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Clinical outcomes of two symmetrical Kera-rings implanted in grade three keratoconus: a retrospective nonrandomized study

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Abstract

Purpose To evaluate the clinical outcomes of implanting two symmetrical Kerarings via a femtosecond laser in grade three keratoconus.

Patients and methods This was a retrospective nonrandomized controlled clinical study. The study included one eye from each of twenty-three patients, all with Grade 3 keratoconus as classified by the Amsler–Krumeich classification. The ICRS surgery was performed with the patient under topical anaesthesia (benoxinate hydrochloride 4 mg/mL 0.4%). A tunnel channel was created by a femtosecond laser using a 60-kHz infrared neodymium glass femtosecond laser at a wavelength of 1053 nm (Abbott Laboratories Inc., Abbott Park, Illinois, USA). Two symmetrical Kerarings (Mediphacos Inc., Belo Horizonte, Brazil) were implanted in all the cases with 160° arcs and 250,300 µm thicknesses according to the corneal thickness at the implantation site. After surgery, the patients underwent a full ocular evaluation on Days 1, 7, and 14 and after one month. For a period of 1 year, corneal topography readings were taken quarterly, and the numbers of Pentacam measurements were averaged.

Results Twenty-three eyes of twenty-three patients were included in this study. The mean value (±SD) of age was 22.8 (±6.84) years. Six (26.09%) eyes were from males, and 17 (73.91%) were from females. The cone location was central for all patients. Spherical error, cylindrical error, spherical equivalent (SE), uncorrected visual acuity (UCVA), and best corrected visual acuity (BCVA) significantly improved after 3, 6, 9, and 12 months compared with the preoperative values (*P* value < 0.001). There was no significant difference in the axial and pachymetry readings before and after surgery. Kmax flattened insignificantly at 3 and 6 months of follow-up, whereas significant flattening was achieved at 9 and 12 months (*P* values = 0.046 and 0.042, respectively). The K mean, K1, K2, anterior elevation, topographic cylinder, and Q value posterior to the corneal surface were significantly lower at the 3-, 6-, 9- and 12-month follow-up visits than preoperatively (*P* value < 0.05). Posterior elevation and the Q value of the anterior corneal surface were significantly greater after surgery (3, 6, 9, and 12 months) than before surgery (*P* value < 0.05). With respect to the Belin ABCD grading system, A and D significantly improved throughout the follow-up visits (3, 6, 9, and 12 months) (*P* value < 0.001), whereas B and C did not significantly differ between the 3-, 6-, 9- and 12-month follow-up visits and the preoperative values.

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Conclusion Grade 3 KC, with the central cone managed with two symmetrical kera-rings, showed favourable results with respect to clinical and topographic outcomes, with improvements in the ABCD staging system of KC.

Keywords Kera-rings, Keratoconus, Central cone, Femtosecond laser

Introduction

Keratoconus (KC) has been classically defined as irreversible, noninflammatory, progressive corneal ectasia; however, more recent studies have detected low-level chronic inflammatory components in the tear films of KC patients, which could support an association between keratoconus and chronic inflammation [1]. This condition is characterized by progressive corneal thinning with inferior corneal steepening, which causes irregular astigmatism, corneal protrusion, and decreased visual acuity; it typically presents in early adulthood and progresses until the third decade of life before it becomes stable [2, 3].

Lines of treatment for KC are variable and are mostly dependent on the time of disease detection, with progression prevention being the mainstay of management. Corneal collagen cross-linking (CXL) is a minimally invasive option, and copper sulfate eye drops (IVMED-80) and extracellular vesicles are noninvasive treatment options. Scleral lenses, intracorneal ring segments, corneal allogenic intrastromal ring segments, and deep anterior lamellar keratoplasty are invasive options for visual rehabilitation [4].

Intracorneal ring segments (ICRS) surgery is a well-tolerated and effective surgical option, offering, in most cases, long-term improvements in refractive and keratometric measurements of patients with keratoconus, and it helps delay corneal transplantation. ICRS are polymethyl methacrylate (PMMA) segments with variable arc lengths (90–340 degrees), widths (150–350 μm), shapes (triangular and hexagonal), and optical zones (5, 6, or 7 mm) [5]

The segments are inserted into the corneal stroma through a manual or femtosecond laser-made channel according to a patient-oriented strategy and empirical nomograms to reduce geometric steepening by inducing an arc-shortening effect [6, 7].

