Comparison of 2 types of intrastromal corneal ring segments for keratoconus

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PURPOSE: To assess the effectiveness and safety of 2 types of 6.0 mm intrastromal corneal ring segments (ICRS) in patients with mild to severe keratoconus.

SETTING: Lebanese American University, Beirut, Lebanon.

DESIGN: Retrospective comparative case series.

METHODS: Eyes had implantation of Intacs SK ICRS (Group 1) or Keraring SI6 ICRS (Group 2). Visual acuity (logMAR), refraction, keratometry, and higher-order aberrations were compared 6 months and 1 year postoperatively.

RESULTS: Group 1 comprised 66 eyes and Group 2, 107 eyes. The groups were comparable preoperatively. One-year postoperatively, the mean uncorrected distance visual acuity improved by 0.62 logMAR ± 0.19 (SD) in Group 1 and by 0.67 ± 0.17 logMAR in Group 2 (P=.211). The mean corrected distance visual acuity improved by 0.12 ± 0.11 logMAR and by 0.08 ± 0.13, respectively (P=.301). The spherical equivalent decreased by a mean of 2.80 ± 2.87 D and 2.65 ± 3.00 D, respectively (P=.572). Keratometry (K) flat and K steep decreased by a mean of 1.51 ± 1.57 D and 2.24 ± 1.61 D, respectively, in Group 1 and by 1.10 ± 2.00 D and 1.44 ± 1.64 D, respectively, in Group 2 (P=.667 and P=.184, respectively). Primary coma root mean square decreased by a mean of 1.09 ± 0.66 μm in Group 1 and 0.99 ± 0.72 μm in Group 2 (P=.716).

CONCLUSION: Both ICRS models significantly improved visual function in patients with keratoconus, with comparable postoperative profiles and no major complications.

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Keratoconus is a bilateral asymmetric degenerative disease of the cornea. It is characterized by localized corneal thinning and steepening that induce irregular astigmatism and by a decrease in visual acuity. In advanced stages, it can lead to corneal scarring.[1,2] The increased prevalence of patients having refractive surgery during the past decade has resulted in the detection of subclinical forms of the disease that were previously unnoticed. The prevalence of keratoconus varies by region. Reports in New Zealand mention a prevalence of 0.7%[3] and in Minnesota of 0.0545%.[4] It is more frequently encountered in the Middle East, with a reported prevalence of 3.3% in an epidemiology study screening a group of Lebanese students with anterior corneal topography.[5]

Except for penetrating and lamellar keratoplasty, few surgical options are available for the treatment of keratoconus. Excimer laser procedures are generally not recommended because of the risk for postoperative ectasia and disease progression.[6,7] Recently, intrastromal corneal ring segments (ICRS) were introduced as an alternative option for the refractive rehabilitation of patients with keratoconus, especially those with poor visual acuity not correctable with glasses and those with contact lens intolerance. One or 2 circular rings of poly(methyl methacrylate) are inserted in the midperipheral corneal stroma. The net result is a flattening effect and regularization of the anterior corneal surface, leading to improved refraction and visual acuity. Many ICRS are available on the international market. They differ in shape, cross-section, curvature, thickness, and arc length.

The purpose of this study was to evaluate and compare the visual, refractive, and keratometric outcomes

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in eyes with mild, moderate, or severe keratoconus that had implantation of 1 of 2 types of ICRS, both of which have an inner optical zone of 6.0 mm.

PATIENTS AND METHODS

This retrospective comparative case series evaluated consecutive keratoconus patients who had ICRS implantation between January 2009 and January 2010 at Laser Vision Center, Beirut, Lebanon. The patients had mild to severe keratoconus and were eligible for ICRS insertion. The Institutional Review Board, Ophthalmic Consultants of Beirut, reviewed and approved the study design. After receiving a full explanation of the procedure, all patients signed an informed consent form for ICRS implantation.

Exclusion criteria were corneal opacification or scars, history of keratitis (any form), peripheral marginal degeneration, previous corneal and/or intraocular surgery, and autoimmune and/or connective tissue disease. Inclusion criteria included all patients with mild to severe keratoconus with clear corneas who had implantation of 1 of the 2 brands of study ICRS.

