ARTICLE

# Femtosecond laser implantation of a 340-degree intrastromal corneal ring segment in keratoconus: Short-term outcomes

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**Purpose:** To evaluate the short-term outcomes of femtosecond laser–assisted implantation of a 340-degree intracorneal ring (ICR) (Keraring) in patients with keratoconus.

**Setting:** Four centers in Iran.

**Design:** Prospective case series.

**Methods:** All cases had implantation of the 340-degree ICR after tunnel creation with a femtosecond laser. The uncorrected (UDVA) and corrected (CDVA) distance visual acuities, sphere, cylinder, manifest refraction spherical equivalent (MRSE), mean keratometry (K), steep K, and flat K were evaluated preoperatively and 1, 3, and 6 months postoperatively.

**Results:** Eighteen eyes of 17 patients were included. The mean follow-up was 4.33 months (range 1 to 6 months). The mean UDVA improved from 0.95 logarithm of the minimum angle of resolution (logMAR) ± 0.33 (SD) to 0.53 ± 0.35 logMAR ($P$ = .001) and the mean CDVA from 0.39 ± 0.22 logMAR to 0.26 ± 0.21 logMAR ($P$ = .09). The mean sphere decreased from −5.08 ± 3.74 diopters (D) to −1.67 ± 2.59 D, the mean cylinder from −5.83 ± 2.02 D to −2.72 ± 1.81 D, and the mean MRSE from −8.03 ± 3.88 D to −3.01 ± 2.82 D ($P$ < .001). The mean K decreased from 51.43 ± 3.59 D to 47.42 ± 3.59 D ($P$ < .001). All patients with a preoperative mean K greater than 55.0 D had worse CDVA.

**Conclusions:** Implantation of a 340-degree ICR using femtosecond laser improved the visual, refractive, and topographic parameters in keratoconic patients. The findings indicate that patients with severe keratoconus (mean K >55.0 D) are not good candidates for this type of ICR.

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Intrastromal corneal ring segments (ICRS) have been successfully used in the management of ectatic corneal disorders including keratoconus.[1] These devices modify the shape and biomechanical properties of the cornea by having an additive effect (arc-shortening effect). This leads to flattening of the central cornea,[2,3] causes central displacement of the corneal apex, and improves contact lens tolerance. In addition, ICRS preserve the prolate corneal shape, decreasing corneal irregularities and maintaining corneal thickness, and the procedure is reversible.[4–6]

There are 2 major types of ICRS, including continuous and noncontinuous. The Myoring (Dioptex GmbH) is the only commercially available continuous ring that is implanted in the corneal stroma through a pocket. It provides a more spherical correction and increases corneal strength compared with noncontinuous rings, and it has been shown to be effective in the long-term visual improvement in patients with keratoconus.[7,8] The second type of ICRS has arc lengths varying from 90 to 355 degrees. The arc length is chosen according to the cone morphology and desired refractive correction. These devices are inserted in the corneal stroma via a tunnel that is created manually or with a femtosecond laser. The major advantage of these rings is preservation of the visual axis. However, corneal crosslinking might be needed in progressive cases because these rings do not increase corneal strength.[2]

Recently, a new intrastromal corneal ring (ICR) (Keraring, Mediphacos Ltda.) with a 340-degree arc length, 5.0 mm internal diameter, 6.4 mm outer diameter, 700 µm base

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width, and 120 μm apex width was introduced. Its triangular design produces a prismatic effect to reflect incoming lights to reduce glare and halos. It is available in 2 thicknesses; that is, 200 μm for eyes with a manifest refraction spherical equivalent (MRSE) of less than −6.00 diopters (D) and the 300 μm for an MRSE of −6.00 D or greater, as recommended by the manufacturer. This modification has 2 potential advantages over the earlier ICR design with an arc length of 355 degrees; that is, it is easier to implant and it causes less wound-site vascularization and melting.[9]

In this interventional case series, we evaluated the short-term refractive, topographic, and visual outcomes of implantation of the 340-degree Keraring ICR with femtosecond laser–assisted tunnel creation in patients with keratoconus.

