

# KeraRing Intrastromal Corneal Ring Segments for Correction of Keratoconus

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**Purpose:** Intrastromal corneal ring segments (ICRSs) are small arc-like implants that are being used increasingly as a minimally invasive treatment for patients with keratoconus. This study assessed the effectiveness of KeraRing implants, a type of ICRS, to treat keratoconus.

**Methods:** Retrospective case series descriptive study of 43 patients (55 eyes) with keratoconus who underwent KeraRing implantation from February 2008 to June 2009. Patients who had intraoperative or postoperative complications and/or did not complete at least 6 months of follow-up were excluded. All patients underwent complete ophthalmologic examinations that included measurement of the uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest refraction, and keratometry before and 2 days, 2 weeks, 1 month, and 3 and 6 months after surgery. The ring segments were chosen based on a nomogram from the manufacturer.

**Results:** Six months postoperatively, the mean UCVA increased significantly ( $P < 0.05$ ) from  $0.10 \pm 0.11$  to  $0.32 \pm 0.25$  and the mean BSCVA increased from  $0.36 \pm 0.23$  to  $0.57 \pm 0.24$  ( $P < 0.05$ ). The mean spherical refractive error significantly ( $P < 0.05$ ) improved from  $-4.85 \pm 2.90$  diopters (D) to  $-1.89 \pm 2.68$  D, and the mean cylindrical refractive error significantly ( $P < 0.05$ ) improved from  $-3.65 \pm 1.70$  D to  $-2.60 \pm 1.62$  D. The mean spherical equivalent significantly ( $P < 0.05$ ) decreased from  $-6.68 \pm 2.93$  D to  $-3.19 \pm 2.75$  D, and the mean keratometry value decreased from  $51.83 \pm 4.14$  D to  $47.27 \pm 3.68$  D. The improvement in the UCVA and BSCVA continued over the 6-month postoperative period, but significant changes occurred only during the first 3 months. These changes occurred in patients with all grades of keratoconus.

**Conclusions:** KeraRing implantation provided significant improvement in visual acuity, spherical equivalent, and keratometry results. This ICRS is an effective treatment for managing keratoconus and might delay or even avoid the need for penetrating keratoplasty.

**Key Words:** keratoconus, KeraRing, intrastromal corneal ring segments

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Keratoconus is a bilateral, noninflammatory, progressive ectatic corneal disorder characterized by thinning and protrusion of the central cornea.<sup>1</sup> These corneal changes result in a mild to severe decrease in the best-corrected visual acuity (BCVA) as a result of progressive myopia, regular and irregular astigmatism, and apical scarring.<sup>2</sup> Most patients can be managed successfully with spectacles or contact lenses, especially in the early stages and with mild forms of the disease. However, when these measures fail to provide adequate vision or patients can no longer tolerate contact lenses, penetrating keratoplasty is an acceptable surgical alternative with high success rates but potential complications.<sup>3</sup>

Intrastromal corneal ring segments (ICRSs) were first introduced to correct mild to moderate myopia,<sup>4,5</sup> and the United States Food and Drug Administration (FDA) approved them to treat low myopia up to  $-3.0$  diopters (D). Implantation of ICRS has been investigated as a surgical option for keratoconus correction to delay or avoid corneal grafting.<sup>6</sup> In June 2004, the FDA approved the use of a special type of ICRS, Intacs (Addition Technology, Inc, Fremont, CA), for the management of keratoconus.

ICRSs act by exerting an “arc-shortening effect” on the corneal lamellae that flattens the central cornea. This procedure is safe and reversible, no corneal tissue is removed, and the central cornea is not invaded.<sup>7</sup>

The types of ICRS differ depending on their curvature, width, and the zone of implantation. KeraRings (Mediphacos, Belo Horizonte, Brazil), originally designed by Pablo Ferrara, are small arc-like segments made of polymethylmethacrylate or camphorquinone-acrylic segments. KeraRings are characterized by triangular cross sections that induce a prismatic effect on the cornea when the flat posterior surface is inserted facing the corneal endothelium. The technical specifications of the device (Table 1) are similar to those of Ferrara intrastromal corneal rings (Mediphacos, Inc). The optical zone provided by the segments is 5.0 mm in diameter.<sup>8</sup> The objective of this study was to assess the efficacy of this ICRS for treating keratoconus.

