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Original research

Objective and subjective assessing efficacy of a lubricating drop in eyes wearing silicone hydrogel contact lenses

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Abstract

Purpose: To investigate the effect of a lubricating drop on optical quality, tear film stability, and subjective symptoms in individuals wearing silicone hydrogel contact lens.

Methods: In this one-day, prospective single-center clinical study, Pre-lens Tear Deformation Time (PL-TDT), Root-Mean-Square (RMS) of Low Order Aberrations (LOA) and High Order Aberrations (HOA), individual twelve Zernike coefficients, and subjective symptoms were assessed in 43 volunteers (mean age 19.58 ± 1.63, 86 eyes) at 6 h after inserting the contact lens and then at 60 min after instilling a lubricating drop (Comfort drops, Avizor, Madrid-Spain).

Results: PL-TDT, LOA-RMS, and HOA-RMS values measured before drop instillation were not significantly different with those measured after drop. None of the Zernike coefficients were significantly different after instilling lubricating drop. Statistically significant decrement in both frequency and severity values in blurry vision, dryness, discomfort, burning, itching, foreign body sensation, excessive blinking, and lacrimation were seen after drop instillation (all $P < 0.05$).

Conclusion: Our results showed that although the lubricating drop did not improve the tear film stability and optical quality in the silicone hydrogel contact lens wearers, subjects experienced a subjective improvement.

Keywords: Lubricating drop; Tear Deformation Time; Symptom; Silicone hydrogel contact lens; Wavefront aberrations

Introduction

The tear film is the most important refractive surface of the eye. Owing to the high difference in refractive index at the air-tear interface, this surface is considered the cardinal refractive component of the eye.[1] Any local or global disruption in the tear film can give rise to both optical (e.g. high order aberration increment) and pathological (e.g. ocular surface inflammations) problems in the eye.[2–4]

Optical changes ultimately lead to degrade the retinal image quality.[5] A healthy, uniform, and stable tear film is crucial to achieve clear retinal image. Visual symptoms such as blurry, foggy, misty, and fluctuating vision experienced with some dry eye patients have been attributed to the tear film alterations.[6,7] Pathological problems induced by the tear film disruptive changes cause a variety of ocular symptoms, such as

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burning, itching, and redness. It has been shown that any intervention in the tear film can prevent optical and pathologic disruptions and alleviate the ocular and visual symptoms.[8–10]

Contact lens induced tear film abnormality (CLITFA) has been known as the main reason for discontinuation of the contact lens wear.[11,12] Approximately fifty percent of contact lens wearers experience symptoms of CLITFA.[13] Lacrimation, burning, itching, blurry vision, foggy vision, fluctuating vision, discomfort, dryness, grittiness, foreign body sensation, and redness are the well-known complaints of the patients suffering from CLITFA.[14,15] Recently-conducted studies showed that subjective CLITFA symptoms are the better diagnostic way than clinical testing.[16,17] In fact, a patient with CLITFA, irrespective of having the subjective symptoms, may have normal results in clinical examination[16]

Lubricating drop instillation is recognized as being the most common strategy in the management of CLITFA.[18,19] Previous studies have demonstrated that these viscous substances do not improve the tear film stability and optical quality for an elongated period.[20,21] A study was conducted by Golding et al. which showed that the efficacy of these drops is lower than 10 min.[20] It has been proven that there is no difference in the efficacy of these lubricating formulations with saline.[20] Some authors reported that the lubricating drops can decrease tear osmolarity, lower protein deposition, and consequently, abate the complaints of the patients.[22–24] Caffrey and Josephson compared the efficacy of ten different lubricating formulations and found no remarkable difference between them.[25] There were a few studies addressing the long-term (such as 1 h) effect of the lubricating drops on the tear film and subjective complaints.

The present study seeks to address the long-term influence of a lubricating drop (Comfort drops, Avizor, Madrid-Spain) on the pre-lens tear film stability, optical quality, and subjective symptoms in inexperienced normal individuals wearing silicone hydrogel contact lenses (Air Optix Aqua, Lotraflicon B, CIBA vision).

Methods

Study design and subjects

Forty-three volunteers (86 eyes), comprised of 24 females and 19 males aged from 18 to 22 years (mean age = 19.58 ± 1.63) from students of Rehabilitation School of Iran University of Medical Sciences were recruited in this one-day prospective single-center study. All of the volunteers were normal and had never worn contact lens before. Having standard visual acuity (10/10), healthy ocular surface, keratometry range from 41 to 45 D, maximum spherical refraction 0.25 D (minus and plus), and cylindrical 0.50 D (minus) were considered inclusion criteria. The volunteers who had ocular surface inflammatory or infectious diseases, dry eye, and intraocular pathologies were excluded. Patients who had undergone corneal refractive surgery and other ocular surgical interventions before the time of enrollment were not eligible for participation. Written informed consent was obtained for each individual before participation. The data obtained and used in this study is in adherence to the Declaration of Helsinki. Ethical clearance was obtained through the Office of Research Ethics at Iran University of Medical Sciences.

