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Kerasoft IC compared to Rose-K in the management of corneal ectasias

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ABSTRACT

Purpose: To determine the efficacy of the KeraSoft® IC (KIC) (Ultravision International Limited, Bedfordshire, UK), a silicone hydrogel contact lens, for the optical management of non-surgical corneal ectasias and to compare it with the Rose-K 2 RGP contact lens.
Methods: In a retrospective study ninety-four eyes fitted with KIC (group A) were compared with seventy-seven eyes fitted with Rose-K® RGP lenses as a control group. Ocular diagnoses, corneal curvature by topography, refraction, best spectacle-corrected visual acuity (BSCVA), and age at time of fitting were noted. Outcome data included average daily wearing time, contact lens complications, visual acuity with the lens (BCLCVA), power of the lenses and length of follow-up.
Results: Differences in either BCLCVA or wearing time could not be statistically established ($p = 0.63$, $p = 0.15$) between both groups. More biomicroscopic complications were found in the RGP group, basically corneal staining ($P < 0.0001$). In the KIC group, BCLCVA was statistically similar between types of ectasia ($p = 0.19$) as well as in mild and moderate keratoconus ($p = 0.45$).
Conclusions: KIC is a good alternative for the optical management of irregular corneal astigmatism in non surgical corneal ectasias such as keratoconus and pellucid marginal degeneration.

1. Introduction

Rigid gas permeable (RGP) contact lenses are considered the primary visual correction tool for clinical keratoconus (KCN) as they provide good vision by forming a new, regular and smooth optical surface [1]. Recently, a new surgical approach has also been proposed [2–4], which, by means of implanting intracorneal rings (ICR), alters the shape of the cornea with the purpose of improving both spectacle corrected and unaided visual acuity (VA). Furthermore, it has been proposed [3] that those keratoconic patients who are RGP intolerant would be excellent candidates for this surgery because an adequate level of VA cannot be achieved with spectacles. It has also been additionally reported [5,6] that ICR implantation could have an impact on RGP wear because of its corneal curvature flattening effect, and this could be especially positive in corneas with keratometry values steeper than 55.00 D [7], the ones that are considered the most difficult cases. Unfortunately, clinical experience would suggest that these modifications in the corneal profile may enormously complicate the fitting procedure [8,9] particularly when RGP lenses are prescribed.

Recent years have provided great improvements in several fields related to specialty contact lenses. New materials, such as high dK RGP materials and silicone hydrogels, as well as new technologies for lathing contact lenses such as quadrantic specific designs as well as custom hydrogel contact lens for the correction of high-order aberrations in certain cases of KCN have been introduced [10].

Recently a new contact lens has been developed called KeraSoft® IC (Ultravision International Limited, Bedfordshire, UK) (KIC). This is a custom-lathed soft silicone hydrogel lens with quadrant-specific design capability, the main features are shown in Table 1. The design allows for the customised selection of the central and peripheral regions in order to properly fit both corneal regions. The periphery of the lens can be alternatively tailored with two different geometries: Full periphery (FP) and sector management control (SMC), which is a quadrantic-specific design that can be individually customised to allow steeper and flatter sectors in the periphery.

We performed a retrospective analysis of data derived from patients seen in our office in order to compare the clinical outcome of this new contact lens design and results to those achieved using Rose-K 2® RGP lenses (Menicon Co. Ltd., Nagoya, Japan). In addition, we also provide more in-depth information related to the clinical performance of this novel design.

2. Materials and methods

2.1. Patient recruitment and evaluation

This study comprised 104 consecutive patients (171 eyes) with non-surgical corneal ectasias in whom either KIC or Rose-K 2

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Table 1
Available parameters of Kerasoft IC.

Overall diameter	Central curvature	Periphery Options	Regimen	Modulus (mPa)	Material
14.00–15.50 mm (0.50 steps)	7.40–9.40 mm (0.20 steps)	– Steep 1–4 – Standard. – Flat 1– 4	3-month/daily wear	0.38	Efrofilcon-A

contact lenses had been fitted, and followed for a minimum of 6 months. To qualify for enrolment in the study the patient could not have a previous history of corneal refractive surgery, cataracts, amblyopia, strabismus or the presence of any disease limiting visual acuity that could negatively impact clinical outcome. Both groups included eyes with nipple or centred cones, oval cones and pellucid corneal marginal degeneration (PMD) based on topographic information. PMD was classified by its characteristic butterfly pattern with against-the-rule astigmatism as reported in previous papers [11].