## PATIENTS AND METHODS

This prospective nonrandomized multicenter case series was performed from September 2014 to January 2016 in Labbafinejad Medical Centre, Negah Eye Hospital, and Basir Eye Hospital, Tehran, and Khatam-Al-Anbia Eye Hospital, Mashhad, Iran. The study protocol was approved by the Ethical Committee, Shahid Beheshti University of Medical Sciences, and adhered to the tenets of Declaration of Helsinki. All patients provided written informed consent after receiving a complete explanation of treatment options and the scheduled procedure.

Patients with a definite diagnosis of keratoconus, older than 19, who had stable disease over the past 6 months, had unacceptable vision with spectacle correction, and who were intolerant to rigid gas-permeable (RGP) contact lens were enrolled in the study in a consecutive manner. The exclusion criteria were previous ocular disease or surgery, corneal opacity or scar, corneal dystrophies, history of ocular herpes, active ocular inflammation, systemic disease (including collagen-vascular disorders, autoimmune disorders, and immunodeficiency), pregnancy, and the use of specific medications (including isotretinoin, amiodarone, sumatriptan). Also, patients with mean keratometry (K) values above 65.0 D or a central corneal thickness (CCT) less than 350 μm were excluded.

### Preoperative Evaluation

Computerized corneal topography (TMS, Tomey GmbH) was performed in all patients to evaluate the maximum (steep K), mean K, and minimum K (flat K); the steep meridian, cone morphology and location; and topographic astigmatism. Also, corneal images were obtained using a dual Scheimpflug system (Galilei G4, Ziemer Ophthalmic Systems AG) or a rotating Scheimpflug camera (Pentacam, Oculus Optikgeräte GmbH) to determine the corneal thickness at the incision site. The MRSE, sphere, refractive cylinder, and uncorrected (UDVA) and corrected (CDVA) distant visual acuities were measured. The CCT was determined by ultrasound pachymetry (SP-3000, Tomey GmbH). Also, a comprehensive ophthalmic examination including slitlamp biomicroscopy, Goldmann applanation tonometry, and dilated fundus examination was performed in all patients. The disease stage was determined according to the Amsler-Krumeich keratoconus classification.[10]

### Surgical Technique

All procedures were performed under sterile conditions in the operating room. Under topical anesthesia using tetracaine eyedrops, a radial incision on the steep meridian was created with a femtosecond laser (FemtoLDV Z6, Ziemer Ophthalmic Systems AG). Then, a circular tunnel (internal diameter 5.5 mm; external diameter 6.7 mm) was made (1.2 mJ; 3 to 4 seconds). The depth of the tunnel was set at 75% of the corneal thickness at the incision site. Next, a 200 μm or 300 μm ICR was implanted (based on manufacturer recommendations stated above) through the tunnel and rotated until it was an equal distance from the incision. At the end of the procedure, a soft bandage contact lens was placed and 1 drop of chloramphenicol 0.5% instilled.

### Postoperative Evaluation

All patients were examined postoperatively after 1 day and 7 days and then at 1 month, 3 months, and 6 months. On the first day, the bandage contact lens was removed and chloramphenicol 0.5% was started every 6 hours and continued for 1 week. In addition, betamethasone 0.1% was administered every 6 hours for the first week and then tapered over 1 month. Patients were evaluated for ring position, wound healing, and early postoperative complications at the first-week examinations. A thorough ophthalmic examination as well as all preoperative measurements (including UDVA, CDVA, MRSE, sphere, cylinder, and topography) were repeated at 1 month, 3 months, and 6 months.

### Statistical Analysis

Data were recorded in SPSS software (version 21, IBM Corp.). Final statistical analysis was performed on data of patients who completed at least 1 month of follow-up. Snellen acuities were converted to logarithm of the minimum angle of resolution (logMAR) for statistical analysis. The mean and SD were calculated with the Student *t* test. The Wilcoxon signed-rank test was used to compare preoperative values and postoperative values. Correlations between the preoperative refraction and K values and the visual outcomes were analyzed using Pearson and Spearman correlation tests. A $P$ value less than 0.05 was considered significant.

## RESULTS

The study included data for 18 eyes of 17 patients. The mean age of the 12 men and 5 women was 31 ± 7 years (range 23 to 43 years). The follow-up was 3 months in 15 eyes and 6 months in 11 eyes; the mean follow-up was 4.50 ± 2.11 months (range 1 to 6 months). The keratoconus was grade II in 8 eyes, grade III in 4 eyes, and grade IV in 6 eyes. The ICR remained well positioned in all eyes during the follow-up. Figure 1 shows an ICR in the proper position.

