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A 2% Oleosome-FGF-2 Fusion Extract Scalp Serum Improves Phototrichogram-Derived Hair Density, Anagen/Telogen Ratio, Hair Shaft Thickness and Scalp Barrier Parameters in Women with Shedding-Prone Hair: A Randomized, Single-Blind, Placebo-Controlled Pilot Study

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Abstract

Background: Hair shedding, reduced perceived hair density, brittle hair prone to falling and scalp discomfort are common concerns in women. Objective instrumental methods such as digital phototrichogram can quantify hair density, anagen/telogen ratio and hair shaft diameter, while scalp hydration, transepidermal water loss (TEWL) and sebum measurements can characterize scalp barrier status.

Objective: To evaluate the efficacy of a 2% Oleosome-FGF-2 fusion extract scalp serum compared with placebo on hair density, anagen/telogen ratio, hair shaft thickness and scalp biophysical parameters over 84 days.

Methods: This randomized, single-blind, placebo-controlled pilot study enrolled 40 healthy female volunteers with telogen effluvium and/or brittle hair prone to falling out, ideally with dry or sensitive scalps. Participants received either 2% Oleosome-FGF-2 fusion extract Scalp Treatment (Serum A; n=20) or placebo scalp treatment (Serum B; n=20) and applied the product twice daily to the scalp for 84 days. Assessments were performed at baseline (T0), day 28 (T28), day 56 (T56) and day 84 (T84). Instrumental endpoints included anagen/telogen ratio, hair density and shaft thickness using C-CUBE Pixience digital imaging, scalp hydration by Corneometer CM825, TEWL by Nano-Tewameter TM300 and sebum level by Sebumeter SM815. Clinical hair-density scoring was performed at T0 and T84 using a 5-point Likert scale aligned with Ludwig-type clinical assessment.

Results: At T84, Serum A increased anagen/telogen ratio by 17.0% vs. -2.6% with placebo, hair density by 33.5% vs. 7.2%, hair shaft thickness by 10.6% vs. -1.6% and scalp hydration by 22.2% vs. -2.9%. Serum A reduced TEWL by 27.2% vs. a 9.2% reduction with placebo and reduced sebum level by 30.2% vs. a 2.7% increase with placebo. Between-group comparisons favored Serum A for anagen/telogen ratio at T56 and T84, hair density at T28, T56 and T84, hair shaft thickness at T84, TEWL at T56 and T84, sebum at T56 and T84 and clinical hair-density assessment at T84. Hydration differed significantly between groups at baseline and at all post-baseline time points. Clinical hair-density scores improved in 90% of Serum A participants and 35% of placebo participants at T84.

Conclusion: In this exploratory randomized placebo-controlled pilot study, twice-daily use of a 2% Oleosome-FGF-2 fusion extract scalp serum for 84 days was associated with improved phototrichogram-derived hair density, anagen/telogen ratio, hair shaft thickness and scalp barrier parameters compared with placebo. Larger double-blind studies with prespecified primary endpoints, individual-level datasets and longer follow-up are warranted.



Keywords: Hair density; Telogen effluvium; Phototrichogram; Scalp serum; Cosmetic dermatology; Transepidermal water loss; Hair shaft thickness; Oleosome; FGF-2

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Introduction

Hair shedding, reduced perceived hair density and fragile hair prone to falling are frequent concerns in women. Telogen effluvium was originally described as increased shedding of telogen hairs and is now understood as a reaction pattern caused by disturbances in hair-cycle timing, with potential triggers including physiologic stress, endocrine or nutritional factors, medications, inflammatory scalp conditions and psychological stress [1-4]. In women, diffuse shedding can coexist with reduced perceived density and with clinical patterns of female-pattern hair loss, commonly described using standardized clinical grading systems such as the Ludwig scale [5,6]. Although many cases are self-limited, persistent shedding and visible density reduction can impair self-image and quality of life, supporting the need for well-tolerated topical cosmetic approaches that can be evaluated objectively [7,8].