The following parameters were measured prior to lens fitting in all patients: age at time of fitting, refraction with the best high contrast spectacle-corrected visual acuity (BSCVA) and simulated keratometries (sim-K). Video-keratography was performed on all patients and the tangential radius of curvature maps was used to define the size and location of the cone using a 1.0 mm grid. Refractions were related to the vertex and converted to polar refractions. The best high contrast contact lens-corrected visual acuity (BCLCVA) was recorded at the time of dispensing. Slit lamp complications were recorded on the Mandell slit lamp grading system [12] and the average wearing time (which was calculated as the mean time for which lenses had been worn over the past three days) was assessed in the latest follow-up. Additionally the power of the lens adjusted to lens tilt was also recorded and converted to polar mode in the Kerasoft group. The study of contact lens wearers was approved by the Institutional Review Board and Informed Consents were signed prior the contact lens fittings were performed.

2.2. Study protocol and fitting procedures

Patients were instructed not to wear any contact lens in the tested eye for at least five days prior to the initial evaluation. Visual acuity was measured with the Acuity Pro version 6.0 (Vision-Science Software, Elk City, OK, USA), a computerised eye acuity chart with random letter presentation and recorded up to level 1.0 (6/6) level in decimal scale that for this study was converted into LogMAR units. Keratometry readings, expressed as Sim-K's in dioptres, were measured with a Keratron Scout using software version 4.1.0 (Opticon 2000 S.p.a., Rome, Italy). In addition, pachymetry was performed centrally and at equal distances above and below the centre of the cornea with a DGH 400 ultrasonic pachymetry unit (DGH Technology Inc., Exton, PA, USA). The minimal criteria used to identify KCN were either the corneal distortion as seen with retinoscopy or the topography as shown with a positive CLMI (Cone Location and Magnitude Index) [13] in the topography. In patients wearing soft contact lenses a high molecular weight fluorescein dye (Fluoresoft®, Holles Laboratories, Cohasset, MA, USA) was used. In RGP evaluation, fluorescein patterns and corneal evaluation was done with saline-soaked fluorescein strips (Haag-Streit, Köniz, Switzerland).

The fitting procedure of the KIC as provided in its technical fitting guide and manufacturer's specifications was followed. A dedicated set of eight lenses is needed for this purpose with power plano, different base curves and peripheral radii. The first lens is chosen based on the geometry of the cornea to be fitted; when the theoretically best-fitting lens is inserted it should be allowed to settle for approximately 5 min and then assessed following the acronym MoRoCCo VA which represents movement, rotation, centration, comfort and VA. Correct fit is achieved when the post-blink movement is no more than 3.0 mm on straight-ahead gaze, as long as the patient is comfortable, the laser mark is vertical, lens is central and vision is steady with no fluctuation. Once this is achieved, the over-refraction and laser mark position following the standard LARS (left add, right subtract) procedure are recorded and a trial lens is ordered from the laboratory. As soon as the lens is received it is again tested on the eye and new crossed-cylinder calculations are performed to confirm until best visual acuity, and, if this is not achieved, lenses are re-ordered taking into account the modifications. A multipurpose solution (ReNu Multiplus, Bausch & Lomb, Rochester, NY, USA) was prescribed for all soft CL patients.

The Rose-K 2 fittings were approached using several diagnostic trial lens sets to account for base curves, overall diameters and peripheral designs. The base curve of the initial trial lens was chosen based on the axial topography map taking into consideration severity and type of cone. Based on the evaluation of initial lens fit on slit lamp and fluorescein images, new trial lens base curves aiming for a light, feather touch and horizontal mid-peripheral bearing at 3 and 9 O'clock was achieved. After that, the periphery was adjusted in order to obtain a roughly 0.5–0.7 mm wide edge lift in 360° and when there was an excessive inferior lift off an ACT® (asymmetric corneal technology) design was ordered. Later, the diameter was assessed to obtain good centration. All lenses were ordered in either Boston ES or Boston XO Material. Cleaning and conditioning solutions (Boston, Bausch & Lomb, Rochester, NY, USA) were both prescribed for all RPG patients. In all cases, regardless of the type of CL fitted, regular follow-ups were established at no less than every six months after dispensing the final set of fitted lenses.