## PATIENTS AND METHODS

We conducted a retrospective case series descriptive study at Jordan University Hospital from February 2008 to June 2009. We reviewed the records of 62 Jordanian patients

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**TABLE 1.** KeraRing Technical Specifications

| Parameter          | KeraRings                     |
|--------------------|-------------------------------|
| Cross section      | Triangular                    |
| Diameter (inner)   | 5.40 mm                       |
| Diameter (outer)   | 6.60 mm                       |
| Implantation depth | 80% of corneal thickness      |
| Arc length         | 90, 120, 160, and 210 degrees |
| Segment thickness  | 0.15–0.35 mm in 0.5-mm steps  |

(75 eyes) who underwent implantation of this ICERS to treat keratoconus. Of these, 43 patients (55 eyes) were included. Fifteen patients (15 eyes) were excluded because they missed their final evaluation visit; 5 additional eyes were excluded because of postoperative complications (1 eye had spontaneous extrusion of 1 ring, 2 had superficial rings requiring reinsertion, and 2 had bacterial keratitis).

All procedures were performed by the same surgeon (M.A.A.) at the Jordan University Hospital. We obtained institutional review board/ethics committee approval before data collection. Table 2 shows the patient characteristics.

All patients had irregular astigmatism with at least 1 classical clinical sign of keratoconus, such as fine deep stromal striae (Vogt striae), localized corneal thinning, progressive corneal thinning resulting in marked irregular astigmatism, bulging of lower eyelid when patient looks down (Munson sign), or conical reflection on the nasal cornea when a penlight is shone from the temporal side (Rizzuti sign). The diagnosis was supported by at least 2 of the Pentacam (Oculus Optikgeräte GmbH, Wetzlar, Germany) corneal topography findings summarized in Table 3.<sup>9–11</sup> All patients had clear central corneas, severely affected visual acuity (VA), contact lens intolerance, and a previous indication for keratoplasty.

A complete ophthalmologic examination performed preoperatively included measurement of the uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest refraction, keratometry, applanation tonometry, corneal topography, and slit-lamp biomicroscopy and indirect ophthalmoscopy. Table 4 shows the preoperative data.

The keratoconus was graded according to the average keratometric value ( $K_{\text{average}}$ ) as follows<sup>12</sup>: grade 1,  $K_{\text{average}} < 48$  D (18.2%); grade 2,  $K_{\text{average}} \leq 48$  D  $\leq 54$  D (56.4%); and

**TABLE 2.** Patient Characteristics

|               | No. (%)          |
|---------------|------------------|
| No. eyes      | 55               |
| Gender        |                  |
| Male          | 21 (38.2)        |
| Female        | 34 (61.8)        |
| Right eyes    | 28 (50.9)        |
| Left eyes     | 27 (49.1)        |
| Age (yr)      |                  |
| Mean $\pm$ SD | 26.65 $\pm$ 6.17 |
| Range         | 17–46            |

**TABLE 3.** Corneal Topography Findings Suggestive of Keratoconus

|  |
|--|
| Keratometric power deviation $> +1.5$  |
| Asymmetric bow tie in the 4-mm central circle of the curvature map if difference is                |
| $> 1.5$ D (when inferior is steeper)   |
| $> 2.5$ D (when superior is steeper)   |
| Readings in the 4-mm central circle of the elevation map of  |
| $> 15$ $\mu\text{m}$ in the front elevation map  |
| $> 20$ $\mu\text{m}$ in the back elevation map   |
| Difference of $> 5$ $\mu\text{m}$ at the same point between front and back elevation maps          |
| Difference between the apex and the thinnest point (in the thickness map) of $> 10$ $\mu\text{m}$  |
| Difference between the thinnest point of the 2 eyes (in the thickness map) of $> 30$ $\mu\text{m}$ |
| Inferior displacement of the thinnest point (in the thickness map) of $> 500$ $\mu\text{m}$        |
| Cornea Q (Prolate/Oblate index) value of $< -1.0$  |

grade 3,  $K_{\text{average}} > 54$  D (25.5%). Table 5 shows patient characteristics according to different grades.

