Original Article

Efficacy of Rose-K lens in enhancing visual acuity and contrast sensitivity in keratoconus

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ABSTRACT

Background: Keratoconus is a progressive, noninflammatory corneal ectasia that is characterized by corneal thinning and conical deformation, which leads to irregular astigmatism, myopia, and reduced visual quality. As the disease progresses, spectacles often become inadequate, necessitating the use of rigid gas-permeable or specialty contact lenses to restore vision. Traditional evaluations rely on high-contrast visual acuity tests, which alone do not capture functional vision impairments. A more comprehensive assessment includes contrast sensitivity (CS), a key predictor of real-world visual performance. The ROSE K2 XL semi-scleral lens offers tailored optical correction for irregular corneas. We investigated its efficacy in enhancing best-corrected distance visual acuity (BCDVA) and CS in patients with keratoconus.

Methods: In this prospective study, we recruited adults with varying keratoconus severities from the Armed Forces Hospital in Oman, between February and December 2024. The patients were fitted with ROSE K2 XL semi-scleral lenses to assess changes in BCDVA and CS. Participants who had undergone prior ocular surgery (except for corneal crosslinking) or who had other corneal pathologies were excluded. Baseline and post-fitting BCDVA were measured using a crowded Keeler logarithm of the minimum angle of resolution (logMAR) chart. CS was assessed using the Pelli–Robson chart under standardized photopic conditions. Keratoconus severity was graded using the Amsler–Krumeich classification system. All examinations were performed by the same experienced optometrist to ensure consistency and to reduce measurement variability.

Results: We enrolled 180 eyes from 90 participants with keratoconus (mean [standard deviation, SD] age: 29.2 [5.4] years; 65.6% [n = 59] female). Disease severity was classified as follows: stage I (n = 16, 8.9%), stage II (n = 52, 28.9%), stage III (n = 70, 38.9%), and stage IV (n = 42, 23.3%). After ROSE K2 XL lens fitting, the mean (SD) BCDVA improved significantly, from 0.90 (0.48) logMAR to 0.10 (0.11) logMAR ($P < 0.001$). The mean (SD) CS also increased significantly, from 0.96 (0.47) log CS to 1.90 (0.16) log CS ($P < 0.001$). Significant improvements in BCDVA and CS were observed across all disease stages (all $P < 0.001$), with the most pronounced gains found in cases of advanced keratoconus (stage IV).

Conclusions: Fitting ROSE K2 XL semi-scleral contact lenses in patients with keratoconus resulted in significant improvements in both BCDVA and CS across all disease severity levels. These findings show the clinical value of semi-scleral lenses for visual rehabilitation of keratoconus, particularly in the advanced stages, where conventional spectacles or lenses may offer limited benefits. Incorporating CS assessment with visual acuity evaluations provides a more comprehensive investigation of real-world visual function, supporting evidence-based lens selection to optimize patient outcomes. Future studies should explore the long-term effects of these lenses on corneal physiology and patient-reported quality of life.

KEYWORDS

corneas, keratoconus, visual contrast sensitivity, visual acuities, contact lens, habilitation

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How to cite this article: ALkhalasi H, Mohamed ZD. Efficacy of Rose-K lens in enhancing visual acuity and contrast sensitivity in keratoconus. Med Hypothesis Discov Innov Optom. 2025 Summer; 6(2): 50-56. DOI: https://doi.org/10.51329/mehdioptometry222.

Received: 12 June 2025; Accepted: 29 July 2025

INTRODUCTION

Keratoconus is an ocular condition characterized by progressive corneal thinning and deformation. It is a noninflammatory corneal ectasia that leads to irregular astigmatism, myopia, and corneal protrusion, ultimately reducing visual quality [1–3]. Keratoconus progression varies according to individual risks and environmental factors [1, 4, 5].

Keratoconus management typically begins with the use of spectacles to correct refractive errors. However, as the disease advances and irregular astigmatism becomes more pronounced, use of rigid gas-permeable (RGP) contact lenses is often necessary to achieve adequate visual correction [1, 4]. Corneal transplantation is considered in the advanced stages, particularly when spectacle correction is insufficient, contact lens wear is intolerable, and visual acuity has deteriorated beyond acceptable limits [6].

