

Intrastromal Corneal Ring Segment in Moderate to Severe Keratoconus: Refractive, Topographic and Aberrometric Changes

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Abstract

Aim: This study evaluates the topographic and aberrometric changes induced by ICRS in patients with moderate and severe keratoconus and analyzes pre-operative factors affecting the refractive and visual outcomes.

Methods: This retrospective, observational, nonrandomized, and single-center case series, included 21 keratoconic eyes of 21 patients implanted with Keraring ICRS (Mediphacos, Belo Horizonte, Brazil), using the manual tunnelization technique and vacuum device. All subjects were examined after 6 months following surgery, including the measurement of uncorrected visual acuity (UCVA), best-Corrected Distance Visual Acuity (CDVA), refractive data, pachymetry, corneal topography, and aberrometry.

Results: The mean age of 21 patients was 31.14±10.65 years, eleven (52%) were male. Kerarings were successfully implanted in all eyes. After 6-month from implantation, significant increase was found in mean UCVA ($P<0.01$) and CDVA ($P<0.01$). There was a statistically significant reduction in refractive cylinder ($P<0.01$), corneal cylinder ($P=0.020$), Kmax ($P<0.01$) and BFS ($P=0.02$). Statistically significant differences were found in several aberrometric parameters for 6-mm pupil, RMS HOA ($P=0.045$), oblique astigmatism ($P=0.009$), vertical coma ($P=0.02$), and oblique trefoil ($P=0.018$).

Conclusion: Analysis of the visual outcomes after Keraring ICRS implantation showed a significant postoperative corneal flattening with a subsequent increase in UCVA and CDVA. Visual, refractive, topographic and aberrometric parameters remarkably change in the 6-month period after Kerarings implantation. Kerarings in this sample have shown to provide a mild visual rehabilitation between 2 and 3 lines, particularly in more advanced cases. Furthermore, flattening of the anterior segment induced by the surgery might be beneficial for contact lens fitting.

Keywords: Keratoconus; Intrastromal corneal ring segments; Keraring; Vacuum system; K astigmatism; Spherical aberration; Coma; Corneal thickness

Introduction

Keratoconus (KC) is a common, progressive corneal disease resulting in chronic thinning and protrusion of the para-central cornea associated with myopia, irregular astigmatism and high order aberration increase [1]. The treatment differs depending on the stage of the disorder. Visual acuity can be improved with spectacles in the early stage of this condition or wearing contact lenses also effective to provide a good vision in moderate KC [2]. When an optical correction is no longer effective, or no contact lenses are well tolerated, several surgical treatments are used for the treatment of KC, including Intracorneal Corneal Ring Segments (ICRS) and corneal collagen cross-linking (CXL) [3,4]. However, KC may eventually require corneal grafting as their severe condition progresses, representing the most common indication for keratoplasty in the developed world [4]. Nowadays, there is a growing interest in treatment options that may delay or defer corneal grafting, including ICRS implantation, originally used to correct moderate-to-severe myopia, by exertion of a re-modelling effect

on the corneal stroma [5-7]. The implantation means the addition of extra material at the mid-peripheral cornea and subsequently reducing steepening of the central area. This re-modelling is intended to decrease refractive error magnitude, improve central corneal surface regularity and, moreover, to increase corneal stability and delay the progression of KC [8]. It has been reported that changes in the corneal stroma induced by ICRS are directly proportional to the thickness and inversely proportional to its diameter and depth of implantation [9,10].

There are several commercially available ICRS that differ in their section shape, diameter, arc length, thickness, and zone of implantation. The Keraring ICRS (Mediphacos, Belo Horizonte, Brazil), is a small, arc-like segment made of polymethyl methacrylate characterized by a 5 to 6mm diameter and unique prismatic design available in different arc lengths (90°, 120°, 160°, 210° and 355°), with variable thickness ranging from 150 to 350mm (in 50mm increments). In the last 10 years, several clinical studies have attempted to demonstrate their efficacy to improve visual function, reducing the magnitude of corneal astigmatism, and flattening the central cornea [11-14]. It has been proposed that the preoperative manifest refraction or best corrected visual acuity are predictive factors with a limited ability to predict the postoperative visual outcome, while aberrometry has been found to have a better predictive potential [15]. The assessment of visual and morphological features should provide valuable insights into the determinants of the correlation between corneal surface properties and the improvement of visual acuity following ICRS surgery. Although this subject has already been studied, there is still a lack of publications concerning the morphometric and visual outcomes after Keraring ICRS implantation using the manual technique, especially in the recent period. Despite new approaches using the increasingly frequent femtosecond techniques, those are not available for many surgeons around the world. In addition, there is still a lack of information concerning the outcomes on severe keratoconus patients. The aim of this study was to contribute to determine how ICRS surgery affect to morphometric corneal parameters and identify factors affecting the topographic and visual outcomes following Keraring ICRS implantation in a north-west of Spain sample.