### Visual Acuity

Table 1 shows the preoperative and final visual acuities and Figure 2, the mean changes in acuity by keratoconus grade. After implantation of ICR, there was a statistically significant decrease in the mean logMAR UDVA ($P = .001$). Postoperatively, the UDVA increased by 2 Snellen lines or more in 12 eyes (66.67%), increased by 1 line in 3 eyes (16.67%), and was unchanged in 3 eyes (16.67%).

The mean logMAR CDVA decreased postoperatively, although the change was not statistically significant ($P = .09$). However, in eyes with a preoperative mean K of 55.0 D or less, the change in CDVA was statistically significant (Table 2). The improvement in CDVA was clinically significant (2 Snellen lines or more) in 9 eyes (50.0%). The CDVA increased 1 Snellen line in 1 eye and did not change in 4 eyes. It decreased by 1 line in 2 eyes and 3 lines in 2 eyes. No eye with grade II keratoconus had worse CDVA postoperatively; however, the CDVA was worse in 1 eye (25.0%) of 4 eyes with grade III and 3 (50.0%) of 6 eyes with grade IV. The mean preoperative mean K value in patients with worse CDVA postoperatively

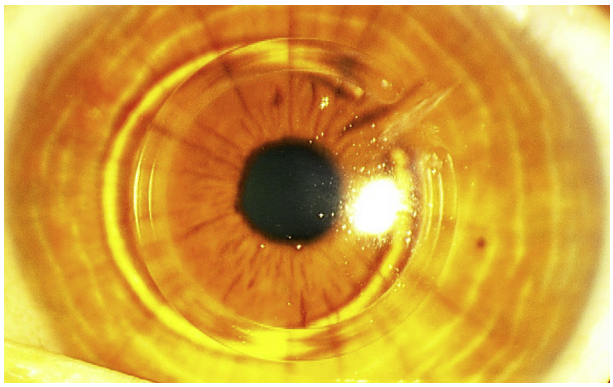

**Figure 1.** Example of the proper positioning of the 340-degree ICRS.

was 55.2 D, which was significantly higher than in patients with improved CDVA (Figure 3). All patients with a preoperative steep K of more than 60.0 D had a decrease in visual acuity after ICR implantation.

The Pearson correlation analysis found a significant correlation between preoperative mean K and postoperative UDVA ($r = 0.632$, $P = .005$) and CDVA ($r = 0.74$, $P < .001$), indicating that a higher preoperative mean K value led to worse postoperative visual acuity. In addition, patients with a higher preoperative MRSE had poorer postoperative UDVA ($r = -0.537$, $P = .022$) and CDVA ($r = -0.508$, $P = .031$). However, there was no significant correlation between preoperative sphere or cylinder and final visual acuity. Furthermore, the Spearman rank correlation analysis showed a significant correlation between an unchanged or worse postoperative CDVA change and higher preoperative mean K ($r = 0.727$, $P = .001$), flat K ($r = 0.702$, $P = .001$), and steep K ($r = 0.678$, $P = .002$) values.

## Refraction

Table 1 also shows the preoperative and final refractive parameters and Figure 2, the mean changes in them by keratoconus grade. Postoperatively, the mean MRSE decreased by 5.02 D and the mean sphere decreased by 3.41 D. Also, the mean refractive cylinder decreased by 3.11 D. Patients with more advanced keratoconus had a more significant reduction in refractive errors (Figure 2). There was a significant correlation between the preoperative MRSE and the refractive correction ($r = 0.686$, $P = .02$).

## Topography

Topographic indices, including topographic cylinder, steep K, flat K, and mean K decreased significantly after 1 month and were then stable at 6 months (Table 1 and Figure 2). There was no significant difference in the change in mean K between the grades of keratoconus.

## Complications

No eye had a significant ring-related complication (eg, rotation, displacement, vascularization, melting, infection) during the follow-up. Ring deposits developed in 4 eyes but were not visually significant.

