



Investigation of the Effects upon Keratometry by Second Generation Silicone Hydrogel Contact Lenses

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Authors' contributions

This work was carried out in collaboration between all authors. Author OGS designed the study, wrote the protocol, and wrote the first draft of the manuscript. Author EK performed the statistical analysis. All authors read and approved the final manuscript.

Research Article

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ABSTRACT

Aim: Detection of keratometric differences induced by daily wear of second generation silicone hydrogel (SiH) contact lens (CL) with hydraclear.

Study Design: Prospective cross-sectional study.

Methodology: The researchers investigated the difference between the keratometric values at equivalent spherical and cylindrical diopters of daily wearers of second generation SiH CL and those in an age-matched control group who wear only spectacles because of SiH CL's stiffer moduli. The study also examined the effect of second generation SiH CLs on the corneal topography. Seventy asymptomatic, biomicroscopically normal eyes of SiH CL wearers and 70 eyes of non-lens wearer control subjects have been included in this study. The SiH CL wearers have been wearing lenses in the range of less than 6 months to 3 years. General Linear Models (GLM) with type III sum of squares was used (SPSS 15.0 for Windows).

Results: Statistical analysis showed no significant difference between two groups regarding keratometric values ($p > 0.05$).

Conclusion: Results suggest that daily wear of second generation SiH CL with hydraclear, which has moderate modulus and higher oxygen permeability, does not affect the central keratometric readings.

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1. INTRODUCTION

Contact lens induced (CL-induced) corneal warpage is defined as a change in corneal contour, which may result in either an increase or a decrease in astigmatism, accompanied by either a generalized flattening or steepening of the cornea [1,2]. Although CL-induced corneal warpage is most frequently associated with rigid CL, approximately 27% of reported cases of corneal warpage have been attributed to hydrogel lens wear [3]. The change in corneal contour may be the result of either mechanical deformation, chronic metabolic insult, or a combination of mechanical and metabolic challenges [4]. Changes in manifest refraction, keratometric shifts and significant topographic pattern differences were reported in the process of corneal warpage [5].

To date, very little has been published about the effects of second generation SiH CL on refraction and corneal curvatures the differences between the keratometric values at equivalent spherical and cylindrical diopters of daily wearers of second generation SiH CL and age-matched controls wearing only spectacles. The purpose of this study is to detect the keratometric differences induced by daily wear of second generation SiH CL with HYDRACLEAR[®] and HYDRACLEAR[®] Plus.

2. METHODOLOGY

This is a prospective case-control study involving one eye of 70 SiH CL wearers and seventy age- and sex-matched controls. The subjects and controls were enrolled in this study after signing an informed consent form. Cohort of the subjects and controls were recruited from the students attending the Middle East Technical University. The approval of the study was obtained from the ethics committee, and the study adhered to the tenets of the Declaration of Helsinki. Inclusion criteria for SiH CL wearers were considered as 20/20 visual acuity with correction, optimum lens fit overlapping the limbus by about 1 mm, no lens surface deposits or post-lens debris, wettability of the entire lens surface, normal findings on biomicroscopic examination with respect to Efron grading scale [6], having no systemic and ocular disorders other than refractive errors and having no history of ocular trauma and surgery. Inclusion criteria for controls were the same as those of the subjects except that the controls were wearing only spectacles and they had not used CL before.

