Int J Ophthalmol, Vol. 8, No. 5, Oct.18, 2015 www. IJO. cn
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·Clinical Research·

Oxygen permeability of soft contact lenses in different pH, osmolality and buffering solution

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Received: 2014-09-12 Accepted: 2015-01-14

Abstract

• AIM: To determine the effect of pH, osmolality, and buffering system on the oxygen permeability (Dk) of soft contact lenses.

• METHODS: Two hydrogel lenses (nelfilcon A and etafilcon A) and 2 silicone hydrogel lenses (lotrafilcon A and balafilcon A) were used in the study. These lenses were incubated in phosphate-buffered saline (PBS) and borate-buffered saline (BBS) solutions adjusted by 0.8 pH increments to a pH in the range of 5.8-9.0 or in hypotonic (280 mOsmol/kg), isotonic (310 mOsmol/kg) and hypertonic (380 mOsmol/kg) PBS solutions. Polarographic method was used for measuring the Dk and lenses were stacked as 4 layers to correct the boundary effect.

• RESULTS: Dk values of all contact lenses measured in BBS solutions were more stable than those in PBS solutions. Especially the etafilcon A lens showed a relative big change compared with other types of contact lenses at the same conditions. When the osmolality of PBS solution increased from hypotonic to hypertonic, Dk of all contact lenses decreased. Variations in Dk existed depending on lens materials, etafilcon A lens was the most affected and nelfilcon A was the least affected by osmolality.

• CONCLUSION: From the result obtained, it is revealed that Dk of contact lenses is changed by the pH, osmolality, and buffering condition of tear. Thus, Dk of contact lens can be varied by the lens wearers´ physiological and/or pathological conditions.

• KEYWORDS: soft contact lens; oxygen permeability; buffer solutions; osmolality; pH

DOI:10.3980/j.issn.2222-3959.2015.05.33

Lee SE, Kim SR, Park M. Oxygen permeability of soft contact lenses in different pH, osmolality and buffering solution. *Int J Ophthalmol* 2015;8(5):1037-1042

INTRODUCTION

Contact lens materials have been developed to be more biocompatible, especially with respect to increased oxygen permeability (Dk). Dk is an intrinsic characteristic of a contact lens to transmit oxygen to the cornea from the atmosphere. Every contact lens is a barrier to oxygen transportation into the eye and can induce hypoxia, which is a cause of clinical problems, such as corneal edema, corneal neovascularization, corneal acidosis, loss of corneal transparency, epithelial keratitis, and endothelial polymegathism [1]. Because of the relatively low Dk of traditional hydrogel lenses, the minimum oxygen requirement of the cornea is not met under closed eyelid conditions. To counteract the potential clinical problems induced by low Dk of conventional hydrogel lens during overnight wear, new types of hydrogel lens materials containing organosilicone moieties in their polymers have been developed [2]. Silicone hydrogel lenses have about 5-10 times the Dk of traditional hydrogel materials and are widely used for extended wear[3].

Physiological conditions like temperature and amount of tear as well as material properties like silicone content and water content can affect Dk. Soft contact lenses are susceptible to the surrounding environment; therefore, the osmolality and buffering components of the packing solutions, deposited proteins, and temperature can affect lens parameters such as total diameter, back optic zone radius, central thickness, and water content [4-6]. These changes in the lens parameters may cause different parameter changes in sequential order. In other words, there is a possibility to change the back optic zone radius varying in total diameter, and water content change, even to bring a change in Dk[5-7].

