

Development and clinical evaluation of green tea hair tonic for greasy scalp treatment

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Synopsis

Green tea has cosmetic benefits that include activities against androgen disorders. A hair tonic containing green tea for reduction of scalp sebum was developed and clinically evaluated. Stable green tea hair tonics were closed-patch tested and clinically evaluated in 20 volunteers for 28 days by using a Sebumeter[®]. Hair tonic base with glycerin and butylene glycol (total 4%) gained the highest consumers' preference was incorporated with green tea extract. All of the products were stable and none caused skin irritation. Green tea hair tonic (2%) significantly ($p \leq 0.024$) lowered scalp sebum for 21 and 28 days following the application, suggesting that this topical therapy of scalp greasiness is safe and efficient.

INTRODUCTION

Green tea (*Camellia sinensis*) has several health benefits including favorable cosmetic properties. The herb is therefore widely used in skin care products for antiaging (1,2) and hydration (3,4), either as the single active agent or in a combination with others (5) for skin disorder treatment. Its potential as a hair growth promoter is considered to be caused by 5 α -reductase activity (6). In addition, the inhibitory effect of tea against the androgen receptor also implies possible treatments for body and oral malodor (7,8).

The clinical setting for hair loss frequently includes oily scalp (6), which is caused by overactive sebaceous glands (9). Excess sebum on the scalp produces the ideal environment for *Malassezia* spp., resulting in itching and dandruff (10). Therefore, an application of cosmetics to reduce scalp greasiness should be used to manage this hair disorder. In particular, products with a long contact time, such as hair tonics, tend to have enhanced efficacy (11). Thus, green tea hair tonic was developed and skin irritation was assessed by means of a single closed-patch test including the tonic preference. Thereafter, the developed product was studied and monitored with a Sebumeter[®] (SM810; CK, Cologne, Germany) in a randomized single-blind, placebo-controlled clinical study.

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MATERIALS AND METHODS

FORMULATIONS AND STABILITY EVALUATION

Base hair tonic containing PEG 40-hydrogenated castor oil, menthol, ethyl alcohol, butylene glycol, glycerine (Namsiang, Bangkok, Thailand), and water was formulated as shown in Table I. The pH values of the formulated hair tonics were determined using a PC Testr 35 (Oakton Instruments, Vernon Hills, IL) multifunction analyzer. Three base formulas were tested and found to be stable after an accelerated stability test that was based on a centrifugation assay (3000 rpm for 30 min) in a Micromax RF centrifuge (Thermo Fisher Scientific, Waltham, MA) and six cycles of heating (45°C) and cooling (4°C) for 48 h for each cycle (11). The hair tonic base was incorporated with green tea extract with 100 mg% of polyphenols (product code: HE-EL11-CAS) supplied by Specialty Natural Products (Chonburi, Thailand). The obtained green tea hair tonics were stability tested as above.

PREFERENCE TESTS

Preference tests for the base hair tonics were carried out with seven female and three male Thai volunteers aged 23–39 years by using a questionnaire with a hedonic scoring system (scores 1–5, where 1 = dislike, 2 = strong preference). The preferred base, which also passed the stability test, was chosen for further hair tonic development (11).

CLINICAL EVALUATION

Inclusion criteria. Healthy Thai volunteers aged between 23 and 39 years were enrolled in the study. All recruited subjects were informed about the study both in writing and verbally, and signed a written consent form that was approved by the ethical committee of the Mae Fah Luang University before enrollment (REH-58062). All of the studies involving human volunteers were in accordance with the Declaration of Helsinki.

Table I
Formulation, Stability, and Preference of Hair Tonic Base

Ingredient	Hair tonic base (% w/w)				
	A	B	C	D	E
PEG 40-hydrogenated castor oil					
Menthol					
Glycerine	4	—	2	4.5	7
Butylene glycol	—	4	2	4.5	7
Ethyl alcohol		▲		▲	▲
Deionized water		91.7 ▼		86.7 ▼	81.7 ▼
Centrifuge			Homogeneous		
Freshly pH	4.10 ± 0.00	4.00 ± 0.00	4.47 ± 0.06	4.40 ± 0.10	4.37 ± 0.12
Heat cool pH	4.47 ± 0.06	4.33 ± 0.06	4.57 ± 0.15	4.47 ± 0.06	4.47 ± 0.06
Overall preference (%)	77.20 ± 6.41	79.60 ± 4.17	84.40 ± 4.79	80.00 ± 5.40	82.20 ± 4.60