Visit 1: preliminary examinations

Both right and left eyes in all subjects initially underwent preliminary examinations, including assessment of Visual Acuity, Refraction, Keratometry, Slit Lamp Examination (SLE), and ocular surface staining with fluorescein. After completing the overall observation of ocular surface by slit lamp, a fluorescein-impregnated strip (Fluorescein, HAAG-STREIT AG, Switzerland) was wetted with unpreserved saline. The strip was applied against the superior bulbar conjunctiva while the patient was instructed to look down. The subject was asked to blink three times to spread the Fluorescein. A wide full aperture of the slit lamp illuminating whole area of the cornea with cobalt blue filter was used for observation. Existence of any staining on the corneal and conjunctival surface was evaluated.

These examination outcomes were recorded on a sheet, including name, age, date, time, case history, visual acuity, refraction, keratometry, slit lamp examination (SLE), Pre-Lens Tear Deformation Time (PL-TDT), and aberrometric measurements.

Those volunteers who possessed inclusion criteria were entered into the study. Based on keratometry values, proper contact lenses (Plano, Lotraflicon B, Air Optix, CIBA vision) were inserted into both right and left eyes. Because of the medium keratometric range (41.00–45.00) selection in this work, the median base curve (8.6 mm) of available silicone hydrogel contact lenses was chosen.[26] After 20 min, fitting characteristics of contact lens including visual acuity, centration, movement, and lens-cornea fitting relationship (with retinoscope and keratometer) were evaluated. Each subject spent 6 h with the contact lenses and came back for a second visit in the afternoon.

Also addressed in the literature, the dryness-related symptoms of contact lens wearers tend to increase with increasing daily wearing time.[27,13] Moreover, in the some of the previous similar studies, the time point of 6 h was considered.[28] Regarding the mentioned reasons, we chose 6-hour contact lens wear to allow the tear film to be sufficiently affected by the contact lens.

Visit 2: measurements over the contact lenses

At this time the subjects were asked to complete a written symptom checklist. This checklist encompassed twelve questions about visual and ocular complaints. All of the questions had been written in Persian language. Blurry vision, vision fluctuation, burning and stinging, itching, redness, discomfort, foreign body sensation and grittiness, excessive blinking, dryness, absolute contact lens intolerance (i.e. during their contact lens wear, how often did their eyes bother them so much that they felt as if they needed to stop whatever they were doing and take out their contact lenses), and eye closure

during the lens wear (i.e. during contact lens wear, how often did their eyes bother them so much that they wanted to close them) were queried.

For each symptom, both frequency and severity of occurrence were questioned (written) from the subjects. Volunteers classified the frequency of each symptom within 0: Never, 1: Rarely, 2: Sometimes, 3: Frequently, and 4: Constantly. If the frequency choice was "rarely" to "constantly", he or she then categorized the severity of symptom coded as 1: Negligible, 2: Mild, 3: Moderate, 4: Severe, and 5: Very severe. All of the questions were in the Persian language. For example, to question about the frequency and severity of the blurry or foggy vision, we used the following questions (translated from Persian to English):

1. During your contact lens wear, how often did your vision blur or fog?

(0) Never (1) Rarely (2) Sometimes (3) Frequently (4) Constantly

When your vision was blurry or foggy with your contact lens, how intense was this blurring?

(1) Negligible (2) Mild (3) Moderate (4) Severe (5) Very severe

This checklist was adopted from several well-documented non-native questionnaire such as Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8)[29] and McMonnies Dry Eye Index.[30,31] To check the validity of the checklist, we sent it to eight native experts in the contact lens field and asked them about its performance.

Optical aberrations were assessed over the contact lens by HUVITZ aberrometer (Autorefractor-Keratometer, HUVITZ, HRK 8000a). This aberrometer utilizes a Shack-Hartmann wavefront sensor and analyzes all low order and some high order aberrations (e.g. Spherical aberration, coma, and trefoil). Root-Mean-Square (RMS) of both low and high order aberrations, Point Spread Functions (PSF), and color aberrometric maps were evaluated for 5.09 mm pupil size.