Contact lenses should be hydrated in tear film when in the eye, but because the tear film is not consistent, the lens parameters can continuously change while the soft contact lenses are worn. Tear film of normal subjects is an isotonic solution (<312 mOsmol/kg), with a pH between 7.14 and 7.82, containing approximately 97 different proteins [8,9]. However, the properties of tear film changes with age, gender, and eye diseases, such as dry eye condition [10,11]. Moreover, hormone changes induced by pregnancy, and caloric intake also affect tear film properties[12,13]. In addition,

Table 1 Characteristics of contact lenses

Parameters	Material type			
	Hydrogel		Silicone hydrogel	
	Focus dailies	1d acuvue	Focus night & day	Purevision
USAN[a]	Nelfilcon A	Etafilcon A	Lotrafilcon A	Balafilcon A
Claimed Dk ($\times 10^{-11}$) [b]	26	21.4	140	101
Water content (%)	69%	58%	24%	36%
Polymer	PVA	pHEMA +MAA	DMA+TRIS+siloxane macromer	NVP +TPVC +NCVE +PBVC
Thickness at -3.00 D (mm)	0.1	0.084	0.08	0.09
FDA Group	Ⅱ	Ⅳ	Ⅰ	Ⅱ
Packing solution				
Buffering agent	Phosphate	Borate	Phosphate	Borate
pH	7.42±0.02	7.27±0.01	7.24±0.02	7.11±0.02
Osmolality	270±1[c] 299[d]	435[d]	302±1[c] 302[d]	316±2[c] 333[d]

PVA: Polyvinyl alcohol; pHEMA: Poly-2-hydroxyethyl methacrylate; MAA: Methacrylic acid; DMA: N,N- dimethylacrylamide; TRIS: Trimethylsiloxy silane; NVP: N-vinyl pyrrolidone; TPVC: Tris-(trimethylsiloxysilyl) propylvinyl carbamate; NCVE: N-carboxyvinyl ester; PBVC: Poly(dimethysiloxy) di (silybut anol) bis(vinyl carbamate). [a] United States Adopted Name; [b]Oxygen permeability value claimed by manufacturer, unit; (cm²/s) (mL O_2/mL×mm Hg); [c]Obtained from Lum *et al*[4]; [d]Obtained from Rogers[15].

the osmotic power shifts with time within the same subject[14]. Because of these tear film variations, contact lenses are exposed to various conditions in the eye. That means the contact lens parameters can vary from time to time, depending on the condition of the eye and the actual parameter values on the cornea can be different from the values indicated by the company.

Therefore, the present study was performed to investigate Dk changes in contact lenses under various physiological conditions, such as pH, osmolality, and buffering system. The purpose of this study is two-fold: 1) to evaluate Dk changes in various physiological conditions, for which the Dks of soft contact lenses were measured in different pH, osmolality, and buffering solutions; 2) to assess whether the Dk change of soft contact lens was dependent on lens materials, for which 4 different soft contact lenses were investigated.

MATERIALS AND METHODS

Lenses Two-hydroxyethyl methacrylate (HEMA)-based contact lenses and 2 silicone hygrogel contact lenses examined in this study are shown in Table 1 [4,15]. Nelfilcon A and lotrafilcon A lenses were commercially packed in phosphate-buffered saline [(PBS), pH 7.42 and 7.24, respectively], and etafilcon A and balafilcon A lenses were stored in borate-buffered saline [(BBS), pH 7.27 and 7.11, respectively]. The back vertex power of all lenses used was -3.00 D.

Contact lenses were incubated in each vial filled with 5 mL of the designated buffer and osmotic level solution for 24h at room temperature to remove any lingering effects from previous packing solutions. After incubation, contact lenses were re-soaked in the same fresh buffer and osmolality solution.

Solutions Isotonic PBS solutions with pH 5.8, 6.6, 7.4, 8.2 and 9.0 were made by properly combining 0.0667 mol/L Na_2HPO_4, 0.0667 mol/L NaH_2PO_4, NaCl and NaOH together. Isotonic BBS solutions in the range of 5.8-9.0 were prepared with 0.1 mol/L H_3BO_3, NaCl, HCl and NaOH.

