https://doi.org/10.15218/zjms.2025.078

# Outcome of intrastromal corneal ring segments implantation in keratoconus: 5 years follow up

Received: 05/05/2025 Accepted: 11/06/2025

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## Abstract

**Background and objective:** Keratoconus (KC) is a progressive non inflammatory bilateral (usually asymmetric) ectatic corneal disease characterized by paraxial stromal thinning, weakening that lead to corneal surface distortion, vision loss primarily from irregular astigmatism and myopia and secondly from corneal scar. The purpose of this study is to evaluate the results of implantation of Intrastromal Corneal Ring ( ICRS) in the cornea, the improvement of visual acuity and long-term mechanical stability results of keratometers values in KC after 5 years follow up of those cases.

**Methods:** In this study ICRS segments were used for the management of KC, the study continued for ten years and each case completed 5 years of follow up, the study started in January 2010 and ended in October 2019, the patients were collected from Erbil Teaching Hospital or from the researcher's private clinic. One or two ICRS were implanted in the keratoconus corneal area. Statistical analysis included preoperative and postoperative keratometry (K) values, and uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA).

**Results:** Forty-six eyes of 37 patients were involved in this study, topographical corneal changes showed by the decrease in the mean of K1, medians of K2 and the mean of K1 &K2 especially in the first postoperative month and remain stable in most of the cases throughout the 5 years period, this was statistically significant by ($P$ <0.001) value. The medians of UCVA increases in the first 3 years and at some time slightly decreases and remain stable throughout the 5 years of follow up but better than before the operations, and this results is also statistically significant by ($P$ <0.001), the medians of CDVA improved from preoperative to postoperative period during the 5years follow up and remain stable, it was statistically significant ($P$ <0.001), and this is emphasized by the number of the eyes had VA gain. The preoperative Mean of K declined from 52.0(±4) to 48.0(±3.3) in postoperative period and that was statistically significant ($P$ <0.001)

**Conclusion:** In this study there was a significant improvement in the visual acuity and keratometric readings of cases with advanced keratoconus and high astigmatism after implantation of ICRS in which the VA did not improved by glasses or contact lenses, subsequently there was improvement of the topographic state of the cornea and quality of vision for long time and thisdelay the need for corneal grafting surgery. so good selection of patients and implanting the proper ICRS by an expert surgeon will minimize the complication to nearly none. Further studies are needed with larger sample and longer period of follow up with new models of rings, nomograms or tissue implantation allograft.

**Keywords:** Intracorneal ring segment; Keratoconus; Keratometry; Visual acuity.

## Introduction

Keratoconus (KC.) is a progressive, bilateral, and non-inflammatory disease is a common disorder, occurs in approximately 1 in 2000 individuals. Typically, the central, inferior para central or inferior midperipheral cornea undergoes progressive thinning and protrusion.[1,2] resulting in a cone – shaped cornea. Considerable variations can occur in

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https://doi.org/10.15218/zjms.2025.078

clinical findings within an affected family. KC. onset occurs during puberty.[3] KC. characterized by corneal steepening and thinning, generating high degree of myopia and irregular astigmatism, thereby severely impairing visual acuity (VA.), today there are several therapeutic options to achieve visual rehabilitation of KC., such as rigid gas-permeable contact lenses, intracorneal ring segment (ICRS) implantation, corneal surface ablation combined with corneal cross linking (CXL).[4-9]

Intracorneal ring segments (ICRS) are biocompatible synthetic elements implanted into corneal stroma to modify its morphology and used to reduce corneal steepening, decreasing irregular astigmatism, and improving visual acuity.[10,11] ICRS indicated in progressive KC,[12,18] in contact lens intolerant patients, post penetrating keratoplasty astigmatism, post Excimer Laser corneal ectasia,[19] post radial keratotomy astigmatism,[20] and in Pellucid marginal corneal degeneration.[21,25]

