ORIGINAL ARTICLE

Comparison of Rigid Gas-permeable Contact Lenses with Soft Hydrogel Contact Lens in Keratoconus and their Impact on Quality of Life

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Abstract

Purpose: To compare the efficacy of rigid gas-permeable (RGP) lens and soft hydrogel lens in patients with keratoconus and to assess their impact on quality of life (QoL).

Setting: Tertiary care referral center.

Materials and methods: A randomized, comparative, clinical interventional trial was conducted in patients with keratoconus. From July 2014 to June 2017, patients were enrolled for this study and were fitted with RGP contact lens (CL) (RoseK© Menicon Limited) or silicone hydrogel lens (Kerasoft© International Limited). The two groups were compared in terms of best spectacle corrected visual acuity (BSCVA), best CL corrected visual acuity (BCLCVA), corneal topography, Schirmer's test, and contrast sensitivity. Quality of life was assessed by asking the patients to fill a self-reported questionnaire.

Results: Forty eyes were enrolled and randomized to the Rose-K and Kerasoft groups. The two groups were comparable with respect to the mean patient age, sex, and mean K values. A statistically significant improvement was observed in BCLCVA in both groups at 6 months ($p < 0.01$). The Kerasoft group had a better comfort score at 6 months' follow-up compared to Rose K ($p < 0.05$). In terms of contrast sensitivity, Rose K group fared better than Kerasoft group ($p = 0.001$).

Conclusion: Both Kerasoft and Rose K groups showed improvement in visual acuity. Kerasoft lens users had better comfort and also required less number of trials before final fit. Rose K lens provided a better contrast sensitivity. We conclude that Kerasoft lens can be considered as a good alternative for optical correction of corneal astigmatism in patients with keratoconus, not tolerating RGP lenses.

Keywords: Kerasoft, Keratoconus, Quality of life, Rose K, Silicone hydrogel.

International Journal of Keratoconus and Ectatic Corneal Diseases (2019): 10.5005/jp-journals-10025-1178

Introduction

Keratoconus is a progressive, noninflammatory ectasia of the cornea associated with myopia and irregular astigmatism.[1,2] Decreased vision and optical distortion are caused due to abnormal corneal shape and scarring. Constant eye rubbing during childhood has also been reported to be associated with this disorder.[3] Contact lens are a modality of choice in 90% of patients due to the corneal surface irregularity and are highly favorable in visual rehabilitation of keratoconus patients.[1,3] Contact lens fitting for irregular corneas is a challenge for CL practitioners.[4] The rigid gas-permeable (RGP) contact lens (CLs) are considered the best solution for patients with irregular corneas because they create a tear layer between the lens and the cornea, forming a new, regular, and smooth optical surface, thereby reducing the higher order optical aberrations of the anterior corneal.[1] In the recent years, great improvements have been made in the field of soft silicone specialized CLs. A new variety of soft CL such as Kerasoft IC® (Ultra Vision International Limited Bedfordshire, UK) lens has been introduced recently which are comfortable and effective in keratoconus and has shown good promise in visual rehabilitation in various corneal ectasias.[5,6]

Since both the Rose K and Kerasoft IC CLs are custom-made lenses with their own unique set of advantages and limitations for a keratoconic eye, we undertook this prospective, randomized, and comparative study to compare the ease of fit, user-friendliness, quality of vision, and their impact on the quality of life (QoL). To date, no prospective or retrospective comparative study has been done on these two highly sophisticated CLs in keratoconus.

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How to cite this article: Yangzes S, Gupta A, Thakur A, *et al.* Comparison of Rigid Gas-permeable Contact Lenses with Soft Hydrogel Contact Lens in Keratoconus and their Impact on Quality of Life. Int J Kerat Ect Cor Dis 2019;8(1):7–11.

Source of support: Nil

Conflict of interest: None

Materials and Methods

A randomized comparative clinical trial was performed between July 2014 and June 2017 to evaluate the efficacy of Rose-K and Kerasoft CLs in keratoconus. All the patients were enrolled after obtaining an informed consent. The study was approved by the Institutional Ethics and Review Committee.

