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Clinical Efficacy of Medicinal Plants Formulations for the Prevention of Androgenetic Alopecia in Korean Individuals

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Abstract: Androgenetic alopecia (AGA) is the most prevalent form of nonscarring alopecia, characterized by a distinct pattern of gradual hair loss. Despite its non-lethal nature, AGA can exert a profound psychosocial impact, particularly on women and younger men, affecting their quality of life. Standard therapeutic approaches for AGA commonly involve the use of finasteride and minoxidil; however, these treatments are often associated with adverse side effects, particularly with prolonged use. In this study, we present the successful management of AGA in a cohort of Korean individuals, comprising both male and female subjects (totaling 52 participants, with 12 exclusions). Significant reductions in the affected AGA area were observed across the cohort, yielding highly satisfactory outcomes. These findings suggest that the treatment modality employed in this study offers a promising alternative for AGA management in the population, demonstrating efficacy irrespective of gender.

Keywords: Androgenetic Alopecia; Male; Female; M2V1 type.

1. Introduction

Androgenetic Alopecia (AGA) is the most common patterned hair loss in both men and women [1]. It is caused by dihydrotestosterone (DHT), which binds to androgen receptors in hair follicles, shrinking them and leading to hair loss. This process is genetically determined, with variations in androgen receptor genes increasing susceptibility. Factors affecting its occurrence include genetics and sensitivity to Androgens [2]. More common in males and females reflexes age > 50, but your hair can start thinning as early in puberty [3]. Treatments like finasteride and minoxidil, which inhibit 5-alpha-reductase, lower DHT levels, and stop additional hair follicle shrinking, can reduce the onset of AGA even while genetics cannot completely prevent it. However, finasteride is less effective in late stages of AGA and may induce adverse effects like sexual dysfunction.

Once the treatment is stopped, its benefits end. Minoxidil, on the other hand, can promote mild regrowth, although out-comes differ and hair loss recurs after quitting use. It is crucial to prevent AGA to lessen its financial, psychological, and social effects [4]. Early prevention can slow hair loss, preserve hair density, and minimize the need for invasive treatments like hair transplants.

Maintaining a balanced diet rich in vitamins and minerals, particularly those supporting hair health, such as biotin and zinc, managing stress, and avoiding harsh hair treatments also support hair health. For significant hair loss, hair transplant surgery may be an option. Early detection and consistent management are key to preserving hair density and quality. In this work, we have developed the anti-hair loss shampoo named "Groilab shampoo" to treat AGA in Korean individuals.

The ingredients in hair loss shampoos, such as *Urtica Dioica* (nettle), *Ginkgo Biloba*, *Sophora*, *Morus Alba* (mulberry), *Coptis Japonica*, *Lindera*, and *Castanea Crenata* (chestnut) etc., were selected for their diverse properties that support hair health and prevent hair loss. Nettle is rich in vitamins and minerals, including silica, which strengthens hair and reduces inflammation [5]. *Ginkgo Biloba* enhances scalp circulation, delivering more nutrients to hair follicles [6, 7]. *Sophora* may help block DHT, the hormone responsible for follicle shrinkage in androgenetic alopecia [8, 9]. *Mulberry* is packed with antioxidants that protect hair from oxidative stress [10, 11]. *Coptis Japonica* has anti-inflammatory and antimicrobial effects, promoting scalp health. *Lindera* improves circulation and balances hormones affecting hair growth [12], while chestnut nourishes and strengthens hair follicles [13]. Together, these ingredients target multiple causes of hair loss, such as DHT buildup, poor circulation, and oxidative stress, making them effective in promoting healthy hair growth.

Often, the diagnosis of AGA relied mainly on clinical presentation and classification. But now using machine learning-based trichoscopy analysis tools in the patient's clinic, we can evaluate quantitative indicators of hair growth in this group [14]. Here, an 18-52-year-old men and women diagnosed with AGA were presented in this case series.

