Cornea Endothelial Cell Morphology in Short-Term Silicone Hydrogel Soft Contact Lens Wearers – Asian Context

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Abstract

Background: Silicone hydrogel lenses enable contact lenses to be worn on extended and continuous wear basis. The literature is scarce on the effect of this lens wear modality on the endothelial cells of the cornea, particularly amongst Asian.

Aims and Objective: The objective of this study is to determine corneal endothelial cell morphological changes amongst silicone hydrogel soft contact lenses in a sample of Malaysian subject.

Methods: Twenty seven (27) silicone hydrogel contact lens wearers were invited to participate in the study. Spectacle lens wearers were recruited as control and matched with respect to age and gender. Specular microscope was used to photograph central, superior, inferior, nasal and temporal corneal endothelium of the subjects. The corneal endothelial cell density, coefficient of variation of endothelial cell size and percentage of hexagonal cells were used as indicators of corneal morphological changes and were compared between the two groups of subjects.

Results: The subjects consisted of contact lens wearers who have worn their silicone hydrogel soft contact lenses up to 24 months on a daily wear basis. The results showed no significant differences in endothelial cell density, coefficient of variation of endothelial cell size and percentage of hexagonal cells between the silicone hydrogel soft contact lens wearers and controls.

Conclusion: Daily wear of silicone hydrogel soft contact lens of 3- 24 months durations does not cause corneal endothelial morphological changes in a sample of Malaysian subjects, probably due to the lens high oxygen transmissibility and short duration of lens wear. This implies that silicone hydrogel lenses are safe to be worn on extended daily wear basis but future studies should examine its long term effects on the Asian eyes.

Key words: Asians, Silicone hydrogel, contact lenses, cornea endothelium morphology, ECD, specular microscope

Introduction

The regularity of corneal endothelial morphology may be affected by the presence of ocular disease, ocular trauma, ocular surgery, contact lens wear, age and race.[1,2,3,4] Among these factors, contact lens wear was frequently associated with the incidence of corneal endothelial morphological changes. [5,6,7] One of the causes may be due to chronic exposure of the cornea to low level of oxygen that can induce permanent corneal endothelium morphological changes.[8] Morphological changes of corneal endothelium are significant as these will affect function of corneal endothelium cells.[9]

Conventional hydrogel soft contact lens wear was known to cause incidence of corneal endothelial polymegathism.[10] Hydrogel soft contact lenses that have low oxygen transmissibility can lead to chronic corneal hypoxia, which will subsequently lead to endothelial changes.[8] A minimum amount of oxygen level must be delivered through the contact lenses to the cornea to prevent these changes. Harvitt and Bonanno[11] suggested that a minimum level of 125 x 10^{-9} cm mLO_2/sec mL mmHg oxygen transmissibility for extended lens wear.

In corneal morphology studies, the endothelial cell density (ECD) was usually used as the parameter to measure the of amount of endothelial cell over specific areas, while coefficient of variation (COV) of endothelial cell size was used as measurement of endothelial cell size variation that estimate the degree of endothelial polymegathism, and the percentage of hexagonal cell was used as measurement of endothelial cell shape variation that estimate the amount of endothelial pleomorphism.

Lee et al.[6] in their comparative study of corneal endothelial changes induced by different durations of daily wear soft contact lenses reported greater COV in contact lens wearers as compared to non-contact lens wearers. A lower ECD on the central cornea (2613.6 ±215.8 cells per mm²) was noted only in contact lens wearers who have worn their lenses for 6 years or more as compared to non-contact lens wearers (2902.5 ±200.5 cells per mm²). The COV of those who had worn their lenses for ten years was also higher (0.33±0.08) compared to non-contact lens wearers (0.26±0.09). Carlson et al.[10] also found that the longer the wearing hours of conventional hydrogel soft contact lenses, the higher is the rate of corneal endothelial polymegathism.