Most studies reported flattening of the anterior cornea by 2.5 D (average mean values) [8] after ICRS implantation, whereas the posterior corneal surface showed an unpredictable response in terms of flattening or steepening [8, 9], with generally large intersubject variability in postoperative corneal topography. Very few studies have evaluated ICRS-induced corneal changes in both the anterior and posterior corneal surfaces and the corneal Q value in relation to the ICRS geometry and implantation parameters [10].

The effect of ICRS implantation on corneal criteria will not only improve the knowledge of the contribution of each corneal surface effect to the resulting quality of vision but also provide insights into the mechanism of action of the ICRS, resulting in a better estimation of postoperative corneal shape, and help improve the predictability of patients' refractive outcomes and the implantation nomogram.

The aim of our study was to evaluate the clinical outcomes of implanting two symmetrical Kerarings via a femtosecond laser in grade three keratoconus.

Patients and methods

This was a retrospective nonrandomized controlled clinical study. The research protocol received ethical approval from the Institutional Review Board of the Sohag Faculty of Medicine (Sohag University, Egypt; ethical approval number **(Soh-MED-24–05–03PD)**) and adhered to the tenets of the Declaration of Helsinki. The surgeries were conducted at a private eye centre (Future Femtolaser Center in Sohag, Egypt).

The study included one eye from each of twenty-three patients, all with Grade 3 keratoconus as classified by the Amsler–Krumeich classification [11].

The Amsler–Krumeich classification is the oldest but still one of the most widely used systems for the identification and assessment of KC progression. This grading system is based on topographic analysis of the anterior corneal surface, corneal thickness, refraction, and biomicroscopy [12].

All the study participants provided written informed consent for their participation in the study and for publication of the study results.

Patients were selected for ICRS surgery with the following inclusion criteria: stable keratoconus (stability defined as no more than 1.00 D change in the mean keratometric readings over the last 12 months) [13] without any other associated ocular or systemic pathology that could affect vision; documented history of corneal cross-linking performed at least 6 months before presentation; spectacle-corrected visual acuity insufficient to carry out daily tasks; contact lens intolerance; a minimum corneal thickness of 350 μm at the thinnest point (TP) and 450 μm at the insertion location; and a mean keratometry (K mean) value less than 59 D; understanding that spectacles or contact lenses may be needed to achieve optimal postoperative visual acuity; and the ability to complete the follow-up.

Clinical examination of the patients included measurements of uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA) in LogMAR, visual refraction, biomicroscopy, fundus evaluation, and topographic and tomographic parameters, such as keratometry measurements, maximum keratometry (K max), mean keratometry (K mean), flat keratometry (K1), and steep keratometry (K2), in addition to anterior and posterior elevation and corneal thickness, the topographic cylinder, and Q values of the anterior (Q anterior) and posterior (Q posterior) corneal surfaces. The ABCD grading system was used. The corneal topography (sagittal map) evaluations were performed by Pentacam (OCULUS Optikgeräte GmbH, Wetzlar, Germany). The Belin ABCD staging system for KC (topometric/KC staging) was developed to thoroughly explain the structural and functional abnormalities observed in KC patients based on tomographic measurements and visual acuity. The letter 'A' indicates the anterior radius of curvature within the 3-mm zone centred on the TP, whereas the letter 'B' represents the posterior radius of curvature within the same 3-mm zone. 'C' represents corneal thickness at the TP, and 'D' represents the distant-best corrected visual acuity [14].

