Contact Lens and Anterior Eye 42 (2019) 670–674

Contents lists available at ScienceDirect

Contact Lens and Anterior Eye

journal homepage: www.elsevier.com/locate/clae

Effects of a semi-scleral contact lens on refraction and higher order aberrations*

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ARTICLE INFO

Keywords:
Aberration
Intra-corneal ring segments
i-Trace
Keratoconus
Penetrating keratoplasty
Radial keratotomy
Semi-scleral contact lens

ABSTRACT

Purpose: To investigate effects of Rose K2 XL semi-scleral contact lenses (Menicon Co.) on visual acuity and higher-order aberrations in eyes with irregular corneas. *Methods*: One hundred and twelve eyes of 84 patients fitted with Rose K2 XL lenses were analysed. Participants were in 4 clinical groups: keratoconus, intra-corneal ring segments, radial keratotomy, and penetrating keratoplasty. Corrected distance visual acuity and ocular aberrations were determined before lens wear and 60 min into lens wear. The i-Trace aberrometer was used to determine aberrations at 4.5 mm pupil size.

Results: There were 55, 22, 19 and 16 eyes in keratoconus, intra-corneal ring segments, radial keratotomy and penetrating keratoplasty groups, respectively. Before lens wear, eyes had poor corrected distance vision acuity (mean and standard deviation +0.55 ± 0.33 logMAR), high negative spherical equivalent refraction (−6.4 ± 3.7 D), high cylindrical errors (4.5 ± 2.2 D), large higher-order root-mean-squared (HO-RMS) aberration (1.5 ± 1.3 μm) and large higher-order aberration components. Cylinder was particular high for the penetrating keratoplasty group (mean 5.9 ± 2.5 D), root-mean-squared third-order coma was lowest for the radial keratotomy group (0.7 ± 1.0 μm), and fourth-order spherical aberration was highly negative for the intra-corneal ring segment group (co-efficient –0.4 ± 0.7 μm). With lens wear, the values changed considerably. Corrected distance visual acuity improved by 0.51 ± 0.31 logMAR, cylinder decreased by 3.6 ± 2.1 D, HO-RMS aberration reduced by 1.1 ± 1.2 μm, and higher-order aberration components decreased considerably. Magnitudes of group changes reflected the magnitudes before lens wear.

Conclusions: Rose K2 XL semi-scleral contact lenses were effective in improving vision and reducing ocular aberrations for eyes with irregular corneas.

1. Introduction

Keratoconus is a progressive, often bilateral condition that affects the cornea by causing progressive thinning particularly slightly inferior to its centre. The condition gives reduced quality of vision and increased higher-order aberration [1–3]. Coma is the predominant higher-order aberration and has been reported to be 3.7 times higher for the cornea than in normal eyes [3,4]. High levels of aberrations have been reported also for people with keratoconus treated with intra-stromal corneal ring segments, and for people having undergone radial keratotomy or penetrating keratoplasty [5].

Rigid gas-permeable contact lenses are very effective in treating patients with irregular corneas. They reduce higher-order aberrations and improve vision by providing a more regular refractive surface in front of the cornea and making another refractive layer of tears between the lenses and the cornea [6]. However they are not suitable for advanced corneal irregularity and can be associated with corneal scarring at the point of contact of the lens and cornea [7]. Piggyback contact lenses, meaning rigid gas permeable lenses are fitted over soft contact lenses, are provided for people who cannot tolerate scleral or rigid gas permeable lenses [8]. They provide better comfort and visual acuity than spectacles and reduce higher-order aberrations [4,5], but increase cost and complicate maintenance and lens storage [8].

Scleral lenses are large diameter rigid gas-permeable lenses, which

* This material (in whole or part) is not under consideration by another journal, is not in press in any other format, and has not been previously published.

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https://doi.org/10.1016/j.clae.2019.06.002
Received 19 February 2019; Received in revised form 23 May 2019; Accepted 11 June 2019

vault over the cornea and limbal area and rest on the conjunctival tissue overlying the sclera. The mid-peripheral and peripheral parts of the lenses are modifiable. In some variants, the peripheral part can be modified to improve stabilization [5]. If the lenses are no more than 6 mm larger than the horizontal visible iris diameter, they are referred to as mini-scleral lenses [9], semi-scleral lenses [10] and corneoscleral lenses [11]. The term "semi-scleral" is used in this paper. Rose K2 XL semi-scleral lenses (Menicon Co. Ltd., Nagoya, Japan) have aspheric optic zones to improve the visual acuity and comfort in patients with irregular corneas [10,11]. This clinical study at a tertiary eye care institute investigates the effect of the Rose K2 XL lenses on higher-order aberrations and refractive correction in keratoconus eyes and in eyes that have intra-corneal ring segments (also ICRS or intacs), radial keratotomy or penetrating keratoplasty.

