HAIR RESTORATION EFFICACY OF SUPPLEMENTS CONTAINING BANANA EXTRACT, PARTHENOLIDE DERIVED FROM FEVERFEW, AND SOY ISOFLAVONE IN HEALTHY JAPANESE
— A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY —

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Abstract

Objective: The objective of this research was to investigate the effectiveness of daily ingestion of a capsule, which contains banana extract, parthenolide derived from Feverfew, and soy isoflavone on hair growth.
Methods: A randomized, placebo-controlled, double-blind study was conducted. To evaluate, the thickness of the hair, the level of sebum around the pore, 6 indexes to score the condition of the scalp (inflammation, rash, amount of dandruff, pore-clogging, sebum capacity and dryness) and the physician's assessments of the change in scalp coverage were measured.
Results: From all of 83 applicants, 43 were eliminated according to the Hamilton's index of thinning hair (for males), or according to the modified Ludwig Type (for females). Among 40 subjects, 4 were withdrawn due to illness or business, and the remaining 36 subjects completed the study (MO＝16: M；8, F；8, Placebo＝20: M；11, F；9). After 12 weeks ingestion, the study showed significant improvement in "the level of sebum around the pore", "the condition of the scalp, including amount of dandruff, pore-clogging, and sebum capacity", and "the physician's assessments of scalp coverage". The result of self-assessment also showed the significant improvement in many items related to hair loss. No adverse effects were observed after the ingestion of the test product.
Conclusion: We found out that, compared with Placebo, the ingestion of the supplement containing banana extract (cycloeucalenone), parthenolide derived from Feverfew, and soy isoflavone for 12 weeks contributed to hair restoration, which is achieved by the improvement of scalp conditions such as pore-clogging, dandruff, and/or itching, and by reducing hair loss. In addition, no safety-related matters occurred during the 12-week test period.

Key words: banana, Feverfew, parthenolide, soy isoflavone, hair growth, hair loss, hair follicles, scalp condition

1. INTRODUCTION

We tend to build up anxiety regarding hair loss with advancing age. Along with slimming products, a substantial amount of products for hair are released and become outdated every day in the current market. Although the problem of hair loss or thinning hair is a physiological phenomenon, still many people are conscious about thin hair or hair loss since the hair effects his/her outward impression. According to the statistics conducted by Itami, et al., about 12.6 million men are aware of thinning hair, about 8 million men are concerned about thinning hair, and about 6.5 million men have experiences of coping with the thinning hair problem[1]. In addition, another study recently reported the mechanism of thin hair: that is, with advancing age the hair follicle stem cells (which play an important role in hair regeneration) stop their self-replication, and this action leads to lack of XVII-type collagen which encourages the transformation of the hair follicle stem cells to cornified cells. As a result, the cornified cells drop out of skin and the hair follicles themselves become "miniature", and eventually the hair becomes thinner and thinner, and finally falls out[2].

Although everyone run the risk of thinning hair with advancing age, the degree of which thinning hair occurs,

ranges from person to person. The risk of thin hair is thought to increase by several factors such as unbalanced dietary habit, irregular living, heavy drinking, smoking, eyestrain due to overuse of electric devices, and/or scalp uncleanliness. For the prevention, some try to change their life style, and others start to use shampoo dedicated to the removal of scalp uncleanliness. In addition, there are some curative medicines against AGA (androgenetic alopecia) in the market[3]. However, since these medicines are only available via prescription, obtaining them is somewhat a hurdle for general consumers. This fact accelerates the need to prevent the thinning hair problem simply by taking supplements. Although many supplements advocating their function of hair restoration are sold in Japan, there are few published reports that discuss its effect and safety for Japanese hair.

Therefore in this study, we examined the effects of hair restoration by ingesting a supplement containing "banana extract" which contains plenty of vitamins, amino acids, and plant sterols[4)5)], which is thought to have function of suppressing male hormones, "parthenolide derived from Feverfew" which is reported to have functions of improving blood flow, suppressing the release of serotonin that is a sort of excitatory transmitter and anti-inflammatory[6)7)], and "soy isoflavone" which is known for its female hormone-like effect[8]. The test method was a randomized, placebo-controlled, double- blind study, using Japanese as its test target.