All the surgeries were performed by the same corneal surgeon (A.M.). The ICRS surgery was performed with the patient under topical anaesthesia (benoxinate hydrochloride 4 mg/mL 0.4%). A tunnel channel was created by a femtosecond laser using a 60-kHz infrared neodymium glass femtosecond laser at a wavelength of 1053 nm (Abbott Laboratories Inc., Abbott Park, Illinois, USA). The intended tunnel depth was estimated to be 80% of the total corneal thickness at the incision site. The inner diameter of the tunnel was 5 mm, and its outer diameter was 5.9 mm. The entry cut had a length of 1.40 mm and a thickness of 1 mm. The axis of the incision was determined on the basis of the steepest meridian. A value of 1.95 J was used for both the ring energy and the entry cut energy [15]. All the keraring segments were the SI-5 model (Mediphacos Inc., Belo Horizonte, Brazil), which is synthesized from poly(methyl methacrylate) and consists of a triangular, cross-sectional design and a 5 mm optical zone. Two symmetrical kerarings with 160° arcs and 250,300 μm widths were implanted in all the patients according to the corneal thickness at the implantation site.

The location of the cone was determined according to the keratometric values and the steep axis. A reference line was drawn along the steep meridian on the sagittal topography map. The type of corneal asymmetry was determined by studying the steep area on each side of the reference meridian. If the reference line separates the steep area into two equal parts, the cone's location is described as 'central'. However, if the line divides the steep area into unequal parts, the cone's location is said to be 'asymmetric' [16].

All patients received antibiotic eye drops containing 0.5% moxifloxacin hydrochloride (Vigamox; Alcon Laboratories Inc., Fort Worth, Texas, USA), steroid eye drops containing 1% prednisolone acetate (Econopred Plus; Alcon Laboratories Inc.), and lubricating eye drops (Systane Ultra; Alcon Laboratories Inc.). During the first week, all topical eye drops were delivered five times daily. The antibiotic eyedrop was discontinued after 1 week, and the steroid eyedrops were gradually tapered to be discontinued within 1 month in all eyes, while lubricating eye drops were applied as needed.

After surgery, the patients underwent a full ocular evaluation on Days 1, 7, and 14 and after one month. For a period of 1 year, corneal topography readings were taken quarterly, and the number of Pentacam measurements was averaged.

Statistical analysis

Statistical analysis was performed with SPSS v26 (IBM Inc., Chicago, IL, USA). The Shapiro–Wilk test and histograms were used to evaluate the normality of the distribution of the data. The quantitative parametric data are presented as the means and standard deviations (SDs) and were compared via paired t tests. Qualitative variables are presented as frequencies and percentages (%). A two-tailed P value < 0.05 was considered statistically significant.

Results

The mean value ($\pm$ SD) of age was 22.8 ($\pm$ 6.84) years. Six (26.09%) patients were male, and 17 (73.91%) patients were female. The eyes were OD in 12 (52.17%) patients and OS in 11 (47.83%) patients. The cone location was central for all patients (central cones were defined as being within a 1.5 mm radius from the centre of the cornea, and peripheral cones were defined as being outside of a 1.5 mm radius from the centre of the cornea, whether symmetrical or not) [17] (Table 1).

According to the Amsler–Krumeich classification, all the included eyes exhibited Grade 3 keratoconus with a cylindrical error (-6.1 ± 2.2), average K value (52.6 ± 4.28), and corneal thickness at the thinnest location (434.8 ± 38.47), and they had no corneal scars [12].

Spherical error, cylindrical error, spherical equivalent (SE), UCVA, and BCVA were significantly better throughout the follow-up schedule (at 3, 6, 9, and 12 months)

Table 1 Demographic data and cone locations of the studied patients

		N = 23
Age (years)		22.8 ± 6.84
Sex	**Male**	6 (26.09%)
	Female	17 (73.91%)
Eye	**OD**	12 (52.17%)
	OS	11 (47.83%)
Cone location	**Central**	23 (100%)

Data are presented as the mean ± SD or frequency (%); *OD* oculus dexter, *OS* oculus sinister

than they were preoperatively (*P* value < 0.001). Axis and pachymetry data were unchanged (Table 2).

A comparison of the original patient data with the post-Kera-ring implantation data revealed that the Kmax flattened postoperatively, with a more significant flattening effect observed at 9 and 12 months of follow-up (3 and 6 months, *P* value = 0.046; 9 and 12 months, *P* value = 0.042). K mean, K1, K2, anterior elevation, topographic cylinder, and the Q value of the posterior corneal surface significantly improved after 3, 6, 9, and 12 months compared with the preoperative values (*P* value < 0.05), whereas the posterior elevation and the Q value of the anterior corneal surface significantly increased after 3, 6, 9, and 12 months compared with the preoperative values (*P* value < 0.05) (Table 3).

