

Contact lens impact on quality of life in keratoconus patients: rigid gas permeable versus soft silicone–hydrogel keratoconus lenses

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Abstract

• **AIM:** To determine the impact of rigid gas permeable (RGP) and silicone–hydrogel keratoconus lenses on the quality of life (QoL) in keratoconus (KCN) patients using the self–reported results from the Contact Lens Impact on Quality of Life (CLIQ) Questionnaire.

• **METHODS:** From January 2013 to April 2013, 27 consecutive KCN patients who wore RGP contact lenses (conflexair100 UV KE Zeiss –Wöhlk) or soft silicone –hydrogel contact lenses (SHCLs) for KCN (KeraSoft IC–Bausch&Lomb or Hydrocone Toris K –Swiss lens) completed the CLIQ questionnaire.

• **RESULTS:** The mean age of 27 patients was 29.6±8.0y. Fifteen patients were RGP user. The groups were comparable with respect to the mean patient age, sex, and mean K values ($P=0.1$, $P=0.8$ and $P=0.1$, respectively). The mean CLIQperson measure was 42.8±5.5 in RGP group and 39.6±5.5 in SHCLs for KCN group ($P=0.06$). CLIQperson measure was positively correlated with steep K value ($r=0.301$, $P=0.04$). When eyes were stratified by visual acuity with contact lenses, the mean CLIQperson measure was 42.01±5.6 in eyes with a visual acuity of 20/20–20/25 ($n=44$) and 38.4±5.26 in eyes with a visual acuity of 20/32 or less ($n=10$; $P=0.097$).

• **CONCLUSION:** RGP lenses and SHCLs for KCN have similar impact on QoL.

• **KEYWORDS:** silicone hydrogel; contact lens; rigid gas permeable; quality of life; keratoconus

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INTRODUCTION

Keratoconus (KCN) is a progressive, asymmetric, noninflammatory condition of the cornea associated with corneal steepening and apical thinning that leads to a decrease in vision secondary to progressive irregular astigmatism^[1]. In very early cases, spectacles or soft lenses with toric designs are adequate to correct myopia and regular astigmatism. As the disease progresses, rigid gas permeable (RGP) contact lenses (CLs) become the primary method of nonsurgical visual rehabilitation, providing good vision by forming a new, regular and smooth optical surface^[2]. A hybrid lens, which has a rigid central portion for obtaining best optics and a soft hydrophilic peripheral skirt to enhance comfort is an alternative to RGP lenses in KCN patients^[3]. Recently, new custom lathed soft silicone–hydrogel CLs (SHCLs) for KCN have been developed. In HydroCone (toris K–Swiss lens), spherical back optic zone with strong aspheric flattening and front toric optic zone are dynamically stabilized by nasal and temporal bumps. In KeraSoft® IC (Bausch&Lomb Incorporated), the periphery of lens can be manipulated independently of the base curve with two different geometries: full periphery and sector management control, which is a quadrantic-specific design that can be individually customized of the periphery, making it able to conform to the shape of any cornea. The soft SHCLs for KCN have been shown to be a good alternative for the optical management of irregular corneal astigmatism^[4].

The increased attention for quality of life (QoL) as an outcome measure has led to the development of numerous questionnaires to assess this construct in the field of ophthalmology. The Contact Lens Impact on Quality of Life (CLIQ) Questionnaire was developed by Pesudovs *et al*^[5] and targeted adults needing refractive correction who did not have other ophthalmic problems. Its reliability and validity has been also established for CL wearers without any ocular disorders. The CLIQ 28-item questionnaire includes not only visual function and limitations in daily activities related to impaired visual function, but also the impact of CLs on patients' lives from various stand points^[5]. The questionnaire

is available online at <http://www.iovs.org/content/suppl/2006/06/22/47.7.2789.DC1>.

The purpose of this current study is to compare the CLIQ based on self-reported results from CLIQ questionnaire in KCN patients who wear standard design RGP lenses and soft SHCLs for KCN.