2. Case Report

In the below case study, we have picked test subjects (Men & Women) by Specific (BASP reliefs). Note that the relatively common type of androgenetic alopecia in men (women also have it less frequently) is referred to simply as M1 or higher, C1 or higher, U1 or higher. The specific type is androgenetic alopecia in men and women diagnosed as V1 or higher or F1 or higher (2) Men diagnosed as 2 or 2A or higher according to the Norwood-Hamilton classification (3) Women diagnosed as 1 or higher according to the Ludwig classification. The selection criteria for test subjects in this study include participants who agree not to use any special hair products or undergo any hair care or manipulation during the study period. Participation is voluntary and requires the individual to sign a consent form after receiving a thorough explanation of the study's purpose and contents. Lastly, the participants must be available for follow-up during the testing period. It is worth mentioning that this study was conducted on individuals experiencing recent hair loss symptoms, with no previous use of related products.

The exclusion criteria for this study involve individuals with specific health conditions or recent medical treatments that could influence the study's outcomes. Subjects with serious acute kidney or heart disease, or chronic conditions such as hypertension or diabetes within the past six months, are excluded due to potential result interference. Pregnant or lactating individuals, those planning to become pregnant, and those with psychiatric or infectious skin diseases are also not eligible. Patients treated with surgery for hair loss, non-oral Finasteride exposure within 6 months prior to baseline (but they were exposed >30 days), or oral Dutasteride ever are excluded. Additionally, participants who have used topical hair growth agents within 1 month or those taking medications such as steroids, vasodilators and relevant drugs were not included. The patient exhibited key signs of androgenetic alopecia, including a receding hairline, crown miniaturization, and persistent shedding, indicative of progressive male-pattern hair loss. Enrolled in a clinical trial, the individual under-went regular monitoring to assess hair growth, shedding rates, and scalp health. This study aims to evaluate treatment efficacy and inform optimal management strategies for androgenetic alopecia.

During the test period, subjects must refrain from using cosmetics and medicines labeled as functional, including aspirin, anti-inflammatory drugs, antihistamines, and steroids (including herbal medicines). They should not change their usual cosmetics or makeup routines and must avoid any skincare, cosmetic, or dermatological procedures. Additionally, participants should minimize high levels of sunlight exposure, avoiding activities such as outdoor swimming, skiing, hiking, and long-term travel.

2.1 Description of patients

We initially recruited 52 subjects who met the selection and exclusion criteria. However, 12 participants (Nos. 02, 03, 04, 10, 11, 12, 22, 38, 40, 42, 45, 48) violated the study protocol by not attending the scheduled visit at week 24. Consequently, the final analysis included 40 participants. The average age of the test subjects was 41.9 years. The age range spanned from a minimum of 22 years to a maximum of 54 years. The visual (high resolution DSLR camera photography) evaluation scores for both the crown and frontal hairline of the test group showed a significant increase up to 70% and 90% by the end of 24 weeks of product use compared to baseline, respectively (Figure 1).

Phototrichogram evaluation results indicated a significant increase in the total hair density (hairs per square centimeter) following the use of the Groilab shampoo. This enhancement was observed at 8 weeks (7%), 16 weeks (18%), and 24 weeks (28%) of application, compared to baseline measurements prior to product use (Figure 2).