## Case Reports

**Case 7** A 29-year-old man with stable keratoconus had unacceptable CDVA in the left eye. The preoperative refraction was −7.50 −10.00 × 150 with a UDVA of 20/400 and CDVA of 20/200. Steep K, flat K, and mean K were 57.5 D, 49.9 D, and 53.4 D, respectively, with a flat axis at 148.4 degrees. Six months after implantation of a 300 µm ICR, the refraction decreased to −1.00 −4.50 × 155 and the UDVA and CDVA increased to 20/100 and 20/40, respectively. Postoperative steep K, flat K, and mean K decreased to 47.6 D, 44.3 D, and 45.9 D, respectively, with a flat axis at 150.1 degrees. Figure 4 shows the preoperative and postoperative rotating Scheimpflug camera keratometry maps.

**Case 3** A 31-year-old man with stable keratoconus, unsatisfactory CDVA, and intolerance to RGP was referred for ICR implantation in the left eye. The preoperative refraction, UDVA, and CDVA were plano −7.00 × 165, 20/400, and 20/50, respectively. Preoperative steep K, flat K, and mean K were 60.02 × 62, 49.55 D, and 54.87 D, respectively. A 200 µm 340-degree ICR was implanted based on the MRSE (−3.50 D). After 6 months, there was a significant decrease in K values (steep K, 53.30 @ 59; flat K, 46.43 D; mean K, 49.87 D). However, refraction did not change significantly (plano −6.00 × 140), the UDVA remained stable (20/400), and the CDVA was worse (20/100).

**Table 1. Mean preoperative and final visual, refractive, and keratometric indices.**

| Parameter | Mean ± SD | | *P* Value* |
|---|---|---|---|
| | Preoperative | Final | |
| UDVA (logMAR) | 0.95 ± 0.33 | 0.53 ± 0.35 | .001 |
| CDVA (logMAR) | 0.39 ± 0.22 | 0.26 ± 0.21 | .09 |
| MRSE (D) | −8.03 ± 3.89 | −3.01 ± 2.81 | <.001 |
| Sphere (D) | −5.08 ± 3.74 | −1.67 ± 2.59 | <.001 |
| Cylinder (D) | −5.83 ± 2.02 | −2.72 ± 1.81 | <.001 |
| Kf (D) | 47.83 ± 3.27 | 45.67 ± 3.46 | .001 |
| Km (D) | 51.43 ± 3.59 | 47.28 ± 3.64 | <.001 |
| Ks (D) | 54.86 ± 4.28 | 49.09 ± 3.83 | <.001 |

CDVA = corrected distance visual acuity (spectacle); Kf = flat keratometry; Km = mean keratometry; Ks = steep keratometry; logMAR = logarithm of the minimum angle of resolution; MRSE = manifest refraction spherical equivalent; UDVA = uncorrected distance visual acuity
*Wilcoxon signed-rank test

