

# Long-term evaluation of Rose K2 contact lens wearers

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## Purpose

The purpose of the study was to evaluate the clinical outcome, fitting characteristics, comfort, and adverse effects of Rose K lenses in keratoconus patients and to demonstrate the clinical and topographic changes that occur on wearing such lenses.

## Participants and methods

A total of 323 keratoconic patients who were prescribed with Rose K2 contact lenses 2 years ago or earlier were enrolled in this retrospective research. They were divided on the basis of usage of the lenses into the wearing and nonwearing groups (255 and 68 patients, respectively). Each group was subdivided according to the follow-up period into two subgroups. The patients' data were collected from their reports and included information on demographic characteristics, fitting characteristics, uncorrected visual acuity, best spectacle-corrected visual acuity, best contact-corrected visual acuity refraction, topographic indices, mesopic vision, and thinnest corneal thickness. Changes in clinical and topographic indices after fitting were evaluated in each group of the wearing and nonwearing patients (with different follow-up periods) by comparison of baseline data with last follow-up. When changes were noted, we compared the degree of changes in the wearing and nonwearing groups with the same follow-up period. The patients' comfort and satisfaction with Rose K2 lenses as well as objective complications and causes of lens discontinuation were recorded.

## Results

Analysis of the data of the wearing patients demonstrated highly significant improvement in visual acuity with Rose K2 lenses. Uncorrected visual acuity was  $0.14 \pm 0.08$ , whereas best contact-corrected visual acuity was  $0.81 \pm 0.1$  ( $P < 0.001$ ). Similarly, contrast sensitivity and glare tests were significantly improved with Rose K2 lenses. Lens-wearing patients demonstrated no significant changes in the first group, whereas the second group revealed a significant increase in the Max.K and inferior–superior values and decrease in pachymetry values. Data of nonwearing patients revealed significant deterioration of all measured parameters. However, higher levels of deterioration were noticed in the second group than in the first. In the second group of wearing and nonwearing patients Max.K and inferior–superior values increased and pachymetry values decreased more significantly in nonwearing patients than in patients wearing Rose K2 lenses. Statistical analysis of the subjective responses indicated a strong acceptance of the lens by most of the patients, whereas persistent discomfort, poor compliance, and lack of patient motivation were the most common reasons for Rose K2 lens discontinuation. Fitting problems due to, in the order of frequency, presence of superficial punctate keratitis, allergies, dry eye, tight lens syndrome, blepharitis, lens decentration, lens scratches or depositions, and breakage or loss were seen.

## Conclusion

The Rose K lens is a proprietary design that is simple to fit. It provides marked visual improvement and notable comfort for keratoconus patients with minimal complications. Properly fitted Rose K contact lenses may contribute to slowing down the progression of keratoconus and even induce some topographical and clinical improvements.

## Keywords:

contact lens, keratoconus, Rose K

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## Introduction

Keratoconus is a noninflammatory, progressive, bilateral, asymmetrical corneal dystrophy that is characterized by paracentral cone-like steepening, distortion, and apical

thinning of the cornea and corneal ectasia. The ectasia leads to significant myopia and irregular astigmatism [1]. The irregular astigmatism created by ectasia of the central cornea is not sufficiently corrected by spectacles.

Hence, the optical correction of keratoconus is a challenging problem to eye-care practitioners [2].

Application of rigid contact lenses is the most common treatment modality in the early stages of keratoconus [3]. As there are many rigid lens designs for keratoconus patients, it is difficult to predict which contact lens design will optimize comfort and visual acuity in any given patient with keratoconus. Further, the success rates and patient suitability for specific lens designs are often based on anecdotal claims and/or retrospective studies [4].

The 'Rose K Lens for Keratoconus' is a proprietary design that has gained popularity since its introduction in the USA in 1995 [5]. It has been reported that Rose K lenses are simple for novice practitioners to fit and that they offer better visual acuity and increased comfort for keratoconus patients compared with other designs for keratoconus patients [6]. Previous studies on Rose K lenses have been conducted on small study populations (20 patients or fewer) and for short periods (<2 years) [7,8]. No study has been conducted on larger populations monitored for a longer period. Also, during follow-up of keratoconic patients wearing Rose K lenses, we noticed no or minimal progression in patients who continued to wear their contact lenses in comparison with patients who had stopped using their lenses. Whether a well-fitted Rose K lens helps in arresting the progression of keratoconus is an important question from the clinical standpoint.