Hair-density outcomes must be interpreted against the biology of the hair follicle as a cycling mini-organ in which epithelial-mesenchymal interactions, dermal papilla activity and growth-factor signaling regulate anagen, catagen, telogen and exogen transitions [9-13]. Dermal papilla cells can induce follicular activity and preclinical studies have implicated fibroblast growth factor signaling, including FGF-2-related pathways, in follicle development, dermal papilla responses and anagen modulation [14-18]. These biological considerations make objective assessment essential in hair-growth and hair-shedding studies because subjective impressions and global photography alone are vulnerable to lighting, hair styling, hair length and expectation effects. Digital phototrichogram and related computer-assisted imaging methods have been widely used to quantify hair density, anagen/telogen distribution and hair shaft diameter in a defined scalp area over time [19-22].

In parallel, scalp biophysical parameters such as stratum corneum hydration, transepidermal water loss (TEWL) and surface sebum provide complementary information regarding scalp barrier status, scalp comfort and the local environment in which hair fibers emerge [23-29]. Oleosome-FGF-2 fusion extract is a cosmetic active ingredient developed by Core Biogenesis for scalp and hair-density applications. The oleosome/oleosin platform is supported by prior biotechnology literature showing that plant seed oil bodies can act as carriers for recombinant proteins and that oleosin-fusion strategies can facilitate recombinant protein localization and

recovery [30-32]. Because the scalp contains numerous follicles and follicular openings are relevant to topical delivery and product distribution, follicular-targeting considerations are also relevant to leave-on scalp formulations [33]. The product evaluated in this manuscript was a 2% Oleosome-FGF-2 fusion extract Scalp Treatment (Serum A). The purpose of this pilot trial was to evaluate whether twice-daily application of the serum over 84 days improves objective hair parameters and scalp biophysical measures in women with shedding-prone hair.

Methods

Study design and setting

This was a randomized, single-blind, placebo-controlled pilot study conducted at Abich S.r.l. Clinical and Cosmetological Trials Center, Vimodrone, Italy. The study period ran from 17 November 2025 to 13 February 2026. The sponsor was Core Biogenesis SAS, Strasbourg, France.

The study was designed as a randomized, single-blind, placebo-controlled pilot study. Participants were blinded to treatment allocation and received either the active scalp serum or the placebo scalp serum in a 1:1 allocation. Randomization and product allocation were conducted by the study center before treatment assignment. Detailed information on randomization-sequence generation, allocation concealment and assessor blinding was limited in the available study documentation and is therefore acknowledged as a reporting limitation of the pilot study.

Participants

Forty healthy female volunteers were enrolled, with 20 allocated to 2% Oleosome-FGF-2 fusion extract Scalp Treatment (Serum A) and 20 allocated to placebo scalp treatment (Serum B). Participants had hair loss due to telogen effluvium and/or brittle hair prone to falling out, ideally with dry or sensitive scalps and were recruited from the Abich volunteer database. Participants were deemed suitable by the study center and were not suffering from pathologies in the examined scalp area.

Exclusion criteria included pregnancy or breastfeeding; local or systemic medication that could affect skin response; signs of irritated skin at the test site; active skin disease that could interfere with study objectives; participation in simultaneous or recent studies that could interfere with evaluation; and medical judgment of non-suitability.



Ethics and consent

The study was conducted in accordance with the Declaration of Helsinki [34]. Ethics approval was obtained from a relevant ethics committee prior to initiation of the study (ethics approval code: REL/0504/2026; date of approval: 01 November 2025). All participants were informed about the purpose of the study, study procedures and possible risks before signing written informed consent. Participants also consented to personal-data processing according to Regulation (EU) 2016/679 (GDPR). The study center implemented precautions to avoid excessive skin reactions or adverse effects and prepared safety measures in case of adverse reactions.

Interventions

Participants applied their assigned product twice daily, morning and evening, for 84 days to the scalp rather than the hair. Participants were instructed not to use other similar products in the analyzed area during the study period.

The active intervention was 2% Oleosome-FGF-2 fusion extract Scalp Treatment (Serum A). The comparator was Placebo Scalp Treatment (Serum B). Both samples were stored at room temperature. The Abich product sample codes were 9625/25-01 and 9626/25-01. Complete INCI compositions of the active and placebo products were documented in the study annex.

