HAIR RESTORATION EFFICACY OF A FOOD CONTAINING MILLET EXTRACT WITH KERATIN POWDER

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Abstract

Objective: We examined the effect of the millet extract with keratin powder for hair restoration.
Methods: A randomized, placebo-controlled, double-blind study was conducted. 5 indexes of score of the scalp condition (inflammation, rash, amount of dandruff, pore-clogging and sebum capacity), the thickness of the hair and subjective reporting of the hair (fallout of the hair in shampooing and daily life, tension of the hair, texture of the hair, sebum capacity of the scalp and itching of the scalp) were evaluated.
Results: From all of 211 applicants, 169 were eliminated according to the Hamilton's index of thinning hair (for men), or questionnaire for the stages of thinning hair (for women). Among 42 subjects, 5 were withdrawn due to disease and the remaining 37 subjects completed the study (Test sample 20: M=11, F=9; Placebo 17: M=10, F=7). After 12 weeks of ingestion, the Test group showed a significant difference in the items of thickness of the hair, rash, pore-clogging and sebum capacity, compared with the Placebo group. Also, the significant difference of inter group was found in subjective evaluation: fallout of the hair in shampooing and daily life, tension of the hair, texture of the hair, sebum capacity of the scalp and itching of the scalp. No adverse effects were observed after the ingestion of the Test food.
Conclusion: These results implied that the Test food was effective for the hair restoration.

Key Words: Hair restoration, Hair growth, Supplement.

1. INTRODUCTION

Generally, hair of both men and women thins with advancing age. This phenomenon is not based on organic diseases but mostly because of a physiological matter, but still many people are conscious about thinning hair or hair removal since hair affects his/her outward impression. According to the statistics, about 12.6 million men are aware of the thinning of the hair, about 8 million men are concerned about thinning hair, and about 6.5 million men have an experience of coping with the thinning hair problem[1]. Their feeling that their appearance is deteriorating is likely to become a huge stress in their group lives and therefore become a risk to diminish their quality of life.

There are some curative medicines against AGA (androgenetic alopecia) on the market as a measure for dealing with the men's thinning-hair problem. However, these medicines have a risk of side effects, and because of this it acts as one of the triggers for the expectation of hair-growth by taking safe ingredients containing food elements.

Studies have revealed that there is a element that reinforces hair growth in several plant-derived ingredients[2)3)], one of which is "millet extract": the ingredient which has been ingested in Europe as "an oral-medicine for hair restoration" through the ages. The millet extract is an extract from millet, a type of Poaceae (grass family), and it contains ingredients such as protein, cystine (an essential amino acid; EAA), and silicon (micro-mineral)[4)5)]. Although many supplements containing the millet extract are sold in Japan, there are few published reports that discuss its effect and safety for Japanese hair.

This study is an examination of the effect of the millet extract for hair restoration. The test targets were Japanese, and the test method was a randomized, placebo-controlled, double-blind study using the supplement containing millet extract with keratin powder.

2. METHOD

2.1. Trial Design

A randomized, placebo-controlled, double-blind study was

Table 1 Nutritional content of the sample per 1800 mg (6 tablets) per day

Item	NICCA	Placebo
Energy	7.5 kcal	4.3 kcal
Protein	0.2 g	0.0 g
Lipid	0.2 g	0.0 g
Carbohydrates	1.2 g	1.7 g
Na	18 mg	0.1 mg

conducted with the aid of a fund from NICCA CHEMICAL CO., LTD. (Tokyo) at two centers (OZ clinic, Tokyo and JACTA, Tokyo).

The study period was 12 weeks, from July 8th to September 30th, 2015.

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 LLP. 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).

2.2.1. Inclusion Criteria

(1) Healthy people aged between 30 and 59 years.
(2) People suffering from thinning hair.

2.2.2. Exclusion Criteria

(1) Individuals undergoing treatment of thinning hair.
(2) Individuals on taking medication, including herbal medicines.
(3) Individuals judged to be unsuitable to participate in the trial by the doctor conducting present study.