2. Methods

This study was approved by the Narayana Nethralaya Institutional Review Board. It adhered to the tenets of the declaration of Helsinki, and written informed consent was obtained from all participants. The study included 115 eyes of 87 patients (44 females and 43 males) who presented with reduced visual function resulting at least in part from higher-order aberrations not improving with conventional treatments of spectacles and soft contact lenses. Eyes were divided into four groups: keratoconus, intra-corneal refractive rings (Addition Technology, Inc, Des Plaines, IL), radial keratotomy, and penetrating keratoplasty. In this study CLEK (Collaborative Longitudinal Evaluation of Keratoconus) criteria were used to grade the severity of keratoconus using i-Trace data, where keratometric measurements < 45 D were graded as 'mild' keratoconus, measurements between 45 and 52 D were graded as 'moderate' keratoconus and measurements > 52 D were classed as 'severe' keratoconus. The patients recruited to the study included 8 with mild keratoconus, 26 with moderate keratoconus and 21 patients with severe keratoconus. The intra-corneal refractive rings group had one ring inserted in the superior cornea and one ring inserted in the inferior cornea at least three years previously as a treatment for moderate keratoconus. The radial keratotomy group had surgeries at an average 15 years previously. The penetrating keratoplasty group had surgeries 3 years ago due to advanced keratoconus and were not being able to tolerate rigid gas permeable or scleral contact lenses. Subjects who were contact lens wearers instructed to stop wearing contact lens at least ten days before the evaluation day.

Three patients (1 female, 2 male, three eyes), one from the radial keratotomy group and two from the penetrating keratoplasty group, were excluded from the analysis as pupil sizes were < 4.5 mm during aberration measurement, leaving 112 eyes of 84 patients: 55 eyes with keratoconus (mean ± standard deviation 26 ± 5 years, range 18–40 years), 22 eyes with intra-corneal ring segments (28 ± 6 years, 17–39 years), 19 eyes with radial keratotomy (40 ± 8 years, 29 to 47 years), and 16 eyes with penetrating keratoplasty (30 ± 5 years, 22 to 39 years).

Subjective refraction was conducted with trial frame lenses under standardized room and chart illumination conditions by one of the authors. Corrected distance visual acuity (CDVA) was measured using an ETDRS chart and given as logarithm of minutes of arc resolution (logMAR). Aberrations were measured with the i.Trace (Tracey Technologies Corp, Houston, TX), with the room light switched off, for 4.5 mm pupils. The iTrace is a combined ray-tracing aberrometer and Placido disc videokeratoscopy, operating at a wavelength of 785 nm [12]. Corrected distance visual acuity and higher-order aberration were assessed prior to, and 60 min after, using Rose K2 XL lenses. Parameters included spherical equivalent refraction (D), cylinder (D), root-mean-squared higher-order aberration (RMS higher-order aberration) up to the 8th-order, root-mean-squared coma (RMS coma) based on the two 3rd-order coma co-efficients, fourth-order spherical aberration co-efficient, root-mean-squared secondary astigmatism, and root-mean-squared trefoil (RMS trefoil) based on the two 3rd-order trefoil co-efficients. Aberrations were determined according to the ISO standard for wave aberrations in ophthalmic optics [13].

2.1. Contact lens assessment

Rose K2 XL (Menicon Z, Menicon Co. Ltd., Nagoya, Japan) semi-scleral diagnostic contact lenses were used for this study. These are non-fenestrated semi-scleral lenses made from tisilfocon A material with DK of 163 and of 0.14 mm centre thickness. The Rose K2 XL lens has an aspheric optic zone and is available in 9 edge lifts. A trial set consisted of 14 lenses having overall diameters between 13.0 and 14.6 mm depending on the back optic zone radius of curvature, with all lenses having a standard edge lift.

