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Effect of Long-Term Soft Contact Lens Wearing on Corneal Endothelial Cells and Central Corneal Thickness

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Abstract

Background: **Long-term use of contact lenses may lead to various changes in the tear layer, conjunctiva, and cornea depending on the oxygen-permeability of lenses. Contact lens-induced- hypoxia and corneal edema caused by acidosis.** ***Aim:*** **to evaluate the effect of long-term, soft contact lens wear on corneal endothelium and corneal thickness aiming at improving the quality of vision in contact lens wearers and keeping their corneas healthy as considered a precious refractive surface of the eye.** ***Patients and Methods:*** **This cross-sectional case-control study included 96 eyes (48 right and 48 left eyes) of 48 participants randomly selected with the age group between 18-30 years, 30 female, and 18 male. Participants were divided into two groups (case and control group) each of which included 48 eyes.** ***Results:*** **There is a statistically significant difference between both groups regarding BCVA (*p*= 0.001). while, the changes in CCT in contact lens wearers were not statistically significant (*p* =0.9) unlike the morphological parameters as CD (P <0.001), CV (p- =0.004), SD (p- =0.001) which shows statistically significant changes. There was no significant difference as regards (CCT), the hexagonal appearance of the cell (HEX%), and average cell area (AVG) between the contact lens wearer and control group. The baseline means of endothelial cell density in group 1 was 2911 ± 244 cells/mm^2, while group 2 was 2610 ± 173 cells/mm^2. There was a statistically significant difference between the case and control group as regards endothelial cell density (ECD) (*p* <0.001). The mean of (CV%) in group 1 was (28 ± 6), while in group 2 was (28 ± 6). There was a statistically significant difference between the contact lens wearer and the control group as regards (CV%) (*p* = 0.004). Conclusion: Long-term soft contact lens use (> 1 year) affects cell density (CD) and morphological features (coefficient of variation (CV), pleomorphism, and polymegathism).**

Keywords: Soft Contact Lens, Corneal Endothelial Cells, Central Corneal Thickness.

Introduction

The human corneal endothelial cells are non-regenerating predominantly hexagonal cells, which cover the posterior surface of the descemet's membrane and face the anterior chamber of the eye. Corneal endothelium is metabolically active and plays an imperative role in maintaining corneal transparency by pumping water from the stroma

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to the aqueous humor and keeping the stroma in the dehydrated level of 70% of water[1]. Consequently, a disturbance of endothelial functions can provoke corneal edema followed by partial or complete loss of transparency when a decrease in endothelial cell density and an abnormal cell mosaic, which may occur after many conditions, can compromise the integrity of the endothelial monolayer, resulting in corneal decompensation with reduced vision. Corneal endothelial cell density and morphology can be analyzed using specular microscope. The specular microscope has been shown to be reliable and reproducible with appropriate calibration of the instrument[2]. Non-contact Specular microscope provides a non-invasive method of morphological analysis of the corneal endothelial cell layer. It gives the measurement of mean cell density (MCD), measurement of coefficient of variation (CV) in the cell size as well as hexagonal appearance of the cell. These parameters provide an index of the functional status of corneal endothelial layer[3]. Contact lenses are the optical devices used to correct refractive errors. They can be divided in two groups: hard and soft contact lenses depending on the material used. Polymethylmethacrylate (PMMA) material which is a plastic material impermeable to oxygen, afterwards gas-permeable hard lens materials were discovered and the first rigid RGP, then new-generation contact lenses manufactured from silicone hydrogel (SH) make a breakthrough with their high oxygen permeability[4]. This study aimed at improving quality of vision in contact lens wearers and keeping their corneas healthy as considered a precious refractive surface of the eye.

Patients and Methods

A Case control study was conducted on patients wearing soft contact lens from more than one year who were attending Outpatient Clinic, Ophthalmology Department, Suez Canal University Hospital, Ismailia, Egypt 2020. This study included 2 groups First group of patients wearing soft contact lenses more than a year 6 hours / day (study group). The other group for cases with no history of soft contact lens wearing (control group). The study included patients wearing soft contact lenses more than a year 6 hours / day (study group) aged 18-30Yrs, of both genders. We have excluded patients with any of the following: Any corneal disease (keratoconus, allergy, dry eye, Fuchs endothelial dystrophy,keratitis, corneal ulcers ,corneal opacity, perforation). Corneal surgeries (LASIK or any refractive surgery, keratoplasty). Systemic disease (diabetes mellitus, hypertension, autoimmune disease, sarcoidosis, Behcet's disease). Any ocular pathology affecting cornea (Acute angle closure Glaucoma). Intraocular inflammation such as anterior and posterior uveitis 7- Pregnancy and lactation. Smolers and those with Mental Illness or on immunosuppressive therapy.