Subjects and Methods

To evaluate the impact and implications of ICRS implantation on the corneal surface, we conducted a retrospective, observational, nonrandomized, and single-center case series of patients implanted with Keraring segments (Mediphacos, Belo Horizonte, Brazil) using the manual technique.

Sample and inclusion criteria

The study was conducted at the Anterior Segment Unit from Hospital de Conxo-Complejo Hospitalario de Santiago de Compostela (A Coruña, Spain), and comprises a total of 21 moderate and severe KC subjects according to the Amsler-Krumeich classification, aged 31.14 ± 10.65 years. The study protocol was approved by the Ethic and Scientific Committees of the University of Santiago de Compostela (Spain) and followed the tenets of the

Declaration of Helsinki. Eligibility criteria included KC subjects, 18 years of age or older, showing reduced spectacle/contact lens best corrected distance visual acuity or contact lens intolerance and maximum corneal power (Kmax) between 49 to 70 D. Diagnosis and grading of the disease was based on corneal topography and slit lamp examination.

Ocular assessment

All patients underwent a complete preoperative examination, including routine evaluation of Snellen Uncorrected Distance Visual Acuity (UDVA), Snellen Best-Corrected Distance Visual Acuity (CDVA), refractive error, fundus examination, slit lamp biomicroscopy, corneal topography and pachimetry with particular attention to the occurrence of ocular adverse events. Topographic analysis was performed using Pentacam (Oculus GmbH, Wetzlar, Germany), which include 3mm-area keratometric readings, corneal astigmatism, kmax, eccentricity, corneal thickness (minimum, apex and central), and several aberrometric parameters. The same protocol was applied preoperative and 6-months after ICRS implantation.

Surgery and postoperative procedures

All surgeries were performed by the same surgeon under sterile conditions with topical anesthesia 0.5% proparacaine hydrochloride solution (Alcaine, Alcon). The appropriate Keraring segments diameter (6-mm diameter), thickness and length (degrees) were selected in accordance with nomogram proposed by the manufactures, and then implanted into the eye. The incisions were always made in the steepest corneal meridian. Corneal tunnelization for ring segment insertion was performed by mechanical technique dissection and a Keraring vacuum device (Mediphacos, Belo Horizonte, Brazil) was employed to stabilize the globe and to keep the plane of dissection of the tunnel by suction. After marking the geometrical center of the cornea, a 1.2mm radial incision was performed using a calibrated diamond blade (Sinsky hook), at the depth of 80% corneal thickness at the steepest meridian. An intrastromal pocket was created using a small incision with a semicircular micro-dissector that operates under suction, until finishing the tunnels in the desired directions (clockwise and counterclockwise dissection) and 6mm in diameter. Once this step was completed, the surgeon removes the suction and the Keraring implant was placed into the pocket using implantation forceps. The pocket was self-sealing and did not require suturing. Subsequently, a PureVision silicone hydrogel bandage contact lens (Bausch & Lomb) was placed on the cornea and then removed 1 day after the surgery. No intraoperative complications occurred. Postoperative treatment comprised betamethasone drops four times a day, topical tobramycin 0.3% (Tobrex, Alcon) four times a day, and preservative-free artificial tears (Artelac Rebalance, Bausch & Lomb, Inc., North Bridgewater, NJ, USA) six times a day. The tobramycin drops were discontinued 1 week after the surgery, while the betamethasone dosage was tapered over a period of 4 to 6 weeks.