In this study a series of keratoconus patients were selected and evaluated in terms of the safety, efficacy, adverse effects, and clinical performance of the Rose K lens by comparing baseline data with clinical and topographic outcomes at the last follow-up visit. We also show the effect of the design of Rose K lenses on the progression of the disease in a comparative study between the wearing and nonwearing groups of patients for a period ranging from 2 to 10 years.

## Participants and methods

### Patients

This retrospective study included all patients who were diagnosed with keratoconus and prescribed Rose K2 contact lenses 2 years ago or earlier. They were selected during their visit to the contact lens clinic at Mansoura Ophthalmic Center, Mansoura University, between January 2012 and August 2012. The study was approved by the ethical committee of the Faculty of Medicine, Mansoura University, and adhered to the tenets of the Declaration of Helsinki.

Keratoconus was diagnosed by positive Rabinowitz indices on topography (TMS-1; Tomey Topographic Modeling System, Waltham, Massachusetts, USA) or by characteristic clinical findings, such as apex protrusion, thinning, and Vogt striae. A total of 375 keratoconic patients were identified. Fifty-two patients who had less than 2 years of follow-up were excluded from the study.

Patients who were still wearing Rose K lenses were included in the lens-wearing group. Keratoconic patients who had stopped wearing Rose K lens were included in the nonwearing group.

The lens-wearing group was divided into two subgroups: patients wearing Rose K lenses for 2–5 years and patients wearing lenses for more than 5 years. The nonwearing group was similarly subdivided into two groups: patients who stopped wearing Rose K lenses 2–5 years ago and patients who discontinued their lenses more than 5 years ago. The ocular examination, contact lens fitting, and recording of data were performed by the same clinician.

### Contact lens fitting

All fittings were performed with a Rose K diagnostic lens set. The set consists of 26 lenses with base curves ranging from 5.1 to 7.6 mm in 0.1 mm increments. All lenses in the fitting set have a standard diameter of 8.7 mm with a standard edge lift design.

According to the fitting guide, the initial lens is 0.2 mm steeper than the average corneal radius of curvature. The aim was to achieve only a 'light feather-touch' between the central lens and the cornea. When an optimal central lens–cornea relationship was obtained, the peripheral edge lift was evaluated. If the trial lens gave a desirable edge lift, a standard edge lift was ordered for that eye. If minimal or excessive edge lift was observed, increased or decreased edge lift was ordered, respectively. After finding the optimal trial lens for each eye, an over-refraction was performed while the patient was wearing the trial lenses. This information was used to determine the contact lens power to be ordered. All Rose K lenses were ordered from David Thomas Company (Northampton, UK).

### Evaluation

The patient data were collected from their reports and included sex, age, date of first visit, and bilaterality of the disease. Fitting data including the base curve, diameter, power, edge lift of the initial dispensed lenses, number of trial lenses for optimum fit, and the need for new lenses during the follow-up period were also recorded from patient sheets.

To assess the progression of the keratoconus, we compared the clinical and topographic data of each subgroup of the wearing and nonwearing patients at baseline and last follow-up. The measurable outcome data were the uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), sphere, cylinder, simulated keratometric readings (Min.K and Max.K), inferior–superior (I-S) value, and pachymetry values at the thinnest location. When progression was confirmed, which was possibly related to wearing the contact lenses and/or due to the duration of the disease, the rate of progression was compared between the different studied groups. Visual outcome and optical performance of the Rose K2 lenses were evaluated by assessment of best contact-corrected visual acuity (BCCVA) with Rose K2, contrast sensitivity, and glare levels of wearing patients (discussed later).

Patient comfort and satisfaction with the Rose K2 lenses were recorded from the maximum daily wearing time, number of lens removals per day, self-reported assessment of comfort (as per a five-point scale in which 5 is very comfortable and 1 is very irritating), and patient preference for continuing usage of their contact lenses. In the nonwearing groups, reasons for discontinuation of lenses were recorded.

Objective complications including superficial punctate keratitis (SPK), corneal epithelial defects or abrasions, corneal edema, pannus, neovascularization, dry eye syndrome (DES), blepharitis, allergies, and tight lens syndrome (TLS) were recorded. Lens problems such as scratches or depositions, decentration, and breakage or tears were also recorded.