Implantation of an intracorneal continuous ring (ICCR) has been shown to be effective in improvement of visual function and reduce the rate of keratoplasty.[26] ICRS are polymetylmetacrylate (PMMA) segments with variable arc-length (90-360 degrees), width (150-350μM), shape (triangular and hexagonal), and optical zone(5,6or7μM). There are many available types of ICRS: INTACS (Addition Technology, Sunnyvale, CA, USA and Ferrara rings (Mediphacos, Belo Horizonte, Brazil),), Kerarings (Mediphacos, Belo Horizonte, Brazil), Also INTACS subdivided to another types and other types of ICRS are available.[27] The segments are inserted in the corneal stroma through a manual or femtosecond laser made channel according to a patient-oriented strategy and empirical nomograms ,offering in most cases long-term improvement in refractive and keratometric measurements are generally qualitative and do not rely on a systematic mechanism to the corneal response to the potential different segment combinations implanted in the cornea.[9]

The objective of this study is to re-evaluate the results of implantation of ICRS in the cornea, the improvement of visual acuity and long term mechanical stability results of keratometers values in KC. eyes of 5 years follow up of those cases.

## Methods

This study was designed as a prospective one, patients were selected for ICRS surgery with the followings:

**Inclusions criteria**: No previous CXL, no improvement in VA. by spectacle, no other ocular or systemic pathology affecting vision, intolerance to contact lenses (stop contact lens wearing 2 weeks before starting our measurement) and progressive corneal steepening and thinning showed by topography.

**Exclusion criteria:** Cases with advanced keratoconus with curvature greater than 65.00 diopters (D), corneal opacity or previous acute hydrops, severe allergy (treated before ring implantation), corneal thickness less than 400μM at implantation area. In this study ICRS segments were used for the management of KC.

**Duration:** The study continued for ten years and each case completed five years of follow up , and it started in January 2010 and ended in October 2019.

**Data collection:** The patients were collected from Erbil Teaching Hospital or from the researcher's private clinic.

A detailed ophthalmological examination was performed including slit lamp examination, tonometry, autorefractometry by Nidek or Topcon machines, Topography either by Galilei or PentacamOculus device to collect the data of corneal image to decide the distribution of ectasia on the surface of the cornea, pachymetry and Keratometry (K1. & K2.).VA. as uncorrected distance (UDVA) before implantation and after implantation of the rings as corrected distance VA. (CDVA) were recorded in different periods of times, 1 month,1 year, 3 years and 5 years by Decimal design of VA.

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The ICRS which used in this study are made of polymethylmethacrylate segments (Visiontech Medical Optics). They vary in thickness (0.15mm, 0.20, 0.3mm, and 0.35mm),width base (0.60-0.65mm),5mm in diameter, the arc was 155° in all cases The selections of the ICRS were done according to the following nomograms.

**Statistical analysis:**

Data were analyzed using the Statistical Package for Social Sciences (SPSS, version 26). The normality of data was checked using the Shapiro-Wilktest; accordingly, non-parametric tests were used when indicated. Repeated measures ANOVA were used to compare readings (of normally distributed data) at different periods. Related-Samples Friedman's Two-Way Analysis of Variance by Ranks was used to compare readings (that were not normally distributed) at different periods. A *P*-value of ≤0.05 was considered statistically significant. Paired t-test to compare between K mean (K1&K2) before and after the implantations of the rings.

**Limitation of the study:** The limited number of patients in this study is because some of patients skipped out during the years and some of them were not regular on follow up.

**Surgical technique:** The ICRS were implanted according to the nomogram in Figure 1, and Table 1 by the same surgeon (J.A.), one or two rings were implanted manually according to the distribution of corneal ectatic area nomogram, the thickness of the ring calculated according to the spherical equivalent (SE), All eyes were operated under local or general anesthesia according to the age, before the anesthesia marking the 90 degree position at limbus in sitting position, central corneal reflex by light of microscope in lying position, marking the tunnels for the rings, multiple readings of corneal thickness along each tunnels were taken, the average corneal thickness measured by portable pachymeter (Tomymachine), the incision entry site done by diamond knife at the steepest topographic axis in

**Table 1** ICRS selection nomogram

| Cone | Thickness (mm) | Diameter (mm) | Intended Correction (D) |
|---|---|---|---|
| | 0.150 | 5.00 | - 2.00 to – 4.00 |
| I | 0.200 | 5.00 | - 4.25 to – 6.00 |
| II | 0.250 | 5.00 | - 6.25 to – 8.00 |
| III | 0.300 | 5.00 | - 8.25 to – 10.00 |
| IV | 0.350 | 5.00 | -10.25 to – 12.00 |