An isotonic solution was made to match the recommendation stated in ISO 10344 (310 mOsmol/kg) [16]. Hypo-osmotic saline solution (280 mOsmol/kg) was chosen within the physiological range (280-320 mOsmol/kg) but at the lowest end of the normal tear range [17]. The concentration of hyper-osmotic solutions was 380 mmol/kg; this osmolality was based on a previous study that averaged osmolality values of lotrafilcon A lenses after 6h wearing; 380 mmol/kg was the highest level of contact lens osmolality in this study [18]. To prepare isotonic, hypotonic and hypertonic solutions, PBS solution were initially made in 10 × concentrations and maintained pH 7.4 with NaOH and diluted with double distilled water to adjust osmolality.

All pH measurements were taken using the pH meter (TW/SP-701, Sun-tex, Taiwan, China) with an accuracy of ±0.05. Three separate 10 mL samples were measured from each solution to obtain a mean pH value. The osmolality of three separate samples were measured using the osmometer (Vapro 5520, Wescor, USA) and the accuracy of measured osmolality was ±0.5 mOsmol/kg.

Measurement of Oxygen Permeability Dk of contact lenses were demonstrated by polarographic method using a modified permeometer (201t O_2 permeometer, Createch, USA). Lenses were stacked to measure the electronic current at various thicknesses. Measurement of Dk was conducted in a temperature and humidity-controlled box (wisecube ® WTH-E 155, Daihan scientific, Korea) at 35℃ and above 95% relative humidity. Polarographic cell (Gaurd ring polarograhpic cell, Reh-deveolment, USA), solutions of the incubated contact lenses and the contact lenses were placed in the box to allow the system to come to temperature equilibrium.

In this study, contact lenses were stacked in 2, 3, and 4 layers to measure different thicknesses of a sample's stable current, which is the same method used to correct a boundary effect in previous studies [19]. Twelve contact lenses in each experiment were allowed 10min to rehydrate in their vial in incubation solution after the measurement. The second measurement was taken 45min later, to allow the lens to fully rehydrate. If these two results were not concordant, a third measurement was made. This process was repeated for 6 stacks of two lenses, for 4 stacks of three lenses and for 3 stacks of four lenses. In each case, electronic thickness gauge (ET-3 electronic thickness gauge, Createch, USA) was used to measure single and multiple layers of contact lens samples. The entire test was repeated twice with different contact lenses.

From sample's stable current, Dk/t was calculated. Origin Pro 8 software (OriginLab, USA) was used for draw a liner graph to t/Dk on the vertical axis and sample thickness in cm on the horizontal axis. Slope of the line and correlation coefficient was obtained though this liner graph [19,20]. The range of Dk used in this study varied between 21.4 and 140 units [10^{-11} cm²/s (mL O_2/mL×mm Hg)]. To compare the differences induced by pH and osmolality, Dks of 4 different contact lenses in buffering solutions with various pHs and osmolalities were normalized as relative Dk/t.

Relative Dk/t = (Dk/t)'/(Dk/t)

Dk/t is the Dk/t value of a contact lens in each buffering system of pH 7.4 or isotonic solution. (Dk/t)' is the Dk/t value of a contact lens after each incubation in solutions with various pHs, osmolalities, or buffering systems.

RESULTS

Oxygen Permeability of Soft Contact Lenses in Different Buffer and pH Solutions In this study, phosphate and borate buffering systems were adjusted to pH levels of 5.8, 6.6, 7.4, 8.2, and 9.0 and were used to investigate the effects of buffering system and pH on Dk.

The Dk values of soft contact lenses in different buffers with pH 7.4 are shown in Table 2. The Dk values of nelfilcon A lens which were commercially stored in PBS was 34.46±3.04 units in PBS (pH 7.4) and 31.08±1.43 units in BBS (pH 7.4), which were around 30% higher than the Dk value provided by the manufacturer. It seems that the manufacturer estimated Dk with a single point polarographic method in which the boundary layer effect was not corrected for and the estimated Dk value was less than the Dk value obtained in our study. In PBS solutions, all Dk values of nelfilcon A lenses determined at various pHs illustrated weak relationship (r_{PBS}=0.332). Otherwise, similar Dk values were obtained for all BBS solutions with different pH levels (r_{BBS}= 0.173; Figure 1).