Figure 1 shows two cases as examples of changes in corneal topographic outcomes before and after surgery.

With respect to the Belin ABCD grading system, (A) significantly flattened during the follow-up period after 3, 6, 9, and 12 months compared with the preoperative values (*P* value < 0.001). (D) improved after ICRS implantation throughout one year of follow-up (*P* value < 0.001). (B & C) did not improve throughout the follow-up period compared to the pre-operative values (Table 4).

Discussion

Keratoconus (KC) is a corneal ectatic disease that endangers young individuals, causing visual impairment, and can be ameliorated in a majority of patients [18].

Kera-ring (ICRS) implantation is a safe, effective, and minimally invasive procedure, especially with the advent of the femtosecond laser. It has been shown to delay or even prevent the need for keratoplasty in patients with KC, conferring significant improvement in visual acuity [19, 20].

In this study, we attempted to evaluate the efficacy of femtosecond laser-assisted ICRS implantation in patients with KC. Twenty-three eyes with Grade 3 KC were included and were followed for 3, 6, 9, and 12 months.

Compared with the preoperative values, the spherical equivalent, UCVA, and BCVA significantly improved throughout the follow-up visits. The improvements in visual acuity (UCVA and BCVA) could be partially explained by improvements in refraction due to corneal flattening and the regularization effect of ICRS implantation. In addition, the improvement in the Q value of the anterior corneal surface was associated with decreased primary spherical aberration and resultant better visual acuity [21]. Our results were consistent with those of Mohamed A Heikal et al., Kubaloglu et al., and Jadidi et al., who reported significant improvements in the

Table 2 Visual data before and after Kera-ring implantation in the studied patients

	Preoperative	After 3 m	After 6 m	After 9 m	After 12 m
Sphere	−5.7 ± 2.66	−1.8 ± 2.81	−2.3 ± 2.8	−2.3 ± 3.03	−2.1 ± 2.83
P value		**< 0.001***	**< 0.001***	**< 0.001***	**< 0.001***
Cylinder	−6.1 ± 2.2	−3.5 ± 2.19	−4.1 ± 2.15	−4.1 ± 2.24	−4.1 ± 2.5
P value		**< 0.001***	**< 0.001***	**< 0.001***	**< 0.001***
Axis (°)	64.8 ± 53.87	75 ± 51.52	74.3 ± 51.69	73.8 ± 47.06	75.2 ± 47.7
P value		0.076	0.069	0.101	0.100
SE (D)	−8.7 ± 3.08	−3.5 ± 3.01	−4.5 ± 3.01	−4.4 ± 3.35	−4.3 ± 3.24
P value		**< 0.001***	**< 0.001***	**< 0.001***	**< 0.001***
UCVA	0.1 ± 0.03	0.2 ± 0.06	0.2 ± 0.08	0.2 ± 0.06	0.2 ± 0.08
P value		**< 0.001***	**< 0.001***	**< 0.001***	**< 0.001***
BCVA	0.3 ± 0.07	0.4 ± 0.09	0.4 ± 0.14	0.4 ± 0.09	0.4 ± 0.11
P value		**< 0.001***	**< 0.001***	**< 0.001***	**< 0.001***
Pachymetry (at the thinnest location) (μm)	434.8 ± 38.47	431.2 ± 34.07	432.1 ± 34.08	433.3 ± 33.57	435.5 ± 33.94
P value		0.405	0.534	0.719	0.873

[*] Significant with *P* value ≤ 0.05. Data are presented as the mean ± SD, *SE* spherical equivalent, *UCVA* uncorrected visual acuity, *BCVA* best-corrected visual acuity

