

Comparison of tear osmolarity and ocular comfort between daily disposable contact lenses: hilafilcon B hydrogel versus narafilcon A silicone hydrogel

Ozge Sarac · Canan Gurdal ·
Basak Bostanci-Ceran · Izzet Can

Received: 29 December 2011 / Accepted: 21 March 2012 / Published online: 7 April 2012
© Springer Science+Business Media B.V. 2012

Abstract The aim of this study was to evaluate tear osmolarity and ocular comfort with two different types of hydrogel daily disposable lenses. The right eyes of 15 first-time contact lens users were included in this prospective study. All eyes wore hilafilcon B silicone hydrogel contact lenses for 8 h (group 1). After 1 week without contact lenses, all eyes wore narafilcon A silicone hydrogel contact lenses for 8 h (group 2). Tear osmolarity measurement was performed before and after 4 and 8 h of each contact lens wear. Ocular comfort was assessed after 4 and 8 h of each contact lens wear. In group 1, the mean baseline, 4- and 8-h tear osmolarity values were 293 ± 10.57 , 303.00 ± 10.5 mOsm/L ($p = 0.023$), and 295.0 ± 1.4 mOsm/L ($p > 0.05$), respectively. In group 2, the mean baseline, 4- and 8-h tear osmolarity values were 294 ± 13.65 , 300.9 ± 11.3 mOsm/L ($p = 0.007$), and 298.80 ± 7.2 mOsm/L ($p > 0.05$), respectively. In group 1, the mean comfort score was 7.20 ± 0.45 and 8.60 ± 0.45 at 4 and 8 h, respectively ($p = 0.038$). In group 2, the mean comfort score significantly decreased from 9.80 ± 0.45 to 7.80 ± 0.84 at 4 h ($p = 0.039$). Both hydrogel and silicone hydrogel daily disposable contact lenses

elevated tear osmolarity during 8 h of contact lens wear. The increase in tear osmolarity with both contact lenses was below the cut-off value for dry eye and was not associated with ocular comfort.

Keywords Daily wear contact lenses · Hydrogel · Silicone hydrogel · Tear osmolarity · Ocular comfort

Introduction

Tear hyperosmolarity has been reported in daily and extended wear of both soft and hard contact lens wearers [1–3]. Recent evidence shows that the rise in tear osmolarity during contact lens wear has been due to various factors such as environmental conditions, tear film factors, contact lens materials and parameters, or wearing schedules [4–7]. It has been suggested that increased tear osmolarity is the hallmark characteristic of contact lens-induced dry eye, which is the most common cause of ocular discomfort in contact lens wearers [8, 9]. Contact lens-induced dry eye symptoms affect up to 78 % of contact lens wearers and nearly 50 % of contact lens dropouts are due to ocular dryness [8, 9]. For this reason managing tear osmolarity may be critical to ensure correct contact lens fitting.

Several studies have investigated tear osmolarity in different types of contact lens wear. A study by Farris

O. Sarac (✉) · C. Gurdal · B. Bostanci-Ceran
2nd Department of Ophthalmology, Ankara Ataturk
Training and Research Hospital, Bilkent, Ankara, Turkey
e-mail: osarac2002@yahoo.com

I. Can
Department of Ophthalmology, School of Medicine,
Bozok University, Yozgat, Turkey

et al. [2] demonstrated a significant increase in tear osmolarity with daily wear hard contact lenses and extended-wear soft contact lenses in aphakic subjects. İskeleli et al. [3] reported elevated tear osmolarity in contact lens wearers wearing daily wear hydrogel soft contact lenses and rigid gas permeable contact lenses. The current study was conducted to demonstrate tear osmolarity and ocular comfort over the course of the day with daily wear silicone hydrogel and daily wear hydrogel contact lenses. An in vitro diagnostic device, the TearLab™ Osmolarity System (TearLab Corporation, San Diego, CA, USA), was used to measure tear osmolarity.

Materials and methods

This study was a prospective, clinic-based study conducted in compliance with the institutional and government review board regulations, informed consent regulations and the Declaration of Helsinki. Written informed consent was obtained from all subjects before clinical evaluation.

