Original Article

Intracorneal ring segment implantation for eyes with keratoconus and corneas thinner than 400 microns

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ABSTRACT

Background: Intracorneal ring segment (ICRS) implantation is a promising and effective treatment option for keratoconus. However, a corneal thickness of less than 400 microns presents a unique challenge. This study assessed the clinical course and visual outcomes in patients with Amsler–Krumeich stage 2 or greater keratoconus and clear corneas, with a minimal corneal stromal thickness of 350 microns but less than 400 microns in the proposed implantation area, up to 6 months after ICRS implantation.

Methods: This non-randomized, prospective, interventional case series was conducted at a single tertiary center, consecutively recruiting patients with keratoconus scheduled for ICRS implantation who fulfilled the eligibility criteria. Detailed ophthalmological assessments were performed at baseline and 6 months postoperatively, including measurements of uncorrected distance visual acuity (UCDVA), best corrected distance visual acuity (BCDVA), and manifest refraction with documentation of the spherical component of the refractive error (in diopters [D]), cylindrical component of refractive error (in diopter cylinder [DC]), and axis of astigmatism (in degrees). Corneal topographic and pachymetric evaluations were performed using Pentacam HR, including keratometry (K) values in D (flat K or K1, steep K or K2, and mean K or Km), corneal astigmatism in DC, central corneal thickness (CCT), and corneal asphericity coefficient (Q value).

Results: We included nine eyes of nine patients with keratoconus and a mean (standard deviation) age of 33.2 (8.2) years (range: 25–44 years). Five patients were women (56%), and four were men (44%). All eyes experienced a statistically significant improvement in the mean visual and refractive outcomes at the 6-month postoperative visit, including UCDVA, BCDVA, sphere, and cylinder (all $P < 0.05$). Similarly, we recorded a statistically significant improvement in the mean corneal tomographic and topographic data, including the K1, K2, Km, CCT, and Q values (all $P < 0.05$). No serious complications occurred for up to 6 months of follow-up. Only one patient complained of night glare, which was successfully treated with pilocarpine 1% eyedrops for 3 months.

Conclusions: ICRS implantation may offer a safe and effective option for selected patients with keratoconus and corneal thickness less than 400 microns, as evidenced by short-term improvements in visual, refractive, topographic, and tomographic parameters. No vision-threatening complications occurred. However, given the case-series study design, limited sample size, and short follow-up period, these findings should be interpreted with caution. Further controlled trials are required to validate these preliminary results.

KEYWORDS

corneas, ectasia, keratoconus, laser corneal surgeries, visual acuities, ocular refraction, corneal topographies, corneal pachymetric measurement

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INTRODUCTION

In advanced keratoconus, the cornea becomes excessively thin, rendering glasses or soft contact lenses insufficient for visual acuity improvement [1]. Under these circumstances, surgical procedures may improve corneal shape and vision. A common surgical intervention for keratoconus is intracorneal ring segment (ICRS) implantation, sometimes referred to as Keraring or Intacs [2, 3]. ICRS implantation entails the insertion of synthetic ring segments into the corneal stroma to straighten the central corneal curvature, diminish astigmatism, and enhance vision [2, 3].

The efficacy of ICRS implantation in enhancing vision and preventing disease progression is widely documented in the literature [4, 5]. Implantation of an ICRS can result in substantial enhancements in best corrected distance visual acuity (BCDVA) and decreases in refractive error, especially in patients with mild-to-moderate keratoconus. Moreover, ICRS implantation is a reversible and less invasive treatment than full-thickness corneal transplant surgery and is a viable alternative for many patients with keratoconus [2, 6, 7].

Corneal thickness is crucial for intracorneal ring planning and success [8]. The corneal stroma must be sufficiently thick to accommodate ring segments without stressing or deforming them. ICRS implantation in individuals with thin corneas may lead to problems such as corneal perforation, elevated intraocular pressure, and poor visual outcomes [9, 10]. Mechanical stress on an already thin cornea can cause gradual thinning or rupture, necessitating corneal transplantation or other invasive surgery [9, 10].

