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ORIGINAL ARTICLE

Specialized Moisture Retention Eyewear for Evaporative Dry Eye

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ABSTRACT

Objectives: To evaluate the suitablity of commercially available moisture retention eyewear for treating evaporative dry eye.

Methods: Eleven patients with evaporative dry eyes were prescibed moisture retention eyewear for 3 months in addition to regular lubricant eye drops. Frequency and severity of dry eye symptoms, corneal fluorescein staining and tear break up time (TBUT) were evaluated at baseline and 3-month post-treatment. Main outcome measure was global symptom score (based on severity and frequency of dry eye symptoms on a visual analog scale) and secondary outcomes were changes in sectoral corneal fluorescein staining and tear break up time (TBUT) from pre-treatment level.

Results: There was a significant improvement in dry eye symptoms after using moisture retention eyewear for 3 months ($p < 0.05$). Corneal fluorescein staining in all five zones of the cornea in both eyes improved significantly ($p < 0.05$). There was no significant improvement in TBUT. Patients used ocular lubricants less frequently ($p < 0.05$) compared to the commencement of the study. Patients found moisture retention eyewear to be useful in relieving dry eye symptoms in windy, air-conditioned environments or when doing vision-related daily tasks.

Conclusions: This study shows that moisture retention eyewear might be a valuable adjunct in management of evaporative dry eye and this new design of commercially available eyewear could have a good acceptability rate.

Keywords: Dry eye syndrome, evaporative dry eye, eyewear, moisture retention, tear film

INTRODUCTION

Dry eye syndrome (DES) is a multifactorial condition manifesting from deficiency in tear production and/or instability in the tear film that results in symptoms of ocular discomfort and potential damage to ocular surface.[1,2] It can cause visual disturbances that can interfere with daily activities[3] and quality of life and associated with a high socio-economic burden.[4,5] Current treatment with topical lubricants and anti-inflammatory medication might be sometimes unsatisfactory in alleviating signs and symptoms of dry eye, especially for those with evaporative dry eye resulting from frequent exposure to environmental stress such as wind, low humidity and air conditioning.[6] Currently an increasing number of options are available for such patients. These include moisture chamber glasses, sleep masks, goggles, night bandages and special contact lenses.[7]

Moisture chamber glasses or moisture retention eyewear made by modifying regular eye glasses, e.g. with an additional wrap around the eyewear, wet sponges or acrylic moisture chamber shields, have shown to be effective in reducing signs and symptoms of dry eye.[8–12] It has been shown that close fitting wrap around frames can effectively increase the peri-ocular humidity[11–13] and maintain the humidity in the vicinity of the eyes up to 98%.[14,15]

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However, these older generation devices were not popular because of poor cosmesis, inconvenience, fogging and poor fitting.

In this study, we aimed to investigate the suitability of new generation moisture retention eyewear for patients with evaporative dry eye.

METHODS

This is a single group, prospective, cohort, interventional clinical study. Eleven adults aged between 21 and 99 years old, who were diagnosed to have evaporative dry eyes at the dry eye clinic in Singapore National Eye Centre, were enrolled in the study.

The sample size to be recruited was calculated using the following online sample size calculator: http://www.dssresearch.com/KnowledgeCenter/toolkitcalculators/samplesizecalculators.aspx (average, one sample module). We used the standard deviation from a previous study.[6] To detect a minimal clinically significant difference of 5% in VAS, with a standard deviation of 19%, based on a probability of 80% and to detect a treatment difference at 5% significance level (two-sided), the total sample size required is nine patients. We recruited 11 patients, allowing for any potential lost to follow up or withdrawal of 2 patients.

Written informed consent was obtained from all participating subjects. The study was approved by the Singhealth Centralized Institutional Review Board. This study was carried out in accordance with the tenets of the Helsinki declaration.

We included the subjects diagnosed with evaporative dry eye (tear break up time (TBUT) <5 s, Schirmer $I>8$ mm),[16] refractory to conventional DES treatment with lubricant eye drops, corneal fluorescein staining present in at least one of the five sectors of the cornea in one eye, at least one out of six dry eye symptoms, ''dryness'', ''grittiness'', ''redness'', ''watering'', ''crusting of lids'' and ''sticking of lids together'' present often or all the time,[17] and Yamaguchi score <2 in any sector of the four lids.[18] We included those with occupational or life style factors requiring frequent exposure to a hyper-evaporative environment such as windy, sunny conditions and frequently involved in vision-related daily activities (e.g. reading, watching television, computer and driving), especially in air-conditioned environments.[3]

We excluded those diagnosed with aqueous tear deficient dry eye (TBUT >5 s and Schirmer $I<8$ mm).[16] We also excluded those unable to use eyewear as instructed due to occupational and social reasons, needed to prescription glasses due to existing refractive error and poor fitting of eyewear due to malformation of facial bone structure. We did not have optical prescription included eyewear in this study. We also excluded the patients previously treated with punctal plugs or punctum cautery, wearing contact lenses or needed to wear contact lens for the duration of the study.