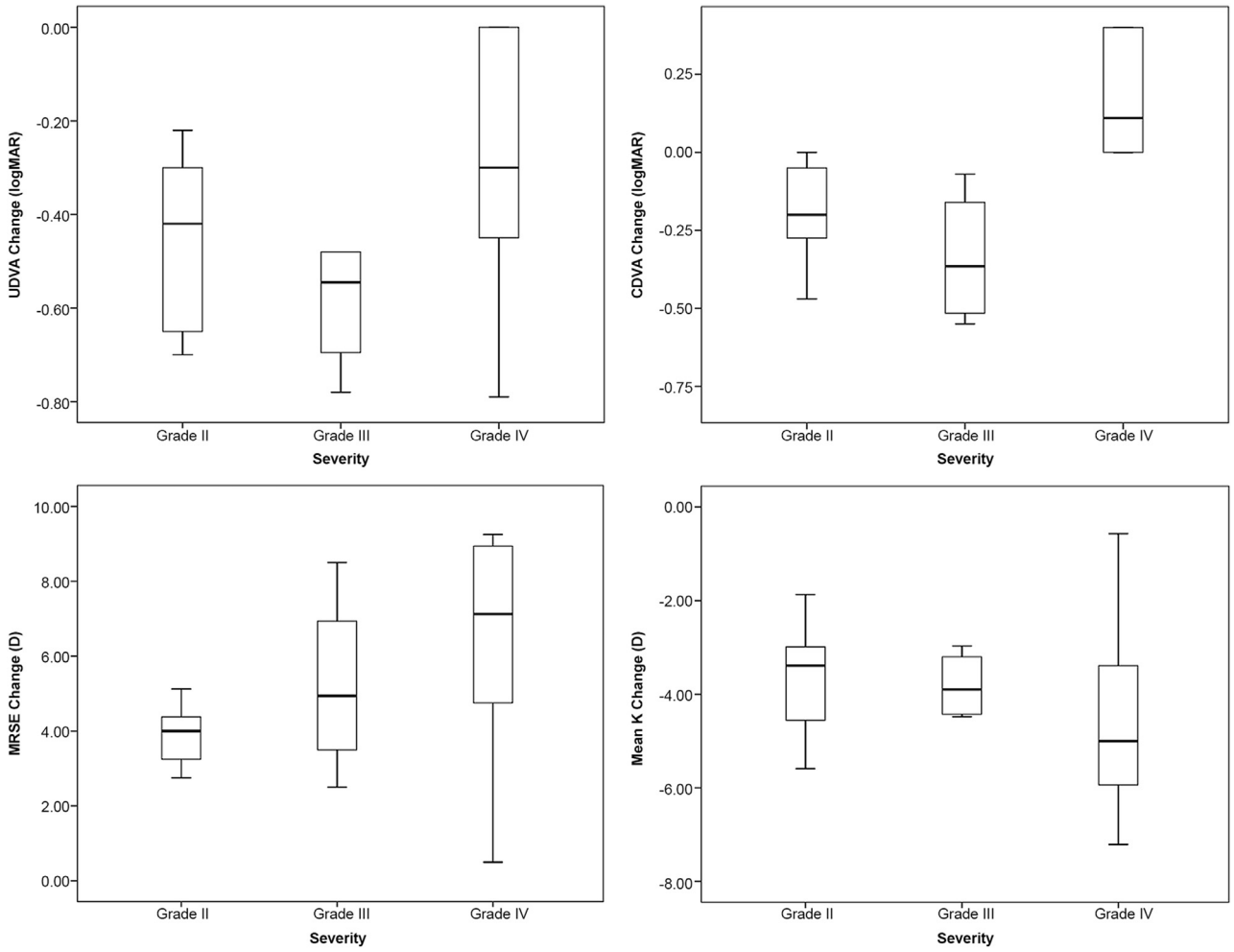


**Figure 2.** Median, minimum, maximum, and interquartile range of changes in UDVA, CDVA, MRSE, and mean K reported after implantation of 340-degree ICRS according to disease severity (CDVA = corrected distance visual acuity [spectacle]; K = keratometry; logMAR = logarithm of the minimum angle of resolution; MRSE = manifest refraction spherical equivalent; UDVA = uncorrected distance visual acuity).

Figure 5 shows the preoperative and postoperative corneal topography.

## DISCUSSION

The 340-degree Keraring is a newly designed model SI-5 ICR that is implanted in the corneal stroma through a tunnel created manually or with a femtosecond laser. Theoretically, the effect of this device is similar to that of Keraring with a 355-degree arc length but allows easier implantation and causes less wound site-related complications, such as vascularization and melting. We evaluated the short-term visual, refractive, and topographic outcomes after femtosecond laser implantation of the new ICR with a 340 degrees arc length in patients with keratoconus. We found a significant

**Table 2. Mean preoperative and final visual, refractive, and keratometric indices in patients with a preoperative mean K value of less than 55.0 D.**

| Parameter | Mean ± SD | | *P* Value* |
|---|---|---|---|
| | Preoperative | Final | |
| UDVA (logMAR) | 0.93 ± 0.36 | 0.43 ± 0.30 | <.001 |
| CDVA (logMAR) | 0.41 ± 0.24 | 0.18 ± 0.15 | .003 |
| MRSE (D) | −7.72 ± 3.92 | −3.10 ± 3.10 | <.001 |
| Sphere (D) | −4.95 ± 3.78 | −1.80 ± 2.78 | <.001 |
| Cylinder (D) | −5.48 ± 2.15 | −2.63 ± 1.78 | <.001 |
| Kf (D) | 46.73 ± 2.76 | 44.83 ± 3.42 | .004 |
| Km (D) | 50.18 ± 2.99 | 46.37 ± 3.62 | <.001 |
| Ks (D) | 53.41 ± 3.62 | 48.19 ± 3.86 | <.001 |