SUBJECTS AND METHODS

Patient Recruitment and Evaluation The study was approved by the ethical committee and was in compliance with the Declaration of Helsinki. The patients wearing RGP or SHCLs for KCN were enrolled over 4mo, between January 1, 2013 and April 30, 2013, when they came for routine follow-up visit and were asked to fill out the CLIQ 28-item questionnaire. The diagnosis of KCN was based on patient history of impaired vision in one or both eyes (history of multiple inadequate spectacle corrections of one or both eyes) caused by progressive myopia and astigmatism and the findings of slit-lamp examination of corneal thinning and protrusion, typically inferiorly or centrally, with or without striae in the posterior stroma (Vogt striae), and iron pigment deposition in the epithelium (Fleisher ring). Diagnosis was confirmed by the evidence of unilateral or bilateral abnormal corneal steepening by elevation-based Scheimpflug imaging system. We excluded patients with a history of previous ocular surgery including penetrating keratoplasty, a history of other corneal disease including CL related corneal infections, dry eye and corneal opacities, patients with a duration of follow-up less than 3mo with the current CLs. After the questionnaire was completed, the information including patient's age, sex, CL type used, duration of follow-up with the latest prescribed CL, Snellen visual acuity with the CL, and steep and flat keratometric readings were also obtained at the same visit.

Contact Lens Types and the Fitting Procedures The Collaborative Longitudinal Evaluation of Keratoconus (CLEK) study group's criteria was used to grade the severity of KCN using the topographical data, where steep keratometric measurements <45 D were graded as "mild" KCN, values between 45-52 D were graded as "moderate" KCN and readings >52 D were classed as "severe" KCN. Lenses wearing by the study patients were divided into two categories: RGP-standard design (conflex air 100 UV KE Zeiss-Wöhlk), and SHCLs [KeraSoft IC (Bausch&Lomb) or HydroCone-Toris K (Swiss lens)].

In standard RGP CL group, the base curve of the initial trial lens was selected based on the average keratometric values on the corneal topography map. After adaptation period of 20min, the dynamic and static fit was evaluated by the examiner. The aim was to achieve a well centered lens that exhibit adequate movement with a blink and provide a fluorescein pattern of apical touch and adequate edge clearance in the periphery.

In SHCLs for KCN group, the initial HydroCone-Toris K lens with a base curve of 8.9 and a diameter of 14.00 (namely toris K12) was chosen in grade 1-2 KCN, while the initial lens with a base-curve of 7.8 and a diameter of 13.7 (namely toris K 34) was chosen in grade 3-4 KCN. Changes in the base-curve and diameter were made according to the movement of the CL *in situ*. When appropriate fit and movement was achieved we waited at least 30min for the over refraction. The initial Kerasoft IC lens was chosen based on the geometry of the cornea to be fitted. Successful fitting of the Kerasoft IC lens was assessed by observing the characteristics of the lens behavior on eye using the acronym MoRoCCoVa which represents movement, rotation, centration and comfort, all of which when optimal, give the best visual acuity. Optimal lens fit characteristics are up to 3 mm post blink lens movement on straight-ahead gaze, the vertical lens mark, the central and comfortable lens and the steady vision. Once it is achieved, the over-refraction was performed.

The 28-item Contact Lens Impact on Quality of Life Questionnaire The CLIQ questionnaire consists of 28 items. Each item has five different choices. Question 1 to 20 are related with CL impact on daily activities, eye symptoms, functional vision, and other psychometric properties. Questions 21 to 28 are related with feeling of well-being in relation to the subject's CL refractive correction. Available at: <http://iovs.arvojournals.org/article.aspx?articleid=2124900>.

For the evaluation of the 28-item CLIQ questionnaire, the analysis performed by following the recommendations of the developers. The items 1 to 20 (lower score is better) have polarity to give an overall 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 scores (2, 2, 3, 4, 5) to items 21 to 28. The average of these 28 items gives the CLIQ raw score. Following formula was used to convert the CLIQ raw score to the CLIQperson measure in 0 to 100 scale (higher score indicates better QoL)^[6].

$$\text{CLIQperson measure} = 34.41 \times \log (\text{CLIQ raw score} / 5 - \text{CLIQ raw score}) + 26.69$$

Statistical Analysis All data were entered into a spreadsheet and statistical analyses were performed with the Number Cruncher Statistical System (NCSS) 2007 (NCSS LLC, Kaysville, Utah, USA). Snellen visual acuity was converted to logMAR visual acuity for statistical analysis. Descriptive statistics were used to compare categorical data and the Student's *t*-test was used for continuous variables. The Mann-Whitney *U* test was used to compare non-parametric variables. The Pearson correlation coefficient was used to detect any correlation between the CLIQperson measure and the patients' characteristics. *P* values ≤ 0.05 were considered statistically significant.

