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Utility of a semi-scleral contact lens design in the management of the irregular cornea

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ABSTRACT

Objectives: To evaluate the utility of the Rose K2 XL semi-scleral contact lens (Menicon Co. Ltd., Nagoya, Japan) in the management of the irregular cornea.
Methods: Twenty-seven subjects (34 eyes) with irregular corneas referred for contact lens fitting were evaluated. A diagnostic trial set was used in the fitting process. Once the trial lens was considered optimal, a final lens was ordered from the manufacturer with the necessary changes in power, edge lift and diameter. We analyzed visual acuity, number of lenses ordered and patients' ability to wear and handle lenses.
Results: Twenty-three subjects (30 eyes) were fitted with the Rose K2 XL lens. Four subjects (4 eyes) decided not to conclude the fitting process for different reasons. Average logMAR visual acuity without correction and with the lens was 0.82 and 0.09, respectively ($p < 0.001$). An average of 1.4 ordered lenses (range 1–3) were necessary to achieve the optimal fit. Nineteen eyes (63%) were fitted with the first lens ordered. Three subjects (13%) had problems with lens handling, and three subjects (4 eyes) abandoned the wear of the lenses after three months due to discomfort (3 eyes) and unsatisfactory visual acuity (1 eye), respectively. Follow-up ranged from 6 to 9 months.
Conclusion: Rose K2 XL semi-scleral contact lens provides good visual acuity and comfort in patients with irregular corneas.

1. Introduction

Contact lens fittings for irregular corneas represent one of the greatest challenges that practitioners have to face. It is widely known that fitting irregular corneas is relatively time consuming and costly, as it generally requires an increased number of patient visits and ordered lenses. Primary corneal ectasia such as keratoconus [1], or pellucid marginal degeneration [2], and irregular corneas resulting from corneal surgery such as keratoplasty [3], post-LASIK ectasia [4] or corneal ring segment implantation [5], can cause high amounts of irregular astigmatism, which leads to poor visual acuity with glasses or conventional soft contact lenses.

Rigid gas-permeable (RGP) contact lenses are considered the best solution for patients with irregular corneas, because they create a tear layer between the lens and the cornea, which masks the corneal irregularity and reduces the impact that higher order optical aberrations of the anterior corneal surface have in the visual function [4]. However, corneal RGP lenses may not be appropriate when corneal irregularity is excessive and the differences in height elevations among corneal sectors are great. Severe corneal distortions fitted with corneal RGP lenses result in lens decentration and/or excessive lens movement and results in poor comfort and unstable visual acuity. Furthermore, corneal RGP lenses could be associated with the onset of corneal scarring [6]. Hybrid lenses and piggyback lens systems might enhance lens stability and wearing comfort, but these techniques increase the cost and complicate lens storage and maintenance [7,8]. Custom soft lenses with aberration control have been proposed as a potential solution in cases of irregular corneas, but they are not easily available [9]. The relatively new special soft lenses for irregular corneas, with high central thickness (0.35 mm or more) also play a role in irregular cornea management, but they are only useful in mild or moderate amounts of irregularity [10].

Fitting large diameter RGP contact lenses improve lens centration, comfort and corneal health, increasing wearing time in cases of high irregular astigmatism [3]. Mini-scleral, semi-scleral and scleral contact lenses constitute safe options in the management of irregular corneas [11–15]. The early complications with the very first scleral lenses (i.e. corneal vascularization and manufacturing problems) have been resolved with modern hyper Dk gas-permeable materials and computer-assisted manufacturing

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technology. Nowadays, manufacturing toric periphery, back toric, front toric or bitoric surfaces has led to a renaissance of the large diameter RGP contact lens [16,17].

The present study describes our experience with the new Rose K2 XL semi-scleral lens in the fitting of irregular corneas in terms of visual acuity, number of ordered lenses, parameters of the final lenses, patients' ability to wear and handle the lenses and adverse events.