2. METHODS

2.1. Trial design

A randomized, placebo-controlled, double-blind study was conducted with the aid of a fund from Kitanotatujin Corporation (Sapporo) at two centers, OZ clinic (Tokyo) and JACTA (Tokyo). The study period was 12 weeks, from December 18, 2015 to March 11, 2016. This study was conducted in accordance with the ethical principles of the declaration of Helsinki. The study protocol was approved by the Institutional Review Board of Pharmaceutical Law Wisdoms (Tokyo). Written informed consent was obtained from all subjects.

The allocation of the test product to the subjects was carried out by the person in charge of allocation. The allocation list was sealed and strictly controlled in a safe deposit box of JACTA until the end of the study.

2.2. Subjects

Healthy subjects participated in the present study. All of the subjects in this study were public volunteers who had enrolled in the monitor bank of CROee Inc. (Tokyo), recruited from November through December in 2015.

2.2.1. Inclusion criteria

(1) Healthy people aged between 30 and 59 years;
(2) Male with Hamilton-Norwood Hair Loss Scale II or III;
(3) Female with modified Ludwig Type 1 or 2.

Hamilton-Norwood Scale[9)10)] is a way of measuring the pattern of baldness in males and is generally accepted. The typical pattern of hair loss is divided into seven categories. The higher the number, the more advanced. Type II indicates minor recessions of the frontal hairline. Type III shows farther frontal hair loss, and is considered cosmetically significant.

On the other hand, Ludwig Type[11)] is the measurement of hair loss for females and is used worldwide. Ludwig Type has 3 different classifications. In Type I, hair loss is considered to be mild. Hair loss may occur on the top and front of the scalp. Such hair loss may be noticeable when the hair is parted down the center of the scalp. In this study we adopted subjects with this type and subjects with a little milder than this type.

2.2.2. Exclusion criteria

(1) Individuals diagnosed with alopecia;
(2) Individuals undergoing treatment of thinning hair;
(3) Individuals taking medication, including herbal medicines;
(4) Individuals who are pregnant or lactating;
(5) Individuals judged to be unsuitable to participate in the trial by the principle investigator.

2.3. Randomization

From all of 83 applicants, 43 were eliminated according to Hamilton-Norwood Hair Loss Scale (for male), or modified Ludwig Type (for female). The inclusion criterion was judged by the principle investigator.

All subjects were sequentially allocated to Group A (n = 20) and Group B (n = 20) based on a random number table. In the process of subject assignment, background factors such as gender, age, and thickness of the hair were taken into consideration to avoid biased distribution. Subjects in Group A ingested placebo and subjects in Group B ingested the test sample for 12 weeks.

2.4. Description of test foods and blinding

The test product "MOSIGN" ("MO") was prepared by Kitanotatsujin Corporation. The amount of daily intake was 4 capsules (1 capsule weighed 260 mg, therefore 4 capsules weighed 1,040 mg). The Placebo did not include banana extract, parthenolide derived from Feverfew, and soy isoflavone. **Table 1** shows the nutritional content of the sample. Both capsules were indistinguishable in shape, color or taste. Capsules were managed by the identification symbol. All involved were blinded.

Table 1　Nutritional content of the sample per 100 g

Item	MO	Placebo
Protein	23.3 g	16.4 g
Lipid	4.3 g	2.2 g
Carbohydrates	60.5 g	76.0 g
Energy	374 kcal	277 kcal
Salt equivalent	0.706 g	0.114 g

Table 2 Schedule for the study

Item \ Term	Screening	Pretrial test	Test period		
			4 w	8 w	12 w
Informed consent	●				
Selection and/or allocation	●				
Thickness of the hair		●	●	●	●
Level of sebum around the pore		●	●	●	●
6 indexes to score the condition of the scalp		●	●	●	●
Physician's assessment of the change in scalp coverage		●	●	●	●
Subjective reporting		●			●
Ingestion of test foods			↔	↔	↔
Log			↔	↔	↔

● : Implementation

↔ : Daily practice during the test period

2.5. Experimental procedures

2.5.1. Experimental protocol

Subjects consumed 4 capsules of the supplement with hot or cold water every day for 12weeks. Subjects were instructed as follows: to take the assigned foods as indicated; to maintain their usual lifestyles and habits; to avoid excessive amounts of food, drink or alcohol; to record a daily diary of their life style during the test period; and to send the diary to the study coordinator.