RESULTS

A total of 27 KCN patients with a mean age of 29.6±8.0y (range, 18-60y) were included in the study. Fifteen patients (30 eyes) were using the RGP lenses whereas 12 patients (24 eyes) were using the SHCLs for KCN. Demographics and clinical characteristics of the study patients are shown in Table 1. The groups were comparable with respect to the mean patient age, sex, and the mean steep K values ($P=0.1$, $P=0.8$ and $P=0.1$ respectively).

The mean steep K value was 52.3±5.3 D in the RGP group and 50.2±4.8 D in the SHCLs for KCN group. The mean±SD logMAR visual acuity with CLs was 0.06±0.05 in the RGP group and 0.1±0.1 in the SHCLs for KCN group. In the RGP group, 28 eyes (93.3%) had a visual acuity equal or better than 20/25 and 2 eyes (6.7%) had a visual acuity of 20/32 whereas in the SHCLs for KCN group, 16 eyes (66.7%) had a visual acuity equal or better than 20/25, 6 eyes (25%) had a visual acuity of 20/32 and 2 eyes (8.3%) had a visual acuity of 20/40. Although the RGP group had a better visual acuity with CLs compared to the SHCLs for KCN group, the result was not statistically significant ($P=0.165$).

The mean CLIQ raw score was 3.7±0.33 in the RGP group and 3.4±0.38 in the SHCLs for KCN group ($P=0.06$). The mean CLIQperson measure was 42.8±5.5 in the RGP group and 39.6±5.5 in the SHCLs for KCN group (Figure 1). Although the mean CLIQperson measure was slightly better in the RGP group, the result was not statistically significant ($P=0.062$).

When all eyes taken into account, the CLIQperson measure was 43.05±4.46 in eyes with a steep K value equal or higher than 52 D ($n=13$), and 40.51±6.1 in eyes with a steep K value less than 52 D ($n=41$) ($P=0.172$). The CLIQperson measure was positively correlated with the steep K value ($r=0.301$, $P=0.04$). When eyes were stratified by visual acuity, the mean CLIQperson measure was 42.01±5.6 in eyes with a visual acuity of 20/20-20/25 ($n=44$) and 38.4±5.26 in eyes with a visual acuity of 20/32 or less ($n=10$) ($P=0.097$).

DISCUSSION

In the current study, although the mean CLIQperson measure was slightly better in the RGP group, statistically similar impact on QoL was found in both groups. The optical performance of SHCLs for KCN has been previously compared to that of RGP lenses. They reported that both lenses provide similar levels of visual acuity [4]. In the current study, we also found statistically similar levels of visual acuity in both groups, however 93.3% of the patients (28/30) wearing RGP had a visual acuity equal or better than 20/25 whereas 66.7% of SHCLs for KCN patients (16/24) had a visual acuity equal or better than 20/25.

The impact of the different types of CLs (RGP, hybrid lenses or soft toric lenses) on QoL in patients with KCN has been reported using self-reported results from the CLIQ questionnaire[7]. Similar CL impact on QoL has been reported in patients with KCN who wear RGP, hybrid lenses, or soft

Table 1 Demographics and clinical characteristics of the study patients

Variables	RGP	SHCLs for KCN	<i>P</i>
Gender			0.8
F	6 (40)	4 (33.3)	
M	9 (60)	8 (66.7)	
Age ($\bar{x} \pm s$)	27.7±6	31.7±11	0.1
Steep K reading (eye)	<i>n</i> =30	<i>n</i> =24	0.1
$\bar{x} \pm s$	52.3±5.3	50.2±4.8	
<45	2 (6.7)	6 (25)	
45-52	20 (66.7)	13 (54.1)	
≥52	8 (26.7)	5 (20.8)	
Visual acuity with CLs			
20/20-20/25	28 (93.3)	16 (66.7)	
20/32	2 (6.7)	6 (25)	
20/40		2 (8.3)	
logMAR ($\bar{x} \pm s$)	0.06±0.05	0.1±0.1	0.165