2. Materials and methods

A total of 27 subjects (34 eyes) were evaluated for Rose K2 XL semi-scleral lens fitting. All subjects presented irregular cornea and were referred for contact lens fitting from other medical services due to either uncomfortable and/or unsatisfactory visual acuity with their current contact lens or for a first contact lens fitting. Eligible subjects were those who were willing to be fitted with a new semi-scleral contact lens. A comprehensive ophthalmic examination was performed on all subjects and it included the assessment of uncorrected and corrected logMAR visual acuities, anterior eye biomicroscopy, fundus examination and corneal topographic analysis using the Pentacam Eye Scanner (Software version 1.16.r:23, Oculus Inc., Wetzlar, Germany). Informed consent was obtained from all subjects prior to the start of all experimental work and data collection. The study followed the Tenets of the Declaration of Helsinki and was approved by the Institutional Ethical Committee Review Board of MGR Doctores Ophthalmology Clinic.

All contact lenses used in the trial were semi-scleral Rose K2 XL lenses, manufactured in tisilfocon A material (Menicon Z, Menicon Co. Ltd., Nagoya, Japan). The lens design features an aspherical optic zone and is available in 9 edge lifts (from double decreased to double increased in 0.5 steps). The trial set consisted of 14 lenses having an overall diameter ranging from 14.6 to 13.0 mm depending on the back optic zone radius (BOZR) (i.e. the diameter increases with increasing BOZR and vice versa). All lenses in the trial set were a standard edge lift.

In eligible subjects, the average 3 mm Sim K's was calculated and rounded to the closest 0.1 mm step (K_m). Following the manufacturer's recommendations, the first trial lens was selected 0.2 mm steeper than K_m. The concave side of the selected trial lens was filled with saline solution and sodium fluorescein (Haag-Streit, Koeniz, Switzerland) and then was inserted on the eye. The central lens-cornea relationship was immediately evaluated. A steeper or flatter BOZR was selected progressively until the highest point of the cornea (apex) showed a light feather touch. Once this central fit was achieved, we evaluated the lens-conjunctiva relationship at the edge of the lens in order to avoid excessive pressure of the conjuctival vessels under the lens. If the edge lift showed an appropriate fit, the lens was allowed to settle on the eye for 40–60 min. After the lens settled down, sodium fluorescein was reapplied and the subject was instructed to blink several times in order to evaluate the fitting. A correct edge lift allowed fluorescein to circulate slowly under the lens. Changes of BOZR or edge lift were performed in cases of either increased central touch or blanching of the sclera at the rim of the lens were detected, respectively. Any grade of apex staining was not tolerated. When the edge lift was excessive or insufficient, the necessary change was decided empirically because all lenses in the trial set had standard edge lift design. After edge lift evaluation, the overall diameter was assessed. The lens should extend 1.5 mm outside the limbus. Once again, in cases where the lens was too small or too big, an appropriate diameter was selected empirically. Finally, the lens movement was evaluated subjectively with the slit-lamp without the use of a graticule. In these large diameter lenses, 0.5 mm or just discernible movement with blinking should be expected. Lens movement was greatly dependent on edge lift. An over-refraction with the selected lens BOZR was then performed and the final lens was ordered taking into account all selected (practically and empirically) parameters. Fig. 1 shows several optimal lens fittings.

Once the ordered lens arrived to the clinic, subjects were scheduled for a dispensing visit. If the lens provided an acceptable fit, the subject was instructed to insert and remove the lens with the plunger, how to clean and maintain the lens with a multipurpose solution and a weekly protein remover (Menicare Plus and Menicare Progent, Menicon Co. Ltd., Nagoya, Japan), he/she was advised to wear the lens no more than 2 h, and finally the subject was rescheduled for another appointment the day after. At this visit, if the lens fit was clinically acceptable, the subject was advised to increase lens wearing time 1 h a day, until complete 8 h, and he/she was scheduled for a second follow-up visit 1 week later. Subjects were advised to go to the visits wearing the lenses enough time for them to be fully settle (i.e. at least 1 h). A lens fit was considered optimal when the subject experienced adequate vision (i.e. at least the same VA that the subject achieved with his/her previous contact lenses. In those subjects who did not wear contact lens previously, at least the same VA that he/she achieved at the fitting visit), comfort (at least 8 h of comfortable wearing time) and the lens did not compromise the ocular health (CCLRU grading scale units <1). An incorrect lens fitting was remedied by changing the contact lens specifications (i.e. BOZR, edge lift, diameter and/or power). This process was repeated as many times as necessary until the lens was considered optimal for dispensing.