2.5.2. Outcome

The objective of this study was to verify the effect of hair growth by ingesting food containing banana extract, parthenolide derived from Feverfew, and soy isoflavone. To evaluate this objective, the thickness of the hair, the level of sebum around the pore, 6 indexes to score the condition of the scalp (inflammation, rash, amount of dandruff, pore-clogging, sebum capacity, and dryness), and the physician's assessments of the change in scalp coverage were measured as the primary outcomes.

The average thickness of the hair was calculated by the following method;

- the crown of the head was cleansed.
- 3 single hairs from an area of 3 cm^2 were cut.
- the circumference of 1 cm from the bottom of the hair was measured, using the digital micro meter (Shinwa Rules Co., Ltd., Niigata) for the computation of the average.

The level of the sebum around the pore in the area of the thinning hair was assessed with photographs taken by a microscope-camera (UK-02, MIYOSHI CORP., Tokyo) by the principle investigator. The assessments were rated on a scale of −4 to +4. The rating was performed as follows: 0＝baseline status, 4＝highly improved, 3＝improved, 2＝moderately improved, 1＝mildly improved −4＝highly deteriorated, −3＝deteriorated, −2＝moderately deteriorated, −1＝mildly deteriorated.

6 indexes to score the condition of the scalp (inflammation, rash, amount of dandruff, pore-clogging, sebum capacity, and dryness) were evaluated with photographs of the area of thinning hair. The principle investigator rated on a scale of 0 to 4, with lower scores indicating a better result.

The physician's assessment of the change in scalp coverage was performed with photographs of the area of the thinning hair. The rating was performed on a scale of −1 to 1, −1＝deteriorated, 0＝no change, 1＝improved.

Subject's self-assessments of the hair and scalp were also observed as the primary outcome. The questionnaire covered: hair fallout during shampooing and in daily life, tension of the hair, texture of the hair, sebum capacity of the scalp and itching of the scalp. They were rated in 9 grades from 1 to 9. Better condition was indicated by a higher grade and poorer condition by a lower grade.

To evaluate the safety of the test sample, adverse events were collected by means of a written questionnaire during the study.

As shown in the test schedule in **Table 2**, parameters on efficacy and safety were measured.

2.6. Data analysis

A full analysis set was adopted in the present study and no sample size design was used. Data was expressed as mean ± SD. For the thickness of the hair, differences from the baseline in the same group were assessed using the paired t-test. Student t-test was used for intergroup comparisons of changes from the baseline. For the level of sebum around the pore and subjective reporting of the hair and scalp condition, changes from baseline in the same group were assessed using Wilcoxon signed-rank test. Mann-Whitney U test was used for intergroup comparisons of changes from the baseline. As for the 6 indexes to score the condition of the scalp and the physician's assessment of the change in scalp coverage, Wilcoxon signed-rank test was conducted for intragroup comparison, and ANOVA for intergroup comparison. Student's t-test was used to compare subject backgrounds between groups.