Forty eyes of 20 patients were enrolled from the Cornea Clinic, Advanced Eye Centre, Postgraduate Institute of Medical Education and Research and were randomized into two groups: Group I: Kerasoft ($n = 20$ eyes) and Group II: Rose K ($n = 20$ eyes). The baseline parameters, including the age and sex distribution, of the

two groups were comparable. Subjects between 15 years and 40 years of age with established diagnosis of keratoconus (based on history, clinical features, and topography) and average K between 47 and 60 diopters were enrolled. Patients suffering from vernal keratoconjunctivitis, hydrops of cornea, allergic disease, giant papillary conjunctivitis, dry eye or other ocular surface disease, central scarring of cornea, those who had undergone a corneal graft in either eye, and unilateral keratoconus were excluded from the study. We also ensured recruiting CL-naive patients, as patients habituated to CLs in the past may affect the feedback in terms of reporting comfort and ease of use. Hence, we excluded patients with history of CL use. Parameters were recorded at the initial visit and at 1 month and 6 months' follow-up. Evaluation parameters included uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BSCVA), best contact lens corrected visual acuity (BCLCVA), slit lamp examination for peripheral vascularization of cornea, cone size and cone position, corneal topography, pachymetry and keratometry (Pentacam; Oculus, Wetzlar, Germany), contrast sensitivity (Pelli Robson chart), Schirmer's test, and tear film breakup time (TFBUT). Contact lens fittings were documented with clinical photographs and the dynamic fit was recorded using slit lamp camera (Eye cap; Haag-Streit, Switzerland). For each eye, objective refraction was followed by subjective refraction, keratometry, and topography (Pentacam, Oculus, Wetzlar Germany). The average of the simulated keratometry (SimK) readings was used to categorize keratoconus into mild (46 to 50D), moderate (51 to 55D), and severe (>56D).

Fitting Procedure

All CL fittings of both groups were performed by a single fitter.

For RoseK2

For Rose K CL fit, the diopteric value of average SimK was converted to radii of curvature (*r*) in millimeters (mm) by the Pentacam (Oculus, Wetzlar Germany) machine. The decision of initial trial lens base curve was made on the basis of mean keratometry in millimeters (mm). Lens was allowed to settle down for 15–20 minutes before clinical assessment on slit lamp. Fitting philosophy involved "three-point touch" in all cases. Final target was to have around 2 to 3 mm of apical touch and horizontal midperipheral bearing at 3 and 9 o'clock, good post blink movement of 1–2 mm, adequate coverage of visual axis, and lens stability on different gaze movements. Total number of trial lenses required before final fit (chair time) was recorded (Fig. 1).

For Kerasoft IC

First trial lens were selected based on mean keratometry readings. Lens was allowed to settle down for 20–30 minutes and assessed on slit lamp. The final fit of Kerasoft IC lens was assessed by observing the characteristic behavior of the lens on the eye using the acronym MoRoCoVa which represents movement, rotation, centration, and comfort, all of which when optimal give the best visual acuity. Good fit consisted of lens covering the cornea uniformly, movement up to 1–2 mm with each blink, and laser mark needed to be at 6 o'clock position (if laser mark decentered, it was noted and mentioned in the final prescription). Left add and right subtract procedure rule was followed (Fig. 2).

At the end, spherical vertex corrected overrefraction was performed. The BCLCVA was noted in both groups by a single expert optometrist (MK). If the stability of lens was confirmed then the order was placed. On receiving the lens, its fit was reassessed and finalized. The patient was followed up at 1 month, 3 months, and 6 months.

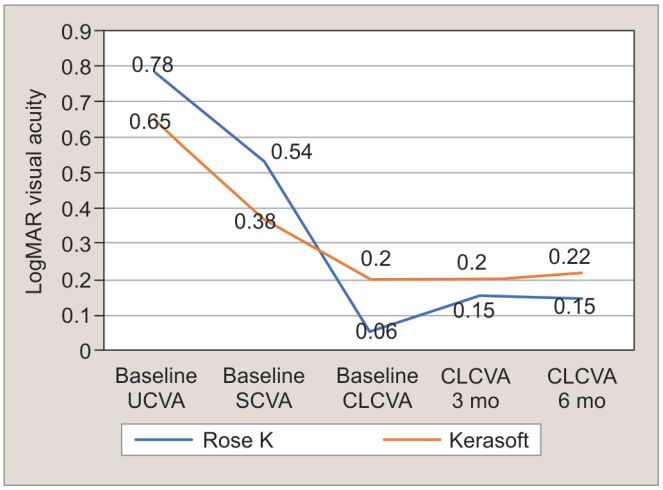

Fig. 1: Vision (logMAR scale) at baseline, 3 months, and 6 months. UCVA, uncorrected visual acuity; SCVA, spectacle corrected visual acuity; CLCVA, contact lens corrected visual acuity; mo, months