Study population

Fifteen randomly selected subjects who presented with a refractive error to the Department of Ophthalmology of Ataturk Training and Research Hospital were included into the study. Subjects were excluded if they had previous history of contact lens use, an ocular surface disorder, a history of ophthalmic surgery or systemic disease, or use of any medication or eye drops known to affect the ocular surface.

After having complete ophthalmologic examinations all eyes wore hilafilcon B (Soflens Daily Disposable, Bausch and Lomb, Rochester, NY, USA) contact lenses for 8 h (group 1). After 1 week without wearing any contact lenses, all eyes wore narafilcon A (1-Day Acuvue® TruEye®, Johnson and Johnson Medical Ltd., New Brunswick, NJ, USA) contact lenses for 8 h (group 2).

Hilafilcon B is a hydrogel material with a water content of 59 %. Its *Dk/t* is 24.0 [at -3.00 diopters (*D*)] at a central thickness of 0.09 mm. Powers of hilafilcon B daily wear contact lenses range from $+6.50$ to -9.0 *D* with a base curve of 8.6 mm. Narafilcon A is a silicone hydrogel material with a water content of 46 % and *Dk/t* of 118 (at -3.00 *D*) at

a central thickness of 0.085 mm. This lens was available in powers ranging from $+0.50$ to -12.00 *D* and in base curves of 8.5 mm.

Comfort assessment

Subjects were asked to use 0–10 anchored analog scales to rate comfort (0 = very uncomfortable to 10 = very comfortable) of each contact lens at 4 and 8 h after contact lens wear.

Tear osmolarity measurement

Tear osmolarity measurement was first taken in each eye before contact lens wear. It was taken again after 4 and 8 h of each contact lens wear. The room temperature was set between 20 and 22 °C, and humidity was maintained at 30–50 %. Subjects were asked to remain within the temperature- and humidity-controlled building for the duration of lens wear. Tear osmolarity was measured with the TearLab™ Osmolarity System. TearLab™ uses 50 nL of tear fluid and displays quantitative osmolarity results in less than 30 s. This ‘lab-on-a-chip’ technology measures tear osmolarity in mOsm/L from the inferior lateral tear meniscus. Electronic Check Cards were used each day prior to the first subject being tested. Normal osmolarity measurements on healthy eyes are <308 mOsm/L. Readings >308 mOsm/L are significant for mild-to-moderate dry eye, and readings >325 mOsm/L indicate severe dry eye disease. TearLab™ measured tear osmolarity at a 95 % correlation to the standard osmometers [10].

Statistical analysis

All data related to the investigated variables are presented as mean \pm standard deviation. For statistical analysis data were taken from the right eyes only. Changes in tear osmolarity and comfort score values within each group, with reference to baseline values were compared by Wilcoxon signed rank test. Groups 1 and 2 were compared with regard to changes in tear osmolarity and comfort score by Mann–Whitney *U* test. Differences were considered statistically significant at $p \leq 0.05$. Statistical analysis was performed using the Statistical Package for Social Sciences software (version 16.0, SPSS, Inc., Chicago, IL, USA).

Results

Fifteen right eyes of 15 subjects were enrolled in the study. The average age of the subjects was 33 ± 7 (age range 22–45) years. There were 9 (60 %) females and 6 (40 %) males.

In group 1, the mean baseline tear osmolarity value was 293 ± 10.5 mOsm/L (Fig. 1). After 4 h of contact lens wear it significantly increased to 303.00 ± 10.5 mOsm/L ($p = 0.023$). After 8 h of contact lens wear it decreased to 295.0 ± 1.4 mOsm/L, although the difference did not reach statistical significance ($p > 0.05$).

In group 2, mean baseline tear osmolarity was 294 ± 13.6 mOsm/L (Fig. 1). It significantly increased to 300.9 ± 11.3 mOsm/L after 4 h of contact lens wear ($p = 0.007$). After 8 h of contact lens wear it decreased to 298.8 ± 7.2 mOsm/L, which was not statistically significant ($p > 0.05$).