In clinical practice, monocular, high-contrast visual acuity remains the most frequently used variable for measuring visual performance. However, this metric does not fully capture the patient's everyday visual experience, as it overlooks other critical aspects of visual function, such as contrast sensitivity (CS) [7, 8]. Previous studies have demonstrated a significant correlation between CS and key daily visual tasks, such as reading, driving, orientation, and mobility, highlighting the importance of incorporating CS testing when assessing the effectiveness of contact lenses [9, 10].

For patients with keratoconus, visual rehabilitation is often most effective with the use of multicurve lenses, such as the ROSE K2 XL™ semi-scleral contact lens (Menicon Co. Ltd., Nagoya, Japan), which outperforms spectacles and other contact lens designs by providing superior binocular resolution and depth perception [11-13]. The ROSE K2 XL is a semi-scleral contact lens specifically designed to address a broad spectrum of irregular corneal conditions. Unlike lenses that rest entirely on the conjunctiva or sclera, the ROSE K2 XL lens is primarily corneal-supported and is positioned immediately inside the limbus. It features an aspheric back optic zone that narrows as the base curve steepens, front surface aberration control, precise edge lift adjustment, and design flexibility to accommodate diverse clinical requirements [12, 13].

In this study, we evaluated both the best-corrected distance visual acuity (BCDVA) and CS to assess the visual performance of patients with keratoconus who were fitted with ROSE-K2 XL contact lenses.

METHODS

This study was conducted at the Armed Forces Hospital in Oman. To assess visual performance before and after fitting ROSE K2 XL semi-scleral contact lenses, patients with varying severities of keratoconus were recruited using a nonprobability convenience sampling method between February and December 2024. Ethical approval for the study was obtained from the Research and Ethics Committee of the University of Buraimi (No. AY23-24COHS-182). All the procedures used adhered to the principles outlined in the Declaration of Helsinki. Written informed consent was obtained from each participant prior to enrollment, and strict measures were taken to ensure participant confidentiality. No physical or psychological harm was incurred by any of the participants.

Eligible participants were adults aged > 18 years who were diagnosed with keratoconus and were deemed suitable candidates for contact lens fitting for visual rehabilitation [14-16]. Patients with prior ocular surgery (excluding corneal crosslinking) or concurrent corneal pathologies were excluded.

Demographic data were recorded at the initial visit. Trained optometrists performed comprehensive baseline ophthalmic evaluations, including the assessment of BCDVA and CS before and after ROSE K2 XL lens fitting [17, 18]. Anterior segment evaluation was conducted using a slit-lamp biomicroscope (Haag-Streit BX 900 slit-lamp; Koeniz, Switzerland). Posterior segment examination employed the same slit-lamp with a condensing lens. The severity of keratoconus was classified using the Amsler–Krumeich system, which categorizes the disease into four clinical stages (I–IV) based on corneal topography, refractive error, pachymetry, and slit-lamp findings [19, 20].

In all participants, BCDVA was assessed by using a crowded Keeler logarithm of the minimum angle of resolution (logMAR) chart (Keeler Ltd., Windsor, UK), placed at 4 m, under standardized photopic conditions [21, 22]. Monocular measurements were used to determine the best-achievable visual acuity, recorded in logMAR notation. To minimize variability, all BCDVA assessments were conducted by the same examiner. CS was measured monocularly using a Pelli–Robson chart (Clement Clarke International, Harlow, UK) [23, 24], positioned at 1 m, under standardized photopic lighting. Participants identified letters with progressively decreasing contrast, and logarithmic CS (log CS) scores were determined based on the last triplet in which at least two of the three letters were correctly recognized. All CS measurements were performed by the same examiner to ensure consistency.

