

Article

Effect of Ultrasonic Moisture Glasses on Dry Eye Signs and Symptoms

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Purpose: This study was undertaken to evaluate the effect of a novel humidifying eyeglass-shaped device—ultrasonic moisture glasses—on dry eye signs and symptoms.

Methods: A total of 18 subjects with dry eye symptoms underwent a crossover test. A water cartridge was set on each temple of the eyeglass-shaped device. All subjects randomly wore the device twice in different settings, each for 10 minutes. Subjects wore the glasses once with the cartridges filled with water (the intervention group), and once with the cartridges empty (the control group). The order was randomized. We evaluated tear film break-up time (TBUT) and fluorescein staining score just before, immediately after, and 10 minutes after wearing the device. We also assessed functional visual acuity (FVA), blink frequency, and visual analog scale (VAS) score just before and immediately after wearing the device.

Results: TBUT, blink frequency, and VAS improved in the intervention group (all $P < 0.001$) and exhibited significant differences between the intervention and control groups.

Conclusions: Wearing the ultrasonic moisture glasses for 10 minutes improved tear stability and decreased dry eye symptoms in this cohort of subjects.

Translational Relevance: These findings show that the ultrasonic moisture glasses are an effective device for improving dry eye signs and symptoms.

Introduction

Dry eye disease is a very common disease that causes eye symptoms, such as dryness and eye strains, and affects quality of life, such as subjective happiness,¹ work performance and productivity,² and quality of sleep.³ The cause of dry eye disease is excessive evaporation of tears and/or poor secretion of tears.⁴ Notably, visual display terminal (VDT) use causes evaporative dry eye: the Osaka study showed that two of three office workers who used smart phones or computers suffered from dry eye diseases.⁵ In addition, aging is one of the risk factors for dry eye disease⁶; thus, it is inevitable that dry eye disease will become more prevalent in our aging societies.

Evaporative dry eye is typically treated with eye drops, such as artificial tears, antibiotics,^{7,8} steroids,⁹

and lipid eye drops,¹⁰ or with warm compresses and lid hygiene.^{11,12} In addition, it can be relieved by raising humidity just around the eyes,¹³ which uses the lowered evaporation rate in conditions of higher humidity.¹⁴ However, it is difficult for many people to install room humidifiers in public places, such as their offices. For the purpose of raising humidity just around the eyes, eyeglass-shaped devices have been previously invented.^{13,15} These devices can humidify around the eyes through natural evaporation from a wet sponge or water cartridges set on the temples, or through limiting airflow over the eyes. However, they cannot control the level of humidity, only raising humidity by a maximum of 20%. Here, we have created ultrasonic moisture glasses that can actively produce mist via ultrasonically vibrating elements; these ultrasonic moisture glasses can quickly raise the humidity around the eyes to greater than 90%.