Development of newer generation of silicone hydrogel soft contact lenses has enabled contact lenses to be worn continuously up to maximum of 30 days since it does not induce any corneal oedema, probably due to its high oxygen transmissibility. [12,13,14] Silicone hydrogel soft contact lens worn on extended wear basis for one year duration was found to have similar COV of endothelial cell size (less than 0.30) with non-contact lens wearers.[15] Refitting of silicone hydrogel soft contact lenses on conventional hydrogel soft contact lens wearers was also found to reduce corneal endothelial polymegathism.[16,17]

On the aspect of percentage of hexagonal cells, Lee et al.[6] reported the percentage of hexagonal cells of hydrogel soft contact lens wearers was less (55.4±6.5%) compared to non-contact lens wearers (70.6±9.4%). However, Yildiz et al.[18] showed no significant difference on the percentage of hexagonal cells between silicone hydrogel soft contact lens wearers and non-contact lens wearers. As silicone hydrogel soft contact lens wearers exhibit similar endothelial morphology with non-contact lens wearers, it can be presumed that extended wear of silicone hydrogel soft contact lenses of one year wearing duration does not cause significant changes on the corneal endothelial morphology.[15,18]

Most of the studies on the effect of silicone hydrogel soft contact lens wear on corneal endothelium morphology were carried out in western countries. Although there is no reason to believe that the effects of contact lenses on the endothelial cells in Asians are different from their western counterparts, some reports have shown ocular responses in Asians such as tear break up time, endothelial stress responses and eye parameters are indeed different.[19,20] To our knowledge this is the first study carried out in Malaysia to investigate the effect of daily wear of silicone hydrogel soft contact lenses on corneal endothelial morphology among young Malaysians adults.

Materials and Methods

Subjects

A total of 54 subjects consisting of 14 males and 40 females (108 eyes) were recruited by convenient sampling to take part in this study. All subjects were recruited at the Optometry Clinic, Faculty of Health Science, Universiti Kebangsaan Malaysia (UKM), Kuala Lumpur. Among the 54 subjects, 27 of them wore silicone hydrogel soft contact lenses on a daily wear basis for at least three months, with minimum wearing hours of 8 hours per day. All subjects were myopes, having healthy cornea, free from any ocular or systemic disease, and did not wear any other types of contact lenses beside silicone hydrogel soft contact lenses. Another 27 subjects consisted of control who wore spectacles. The age and gender of control subjects were matched with the experimental subjects. Any subjects who had history of ocular disease or trauma, systemic disease, less than 18 years old were excluded from the study.

Informed consent was obtained from each of the subjects prior to the study. Ethical approval was obtained from UKM ethical committee (UKM 1.5.3.5/244/NN-011-2013) on the use of human subjects and followed the tenets of Declaration of Helsinki.

Procedure

Routine preliminary examinations such as history taking, visual acuity, keratometry, refraction and determination of subjects' contact lens parameters were carried out prior to photography of corneal endothelium. The history taking included demography, determination of contact lens type, contact lens wearing modality and duration of subjects' contact lenses wear, presence of any ocular disease or injury as well as presence of any systemic disease. The experimental subjects were required to lay off their contact lenses for at least 2 hours prior to photography of corneal endothelium to eliminate the presence of any corneal endothelial bleb responses.

TOPCON Non-Contact Specular Microscope SP-3000P was used in this study to photograph the corneal endothelium. The specular microscope is equipped with five fixation targets, with one central and four peripheral fixation targets located on 12, 3, 6 and 9'o clock direction. Subjects were instructed to rest their chin on the chin-rest and fixate on the in-built target in the specular microscope. Subjects first fixated the central fixation target with the right eye and the central corneal endothelium was photographed. Infrared sensor within the specular microscope enabled the specular microscope to automatically aligned and centre the instrument at appropriate working distance in order to obtain clear corneal endothelium images. A corneal area of 8mm x 8mm was photographed automatically after the auto-tracking system had focused on the intended-capture corneal area. Three consecutive photos were photographed. Subjects were then instructed to fixate at the peripheral fixation targets at 12, 3, 6 and 9'o clock direction consecutively and thus allowed the endothelial photography of inferior, nasal, superior and temporal corneal endothelium. Three consecutive photos were photographed for each gaze direction of subjects. After the endothelial photography on the right eye was completed, the procedure was repeated for the left eye. All of the photographed corneal endothelial images were transferred from the specular microscope to the attached computer for corneal endothelium analysis.