Contrast Sensitivity Testing

Each subject's contrast sensitivity was tested pre- and post-CL at each visit using Pelli Robson contrast sensitivity chart at a test distance of 1 m and the chart luminance was 64 cd/m^2. Estimation of contrast sensitivity was done by log contrast value of the last triplet on which the subject correctly identifies at least two of the three letters.[7]

Comfort Score Questionnaire

The 28-item contact lens impact on quality of life (CLIQ) questionnaire was used to evaluate the QoL in the subjects. The questionnaire is available online at website: http://iovs.arvojournals.org.article.aspx?articleid=2124900.[8]

The primary outcome measure was the change in the visual acuity at last follow-up as measured on the LogMAR visual acuity scale.

The secondary outcome measure involved change in comfort score, contrast sensitivity, Schirmer's test, and TFBUT. Any adverse events were recorded.

Statistical Analysis

The study was a prospective, randomized, comparative and interventional study. At the conclusion of the study, data from Excel datasheet was transferred to SPSS 2 (version 20.0; SPSS for Windows, Armonk, NY). The arithmetic mean and standard deviation were calculated for all the descriptive parameters. Chi-square test was used to determine the significance of association between categorical variables. Student's *t* test was applied for variables measured on an interval scale. Mann–Whitney *U* test was used to analyze two dependent variables. One-way analysis of variance was used to compare two independent variables. Descriptive analysis was presented as mean ± standard deviation. For the 28-item CLIQ questionnaire, the analysis performed followed the recommendations of the developers. The items 1–20 (lower score is better) have polarity opposite that of items 21–28 (higher score is better), so items 1–20 are reverse in polarity to give an overall

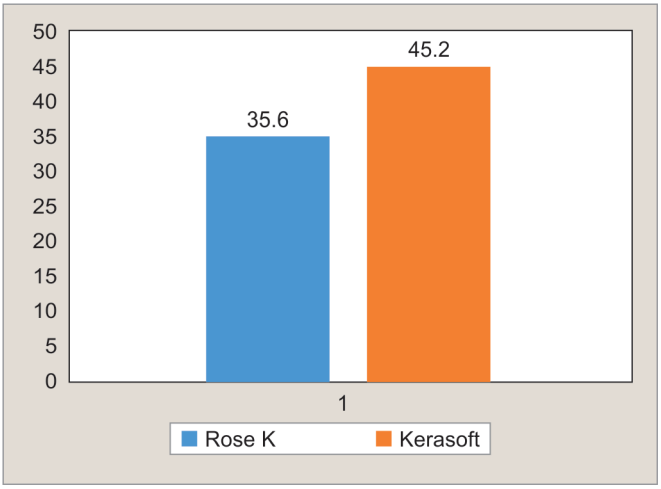

Fig. 2: CLIQ person measures scores in Rose K and Kerasoft groups

higher score for better QoL. Therefore, for categories (1,2,3,4,5) assign (5,4,3,3,3) to the first 20 items and score (2,2,3,4,5) to items 21 to 28. The average of these items gave $CLIQ_{raw\ score}$. We converted $CLIQ_{raw\ score}$ to $CLIQ_{person\ measure}$ whose scale ranged from 0 to 10 (higher score indicated better QoL) using the following formula.

$$CLIQ_{person\ measure} = 34.41 \times Log\left(CLIQ_{raw\ score}/5 - CLIQ_{raw\ score}\right) + 26.69$$

Kruskal–Wallis test was used to compare the mean $CLIQ_{person\ measure}$.

Statistical significance was determined as $p < 0.05$.