2.2 Test product ingredients

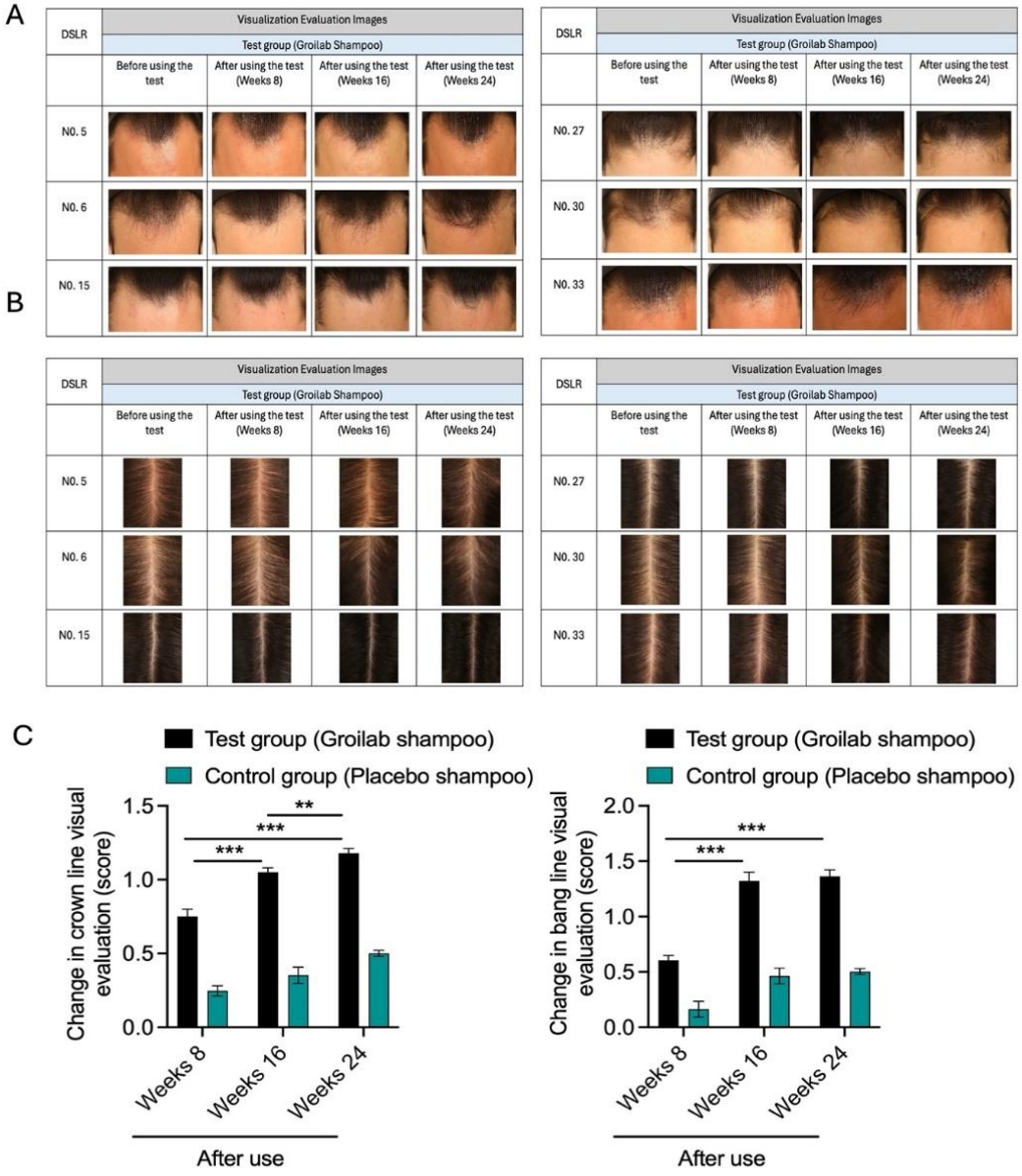
Purified water, Sodium C14-16 olefin sulfonate, coco-betaine, glycerin, lauryl betaine, caffeine, C12-13 Alketh-9, Fragrance, tetradecene, potassium benzoate, hexadecene, sodium chloride, citric acid, menthol, polyquaternium-67, butylene glycol, sorbitol, Panthenol, salicylic acid, coco-glucoside, acrylate copolymer , caprylyl glycol, ethylhexylglycerin, niacinamide, decyl glucoside, disodium EDTA, Ginkgo Biloba leaf extract, 1,2-hexanediol, Coptis Japonica (yellow lotus) root extract, Moris alba (mulberry) bark extract, Scutellaria Baicalensis root extract, Sophora Flavescens (Sophora) root extract, Urtica Dioica (nettle) leaf extract, glyceryl caprylate, Albizia Julibrissin Bark extract, Castanea Crenata (chestnut) bark extract, Lindera Strychnifolia root extract. For control (placebo shampoo), purified water, Sodium C14-16 olefin sulfonate, coco-betaine, glycerin, sodium benzoate, citric acid caprylyl glycol, ethylhexylglycerin, disodium EDTA were combined.