IMAGEnet Cell Analysis Software is built within the computer for corneal endothelial cell analysis. Subjects' endothelial cells were viewed with 150X magnification. Corneal endothelial cell measurements such as ECD, COV of endothelial cell sizes, endothelial cell hexagonality, maximum and minimum endothelial cell sizes and average endothelial cell sizes were analysed and the mean results were recorded. The endothelial cell analyses of experimental subjects were compared with that of control.

Statistical analysis

Shapiro-Wilk normality test was used and the data was found normally distributed. Paired

-t test was used to determine whether there was any statistically significance difference in ECD, COV and percentage of hexagonal cells between right and left eyes of the subjects. The mean ECD, the COV of endothelial cell sizes and percentage of hexagonal cells between experimental subjects and control subjects were analysed and compared with the use of MANOVA test SPSS version 16. A two-tailed probability of 0.05 or less was considered statistically significant.

Results

Demography

The demographic data of experimental and control subjects were shown in Table 1. Except for refractive error, the experimental subjects and controls were matched in terms of age and gender. Mohammad-Salih[21] showed that age has an effect on ECD and corneal morphology in normal Malays but not gender. However difference in ECD was found significant between genders in Filipino eyes.[22] Sheng & Bullimore[4] reported that refractive error did not influence morphological changes between contact lens and non- contact lens wearers.

All subjects were young adults 20-26 years old, who have worn their silicone hydrogel lenses for a period of 3-24 months.

Types of silicone hydrogel soft contact lens used

Different brands of silicone hydrogel soft contact lenses were used by experimental subjects in this study, as shown in the Table 2. Although silicone hydrogel lenses can be worn on continuous wear basis up to 30 days without taking them off, all the experimental subjects wore their lenses on a daily wear basis regardless of the brand of their contact lens. A study by Mohidin & Fung[23] showed none of the contact lens practitioners in Malaysia recommended continuous lens wear modality for all contact lens types including silicone hydrogel lenses.

Data normality distribution

Using Shapiro-Wilk test, the data was found to be normally distributed as shown in Table 3 ($p > 0.05$).

Comparison between right and left eyes

Paired-t tests showed no significant differences between right and left eyes ($p > 0.05$) for both experimental and control subjects (Table 4), thus only the right eye was used in the subsequent analysis.

Comparison between experimental and control subjects

Multivariate analysis of variance (MANOVA) was used to compare the mean COV of endothelial cell size, mean ECD and percentage of hexagonal cells between silicone hydrogel soft contact lens wearers and control subjects (Table 5). The results showed no significant differences in all the parameters measured between the two groups ($p > 0.05$).

Discussion

The results showed no significant differences in corneal morphology (ECD, COV and percentage of hexagonal cells) at different locations of the cornea in subjects after wearing silicone hydrogel lenses when compared to controls. Changes effected on the cornea as results of contact lens wear have been attributed to chronic hypoxia occurring after prolonged contact lens wear and also due to low oxygen permeability of the lens materials. In this study the short duration of lens wear (3-24 months) and the high oxygen transmissibility of the silicone hydrogel lenses possibly prevented such changes. The results were also in agreement with previous studies by Carlson et al.[15] and Yildiz et al.[18] who showed no significant differences in ECD of silicone hydrogel lens wearers compared to controls.