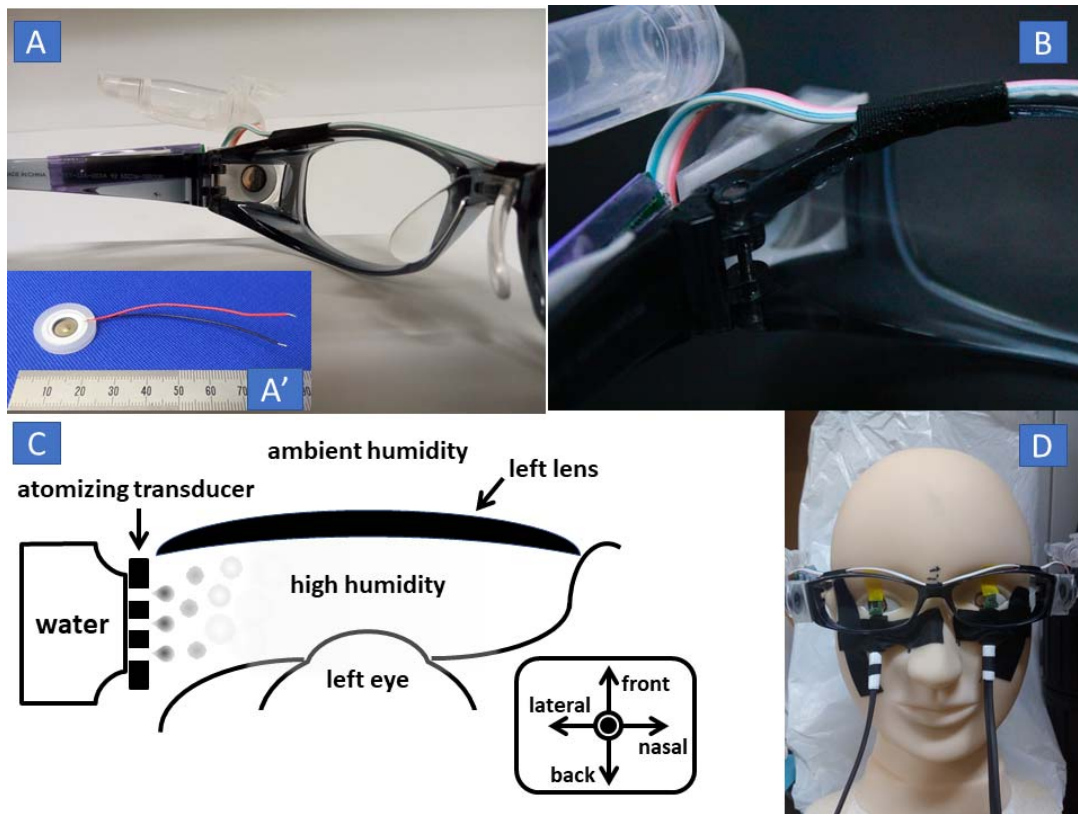


Figure 1. Ultrasonic moisture glasses. (A) An interior view of the glasses is shown. (A') An ultrasonic atomizing transducer is shown. (B) Water mist is shown, ejected from the window. (C) The operation schematic is shown. (D) Measurement of the humidity around the eyes of a mannequin is shown.

The aim of this study was to evaluate the effect of the ultrasonic moisture glasses on dry eye symptoms, as well as on objective measurements of disease severity, such as tear film break-up time (TBUT), functional visual acuity (FVA), blink frequency, and fluorescein staining score.

Methods

Development of a Novel Device for Dry Eye Disease, “Ultrasonic Moisture Glasses”

Device Structure

We have developed a novel humidifying eyeglass-shaped device that can be worn comfortably and can alleviate dry eye symptoms; we named this device “ultrasonic moisture glasses.” Water cartridges and ultrasonic piezoelectric transducers (KS-W16-108K4D8W; Dongguan Cosson Electronic Plastic Co. Ltd., Dong Guan, China) are placed on both sides of the temples of the “JINS MOISTURE” glasses (MST-13A-003; JINS Inc., Tokyo, Japan), as shown in Figure 1A. Figure 1 shows the details of the

glasses. The water cartridge is a 1.5-mL Eppendorf tube (Watson Co. Ltd., Tokyo, Japan). Figure 1A' shows the transducer, which has a disc-like shape, with a diameter of 16 mm. The periphery of the transducer is covered with silicone rubber; it is fabricated from lead zirconate titanate and ultrasonically vibrates at 108 kHz because of the inverse piezoelectric effect. A plastic tube connects the water cartridge and the transducer. The transducer atomizes the water; the mist is then ejected through the transducer and the window on the temple to reach the space in front of the eye (Figs. 1B, 1C). Thus, the humidity around the eye increases.

Measurements of Humidity

We investigated the relative humidity in the space in front of the eyes. Figure 1D shows a mannequin wearing ultrasonic moisture glasses and digital sensors of humidity. A digital sensor of humidity (SHT-21; Sensirion AG, Staefa ZH, Switzerland) was attached in front of each eye. An evaluation kit (EK-H4, Sensirion AG) was used to monitor the humidity.

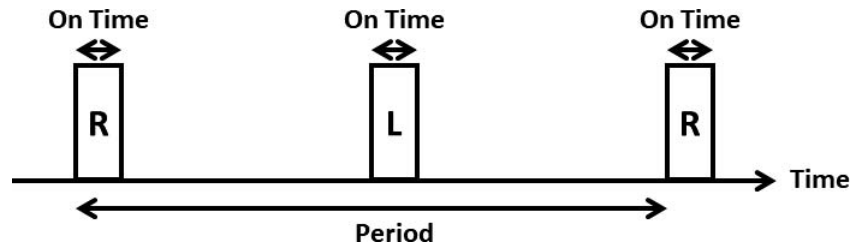


Figure 2. Transducers on the right and left vibrate alternately with the same On Time and Period.

