

Original research

Estimation of the hybrid lens parameters through rigid gas permeable lens fitting

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Abstract

Purpose: To estimate the fitting parameters of the hybrid contact lens in patients with corneal ectasia using the rigid gas permeable (RGP) lens.

Methods: Thirty-four eyes with corneal ectasia were evaluated in this study. The patients were examined once with the RGP lens and once with the hybrid contact lens. The relationship between the base curvature of the RGP and the vault of the hybrid lens and the correlation between their powers were analyzed.

Results: We found a linear relationship between the base curvature of the RGP lens and the vault of the hybrid lens ($P < 0.001$) ($R^2 = 0.45$). Moreover, we found a correlation between the power of the RGP and hybrid lens ($P < 0.001$) ($R^2 = 0.4$). However, a 0.5 mm decrease in the base curvature radius of the RGP lens increased the vault of the hybrid lens by 72 μ .

Conclusion: The results of this study could be used for better and faster selection of the first hybrid contact lens.

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Keywords: Keratoconus; Hybrid lens; Rigid gas permeable lens; Corneal ectasia

Introduction

Contact lenses have been long used to improve visual conditions in corneal ectasia.^{1–4} The visual needs of the patients cannot be met only with the Rigid gas permeable lens when Keratoconus becomes more severe. In other words, the

corneal topographic status of the patients does not allow the contact lens to be placed on the corneal surface properly.^{5–7}

There are two types of primary and secondary corneal ectasia. Keratoconus and pellucid degeneration are examples of primary ectasia resulting from refractive surgery and ring implantation. Keratoplasty is an example of secondary ectasia.^{8–11}

Irregular astigmatism developed after ectasia, which is not corrected with glasses and the soft contact lens, impairs the patient's vision.^{1,12} Mini-scleral, semi-scleral, and scleral contact lenses constitute safe options in the management of irregular corneas. In addition, heavy costs and the emotional stress of the corneal graft operation made primary visual care providers design lenses that provide the patients with the comfort of the soft lenses and the optical quality of the hard lenses.¹³

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In this regard, a new generation of contact lens known as ClearKone (SynergEyes Inc., Carlsbad, CA) are third-generation hybrid lens platform; the design was launched in 2010 and is indicated for corneal ectasia. However, these lenses are relatively expensive to manufacture, and examination of the patients is time-consuming. For this reason, fitting of such lenses should be very efficient with minimal errors.^{14,15} One of the most difficult clinical procedures in ophthalmology is fitting the contact lens on irregular, operated, and damaged corneas.⁶ Considering the very novel clinical use of these lenses, it is important to derive the necessary criteria for proper fitting of these lenses from the data of the patients who have recently used them. The data could be then provided as formulas or protocols to colleagues in this field to prevent misfitting of the lens and the waste of money and time, which cause stress and mistrust in patients.

Certainly the first treatment option for these patients is the use of the RGP lens.^{16–19} This article reports a novel technique that uses RGP lens parameters to optimize the efficiency and accuracy of the lens-fitting process in clinical practice for the management of corneal ectasia.

Methods

This cross-sectional study was performed in Noor Eye Hospital, Tehran, Iran. Some patients had previously used the contact lens, and some visited in the Contact Lens Clinic for the first time.

After receiving an explanation of the objective of the study, the patients were requested to sign informed consent forms. Then primary examinations were performed to ensure the eligibility of the participants using inclusion and exclusion criteria.

Inclusion criteria were a diagnosis of corneal ectasia by an ophthalmologist, having a standard fit with the ClearKone SynergEyesTM 20 and having a standard fit with the RGP lens.²¹ The exclusion criteria of the study were impossibility of Javal keratometry, use of the mydriatic drops, and corneal staining.

The slit lamp (Haag-Streit BM 900, Koeniz, Switzerland) was used to make a diagnosis of Keratoconus. The diagnostic criteria were observation of its signs including the retinoscopy reflex (Heine Beta 200, Cologne, Germany), stromal thinning of the corneal, Fleischer ring, apical stromal scar, Vogt striae, and corneal topography by the Pentacam-HR (Oculus, Wetzlar, Germany). Patients had been previously diagnosed with Keratoconus, presenting grade I to grade III according to the Keratoconus severity score grading scale.²² Other patients had

Table 1
The number and percentage of the evaluated diseases.

Disease	Number	Percentage
Keratoconus	27	79.4
Unsuccessful LASIK	3	8.8
Unsuccessful graft	2	5.9
Unsuccessful radial keratotomy	1	2.9
Trabeculectomy	1	2.9

the history of different operations which resulted in corneal ectasia. The characteristics of their disease and the frequency of the patients are shown in Table 1.