The mean central corneal ECD for silicone hydrogel soft contact lens wearers and non-contact lens wearers in this study were 3104.00 ±210.39 cells/mm² and 3048.20 ±232.60 cells/mm² respectively. Studies by Ayala et al.[24] and Gutierrez et al.[25] reported that normal endothelial cell density on central corneal endothelium was about 3000 to 3500 cells/mm² in young adults, well within the range found in this study. However it is different from that reported by Mohammad-Salih[21] who quoted ECD of 2783±286 cell/mm^2 in normal Malay eyes within the same age group. The difference could be due to the sample used in Mohammad-Salih's study. Their group consisted of Malays only whilst in this study the subjects were of mixed ethnicity.

The COV of endothelial cell size is a useful measure of the variability of endothelial cell sizes[6,10,22]. Lee et al.[6] found that the COV of endothelial cell size was the first sign of observable corneal endothelial morphological changes induced by conventional hydrogel soft contact lenses. In their study subjects who wore hydrogel soft contact lens wearers on daily wear modality for one year showed a significantly greater value of COV of endothelial cell size when compared with non- contact lens wearers. However the proportion of hexagonal cells and the mean ECD were significantly different from the non-contact lens wearers only amongst those who have worn their hydrogel soft contact lens wearers for 6 years and more. Based on these findings, Lee et al.[6] suggested that COV of endothelial cell size appeared to be the most sensitive measurement to detect early corneal endothelial morphological changes. In this study no significant difference in COV was seen between the contact lens wearers and control, most probably due to silicone lens materials which has a high DK/t value that permitted enough oxygen necessary for corneal metabolism thus prevented hypoxia and morphological changes of the endothelial cells. The short duration and daily wear modality may also contribute to the findings.

Stocker and Schoessler[5] suggested that the COV of endothelial cell size on central corneal endothelium for non-contact lens wearers who are free from any ocular disease is always less than 0.30, or 30%. However, in this study the COV of endothelial cell size for central corneal endothelium was slightly higher (39.53 ± 3.36%) for non-contact lens wearers. Results from Mohammad-Salih[21] study also showed a higher COV (63.5±23.2%) in normal Malays within the same age group. The finding was also noted by Samaneh[26] who showed that ethnicity seem to contribute to differences in COV, with the Malays having higher COV of endothelial cells compared to Chinese. Based on NIBUT findings [19,27] Asian eyes were shown to have NIBUT values less than Caucasian, which may indicate drier eyes. This could have contributed to the higher COV values in Asian. Dry eyes effected the measurement of specular microscopy, as the reflected light beam from the corneal surface in dry eyed subjects might be deviated due irregular reflective surface leading to less than optimum reflection of the beam coming out from the specular microscopy.

In this study the age and gender of experimental and control subjects were matched to control the influence of age and gender on the endothelial morphology. Sheng & Bullimore[4] reported the COV of endothelial cell sizes was influenced by age and duration of contact lens wear but not refractive error. There were mixed reports on gender affecting COV of endothelial cell sizes.[21,22]

On the percentage of hexagonal cells, this study found no significant difference in the percentage of hexagonal cells between the silicone hydrogel contact lens wearers (59.74±3.30%) and non-contact lens wearers (59.59±3.44%). The results are similar to that of Schoessler et al.[28] that showed that silicone elastomer soft contact lenses with extremely high oxygen transmissibility produced no morphological changes on corneal endothelium. In this study most of the Dk/t of the silicone hydrogel lenses worn by subjects were quite high (range 101 to 175 x 10^{-9}cm mLO_2/sec mL mmHg); some were higher than the value recommended by Harvitt & Bonanno[11] for extended wear. The duration of lens wear was also short (3-24months).

Conclusion

In conclusion, daily wear of silicone hydrogel soft contact lenses did not cause significant corneal endothelial morphological changes in the Malaysian sample, probably due to its high oxygen permeability and transmissibility as well as short duration of lens wear. Since the tear characteristics of Asians are different, future study should examine the long-term effects of continuous wear of silicone hydrogel soft contact lens on the endothelial cells.