The subjects were wearing second and third generation SiH CL with HYDRACLEAR[®] and HYDRACLEAR[®] Plus on a daily basis ranging from 5 to 15 hours. They were wearing either galyfilcon A (Acuvue^R AdvanceTM Vistakon, Jacksonville, FL) or senofilcon A (Acuvue^R OasysTM Vistakon, Jacksonville, FL) as spherical and toric designs. The purpose of including cases wearing second generation SiH CL rather than the first generation is the presence of surface treatment agent HYDRACLEAR[®] in the second generation SiH CL (Acuvue Advance) and HYDRACLEAR[®] Plus (Acuvue Oasys), as well as the abundance of cases wearing second generation rather than the third generation SiH CL. The modulus is defined as the degree of CL material's flexibility, or its resistance to being deformed [7]. The modulus of the Acuvue Advance (43g/mm^2) is comparable to a hydrogel lens and the Acuvue Oasys (modulus of 72g/mm^2) may affect the cornea differently. In addition, the oxygen transmissibility of these materials are higher than hydrogel lenses (approx. 25×10^{-9}) and lower than first generation SiH lenses (approx. 170×10^{-9}), where the Acuvue Advance has a

value of 86 barrer/mm and the Acuvue Oasys a value of 147barrer/mm which will also affect the results.

The contact lens wearers were using one of the following multipurpose solutions: either OPTI-FREE® Replenish® (Alcon Laboratories) or Aquify® multi-purpose solution (Ciba Vision).

One eye of each SiH CL wearer and control was included in this study. Each eye of an SiH CL wearer was assessed immediately after CL removal. They had had the SiH CL on for less than an hour, which was a drawback of this study. The manifest refractive states of the SiH CL wearers and controls were evaluated by Retinomax 2 Handheld autorefractometer (Nikon Inc, Japan). Retinomax K-plus2 autokeratometer (Nikon Inc. Japan) was used for the determination of both horizontal (K1) and vertical (K2) keratometric values of the SiH CL wearers and controls one hour after they woke up. The mode of spherical and cylindrical refractive error was used as the cutoff point for grouping. The controls and SiH CL wearers were grouped for the statistical analysis with respect to the most observed spherical power which was -2.00 diopter (D) as above and below -2.00 D. (Fig. 1) They were also grouped for the statistical analysis with respect to the cylindrical power as above and below -0.75 D related to wear of toric lenses at diopters -0.75 D or above. (Fig. 1) Fig. 1 indicated that the number of SiH CL wearers and controls with respect to the spherical and cylindrical power groups (cells) were not equal. In order to perform univariate analysis of variance with unbalanced design for K1 and K2 keratometric values, General Linear Models (GLM) with type III sum of squares was used (SPSS 15.0 for Windows). Within the analysis, the spherical and cylindrical values were considered as fixed effects, and $p < 0.05$ was considered statistically significant.

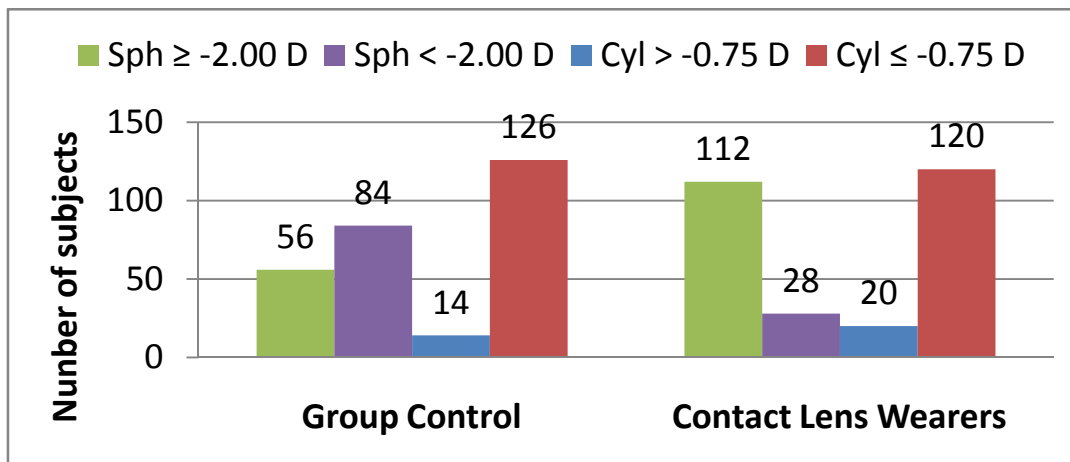


Fig. 1. The number of silicone hydrogel contact lens wearers and controls with respect to the spherical and cylindrical values

