



# Quality of Life in Keratoconus Patients; A Comparison Between Spectacle, Rigid Gas-Permeable Lens, and Corneal Stromal Ring Segment Implantation

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## Abstract

**Objectives:** To compare vision-related quality of life (QoL) in keratoconus patients managed by spectacles, rigid gas permeable (RGP) lenses, and intra-corneal ring segment (ICRS) implantation.

**Methods:** In a cross-sectional study, 67 patients (39 females) with moderate-to-severe keratoconus (mean age:  $28.50 \pm 7.30$  years) were included. Patients were divided into three groups: Spectacles, RGP lenses, and ICRS, based on their treatment modalities. Binocular visual acuity and vision-related QoL were assessed using the Persian version of the Vision Function Questionnaire-25 (VFQ-25). Group comparisons were performed using appropriate statistical tests.

**Results:** The VFQ-25 mean  $\pm$  standard deviation total scores were  $80.69 \pm 13.89$  for the spectacle group,  $78.06 \pm 14.71$  for the RGP lens group, and  $72.60 \pm 13.95$  for the ICRS group ( $p > 0.05$ ). The ICRS group demonstrated significantly higher social function ( $91.17 \pm 15.44$ ) and dependency scores ( $92.64 \pm 17.14$ ) compared to the RGP group ( $p < 0.05$ ). No significant differences were observed in other VFQ-25 domains or total scores among the three groups.

**Conclusion:** Spectacles, RGP lenses, and ICRS implantation provide comparable overall vision-related QoL in keratoconus patients. While no significant difference was found in total QoL scores, the ICRS group exhibited superior social function and dependency scores, suggesting a potential advantage in these specific QoL domains.

**Keywords:** Intra corneal ring segment implantation, keratoconus, lens, quality of life, spectacle

## Introduction

Keratoconus is a non-inflammatory, asymmetric, bilateral corneal ectasia, in which the cornea protrudes, becoming thinner, steeper, and more irregular. This results in a deterioration of visual acuity (VA) that cannot be corrected with spectacles or contact lenses in the later stages of the disease. It typically occurs in the second decade of life and

may progress into adulthood (1). The deterioration in VA, contrast sensitivity, (2), and tear film quality (3) associated with keratoconus can reduce visual function, limit social interactions, and lead to a reduced quality of life (QoL) (4, 5).

Currently, various management strategies are available to improve VA in patients with keratoconus. These include: (1) optical management with spectacles or gas-permeable

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(GP) contact lenses, and (2) surgical treatments such as intra-corneal ring segment (ICRS) implantation or corneal transplantation (6-8). Additionally, corneal cross-linking has been introduced as an effective procedure that halts disease progression (6-8). Appropriate management options are selected based on the severity of the disease, (6-8), the patient's age, the practitioner's experience, (9,10), and the cost of treatments (11).

Early and mild keratoconus patients are typically managed well with spectacles, (7, 8), but as the disease progresses, management becomes more challenging. For patients with moderate to severe keratoconus, options such as spectacles, GP lenses, and ICRS (12) are considered. In advanced keratoconus cases, patients may achieve acceptable VA through modern contact lenses, such as scleral lenses, or through corneal transplantation (13). The clinical outcomes, benefits, and side effects of each treatment modality have been thoroughly discussed in previous studies (14, 15).

In patient management, in addition to clinical outcomes, patient-reported outcomes and their perception of results are becoming increasingly important (16). The National Eye Institute developed the Vision Function Questionnaire-25 (VFQ-25) to evaluate vision-related QoL in a multi-dimensional fashion in visually impaired patients (17). Previous studies have discussed the application of the VFQ-25 in keratoconus patients and the improvements in patient-reported QoL following appropriate management (18, 19).

The deterioration of visual function associated with keratoconus can affect the patient's QoL in multiple dimensions (4, 5). Therefore, to enhance our understanding of patient satisfaction, this study compares spectacles, RGP lenses, and ICRS in moderate-to-severe keratoconus patients. VA and vision-related QoL scores were assessed and compared. The results of this study may provide valuable insights into the management strategies for keratoconus patients, offering a better understanding of their perspectives on the disease, and helping guide decisions for recommending appropriate treatments.

## Methods

In this cross-sectional study, patients with bilateral keratoconus were enrolled from those referred to the Poostchi Cornea Clinic, Shiraz University of Medical Sciences, Iran. The study protocol was in accordance with the tenets of the Declaration of Helsinki and was approved by the local ethics committee at Shiraz University of Medical Sciences. Written informed consent was obtained from all participants.