Outcomes and assessments

Instrumental assessments were conducted at T0, T28, T56 and T84. For phototrichogram-based endpoints, measurements were performed two days after shaving the selected scalp area. The selected scalp area was 0.5 cm². Environmental temperature and humidity were monitored and maintained under standard conditions at each measurement time point, consistent with the need to control environmental variables during noninvasive skin water-balance measurements [23-25].

Anagen/telogen ratio, hair density and hair shaft thickness were measured with C-CUBE Pixience. The C-CUBE system captures standardized high-resolution scalp images using controlled lighting and software-assisted morphometric analysis. In the digital phototrichogram protocol, anagen hairs show visible regrowth after approximately 48 hours whereas telogen hairs do not show appreciable growth; this principle is consistent with established phototrichogram and computer-assisted hair-growth analysis methods [19-22].

Scalp hydration was measured with Corneometer CM825 (Courage + Khazaka, Germany). TEWL was measured with Nano-Tewameter TM300 (Courage + Khazaka, Germany). Sebum level was measured with Sebometer SM815 (Courage + Khazaka, Germany). These endpoints were included because noninvasive biophysical

measurements are commonly used in cosmetic science to characterize skin/scalp water balance, barrier function and surface lipid status [23-29]. Clinical hair-density evaluation was performed at T0 and T84 on a 1-5 Likert scale, where 1 represented very low density/poor coverage and 5 represented very high density/maximum coverage, based on Ludwig-type clinical assessment [6]. Standardized scalp photographs were acquired at T0 and T84 using a Canon camera.

Statistical analysis

Group means, percentage changes from baseline and p values were summarized for each endpoint. Within-group comparisons were performed using t-tests for instrumental outcomes and Wilcoxon tests for clinical hair-density scores. Between-group comparisons were performed using t-tests for instrumental outcomes and Wilcoxon tests for clinical hair-density scores. Unless otherwise specified, p values are reported as two-sided and unadjusted for multiplicity. Given the exploratory pilot design and the number of endpoints evaluated, inferential results should be interpreted as hypothesis-generating.

Results

Participant disposition and baseline values

Forty female participants were randomized and included in the analysis, with 20 assigned to Serum A and 20 assigned to Serum B. The analysis population comprised all participants included in the study dataset. Baseline mean values for instrumental endpoints are shown in **Table 1**.

Table 1: Mean baseline values by group.

| Endpoint | Serum A baseline | Serum B baseline |
|---|------------------|------------------|
| Anagen/telogen ratio | 8.4 | 8.3 |
| Hair density, hairs/cm ² | 127.1 | 135.2 |
| Hair shaft thickness, micrometers | 80.5 | 83.5 |
| Scalp hydration, arbitrary units | 25.4 | 18.7 |
| Nano TEWL, g/h/m ² | 9.8 | 11.9 |
| Sebum level, micrograms/cm ² | 23.3 | 26.5 |

Hair-cycle and hair-density outcomes

Serum A increased mean anagen/telogen ratio from 8.4 at baseline to 9.8 at T84, corresponding to a 17.0% increase. Placebo changed from 8.3-8.1, corresponding to a 2.6% decrease. Between-group comparisons were not significant at T0 or T28, but favored Serum A at T56 (p=0.0212) and T84 (p=0.0005).

Serum A increased mean hair density from 127.1 hairs/cm² at baseline to 169.6 hairs/cm² at T84, corresponding to a 33.5% increase. Placebo increased



from 135.2 to 145.0 hairs/cm², corresponding to a 7.2% increase. Between-group comparisons favored Serum A at T28 (p=0.0439), T56 (p=0.0484) and T84 (p=0.0488), with no significant baseline difference (p=0.5086).

Serum A increased mean hair shaft thickness from 80.5 micrometers at baseline to 89.0 micrometers at T84, corresponding to a 10.6% increase. Placebo decreased from 83.5 to 82.2 micrometers, corresponding to a 1.6% decrease. Between-group comparison favored Serum A at T84 (p=0.0291).