Visual acuity was analyzed with and without the habitual correction and with the Rose K2 XL lens. The relationship between mean central K and BOZR, the success rate with the first lens ordered and the final lens parameters, patients' ability to wear and handle the lenses, and the occurrence of adverse events were also analyzed.

2.1. Statistical analysis

Differences in logMAR VA with and without correction, between eyes and between habitual contact lenses and Rose K2 XL lens in the previous contact lens wearers were undertaken using paired *t*-tests. Statistical analyses were performed using SPSS 15.0 software (SPSS Inc, Chicago, IL, USA). The level of statistical significance was taken as $p < 0.05$.

3. Results

Nineteen male (70%) and 8 female (30%) patients with irregular corneas were included in the fitting trial (34 eyes). The mean age ± SD was 33.82 ± 13.8 years (range 14–67). After the fitting evaluation trials, 4 subjects (4 eyes) were not fitted with Rose K2 XL lens. One of them because a toric periphery was necessary and this was not available at the time of the study; two because the VA did not improve with the Rose K2 XL lens compared to the habitual RGP corneal lens and one because the patient preferred to wear their habitual piggy back lens system. The remaining 23 subjects (30 eyes) were fitted with the Rose K2 XL lens. Table 1 shows

Table 1
Cause of the corneal irregularity.

Condition	Number of eyes
Corneal ring segment	9
Keratoconus	10
Keratoplasty	4
Pellucid marginal degeneration	3
Post LASIK ectasia	4

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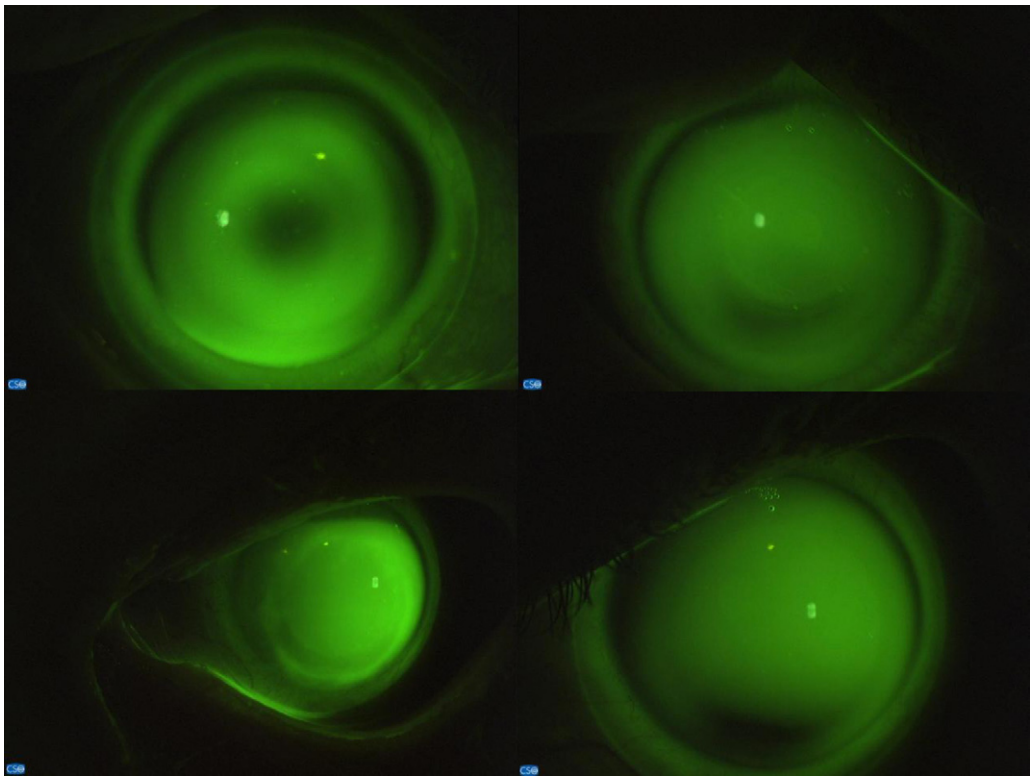