Table 2 The measured Dks of soft contact lenses in different buffering systems

USAN[a]	Buffering systems	Dk[b] in pH 7.4
Nelfilcon A	PBS	34.46±3.04[c]
	BBS	31.08±1.43
Lotrafilcon A	PBS	139.40±23.46[c]
	BBS	137.39±15.97
Etafilcon A	PBS	21.80±1.23
	BBS	23.68±2.08[c]
Balafilcon A	PBS	96.79±1.10
	BBS	94.37±4.76[c]

Values are expressed as mean ± SD. [a]United States Adopted Name; [b](cm²/s) (mL O_2/mL×mm Hg); [c]Measurement in buffering system equivalent to packaging buffer solution.

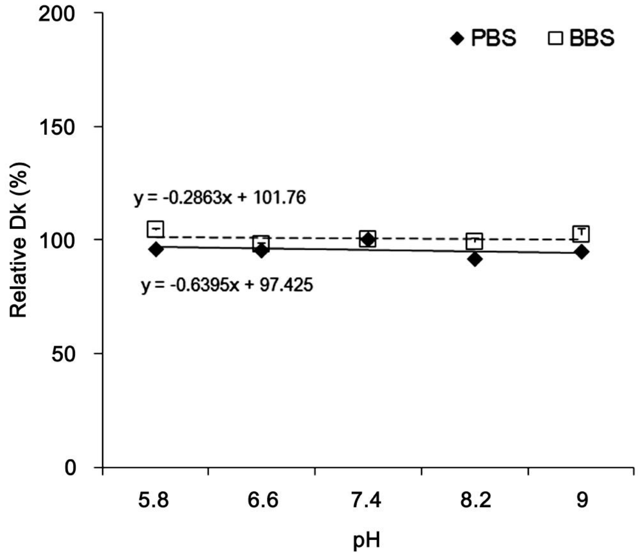

Figure 1 The relative Dks of nelfilcon A lens in different buffering systems with various pHs.

The Dk value of the lotrafilcon A lens in PBS was a little bit higher than that in BBS at pH 7.4 (Table 2). In BBS solutions, relative Dk values of lotrafilcon A lenses were shown no difference with same pH scales, while those in PBS solutions were shown weak relationship (r_{BBS}= 0.318, r_{PBS}= 0.007; Figure 2).

The Dk value of the etafilcon A lens, which was commercially stored in BBS, was measured at 23.68±2.08 units in BBS (pH 7.4). The Dk value claimed by the manufacturer for etafilcon A lens fell within the 95% confidence interval of the measured value and the Dk values in both solutions, varied depending on pH. (r_{PBS}=0.844, r_{BBS}= 0.500). However the values were more influenced in PBS than BBS. A measured Dk value in a pH 5.8 solution decreased by 30% compared to the Dk value in a pH 7.4 solution, and in pH 9.0 solutions, the Dk increased by as much as 175% of that of etafilcon A lens in pH 7.4 (Figure 3).

The Dk value of the balafilcon A lens, which was commercially stored in BBS, was estimated a little bit lower in BBS than in PBS at pH 7.4 (Table 2). The Dks of the balafilcon A lenses were more stable in PBS than in BBS

