·Clinical Research·

Comparison of the effects of first and second generation silicone hydrogel contact lens wear on tear film osmolarity

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Abstract

• **AIM: To compare the effects of first and second generation silicone hydrogel (SiH) contact lens wear on tear film osmolarity.**

• **METHODS: The healthy subjects who have never used contact lenses before were enrolled in the study. Tear film osmolarity values of 16 eyes (group 1) who wore first generation SiH contact lenses were compared with those of 18 eyes (group 2) who wore second generation SiH contact lenses after three months follow-up.**

• **RESULTS: Before contact lens wear, tear film osmolarity of groups 1 and 2 were 305.02±49.08 milliosmole (mOsm) and 284.66±30.18mOsm, respectively. After three months of contact lens wear, osmolarity values were found 317.74±60.23mOsm in group 1 and 298.40±37.77mOsm in group 2. Although osmolarity values for both groups of SiH contact lens wear after three months periods were slightly higher than before the contact lens wear, the difference was not statistically significant.**

• **CONCLUSION: Contact lens wear may cause evaporation from the tear film and can increase tear film osmolarity leading to symptoms of dry eye disease. In the current study, there is a tendency to increase tear film osmolarity for both groups of SiH contact lens wear, but the difference is not statistically significant.**

• **KEYWORDS:** dry eye; silicone hydrogel contact lens; contact lens related dry eye; tear film osmolarity

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INTRODUCTION

Tear film hyperosmolarity is one of the objective parameters recommended by the National Eye Institute (NEI) committee to define dry eye and has the potential to be accepted as a gold standard for the disease [1-3]. It correlates with dry eye severity and it could be used as a biomarker[4]. Some tear film disorders cause ocular surface damage in the presence of normal lacrimal function which is called as evaporative dry eye (EDE)[1]. The reasons for EDE include surface disorders resulting from oil deficiency (absent glands, distichiasis, posterior blepharitis, obstructive meibomian gland disease), lid related (blink abnormalities, including video display terminal, aperture abnormalities, lid surface incongruity), surface change (xerophthalmia) and contact lens wear, including drying of the ocular surface under a high water content soft lens[5,6].

Aside from the obvious desiccative effects of elevated tear osmolarity, a hyperosmolar tear film can activate intracellular stress kinases in the epithelial cells of the ocular surface such as c-jun n-terminal kinase; these are potent regulators of inflammation and apoptosis [2]. Thus, bathing the ocular surface in a hyperosmolar tear leads to inflammation of the ocular surface and a loss of normal apoptotic control in cell renewal. In addition, it is thought that an increase in tear film osmolarity adversely affects mucin structure and function and lipid-tear film interactions[5].

Tear film osmolarity may be elevated secondary to decreased tear secretion because of lacrimal gland diseases or increased tear film evaporation resulting from exposure, blink abnormalities, ocular surface changes, meibomian gland disease or contact lens wear[1,7]. Contact lenses rest within the tear film, safety and performance of contact lenses are strictly dependent on the quality and quantity of the tear film. Contact lenses themselves have a potential to alter the integrity and stability of the tear film, which in turn affect the ocular surface as well as the contact lens itself[8,9].

All contact lenses divide the tear film into two compartments, pre-lens tear film (PLTF) and post-lens tear film (POLTF). The lipid layer of tear film is supposed to be altered by the presence of a contact lens. Alteration of lipid layer leads to increased evaporation of the PLTF, followed by contact lens dehydration and depletion of the POLTF by absorption into the contact lens [10]. This may be the mechanism of contact lens-related dry eye.

During contact lens wear, it has been shown that the osmolarity of the tear film can increase [11-14]. Increased tear film osmolarity has been generally attributed to an enhanced evaporation rate that results from an unstable prelens tear film, and some have advocated that tear osmolarity should be an essential part of tear film studies in contact lens wearer[2].

Reduced sensory function facilitates drying by two mechanisms: sensory loss causes decreased tear secretion and, when occurring bilaterally, reduces the blink rate [15]. Decreased corneal sensitivity is a feature of contact lens wear and most likely cause for increased tear film osmolarity, particularly among users of hard contact lenses and extended wear soft contact lenses [11]. Contact lenses themselves ultimately alter the integrity and stability of the tear film, which in turn affect the ocular surface as well as the contact lens itself [4,8,9]. Human tear film is rather unstable, but it is regenerated by frequent blinking and when a contact lens is placed in the eye, the lens alters the normal structure of the tear film and affects its rate of evaporation[16].

