Original Article

Hybrid Contact Lenses for Visual Management of Patients after Keratoplasty

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Abstract

Aim: This study aims to report the outcomes of new-generation hybrid contact lenses for visual rehabilitation of postkeratoplasty patients. **Materials and Methods:** Twenty eyes of twenty postkeratoplasty patients were fitted with hybrid lenses. Each patient's keratometric values, ocular surface irregularity indices, central corneal thickness (CCT), uncorrected visual acuity (UCVA), spectacle-corrected visual acuity, contact lens-corrected visual acuity, contact lens fitting data, and contact lens daily wearing time were recorded. Follow-up examinations were performed at 1st week, 1st month, and 3rd month visit after successful fitting of the lenses. **Results:** The mean age of the patients was 38.42 ± 4.89 years. The mean spherical component of refractive error was −4.46 ± 2.1 D, and the mean astigmatism was −5.31 ± 1.55 D. The median UCVA was 1.00 logarithm of the minimum angle of resolution (logMAR) which improved to 0.40 logMAR after spectacle correction. The median visual acuity with hybrid contact lenses was 0.05 logMAR. The median CCT was 544.4 μm and increased to 549.2 μm at 3 months after contact lens wear. The difference was not statistically significant (P = 0.38). The mean follow-up of patients was 4.32 ± 0.45 months. Eighteen of twenty patients reported a mean of 8.37 ± 1.95 h comfortable wearing time per day during this period. Two patients discontinued contact lens wearing due to conjunctival hyperemia. No graft-related complications such as decompensation, rejection, and infection were documented during the follow-up period. **Conclusion:** The new-generation hybrid contact lenses can be considered helpful in the visual management of postcorneal graft patients, particularly who are unable to achieve an adequate visual outcome with spectacles.

Keywords: *Contact lens complications, hybrid contact lens, irregular cornea, penetrating keratoplasty, postkeratoplasty astigmatism*

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Introduction

Penetrating keratoplasty (PK) or corneal graft involves the replacement of abnormal host tissue by donor corneal tissue. The main goal of PK is visual rehabilitation. However, despite recent improvements, the poor visual outcome remains a major challenge in some patients (15%–31%) after PK who develop postoperative astigmatism >5 D.[1-4] As a result, many postgraft patients need some means other than spectacles to improve their vision.[2,4] Contact lenses are usually the first nonsurgical choice in such conditions.[5,6] However, postsurgical fitting of contact lens is challenging because the corneal topography is greatly changed in the area of wound due to the scar between the graft and the host cornea.[5,6] Various types of lenses (soft, rigid, semiscleral, and scleral) have been fitted on postkeratoplasty eyes.[5,7-14] Hybrid contact lenses aim to combine the preferred properties of rigid and soft contact lenses.[15] The central part of the lens is made of the same type of material as rigid gas permeable (RGP) lenses, so oxygen can easily pass

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through. The peripheral part, which is soft lens material, leans on the sclera and maintains centration.

The aim of the current study is to evaluate the visual function after UltraHealth (SynergEyes, Inc., Carlsbad, CA) hybrid contact lens fitting in postkeratoplasty corneas.

Materials and Methods

Twenty postcorneal graft patients, who had astigmatism more than 4 D after suture removal (at the end of 1 year), and whose visual acuities were insufficiently corrected with spectacles, were included in this study. All patients had been prescribed UltraHealth hybrid lenses. The study protocol was approved by the Institutional (Ankara Education and Research Hospital) Review Board and followed the tenets of the Declaration of Helsinki which is revised in 2000 (available at http://www.wma.net/e/policy/17-c_e.html). All patients signed the informed consent. The patients' sex, age, and background diseases leading to corneal graft were recorded. The anterior corneal profile was evaluated by Pentacam HR corneal topography (Oculus, Wetzlar, Germany), and keratometric values of steep and flat axes as well as surface irregularity indices were recorded. To examine the hypoxic corneal changes following contact lens wear, central corneal thickness (CCT) was measured by Pentacam before and at 3-month visit immediately following minimum 5 h of contact lens wear. Uncorrected visual acuity (UCVA), spectacle-corrected visual acuity (SCVA), contact lens-corrected visual acuity (CLCVA), and each patient's lens fitting parameters were documented. Visual acuity outcomes are reported in logarithm of the minimum angle of resolution (logMAR) values for statistical analysis.

Patients were fitted with the UltraHealth (SynergEyes, Inc., Carlsbad, CA, USA) hybrid lenses according to the manufacturer's guidelines. The fitting of these lenses is based on the concept of sagittal depth in relation to the cornea. Lens selection is determined by slit-lamp examination of fluorescein patterns to evaluate apical touch versus apical clearance. The initial trial lens was 100–150 μm above the apex of the cornea because the skirt is expected to settle between 30 and 60 μm during wear. The final lens is expected to vault the cornea by about 50 μm. After determining the vault needed to clear the cornea, the skirt curvature is determined also through observations using sodium fluorescein that fits onto the sclera to create an appropriate landing zone. The soft silicone hydrogel skirt helps center the RGP lens, and there should be a thin bearing ring at the inner landing zone [Figure 1]. The UltraHealth hybrid lens materials and parameters are shown in Table 1.

