

Transdermal delivery of a new hair growth promoting solution in patients with hair loss

Dong Hyun Ahn, Insoo Kang

ABSTRACT

Introduction: Male pattern alopecia or hair loss has been treated using various treatment approaches including hair transplantation, oral medications, sprays, mesotherapy and stem cell therapy. However, response rates to such treatments are variable. **Case Series:** In this case series, 6 Korean patients (5 males and 1 female) with hair loss were treated for three months with hair growth promoting Mr. Care Hair Vital Ampoule® or Mr. Care Hair Vital Ampoule plus® (Mr. Care Co., Seoul, South Korea) using the high-pressure transdermal delivery system JetPeel™ (TavTech Ltd., Yehud, Israel). Either Mr. Care Hair Vital Ampoule or Mr. Care Hair Vital Ampoule plus was sprayed on the affected area(s) of the scalp once a week for three months via the Jet Peel™ system. **Conclusion:** We found that all the patients had less hair loss and thicker hair after this treatment. Based on our findings, we believe that additional placebo-controlled studies are needed to evaluate the efficacy of our combination treatment.

Keywords: Hair loss, Hair growth promoting solution, Hair growth, Transdermal delivery

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INTRODUCTION

Hair loss is common in the general population [1–3]. Although it can occur due to various medical conditions and medications, the most common type of hair loss is male pattern hair loss. The number of scalp hairs that undergoes a cycle of falling out and growing in a lifetime is approximately 100,000–150,000 [1]. Typically, 50–60 hairs fall out of the scalp a day. Alopecia or hair loss is clinically suspected if >100 hairs fall out in a day [1, 3]. The most common form of androgenic alopecia in men is retraction of both sides of the frontal hairline showing M-shaped or vertex hair loss [3]. In most women, hair loss spreads throughout the scalp from the vertex area [3]. Possible causes of hair loss include functional deterioration of hair follicles and impaired local blood flow in the scalp secondary to scalp tension, malnutrition, stress, medications, genetic factors, chemicals and diseases [3].

In addition to cosmetic concerns, hair loss can affect mood and quality of life [3]. In fact, different approaches have been used to treat male pattern alopecia or hair loss [3], including hair transplantation [3], sprays [3, 4], oral medications [3, 5–7], mesotherapy [1, 8, 9] and stem cell therapy [2]. However, these treatments frequently involve injections [10], surgeries [11] and/or oral medications with variable response rates. Here, we report in 6 Korean patients (5 males and 1 female) with hair loss who were treated for 3 months with a combination of hair growth promoting Mr. Care Hair Vital Ampoule® or Mr. Care Hair Vital Ampoule plus® (Mr. Care Co., Seoul, South Korea) using the JetPeel™ [12] high-pressure transdermal delivery system (TavTech Ltd., Yehud, Israel). Our primary objective was to report the effect of a new hair growth promoting solution for hair loss.

CASE SERIES

The present study is a retrospective case series including six patients. All the participants provided written informed consent to participate in the study. Patient consent was obtained for treatment with the new hair growth promoting solution as well as the use of their clinical data. This method is repeatable and reproducible. The diagnosis of hair loss was made on physical examination. The SM-Q925S camera (Samsung Electronics Co. Ltd., Gyeonggi-do, Korea) and APM-AH-300 diagnostic system (phototrichogram) (Aram Huvis Co. Ltd., Gyeonggi-do, Korea) were used to evaluate the clinical features of hair loss type, scalp condition, hair density, scalp keratin, scalp blood vessel exposure, pore condition, hair thickness and hair shaft cuticle. We excluded patients if they had been treated for hair loss with topical and/or oral medications, including minoxidil, prostaglandin analogs, finasteride, dutasteride and anti-androgens; mesotherapy (including microneedle treatment) and intra-perifollicular injection therapy; laser/light-based therapy, including fractionated laser treatment and low-level light therapy; intra-perifollicular platelet-rich plasma preparation injection and hair transplantation in the previous six months. After obtaining written informed consent, we applied either Mr. Care Hair Vital Ampoule, (6 ml mixture of human stem cell culture media (2 ml), panthenol, niacinamide, biotin and zinc sulfate) or Mr. Care Hair Vital Ampoule plus (6 ml mixture of human stem cell culture media (3 ml), panthenol, niacinamide, biotin and zinc sulfate) to the frontal, mid and vertex areas of the scalps of three patients in group 1 (Mr. Care Hair Vital Ampoule, mean patient age, 52 years, range, 51–54 years) and 3 patients in group 2 (Mr. Care Hair Vital Ampoule plus, mean patient age, 40 years; range, 33–49 years) using the JetPeel system (microdroplet: 5~20 micron, pressure: 90 PSI, velocity: 200 m/s).