Data Analysis

The Shapiro-Wilk normality test was implemented to assess all data sets for normal distribution. The categorical variables (sex and

number of right and left eyes) are expressed as frequencies. The continuous variables (age and the pre- and postoperative UDVA, CDVA, sphere, cylinder, spherical equivalent, K1, K2, Kmean, Kmax, corneal pachometry and aberrometric measurements) are expressed as means with Standard Deviations (SD) for easier comparisons and interpretation with the existing literature. The differences between the preoperative and postoperative measurements were compared using paired t-tests when parametric statistical analysis was possible, and the Wilcoxon Signed ranks test for non-parametric evaluation. Pearson or Spearman correlation coefficients were used to evaluate correlation between different variables, depending on whether normal distributions of data were observed. For statistical purposes, P value less than 0.05 was considered statistically significant. SPSS v.24.0.0.0 (IBM Corporation, Armonk NY) and

Excel v.15.0 (Microsoft Corporation, Redmond WA) software were used for all statistical analysis and graphs.

Results

Visual and refractive parameters

A summary of the visual and refractive changes in eyes implanted with keraring segments are shown in Table 1. Both, mean UDVA and CDVA were significantly increased following 6-months after ICRS implantation. Mean preoperative sphere, corneal cylinder and manifest spherical equivalent were significantly decreased at 6-months after surgery. However, when vector decomposition of refraction was performed J0 and J45 vectors changes were not statistically significant.

Table 1: Refractive changes data before and 6-months after surgery.

UDVA (uncorrected distance visual acuity); CDVA (corrected distance visual acuity); MRSE (manifest refractive spherical equivalent); J0 (Humphrey vector cross cylinder compound fixed at 0°/90°); J45 (Humphrey vector cross cylinder compound fixed at 45°/135°); D (dioptre)

^aPaired samples t-test; ^bWilcoxon signed rank test

Variable	Preoperative	Postoperative	Change	P
UDVA (Snellen)	0.12±0.15	0.35±0.19	0.23±0.09	<0.001 ^b
CDVA (Snellen)	0.47±0.21	0.68±0.17	0.21±0.18	0.005 ^a
Sphere (D)	-3.43±2.21	-2.27±2.55	1.16±2.36	0.023 ^b
Cylinder (D)	-5.42±1.94	-2.08±1.48	3.33±1.53	0.002 ^a
MRSE (D)	-5.14±2.69	-3.32±2.50	1.82±2.58	0.004 ^a
J0 (D)	0.18±1.97	-0.07±1.07	-0.24±2.01	0.584 ^a
J45 (D)	-0.02±2.17	-0.10±0.73	-0.08±2.05	0.867 ^a

Topographic parameters and postoperative outcomes

Table 2 summarizes topographic and pachometric data preoperative and 6-months after Kerarings implantation. As shown in Figure 1, the Kerarings flattening effect was more evident in the steepest 3-mm area (P=0.05) when compared with the mean 3-mm keratometry readings with a 1.94 D decrease effect on the anterior corneal astigmatism (P<0.001). The stronger flattening effect was observed on the maximum keratometry readings when compared pre- and postoperative values (P<0.001). A similar trend was observed in the radius of anterior Best Fit Sphere (BFS) preoperative and 6-month after surgery (P=0.020). Mean

Central Corneal Thickness (CCT) showed a slightly higher increase (2.0%), although non-clinically significant after 6-months of ICRS implant. A similar trend was observed for apex (P=0.186) and minimum corneal thickness (P=0.067). As expected, significant correlations were found between postoperative outcomes and preoperative topographic corneal parameters, as well as segment parameters (Table 3). Using the nomograms for ICRS implantation recommended by the manufacture, we found a moderate correlation between the thicker Keraring segments and changes in manifest cylinder (r=0.491; P=0.023) and changes in BFS (r=0.440; P=0.046).

Table 2: Summary of the topographic and pachometric data after 6-months Keraring implantation.

K1 (corneal power in the flattest 3-mm area); K2 (corneal power in the steepest 3-mm area); k2-k1 (mean corneal astigmatism in the 3-mm area); Km (mean corneal power in the 3-mm area); Kmax (maximum corneal power in the 8-mm area); BFS (best-fit sphere); CCT (central corneal thickness); D (dioptre); µm (microns)

^aPaired samples t-test; ^bWilcoxon signed rank test

Variable	Mean±SD			P
	Preoperative	Postoperative	Change	
K1 (D)	46.02±3.47	46.01±3.15	-0.01±2.18	0.992 ^a
K2 (D)	51.34±4.55	49.41±3.25	-1.93±3.39	0.050 ^b
K2-K1 (D)	05.32±2.37	03.38±2.41	-1.94±3.50	0.020 ^a
Km (D)	48.49±3.70	47.71±2.97	-0.78±1.98	0.095 ^a
Kmax (D)	57.40±6.44	51.97±4.01	-5.43±5.16	<0.001 ^a