Operating Conditions

The ultrasonically vibrating elements on the device vibrate cyclically for a set vibration time (On Time) with a set interval period (Period). The Period can be set independently of the On Time. The On Time and Period are the same on the right and left sides, but the On Times of both sides alternate by one-half Period (Fig. 2).

Study Protocol

Ethics

Each subject received written and oral information about the study and provided written consent to participate. This study followed the tenets of the Declaration of Helsinki, and the Ethical Committee of Keio University School of Medicine, Tokyo, Japan, approved the prospective protocol.

This study is registered with the University Hospital Medical Information Network in Japan (registration number UMIN000029408).

Test Subjects

Adult volunteers with dry eye symptoms were recruited; 18 subjects with dry eye symptoms without any other ocular diseases (8 male and 10 female, aged 22 to 59, mean \pm standard deviation [SD]: 38.7 ± 11.5) were enrolled. Subjects with any ocular diseases, except dry eye disease, were excluded. Subjects who had undergone LASIK surgery in the past 3 months were also excluded. Contact lens-wearing subjects removed their contact lenses 60 minutes before performing the experiments. Almost all (16 of 18 participants) were diagnosed with dry eye, on the basis of diagnostic criteria from the Asia Dry Eye Society (dry eye symptoms and TBUT ≤ 5 seconds).¹⁶ No participants were currently undergoing dry eye treatment. All participants of this study exhibited mild dry eye (TBUT 2.9 ± 1.8 seconds, epithelial damage score 0.22 ± 0.49 points). There were no cases of severe dry eye, meibomian gland dysfunction (MGD), or Sjögren syndrome. All participants were VDT users who had been exposed for more than 8 hours.

Intervention

We evaluated the efficacy of moisture mist glasses on dry eye symptoms and signs. We randomly allocated the subjects into two groups, intervention and control, and asked them to wear the glasses for 10 minutes. Then, we exchanged them from one group to the other group, during the course of the trial. The intervention group was as follows: subjects wearing ultrasonic moisture glasses where the cartridge was filled with water. The control group was as follows: subjects wearing ultrasonic moisture glasses without water in the cartridge. We compared the data between the intervention and control groups. Moreover, we compared the data of two measurement time points (immediately after and 10 minutes after) with the initial time point (before) in the same group.

Evaluation Items

Ocular Surface Symptoms. We used visual analog scale (VAS) score to evaluate ocular surface symptoms. The VAS scores we used included dryness, difficulty in keeping eyes open, foreign body sensation, pain, redness, lacrimation, discharge, itchiness, haze, glare, heaviness, and eyestrain. The VAS score scale ranges from 0 to 100. The left end of the scale indicates that the subject experienced no symptom of that category; this VAS score is 0. The right end indicates that the subject experienced an intolerable level of symptoms in that category; this VAS score is 100. We checked VAS score just before, immediately after, and 10 minutes after wearing the glasses.

Ocular Surface Parameters. A single experienced investigator (MK) evaluated TBUT and keratoconjunctival epithelial damage, based on fluorescein staining scores for the cornea and conjunctiva (using previously described methods¹⁷), just before, immediately after, and 10 minutes after wearing the glasses. For these examinations, we used test strips containing fluorescein sodium (Fluores Ocular Examination Test Paper; Ayumi Pharmaceutical Co., Tokyo, Japan).

Table 1. Changes in Tear Film Break-Up Time (s) Between the Two Groups

	Before (A)	(B) – (A)	After (B)	(C) – (A)	10 min (C)	<i>P</i> Value ^a (A vs. B)	<i>P</i> Value ^a (A vs. C)
Intervention	2.9 ± 1.8	2.1 ± 1.5	5.1 ± 2.2	2.4 ± 1.8	5.4 ± 2.2	<0.001	<0.001
Control	3.2 ± 2.2	–0.13 ± 0.57	3.1 ± 2.1	–0.22 ± 0.69	3.0 ± 2.1	0.18	0.097
<i>P</i> value ^b	0.374	<0.001	0.105	<0.001	0.086		

Values are mean ± SD. *P* < 0.05 was considered statistically significant.