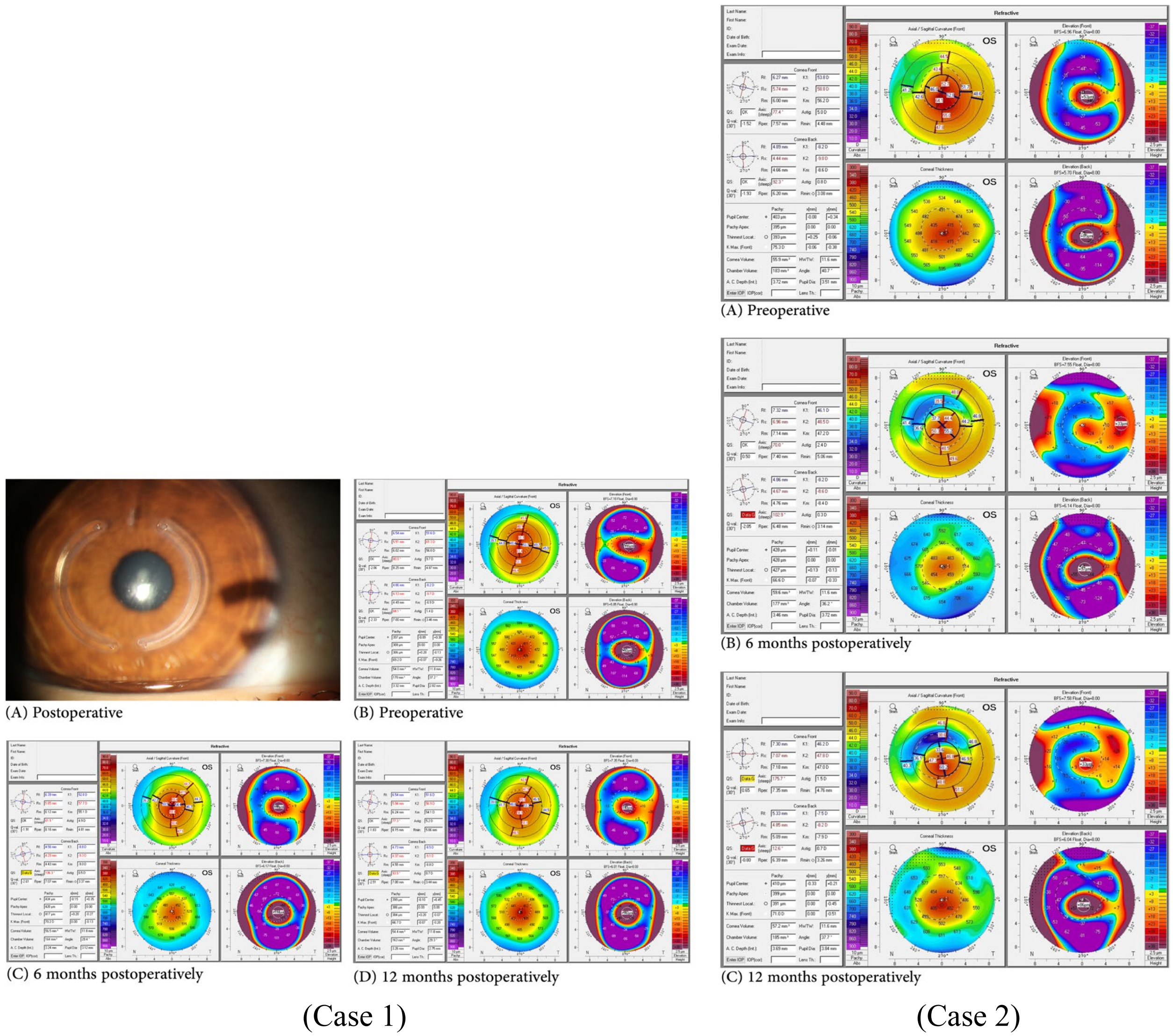

Fig. 1 Shows two cases. Case 1: **A** Postoperative photo-slit lamp photo after 2 symmetrical Kerarings were implanted. **B** Preoperative Pentacam. **C** Postoperative Pentacam after 6 months. **D** Postoperative Pentacam after 12 months. Case 2: **A** Preoperative Pentacam. **B** Postoperative Pentacam after 6 months. **C** Postoperative Pentacam after 12 months

mean LogMAR UCVA and BCVA following Keraring implantation for 6 months, whereas in our study, the patients were followed for 12 months [22–24].

Keratometry readings (K max, K mean, K1, and K2) all flattened during the follow-up period, which is consistent with previous studies reporting that Kera-rings have a significant corneal flattening effect and manifest the ability to change the geometry of corneal tissue, especially in those with advanced disease grades, which could continue up to one year postoperatively [22, 25–27].