In the second stage, all eyes were fitted with the same Boston XO (Bausch & Lomb Inc., Rochester, NY, USA) tri-curve RGP lens design and material with 9.60 diameter, and different base curvatures were tested to achieve a three-point touch fit based on fluorescein pattern. After that, the patient received over refraction on the lens.

In the third stage, fitting of the ClearKone SynergEyesTM started 10–15 min after removing the RGP lens according to the manufacturer's instructions with a vault of 250 μ and medium skirt. The available parameters are included in Table 2.²³ The fitting of the ClearKone lens is based on the concept of sagittal depth in relation to the cornea. Proper fitting of the ClearKone depends on choosing a lens with sagittal depth that is sufficient to clear the elevation of the cone based on observation of the lens using sodium fluorescein. This is achieved by first determining the vault needed to clear the cone, and then by determining the skirt curvature, as well as through observations using sodium fluorescein that fits onto the sclera to create an appropriate landing zone.²⁴ In other words, the lens was changed repeatedly to achieve optimal fitting indicated by: 1- clearance in the center of the hard lens as the edge of the pupil could be seen; 2- fluorescein fading in the internal junction of the hard and soft parts; 3- non folding of the skirt in the junction of the hard and soft parts; and 4- power of the lens determined by over refraction. Data were analyzed with SPSS IBM version 22. P values less than 0.05 were considered significant. Fig. 1 shows the patient's eye, and Fig. 2 presents the used lens.

The Ethics Committee of Iran University of Medical Sciences approved the study protocol, which was conducted in accord with the tenets of the Helsinki Declaration. All participants signed a written informed consent.

Results

In this study, 34 eyes of 26 men and 8 women with a mean age of 30 years (range: 19–47 years) were evaluated. They had corneal ectasia and irregularity and were referred by

Table 2
Technical details of ClearKone lens.

Brand	ClearKone
Manufacturer	SynergEyes
Material (rigid gas permeable Center)	Paflucocon D
Material (soft skirt)	Hem-iberfilcon A
Water content (rigid gas permeable center)	<1%
Water content (Soft skirt)	27%
Oxygen permeability (rigid gas permeable center)	100
Oxygen permeability (Soft skirt)	9.3
t mm	0.18 to 0.39
Power, D	+20.00 to -20.00 D
Overall diameter, mm	14.50
Vault, mm	0.05 to 0.75
Base curve radius (soft skirt)	Steep medium and flat

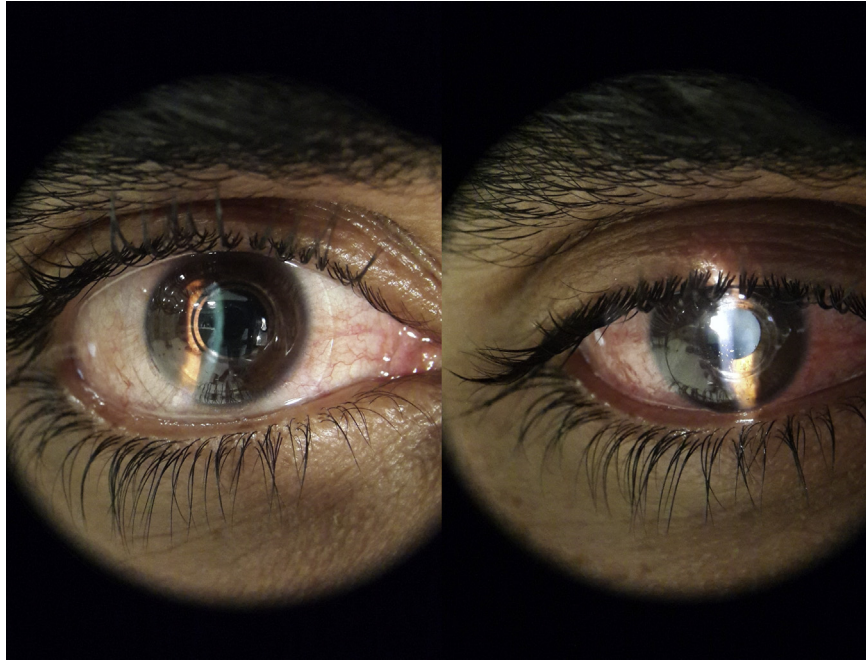


Fig. 1. Hybrid lens on the eye.



Fig. 2. Hybrid lens over the plunger and filled with fluorescein.

ophthalmologists to receive contact lenses. The descriptive statistics of the study patients is shown in Table 3.

A vault of 250 μm was appropriate in most patients (n = 19), and dispersion in lower or higher vaults was almost similar. The lowest and the highest base curvature of the hard lens were 6.50 and 8.40 mm, respectively. The mean keratometric reading was 7.43 mm ± 0.79. Dispersion of base curvature in other cases was great. A steep skirt was prescribed in 30 eyes, and a medium skirt was prescribed in 4 eyes. No patient required a flat skirt.