List of abbreviations

Dk/t: Oxygen trasmissibility

IRB permissions
This study was approved by the Medical ethics committee of Universiti Kebangsaan Malaysia (UKM 1.5.3.5/244/NN-011-2013).

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Table 1: Demographic data

***SiHy wearers** (N= 27)				**Control** (N= 27)		
	Males (N= 7)	Females (N= 20)	Total (N= 27)	Males (N= 7)	Females (N= 20)	Total (N= 27)
Age (Years)						
Mean±S.D.	23.71±0.75	22.90±0.23	23.11±1.34	22.86±0.59	22.50±0.54	22.59±1.19
Range	21- 26	20- 25	20-26	20- 25	20- 24	20-25
Rx (myopia)(D						
Mean±S.D.	3.36±1.27	4.66±2.47	4.32±2.27	2.54±1.67	2.28±2.08	2.34±1.96
Range	1.75 – 5.00	1.50 – 10.50	1.75 -10.50	0.75 – 4.50	0.75 – 7.50	0.75 - 7.50
Rx (WTR astig)(D)						
Mean±S.D.	0.57±0.76	0.38±0.34	0.43±0.47	0.36±0.40	0.39±0.34	0.38±0.35
Range	0.00 – 2.25	0.00 – 1.00	0.00-2.25	0.00 – 1.00	0.00 – 1.00	0.00-1.00
Wearing hours						
Mean±S.D.	11.14±1.07	11.30±1.17	11.26±1.13	-	-	-
Range	10 – 12	10 – 14	10- 14	-	-	-
Wearing durations (months)						
Mean±S.D.	9.29±3.77	12.10±7.00	11.37±6.37	-	-	-
Range	4 - 12	3 - 24	3-24	-	-	-

*SiHy-Silicone Hydrogels

Table 2: Brands of silicone hydrogel soft contact lens wore by subjects

Brand of silicone hydrogel soft contact lens	Lens materials	Water content (%)	Dk ($x10^{-11}$ cm^2/sec)	Dk/t ($x10^{-9}$ cm mlO_2/sec ml mmHg) (with reference to -3.00D)	Number of subjects
Focus Night and Day (CIBA VISION)	Lotrafilcon A	24	140	175	4
Air Optix Aqua (CIBA VISION)	Lotraficon B	33	110	138	10
Acuvue TruEye (Vistakon)	Narafilcon A	46	100	118	3
Acuvue Oasys (Vistakon)	Senofilcon A	38	103	147	5
PureVision (Bausch & Lomb)	Balafilcon A	36	99	101	3
Biofinity (CooperVision)	Comfilcon A	48	128	160	3

Table 3: Data normality distribution test (Shapiro-Wilk)

Subject			**p value**
*SiHy wearers	**ECD**	0.107	
	Central	0.271	0.107
	Superior	0.016	0.271
	Inferior	0.346	0.160
	Nasal	0.151	0.346
	Temporal		0.151
	COV		
	Central		0.155
	Superior		0.019
	Inferior		0.537
	Nasal		0.336
	Temporal		0.124
	% Hexagon cells		
	Central		0.062
	Superior		0.300
	Inferior		0.500
	Nasal		0.127
	Temporal		0.072
Controls	**ECD**		
	Central		0.159
	Superior		0.455
	Inferior		0.669
	Nasal		0.387
	Temporal		0.198
	COV		
	Central		0.109
	Superior		0.070
	Inferior		0.652
	Nasal		0.090
	Temporal		0.090
	% Hexagon cells		
	Central		0.134
	Superior		0.061
	Inferior		0.080
	Nasal		0.068
	Temporal		0.080

*SiHy: Silicone Hydrogels

Table 4: Comparison between right and left eyes of experimental and control subjects