Multiplicity according to the occasions was not

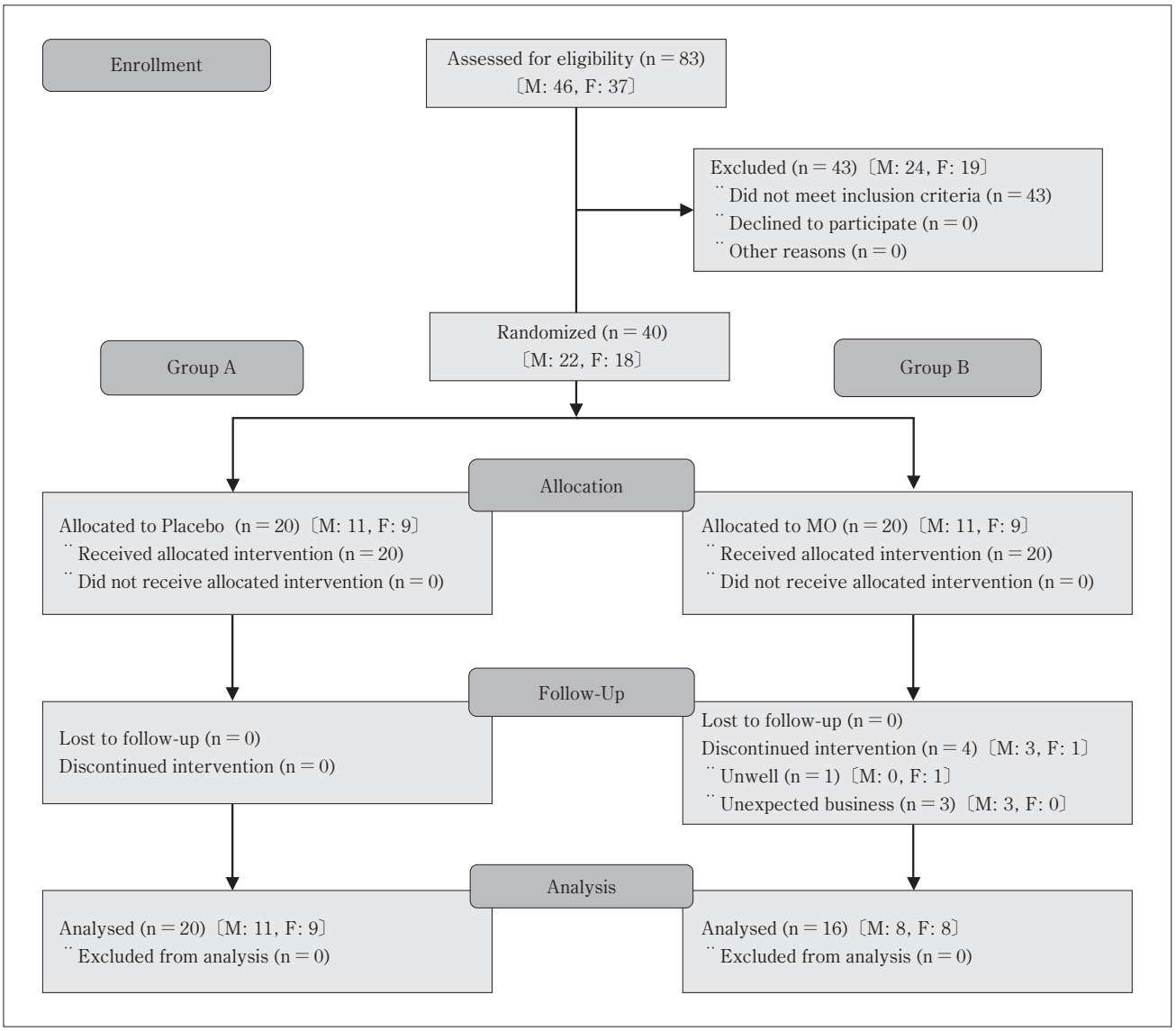

Fig. 1　Flow diagram of subject disposition

Table 3　Subject demographics

Item	Unit	Placebo	MO
Subjects	numbers	20	16
Male: female*	numbers	11:9	8:8
Age*	years	44.4 ± 9.3	48.3 ± 7.8
Thickness of the hair*	mm	0.0394 ± 0.0128	0.0474 ± 0.0118

mean ± SD

* No significant difference

adjusted. Any subjects with missing values were eliminated from the analysis. Statistical analyses were performed using Statcel 3 (Yanai, 2011). The results were considered significant at a < 5% level in the two-sided test.