Table 3
Descriptive statistics of the study patients.

	Minimum	Maximum	Mean	Standard deviation	Mode
Maximum keratometry (mm)	6.55	9.75	7.765	0.753	7.45
Minimum keratometry (mm)	5.95	9.30	7.097	0.846	6.18
Mean keratometry (mm)	6.25	9.53	7.435	0.797	7.17
Hard lens base curve (mm)	6.50	8.40	7.745	0.493	7.80
Hard lens power (D)	-14.00	+1.75	-3.367	3.310	-4.00
SynergEyes lens power (D)	-15.50	+3.50	-4.83	3.905	-2.00
SynergEyes lens vault (μm)	150	600	277.94	104.585	250

Formula 1. Vault SynergEyes Lens
(μm) = 1397-144.477(B.C of RGP lens (mm)).

Formula 1 shows a linear relationship between the ClearKone SynergEyes™ lens vault and base curvature of the RGP lens (P < 0.001) (R² = 0.45).

Formula 2. : Power SynergEyes Lens
(D) = -2.26 + 0.762(Power of RGP lens (D)).

Formula 2 suggests a correlation between the power of the RGP lens and ClearKone SynergEyes™ lens (P < 0.001) (R² = 0.4).

Discussion

In this study, we evaluated the relationships between the parameters of the RGP lens and ClearKone SynergEyes™ hybrid lens to find a way for faster and easier fitting of the ClearKone SynergEyes™ hybrid lens using the RGP lens parameters. We found no studies regarding the prescription of the ClearKone SynergEyes™ lens using the RGP lens parameters. The manufacturer suggests a vault of 250 μm as the first choice. Although this suggestion is good in some patients,

it does not apply in others. According to Formula 1 and 2, changes in the base curvature or power of the RGP lens are correlated with the vault and power of the hybrid lens. The relationship between the parameters is linear and on average, a 0.5 mm decrease in the base curvature radius of the RGP lens increases the vault of the hybrid lens by 72 μm . Moreover, we found a relationship between the power of the RGP and hybrid lens; the power of the hybrid lens was more positive than the power of the hard lens.

However, according to R^2 , the results of this study cannot be used to determine (empirical method) the precise parameters of the ClearKone SynergEyes™ lens and its fitting, but can be used to select the first hybrid lens faster. The results of this investigation could be used to calculate the required vault in a very simple way.

We found that there was no correlation necessarily between the mean base curvature of the cornea and vault. Previous studies have reported similar findings. Moreover, corneas with rather similar ectasia have reached optimal fitting at different vaults.^{20,24}

Frequent placing and removing the ClearKone SynergEyes™ hybrid lens is time consuming and requires patience. On the other hand, the first treatment choice for a patient with corneal ectasia is to use a RGP lens.^{16–19} Therefore, most of these patients have already tried the RGP, and the parameters of the RGP lens can be used for easier fitting of the ClearKone SynergEyes™ hybrid lens. Using this new clinical finding, ophthalmologists can choose a trial ClearKone SynergEyes™ hybrid lens that is closer to the final prescription and therefore spend less time on fitting the hybrid lens.

The advantages of the ClearKone SynergEyes™ over other lenses are the comfort and good vision when using the lens.^{23,25} On the other hand, the process of fitting the ClearKone SynergEyes™ lens is very tiring and time consuming, which can affect patient decision to use this treatment option. This study tried to shorten the process of finding the appropriate final lens to persuade patients to use this method.

Due to the design and reverse curvature of the hybrid lens, most of the lens power is provided by the tear layer, which increases the optical quality, transmissibility of oxygen, and efficiency of these lenses.^{26,27} Moreover, it prevents mechanical abrasion through creating a little space between the coned (ectatic) part and the hard lens, which is why the patients prefer the hybrid lens over the hard lens as reported by Hashemi et al.²⁸

A study was conducted to estimate the vault based on the data of corneal elevation.²⁴ Although the results of this study provide a very accurate estimation ($R^2 = 0.96$) of the first vault based on the results of topography, it imposes heavier costs on the patients since the Pentacam is not available everywhere, and the point-to-point data that the device provides from the cornea may sometimes be misleading as it does not provide the data in a global fashion. Our research showed how the parameters of the hard lens of the patient can be used to select the best first vault, which is more practical and clinical than the above-mentioned method.

The small sample size and lack of follow-up were limitations of the study.

According to the results of our study, the fitting parameters of the RGP lens can be employed to estimate the parameters of the ClearKone SynergEyes™ lens. According to our study, most of these patients are young (with a mean age of 30 years) and in active years of their lives and have social and educational problems due to their condition. Therefore, accurate and correct fitting of the ClearKone SynergEyes™ lens can satisfy their needs.

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