In silicone hydrogel (SiH) lenses, silicone hydrogels combine the high Dk of silicone with other material characteristics of conventional hydrogel. Most important properties of new contact lenses are high oxygen transfer capacity and low water content. These properties may improve the comfort of wearing contact lenses. However, disadvantage of these lenses is higher rigidity moduli due to high silicone content. First generation SiH contact lenses have lower water content and higher rigidity moduli when compared with second generation SiH contact lenses. Second generation SiH contact lenses are more comfortable even though their oxygen permeability are lower than that of first generation SiH contact lenses. Because they have increased water contents and reduced moduli. The mechanical and surface properties can be thought of as being in between those of conventional hydrogels and first generation silicone hydrogels [17]. It was hypothesized that contact lens wear leads to changes in structure or production of the meibomian glands, which leads to alterations in the lipid layer thickness and tear film instability, an increase in tear film osmolarity, and dehydration of hydrogel lenses. This process, in turn, leads to the commonly reported symptoms of dryness in contact lens wearers[17].

The diagnostic accuracy of tear film osmolarity was found to be higher than that of the other tests evaluated in normal versus dry eye diagnosis [16]. Tomlinson and Cedarstaff [18] were the first to attribute an increase in evaporation from the eye to contact lens wear. Individuals without objective sign of dry eye or subjective symptoms may experience classic dry eye disease while wearing contact lenses.

Tear film osmolarity can be measured using a number of techniques. Freezing point depression method is a well-known and reliable technique for tear film osmolarity measurement[12].

In this study, we aimed to compare the effects of first and second generation SiH contact lens wear on tear film osmolarity by using freezing point depression technique.

SUBJECTS AND METHODS

Subjects The patients who applied to our clinic consecutively with refraction disorder and have never used contact lenses before were enrolled in the study. Patients with pathological findings in biomicroscopical examination were excluded. Sequential randomization was used to split the cases into two groups. Only one eye of each participant was included in the study. If both eyes were eligible; right eye was chosen. Additional exclusion criteria included use of any topical or systemic medication or a history of systemic or ocular disease except refractive error. After our study protocol was approved from the university ethics committee, 34 eyes of 34 patients were evaluated in two different groups according to use the type of contact lens worn with 16 eyes in group 1 and 18 eyes in group 2. Group 1 consisted of 16 subjects (10 female and 6 male) who were randomly selected to use first generation SiH contact lens (Focus-Night & Day™-CIBA-Vision, Duluth, GA, USA). Group 2 consisted of 18 subjects (10 female and 8 male) who were randomly selected to use second generation SiH contact lens (Air Optix™- CIBA -Vision). Lens data are shown in Table 1. Tear samples were collected from these subjects for measurement of tear film osmolarity. Then, SiH contact lenses for both groups were worn on a daily wear (overnight) basis. Even though the lenses could be used either overnight or continuous basis; in our practice we usually advice patients to use the lenses on overnight basis. The difference between the two wearing patterns regarding the effect on tear film osmolarity is not known. After three months follow-up, tear film osmolarity measurements were repeated from the subjects who have not any complications secondary to the contact lens wear.

Methods All tear samples were collected between 1-3 p.m. in order to eliminate diurnal variations. Tear samples were collected under the fixed illumination of a biomicroscope lamp from the inferior meniscus of the eye, using glass microcapillary (hematocrit) tubes (Vitrex-6 Modulohm a/s-Denmark). Care was taken to avoid touching the corneal or conjunctival surface, and anesthetics were not used.