2.3. Data collection and analysis

Parameters evaluated in both groups included age, BSCVA, BCLCVA, keratometry readings, number of wearing hours and biomicroscopic complications. ##Additionally, the Kerasoft-IC group included the number of diagnostic lenses required before ordering the final lenses, refraction at time of the fitting adjusted to vertex distance, power of the lenses and specific information about the dispensed contact lenses. This group was subanalysed taking into consideration the shape of the cornea. Additionally, all keratoconus (no PMD) were categorised taking into consideration the standard severity scale based on the mean keratometry in three groups; mild (average sim $K < 45$ D), moderate (average sim K 45–52 D) and severe (average sim $K > 52$ D). Calculations were performed with the GraphPad Prism version 5.00 for Windows (GraphPad Software, San Diego, CA, USA) and Microsoft Excel (Excel; Microsoft, Redmond, VA, USA).

3. Results

In total, forty-four patients (77 eyes) with a mean age of 36.5 ± 5.3 (mean ± SD) were fitted with Rose-K 2 RGP contact lenses and had a mean follow-up of 14.3 ± 3.8 months. Sixty patients (94 eyes) with a mean age of 35.5 ± 8.0 were fitted with Kerasoft contact lenses and had a mean follow-up of 10.3 ± 2.3 months. Statistical analysis revealed no significant differences in age between the two groups ($p = 0.65$) (Table 2).

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Table 2
Comparison of data (Mean ± Standard deviation) in eyes that underwent Kerasoft-IC fitting versus the Rose-K 2 group.

	KERASOFT-IC (n = 94 eyes)	ROSE-K (n = 77 eyes)	P value*
Age (y)	35.5 ± 8.0	35.9 ± 9.4	0.65
Sim-K flat	44.78 D ± 4.81	46.50 D ± 5.26	0.10
Sim-K steep	47.90 D ± 3.70	49.00 ± 3.42	0.08
BSCVA	Log MAR 0.33 ± 0.27	Log MAR 0.40 ± 0.26	0.45
BCLCVA	Log MAR 0.04 ± 0.07	Log MAR 0.04 ± 0.07	0.63
Wearing time (hrs)	11.6 ± 1.5	11.1 ± 1.5	0.15

D, dioptre; BSCVA, best spectacle-corrected visual acuity; BCLCVA, best contact lens corrected visual acuity.
* t-test used for data with normal distribution, Wilcoxon test used for data without normal distribution.

Table 3
Comparison (mean ± standard deviation) between refraction (at vertex) and power of contact lens adjusted to axis rotation in eyes that underwent Kerasoft-IC fitting.

	Refraction	Contact lenses	Correlation coefficient
Sphere	−3.85 ± 5.27 D	−4.44 ± 5.23 D	0.84
Cylinder	−3.30 ± 2.27 D	−3.21 ± 2.15 D	0.52
Axis	91.9 ± 46.1°	89.6 ± 54.7°	0.61
M	−5.43 ± 4.91	−6.08 ± 5.36	0.66
J0°	−0.63 ± 1.32	0.08 ± 1.46	0.53
J45°	0.15 ± 1.35	0.14 ± 1.22	0.60

D, dioptres.

3.1. Rose-K group

A summary of the results for this group, including the mean and range for each parameter, is presented in Table 2. This group included 30 (38.9%) centred cones, 35 (44.4%) oval cones and 12 (15.5%) PMD. With regards to the overall goal of the study, the BCLCVA was LogMAR 0.04 ± 0.07 (20/22) and wearing time was 11.1 ± 1.5 h a day.

3.2. Kerasoft-IC group

A summary of the results for this group, including the mean and range for each parameter, is also presented in Table 2. This group included 29 (30.8%) centred cones, 45 (47.8%) oval cones and 20 (21.2%) PMD cases. With regards to the overall goal of the study, the BCLCVA was LogMAR 0.04 ± 0.07 (20/22) and wearing time was 11.6 ± 1.5 h a day.