Preoperative Assessment

Patients were asked to remove contact lenses for at least 2 weeks before topographic examinations. Preoperative screening consisted of a complete ophthalmic workup including uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest and cycloplegic refractions, and anterior and posterior segment evaluations with dilated fundus examinations. All patients also had Placido-disk Scheimpflug topography using the Pentacam device (Oculus, Optikgeräte GmbH).

Keratoconus Staging

The modified Amsler-Krumeich keratoconus classification system[8] was used to grade the keratoconus. The classification has 4 stages as follows: stage I, mild with a mean central keratometry (K) reading of 48.0 diopters (D) or more, root-mean-square (RMS) coma between 1.5 μm and 2.5 μm, and no scarring; stage II, moderate with a mean central K reading between 48.0 D and 53.0 D, RMS coma between 2.5 μm and 3.5 μm, minimum pachymetry of more than 400 μm, and no scarring; stage III, a mean central K reading of 55.0 D or less, RMS coma of 4.5 μm or less, minimum pachymetry between 300 μm and 400 μm, and no scarring; stage IV, severe with a mean central K reading of more than 55.0 D, RMS coma of more than 4.5 μm, minimum pachymetry approximately 200 μm, and central corneal scarring. Patients were placed in 1 of 2 subgroups based on keratoconus severity as follows: mild to moderate (stages I and II) and moderate to severe (stages III and IV). Patients with central corneal scarring were excluded.

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Intrastromal Corneal Ring Segments

The study used Intacs SK ICRS (Addition Technology, Inc.) (Group 1) and Keraring SI6 ICRS (Mediphacos Ltda.) (Group 2). The older Intacs ICRS model has a hexagonal cross-section and a fixed arc length of 150 degrees and is available in segment thicknesses between 250 μm and 450 μm. The segments are usually implanted in a 7.0 mm optical zone and at 30-degree angulation (ie, zero degree relative to the corneal lamellae). The newer model used in this study is inserted in a 6.0 mm optical zone and has an elliptical cross-section. Its design and proximity to the visual axis allow correction of larger amounts of refractive errors (especially myopia).[9,10]

The older Keraring ICRS has a triangular cross-section and is available in segments of variable thicknesses (150 μm to 350 μm) and arc lengths (90 degrees to 210 degrees). It is usually implanted in a 5.0 mm optical zone and at zero-degree angulation (ie, 30 degrees relative to the corneal lamellae). The newer model used in this study is implanted in a 6.0 mm optical zone and has a modified scalene triangular cross-section and a wider base.

Surgical Technique

The same surgeon (W.H.) performed all ICRS implantations. The eye to be treated was prepared with a topical anesthetic agent and an iodine solution, after which an eyelid speculum was placed. The geometric center of the cornea was marked.

All tunnels were created with a femtosecond laser (Intralase FS60, Abbott Medical Optics, Inc.). The docking ring of the laser was centered on the pupillary axis in Group 1 and on the visual axis in Group 2, as recommended by the respective manufacturers. The incision was performed on the steepest axis, and a 360-degree tunnel was created at a mean depth of 70% of the thinnest corneal pachymetry in the midperipheral area where the ICRS were to be inserted. The suction was then released, and the cone and docking ring were removed from the eye. The ICRS were soaked in moxifloxacin hydrochloride 0.5% and inserted in the tunnel using a forceps and spatulas provided by the respective manufacturers. The number of segments (1 or 2) and the thickness of the ICRS in Group 1 and the thickness and arc lengths of ICRS in Group 2 were chosen according to the published nomograms defined by the respective manufacturers. A10-0 nylon suture was used to close the incision site in Group 1. Sutures were removed at 2 months based on the ICRS manufacturer's recommendations, even though the wounds showed signs of healing before that time. The incision site was left unsutured in Group 2.

A bandage contact lens was placed on all eyes and removed after 24 hours. Patients were instructed to use dexamethasone sodium phosphate 0.1% eyedrops and moxifloxacin hydrochloride 0.5% eyedrops 4 times daily each for 7 days followed by a progressive taper over the next 10 days.

Postoperative Assessment

Postoperatively, all patients were examined at 1 day and 1, 6, and 12 months. Some patients had more frequent visits. The UDVA, CDVA, manifest refraction, K readings, and

corneal coma RMS were measured. Keratometric readings and coma values were obtained from Placido-disk Scheimpflug topography (Pentacam).