In this study, for the initial trial lens, central vault value was chosen according to steep *K* value and then altered to obtain a lens that would be ideal or appropriately fit. For those with a steep *K* value of 50–53 D, we started with 250 μ vault lens, and for steep *K* of more than 53 D, we started with 350 μ vault lens. Higher vault lens was tried if the apical bearing was noted. We started with 8.4 mm flat skirt for skirt fitting, then a steeper skirt was tested if heavy inner landing zone bearing was noted. If pooling was noted, a flatter skirt was tested until appropriate fitting was achieved. After determination of acceptable vault and skirt value, the patients were allowed to use the lenses for more than 1 h, and then overrefraction was performed to prescribe the final lens refractive power.

Follow-up visits were performed at 1 week, 1 month, and 3 months after successful fitting of the lenses. At each visit, CLCVA, comfortable wearing time, lens position, lens movement, and graft condition were recorded.

Data were analyzed by Statistical Package for Social Sciences software version 15. (SPSS Inc., Chicago, IL, United States of America). The variables were investigated using analytical methods (Shapiro–Wilk test) to determine whether or not they are normally distributed. Since UCVA, SCVA, CLCVA, and CCT were not normally distributed, they were presented as medians, and the Wilcoxon test was performed to test the significance of pairwise differences (UCVA vs. CLCVA and SCVA vs. CLCVA). An overall $P < 0.05$ was used to infer statistical significance.

Results

Twenty post-PK eyes of twenty patients (12 males and 8 females) were fitted with UltraHealth hybrid contact lenses. The mean age of the patients was 38.42 ± 4.89 years, ranging from 24 to 46 years. Background diseases leading to corneal graft were keratoconus in 18 patients and macular corneal dystrophy in two patients. All of the eyes received full-thickness corneal grafts and the mean graft size was 7.40 ± 0.20 mm. The mean follow-up period was 4.32 ± 0.45 months (3–5 months).

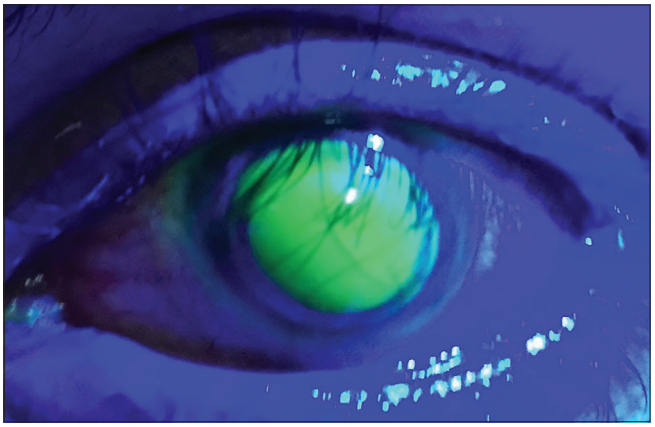

Figure 1: Photograph of the ideal fitting of UltraHealth hybrid lens

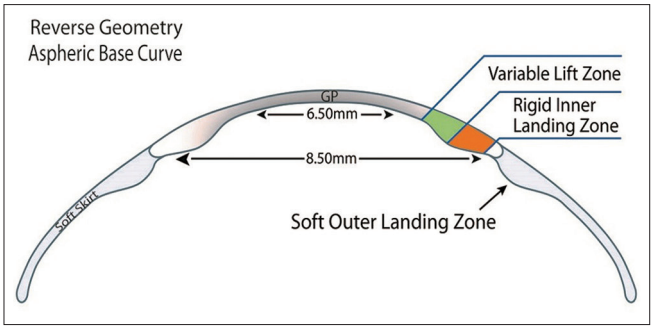

Figure 2: UltraHealth hybrid contact lens design (with permission of Tina Sharp from Synerg Eyes)

The median UCVA and SCVA were 1.00 logMAR (0.52–1.80) and 0.40 logMAR (0.22–1.20), respectively. The mean spherical component of refractive error was −4.46 ± 2.1 (ranging from −1.0 to −10.0 D), and the mean astigmatism was − 5.31 ± 1.55 (ranging from −4.0 to −9.0 D). The mean flat keratometric value and the mean steep keratometric value were 47.3 ± 4.1 D and 53.12 ± 5.1 D, respectively. Corneal surface irregularity indices (index of surface variance, index of vertical asymmetry, index of height asymmetry, and index of height decentration) were high in all patients [Table 2]. Before contact lens fitting, the median CCT was 544.4 μm which increased to 549.2 μm at 3 months after contact lens fitting. The difference was not statistically significant (P = 0.38).