2.2.3. Efficacy Eligibility

With respect to the analysis of efficacy, we set the following criteria of exclusion:

(1) Participants who consumed less than 80%of the expected dose;
(2) Participants without adequate records;
(3) Participants who fell under the exclusion criteria after enrollment;
(4) Participants who had justifiable reason for exclusion.

2.3. Randomization

Subjects who fulfilled the eligibility criteria were 211 persons.

The inclusion criterion was judged by the principle investigator.

All subjects were sequentially assigned based on a random number table to one of the masked products and randomized to group P (Placebo: 21) and group T (Test sample: 21).

The allocation was pre-assigned on the basis of randomized numbers.

2.4. Description of test foods and blinding

The test food is a tablet containing millet extract with keratin powder. Daily intake was 6 tablets per day (1 tablet contains 300mg, therefore 6 tablets contain 1800 mg). The Placebo include neither millet extract nor keratin powder. **Table 1** shows the nutritional content of the sample.

Both tablets were indistinguishable in shape, color or taste.

Tablets were managed by an identification symbol. All involved were blinded.

2.5. Experimental Procedures

2.5.1. Experimental protocol

Subjects consumed 6 tablets 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 maintain a daily record of lifestyle factors during the test period; and to send the diary to the study coordinator every Friday (or Thursday night) by mobile email.

2.5.2. Outcome

The objective of this study is to verify the effect of hair growth by ingesting food containing millet extract with keratin powder.

To evaluate this objective, 5 score indexes of the scalp condition (inflammation, rash, amount of dandruff, pore-clogging and sebum capacity) were measured as the primary outcomes.

The thickness of the hair and subjective reporting of the hair was also observed as the primary outcome.

The questionnaire covered: fallout of the hair due to shampooing, fallout of the hair in daily life, tension of the hair, texture of the hair, sebum capacity of the scalp and itching of the scalp.

Blood biochemical and urine parameters were recorded to evaluate the safety of the test foods as the secondary outcome.

2.6. Data Analysis

All analyses were performed on the on-treatment population in the study.

Data were expressed as mean ± SD. For the thickness of the hair, changes from the baseline in the same group were assessed using the paired t-test. Student's t-test was used for intergroup comparisons of changes from the baseline. For the 5 score indexes of the scalp condition (inflammation, rash, amount of dandruff, pore-clogging and sebum capacity), and subjective reporting of hair and scalp condition, changes from baseline in the same group were assessed using Wilcoxon signed-rank test. The Mann–Whitney U test was used for intergroup comparisons of changes from the baseline. For