### Contrast and glare sensitivity test

The test was carried out using the Mesotest II (Oculus, Arlington, Germany), which consists of Landolt rings of different contrast levels presented in front of a low-brightness backdrop. There are four contrast levels: 1:23, 1:5, 1:2.7, and 1:2, which represent the ratio between the light intensity of the optotypes and the backdrop. There are eight tests (four without and four with glare). Test 1, with contrast level 1:23, is the most easily recognized. For statistical purposes, each level of the contrast or the glare test was given a score starting from 20% of the 1:23 level to 100 of the 1:2 level.

## Results

A total of 622 eyes from 323 keratoconic patients met the entry criteria. Overall, the lens-wearing group consisted of 493 eyes from 255 patients and the nonwearing group consisted of 129 eyes from 68 patients. No significant difference was observed in patient age or sex between the studied groups. Demographic characteristics of the patients and subgroups are summarized in Table 1.

Fitting parameters of the studied lenses are recorded in Table 2. It revealed that wearing patients changed their lenses on average 1.1 times in the first group (1–3 times) and 2.9 times in the second group (2–4 times) from the time of commencement of use of Rose K2 lenses. It also demonstrated that we need an average of nearly two trial lenses to reach a successful fit with Rose K2 lenses (1–3 trial lenses).

In the first group of lens-wearing patients, the UCVA, BSCVA, and BCCVA increased, whereas the sphere, cylinder, Min.K, Max.K, I-S values, and the thinnest corneal thickness decreased in the last follow-up visit in comparison with baseline values, but these changes were not significant. Similarly, there was no significant change in the contrast sensitivity and glare tests in this group between baseline and last follow-up values (Table 3).

The second group of lens-wearing patients demonstrated a decrease in UCVA, BSCVA, BCCVA, and the thinnest corneal thickness and an increase in sphere, cylinder, Min.K, Max.K, and I-S values in the last follow-up visit

**Table 1 Patients characteristics**

Characters	Wearing group		Nonwearing group	
	Group 1	Group 2	Group 1	Group 2
Number of patients	135	120	35	33
Number of eyes	262	231	66	63
Bilaterality	127	111	31	30
Age (years)	22 ± 5	28 ± 7	24 ± 6	27 ± 3
Sex (female : male)	70 : 65	67 : 53	18 : 17	16 : 17
Duration (years)	3.1 ± 2.2	7.3 ± 2.8	2.9 ± 1.9	6.9 ± 3.4

**Table 2 Rose K lens parameters in wearing patients**

Parameters	Group 1	Group 2
Overall diameter (mm)	8.7 or 8.3	8.7 or 8.3
Base curve (mm)	5.4–7.3	4.9–7.2
Power (D)	–2.5 to –22.5	–3.25 to –26.5
Edge lift	Standard or increased	Standard or increased
Number of orders	1.1 ± 1.2 (1–3)	2.9 ± 1.3 (2–4)
Ease of fitting (number of trial lenses)	1.8 ± 1.2 (1–3)	1.9 ± 1.1 (1–3)

compared with baseline parameters. However, only Max.K ( $53.1 \pm 4.6$ – $55.8 \pm 4.9$  D), I-S value ( $4.8 \pm 1.7$ – $5.4 \pm 1.8$  D), and the thinnest corneal thickness ( $435 \pm 54$ – $398 \pm 51$   $\mu$ m) reached significant levels ( $P < 0.05$  in all values) (Table 3).

Analysis of the data of the wearing patients demonstrated highly significant improvement in the visual acuity with Rose K2 lenses. UCVA was  $0.14 \pm 0.08$ , whereas BCCVA was  $0.81 \pm 0.1$  ( $P < 0.001$ ). Similarly, contrast sensitivity and glare tests were significantly improved with Rose K2 lenses. They increased from  $25.3 \pm 5.6$  and  $12.1 \pm 4.3\%$  before fitting to  $76.6 \pm 5.2$  and  $43.1 \pm 7.3\%$  after fitting ( $P < 0.001$ ).

