



The Effect of ChromaGen Contact Lenses on Corneal Clarity: A Corneal Densitometry

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Abstract

Objectives: The purpose of this study is to investigate the effect of ChromaGen contact lens (CCL) on corneal clarity, expressed through the measurement of corneal densitometry (CD) values.

Methods: This study included 22 eyes of 22 patients with congenital red-green color vision deficiency who were admitted to our clinic for the CCL trial. After a detailed ophthalmological examination and CD measurement with Pentacam HR (Oculus Optikgerate GmbH, Wetzlar, Germany), the most appropriate CCLs were defined through pseudisochromatic plates and inserted for 2 h. The CD measurement was repeated after the removal of the CCL. Comparison was made of CD values before and after the insertion of the most appropriate CCL. The after-CCL/before-CCL ratio was calculated, and the effect of CCL type on this ratio was investigated.

Results: The after-CCL values were higher in the anterior, central, posterior, and total thickness of the 0–2 mm concentric zone ($p=0.044$, $p=0.040$, $p=0.021$, and $p=0.032$, respectively) when compared to the before-CCL values. There was no statistically significant difference between before-CCL and after-CCL values in any layer of the 2–6, 6–10, and 10–12 mm concentric zones ($p>0.05$, for all). After-CCL/before-CCL ratios were similar in the Magenta2 (M2), Magenta3 (M3), and Violet3 (V3) types of CCLs ($p>0.017$).

Conclusion: Usage for 2 h of CCL was observed to increase CD values in all layers of the 0–2 mm concentric zone irrespective of the type of CCL. Further studies with longer follow-up are required to determine the long-term effects and detect differing effects of CCL with different base curves.

Keywords: ChromaGen contact lens, color vision deficiency, corneal densitometry, corneal topography, pentacam

Introduction

The ChromaGen contact lens (CCL) system (ChromaGen Ltd., Chester, UK) is a tinted soft lens system designed to assist color perception in patients with congenital color vision deficiencies (CVDs). CCLs are available in both contact lens and spectacles form. These lenses use haploscopic

filters to provide different light transmittance for different wavelengths, so luminous contrast occurs between colored objects and the background. In this way, the color perception ability of patients with CVD increases for red and green colors without any change in cone photopigment sensitivity. For patients facing occupational or daily task limitations, the use of these filters is becoming increasingly popular (1).

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The measurement of corneal densitometry (CD) is a new concept to evaluate corneal transparency, which is the result of a complex organization, including regular spacing of the extracellular matrix and collagen fibrils and balanced keratocyte components, and a high level of corneal light backscatter can be observed even in the absence of haze or scar (2). The Pentacam HR (Oculus; Optikgerate GmbH, Wetzlar, Germany) provides information on CD and transparency. The Scheimpflug imaging technique is currently used in Pentacam HR as a non-invasive system that gives an output of numerical values. It measures the intensity of backscattered light from different parts of the cornea (3,4). Changes in corneal light backscatter have been shown in various ocular or systemic diseases such as keratoconus, diabetes mellitus, and pseudoexfoliation syndrome (5-7).

The potential effects of CCL on ocular surface are not known exactly because studies in this area are very limited. Any optimum or maximum duration to safely wear this contact lens for corneal clarity is not yet described, and both ophthalmologists and patients still have important questions concerning the instructions for using CCL. The purpose of this study was to investigate the changes on CD after the insertion of CCL in patients with congenital red-green CVD. Investigating the effect of CCL on corneal clarity may be useful in the enhancement of knowledge about this contact lens system and may help safe use for patients or improve material properties and manufacturing.

Methods

This prospective study was carried out at a tertiary referral center in Turkey with the approval given by the Local Research Ethics Committee. The purpose and method of the study were explained to the patients in detail, and written informed consent was obtained for each subject. All procedures were carried out in accordance with the Helsinki Declaration for human subjects.

