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CORNEA

Evaluation of rigid gas permeable lens fitting in keratoconic patients with optical coherence tomography

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Abstract
Purpose To assess fitting of rigid gas permeable (RGP) lenses in patients with keratoconus, using spectral domain optical coherence tomography (SD-OCT).
Methods The study was conducted on 30 eyes of 30 keratoconic patients fitted with RGP lenses, namely Rose K2 lens. Biomicroscopic examination with and without RGP lens was done. Fluorescein pattern was examined to determine the fitting, if ideal (three-point light touch), steep (central fluorescein pooling) or flat (central heavy bearing touch). Post-lens tear film thickness was measured centrally and at the lens edges using SD-OCT. Patient's comfort was assessed and graded.
Results Mean central post-lens tear film thickness was 35.1±7.3 μ in patients with ideal fitting. Mean post-lens tear film thickness of 50.4±8.2 μ and 25.3±6.1 μ was noted in patients with steep and flat fitting, respectively. Mean post-lens tear film thickness of 102.5±12.1 μ, 85.4±11.4 μ, 135.6 ±13.3 μ was demonstrated in eyes with ideal, steep and flat edge lift, respectively. Tear film thickness under the edges was significantly (p=0.04) lower in patients unsatisfied with their contact lenses.
Conclusion SD-OCT can image and measure the tear film thickness in keratoconic patients with different fitting patterns of RGP lenses. OCT- guided fitting can be used to evaluate and modify the lens parameters to increase patient satisfaction. Lens intolerance may be related to edge lift rather than central fitting.

Keywords Cornea · Keratoconus · Optical coherence tomography · Rigid · Tear film

Introduction

The rigid gas permeable (RGP) lens used in keratoconic patients has unique fitting characters; namely, three points touch, with light touch of the lens at the corneal apex (to minimize apical breakdown), intermediate clearance, and a band of touch at the junction of the optical zone and the secondary curve. Edge lift, which is the relationship between the lens edge and the corneal surface, is another important factor sharing in the success of contact lens fitting and determining patient comfort and maximum wearing time [1].

The Rose K Lens for keratoconus is a proprietary design that has gained popularity since its introduction in the United States in 1995. The reported benefits of this lens are that it is simple for novice practitioners to fit and that it offers better visual acuity. Rose K2 is a unique design of RGP lens in which edge lift can be ordered in a variable parameter independently from the central base curve (standard, decreased or increased edge lift). The presence of flexible parameters that can be modified to achieve the best central and peripheral fit increase patient comfort compared with other designs for keratoconus [2].

Post-lens tear film thickness and the relationship between the lens edge and ocular surface may result in different levels of ocular comfort. If the post-lens tear film is diminished, as in tight lens fitting or contact lens related dry eye, the accumulation of debris and inflammatory mediators may pose a significant threat to the ocular surface, involving ocular infection, inflammation, or mechanical desiccation, which is considered as one of the most common causes of lens discontinuation [1, 3, 4].

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Slit lamp biomicroscopy may not be enough to precisely evaluate contact lens fitting, lens centration, movement and coverage [5]. Recent studies proved high repeatability and reproducibility of anterior ocular biometric measurements with 2-dimensional and 3-dimensional optical coherence tomography [6, 7].

Anterior segment optical coherence tomography (OCT) provides high-resolution, and cross-sectional images of corneal structures with possible measurement of pre-lens and post-lens tear film thickness [8].

The purpose of this study is to assess the fitting of RGP lens in patients with keratoconus by measuring the post lens-tear film thickness centrally and at the edges, using spectral-domain optical coherence tomography (SD-OCT).

Subjects and methods

The study was conducted on 30 eyes of 30 keratoconic patients fitted with special design of RGP lenses, namely Rose K2 lens (David Thomas, UK). They were fitted with 8.7 mm diameter lenses, base curve ranged from 5.4 to 7.2 mm and with variable edge lift (standard, increased or decreased).

According to specific manufactures fitting guidelines [9], optimum edge lift produces a fluorescein ring under the edge 0.5–0.7 mm wide. Standard lift will fit most of Rose K lens fittings. If, however, edge lift is inadequate, increased edge lift must be used .If edge lift is excessive, decreased lift should be ordered.