Table 2: Mean instrumental hair outcomes over time and percentage change at T84 versus T0.

| Endpoint | Group | T0 | T28 | T56 | T84 | T84 vs. T0 |
|-------------------------------------|-----------------|-------|-------|-------|-------|------------|
| Anagen/telogen ratio | Serum A | 8.4 | 9.6 | 9.7 | 9.8 | 17.00% |
| Anagen/telogen ratio | Serum B placebo | 8.3 | 8.7 | 8.6 | 8.1 | -2.60% |
| Hair density, hairs/cm ² | Serum A | 127.1 | 169.8 | 168.6 | 169.6 | 33.50% |
| Hair density, hairs/cm ² | Serum B placebo | 135.2 | 144.7 | 144 | 145 | 7.20% |
| Hair shaft thickness, micrometers | Serum A | 80.5 | 84.5 | 87 | 89 | 10.60% |
| Hair shaft thickness, micrometers | Serum B placebo | 83.5 | 82.8 | 82.1 | 82.2 | -1.60% |

Table 3: Within-group p values for instrumental hair outcomes.

| Endpoint | Group | T0 vs. T28 | T0 vs. T56 | T0 vs. T84 |
|----------------------|-----------------|------------|------------|------------|
| Anagen/telogen ratio | Serum A | <0.0001 | 0.0013 | 0.0004 |
| Anagen/telogen ratio | Serum B placebo | 0.0198 | 0.8717 | 0.8012 |
| Hair density | Serum A | <0.0001 | <0.0001 | <0.0001 |
| Hair density | Serum B placebo | 0.1123 | 0.1151 | 0.1539 |
| Hair shaft thickness | Serum A | 0.0203 | 0.0101 | 0.0027 |
| Hair shaft thickness | Serum B placebo | 0.6989 | 0.2104 | 0.1835 |

Table 4: Between-group p values for instrumental hair outcomes.

| Endpoint | T0 | T28 | T56 | T84 |
|----------------------|--------|--------|--------|--------|
| Anagen/telogen ratio | 0.8774 | 0.0972 | 0.0212 | 0.0005 |
| Hair density | 0.5086 | 0.0439 | 0.0484 | 0.0488 |
| Hair shaft thickness | 0.327 | 0.5856 | 0.117 | 0.0291 |

Scalp hydration, TEWL and sebum outcomes

Serum A increased scalp hydration from 25.4 to 31.0 arbitrary units at T84, corresponding to a 22.2% increase, while placebo decreased from 18.7 to 18.2 arbitrary units, corresponding to a 2.9% decrease. Inter-group comparisons were statistically significant at baseline (p=0.0165) and at all post-baseline time points (T28 p=0.0005; T56 p<0.0001; T84 p<0.0001). Because baseline hydration differed significantly between groups, this endpoint is interpreted cautiously.

Serum A reduced TEWL from 9.8 to 7.1 g/h/m² at T84, corresponding to a 27.2% decrease, while placebo decreased from 11.9 to 10.8 g/h/m², corresponding to a 9.2% decrease. Between-group comparisons favored Serum A at T56 (p=0.0015) and T84 (p=0.0073).

Serum A reduced sebum level from 23.3 to 16.3 micrograms/cm² at T84, corresponding to a 30.2% reduction, while placebo increased from 26.5 to 27.3 micrograms/cm², corresponding to a 2.7% increase. Between-group comparisons favored Serum A at T56 (p=0.0484) and T84 (p=0.0449).

Table 5: Mean scalp biophysical outcomes over time and percentage change at T84 versus T0.

| Endpoint | Group | T0 | T28 | T56 | T84 | T84 vs. T0 |
|---|-----------------|------|------|------|------|------------|
| Scalp hydration, arbitrary units | Serum A | 25.4 | 29.8 | 30.2 | 31 | 22.20% |
| Scalp hydration, arbitrary units | Serum B placebo | 18.7 | 20.1 | 18.4 | 18.2 | -2.90% |
| Nano TEWL, g/h/m ² | Serum A | 9.8 | 8.4 | 7.2 | 7.1 | 27.20% |
| Nano TEWL, g/h/m ² | Serum B placebo | 11.9 | 10.7 | 11.6 | 10.8 | 9.20% |
| Sebum level, micrograms/cm ² | Serum A | 23.3 | 19.7 | 16.5 | 16.3 | 30.20% |
| Sebum level, micrograms/cm ² | Serum B placebo | 26.5 | 26.9 | 27.3 | 27.3 | 2.70% |