Despite these concerns, several studies have suggested that ICRS implantation may still benefit certain patients with thin corneas [11, 12]. In such cases, careful preoperative assessment, including detailed topographic and tomographic analyses, is crucial for determining the suitability of the procedure. Furthermore, advances in ring design, surgical techniques, and postoperative management have improved the outcomes of certain patients with thin corneas, offering the potential to delay or prevent the need for corneal transplantation [12-14].

Although ICRS implantation is promising as an effective treatment for keratoconus, a corneal thickness of less than 400 μm presents unique challenges [12]. We evaluated the 6-month clinical course and visual outcomes following ICRS implantation in patients with stage 2 or greater keratoconus, clear corneas, and a minimal corneal stromal thickness of 350 μm but less than 400 μm in the proposed implantation area.

METHODS

This non-randomized, prospective, interventional case series was conducted at a single tertiary center from August 2023 to October 2024, consecutively recruiting patients with keratoconus scheduled for ICRS implantation. The study adhered to the principles of the Declaration of Helsinki and received ethical approval from the Damietta Faculty of Medicine, Al-Azhar University, Damietta, Egypt. Written informed consent was obtained from each individual at the time of recruitment.

We included eyes with stage 2 or greater keratoconus (according to the Amsler–Krumeich classification) [15] with clear corneas, contact lens and glasses intolerance, a minimal corneal stromal thickness of 350 μm but less than 400 μm in the proposed implantation area, with or without a history of corneal collagen cross-linking (CXL), and patient age > 18 years. The exclusion criteria were history of any corneal surgery except CXL; history of infectious keratitis, retinal detachment, or glaucoma; and breastfeeding or lactation.

All patients underwent a complete medical history review, demographic data collection, and general examination. Detailed ophthalmological assessments were performed at baseline and 6 months postoperatively, including the measurement of uncorrected distance visual acuity (UCDVA) and BCDVA using a Snellen chart (Auto Chart Projector, CP 670; Nidek Co., Ltd., Gamagori, Japan) and recorded in decimal notation. Manifest refraction was conducted using a commercial autorefractor (KR-800; Topcon, Japan), and the recorded data included the spherical component of the refractive error (in diopters [D]), cylindrical component of the refractive error (in diopter cylinder [DC]), and axis of astigmatism (in degrees). Corneal topographic and pachymetric evaluations were accomplished using the Scheimpflug imaging-based system, Pentacam HR (Oculus Optikgerate GmbH, Wetzlar, Germany), including keratometry (K) values in D (flat K or K1, steep K or K2, mean K or Km); corneal astigmatism in DC; central corneal thickness (CCT) in μm; and corneal asphericity coefficient (Q value) at the baseline and 6-month postoperative visits.

A senior fellowship-trained corneal subspecialist (A.F.E.) performed all operations using topical anesthetic eye drops (benoxinate hydrochloride 0.4%, Benox; Epico, Egypt). An FS 200 femtosecond laser platform (Alcon Laboratories, Inc., Fort Worth, TX, USA) was used to generate the corneal tunnels. To maintain at least 100 μm of corneal tissue under the tunnels, the corneal tunnels were made at 70% of the corneal depth. In all cases, Keraring segments from Mediphacos in Belo Horizonte, Brazil, were implanted. The number of segments, their diameters (SI5 or SI6), arc lengths, and thicknesses were chosen based on the manufacturer's nomogram and the measured scotopic pupil size [16]. Topical 0.5% moxifloxacin (Vigamox; Alcon Pharmaceuticals, Fort Worth, TX, USA) was instilled intraoperatively. Postoperatively, tobramycin 0.3%/dexamethasone 0.1% (Tobradex®; Alcon Laboratories Inc., Fort Worth, TX, USA) eyedrops were prescribed four times daily for 2 weeks.

Statistical analyses were performed using IBM SPSS Statistics for Windows (version 26.0; IBM Corp., Armonk, NY, USA). The normality of data distribution was tested using the Kolmogorov–Smirnov test. Qualitative data are presented as numbers and percentages. Quantitative data are presented as means and standard deviations (SDs). Statistically significant differences between the baseline and 6-month postoperative visual, refractive, topographic, and tomographic parameters were determined using a paired *t*-test. *P*-values < 0.05 were considered significant.

RESULTS

We included nine eyes of nine patients with keratoconus and a mean (SD) age of 33.2 (8.2) years (range: 25–44 years). Five patients were women (56%), and four were men (44%) (Table 1).