Twelve Zernike coefficients, comprising de-Oblique astigmatism Z(2,-2), defocus Z (2,0), rule astigmatism Z (2,2), oblique trefoil Z (3,-3), vertical coma Z(3,-1), horizontal coma Z(3,1), horizontal trefoil Z(3,3), oblique tetrafoil Z(4,-4), oblique 2nd astigmatism Z(4,-2), spherical aberrations Z (4,0), rule 2nd astigmatism Z(4,2), and horizontal tetrafoil Z (4,4) were measured singly.

To assess stability of the tear film, Tear Deformation Time technique[32] was utilized in this study. The reflected image formed by contact lens surface after focusing of the Javal-Schiotz keratometer becomes lucid and regular immediately after blinking. If the individual holds his or her eyes open, and the examiner maintains the image of the keratometer mire in focus, after a period, the image will become irregular and distorted. The longer the eye opening time, the more distorted the catoptric image. The time taken for observation of the first distortion in the reflected image was termed Tear Deformation Time (TDT). This procedure was repeated three times for each eye, and mean value of them was recorded as the Pre-Lens Tear Deformation Time (i.e. TDT measurement over the contact lens surface).

The Javal-Schiotz keratometer mire image covers only 3 mm of the corneal diameter (approximately 8% of corneal area). Even though the TDT technique does not evaluate the tear film over the whole surface of the cornea, the most important part of the cornea is measured. The central optical zone of the cornea is optically and visually the main part of the cornea. Accordingly, tear film alterations over this area can lead to the prime optical and visual disturbances. It must be noted that the TDT technique has many pros, such as noninvasive nature, easiness, basal tear film assessment, availability, inexpensiveness, no usage of Fluorescein, and accessibility in the clinic (no need for paraclinical equipment). It appears that the benefits clearly outweigh its drawbacks.

After completing the three aforementioned steps in the second visit, one drop of the lubricating drop (Comfort drops, Avizor, Madrid-Spain) was instilled into both eyes over the contact lens.

Visit 3: post-drop measurements

Aberrometry and Pre-Lens Tear Deformation Time (PL-TDT) were repeated 60 min after drop instillation. Since the previous authors had chosen lower time points (such as 5 or 10 min) for assessing the efficacy of the lubricating drops, we decided to choose a longer interval (1 h) after drop instillation. We attempt to answer the question whether or not the lubricating drop improves tear film and gives comfort in a longer period of time. Symptom checklist was completed by the subjects again. At the end time, contact lenses were removed from the eyes.

Statistical analysis

To statistically analyze the obtained data, SPSS software version 16 was used. One-Sample Kolmogorov-Smirnov test was performed to test the normality of distributions. All of the low order aberration- root mean square (LOA-RMS), high order aberration-root mean square (HOA-RMS), Zernike coefficients, and PL-TDT data were normally distributed. To compare the coupled findings, the paired samples *t*-test was used. Frequency and severity of the symptoms were not distributed normally. Wilcoxon two related samples test was used to compare symptoms of the pre-drop condition with those measured after drop instillation. The frequency or severity values of the all questions were not summed together, rather each of the symptoms was analyzed individually.

Results

The data obtained from all of the 43 subjects were analyzed. Mean spherical refractive error for right and left eyes were -0.02 ± 0.17 and 0.07 ± 0.24 Diopters (D), respectively. Mean cylindrical refractive error for the right eye was -0.26 ± 0.22 D and -0.31 ± 0.28 D for the left eye. In our subjects, mean keratometric power for right eyes was 43.15 ± 0.91 D and 43.17 ± 0.97 D for left eyes.

Descriptive statistics for all parameters of study were calculated. Mean (M) and standard deviation (SD) of LOA-RMS, HOA-RMS and PL-TDT values are presented in Table 1.

As shown in Table 1, in both right and left eyes in both before and after drop conditions, LOA values were higher than the HOA ones. Based on the results of the paired samples *t*-test, all of the differences were statistically significant (OD: pre-drop $P = 0.025$/post-drop $P = 0.011$, OS: pre-drop $P = 0.042$/post-drop $P < 0.0001$).

To investigate the effect of the drop on the aberrometric RMS values paired samples *t*-test was performed. LOA-RMS and HOA-RMS values measured before drop were not significantly different from those measured after drop instillation.

PL-TDT values of the pre-drop and post-drop situations were compared (Paired samples *t*-test). It was found that there were no significant differences between them in right and left eyes.

Mean and standard deviation of the twelve Zernike coefficient values measured before and after drop instillation are summarized in Table 2. To statistically compare the polynomials measured before drop with those yielded after drop instillation, paired samples *t*-test was used. None of them showed significant change 60 min after drop instillation.