Study Subjects

This prospective study was conducted on patients with congenital red-green CVD admitted to our clinic for the trial of CCL from 2014 to 2016. Subjects with any history of ocular diseases, surgery, or drug use that could affect color perception and with chronic systemic diseases were excluded from the study. A detailed ophthalmological evaluation was performed in all cases, including best-corrected visual acuity (BCVA), tonometry, biomicroscopy, and fundoscopy. Patients with any ocular disorders that may affect color perception, corneal clarity, shape, and keratometric pattern, such as cataracts, optic neuropathies, keratitis, keratoconus, corneal dystrophies, and degenerations, were also excluded. The BCVA of all subjects was a minimum of 0.00 log-

MAR, and none had spherical refractive error $\geq 2D$ or cylindrical $\geq 1D$. Finally, 22 eyes (only right eyes) of 22 young male subjects with congenital red-green CVD who had never previously worn contact lenses were included in this study. The type and extent of congenital red-green CVDs were determined. At the same time of the day (between 2 and 4 pm), under the same ambient conditions, after the obtaining of baseline values of CD, appropriate CCL was determined and was inserted for 2 h. After the removal of CCL, CD measurement was repeated, and all examination procedures were completed on the same day.

Color Vision Deficiency

The HRR 4th edition plates (Richmond Products, Albuquerque, NM) were performed under a standardized illumination of a daylight illuminator and were kept 60–75 cm away from the patient at right angles to the line of sight. The HRR plates include 24 test plates showing one or two geometric symbols (except for plate 4) (8). The first four demonstration plates are not scored because they can be discriminated by every subject regardless they have CVD or not. The next six plates screen for the tritan and protan-deutan defects. The following 14 diagnostic plates recognize the type and extent of CVD; 18 symbols are present in the first 10 diagnostic plates and are used for subjects with red-green CVD. Three questions were asked: "How many colored symbols do you see here?" "What are they?" and "Where are they?." Three seconds were given to respond for each plate. For the 18 symbols on the 10 diagnostic plates, the number of recognized symbols was counted and the type and extent of red-green CVD were determined.

CD

Corneal topography was performed at baseline (before-CCL insertion) and immediately after-CCL removal by Pentacam HR. Pupillary dilation was not performed, and all measurements were made under standard dim light conditions by the same experienced operator. Although several parameters of the cornea can be measured with Pentacam HR, the change in the CD was examined in particular. The cornea was divided into four concentric zones for CD measurement. The first zone consisted of a 2 mm diameter circular area in the center of the cornea. The other zones were annular shaped and surrounded the previous area. The radius of the second, third, and fourth zones was 6 mm, 10 mm, and 12 mm, respectively. This analysis also provided densitometry values of the cornea at three different depths. The anterior layer consisted of a 120 μm thickness of the superficial region. The posterior layer consisted of the 60 μm thickness of the innermost region. The central corneal layer is located between these two layers. The CD values were denoted as pixel luminance per unit volume in the Scheimpflug image,

and they were given in grayscale units. This measurement ranges from 0 (maximum transparency) to 100 (completely opaque cornea), according to the amount of corneal light backscattering.

CCL Trial

The CCL is made of Benz G-5X, 55% hioxifilcon 4A, and it has a Dk value of 28. The total diameter of CCL is 14.5 mm and 8.30 mm, 8.60 mm, and 8.90 mm base curve alternatives are available on the market. There are tinted areas in the middle of CCL with a diameter of 6 mm or 7 mm. The tints of haploscopic filters are tones called Magenta2 (M2), Magenta3 (M3), and Violet3 (V3), from light to dark, respectively.

The CCL trial was performed after the baseline examination of corneal topography. CCLs with three different tinted filters were inserted randomly with an 8.60 mm base curve and a 7 mm tinted area as standard because the parameters of CCL in the placed trial set were restricted. The number of recognized symbols on HRR test plates was recorded after the insertion of M2, M3, and V3 CCLs. The most appropriate CCL for each eye was defined as the preferred CCL by comparing the number of recognized symbols on the HRR test plates after the insertion of M2, M3, and V3 CCLs. The preferred CCLs were inserted again for 2 h for each eye to trial.