When comparing mean tear osmolarity between groups 1 and 2, the 4- and 8-h contact lens wear values did not show any statistically significant difference ($p > 0.05$).

The mean comfort scores in group 1 were 7.20 ± 0.45 and 8.60 ± 0.45 after 4 and 8 h of contact lens wear, respectively. The increase was statistically

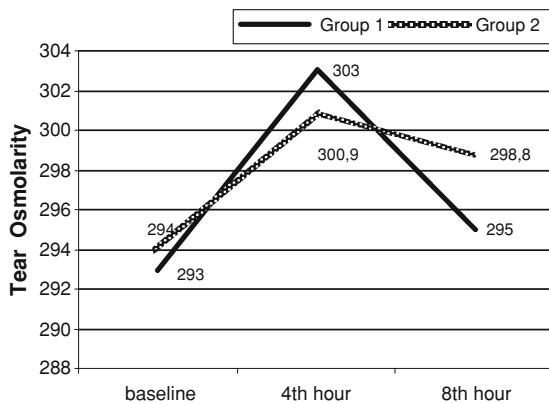
significant ($p = 0.038$) (Fig. 2). In group 2, the mean comfort score was 9.8 ± 0.45 after 4 h of contact lens wear and decreased significantly to 7.8 ± 0.84 after 8 h ($p = 0.039$) (Fig. 2).

The mean comfort scores of groups 1 and 2 after 4 h of contact lens wear show a statistically significant difference with group 2 having a higher score ($p = 0.021$). In contrast, however, after 8 h of contact lens wear, the comfort score of group 1 was significantly higher than group 2 ($p = 0.041$).

Discussion

Successful contact lens wear primarily depends on a stable tear film. However numerous studies have shown that contact lens wear alters the normal structure of the tear film and increases its rate of evaporation [1–3, 11]. This, in turn, may have clinical consequences like ocular discomfort, ocular surface damage, and contact lens-induced dry eye [10, 12].

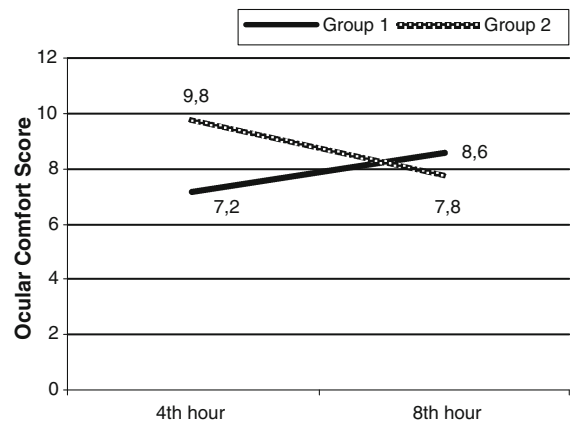
Contact lens-induced dry eye is the leading cause of contact lens discontinuation. Although the exact mechanism of this disorder is still controversial, recent studies have proposed various mechanisms for its presence. It has been stated that an osmotic gradient



Group 1: Subjects wearing hilafilcon B hydrogel daily disposable contact lenses

Group 2: Subjects wearing narafilcon A silicone hydrogel daily disposable contact lenses

Fig. 1 The mean tear osmolarity values in groups 1 and 2 were increased after 4 h of contact lens wear (group 1, $p = 0.023$; group 2, $p = 0.007$). After 8 h the mean tear osmolarity values decreased in both groups; however, the difference did not reach statistical significance ($p > 0.05$)



Group 1: Subjects wearing hilafilcon B hydrogel daily disposable contact lenses

Group 2: Subjects wearing narafilcon A silicone hydrogel daily disposable contact lenses

Fig. 2 The mean ocular comfort score in group 1 was increased after 8 h ($p = 0.038$). In contrast with group 1, however, the 4-h mean comfort score in group 2 decreased significantly after 8 h ($p = 0.039$)

can occur between the contact lens and the tear film due to the evaporation of water from the contact lens by breaking up the pre-lens tear film on the contact lens surface. This osmotic gradient can cause an increase in tear osmolarity [4]. The contact lens material may also affect tear osmolarity as higher water content and thin contact lenses dehydrate easily [5, 6]. It has also been suggested that contact lens wear reduces corneal sensitivity which down-regulates the lacrimal gland and results in decreased tear production [7]. All of these factors have the potential to cause a rise in tear osmolarity in contact lens wearers.