## Surgical Technique

We chose KeraRing segments based on the nomogram provided by the manufacturer. The thickness of the segment was decided based on the distribution of the ectatic area and the spherical equivalent (SE).

The surgical procedure was carried out under sterile conditions and topical anesthesia in all but 2 patients who were extremely anxious and requested general anesthesia. All patients provided informed consent before the procedures were performed. The Purkinje reflex was chosen as the central point and was marked on the biomicroscope using a methylene blue-tinted Sinskey hook. We used a 5-mm marker to locate the exact ring channel. The corneal thicknesses at the incision and tunnel sites were determined by a preoperative corneal topography thickness map generated by the Pentacam. The tunnel depth was set at 80% of the thinnest corneal thickness in the tunnel. An incision was made on the steepest topographic axis using a diamond knife with a 1-mm square blade. Intrastromal pockets were made using a Suarez spreader. Tunnels were created manually using right and left spatulas. One or 2 segments were implanted according to the distribution of the ectatic area on the corneal surface

**TABLE 4.** Mean Preoperative Data

| Preoperative         | Mean  | SD   | Range         |
|----------------------|-------|------|---------------|
| UCVA                 | 0.10  | 0.11 | 0.03 to 0.50  |
| BSCVA                | 0.36  | 0.23 | 0.03 to 0.80  |
| Sphere               | -4.85 | 2.90 | -10.0 to 3.0  |
| Cylinder             | -3.65 | 1.70 | -8.0 to 0.0   |
| SE                   | -6.68 | 2.93 | -13.0 to 0.0  |
| $K_{\text{max}}$     | 54.60 | 4.56 | 46.0 to 67.0  |
| $K_{\text{min}}$     | 49.06 | 4.01 | 41.0 to 60.0  |
| $K_{\text{average}}$ | 51.83 | 4.14 | 44.5 to 62.75 |

**TABLE 5.** Preoperative Data According to Different Keratoconus Grades

| Variable             | Grade 1<br>(Mean ± SD) | Grade 2<br>(Mean ± SD) | Grade 3<br>(Mean ± SD) |
|----------------------|------------------------|------------------------|------------------------|
| UCVA                 | 0.11 ± 0.13            | 0.12 ± 1.20            | 0.05 ± 0.02            |
| BSCVA                | 0.56 ± 0.22            | 0.35 ± 0.21            | 0.24 ± 0.16            |
| Sphere               | -2.43 ± 3.23           | -5.17 ± 2.58           | -5.89 ± 2.52           |
| Cylinder             | -3.43 ± 1.44           | -3.90 ± 2.04           | -3.25 ± 0.727          |
| SE                   | -4.14 ± 2.74           | -7.12 ± 2.77           | -7.52 ± 2.54           |
| K <sub>max</sub>     | 48.00 ± 1.20           | 54.16 ± 1.90           | 60.31 ± 2.83           |
| K <sub>min</sub>     | 43.68 ± 1.48           | 48.52 ± 1.72           | 54.11 ± 2.83           |
| K <sub>average</sub> | 45.84 ± 1.05           | 51.34 ± 1.54           | 57.21 ± 2.40           |

using Albertazzi forceps. The manufacturer provided all instruments.

The segments were implanted uneventfully in all cases. A hydrogel soft bandage contact lens (Soflens 59; Bausch & Lomb, Surrey, UK) was placed immediately at the end of surgery in all cases, and combined antibiotic/steroid eye drops (3 mg/mL of tobramycin and 1 mg/mL of dexamethasone; Tobradex; Alcon Cusi, Barcelona, Spain) were used 4 times daily for 2 weeks. Patients were instructed to avoid eye rubbing. On the second postoperative day, we removed the contact lens and performed biomicroscopy to evaluate wound healing and segment migration. At 2 weeks, 1 month, and 3 and 6 months after surgery, we measured the manifest refraction, UCVA, BSCVA, keratometry, and topography.