Data Analysis

The effectiveness of ICRS implantation in correcting astigmatism was evaluated by a vectorial astigmatism outcomes analysis that uses 3 fundamental vectors as follows: target-induced astigmatism (TIA) vector, surgically induced astigmatism (SIA) vector, and difference vector, as described by Alpins.[11] The TIA represents the intended astigmatic change (magnitude and axis) induced by surgery. The SIA represents the actual astigmatic change (magnitude and axis) induced by surgery. The difference vector represents the astigmatic change (magnitude and axis) that would enable the initial surgery to achieve the intended target (vectorial difference).

Errors in treatment measurements were also calculated. These included the magnitude of error and the angle of error. The magnitude of error is the arithmetic difference between the magnitudes of the SIA and TIA. It is positive for overcorrections and negative for undercorrections. The angle of error is the angle described by the 2 vectors SIA and TIA. It is positive if the achieved correction is on an axis counterclockwise to where it was intended and negative if the achieved correction is on an axis clockwise to where it was intended. The index of success of the astigmatic treatment was calculated by dividing the difference vector by the TIA. An index of success of zero means total astigmatism correction.

Statistical Analysis

Statistical analysis was performed using SPSS for Windows software (version 16.0, SPSS, Inc.). The Student *t* test for paired data was used to compare parameters. A 2-tailed probability of 0.05 or less was considered statistically significant.

RESULTS

The study enrolled 173 eyes of 120 patients. Group 1 (Intacs SK ICRS) comprised 66 eyes of 40 patients and Group 2 (Keraring SI6 ICRS), 107 eyes of 80 patients. In Group 1, 2 segments were inserted in 53 eyes and 1 segment was inserted in 13 eyes. In Group 2, 2 segments were inserted in 80 eyes and 1 segment was inserted in 27 eyes. Sixty-four patients (53%) in Group 1 were men, and 17 patients (43%) in Group 2 were men. The mean age of the patients was 29.27 years ± 10.10 (SD) and 29.00 ± 11.00 years, respectively. The 2 groups were comparable in sex and age ($P = .213$ and $P = .915$, respectively). Table 1 shows preoperative refractive characteristics and keratoconus classification by group.

Visual Acuity

The UDVA and CDVA showed a significant improvement from baseline to the 6-month follow-up visit in both groups, with no trend toward regression at the 1-year follow-up visit (Tables 2 and 3). There was no statistically significant difference in preoperative or postoperative UDVA or CDVA between the 2 groups ($P = .489$ and $P = .089$, respectively). At the 1-year follow-up, the UDVA improved by a mean of 0.62 ± 0.19 logMAR in Group 1 and 0.67 ± 0.17 logMAR in Group 2 ($P = .211$). The CDVA improved by

Table 1. Between-group comparison of preoperative refractive characteristics and keratoconus classification.

Parameter	Group 1 (66 Eyes)	Group 2 (107 Eyes)	*P* Value
Visual acuity and refraction			
UDVA (logMAR)	0.92 ± 0.23	0.90 ± 0.14	.49
CDVA (logMAR)	0.30 ± 0.21	0.24 ± 0.15	.09
Manifest shere (D)	−7.07 ± 5.45	−6.84 ± 4.08	.75
Manifest cylinder (D)	4.07 ± 2.28	3.83 ± 2.04	.47
SE (D)	−5.03 ± 5.07	−4.92 ± 3.73	.87
K (flat) (D)	48.55 ± 5.34	47.04 ± 4.20	.12
K (steep) (D)	52.47 ± 5.70	51.03 ± 4.35	.06
CCT (µm)	467.31 ± 38.60	477.95 ± 47.60	.13
Thinnest pachymetry (µm)	435.95 ± 49.19	437.52 ± 51.80	.84
Anterior elevation (µm)	32.84 ± 11.37	28.16 ± 12.54	.12
Posterior elevation (µm)	71.40 ± 27.61	62.46 ± 26.98	.10
Primary coma RMS (µm)	3.61 ± 1.05	3.07 ± 1.35	.10
Amsler-Krumeich classification, n (%)			.27
Mild–moderate	39 (59)	72 (67)	
Moderate–severe	27 (41)	35 (33)	

CCT = central corneal thickness; CDVA = corrected distance visual acuity; K (flat) = keratometry in the flat axis; K (steep) = keratometry in the steep axis; RMS = root mean square; SE = spherical equivalent; UDVA = uncorrected distance visual acuity
Means ± SD

Table 2. Refractive outcomes at 6 months and 1 year in Group 1.

