Corneal aberrometric and refractive performance of 2 intrastromal corneal ring segment models in early and moderate ectatic disease

David P. Piñero, MSc, Jorge L. Alió, MD, PhD, Bassam El Kady, MD, PhD, Inmaculada Pascual, PhD

PURPOSE: To evaluate and compare visual, refractive, and corneal aberrometric outcomes after implantation of 2 types of intrastromal corneal ring segments (ICRS) in eyes with early to moderate ectatic disease.

SETTINGS: Vissum Corporation-Instituto Oftalmológico de Alicante, Alicante, Spain.

METHODS: This retrospective analysis comprised consecutive eyes with grade I or grade II corneal ectasia (keratoconus, pellucid marginal degeneration, ectasia after laser in situ keratomileusis) that had Intacs (Group I) or KeraRings (Group K) ICRS implantation using femtosecond technology. Visual, refractive, and corneal aberrometric outcomes were analyzed and compared between groups over a 6-month follow-up.

RESULTS: Group I had 17 eyes and Group K, 20 eyes. One month postoperatively, there was a statistically significant reduction in sphere in both groups (P<.02). At 6 months, there was a statistically significant reduction in manifest cylinder in Group K that was consistent with the significant reduction in corneal astigmatic aberration (both P<.04). The uncorrected distance visual acuity increased significantly in Group K (P=.04) but not in Group I; 41.18% of eyes in Group I and 52.94% in Group K gained 1 or more lines of corrected distance visual acuity. Both groups had significant corneal flattening (P<.02). At 1 month, the mean primary spherical aberration was 0.17 μm ± 0.52 (SD) in Group I and 0.40 ± 0.35 μm in Group K; the difference was statistically significant (P<.01).

CONCLUSION: Astigmatism correction in early to moderate ectatic corneas was more limited with the Intacs ICRS, which induced negative primary spherical aberration in the initial postoperative period.

Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned.


Intrastromal corneal ring segment (ICRS) implantation has been evaluated as an additive surgical procedure for corneal ectasia resulting from keratoconus1–20 or pellucid marginal degeneration (PMD)21–27 or occurring after laser in situ keratomileusis (LASIK)28–36. The procedure is an alternative in keratoconus cases, with the goal being to delay or prevent the need for corneal grafts.7,8 Implantation of ICRS can improve visual acuity and reduce refractive errors and mean keratometry (K) values. The segments act as spacers between bundles of corneal lamellae, shortening the central arc length in a manner proportional to the thickness of the segment (Silvestrini TA, et al. IOVS 1994; 35:ARVO Abstract 3557). The arc-shortening effect flattens the central portion of the anterior corneal surface and steepens the peripheral area adjacent to the ring insertion site.37,38 Segments with a short arc-length are effective in the correction of astigmatism,1,8,17 inducing less corneal flattening and change in corneal toricity due to the structural configuration of corneal collagen (predicted by finite element modeling).39

Three types of ICRS have been evaluated in the management of keratoconus.40 The first, Intacs segments (Addition Technology, Inc.), consist of a pair of semicircular pieces of poly(methyl methacrylate), each having a circumference arc length of 150 degrees and a hexagonal transverse shape. Each segment has an external diameter of 8.10 mm, an internal diameter of 6.77 mm, and variable thickness (0.25 to 0.45 mm in...
0.05 mm increments) that allows modulation of the refractive effect.41 Another Intacs design, Intacs SK, was recently developed. These ICRS have an inner diameter of 6.00 mm, an oval cross-section, and 2 thicknesses: 400 µm for K values of 57.0 to 62.0 diopters [D] and cylinder value <5.0 D and 450 µm for K values >62.0 D and cylinder value >5.0 D.41 The other 2 ICRS types are Ferrara rings (Ferrara Ophthalmics) and KeraRings (Mediphacos, Ltda.). Both have a triangular cross-section that theoretically induces a prismatic effect to reduce photic phenomena18 and are available in different thicknesses and arc lengths for customization based on the individual case. KeraRings ICRS have an external diameter of 4.40 mm, an internal diameter of 5.60 mm, and a thickness between 0.15 and 0.35 mm in 0.05 mm increments. An arc length of 90, 120, 160, and 210 degrees can be chosen depending on the topographic pattern and level of astigmatism. Good outcomes have been reported with all 3 types of ICRS1-36, however, to our knowledge, a comparison of results has not been published.