Methods

All enrolled patients were evaluated by detailed ophthalmic examination by detailed history. Visual acuity assessment: unaided and best corrected using snellen chart then using decimal natation for interpretation. Refraction: using Autorefractometer (NIDEK ARK-510A made in japan). Examination of lids, orbit, lacrimal system, ocular motility. Slit-Lamp biomicroscopic examination (Topcon slit lamp SL-D7 made in JAPAN): full examination of the anterior segment will be performed for tear film (tear film break up

time, Schimer's test), cornea, sclera, anterior chamber, iris , pupil , lens. Intra-ocular pressure measurement: using Goldman applanation tonometer (HAAG-STREIT international.)

Fundus examination
Indirect ophthalmoscope (APPASAMY ASSOCIATES India). Volk's non-contact double aspheric biconvex lens (power: + 90).

Investigations: Specular microscopy
Corneal endothelial cell analysis was carried out by using A non-contact specular microscope: (NIDEK CEM -530 Hiroishi ,Gamagori, Aichi, Japan). The corneal endothelial cell count and morphology measurements were done using a noncontact specular microscope. Examination of the cells by specular microscopy allows the evaluation of endothelial cell count, cell density, variation in size (polymegathism), and variation in shape (pleomorphism).

Study procedures
Each of contact lens wearer group (study group) and non-wearer one (control group) were informed about procedure before doing it. With the specular microscopy, the patient was seated with the chin on the chin rest and slightly pressing the forehead into the headband and was asked to look into the built-in fixation target. The head position was adjusted and automatic focusing was done so that the image of the pupil on the monitor was in clear focus and within the aiming circle visible on the monitor. Corneal morphology and structure measurements were taken by center method. At proper alignment and focus, the instrument took both specular microscope and corneal thickness measurements. *Between three successive measurements, the patient was asked to relax and blink a few times.

Statistical Analysis

Data was presented as appropriate e.g using tabular and graphic presentations. Gathered data was processed using Statistical Package for the Social Sciences (SPSS) version 20.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics was expressed in: Number (No), percentage (%) mean ($\bar{x}$) and standard deviation (SD). While, Analytic statistics e.g. Mann Whitney's test was used for comparison of quantitative variables between two groups of not normally distributed data, and Chi-square test ($\chi 2$) was used to study association between qualitative variables. Whenever any of the expected cells were less than five, Fischer's Exact test was used. A probability value (p-value) < 0.05 was considered statistically significant.

Ethical consideration

The Research Ethics Committee of Suez Canal University approved the protocol of this thesis. The study followed the declaration of Helsinki.

Results

Participants were divided into two groups (study group (group A) and control group (group B)) each of them included 48 eyes. The mean age of study group was 23.5 ± 3.1 years. While, of control group was 23.7 ± 3.5 years. No statistically significant difference was found between both groups as shown in table 1. Gender was the same in study group as well as control group ;18(37.5%) for males while 30 (62.5%) for females. No statistically significant difference was found between both groups as in table 1. In table 2, Mean of

visual acuity in study group was 0.35 ± 0.17 and 0.4 ± 0.14 in control group with no statistically significant difference was found between both groups regarding visual acuity.

Table 1: Age and gender of patients

Variable	Study group	Control group	Test of significance	P value
Age (Yrs.)	23.5 ± 3.1y	23.7 ± 3.5	t-test	0.1
Gender				
Male	18 (37.5%)	18 (37.5%)	χ^2	0.5
Female	30 (62.5%)	30 (62.5%)		

Data are presented as mean ± SD or frequency and percent. χ^2: Chi-square. P value is significant <0.05

Table (2), regarding Best corrected visual acuity (BCVA), the mean BCVA of study group was 0.7 ± 0.1. while in control group was 0.8 ± 0.2. There is a statistically significant difference between both groups regarding their best corrected visual acuity (p value=0.001). The mean spherical error of refraction was different between both groups (- 0.94 ± 1.8D versus -0.97 ±0.91D). A statistically significant difference was found between both groups regarding their cycloplegic spherical equivalent of refraction (Table 2). The most frequently reported mean cycloplegic spherical equivalent of refraction was -2 among study group, and -1 among control group (Figure 1).