3. Discussion and conclusions

Androgenetic alopecia (AGA) manifests differently in males and females and is classified using distinct scales [15]. In men, AGA typically starts as thinning at the temples, which progressively affects the vertex of the scalp. In contrast, women generally experience diffuse thinning between the frontal scalp and vertex, often preserving the frontal hairline and resulting in a more noticeable scalp. This condition is notably prevalent among menopausal women, characterized by diffuse thinning without significant hairline recession, and rarely leading to complete hair loss [16].

The Ludwig pattern [17] in women features a generalized reduction in hair density, especially at the frontal scalp and crown, creating a visibly widened frontal part. Various treatment options are available for AGA, including oral and topical medications, hormonal therapies, nutraceuticals, Platelet-rich Plasma (PRP), exosomes, microneedling, and more invasive methods such as hair transplantation [18]. To overcome such challenges, earlier we figured out some natural products which have the potential to prevent hair loss [19]. To extend and verify further, this study was conducted to evaluate the efficacy of Groilab Shampoo containing those natural compounds, commissioned by Gragem Co., Ltd., in alleviating hair loss symptoms in several Korean patients, diagnosed with AGA over a 24-week period. Participants were instructed to report any side effects, which were monitored and managed appropriately to ensure their safety throughout the study.

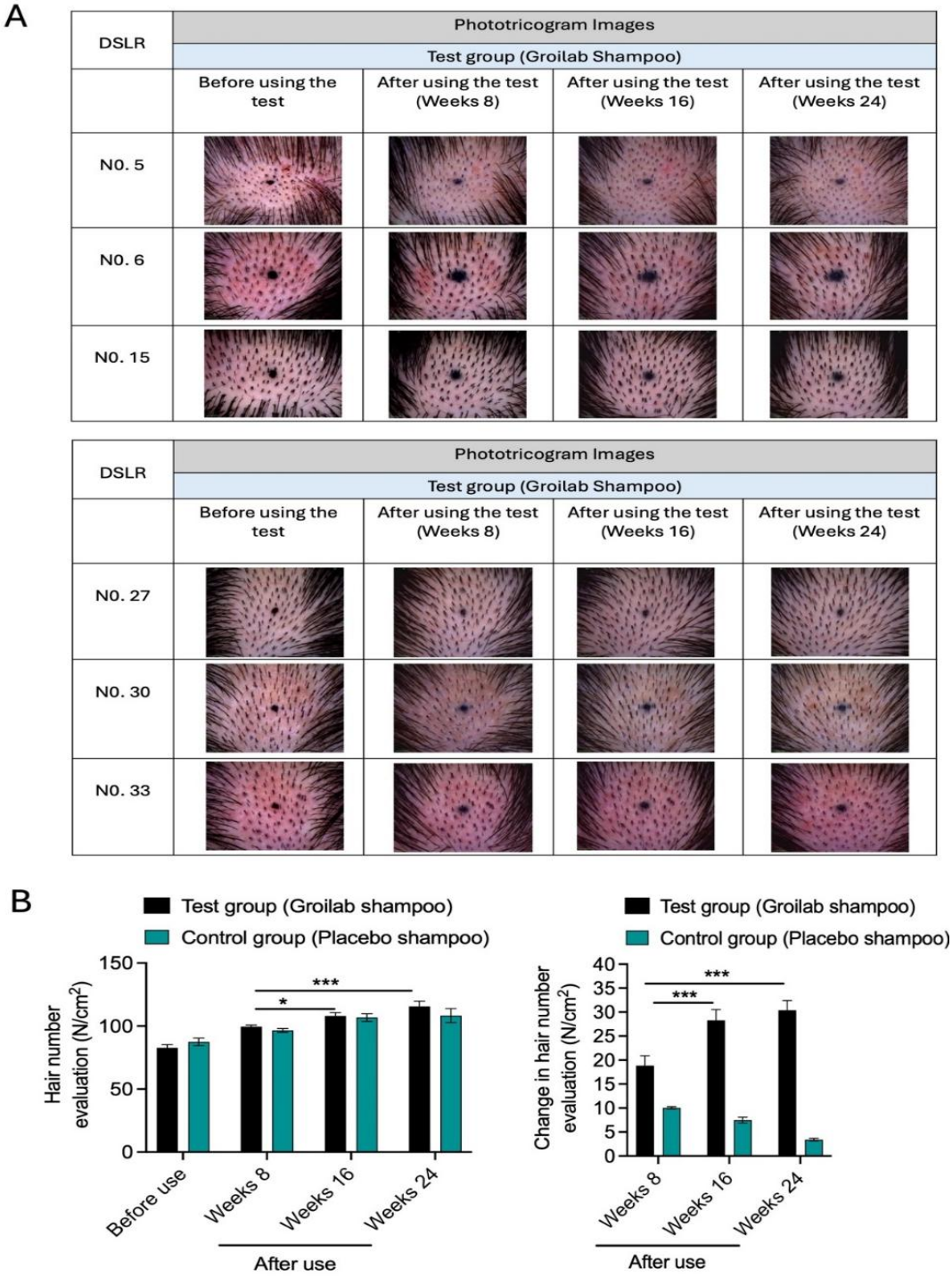
Figure 1. Visualization evaluation of the crown of the head and frontal line from weeks 8 to weeks 24th after control and Groilab shampoo treatment by the dermatologist. Statistical comparisons were made using Two-way ANOVA with Tukey's multiple comparison test. **p<0.01, ***p<0.001. Tukey's multiple comparisons showed that week 24th had significantly higher scores than week 8th (M=-0.76,95% CI [-0.89,-0.63], p=0.001). A two-way ANOVA revealed a significant interaction of treatment was (F (2,12)=24.05, 95% CI [0.66,0.78].