The aim of the present study was to evaluate and compare the visual, refractive, and corneal aberrometric outcomes after implantation of 2 types of ICRS using femtosecond laser technology in corneas with early to moderate ectatic disease. To our knowledge, this is the first study comparing the effect of the 2 ICRS in ectatic corneas.

PATIENTS AND METHODS

Consecutive eyes that had ICRS implantation for corneal ectasia from September 2006 to June 2007 at Vissum Corporation-Instituto Oftalmológico de Alicante were analyzed retrospectively. The institute’s ethical board committee approved the study, and all patients provided informed consent that included approval for the use of clinical information in scientific studies.


From Vissum Corporation-Instituto Oftalmológico de Alicante (Piñero, Alió), Departamento de Óptica, Farmacología y Anatomía (Piñero, Pascual), Universidad de Alicante, and Division of Ophthalmology (Alió), Universidad Miguel Hernández, Alicante, Spain; Ain Shams University (El Kady), Cairo, Egypt.


Corresponding author: Jorge L. Alió, MD, PhD, Avenida de Denia s/n, Edificio Vissum, 03016 Alicante, Spain. E-mail: jialio@vissum.com.

The corneal ectasia in the study eyes was the result of keratoconus or PMD or occurred after LASIK. Cases were classified according to the Amsler-Krumeich and Alió-Shabayek42 grading systems. The eyes were divided into 2 groups based on the type of ICRS implanted: Intacs (Group I) or KeraRings (Group K).

The keratoconus diagnosis was based on corneal topography and slitlamp observation (asymmetric bow-tie pattern with or without skewed axes; presence of stromal thinning, conical protrusion of the cornea at the apex, Fleischer ring, Vogt striae, or anterior stromal scar).43 The PMD diagnosis was made according to slitlamp observation (inferior corneal thinning and ectasia above the area of maximum thinning), corneal topography (butterfly pattern, very steep contour in the peripheral inferior cornea with high keratometric powers radiating toward the center from the inferior oblique meridians), and refractive findings (significant against-the-rule astigmatism with a loss of corrected distance visual acuity [CDVA]).43 Post-LASIK ectasia was diagnosed when the following findings were observed: corneal thinning on slitlamp examination, unstable topographic steepening (>1.0 D during each 6-month follow-up), progressive corneal thinning on ultrasound pachymetry, decreased distance visual acuity, and unstable refraction (>0.5 D spherical equivalent [SE] during each 6-month follow-up).44 In all cases, the indication for ICRS implantation was reduced CDVA, contact lens intolerance, or both.

Preoperative and Postoperative Protocols

A comprehensive preoperative examination was performed that included Snellen uncorrected distance visual acuity (UDVA) and CDVA, manifest refraction, slitlamp biomicroscopy, Goldmann tonometry, fundus evaluation, ultrasound pachymetry, and corneal topographic and aberrometric analysis with the CSO topography system with EyeTop2005 software (Compagnia Strumenti Oftalmici). The topographer analyses 6144 corneal points in a circular annulus defined by an inner radius of 0.33 mm and an outer radius of 10.00 mm with respect to corneal vertex. The software converts the corneal elevation profile into corneal wavefront data using Zernike polynomials with expansion up to the 7th order. In this study, aberration coefficients and root-mean-square (RMS) values were calculated for a 6.0 mm pupil. The following topographic and aberrometric data from the topographer were evaluated and recorded: corneal dioptric power in the flattest meridian for the 3.0 mm central zone (K1); corneal dioptric power in the steepest meridian for the 3.0 mm central zone (K2); mean corneal power in the 3.0 mm zone (KM); astigmatism RMS; primary coma RMS computed for Zernike terms Z(3,±1); coma-like RMS computed for 3rd-, 5th-, and 7th-order Zernike terms; spherical-like RMS computed for 4th- and 6th-order Zernike terms; and residual RMS computed for all Zernike terms except those corresponding to primary coma and spherical aberration. The Zernike coefficient for primary spherical aberration Z(4,0) with its sign was also recorded.