After written informed consent, eligible patients were prescribed moisture retention eyewear daily for 3 months in addition to their usual dry eye treatment. We ordered a new generation of moisture retention eyewear developed by 7eye® (Pan-Optyx, Inc. Pleasanton, CA, USA) for ''dry eye and Sjogren's syndrome'' online (http://www.7eye.com/home.-php?cat=267/). This eyewear contained a closely fitting air shield, Orbital Seal™ made of foam with rugged, non-air permeable construction to retain moisture and reduce evaporation of tears (including artificial tear supplements) by limiting the air flow over the eyes (Figure 1). We selected this particular type of eyewear as this has shown to be effective in relieving dry eye symptoms in a study conducted in USA (http://www.ophthalmologymanagement.com/articleviewer.aspx?articleid=86091), and low profile (concealed linings) less noticeable foamy air shield provides better cosmesis. Different designs and adjustable frames facilitate a good fitting. Patients were able to try the eyewear with six different adjustable frames to fit a particular facial structure. Patients were also able to select from lenses with different tints or non-tinted that suited their working environment.

FIGURE 1 Moisture retention eyewear with removable air shield.

The primary outcome was the "Symptom Assessment in Dry Eye" (SANDE) score[19] quantifying the frequency and severity of dry eye symptoms, utilizing a 100-mm visual analog scale (VAS) ranging from rarely/very mild to all the time/very severe. This was recorded from each patient before the commencement of the study and at the end of 3 months after wearing moisture retention eyewear. We administered the first version of the questionnaire to assess the dry eye symptoms at base line and the second version of questionnaire, at the end of 3 months to asses any differences in dry eye symptoms from pre-treatment. In each questionnaire, patients were asked to put a mark on the two given 100 mm lines to depict the extent of their symptoms separately in terms of frequency and severity. We then calculated a global score (SANDE score) by multiplying the frequency score by the severity score and taking the square root of the results.

Corneal fluorescein staining and TBUT were also recorded as secondary outcomes to investigate the efficacy of this new modality in alleviating the clinical signs of dry eye at the end of 3 months of wearing moisture retention eye wear versus commencement of the study. Corneal fluorescein staining was recorded using Baylor grading score,[20] which provides for a range of fluorescein staining from 0 to 4, with an additional one point for confluent staining or filaments in each of the five sectors of the cornea in each eye, individually and total. Three TBUT measurements were made for each eye and the average of the three measurements was taken as the mean value.[21]

At the end of 3 months, acceptability of using moisture retention eyewear to relieve dry eye symptoms in terms of comfort, convenience and cosmesis were also recorded in a 0–9 Likert scale, where 0 represented "very acceptable", 4–5 was "moderate" and 9 was equivalent to "not at all acceptable".[22] Patients were asked to record the number of hours using the eyewear during the 3-month treatment period on a detailed diary (with hourly slots). They were also asked to record the type of activities involved and the environment in the diary. In addition, the number of eye drops for each type of dry eye medication instilled per day was also recorded in the diary.

Mann–Whitney *U*-test was used to analyze the changes following 3 months of treatment. Significance level was set at alpha = 0.05. SPSS ver. 17 (IBM, Chicago, IL) was used for the analysis.

RESULTS

A total of 11 patients (4M, 7F) aged between 21 and 99 years (mean age 44 years) were recruited in the study. Six were Chinese, two were Malay and three were Indians. One patient withdrew from the study after enrollment due to social reasons. Mean Schirmer *I* values in right eye and left eye at baseline were 10.0 mm (SD: 9.77) and 11.5 mm (SD: 10.35), respectively.

Outcome measures (pre-treatment versus post-treatment) are shown in Table 1. There was a significant improvement in overall symptom scores in all the patients after using moisture retention eyewear for 3 months ($p < 0.05$). Corneal fluorescein staining in all the five zones of corneas in both eyes improved significantly at the end of 3 months (all $p < 0.05$). However, there was no significant improvement ($p > 0.05$) in TBUT after 3 months. Patients used ocular lubricants less frequently after wearing the eyewear, compared to the commencement of the study ($p < 0.05$). Four patients were using Refresh plus® (Allergan Inc, Irvine, CA) eye drops, five patients were using Tears natural free® (Alcon Inc, Fort Worth, TX) eye drops and two patients were on Systane® (Alcon Inc, Fort Worth, TX) eye drops.

In free-response section, six patients commented that they found the moisture retention eyewear to be useful in relieving dry eye symptoms in windy, air conditioned environments or when doing vision-related daily tasks such as watching television and using computer. Acceptability rate of wearing moisture retention eye wear on daily basis to relieve dry eye symptoms was 72% (Likert score 6.48). Average number of hours wearing moisture retention eyewear was 3.9 h (SD: 2.89) per day per person.

