Japanese Review of Clinical Ophthalmology Vol. 98, No. 11 (11/2004) Supplement

Clinical Study of Ocular Function With Food Product Containing Black Soybean Hull Extract

Takashi SAKIMOTO, Yasushi KOJIMA, Yukiyo KASHIWABARA, Chieko CHIKUI

Japanese Society of Clinical Ophthalmology

Clinical Study of Ocular Function With Food Product Containing Black Soybean Hull Extract

Takashi SAKIMOTO,* Yasushi KOJIMA,** Yukiyo KASHIWABARA,** Chieko CHIKUI**

I. Introduction

As the number of individuals using VDT (visual display terminals) increases, research investigations concerning diagnosis of asthenopia and methods for evaluation have been reported.
However, all aspects of asthenopia are not fully understood, and the problem has been treated as a single syndrome characterized primarily by an ocular nonspecific complaint. Suzumura[1)] classified the causes of asthenopia into three groups relating to visual organ factors (ocular capability), external environmental factors (visual conditions), and internal environmental factors and psychological factors (endurance) and explained asthenopia as an imbalance of these three elements.
Other reports on treatment of asthenopia have also been made, but there is currently no established method of treatment.
Another recent topic is foods with a notable effect of eliminating "ocular fatigue" and restoring vision. These include anthocyanin glycosides, natural pigments derived from a number of plants. The physiological functions of these substances have interested researchers from various countries.
In particular, anthocyanin extract from bilberries has been approved as a pharmaceutical in Italy, France, and New zealand and is used to treat night blindness, capillary fragility, cerebrovascular disorders, and peptic ulcers.
In Japan, Kajimoto[2)] et al. reported that blueberry extract used in asthenopia and psychological strain had an improving effect.
Based on the fact that the physiological activity of the black soybean hull extract in our clinical study (cyanidin-3-glucoside) includes promotion of rhodopsin resynthesis and capillary strengthening, and that this substance is an anthocyanin glycoside and contains upwards of 90% cyanidin-3-glucoside, reportedly the anthocyanin highest in antioxidant activity, we surmised that cyanidin-3-glucoside would improve visual function and have an antioxidant effect.
We report good results obtained from a clinical investigation using foods containing black soybean hull extract, noted particularly for its effect on visual function.

II. Subjects and Method

Subjects were primarily individuals who used a VDT (visual display terminal), and prior to the study, the studied food, and the significance, content, and purpose of the study were explained. On this basis, potential subjects provided written consent (with signature or signature seal) given freely and of their own will. Subjects were selected on the basis of selection criteria and exclusion criteria pertaining to the Study Design and comprised 33 healthy males and females age 20-55 years who complained of asthenopia.
The studied food used, a food containing black soybean hull extract (non-genetically modified), was a soft capsule containing a black soybean hull extract (Kuromanin®-10) provided by Functional Material Laboratory Co., Ltd (120mg as Kuromanin®-10 in 1 granule, 12mg as anthocyanin).
Ingestion was a total 3 capsules per day, 2×/day (1 capsule in morning, 2 capsules in afternoon at approximately 3 p.m.) for 28 days.
Ingestion of other supplements was prohibited, but there were no specific food restrictions. The study was performed as a simple administration study by 32 subjects (1 dropout prior to ingestion), and complete ingestion of the distributed, studied food was confirmed at the end of the study.

Study Design

The study parameters and study schedules shown in Figure 1 were completed for 32 subjects (10 males, 22 females) from whom consent was obtained (study facility: Shinjuku-Minamiguchi Sakimoto Eye Clinic).
In the study, a pre-study was completed on the day prior to the start of ingestion according to a schedule sheet for each subject. Ingestion of the studied food was initiated the following day based on the method described above.
A survey of subjective symptoms or ocular function screening was performed for 32 subjects and 64 eyes (right eye, left eye).
Test parameters/survey parameters and method
Prior to the start of ingestion, the age, sex, status of eyeglasses use, and dominant eye to each subject were ascertained, a subjective symptom survey sheet (pre-ingestion) was submitted, and a physician interview was carried out. Thereafter, the ocular function screening shown in Table 1 was performed on the day before initial ingestion and at 2 and 4 weeks after the start of ingestion.

* Shinjuku Minamiguchi Sakimoto Eye Clinic Reprint requests to: Keitwo Communications Co., Ltd. Sanshusha Bldg. 3F, 1-12-2 Uchikanda, Chiyoda-ku, 101-0047
** Keitwo Communications Co., Ltd.