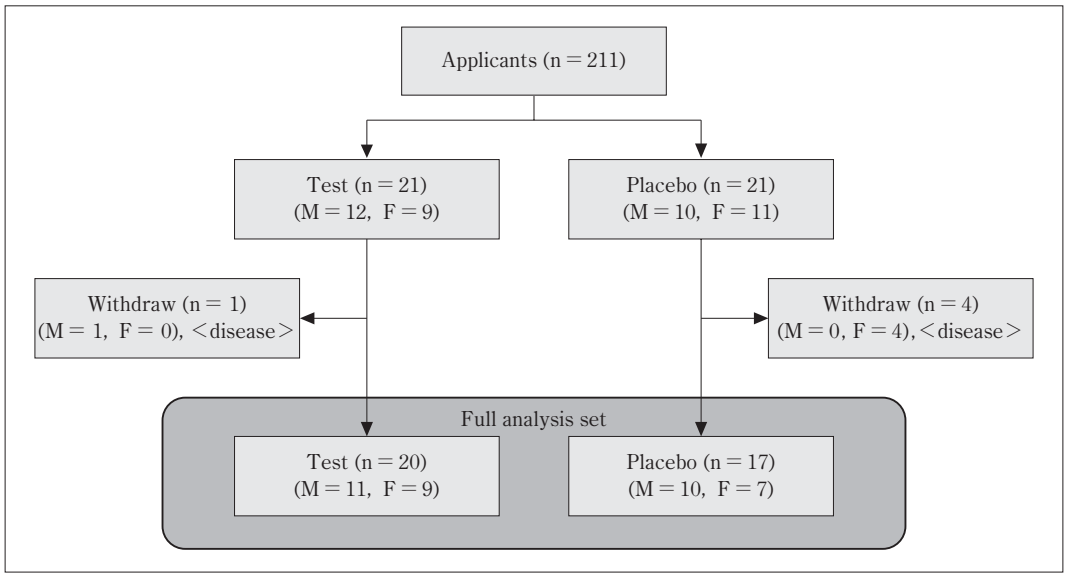

Fig. 1　Flow diagram of subject disposition

Table 2　Subject demographics

Item	Unit	Test	Placebo
Subjects*	−	20	17
Male : Female*	−	11 : 9	10 : 7
Age	years	47.7 ± 7.9	47.7 ± 7.4
Thickness of the hair	mm	0.046 ± 0.008	0.051 ± 0.011

* Number of subjects
mean ± SD

biochemical analyses of blood and urine, changes from the baseline in the same group were assessed using the paired t-test, with Student's t-test used for intergroup comparisons of changes from the baseline. Student's t-test was used to compare subject backgrounds between groups. Statistical analyses were performed using Statcel 3 (Yanai, 2011). The results were considered significant at the < 5% level in the two-sided test.

3. RESULT

3.1. Participant Demographics

From all of 211 applicants, 169 were eliminated according to the Hamilton's index of thinning hair (for men), or questionnaire for the stages of thinning hair (for women).

The 42 subjects were randomly assigned to intervention groups and made a start with ingestion. 5 were withdrawn due to disease and the remaining 37 subjects completed the study. Thus, data obtained from 37 subjects (Test group; 20, Placebo group; 17) were used for efficacy analysis (**Fig. 1**). There were no significant differences in gender ratios, the mean age or thickness of the hair between groups (**Table 2**).

3.2. Thickness of the hair, the 5 score indexes of the scalp condition

Table 3 shows the results of the test. No significant difference was observed between the two groups in the thickness of the hair as well as all 5 score indexes at the baseline. After 12 weeks of ingestion, the Test group showed a significant difference in the items of thickness of the hair, rash, pore-clogging and sebum capacity, whereas the Placebo group showed a significant difference (decrease of the data amount) in thickness of the hair but no differences in all the other items. In the intergroup difference, the thickness of the hair, rash, pore-clogging and sebum capacity changed significantly after 12 weeks of ingestion.

3.3. Questionnaire analyses

The result of questionnaire analyses is shown in **Table 4**. The data of the Test group showed a significant difference in all six items of "fallout of the hair due to shampooing", "fallout of the hair in daily life", "tension of the hair", "texture of the hair", "sebum capacity of the scalp" and "itching of the scalp" after 12 weeks of ingestion. Moreover, all six items changed significantly in the intergroup differences.

Table 3 Results of the test

Item (unit)	Group	Baseline	12 weeks	Intragroup difference (P-value)	Intergroup difference (P-value)
Thickness of the hair (mm)	Test Placebo	0.046 ± 0.008 0.051 ± 0.011	0.051 ± 0.009 0.045 ± 0.010	0.003 ** 0.003 **	< 0.001 ##
Inflammation (index)	Test Placebo	0.1 ± 0.3 0.1 ± 0.3	0.0 ± 0.0 0.1 ± 0.3	0.180 —	0.604
Rash (index)	Test Placebo	0.5 ± 0.5 0.3 ± 0.5	0.1 ± 0.2 0.4 ± 0.5	0.012 * 0.361	0.021 #
Amount of dandruff (index)	Test Placebo	0.1 ± 0.3 0.2 ± 0.4	0.0 ± 0.0 0.2 ± 0.4	0.180 —	0.626
Pore-clogging (index)	Test Placebo	1.4 ± 0.9 1.7 ± 0.7	0.3 ± 0.5 1.5 ± 0.7	< 0.001 ** 0.345	0.002 ##
Sebum capacity (index)	Test Placebo	0.5 ± 0.5 0.6 ± 0.6	0.1 ± 0.2 0.8 ± 0.6	0.008 ** 0.361	0.011 #

n = 37
mean ± SD
*: $p < 0.05$, **: $p < 0.01$ versus baseline
#: $p < 0.05$, ##: $p < 0.01$ intergroup differences between changes from baseline