One out of seven patients who wore glasses outdoors complained of discomfort due to sweat when wearing moisture retention eyewear in sunny outdoor environment and one patient complained of tight fitting of the eyewear, which can be alleviated by a better selection of another fit of eyewear. No other adverse events were reported in any of the patients following treatment. None of the patients complained of fogging.

DISCUSSION

In this study, we found that dry eye symptoms improved significantly, after wearing moisture retention eyewear for 3 months. Patients found moisture retention eyewear to be useful in relieving dry eye symptoms in windy, air conditioned environments or when doing vision-related daily tasks such as watching television and using computer. Among the objective clinical signs, corneal fluorescein staining in both eyes improved to a significant extent, but not the TBUT. The requirement for using ocular lubricants by patients to relieve dry eye symptoms also reduced significantly after wearing eyewear for 3 months.

TABLE 1 Outcome measures (pre-treatment versus post-treatment).

Outcome measures	Pre-treatment Mean (SD) Median (range) $N = 10$	Post-treatment Mean (SD) Median (range) $N = 10$	p* Values
Dry eye symptoms			
Frequency	75.30 (21.30)	35.59 (22.01)	0.004**
	81.50 (35.00–98.00)	30.40 (0.00–74.60)	
Severity	68.5 (18.54)	31.90 (23.11)	0.002**
	65.5 (40.00–96.00)	30.72 (0.00–81.00)	
SANDE score	71.36 (18.50)	32.04 (22.08)	0.002**
	71.36 (18.50)	32.04 (22.08)	
	72.35 (43.5–95.50)	30.56 (0.00–77.74)	
Corneal fluorescein staining (Baylor)			
Right nasal	1.5 (1.35)	0.4 (0.97)	0.040*
	2.0 (0.0–3.0)	0.0 (0.0–3.0)	
Right central	1.5 (1.08)	0.4 (0.97)	
	2.0 (0.0–3.0)	0.0 (0.0–3.0)	
Right temporal	1.5 (1.18)	0.4 (0.97)	0.012*
Right temporal	2.0 (0.0–3.0)	0.0 (0.0–3.0)	
Right superior	2.0 (1.16)	0.5 (0.85)	0.001**
	2.0 (0.0–4.0)	0.0 (0.0–2.0)	
Right inferior	2.9 (0.99)	0.9 (1.10)	<0.001***
	2.5 (2.0–4.0)	0.5 (0.0–3.0)	
Left nasal	1.4 (1.08)	0.2 (0.63)	0.009**
	2.0 (0.0–3.0)	0.0 (0.0–2.0)	
Left central	2.1 (1.10)	0.4 (0.84)	0.002**
	2.0 (0.0–4.0)	0.0 (0.0–2.0)	
Left temporal	1.4 (1.08)	0.2 (0.63)	0.001**
	2.0 (0.0–3.0)	0.0 (0.0–2.0)	
Left superior	2.0 (1.05)	0.5 (0.68)	<0.001***
	2.0 (0.0–4.0)	0.0 (0.0–2.0)	
Left inferior	3.1 (1.20)	1.7 (0.95)	<0.001***
	3.0 (2.0–5.0)	2.0 (0.0–3.0)	
Right tear break up times (s)	2.2 (0.63)	2.5 (0.53)	0.193
	2.0 (1.0–3.0)	2.5 (2.0–4.0)	
Left tear break up times (s)	2.5 (0.85)	2.7 (0.95)	0.555
	3.0 (1.0–3.0)	3.0 (1.0–4.0)	
Frequency of lubricants (per day)	8.0 (4.30)	4.5 (3.92)	0.035*
	8.50 (0.0–14.0)	4.5 (0.0–11.0)	

SANDE score was obtained by multiplying the frequency score by the severity score and taking the square root of the results.[19]
*Statistically significant at $p < 0.05$.
**$p < 0.01$.
***$p < 0.001$.

Comparison with Previous Studies

A previous questionnaire survey ($n = 22$) on severe dry eye patients showed improvement in the severity of dry eye symptoms from 5.9 to 3.2 (10 being the most severe) after wearing eyewear for 4 h a day for 1 month (http://www.eyeworld.org/article.php?sid=3057. Vanessa C. Innovation Spotlight Two new products aim to soothe dry eyes. EyeWorld EyeWorld news service: Fairfax 2006). The report did not define the ''severe'' dry eye. As in our study, there was no parallel control group.

Another study found that dry eye symptoms were reduced by 57%, as perceived by patients' self-assessment survey after wearing the eyewear for 1 month. All patients reported improvement in symptoms when wearing the protective eyewear, and in 30% of these patients overall symptoms were completely eliminated (http://www.ophthalmologymanagement.com/articleviewer.aspx?articleid=86091). Both of the above studies used 7eye® eyewear which was previously known as Panoptx®. Results are not published in a peer reviewed scientific journal.