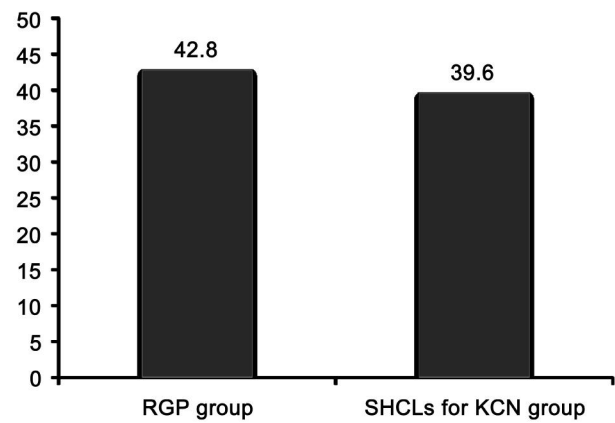


Figure 1 CLIQperson measure scores in both groups.

toric lenses with the mean CLIQperson measure of 45.5±8.2, 45.4±7.5 and 48.4±10.5, respectively. In the current study, the CLIQperson measure was 42.8±5.5 in the RGP group and 39.6±5.5 in the SHCLs for KCN group, slightly less than the CLIQperson measures previously reported. Another interesting finding of the current study was that better CLIQperson measure (43.05±4.46) has been found in eyes with a steep K value equal or higher than 52 D compared to that in eyes with a steep K value less than 52 D (CLIQperson measure of 40.51±6.1). These results may be interpreted that the positive impact of CLs on QoL increases as the disease progresses because of the worse vision without CLs or that adaptation of the KCN patients to their disease over time results in the reduced anxiety. Supporting these postulations, better CLIQperson measure scores reported from the previous study may be because that 52.1% of the eyes included in the study had a steep K value higher than 52 D compared to 24.0% of eyes in the current study.

Until the 1980s, visual acuity was the only outcome of interest in ophthalmology. Since then, many clinicians have come to the conclusion that measures such as visual acuity may not capture all important aspects of vision function from a patient's perspective [8]. The impact of KCN on the

vision-related QoL of persons affected with this disease has been investigated by CLEK study group^[9-11]. Although 77.9% of the study patients had a best corrected visual acuity of 20/40 or better in both eyes, significant impairment in vision-related QoL, with an average score comparable to the category 3 and category 4 age-related macula degeneration, has been shown by the CLEK study group^[10]. CL usage in patients with KCN improves visual acuity and most probably QoL^[12,13]. In the CLEK study, it has been reported that 73% of patients who wore RGP lenses at baseline had significantly higher vision-related QoL scores than noncontact lens wearer KCN patients and significantly lower scores than a reference group of RGP wearers without KCN. However, they also reported significantly lower scores for ocular pain among CL wearers, indicating that CL wearers report worse ocular discomfort^[10].

Even with the variety of design currently available, RGP lenses are often difficult to fit for corneas with KCN. Patients sometimes experience discomfort perhaps due to increased lid sensitivity, which may lead to RGP intolerance^[14,15]. New CL materials such as silicone hydrogels as well as new technologies for lathing CLs such as quadrant specific design are believed to improve comfort for CL wearers. Interestingly, in our study, CL related QoL was similar in both group. It is thought that, besides the lens comfort, visual performance of the lenses has an important impact on CL related QoL. Visual performance and ocular aberrations in KCN patients using soft toric CL and RGP have been compared previously. It was reported that RGP lenses provide superior visual performance and greater reduction of 3rd order aberrations compared to soft toric CLs in KCN patients^[16]. RGP lenses can mask most of the corneal aberrations, induced by KCN by replacing the irregular, keratoconic corneal surface with a regular refractive surface of the RGP lenses and a liquid tear-lens^[17-19]. However, compared with normal eyes, the visual performance in a keratoconic eye with a RGP CLs degrades, even if the corrected visual acuity is good. The degradation can be related to residual corneal aberrations in a keratoconic eye with a RGP CL^[20]. To improve the quality of vision in keratoconic eyes, reducing the higher order aberrations is important; custom CLs can be a solution^[21]. Further studies with a larger sample are needed to detect real differences of QoL in KCN patients who wear different type of CLs. Besides this, in an attempt to better describe the optical performance of CLs and its impact on CL-related QoL in KCN, other tests such as low contrast visual acuity, contrast sensitivity and higher order aberrations can also help.

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