Fig. 1. An optimal lens fitting shows a light feather apex touch and an overall diameter that extends 1.5 mm outside the limbus. The fitting at the up left is a keratoconus, up right is a post corneal ring segment, down left is a keratoplasty and down right is a pellucid marginal degeneration.

the cause of corneal irregularity for all subjects. Table 2 shows the habitual correction at the time of the initial examination.

The mean logMAR VA for the entire group without correction and with Rose K2 XL lens was 0.82 and 0.09, respectively ($p < 0.001$). In the group of previous contact lens wearers (19 eyes), mean logMAR VA with habitual contact lenses and with Rose K2 XL was 0.14 and 0.10, respectively ($p = 0.079$).

Mean central keratometry and mean lens BOZR were 7.24 ± 1.03 and 6.79 ± 0.4 ($p = 0.76$), respectively. Fig. 2 shows the mean central keratometry vs. lens-BOZR relationship for all subjects.

An average of 2.7 ± 0.73 visits (range 2–4) were necessary to carry out the lens fitting. An average of 2.9 ± 1.6 trial lenses per eye (range 1–4) were needed to decide the ordered lens. An average of 1.4 ± 0.56 ordered lenses (range 1–3) were necessary to achieve the optimal fitting. Nineteen eyes (63.3%) were successfully fitted with the first ordered lens. Ten eyes (33.3%) needed two ordered lenses and one eye (3.3%) needed three ordered lenses. The causes for reordered lenses were: increased edge lift (3 lenses, 25%), decreased edge lift (3 lenses, 25%), steeper BOZR (5 lenses, 42%) and increased power (1 lens, 8%). Table 3 shows the parameters of the final lenses.

Three subjects (13%) had handling concerns during the trials, specifically with the insertion of the lens. Three subjects (10%) broke the lens during the follow-up period. The mean wearing time was 9.3 ± 2.2 h a day (range 8–12).

Table 2
Habitual correction at the time of initial evaluation.

Mode of visual correction	Number of eyes
No correction	11
Soft toric lens	1
Corneal RGP	5
Piggy back	8
Semi-scleral	4
Full scleral	1

During the time of follow-up, 2 eyes (6.66%) presented an adverse event. One subject suffered a corneal abrasion during lens insertion and another subject had a conjunctival injury induced during lens removal.

4. Discussion

In the last decade, improvements in RGP materials and manufacturing processes have spawned a renewed interest in large diameter lenses [18,19]. Large diameter RGP contact lenses provide excellent levels of VA and respect corneal health, no matter the diameter of the lens [20–23].

In the present study, the Rose K2 semi-scleral contact lens improved VA in patients with irregular corneas compared to VA without correction. Nineteen of 30 eyes were wearing contact lenses before being fitted with Rose K2 XL, and 18 of them wore RGP contact lenses (corneal, piggy back system, semi-scleral and scleral). When the VA provided by Rose K2 XL is compared with other contact lens modalities there was no statistically significant difference in performance. In the past, it has been reported that scleral contact lenses provided worse VA than corneal RGP lenses

Table 3
Parameters of the final lenses.