3. RESULTS

3.1. Participant demographics

The 40 subjects were randomly assigned to intervention groups and made a start with ingestion. 4 were withdrawn due to being unwell or unexpected business, and the remaining 36 subjects completed the study. Thus, data obtained from 36 subjects (MO; 16, Placebo; 20) was

Table 4 Changes in the thickness of the hair and the level of sebum around the pore

Item (unit)	Time point	Values/ Scores		P-value[2)]
		MO (n = 16)[1)]	Placebo (n = 20)[1)]	
Thickness of the hair (mm)	Baseline	0.0394 ± 0.0128	0.0474 ± 0.0118	
	4-week	0.0418 ± 0.0111	0.0459 ± 0.0078	
	⊿ 0-4 w	0.0024 ± 0.0147	− 0.0015 ± 0.0078	0.316
	8-week	0.0720 ± 0.1016	0.0643 ± 0.0987	
	⊿ 0-8 w	0.0326 ± 0.1033	0.0169 ± 0.0973	0.642
	12-week	0.0489 ± 0.0124 **	0.0663 ± 0.0978	
	⊿ 0-12 w	0.0095 ± 0.0087	0.0189 ± 0.1018	0.716
Level of sebum around the pore (score)	Baseline	0.00 ± 0.00	0.00 ± 0.00	
	4-week	0.13 ± 0.50	− 0.15 ± 0.49	
	⊿ 0-4 w	0.13 ± 0.50	− 0.15 ± 0.49	0.286
	8-week	0.44 ± 0.63 *	− 0.30 ± 0.57 *	
	⊿ 0-8 w	0.44 ± 0.63	− 0.30 ± 0.57	0.007 ##
	12-week	0.56 ± 0.63 *	− 0.35 ± 0.59 *	
	⊿ 0-12 w	0.56 ± 0.63	− 0.35 ± 0.59	< 0.001 ##

Values and scores are expressed as the mean ± SD.

1) * $p < 0.05$, ** $p < 0.01$ against baseline.

2) ## $p < 0.01$ between-group difference in change from baseline.

Table 5 6 indexes to score the condition of the scalp

Item	Group	Scores				p-value[2)]
		Baseline	4-week[1)]	8-week[1)]	12-week[1)]	Time × Group
Inflammation	MO	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.499
	Placebo	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.05 ± 0.22	
Rash	MO	0.19 ± 0.54	0.00 ± 0.00	0.06 ± 0.25	0.00 ± 0.00	0.779
	Placebo	0.20 ± 0.52	0.15 ± 0.49	0.15 ± 0.37	0.00 ± 0.00	
Amount of dandruff	MO	0.25 ± 0.68	0.13 ± 0.34	0.00 ± 0.00	0.00 ± 0.00	0.018 #
	Placebo	0.05 ± 0.22	0.00 ± 0.00	0.20 ± 0.41	0.05 ± 0.22	
Pore-clogging	MO	1.13 ± 0.72	1.00 ± 0.82	0.69 ± 0.70 *	0.63 ± 0.72 *	< 0.001 ##
	Placebo	0.75 ± 0.64	0.75 ± 0.55	0.75 ± 0.55	0.95 ± 0.60	
Sebum capacity	MO	0.88 ± 0.72	0.50 ± 0.63 *	0.38 ± 0.62 *	0.25 ± 0.45 *	< 0.001 ##
	Placebo	0.75 ± 0.44	0.75 ± 0.44	0.85 ± 0.49	0.90 ± 0.45	
Dryness	MO	0.19 ± 0.54	0.06 ± 0.25	0.00 ± 0.00	0.00 ± 0.00	0.085 ‡
	Placebo	0.05 ± 0.22	0.05 ± 0.22	0.05 ± 0.22	0.05 ± 0.22	

MO; n = 16, Placebo; n = 20

Scores are expressed as the mean ± SD.

1) * $p < 0.05$ intra-group differences against baseline.