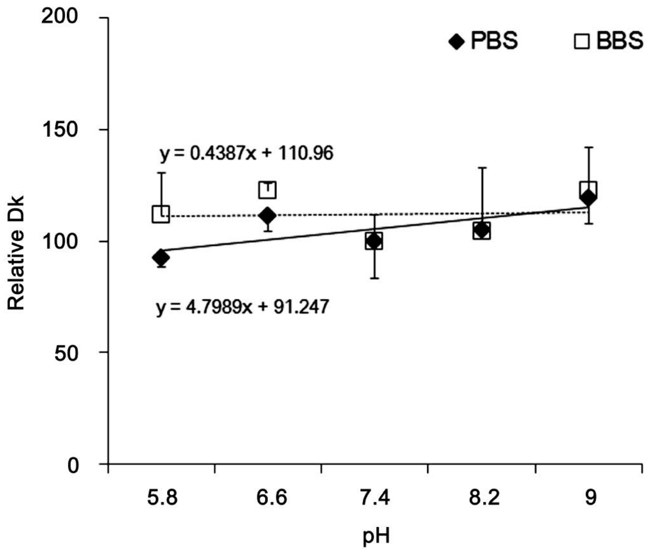

Figure 2 The relative Dks of lotrafilcon A lens in different buffering systems with various pHs.

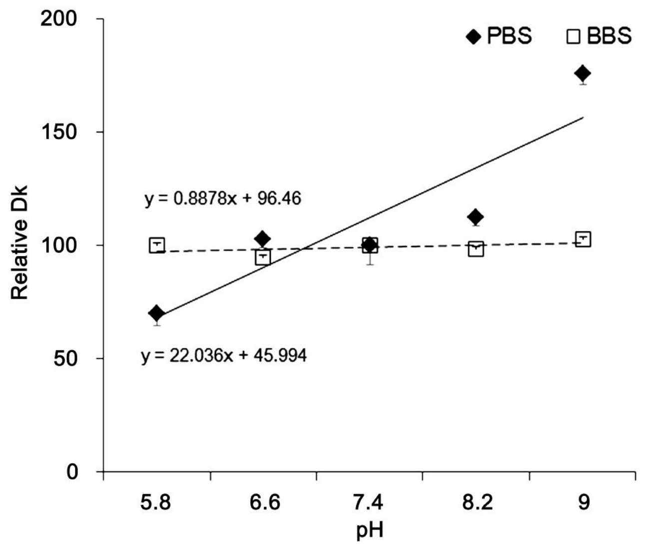

Figure 3 The relative Dks of etafilcon A lens in different buffering systems with various pHs.

with respect to pH change (r_{PBS}=0.768, r_{BBS}=0.815; Figure 4). The Dk values showed a decreasing tendency according to the buffer system when the pH increased from 5.8 to 9.0. The Dk values of contact lenses in BBS solution were more stable against pH change compared to the values in PBS solutions.

Oxygen Permeability of Soft Contact Lens in Solutions with Different Osmolality Dk values of all contact lenses decreased to a greater or lesser degree when the osmolality in PBS increased from hypotonic to hypertonic. The regression line regarding relative Dk and osmolality of solutions was plotted to display the differences in Dks between contact lenses (Figure 5). In hypotonic solution, Dk values of lotrafilcon A and balafilcon A increased by 3.36% and 4.65% of values obtained in isotonic solutions, respectively, but Dk values of nelfilcon A and etafilcon A lenses were not changed considerably -0.61% and 0.32%, respectively. The Dk values of contact lenses in hypertonic solutions decreased from 3.94% to 17.87%, except for nelfilcon A lens (0.67%).

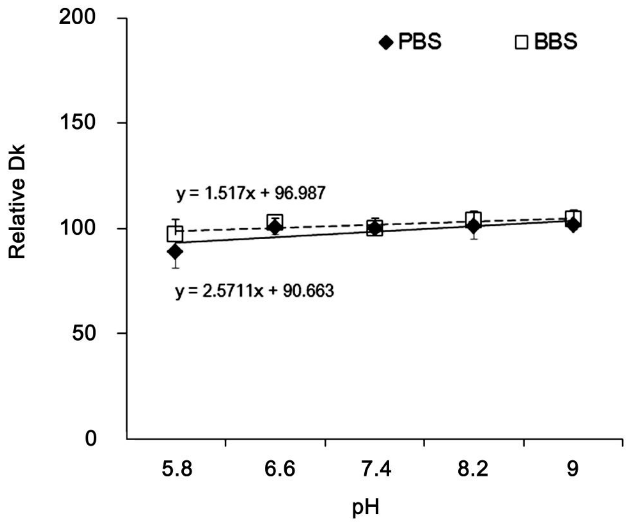

Figure 4 The relative Dks of balafilcon A lens in different buffering systems with various pHs.