Subjects		Right eye	Left eye	p-value
SiHy wearers (N= 27)	**ECD**	Mean ±S.D.	Mean±S.D.	
	Central	3104.00±210.39	3103.00±247.75	0.968
	Superior	3479.90±214.06	3406.50±209.41	0.881
	Inferior	3124.40±198.08	3148.90±221.93	0.340
	Nasal	3221.10±221.69	3236.80±187.33	0.573
	Temporal	3213.00±187.88	3231.60±188.99	0.703
	COV	Mean±S.D.	Mean±S.D.	
	Central	38.17±4.43	38.57±4.49	0.423
	Superior	41.56±5.19	41.63±4.67	0.774
	Inferior	39.76±3.53	39.85±3.49	0.726
	Nasal	38.42±4.46	38.69±4.69	0.443
	Temporal	41.43±4.73	41.56±5.40	0.661
	%Hexagon cells	Mean±S.D.	Mean±S.D.	
	Central	59.74±3.30	59.56±2.72	0.394
	Superior	51.85±3.21	51.81±2.86	0.866
	Inferior	53.89±3.37	53.85±2.92	0.866
	Nasal	57.96±3.29	57.78±3.04	0.394
	Temporal	56.30±3.36	56.19±2.88	0.611
Control subjects (N= 27)	**ECD**	Mean±S.D.	Mean±S.D.	
	Central	3048.20±232.60	3108.60±200.74	0.128
	Superior	3389.20±278.74	3345.10±268.92	0.133
	Inferior	3056.30±237.36	3049.90±250.70	0.947
	Nasal	3131.00±218.83	3138.90±231.18	0.733
	Temporal	3099.20±278.40	3105.50±243.00	0.755
	COV	Mean±S.D.	Mean±S.D.	
	Central	39.53±3.36	39.98±3.62	0.062
	Superior	42.98±4.16	42.69±4.00	0.177
	Inferior	39.90±4.20	39.82±4.30	0.728
	Nasal	39.73±5.09	39.90±5.06	0.414
	Temporal	41.03±4.73	40.92±5.05	0.672
	%Hexagon cells	Mean±S.D.	Mean±S.D.	
	Central	59.59±3.44	59.30±3.06	0.187
	Superior	50.81±3.88	50.59±3.59	0.327
	Inferior	52.93±3.90	52.70±3.58	0.327
	Nasal	57.56±3.73	57.19±3.32	0.096
	Temporal	55.78±3.62	55.33±3.34	0.143

Table 5: Comparison of ECD, COV and % Hexagon cells between experimental and control subjects (MANOVA)

	Position	SiHy wearers (N= 27)	Control subjects (N= 27)	p value
ECD		Mean±S.D.	Mean±S.D.	
	Central	3104.00±210.39	3048.20±232.60	0.433
	Superior	3479.90±214.06	3389.20±278.74	
	Inferior	3124.40±198.08	3056.30±237.36	
	Nasal	3221.10±221.69	3131.00±218.83	
	Temporal	3213.00±187.88	3099.20±278.40	
COV		Mean±S.D.	Mean±S.D	
	Central	38.17±4.43	39.53±3.36	0.210
	Superior	41.56±5.19	42.98±4.16	
	Inferior	39.76±3.53	39.90±4.20	
	Nasal	38.42± 4.46	38.42±4.46	
	Temporal	41.43±4.73	41.43±4.73	
%Hexagon cells		Mean±S.D.	Mean±S.D.	
	Central	59.74±3.30	59.59±3.44	
	Superior	51.85±3.21	50.81±3.88	
	Inferior	53.89±3.37	52.93±3.90	0.504
	Nasal	57.96±3.29	57.56±3.73	
	Temporal	56.30±3.36	55.78±3.62	

(ECD: $F(5,48)= 0.908$, $p> 0.05$, Wilk's lambda= 0.914, partial eta square= 0.086; COV: $F(5,48)= 1.493$, $p> 0.05$,Wilk's lambda= 0.865, partial eta square= 0.135; % hexagon cells: $F(5,48)= 0.877$, $p> 0.05$, Wilk's lambda= 0.916, partial eta square= 0.084)