Keratoconus was diagnosed according to the Rabinowitz criteria(20). Based on these criteria, keratoconus patients were classified into four groups: Mild (steep keratometry ( $K$ )  $< 45D$ ), moderate ( $45 < \text{steep } K < 52D$ ), severe ( $52 < \text{steep}$

$K < 62D$ ), and advanced ( $K > 62D$ ). In the present study, the inclusion criteria were moderate and severe keratoconus patients who had received appropriate optical or surgical treatments for more than 1 year. The exclusion criteria included keratoconus patients with steep  $K < 45D$  or  $> 62D$  (mild and advanced keratoconus), patients with a history of keratoplasty, and those with other ocular or systemic diseases that significantly affected the patients' QoL or mental well-being.

Patients were classified according to their management modalities into three groups: spectacle, RGP lens, and ICRS. Patients in the RGP lens group used simple spherical RGP lenses (Bausch and Lomb Incorporated, Rochester, NY, USA). All ICRS surgeries were performed by the same corneal specialist surgeon (Sh.B). The Keraring segments (Keraring, Mediphacos, Belo Horizonte, Brazil) were implanted using mechanical dissection. Patients in the ICRS group used spectacles if required. The mean sphere, cylinder, and keratometry findings (flat  $K$  and steep  $K$ ) for both the right and left eyes were measured. The three groups were matched according to age and gender. The spectacle and RGP lens groups were further matched based on the calculated sphere, cylinder, flat  $K$ , and steep  $K$  values. Since the candidates for ICRS surgery are patients with moderate to severe keratoconus, this group can be considered as having similar characteristics to the other groups.

Refraction, uncorrected, best-corrected, and habitual VA, as well as Pentacam HR (Oculus; Optikgeräte GmbH, Wetzlar, Germany) imaging, were obtained for all patients. VA was recorded using the logarithm of the minimum angle of resolution (LogMAR) scale. Binocular VA was used for the analysis. We utilized the 25-item Persian version of the VFQ, a short-form version of the 51-item VFQ. This version was divided into 12 subscales: General health (2 items), general vision (2 items), ocular pain (2 items), near vision (6 items), distance vision (6 items), vision-specific social functioning (3 items), vision-specific mental health (5 items), vision-specific role difficulties (4 items), vision-specific dependency (4 items), driving (3 items), color vision (1 item), and peripheral vision (1 item). Subscale responses were graded from 0 to 100, with higher VFQ scores representing better QoL. The items were averaged to form subscales, and the sum of the averages resulted in the total score. The Persian version of the VFQ-25 questionnaire has previously demonstrated good validity and reliability in the Iranian population (21). After a comprehensive explanation, each patient completed a hard copy of the questionnaire.

## Statistical Analysis

Descriptive data were presented as means, standard deviation (SD), and percentages. The normality of the data was evaluated using the Shapiro-Wilk test. The comparison be-

tween the VFQ-25 scores and clinical data was performed using the non-parametric Kruskal–Wallis test and Mann–Whitney U test. All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) 18.0 for Windows (SPSS Inc., Chicago, Illinois, USA).

## Results

Sixty-seven eligible keratoconus patients (57% female) with a mean age of  $28.50 \pm 7.30$  years were included in the study. Among these, 35 patients (19 females, 16 males) with a mean age of  $26.30 \pm 6.50$  years were managed with spectacles, 15 patients (11 females, 4 males) with a mean age of  $27.40 \pm 6.90$  years were managed with GP lenses, and 17 patients (9 females, 8 males) with a mean age of  $28.90 \pm 7.10$  years were managed with ICRS ( $p > 0.05$ ). The mean  $\pm$  SD values of refractive and keratometry parameters, along with demographic characteristics of the keratoconus patients, are provided in Table 1.

The mean binocular uncorrected VA in the ICRS, spectacle, and RGP lens groups were  $0.24 \pm 0.18$ ,  $0.5 \pm 0.3$ , and  $0.7 \pm 0.4$  LogMAR, respectively. The differences between the three groups were statistically significant ( $p < 0.05$ ). The mean binocular best-corrected VA (BCVA) in the ICRS, spectacle, and RGP lens groups were  $0.04 \pm 0.06$ ,  $0.1 \pm 0.2$ , and  $0.2 \pm 0.1$  LogMAR, respectively. The differences between the ICRS and RGP lens groups were statistically significant ( $p < 0.001$ ). The habitual VA in the ICRS, spectacle, and RGP lens groups was  $0.11 \pm 0.12$ ,  $0.20 \pm 0.22$ , and  $0.22 \pm 0.15$  LogMAR, respectively. The differences between the ICRS and RGP lens groups were marginally significant ( $p = 0.05$ ). In our sample, 65% of the patients managed with ICRS achieved BCVA of 0 LogMAR (20/20), while this rate was 45% in the spectacle group and 20% in the GP lens group.