Anterior BFS (D)	43.55±3.05	42.40±2.24	-1.05±2.56	0.020 ^b
Eccentricity	0.88±0.32	0.75±0.33	-0.13±0.36	0.079 ^b
CCT (mm)	478±39	487±58	9.10±49.73	0.412 ^a
CTapex (mm)	462±41	478±62	15.95±53.41	0.186 ^a
CTmin (mm)	448±40	461±47	12.90±30.57	0.067 ^a

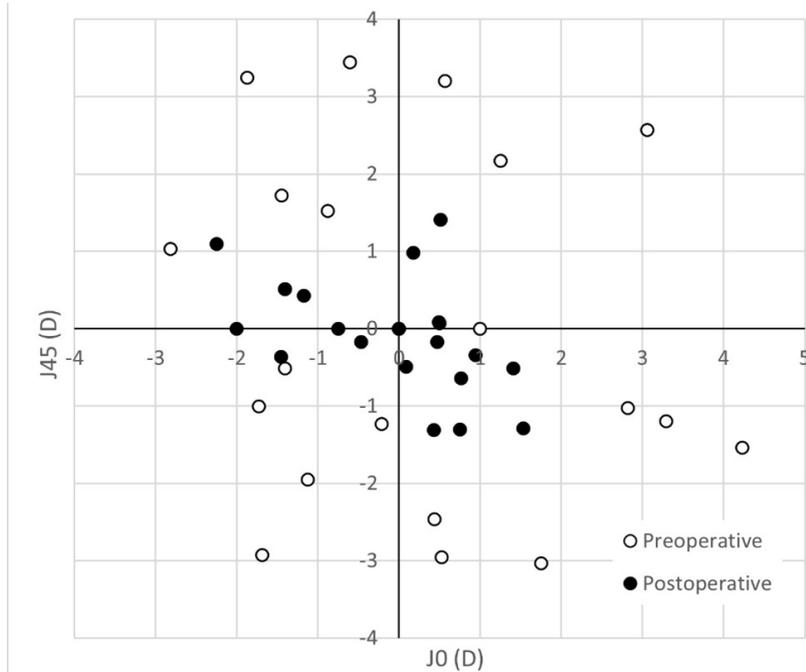


Figure 1: Humphrey vector cylinder compound of the refraction showing a remarkable less dispersion for postoperative values.

Table 3: Statistically significant correlations of the 6-month postoperative outcomes with preoperative topographic, aberrometric and Keraring segment parameters.

UDVA (uncorrected distance visual acuity); CDVA (corrected distance visual acuity); MRSE (manifest refractive spherical equivalent); TKS (thicker Keraring segment); K2 (corneal power in the steepest 3-mm area); K2-K1 (mean corneal astigmatism in the 3-mm area); Km (mean corneal power in the 3-mm area); Kmax (maximum corneal power in the 8-mm area); BFS (best-fit sphere); CA (corneal astigmatism); RMS (root mean square); HOA (higher order aberration); D (dioptrre); μm (microns); Zernike terms (Zordermode)

^aPearson correlation; ^bRho Spearman

Variable	Correlation ^{a,b}	Correlation Coefficient	P
Change in CDVA (Snellen)	Preop K2	0.51	0.018 ^a
	Preop Km	0.507	0.019 ^a
	Preop Kmax	0.502	0.021 ^a
	Preop CTapex	-0.641	0.002 ^a
	Preop CTmin	-0.65	0.001 ^a
	Preop Primary Vertical CA Z ₂ ²	-0.78	<0.001 ^a
	Preop 4 th -order spherical aberration Z ₄ ⁰	-0.54	0.011 ^a
Change in manifest Cylinder (D)	Preop Cylinder	-0.657	0.001 ^a
	Preop MRSE	-0.437	0.047 ^a
	Preop K2	0.482	0.027 ^a
	Preop kmax	0.582	0.006 ^a
	Preop Primary Oblique CA Z ₂ ⁻²	-0.444	0.044 ^a
	Preop Horizontal Coma Z ₂ ²	-0.574	0.006 ^a
	TKS	0.491	0.023 ^a