Any subject with systemic or ocular disease, or previous history of dry eye, were excluded from the study. A screening visit was scheduled after 10 AM to ensure that corneal edema induced by night sleeping had dissipated. Selected patients were instructed to wear their RGP lenses at least 4 weeks before the examination. After 4 weeks, lens-fitting relationships have been stabilized, because RGP lens wear has been shown to induce corneal topographic changes in patients with keratoconus (which influences the examiner's interpretation of the lens fit) [10, 11]. The study procedure was explained to all participants. Informed consent was obtained from each subject after approval was obtained from the ethical committee, University of Mansoura.

A Biomicroscopic examination with and without RGP lens was done to determine the health of the cornea and fitting parameters such as lens movement and lens centration. Fluorescein pattern was examined to determine the lens fitting. Accordingly, they were classified into three groups; the first group with ideal fitting (three points light touch) (Fig. 1a), the second group with steep fitting (central fluorescein pooling) (Fig. 1b), and the third group with flat fitting (central heavy bearing touch) (Fig. 1c).

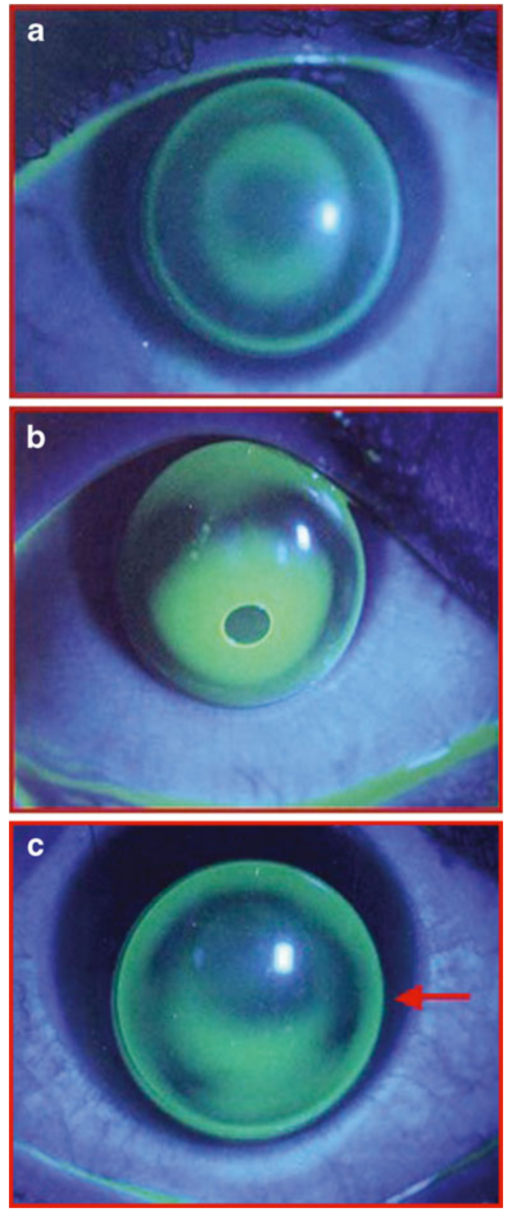

Fig. 1 Rose-K2 lens fitting patterns in eyes with keratoconus. **a** Ideal central fitting and ideal edge lift; **b** Steep central fitting (central fluorescein pooling) with tight edge lift; **c** Flat central fitting and increased width of fluorescein ring (*arrow*), indicating loose edge lift

Moreover, the post-lens tear film underneath the lens edge was evaluated in each patient, and accordingly they were classified into three groups: ideal edge lift, steep edge lift and flat edge lift.

All studied patients have been imaged by one ophthalmologist having no information about their contact lens fitting. All subjects were examined with SD-OCT (3D-OCT2000, Topcon corp, Tokyo, Japan), originally designed for posterior segment examination with adaptor to allow for anterior segment examination. Topcon OCT measurements have been shown to be highly repeatable [12]. This system has approximately 5 μ axial resolution, 20 μ horizontal resolution and acquires 18,700 axial scan per second. The adaptor is attached to the headrest, thus increasing the working distance slightly. Subjects were asked to rest their chin on the chin-rest of the OCT. Then, they were instructed to fixate on a central target and to blink every 6 s. Uniform blink interval was used, because variations in the blink interval during consecutive measurements would make statistical analysis difficult. Measurement was done manually, using computer-controlled caliper incorporated in the software analysis. Measurements were taken directly perpendicular to the central part of the corneal and contact lens surfaces, between the posterior surface of lens and the anterior surface of the cornea. The same measurement was taken at the edge of the lens. Measurements were performed three times for each subject and each subject was given at least a 10-minutes rest between measurement sessions.