Table 1 Silicone hydrogel contact lens data

Groups	Trade name	Material	Water content (%)	Modulus(MPa)	Dk/t value
Group 1	Focus-Night &Day™ (CIBA-Vision)	Lotrafilcon A	24	1.2	175×10^{-9}
Group 2	Air Optix™ (CIBA-Vision)	Lotrafilcon B	33	1.0	138×10^{-9}

Table 2 Mean age, tear film BUT and Schirmer test values of the subjects $\bar{x}\pm s$

Lens groups	Age(a)	Schirmer test (mm)		Tear film BUT (s)	
		Before wear CL	After wear CL	Before wear CL	After wear CL
Group 1	25.9±3.1	16.7±4.1	15.9±3.40	12.1±3.10	12.4±3.20
Group 2	25.4±2.9	17.2±4.0	16.5± 2.90	13.2± 3.25	13.6±3.30

Group 1: First generation SiH contact lens; Group 2: Second generation SiH contact lens; CL: Contact lens.

Table 3 Comparison of tear film osmolarity values before and after the contact lens wear in the groups $\bar{x}\pm s$

Lens groups	Tear film osmolarity (mOsm)		% increase	^{1}t	^{1}P
	Before wear CL	After wear CL			
Group 1 (n=16)	305.02±49.08	317.74±60.23	4.2	0.63	0.536
Group 2 (n=18)	284.66±30.18	298.40±37.77	4.8	1.20	0.282
^{2}P	0.151	0.281			
^{2}t	1.43	0.30			

[1]Paired samples *t*-test; [2]Independent samples *t*-test.

To decrease the risk of evaporation, tear sample in the microcapillary tubes were immediately transferred into a small-volume Eppendorf tube by using an automatic micropipette at normal room temperature and stored at -20℃ until the day of measurement. Before the analysis of osmolarity, all samples were thawed and kept at room temperature for 30min. Forty microliters tear film was diluted six fold with demineralized water just before analysis and then mixed by a shaker. The osmolarity of the tear film samples were determined by the freezing point depression technique using an auto-osmometer (OM-6030 AUTO STAT; Daiichi, Kyoto, Japan). The osmometer was calibrated by using deionized water and two standard solutions. The recorded data were multiplied by six to obtain the tear film osmolarity values. The results are expressed as milliosmole (mOsm)[19].

Schirmer test without topical anesthesia and tear film break-up time (BUT) were also evaluated in the subjects before contact lens wear and after three months SiH contact lens wear. These tests and tear film collection for osmolarity measurement were performed in different days immediately after the subjects removed their contact lenses.

To measure BUT, Fluorescein strip moistened with non-preserved saline solution is instilled into the lower fornix. The subjects were asked to blink several times. The tear film is examined with a broad beam and a cobalt blue filter. The BUT is the interval between the last blink and the appearance of the first randomly distributed dry spot. A BUT of less than 10s is abnormal[20]. The measurements were made three times, and the mean was used in statistical analysis.

Schirmer test involves measuring the amount of wetting of a special filter paper. The filter paper is folded 5mm from one end and inserted at the junction of the middle and outer third of the lower lid, taking care not to touch the cornea or lashes. Less than 10mm of wetting after 5min without anesthesia is considered abnormal[20].

Statistical Analysis Statistical analysis in tear film osmolarity, independent samples *t*-test was used to compare variables between two groups and, variables measured before and after contact lens wear were compared by using paired *t*-test for each group. Paired *t*-test was also used for statistical analyses of Schirmer test and BUT.

RESULTS

Mean ages of the patients, tear film BUT and Schirmer test values of the subjects are shown in Table 2. Mean ages of the group 1 and group 2 were 25.9±3.1 years and 25.4±2.9 years, respectively. Mean ages of the subjects did not show any statistically significant difference between the groups (P>0.05). Mean of the Schirmer test values of the group 1 and group 2 were 16.7±4.1mm and 17.2±4.0mm before the SiH contact lens wear and 15.9±3.40mm and 16.5±2.90mm after the contact lens wear, respectively. Mean of the BUT values of the group 1 and group 2 were 12.1±3.10s and 13.2±3.25s before the SiH contact lens wear and 12.4±3.20s and 13.6±3.30s after the contact lens wear, respectively. A BUT value of less than 10s is considered abnormal and Schirmer test value of less than 10mm of wetting is considered abnormal. In the current study, Schirmer test and BUT results were normal and did not show statistical significant difference before and after the SiH contact lens wear for both groups (Table 2, P>0.05).