A single experienced examiner performed all fitting in accordance with the manufacturer's fitting guide. Rose K2 XL lenses were inserted with preservative-free saline and sodium fluorescein, without an air bubble present, and assessed using a slit-lamp biomicroscope. The central lens-cornea relationship was evaluated. On the basis of this fitting, lenses with smaller or larger back optic zone radii of curvature were tested progressively until the highest point of the cornea (apex) showed a light feather touch. Once this central fit was achieved, the lens-conjunctiva relationship at the edge of the lens was evaluated to check for excessive pressure of the conjunctival vessels under the lens. After an adequate fit was obtained, the lens was allowed to settle for 60 min and was re-examined using the slit lamp to check that the lens was centered and free from air bubbles. This trial lens was used for aberration measurements.

2.2. Statistical analysis

Statistical analyses were performed using the commercial software SPSS version 23 (Chicago, Illinois, USA). Kolmogorov-Smirnov and Shapiro-Wilks tests for normality of data were conducted for all combinations of groups and parameters: as more than two-thirds of the combinations showed significance ($p < 0.05$) non-parametric analyses were used throughout. The Wilcoxon signed ranks test was used for each group to compare results before Rose K2 XL lens wear and during lens wear. Analyses of variance using the Kruskal-Wallis H test compared differences between four independent groups before lens wear, during lens wear, and for the difference between lens wear and before lens wear. Where group was found to have a significant effect, post-hoc pair-wise tests were conducted using Holm-Bonferroni correction.

Results are given for all 112 eyes. Effects of using one eye of each of the 84 participants are indicated in the Discussion.

3. Results

Fig. 1 shows typical examples of eyes with the different conditions. Results are shown in Tables 1–3, which have the results before Rose K2 XL lens wear, during lens wear, and for the difference between lens wear and before lens wear, respectively. Fig. 2 show the higher-order parameters before and during lens wear for a) keratoconus b) intra-corneal ring segments, c) radial keratectomy and d) penetrating keratoplasty.

Before lens wear, as shown in Table 1, all groups had poor CDVA (mean and standard deviation +0.55 ± 0.33 logMAR across the groups), highly negative spherical equivalent refractions (−6.4 ± 3.7 D), high cylinder (4.5 ± 2.2 D), and large higher-order aberrations (HO RMS aberration 1.5 ± 1.3 μm, RMS coma 1.0 ± 0.9 μm, RMS secondary astigmatism 0.3 ± 0.4 μm and RMS trefoil 0.6 ± 0.7 μm). There were significant effects of group for cylinder, RMS coma, and spherical aberration co-efficient. For the cylinder, the values for the penetrating keratoplasty group (5.9 ± 2.5 D) were larger ($p = 0.03$) than for the keratoconus group (4.1 ± 1.9 D). For RMS coma, the values for the radial keratotomy group were significantly lower