Postoperative visits were scheduled for 1 day and 3, 6, and 12 months. On the first postoperative day, UCVA measurements and a slitlamp examination (ICRS position and corneal integrity) were performed. The remaining postoperative visits included UDVA and CDVA measurements, manifest refraction, a slitlamp examination, and corneal topographic and aberrometric analysis.
Surgical Technique

The same experienced surgeon (J.L.A.) performed all procedures using topical anesthesia. The incision was placed on the steepest meridian. Corneal tunnelization was performed with a 30 kHz femtosecond system (IntraLase, IntraLase Corp.). Tunnels with an inner diameter of 6.6 mm and an outer diameter of 7.8 mm were used in Group I, and tunnels with diameters of 4.8 mm and 5.7 mm, respectively, were used in Group K. The number (1 or 2) and the thickness of ICRS in Group I were selected using previously defined criteria (Table 1). In Group K, the manufacturer’s nomogram was used (Table 2). All ICRS in Group K had an arc length of 160 degrees.

All patients were prescribed topical ciprofloxacin every 8 hours for 2 days preoperatively. Postoperatively, topical tobramycin–dexamethasone eyedrops were used every 6 hours for 1 week and a topical lubricant was used every 6 hours for 1 month.

Statistical Analysis

Statistical analysis was performed using SPSS software for Windows (version 15.0, SPSS, Inc.). Normality of all data samples was first checked by the Kolmogorov-Smirnov test. When parametric analysis was possible, the Student t-test for paired data was used for all comparisons between preoperative and postoperative parameter. The Student t-test for unpaired data was used to compare outcomes between groups.

When parametric analysis was not possible, the Wilcoxon rank-sum test was used to assess the significance of differences between preoperative and postoperative data and the Mann-Whitney test was used for comparison between groups. A P value less than 0.05 was considered statistically significant in all comparisons.

In cases of ICRS explantation, data from visits after explantation were not included in the statistical analysis to prevent bias in the final results.

RESULTS

Patient Characteristics

The study evaluated 37 eyes of 28 patients; the corneal ectasia was unilateral in 28 cases and bilateral in 9 cases. The mean age of the 19 men (67.86%) and 9 women (32.14%) was 31.56 years (SD) (range 15 to 56 years). The distribution of right eyes and left eyes was balanced (17 and 20, respectively). Group I comprised 17 eyes (44.74%) and Group K, 20 eyes (52.63%). One segment was implanted in 5 eyes (29.41%) in Group I and 8 eyes (40.00%) in Group K. Two segments were implanted in 12 eyes (70.59%) and 12 eyes (60.00%), respectively. No intraoperative complications occurred.

Cone opacity was observed in 1 eye (8.22%). The Amsler-Krumeich cone grade was I in 23 eyes (62.16%) and II in 14 eyes (37.84%); 11 eyes in Group I and 12 eyes in Group K had cone grade I, and 6 eyes and 8 eyes, respectively, had cone grade II. Based on corneal aberrations and the Alió-Shabayek system, 19 eyes (51.35%) had cone grade I and 18 eyes (48.65%), cone grade II. Keratoconus was present in 26 eyes (13 eyes in each group), PMD in 6 eyes (2 Group I; 4 Group K), and post-LASIK ectasia in 5 eyes (2 Group I; 4 Group K).

Group I

Figure 1 shows the sphere, cylinder, and SE in Group I over time. One month postoperatively, there was a statistically significant reduction in sphere and SE over preoperative values (both P < .02, paired Student t test). At 6 months, there was a statistically

### Table 1. Intacs nomogram.

<table>
<thead>
<tr>
<th>Corneal Topography Pattern (Axial Map)</th>
<th>Indication*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steepening area not involving 180-degree meridian of cornea (inferior cone)</td>
<td>1 segment: 0.45 mm thick</td>
</tr>
<tr>
<td>Steepening extending at least 1.0 mm above and beyond 180-degree meridian (central cone)</td>
<td>2 segments: 0.45 mm thick</td>
</tr>
</tbody>
</table>

*The number and the thickness of the segments were selected based on the corneal topographic pattern of the inferior or central cone (axial or sagittal map).