### Statistical Analysis

Data analysis was carried out using SPSS version 17 for Windows (SPSS, Inc, Chicago, IL). The Student *t* test for paired data was used to compare the preoperative and postoperative data. *P* < 0.05 was considered statistically significant.

## RESULTS

### Visual Outcomes

At the 6-month follow-up examination, the mean UCVA increased from 0.10 ± 0.11 to 0.32 ± 0.25 (*P* < 0.05) (Table 6). The mean BSCVA increased from 0.36 ± 0.23 to 0.57 ± 0.24 (*P* < 0.05). The BSCVA remained at the preoperative level in

4 eyes (7.3%) and increased in 48 eyes (87.3%). Of these, 31 eyes (56.4%) gained 2 to 4 lines of VA and 3 eyes (5.5%) gained 5 to 8 lines of VA. Three eyes (5.5%) had a 1-line decrease in BSCVA; however, all 3 gained 1 to 3 lines of UCVA. Of these 3 patients, 1 had grade 3 keratoconus, 1 had mild amblyopia, and 1 had good preoperative BSCVA (0.7) with a significant decrease in SE from -7.25 to -2.5 D (Fig. 1).

A comparison of the preoperative UCVA to that at 1 month postoperatively showed a significant (*P* < 0.05) improvement from 0.10 ± 0.11 to 0.27 ± 0.22. The BSCVA also improved significantly (*P* < 0.05) from 0.36 ± 0.23 to 0.48 ± 0.22. A comparison of the preoperative BSCVA and the UCVA and the data 3 months postoperatively showed significant improvements in the UCVA and BSCVA from 0.10 ± 0.11 and 0.36 ± 0.23 to 0.35 ± 0.24 and 0.57 ± 0.25, respectively (Table 6).

A comparison between the data at 1 and 3 months postoperatively showed significant improvements in the UCVA and BSCVA from 0.27 ± 0.22 and 0.48 ± 0.22 to 0.35 ± 0.24 and 0.57 ± 0.25, respectively (*P* < 0.05 for both comparisons). When comparing the data at 1 month and 6 months postoperatively, the UCVA and BSCVA improved from 0.27 ± 0.22 and 0.48 ± 0.22 to 0.32 ± 0.25 and 0.57 ± 0.24, respectively (Table 7). A comparison of the data between 3 and 6 months postoperatively showed that the UCVA changed from 0.35 ± 0.24 to 0.32 ± 0.25 and the BSCVA from 0.57 ± 0.25 to 0.57 ± 0.24, neither of which reached significance (*P* = 0.67 and *P* = 0.58, respectively; Table 8).

### Refractive Outcome

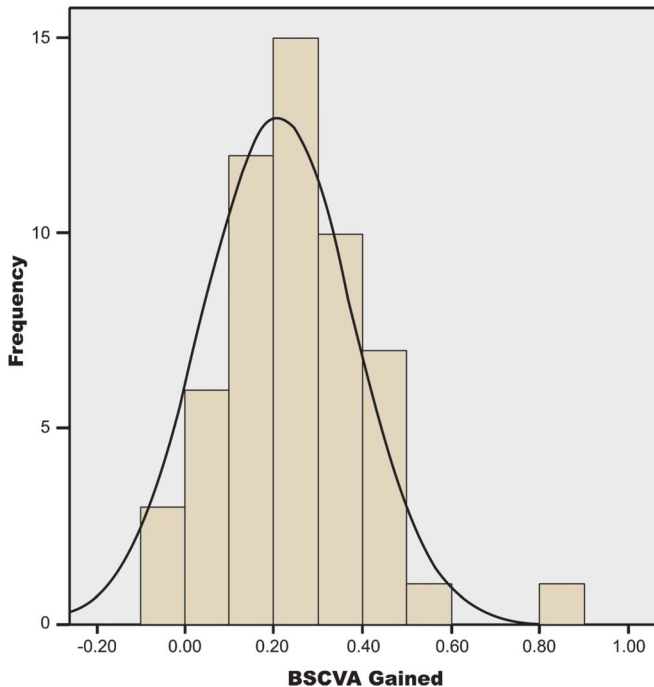
Six months postoperatively, the mean spherical refractive error improved from -4.85 ± 2.90 D to -1.89 ± 2.68 D (*P* < 0.05), and the mean cylindrical refractive error improved from -3.65 ± 1.70 D to -2.60 ± 1.62 D (*P* < 0.05). The mean SE decreased from -6.68 ± 2.93 D to -3.19 ± 2.75 D (*P* < 0.05).