The number of diagnostic lenses that were required to order from the manufacturer's laboratory before the final lens prescription was obtained was 2.6 ± 0.8 per eye. A high correlation (Pearson correlation test, r = 0.54, p < 0.0001) was found between a larger number of diagnostic lenses being needed, and consequently more fitting follow-ups, and a lower baseline BSCVA. Assessment of the difference between spectacle refraction at vertex and contact lens power (Table 3) showed a moderate correlation between all included parameters.

Additionally, we subdivided this group to obtain further information. Corneal ectasias were divided in three sub-cohorts, centred or nipple cones (n = 29), oval cones (n = 45) and PMD cases (n = 20). Table 4 shows the results within the different types of cone. The difference in BCLCVA among sub-groups was not considered significant (ANOVA test p = 0.19) showing equivalent levels of VA with the Kerasoft-IC contact lens. When the base curve of the fitted KIC lenses was analysed a statistically significant difference between subgroups were found (ANOVA test p = 0.03). Assessment of the peripheral systems showed that FP lenses were used in all centred cones, in 66% of the oval cones and in 60% of the PMD cases.

Also all cases of keratoconus were analysed taking into consideration the severity of the disease. In our cohort, there were 22 eyes with mild forms, 46 eyes with moderate and 6 eyes with severe keratoconus. Table 5 shows the results by severity of the keratoconus. The mild and moderate cases did not show a statistically significant difference in BCLCVA (t test p = 0.45) although more severe presentations showed worse BCLCVA (ANOVA p = 0.02) than in both milder presentations.

Table 5
Results based on the severity of keratoconus (mean ± standard deviation) with Kerasoft-IC.

Type	BCCLVA
Mild keratoconus (n = 22)	LogMAR 0.02 ± 0.06
Moderate keratoconus (n = 46)	LogMAR 0.04 ± 0.07
Severe keratoconus (n = 6)	LogMAR 0.12 ± 0.08

BCCLVA, best contact lens corrected visual acuity.

Table 6
Biomicroscopic complications in eyes fitted with Kerasoft-IC and Rose-K contact lenses for keratoconus.

	Kerasoft-IC	Rose-K	
Biomicroscopic complications	Neovascularisation	• Grade 1: 3 eyes	• Grade 1: 4 eyes
	Staining	• Grade 1: 4 eyes	• Grade 1: 15 eyes • Grade 2: 6 eyes
	Injection	• Grade 1: 2 eyes	• Grade 1: 5 eyes

3.3. Comparison of groups

Comparative data for the Kerasoft-IC and Rose-K groups for this study are summarised in Table 2. Differences in either BCLCVA or wearing time between both groups could not be statistically established between the two groups (Wilcoxon test p = 0.63, t-test p = 0.15).

When biomicroscopic complications were reviewed (Table 6), grade 2 or higher complications were only found with RGP contact lenses. More interesting was the presence of more cases and more severe corneal staining with the rigid lenses of the RGP control group (Mann–Whitney Test, P < 0.0001).

4. Discussion

When BCLCVA was compared between the control group and the Kerasoft-IC group, it was found that both lenses provide outcomes with statistically similar levels of visual acuity and reported wearing times. The Rose-K lenses have been tested and fitted extensively

Table 4
Results based on the type of ectasia (mean ± standard deviation) in non-surgical ectasias with Kerasoft-IC.

TYPE	BCSVA	BCCLVA	P value*	BC	Periphery system percentage
Nipple cones (n = 29)	LogMAR 0.46 ± 0.32	LogMAR 0.06 ± 0.08	<0.0001	8.20 ± 0.20	100% FP
Oval cones (n = 45)	LogMAR 0.30 ± 0.23	LogMAR 0.03 ± 0.06	<0.0001	8.30 ± 0.20	66% FP
PMD (n = 20)	LogMAR 0.19 ± 0.21	LogMAR 0.04 ± 0.07	<0.0001	8.35 ± 0.20	60% FP

BSCVA, best spectacle-corrected visual acuity; BCCLVA, best contact lens corrected visual acuity, BC, base curve in millimetres; FP, Full periphery.
* Wilcoxon test used.