CDVA = corrected distance visual acuity (spectacle); Kf = flat keratometry; Km = mean keratometry; Ks = steep keratometry; logMAR = logarithm of the minimum angle of resolution; MRSE = manifest refraction spherical equivalent; UDVA = uncorrected distance visual acuity
*Wilcoxon signed-rank test

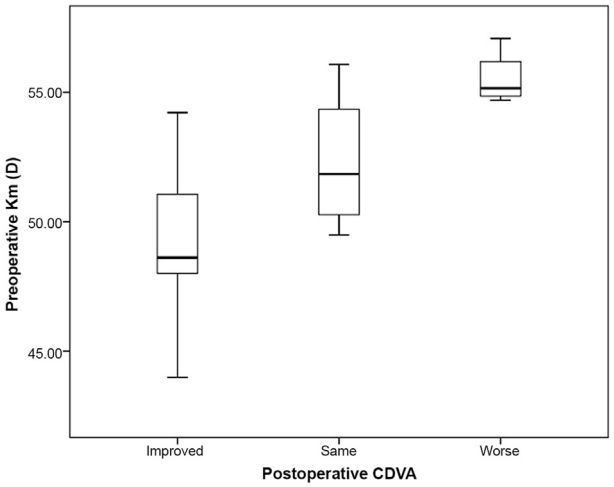


**Figure 3.** Median, minimum, maximum, and interquartile range of preoperative reported mean K in patients with worse, same, or improved CDVA after implantation of 340-degree ICRS (CDVA = corrected distance visual acuity [spectacle]; Km = mean keratometry).

improvement in visual acuity, refraction, and keratometric indices in the first postoperative month, and the improvements remained stable for 6 months.

To our knowledge, no published study has reported the outcomes of the new 340-degrees ICR in keratoconus. However, 2 meeting presentations reported preliminary results in 2015. Coskunseven[A] implanted the 340-degree ICR in 11 eyes (7 patients) with central and paracentral cone keratoconus; the result was a significant improvement in visual acuity, refraction, and mean K values. Santos et al.[B] compared the outcomes of implantation of the 340-degree ICR with 2 methods (pocket versus tunnel). The initial results in 12 eyes with a mean follow-up of 4.1 months (range 3 to 12 months) showed no significant difference in visual and keratometric outcomes between the 2 implantation methods. These results were similar to those in our study. However, the details of these 2 studies have not yet been published. Our short-term outcomes were comparable to those previously reported for continuous and noncontinuous ICRS with both manual and femtosecond laser techniques.[11–15]

As a noncontinuous long arc ICR, the 340-degree ICR is most similar to Keraring 355-degree segment (Mediphacos Ltda). Jadidi et al.[13] reported short-term outcomes of implantation of the 355-degree ICR with femtosecond laser–assisted pocket creation in 15 eyes with mild to moderate keratoconus (mean K, 45.0 to 52.0 D). They found significant improvement in visual, refractive, and keratometric indices after 6 months with no postoperative complications. Implantation of this ring through a femtosecond laser–created pocket was associated with a high rate of complications, including corneal melting and scarring, corneal deposits, and neovascularization, which are attributed to proximity of the ring to the incision site.[9] On the other hand, implantation through a pocket might induce interface-related problems, such as decreased contrast sensitivity and decreased quality of vision. The 340-degree ICR prevents these drawbacks while achieving similar clinical outcomes.

The most important indicator of visual acuity worsening in our cases was the preoperative K value. All cases with worse CDVA postoperatively had a preoperative mean K greater than 55.0 D and steep K greater than 57.0 D (ie, had Amsler-Krumeich grade IV disease). There is no consensus about the criteria for ICRS implantation in patients with keratoconus. Although most studies report the effectiveness of ICRS implantation in eyes with mild to moderate keratoconus, its benefits in severe cases is controversial. In a study of Intacs ICRS (Addition Technology. Inc.) by Alió et al.,[16] eyes with mean K values of 53.0 D or less had better visual outcomes than those with mean K values of 55.0 D or more. Other studies of Intacs implantation[11,17] report similar results. In contrast, several studies[18–20] found the Keraring and Ferrara ring (Ferrara Ophthalmics Ltd.) to be effective in patients with severe keratoconus.