Table 6: Within-group p values for scalp biophysical outcomes.

| Endpoint | Group | T0 vs. T28 | T0 vs. T56 | T0 vs. T84 |
|-----------------|---------|------------|------------|------------|
| Scalp hydration | Serum A | 0.0045 | 0.0003 | 0.0001 |



| | | | | |
|-----------------|-----------------|--------|--------|--------|
| Scalp hydration | Serum B placebo | 0.4481 | 0.8908 | 0.7808 |
| Nano TEWL | Serum A | 0.1933 | 0.0081 | 0.0124 |
| Nano TEWL | Serum B placebo | 0.0845 | 0.7657 | 0.2019 |
| Sebum level | Serum A | 0.1973 | 0.0041 | 0.0171 |
| Sebum level | Serum B placebo | 0.9188 | 0.6485 | 0.7929 |

Table 7: Between-group p values for scalp biophysical outcomes.

| Endpoint | T0 | T28 | T56 | T84 |
|-----------------|--------|--------|---------|---------|
| Scalp hydration | 0.0165 | 0.0005 | <0.0001 | <0.0001 |
| Nano TEWL | 0.12 | 0.0947 | 0.0015 | 0.0073 |
| Sebum level | 0.5543 | 0.1871 | 0.0484 | 0.0449 |

Clinical hair-density evaluation

Clinical evaluation showed a statistically significant improvement in hair density for Serum A, with the median score increasing from 2.0 at baseline to 3.5 at T84 (mean 1.9 to 3.3; SD 0.5 to 0.7; Wilcoxon $p < 0.0001$). Hair density improved in 90% of Serum A participants at T84. In the placebo group, the median clinical hair-density score remained 2.0 at baseline and T84 (mean 2.1 to 2.3; SD 0.6 to 0.6), with improvement in 35% of participants; the within-group change was not statistically significant (Wilcoxon $p = 0.0781$). Between-group clinical-density

scores favored Serum A at T84 ($p < 0.0001$).

Table 8: Clinical hair-density evaluation at T0 and T84.

| Endpoint/analysis | Serum A | Serum B placebo |
|----------------------------------|--------------|-----------------|
| Median T0 | 2 | 2 |
| Median T84 | 3.5 | 2 |
| Mean T0 | 1.9 | 2.1 |
| Mean T84 | 3.3 | 2.3 |
| SD T0 | 0.5 | 0.6 |
| SD T84 | 0.7 | 0.6 |
| Within-group p value | <0.0001 | 0.0781 |
| Participants improved at T84 | 90% | 35% |
| Participants not improved at T84 | 10% | 65% |
| Between-group comparison at T84 | $p < 0.0001$ | $p < 0.0001$ |

Participant questionnaire

In the participant questionnaire, Serum A users reported more favorable subjective responses than placebo users on scalp comfort and perceived hair outcomes. For key perceived efficacy items, 95% of Serum A users agreed or strongly agreed that the product helped reduce hair loss and 95% agreed or strongly agreed that it made hair feel stronger and healthier. Subjective questionnaire results were considered exploratory because the study was single-blind and these outcomes are vulnerable to expectation effects.

Table 9: Serum A questionnaire responses.