Table 4 Results of questionnaire analyses

Item (unit)	Group	Baseline	12 weeks	Intragroup difference (P-value)	Intergroup difference (P-value)
Fallout of the hair due to shampooing	Test Placebo	3.8 ± 1.3 3.6 ± 1.7	5.2 ± 1.7 3.4 ± 1.4	0.004 ** 0.161	< 0.001 ##
Fallout of the hair in daily life	Test Placebo	4.0 ± 1.1 3.8 ± 1.7	5.4 ± 1.8 3.8 ± 1.6	0.003 ** 0.753	0.017 #
Tension of the hair	Test Placebo	3.0 ± 1.2 3.4 ± 1.2	4.4 ± 1.6 3.6 ± 1.4	0.002 ** 0.249	0.014 #
Texture of the hair	Test Placebo	3.7 ± 1.5 3.3 ± 1.3	5.0 ± 1.5 3.4 ± 1.5	0.003 ** 0.593	0.008 ##
Sebum capacity of the scalp	Test Placebo	3.7 ± 1.5 4.2 ± 1.9	5.3 ± 1.6 4.2 ± 1.6	0.002 ** 0.715	0.012 #
Itching of the scalp	Test Placebo	4.3 ± 1.8 5.0 ± 2.1	6.1 ± 1.6 5.1 ± 1.4	0.001 ** 0.799	0.034 #

n = 37
mean ± SD
**: $p < 0.01$ versus baseline
#: $p < 0.05$, ##: $p < 0.01$ intergroup differences between changes from baseline

3.4. Blood and Urine Test

Table 5 and **6** shows the blood biochemical and urine parameters. A significant difference was observed in the changes of CK (CPK), Total Cholesterol, Sodium and calcium of the Test group after 12 weeks of ingestion. However, since the difference was within a range of baseline and just a shade of difference, the investigator judged it as the range of physiological variation (or clinically safe). For the urine parameter, no significant change was detected in Specific Gravity and pH.