3. RESULTS

Demographic data, the mean (standard deviation, SD) of age, keratometric (K1 and K2) values, spherical and cylindrical values of SiH CL wearers and controls were shown in Table 1. Seventy SiH CL wearers (46 female, 24 male) had a mean (SD) age of 22.3 (2.82) years, and 70 controls (39 female, 31 male) had a mean (SD) age of 22.9 (3.91) years. The ranges

of spherical and cylindrical values for SiH CL wearers were between -8.75 D - 0.00 D and -1.75 D - 0.00 D, respectively. The ranges of spherical and cylindrical values for controls were between -8.75 D - +0.50 D and -1.75 D - +0.25 D, respectively. K1 and K2 values of SiH CL wearers and controls were analysed by General Linear Model procedure to test the differences between K1 and K2 values of SiH CL wearers and controls (Table 2). As a result of the GLM test, no significant differences were observed on K1 and K2 values for both groups ($p=0.802$ and $p=0.222$). Using the same procedure, K1 and K2 values of SiH CL wearers and controls at and above or below the spherical power of -2.00 D were analyzed by means of GLM used for unbalanced designs to examine whether there was a statistically significant difference. No statistically significant difference was found ($p=0.101$, $p=0.254$). Similarly, K1 and K2 values of SiH CL wearers and controls at and below or above the cylindrical power of -0.75 D were analyzed by unbalanced analysis of variance. No statistically significant difference was found between K1 values of SiH CL wearers and controls at and below or above -0.75 D ($p = 0.598$, Table 2). There was no statistically significant difference between K2 values of SiH CL wearers and controls at and below or above -0.75 D ($p = 0.160$, Table 2). Additionally, K1 and K2 values of the subjects enrolled in this study were analyzed with respect to spherical power at and above or below -2.00 D, and the results showed that there was no significant difference between K1 and K2 values of two spherical groups ($p=0.088$ and 0.134 , Table 2). However, with respect to cylindrical groups, K1 and K2 values were statistically different ($p=0.00$ and $p=0.00$, Table 2). Keratometric changes of SiH CL wearers were analyzed with respect to total duration of SiH CL wear and SiH CL daily wearing time, and the following descriptive statistics were obtained: 25.7% of the subjects were wearing SiH CL for 3 years, 24.3 % for 2 years, 18.5% for 1.5 years, 17.1% for 1 year, 8.8% for 6 months and 5.6% for less than 6 months. Additionally, 35.7% of the subjects were wearing their lenses for 15 hours/day, 48.2% for 8 hours/day, and 16.1% for less than 8 hours/day. To test both the effects of total duration and daily wearing time on K1 and K2 values, total duration and daily wearing time are divided into two period by setting 3 years and 24 hours as constraint. The time effect of SiH CL wear on K1 and K2 values was analyzed according to two time period (total duration <3 and total duration ≥ 3), and no significant time effect was found on both K1 and K2 values with respect to total duration ($p=0.436$ and $p=0.920$) and daily wearing time ($p = 0.305$ and $p=0.619$) of SiH CL.

Table 1. Demographic data, the mean (standard deviation) of age, keratometric (K1 and K2), spherical and cylindrical values of the controls and silicone hydrogel contact lens wearers

Subjects	Controls	Contact lens wearers
Number	70(39F,31M)	70 (46F,24M)
Mean(SD) of age, years	22,9 ± 3,91	22,3 ± 2,82
Mean(SD) of K1, mm	7,927 ± 0,273	7,919 ± 0,256
Mean(SD) of K2, mm	7,745 ± 0,269	7,709 ± 0,239
Mean(SD) of Spherical value, diopters	-1,791 ± 1,382	-3,336 ± 1,759
Mean(SD) of cylindrical value, diopters	-0,429 ± 0,338	-0,504 ± 0,357