Data of eligible participants were entered into a Microsoft Excel spreadsheet (Microsoft Corp., Redmond, WA, USA), with identifying information stored separately and accessible only to the principal investigator. Each eye fitted with a ROSE K2 XL lens was assigned a unique code for individual analysis. Statistical analyses were performed using SPSS Statistics software for Windows (version 23.0; IBM Corp., Armonk, NY, USA). The Shapiro–Wilk test was used to assess the distribution normality of continuous data. Descriptive statistics were used to summarize the sample, with categorical variables presented as frequencies and percentages and continuous variables presented as means and standard deviations (SDs). Paired *t*-tests were used to compare visual acuity and CS before and after contact lens fitting, with a P-value < 0.05 considered as statistically significant.

RESULTS

Table 1. Demographic characteristics of study participants grouped by keratoconus staging

Keratoconus staging, n (%)	Male / Female, n (%)	Age (y), Mean ± SD
I, 16 eyes (8.9)	6 (37.5) /10 (62.5)	27.7 ±3.7
II, 52 eyes (28.9)	21 (40.4) / 31 (59.6)	30.7 ±6.6
III, 70 eyes (38.9)	20 (28.6) / 50 (71.4)	29.6 ± 5.0
IV, 42 eyes (23.3)	15 (35.7) / 27 (64.3)	27.3 ± 4.0
Total, 180 eyes (100.0)	62 (34.4) / 118 (65.6)	29.2 ± 5.4

Abbreviations: n, numbers; %, percentage; y, years; SD, standard deviation. Note: The severity of keratoconus was classified using the Amsler–Krumeich system, which categorizes the disease into four clinical stages (I–IV) based on corneal topography, refractive error, pachymetry, and slit-lamp findings [19, 20].

Table 2. Changes in variables in patients with keratoconus who were fitted with ROSE K2 XL contact lens

Keratoconus staging, n (%)	Variable	Before fitting, Mean ± SD	After fitting, Mean ± SD	*P*-value
I, 16 eyes (8.9)	BCDVA (logMAR)	0.26 ± 0.73	0.03 ± 0.48	**< 0.001**
	CS (log CS)	1.74 ± 0.10	2.00 ± 0.00	**< 0.001**
II, 52 eyes (28.9)	BCDVA (logMAR)	0.52 ± 0.08	0.12 ± 0.09	**< 0.001**
	CS (log CS)	1.28 ± 0.15	1.90 ± 0.16	**< 0.001**
III, 70 eyes (38.9)	BCDVA (logMAR)	0.88 ± 0.11	0.09 ± 0.10	**< 0.001**
	CS (log CS)	0.97 ± 0.15	1.92 ± 0.14	**< 0.001**
IV, 42 eyes (23.3)	BCDVA (logMAR)	1.66 ± 0.24	0.12 ± 0.13	**< 0.001**
	CS (log CS)	0.25 ± 0.11	1.86 ± 0.19	**< 0.001**
Total, 180 eyes (100.0)	BCDVA (logMAR)	0.90 ± 0.48	0.10 ± 0.11	**< 0.001**
	CS (log CS)	0.96 ± 0.47	1.90 ± 0.16	**< 0.001**

Abbreviations: BCDVA, best-corrected distance visual acuity, logMAR, logarithm of the minimum angle of resolution; SD, standard deviation, log CS, logarithmic contrast sensitivity unit. Note: The severity of keratoconus was classified using the Amsler–Krumeich system, which categorizes the disease into four clinical stages (I–IV) based on corneal topography, refractive error, pachymetry, and slit-lamp findings [19, 20].

A total of 180 eyes from 90 participants (31 [34.4%] male; 59 [65.6%] female) diagnosed with keratoconus were enrolled in the study. Their mean (SD) age was 29.2 (5.4) years (Table 1), ranging 20–45 years. The largest age group comprised participants aged 26–30 years (n = 41; 45.6%). Participants aged < 25 years accounted for 16.7% (n = 15) of the study sample, those aged 31–35 years represented 26.7% (n = 24), those aged 36–40 years comprised 6.7% (n = 6), and the remaining 4.4% (n = 4) were > 40 years.

All eyes were fitted with ROSE K2 XL semi-scleral contact lenses and were categorized according to disease severity based on the Amsler–Krumeich classification (Table 1). Most eyes were classified as stage III (n = 70, 38.9%), followed by stage II (n = 52, 28.9%), stage IV (n = 42, 23.3%), and stage I (n = 16, 8.9%). The mean age of the participants was comparable across disease stages, ranging from 27.7 years in stage I to 27.3 years in stage IV (Table 1).