### Table 2. KeraRings nomogram.

<table>
<thead>
<tr>
<th>Spherical Equivalent (D)</th>
<th>Ectasia Limited to One Half of Cornea</th>
<th>7/14 of Ectasia in One Half and 1/4 in Other Half of Cornea</th>
<th>2/3 Ectasia in One Half and 1/3 in Other Half of Cornea</th>
<th>Ectasia Distributed Evenly in Both Halves of Cornea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than −10.0</td>
<td>25/35</td>
<td>25/35</td>
<td>30/35</td>
<td>35/35</td>
</tr>
<tr>
<td>−8.0 to −10.0</td>
<td>20/30</td>
<td>20/30</td>
<td>25/30</td>
<td>30/30</td>
</tr>
<tr>
<td>−6.0 to −8.0</td>
<td>15/25</td>
<td>15/25</td>
<td>20/25</td>
<td>25/25</td>
</tr>
<tr>
<td>−2.0 to −6.0</td>
<td>0/20</td>
<td>0/20</td>
<td>15/20</td>
<td>20/20</td>
</tr>
</tbody>
</table>

*The number and thickness of segments were selected based on the topographic distribution of the ectasia and the spherical equivalent. To define the distribution of the ectasia, the axial or sagittal topographic map was divided in half using the steepest meridian as axis of separation.
significant regression in the achieved spherical correction ($P < .01$, paired Student $t$ test). There were no statistically significant changes in cylinder at any postoperative follow-up ($P \geq .53$, paired Student $t$ test).

There were no statistically significant changes in UDVA ($P \geq .72$, paired Student $t$ test) or CDVA ($P \geq .32$, paired Student $t$ test) at any postoperative follow-up (Figure 2). At 3 months, 6 eyes (35.29%) gained 1 or more lines of CDVA; by 6 months, 7 eyes (41.18%) had gained 1 or more lines of CDVA (Figure 3). Two eyes (11.76%) lost lines of CDVA at 3 months and 6 months.

Figure 4 shows the K readings over time. The mean, flattest, and steepest K readings were statistically significantly lower at 1 month than preoperatively ($P \leq .01$, paired Student $t$ and Wilcoxon test). Although no further statistically significant changes occurred, there was slight regression of the achieved flattening at 3 months ($P \geq .12$, paired Student $t$ test). Figure 5 shows the corneal aberrometry results over time. The only statistically significant change was negativization of primary spherical aberration at 1 month ($P = .02$, paired Student $t$ test). From 1 month to 6 months, there was a change in primary spherical aberration toward positive values ($P = .19$, paired Student $t$ test) and a slight reduction in almost all aberrometric coefficients ($P \geq .38$, paired Student $t$ test).

**Group K**

Figure 1 shows the sphere, cylinder, and SE in Group K over time. One month postoperatively, there was a statistically significant reduction in sphere and SE
At 6 months, there was a slight, but not statistically significant, regression in the achieved spherical correction ($P > .17$, Wilcoxon test). There was a nonsignificant reduction in cylinder at 1 month ($P = .22$, Wilcoxon test). However, at 3 months, the reduction in cylinder was statistically significant ($P < .01$, Wilcoxon test). In addition, there was a statistically significant regression in cylindrical correction from 3 months to 6 months ($P = .05$, Wilcoxon test).

The UDVA was statistically significantly better 1 month postoperatively than preoperatively ($P = .04$, paired Student $t$ test); there were no further significant changes in UDVA ($P = .48$, paired Student $t$ test) (Figure 2). The CDVA was statistically significantly better at 3 months ($P = .02$, Wilcoxon test); 10 eyes (55.55%) gained 1 or more lines of CDVA at 3 months and 9 eyes (52.94%) gained 1 or more lines at 6 months (Figure 6). Two eyes (11.76%) lost lines of CDVA at 3 months and 6 months.

Figure 4 shows the K readings over time. The mean, flattest, and steepest K readings were statistically significantly lower at 1 month than preoperatively ($P < .02$, paired Student $t$ and Wilcoxon test). No further statistically significant changes in K values occurred ($P > .64$, paired Student $t$ test).