Change in MRSE (D)	Preop Sphere	-0.612	0.003 ^b
	Preop Cylinder	-0.475	0.029 ^b
	Preop MRSE	-0.668	0.001 ^b
	Preop Vertical Coma Z_3^{-1}	-0.622	0.003 ^b
Change in Mean Kmax (D)	Preop K2	-0.687	0.001 ^a
	Preop K2-K1	-0.643	0.002 ^a
	Preop Kmax	-0.782	<0.001 ^a
	Preop Eccentricity	-0.483	0.027 ^a
	Preop 4 th -order spherical aberration Z_4^0	0.574	0.007 ^a
Change in Mean K2-K1 (D)	Preop K2	-0.545	0.011 ^a
	Preop K2-K1	-0.498	0.022 ^a
	Preop Kmax	-0.728	<0.001 ^a
Change in Mean BFS (D)	Preop Kmax	-0.634	0.002 ^b
	Preop 4 th -order spherical aberration Z_4^0	0.466	0.033 ^b
	Preop RMS HOA	-0.437	0.048 ^b
	TKS	0.44	0.046 ^b
Change in Vertical Coma Z_3^{-1} (mm)	Preop Primary Oblique CA Z_2^{-2}	0.461	0.035 ^a
	Preop Vertical Coma Z_3^{-1}	0.871	<0.001 ^a
	TKS	0.588	0.005 ^a
Change in Oblique Trefoil (mm)	Preop Sphere	-0.636	0.026 ^a
	Preop MRSE	-0.583	0.046 ^a

Aberrometric parameters and postoperative outcomes

Table 4 summarizes aberrometric data before and 6-months after surgery. A significant decrease was observed in the mean RMS high order aberrations values (P=0.045). The vertical coma, oblique trefoil and oblique corneal astigmatism became, on average, less positive after surgery (P=0.020, P=0.018 and P<0.01 respectively). No significant changes were observed in total RMS or other residual aberrations. Negative significant correlations were found between postoperative change in best CDVA and

several preoperative aberrometric corneal parameters (Table 3), such as primary vertical corneal astigmatism (r=-0.780; P<0.001), and spherical aberration (r=-0.540; P=0.011). Figure 2 shows the negative relationship between change CDVA and the significant correlated aberrometric factors. Similarly, negative correlations were found between MRSE or change in manifest cylinder and different preoperative aberrometric corneal parameters. Scatter grams showing the negative relationship between change in MRSE or manifest cylinder and preoperative coma can be seen in Figure 3.

