Effects of rigid high gas-permeable contact lens wear on progression in patient with keratoconus

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Abstract

Wearing Rigid High Gas-Permeable Contact Lens (RGPCL) is a primary method of vision rehabilitation in keratoconus eyes. The aim of the study is to investigate the effects of using RGPCL on the topographical variations at the keratoconus progress. All patients had undergone ophthalmic examination including corneal topography, and their medical history and keratoconus characteristics were documented. Fifty-one eyes of those who wore RGPCL without any problems and 42 eyes of those who did not wear any lenses were evaluated retrospectively. It was accepted that the follow-up period was terminated when patients received any treatment or change lenses. The mean follow-ups were 36.5±12.7 and 38.4±14.6 months in the control and lens-wearing samples, respectively. The changes in topographic indices were compared from the baseline to the final visit. The difference between spectacle-best corrected visual acuity was not significant in both groups from baseline to final visit (p>0.05). In the RGPCL wearing group, apical keratometric power (Kmax) increased from mean 51.86±3.70 diopter (D) to 52.54±3.85 D at the sagittal map in the following period, but this difference was not significant (p>0.05). Similarly, in the control group, Kmax increased from mean 52.14±2.51 D to 52.94±3.02 D, and this difference was not significant (p>0.05). Lens-wearing and control group mean keratometry values increased from 47.36±1.7 D and 47.17±1.65 D to 47.94±2.05 D and 47.74±1.76 D, respectively (p>0.05). Pachymetry at the thinnest corneal point decreased significantly in both groups from baseline to final visit (p=0.008, p=0.01). In conclusion, the comfortable usage of RGPCL has no effect on the progression of keratoconus.

Keywords: Cornea, keratoconus, keratometry, rigid, gas-permeable, contact lens, topography

Introduction

Keratoconus disease is a progressive non-inflammatory problem that diagnosed with the anterior conical cornea ectasia and presence of thinning in the central zone [1]. The abnormal corneal structure that develops as a result of keratectasia leads to irregular astigmatism and reduces the quality of vision [2]. Visual quality cannot be improved in most patients with glasses and soft contact lenses. Rigid High Gas-Permeable Contact Lenses (RGPCL) and their new generation productions (rose k, orbiflex etc.) which provide geometric surface compatibility of these lenses are still the first-choice treatment for vision rehabilitation. RGPCL can be classified, with respect to total diameter, as scleral contact lens, intralimbal (pancorneal) contact lens and corneal contact lens [3]. In this paper, we discuss corneal contact lens because this type is widely used.

Computerized corneal topography is advanced system that displays a color-coded surface map of almost all corneal layers with quantitative values [4]. Combining this information with family history, biomicroscopy and retinoscopy examination makes the diagnosis of keratoconus and subclinical keratoconus easier. There is an insidious progression in keratoconus over time, it can be easily detected with the scheimpflug based system. In addition, the selection of contact lenses can be optimized with these possibilities offered by the devices, the effect of the treatments (uv cross-linking, intacs. etc) on the progression of keratoconus can be followed, and surgical treatment indication area can be expanded with new alternative methods [5].
Although the development of other treatment methods continues rapidly, the application of RGPCL is still the primary treatment option for vision quality [6]. The usage of rigid contact lenses in individuals with keratoconus has become compatible in recent years, with the production of highly gas permeable and ultraviolet light-blocking RGPCL materials that do not disrupt the corneal physiology [7]. However, little is known regarding the effect of rigid contact lens wear on keratoconus progression over a long time. In this study, we examined the effect of long-term comfortable use of RGPCL on the progression of keratoconus by using corneal topography.

Material and Methods

Prof. Dr. Cemil Tascioglu City Hospital Ethics Committee (ref no: 2022/258) allowed this study to be conducted. The records of 72 patients who received a keratoconus diagnosis between July 2006 and June 2021 were admitted to the ophthalmology departments of Prof. Dr. Cemil Tascioglu City Hospital (Okmeydani Training and Research Hospital) and Beyoglu Eye Training and Research Hospital, were retrospectively reviewed through the hospital's electronic database.

Study Population and Data Collection

The medical records of each participant were reviewed. A comprehensive ophthalmologic examination including best corrected distance visual acuity testing, slit lamp biomicroscopy and fundoscopic examination was also performed. Scheimpflug camera (Pentacam; Oculus, Wetzlar, Germany and Sirius®; Cso, version 1.2, Florence, Italy) was used for corneal topography measurements of all patients. Only imaging with a quality check resulting in ‘OK’ was included in this study. Positive topographic indices and typical clinical signs such as superficial scarring, Vogt's striae, a Fleischer ring, and apex protrusion or thinning were used to identify keratoconus. The Contact Lens Association of Ophthalmologists’ standards were used to classify the phases of keratoconus [8]. In our research, only the individuals with keratoconus whose keratometric values were K >47.5 Dioptre (moderate or severe stage) included. Patients who were treated with any modality (uv-crosslink, corneal intacs implantation etc.) or wore lenses before the initial examination were not included in the study. Patients with corneal scarring, history of previous ocular surgery, or other ocular pathologies were eliminated from the investigation. Individuals with a record of any concurrent systemic diseases such as atopy, diabetes mellitus, hypertension were also excluded.