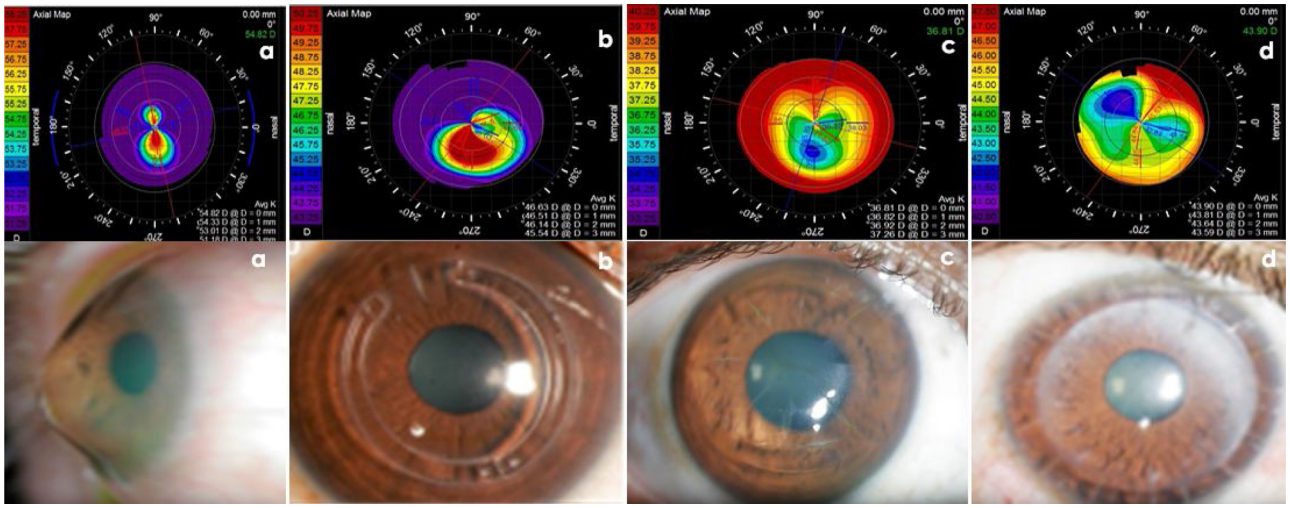

Fig. 1. Axial topography maps and images for typical examples of a) keratoconus, b) intra-corneal ring segments, c) radial keratotomy, and d) penetrating keratoplasty.

(0.7 ± 0.1 μm) than those for the keratoconus group (mean 1.1 ± 0.9 μm) and the intra-corneal ring egments group (1.2 ± 0.8 μm), with respective p values of 0.02 and 0.005. For spherical aberration co-efficient, the intra-corneal ring segments group had highly negative values (mean −0.4 ± 0.7 μm) that were significantly different from those for the radial keratotomy group (+0.1 ± 0.3 μm) and for the penetrating keratoplasty group (+0.0 ± 0.4 μm), with respective p values 0.001 and 0.005.

Upon lens wear, the absolute values reduced considerably for nearly all parameters, with changes being significant for the combined groups and within groups except for radial keratotomy (RMS coma, spherical aberration co-efficient, RMS secondary astigmatism) and penetrating keratoplasty (spherical aberration co-efficient) (Table 2). In particular, CDVA had near normal values (mean and standard deviation +0.04 ± 0.08 logMAR for combined groups), and spherical equivalent (−1.6 ± 1.2 D) and cylinder (0.9 ± 0.8 D) were much lower than the pre-lens wear values. With lens wear, there were significant effects of group for spherical equivalent and cylindrical refraction, but not for any of the higher-order parameters (Table 2). For the cylinder, the values for the intra-corneal ring segments group (1.3 ± 0.7 D) were higher (p = 0.002) than those for the keratoconus group (0.7 ± 0.6 D).

There was a significant effect of group on change with lens wear for RMS coma and spherical aberration coefficient (Table 3). For RMS coma, there were smaller changes for the radial keratotomy group (mean and standard deviation −0.3 ± 0.9 μm) than for the keratoconus group (mean −0.8 ± 0.8 μm) and for the intra-corneal ring segments group (mean −0.8 ± 0.7 μm), with respective p values of 0.005 and 0.003; this finding reflects the values before lens wear being lower for the radial keratotomy group. For the spherical aberration co-efficient, there were larger changes for the ICRS group (+0.5 ± 0.7 μm) than for the radial keratotomy group (mean −0.1 ± 0.3 μm) and the penetrating keratoplasty group (+0.0 ± 0.3 μm), with respective p values of 0.001 and 0.05); this finding reflects the large negative spherical aberration of the intra-corneal ring segments group before lens wear.

4. Discussion

This is the first study on the impact of the Rose K2 XL lenses on high order aberrations for different corneal conditions. In this study participants with keratoconus, or those who had undergone intra-corneal ring segment treatment, radial keratotomy or penetrating keratoplasty, had poor corrected distance vision acuity (mean +0.55 logMAR), high negative spherical equivalent refraction (−6.5 D), high cylindrical errors (mean 4.5 D), large RMS higher-order aberration (mean 1.5 μm), and large important higher-order aberration components. Cylinder was particular high for the penetrating keratoplasty group (mean 5.9 D), RMS coma was lowest for the radial keratotomy group (mean 0.7 μm),

Table 1
Parameters before Rose K2 XL lens wear (mean ± standard deviation).