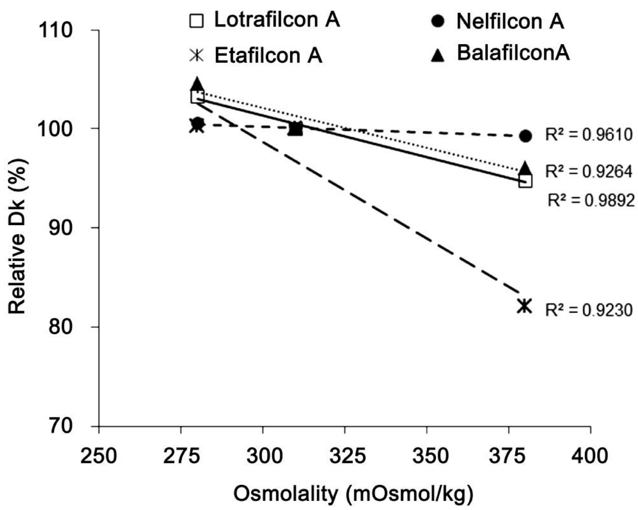

Figure 5 The relative Dks of contact lenses in different osmotic solution.

DISCUSSION

The packing saline for soft contact lenses commonly consists of either PBS or BBS. PBS is known for its physiological compatibility [21]. International Standards Organization (ISO) recommended PBS for measuring soft contact lens parameters. On the other hand, BBS is an anti-fungal agent and preservative-enhancing additive, and therefore, it minimizes the use of increased concentrations of preservative in the ophthalmic solution[22]. For these characteristics, BBS is preferred by many manufacturers as a packaging solution.

In the present study, Dk values of all lenses were more stable in BBS solution than PBS. Regarding pH in buffered solution, the Dk value of etafilcon A lens (ionic and high water content) was more influenced by pH change compared to other lenses, especially in PBS solution. In the case of nelfilcon A (non-ionic and high water) lens, however, Dk value was more stable than those of other contact lenses with different pHs in both PBS and BBS solutions.

In a study by Garrett and Milthorpe[23], the effect of pH on the swelling of contact lenses was determined. In their study, 3 types of contact lenses-tefilcon (FDA group I), vifilcon A (FDA group IV), and etafilcon A (FDA group IV)-were used: diameters of these lenses decreased in a solution with pH 2 while they increased in a solution with pH 11. Generally, in a HEMA monomer, oxygen is transported through the water-filled channels of the swollen gel; therefore, water content is a key factor for Dk of polyHEMA-based hydrogel contact lens [24]. Due to its high water content, the Dk of etafilcon A lens can be changed more compared with other contact lenses in the present study. However, other factors, besides water content, could be responsible for Dk changes since Dk of nelfilcon A lens was stable at different pHs, despite its high water content.

Other factors can be responsible for the relationship between lens material and ionic property. Tranoudis and Efron [6] demonstrated Dk stability of hydrogel contact lenses made from different materials after wearing. In case of the contact lens made from HEMA and MAA materials which are the same monomer of contact lenses in this study (etafilcon A), the parameter was statistically less stable than the other materials. This finding is similar with the present study that the Dk of etafilcon A (pHEMA+MAA) lens showed dramatic change in different pH and osmolality solutions. Water content is a critical factor of Dk in hydrogel contact lenses. However, in Tranoudis and Efron's study[6], the Dk of contact lenses composed of HEMA/VP 70% was more stable than other materials, despite their water content was the most in the experiment. That is to say those, contact lenses' monomer have relatively large effect on Dk variation. HEMA is known as an extremely stable hydrogel and variations in different situations, such as temperature, pH and tonicity has an influence on its water content [25,26]. The stability of material can become changed by the combination of monomers. Moreover, the different types of packing solutions have an effect on the lenses' Dk value in various situations [4].