Both hair growth promoting agents were registered previously as hair care products (cosmetics) in Korea, and Mr. Care Hair Vital Ampoule plus was also FDA (Voluntary Cosmetic Registration Program [VCRP]) registered in the U.S. The transdermal delivery system JetPeel was already attempted transdelivery of other solutions; JetPeel-assisted topical minoxidil is effective during the treatment of androgenetic alopecia. Either Mr. Care Hair Vital Ampoule or Mr. Care Hair Vital Ampoule plus was sprayed on the affected area(s) of the scalp once a week for three months via the JetPeel system. Before each treatment, we cleaned the scalp with normal saline. Local anesthesia was not used in the procedures. The patients were advised to refrain from using other hair loss products during the treatment and follow-up periods. Digital images of the scalp and hair were captured at x1 and x60–x200 magnification using a computerized microscope to objectively evaluate the images at baseline and at one week after the final treatment. The Aram Viewer (Aram Huvis) computerized software was used to capture the

digital images. The camera was positioned at the balding area (usually the vertex area) of the scalp. Next, relative values for hair counts and thickness were measured. The patients were asked about any side effects associated with treatment, including scalp redness, edema, crusting, hair loss, allergic reaction, etc. The patients in both groups demonstrated considerable improvement in both hair counts and hair thickness compared to baseline values at one week after the final treatment session. The treatment session took ≤ 20 min. No patient in either group reported pain during the treatment. No other possible side effects, including infection, itching, allergic reaction and progression of hair loss, were reported by the six patients.

Representative cases of treatment groups 1 and 2 are shown below. Figure 1 presents changes in hair growth as measured by gross and microscopic hair examinations in a 54-year-old male patient who received 6 cc (1 ampule) of Mr. Care Hair Vital Ampoule weekly for three months using the JetPeel transdermal delivery system (group 1). Another case with vertex alopecia responded to the same treatment, resulting in hair growth (Figure 2). Interestingly, the treatment also promoted hair growth in a male patient with alopecia areata (Figure 3). We noticed similar improvements in patients in group 2, including a patient with failed hair transplantation, who received 6 cc (1 ampule) of Mr. Care Hair Vital Ampoule plus weekly for three months using the same transdermal delivery system. For example, a 33-year-old female patient with vertex alopecia was treated using the protocol for group 2. The treatment resulted in substantial hair growth (Figure 4). In addition, a 49-year-old male patient who previously received two sessions of hair transplantation underwent our weekly treatment for three months with Mr. Care Hair Vital Ampoule plus. He exhibited hair growth in the vertex as shown by gross and microscopic hair exams (Figure 5), suggesting that our treatment might have benefit to patients who have previously failed hair transplantation. Overall, the responses we noted in our cases support the role of Mr. Care Hair Vital Ampoule and Mr. Care Hair Vital Ampoule plus in improving different types of alopecia including male pattern, female pattern, alopecia areata, and hair that has failed hair transplantation.

DISCUSSION

Currently, the most commonly utilized method for treating alopecia is hair transplantation surgery where the patient's own hair is transplanted on to the scalp. In addition, drug treatment with minoxidil and propecia is prescribed regularly. Minoxidil dilates the blood vessels to increase the nutrient supply to hair follicles and has a potassium channel opening effect to induce hair growth [4], and propecia has a dihydrotestosterone (DHT) formation inhibitor effect to induce hair growth [6, 7]. Recently, gene therapy performed by a method of delivering alopecia-associated genes to the follicles