Irritation test. A closed-patch test was performed in the same group of volunteer that participated in the preference test. Base hair tonic was tested with different green tea concentrations. Water was used as a negative control, whereas 3% sodium lauryl sulfate (Namsiang) was the positive control. Observation was made immediately after removal of the Finn chamber[®] (8 mm, SmartPractice, Phoenix, AZ), and at 24, 48, and 72 h after removal. The mean irritation index (MII) was calculated (12).

Efficacy evaluation. Twenty healthy Thai volunteers (10 female and 10 male) aged between 23 and 35 years were included. All subjects were allergy free for 1 week, and had not used steroids or topical products for oily or greasy scalp treatment for 4 weeks prior to study enrollment. Subjects who were pregnant, lactating, or dieting were excluded from the study, as were those who reported smoking or drinking of liquor. The subjects were advised not to apply any product onto the scalp the night before starting the study. All subjects were tested for scalp greasiness at baseline using a Sebumeter[®]. The measurement was performed in triplicate at different positions on the same side of the head. The subjects were acclimatized in a waiting room ($20 \pm 1^\circ\text{C}$ and 40–60% relative humidity) for 30 min before scalp measurements were carried out under the same conditions. A randomized single-blind placebo-controlled study was designed and the volunteers were requested to apply hair tonic once in the morning by a split-head procedure for intraindividual comparative trails. The volunteers were directed to use five drops of the green tea hair tonic on one side of the head and the same quantity of base tonic on the other side. The control cleansing shampoo (No More Tears; Johnson & Johnson, Bangkok, Thailand) was provided and used for hair washing (10 g/wash) at 2-day intervals (11). Subjects who showed less than 90% compliance with the assigned product were excluded from the study. Efficacy evaluation was conducted on days 7, 14, 21, and 28 using the Sebumeter[®].

STATISTICAL ANALYSIS

The parameters were compared and analyzed using post hoc tests for stability and preference. Independent sample *t*-test was for efficacy evaluation. Significance was set at a confidence level of 95%, and data were expressed as mean \pm standard error.

RESULTS AND DISCUSSION

The tonic base formulation was developed by variation of humectant (glycerine and butylene glycol) content, as shown in Table I. All of the tonics were clear, colorless liquids that remained stable following centrifugation assay. Thereafter, accelerated stability tests were performed using repeated heating–cooling cycles, and higher pH was observed in all of the formulations. Preferences for the hair tonics were examined for spreadability, skin absorption, greasiness, color, and odor. Tonic C gained the highest preference for spreadability, skin absorption, and greasiness, but preferences for color and odor were comparable. An increase of humectant contents was found to reduce the scores of all preference criteria. Therefore, hair tonic base C was further developed into green tea hair tonic. Various proportions of green tea extract (2–7%), delineated by the reported facial sebum reduction (13–15), were incorporated into base C using butylene glycol (Table II). The increased content of the extract did not affect the product pH ($p > 0.05$) and all of the green tea hair tonics remained stable.

Table II
Green Tea Hair Tonic Stability

Parameter	Green tea hair tonic			
	C1	C2	C3	
Green tea extract (%)	2	4.5	7	
Centrifuge		Homogeneous		
pH	Freshly	4.90 ± 0.10	4.83 ± 0.06	4.97 ± 0.06
	Heat cool	5.03 ± 0.06	5.03 ± 0.06	5.00 ± 0.10

Skin irritation was examined using a single closed-patch test (12), and all of the green tea (C1–C3) and base (C) hair tonics were negative (similar to water; MII = 0), in contrast to the positive control (sodium lauryl sulfate; MII = 0.5). Hair tonic containing 2% green tea extract was clinically trialed for its antioily scalp efficacy. A similar 2% green tea extract has been reported as an efficient treatment for acne (13).