The topographic keratometric (K) values showed clinically significant decreases in higher keratometric reading (K<sub>max</sub>), lower keratometric reading (K<sub>min</sub>), and average keratometric reading (K<sub>average</sub>). The mean K<sub>max</sub> decreased from 54.60 ± 4.56 to 48.85 ± 4.45, the mean K<sub>min</sub> decreased from 49.06 ± 4.01 to 45.69 ± 3.25, and the mean K<sub>average</sub> decreased from 51.83 ± 4.14 D to 47.27 ± 3.68 D.

A comparison of the preoperative variables with those at 1 month postoperatively showed a significant (*P* < 0.05 for

**TABLE 6.** Data at 1, 3, and 6 Months Postoperatively (Mean ± SD) Compared With Preoperative Data With Their *P* values

| Variable             | 1 mo Postoperatively |          | 3 mo Postoperatively |          | 6 mo Postoperatively |          |
|----------------------|----------------------|----------|----------------------|----------|----------------------|----------|
|                      | Mean ± SD            | <i>P</i> | Mean ± SD            | <i>P</i> | Mean ± SD            | <i>P</i> |
| UCVA                 | 0.27 ± 0.22          | <0.05    | 0.35 ± 0.24          | <0.05    | 0.32 ± 0.25          | <0.05    |
| BSCVA                | 0.48 ± 0.22          | <0.05    | 0.57 ± 0.25          | <0.05    | 0.57 ± 0.24          | <0.05    |
| Sphere               | -1.97 ± 3.05         | <0.05    | -2.25 ± 3.05         | <0.05    | -1.89 ± 2.68         | <0.05    |
| Cylinder             | -2.29 ± 1.66         | <0.05    | -1.99 ± 2.14         | <0.05    | -2.60 ± 1.62         | <0.05    |
| SE                   | -3.11 ± 3.13         | <0.05    | -3.25 ± 3.53         | <0.05    | -3.19 ± 2.75         | <0.05    |
| K <sub>max</sub>     | 47.97 ± 4.01         | <0.05    | 48.97 ± 4.27         | <0.05    | 48.85 ± 4.45         | <0.05    |
| K <sub>min</sub>     | 44.84 ± 3.37         | <0.05    | 45.55 ± 3.99         | <0.05    | 45.69 ± 3.25         | <0.05    |
| K <sub>average</sub> | 46.40 ± 3.49         | <0.05    | 47.26 ± 3.84         | <0.05    | 47.27 ± 3.68         | <0.05    |



**FIGURE 1.** Diagram showing change in BSCVA at the 6-month postoperative examination (mean = 0.21, SD = 0.17, N = 55).

both comparisons) improvement in the mean spherical refractive error to  $-1.97 \pm 3.05$  D and in the mean cylindrical refractive error to  $-2.29 \pm 1.66$  D. The mean SE decreased to  $-3.11 \pm 3.13$  D ( $P < 0.05$ ). The topographic K values decreased significantly: the mean  $K_{\max}$  decreased to  $47.97 \pm 4.01$ , the mean  $K_{\min}$  to  $44.84 \pm 3.37$ , and the mean  $K_{\text{average}}$  to  $46.40 \pm 3.49$  D.