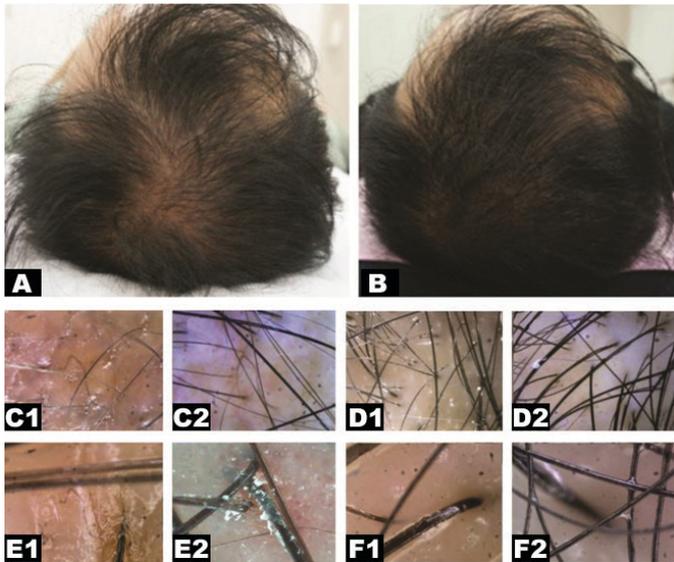


Figure 1: Picture A was taken before treatment and B was taken after 3 months of treatment (original magnification x1 [above]). Pictures C1, C2, D1, D2, E1, E2, F1, and F2 were taken with a hair analyzer, APM-AH-300 diagnostic system (phototrichogram) at the vertex. Pictures C1 and C2 and E1 and E2 were taken before treatment and D1 and D2 and F1 and F2 were taken 1 week after the last treatment (original magnification x60 [C1, C2, D1, D2], x200 [E1, E2, F1, F2]).

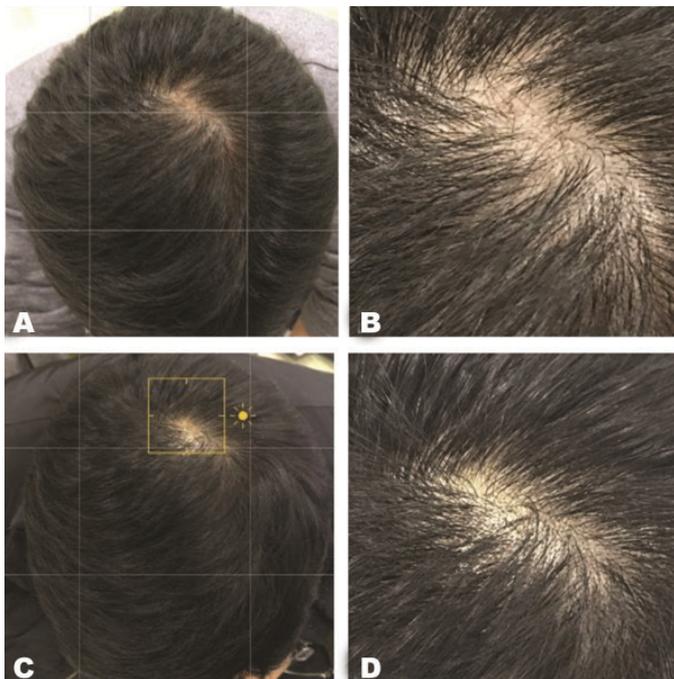


Figure 2: Pictures A and B were taken before treatment and C and D were taken 1 week after the last treatment of 51-year-old man who was treated once a week for three months by spraying his scalp with 6 cc of Mr. Care Hair Vital Ampoule via the JetPeel system (group 1).

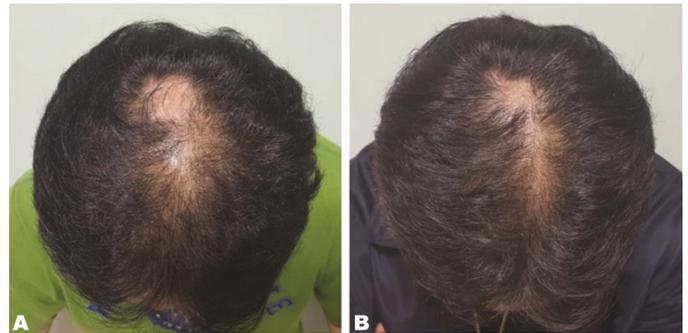


Figure 3: Picture A was taken before treatment and B was taken three months after the last treatment (original magnification x1) of 51-year-old man who had hair loss including alopecia areata and was treated once a week for three months by spraying his scalp with 6 cc of Mr. Care Hair Vital Ampoule using the JetPeel system (group 1).

