

Fitting Of Challenging Corneas With Special Design Of Rigid Gas Permeable (RGP) Lens

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ABSTRACT

Purpose: To study the safety and efficacy of a new design of RGP lens namely Rose K irregular cornea (IC) in management of corneas with high degree of irregular astigmatism.

Subjects and Methods: The study was made in 66 eyes of 40 patients with irregular astigmatism. The selection criterion was to obtain a sample population with irregular astigmatism that was unlikely to be corrected with spectacles or conventional contact lens. A complete ophthalmologic exploration, which included topography, was made. All eyes were fitted with Rose K IC after measuring precisely lens parameters according to a special trial set of this design. Refraction, visual acuity before and after fitting, maximum wearing time, contact lens related problems and patient satisfaction were analyzed.

Results: The studied eyes included eyes with high degree of irregular astigmatism due to keratoconus (oval and globus type) in 42 eyes (63.6%), corneal injuries in 6 eyes (9.1%), pellucid marginal degeneration (PMD) in 12 eyes (18.2%), and post Lasik ectasia in 6 eyes (9.1%). After fitting of the eyes with the RGP lens, there was a significant improvement in the visual acuity (VA) in all fitted eyes ($p < 0.001$). 97% of the patients gained more than 3 lines after fitting with the lenses. Study of spherical and astigmatic errors showed also a highly significant improvement ($p < 0.001$). Statistical analysis of the subjective responses indicated a strong acceptance of the lens by all subjects.

Conclusion: Rose K IC proved to be effective in correcting high degree of corneal astigmatism caused by a variable number of challenging corneal conditions with high visual performance and good patient comfortability

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Introduction

Irregular astigmatism is a cause of vision loss. Surgical options to improve the irregular corneal conditions include intrastromal corneal rings, thermocauterisation, and a great variety of different types of keratoplasty [1-3]. None of the present methods of treatment reliably achieves an optimum visual result. Thus, surgical intervention should be delayed as long as possible.

The non-surgical approaches to the management of the high and irregular astigmatism as in patients with keratoconus, PMD, trauma or post Lasik ectasia include spectacles and different groups of contact lenses [4,5]. Patients with high or irregular astigmatism cannot be corrected with spectacles. Correction with contact lenses is the treatment of choice and the key to visual success in most cases[6-9]. The challenge is to maintain the patient with an acceptable tolerance together with adequate visual acuity in corneas in continuous change. Among the different kinds of contact lenses a rigid gas permeable lens may be the correction of choice, since this type of lens provides good visual acuity, corrects high degrees of regular and irregular astigmatism, has high oxygen permeability, and, in comparison with soft contact lenses, carries a lower risk of microbial keratitis (incidence 1/10000) and corneal neovascularization [10].

Because of the special conditions, leading to changes of the inferior corneal surface, in most cases only a special designs of rigid gas permeable contact lenses with a reverse geometry design can lead to optimal fit and visual results.

The study aim to assess the safety and efficacy of a new design of RGP lens namely Rose K irregular cornea (IC) in management of such challenging corneas with high degree of irregular astigmatism.

Subjects and Methods

The study was carried out on 66 eyes in 40 patients with irregular astigmatism of all the etiologies listed in our ophthalmological clinic in Mansoura Ophthalmic Center, Mansoura University. The inclusion criterion accepted all irregular astigmatism unable to achieve good visual acuity (VA) with spectacles or standard design contact lenses.

The following parameters were quantified: eye (right/left), laterality (unilateral/bilateral), sex, irregular astigmatism etiology, visual acuity (AV) pre- and post fitting refraction, pre and post keratometric readings, contact lens related problems and patient satisfaction which was considered as a success with the verification of tolerance during a working day (at least eight hours) for one month and patient preference to continue wearing his lenses or not.

The causes of irregular astigmatism were divided into four groups: keratoconus, PMD, post Lasik ectasia and corneal traumatism.

The refraction was obtained by means of an objective automatic refractometer, with the graduation fine-tuned by subjective analysis with the E Snellen optotypes. Corneal topography was performed using TMS-2 Topographic Modeling System-II (*Tomey, U.S.A*)

Contact Lens Fitting and Follow-Up

After eligibility was confirmed at the initial visit, the contact lens fitting process was begun. All eyes were fitted with a reverse-geometry lens design namely Rose K IC after measuring precisely lens parameters according to a special trial set of this design.

The diagnostic fitting set is a standardized fitting set that can be ordered from contact lens laboratories that manufacture Rose K lenses. The set consists of 19 lenses with base curves (BC) ranging from 6.5 (56.25 D) to 8.4 (40.25). All lens overall diameters in the fitting set are 11.2mm with changing power to approximate final lens power. All lenses in the fitting set have a standard edge lift design. However, we can order the lens with a BC ranging from 5.7mm to 9.3mm, with diameter ranging from 9.4mm to 12mm, with any power and with standard, flat or steep edge lift.