By using Wilcoxon two related samples test, frequencies of the following symptoms were compared: blurry vision, fluctuating vision, discomfort, burning, itching, foreign body sensation, dryness, redness, excessive blinking, lacrimation, absolute intolerance experience, and eye closure. Significant decrease in blurry vision ($P = 0.013$), dryness ($P = 0.013$), discomfort ($P < 0.0001$), burning ($P = 0.039$), itching ($P = 0.031$), foreign body sensation ($P < 0.0001$), excessive blinking ($P = 0.003$), and lacrimation ($P = 0.009$) were seen (Fig. 1).

Statistically significant decrement in severities of blurry vision ($P = 0.029$), dryness ($P = 0.031$), discomfort ($P = 0.002$), burning ($P = 0.005$), itching ($P = 0.023$), foreign body sensation ($P = 0.001$), and lacrimation ($P = 0.003$) were detected (Fig. 2).

Before and after drop TDT values significantly correlated in both right (Spearman rho = 0.664, $P < 0.0001$) and left (Spearman rho = 0.588, $P < 0.0001$) eyes. Moreover, TDT values of the two eyes were significantly correlated in both before (Spearman rho = 0.912, $P < 0.0001$) and after (Spearman rho = 0.888, $P < 0.0001$) drop status.

Discussion

Our present survey reveals no improvement in tear film stability by the instilled lubricating drop after 60 min of instillation. It seems that these findings corroborate the previously conducted studies reporting that the lubricating drop increases tear stability for a short time.[20,28] Although the lubricating drops did not prolongedly improve tear stability, their deposit removal and rinsing effect are important. In fact, the lubricating drop reduces lysozyme and protein deposits from the lens surface, rinses away denatured materials such as lysozyme, removes all of the intrinsic and extrinsic debris, and flushes waste metabolic substances out from beneath the lens.[18,23] These effects may inhibit deterioration of the contact lens surface wettability by preventing the collection of more deposits and debris over the time.

Both LOA-RMS and HOA-RMS in our study did not show significant changes by the lubricating instillation. Some studies have demonstrated that lubricant drops decrease optical aberrations,[25] upgrade retinal image quality, and improve psychophysical functioning of the eye such as visual acuity[8] and contrast sensitivity[33] for a short time. All of the mentioned effects occurred at lower than 15 min. We allowed longer time (i.e. 60 min) after drop instillation and found no increment in image quality. The most possible reason for reducing blur complaint despite the unchanged maintaining of aberrations is the time elapsed from instillation. It seems the subjects felt better vision in a short period after instillation. As we did not assess the aberrations several times in 60 min post-drop period, there is no information about aberration change in 5 min, 10 min, and other part times after drop. We intended to investigate the long-term influence of drop in this research; therefore, the short-term alterations in aberrometric parameters was not addressed.

In this present study, symptom abatement by instillation of comfort drop was found. Our results are in line with many other studies.[18,22,24] Efron et al. reported that lubricating drop eliminated symptoms for a short-term period after instillation.[34] It seems that the main difference between our survey and previous studies is the time considered after drop instillation. We chose a prolonged time to answer the question if the optical and lubricating impacts of the lubricating drops are stable as long as 60 min or not.

The most frequent symptoms in both before and after drop instillation were foreign body sensation and discomfort. This indicates that foreign body sensation and discomfort are the main symptoms in the contact lens adaptation period. Moreover, these two symptoms allocated the highest values of severities to themselves in both pre-drop and post-drop

Table 1
Mean and standard deviation for high order aberration, low order aberration, and Tear Deformation Time of both right and left eyes before and after drop instillation.

	Right eye			Left eye		
	LOA (μm)	HOA (μm)	TDT (sec)	LOA (μm)	HOA (μm)	TDT (sec)
Before drop	0.268 ± 0.147	0.230 ± 0.147	4.98 ± 2.04	0.198 ± 0.110	0.157 ± 0.094	5.13 ± 2.64
After drop	0.272 ± 0.196	0.215 ± 0.190	5.15 ± 2.60	0.195 ± 0.097	0.112 ± 0.056	5.69 ± 3.45
P value[a]	0.921	0.653	0.499	0.867	0.506	0.308

LOA, Low Order Aberration; HOA, High Order Aberration; TDT, Tear Deformation Time; Sec, Second; μm, Micrometer.
[a] Paired *t* test.

Table 2
Mean and standard deviation values of the twelve Zernike polynomials (μm) measured before and after instillation of the rewetting comfort drop.