The mean interval between PK and contact lens fitting was 19.2 ± 6.6 months. The fitting mean vault value was 475 ± 55.6 (300–550), and skirt curvatures were medium in twelve patients, steep in six patients, and flat in two patients.

The median CLCVA was 0.05 logMAR (0.00–0.70 logMAR) after lens fitting, and CLCVA remained almost constant throughout the follow-up. Because of amblyopia, which was confirmed with pinhole test, visual acuity did not improve more than 0.70 logMAR level in two eyes. Amblyopia was attributed to previous anisometropic ametropia. There was a statistically significant difference between UCVA (1.00 logMAR) and CLCVA (0.05 logMAR) (P = 0.0001). A comparison of prefitting SCVA (0.40 logMAR) and CLCVA (0.05 logMAR) showed a statistically significant difference (P = 0.0001). Visual and keratometric data are presented in Table 3. Eighteen of twenty patients reported a mean 8.37 ± 1.95 h (4–13 h) comfortable wearing time per day during this period. Two patients suffered from conjunctival hyperemia and contact lens intolerance after 4 or 5 h of wearing the lenses. Causes of contact lens intolerance were vault reduction and corneal contact at the transition zone. These two patients discontinued contact lens wearing. No graft-related complications such as decompensation, rejection, corneal edema, and infection were documented during the follow-up period.

Table 1: The properties and parameters of UltraHealth™ hybrid contact lens, as stated by the manufacturer

Lens Parameters	Lens Properties
Lens material	Rigid gas permeable center (130 Dk) Silicone hydrogel soft skirt (84 Dk)
Diameter	14.5 mm
Skirt curves	8.7 flat 2 8.4 flat 8.1 medium 7.9 steep
Lens power	+10.00-−20.00 D
Vault values	50, 100, 150, 200, 250, 300, 350, 400, 450, 500, 550
Wear and replacement	Daily wear, replace at 6 months

Dk=Oxygen permeability

Table 2: Results of corneal surface irregularity indices of postkeratoplasty patients by scheimpflug camera, and index limit values

Index	Result	Abnormal	Pathological
ISV	110.0±20.2	≥37	≥41
IVA	1.12±0.29	≥0.28	≥0.32
IHA	33.8±8.6	≥19	>21
IHD	0.114±0.01	≥0.014	>0.016

ISV=Index of surface variance; IVA=Index of vertical asymmetry; IHA=Index of height asymmetry; IHD=Index of height decentration

Table 3: Visual and keratometric data of postkeratoplasty patients fitted with UltraHealth™ hybrid contact lenses

	Mean±SD	Range
Age (year)	38.42±4.89	24-46
K_1 (D)	47.3±41	41-52
K_2 (D)	53.12±5.1	47-65
UCVA (logMAR)	1.00 (median)	0.52-1.80
SCVA (logMAR)	0.40 (median)	0.22-1.20
CLCVA (logMAR)	0.05 (median)	0.00-0.70
Daily CL wear time (h)	8.37±1.95	4-13
Follow-up period (month)	4.32±0.45	3-5
Median corneal thickness (μm) before CL fitting	544.4	484-615
Median corneal thickness (μm) 3 months after CL fitting	549.2	497-633

K_1=Flat K reading; K_2=Steep K reading; UCVA=Uncorrected visual acuity; SCVA=Spectacle-corrected visual acuity; CLCVA=Contact lens-corrected visual acuity; CL=Contact lens; LogMAR=Logarithm of the minimum angle of resolution; SD=Standard deviation

Discussion

Smiddy *et al*. reported that more than 50% of patients would need to wear contact lenses after successful keratoplasty.[16] Post-PK corneas have variable curvatures both centrally and at the wound margins,[5] which are

frequently featured by the centrally flat and peripherally steep pattern.

All of our patients demonstrated abnormal ocular surface indices obtained by Pentacam which demonstrate severe corneal irregularity. Irregular astigmatism is the most frequent cause of decreased visual acuity after keratoplasty. In our series, the mean UCVA after keratoplasty was 1.00 logMAR which only improved to a mean 0.40 logMAR with spectacles. Spectacles are often insufficient to rehabilitate the visual acuity of the grafted eye. In those cases, contact lenses may be required to improve vision. Different types of contact lenses have been fitted on postkeratoplasty eyes.[5,7-11] Soft contact lenses have limited role in correcting postoperative corneal irregularity as they tend to drape over the surface of the cornea and result in poor visual acuity.[8] The RGP lenses provide correction of the corneal surface, but in severe cases of corneal irregularity, it is difficult to fit the RGP lens, and desirable centration may not be achieved. Furthermore, lens intolerance, physical damage to the corneal epithelium, and relative smaller diameter were the other disadvantages of these lenses in postkeratoplasty patients.[4,17]