The greasiness of skin can be assessed by several methods, including the use of absorbent paper pads, photometric assessment, bentonite clay, or lipid-sensitive tapes. Of these methods, Sebumeter[®] (photometric method) is the most commonly used (16). Sebum content of the scalp was shown to reduce from the baseline (day 0) following the application of hair tonic (Figure 1). Greasiness of the scalp continued to reduce significantly below the baseline after 21 and 28 days of application ($p = 0.024$ and 0.008). Although the base hair tonic was able to reduce the scalp sebum, no significant improvement was observed ($p > 0.05$). Consequently, the antioily scalp efficacy was calculated from the baseline, as shown in Figure 2. The green tea hair tonic efficacy was obviously better than placebo, particularly after 28 days of treatment ($p = 0.031$).

Oily scalp was successfully treated with the developed hair tonics. The green tea tonic and hair tonic base were able to reduce the sebum content, and the antioily scalp efficacy of the green tea hair tonic was 20% better than the tonic base (Figure 2). However, the observed efficacy was higher than the consumer satisfaction level (10%; 17). Furthermore, the sebum reducing ability of this green tea hair tonic was better than 3% and 5%

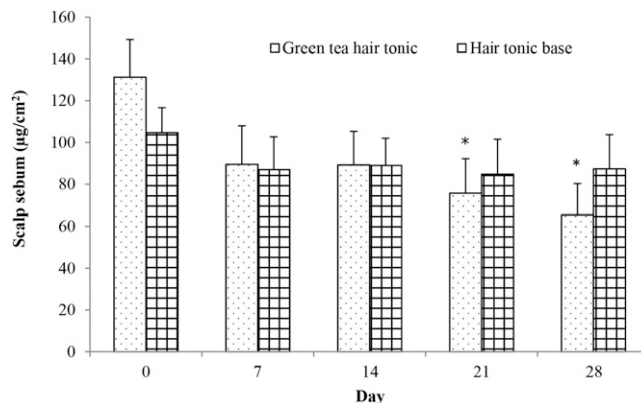


Figure 1. Sebum content of scalp at different time interval.

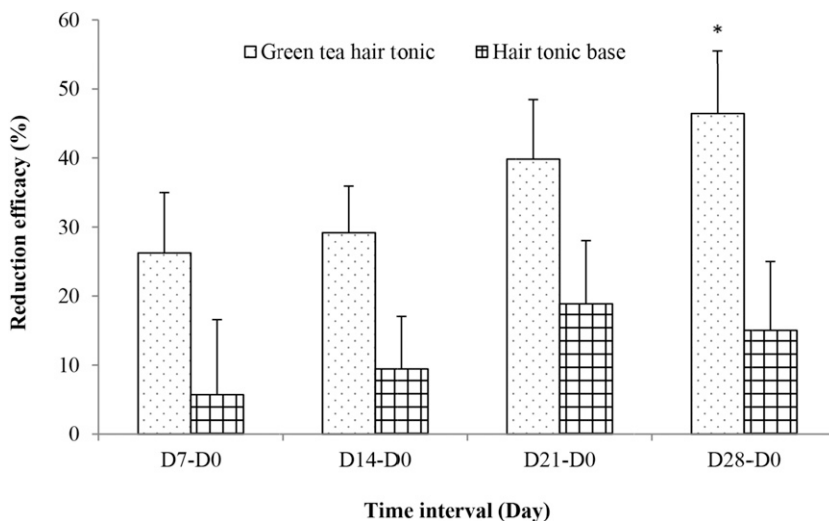


Figure 2. Efficacy of scalp sebum reduction.

green tea emulsions that were tested on the face (approximately 35% for 28 days and 29% for 30 days of treatment; 14,15).

Topical therapy of oily scalp by application of a green tea hair tonic has been proposed. Overgrowth of sebaceous glands generates suitable conditions for proliferation of *Malassezia* spp. and such conditions should be suppressed accordingly. Scalp and hair disorders such as itching, dandruff, and hair loss can, therefore, be treated with the proposed green tea hair tonic. The clinical efficacy of the green tea hair tonic might be enhanced at higher concentrations (4.5% and 7%) along with the increased antioil efficacy and a lack of skin irritation, although the 2% green tea may be more feasible from an economic perspective. Further assessment of the suppression of oil on the scalp or face by these preparations is necessary.

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