2) ‡ $p < 0.1$, # $p < 0.05$, ## $p < 0.01$ between-group difference

used for efficacy analysis (**Fig. 1**). There were no significant differences in the mean age, gender ratios, or Thickness of the hair between groups. (**Table 3.**)

3.2. Thickness of the hair, Level of sebum around the pore

Table 4 shows the changes in the thickness of the hair and the level of sebum around the pore.

After 12 weeks ingestion, the values of the MO showed a significant difference in the thickness of the hair, whereas the Placebo showed no differences. As for the level of sebum around the pore, the values of the MO showed a significant difference of plus at week 8 and 12, whereas the Placebo group showed that of minus at week 8 and 12. Moreover the differences in change between the two

Table 6　Scalp coverage

Group	Scores				p-value[2)]
	Baseline	4-week[1)]	8-week[1)]	12-week[1)]	Time × Group
MO	0.0 ± 0.0	0.2 ± 0.4	0.4 ± 0.5 *	0.3 ± 0.4 †	0.029 #
Placebo	0.0 ± 0.0	0.1 ± 0.2	0.1 ± 0.3	0.1 ± 0.3	

MO; n = 16, Placebo; n = 20

Scores are expressed as the mean ± SD.

1) † $p < 0.1$, * $p < 0.05$ intra-group differences against baseline.

2) # $p < 0.05$ between-group difference

Table 7　Results of questionnaire analyses

Item	Time points	Scores		P-value[2)]
		MO（n = 16）[1)]	Placebo（n = 20）[1)]	
Hair fallout during shampooing	Baseline	5.0 ± 1.6	5.1 ± 0.9	
	12-week	6.1 ± 1.3 *	4.9 ± 1.1	
	⊿ 0-12 w	1.1 ± 1.3	− 0.2 ± 0.6	< 0.001 ##
Hai fallout in daily life	Baseline	4.9 ± 1.3	5.0 ± 0.6	
	12-week	5.9 ± 1.1 *	4.8 ± 0.8	
	⊿ 0-12 w	1.1 ± 1.5	− 0.2 ± 0.5	0.001 ##
Tension of the hair	Baseline	5.1 ± 1.1	4.8 ± 0.8	
	12-week	6.1 ± 1.0 **	4.6 ± 0.8	
	⊿ 0-12 w	1.0 ± 1.2	− 0.2 ± 0.7	0.002 ##
Texture of the hair	Baseline	5.1 ± 1.2	5.0 ± 0.9	
	12-week	6.1 ± 0.9 *	4.8 ± 1.2	
	⊿ 0-12 w	0.9 ± 1.2	− 0.2 ± 0.6	0.004 ##
Sebum capacity of the scalp	Baseline	4.9 ± 1.2	4.9 ± 0.9	
	12-week	5.6 ± 1.4 †	4.9 ± 1.0	
	⊿ 0-12 w	0.7 ± 1.4	0.0 ± 0.6	0.027 #
Itching of the scalp	Baseline	5.3 ± 1.4	5.2 ± 1.3	
	12-week	6.0 ± 1.1 *	5.0 ± 1.3	
	⊿ 0-12 w	0.8 ± 1.2	− 0.2 ± 0.4	0.0104 #

Scores are expressed as the mean ± SD.

1) † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$ against baseline.

2) # $p < 0.05$, ## $p < 0.01$ between-group difference in change from baseline.

groups illustrated significant difference at week 8 and 12.

3.3. 6 indexes to score the condition of the scalp

Table 5 shows the results of 6 indexes to score the condition of the scalp.

The values of the MO showed a significant difference in the items of "pore- clogging" at week 8 and 12, and in that of "sebum capacity" at week 4,8 and 12, whereas the Placebo showed no significant difference in all items. In addition, the intergroup analysis of changes after 12 weeks presented a significant difference in the items including "Amount of dandruff", "Pore-clogging", and "Sebum capacity". "Dryness" tended to decrease.

3.4. The physician's assessment of the change in scalp coverage.

The physician's assessment of the change in scalp coverage is shown in **Table 6**.

Significant differences were observed in the intragroup analyses of the MO at week 8 and 12. Furthermore, the intergroup comparison of changes after 12 weeks showed a significant difference.