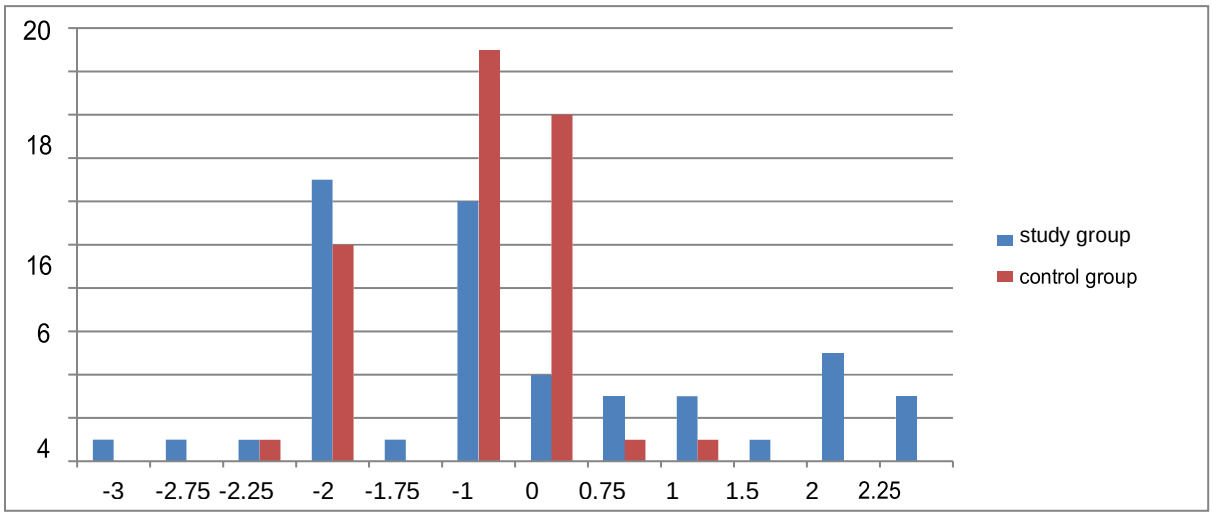

Figure 1: Distribution of cycloplegic spherical equivalent of refraction scores in study group and control group

The mean duration of lens wearing among study group was 3 ± 1.5 years. 30 eyes (62.5%) have been wearing lenses for a period ranged between 1-3 years, while 18 eyes (37.5%)have been wearing it for more than 3 years (figure 2). The mean Central Corneal Thickness (CCT) was 523 ± 32 among study group and 522 ± 30 among control group. No statistically significant difference was found between both groups regarding CCT (Table 3). The mean Corneal endothelial Cell Density (CD) was significantly higher among

study group (2911 ± 244) while in control group was (2610 ± 173). There was a statistically significant difference between study group and control group regarding CD (Table 3). Mean of Coefficient of variation (CV) was 28 ± 6 among study group and 31 ± 5 among control group, with a statistically significant difference between both groups (Table 3). The mean of Hexagonality (HEX) was higher among control group (59 ± 12) than study group (56 ± 15). There is no statistically significant difference between both groups (Table 3). The mean of Standard Deviation of cell area (SD) was higher among control group (124 ± 30) than study group (104 ± 26).There is a statistically significant difference between both groups (Table 3). The mean of average cell area (AVG) was higher among controls group (402 ± 66) than study group (398 ± 74). There is no a significant difference between study group and control group regarding AVG (Table 3).