The Q value of the anterior corneal surface was significantly improved, with a value of (−0.6 ± 0.63) instead of (−1.3 ± 0.5) preoperatively, and it was closer to the ideal prolate structure, with a Q value (−0.46) that decreased the primary spherical aberration of the eye and helped improve visual acuity postoperatively [21].

We reported flattening in the anterior corneal elevation and anterior and posterior corneal radius of curvature, although the difference was statistically insignificant for the posterior radius of curvature. This flattening effect can be explained by the fact that the ring segments acted as spacers between the corneal lamellae and consequently reduced the arc length of the central lamellae, which is in agreement with the findings of most previous studies [28, 29].

Table 3 Keratometry measurements before and after Kera-ring implantation in the studied patients

	Preoperative	After 3 m	After 6 m	After 9 m	After 12 m
K max (D)	63.7 ± 9.02	61.9 ± 7.49	61.8 ± 7.5	61.7 ± 7.19	61.7 ± 7.42
P value		0.061	0.051	**0.046***	**0.042***
K mean (D)	52.6 ± 4.28	48.9 ± 3.87	49 ± 3.95	48.9 ± 3.86	48.9 ± 3.6
P value		**< 0.001***	**< 0.001***	**< 0.001***	**< 0.001***
K1 (D)	50.3 ± 4.12	47.2 ± 3.86	47.1 ± 3.86	47.1 ± 3.82	46.8 ± 3.6
P value		**< 0.001***	**< 0.001***	**< 0.001***	**< 0.001***
K2 (D)	55.3 ± 4.77	50.7 ± 4.22	50.9 ± 4.36	50.7 ± 4.25	51 ± 4.24
P value		**< 0.001***	**< 0.001***	**< 0.001***	**< 0.001***
Anterior elevation	36 ± 13.79	27.4 ± 10.92	27.2 ± 10.29	27 ± 10.59	26.4 ± 11.2
P value		**< 0.001***	**< 0.001***	**< 0.001***	**< 0.001***
Posterior elevation	69.7 ± 28.51	78.4 ± 30.51	79.3 ± 32.23	77.7 ± 32.77	79.3 ± 33.31
P value		**0.006***	**0.008***	**0.022***	**0.006***
Topographic cylinder (D)	5 ± 2.39	3.5 ± 2.2	3.8 ± 2.4	3.6 ± 2.48	4.2 ± 3.21
P value		**0.002***	**0.019***	**0.016***	0.218
Q value anterior corneal surface	−1.3 ± 0.5	−0.6 ± 0.64	−0.6 ± 0.66	−0.6 ± 0.63	−0.6 ± 0.73
P value		**< 0.001***	**< 0.001***	**< 0.001***	**< 0.001***
Q value posterior corneal surface	−1.5 ± 0.59	−1.7 ± 0.66	−1.7 ± 0.65	−1.7 ± 0.65	−1.7 ± 0.62
P value		**< 0.001***	**< 0.001***	**0.002***	**0.002***

[*] Significant with *P* value ≤ 0.05. Data are presented as the mean ± SD. *K max* maximum keratometry, *K mean* mean keratometry, *K1* flat keratometry, *K2* steep keratometry

Increased posterior corneal elevation and posterior corneal surface asphericity coefficient (Q value) were observed in our study, which is inconsistent with other studies reporting flattening of the posterior corneal surface [30, 31].

The increase in posterior corneal surface topographic values was consistent with studies reporting steepening of the posterior corneal surface following ring implantation, which could be attributed to the persistence of the cone shape on the posterior corneal surface despite its correction on the anterior corneal surface. Although anterior and posterior corneal surfaces are expected to be flattened in most cases of ICRS implantation, we should keep in mind that ectatic corneal disorders are unpredictable and that ICRS implantation might always give rise to unexpected refractive results [32, 33].

D (best-corrected distance visual acuity) improved after ring implantation, which was consistent with most of the studies reporting statistically significant improvement in distance-corrected visual acuity. We mentioned previously that the flattening effect of the ring improved keratometric readings, the anterior radius of curvature, anterior corneal elevation, and the Q value of the anterior corneal surface and significantly improved the visual acuity of the patient [21–24].