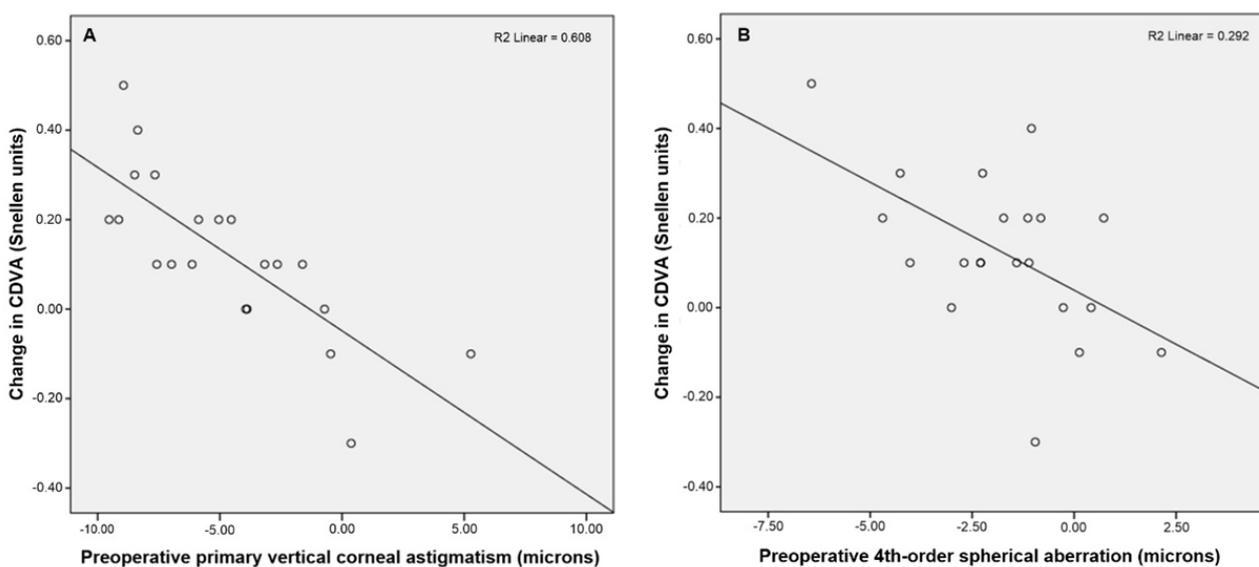
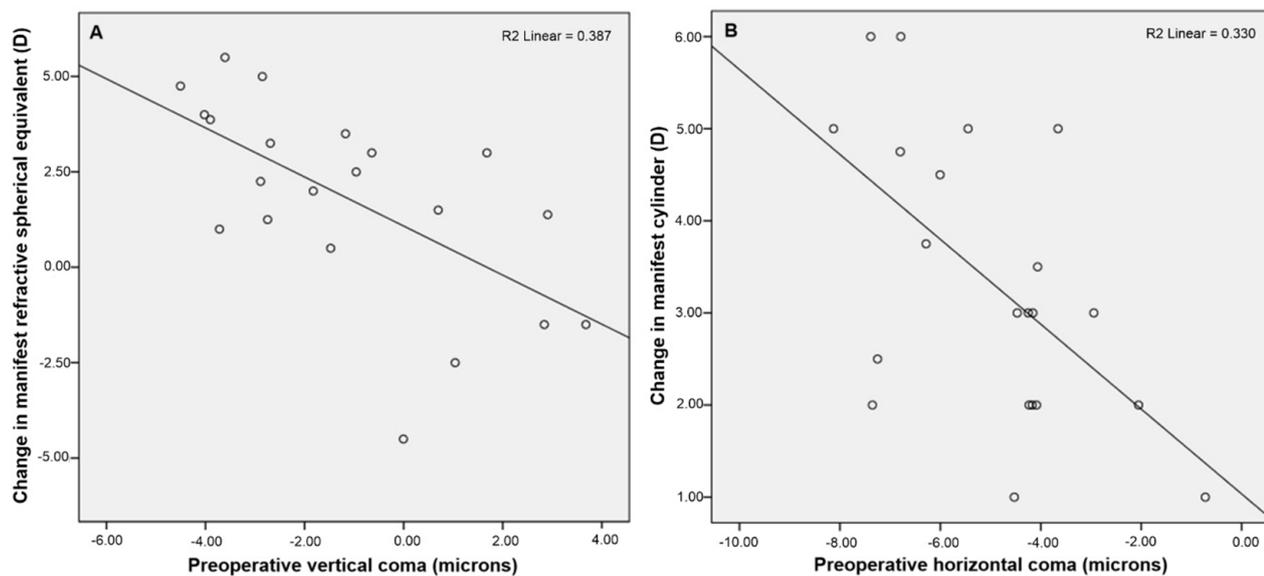


Figure 2: Scatter grams showing the relationship between the change in the best corrected distance visual acuity and: A) Preoperative primary vertical corneal astigmatism; B) Spherical aberration.

Table 4: Summary of the corneal aberrometric data after 6-months Keraring implantation.RMS (root mean square); HOA (higher order aberration); μm (microns); Zernike terms ($Z_{\text{order}}^{\text{mode}}$)^aPaired samples t-test

Variable	Mean \pm SD			P
	Preoperative	Postoperative	Change	
RMS HOA (mm)	5.20 \pm 1.92	3.98 \pm 2.08	-1.22 \pm 2.63	0.045 ^a
Vertical coma Z_3^{-1} (mm)	3.15 \pm 2.50	1.30 \pm 1.31	-1.85 \pm 1.83	0.020 ^a
Horizontal coma Z_3^1 (mm)	4.99 \pm 1.91	4.07 \pm 2.92	-0.92 \pm 1.16	0.111 ^a
Primary spherical aberration Z_4^0 (mm)	1.76 \pm 2.00	1.54 \pm 1.59	-0.22 \pm 1.73	0.657 ^a
Primary Vertical CA Z_2^2 (mm)	4.72 \pm 3.81	3.31 \pm 4.03	-1.41 \pm 1.56	0.171 ^a
Primary Oblique CA Z_2^{-2} (mm)	3.02 \pm 3.12	0.63 \pm 2.54	-2.39 \pm 1.86	0.009 ^a
Oblique Trefoil Z_3^3 (mm)	0.72 \pm 1.28	0.14 \pm 1.37	-0.58 \pm 0.91	0.018 ^a

**Figure 3:** Scatter grams showing the relationship between: A) The change in manifest refractive spherical equivalent and preoperative vertical coma; B) The change in manifest cylinder and preoperative horizontal coma.