The mean (SD) BCDVA of the total cohort improved significantly from 0.90 (0.48) logMAR before to 0.10 (0.11) logMAR after lens fitting ($P < 0.001$). Similarly, the mean (SD) CS increased significantly from 0.96 (0.47) log CS to 1.90 (0.16) log CS after fitting the lenses ($P < 0.001$). Statistically significant improvements in both BCDVA and CS were observed across all disease stages following contact lens fitting (all $P < 0.001$), as shown in Table 2.

The BCDVA improved significantly in all stage groups (all $P < 0.001$). The greatest improvement was observed in the eyes in stage IV, where the mean (SD) BCDVA improved from 1.66 (0.24) logMAR to 0.12 (0.13) logMAR ($P < 0.001$). The smallest improvement was noted in eyes in stage I, with the mean (SD) improving from 0.26 (0.73) logMAR to 0.03 (0.48) logMAR ($P < 0.001$) (Table 2).

Similarly, the CS improved significantly across all stages (all $P < 0.001$). The most marked gain occurred in the eyes in stage IV, where the mean (SD) CS increased from 0.25 (0.11) log CS to 1.86 (0.19) log CS ($P < 0.001$). The least pronounced gain was observed in the eyes in stage I, improving from 1.74 (0.10) log CS to 2.00 (0.00) log CS ($P < 0.001$) (Table 2).

DISSCUSSION

This study demonstrated that fitting ROSE K2 XL semi-scleral contact lenses in patients with varying severities of keratoconus improved their visual performance significantly. Both BCDVA and CS showed significant enhancement postfitting across all disease stages, with the most pronounced improvements observed in advanced keratoconus (stage IV), highlighting the effectiveness of this lens even in cases of severe corneal irregularity. Our findings support the use of ROSE K2 XL lenses as an effective nonsurgical option for visual rehabilitation in patients at any stage of keratoconus, addressing both high-contrast acuity and functional visual quality.

Our findings aligned closely with those of Romero-Jimenez et al. [17], who reported significant improvements in visual acuity in 34 eyes of 27 patients with irregular corneas that were fitted with ROSE K2 XL semi-scleral lenses. In their study, the mean logMAR visual acuity improved significantly, from 0.82 to 0.09 logMAR, which was comparable to the significant improvement observed in our cohort (from 0.90 to 0.10 logMAR). While Romero–Jimenez et al. [17] primarily focused on visual acuity and lens handling [17], our study extended this evidence by also demonstrating significant enhancement in mean CS, from 0.96 to 1.90 log CS, underscoring the broader functional benefits of ROSE K2 XL lenses in management of keratoconus across all severities.

Our results were also consistent with those reported by de Luis Eguileor et al. [25], who investigated ROSE K2 XL lenses in 15 eyes of 15 patients with irregular corneas, who were intolerant to conventional gas-permeable corneal lenses. They observed a significant improvement in the mean (SD) visual acuity, from 0.31 (0.18) logMAR to 0.06 (0.07) logMAR, alongside enhanced patient-reported visual function (the visual function index [VF-14] score increased significantly, from 72.74 to 89.31) [25]. The Amsler–Krumeich classification demonstrated the strongest correlation with other keratoconus severity grading systems in a study of 2073 keratoconus cases [12]. Accordingly, we adopted this classification [12] to grade disease severity in the present study. Our study demonstrated significant improvements in BCDVA. Importantly, by additionally evaluating CS, which improved significantly in all participants at each keratoconus stage, our study highlights broader improvements in functional vision beyond high-contrast acuity, further supporting the clinical value of ROSE K2 XL lenses in keratoconus rehabilitation.