Throughout the test, no adverse reactions, such as contact dermatitis or irritant contact dermatitis, were reported or observed among the participants. Based on hair count data and expert visual evaluation scores, Groilab shampoo appears to be effective in alleviating hair loss symptoms. The absence of adverse reactions, combined with positive outcomes in hair count and expert evaluations, suggests that this product could be considered in treatment plans for hair loss management. One of the main limitations of this study is that this study was conducted in Korean individuals only with a small sample size and relatively short study duration, which may limit the generalizability of the findings to other racial or ethnic groups with different hair types or genetic predispositions. Future

research should include more diverse populations to enhance the applicability of the results.

Figure 2. Phototrichogram evaluation of total hair numbers (number/cm2) in Korean individuals from weeks 8 to weeks 24th after using control and Groilab shampoo treatment measured by Folliscope (LeadM, Republic of Korea). Statistical comparisons were made using Two-way ANOVA with Tukey's multiple comparison test. *p<0.05, ***p<0.001. Tukey's multiple compari-sons showed that week 24th had significantly higher scores than week 8th (M=-11.54,95% CI [-14.84,-8.23], p=0.001). A two-way ANOVA revealed a significant interaction of treatment effect was (F (2,12)=55.74, 95% CI [17.29,20.41].



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Research Ethics Committee Approval: The clinical application tests for the studies were led by Human Skin Clinical Trial Center located in Seoul, Korea. All tests were conducted according to the clinical trial plan, the good clinical practice (GCP) guideline, the related regulations of Ministry of Food and Drug Safety (MFDS), and the standard operating procedure (SOP) of the clinical trial center. The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of Human Skin Clinical Trial Center Co., Ltd. (Protocol Code HM-IRB-P23-0173 and Date of Approval: 20 October 2023). Informed consent was obtained from all subjects involved in the study to publish this paper.

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Conflicts of Interest: The authors declare no conflicts of interest.

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