Comparison of Hybrid Contact Lenses and Rigid Gas-Permeable Contact Lenses in Moderate and Advanced Keratoconus

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Abstract

Objectives: We aimed to compare the clinical results and topographic data of the new generation hybrid contact lens (HCL) and rigid gas-permeable contact lens (RGPCL) in patients with moderate and advanced keratoconus.

Materials and Methods: In this prospective study, HCL users comprised group 1 and RGPCL users comprised group 2. Snellen uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), and lens-corrected visual acuity (LCVA); manifest spherical-cylindrical values; corneal topography measurements (flat keratometry [K1], vertical keratometry [K2], mean K, maximum K [Kmax], central corneal thickness [CCT], and thinnest corneal thickness [TCT]); and cone location were recorded.

Results: The study included 83 eyes of 51 patients in group 1 and 61 eyes of 40 patients in group 2. The groups were similar in age and gender (p>0.05). Mean LCVA (logMAR) was significantly lower than BCVA in both groups (p<0.001). The mean visual gain with contact lenses (Snellen chart) was 3.4±1.8 lines in group 1 and 4.0±2.1 lines in group 2. There was no significant difference between the two groups in BCVA, LCV A, or lines gained (p>0.05). There was also no significant difference between the two groups in terms of keratoconus stages, mean Kmax, CCT, TCT, or cone location (p>0.05), while mean UCVA (logMAR) and mean K were higher in group 2 (p<0.05). In both groups, the visual gain with lenses was higher in eyes with central cones, and there was significantly greater visual increase in group 2 (p=0.039).

Conclusion: In moderate and advanced keratoconus, HCLs improved vision as much as RGPCLs and both lenses were more effective for central cones. Nevertheless, longer term of follow-up and larger numbers of patients are needed for long term follow-up results of HCL.

Keywords: Rigid gas-permeable contact lens, hybrid contact lens, keratoconus

Introduction

Keratoconus is a bilateral, asymmetric, progressive ectatic disease characterized by steepening and thinning of the cornea. In keratoconus, stromal thinning and steepening alter the refractive properties of the cornea and cause irregular astigmatism that cannot be corrected with glasses. Because of the irregular astigmatism, contact lens fitting for keratoconus patients requires time and patience on the part of both patient and physician. Nevertheless, keratoconus lenses are preferred because they improve vision beyond what can be achieved with glasses and even help patients avoid surgical treatment options. Therefore, soft or rigid contact lenses are recommended before surgery to provide visual rehabilitation, especially for patients with moderate to advanced keratoconus.

Keratoconus lenses offer visual rehabilitation by providing a new optical surface, either through contact with the cornea or by masking irregularities with the tear film between the cornea and the lens. Although options vary according to disease stage, there are currently five different types of contact lenses for keratoconus patients. The first of these are rigid gas-permeable contact lenses (RGPCLs), which have been used for decades. Soft toric lenses, hybrid contact lenses (HCLs), scleral lenses, and custom-made keratoconus lenses have also been introduced into clinical practice in addition to RGPCLs. Soft contact lenses are especially effective in early to moderate keratoconus, while RGPCLs, HCLs, and scleral contact lenses are more...
effective in moderate to advanced keratoconus. According to the Global Keratoconus Consensus in 2015, RGPCLs are the first option for patients who are unable to achieve adequate vision and comfort with glasses or contact lenses. However, some patients cannot tolerate these lenses. HCLs were first produced in the 1980s to combine the comfort of soft lenses and the effectiveness of RGPCLs. Due to complications related to the design and low oxygen permeability of the first HCLs, next-generation HCLs were produced in the 2010s. These next-generation HCLs have high oxygen permeability and consist of a rigid lens material that corrects central corneal irregularity and a soft lens material that provides peripheral comfort and lens centration. The SynergEyes KC (SynergEyes Inc., Carlsbad, CA, USA) was the first of the next-generation HCLs and was followed by the ClearKone (Paragon Vision Sciences, Mesa, AZ, USA), UltraHealth (SynergEyes Inc., Carlsbad, CA, USA), AirFlex (SwissLens, Prilly, Switzerland), and Eyebrid Silicone (Laboratoire LCS; France) HCLs. In the AirFlex HCL, the rigid gas-permeable material is Roflufocon D and the surrounding soft lens material is silicone hydrogel (Filcon V5). It has a spherical, front/back bitoric design, blocks ultraviolet light, and has high oxygen permeability (central Dk: 100x10^6, peripheral Dk: 50x10^11 (cm^2/s) x (mLO2/mL x mmHg)). The water content is 50%. The rigid lens has a base curve ranging from 5.50 to 10.00 mm (0.05 mm steps) and a diameter of 8.5 mm for irregular corneas and 10.0 mm for regular corneas. The total diameter is 14.9-15.50 mm and the central thickness is 0.20 mm. There are four options for the skirt curve: very flat (J +1.0), flat (J +0.5), standard (J 0.0), and steep (J -0.5).