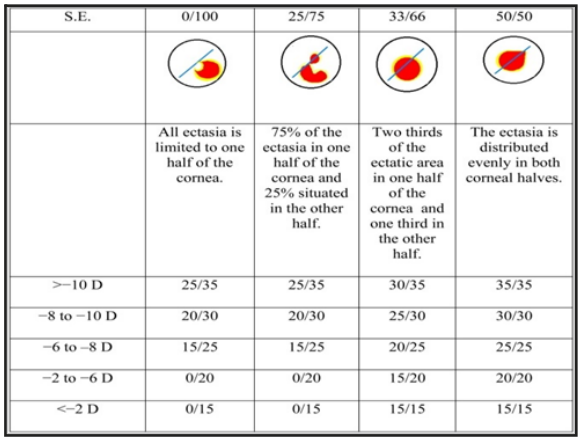


**Figure 1** Nomogram for selection of ICRS based on spherical equivalent (S.E.) and ectasia distribution

https://doi.org/10.15218/zjms.2025.078

a depth about 75% of the corneal thickness which calculated as average by pachymeter, ICRS implanted under sterile conditions with special forceps and Sinskey hook guiding the ring segments by its holes to their final position in the tunnel, and finally contact lens left for 7 days after the procedure. No surgical complications such as anterior chamber perforation occurred, all eyes showed excellent corneal tolerance with no extrusion, migration, or visualization around the incision or the tunnels. Also neither corneal ulcers nor stromal necrosis superficial to the segment were observed. Postoperatively patients kept on topical Moxifloaxacine, Fluoromethalone and artificial tear drops. Patients were reviewed in the first day and 1 week postoperatively with slit lamp biomicroscopy for wound healing and evaluation of segments migration and removal of contact lens. UDVA, CDVA, keratometry &topography were repeated at 1 month, one year, 3 years and 5 years .

**Ethical consideration**: informed consent were taken from all participants in this study, the procedure, risks, and benefits were explained to the patients.

## Results

Forty-six eyes of 37 patients with KC. were operated for rings implantation. Nine patients had bilateral surgery and 28 patients, unilateral surgery. In unilateral cases, the other eyes that not implanted were corrected by either contact lenses or glasses. Some cases achieved follow up for more than 5 years but this study selected 5 years follow up to include more cases. 0.15mm segment thickness was implanted for 11 eyes, 0.2mm segment for 14 eyes, 0.25mm segment in 46 eyes, 0.3mm segment in 14 eyes and 0.35mm segment in 4 eyes, with no complications during the surgery or post operatively.

The topographical corneal changes are clear flatting in all eyes and that's appear by the decrease in the mean of K1, 49.4 D before intervention (day zero), to 46.9 D at one month, 46.8 at one year and the increased to 47D at 5 years the differences between the base line measurement (day zero) with all other readings was significant. (*P* <0.001) but, the difference between the other readings (1 month, 1 year, 3 years & 5 years) were not significant (*P* >0.05). more details are shown in Table 2.

**Table 2** K1(D) measurements at different periods

| | Mean | SD | *P** | Groups | *P*** | Groups | *P*** |
|---|---|---|---|---|---|---|---|
| K1 (0)† | 49.4 | 3.7 | | 0 vs 1M | < 0.001 | 1M vs 3Y | 1.000 |
| K1(1Month) | 46.9 | 3.8 | | 0 vs 1Y | < 0.001 | 1M vs 5Y | 1.000 |
| K1 (1 year) | 46.8 | 3.4 | < 0.001 | 0 vs 3Y | < 0.001 | 1Y vs 3Y | 0.741 |
| K1 (3 years) | 47.0 | 3.1 | | 0 vs5Y | < 0.001 | 1Y vs 5Y | 0.137 |
| K1 (5 years) | 47.1 | 3.2 | | 1M vs 1Y | 1.000 | 3Y vs 5Y | 0.153 |

† Pre-operative period. *Calculated by repeated measures ANOVA test. **Calculated by the post-hoc Bonferroni test

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Nearly the same pattern can be applied for table 3 were its evident that there was a significant decrease of median K2 from 54.4D before the intervention to 50.2D after 5 years (*P* <0.001) and this is shown in table 3.

Table 4 shows that the medians of UCVA was 0.03 before intervention. There were significant (*P* <0.001) improvement after 1 month, 1 year, 3 years, 5 years to become 0.25, 0.28, 0.25, and 0.25 respectively. No significant differences were detected between the readings at 1 month, 1 year, 3 years, 5 years. (*P* >0.05). More details shown in table 4.