Evaluation of the variables at 3 months postoperatively showed a decrease in the mean spherical refractive error to  $-2.25 \pm 3.05$  D and in the mean cylindrical refractive error mean to  $-1.99 \pm 2.14$  D ( $P < 0.05$  for both comparisons). The mean SE decreased to  $-3.25 \pm 3.53$  D ( $P < 0.05$ ). Significant decreases in  $K_{\max}$ ,  $K_{\min}$ , and  $K_{\text{average}}$  occurred: the mean  $K_{\max}$  decreased to  $48.97 \pm 4.27$ , the mean  $K_{\min}$  to  $45.55 \pm 3.99$ , and the mean  $K_{\text{average}}$  to  $47.26 \pm 3.84$  D.

A comparison of the refractive variables between 1 month and 3 months did not show any significant changes.

**TABLE 7.** Data at 3 and 6 Months Postoperatively (Mean  $\pm$  SD) Compared With 1 Month Postoperatively With Their  $P$  values

| Variable             | 3 mo Postoperatively |       | 6 mo Postoperatively |       |
|----------------------|----------------------|-------|----------------------|-------|
|                      | Mean $\pm$ SD        | $P$   | Mean $\pm$ SD        | $P$   |
| UCVA                 | 0.35 $\pm$ 0.24      | <0.05 | 0.32 $\pm$ 0.25      | <0.05 |
| BSCVA                | 0.57 $\pm$ 0.25      | <0.05 | 0.57 $\pm$ 0.24      | <0.05 |
| Sphere               | $-2.25 \pm 3.05$     | 0.667 | $-1.89 \pm 2.68$     | 0.988 |
| Cylinder             | $-1.99 \pm 2.14$     | 0.356 | $-2.60 \pm 1.62$     | 0.316 |
| SE                   | $-3.25 \pm 3.53$     | 0.981 | $-3.19 \pm 2.75$     | 0.708 |
| $K_{\max}$           | $48.97 \pm 4.27$     | 0.276 | $48.85 \pm 4.45$     | 0.215 |
| $K_{\min}$           | $45.55 \pm 3.99$     | 0.594 | $45.69 \pm 3.25$     | 0.347 |
| $K_{\text{average}}$ | $47.26 \pm 3.84$     | 0.292 | $47.27 \pm 3.68$     | 0.208 |

**TABLE 8.** Comparison of 6-Month Postoperative Data With 3-Month Postoperative Data (Mean  $\pm$  SD) With Their  $P$  values

| Variable             | 6 mo Postoperatively |       |
|----------------------|----------------------|-------|
|                      | Mean $\pm$ SD        | $P$   |
| UCVA                 | 0.32 $\pm$ 0.25      | 0.666 |
| BSCVA                | 0.57 $\pm$ 0.24      | 0.576 |
| Sphere               | $-1.89 \pm 2.68$     | 0.238 |
| Cylinder             | $-2.60 \pm 1.62$     | <0.05 |
| SE                   | $-3.19 \pm 2.75$     | 0.911 |
| $K_{\max}$           | $48.85 \pm 4.45$     | 0.575 |
| $K_{\min}$           | $45.69 \pm 3.25$     | 0.650 |
| $K_{\text{average}}$ | $47.27 \pm 3.68$     | 0.986 |

When the same variables were compared between 3 and 6 months postoperatively, only the change in the mean cylinder refractive error was significant ( $P < 0.05$ ); the changes in the mean spherical refractive error, SE,  $K_{\max}$ ,  $K_{\min}$ , and  $K_{\text{average}}$  were not significant (Table 8).

All study parameters showed significant improvements at 1 month postoperatively. However, only the UCVA and BSCVA continued to show significant improvements at 3 months. At 6 months, no parameters showed a significant change from 3 months except for the cylinder.