The oxygen is mainly transferred through the siloxane domain which is the hydrophobic pores in silicone hydrogel materials while this is diffused through hydrophobic part of conventional contact lens. A study of Pozuelo *et al* [24] said that the hydrophilic phase would be resistance of oxygen diffusion compared with the hydrophobic phase in silicone hydrogel materials. Consequently, silicone hydrogel contact lenses were less affected by the water content of material compared with hydrogel lenses. And it can be seen on the present result that silicone hydrogel contact lenses were more stable than a hydrogel contact lens (etafilcon A) in various incubation solution.

This study was also performed to investigate the effect of osmolality on Dk of soft contact lenses. Dk values of etafilcon A and nelfilcon A lenses, which have high water content but different ionic properties, exhibited dissimilar patterns. With changing osmolality, the Dk of nelfilcon A (non-ionic) lenses was more stable than that of etafilcon A (ionic) lenses. In a study by Lum *et al* [4], the effects of packing solution osmolality and buffering agent on soft contact lens parameters were determined, and etafilcon A lens showed the largest change in parameters compared to other lenses; the ionic contact lenses were greatly predisposed to osmolality shift[8,27]. Dk values of lotrafilcon A and balafilcon A lenses (low water content, silicon hydrogel lens) similarly decreased when the osmolality of soaking solution increased from hypotonic to hypertonic, regardless of the ionic or non-ionic characteristic.

When a contact lens is in the eye, the osmolality of the contact lens changes resulting in evaporation of the lens's water and possibly increased contact lens osmolality [28]. In a previous study, the osmolality of lotrafilcon A lens after 6h wear was maximally increased to 384 mmol/kg (average 347 mmol/kg), which was higher than normal tear film osmolality. In our study, because the Dk value of the lotrafilcon A lens decreased in hypertonic solution, it is assumed that the actual Dk value on the cornea would be less than the value indicated by the manufacturer.

Dk values of all contact lenses used in this study decreased at different rates when the osmolality increased from hypotonic (280 mOsmol/kg) to hypertonic (380 mOsmol/kg). The increase in Dk differed according to the lens material, and these variations did not correlate with the water content of the lens material. The nelfilcon A lens (high water, non-ionic) was more stable than other contact lenses, while the Dk of the etafilcon A lens (high water, ionic) changed along with osmolality.

The Dk values of silicone hydrogel lenses were less affected due to higher Dk than etafilcon A lens (conventional hydrogel lens). This result would be demonstrated by different oxygen transferring system in two types of contact lenses-silicon hydrogel and conventional hydrogel contact lens-like a study of Pozuelo *et al* [24]. Furthermore, according to the difference of Dk values of hydrogel contact lenses-nelfilcon A and etafilcon A- in each pH and osmolality solution, the amount of change was different. It could be consecrated by the characteristic of contact lenses' monomer.

The properties of tear film can be altered by various environmental factors. Osmolality, pH, and property of tear film can be altered by physiological factors such as age, gender, eye disease, and hormones [10-13], and they can differ within the same individual according to biorhythms. This means that tear conditions that surround contact lenses change every minute. In the present study, the Dks of contact lenses were found to have different values according to the osmolality and pH of a solution, which differed from the Dks provided by manufacturers. This suggests that the real Dks of contact lenses in the eye can be different from the provided values because of the changing properties of tear film.

Moreover, Dk changes of contact lenses by the osmolality, pH, and buffering condition of tear have greater repercussion of clinical problems in traditional hydrogel lenses due to relativity low Dk (in particular etafilcon A lens in this study). However, these changes on silicone contact lenses should be less affected due to higher Dk. Further investigation is necessary to quantify the effects of these changes.

ACKNOWLEDGEMENTS

Conflicts of Interest: Lee SE, None; **Kim SR**, None; **Park M**, None.

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