SD: standard deviation

Table 2. p-values of the corresponding general linear models analysis conducted for the keratometric values K1 and K2 between the controls and silicone hydrogel contact lens wearers with respect to the spherical and cylindrical values

Keratometric values	Group	Spherical group		Cylindrical group		p-value
		<-2.00	>=-2.00	<= -0.75	>-0.75	
K1	Control	,101		,598		0.802
	CLW					
	p-value	,088		,000		
K2	Control	,254		,160		0.222
	CLW					
	p-value	,134		,000		

CLW: Contact lens wearers

4. DISCUSSION

All SiH CLs were known to share the hallmark of higher oxygen permeability, but notable diversity was reported in each SiH material's polymer chemistry, including first generation SiH CLs (balafilcon A, lotrafilcon A), second generation SiH CLs (galyfilcon A, senofilcon A, lotrafilcon B) and third generation SiH CLs (comfilcon A, enfilcon A) [8]. Second generation SiH CLs were known to be differentiated from the first-generation SiH CL with incorporation of a long-chain, high-molecular-weight polyvinyl pyrrolidone (HYDRACLEAR[®] and HYDRACLEAR[®] Plus), which serves as an internal wetting agent [9]. This diversity in the chemical compositions of SiH polymers was considered to cause variations in their clinical performances in challenging environments [8,9]. Prevalence of ocular surface symptoms, signs, and uncomfortable hours of wear in hydrogel CL wearers have been shown to be alleviated by refitting them with a second generation SiH CL [10]. However, biocompatibility, effect on the corneal homeostasis, and mechanical interaction of SiH CLs with ocular tissue were considered as issues for further investigations [11].

In this study, corneal topographical changes induced by first and second generation SiH CLs in 19 eyes of 10 patients after 3 months of daily wear have been compared with those caused by monthly disposable conventional hydrogel lenses over a 3-month period [12]. First and second generation SiH CLs were found to show greater corneal stability than hydrogel monthly disposable CLs regarding mean keratometry, corneal astigmatism, corneal eccentricity, superficial regularity and superficial asymmetry indices [12]. However, complications related to the mechanical properties of first generation SiH were reported in three patients in the follow-up time [12].

The effect of second generation SiH CLs on the corneal stability with respect to the ametropic eyes of non-CL wearers has not been studied before. We compared the keratometric values of those who wear second generation SiH CL on a daily basis with those in the control group with ametropic eyes and wearing only spectacles. We chose subjects with ametropic eyes and who have not worn CL before. The purpose of doing so was to eliminate the mechanical interaction of any type of CL with the ocular surface.

Previous studies have either compared the clinical performance of different types of SiH CL or compared the clinical performance of soft hydrogel CL with SiH CL [13,14]. Up to date comparative studies between SiH CL wearers and non-CL wearers regarding the corneal indices have not been reported yet. Our study compares the keratometric values of the second generation SiH CL wearers with the keratometric values of the subjects having

refractive errors at equivalent spherical and cylindrical diopters. The purpose of making comparisons at equivalent spherical and cylindrical diopters is to examine the relationship between keratometric measurements and the refractive power only. The linear correlations of keratometric values with both spherical and cylindrical powers have been disclosed [15,16]. Our study revealed no significant differences between the keratometric values of K1 and K2 at equivalent spherical and cylindrical diopters of second generation SiH CL daily wearers and those with ametropic eyes and wearing only spectacles.

5. CONCLUSION

Daily wear of second generation SiH CL with hydraclear, which have moderate modulus and higher oxygen permeability, does not affect the central keratometric readings. Corneal topographic changes may have revealed other differences since central K readings do not represent the total topographic effect.

CONSENT

All authors declare that 'written informed consent was obtained from the patient (or other approved parties) for publication of this case report and accompanying images.

ETHICAL APPROVAL

All authors hereby declare that all experiments have been approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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