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 ORIGINAL ARTICLE

Single-Center, Open-Label Study to Evaluate Improvement of Hair Appearance With Novel Hair Growth Serum

Suleima Arruda MD,[a] Alyssa Swearingen MD,[a] Zahyaa Elmadany BS,[a] Anna Nakagama BS,[a] Emely Alvarado Lemoine BS,[a] Sophia Clara Valmeus BS,[a] Neil Sadick MD[a,b]

[a]Sadick Dermatology and Sadick Research Group; New York, NY
[b]Weill Cornell Medical College, President of Sadick Dermatology; New York, NY

ABSTRACT

Background: REVIVV® is a topical hair growth serum with a proprietary formula of botanicals that addresses multiple factors involved in hair loss pathophysiology. This open-label, prospective, single-center study evaluated the efficacy of REVIVV®, a topical hair growth serum, in 20 adults (10 male, 10 female) with mild to moderate hair loss over 6 months. Participants applied the serum twice daily, and assessments were conducted at baseline, 4, 12, and 24 weeks. Dermatologist evaluations and patient self-assessments of hair quality and growth were performed using a 7-point Likert scale. Results Investigator-rated improvements in hair quality and growth increased from 0.75 and 0.81 at 4 weeks to 1.73 and 1.83 at 24 weeks, respectively. Patient-reported assessments showed that 85% of participants noted improved hair quality and growth at 24 weeks, with 50% reporting great improvement. Patient satisfaction was high, with 80% of participants being moderately or greatly satisfied at 4 weeks, increasing to 95% at 24 weeks. No adverse events related to the serum were reported throughout the study. The results demonstrate that twice-daily application of REVIVV® over 6 months is associated with increased hair growth and improved hair quality suggesting that REVIVV® may be an effective, non-pharmacological option for individuals seeking to improve hair growth and quality.

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INTRODUCTION

Hair loss is a prevalent issue affecting both men and women, often leading to considerable psychological distress. The causes of hair loss are multifaceted, encompassing medical conditions, medications, emotional and physical stress, post-partum, hormonal changes, aging, damage from styling or processing, or all in combination.[1,2] This process leads to an alteration in the hair cycle, with a shortening of the anagen phase, a lengthening of the latency period, and miniaturization of the hair shaft turning from terminal into vellus-like hair. Perifollicular inflammation and immune deposits have also been shown to contribute to the pathophysiology.[3]

Pharmacological treatments for hair loss like finasteride and minoxidil are available but have side effects and their mechanisms of action are not well understood. Vitamins, minerals, and other nutrients are frequently used in a large range of products claiming to be efficient against hair loss but data from prospective intervention studies remain scarce.[4-8]

REVIVV® is a topical serum supplement, containing vitamins, minerals, proteins, and nutraceutical-grade botanical bioactives designed to restore hair health. The formulation of botanicals includes potent anti-inflammatory, anti-stress adaptogenic, antioxidant, and DHT-inhibiting properties tailored to the specific needs of men and women. A previous study demonstrated that twice daily application of REVIVV over 8 weeks resulted in a statistically significant increase in hair thickness in the crown and vertex of the scalp in both males and females with androgenetic alopecia. Results also showed high patient satisfaction. Given these findings, we were interested in exploring the benefits of prolonged use of REVIVV.[9]

The present study aimed to evaluate the degree of change in hair growth and hair quality observed by patients and physicians after using REVIVV hair growth serum for 6 months. Patient satisfaction, safety, and tolerability were also assessed.

MATERIALS AND METHODS

Study Design

This was an open-label, prospective, single-center study in adult subjects. The study was conducted in one dermatologic office in New York City from May 2023 to March 2024 and a total of 20 evaluable subjects were enrolled. This study was conducted in accordance with the International Conference on Harmonization Harmonized Tripartite Guideline for Good Clinical Practice, the Declaration of Helsinki, and applicable national

laws and regulations. All subjects provided written, informed consent to use their information in the current study, including photography.