Parameter	Combined groups (112)	Keratoconus (55)	Intra-corneal ring segments (22)	Radial Keratotomy (19)	Penetrating Keratoplasty (16)	p-value*
Corrected distance visual acuity (logMAR)	+0.55 ± 0.33	+0.57 ± 0.34	+0.50 ± 0.25	+0.47 ± 0.31	+0.63 ± 0.37	0.43
Spherical equivalent (D)	−6.44 ± 3.70	−6.50 ± 3.83	−4.94 ± 2.55	−7.01 ± 4.01	−7.66 ± 3.82	0.13
Cylindrical refraction (D)	4.49 ± 2.16	4.05 ± 1.93	4.58 ± 2.20	4.42 ± 2.12	5.94 ± 2.46	0.05#
HO-RMS aberration (μm)	1.52 ± 1.34	1.59 ± 1.39	1.66 ± 1.06	1.10 ± 0.92	1.57 ± 1.89	0.28
RMS coma (μm)	0.99 ± 0.87	1.11 ± 0.91	1.22 ± 0.75	0.65 ± 0.96	0.67 ± 0.62	0.002##
spherical aberration co-efficient (μm)	−0.11 ± 0.51	−0.07 ± 0.49	−0.44 ± 0.65	+0.08 ± 0.26	+0.03 ± 0.41	< 0.001###
RMS secondary astigmatism (μm)	0.32 ± 0.38	0.36 ± 0.39	0.35 ± 0.32	0.15 ± 0.13	0.35 ± 0.54	0.06
RMS trefoil (μm)	0.63 ± 0.70	0.63 ± 0.68	0.51 ± 0.32	0.48 ± 0.37	0.94 ± 1.23	0.66

* Significance of group on variable. Where significance was found, post-hoc pair-wise comparisons were made and significant results are given according to the following symbols:

\# penetrating keratoplasty > keratoconus.

\## radial keratotomy < keratoconus, intra-corneal ring segments.

\### intra-corneal ring segments < radial keratotomy, penetrating keratoplasty.

Table 2
Parameters during Rose K2 XL lens wear (mean ± standard deviation).

Parameter	Combined groups (112)	Keratoconus (55)	Intra-corneal ring segments (22)	Radial Keratotomy (19)	Penetrating Keratoplasty (16)	p-value*
Corrected distance visual acuity (**logM**AR)	+0.04 ± 0.08	+0.03 ± 0.07	+0.04 ± 0.08	+0.05 ± 0.08	+0.07 ± 0.10	0.65
Spherical equivalent (D)	−1.59 ± 1.21	−1.14 ± 0.72	−2.25 ± 1.32	−1.90 ± 1.85	−1.84 ± 0.88	**0.001**#
Cylindrical refraction (D)	0.90 ± 0.80	0.69 ± 0.60	1.25 ± 0.70	0.96 ± 1.13	1.06 ± 0.96	**0.005**##
HO-RMS aberration (μm)	0.44 ± 0.26	0.42 ± 0.28	0.49 ± 0.23	0.50 ± 0.23	0.37 ± 0.25	0.16
RMS coma (μm)	0.33 ± 0.23	0.32 ± 0.24	0.40 ± 0.26	0.34 ± 0.22	0.21 ± 0.16	0.06
spherical aberration **co**-efficient (μm)	+0.06 ± 0.11	+0.08 ± 0.12	+0.03 ± 0.09	+0.03 ± 0.12	+0.05 ± 0.11	0.26
RMS secondary astigmatism (μm)	0.08 ± 0.07	0.07 ± 0.07	0.09 ± 0.06	0.10 ± 0.10	0.08 ± 0.07	0.39
RMS trefoil (μm)	0.14 ± 0.13	0.12 ± 0.12	0.15 ± 0.11	0.16 ± 0.12	0.16 ± 0.18	0.34

* Significance of group on variable. Where significance was found, post-hoc pair-wise comparisons were made and significant results are given according to the following symbols:
# keratoconus > intra-corneal ring segments, penetrating keratoplasty.
keratoconus < intra-corneal ring segments (mean ± standard deviation).

and the spherical aberration was highly negative for the intra-corneal ring segment group (mean co-efficient –0.4 μm).

Fitting the Rose K2 XL lenses improved corrected distance visual acuity by a mean 0.51 logMAR to near normal levels, decreased cylinder (3.6 D), and reduced RMS higher-order aberration (1.1 μm) and its important components. The magnitude of improvement in corrected distance visual acuity was similar to that reported by Romero-Jiménez and Flores-Rodríguez with the lens for a range of irregular corneal conditions [10]. The magnitudes of changes in the groups reflected the magnitudes of values before lens wear, that is, the largest changes in aberrations occurred for the largest aberrations before lens wear. Thus, the Rose K2 XL can improve both visual acuity and visual quality considerably in patients with irregular corneas in whom conventional therapies have failed.