3.5. Adverse Event

During the test period five subjects discontinued the test

Table 5　Changes in biochemical blood test

Item	Unit	Std. Value	Gender	Group	Baseline	12 weeks
					mean ± SD	mean ± SD
Total Bilirubin	mg/dL	0.2–1.2	M/F	Test Placebo	0.72 ± 0.26 0.54 ± 0.16	0.70 ± 0.22 0.56 ± 0.21
Total Protein	g/dL	6.5–8.3	M/F	Test Placebo	7.3 ± 0.4 7.5 ± 0.2	7.4 ± 0.3 7.5 ± 0.4
Albumen	g/dl	3.8–5.3	M/F	Test Placebo	4.6 ± 0.4 4.5 ± 0.3	4.6 ± 0.3 4.5 ± 0.3
AST (GOT)	U/L	8–38	M/F	Test Placebo	23.6 ± 7.7 20.9 ± 5.1	23.4 ± 9.6 22.6 ± 8.1
ALT (GPT)	U/L	4–43	M/F	Test Placebo	21.6 ± 12.3 20.8 ± 15.0	23.6 ± 21.8 23.6 ± 19.4
ALP	U/L	110–354	M/F	Test Placebo	218.9 ± 56.9 207.9 ± 48.1	236.1 ± 79.2 † 209.1 ± 45.3
LD (LDH)	U/L	121–245	M/F	Test Placebo	178.5 ± 30.3 176.4 ± 31.5	171.6 ± 24.8 179.2 ± 26.5
γ-GT (γ GTP)	U/L	86 and under	M	Test Placebo	34.2 ± 26.4 61.2 ± 85.1	32.5 ± 20.7 56.3 ± 66.9
		48 and under	F	Test Placebo	29.6 ± 22.8 22.4 ± 11.3	36.7 ± 40.9 20.1 ± 7.3
CK (CPK)	U/L	38–196	M	Test Placebo	138.7 ± 42.1 165.1 ± 99.2	197.4 ± 106.3 * 143.2 ± 59.1]#
		30–172	F	Test Placebo	92.1 ± 41.5 88.0 ± 37.0	73.0 ± 25.0 * 84.7 ± 23.1
Total Cholesterol	mg/dL	130–219	M/F	Test Placebo	202.7 ± 37.7 210.0 ± 24.9	213.2 ± 43.2 * 214.1 ± 24.0
Neutral Fat (TG)	mg/dL	30–149	M/F	Test Placebo	116.9 ± 39.5 145.9 ± 124.1	118.2 ± 59.4 138.4 ± 102.2
Sodium	mEq/L	135–150	M/F	Test Placebo	145.8 ± 1.6 146.0 ± 1.4	144.5 ± 1.8 ** 144.1 ± 1.9 **
Chloride	mEq/L	98–110	M/F	Test Placebo	106.1 ± 2.2 105.7 ± 1.5	105.2 ± 2.0 † 105.4 ± 1.2
Potassium	mEq/L	3.5–5.3	M/F	Test Placebo	4.0 ± 0.3 4.1 ± 0.3	4.1 ± 0.3 4.2 ± 0.3
Calcium	mg/dL	8.4–10.2	M/F	Test Placebo	9.7 ± 0.3 9.7 ± 0.3	9.9 ± 0.3 * 9.8 ± 0.4
Inorganic Phosphorus	mg/dL	2.5–4.5	M/F	Test Placebo	3.5 ± 0.4 3.5 ± 0.5	3.5 ± 0.5 3.5 ± 0.5
Urea Nitrogen	mg/dL	8.0–22.0	M/F	Test Placebo	14.4 ± 2.7 13.5 ± 2.5	15.6 ± 3.9 † 14.1 ± 3.9
Creatinine	mg/dL	0.61–1.04	M	Test Placebo	0.88 ± 0.13 0.91 ± 0.08	0.86 ± 0.14 0.89 ± 0.10
		0.47–0.79	F	Test Placebo	0.61 ± 0.09 0.70 ± 0.07	0.60 ± 0.09]‡ 0.64 ± 0.06 *
Blood Sugar (Serum)	mg/dL	60–109	M/F	Test Placebo	73.3 ± 12.6 73.7 ± 16.1	75.5 ± 10.7 66.6 ± 16.2

n = 37
† : $p < 0.1$, *: $p < 0.05$, **: $p < 0.01$ versus baseline
‡ : $p < 0.1$, #: $p < 0.05$ intergroup differences between changes from baseline

Table 6 Transition of Urinalysis

Item	Unit	Std. Value	Gender	Group	Baseline mean ± SD	12 weeks mean ± SD
Specific Gravity	mg/dL	1.010–1.025	M/F	Test Placebo	1.0190 ± 0.0068 1.0185 ± 0.0061	1.0213 ± 0.0089 1.0174 ± 0.0064
pH	g/dL	4.5–8.0	M/F	Test Placebo	5.9 ± 0.9 6.0 ± 0.8	6.4 ± 0.8 † 6.4 ± 0.7*

n = 37

† : $p < 0.1$, * : $p < 0.05$ versus baseline

due to sickness, but symptoms such as a cold were seen as unserious. The investigator judged that the relationship between the symptom and the intervention of the test product can be ruled out.

4. DISCUSSION

We conducted a randomized, placebo-controlled, double-blind study examining the efficacy of a tablet-type supplement containing millet extract with keratin powder on hair restoration of Japanese men and women. The primary outcome of the study was the significant differences in the intergroup analysis of changes of the thickness of the hair, scalp condition such as rash, pore-clogging, sebum capacity and the questionnaire analyses, and it suggested there had been a trend toward hair restoration in the ingestion of the test product.

In addition, as the secondary outcome, the observation of clinical findings such as the blood and urine test revealed no abnormal change had been triggered by the ingestion of the test products.

The study revealed there were significant differences in the actual thickness of the hair, scalp condition (i.e. rash, pore-clogging and sebum capacity) and the questionnaire analyses (i.e. fallout of the hair due to shampooing, fallout of the hair in daily life, tension of the hair, texture of the hair, sebum capacity of the scalp and itching of the scalp). As for the data result of "thickness of the hair", it showed the significant difference of plus in the Test group and that of minus in the Placebo group: as this study selected the person who are aware of their thinning hair, it can be assumed that in the Placebo group the thickness of the hair declined due to the phenomenon such as the advancing age, and in the Test group, on the other hand, it gained as a result of the ingestion of the test product.