Results

A total of 20 keratoconus patients were enrolled. The patients in both groups were comparable in terms of age, i.e., Rose K mean age 23.15 ± 4.73 years (range 15–28) and Kerasoft IC 24.9 ± 7.32 years (17–34). Ten patients (20 eyes) were of Rose K group, whereas 10 patients (20 eyes) were assigned to the keratoconus IC group. No statistically significant differences were observed in sex distribution ($p = 0.45$) and the mean steep K values in both groups ($p = 0.12$). At presentation, the refractive error of each eye was noted. Table 1 describes the baseline characteristics of each group. In our study, the mean spherical refractive error in Rose K group was −6.05 ± 4.98 (range −1.5 to −13.0D) and in the Kerasoft group was −4.94 ± 4.1D (−1 to −11DC) ($p = 0.29$). The mean cylindrical refractive error in Rose K group was −3.51 ± 1.73 (−2.0 to −6.0DC) and in the Kerasoft group was −2.16 ± 1.87D (−1.5 to −6.0DC; $p = 0.59$. No statistically significant difference was observed in the baseline spherical equivalent in both the groups ($p = 0.44$). A significant improvement in LogMAR visual acuity with CL was observed at 1 month, 3 months, and 6 months in both the groups ($p = 0.01$) (Fig. 1). The mean steep K ranged from 47 to 69D in Rose K group and 44.6 to 70D in the Kerasoft group. The mean ± SD LogMAR visual acuity with CLs at 6 months was 0.22 ± 0.19 in Kerasoft group and 0.15 ± 0.91 with the RGP group. Visual acuity of 20/40 or better was achieved in 18 eyes (90%) in the Kerasoft group and in 19 eyes (95%) in the Rose K group.

In case of Rose K lenses, the contrast sensitivity improved from 0.68 ± 0.4 at the baseline visit to 1.38 ± 0.15 at the 6th month follow-up ($p < 0.01$). With Kerasoft lenses, the contrast sensitivity improved from 0.61 ± 0.21 at the baseline visit to 1.68 ± 0.14 at the 6th month follow-up ($p < 0.01$). Even though the two lens groups were comparable at the baseline visit ($p = 0.61$), Rose K lens had significantly better contrast sensitivity than the Kerasoft lens at 1 month ($p = 0.001$) and at 6 months ($p = 0.002$) follow-up (Table 2).

The patients were asked to fill out a CLIQ questionnaire and grade ocular comfort with their respective lenses at each follow-up visit. Both groups were comparable in terms of comfort score at baseline ($p = 0.57$). The mean CLIQ raw score was 35.60 ± 3.37 in Rose K and 45.20 ± 1.58 in Kerasoft group ($p = 0.02$). Kerasoft group had significantly better comfort score compared to the Rose K group (Fig. 2).

The mean number of trial lenses required to finalize Rose K lens parameters was significantly more (3.6 ± 0.32) than the Kerasoft lens group (2.15 ± 0.58; $p < 0.001$). This signified that Kerasoft IC lenses fitting consumed significantly less chair time or less number of trials compared to Rose K lens fitting (Table 3).

Table 1: Baseline parameters of the patients in both groups prior to contact lens fitting

Parameter	*Kerasoft*	*Rose K*	*p value*
Age	24.9 ± 7.3	23.15 ± 4.73	0.48
Sex (M:F)	7:3	5:5	
Spherical error (DS)	−4.94 ± 4.1	−6.05 ± 4.98	
Cylindrical error (DC)	−2.16 ± 1.87	−3.51 ± 1.73	
BSCVA	0.38 ± 0.27	0.54 ± 0.26	0.47
Mean SimK	55.05 ± 8.62	55.58 ± 7.31	0.43
Steep K	*n* = eyes	*n* = eyes	
46–50D	8	6	
51–55D	4	8	
>56D	8	6	
Total (20 eyes)	10	10	
Pachymetry	412.80 ± 11.69	426.25 ± 11.87	0.77
Type of cone			
Globus	8	9	
Nipple	12	11	
Schirmer's	19.55 ± 3.53	17.3 ± 2.69	
TFBUT	13.47 ± 1.04	13.46 ± 1.06	0.97
Contrast sensitivity (baseline)	0.61 ± 0.21	0.68 ± 0.4	0.61

M:F, male–female; BSCVA, best spectacle corrected visual acuity; SimK, simulated keratometry; TFBUT, tear film breakup time

Table 2: Contrast sensitivity: Rose K2 vs Kerasoft IC contact lens

	Baseline (0)	*3 months (1)*	*6 months (2)*	*p value (0 vs 2)*
Rose K (*n* = 20)	0.68 ± 043	1.45 ± 0.14	1.48 ± 0.15	$p < 0.01$
Kerasoft (*n* = 20)	0.66 ± 0.21	1.32 ± 0.13	1.35 ± 0.14	$p < 0.01$
p value	0.61	0.001	0.002	