Design and Procedure

The first group in the study consisted of patients who underwent rigid lens fitting test after ophthalmological examination, were prescribed appropriate lenses, and wore these lenses daily for at least 8 hours without any problems during the follow-up. The second group consisted of control patients who were diagnosed with moderate or severe keratoconus and without wearing lenses. The contact lenses used by the patients were Conflex-air 100 UVK contact lens (Zeiss, Obaerkochen, Germany), Net lens NLK 100 GP (Net Lens Optic, Istanbul, Turkey), Or biflex K (Swisslens S.A., Switzerland) and Rose K2 (Blanchard Lab, California, USA). These lenses have an advanced ultraviolet light-blocking and have an aspherical back surface geometry that increases peripherally. They are hydrophobic lenses and made of a flour-silicone methacrylate copolymer that enhances oxygen permeability due to its balanced component structure. (Dk:100). Based on the topographic index, RGPCLs were fitted in accordance to three-point touch principle with a gentle apical touch.

The sample of the study included 38 patients (21 women, 17 men) with 51 eyes in the RGPCL group, and 34 patients (19 women, 15 men) with 42 eyes in the control group. It was accepted that the follow-up period was terminated if a treatment (uv cross-linking, intracorneal ring placement, keratoplasty etc.) was applied to the patients or if the lens they used was changed. It was seen in the patient's clinical records that in the last visit of the patients using RGPCL, their lenses were removed for two weeks, and after being followed up with artificial tear drops, corneal topography and full ophthalmological examinations were performed. Whichever device was used for corneal topography in the first examination of the cases, the same device was used in the last visit. Examination findings including spectacle-corrected visual acuity, the keratometry power of the cone (Kmax), pachymetry at the thinnest corneal point and mean keratometry (Km) at sagittal map were evaluated during the follow-up.

Statistical Analysis

The results for every parameter were displayed as mean ±standard deviation (SD). For statistical analysis, the chi-square test was employed to compare the frequencies and percentages of the groups. The Kolmogorov-Smirnov test was used in the analysis of the normal distribution, and the follow-up paired t test was performed to compare the mean values of the variables for the groups. SPSS for Windows was used to conduct all statistical analyses (version: 20.0). The significance level was set at a p<0.05.

Results

In group 1, patients with a mean age of 27.24±8.26 years at first examination were followed up for a mean of 38.4±14.6 months after RGPCL; in group 2, patients with a mean age at initial examination of 26.88±7.57 years were followed for a mean period of 36.5±12.7 months. There was no statistically significant difference between the groups in terms of mean age and duration of follow-up (respectively p=0.780, p=0.602). (Table 1) The mean number of hours of wearing RGPCL daily was 10.4±2.6 hour (8–15 hr.)

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The mean best spectacle correction of vision at first admission and at the end of follow-up were 0.4±0.18 and 0.37±0.16, respectively, in the 1st group on the Snellen chart; in group 2, they were 0.35±0.12.
and 0.34±0.15, respectively (both p>0.05). During the follow-up period, Kmax in the 1st group progressed from 51.86±3.70 Diopter (D) to 52.54±3.85 D in the last visit, it was determined that the Km value increased from 47.36±1.7 D to 47.94±2.05 D, and the thinnest pachymetry decreased from 435.16±8.70 µm to 416.35±9.85 µm. In the 2nd group, the initial Kmax progressed 52.14±2.51 D to 52.94±3.02 D at the last follow-up; it was determined that the Km value increased from 47.17±1.65 D to 47.74±1.76 D, and the thinnest pachymetry decreased from 429.37±9.26 µm to 408.35±8.06 µm at the last visit. In both groups, only the change in pachymetry value was statistically significant (p=0.03, p=0.02; respectively) (Figure 1 and 2).

![Figure 1. Mean Kmax,Km values at baseline and last visit](image)

![Figure 2. Mean Pachymetry values at baseline and last visit](image)

**Discussion**

Scheimpflug camera rotates 360 degrees and has a slit light that shines 25 meridional slits through the cornea [4]. The corneal radii for each location on the topographic surface map may then be calculated thanks to this feature. Thus cornea topographic indices are crucial for assessing the severity and development of keratoconus [9]. Risk factors for the development of keratoconus on cornea topography include increases in central corneal curvature, refractive power, and corneal irregularity with cone expansion [10,11]. Nevertheless, further clinical information, such as corneal scarring, corneal signs, and spectacle visual acuity are required to validate the development and progression of keratoconus [12]. Previous studies reported the prevalence of corneal scarring in keratoconus from 24 to 29% [8]. Wearers of RGPCLs had the least percentage of contact lens-related microbial keratitis, followed by those using soft lenses and overnight soft lenses [13]. In the literature, cases of keratitis have been reported in some keratoconus patients with mini-scleral lens wearers [14].