All eyes demonstrated a statistically significant improvement in the mean visual and refractive outcomes at the 6-month postoperative visit, including UCDVA, BCDVA, sphere, and cylinder, as presented in Table 2 (all $P < 0.05$). Similarly, we recorded statistically significant improvements in the mean corneal tomographic and topographic data, including K1, K2, Km, CCT, and Q value, as demonstrated in Table 3 (all $P < 0.05$). Table 4 presents the detailed demographic and clinical characteristics of each participant. No serious complications occurred during the 6-month follow-up. Only one patient (Patient 2, Table 4) reported postoperative night glare. The symptoms were managed with topical pilocarpine 1% eye drops administered over 3 months, resulting in complete resolution without recurrence.

Table 1. Demographic characteristics of study participants

Variables	Values
Age (y), Mean ± SD (Range)	33.2 ± 8.2 (25 to 44)
Sex (Men / Women), n (%)	4 (44%) / 5 (56%)

Abbreviations: y, years; SD, standard deviation; n, number of participants; %, percentage.

Table 2. Comparison of baseline and 6-month postoperative visual and refractive parameters

Variables	Baseline	6 months postoperative	*P*-value
UCDVA (decimal), Mean ± SD	0.2 ± 0.2	0.3 ± 0.1	**0.002**
BCDVA (decimal), Mean ± SD	0.4 ± 0.2	0.6 ± 0.2	**0.002**
Sphere (D), Mean ± SD	- 4.50 ± 2.50	-3.50 ± 1.90	**0.001**
Cylinder (DC), Mean ± SD	- 4.00 ± 4.40	-2.60 ± 1.50	**0.001**

Abbreviations: UCDVA, uncorrected distance visual acuity; BCDVA, best corrected distance visual acuity; sphere, spherical component of the refractive error; D, diopter; cylindrical component of the refractive error; DC, diopters cylinder. Note: *P*-values < 0.05 are shown in bold.

Table 3. Comparison of baseline and 6-month postoperative corneal topographic and tomographic parameters

Variables	Baseline	6 months postoperative	*P*-value
K1 (D), Mean ± SD	50.4 ± 3.1	46.7 ± 3.2	**0.002**
K2 (D), Mean ± SD	55.5 ± 4.9	49.1 ± 3.5	**0.001**
Km (D), Mean ± SD	52.8 ± 3.9	47.8 ± 3.2	**0.001**
CCT (μm), Mean ± SD	380.6 ± 19	396.8 ± 26.8	**0.01**
Q-value	- 1.3 ± 0.6	- 0.61 ± 0.6	**0.005**

K1, flat keratometry value; D, diopter; SD, standard deviation; K2, steep keratometry value; Km, mean keratometry value; CCT, central corneal thickness; Q-value, corneal asphericity coefficient. Note: P-values < 0.05 are shown in bold.

Table 4. Individual demographic and clinical characteristics of study participants