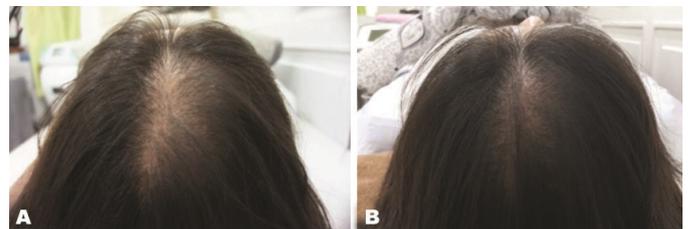


Figure 4: Picture A was taken before treatment and B was taken one week after the last treatment (original magnification x1) of 33-year-old woman who had hair loss around the vertex and was treated once a week for three months by spraying her scalp with 6 cc of Mr. Care Hair Vital Ampoule plus using the JetPeel system (group 2).

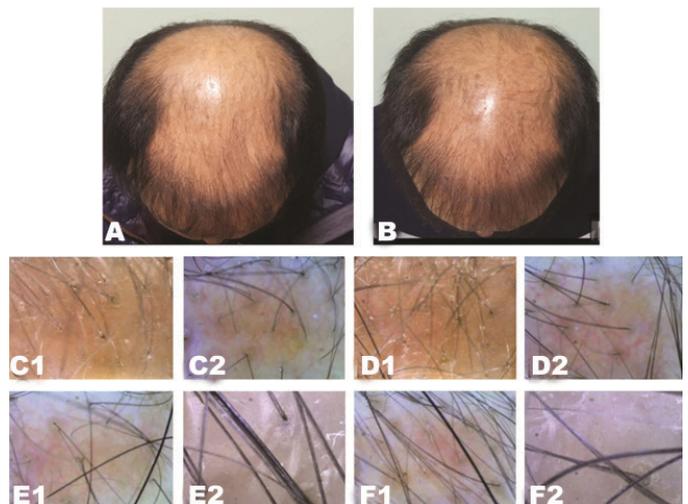


Figure 5: Picture A was taken before treatment and B was taken one week after the last treatment (original magnification x1) (above) of 49-year-old man who had two previous hair transplants and progressive hair loss. He was treated once a week for three months by spraying his scalp with 6cc of Mr. Care Hair Vital Ampoule plus using the JetPeel system (group 2). Pictures C1, C2, D1, D2, E1, E2, F1, and F2 were taken with a hair analyzer, APM-AH-300 diagnostic system (phototrichogram) at the top of the vertex. Pictures C1 and C2 and E1 and E2 were taken before treatment and D1 and D2 and F1 and F2 were taken one week after the last treatment (original magnification x60 (C1, C2, D1, D2), x200 (E1, E2, F1, F2)).

or inhibiting gene expression has been developed, but therapeutic efficacy and safety are uncertain, and the cost of treatment is high, as it is extremely complicated clinically to apply gene therapy [13]. Moreover, a method using stem cells has recently been introduced [14]. Currently, in most cases the stem cell method of treating alopecia is performed by directly injecting the stem cells into an alopecia or hair less site to induce differentiation of follicular cells. However, this method has disadvantages in that treatment is impossible without the use of autologous stem cells, a therapeutic effect is not continuously maintained and it is not time or cost effective [14]. To solve these problems, a method using a culture solution (instead of the stem cells) [15–18], which is produced at the time of stem cell culturing has been performed; however, the efficiency of this method for commercial production is not known yet. Fukuoka et al. [18] demonstrated that treatment with adipose-derived stromal vascular cell-conditioned media effectively activated hair regeneration; this media is rich in growth factors such as vascular endothelial growth factor, hepatocyte growth factor, platelet-derived growth factor and insulin-like growth factor 1. The injected cells might release growth factors, thus, promoting vascularization, encouraging the formation of new capillaries, increasing hair production and improving the blood supply to the scalp [19].

This provides an ideal environment for hair follicles to grow new, denser and healthy hairs [19]. Moreover, a study on female pattern hair loss treated with adipose-derived stromal vascular cell-conditioned media exhibited increased hair density and thickness [20]. Based on these articles, we aimed to contribute to hairloss management by utilizing a new hair growth promoting solution synthesized with various growth factors from human stem cell-conditioned media and biotin [21], zinc [21], niacinamide [22, 23] and panthenol [23]. Biotin is a coenzyme for carboxylase enzymes that assist various metabolic reactions involved in fatty acid synthesis, branched-chain amino acid catabolism, and gluconeogenesis, which is important for maintenance of healthy skin and hair [24]. Panthenol has hygroscopic properties and a moisture-retaining capability [25]. Hyperthyroidism is a common and well recognized cause of diffuse hair loss. Zinc and other trace elements including copper and selenium are required for the synthesis of thyroid hormones [26].