Table 4 shows the results of the nonwearing groups. The first group revealed significant deterioration of all measured parameters in the form of decreases in UCVA, BSCVA, and thinnest corneal thickness and increase in sphere, cylinder, Min.K, Max.K, and I-S values.

To highlight the effect of duration in the progression of the disease, we compared the changes in parameters in the two groups of nonwearing patients. They revealed a more significant increase in the sphere, cylinder, K readings, and I-S value in the second group compared with the first group. Similarly, more decrease in the UCVA, BSCVA, and pachymetry values were recorded in the second group; for example,  $P$  values for Max.K, I-S value, and pachymetry in the first group were 0.04, 0.04, and 0.03, respectively, whereas in the second group these values were 0.008, 0.003, and 0.002, respectively.

On comparing the changes in the second group of wearing and nonwearing patients, in order to document the Rose K2 effect in progression, we found that Max.K and I-S values had increased and the pachymetry value had decreased more significantly in the nonwearing patients ( $P = 0.008$ , 0.003 and 0.002, respectively) than in patients wearing Rose K2 lenses ( $P = 0.03$ , 0.03 and 0.04, respectively). Moreover, other parameters deteriorated

**Table 3 Measured parameters of wearing patients (mean  $\pm$  SD)**

Parameters	Group 1			Group 2		
	Baseline	Last FU	<i>P</i> value	Baseline	Last FU	<i>P</i> value
UCVA	0.14 $\pm$ 0.08	0.15 $\pm$ 0.07	0.12	0.15 $\pm$ 0.08	0.11 $\pm$ 0.06	0.09
BSCVA	0.33 $\pm$ 0.11	0.35 $\pm$ 0.10	0.19	0.29 $\pm$ 0.12	0.22 $\pm$ 0.13	0.07
BCCVA	0.81 $\pm$ 0.1	0.83 $\pm$ 0.2	0.21	0.8 $\pm$ 0.2	0.78 $\pm$ 0.3	0.21
Sphere (D)	-4.20 $\pm$ 2	-4.11 $\pm$ 2	0.45	-5.2 $\pm$ 2	-5.4 $\pm$ 1	0.42
Cylinder (D)	-5.9 $\pm$ 1.4	-5.7 $\pm$ 1.3	0.37	-5.6 $\pm$ 1.3	-5.9 $\pm$ 1.6	0.11
Min.K (D)	47.8 $\pm$ 1.8	46.9 $\pm$ 1.7	0.15	48.9 $\pm$ 1.6	50.1 $\pm$ 1.5	0.14
Max.K (D)	51.1 $\pm$ 3.7	50.9 $\pm$ 2.8	0.24	53.1 $\pm$ 4.6	55.8 $\pm$ 4.9	0.03*
I-S value (D)	4.5 $\pm$ 1.2	4.3 $\pm$ 1.1	0.43	4.8 $\pm$ 1.7	5.4 $\pm$ 1.8	0.03*
Thinnest corneal thickness ( $\mu$ m)	423 $\pm$ 33	412 $\pm$ 42	0.13	435 $\pm$ 54	398 $\pm$ 51	0.04*
Contrast sensitivity (%) <sup>a</sup>	25.3 $\pm$ 5.6	26.1 $\pm$ 7.2	0.23	29.4 $\pm$ 6.4	27.6 $\pm$ 5.7	0.12
Glare (%) <sup>a</sup>	12.1 $\pm$ 4.3	12.9 $\pm$ 5.6	0.51	18.3 $\pm$ 5.5	17.8 $\pm$ 6.7	0.33
Contrast sensitivity (%) <sup>b</sup>	76.6 $\pm$ 5.2	77.6 $\pm$ 6.2	0.38	75.9 $\pm$ 5.1	73.6 $\pm$ 7.8	0.41
Glare (%) <sup>b</sup>	43.1 $\pm$ 7.3	44.5 $\pm$ 7.6	0.44	40.3 $\pm$ 6.9	38.9 $\pm$ 6.6	0.23

BCCVA, best contact-corrected visual acuity (decimal measures); BSCVA, best spectacle-corrected visual acuity; FU, follow up; I-S, inferior-superior; UCVA, uncorrected visual acuity.

\*Significant at  $P \leq 0.05$  (paired *t*-test).

<sup>a</sup>Without contact lens.

<sup>b</sup>With contact lens.