^a Indicates paired *t*-test.

^b Indicates unpaired *t*-test.

We performed the fluorescein staining procedure after applying two drops of saline solution to the test strip. We then shook the strip vigorously and made a gentle contact between its edge and the inferior temporal lid margin. After blinking three times to facilitate adequate mixing of the fluorescein dye with tears, the patient was verbally instructed to gently close and then quickly open the eye. TBUT was measured three times, and the mean value was used for the following analysis. The cornea and the conjunctiva fluorescein staining scores were graded from 0 (none) to 3 (severe).

FVA. An FVA measurement system (Kowa, Aichi, Japan) was used to assess the time course of changes in continuous visual acuity for 1 minute. In this method, Landolt optotypes are presented on the monitor and their sizes change, depending on the correctness of the responses.¹⁸ We measured FVA just before and immediately after the wearing the glasses. We also checked blink frequency while measuring FVA.

Statistical Analysis

Both eyes of each subject were examined and the scores of both eyes were used. The results were statistically analyzed by paired or unpaired *t*-tests. A *P* value < 0.05 was set as the threshold of significance. All data were expressed as the mean ± SD. All statistical analyses were performed using SPSS statistics software, version 22 (IBM Corp., Armonk, NY).

Results

Determination of Operating Conditions for High Humidity

We expected that the humidity that ultrasonic moisture glasses produce would be roughly propor-

tional to the ratio (Ratio) of an On Time to a Period. We observed this tendency in the measurements of humidity, using a mannequin in various conditions. Representative results of the measurements are shown in [Figure 3](#). When the device was switched on, the humidity began to rise instantly. The humidity increased more quickly when the Ratio was higher. When the Ratio was greater than 1.0%, the humidity reached 90% ([Fig. 3B](#)). Similar results were observed among human several subjects; these are represented in [Figure 3D](#).

Determination of Operating Conditions for the Clinical Study

For the clinical study, we attempted to determine settings in which we could observe clear clinical results. There is a linear decreasing relationship between the tear evaporation rate from the ocular surface and the surrounding humidity.¹⁴ Thus, we considered a high Ratio to be useful because it resulted in high humidity around the eyes. However, when the Ratio was greater than 10%, the mist became excessive and the face of the subject became wet. For our clinical study, we chose the setting of 8.4 ms for the On Time and 250 ms for the Period; these were equivalent to 3.4% of the Ratio. In addition, we adjusted the wearing time to 10 minutes after preliminary trials by comparing TBUT.

Changes in Evaluation Items

Changes in TBUT are shown in [Table 1](#). In the intervention group, TBUT significantly improved from 2.9 (SD: 1.8) to 5.1 (SD: 2.2), immediately after wearing the glasses (*P* < 0.05), and to 5.4 (SD: 2.2) after 10 minutes (*P* < 0.05). In contrast, the control group showed no significant changes of TBUT. Changes in fluorescein staining score are shown in [Table 2](#). There were no significant changes in each group, or between the two groups. [Table 3](#) shows the