It's evident in table 5 that there was significant (*P* <0.001) improvement in the median of CDVA starting from 0.25 before intervention to 0.5 at 1 month, 1 year, 3 years, and 5 years. All the differences between the medians at 1 month, 1 year, 3 years and 5 years, were not significant (*P* >0.05). more details presented in table 5.

**Table 3** K2(D) measurements at different periods

| | Medians | Mean ranks | *P** | Groups | *P*** | Groups | *P*** |
|---|---|---|---|---|---|---|---|
| K2 (0)† | 54.4 | 4.96 | | 0 vs 1M | < 0.001 | 1M vs 3Y | 0.843 |
| K2 (1Month) | 49.7 | 2.38 | | 0 vs 1Y | < 0.001 | 1M vs 5Y | 0.011 |
| K2 (1 year) | 49.4 | 2.0 | < 0.001 | 0 vs 3Y | < 0.001 | 1Y vs 3Y | 0.176 |
| K2 (3 years) | 49.8 | 2.45 | | 0 vs 5Y | < 0.001 | 1Y vs 5Y | < 0.001 |
| K2 (5 years) | 50.2 | 3.22 | | 1M vs 1Y | 0.249 | 3Y vs 5Y | 0.019 |

† Pre-operative period. *Calculated by Related-Samples Friedman's Two-Way Analysis of Variance by Ranks. **Calculated by the post-hoc Bonferroni test.

**Table 4** UDVA measurements at different periods

| | Medians | Mean ranks | *P** | Groups | *P*** | Groups | *P*** |
|---|---|---|---|---|---|---|---|
| UDVA (0)† | 0.03 | 1.03 | | 0 vs 1M | < 0.001 | 1M vs 3Y | 0.531 |
| UDVA(1Month) | 0.25 | 3.36 | | 0 vs 1Y | < 0.001 | 1M vs 5Y | 0.817 |
| UDVA(1 year) | 0.28 | 3.76 | < 0.001 | 0 vs 3Y | < 0.001 | 1Y vs 3Y | 0.553 |
| UDVA(3 years) | 0.25 | 3.57 | | 0 vs 5Y | < 0.001 | 1Y vs 5Y | 0.147 |
| UDVA (5 years) | 0.25 | 3.28 | | 1M vs 1Y | 0.222 | 3Y vs 5Y | 0.391 |

† Pre-operative period. *Calculated by Related-Samples Friedman's Two-Way Analysis of Variance by Ranks. **Calculated by the post-hoc Bonferroni test.

**Table 5** CDVA measurements at different periods

| | Medians | Mean ranks | *P** | Groups | *P*** | Groups | *P*** |
|---|---|---|---|---|---|---|---|
| CDVA (0)† | 0.25 | 1.31 | | 0 vs 1M | < 0.001 | 1M vs 3Y | 0.271 |
| CDVA(1Month) | 0.50 | 3.28 | | 0 vs 1Y | < 0.001 | 1M vs 5Y | 0.841 |
| CDVA(1 year) | 0.50 | 3.56 | < 0.001 | 0 vs 3Y | < 0.001 | 1Y vs 3Y | 0.790 |
| CDVA(3 years) | 0.50 | 3.64 | | 0 vs 5Y | < 0.001 | 1Y vs 5Y | 0.301 |
| CDVA (5 years) | 0.50 | 3.21 | | 1M vs 1Y | 0.405 | 3Y vs 5Y | 0.194 |

† Pre-operative period. *Calculated by Related-Samples Friedman's Two-Way Analysis of Variance by Ranks. **Calculated by the post-hoc Bonferroni test.

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In figure 2 shows that the preoperative Mean of K declined from 52.0(±4) to 48.0 (±3.3) in postoperative period and that was statistically significant (*P* ≤0.001).