**Table 4 Measured parameters of nonwearing patients (mean  $\pm$  SD)**

Parameters	Group 1			Group 2		
	Baseline	Last FU	<i>P</i> value	Baseline	Last FU	<i>P</i> value
UCVA	0.19 $\pm$ 0.06	0.11 $\pm$ 0.07	0.04*	0.2 $\pm$ 0.03	0.09 $\pm$ 0.05	0.005*
BSCVA	0.39 $\pm$ 0.09	0.23 $\pm$ 0.08	0.03*	0.38 $\pm$ 0.11	0.20 $\pm$ 0.12	0.007*
Sphere (D)	-3.90 $\pm$ 2	-4.20 $\pm$ 1.9	0.03*	-4.4 $\pm$ 2.2	-5.6 $\pm$ 2.3	0.006*
Cylinder (D)	-4.9 $\pm$ 0.2	-5.4 $\pm$ 0.6	0.02*	-4.3 $\pm$ 0.7	-5.8 $\pm$ 0.3	0.009*
Min.K (D)	45.3 $\pm$ 1.2	48.1 $\pm$ 1.7	0.02*	44.8 $\pm$ 1.1	48.9 $\pm$ 1.2	0.007*
Max.K (D)	51.1 $\pm$ 3.1	54.5 $\pm$ 2.7	0.04*	49.1 $\pm$ 3.9	53.3 $\pm$ 4.1	0.008*
I-S value (D)	5.1 $\pm$ 1.2	5.9 $\pm$ 1.7	0.04*	4.9 $\pm$ 1.4	6.1 $\pm$ 1.6	0.003*
Thinnest corneal thickness ( $\mu$ m)	415 $\pm$ 45	385 $\pm$ 51	0.03*	410 $\pm$ 44	366 $\pm$ 39	0.002*

BSCVA, best spectacle-corrected visual acuity; FU, follow up; I-S, inferior-superior; UCVA, uncorrected visual acuity.

\*Significant at  $P \leq 0.05$  (paired *t*-test).

**Table 5 Parameters of patient satisfaction in the wearing group (last FU)**

Parameters	Value
MWT/D (h)	10.3 $\pm$ 3.2
Comfort score	4.2 $\pm$ 0.6
Patient preference (%)	92
Number of lens removal/day	2 $\pm$ 1

MWT/D, maximum wearing time per day.

significantly in the nonwearing group, whereas they did not change significantly in the wearing patients.

Statistical analysis of the subjective responses indicated a strong acceptance of the lens by most of the patients. The maximum wearing time/day was 10.3  $\pm$  3.2 h in all studied patients. Self-reported assessment of comfort, which was given by a five-point scale, indicated a high degree of comfort with the Rose K design (4.2  $\pm$  0.6). The average number of removal of lenses/day was only 2  $\pm$  1. Of the studied patients 92% preferred to continue using their contact lenses, whereas only 8% of patients asked for another option than contact lenses (Table 5).

Reasons for continuing Rose K2 lenses have been recorded in Table 6. Persistent discomfort was the most common reason (47.1%), followed by poor compliance and lack of patient motivation to wear contact lenses (27.9%). Other

**Table 6 Causes of discontinuing Rose K lens wearing**

Causes	Number of patients [ <i>n</i> (%)]
Discomfort	32 (47.1)
Bad compliance and lack of motivation	19 (27.9)
Handling difficulties	9 (13.2)
Cost	5 (7.4)
Visual problems	3 (4.4)

**Table 7 Complications in eyes fitted with Rose K2**

Complications	Number of patients [ <i>n</i> (%)]
Superficial punctate keratitis	43 (16.9)
Allergies	38 (14.9)
Dry eye syndrome	37 (14.5)
Tight lens syndrome	26 (10.2)
Blepharitis	25 (9.8)
Lens decentration	20 (7.8)
Lens scratches/deposits	10 (3.9)
Broken/torn/lost lens	6 (2.4)
Edema/pannus/neovascularization	0

reasons included difficulties in handling (13.2%) and the high cost of Rose K lenses (7.4%). Finally, 4.4% of the patients complained of visual problems such as halos, glare, or blurred vision.