Patient	Age	Sex	KCN Stage	H/O CXL	Baseline	6 months postoperative
1	25 y	Woman	Stage 3	Yes	UCDVA: 0.1 decimal BCDVA: 0.3 decimal Sphere: - 4.00 D, Cylinder: 7.00 DC K1: 54.3 D, K2: 60.9 D, Km: 57.4 D CCT: 381 µm Q-value: - 1.42	UCDVA: 0.2 decimal BCDVA: 0.6 decimal Sphere: - 2.75 D, Cylinder: 0.60 D K1: 49.5 D, K2: 50.1 D, Km: 49.8 D CCT: 403 µm Q-value: - 0.90
2	25 y	Woman	Stage 3	Yes	UCDVA: 0.3 decimal BCDVA: 0.5 decimal Sphere: - 1.75 D, Cylinder: 8.00 DC K1: 50.4 D, K2: 57.7 D, Km: 53.8 D CCT: 397 µm Q-value: - 1.42	UCDVA: 0.4 decimal BCDVA: 0.7 decimal Sphere: - 1.00 D, Cylinder: 3.00 DC K1: 46.0 D, K2: 48.6 D, Km: 47.2 D CCT: 417 µm Q-value: - 0.50
3	39 y	Woman	Stage 4	No	UCDVA: 0.05 decimal BCDVA: 0.2 decimal Sphere: - 4.75 D, Cylinder: - 6.00 K1: 52.8 D, K2: 58.3 D, Km: 55.4 D CCT: 350 µm Q-value: - 1.70	UCDVA: 0.3 decimal BCDVA: 0.4 decimal Sphere: - 4.00 D, Cylinder: - 2.50 DC K1: 44.3 D, K2: 46.3 D, Km: 45.3 D CCT: 369 µm Q-value: - 0.19
4	31 y	Woman	Stage 2	Yes	UCDVA: 0.2 decimal BCDVA: 0.4 decimal Sphere: - 2.50 D, Cylinder: - 2.50 DC K1: 44.1 D, K2: 46.2 D, Km: 45.1 D CCT: 350 µm Q-value: - 0.70	UCDVA: 0.3 decimal BCDVA: 0.9 decimal Sphere: - 1.75 D, Cylinder: - 3.00 DC K1: 40.2 D, K2: 43 D, Km: 41.5 D CCT: 367 µm Q-value: - 0.18
5	39 y	Man	Stage 3	No	UCDVA: 0.1 decimal BCDVA: 0.5 decimal Sphere: - 3.00 D, Cylinder: -2.50 DC K1: 49.6 D, K2: 52.0 D, Km: 50.8 D CCT: 398 µm Q-value: - 1.30	UCDVA: 0.3 decimal BCDVA: 0.7 decimal Sphere: -2.25 D, Cylinder: 0.50 DC K1: 46.4 D, K2: 46.9 D, Km: 46.6 D CCT: 415 µm Q-value: - 0.30
6	26 y	Man	Stage 4	No	UCDVA: 0.3 decimal BCDVA: 0.4 decimal Sphere: - 3.25 D, Cylinder: 7.00 DC K1: 54.0 D, K2: 60.7 D, Km: 57.1 D CCT: 392 µm Q-value: - 2.40	UCDVA: 0.3 decimal BCDVA: 0.5 decimal Sphere: - 3.00 D, Cylinder: 3.50 DC K1: 51.1 D, K2: 54.6 D, Km: 52.8 D CCT: 412 µm Q-value: - 2.20
7	26 y	Man	Stage 3	No	UCDVA: 0.7 decimal BCDVA: 0.9 decimal Sphere: - 4.50 D, Cylinder: 8.00 DC K1: 50.4 D, K2: 58.5 D, Km: 54.1 D CCT: 395 µm Q-value: - 2.02	UCDVA: 0.8 decimal BCDVA: 1.0 decimal Sphere: - 4.00 D, Cylinder: 2.00 DC K1: 47.2 D, K2: 48.8 D, Km: 48.0 D CCT: 432 µm Q-value: - 0.20
8	44 y	Man	Stage 3	No	UCDVA: 0.05 decimal BCDVA: 0.2 decimal Sphere: - 8.00 D, Cylinder: 3.00 DC K1: 48.1 D, K2: 50.9 D, Km: 49.5 D CCT: 368 µm Q-value: - 0.20	UCDVA: 0.1 decimal BCDVA: 0.3 decimal Sphere: - 6.00 D, Cylinder: 3.00 DC K1: 49.1 D, K2: 50.9 D, Km: 49.5 D CCT: 368 µm Q-value: - 0.20
9	44 y	Woman	Stage 3	No	UCDVA: 0.1 decimal BCDVA: 0.4 decimal Sphere: - 9.00 D, Cylinder: 4.50 DC K1: 50.1 D, K2: 54.3 D, Km: 52.1 D CCT: 395 µm Q-value: - 1.10	UCDVA: 0.2 decimal BCDVA: 0.5 decimal Sphere: - 7.00 D, Cylinder: 5.50 DC K1: 47.3 D, K2: 52.8 D, Km: 49.9 D CCT: 377 µm Q-value: - 0.50

Abbreviations: y, years old; KCN, keratoconus; H/O, history of; CXL, corneal collagen cross-linking; UCDVA, uncorrected distance visual acuity; BCDVA, best corrected distance visual acuity; sphere, spherical component of the refractive error; D, diopter; cylindrical component of the refractive error; DC, diopters cylinder; K1, flat keratometry value; D, diopter; K2, steep keratometry value; Km, mean keratometry value; CCT, central corneal thickness; Q-value, corneal asphericity coefficient. Note: Staging of KCN is according to the Amsler–Krumeich classification [15].