Like many former studies, a gradual increase in corneal curvature and a decrease in visual acuity were observed in the CLEK study in patients with keratoconus [15]. Scratching triggers inflammation, the progression in the pediatric age group is higher than in adults due to excessive rubbing [16]. Inflammatory cytokines and some enzymes released during recurrent corneal epithelial damage are known to have an important role in the apoptosis of keratocytes in addition to the cells in the stromal layer [17]. So, in the natural course of this disease, there is an increase in topographical indices, albeit more or less [2]. We observed an increase in the Kmax and Km values of the eyes in both group but they were not statistically significant. In their study Maguire et al. supported that if the contact lens fitment is insufficient for the cone, the corneal curvature may gradually increase [25]. McKay et al., corneal fibroblasts of keratoconus patients were more vulnerable to hypoxia-induced oxidative stress than healthy controls, which caused their corneas to thin [22]. Pflugfelder et al. also observed that contact lens wearers had much thinner cornes than non-contact lens wearers [23]. Dogan et al. noted that during the follow-ups at the thinnest point of the cornea, there was no statistically significant difference between keratoconus patients wearing RGPCL and those who did not. The corneal thickness of keratoconus patients wearing RGPCL was significantly lower than that of the normal control group. With these results, they argued that RGPCL had no effect on keratoconus patients' corneal thickness [24]. In their study Hwang et al. found that the wearing of RGPCL had no impact on Kmax and Km values [18]. Ramdas et al. suggested that in eyes fitted with RGPCL all assessed K-values were significantly higher at follow-up compared with baseline. However, in the same study it was noted that no significant differences were found between baseline and follow-up in eyes fitted with pancorneal RGPCL, even there was an increase in K-values [19]. Kamar et al. noted in their study that the mean vertical and horizontal Km did not significantly change by the time of the last visit in the RPGCL wearing group [20].

The decrease in pachymetry values observed in the development and progression of keratoconus is probably due to the thinning of the stromal layer after epithelial trauma [21]. According to McKay et al., corneal fibroblasts of keratoconus patients were more vulnerable to hypoxia-induced oxidative stress than healthy controls, which caused their corneas to thin [22]. Pflugfelder et al. also observed that contact lens wearers had much thinner cornes than non-contact lens wearers [23]. Dogan et al. noted that during the follow-ups at the thinnest point of the cornea, there was no statistically significant difference between keratoconus patients wearing RGPCL and those who did not. The corneal thickness of keratoconus patients wearing RGPCL was significantly lower than that of the normal control group. With these results, they argued that RGPCL had no impact on keratoconus patients' corneal thickness [24]. In their study Hwang et al. found that the wearing of RGPCL had no effect on Kmax and Km values [18]. Ramdas et al. suggested that in eyes fitted with RGPCL all assessed K-values were significantly higher at follow-up compared with baseline. However, in the same study it was noted that no significant differences were found between baseline and follow-up in eyes fitted with pancorneal RGPCL, even there was an increase in K-values [19]. Kamar et al. noted in their study that the mean vertical and horizontal Km did not significantly change by the time of the last visit in the RPGCL wearing group [20].

Wearing of contact lens can lead to worsening of keratoconus in conjunction with the way of application. A mistake in the apex contact point will cause a gradual increase in corneal curvature. In their study Maguire et al. supported that if the contact lens fitment is insufficient for the cone, the corneal curvature may gradually rise [25]. According to the consistent findings of McMonnies, aberrant friction and damage brought on by contactation may advance keratoconus [26]. Apical bearing fitting can cause weakening, loss of stiffness, abnormal apoptosis, and persistent apical epitheliopathy. Apical clearance fitting may cause enlarge
The keratoconus progression. In addition, with the reduction of oxidative stress on the cornea, perhaps the long-term comfortable usage of rigid lenses has been provided.

Study Limitations

One of the limitations of the study is its retrospective design. Because we conducted the study using patient records, we could not detect all predictive markers in patients. And, four basic parameters were used in the study, different parameters in corneal topography can also be used. Another limitation is limited patient population. We especially wanted to emphasize the use of RGPCL in our study, so only moderate and advanced keratoconus patients were included. In addition, these patients frequently apply to different centers and receive other treatments, but we terminated the follow-up process when the patients were treated differently or the contact lens they used was changed. As a result of this approach, the follow-up period and the study population decreased.

Conclusion

As a result, RGPCL is the most appropriate non-surgical treatment choice for keratoconus. We evaluate that our results are due to the decrease of irritation with comfortable use of lenses, the reduction of long-term sun exposure with ultraviolet-light protection, and the minimization of oxidative stress that occur in the corneal layers with high oxygen permeability. We believe that this investigation will advance the literature in terms of giving an insight regarding the comfortable usage of RGPCL in patient with keratoconus.

Conflict of interests

The authors declare that there is no conflict of interest in the study.

Financial Disclosure

The authors declare that they have received no financial support for the study.

Ethical approval

The study protocol was approved by the Prof. Dr. Cemil Tascioglu City Hospital ethics committee (Ethics approval no: 2022/256)

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