In this study, we aimed to compare the clinical results and topographic data of the next-generation AirFlex HCL and the Rose K2 RGPCL in patients with moderate to advanced keratoconus.

Materials and Methods

This prospective study was conducted in the Cornea Unit of the Ankara Bilkent City Hospital Clinic of Ophthalmology and adhered to the principles of the Declaration of Helsinki. Ethics committee approval for the study was obtained from the Clinical Research Ethics Committee of the Ankara Yildirim Beyazit University Faculty of Medicine. Patients fitted with the AirFlex HCL (SwissLens, Prilly, Switzerland) and Rose K2 RGPCL (Menicon, Co., Ltd., Nagoya, Japan) in our clinic for the treatment of keratoconus were included in the study. Written informed consent was obtained from all patients. The diagnosis of keratoconus was made in the presence of at least one of the clinical findings (Muson’s sign, scissor reflex on retinoscopy, corneal thinning, Fleischer ring, striae of Vogt, prominent corneal nerves, Rizzutti’s sign) and with corneal tomography (Sirius® Scheimpflug tomography, Italy). Patients with moderate and advanced keratoconus who had a visual gain of at least two lines on the Snellen chart with the HCL or RGPCL and used these lenses for at least 6 months (at least 8 hours per day) were included in the study. Patients with BCVA of 0.6 decimal or higher on the Snellen chart; those with hard contact lens use in the last month or soft contact lens use in the last week; those who were in the first 6 months of collagen cross-linking (CXL) treatment; those with progression of keratoconus, history of herpetic keratitis, topical drugs use, keratitis, dry eye, blepharitis, glaucoma, and macular or optic disc disease that would affect vision; and those who did not attend regular follow-ups were excluded from the study. Contact lens fitting was performed by the same experienced ophthalmologist. Maximum keratometry (Kmax) values of 47 diopters (D) or less were evaluated as mild, 47-52 D as moderate, and 52 D or more as advanced keratoconus. Cone location was classified as central for cones within the central 3 mm area in the anterior corneal tangential curvature map on corneal topography and paracentral for those outside this area.

Before lens use, all patients’ uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), manifest sphere and cylinder values (Topcon KR 8000 Autorefractor Keratometer), biomicroscopic anterior segment and fundus examination findings, and corneal topography measurements (flat keratometry [K1], steep keratometry [K2], mean keratometry [Kmean], Kmax, cone location, central corneal thickness [CCT], and thinnest corneal thickness [TCT]) were recorded. After lens fitting, patients were scheduled for follow-up at 1 week, 1 month, and every 3 months thereafter. Lens-corrected visual acuity (LCVA) at final follow-up, complications associated with contact lens use, lens parameters, and lens use durations were recorded.