Table 3: Number of trial lenses: Rose K vs. Kerasoft contact lens group

	No. of trials
Rose K	3.6 ± 0.827
Kerasoft	2.15 ± 0.58
	$p < 0.001$

Discussion

The present study was a prospective, randomized, comparative, and interventional clinical trial undertaken to evaluate two commonly used CLs in keratoconus, namely, Rose K and Kerasoft CL. We tried to evaluate whether any statistically significant difference exists between these lenses in terms of visual outcome as well as the patient comfort as judged by the patients themselves using a questionnaire. Fatima et al.[9] in a retrospective study to assess the demographic profile of patients with keratoconus concluded that CLs are a good modality of treatment and can reduce the requirement for penetrating keratoplasty. Ozkurt et al.[10] and Hwang et al.[11] have reported that the logMAR visual acuity in the group using RGP was significantly better than in the control group. In another study on Rose K CL in keratoconus, Jain et al.[12] found that 36 (94.7%) of 38 eyes achieved a visual acuity of 20/40 or better. Betts et al.[13] in their study concluded that no difference was observed in the visual acuity improvement with the Rose K lenses compared with the patients' habitual lenses. In our study, all the patients were CL naive and visual acuity of >20/40 was achieved in 90% patient in Kerasoft group and 95% in Rose K group.

No significant change was observed in the corneal thickness in both groups over a follow-up period of 6 months. A long-term follow-up may be more useful in evaluating the effect of lens wear on the corneal thickness. Hwang et al.[11] in their study on the use of RGP lens in keratoconus also found that the thinnest corneal thickness in the lens wearing group decreased over a period of 22.6 months in all grades of keratoconus but the change was not significant. In both the groups, a significant improvement was observed in the comfort score at 6-month follow-up visit ($p < 0.001$ for each group) as compared to the baseline visit. Erdurmus et al.[14] assessed the impact of the different types of CLs on QoL in patients with keratoconus based on self-reported results from the CLIQ questionnaire. They found a similar CL impact on the QoL in subjects with keratoconus who wore RGP, hybrid, or soft toric CLs. In another study by Yildiz et al.,[15] CL impact on QoL in keratoconus patients was studied and the RGP lenses were compared to soft silicone hydrogel lenses, and they did not find any statistically significant difference in the comfort score between the two lenses. In our study, the patients using Kerasoft IC were more comfortable compared to those using Rose K lenses. Contrast sensitivity was recorded on Pelli-Robson contrast sensitivity chart,[7] and we found that both the CLs were associated with a significant improvement at 6 months follow-up in comparison to the baseline value without lenses. The present study suggests that Rose K lenses provide better contrast sensitivity in comparison to Kerasoft lens. The number of trial lenses required before finalizing the fit was recorded for each lens type. Less chair time was required in fitting the Kerasoft as compared to Rose K. Rose K lenses were initially claimed to have 80–90% first-fit success rate.[4] However, further clinical studies did not substantiate the high first-fit success rate.[10,13] The number of trial lenses required before finalizing the fit was recorded for each lens type. The mean number of trial lenses required to finalize Rose K lens parameters (3.6 ± 0.32) was significantly more than the Kerasoft IC lens group (2.15 ± 0.58) ($p < 0.001$). Thus, less chair time was required in fitting the Kerasoft IC as compared to Rose K. According to Jain et al.,[12] Rose K lenses were initially claimed to have 80–90% first-fit success rate. However, other clinical studies did not substantiate that high first-fit success rate.[4,5] Fernandez-Velazquez et al.[5] evaluated the number of trials required in fitting Rose K and Kerasoft IC and found an average of three diagnostic lens fit was required per eye before the final prescription could be made. Edge modification is a unique feature of Rose K lens. Peripheral fit affects the comfort much more than the central fit. In our study, we did not need to use the edge modification in any eye in Rose K group. This edge modification is not an option in Kerasoft CL. Gupta et al.[16] did a prospective comparative study between Rose K and Soper (RGP) lenses. They concluded that Rose K CL was significantly better than Soper in terms of the ease of fitting, patient comfort, contrast sensitivity, and the number of trials required.

Limitations of our study include small sample size and short follow-up. Future studies with larger sample size and longer follow-up may help in understanding the behavior and success rate of both lenses.