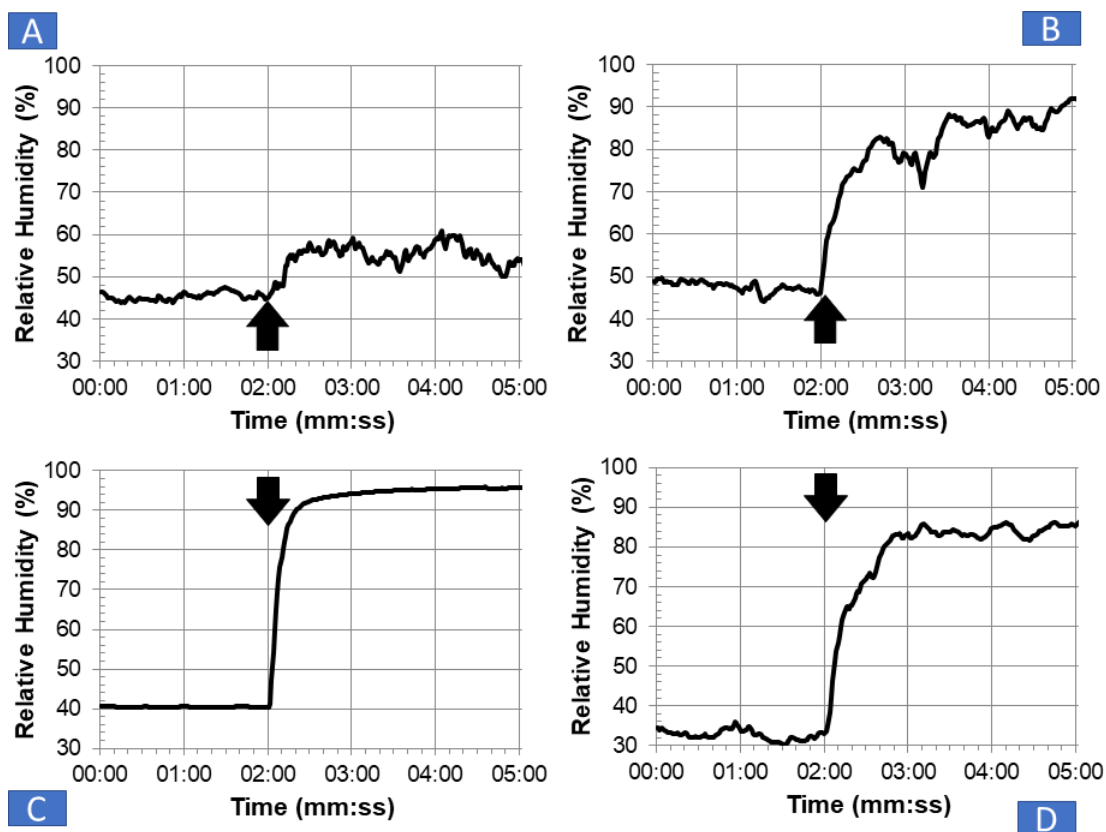


Figure 3. Changes in the relative humidity around the eye of a mannequin (A–C) or one of the authors (D). In each panel, the transducer was turned on after 2 minutes, as indicated by an arrow. (A) The setting was as follows: the ratio of the On Time to the Period was 0.1% (0.1 ms/98 ms). (B) The setting was as follows: the ratio of On Time to Period was 1.1% (1.1 ms/98 ms). (C and D) The settings were as follows: the ratio of On Time to Period was 3.4% (8.4 ms/250 ms).

changes in FVA (in logMAR units) between the two groups; changes in blink frequency (blinks/min) are shown in Table 4. Although FVA did not change significantly, blink frequency improved significantly, from 18 (SD: 9) to 13 (SD: 7), after wearing the glasses ($P < 0.05$). Conversely, within the control group, there were no significant changes. Changes in VAS score (total) are shown in Table 5. Among VAS scores, there were significant improvements in those indicating dryness, foreign body sensation, pain,

discharge, itchiness, haze, heaviness, and strain. However, there were no improvements in VAS scores regarding difficulty in keeping eyes open, redness, lacrimation, and glare. Notably, no symptoms improved in the control group.

Discussion

In this study, we showed that wearing ultrasonic moisture glasses for 10 minutes improved tear

Table 2. Changes in Fluorescein Staining Score Between the Two Groups

	Before (A)	(B) – (A)	After (B)	(C) – (A)	10 min (C)	P Value ^a vs. (B)	P Value ^a (A) vs. (C)
Intervention	0.22 ± 0.49	0.00 ± 0.00	0.22 ± 0.49	–0.060 ± 0.23	0.17 ± 0.45	NA	0.16
Control	0.33 ± 0.53	–0.01 ± 0.37	0.33 ± 0.56	–0.060 ± 0.23	0.28 ± 0.51	0.89	0.16
P value ^b	0.374	0.89	0.105	1.0	0.086		

Values are mean ± SD. $P < 0.05$ was considered statistically significant.

^a Indicates paired t -test.