Our findings are further consistent with those of Abou Samra et al. [26], who evaluated ROSE K2 XL lens use in 36 eyes of 36 patients with irregular corneas. They reported a significant improvement in the mean (SD) visual acuity from 0.95 (0.09) logMAR without correction to 0.04 (0.05) logMAR after 6 months of contact lens wear, alongside significant improvement in mesopic and aberrometric outcomes [26]. Similarly, our study demonstrated a significant improvement in BCDVA. Our study uniquely adds evidence of significant CS gain, highlighting the broader functional visual benefits of ROSE K2 XL lenses. Abou Samra et al. [26] documented good daily wearing times and high patient satisfaction, reinforcing the clinical utility of ROSE K2 XL lenses for keratoconus management [26].

Our results are also in line with those of Kumar et al. [18], who compared multiple advanced contact lens designs, including the ROSE K2, in 28 individuals with bilateral mild to advanced keratoconus (age: 20–28 years; 15 males) patients and reported that all contact lenses significantly improved visual acuity and CS relative to spectacles. They found comparable improvements among ROSE K2, conventional RGP, and scleral lenses, regardless of disease severity, suggesting that nonvisual factors, such as comfort and cost may ultimately influence lens choice [18]. Similarly, our study confirmed significant gains in BCDVA and CS with ROSE K2 XL lenses, highlighting both their visual efficacy and the importance of individualized lens selection in clinical practice.

Our study focused on ROSE K2 XL lenses, which aligns with a growing body of research exploring the clinical utility, optical impact, and physiological safety of this contact lens design for irregular corneas. Kumar et al. [27] demonstrated a significant improvement in corrected distance visual acuity and a considerable reduction in higher-order aberrations after ROSE K2 XL lens fitting, across diverse corneal conditions, in 120 eyes of 84 patients with keratoconus, intracorneal ring segments, radial keratotomy, or penetrating keratoplasty [27]. Similarly, Devi et al. [28] studied 15 eyes with mild to moderate keratoconus in patients with an age ranging 20–28 years. They reported that ROSE K2 lenses achieved peak image quality, comparable to that achieved with scleral and conventional RGP contact lenses, surpassing KeraSoft IC® designs, although residual lower-order aberrations and coma limited full normalization, as compared to control eyes [28]. Beyond vision, corneal physiology remains a central concern. De Luis Eguileor et al. [29] followed 16 eyes that were intolerant to conventional gas-permeable corneal contact lenses. These eyes were then fitted with ROSE K2 XL contact lenses for a year. They observed a mean reduction in the vault over time, but noted almost stable corneal thickness and no limbal stem cell deficiency, which affirmed the safety of these lenses [29]. In contrast, Elagamy and AlOmair [30] identified endothelial cell morphometric changes and corneal thinning in long-term ROSE K2 wearers with mild (18 eyes) to moderate (20 eyes) keratoconus. Their findings underscored the need to consider oxygen transmissibility and wearing duration [30]. Vincent et al. [11] highlighted that, for scleral trial lenses (Epicon LC, ROSE K2 XL, and ICD 16.5), contact lens thickness varies with power and design; such variability can influence oxygen delivery and should guide fitting strategies [11]. The fitting methodology was also refined. Romero–Jimenez et al. [31] found that the use of the first definite apical clearance lens improved the optimal fit rates of the ROSE K2 contact lens in keratoconus. Spectral-domain optical coherence tomography-guided fitting, as shown by Elbendary and Abou Samra [32], helped to optimize the tear film thickness and edge lift, thus improving comfort and satisfaction. Technological advances have ensured further improvements in efficiency. Artificial intelligence models developed by Risser et al. [33] and Abadou et al. [34] could accurately predict the base curves and posterior curvature of ROSE K2 lenses for patients with keratoconus, which outperformed the manufacturer's recommendations, could shorten chair time, and improve first-fit success. Another study demonstrated the stability of corneal keratometry and pachymetry within 1 week after conventional RGP or ROSE K2 lens wear cessation in 29 eyes of 20 patients with mild to severe keratoconus [35]. Furthermore, piggyback fitting of Senofilcon-A soft lenses with ROSE K2 contact lenses in eyes with keratoconus reduced the final RGP power, without changing visual acuity [36]. Moreover, the macular and retinal nerve fiber layer optical coherence tomography metrics remained unchanged after correction of irregular astigmatism with ROSE K2 contact lenses in eyes with keratoconus [37]. Comparative studies [13] have further confirmed that ROSE K2 lenses provide visual outcomes comparable with those of the silicone hydrogel KeraSoft IC® contact lens, although with more biomicroscopic complications, such as corneal staining [13]. Collectively, these studies reinforced our findings that ROSE K2 XL lenses achieve substantial visual rehabilitation and CS gains. On the other hand, individualized fitting, technological tools, and ongoing monitoring remain essential for maximizing safety, comfort, and long-term corneal health when using these lenses.