Fifty-six and twenty-eight of participants had one and two eyes tested, respectively. As it would be expected that there would be similarity between the two eyes of individuals, the analysis was repeated after removing the left eyes of participants for whom both eyes were tested. Findings were affected little, except that the effect of group on RMS coma before lens wear was no longer significant ($p = 0.02$ became $p = 0.23$) and the before wear/during lens wear differences in RMS coma were no longer significant for the radial keratotomy group with the keratoconus and ICRS groups ($p = 0.005$ and 0.003 became $p = 0.44$ and 0.10).

Using intra-corneal ring segments in keratoconus can decrease corneal irregularity and improve visual acuity, [14] with one study reporting improvement of corrected distance visual acuity in 50% of subjects [15]. One study found that higher order aberrations such as coma and spherical aberration increase [16] and another reported high negative spherical aberration (coefficient −2.0 μm at 6.5 mm pupil size) in a patient with a Ferrara intra-corneal ring [17]. The most notable finding with the intra-corneal ring segments group was the very high level of negative spherical aberration (mean −0.4 μm) and its almost complete correction during wear with the Rose K2 XL (mean +0.03 μm).

With radial keratotomy, corneas undergo considerable central flattening that is associated with high higher-order aberration, particularly spherical aberration [18] leading to mild to severe vision impairment and visual symptoms such as glare and ghosting [18]. In normal eyes, nearly 90% of ocular aberrations arise from the anterior surface of the cornea, and this percentage is much higher in radial keratotomy [19]. The radial keratotomy group had the lowest HO-RMS aberration of all the groups, and although the effect of group was not significant ($p = 0.28$), its RMS higher-order aberration was considerable lower (mean 1.1 μm) than for other groups (1.6 μm).

Penetrating keratoplasty has been found to induce high levels of astigmatism, coma and trefoil [20–22]. Cylinder was particular high in penetrating keratoplasty group (mean 5.9 D) and was significantly greater than for the keratoconus group ($p = 0.03$). Trefoil was higher for the penetrating keratoplasty than for the other groups, although differences were not significant.

Because of the use of trial semi-scleral lenses, there were residual spherical equivalent refractions (mean and standard deviation −1.6 ± 1.2 D). It is likely that incomplete correction would have small effects on the higher-order aberrations.

Development of new lens designs and materials has improved visual

Table 3
Changes in parameters with wearing of Rose K2 XL lenses (mean ± standard deviation).

Parameter	Combined groups (112)	Keratoconus (55)	Intra-corneal ring segments (22)	Radial Keratotomy (19)	Penetrating Keratoplasty (16)	p-value*
Corrected distance visual acuity (logMAR)	−0.51 ± 0.31	−0.54 ± 0.34	−0.46 ± 0.27	−0.42 ± 0.29	−0.57 ± 0.30	0.32
Spherical equivalent refraction (D)	+4.86 ± 3.57	+5.36 ± 3.61	+2.69 ± 2.48	+5.11 ± 4.04	+5.81 ± 3.19	0.005#
Cylindrical refraction (D)	−3.59 ± 2.08	−3.36 ± 1.83	−3.33 ± 2.11	−3.46 ± 1.93	−4.88 ± 2.69	0.22
HO-RMS aberration (μm)	−1.08 ± 1.21	−1.18 ± 1.21	−1.17 ± 0.98	−0.61 ± 0.79	−1.20 ± 1.76	0.09
RMS coma (μm)	−0.66 ± 0.79	−0.79 ± 0.81	−0.82 ± 0.68	−0.31 ± 0.91	−0.45 ± 0.52	0.001##
spherical aberration co-efficient (μm)	+0.16 ± 0.54	+0.16 ± 0.54	+0.48 ± 0.70	−0.06 ± 0.26	+0.01 ± 0.35	0.001###
RMS secondary astigmatism (μm)	−0.24 ± 0.37	−0.29 ± 0.36	−0.26 ± 0.33	−0.05 ± 0.15	−0.27 ± 0.53	0.06
RMS trefoil (μm)	−0.49 ± 0.68	−0.52 ± 0.66	−0.36 ± 0.31	−0.32 ± 0.38	−0.78 ± 1.18	0.39

* Significance of group on variable. Where significance was found, post-hoc pair-wise comparisons were made and significant results are given according to the following symbols:
# intra-corneal ring segments < keratoconus, penetrating keratoplasty.
radial keratotomy > keratoconus, intra-corneal ring segments.
intra-corneal ring segments > radial keratotomy, penetrating keratoplasty.