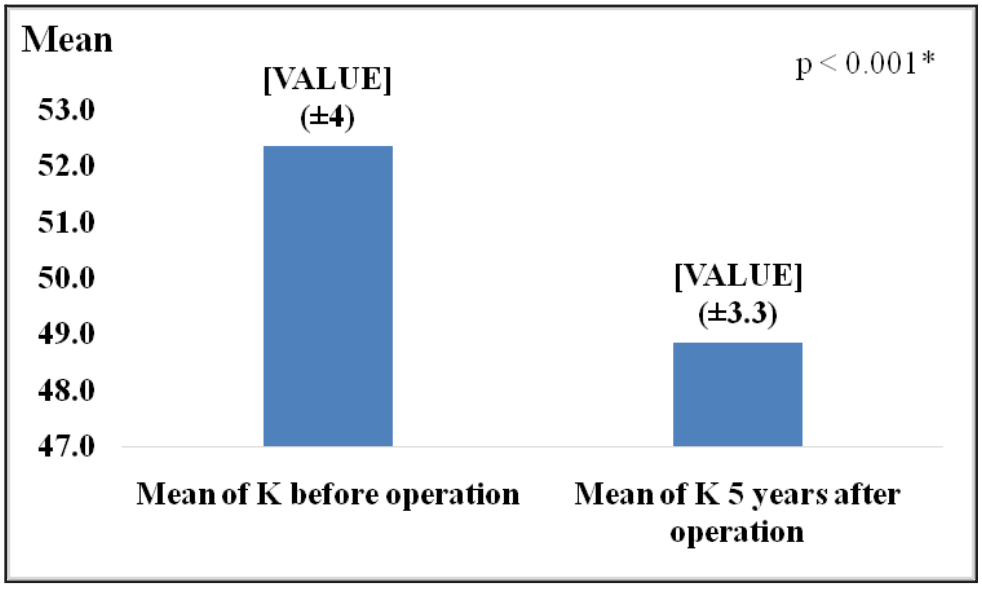
## Discussion

Many studies showed that ICRS implantation improve the visual function (UDVA and CDVA) in myopia and astigmatism by decreasing steepness of the cornea and this appear clearly through lowering keratometric readings, biomechanical stability of the cornea for long time and lowering the irregularity of the cornea especially in cases of keratoconus with high astigmatism.

In this study there was no significant complications and the results agree with other studies, Jorge L Alio et al (48 months of long follow up) reported that the mean of best spectacle-corrected visual acuity increased (BSCVA) from 0.46 preoperatively to 0.66 postoperatively (*P* ≤0.0010). The average K-value was 3.13D (*P* ≤0.001). Mean decrease of inferior-superior asymmetry was 2.81 diopters (D) (*P* ≤0.02), and mean difference between 6 and 36 months (stability) showed no significant difference regarding BSCVA (*P* ≤0.5) and inferior superior asymmetry (*P* ≤0.6). Intact ICRS increased the BSCVA and decrease the inferior superior. asymmetry with stability up to 36 months. [28]

Our study results were comparable to Min-Ji Kang, Yong-Soo Byun, et al results of 5 years postoperatively follow up which reveals that the UDVA, spherical and spherical equivalent were improved (*P* <0.05). On the other hand, CDVA was also improved for the five years period (*P* <0.05). Topographic keratometry was flattened and corneal irregularity indices were improved at five years (all *P* <0.05). Coma RMS was improved (*P* <0.05) continuously for five years.[30]

Our study matching the study done by E.L. Warrak, H.A. Serhan, et al, studied 932 eyes of 659 patients , mean total follow up time 3.02 years, 41 eyes had a total follow up of over 10 years, both UCVA and BCVA improved significantly after ICRS implantation (*P* <0.01) in majority of eyes, only 18 eyes (2.66% of eyes of patients under 35 years of age) were found to have progression of keratoconus based on postoperative topographic data (Mean age 23.00 years,




*Calculated by paired t-test.

**Figure 2** Mean of K(D) before the operation and five years after it

55.6% female, total follow up 2 to 10 years).[31]

There is ongoing improvement in the vision of ICCR patients during the first year and the next few years after surgery this because most of the patients used to the ICCR diameter of 5.0mm; this adaptation also decrease the common side effects of ICCR such as glare and night vision problems

## Conclusion

The implantation of ICRS are safe, effective, has low complication rate and indicated in advanced cases of keratoconus especially with high astigmatism in which the VA did not improved by glasses or contact lenses, and to improve the topographic state of the cornea and quality of vision for long time and delay the need for corneal grafting surgery, so good selection of patients and implanting the proper ICRS by an expert surgeon will minimize the complication to nearly none.

Further studies are needed with larger sample and longer period of follow up with new models of rings, nomograms or tissue implantation allograft

## Competing interests

The author declares that he has no competing interests.

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