3.5. Subject's self-assessment

The result of subject's self-assessment is shown in **Table 7**.

Changes from week-0 values in all six items of "Hair fallout during shampooing", "Hair fallout in daily life", "Tension of the hair", "Texture of the hair", "Sebum

capacity of the scalp", and "Itching of the scalp" were significantly greater in the MO than in the Placebo after 12 weeks ingestion.

3.6. Safety

No adverse effects associated with the test product were observed in the course of the reporting.

4. DISCUSSION

We conducted a randomized, placebo-controlled, double-blind study examining the efficacy of a supplement containing banana extract (cycloeucalenone), parthenolide derived from Feverfew, and soy isoflavone, on hair restoration of Japanese men and women.

As the primary outcome, the study showed the significant improvement in "the level of sebum around the pore", "the condition of the scalp of amount of dandruff, pore-clogging, and sebum capacity", and "the physician's assessments of scalp coverage". The result of self-assessment also showed significant improvement in many items related to hair loss. Therefore this suggests that there is a trend toward hair restoration whit the ingestion of the test product. In addition, as the secondary outcome, the fact that no adverse event had occurred during the test period proved that no abnormal change is triggered by the ingestion of the test product.

Main Findings

This study indicates the possibility of hair restoration by the ingestion of the test products containing banana extract (cycloeucalenone), parthenolide derived from Feverfew, and soy isoflavone. After 12-week ingestion of the test product, it showed significant differences between groups in "level of sebum around the pore", and "the condition of the scalp of amount of dandruff, pore-clogging, and sebum capacity". As for "thickness of the hair", MO showed the significant differences in the results after 12-week ingestion compared to those at the beginning, whereas there was no significant difference in Placebo. In addition, the ingestion of the test product tended to improve in "Dryness" of the condition of the scalp. Furthermore, "Scalp coverage" showed improvement after 12-week ingestion. The result of the self-assessment also showed significant differences in items such as "Hair fallout during shampooing", "Hair fallout in daily life", "Tension of the hair", "Texture of the hair", "Sebum capacity of the scalp", and "Itching of the scalp", which supports the self-assessment that the condition of the hair and scalp had improved and the amount of hair loss had decreased. Based on the above, it can be said that 12-week ingestion of the test product improved the scalp condition such as pore-clogging, dandruff, or itching and also improved one's subjective impressions of their hair/scalp condition and the amount of hair loss; these results indicate the test product likely has hair restorative properties.

The test product contains banana extract (cycloeucalenone), parthenolide derived from Feverfew, and soy isoflavone. Although the reasons for increasing the amount of hair loss may vary depending on the type of hair loss among males/females, it is thought that androgen is one of the key factors for the growth of a beard, chest hair, terminal hair on the four limbs, hair of the frontal cortex and top of the head [12]. Testosterone, which is as a male hormone, is metabolized to the stronger hormone of dihydrotestosterone by the function of 5α-reductase. It is said that when the dihydrotestosterone combines with the androgen receptor and moves to the nucleus of Follicle Dermal Papilla Cells, the alopecia factor is discharged from the cells, damages the hair root and eventually causes atrophy (loss of hair) [13]. Banana extract is reported to contain cycloeucalenone, a type of phytosterol [14]. It is reported that phytosterol has a function of inhibiting the activity of 5α-reductase and preventing hair loss [15]. In addition, bananas may possibly be an agent for hair regeneration since it contains plenty of glutamic acid and arginine which are both constituent amino acids of the hair [16][17]. It also contains vitamins and minerals such as Vitamin B2 which accelerates hair metabolism and Vitamin B6 which stimulates the generation of protein [18][19]. In addition, parthenolide contained in Feverfew is a plant- derived sesquiterpene lactone and has a function of anti-inflammatory properties [20]. Parthenolide also functions as an inhibitor of a protein complex called nuclear factor- kappa B, which is converted to testosterone and dihydrotestosterone [21][22]; in other words, it prevents the hair loss by the same functional mechanism as the cycloeucalenone contained in the banana extract. Soy isoflavone is a type of polyphenol which has a structural similarity to the female hormone (estrogen), and it is reported that since it functions the same as a female hormone internally, as appropriate, it suppresses the dihydrotestosterone [23]. Therefore, the prevention of hair loss as a result of suppression of the dihydrotestosterone is to be expected. There are reports that male hormone such as dihydrotestosterone stimulates sebum secretion of scalp [24][25]. It is considered that the ingestion of test product suppresses the dihydrotestosterone and sebum secretion of scalp, eliminates the pore-clogging, leads to the improvement of scalp condition and eventually contributes to maintaining good quality hair. Achieving this quality of hair may be a result of the provision of good nutrition for hair using elements found in bananas. In addition, since there is a report that isoflavones promote hair growth by increasing the insulin-like growth factor (IGF-I) production in hair follicles [26], it is reasonable to consider that the ingestion of the test product has promoted the hair growth and affected the quality of hair positively.