Mean tear film osmolarity values are shown in Table 3. Before the period of SiH contact lens wear, the tear film osmolarity values of group 1 and 2 were 305.02±49.08 and

284.66±30.18mOsm, respectively. After the three months of contact lens wear, these values were measured as 317.74±60.23mOsm in group 1 and 298.40±37.77mOsm in group 2. There was no statistically significant difference between the initial values (before the contact lens wear) of the groups (t=1.43, P=0.151). The difference of the subjects' final measurements were also not statistically significant between two groups (t=0.30, P=0.281). Although mean osmolarity value of group 2 (second generation) were lower than those of group 1 (first generation), there was also no significantly difference between the values before and after the contact lens wear for both group 1 (t=0.63, P=0.536) and group 2 (t= 1.20, P=0.282, Table 3).

DISCUSSION

Farris[12] reported an abnormally elevated tear film osmolarity in normal individuals wearing hard contact lenses and extended-wear soft contact lenses. A significant increase of tear film osmolarity could not be confirmed in patients who use daily wear soft contact lenses.

It was reported that low-water-content or thick lenses dehydrate less than high-water-content or thin lenses [21]. Because silicone hydrogels are classified as low-water-content contact lenses (24%-36%), contact lens dehydration and dryness symptoms were expected to be less with these lenses[22].

In the current study with two groups of SiH contact lens (first and second generation), tear film osmolarity slightly increased after the SiH contact lens wear for three months period but the difference was not statistically significant. A few studies reported that SiH contact lenses dehydrate at a slower rate and to a lesser extent than conventional hydrogel materials. Furthermore, wearers of SiH contact lenses reported to felt their lenses less dry than their previous conventional lenses, despite considerably longer wearing durations[23].

In a meta-analysis, Tomlinson *et al* [24] reported cut-off tear film osmolarity value for dry eye as 316mOsm. The initial and final mean tear film osmolarity in both groups were within normal limits. The tear film osmolarity value increases with contact lens wear in both groups were similar (4.2% for group 1 versus 4.8 % for group 2). This result may be due to silicone hydrogel lens surface biocompatibility, lens movement, dehydration resistance, wettability, and elastic modulus [5,22]. Studies with higher number of cases are needed to reach a more definitive conclusion.

In a study performed with hydrogel contact lenses, with different water content and thickness, tear-fluid osmolarity was reported to increase from baseline level. This hyperosmotic change was attributed to an increase in water evaporation resulting from distribution of the tear film by the contact lens. All contact lenses produced a similar effect on the tear-fluid osmolarity except the thick lens of high water content, which induced a greater hyperosmotic change[10]. But, in another study with frequent replacement daily wear soft contact lenses with low (38%) and high (55%) water content and rigid gas permeable contact lenses with a high Dk value, the tear film osmolarity was observed to increase significantly compared with the baseline level but there was no significant difference observed among lens groups[14].

Both our tear collection method and analytical techniques may have some disadvantages in determining the absolute values of tear osmolarity, because reflex tearing and evaporation may have been induced by the slit-lamp illumination. This can then change the osmolarity values of the collected samples. Also, the six fold dilution of the collected samples with demineralized water may have added additional error to the absolute values of the results; this dilution can theoretically cause a six fold decrease in the exact value of the osmolarity. However, multiplying the obtained results by six, as was done in our technique, causes a systematic error of 1-6mOsm. Because the normal osmolarity value of tear fluid is approximately 300mOsm (285-316mOsm), a systematic error of 6mOsm is an error of about 2%[24]. This percentage is within the acceptable range (0%-2%mOsm).

Tomlinson *et al* [25] had showed that, tear film osmolarity measured with the electrical impedance correlates well with the freezing point depression technique. Therefore, in the current study, freezing point depression technique was appropriate to measure tear film osmolarity. In our technique, some disadvantages in determining the absolute values of tear film osmolarity can be eliminated by using new techniques in further studies.

In conclusion, contact lens wear has a potential to alter the normal structure of the tear film. Increased rates of evaporation from the tear film can increase tear film osmolarity and create dry eye disease independent of abnormalities of aqueous tear secretion. In the current study, first and second generation SiH contact lens wear for three months period slightly increased tear film osmolarity, but these changes are limited and not statistically significant. In addition the difference of the each subject's initial and final (after three months) measurement was not statistically significant between two groups. Further studies are required to better understand the change of tear film osmolarity values for long term silicone hydrogel contact lens wear.

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