In a study conducted in the USA using special micro-environment glasses for 30 min to treat dry eye associated with computer use, an improvement in comfort scores, TBUT, fluorescein and lissamine green staining were observed.[23]

The above short-term studies did not employ a validated standard questionnaire for dry eye and also did not evaluate the frequency of the symptoms.

In our study, there was no significant improvement in TBUT. It may be that TBUT needs a larger sample

size since it is harder to change, and measurement of TBUT in a clinic may have a lot of noise compared to a controlled environment. What is not measured was the amount of tear evaporation while wearing eyewear, which is likely to be reduced due to the closely fitting air shield.

A previous study has shown that wearing modified swimming goggles for 60 min increased the lipid layer thickness in the tear film significantly with a moderate to total relief in dry eye symptoms, by increasing the peri-ocular humidity.[24]

Limitations of this study were that we did not test specific visual function due to tint of the lenses, as the tint of the lenses is slightly different in each pair of eyewear. Patients selected lenses with different tints that suit their working environment. We also did not measure the tear film osmolarity. Currently, this is not a part of our standard clinical practice. As this is an unmasked study, in order to minimize the bias, examiners were masked to the previous reading when the new reading is taken. Pre- and post-treatment data were documented in separate sheets on the separate sections of the trial case records. SANDE questionnaire has been previously used in a single group study conducted in an identical way to chronic dry eye patients and statistically significant change was observed then.[25] For that reason, we do not think there is inherently a placebo effect. Apart from the moisture retention eyewear, other factors such as changes in the environment (e.g. wind, exposure due to reading) as well as frequency of lubricants can affect the signs and symptoms of dry eye observed. Therefore, improvement in dry eye due to placebo observed in some studies probably may not be due to the single group design, but rather due to the changes in the environment and frequency of lubricant use, after being recruited in a trial. We did not do subgroup analysis to see the association between the severity of dry eye and number of hours, type of activities involved and environment as the sample size was too small. Another limitation is that we did not have a comparison group in this study. The conventional shield sport spectacles are not popular or commonly available in Singapore. Therefore, in the present context, comparing with conventional shield sport spectacles may not be ideal as this is not the current standard. In our population, only ametropic people wear prescription glasses on a consistent basis. We could not randomize ametropes into groups with or without moisture chamber because all our moisture eyewear were preordered and did not have optical correction incorporated. To investigate additional benefits of this moisture retention eyewear over other similar devices (e.g. micro-environment glasses, TranquilEyes® goggles and TranquiEyes® Moisture release eyewear) further studies involving a parallel comparison group are required. Currently, none of the above eyewear is commercially available in Singapore.

Comparison with Other Commercially Available Products

Micro-environment glasses (MEGS): This eyewear is made by attaching silicon rubber shields to the sides of the regular glasses. The shields are quite visible, cosmetically less appealing and comparatively expensive. MEGS do not have adjustable frames and may not fit on certain facial structures. Lenses are not available in different tints or polarization that suits different lighting conditions but can be customized with prescription, anti-glare, tint or anti-fog features after the purchase (http://www.seefit.net/).

TranquilEyes® goggles: This contains rubber eyecups with a viscoelastic foam seal that adds moisture and help hold lids closed. Goggles are suitable for patients with evaporative dry eye due to exposure from poor lid closure and can only be used while sleeping. This can be used for hot compress in patients with MGD and also the least expensive (http://tranquileyes.net.au/products-page/goggles/).

TranquilEyes® Moisture release eyewear: This has two vented chambers that contain pieces of foam. The chambers are soaked in water and placed back into the frame where they are positioned to release the moisture around the eyes continuously for 4–6 h. Lenses have anti-fog coating. This eyewear has good cosmesis and comparatively cheap. This comes with only one type of non-adjustable frame and two different tints (http://tranquileyes.net.au/products-page/moisture-release-eyewear/).

Clinical Significance and Conclusions

This study shows that moisture retention eyewear might be a valuable adjunct in the management of evaporative dry eye. However, the results must be interpreted cautiously because of the low sample size. Adjustable frames were suitable for different facial structures. However, in certain cases, such as patients residing in warm climates may feel discomfort due to sweat, as evidenced by one patient in our study. Unlike the traditional forms of moisture retention eyewear, this new eyewear is available in an array of adjustable frames and lenses (both plano and prescription) facilitating a good fitting for different facial structures and suitable for different working environments, with an additional benefit of UV protection. A low profile (concealed linings) and less noticeable foamy air shield provides better cosmesis, and will increase the compliance. The foamy portion that contacts the face is removable, washable and replaceable, hence suitable for long-term use.

DECLARATION OF INTEREST

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