Lens Fitting Procedure

AirFlex HCL fitting was done based on the manufacturer’s instructions. In the first lens trial for keratoconus patients, a lens base curve 0.2 mm flatter than the patient’s Kmean and the standard skirt curve (J 0.0) is used. The lens is put in place using a special applicator with the patient sitting upright or with the head tilted forward and face parallel to the floor. It is very important not to put pressure on the patient’s eye during the initial fitting. Applying pressure to the eye may negatively affect both comfort and vision. After 30 minutes, sodium fluorescein is instilled and the patients are examined under cobalt blue lamp at a 30° angle to the biomicroscope. Three main points are considered when evaluating the lens. The first is lens centration; the lens must cover the entire cornea. With HCLs, lens centration is provided by the soft skirt that extends from sclera to sclera. The second point is lens movement. As with soft contact lenses, the movement of the lens ensures tear exchange beneath the lens. With each blink, lens movement of 0.3-0.4 mm is desired. If the lens is tight, the base curve is flattened/increased, and if it is loose, the basic curve is steepened/decreased. If lens centration or movement is still not as desired, the skirt curve is changed. Steepening the lens skirt curve prevents the lens from adhering to the ocular surface and increases lens movement, while flattening reduces lens movement. A tight
lens fitting will not allow for tear exchange beneath the lens and thus may cause corneal edema and limbal vascularization with prolonged use. The third point is fluorescein staining pattern. Unlike the previous vault-based HCLs, full contact between the AirFlex HCL and cornea or minimal fluorescein pooling (0.07-0.10 mm) in the center is desired. This enables assessment with a biomicroscope, as with soft contact lenses. If there is excessive fluorescein pooling in the center, the base of the lens is flattened. There should be a fluorescein band (communication for tear exchange) of 1-2 mm around the rigid lens component. If this band is less than 1 mm wide, it indicates a steep lens and the base curve should be increased by 0.1 mm; a band wider than 2 mm indicates a flat lens and the base curve should be reduced by 0.1 mm. Anterior segment images of the HCL fitted to a patient with advanced keratoconus are shown in Figure 1. The Rose K2 is a RGPCL made of Menicon Z. It has an aspheric surface, Dk value of $163 \times 10^{-11}$ (cm$^3$/s) x (mLO/(mL x mmHg)), back optic zone radius (BOZR) of 4.30-8.60 mm, and diameter of 7.90-10.40 mm. It is designed with standard, flat, or steep edge lift. According to the manufacturer’s instructions for fitting the Rose K2, the first lens is selected with a BOZR 0.20 mm steeper than the Kmean and is applied to the eye. After 30 minutes, sodium fluorescein is instilled and the patients are examined under cobalt blue lamp at the biomicroscope. Lens centration, movement, and fluorescein staining pattern are examined. Although a three-point contact pattern is more preferred in fluorescein staining, the BOZR is flattened/increased or elevated/decreased at 0.1 mm intervals until apical contact or two-point contact (apical gap/peripheral contact) is achieved. Finally, corneal staining is evaluated with fluorescein drops after removing the lenses. Anterior segment images of the RGPCL fitted to a patient with advanced keratoconus are shown in Figure 2. For both lenses, after determining the appropriate parameters, lens refraction is performed with an autorefractometer. If the values measured by autorefractometer over the contact lens are above 4 D, the vertex calculation is included and the spherical power of the contact lens is determined. In the lens prescription, the base curve, total lens diameter, skirt curve, spherical power, and lens brand are recorded.

Statistical Analysis

The data were recorded and analyzed using SPSS version 21.0 (IBM Corp., Armonk, NY, USA) and MedCalc version 12.3 (MedCalc Software bvba, Ostend, Belgium). Normality of data distributions were analyzed using Kolmogorov–Smirnov test. The data were expressed as mean and standard deviations. Chi-square, paired-samples t, Mann-Whitney U, and Kruskal-Wallis tests were used for data comparisons. Analyses were performed with a 95% confidence interval and a p value less than 0.05 was considered statistically significant.

Results

The study included 144 eyes of 91 patients. Those who used HCLs were in group 1 (83 eyes of 51 patients) and those who used RGPCLs were in group 2 (61 eyes of 40 patients). The mean duration of lens use was 15.63±9.4 months in group 1 and 14.39±8.8 months in group 2 (p=0.05). The demographic characteristics and manifest refraction values of all patients are presented in Table 1. The two groups were similar in terms of age and sex (p>0.05, Table 1). Manifest cylinder values were significantly higher in group 2 (p=0.023, Table 1). The mean logMar UCVA, BCVA, and LCVA values and topographic data of all patients are shown in Table 2. While there was no significant difference between the two groups in mean BCVA, LCVA, or Snellen lines gained with lenses (p>0.05, Table 2), mean UCVA was significantly higher in group 2 (p=0.004). There was no significant difference between the two groups in terms of mean Kmax, CCT, TCT, cone location, or keratoconus stages (p>0.05, Table 2). Kmean values were significantly higher in group 2 (p=0.039, Table 2). In both groups, the mean logMAR LCVA was lower than BCVA (p<0.001). The mean visual gain on Snellen chart with contact lenses was 3.4±1.8 lines in group 1 and 4.0±2.1 lines in group 2 (p=0.067) (Table 2). None of the patients had limbal vascularization, corneal edema, or keratitis associated with contact lens use.

Figure 3 shows the mean logMAR vision levels of groups 1 and 2 according to keratoconus stage. In group 1, patients with moderate and advanced keratoconus did not differ in mean UCVA (p=0.205) or LCVA (p=0.711), while mean BCVA was significantly higher in patients with advanced keratoconus than in patients with moderate keratoconus (p=0.046). In group 2, there was no significant difference in mean UCVA values between moderate and advanced keratoconus patients (p=0.260), while BCVA and LCVA were significantly higher in patients with advanced keratoconus (p=0.029 and p=0.012, respectively). In both groups, mean LCVA values were significantly lower than BCVA values for both keratoconus stages (p<0.001 for all) (Figure 3).