C did not change throughout the follow-up period compared with the preoperative value, which is in agreement with previous studies reporting that central

Table 4 ABCD grading system before and after Kera-ring implantation in the studied patients

	Preoperative	After 3 m	After 6 m	After 9 m	After 12 m
A	6.22 ± 0.04	6.35 ± 0.05	6.34 ± 0.04	6.33 ± 0.06	6.32 ± 0.08
P value		**< 0.001***	**< 0.001***	**< 0.001***	**< 0.001***
B	5.07 ± 0.04	5.05 ± 0.03	5.04 ± 0.06	5.03 ± 0.08	5.04 ± 0.06
P value		0.20	0.43	0.64	0.15
C	434.8 ± 38.47	431.2 ± 34.07	432.1 ± 34.08	433.3 ± 33.57	435.5 ± 33.94
P value		0.405	0.534	0.719	0.873
D	0.3 ± 0.07	0.4 ± 0.09	0.4 ± 0.14	0.4 ± 0.09	0.4 ± 0.11
P value		**< 0.001***	**< 0.001***	**< 0.001***	**< 0.001***

[*] Significant with *P* value ≤ 0.05. Data are presented as the mean ± SD. A: Anterior radius of curvature within the 3-mm zone centred on the TP. B: Posterior radius of curvature within the same 3-mm zone. C: Corneal thickness at the TP. D: Best corrected distance visual acuity

corneal thickness does not significantly change with preoperative status [32, 34, 35].

Post-ICRS implantation, an abnormal accumulation of fibrotic extracellular matrix components and proteinases near the ICRS has been reported, suggesting ongoing lysis and remodelling of the corneal stroma. Although the corneal thickness is proposed to be thickened by the spacer effect of rings, the decrease related to remodelling of the corneal stroma could explain the statistically unchanged values of corneal thickness in those patients [36].

ICRS surgery is known to be able to flatten the central portion of the anterior corneal surface and displace the peripheral area adjacent to the ring insertion forward, with a greater flattening effect exerted by the end point of each segment of the Kera-rings via traction force on the corneal surface. In addition, the presence of the corneal inlay itself within the corneal stroma may provide biomechanical support for corneal tissue [37].

Not only was objective improvement (corneal topographic changes) observed, but subjective improvement was also noticed via postoperative patient satisfaction. ICRS improved visual acuity and contrast sensitivity by improving corneal high-order aberrations and helped restore corneal regularity.

In this study, patients had a Grade 3 central cone, which is the area to be flattened with ICRS, with the cone location itself helping to achieve a significant stable objective and subjective improvement. In addition, two symmetrical Kera-rings were selected as the method of treatment for favourable results because the flattening effect exerted by the end point of each segment produces traction force on the corneal surface.

Conclusion

Grade 3 KC, in which the central cone is managed with two symmetrical Kera-rings, showed favourable results with respect to clinical and topographic outcomes, with improvements in the ABCD staging system of KC.

Authors' contributions

Dr. Amr Mounir was the main surgeon, contributed to the preparation of the study protocol and he is the corresponding author. Dr. Ibrahim Amer contributed to the conceptualization of the paper, the statistical analyses and revised the manuscript. Dr.Alaa Mahmoud revised the manuscript, contributed to preparation of the study protocol. Dr. Islam Awny conducted statistical analyses and revised the manuscript. Dr. Elshimaa A.Mateen Mossa drafted the manuscript and contributed to preparation of the study protocol and conducted statistical analyses. All authors read and approved the final manuscript.

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Data availability

The datasets used or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study followed the tenets of the Declaration of Helsinki, and the approval of the ethics committees was obtained from the "Medical Research Ethics Committee" of Sohag Faculty of Medicine, Sohag University under IBR Registration number: (Soh-MED-24-05--03PD).

All methods were carried out in accordance with relevant guidelines and regulations. We obtained written informed consent from all participants after the methods and purpose of the research were explained, allowing sufficient time for questions and ensuring clarity.

Consent for publication

All the authors agree to publish this research article.

Competing interests

The authors declare no competing interests.

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