Fitting problems in eyes fitted with Rose K2 are presented in Table 7. They included, in the order of frequency, SPK

(16.9%), allergies (14.9%), DES (14.5%), TLS (10.2%), blepharitis (9.8%), lens decentration (7.8%), and lens scratches or depositions (3.9%). Broken or lost contact lenses were recorded as reasons in 2.4% of Rose K2 lens wearers. No cases of pannus, neovascularization, corneal edema, or ulcers were noted in the current study.

## Discussion

Although the best available management option for visual rehabilitation of keratoconus patients is rigid gas permeable (RGP) lenses, fitting of RGP lenses in these eyes with altered corneal topography is challenging and require more chair time [9]. The unusual profile of the keratoconic cornea does not allow the use of conventional RGP lenses with their large back optic zones because they cause misalignment and subsequent tear pooling and sealing between the back surface of the RGP lens and the cornea [10]. Therefore, decentration and central touching make fitting difficult. The Rose K lens design has up to six different curves across the back surface of the lens and a decreasing optic zone as the base curve steepens to try to align the back surface of the lens as accurately as possible with the unusual shape of the keratoconic cornea [6,11].

The ease of fitting Rose K lens and reduced chair time in keratoconus patients are considered as the main advantages of this design. In our series, the number of trials taken to finalize Rose K lens parameters ranged from 1 to 3 trial lenses, which was similar to the previously reported data [7,8,11].

As regards visual acuity, it was significantly improved with Rose K lenses. UCVA was  $0.14 \pm 0.08$ , whereas BCCVA was  $0.81 \pm 0.1$  ( $P < 0.001$ ). These measurements are slightly better than the previously reported results of visual acuity measurements under similar conditions [7].

To the best of our knowledge, this is the first study to measure the mesopic vision and glare tests in patients wearing Rose K lenses. Similarly, contrast sensitivity and glare tests were significantly improved with Rose K2 lenses. They increased from  $25.3 \pm 5.6$  and  $12.1 \pm 4.3\%$  before fitting to  $76.6 \pm 5.2$  and  $43.1 \pm 7.3\%$  after fitting ( $P < 0.001$ ).

Comfort with special lens design is difficult to measure. Some indices of comfort (wearing time and number of lens removals/day) may not be sensitive to subjective changes in comfort as patients with keratoconus tend to wear their contact lenses for most part of the day to achieve acceptable vision despite discomfort [7]. Nevertheless, our results indicated a strong acceptance of the lens by most of the patients. The maximum wearing time/day was  $10.3 \pm 3.2$  h. Self-reported assessment of comfort indicated a high degree of comfort with the Rose K design ( $4.2 \pm 0.6$ ). In all, 92% of the studied patients preferred to continue using their contact lenses, whereas only 8% of patients asked for a change. Our results go hand with hand with previously reported data that indicated a high degree

of comfort in patients wearing Rose K lenses with more than 10 h of daily wearing [7,11,12].

Contact lens wear itself may cause progression of keratoconus, regardless of the fitting method. A progressive increase in the corneal curvature might develop if the contact lens fitting is inadequate for the cone [13]. In fact, we observed stability or even some regression in our patients fitted with Rose K lenses. This is the reason why we investigated topographic changes after lens use in patients with keratoconus; we found that the UCVA, BSCVA, and BCCVA increased in the first group of lens-wearing patients, whereas the sphere, cylinder, Min.K, Max.K, and I-S values decreased over an average period of  $3.1 \pm 2.2$  years. However, they did not reach significant levels. In contrast, in the first group of nonwearing patients assessed over a similar average period ( $2.9 \pm 1.9$ ) all the measured parameters significantly deteriorated in the form of decrease in UCVA, BSCVA, and thinnest corneal thickness and increase in sphere, cylinder, Min.K, Max.K, and I-S values. Stability of or improvements in topographic parameters were noted in previous studies. In one study, Sim Kmax, Sim Kmin, apical power, astigmatic index, and anterior elevation significantly decreased in the wearing group compared with the control group over the mean follow-up period of 22.6 months [14]. Another study showed that the change in Sim K during follow-up of 11.4 months was not statistically significant [15].