Statistical Analysis

The data were analyzed by the Statistical Package for the Social Sciences 22.0 software (IBM Corp., New York, USA). Descriptive statistics were given as mean±standard deviations and minimum-maximum values. The Kolmogorov-Smirnov test was used to test the normal distribution of the variables. In analysis, as the numerical data did not conform to normal distribution, non-parametric tests were used. The CD measurements both before and after the trial of CCL (groups were defined as before-CCL and after-CCL) were compared using the Wilcoxon test. A new variable group was formed of the after-CCL/before-CCL ratio to reveal the rate of the change of CD. The Kruskal-Wallis H test was used to determine the effect of the type of CCL on the after-CCL/before-CCL rates. Statistical significance was set at $p < 0.05$ for the Wilcoxon test and $p < 0.017$ for the Kruskal-Wallis H test after the Bonferroni correction. It has been found that at least 17 eyes are needed for each group in the study as a result of a priori power analysis through Power and Sample Size Calculation 11.0 software (NCSS, LLC, Kaysville, Utah, USA). The current study includes 22 eyes for each group to investigate the effect of CCL on corneal clarity, and the power of the study was found accordingly as 87.6%.

Results

The study included 22 eyes (only right eyes) of 22 male patients with congenital red-green CVD with a mean age of 26.59 ± 9.64 years (10–46 years), who completely met the inclusion criteria. The mean spherical equivalent was -0.23 ± 0.94 D (-2.25 – $+2.00$ D) and the mean BCVA was -0.07 ± 0.10 logMAR (-0.30 – 0.00 logMAR). Deutan defect was present in 19 eyes and protan defect was present in three eyes. The extent of congenital CVD was medium in seven eyes (all eyes had deutan defect) and strong in 15 eyes (12 had deutan defect and three had protan defect). After the insertion of each CCL and recording the number of recognized symbols on HRR, the appropriate CCL was defined for each eye. The M2, V3, and M3 CCLs were the most appropriate CCLs for 5, 7, and 10 eyes, respectively.

The CD was measured before and after the insertion of CCL using Pentacam HR. The measurements are presented in Table 1 as before-CCL and after-CCL groups. The CD val-

Table 1. Comparison of the CD measurements (Grayscale Units) in both groups

	Before-CCL	After-CCL	p
Anterior 120 μ m			
0–2 mm	18.38±1.41	18.88±1.54	0.044*
2–6 mm	16.67±0.98	16.83±1.24	0.192
6–10 mm	16.25±3.08	16.11±2.84	0.342
10–12 mm	28.96±8.83	29.21±9.65	0.228
Total diameter	18.72±2.19	18.43±2.98	0.385
Center			
0–2 mm	11.72±1.08	11.90±0.81	0.040*
2–6 mm	10.59±0.75	10.64±0.76	0.268
6–10 mm	10.67±1.68	10.53±1.71	0.173
10–12 mm	16.63±3.82	16.55±3.87	0.195
Total diameter	11.73±1.17	11.73±1.27	0.418
Posterior 60 μ m			
0–2 mm	9.42±0.84	9.73±0.76	0.021*
2–6 mm	8.77±0.55	8.94±0.63	0.056
6–10 mm	9.58±1.36	9.57±1.49	0.404
10–12 mm	12.56±2.58	12.53±2.70	0.254
Total diameter	9.74±0.94	9.82±1.04	0.178
Total thickness			
0–2 mm	13.18±1.07	13.50±0.92	0.032*
2–6 mm	12.02±0.72	12.13±0.78	0.157
6–10 mm	12.18±1.94	12.07±1.94	0.266
10–12 mm	19.38±4.61	19.42±5.02	0.218
Total diameter	13.39±1.31	13.48±1.52	0.212

CD: Corneal densitometry; CCL: ChromaGen contact lens.

ues were statistically significantly higher in the anterior, central, posterior, and total thickness of the 0–2 mm concentric zone ($p=0.044$, $p=0.040$, $p=0.021$, and $p=0.032$, respectively) when compared to the before-CCL values. There was no statistically significant difference between before-CCL and after-CCL values in any layer of the 2–6, 6–10, and 10–12 mm concentric zones ($p>0.05$, for all).

The calculation of after-CCL/before-CCL rates in terms of preferred CCL is presented in Table 2. The after-CCL/before-CCL rates were similar in the M2, M3, and V3 groups ($p>0.017$).