When comparing the 8 variables preoperatively and 6 months postoperatively regarding keratoconus grades, only the change in the mean cylindrical refractive error was not significant ( $P = 0.74$ ) in patients with grade 3 keratoconus; all changes were significant in patients with grades 1 and 2 keratoconus (Table 9).

## DISCUSSION

ICRSs have gained in popularity for treating keratoconus since Nosé et al<sup>13</sup> first tried implanting the devices. The procedure does not attempt to treat or eliminate the existing disease but to improve VA to acceptable limits that might delay if not eliminate the need for keratoplasty. ICRSs achieve this effect by inducing corneal flattening with addition of tissue to the corneal periphery (Barraquer thickness law).<sup>14,15</sup> This thickening also displaces the corneal apex closer to its physiological position in front of the pupil by reducing the paracentral ectasia commonly seen in keratoconic corneas.<sup>16</sup>

One advantage of this procedure is its reversibility<sup>17</sup>; that is, the segments can be removed easily if results are unacceptable or complications develop, with recovery of preoperative corneal and refractive parameters after explantation in most cases. Other advantages include preservation of the central cornea and all stromal layers, preservation of an intact globe, and rapid visual rehabilitation postoperatively. However, the predictability of the procedure is low and results vary.<sup>8,10,18</sup>

Siganos et al,<sup>16</sup> who studied 26 keratoconic eyes implanted with Ferrara rings, which are similar to KeraRings to correct accompanied astigmatism, reported that the mean UCVA and BCVA improved from  $0.07 \pm 0.08$  and  $0.37 \pm 0.25$  to  $0.30 \pm 0.21$  and  $0.60 \pm 0.17$ , respectively, 6 months postoperatively in 24 eyes. In 2008, Coskunseven et al<sup>8</sup> reviewed 50 eyes that underwent KeraRing implantation using



**TABLE 9.** Changes at 6 Months Postoperatively According to Keratoconus Grade With Their *P* values

| Variable             | Grade 1, N = 10 |          | Grade 2, N = 31 |          | Grade 3, N = 14 |          |
|----------------------|-----------------|----------|-----------------|----------|-----------------|----------|
|                      | Mean ± SD       | <i>P</i> | Mean ± SD       | <i>P</i> | Mean ± SD       | <i>P</i> |
| UCVA                 | 0.46 ± 0.31     | <0.05    | 0.34 ± 0.25     | <0.05    | 0.17 ± 0.11     | <0.05    |
| BSCVA                | 0.78 ± 0.24     | <0.05    | 0.59 ± 0.23     | <0.05    | 0.39 ± 0.10     | <0.05    |
| Sphere               | -0.58 ± 2.04    | <0.05    | -1.62 ± 1.87    | <0.05    | -3.43 ± 3.86    | <0.05    |
| Cylinder             | -2.38 ± 1.13    | <0.05    | -2.47 ± 1.69    | 0.003    | -3.05 ± 1.78    | 0.735    |
| SE                   | -1.76 ± 1.88    | <0.05    | -2.86 ± 1.92    | <0.05    | -4.96 ± 3.91    | <0.05    |
| K <sub>max</sub>     | 44.52 ± 1.78    | <0.05    | 48.04 ± 2.83    | <0.05    | 53.74 ± 4.42    | <0.05    |
| K <sub>min</sub>     | 42.12 ± 2.09    | <0.05    | 45.361 ± 2.49   | <0.05    | 48.964 ± 2.25   | <0.05    |
| K <sub>average</sub> | 43.32 ± 1.84    | <0.05    | 46.70 ± 2.40    | <0.05    | 51.354 ± 3.120  | <0.05    |

a femtosecond laser and followed up the patients for at least 1 year postoperatively; 68% had a 1- to 4-line gain in BCVA at their last follow-up visit. We found that implantation of KeraRings in patients with keratoconus provided significant improvements in UCVA and BSCVA that continued throughout the 6-month follow-up period; the mean UCVA increased from  $0.10 \pm 0.11$  to  $0.32 \pm 0.25$  ( $P < 0.05$ ), and the mean BSCVA increased from  $0.36 \pm 0.23$  to  $0.57 \pm 0.24$  ( $P < 0.05$ ). The significant improvements stopped at the 3-month postoperative follow-up visit.