Patient's comfort has been also assessed and the studied patients were classified into three grades. Grade 1 included patients who were satisfied and not complaining about their comfortable lenses, with maximum wearing time 8 h or more per day. Grade 2 included patients with mild to moderate lens awareness, tearing upon lens insertion, blinking, and slight redness. The patients in this group could continually wear lenses for at least 4 h without or with minor complaint. Grade 3 included patients unable to wear lenses for more than 4 h/day, due to severe irritation and redness on wearing the lenses. Those patients were not satisfied and markedly complained about the lenses.

Data analysis

Repeated-measurements analysis of variance Kruskal-Wallis was performed to determine whether there were differences in the tear film thickness among the different patients groups. Data were presented as mean±SD for all the variables at each time point. $P<0.05$ was considered significant (all analyses: SPSS ver. 13.0; SPSS Inc., Chicago, IL).

Results

Thirty eyes of 30 keratoconic patients (16 females and 14 males) were included in the study. Mean age was 24±4 years.

Cross-sectional images of the central cornea and contact lens were obtained. Post-lens tear film between the posterior surface of contact lens and the central part of the cornea was clearly visualized. Similarly, the tear film between the lens edge and anterior surface of the cornea was shown.

According to fluorescein pattern at the center of the lens, 17 eyes showed ideal fitting, five eyes showed steep fitting and eight eyes showed flat fitting.

Optical coherence tomography measurements (Fig. 2a, b, c) could differentiate between the three fitting patterns. Mean central post-lens tear film thickness was 35.1±7.3 μ in patients with ideal central feathery touch with fluorescein. On the other hand, post- lens tear film thickness of 50.4±8.2 μ and 25.3±6.1 μ was noted in patients with steep