Patients

Enrolled subjects were male and female adults aged 18 to 65 years of age with mild to moderate hair loss. Subjects with a history of surgical correction of hair loss on the scalp, history of autoimmune disease, previous clinical diagnosis of alopecia areata, scarring forms of alopecia, or hair loss for other reasons in the treatment area were excluded. Use of anti-androgenic therapies and other products or devices purported to promote scalp hair growth within 30 days prior to the study and for the duration of the study was not permitted. If patients received low-level lasers within 6 months prior to study start, they were not included. Enrolled participants were instructed not to use medicated shampoos or conditioners, or other medications that could potentially cause hair loss or affect hair growth.

Treatment

Participants applied the REVIVV Hair Growth Serum to the scalp twice daily for 6 months, in accordance with the product's instructions for use.

Assessments

Adverse events were monitored throughout the study. A dermatologist completed live assessments and assessments of standardized photographs using a Canfield imaging system. Evaluation included global hair growth improvement and hair quality improvement at the baseline visit, and 4 weeks, 12 weeks, and 24 weeks after the baseline visit. These assessments were performed using a 7-point Likert scale (greatly increased/improved, moderately increased/improved, slightly increased/improved, no change, slightly decreased/worsened, moderately decreased/worsened, and greatly decreased/worsened).

Patient questionnaires were completed at 4 weeks, 12 weeks, and 24 weeks after the initiation of treatment. Participants assessed hair quality using a 7-point Likert scale (greatly increased/improved, moderately increased/improved, slightly increased/improved, no change, slightly decreased/worsened, moderately decreased/worsened, and greatly decreased/worsened). Satisfaction with the study treatment was also assessed using a 7-point Likert scale (extremely satisfied, moderately satisfied, slightly satisfied, no change, slightly unsatisfied, moderately unsatisfied, greatly unsatisfied).

Statistical Analysis

Qualitative and quantitative analyses were performed. Evaluations of mean change of parameters from baseline to follow-up were analyzed using Wilcoxon signed-rank test. Values of $P \leq 0.05$ were considered statistically significant.

RESULTS

Of the 20 patients enrolled in the study, 10 were female and 10 were males, with 22% of patients having Fitzpatrick skin type IV-VI. The average investigator-rated improvement for hair quality was 0.75, and for hair growth, 0.81 at 4 weeks post-baseline. Improvement continued to increase to 1.69, 1.53, and 1.73, 1.83 for hair quality and hair growth at weeks 12 and 24 weeks, respectively (Figure 1A).

Patient-reported assessments of improvement were also positive. After 4 weeks of twice-daily use, 70% (n=9) of patients reported their hair quality had improved and 77% (n=10) of patients noted their hair growth increased (slightly, moderately, or greatly). After 24 weeks 85% (n=11) of patients noted their hair quality and hair growth increased slightly (8%), moderately (34%), and greatly (50%) (Figure 1B).

FIGURE 1. (A) Investigator-rated improvement of hair quality and hair growth. (B) Patient-rated improvement of hair quality and hair growth.

