

Report

Open-label study of effects of dietary supplement with water shield extract and sake cake powder on the skin condition of healthy adult females

Akiko Takashima ¹, Kimihiko Sano ¹, Masayo Murakami ², Fuyumi Matsui ³, Akira Sasaki ³, Saori Takahashi ³, Masanori Kumagai ³, Keishi Hata ^{3,*}

¹ Sano Inc., 3-4-2 Oroshi-machi, Akita, 010-0061, Japan, ² Noshiro Kousei Medical Center, Kamimaedachinai, Ochiai, Noshiro City, Akita 016-0014, Japan, ³ Akita Research Institute of Food & Brewing, 4-26 Sanuki, Araya-machi, Akita 010-1623, Japan

Received November 29, 2018; Accepted December 26, 2018

We studied the effects of a dietary supplement (JUNSAIKOMACHI) containing water shield extract and sake cake dry powder on the skin condition of 28 healthy adult females. The analysis by visual analogue score revealed that continued intake of JUNSAIKOMACHI for 14 days markedly improved “dry skin” and “makeup finishing”, and after 28 days improved 9 symptoms including “dull skin” compared with the subjects’ skin conditions before the trial.

Keywords: Water shield, Sake cake, Open-label clinical study, Visual analogue scale

Introduction

We previously demonstrated that administration of a dietary supplement containing water shield extract (ORYZA OIL & FAT CHEMICAL CO., LTD) and sake cake dry powder (AKITAMEIJYO CO., LTD) markedly increased the number of days with defecation and defecation frequency compared with a placebo group. Furthermore, the subjects simultaneously reported improvement of skin conditions such as “noticeable pores” by intake of the supplement ^{1, 2}. Based on these results of human clinical tests, we developed a stick jelly type of dietary supplement containing water shield extract and sake cake dry powder, named “JUNSAIKOMACHI” ³. However, the effects of JUNSAIKOMACHI on human QOL and skin condition have not been clarified. In the present paper, we evaluated the effects of JUNSAIKOMACHI on the skin condition of 28 healthy adult females by a subjective survey in

a before–after clinical test.

Clinical test

The twenty-eight adult female subjects were aged 31–58 years. Assessment of lifestyle and health questionnaires revealed no medical history of serious disease, allergic dermatitis, or dietary intake of supplements that affect skin condition.

Key exclusion criteria were as follows:

- ✧ The candidate was currently taking drug or dietary supplements for a skin condition.
- ✧ The candidate currently had, or had a history of, diabetes, liver disease, kidney disease, heart disease and/or any other metabolic disease.
- ✧ The candidate was pregnant or intended to become pregnant or to breastfeed during the study period.
- ✧ The candidate currently had an allergy to rice and/or apple.

*To whom correspondence should be addressed:

E-mail: hata@arif.pref.akita.jp

- ✧ The candidate had participated in another clinical study within the previous month.

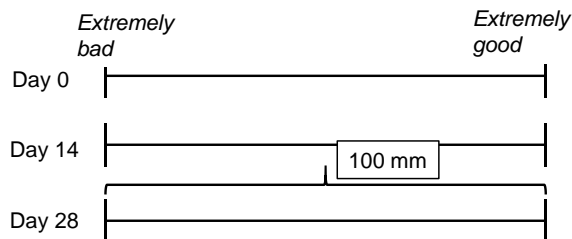
This clinical trial was performed in accordance with the 6th revision of the Declaration of Helsinki (2008). Subjects provided written informed consent and the study was approved by the ethics committee of Akita Research Institute of Food and Brewing (Approval No. H29-01), without contribution to the clinical test. The study was performed based on the following schedule: 28 subjects were administered one packet/day of JUNSAIKOMACHI for 28 days, and their subjective reports of 16 symptoms of skin condition were assessed using visual analogue scores (VAS, Fig. 1) ranging from 0 mm (representing an extremely bad condition) to 100 mm (representing an extremely good condition). VAS were determined pre-intervention (Day 0), and on Days 14 and 28.

Results and discussion

The VAS in the present trial are summarized in Table 1. The normal distribution and homogeneity of variance of VAS for all queries at Days 0, 14 and 28 were confirmed by Shapiro-Wilk's and Bartlett's tests, respectively, and statistical analysis was performed by one-way ANOVA with Tukey's multiple comparison test.