In our study, we could successfully fit both Rose K and Kerasoft lens in all the eyes of keratoconus enrolled for the study. In most of the prospective studies done in the past, the success rate in the fitting of CL for keratoconus was less than 100%.[6–8,17] In our study, even the severe cases achieved good visual acuity and comfortable fit. To conclude, both the lenses provide comparable visual acuity gain in keratoconus. Kerasoft is associated with better patient comfort, whereas Rose K provides better contrast sensitivity. Hence, Kerasoft lenses may be a good alternative to Rose K lenses, even in severe keratoconus cases and in eyes not tolerating Rose K lenses.

References

1. Zadnik K, Barr JT, Gordon MO, et al. Biomicroscopic signs and disease severity in keratoconus. Cornea 1996;15(2):139–146. DOI: 10.1097/00003226-199603000-00006.
2. Krachmer JH, Feder RS, Belin MW. Keratoconus and related noninflammatory corneal thinning disorders. Surv Ophthalmol 1984;28(4):293–322. DOI: 10.1016/0039-6257(84)90094-8.
3. Rabinowitz YS. Keratoconus. Surv Ophthalmol 1998;42(4):297–319. DOI: 10.1016/s0039-6257(97)00119-7.
4. Rabinowitz YS, Garbus JJ, Garbus C, et al. Contact lens selection for keratoconus using a computer assisted videophotokeratoscope. CLAO J 1991;17(2):88–93.
5. Fernandez-Velazquez FJ. Kerasoft IC compared to Rose-K in management of corneal ectasias. Contact Lens Anterior Eye 2012;35(4):175–179. DOI: 10.1016/j.clae.2012.02.005.
6. Gonzallez-Meijome JM, Jorge J, de Ameida JB, et al. Soft contact lens for keratoconus: case report. Eye Contact Lens 2006;32(3):143–147. DOI: 10.1097/01.icl.0000179707.85290.f4.
7. Pelli DG, Robson JG, Wilkins AJ. The design of a new letter chart for measuring contrast sensitivity. Clin Vision Sci 1988;2:187–199.
8. Pesudovs K, Garamendi E, Elliot DB. The contact lens impact on quality of life (CLIQ) questionnaire: development and validation. Invest Ophthalmol Vis Sci 2006;47(7):2789–2796. DOI: 10.1167/iovs.05-0933.
9. Fatima T, Acharya MC, Mathur U, et al. Demographic profile and visual rehabilitation of patients with keratoconus attending contact lens clinic at a tertiary eye care centre. Contact Lens Anterior Eye 2010;33(1):19–22. DOI: 10.1016/j.clae.2009.09.004.
10. Ozkurt YB, Sengor T, Kurna S, et al. Rose K contact lens fitting for keratoconus. Int Ophthalmol 2008;28(6):395–398. DOI: 10.1007/s10792-007-9156-4.
11. Hwang JS, Lee JH, Wee WR, et al. Effects of multicurve RGP contact lens use on topographic changes in keratoconus. Korean J Ophthalmol 2010;24(4):201–206. DOI: 10.3341/kjo.2010.24.4.201.
12. Jain AK, Sukhija J. Rose-K contact lens for keratoconus. Indian J Ophthalmol 2007;55(2):121–125. DOI: 10.4103/0301-4738.30706.
13. Betts AM, Mitchell GL, Zadnik K. Visual performance and comfort with the Rose K lens for keratoconus. Optom Vis Sci 2002;79(8):493–501. DOI: 10.1097/00006324-200208000-00011.

14. Erdurmus M, Yildiz EH, Abdalla YF, et al. Contact lens related quality of life in patient with keratoconus. Eye and Contact Lens 2009;35(3):123–127. DOI: 10.1097/ICL.0b013e31819d1dd0.
15. Yildiz HE, Erdurmus M, Elibol ES, et al. Contact lens impact on quality of life in keratoconus patients: rigid gas permeable versus soft silicone hydrogel keratoconus lenses. Int J Ophthalmol 2015;8(5):1074–1077. DOI: 10.3980/j.issn.2222-3959.2015.05.38.
16. Gupta R, Sinha R, Singh P, et al. Rose K versus soper contact lens in keratoconus: arandomized comparative trial. Middle East Afr J Ophthalmol 2014;21(1):50–55. DOI: 10.4103/0974-9233.124095.
17. Sudharman PM, Rathi V, Dumapati S, et al. Lenses for keratoconus- an Indian experience. Eye Contact Lens 2010;4(4):220–222. DOI: 10.1097/ICL.0b013e3181e5cd0b.