Figure 7 shows the corneal aberrometry results over time. The only statistically significant change was a reduction in astigmatism RMS at 1 month ($P = .04$, paired Student $t$ test). Slight reductions in primary coma and coma-like RMS were also observed at 1 month ($P > .84$, paired Student $t$ test). Primary spherical aberration and spherical-like RMS increased at 1 month and then decreased progressively over the subsequent follow-up ($P > .21$, paired Student $t$ and Wilcoxon test).

Comparative Analysis

There were no statistically significant differences between Group I and Group K in any preoperative visual or refractive parameter ($P > .07$, unpaired Student $t$ and Wilcoxon test). There was a statistically significant difference in primary spherical aberration between groups at 1 month ($P < .01$, unpaired Student $t$ test), with a clear tendency toward negative spherical aberration in Group I. At 6 months, the K1 and safety index values were statistically significantly higher in Group K than in Group I ($P < .04$, unpaired Student $t$ test).
There were no statistically significant differences between groups in cylinder or astigmatism RMS, probably due to high variability of these parameters and the small sample size \((P \geq .07,\) unpaired Student \(t\) and Wilcoxon tests). At 1 month, the mean change in astigmatism RMS was \(-0.23 \pm 0.74\) \(\mu\)m in Group I and \(-0.99 \pm 1.01\) \(\mu\)m in Group K; the difference was statistically significant \((P = .04,\) Wilcoxon test).

**Complications**

Explantation of the ICRS was performed in 3 eyes \((8.11\%),\) all in Group K. In 1 of the cases, the ICRS were explanted because of secondary extrusion after a bacterial keratitis that had been appropriately treated with an intensive fortified antibiotic–corticosteroid combination. In the other 2 cases, explantation was performed because of a poor postoperative visual outcome. Corneal melting and corneal neovascularization were not observed in any case.

**DISCUSSION**

In 2000, Colin et al.\(^{20}\) reported the first results of ICRS implantation in eyes with keratoconus. They found a reduction in the corneal steepening and astigmatism associated with keratoconus. Since then, several studies\(^1{–36}\) have confirmed the efficacy and safety of ICRS implantation in reducing spherocylindrical error and corneal steepening in the short term and long term. However, predicting the amount of flattening and refractive change induced by ICRS in ectatic corneas remains complicated. The mechanism of action of ICRS in ectatic corneas is not the same as in normal corneas. The stromal structure is altered in ectatic corneas, having a nonorthogonal lamellar architecture\(^{45}\); this makes it more difficult to predict the ICRS’ mechanism of action. More studies of the effect of ICRS on the ectatic corneal structure are necessary to define a predictable ICRS implantation nomogram.

In the present study, we analyzed and compared the short-term refractive and aberrometric performance of 2 types of ICRS—Intacs (Group I) and KeraRings (Group K)—in ectatic corneas (keratoconus, PMD, post-LASIK ectasia). To our knowledge, this is the first study comparing the effect of the 2 types of ICRS.

Postoperatively, sphere and SE were significantly reduced in both groups. The spherical correction has been reported by others\(^{2,4,5,9,10,12}\). In addition, there was slight but not significant regression of the achieved spherical correction at 6 months in both groups, a finding also reported in medium-term studies of Intacs ICRS in keratoconic eyes.\(^{7,8,11,15}\) Cylinder decreased significantly in Group K but not in Group I, indicating that Intacs ICRS are more limited in terms of correcting astigmatism. This supports findings in previous studies\(^4,6\) which found a nonsignificant change in manifest astigmatism after Intacs ICRS implantation in eyes with keratoconus. However, other studies\(^2,9–12,19,43\) report significant changes in manifest astigmatism with this type of ICRS. The reason for the discrepancy could be the difference in the severity of the cases between our study and the previous studies. Our study included only mild to moderate cases, whereas many of the other studies included cases with keratoconus grade III and IV. In addition, we included only cases with low or moderate corneal asymmetry (Alió-Shabayek classification, low magnitude of coma-like aberrations).