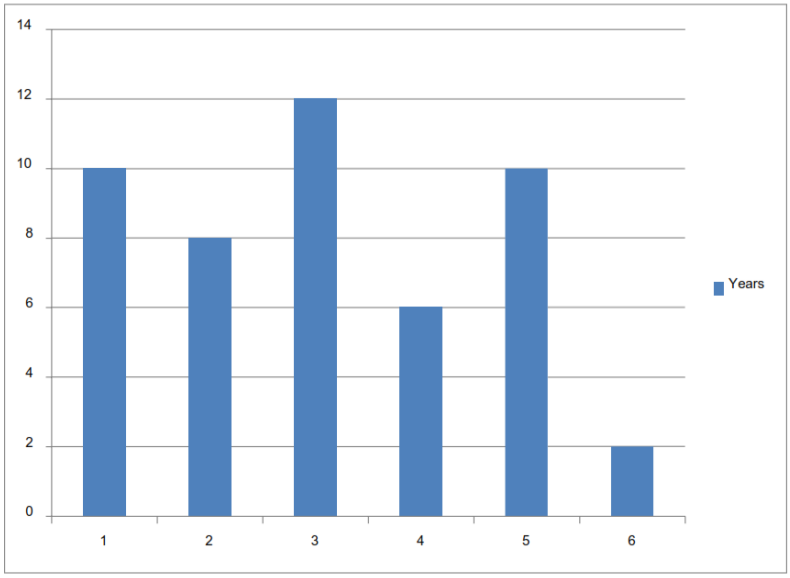

Figure 2: Duration of lens wearing among study group

Table 2: Visual acuity, BCVA and cycloplegic spherical equivalent of refraction in study group *vs.* control group

Variable	Study group (N=48)	Control group (N=48)	Test of significance	P value
Visual acuity (Decimal)	0.35 ± 0.17	0.4 ± 0.14	t-test	0.1
BCVA	0.7 ± 0.1	0.8 ± 0.2	t-test	**0.001**
Spherical equivalent	-0.94 ± 1.8D	- 0.97 ± 0.91D	t-test	0.2

Data are presented as mean ±SD. P value is significant <0.05. BCVA: best corrected visual acuity.

Discussion

In our study we evaluate the effect of long-term contact lens wear on corneal endothelium and corneal thickness aiming at improving quality of vision in contact lens wearers

and keeping their corneas healthy as considered the main refractive surface of the eye. Concerning BCVA, 75% of the group A had BCVA of 0.63, while in group B represented 56%. 25% of group A had normal visual acuity; whereas 50% in group B . There is a statistically significant difference between both groups regarding their BCVA. (P= 0.001). Spherical error of refraction was more among group A. Almost all group A had spherical error of refraction (92%), while in group B was (67%). A statistically significant difference was found between both groups regarding their spherical error of refraction. (- 0.97±0.91D *vs* -0.9±1.4D). (p =0.2). on-contact specular microscopy was used to evaluate Central corneal thickness, Endothelial cell density, Coefficient of Variation and percentage of hexagonal cells, average cell area standard deviation of cell area. mean CCT among study group was 523±32 µm, while control group was 522±30µm

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Table 3: Comparison between different parametes in the Study group vs the control group

Variable	Study group (N=48)	Control group (N=48)	P value*
Central Corneal Thickness (CCT)	523 ± 32	522 ± 30	0.9
Corneal endothelial Cell Density	2911 ± 244	2610 ± 173	**<0.001**
Coefficient of variation (CV)	28 ± 6	31 ± 5	**0.004**
Hexagonality (HEX)	56 ± 15	59 ± 12	0.2
Standard Deviation of cell area (SD)	104 ± 26	124 ± 30	**0.001**
Average Cell area (AVG)	398 ± 74	402 ± 66	0.8

*Data are presented as mean ± SD, P value is significant <0.05. *= t-Test*
Normal CV is <40. Normal hexagonality is > 50%. Normal SD is ≤ 120. Normal average cell area is 200-500.

There was no statistically significant difference between group 1 and group 2 as regard (CCT) (P value = 0.9). Mohd-Ali, B. and Chen, L.Y., 2020 reported that a total of 72 subjects and 24 non- CL wearers (control) participated in this study. The gender distribution for study subjects was 13 males and 59 females, with a mean age 22.15 ± 1.84 years old. The mean refraction was –1.86 ± 1.25DS. The duration of wearing CL ranged from 1 to 9 years. Subjects were later divided into 2 groups following duration of CL wear: Group 1 (<5 years) and Group 2 (≥5 years) for analysis purposes. No significant change was found in CCT. CCT (um) p =0.01. Statistical analysis between groups using ANOVA showed significant differences (p < 0.05) in all parameters except for CCT (SCL, p = 0.829). CCT was not affected by CL material (p = 0.468) and wear duration (p = 0.183)[5]. Ahmad, A., et al. 2018 The results of this study showed no significant difference in the corneal central thickness between subjects wearing soft hydrogel contact lenses and spectacles before and after 6 months of contact lens wear. Baseline (p value 0.41 ,6 months 0.87)[6]. Turhan, S.A., et al. 2020 With contact lens wear, no significant change occurred in the corneal and epithelial thickness during the day (all p values>0.05). There was no statistically significant difference in the epithelial thickness among the groups wearing different contact lens types (p>0.05). The corneal epithelial thickness is