In recent years it has been accepted that tear hyperosmolarity is one of the causative mechanisms for the occurrence of dry eye [13–16]. Increased tear osmolarity has been demonstrated to stimulate the production of inflammatory factors such as interleukin 1β , tumor necrosis factor- α , and matrix metalloproteinase-9, and activates the mitogen-activated protein kinase (MAPK) signaling pathways in the ocular surface epithelial cells [13]. The activation of MAPK signaling pathways along with inflammatory factors are known to lead to ocular surface damage and dry eye [14].

Previous studies measuring tear osmolarity in contact lens wearers demonstrated increased tear osmolarity during wear time [1, 3, 11, 17]. Similar results with both hydrogel and silicone hydrogel daily disposable contact lenses were obtained in our study. The contact lens wearing period in this study was 8 h. All of the subjects were first-time contact lens wearers. Tear osmolarity measurement and comfort score assessment were made after 4 and 8 h of contact lens wear. We detected higher tear osmolarity values after 4 h for both types of lenses; however, they did not reach the cut-off value for dry eye [15]. After 8 h, an insignificant reduction was observed in tear osmolarity values.

The mean comfort score with daily disposable hydrogel lenses significantly increased from 4 to 8 h during the course of the day. In contrast with the hydrogel lenses, the mean comfort score of the daily disposable silicone hydrogel lenses significantly decreased in the same time period. We were unable to find any association between tear osmolarity and ocular comfort. A study by Stahl et al. [18] also demonstrated no association between elevated tear osmolarity and ocular comfort after 6 h of contact lens wear although the level of tear osmolarity after contact

lens wear was detected as above the cut-off value for dry eye. They found a significant association between ocular comfort and contact lens osmolarity which is a combination of pre- and post-lens tear film and the bulk of the contact lens.

In this study we used the Tear-LabTM Osmolarity System which uses a novel method of measuring tear osmolarity in contact lens wearers. It is a nanotechnology-based, point-of-care testing diagnostic instrument that can measure tear osmolarity noninvasively. It also has a positive predictive value of disease severity of approximately 90 % (94 % specificity) versus ≤ 30 % for other commonly used dry eye tests [15]. Tear osmolarity was found to be the single best marker of dry eye severity in normal, mild/moderate, and severe dry eye patients [19]. It has been proven to be the most accurate method for diagnosing and following dry eye patients [19–23]. The Tear-LabTM Osmolarity System has been evaluated in the diagnosis of dry eye in recent studies [20–22]; however, it has not been used to measure tear osmolarity in contact lens wearers.

This study has some limitations. One of the limitations is that the number of the participants was low. Another limitation is the duration of the contact lens wear; we evaluated the effects of daily wear contact lenses only 4 and 8 h after contact lens wear, which was a relatively short period of time. Despite these limitations, we believe that this study provided information about the effects of daily disposable hydrogel and silicone hydrogel contact lenses on tear osmolarity and ocular comfort.

In summary, the present study examined tear osmolarity in contact lens wearers wearing silicone hydrogel and hydrogel daily disposable lenses, and assessed the impact of tear osmolarity on ocular comfort during short-term wear. It was shown that both hydrogel and silicone hydrogel daily disposable lenses elevated tear osmolarity after 4 h of contact lens wear which was thought to be the time point where daily wear contact lenses change their tear osmolarity values. Our findings provide evidence that the increase in tear osmolarity with either hydrogel or silicone hydrogel daily disposable lenses was below the cut-off value for dry eye after 8 h and was not associated with ocular comfort. Further studies with larger patient groups, with longer contact lens wearing time are needed.

Acknowledgments None of the authors have any financial support. The study does not have any sponsor.

Conflict of Interest None of the authors have any declarations of interest.