Discussion

The effects of different tinted CCLs on corneal clarity of patients with different type and extent of congenital red-green CVDs were investigated in this study by measuring CD values before and after the insertion of CCL. There are many

studies in the literature that have investigated the change in CD in different patient groups (9–11). CD measurement with Pentacam HR is a useful and objective tool for the evaluation of corneal transparency (12). Irregularities between the corneal layers can cause decreased visual acuity and glare due to increased light backscattering. Corneal haze-associated corneal light scattering may be provoked by disruption of the collagen matrix in corneal edema and scarring process (13). Moreover, various conditions, including corneal ectatic disorders, corneal scars, corneal infiltrates, and corneal deposits in monoclonal gammopathies, can be reasons for increased light backscattering (14,15). In the current study, CD values were seen to be higher after-CCL when compared to before-CCL, although there was no evident haze or scar. However, to the best of our knowledge, this is the first study to evaluate the change in corneal transparency after the insertion of CCL.

Contact lens wear may cause corneal hypoxia and hypercapnia because of restricted delivery of oxygen and carbon dioxide (16). Even highly oxygen transmissible rigid and soft lenses have the potential to affect epithelial homeostasis (17). While the long-term effects include thinning and opacities, the short-term effects of contact lens wear on the corneal stroma include acidosis, edema, and striae (18). In disruption of corneal oxygen-dependent metabolism for short-term, increased osmotic pressure in corneal stroma caused by the accumulation of lactic acid leads to water retention and corneal swelling (19). Corneal acidosis may result in changes in corneal morphology in localized areas of different layers (20). The change in corneal morphology is not uniform and it occurs more centrally than peripherally (21,22). Moezzi et al. (23) revealed that immediately after the removal of soft lenses, maximum corneal swelling occurs in the central part of the cornea and decreases gradually toward the periphery. A significant increase in CD after 2 h CCL wear was found in this study similar to findings of recent studies. The increase in CD was more in central portions of total corneal diameter. The most plausible explanation of the result of the current study is that atmospheric oxygen, limbal vessels, and aqueous humor jointly provide the metabolic requirements of the cornea and morphological deformations caused by any blockage in providing metabolic requirements occur first in the anterior and central region of the cornea. These anterior and central regions of the cornea are the furthest regions from limbal vessels and aqueous humor and the nearest region to cause blockage for atmospheric oxygen. Another reason may be the presence of different intensities of tinted area on CCL. If tinted area is more intense in the central portion than peripheral portion, it can be expected to obtain a maximum effect on color discrimination and minimum decrease in retinal illumination, and anterior and cen-

Table 2. The calculation of after-CCL/before-CCL rates in terms of preferred CCL

	M2	M3	V3	p
Anterior 120µm				
0–2 mm	1.01±0.04	1.05±0.11	1.03±0.06	0.721
2–6 mm	1.00±0.05	1.02±0.07	1.01±0.04	0.713
6–10 mm	0.98±1.00	0.99±0.07	1.01±0.06	0.626
10–12 mm	1.05±0.25	1.08±0.20	0.95±0.24	0.593
Total diameter	1.01±0.09	0.97±0.16	1.00±0.06	0.754
Center				
0–2 mm	1.00±0.03	1.03±0.07	1.02±0.05	0.903
2–6 mm	0.99±0.04	1.01±0.04	1.01±0.03	0.592
6–10 mm	0.98±0.08	0.99±0.06	0.99±0.05	0.904
10–12 mm	1.02±0.14	1.05±0.12	0.95±0.22	0.616
Total diameter	1.00±0.05	1.01±0.06	0.99±0.06	0.921
Posterior 60 µm				
0–2 mm	1.06±0.07	1.04±0.10	1.02±0.06	0.582
2–6 mm	1.04±0.08	1.01±0.06	1.02±0.06	0.650
6–10 mm	1.03±0.08	0.98±0.07	1.01±0.05	0.356
10–12 mm	1.05±0.09	1.01±0.11	0.97±0.17	0.660
Total diameter	1.04±0.06	1.00±0.07	1.01±0.06	0.401
Total thickness				
0–2 mm	1.02±0.04	1.04±0.09	1.02±0.05	0.698
2–6 mm	1.00±0.05	1.01±0.06	1.01±0.03	0.766
6–10 mm	0.99±0.09	0.99±0.06	1.00±0.04	0.869
10–12 mm	1.04±0.19	1.05±0.14	0.95±0.21	0.549
Total diameter	1.01±0.08	1.01±0.07	1.00±0.05	0.877

CCL: ChromaGen contact lens; M2: Magenta2; M3: Magenta3; V3: Violet3.

tral regions of the cornea become more exposed to tint or haploscopic filter-related negative effects of CCLs. On the other hand, any information confirming different intensities of tinted area could not be achieved from the manufacturers.