Figure 4 shows the logMAR visual acuity levels of groups 1 and 2 according to cone location. In group 1, there was no significant difference in mean UCVA and LCVA values between patients with central and paracentral cones (p=0.146 and p=0.733, respectively). The mean BCVA was significantly higher in group 1 patients with central cones (p=0.024). In group 2, the mean UCVA and BCVA values were significantly higher in patients with central cones (p=0.012, p=0.010, respectively), while there was no significant difference in mean LCVA between patients with central and paracentral cones (p=0.533) (Figure 4).

Table 1

<table>
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<tr>
<th>Characteristic</th>
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<tr>
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<td>45.1±16</td>
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<td>Sex (male/female)</td>
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<td>28/12</td>
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<tr>
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<tr>
<td>Kmean (D)</td>
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<td>LogMAR BCVA</td>
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<td>0.1±0.3</td>
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<tr>
<td>LogMAR LCVA</td>
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Table 2

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<td>RGPCLs</td>
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<tr>
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<td>LogMAR LCVA</td>
<td>0.1±0.2</td>
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Figure 1. Anterior segment biomicroscopic image (a) and cobalt blue fluorescein staining pattern (b) of an AirFlex hybrid contact lens on the left eye of a patient with advanced keratoconus.
The mean visual gain on Snellen chart with contact lenses (difference between BCVA and LCVA) in patients with central and paracentral keratoconus was 0.36 and 0.28 lines in group 1 (p=0.135) and 0.43 and 0.20 lines in group 2 (p=0.003), respectively. The visual gain in patients with central cones was significantly greater in group 2 than in group 1 (p=0.039).

### Discussion

Keratoconus is a serious corneal disease that is more prevalent in young patients, can progress if left untreated, and results in corneal transplantation surgery when glasses or contact lenses do not provide sufficient visual improvement. As most keratoconus patients are young, it leads to serious psychological problems and job loss. Today, with the widespread use of modern corneal topographers, keratoconus patients are diagnosed earlier than in the past, and treatment with CXL halts progression of the disease. However, untreatable advanced keratoconus, the formation of corneal haze after CXL, and irregular corneas following penetrating keratoplasty, intracorneal rings, and Excimer laser surgery also occur at a substantial rate. Here, rigid contact lenses...
(RGPCLs, HCLs, scleral contact lenses) provide a healthy optical surface either by contact with the cornea or by the masking effect of the tear film between the cornea and lens, which eliminates corneal irregularities and provides visual improvement.

Contact lens fitting in keratoconus patients is a tedious process for both practitioner and patient because of the irregular shape of the cornea. Therefore, it is important to decide which lens to start with for keratoconus patients. All keratoconus lenses have their own advantages and disadvantages. Customized soft toric lenses provide greater comfort than other lenses but have a limited effect on irregular corneas. Therefore, they are preferred in early keratoconus. RGPCLs are used most commonly for keratoconus. RGPCLs provide significant visual gain by reducing corneal irregularities and higher-order aberrations. However, these lenses cannot be tolerated by some patients due to hypertrophic scarring, erosion, and epithelial damage after apical contact with the cornea. The apical contact approach in RGPCL fitting utilizes a large diameter lens and flat base curve, but this may cause corneal epithelial erosion and apical hypertrophic scar. A smaller lens diameter and steep base curve provides an apical vault, thereby reducing the complications associated with rigid contact lenses, but the most common problem with this approach is the mechanical and hypoxic complications caused by adherence of the lens edge to the peripheral cornea. In the three-point contact approach, there are two more points of contact opposed at 180 degrees in addition to central contact, thus distributing the load from the center to other healthy areas of the cornea and providing maximum apex protection. For this reason, the three-point contact approach is the most preferred. We also use this approach in clinical practice.