Discussion

The decrease in visual quality in subjects with keratoconus is not only due to low-order aberrations (sphero-cylindrical refractive error) resulting from corneal protrusion but is also due to high-order ones. This is practically explained by the fact that spectacles in most cases are not able to provide full correction. This study evaluated the effect of Kerarings (mechanical implantation with a vacuum device) on visual, refractive, topographic and aberrometric outcomes in patients with KC and high myopia 6-months after ICRS surgery.

Visual acuity and refractive parameters

The current study showed a significant reduction in manifest sphere, cylinder and spherical equivalent which are in agreement with previous authors [15-20]. Consistent with the significant reduction in refraction, our study showed a significant improvement from 2 to 3 lines in UCVA and CDVA, which is consistent with other studies reporting greater increase in UDVA than in CDVA, [16] while other authors have observed better results in CDVA than UDVA [17].

Factors justifying these differences could be attributed to variations in the structure and thickness of the segments, distance from the center, as well as orientation and symmetry in the insertion of the rings [18]. In fact, baseline disease severity and the pattern of ectasia are so heterogeneous in keratoconic eyes, that generalizations are not possible or may have not sense. A significant finding in this study is that visual acuity changes have been higher for those patients with more severe stages of the disease. This finding agrees with the current approaches for sequential KC treatment that assumes other treatments for early forms of KC including corneal cross-linking and contact lenses, leaving ICRS when the disease is already stable and eventually more advanced [19]. An improvement in UDVA is attributable mostly to a reduction in lower order aberrations (MRSE, sphere or cylinder), while an improvement in CDVA is attributed to reduction in corneal aberrations (primary spherical aberration, corneal astigmatism, or coma).

Topographic parameters and postoperative outcomes

In the majority of studies, ICRS implantation induces a significative reduction in Km and Kmax readings between 2 to 5

D, with a significant astigmatic reduction between 1.5 to 2.75 D, allowing an improvement of visual acuity ranging to 1 to 7 lines in CDVA [9-10,19-21]. This high variation in visual performance depends on KC stage, cone location, astigmatism characterization and ICRS type [19-22]. The present investigation shows a no significant Km reduction by 0.78 D, but a significant Kmax reduction by 5.43 D with a decreased corneal astigmatism by close to 2.00 D associated with astigmatic reduction by 3.33 D. Associated with those changes, in this study, we found an improvement of 0.21 Snellen units between pre-operative and post-operative UDVA which is in agreement with most of the reviewed literature [19-21]. However, Km change in this study seems to be lower than that found by other authors, probably because we have more severe cases, with higher preoperative corneal astigmatism and poorer pre-operative corrected and uncorrected visual acuity, so the factors in relation to the characteristics of the subjects with KC may be behind these differences. The present study shows that reduction of corneal astigmatism is the main factor justifying the improvement in visual acuity. This reduction has been found in most of the eyes (19 out of 21) except one eye without measurable changes and another eye with a significant increase in astigmatism. Reduction ranged from 0 to 10 D of cylinder. In line with arguments of different indications for different stages of KC, the role of ICRS in corneal stabilization has also been object of interest by the ophthalmological community and has been proposed that maximum curvature and thinnest corneal thickness might be used as indicators for KC stabilization/progression [23]. In the present study, we observed a reduction in Kmax and an increase in the corneal thickness parameters. However, as we did only make a single measurement after surgery, the present study cannot verify the effect of ICRS in corneal stability overtime due to the relatively short follow-up period. Several studies investigating the potential role of ICRS in disease stabilization found that implantation of ICRS does not significantly influence progressive keratoconus in young patients with confirmed progression of the disease [24-26]. Since other authors found ICRS implantation to be a stable procedure for restoring vision in patients with KC, this matter should be further investigated [27].