Parameter	Mean ± SD		*P* Value (Preop–6 Mo)	Mean ± SD	*P* Value (6 Mo–1 Y)
	Preop	6 Mo		1 Y	
UDVA (logMAR)	0.92 ± 0.23	0.32 ± 0.15	<.001	0.30 ± 0.14	.30
CDVA (logMAR)	0.30 ± 0.21	0.19 ± 0.13	.015	0.18 ± 0.15	.86
Manifest sphere (D)	−7.07 ± 5.45	−4.75 ± 2.97	.0001	−3.60 ± 2.30	.72
Manifest cylinder (D)	4.07 ± 2.28	2.81 ± 1.18	.005	3.08 ± 1.23	.17
SE (D)	−5.03 ± 5.07	−3.35 ± 3.02	.001	−2.06 ± 1.90	.45
K (flat) (D)	48.55 ± 5.34	46.62 ± 4.67	.0001	46.55 ± 4.88	.80
K (steep) (D)	52.47 ± 5.70	50.06 ± 5.69	.0001	50.50 ± 8.49	.84
CCT (µm)	467.31 ± 38.60	468.89 ± 45.95	.512	452.10 ± 29.03	.10
Thinnest pachymetry (µm)	435.95 ± 49.19	448.37 ± 52.32	.012	443.02 ± 29.12	.21
Anterior elevation (µm)	32.84 ± 11.37	25.01 ± 12.06	.002	26.01 ± 6.12	.66
Posterior elevation (µm)	71.40 ± 27.61	62.37 ± 26.78	.033	63.10 ± 20.02	.90
Primary coma RMS (µm)	3.61 ± 1.05	—	—	2.52 ± 1.18	—

CCT = central corneal thickness; CDVA = corrected distance visual acuity; K (flat) = keratometry in the flat axis; K (steep) = keratometry in the steep axis; RMS = root mean square; SE = spherical equivalent; UDVA = uncorrected distance visual acuity

a mean of 0.12 ± 0.11 logMAR in Group 1 and 0.08 ± 0.13 logMAR in Group 2 (P=.301) (Figure 1).

Refraction

There was no statistically significant difference in preoperative refraction between Group 1 and Group 2 (P>0.470) (Table 1). The manifest sphere and manifest cylinder showed a significant improvement from baseline to the 6-month follow-up visit in both groups, with no trend toward regression at 1 year (Tables 2 and 3).

There was no statistically significant difference in the components of the vectorial analysis of astigmatism between the 2 groups at the 1-year follow-up evaluation except in the magnitude of error (P=.0001) and the angle of error (P=.0003) (Table 4). Overall, the mean decrease in SE was 2.80 ± 2.87 D in Group 1 and 2.65 ± 3.00 D in Group 2, with no statistically significant difference between the 2 groups (P=.572).

The results were similar in the subgroup with mild to moderate keratoconus, with no statistically significant difference between Group 1 and Group 2 (Table 4). In patients with moderate to severe keratoconus, the postoperative cylinder was statistically significantly higher in Group 2 (Table 4).

Topography

Flat and steep K values, anterior elevation, and posterior elevation showed a significant improvement from baseline to the 6-month follow-up visit in both

Table 3. Refractive outcomes at 6 months and 1 year in Group 2.