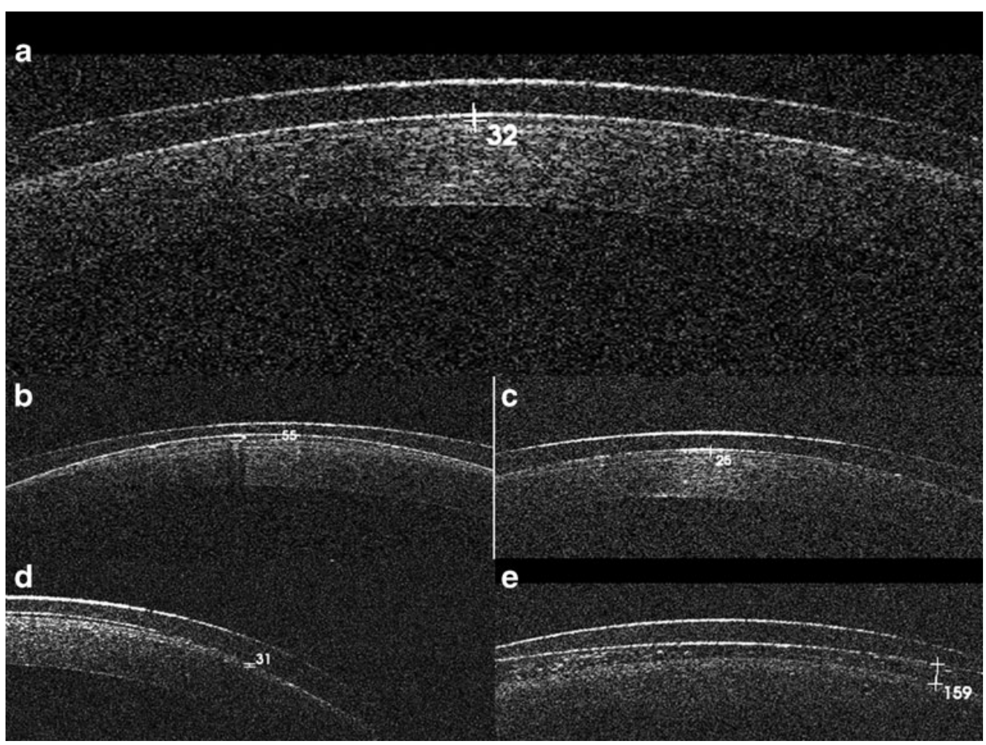

Fig. 2 Post-lens tear film thickness in keratoconic eyes with different Rose-K2 lens fitting patterns using spectral-domain optical coherence tomography (SD-OCT). **a** Central post-lens tear film thickness in an eye with ideal fitting; **b** Central post-lens tear film thickness in an eye with steep fitting; **c** Central post-lens tear film thickness in an eye with flat fitting; **d** Peripheral post-lens tear film thickness in an eye with steep edge lift; **e** Peripheral post-lens tear film thickness in an eye with flat edge lift

Table 1 Post- lens tear film thickness measured by spectral domain optical coherence tomography (SD-OCT) in keratoconic patients with different fitting types of Rose-K2 lenses

Fitting	OCT			P
Central (mean±SD)	**Ideal (*N*=17)**	**Steep (*N*=5)**	**Flat (*N*=8)**	0.02
	35.1±7.3 µ	50.4±8.2 µ	25.3±6.1 µ	
Edge Lift (mean±SD)	**Ideal (*N*=15)**	**Tight (*N*=4)**	**Flat (*N*=11)**	0.01
	102.5±12.1 µ	85.4±11.4 µ	135.6±13.3 µ	

Kruskal-Wallis

P is significant at < 0.0 5

and flat fitting, respectively. The difference was statistically significant (p=0.02) among the three studied groups (Table 1).

According to fluorescein pattern at the edge of the lens, ideal edge lift was detected in 15 eyes, steep edge lift was detected in four eyes and flat edge lift was detected in 11 eyes.

Optical coherence tomography measurements could differentiate between the three fitting patterns at the edge (Fig. 2d, e). The estimated tear film thickness in contact lenses with ideal edge lift was 102.5±12.1 µ. On the other hand, post-lens tear film thickness of 135.6±13.3 µ was demonstrated in loosely fitted lens with excessive movement, and a thickness of 85.4±11.4 µ was noted in tightly fitted lens with little movement. The difference was statistically significant (p=0.01) among the three studied groups (Table 1).

Central and peripheral post-lens tear film thickness were measured against different grades of patient satisfaction. No statistically significant difference was found in the central post-lens tear thickness between the three studied groups. The peripheral tear film thickness was significantly (p=0.04) lower in the third group of patients (Grade 3) who were unsatisfied with their contact lenses (Table 2).

Discussion

Although the Rose K lenses have been tested and fitted extensively worldwide and have shown excellent levels of visual acuity compared to other RGP designs [13], a recent study detected a larger number of biomicroscopic complications, mainly corneal staining with fluorescein, when compared to soft contact lens cohort [14].

The ideal fit of Rose K2 lenses in keratoconic patient, the “three-point touch,” is dependent mainly on the post-lens tear film, which is difficult to precisely assess with biomicroscopic examination [1]. Also, dryness and discomfort are two major reasons associated with premature contact lens discontinuation [15]. Therefore, measurement of this layer comes to be very important from the clinical point of view.

OCT has been used to measure corneal and epithelial thickness in a variety of studies, including those investigating diurnal variations and changes after contact lens wear, both centrally and topographically [16–19].

Based on the high-speed of the current OCT instrument, the post-lens tear film thickness was successfully measured under the central part and under the edges as well.

OCT measurements both centrally (ideal: 35.1 µ; steep: 50.4 µ; flat: 25.3 µ) and under the edge (ideal: 102.5 µ; steep: 85.4 µ; flat: 135.6 µ) could differentiate between the three fitting patterns in keratoconic eyes. To the best of our knowledge, this is the first time OCT has been used for directly measuring the post-lens tear film thickness in keratoconic patients fitted with special design RGP lens (Rose K2), without the aid of artificial tears to evaluate precisely different types of fitting patterns, either in the central fit or the variable edge lift in such eyes.