With HCLs, their soft skirt provides centration and comfort while the rigid central component provides a healthy optical surface like RGPCLs. Complications related to both the lens designs and low oxygen permeability were fairly common with the first-generation HCLs produced in the 1980s (Saturn II; Barnes Hind, Inc., CA, USA) and SoftPerm; SBH, Sunnyvale, CA, USA). Separation of the lens at the fusion site was the most common complication with the first HCL. Cohen et al. reported three cases of Acanthamoeba keratitis (one requiring therapeutic keratoplasty) in SoftPerm HCL users. Corneal edema due to tight lens application was observed in keratoconus patients as a result of using HCLs with hydrogel polymer skirts. Fortunately, the incidence of lens-related complications has decreased with current next-generation HCLs due to their stronger fusion zone, high oxygen permeability, silicone hydrogel skirt design, and different skirt curves for better fit. Of the next-generation HCLs, the UltraHealth HCL has a reverse geometry design and two basic parameters, vault value and skirt curvature. The AirFlex HCL and EyeBrid HCL have the same characteristics and two basic parameters, the base curve and skirt curve.

In this study, we aimed to compare the topographic data and clinical results of the next-generation AirFlex HCL and Rose K2 RGPCL fitted to patients with moderate to advanced keratoconus in our center. We observed that the HCL and RGPCL provided similarly significant visual gains in patients with moderate to advanced keratoconus. Hassani et al. compared 20 keratoconus patients using an HCL and 20 using an RGPCL and found that both lenses provided similar visual gains, consistent with our study. Uçakhan and Yeşiltaş conducted a study with 33 patients (47 eyes) with irregular astigmatism who discontinued RGPCL use (due to intolerance in 68% and RGPCL failure in 32%) and were fitted with the AirFlex or EyeBrid Silicone HCL. They reported a 92% success rate after a mean of 10 months of use and 72% of the patients continued to use the HCL. In their study, the mean visual acuity with the HCL was 0.05 logMAR. Consistently, this value was 0.08 in our study, despite all patients having moderate or advanced keratoconus. Kloor et al. evaluated 54 patients (102 eyes) treated with next-generation HCLs (SynerEyes KC and ClearKone) and found that HCLs were reliable and provided high visual gain for keratoconus patients, consistent with our study. However, the lens discontinuation rate was 37.8% in their study, the most common reason for which was that the lens was uncomfortable. In our study, no patients had limbal vascularization, corneal edema, or keratitis related to the use of the AirFlex HCL. Other studies conducted with next-generation HCLs also demonstrated none of these complications, as in our study. Consistent with our study, they demonstrated that cone location affected lens discontinuation rate which was 37.8% in their study. However, the lens discontinuation rate was 37.8% in their study, the most common reason for which was that the lens was uncomfortable. In our study, no patients had limbal vascularization, corneal edema, or keratitis related to the use of the AirFlex HCL. Other studies conducted with next-generation HCLs also demonstrated none of these complications, as in our study.
with paracentral cones compared to the RGPCL. This may be attributable to the fact that the HCL's soft skirt improves centration and has a wider effect area.

These lenses may be inadequate in conditions that exceed the landing zone of the HCL, such as advanced pellucid marginal degeneration and keratoglobus. Again, the disadvantages of these lenses are that a special applicator is needed, lens fitting can take longer than with other RGPCLs, and the lenses are costly and their use is limited to 6 months.

**Study limitations**

Limitations of this study include the need for a larger patient sample with longer follow-up, and the lack of a questionnaire evaluating the comfort of lens use.

**Conclusion**

In our study comparing an HCL and RGPCL in moderate and advanced keratoconus, we observed that they were similar in terms of clinical fitting difficulties and that the HCL provided as much visual gain as the RGPCL. In light of the topographic data, both lenses provided more visual gain in patients with central cones, while the HCL provided greater visual gain than the RGPCL in patients with paracentral cones. In conclusion, our results demonstrate that RGPCLs are practical and reliable lenses with high optical success and continue to be the first-line option among the currently available keratoconus lenses. With new technology that combines the positive properties of rigid and soft lens materials in a single lens, next-generation HCLs have now become almost competitive with RGPCLs. Nevertheless, for HCLs to continue to compete, studies including larger patient groups with longer follow-up and investigating the effects of HCLs on the cornea and ocular surface are needed.

**Ethics**

**Ethics Committee Approval:** This prospective study was conducted in the Cornea Unit of the Ankara Bilkent City Hospital Clinic of Ophthalmology and adhered to the principles of the Declaration of Helsinki. Ethics committee approval for the study was obtained from the Clinical Research Ethics Committee of the Ankara Yıldırım Beyazıt University Faculty of Medicine (number: 26379996/223, date: 12.09.2018).

**Informed Consent:** Written informed consent was obtained from all patients.

**Peer-review:** Externally and internally peer reviewed.

**Authorship Contributions**


**Conflict of Interest:** No conflict of interest was declared by the authors.

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