| Question | Strongly agree | Agree | Neutral | Disagree | Strongly disagree |
|---|----------------|-------|---------|----------|-------------------|
| Has the product reduced scalp itching? | 10% | 40% | 35% | 10% | 5% |
| Has the product reduced scalp dryness? | 25% | 45% | 20% | 5% | 5% |
| Has the product reduced discomfort or sensitivity on the scalp? | 20% | 50% | 30% | 0% | 0% |
| Has the product reduced redness or visible irritation of the scalp? | 15% | 45% | 40% | 0% | 0% |
| Has the product improved overall scalp comfort? | 30% | 55% | 10% | 5% | 0% |
| Has the product helped reduce hair loss? | 40% | 55% | - | 5% | 0% |
| Has the product made your hair feel stronger and healthier? | 30% | 65% | - | 5% | 0% |
| Has the product made your scalp feel fresher and cleaner? | 20% | 50% | - | 30% | 0% |
| Is the product easy to apply? | 35% | 65% | - | 0% | 0% |
| Does the product have a pleasant texture? | 25% | 65% | - | 10% | 0% |
| Is the product fragrance pleasant? | 15% | 70% | - | 15% | 0% |
| Does the product absorb easily without leaving residue or greasiness? | 15% | 50% | - | 20% | 15% |
| Does the product leave a pleasant feeling on the scalp after application? | 20% | 60% | - | 20% | 0% |

For Serum A, the overall product rating distribution was: 1=0%, 2=0%, 3=0%, 4=0%, 5=0%, 6=15%, 7=25%, 8=25%, 9=10% and 10=25%. A total of 100% of Serum A participants said they would recommend the product. A

total of 10% reported undesirable effects and 90% did not; the reported undesirable effect was that the product left the hair feeling slightly heavy.



Table 10: Serum B placebo questionnaire responses.

| Question | Strongly agree | Agree | Neutral | Disagree | Strongly disagree |
|---|----------------|-------|---------|----------|-------------------|
| Has the product reduced scalp itching? | 5% | 5% | 60% | 30% | 0% |
| Has the product reduced scalp dryness? | 0% | 20% | 40% | 40% | 0% |
| Has the product reduced discomfort or sensitivity on the scalp? | 0% | 35% | 55% | 10% | 0% |
| Has the product reduced redness or visible irritation of the scalp? | 5% | 25% | 45% | 10% | 15% |
| Has the product improved overall scalp comfort? | 0% | 45% | 15% | 25% | 15% |
| Has the product helped reduce hair loss? | 15% | 30% | - | 35% | 20% |
| Has the product made your hair feel stronger and healthier? | 10% | 30% | - | 35% | 25% |
| Has the product made your scalp feel fresher and cleaner? | 0% | 35% | - | 50% | 15% |
| Is the product easy to apply? | 20% | 75% | - | 0% | 5% |
| Does the product have a pleasant texture? | 10% | 40% | - | 40% | 10% |
| Is the product fragrance pleasant? | 15% | 40% | - | 35% | 10% |
| Does the product absorb easily without leaving residue or greasiness? | 5% | 20% | - | 50% | 25% |
| Does the product leave a pleasant feeling on the scalp after application? | 5% | 25% | - | 45% | 25% |

For Serum B placebo, the overall product rating distribution was: 1=0%, 2=0%, 3=5%, 4=10%, 5=45%, 6=25%, 7=5%, 8=5%, 9=5% and 10=0%. A total of 30% of Serum B participants said they would recommend the product and 70% said they would not. A total of 15% reported undesirable effects and 85% did not; the reported undesirable effect was that the product left hair slightly dry and difficult to brush.

Discussion

This randomized, single-blind, placebo-controlled pilot study suggests that twice-daily application of a 2% Oleosome-FGF-2 fusion extract scalp serum for 84 days may improve objective hair parameters and scalp biophysical measures in women with shedding-prone hair. The most commercially and clinically meaningful finding was the improvement in mean hair density at T84, with a 33.5% increase from baseline in the active group compared with 7.2% in the placebo group. Improvements were also observed in anagen/telogen ratio and hair shaft thickness, suggesting that the observed density change was accompanied by hair-cycle and hair-fiber changes rather than by a single isolated measurement. This interpretation is consistent with the broader understanding that hair density reflects both the number of visible fibers and the distribution of follicles across hair-cycle phases [1-4,9-13].

The timing of the response is notable. The hair-density effect was already apparent at T28 and remained stable through T56 and T84. This pattern could be consistent with improved retention of existing fibers, reduced shedding, improved visibility or counting of emerging hairs, changes in scalp microenvironment or a combination of these mechanisms. Although FGF-family signaling has been implicated in hair-follicle biology and preclinical hair-growth models [15-18], the present study did not include mechanistic biomarkers, follicular imaging of active localization or molecular readouts. Therefore, mechanism cannot be concluded from the clinical data alone.