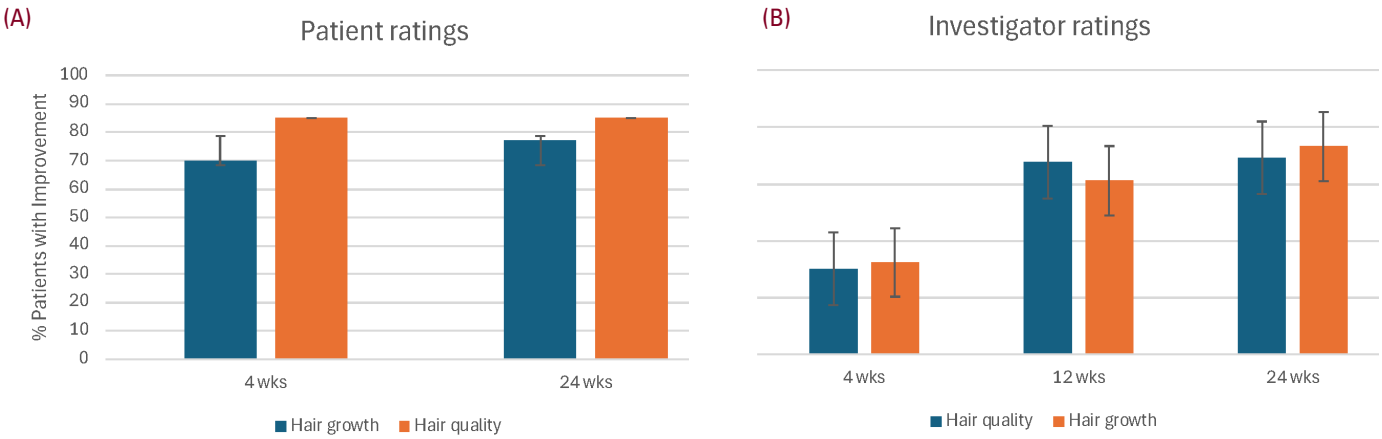


FIGURE 2. Global image of a 50-year-old male showing improvement in hair appearance at baseline and 24 weeks following use of REVIVV topical serum twice daily.

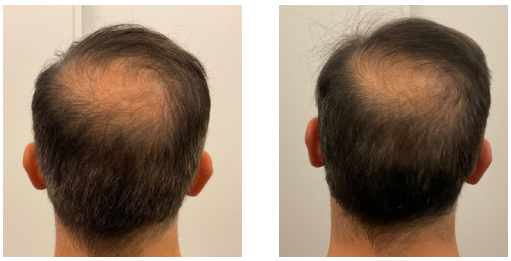


FIGURE 3. Global image of a 45-year-old female showing hair growth at baseline and 24 weeks following the use of REVIVV topical serum twice daily.

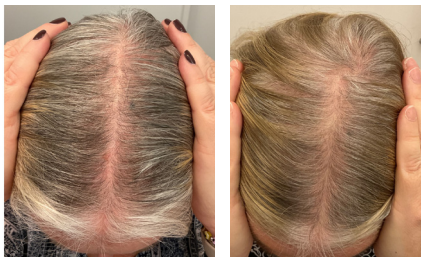
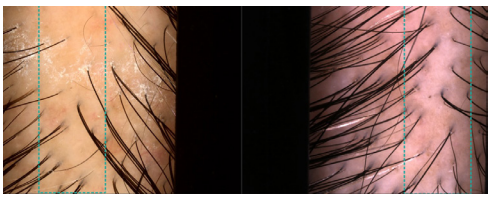


FIGURE 4. Trichoscopy showing improved hair appearance at 24 weeks post twice daily use of REVIVV from baseline.



Eighty percent of patients were moderately/greatly satisfied with the treatment at 4 weeks post-baseline and this number increased to 95% at the 24-week follow-up. Before and after photos from representative patients using twice daily REVIVV for 24 weeks are shown in Figures 2 to 4.

No adverse events or serious adverse events related to the REVIVV serum were reported. Subjects reported no signs of irritation, redness, or discomfort using the REVIVV serum during the duration of the study.

DISCUSSION

Twice-daily use of the REVIVV topical hair growth serum over 6 months led to improved global hair quality and growth, as demonstrated by both investigator and patient assessments. In this study, over half of participants observed an increase in hair growth after 4 weeks of twice-daily application and these results were sustained after 24 weeks of continuous use. High patient satisfaction ratings further validate the positive product feedback reported in the real-world study.

Although pharmacological agents for hair loss exist, patients are increasingly seeking non-pharmacological products with natural ingredients, as well as cost-effective therapies. Given the multifactorial nature of hair loss, employing a multipronged approach is crucial for achieving the most effective results.

The REVIVV topical hair growth serum's proprietary formula comprises botanicals with antiandrogenic properties tailored to the specific needs of men and women. It offers a high-compliance product that can be combined with oral medications or laser light therapies.

Limitations of this study include its completion at a single site, the lack of a placebo group, and a small sample size, which may limit the generalizability of the findings.

Future studies should investigate the reproducibility of these results with larger populations.

CONCLUSION

In conclusion, the proprietary formula of botanicals in the REVIVV hair serum addresses multiple factors involved in the complex pathophysiology of hair loss. These results demonstrate that twice-daily application of REVIVV over 6 months is associated with increased hair growth and improved hair quality, with no reported side effects.

DISCLOSURES

Dr Sadick is an advisor of WeThrivv. Dr Arruda, Dr Swearingen, Ms Elmadany, Ms Nakagama, Ms Lemoine, Ms Valmeus have nothing to disclose

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AUTHOR CORRESPONDENCE

Neil Sadick MD

E-mail:..... nssderm@sadickdermatology.com