	Mean ± SD			
	Right eye		Left eye	
	Predrop	Postdrop	Predrop	Postdrop
Oblique Astigmatism	0.030 ± 0.157	0.030 ± 0.194	0.017 ± 0.087	0.005 ± 0.102
Defocus	−0.032 ± 0.182	0.005 ± 0.197	0.046 ± 0.157	0.019 ± 0.153
Vertical Astigmatism	0.057 ± 0.132	0.041 ± 0.191	0.029 ± 0.119	0.053 ± 0.112
Oblique Trefoil	0.044 ± 0.127	0.048 ± 0.167	−0.024 ± 0.097	−0.033 ± 0.102
Vertical Coma	−0.021 ± 0.179	−0.066 ± 0.232	0.040 ± 0.116	0.047 ± 0.090
Horizontal Coma	−0.011 ± 0.077	−0.004 ± 0.104	−0.009 ± 0.048	−0.015 ± 0.065
Horizontal Trefoil	0.020 ± 0.057	0.003 ± 0.092	−0.010 ± 0.051	−0.013 ± 0.039
Oblique Quadrafoil	0.003 ± 0.025	0.009 ± 0.031	−0.001 ± 0.021	−0.009 ± 0.025
Oblique 2nd Astigmatism	0.002 ± 0.018	0.001 ± 0.017	0.001 ± 0.012	0.003 ± 0.013
Spherical Aberration	0.031 ± 0.025	0.034 ± 0.028	0.020 ± 0.022	0.019 ± 0.037
Vertical 2nd Astigmatism	−0.007 ± 0.028	−0.001 ± 0.041	−0.000 ± 0.025	−0.004 ± 0.021
Horizontal Quadrafoil	0.004 ± 0.025	0.011 ± 0.028	−0.000 ± 0.017	0.005 ± 0.028

SD, Standard Deviation; μm, Micrometer.

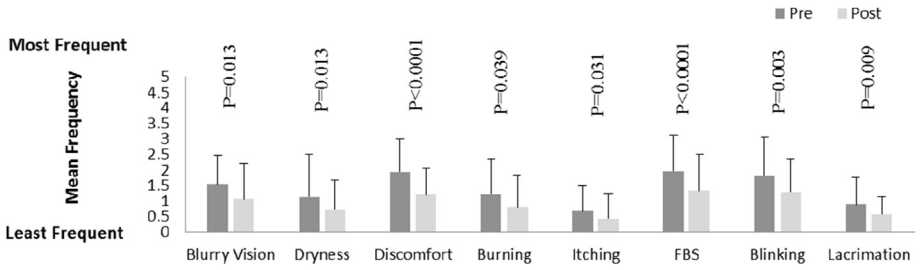

Fig. 1. Comparison of frequencies of the symptoms before and after drop instillation. All of the differences were statistically significant.

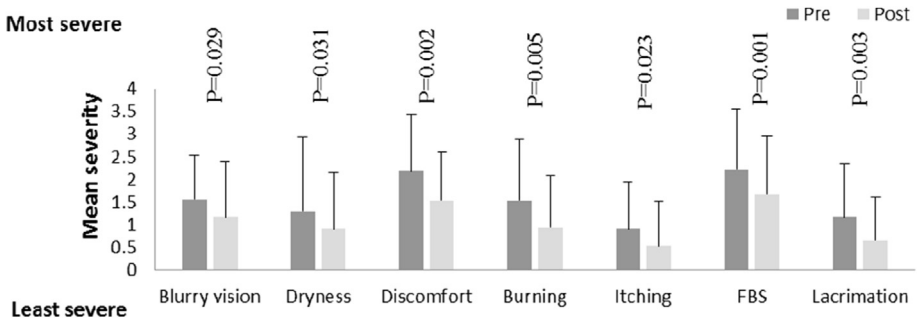

Fig. 2. Comparison of severities of the symptoms before and after drop instillation. All of the differences were statistically significant.

conditions. It appears that clinical experience in the contact lens field authenticates these findings.

Our study has several limitations. The sample size is small, and the effect of the drop on long-term contact lens users is unknown. We did not enter a control group in this study. It can be considered in similar future studies. We also used a commercially available eye drop. Other types of eye drops may have different effects on the tear film changes.

In summary, the lubricating drops seem to be a proper management for contact lens-induced tear film problems. Although this drop may not improve optical quality and tear film stability for an elongated time, it alleviates subjective complaints. Since the subjective symptoms are the best diagnostics for contact lens-related tear film problems, the improvement of the comfort by instilling this drop can be the most acceptable reason for its administration.

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