In our study, patients with more severe disease had a more significant decrease in the MRSE and sphere and less improvement in visual acuity. Implantation of a corneal ring in an already biomechanically altered cornea might induce further irregular astigmatism, which can result in decreased CDVA. Measurement of preoperative and postoperative higher-order aberrations (HOAs) can be useful to explain this finding.

In conclusion, implantation of the Keraring 340-degree ICR was safe and effective in the management of refractive errors in patients with mild to moderate keratoconus with

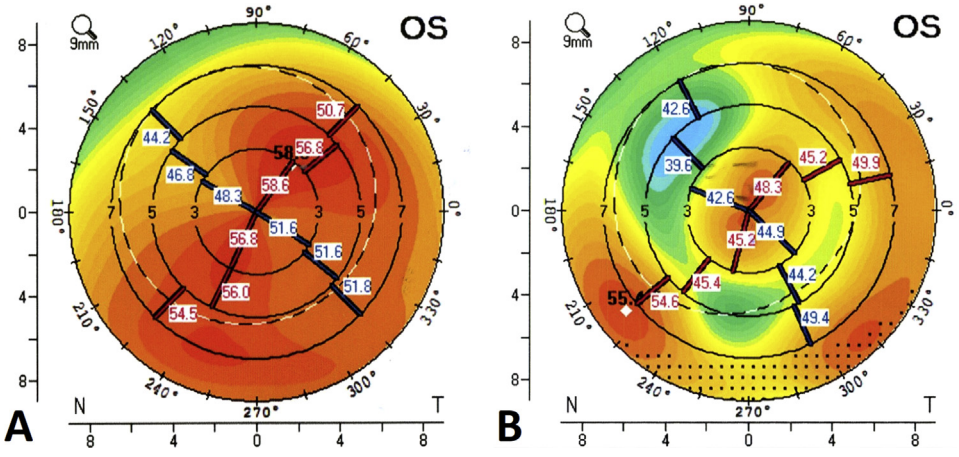


**Figure 4.** Rotating Scheimpflug camera keratometry map of Case 7 before (*A*) and after (*B*) implantation of the 340-degree ICR (N = nasal; T = temporal).

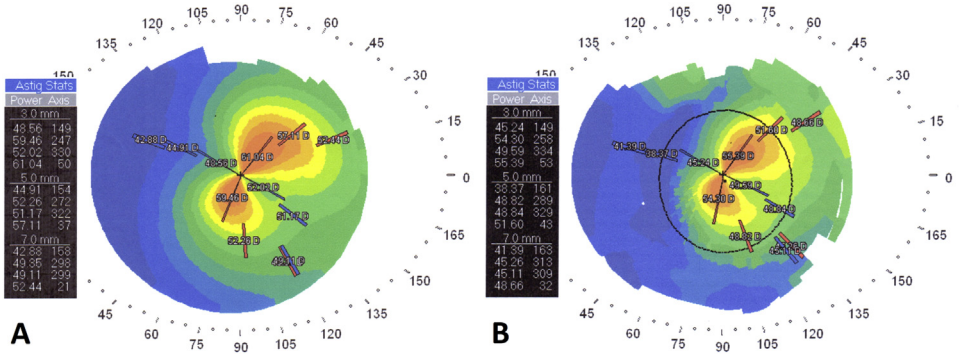


**Figure 5.** Corneal topography of Case 3 before (*A*) and after (*B*) implantation of the 340-degree ICR.

a central or paracentral cone. However, implantation of this ring is not recommended in severe cases, especially in eyes with a mean K more than 55.0 D or a steep K more than 60.0 D. Evaluation of preoperative and postoperative HOAs might elucidate the cause of poor visual outcomes in severe cases. Randomized clinical trials of a larger number of patients with a longer follow-up are recommended to compare the results of this type of ICR with other types, especially those with continuous rings.

### WHAT WAS KNOWN

- Femtosecond laser implantation of ICRS is a safe and effective method for vision correction in keratoconus.

### WHAT THIS PAPER ADDS

- The 340-degree ICR improved vision in patients with mild to moderate keratoconus; however, implantation of this ring is not recommended in severe cases.

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