Based on the above, it can be said that the 12 weeks ingestion of the test product improved the scalp condition such as pore-clogging and sebum capacity, increased the amount of hair and improved one's subjective impressions against quantity and quality of the hair; these results indicate the test product possibly owns a function of hair restoration.

The millet extract, which is contained in the test product, is rich in proteins, minerals and vitamins. Among them, there are the ingredients such as cystine (sulfur amino acid), methionine, silicon and rosmarinic acid[6)7)]. Keratin (one of the proteins) constitutes approximately 90% of human hair[8)], and the principal amino acids included in keratin are cystine and methionine[9)]. This fact means the millet extract with keratin powder contained in the test product is an essential "material" for production of human hair. There are some other studies conducted that show ingesting keratin itself is a method of hair restoration[10)].

In addition, it is reported that silicon and rosmarinic acid, both of which are also a part of the millet extract, have some contribution to the hair condition. Silicon has a function of strengthening the combination of collagen; lack of silicon accelerates fallout of the hair or splitting of the nail[11)]. Rosmarinic acid, on the other hand, is known for its functions of anti-oxidation or blood circulation promotion[12)], and it is expected to encourage the blood circulation of the scalp and improve the scalp condition. A certain published report illustrates that the millet extract contributes to the medical treatment for alopecia of a cancer patient[13)].

Based on the above discussion, it is assumed that the ingestion of the test product containing the millet extract with keratin powder positively created an environment of hair restoration and achieved the expected level of hair restoration.

And in this study, it was observed that based upon clinical findings such as the blood and urine test, no abnormal change was triggered by ingestion of the test product. In the blood test, some variables such as CK (CPK), Total Cholesterol, Sodium and Calcium changed from baseline after the ingestion, however both changes were considered as a minor change and therefore the investigator ruled out any relationship with the test product. In the urine test, on the other hand, no significant change was observed. Although five subjects discontinued the test during the test period due to sickness, the sickness such as a cold was unserious, and the investigator ruled out any relationship with the test product. These results indicated the safety of the intake of the test product containing millet extract with keratin powder for the 12-week test period.

It is known that the mechanism of hair removal or hair

growth generally differs between men and women[14)15)]. For the treatment of AGA (androgenetic alopecia), for example, it is said that finasteride is effective since it inhibits the male hormone dihydrotestosterone, but for female, it is ineffective. In addition, for the women during pregnancy, the usage of finasteride can trigger off an adverse effect on the sexual organs of the male fetus, and the usage for men can cause side effects such as erectile dysfunction and/or liver dysfunction. Therefore it cannot be used without supervision of doctors and/or a pharmacist[16)].

This study included both men and women as its subjects and the results indicated the function of hair restoration in both sexes, without any serious safety-related matters. The millet extract contained in the test product is the extract from millet, which has been popular as one of the "Gokoku (five main cereals)" among Japanese, which has been used as food in Europe through the ages[4)17)]. Keratin, contained in the millet extract with keratin powder, is the protein necessary for the constitution of hair and nail of humans.

Therefore, the test result of this study should be usable for the anti-hair-thinning food products which can be safely taken by men/women aware of thinning hair.

However, this study could not help us understand how the hair restoration was affected by an interaction between the millet extract and keratin when both are ingested at the same time, or an interaction between those and the other ingredients in the test product. The action mechanism of the hair restoration by the test product in this study, therefore, is merely a speculation, and it is recommended that higher-accuracy evidence should be accumulated throughout clarifying the action mechanism of each ingredient.

In addition, although there was a significant difference observed in the result of thickness of the hair, the increase level of the hair thickness by the ingestion of the test product was slight. Therefore the ingestion test for a longer-period should be conducted to validate this evidence.

In conclusion, we found out that the intake of the supplements containing millet extract with keratin powder for 12 weeks contributed to the improvement of human hair restoration, compared with the Placebo. In addition, no safety-related matters occurred during the 12-weeks test period.

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