To the best of our knowledge, these findings have not been recorded over a long term ( $>5$  years). Accordingly, we studied the changes that occurred in both wearing and nonwearing patients over an average period of  $7.3 \pm 2.8$  and  $6.9 \pm 3.4$  years, respectively. The second group of lens-wearing patients demonstrated a decrease in UCVA, BSCVA, BCCVA, and the thinnest corneal thickness and an increase in sphere, cylinder, Min.K, Max.K, and I-S values in the last follow-up visit compared with baseline parameters. However, only the Max.K, I-S value, and the thinnest corneal thickness reached a significant level (Table 3). This indicates that keratoconus progresses in the long term despite wearing contact lenses. However, we found that Max.K and I-S values increased and the pachymetry value decreased more significantly in the nonwearing patients ( $P = 0.008$ ,  $0.003$ , and  $0.002$ , respectively) than in patients wearing Rose K2 lenses ( $P = 0.03$ ,  $0.03$ , and  $0.04$ , respectively). Moreover, other parameters deteriorated significantly in the nonwearing group, whereas they did not change significantly in the wearing patients.

Hence, it is unlikely that multicurve lenses such as Rose K lenses with minimal apical touch fitting contribute to progression of keratoconus [14]. Our results indicated that a well-fitted RGP may contribute to slowing down the progression of keratoconus and may even lead to regression of the topographical and clinical parameters in the short term.

To confirm whether the regression effect is irreversible or temporary, lens wearing should ideally be avoided for at least 3 months, and the topographic indices should be re-evaluated. However, the cessation of lens wear is not

ethical, as poor visual acuity would be intolerable. In the present study, all topographic evaluations were performed 1 h after lens removal. Although our evaluation did not include full cessation of contact lens use before the examination, we believe that it still provides useful information for understanding the likelihood of progression of keratoconus with contact lens use.

Depending on the degree of contact, apical support fittings may induce epithelial trauma. Persistent epithelial damage can produce inflammatory cytokines and degrading enzymes, resulting in apoptosis of keratocytes and stromal thinning, which have a role in the pathogenesis or progression of keratoconus. However, we adopted a three-point touch fitting method for use in our patients and found that the topographic indices of the first group of wearing patients did not show any significant changes; hence, a three-point touch is less likely to induce epithelial trauma in the cone apex compared with apical clearance fitting [16]. Although thinning of the cornea was significant in the long-term follow-up of both wearing and nonwearing patients, it was less significant in patients wearing Rose K lenses, which indicates the role of Rose K lenses in slowing down the progression of keratoconus.

Another important factor to be considered when assessing keratoconus progression is age. Longitudinal studies have shown a flat K slope in patients younger than 35 years that is greater than that of patients older than 35 years [17]. In our study, the mean ages of the lens-wearing and control groups were not significantly different, with both being less than 30 years. Therefore, our study on the progression of keratoconus does not appear to be influenced by age.

Although RGP lenses provide good visual acuity, discomfort and poor corneal physiological response lead to discontinuation of these lenses in many patients (47.1% in our study). However, recruitment may have been biased as this sample of patients presented with complaints about the discomfort they were experiencing from their contact lenses. Also, patients who had been fitted with Rose K lenses recently were excluded from the study. Nevertheless, contact lens discomfort constitutes a significant obstacle to effective management of keratoconus [8].

Poor compliance of patients with respect to cleaning of contact lenses, wearing schedules, and frequent follow-up was reported as the second reason for lens discontinuation (27.9%). Difficulty with lens handling and expensive cost of the lens, which is not covered under Governmental Health Insurance in Egypt, appears to be important reasons for lens discontinuation (13.2 and 7.4%, respectively). Finally, a few patients (4.4%) complained of visual problems in the form of haloes, glare, and blurred vision, which is in agreement with previous studies [8].

Table 7 demonstrates the recorded complications of Rose K contact lenses. They included, in the order of frequency, SPK, allergies, DES, TLS, blepharitis, lens decentration, lens scratches or depositions, and breakage or loss. Such complications occurred in small percentages of patients, as previously described in studies conducted on patients wearing Rose K lenses [7,8].

In conclusion, our results suggest that the Rose K lens is a proprietary contact lens design that is simple for practitioners to fit. It improves the quantity and quality of vision and provides notable comfort for keratoconus patients with minimal complications. Properly fitted Rose K contact lenses may contribute to slowing down the progression of keratoconus and may even induce some topographical and clinical improvements.

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## Acknowledgements

### Conflicts of interest

There are no conflicts of interest.

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