The objective of our study is to present a new hair growth promoting solution, which is composed of proper formation of multiple ingredients helpful for hair growth promotion, can be delivered to hair follicles and be useful for hair loss patients. Even if new hair growth promoting solution is applied to the scalp, it may slow down and manage the progression of hair loss. As hair loss varies depending on the patient's sex, age, cause, and degree of progression, it is considered to serve as a complementary treatment even if this treatment cannot have an absolute effect on all hair loss patients. However,

it might serve as an assistive treatment for alopecia. Our study has limitations such as small sample size and no control cases. Additional studies addressing these points are warranted.

CONCLUSION

Further investigation is required to evaluate the effects of this new hair growth promoting solution for hair loss, and placebo-controlled studies are needed to evaluate the efficacy of a new hair growth promoting solution.

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Author Contributions

Dong Hyun Ahn – Conception of the work, Design of the work, Acquisition of data, Analysis of data, Interpretation of data, Drafting the work, Revising the work critically for important intellectual content, Final approval of the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Insoo Kang – Design of the work, Drafting the work, Revising the work critically for important intellectual content, Final approval of the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Guarantor of Submission

The corresponding author is the guarantor of submission.

Source of Support

None.

Consent Statement

Written informed consent was obtained from the patient for publication of this article.

Conflict of Interest

DH Ahn has a pending patent application for solution “Hair Growth promoting Composition” in USA. I. Kang is an advisor of Mr. Care Co. and DH Ahn is the director of Mr. Care Co.

Data Availability

All relevant data are within the paper and its Supporting Information files.

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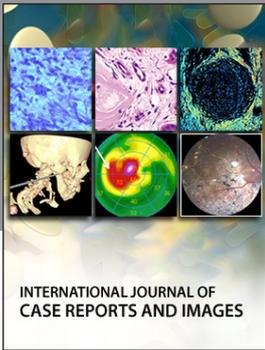
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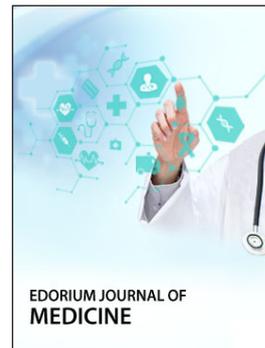
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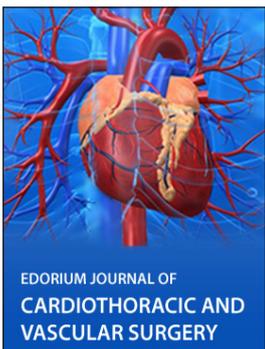
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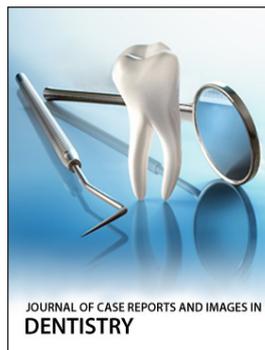
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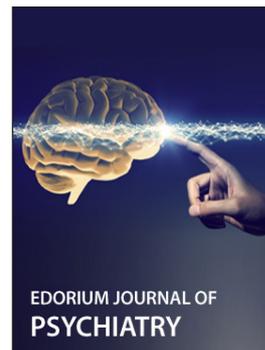
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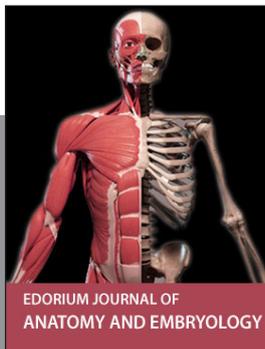
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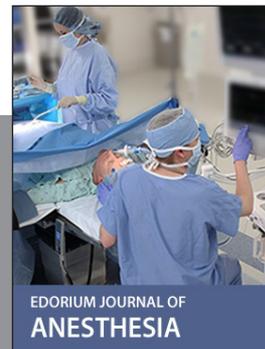
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