The mean  $\pm$  SD of VFQ-25 scores for the treatment groups are presented in table 2 and figure 1. Our main findings revealed significant differences in the social functioning and dependency domains (Table 2). The RGP lens group showed

**Table 1.** Clinical characteristics of keratoconus patients

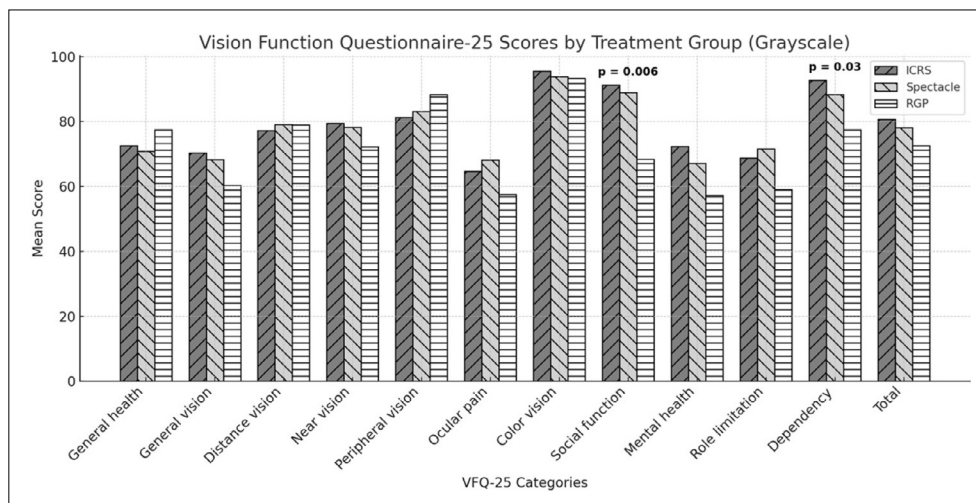
Groups clinical characteristics	ICRS (n=17)	Spectacle (n=35)	RGP lens (n=15)	p (n=15)
Sphere	$-0.36 \pm 2.22$	$-2.07 \pm 2.03$	$-1.79 \pm 1.64$	0.49
Cylinder	$-2.94 \pm 1.53$	$-3.44 \pm 1.74$	$-3.33 \pm 1.54$	0.76
Flat keratometry	$43.35 \pm 2.37$	$46.19 \pm 2.87$	$46.29 \pm 2.60$	0.83
Steep keratometry	$46.16 \pm 2.11$	$49.89 \pm 2.94$	$48.89 \pm 2.79$	0.57

ICRS: Intra corneal ring segment; RGP: Rigid gas permeable.

**Table 2.** The mean  $\pm$  standard deviation of vision function questionnaire-25 scores of treatment groups

Groups VFQ-25 areas	ICRS (n=17)	Spectacle (n=35)	Rigid gas permeable lens (n=15)	p
General health	$72.50 \pm 18.34$	$70.81 \pm 17.71$	$77.50 \pm 18.07$	0.33
General vision	$70.29 \pm 18.95$	$68.25 \pm 15.50$	$60.33 \pm 22.94$	0.39
Distance vision	$77.20 \pm 19.49$	$79.05 \pm 19.31$	$78.88 \pm 15.62$	0.92
Near vision	$79.41 \pm 22.93$	$78.22 \pm 21.06$	$72.22 \pm 19.77$	0.48
Peripheral vision	$81.25 \pm 23.27$	$83.12 \pm 22.20$	$88.33 \pm 16.00$	0.65
Ocular pain	$64.70 \pm 28.37$	$68.12 \pm 20.59$	$57.50 \pm 23.52$	0.62
Color vision	$95.58 \pm 13.21$	$93.75 \pm 14.70$	$93.33 \pm 17.59$	0.7
Social function	$91.17 \pm 15.44$	$88.95 \pm 16.16$	$68.33 \pm 24.43$	0.01
0.006*, 0.01 <sup>ψ</sup>				
Mental health	$72.35 \pm 26.69$	$67.12 \pm 22.55$	$57.33 \pm 29.57$	0.18
Role limitation	$68.75 \pm 26.14$	$71.56 \pm 21.55$	$59.02 \pm 28.14$	0.55
Dependency	$92.64 \pm 17.14$	$88.28 \pm 18.13$	$77.50 \pm 27.32$	0.05, 0.03 <sup>ψ</sup>
Total	$80.69 \pm 13.89$	$78.06 \pm 14.71$	$72.60 \pm 13.95$	0.34

\*Significant P-value between spectacle and lens groups. <sup>ψ</sup>Significant P-value between ICRS and lens groups. ICRS: Intra corneal ring segment, VFQ-25: Vision function questionnaire-25.