References

- Martin DK (1987) Osmolality of the tear fluid in the contralateral eye during monocular contact lens wear. *Acta Ophthalmol (Cph)* 65:551–555
- Farris RL (1986) Tear analysis in contact lens wearers. *CLAO J* 12:106–111
- İskeleli G, Karakoc Y, Aydin O et al (2002) Comparison of tear-film osmolality in different types of contact lenses. *CLAO J* 28:174–176
- Stahl U, Ho A, Brent G et al (2007) Measurements of solutions and contact lenses with a vapor pressure osmometer. *Optom Vis Sci* 84:321–327
- Ramamoorthy P, Sinnott LT, Nichols JJ (2010) Contact lens characteristics associated with hydrogel lens dehydration. *Ophthalmic Physiol Opt* 30:160–166
- Gonzalez-Meijome JM, Lopez-Aleman A, Almeida JB et al (2009) Dynamic in vitro dehydration patterns of unworn and worn silicone hydrogel contact lenses. *J Biomed Mater Res B* 90:250–258
- Gilbard JP, Gray KL, Rossi SR (1986) A proposed mechanism for increased tear-film osmolality in contact lens wearers. *Am J Ophthalmol* 102:505–507
- Guillon M, Maissa C (2005) Dry eye symptomatology of soft contact lens wearers and nonwearers. *Optom Vis Sci* 82:829–834
- Chalmers RL, Begley CG (2006) Dryness symptoms among an unselected clinical population with and without contact lens wear. *Contact Lens Anterior Eye* 29:25–30
- Nichols JJ, Sinnott LT (2006) Tear film, contact lens, and patient-related factors associated with contact lens-related dry eye. *Investig Ophthalmol Vis Sci* 47:1319–1328
- Korb DR (1994) Tear film–contact lens interactions. *Adv Exp Med Biol* 350:403–410
- Fonn D, Situ P, Simpson T (1997) Hydrogel lens dehydration and subjective comfort and dryness ratings in symptomatic and asymptomatic contact lens wearers. *Optom Vis Sci* 38:1–8
- Luo L, Li DQ, Doshi A et al (2004) Experimental dry eye stimulates production of inflammatory cytokines and MMP-9 and activates MAPK signaling pathways on the ocular surface. *Investig Ophthalmol Vis Sci* 45:4293–4301
- Pflugfelder SC, Farley W, Luo L et al (2005) Matrix metalloproteinase-9 knockout confers resistance to corneal epithelial barrier disruption in experimental dry eye. *Am J Pathol* 166:61–71
- Tomlinson A, Khanal S, Ramaesh K et al (2006) Tear film osmolality: determination of a referent for dry eye diagnosis. *Investig Ophthalmol Vis Sci* 47:4309–4315
- The definition and classification of dry eye disease: report of the Definition and Classification Subcommittee of the International Dry Eye Workshop (2007) *Ocul Surf* 5:75–92
- Miller WL, Doughty MJ, Narayanan S et al (2004) A comparison of tear volume (by tear meniscus height and phenol red thread test) and tear fluid osmolality measures in non-lens wearers and in contact lens wearers. *Eye Contact Lens* 30:132–137
- Stahl U, Willcox MDP, Naduvilath T et al (2009) Influence of tear film and contact lens osmolality on ocular comfort in contact lens wearers. *Optom Vis Sci* 86:857–867
- Sullivan BD, Whitmer D, Nichols KK et al (2010) An objective approach to dry eye disease severity. *Investig Ophthalmol Vis Sci* 51:6125–6130
- Benelli U, Nardi M, Posarelli C et al (2010) Tear osmolality measurement using the TearLab Osmolarity System in the assessment of dry eye treatment effectiveness. *Contact Lens Anterior Eye* 33:61–67
- Meesmer EM, Bulgen M, Kampik A (2010) Hyperosmolality of the tear film in dry eye syndrome. *Dev Ophthalmol* 45:129–138
- Versura P, Profazio V, Campos EC (2010) Performance of tear osmolality compared to previous diagnostic tests for dry eye diseases. *Curr Eye Res* 35:553–564
- Liu H, Begley C, Chen M et al (2009) A link between tear instability and hyperosmolality in dry eye. *Investig Ophthalmol Vis Sci* 50:3671–3679