^b Indicates unpaired t -test.

Table 3. Changes in Functional Visual Acuity (in logMAR Units) Between the Two Groups

	Before (A)	(A) – (A)	After (B)	P Value ^a
Intervention	0.11 ± 0.17	–0.010 ± 0.15	0.10 ± 0.21	0.72
Control	0.14 ± 0.22	–0.05 ± 0.16	0.09 ± 0.16	0.09
P value ^b	0.47	0.30	0.94	

Values are mean ± SD. $P < 0.05$ was considered statistically significant.

^a Paired *t*-test.

^b Unpaired *t*-test.

stability and decreased dry eye symptoms. Dry eye disease comprises a combination of unpleasant symptoms and unstable tear film. A cutoff value of TBUT is less than 5 seconds for the diagnosis of dry eye.¹⁶ Wearing ultrasonic moisture glasses for 10 minutes improved TBUT, blink frequency, and VAS. Improvement of TBUT suggests better maintenance of the tear film, which is a barrier to protect the eye from stressors; poor maintenance causes various unpleasant symptoms. Thus, prolonging TBUT can alleviate dry eye symptoms. In addition, there is a negative correlation between TBUT and blink frequency.¹⁹ Reductions in blink frequency indicate that the tear film has become stabilized. By wearing ultrasonic moisture glasses, humidity around the eyes increased and the evaporation rate decreased¹⁴; thus, TBUT improved. Ultrasonic moisture glasses are novel because they can significantly humidify the region around our eyes, both actively and quickly. Some conventional eyeglass-shaped devices allow humidification by natural evaporation; however, they cannot control the level of humidity, only raising it by a maximum of 20%.^{13,15} However, ultrasonic moisture glasses can rapidly raise humidity to 90%. The glasses may prolong TBUT without dynamic changes in the tear film, including in the lipid layer,^{20,21} as observed during usage of artificial tears. Thus, patients may not experience dryness or

a decrease in visual acuity, which occurs just after using eye drops. Here, we fixed the setting of the vibrating system as follows: 8.4 ms on and 241.6 ms off, alternated over 10 minutes. However, there may be better settings; thus, we will test the glasses in various settings and for longer wearing time. In the present circumstances, this device weighs 52 g, even when the cartridges are empty; thus, it may be too heavy for extended wear. However, further technical improvement can lighten the device and change its design so that patients can wear it for an extended duration. The limitations of this study are as follows: the number of subjects was small and not all the subjects had short TBUT. Importantly, we observed variable effectiveness, as the maximum improvement of TBUT in the moisture mist glass condition was 4.7 seconds, whereas the minimum was 0. If we recruited only subjects whose TBUT was short, the observed improvement of TBUT may have been more significant. We plan to investigate effectiveness in other populations in the near future, including ocular surface examinations and Schirmer test. We are planning further studies with a greater number of subjects, which include consideration of the severity and etiology of dry eye. In addition, although eyeglass fittings were acceptable because participants demonstrated similar face shapes in this study, we should consider eyeglass fitting with

Table 4. Changes in Blink Frequency (Blinks/Min) Between the Two Groups

	Before (A)	(B) – (A)	After (B)	P Value ^a
Intervention	18 ± 9	–5.0 ± 6.9	13 ± 7	<0.001
Control	19 ± 9	–1.6 ± 6.0	20 ± 10	0.12
P value ^b	0.70	<0.001	0.01	

Values are mean ± SD. $P < 0.05$ was considered statistically significant.

^a Paired *t*-test.

^b Unpaired *t*-test.

Table 5. Visual Analog Scale Score (Total) Between the Two Groups

	Before (A)	(B) – (A)	After (B)	P Value ^a
Intervention	277 ± 182	–63.9 ± 100	134 ± 136	<0.001
Control	241 ± 198	–7.22 ± 30.1	225 ± 203	0.162
P value ^b	0.642	0.002	0.136	

Values are mean ± SD. $P < 0.05$ was considered statistically significant.

^a Paired *t*-test.

^b Inpaired *t*-test.

another face shape population to maintain humidity.

In conclusion, our ultrasonic moisture glasses may be effective for improving dry eye signs and symptoms.

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