In our study, Intacs ICRS were not as effective as KeraRings ICRS in controlling astigmatism. This finding is not surprising given that these ICRS are placed farther from the corneal center, reducing the effect of the segments. Patel et al.\(^{38}\) predicted this, although it has not been proven in clinical practice. Ruckhofer et al.\(^{17}\) proposed using short arc-length segments (120 degrees) for Intacs ICRS to achieve more effective astigmatism correction. This modification led to a significant reduction in keratometric cylinder. KeraRings ICRS have 4 arc-length options (90 degrees, 120 degrees, 160 degrees, 210 degrees), allowing more accurate surgical planning and more effective astigmatism control. In addition, there was a statistically significant regression in cylindric correction from 3 months to 6 months in Group K \((P = .05)\). One reason for the regression might be progression of the cone. If this is the case, the ICRS did not stop progression of the cone; however, longer follow-up is needed to confirm this.

The UDVA increased significantly in Group K but not in Group I, which is consistent with the higher magnitude of astigmatic correction in Group K. Furthermore, the CDVA increased significantly only in Group K, which is consistent with the significantly higher safety index in this group at 6 months. We found a significant increase in CDVA after KeraRings ICRS implantation in eyes with early, moderate, or advanced keratoconus.\(^5\)

Other studies\(^2,8–12,15,22,44\) report a significant increase in CDVA after Intacs ICRS implantation in different and heterogenous groups of ectatic eyes. In our study, safety was good with both types of ICRS, with 41.18% of eyes in Group I and 52.94% in Group K gaining 1 or more lines of CDVA at 6 months.

Regarding corneal curvature, the mean K values were significantly lower with both types of ICRS, which supports the changes in corneal curvature reported by other studies of ICRS.\(^2,4–12,15,22,29,33,44\) Therefore, both ICRS induce significant central flattening, which explains the significant reduction in the spherical error. In our series, this flattening effect was maintained during the 6-month follow-up.
In addition to visual and refractive outcomes, we analyzed the aberrometric changes at the anterior corneal surface. This is the first refractive interface (air–cornea) and is the most important contributor to the total power of the eye due to the large difference in the refractive index at this point. In highly aberrated corneas, such as in cases of corneal ectasia, the anterior corneal surface is the most important source of optical aberrations in the eye. Thus, analysis of these optical errors is mandatory to gain a better understanding of patients’ visual complaints after ICRS implantation. We observed different aberrometric changes in the short term with both types of ICRS. Intacs ICRS induced significant negativization of the primary spherical aberration, whereas KeraRings ICRS induced a slight and nonsignificant increase, but with a positive sign. The significant difference in this aberration between the groups lessened progressively during the subsequent follow-up. There are significant differences between the 2 types of ICRS, including the cross-section shape (hexagonal versus triangular) and inner diameter (6.6 mm versus 4.8 mm). These factors might account for the differences in aberrometry.

With both types of ICRS, primary coma and coma-like aberrations were lower 6 months postoperatively than preoperatively; however, the changes did not reach statistical significance. The reduction in coma-like errors occurred at 6 months in Group I but immediately after implantation in Group K. This could explain why Group K had a significant improvement of CDVA at 3 months but Group I did not. Primary coma has a very negative impact on visual acuity because it induces optical blur. In a previous study, we found a significant reduction of higher-order aberrations after KeraRings ICRS implantation using the femtosecond laser technology in eyes with keratoconus; however, the reduction was significant only in eyes with a magnitude of coma aberration greater than 3.0 μm.

In conclusion, both types of ICRS used in our study were safe and effective in reducing spherical error and inducing central corneal flattening in early to moderate ectatic corneas (eyes with low levels of coma-like aberrations). However, the ability of Intacs ICRS to correct astigmatism in these eyes was more limited; this ICRS model induced negative primary spherical aberration in the early postoperative period, although this tendency disappeared by 6 months. In addition, coma-like aberrations tended to decrease after ICRS implantation, and the change occurred more rapidly with the KeraRings ICRS. Studies with a longer follow-up are needed to confirm the stability of visual, refractive, and aberrometric outcomes over the long term. Also, more studies of refractive and aberrometric results with short arc-length ICRS are needed to confirm their effectiveness in correcting astigmatism.

The reduction in segment diameter seems to be key to more effective control of astigmatism. However, if the segments are nearer from the pupil margins, visual quality can be adversely affected because scattered rays of light by the ICRS could reach the retina, inducing blur and glare sensation. Therefore, a compromise between ring effect and visual quality should be defined to achieve more efficacious control of the spherical-cylindrical error without inducing photic phenomena.

REFERENCES