All colors of CCLs are made of Benz G-5X, 55% hioxifilcon 4A. There are 8.30 mm, 8.60 mm, and 8.90 mm base curve alternatives available on the market. The values of Dk and lens thickness are also the same in all colors of CCLs. Even so, the color of CCL effects on CD measurements was investigated in this study because reflection, refraction, and absorption properties are not the same in different colors of CCLs with different haploscopic filter systems. The results revealed that the color of the tinted area did not affect the CD measurements. In the current study, CCLs with a 14.5 mm total diameter, 7 mm tinted area, and 8.60 mm base curve were used because only these parameters were included in the trial set. CCLs with the same parameters were applied to all subjects without consideration of the corneal parameters, which may be problematic for some. These contact lenses may be flat for some cornea and excessive central touch may be a reason why CD values significantly changed in the anterior and central regions of the cornea. Probably, this has a minor effect on the outcomes of the study because 14.5 mm total diameter and 8.60 mm base curve option may be considered as average values to fit for overall population; moreover, if the parameters are not fit for some subjects, 2 h is a very limited duration to observe the negative effects of the contact lens on the cornea. Nevertheless, insertion of CCL without consideration of the corneal parameters should be considered a limitation.

The current study also has some limitations. First of all, it does not have a control group of untinted lenses of the same material. It is likely comparing tinted and untinted lenses will more clearly reveal the effect of haploscopic filter addition on soft contact lens on corneal clarity. This study did not investigate two different CD measurements within 2-h intervals of the same subject who did not wear contact lens to exclude the effect of random differences between measurement times. Sleep cycles of the patients were not questioned and the duration between waking up and CCL trial was not standardized. Although CCL application was performed in hospital conditions by a trained physician and after informed consent of volunteers, to use a trial set is not the best way to evaluate the effects of the lens on cornea because of potential wear and hygiene-related problems. The range in the ages of patients was wide and this can be considered a factor that can affect the outcomes. The sample size is relatively large when considered in a rare patient group and enough to provide reliable results in investigation the effect of CCL on corneal clarity, nevertheless, it is small to generalize the effects of different lens types on CD measure-

ments. In addition, insertion of different tinted lenses to the same patient on different days will give more reliable information to exclude individual responses in different subjects. This study did not answer questions such as how long are the effects of CCL and what is the clinical impact of these statistically significant changes of CD parameters. Consecutive measurements after-CCL trial may answer the first question. For the second question, to investigate the clinical impacts of CD changes requires different procedures which evaluate the visual function and ocular surface morphology. Moezzi et al. (23) mentioned that soft lens wear may change corneal morphology through corneal topography. They also compared the clinical impact of after 8-h cosmetic lens wear with not wearing lens group and stated that there were no significant levels of corneal swelling, endothelial bleb, corneal staining, limbal, or bulbar hyperemia between groups (24). In this study, the patients' visual function and ocular surface morphology were not investigated, but these preclinical changes in the results of this study can be a potential risk in long-term extensive use of CCL.

Conclusion

Despite all the aforementioned limitations, to the best of our knowledge, this is the first study to demonstrate the effect of CCL on corneal transparency. The use of any colored CCL for 2 h was seen to increase the CD values in central portions of total corneal diameter. Differently designed further studies with larger sample sizes are needed to be able to detect the effect of different parameters of CCL on corneal morphology more clearly.

Disclosures

Ethics Committee Approval: This prospective study was carried out at a tertiary referral center in Turkey with the approval given by the Local Research Ethics Committee. The purpose and method of the study were explained to the patients in detail, and written informed consent was obtained for each subject. All procedures were carried out in accordance with the Helsinki Declaration for human subjects.

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