Finally, because of the flattening induced by this technique, there is another important beneficial outcome. Considering the limited improvement in UDVA and CDVA obtained by the ICRS implantation, contact lenses are usually necessary to complement the rehabilitation. This strategy has proved to be successful in previous publications, using different materials and fitting approaches [28-29]. The topographic findings from this study might be also relevant on this regard as we have found a reduction in maximum keratometric reading and reduction in anterior corneal astigmatism. This might have implications in contact lens fitting at different levels. First, the flattening effect observed in the flattening for the steepest meridian by 1.90 D and by over 5.50 D in the Kmax parameter. This flattening is also observed in the BFS parameter with a reduction of nearly 1.00 D. This represents a flattening of the overall corneal curvature that might improve the fitting of a corneal rigid gas permeable contact lens. Second, reduction of anterior corneal astigmatism nearly 2.00 D might also improve the

fitting of the contact lens as it is usual to find a steep fitting along the flattest meridian. From the fitting point of view, we hypothesize that a reduction of nearly 0.20 mm in the steepest curvature, 0.40 mm in corneal astigmatism might improve corneal lens fitting. However, we acknowledge that the presence of the ICRS, thickening the mid-peripheral cornea, might also present a challenge to the fitting as the location of these segments might create a mechanical conflict with the underlying corneal tissue. However, this might be overcome using larger diameter lenses supported by the peripheral cornea outside the 5-6 mm of the ICRS tunnel.

Aberrometric parameters and postoperative outcomes

When corneal aberrations were analyzed, vertical coma, primary oblique corneal astigmatism and trefoil decreased 6-months after surgery, as the main aberrometric changes found in this study. In addition, we found a significant postoperative RMS HOA at 6 mm improvement while no changes were observed in other residual aberrations which supports the findings of some authors and contradicts others [15,20]. The predominant aberrometric defect in KC is the coma aberration, particularly its vertical component, such is the case that Alió and Shabayek used this parameter to modify the classic Amsler-Krumeich classification for KC, introducing coma aberration as one of the indicators [30]. Coma has been found to be decreased in the short-term and the long-term periods after ICRS implantation [8,17,21]. Since different authors have demonstrate that coma has a negative effect on visual acuity [24], the reduction in coma aberration, especially in vertical coma, might also explain the improvement in CDVA found in this investigation, which is in agreement with other authors [20,23,25]. However, there are other studies reporting no significant changes in any corneal aberrometric parameter after ICRS implantation by mechanical tunnelization, which is contradictory to the findings of the present study [15]. That study found that mechanical tunnelization specifically for Intacs implantation in eyes with early to moderate KC has limited the potential aberrometric correction because the procedure itself generated new aberrations, particularly negative primary spherical aberration, and primary coma, but this trend was not specifically confirmed for Kerarings because the limitations of the study for this segment type. Other factors could explain these differences, for example, we may have included more moderate and severe cases and observed less complications compared with previous studies. Another possible explanation, as mentioned above, could be the characteristics of the segments as well as orientation and symmetry in the ICRS insertion [18,26].

Limitations

A limitation of this study is the reduced sample size. However, based on our initial estimations, the sample was powered to observe at least 1 line of improvement in visual acuity with 18 eyes enrolled. A further limitation might be considered the fact that the implantation mode has been manual while femtosecond laser-assisted technology might be considered the reference for ICRS implantation. In fact, femtosecond laser can assist in a better prediction of the depth and area of implantation, minimizes procedure duration, and reduces the risk of inflammation, but

previous research has failed to demonstrate superiority in visual outcomes when compared with manual implantation [15]. In addition, an alternative to the manual approach is to use a vacuum device, such as the employed in this study to stabilize the globe during creation of the corneal tunnel to obtain better visual acuity and more controlled corneal shape, however more research is required in this area to evaluate and compare the clinical outcomes. Furthermore, we bear in mind that still nowadays most of the implantations are made with manual technique including many tertiary reference hospitals as is our case.

In conclusion, analysis of the outcomes after Kerarings implantation showed a significant postoperative corneal flattening with a subsequent increase in UCVA and CDVA. Visual, refractive, topographic and aberrometric parameters remarkably change in the 6-month period after Keraring ICRS implantation. Correlations between visual outcomes and preoperative parameters suggest a stronger effect in KC patients with higher K2, Km or Kmax values as well as higher astigmatism, coma, and spherical aberration, which imply patients with more severe stages of the disease.

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