In recent years, some studies reported the successful use of scleral contact lenses (SCLs) for correcting refractive errors of post-PK patients.[7,11,18] Alipour *et al*. described mini-SCL fitting in 56 eyes of postkeratoplasty patients and observed a visual improvement from 1.05 logMAR (UCVA) to 0.17 logMAR (CLCVA).[7] Rocha *et al*. reported that 26 eyes (96.3%) in their study achieved a visual acuity of ≥0.30 logMAR, and 21 eyes (77%) achieved an improvement of ≥2 visual acuity lines relative to the best SCVA.[19] However, the failure of contact lens usage rates varies. Alipour *et al*. reported a failure rate of 75% (among 56 eyes studied, lenses were ordered for only 23 eyes, and of these, lens usage was continued in only 14 eyes of 11 patients). In that study, only reported complaints were conjunctival hyperemia, and no graft-related complications such as rejection or decompensation occurred.[7] Rocha *et al*. described a 14.8% of usage failure, and they reported no corneal graft rejection during 6-month follow-up period.[19] The major complaints related to scleral lenses were difficulty with lens insertion or removal and its cost.

Hybrid contact lenses with the ability of vaulting the whole cornea and bigger diameter can be effective in post-PK patients.[20] Hybrid contact lenses present a rigid central part and soft skirts, extending from the central rigid zone to the edge of the lens. The central part of the lens is made of the same type of material as RGP lenses, so that oxygen can easily pass through. The peripheral part, which is soft lens material, leans on the sclera and maintains centration.

The UltraHealth hybrid lens is the most recent marketed hybrid lens, and it has some unique properties to previous hybrid lenses, according to the manufacturer's instructions. It incorporates reverse geometry, aspheric RGP lens that vaults corneal irregularities and provides a lift which is twice of previous hybrid design. The vault design of UltraHealth hybrid contact lens varies from a fixed vault system (vaults 50–250, aspheric) to a variable vault system (vaults 300–550, reverse geometry) [Figure 2]. Moreover, the more aggressive reverse geometry design may allow the lens to clear the majority of ectasias. Other difference of UltraHealth lenses from previous hybrid lenses is the high oxygen transmission (130 Dk for RGP center and 84 Dk for silicone hydrogel soft skirt).

Very limited studies about the usefulness of hybrid contact lenses for the visual rehabilitation of patients with significant corneal irregularity after keratoplasty have been reported.[20-22] Most of the articles about the use of hybrid contact lenses are focused on their use in keratoconus and are related to the previous model of hybrid contact lenses.[23-28] Those contact lenses were associated with some problems such as limitation in oxygen permeability and breaking of the transition zone between the RGP part and soft skirt part.[26-28] SynergEyes (ClearKone) hybrid contact lenses have been favorably compared to traditional RGP lenses for patients with irregular corneas. An average improvement of four lines over SCVA was achieved, and 79.5% of patients reported improved comfort compared to the rigid lens design.[22]

To the best of our knowledge, this is the first study to demonstrate the applicability of the new-generation hybrid contact lens of reverse geometry for visual rehabilitation of postkeratoplasty patients with significant corneal irregularity and unsatisfactory visual acuity. We were able to achieve acceptable contact lens fitting and improvement of the visual acuity in all of our patients. Median CLCVA of 0.05 logMAR or better with the final contact lens was achieved in 80% of patients with good wearing time. Approximately 8 h of daily wear was reported by 18 of 20 patients without any discomfort, which is sufficient for many daily activities.

Despite the good clinical performance in visual rehabilitation, clinicians should be aware of the potential complications with this fitting approach. These include corneal indentation in the transition zone between the rigid and the soft material, typically associated with a loss of vaulting over time. Inappropriate fitting of contact lenses presents a potential risk for the development of epithelial defects, corneal infiltrates, vascularization, and graft rejection or failure.[5,11]

In our case series, there were no cases of infectious keratitis or graft rejection, but due to the loss of vaulting, epithelial trauma was present in two patients and these two patients discontinued contact lens wearing. Except these two cases, other patients achieved a good wearing time. A small amount of increase in corneal thickness was recorded, but it was not clinically significant. Two limitations of this study are small sample size and short follow-up period. It would be necessary to conduct further long-term clinical studies about the use of hybrid contact lenses in the visual rehabilitation of post-PK patients and to evaluate the possible complications.

Conclusion

The new-generation hybrid contact lenses can be considered helpful in the visual management of postcorneal graft patients, particularly who are unable to achieve an adequate visual outcome with spectacles. The main factors that may have contributed to this successful outcome are its aspheric reverse geometric design, with apical clearance, and the soft skirt and large diameter which contribute to centration and stability of the lens over the cornea.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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