Pre-lens and post-lens tear film thickness have been measured with different methods, mainly in soft contact lens wearers [20]. True thickness of the post–lens tear film remains controversial, with widely different published results using different techniques such as optical pachymetry (11.5 µ) [21] , confocal microscopy (41–46 µ) [22] , and interferometry (2.34 µ) (34–45 µ) [23, 24]. The reason for these controversial results may be due to different sample sizes or difficulty of the measurement of tear film thickness. Different measurement techniques may

Table 2 Post-lens tear film thickness measured by spectral domain optical coherence tomography (SD-OCT) in keratoconic patients fitted with Rose-K2 lenses according to their grade of satisfaction

OCT	COMFORT			P
	G1(15)	G2 (10)	G3 (5)	
Central (mean± SD)	39.6±9.2 µ	36.4±8.3 µ	35.5±12.1 µ	0.3
Peripheral (mean± SD)	122.3±18.4 µ	118.5±16.3 µ	86.3±11.2 µ	0.04

Kruskal-Wallis

P is significant at < 0.0 5

G1 grade 1

G2 grade 2

G3 grade 3

be another factor; for example, pachymetry measurements which may include the mucin layer whereas OCT probably does not.

Wang et al. measured post-lens tear film thickness in 40 non-contact lens wearers using an older version of OCT (Carl Zeiss Meditec, Dublin, CA) and two different types of soft lenses. The reported measurements were much thinner than in the present study (4.5–4.7 μ) [25]. Similar results were recorded by Chen et al. [8], using ultrahigh resolution OCT for measuring pre-lens and post-lens tear film thickness under soft contact lenses.

One possible explanation for the reported lower result is that the thickness was measured indirectly as the distance between each two peaks of reflectivity, which were converted to micrometers by the factor 1.13. Also, the central 50 axial scans (0.30-mm width) were removed to avoid the disturbance of the central specular hyper-reflective reflex of each image. So, the central axial scans were not included in the measurement. In the current study, we measured the thickness directly from cross-sectional images of the cornea in fully adapted eyes with their RGP lenses, and measurements were limited to the central points of the scan.

Different lens nature (soft versus hard), base curves (steeper versus flatter) and designs may contribute to the variable outcome results. Wang et al. [5], using ultrahigh resolution OCT, recorded different thickness of post- lens tear film under the lens edge (8 μ, 59 μ) with different types of soft lenses (Purevision and Acuvue) and base curves (8.6 mm and 8.3), respectively. The difference was also remarkable for central tear film thickness (32 μ) and under the edge (125 μ) of RGP lenses. It is noticeable that values obtained in the ideal fit pattern in the present study are close to that obtained by Wang et al. [5] in eyes fitted with RGP lenses. Different edge lift fit in Rose K2 lens could also contribute to different results from the conventional RGP lens with standard edge lift.

In the current study, the relationship between the post-lens tear film thickness measured by the OCT and patient satisfaction was studied. A significant decrease in the tear thickness under the edge of the fitted lens was demonstrated in the third group (unsatisfied patients), which indicates that the lens intolerance and discomfort may be related to the edge lift rather than the central fitting. This goes hand in hand with the clinical experience that demonstrates patient discomfort and irritation with tight lens edge [26, 27].

The limitations of this study include the small number of patients. This is a small-scale study conducted on a convenient purposive sample. So, the results of this study are preliminary and cannot be generalized to larger populations. Also, the low prevalence of steep and flat fitting patterns in our sample was mandatory, since all patients were already fitted according to subjective fluorescein pattern to get the ideal fitting. Those eyes (with steep or flat fitting) could not be obtained except through already fitted cases. A large scale multicenter study with large sample size is recommended.

In summary, SD-OCT is considered a non-invasive promising tool to image and precisely measure the tear film thickness in keratoconic patients having different fitting patterns with RGP lenses. Such data can help practitioners to evaluate and modify the lens parameters to increase patient comfort and satisfaction. Examining the configuration of the lens edge and its interaction with the ocular surface may lead to a better understanding of lens designs and tightness of lens fitting that determine the rate of tear exchange underneath the lens. Advancement of lens manufacture will refine and extend the ability to study contact lens tear dynamics and fitting characterization.

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Conflict of interest The authors declare that they have no conflict of interest.

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