The initial lens that was applied to each eye in the diagnostic fitting was based on the recommendations of the fitting guide. We choose first trial lens 0.3 mm flatter than the steepest corneal meridian and then assess the lens according to the following parameters

- Central fit and any heavy corneal contact areas
- Peripheral fit: particularly noting tight and loose areas
- Diameter: should sit approx. 1mm inside the limbus
- Location: tends to locate over steepest point on cornea
- Movement: Must move sufficiently to achieve tear exchange

We Use high Dk materials e.g. Boston XO2 in all fitted lenses.

After finding the optimal trial lens for each eye, an over refraction was performed while the subject was wearing the trial lenses. This information was used to determine the contact lens power to be ordered.

If the ordered base curve was not available in the fitting set, the trial lens with a base curve closest to the ordered lens was used for the over-

refraction, and the power was compensated in the ordered lens. All Rose K lenses were ordered from David Thomas Contact Lens Company, UK.

After the ordered lenses arrived in our clinic, subjects were scheduled for dispensing visits. If the first lens gave acceptable fit, vision, and comfort, the subject was scheduled for follow-up in 2 weeks. If fit, vision, and comfort were still acceptable after 2 weeks of wear, the subject was scheduled for the final study visit, about 2 months after the initial dispensing visit. If the first ordered lenses were not acceptable, the lenses were reordered with the appropriate changes. The subject was scheduled for another dispensing visit when the new lenses arrived.

Results

The study was carried out on 66 eyes in 40 patients (22 female and 21 male) with an average age 23 ± 7 years. The studied eyes included eyes with high degree of irregular astigmatism due to keratoconus (oval and globus type) in 42 eyes (63.6%) of 22 patients, PMD in 12 eyes (18.2%) of 7 patients, post Lasik ectasia in 6 eyes (9.1%) of 5 patients, and corneal injuries in 6 eyes (9.1%) of 6 patients.

Of all patients, 26 patients were fitted bilaterally while 14 patients were fitted in only the one affected eye.

UAVA, Maximum and Minimum keratometric reading and objective refractometry were summarized in table 1.

Table 2 revealed the fitting parameters used in the studied eyes. The base curves of the used lenses ranged from 6.2mm to 7.4mm. We used only the standard diameter (11.2 mm) in all ordered lenses. As regard the edge lift 60 eyes (90.1%) were fitted with standard edge lift while only 6 eyes (0.9%) were fitted with flat edge lift.

Post fitting characteristics including the BCVA, Spherical and cylindrical errors were recorded and compared with the pre fitting data in table 3. Also maximum wearing time per day in hours (MWT/d) and patient preference were demonstrated.

Comparing the pre and post fitting results revealed a significant improvement in the visual acuity (VA) in all fitted eyes. The mean VA improved significantly in all studied groups ($p < 0.001$). 97% of the patients gained more than 3 lines after fitting with the lenses. Study of spherical and astigmatic errors showed also a highly significant improvement ($p < 0.001$).

Statistical analysis of the subjective responses indicated a strong acceptance of the lens by most of subjects. The maximum wearing time per day was ≥ 8 hours per day in all studied patients. 36 patients (90%) prefer to continue using their contact lenses while only 4 patients asked for another option rather than contact lenses.

Complications of the Rose K IC were recorded in table 4. They included allergies in 6 eyes, superficial punctate keratitis (SPK) in 2 eyes, epithelial abrasion in 3 eyes, tight lens syndrome in 6 eyes, handling difficulties in 4 eyes and broken lens in one eye.

Discussion

Correcting an irregular astigmatism is a challenge for the ophthalmologist. In most cases, spectacles with adequate correction failed to improve the VA, leaving contact lenses as the sole option for treatment before the surgery. For this reason, all the options for contact lenses must be explored for each eye with irregular astigmatism.

We studied in the current research difficult corneal cases in which standard soft or rigid spherical contact lenses are not viable options for good vision or patient comfort. The high degree of irregular astigmatism renders soft contact lenses a less attractive choice. A common problem with standard spherical GP lenses in such patients is excessive inferior lens edge standoff and resultant unstable centration, which could lead to lens dislocation when blinking. The obvious shortcomings of fitting such challenging corneas with smaller optic zones and overall diameters design are the narrower fields of view, ghosting, and the change of vision as the lens moves over the pupil with the blink. Larger GP lenses with flatter base curves have been fit successfully on these patients because larger lenses provide for better stabilization.[2,4]. In the current research, all used lenses had BC 6.4 or flatter and a diameter 11.2mm

Reverse-geometry rigid GP lenses provide patients with improved peripheral fit, adequate comfort, and optimal visual acuity. The principle advantage with the reverse-geometry lens design in these cases is its steeper peripheral curves, which allow for a better alignment of the peripheral cornea. Reducing edge standoff discourages lens dislocation, lens intolerance, or even lens loss when blinking [5,11,12].