	Base curve	Diameter	Power
Mean	6.79	14.66	−8.76
SD	0.43	0.66	4.89
Minimum	6.00	13.00	−18.00
Maximum	7.80	16.00	−0.75

Edge lift design

Standard	Standard flat	Standard steep	Double steep
11(36.7%)	9(30.0%)	5(16.7%)	5(16.7%)

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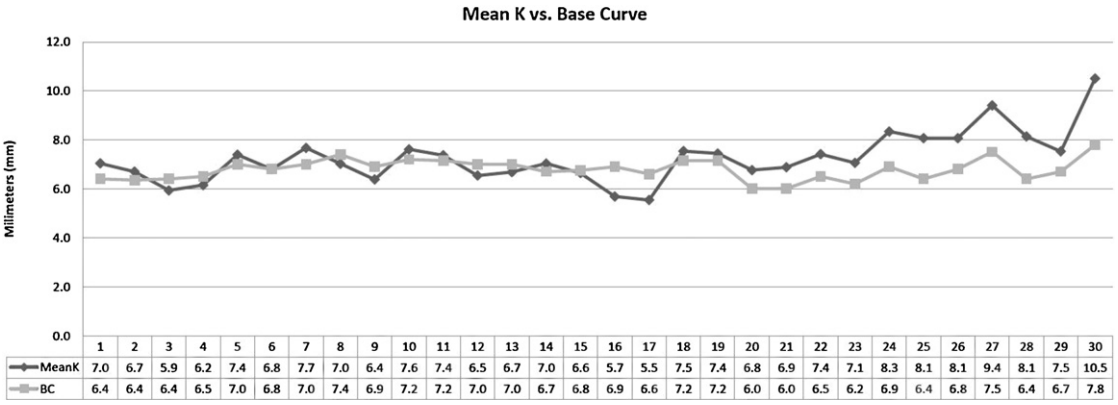

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
MeanK	7.0	6.7	5.9	6.2	7.4	6.8	7.7	7.0	6.4	7.6	7.4	6.5	6.7	7.0	6.6	5.7	5.5	7.5	7.4	6.8	6.9	7.4	7.1	8.3	8.1	8.1	9.4	8.1	7.5	10.5
BC	6.4	6.4	6.4	6.5	7.0	6.8	7.0	7.4	6.9	7.2	7.2	7.0	7.0	6.7	6.8	6.9	6.6	7.2	7.2	6.0	6.0	6.5	6.2	6.9	6.4	6.8	7.5	6.4	6.7	7.8

Fig. 2. The eyes 1–9 represent the subjects with corneal ring segments, the eyes 10–19 represent keratoconus, the eyes 20–22 pellucid marginal degeneration, the eyes 23–26 keratoplasty and the eyes 27–30 post LASIK ectasia.

due to the thick tear layer under the lens and lens flexure [23]. However, this statement has been refused thereafter [24]. Semi-scleral contact lenses create a tear layer under the lens thinner than scleral contact lenses (30–50 μm vs. 150–200 μm) [25], and we did not find any evidence of lens flexure in the fitted lenses. Thus detriment in VA with this design was not expected.

In the whole group, mean central keratometry and mean lens BOZR were 7.24 and 6.79, respectively. However, when we analyzed the lens-cornea relationship segregating by cause of corneal irregularity, we found great differences between lens BOZR and mean central curvature. In corneal ring segments and keratoconus, the difference between central keratometry and lens BOZR were 0.03 and 0.16 mm on average, respectively. However, in pellucid marginal degeneration, keratoplasty and post-LASIK ectasia, the difference between central keratometry and lens BOZR were 0.84, 1.29 and 1.67 mm on average, respectively. The main goal of the central lens-cornea relationship was to achieve a light feather touch over the corneal apex. In keratoconus, the corneal apex is usually located in the central and inferior-temporal part of the cornea [26], and in corneal ring segments the highest corneal elevation is located over the ring segment [5]. However, in pellucid marginal degeneration, the corneal apex is located inferiorly [2] and central cornea is flatter than in keratoconus, and this forces to fit a steeper lens BOZR in order to increase sagittal depth and avoid excessive apical bearing. Similarly, in post-graft corneas [3], and post-LASIK ectasia [4], central corneal curvature used to be much flatter than in keratoconus, but the corneal apex protrusion compels to fit a steep lens BOZR to increase sagittal depth and avoid excessive apical bearing and corneal staining. Although the sample size for each corneal condition is small, we believe our data could represent a trend in semi-scleral contact lens fitting.