not affected by daily disposable soft contact lenses. Regardless of the lens type, CL wear had no effect on the corneal and epithelial thickness (p>0.05). There was no significant difference in the epithelial thickness among the groups (p>0.05)[7]. The baseline means of corneal endothelial cell density in study group (group A) was 2911 ± 244 cells/mm2, while control group (group B) was 2610 ± 173 cells/mm2. There was statistically significant difference between case and control group as regard endothelial cell density (ECD) (P value <0.001). Mohd-Ali, B. and Chen, L.Y., 2020 A total of 72 subjects and 24 non-CL wearers (control) participated in this study. The gender distribution for study subjects was 13 males and 59 females, with a mean age 22.15 ± 1.84 years old. The mean refraction was −1.86 ± 1.25DS. The duration of wearing CL ranged from 1 to 9 years. Subjects were later divided into 2 groups following duration of CL wear: Group 1 (<5 years) and Group 2 (≥5 years) for analysis purposes. Statistical analysis between groups using ANOVA showed moderate but significant relationship (p<0.01)between ECD and duration of CL wear[5]. Ahmad, A., et al. 2018 This study found no significant change in corneal endothelial cell morphology after 6 months of wearing SH contact lenses. Statistical analysis showed no significant difference in measurements at baseline (P=0.13) and at 6 months (P=0.08) between both groups. Statistical analysis revealed no significant difference (P>0.05) in measured between both groups[6]. in our opinion this difference is due to different contact lens duration(6 months). Mondal, M.A. and Mandal, M.R.,2020 tells that ECD cell area was not statistically significant and also there was no clinically significant difference. Yagmur, M., et al 2011 did not detect a significant difference between endothelial cellular densities of contact lens wearers and non-wearers. None of the patients were wearing contact lenses for10 years; this might be the reason for the insignificance of endothelial cellular density between the groups.[8] In our opinion this difference is due to different sample size (284 eyes of 142 participants). The mean of coefficient of variation (CV%) in group A was (28 ± 6), while in group B was (28 ± 6). There was statistically significant difference between contact lens wearer and control group as regard (CV%) (P value = 0.004). Mohd-Ali, B. and Chen, L.Y., 2020 Statistical analysis showed significant alterations COV of CL wearers (p < 0.05), with more changes found in HCL and Group 2 wearers. Correlation analysis also showed moderate but significant relationship (p<0.01) between COV (r=-0.460) and duration of CL wear. Statistical analysis using two-way ANOVA showed that CL material and wear duration significantly changed COV (, p < 0.001) of endothelial cells,with greater changes induced by HCL and Group 2 (≥5 years) wearers compared with the other groups[5]. Ahmad, A., et al 2018 in contrary to our results , said that there is insignificant change in COV at baseline p value 0.4 and after 6 months of wearing hydrogel contact lenses p value 0.9. Statistical analysis revealed no significant difference (P>0.05) in all parameters measured between both groups. COV (%)Baseline 0.43 and 6 months 0.92)[6]. The percentage of hexagonal cells (HEX%) in control group showed mean= 59 ±12% while in study group was 56 ± 15%.There was no significant difference statistically between the two studied groups (P value =0.2). Alotaibi, B.S. et all. the difference in endothelial cellular hexagonal

ity between soft contact lenses (SCL) group and control group in our study was significant HEX (P=0.03). The numbers of hexagonal cells generally downgraded to about 50-60% of the endothelial mosaic, and they also tend to deviate from the typical hexagonal pattern[9] In our opinion this difference is probably due to different sample size and duration of lens wear. Standard deviation of cell area in study group showed mean=104 ± 26 while in control group was 124 ± 30.There was statistically significant difference between studygroup and control group as regard (SD) (P= 0.001). Average cell area (AVG) in study group showed mean= 398 ± 74 while in control group was 402 ± 66.There was no significant differenc statistically between the two studied groups (P= 0.8). There are no previous studies mentioned effect on Standard deviation of cell area (SD) and Average cell area (AVG) after wearing soft contact lenses. There were some limitations to our study as Conflicting results among studies that might be due to; different number of eyes (sample size), duration of contact lens wear, Measurement devices slit scanning or laser scanning confocal microscopy, Techniques for image acquisition and disease severity.

Conclusion

Long term soft contact lens use (more than a year) affects cell density (CD) and morphological features (coefficient of variation (CV), pleomorphism and polymegathism).

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