The scalp barrier results are supportive but should be interpreted carefully. Serum A improved hydration and reduced TEWL and sebum compared with placebo. These findings may suggest improved scalp comfort and barrier status, which could be relevant in shedding-prone subjects with dry or sensitive scalp characteristics. Such endpoints are commonly used in cosmetic science and scalp research, but they are sensitive to baseline differences, environmental conditions, anatomical site, age and skin/scalp condition [23-29]. Because baseline hydration differed between groups, hydration results were interpreted with particular caution.

Compared with many cosmetic hair studies, the present study has strengths: Placebo control, repeated instrumental assessments, objective phototrichogram-derived endpoints, biophysical scalp measures and a clinically interpretable 84-day follow-up. The study also has limitations. The sample size was small, the design was single-blind rather than double-blind, only women were enrolled, the duration was limited to 84 days and detailed reporting of randomization-sequence generation, allocation concealment, compliance and adverse-event tabulation was limited. The analysis was based on group-level summary statistics rather than individual-level mixed-model estimates with confidence intervals. Multiple endpoints and repeated time-point testing also create multiplicity concerns. For these reasons, the findings are best interpreted as exploratory and hypothesis-generating rather than definitive [35].

The appropriate interpretation of these findings is that Oleosome-FGF-2 fusion extract improved objective cosmetic hair-density and scalp-quality parameters in women with shedding-prone hair in a placebo-controlled pilot study. The findings do not establish disease-modifying efficacy for alopecia and are not therapeutic proof. Future confirmatory trials are warranted using a double-blind design, a larger population, prespecified primary endpoints at month 3 or month 6, complete CONSORT reporting and blinded centralized phototrichogram analysis [19-22,35].



Conclusions

In women with telogen effluvium and/or brittle hair prone to falling out and dry or sensitive scalp characteristics, 84 days of twice-daily 2% Oleosome-FGF-2 fusion extract scalp serum use was associated with improved phototrichogram-derived hair density, anagen/telogen ratio, hair shaft thickness, scalp hydration, TEWL, sebum level and clinical hair-density evaluation compared with placebo. The findings support further investigation of Oleosome-FGF-2 fusion extract as a cosmetic scalp intervention for improving hair-density and scalp-quality parameters. Larger double-blind randomized trials with prespecified endpoints and complete individual-participant statistical analysis are needed to confirm these exploratory results.

Supplementary Materials

No supplementary materials are submitted with this manuscript. Deidentified individual participant data may be made available upon reasonable request subject to privacy, GDPR and proprietary commercial restrictions.

Author Contributions

Conceptualization: A.R.; Methodology: A.R., M.Buc., S.B. and M.Bal.; Investigation: M.Buc., S.B. and M.Bal.; Resources: A.R.; Data curation: M.Buc., S.B. and M.Bal.; Writing-original draft preparation: A.R.; Writing-review and editing: A.R., M.Buc., S.B. and M.Bal.; Project administration: A.R., M.Buc., S.B. and M.Bal.; Funding acquisition: A.R. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki. Ethics approval was obtained from a relevant ethics committee prior to initiation of the study (ethics approval code: REL/0504/2026; date of approval: 01 November 2025).

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study. Participants also consented to personal-data processing according to Regulation (EU) 2016/679 (GDPR). Consent for publication of identifiable material was not applicable because no identifiable participant images or individual-level identifiable data are included in this manuscript.

Data Availability Statement

The data presented in this study are available on request from the corresponding author due to privacy, GDPR and proprietary commercial restrictions.

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Conflicts of Interest

Core Biogenesis SAS sponsored the study, provided the active ingredient, owns or commercializes Oleosome-FGF-2 fusion extract and funded the work. Alexandre Reeber is affiliated with Core Biogenesis SAS. Abich Life Analytics S.r.l. conducted the clinical/cosmetological study. Additional author disclosures are provided separately in the journal disclosure forms.

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