Implantation of KeraRings also resulted in significant improvements in SE and K values that occurred at 1 month postoperatively and failed to show any significant improvement thereafter. Despite the fact that UCVA and BSCVA continued to change significantly between 1 month and 3 months postoperatively, no refractive variables changed significantly during this period.

These 2 observations supported the idea that there is a benefit associated with earlier postoperative rehabilitation for patients implanted with ICRSs because most changes occurred by 1 month postoperatively. This does not eliminate the fact that postoperative results are prone to fluctuations and daily variations. Barach et al<sup>19</sup> reported that the UCVA varied up to 4 lines without an obvious pattern of progression over a 2-month follow-up period in 10 eyes of 6 patients who underwent implantation of ICRSs for myopia ranging from -1.00 to -3.50 D. Baikoff et al<sup>20</sup> did not find an explanation for their observation of the tendency of eyes with implanted ICRSs to have an evening myopic shift as late as 1 year after implantation. This might explain the frequent complaints of fluctuating VA by patients over the first few months postoperatively. A longer follow-up period might be needed to study the long-term effect of these variations on VA and patients satisfaction.

ICRS implantation might be a suitable surgical option for patients with keratoconus and clear central corneas who are contact lens intolerant. This might delay or even avoid the need for penetrating keratoplasty. The best results were seen in our keratoconus patients with  $48 \text{ D} \leq K_{\text{average}} \leq 54 \text{ D}$ .

Implantation of ICRSs does not always improve visual and refractive characteristics. In the current study, 3 eyes (5.5%) had a 1-line decrease in BSCVA; however, all 3 gained from 1 to 3 lines of UCVA. Of these 3 patients, 1 had grade 3 keratoconus, 1 had mild amblyopia, and 1 had a good

preoperative BSCVA (0.7), with a significant decrease in his SE from -7.25 to -2.5 D. None of these patients requested explantation.

We excluded 5 eyes from statistical analysis because of postoperative complications (1 eye had spontaneous extrusion of 1 ring, 2 eyes had superficial rings that needed reinsertion, and 2 eyes had bacterial keratitis). At a mean (SD) follow-up of 13 ( $\pm 8.7$ ) months for 51 keratoconus eyes that were implanted using Ferrara intrastromal corneal ring segments (ISCRs), Kwitko and Severo<sup>21</sup> reported 10 eyes (19.6%) with segment extrusion, 2 eyes (3.9%) with segment decentration, 1 eye (1.9%) with bacterial keratitis, and 1 eye (1.9%) with disciform keratitis. Shabayek and Alió<sup>22</sup> did not report any of the decentration or extrusion complications even 6 months after ICRS implantation by femtosecond laser for 21 keratoconus eyes. Complications, such as segment decentration or extrusion, might be avoided by using the femtosecond laser to create the segment tunnel because this might avoid variations in depth of implantation all through the tunnel. The femtosecond laser will also provide precise tunnel dimensions, width, and diameter. Other possible complications that might be encountered after ICRS implantation include asymmetric positioning of the segments, migration of segments, and development of conjunctivitis, keratitis, or even hydrops.<sup>23</sup> A 6-month follow-up might not be enough to comment on all possible postoperative complications. Kymionis et al<sup>24</sup> retrospectively studied 17 eyes of 15 keratoconus patients; after 5 years, ICRS implantation improved UCVA, BSCVA, and refraction in the majority of the keratoconus patients. There was no evidence of progressive sight-threatening complications in their study.

In conclusion, our study showed that intrastromal implantation of KeraRings significantly decreased SE and keratometric values ( $K_{\text{max}}$ ,  $K_{\text{min}}$ , and  $K_{\text{average}}$ ) and significantly increased UCVA and BSCVA in patients with all grades of keratoconus. Initiating visual rehabilitation by 3 months postoperatively is reasonable because most of induced refractive changes stabilize by that time.

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