Numerous studies have established that keratoconus is associated with reduced CS, which is attributable to increased higher-order aberrations, even when the BCDVA remains relatively preserved [38, 39]. A recognized limitation of corneal RGP lenses is the decline in visual quality when the lens decentrates or tilts, which can induce higher-order aberrations. While the Snellen acuity may remain unaffected, CS often diminishes under these conditions [40]. In the present study, the mean (SD) CS improved significantly from 0.96 (0.47) log CS to 1.90 (0.16) log CS after ROSE K2 XL lens fitting. Use of this lens design yielded a significant enhancement in CS. This contrasted with the findings of Wei et al. [41], who studied 120 eyes with keratoconus or suspected keratoconus, of which 46 were fitted with ROSE K2RGP lenses, while the remainder were fitted with other lens types. They reported persistent CS reduction in eyes with keratoconus as compared to the keratoconus suspect group, despite achieving good visual acuity [41]. Our results were consistent with those of studies assessing BostonSight scleral lenses, which reported significant improvements in higher-order aberrations, BCDVA, and CS in patients with keratoconus who were fitted with these scleral lenses [42, 43]. These outcomes likely reflect the advanced design features of specialized lenses that can better neutralize corneal irregularities and aberrations.

One of the principal strengths of this study was its relatively large sample size, which enhanced the robustness of our findings and allowed for meaningful subgroup analyses across keratoconus severity stages. By incorporating both BCDVA and CS, this study offered a more comprehensive evaluation of functional visual outcomes than would be afforded by assessing visual acuity alone. However, this study had some limitations. The study cohort was limited to patients aged 20–45 years, which may affect the generalizability of the results to younger or older populations. Additionally, the focus on short-term visual outcomes precluded conclusions regarding long-term lens tolerance, physiological changes, and complication rates. Finally, the absence of a control group or comparison with alternative lens designs limited the ability to attribute improvements exclusively to the ROSE K2 XL lenses. Future research should include randomized controlled studies with longer follow-up periods in order to assess sustained efficacy, ocular health, and patient-reported outcomes, as well as to provide direct comparisons with other contemporary lens designs to guide clinical decision-making.

CONCLUSIONS

This study demonstrated that ROSE K2 XL semi-scleral contact lenses offer significant improvements in visual performance in patients with keratoconus, as reflected by enhanced BCDVA and significantly increased CS. By addressing both high-contrast acuity and functional vision under everyday conditions, these lenses can effectively mitigate the visual disturbances commonly associated with irregular astigmatism and corneal distortion. Consequently, patients benefit from clearer vision and greater independence in daily activities, such as reading, driving, and navigation. Our findings indicate the potential of ROSE K2 XL lenses as a noninvasive alternative to surgical interventions, particularly for individuals for whom conventional spectacles or lenses may offer limited benefit or those presenting with advanced disease stages. While these results reinforce the clinical value of this lens design for keratoconus management, longitudinal and comparative studies are warranted to establish its long-term safety and performance relative to emerging contact lens technologies and surgical options, as well as patient satisfaction.

ETHICAL DECLARATIONS

Ethical approval: Ethical approval for the study was obtained from the Research and Ethics Committee of the University of Buraimi (No. AY23-24COHS-182). All the procedures used adhered to the principles outlined in the Declaration of Helsinki. Written informed consent was obtained from each participant prior to enrollment, and strict measures were taken to ensure participant confidentiality. No physical or psychological harm was incurred by any of the participants.

Conflict of interests: None.

FUNDING

None.

ACKNOWLEDGMENTS

None.

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