Based on the above discussion, it is thought that the functions of each ingredient contained in the test product, and mutual effects among them, both contributed to hair

restoration.

Secondary Findings

In this study, adverse events were collected by means of a written questionnaire during the study, and no abnormal change caused by the test product was observed during the ingesting period. During the test period four test subjects discontinued the test. The reasons for discontinuance were personal ones such as illness (catching a cold) or business-related matters, and it had nothing to do with the ingestion of the test product. These results indicated the safety of the ingestion of the test product for the 12-week test period.

General Information

Generally, the hair appearance plays quite an important role in one's first impression to others, therefore hair health may significantly effects one's quality of life (QOL). In clinical practice medicine with an active ingredient of finasteride which suppresses 5α - reductase is widely used, but at the same time, many reports point out that its usage also triggers several side effects such as ED (erectile dysfunction), liver dysfunction, cancer, depressive symptoms, and/or sterility [27)-29)]. In addition, since finasteride is absorbed into the body via percutaneous absorption, the ingestion of finasteride by a pregnant women can trigger adverse effects on normal development of the sexual organs of a fetus [30)31)].

There were no abnormal changes observed after the ingestion of this test product for 12 weeks. Also, the ingredients contained in the test product such as banana and soybeans are foods we eat quite regularly. Feverfew, on the other hand, is not a common food in Japan, but is widely consumed as a herb in the place of origin and therefore the safety is verified. Although the degree of effectiveness might be somewhat gradual compared to that of medicine, ingesting the food products expected to suppress 5α - reductase, and a lower risk of the abnormal change which can contribute not only to preventing hair loss but also to improving our QOL.

Limitations

The problem of thinning hair has several types which differ between men and women, and the process of hair loss varies depending on these types [32)-35)]. In some types the hair loss occurs even without any involvement of male hormones. Therefore the result of this study should not apply to every type of hair loss or thinning hair problem. In addition, although the test product used for this study contains ingredients which are viewed as having several functionalities, we have not yet discovered the mutual influence among them when ingested simultaneously, or how the mutual influence between these ingredients and the other components of the test product affected the hair restoration. Therefore, it can be said that the functional mechanism found in this study is merely a speculation based on knowledge of each ingredient, and it is necessary to further scrutinize the functional mechanism by various methodologies including in vivo- / in vitro study.

5. CONCLUSION

In conclusion, we found out that, compared with Placebo, the ingestion of the supplement containing banana extract (cycloeucalenone), parthenolide derived from Feverfew, and soy isoflavone for 12 weeks contributed to the hair restoration, which is achieved by the improvement the scalp condition such as pore-clogging, dandruff and/or itching, and by reducing hair loss. In addition, no safety-related matter occurred during 12-week test period.

CONFLICT OF INTEREST

All parts of this study were funded by Kitanotatsujin Corporation. Katsuhisa Kinoshita is a principal, Asako Horikawa is a director, and Kenji Kunishige is an employee of them. All authors state that the study was conducted in the absence of any other relationships that could be interpreted as a conflict of interest.

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