Reverse-geometry contact lenses were originally designed for orthokeratology and for fitting post-refractive surgery (radial keratotomy [RK]) patients. The most well known type is the OK series (Contex, Inc., Sherman Oaks, CA). Another popular type is the Plateau lens (Menicon, Clovis, CA) [11]

In the present study we evaluate the safety and efficacy of a new design of RGP lens namely Rose K IC lens which is an intralimbal RGP lenses incorporating large diameter, large optic zones, reverse geometry design and aberration-controlling optics to improve vision and enhances wearing time and comfort. In our study, we demonstrated improvement of BCVA in 100% of the studied patients (97% gained ≥ 3 lines) . All patients can wear their contact lenses for 8 hours or more per day. 90% of them prefer to continue with their contact lenses long life.

However, Contact-lens wear in these cases has a potential risk of complications including epithelial defects, corneal ulcers, edema and neovascularization [13]. Few complications associated with contact lenses were seen in our cases. Allergies were recorder in 9.1 % of fitted eyes; most of them were mild to moderate and can be managed with topical steroids and or antihistaminic drops. Tight lens syndrome was demonstrated in 9.1% of the eyes, which led to epithelial erosions in 3 eyes. All complained cases responded properly to topical lubricant drops or gel. SPK was noted in only 2 eyes, which well treated with topical steroid and lubricant drops. Handling difficulties were recorder in 4 eyes especially in removal of the contact lenses and one lens was broken while wearing the lenses.

As conclusion of our study, it can be said that contact lenses continue to play a relevant role in the treatment of irregular astigmatism [14-16]

because they improve the VA of these patients and exhibit lower risks than surgical procedures such as corneal rings and keratoplasty. Rose K IC (reverse-geometry) contact lens can be a useful tool in fitting of challenging corneas with irregular astigmatism as pellucid marginal degeneration, large oval, sagging keratoconus, keratoglobus, , LASIK-induced ectasia, post PRK, and post-trauma cases. They provide most of patients with good tolerance together with adequate VA

Tables

Table 1: Patients Characteristics

Character	Keratoconus	PMD	Post Lasik Ectasia	Trauma
No. of patients	22	7	5	6
No. of eyes	42	12	6	6
Bilaterality	20	5	1	0
Age	22±5	32±7	27±6	21±3
Sex (F:M)	13:9	4:3	4:1	1:5
UCVA	0.1±0.2	0.1±0.1	0.2±0.1	0.05±0.1
Max K	49.3±4.3	48.8±5.5	43.6±2.3	44.5±2.1
Min K	43.2±5.1	42.4±4.2	39.1±3.8	41.7±2.9
Sph.	-4.7±2.2	-3.9±2.3	-2.8±2.6	-2.2±1.9
Cyl.	-3.6±2.1	-6.5±2.2	-3.2±2.7	-4.2±2.3

Table 2 : Fitting parameters of Rose K IC lens

Lens parameter		<i>Mean ± SD</i>	
<i>Base curve</i>	Keratoconus	6.40± 0.2	
	<i>PMD</i>	6.60± 0.2	
	<i>Post Lasik</i>	7.00± 0.3	
	<i>Trauma</i>	7.20 ±0.3	
		<i>No. of eyes</i>	<i>(%)</i>
<i>Diameter</i>	<11.2 mm	0	0
	11.2 mm	66	100
	>11.2 mm	0	0
<i>Edge lift</i>	<i>Standard</i>	60	90.1
	<i>Flat</i>	6	0.9
	<i>Steep</i>	0	0

Table 3: Comparison of Pre and Post Fitting Characteristics

Character	Keratoconus		PMD		Post Lasik Ectasia		Trauma	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
VA	0.1	0.9*	0.1	0.8*	0.2	0.9*	0.05	0.7*
Sphere	-4.7	-0.5*	-3.9	-0.5*	-2.8	-0.25*	-2.2	-1*
Cylinder	-3.6	-0.5*	-6.5	-0.75*	-3.2	-0.25*	-4.2	-1.2*
MWT/d (h)	11±3		9±2		8±2		8±1	
Patient Preference (No)	20		6		4		6	

- significant at $p \leq 0.05$ (paired T test)
- VA: Visual Acuity
- MWT/d: Maximum Wearing Time /day

Table 4: Complications of Rose K IC lens

Complications	No. Eyes (%)
Allergies	6 (9.1%)
Superficial punctate Keratitis (SPK)	2 (3 %)
Epithelial abrasion	3 (4.5%)
Tight lens syndrome	6 (9.1%)
Handling difficulties	4 (6%)
Broken CL	1(1.5%)

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