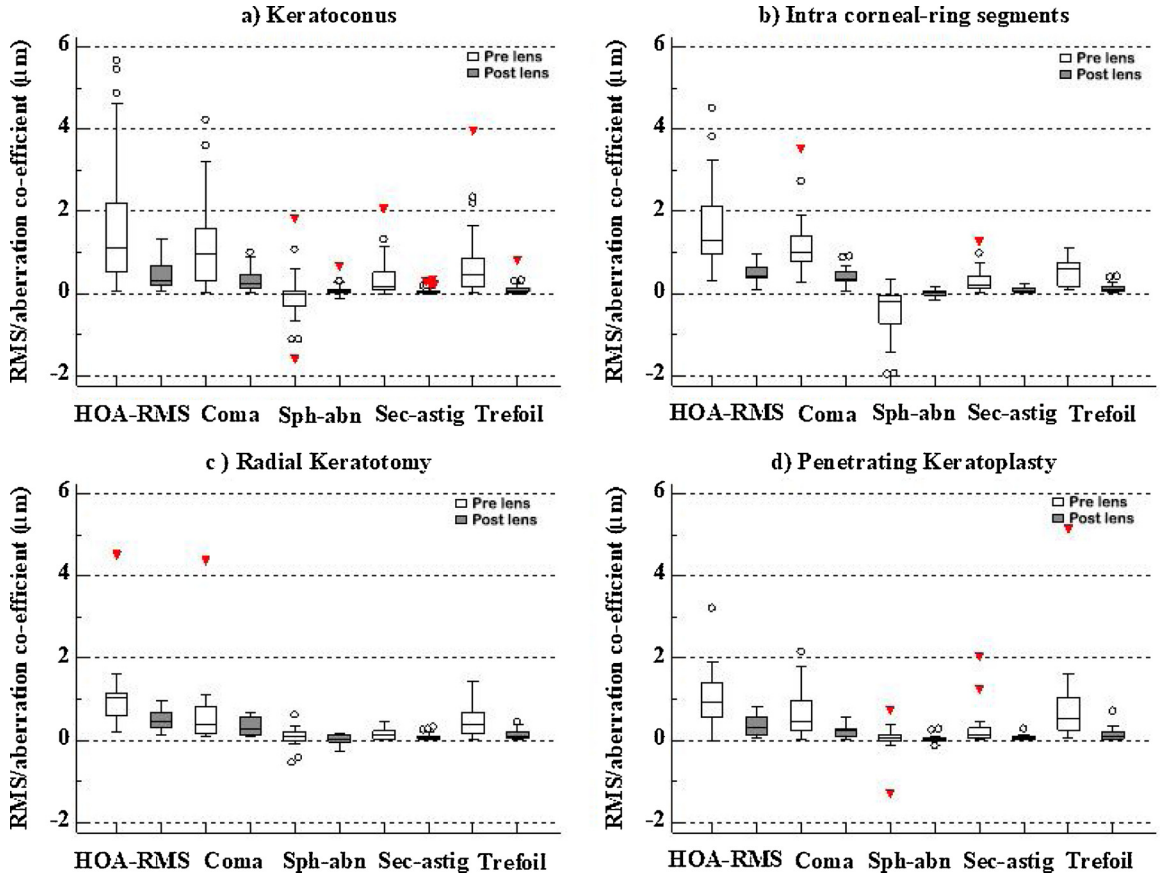

Fig. 2. Box plots showing the distribution of higher-order aberration parameters before Rose K2 XL lens wear and during Rose K2 XL lens wear for a) keratoconus, b) intra-corneal ring segments, c) radial keratotomy, and d) penetrating keratoplasty. The boxes represent values from the lower to the upper quartile, the middle lines represent medians, the whiskers represent 1.5 times the interquartile range away from the lower and upper quartiles, the circles represent most of the values outside the whiskers, and the red triangles represent values 3 times the interquartile range beyond the whiskers. In the interest of restricting the vertical scale, a value of 8.1 µm for higher-order aberration (HO-RMS) in penetrating keratoplasty has been omitted.

acuity, patient comfort and satisfaction for different corneal conditions. Semi-scleral contact lenses, such as the Rose K2 XL lens, have been successful in management of irregular corneal groups [11]. An extension of this work is to compare other scleral lenses with the Rose K2 XL lenses in correcting irregular corneas.

Declaration of Competing Interest

The authors and co-authors have no conflict of interest or any commercial interest for any of the material discussed.

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