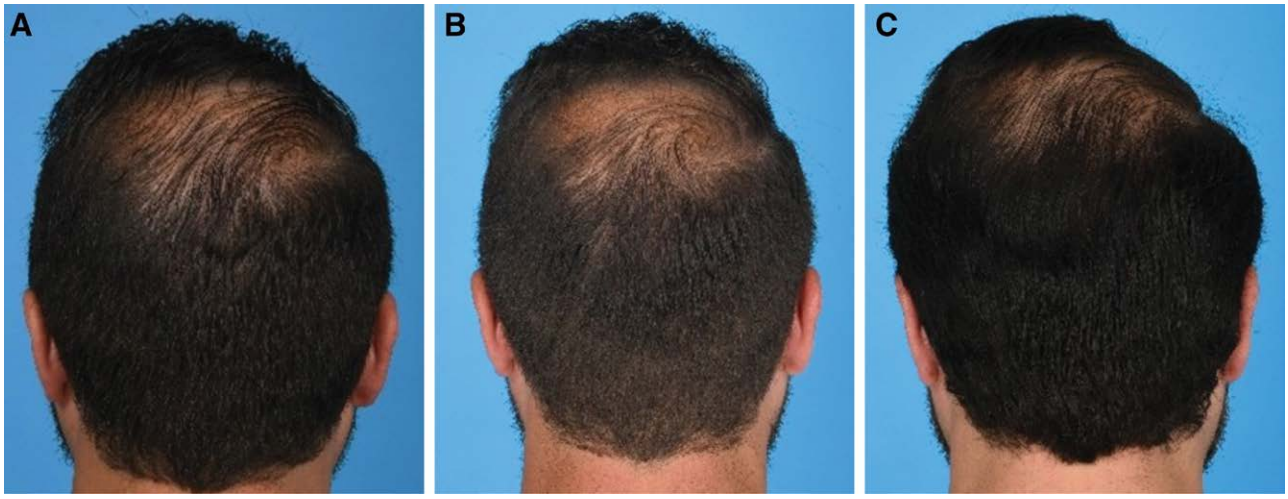

Fig. 7. Before and after photographs (baseline [A], month 6 [B], and 3 months postactive HPE [C]) of a 31-year-old man who was initially randomized to the placebo group for 6 months and then crossed over to HPE for 3 months.

In this double-blind, placebo-controlled pilot study, blinded investigator assessments showed significant improvements within the HPE group for hair density, scalp coverage, volume/fullness, hair appearance, and breakage/damage, which increased over the 9-month study period. Although the control group was small and did have some within-group improvements due to the natural progression of hair growth, there was a noted improvement once the control participants crossed over to HPE. Blinded participants within the HPE group reported significant improvements in their hair health, including density, volume fullness, scalp coverage, scalp health, thickness, amount, quality, color, dryness, strength, and overall health of the hair. Notably, HPE participants

had significantly improved hair color at months 3 and 6, whereas there were no improvements in the control group. Independent physicians assessed hair density, volume, scalp coverage, and overall appearance through a blinded photographic review. The HPE group showed greater improvements at months 3 and 6 in comparison to the control. Distinct blinded assessments were supported by data from the Canfield HairMetrix device, which showed a statistically significant increase from baseline within the active HPE group for hairs per square centimeter, hair width, follicle unit per square centimeter, and average hairs per FU.

Research and treatments for AGA continue to evolve, driven by advancements in the understanding of hair biology, drug delivery systems, and personalized care. With a multidisciplinary approach that integrates clinical expertise, scientific innovation, and patient empowerment, topical therapies hold promise as part of a comprehensive strategy for managing AGA and improving the quality of life for individuals affected by this common hair disorder.

Treatments such as laser therapy, PRP, and microneedling have also shown promise in increasing terminal hair density; however, these are invasive procedures with associated pain and have shown variable results in differing patient populations. Topical actives have gained attention for their convenience, local site of action, and fewer systemic side effects. However, the effectiveness of these active ingredients varies widely among individuals, as genetic factors, hormones, and underlying medical conditions may influence the response period. This study demonstrates that topical HPE is safe and effective as a topical cosmetic avenue for thinning hair. Future investigations will include a larger population with Fitzpatrick skin phototypes V and VI and powered randomization for evaluation.

CONCLUSIONS

This study demonstrates that topical HPE (plated) hair serum with Renewosome technology significantly improves hair density, volume fullness, and hair and scalp health and is safe and well tolerated.

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DISCLOSURES

Eaton-Jankov, Secic, Bell, and Dr. Wyles are consultants for Rion Aesthetics, Inc. Dr. Behfar and the Mayo Clinic have an ownership interest in Rion, Inc., and Rion Aesthetics, Inc. The other authors have no financial interest to declare in relation to the content of this article. This study was funded, in part, by Rion Aesthetics, Inc. (Rochester, MN).

ETHICAL APPROVAL

The authors confirm that the ethical policies of the journal, as noted on the journal's author guidelines page, have been adhered to, and the appropriate ethical review committee approval has been received. Approval was obtained from Sterling Institutional Review Board. Informed consent was obtained from all participants. All participants provided photography consent.

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