An average of 2.7 visits and 2.9 trial lenses per eye were necessary to carry out the lens fitting, which matches with previous reports about fitting scleral lenses [13] and corneal RGP lenses [27]. An average of 1.4 ordered lenses were necessary to achieve the optimal fitting and 19 eyes (63.3%) were successfully fitted with the first ordered lens, which is in agreement with a 57% success rate in scleral lenses [13]. In the past, a 33% success rate with the first lens ordered was reported in corneal RGP lenses for keratoconus [28]. Modern materials, computer-assisted manufacturing processes and accurate fitting guides facilitate lens fitting, which lead to an increase in the success rate. Despite the fact that contact lens fitting in irregular corneas could be a challenge for practitioners, our data demonstrates that fitting semi-scleral lenses does not increase the number of visits, trial lenses or ordered lenses needed compared with corneal RGP lenses.

Edge lift and lens BOZR were the main causes for reordered lenses. The evaluation of the edge lift is a learning process. It is only when a different edge lift is ordered that the practitioner is able to learn how the peripheral fit changes by flattening or steepening this parameter. This learning curve is unavoidable. In this trial, 5 lenses were reordered because a steeper BOZR was necessary to eliminate excessive apical bearing. We believe that the necessity of making changes in lens BOZR could be avoided by increasing the time the lens was allowed to settle down on the eye during the fitting visit (i.e. 2 h).

The wearers were trained to insert and remove the lenses using a small plunger because it was thought that this was most effective and efficient way to handle this large diameter lenses. Most of them were able to do it in one training session and, at the time of dispensing, all subjects were able to insert and remove the lenses without problems. However, three subjects needed three training sessions because the VA of the fitted eye was very low, and the fellow eye was blind. In these cases, large diameter lens insertion may represent a serious challenge, mainly due to lid interference. Increasing the number of training sessions is highly recommended to help solve this issue.

Three lenses were broken during the follow-up period. These hyper Dk RGP lens are very thin (0.1 mm of central thickness). All subjects who broke their lenses were previous corneal RGP wearers, so it is possible that they handled the lens in the same way as their smaller corneal lenses. Semi-scleral lenses are more fragile than corneal lenses and the wearers, especially those who wear other types of lenses, should be trained to handle these larger lenses more carefully than smaller ones, avoiding strong digital rubbing during lens cleaning.

Two subjects presented with mild adverse events related to insertion and removal of the lens during the follow up period. One subject had a central self-inflicted corneal abrasion during lens insertion, and another subject had a self-inflicted conjunctival injury during removal of the lens. Both events completely resolved within five days of discontinuing lens wear. Despite the fact that all subjects were extensively trained in lens insertion and removal, large diameter lenses are more difficult to handle than corneal lenses. Thus, wearers must understand the importance of following the instructions provided by their practitioner to avoid potential adverse events.

In conclusion, the Rose K2 XL semi-scleral contact lenses provide good vision and comfort for patients with irregular corneas. The results with this lens suggest that the fitting process is efficient, effective and it does not increase the number of patient visits, trial lenses or ordered lenses. The lenses may avoid the necessity of fitting piggyback lens systems. Therefore, we consider Rose K2 XL lens a good option for patients with irregular cornea. Future studies with a greater sample size and a longer follow-up are recommended to

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confirm our results and the safety of this type of contact lens and the proposed fitting protocol.

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