**Figure 1.** Comparison of vision function questionnaire-25 scores of treatment groups.

a statistically lower score in the social functioning domain compared to the ICRS and spectacle groups ( $p=0.006$  and  $p=0.01$ , respectively). Additionally, RGP lens wearers had a significantly lower score in the dependency domain compared to the ICRS group ( $p=0.03$ ).

The mean total scores in the ICRS, spectacle, and RGP lens groups were  $80.69 \pm 13.89$ ,  $78.06 \pm 14.71$ , and  $72.60 \pm 13.95$ , respectively ( $p>0.1$ ). The mean scores for general vision, distance vision, near vision, and peripheral vision across the three treatment modalities were at least 70, except for the general vision score in the RGP lens group, which was 60.33. The highest scores were observed in the peripheral vision item across all three treatment modalities. There were no statistically significant differences between the three treatment modalities in visual function scores. The lowest mean scores across the three treatment modalities were in the items of general vision, ocular pain, mental health, and role limitations. The mean scores for all of these items were  $<72$ .

The mean scores of color vision were  $>93$  in three keratoconus treatment modalities ( $p>0.05$ ). Since the majority of patients did not drive (for non-eye-related reasons), we omitted this subscale according to the suggestion of a previous study (22).

## Discussion

Based on the results of the present study, we found significant differences in scores between the groups in the social functioning and dependency domains, with the ICRS group having the highest scores, followed by the spectacle and GP lens groups.

The RGP lens wearers had the lowest total score in the visual function questionnaire, although the difference did not reach statistical significance. This group had the lowest scores in seven out of the eleven items on the questionnaire

(two of which were previously mentioned as significant). Regarding the ocular pain item, RGP lens wearers showed the lowest scores, likely due to foreign body sensation, dryness, and lens deposits. Other studies have also reported a drop in the ocular pain score for RGP lens wearers (4, 23, 24). Wu et al. (18) found that in RGP lens wearers, there were no significant differences in vision-related QoL between mild and moderate keratoconus cases, but severe keratoconus patients had significantly lower vision-related QoL scores. In terms of color vision, this group had scores similar to the other groups, indicating that the chromatic aberrations caused by the three modalities did not result in noticeable differences. Other studies have reported similar findings regarding color vision (4). Only one study, involving patients who underwent penetrating keratoplasty, reported a decrease in color vision scores (25). As for peripheral vision, the best score was obtained in the RGP lens group, probably due to the absence of the spectacle rim and the creation of a more uniform ocular surface.

The spectacle wearers had higher total scores compared to the RGP lens wearers, although the difference was not statistically significant. In terms of ocular pain, the spectacle group achieved the highest score, indicating less pain experienced by spectacle wearers. Since spectacles do not make contact with the corneal surface, they cause less discomfort. Additionally, in terms of distance vision, the spectacle group obtained the highest score. The use of high refractive index aspheric lenses for high astigmatism (26, 27) may have contributed to these findings. These lenses are heavier and thinner, improving the shape factor magnification. These results suggest that, despite the moderate and severe stages of keratoconus in our patients, spectacles still provide a good vision-related QoL. Moreover, spectacles remain a more common and acceptable mode of management compared to RGP lenses.

Although not statistically significant, the group of patients managed with ICRS had the highest total score in the vision function QoL questionnaire. The highest scores were observed in the social function and dependency domains, and the differences between the three groups were statistically significant. In the VFQ-25, vision-related social function is defined by two questions. The first question asks about the individual's ability to perceive other people's reactions to their speech, while the second question asks about the difficulty an individual may experience in communicating with others at a party, meeting, or restaurant due to vision issues. The ICRS group was better able to see others' facial expressions compared to the other groups, which may have made them more comfortable and confident in their communications. Regarding dependency, the nature of ICRS treatment reduces the patient's reliance on optical aids. A previous study reported an improvement in QoL after ICRS surgery (18). The better VA achieved with ICRS may have contributed to the higher scores in both the social function and dependency domains. Other studies (11) have also reported that improved VA is closely related to better QoL scores (4, 5).

The study's limitation was its relatively small sample size. However, the appropriate matching of the three treatment groups allowed for a reasonable comparison between them. This study is the first to address a comparison of QoL in patients with moderate to severe keratoconus who were managed with spectacles, RGP lenses, and ICRS.

## Conclusion

In conclusion, for moderate and severe keratoconus cases, management with spectacles, RGP lenses, and ICRS all provide good vision-related QoL. ICRS offers the most significant improvement in the social function and dependency domains. Spectacles provide a slightly better, but not significantly different, vision-related QoL compared to RGP lenses. The appropriate management should be selected based on the patients' individual needs.

## Disclosures

**Ethics Committee Approval:** The study protocol was in accordance with the tenets of the Declaration of Helsinki and was approved by the local ethics committee at Shiraz University of Medical Sciences. Written informed consent was obtained from all participants.

**Conflict of Interest:** None declared.

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