DISCUSSION

Nine eyes of nine patients with keratoconus (mean age: 33.2 years; 56% female) and minimal stromal thickness ranging from 350–400 μm underwent ICRS implantation. At the 6-month follow-up, all eyes demonstrated statistically significant improvements in visual and refractive outcomes and corneal topographic and tomographic parameters. No serious complications were reported; however, one patient experienced night glare, which was successfully managed with the administration of pilocarpine 1% eye drops for 3 months.

Over the past 20 years, innovations in keratoconus care have emphasized the prevention of corneal transplantation. Although the prognosis of keratoplasty in keratoconus is favorable, the operation is intricate and involves heightened inflammatory responses and increased risks of infection and corneal graft rejection [17]. Numerous studies have validated the efficacy of CXL and the fitting of specialized contact lenses, including scleral lenses, for the treatment of keratoconus [18-21]. Similarly, certain studies have demonstrated the efficacy of ICRS implantation in keratoconus, facilitating regularization of the corneal surface, enhancement of visual quality, and increased tolerance of contact lenses [22-24]. We observed significant improvements in visual, refractive, atopographic, and tomographic parameters 6 months after ICRS implantation in eyes with keratoconus and thin corneas.

ICRS implantation is not intended to prevent the advancement of corneal ectatic diseases, despite reports of the long-term efficacy of this procedure [16]. How the ICRS works biomechanically is unknown; however, in practice, the cornea flattens significantly at the segment's insertion hemimeridian [2, 25]. Thus, a symmetric positioning of the ring flattens the cornea in all areas, whereas the placement of a single segment flattens the cornea along the meridian and steepens it at an angle of 180° [26]. In our series, we detected a significant short-term postoperative improvement in keratometry values.

Long-term stability has been reported following ICRS implantation in eyes with progressive keratoconus [26-29], with 92.9% of the eyes exhibiting no postoperative progression; however, 18 eyes experienced keratoconus instability after ICRS implantation. Although visual, refractive, and topographic characteristics improved in the short term, regression was detected after 5 years, suggesting that ICRS implantation may not significantly affect progressive keratoconus in young patients with verified progression [26-29]. Based on the outcomes of studies with long-term follow-up after ICRS implantation [26-29] and considering the significant short-term clinical improvements in our patients with keratoconus, caution is advised about generalizing our findings to all eyes with keratoconus and thin corneas.

Because ICRS implantation is challenging and controversial, especially in patients with thin corneas [12], this study investigated the visual and clinical outcomes of ICRS insertion in patients with keratoconus and thin corneas. We observed no adverse events up to 6 months post-implantation, and the eyes experienced considerable enhancement in visual and refractive parameters, demonstrating that this treatment for keratoconus could be safe and effective in the short term. Ongoing improvement in visual function after ICRS implantation is likely due to adaptation to the ICRS diameter, which reduces side effects, such as glare and night-vision issues [2, 30, 31]. This hypothesis would explain our patients' subjective reports of improved vision and fewer adverse effects over time. This is in agreement with the findings of Barbara et al. [13], who assessed the refractive and visual outcomes of nine eyes with keratoconus and a mean (SD) corneal thickness of 424.22 (26.06) μm. They found a significant improvement in the mean (SD) UCDVA from 0.95 (0.21) logarithm of the minimum angle of resolution (logMAR) preoperatively to 0.34 (0.31) logMAR postoperatively. Moreover, they reported a significant improvement in the mean (SD) BCDVA from 0.35 (0.10) logMAR preoperatively to 0.15 (0.14) logMAR postoperatively [13].

Sardina et al. [32] recently included 31 eyes of 25 patients with keratoconus (age range: 15–50 years) who underwent implantation of ICRSs with variable thickness and base. They found a statistically significant improvement in both UCDVA and BCDVA [32]. Similarly, Prisant et al. [33] included 104 eyes with keratoconus that underwent ICRS (Keraring AS) implantation. They reported an improvement in UCDVA and BCDVA from 0.82 and 0.31 logMAR, respectively, to 0.46 and 0.2 logMAR, respectively [33]. Vega-Estrada et al. [34] assessed the outcomes of 30 eyes of 26 patients with keratoconus, reporting an improvement in the mean (SD) UCDVA and BCDVA from 0.08 (0.22) and 0.24 (0.29) decimal, respectively, to 0.22 (0.16) and 0.43 (0.18) decimal, respectively [34].