Significant differences in symptoms of "oily face", "frequent pimples", "spots and freckles", "fine lines around eyes", "corner of eyes sagging", "cheeks sagging" and "corners of mouth sagging" were not observed. Marked improvements were recognized in "dry skin" and "makeup finishing" of healthy adult females by administration of JUNSAIKOMACHI in the first 14 days. Further intake of JUNSAIKOMACHI up to 28 days significantly affected 9 symptoms, and a marked difference in VAS of "makeup runs easily" was observed between Day 14 and Day 28.

➤ Dull skin



➤ Dry skin

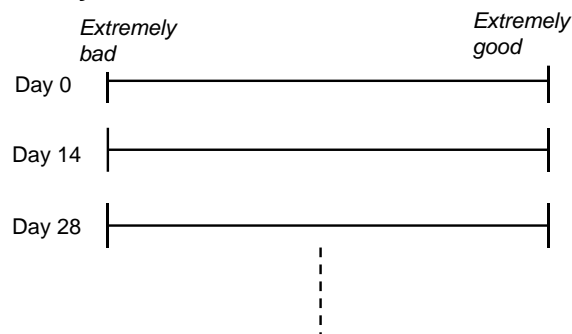


Fig. 1 Visual analog scale to determine skin condition

We previously reported that administration of tablets containing water shield extract and sake cake dry powder at the same dose as in JUNSAIKOMACHI improved "noticeable pores", "elasticity and/or gloss of skin", "desiccated and gritty skin" and "makeup runs easily" compared with a placebo group. However, those tablets did not affect "oily face". The data from administration of JUNSAIKOMACHI supported the results of our previous placebo-controlled double-blind test.

Table 1. Improvement effects of JUNSAIKOCHI on human female skin condition

Symptom	VAS (mm, means \pm SEM)		
	Day 0	Day 14	Day 28
Dull skin	33.2 \pm 2.3	39.5 \pm 2.6	48.1 \pm 3.0***
Dry skin	36.8 \pm 2.9	46.2 \pm 2.6*	54.1 \pm 2.6***
Skin texture	31.6 \pm 2.7	40.3 \pm 2.8	46.6 \pm 3.0**
Elasticity and/or gloss of skin	31.9 \pm 3.0	39.0 \pm 2.6	47.3 \pm 3.2**
Rough skin	38.1 \pm 4.0	46.3 \pm 3.8	53.4 \pm 3.3*
Desiccated and gritty skin	38.2 \pm 4.1	47.3 \pm 3.9	57.7 \pm 3.4**
Oily face	45.4 \pm 4.6	52.3 \pm 4.1	56.4 \pm 3.6
Frequent pimples	48.7 \pm 4.3	51.6 \pm 4.6	56.0 \pm 4.6
Spots and freckles	27.3 \pm 3.0	29.8 \pm 2.7	35.5 \pm 3.5
Noticeable pores	21.7 \pm 2.3	28.1 \pm 3.0	35.2 \pm 4.0**
Makeup finishing	36.6 \pm 2.8	45.5 \pm 3.2*	55.5 \pm 3.0***
Make-up runs easily	31.1 \pm 3.1	37.4 \pm 3.1	48.6 \pm 3.5***,§
Fine lines around eyes	33.7 \pm 3.6	37.4 \pm 3.4	41.8 \pm 3.8
Corner of eyes sagging	33.8 \pm 3.1	36.6 \pm 3.0	40.1 \pm 3.5
Cheeks sagging	31.9 \pm 2.8	34.5 \pm 2.8	36.8 \pm 3.0
Corners of mouth sagging	35.8 \pm 3.2	38.0 \pm 3.2	42.3 \pm 3.4

The data represent means \pm S.E.M. * p <0.05, ** p <0.01, *** p <0.001 vs Day 0, § p <0.05 vs Day 14

References

1. Takashima A., Sano K., Murakami M., Uehara K., Sasaki A., Hiwatashi K., Kumagai M., Hata K., *Shouyakugakuzasshi*, 71, 94-99 (2017)
2. Takashima A., Sano K., Murakami M., Hata K., *Food processing and ingredients*, 52 (9), 72- 74 (2017)
3. Takashima A., Sano K., Murakami M., Matsui F., Sasaki A., Takahashi S., Kumagai M., Hata K., *J. Biol. Macromol.*, 18, 11 – 12 (2018)

Communicated by Ueno Hiroshi