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wordwide and have shown excellent levels of VA and better confort than other RGP designs [14,15]. Nevertheless the present study found the Rose-K lenses were associated with a larger number of biomiscrocopic complications, mainly corneal staining with fluorescein, than were the soft contact lens cohort. Additionally, higher fluorescein and rose bengal staining scores have been reported with KCN [16,17] and this could be associated with an increased risk of scarring regardless of the RGP fitting philosophy as showed previously [16]. Wilson and Kim [18] suggested that epithelial trauma might be responsible for premature keratocyte apoptosis and further stromal changes in keratoconus. Cytokine concentration has been reported [19] to be higher in the tears of KCN patients wearing RGP's than in non-wearers and this could reflect some degree of inflammation related to this modality of wear. The clinical outcomes presented in the present report suggest a promising role in the management of irregular astigmatism for specialty silicone hydrogel contact lenses like the new KeraSoft-IC given the achieved BCLCVA, average daily wearing time, and lack of major biomicroscopic complications observed in this study.

When eyes fitted with KIC were analysed taking into consideration ectasia type of (centred, oval corneas and PMD) the BCLCVA in these three sub-groups was consistent and similar showing that this design was adequate for different types of corneal ectasias. When all keratoconus were analysed based on keratometry severity we found that BCLCVA was similar in mild and moderate cases. These results could show a better role for vision rehabilitation for KIC in mild and moderate keratoconus.

Although the fitting procedure of the KIC is based on soft toric lenses, this design has its own specific behaviour and must be mastered by the clinician wishing to fit these lenses. Moreover, based on our findings, a clinician who initially fits KeraSoft IC lenses can expect to require as many as three diagnostic lenses per eye to determine all the appropriate parameters (power, base curve, periphery design and overall diameter) before a final prescription can be made. A direct relation was found between worse BSCVA and the need for a larger number of trial lenses. Regarding the power of the contact lens, this cannot be directly calculated from the spectacle lens correction. There were wide variations in all parameters involved. A possible explanation for this phenomenon is either the creation of a tear meniscus behind the lens (some-what similar to what can occur with rigid gas permeable lenses) or the way in which the irregular cornea refracts when its surface is smoothed by the lens. This observation demonstrates that these lenses cannot be fitted empirically without proper lens fitting trials. Other key factors for the fitting of these lenses are the base curve and periphery system. Assessment of the correct base curve is very important in order to obtain proper and stable vision with the lens in place. Our study revealed a very distinctive behaviour in which centred cones required relatively steeper base curves (8.00 mm and 8.20 mm) and oval cones and PMD flatter curves. The peripheral fit is also critical and is one of the key factors in the performance of this design in terms of comfort and contact lens behaviour. The periphery should not be tight on the conjunctiva or too flat. Decreased wearing time, lens awareness and fluctuating vision could be caused by an erroneous periphery. In nipple cones, where the area of ectasia was very central with a rather spherical periphery, there was no need for SMC geometries. In this group, the most ordered periphery style was the standard one. In severe nipple cones, in our experience, a rather steep base curve (i.e. 7.60 mm) with a Flat periphery (i.e. Flat-2) produced the best fit and consequently the best and most stable BCLCVA. Oval cones and PMD required more lenses with SMC peripheries, reflecting the peripheral corneal affectation with high irregularity and asymmetry in both groups. Thus the correct topographical determination of the ectasic pattern is crucial to establishing the proper geometry of the periphery of the fitted lens.

Future studies involving this lens should consider other factors in vision such as aberration correction, quality of life, and low contrast visual acuity as well as the role of KIC in the optical management of keratoconus with ICT. With experience and clinical expertise related to toric soft contact lenses, KIC contact lenses can be a successful contact lens tool for the management of IA and added to clinical practice.

5. Limitations of this study

One weakness of our study is the heterogeneity of the patient population. In an attempt to address this shortcoming, we performed subgroup analysis, but because of the small size of the groups, we were unable to detect significant differences in clinical outcomes.

A second shortcoming of this study is our inability to clearly differentiate, in some cases, between oval cones and PMD. It has been reported [20] that a "claw-shaped" pattern in corneal topography may not be diagnostic of PMD and that such patterns can also be found in keratoconus.

A third shortcoming of this study could be the learning curve. Fitting contact lenses in keratoconic corneas can be quite difficult. The technology involved in KeraSoft-IC is very new and is critical to realize that these lenses do not behave the same as standard toric soft contact lenses. Thus some points, such as determination of contact lens parameters, correct over-refractions and better levels of BCLCVA, may improve with the increased experience of the practitioner.

Conflict of interest

The author has no conflict of interest associated with any of the information regarding products discussed in this manuscript.

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