According to refractive outcomes, classic and VT-ICRS implantations improve manifest refraction by reducing central corneal curvature [13]. In our study, statistically significant improvements in the sphere and cylinder components of refraction were observed 6 months postoperatively. Abdellah et al. [35] followed 38 eyes with keratoconus for 6 years after femtosecond laser-assisted implantation of a 355° ICRS (Keraring). In agreement with our study, they found a significant improvement in the mean (SD) sphere and cylinder from - 9.68 (3.08) D and - 5.82 (1.55) DC, respectively, to - 7.45 (3.2) D and - 4.32 (1.24) DC, respectively, at 3 years postoperatively [35]. For 5 years, Kang et al. [36] followed 30 eyes with keratoconus that had undergone ICRS implantation. They reported a significant improvement in the mean (SD) sphere from - 5.521 (4.791) D preoperatively to - 4.9 (4.0) D after 5 years [36]. Utine et al. [37] evaluated the visual, refractive, and corneal asphericity changes after ICRS implantation in 42 eyes with keratoconus and found a statistically significant improvement in the mean (SD) cylinder from - 5.89 (2.40) DC preoperatively to - 2.27 (1.66) DC postoperatively [37], which is consistent with our findings.

According to the tomographic data, the mean K1 and K2 values significantly improved in our participants. In agreement with our results, Barbara et al. [13] found a significant improvement in the mean (SD) K2 from 51.94 (5.43) D preoperatively to 49.20 (5.78) D postoperatively. Larco et al. [17] found a significant postoperative improvement in K1 and K2 values, from 49.53 (5.48) D and 55.38 (5.56) D preoperatively, respectively, to 48.28 (5.35) D and 50.98 (5.71) D, respectively [17]. Daxer et al. [12] observed that the mean (SD) K improved from 48.96 (3.42) D preoperatively to 43.20 (2.99) D 1 year postoperatively [12].

Nonetheless, one must consider the possible problems associated with the ICRS. Complications may include infection, corneal thinning, corneal perforation, segment extrusion, and induced astigmatism [13]. In the present study, no serious complications were observed during follow-up. Complications can be mitigated through appropriate patient selection, surgical methodology, and postoperative care. Patients must be adequately informed about the potential risks and benefits of ICRS implantation before treatment [13].

This prospective interventional case series suggests that ICRS implantation may be safe and effective during the short term for selected individuals with keratoconus and corneal thickness less than 400 μm. Significant improvements were observed in the visual, refractive, topographic, and tomographic parameters without vision-threatening complications. However, these findings should be interpreted with caution because of our small sample size, absence of a control group, and brief follow-up duration. Larger controlled studies with longer follow-up periods are warranted to confirm these preliminary outcomes. Long-term follow-up is crucial for excluding corneal melting and ring migration or extrusion. Moreover, no validated questionnaires were used to evaluate changes in symptomatology. Despite these limitations, this study contributes novel insights into corneal tomographic and topographic alterations to the existing peer-reviewed literature on the clinical effects of ICRS implantation in patients with keratoconus and thin corneas. Further controlled trials are required to validate these preliminary results.

CONCLUSIONS

ICRS implantation may be viable and safe for managing keratoconus in patients with corneal thickness of less than 400 μm over 6 months. Significant improvements were observed in visual acuity, refractive error, and corneal topographic and tomographic parameters, with no sight-threatening complications. Nonetheless, these findings should be interpreted with caution, and larger controlled studies with extended follow-up periods are necessary to validate the long-term safety and efficacy of this intervention.

ETHICAL DECLARATIONS

Ethical approval: This study adhered to the principles of the Declaration of Helsinki and received ethical approval from the Damietta Faculty of Medicine, Al-Azhar University, Damietta, Egypt. Written informed consent was obtained from each individual at the time of recruitment.

Conflict of interest: None.

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