Parameter	Mean ± SD		*P* Value (Preop–6 Mo)	Mean ± SD	*P* Value (6 Mo–1 Y)
	Preop	6 Mo		1 Y	
UDVA (logMAR)	0.90 ± 0.14	0.23 ± 0.13	<.001	0.24 ± 0.18	.70
CDVA (logMAR)	0.24 ± 0.15	0.16 ± 0.16	.005	0.16 ± 0.13	.90
Manifest sphere (D)	−6.84 ± 4.08	−3.19 ± 2.22	.0001	−3.10 ± 1.94	.52
Manifest cylinder (D)	3.83 ± 2.04	2.24 ± 1.18	.0001	1.90 ± 1.02	.24
SE (D)	−4.92 ± 3.73	−2.07 ± 2.06	.0001	−2.13 ± 1.08	.12
K (flat) (D)	47.04 ± 4.20	46.25 ± 3.39	.001	45.80 ± 1.24	.80
K (steep) (D)	51.03 ± 4.35	49.76 ± 3.97	.0001	49.83 ± 1.93	.60
CCT (µm)	477.95 ± 47.60	469.41 ± 51.21	.795	466.11 ± 29.71	.21
Thinnest pachymetry (µm)	437.52 ± 51.80	448.94 ± 52.90	.0001	447.83 ± 29.34	.10
Anterior elevation (µm)	28.16 ± 12.54	21.97 ± 11.39	.0001	22.67 ± 9.40	.68
Posterior elevation (µm)	62.46 ± 26.98	60.97 ± 21.59	.003	61.10 ± 19.94	.82
Primary coma RMS (µm)	3.07 ± 1.35	—	—	2.08 ± 1.17	—

CCT = central corneal thickness; CDVA = corrected distance visual acuity; K (flat) = keratometry in the flat axis; K (steep) = keratometry in the steep axis; RMS = root mean square; SE = spherical equivalent; UDVA = uncorrected distance visual acuity

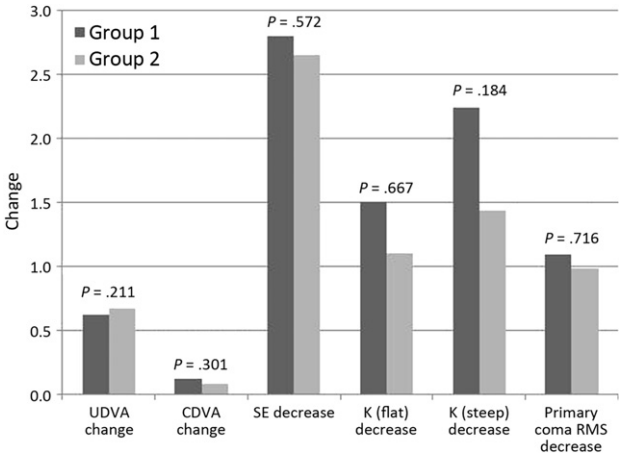

Figure 1. Relative change in visual acuity (logMAR), SE, corneal curvature, and coma at 1 year by group (CDVA = corrected distance visual acuity; K (flat) = keratometry in the flat axis; K (steep) = keratometry in the steep axis; RMS = root mean square; SE = spherical equivalent; UDVA = uncorrected distance visual acuity).

groups, with no trend toward regression at 1 year (Tables 2 and 3). There was no statistically significant difference between the groups in flat or steep K values, central corneal thickness, thinnest pachymetry, anterior elevation, or posterior elevation at any measured time point (Tables 1 and 4).

Overall, the mean decrease was 1.51 ± 1.57 D in K (flat) and 2.24 ± 1.61 D in K (steep) in Group 1 and 1.10 ± 2.00 D and 1.44 ± 1.64 D, respectively, in Group 2. There was with no statistically significant difference between the 2 groups ($P = .667$ and $P = .184$, respectively).

Higher-Order Aberrations

Primary coma RMS was improved significantly from preoperatively to 1 year postoperatively in both groups. There was no statistically significant difference between the 2 groups at baseline or at the 1-year follow-up visit ($P = .267$ and $P = .319$, respectively) (Tables 1 to 4). Overall, the decrease in primary coma RMS was 1.09 ± 0.66 µm in Group 1 and 0.99 ± 0.72 µm in Group 2 ($P = .716$) (Figure 1).

Complications

Perioperative complications occurred in 6 eyes (3.47%). Deep implantation occurred in 2 eyes. In the first eye, microperforation was encountered during femtosecond laser channel creation. Thus, the procedure was stopped. A channel was successfully created the next day at a depth 50 µm anterior to the original depth. In the second eye, localized endothelial dysfunction occurred over the area of the inferior ring, leading to a crescent of pseudophakic-like bullous keratopathy. The ring was explanted and reimplanted at 1 month at a depth 50 µm anterior to the original depth.

The implanted segments broke during implantation in 3 eyes (2 Keraring SI6 segments of 210-degree arc length and 150 µm thickness and 1 Intacs SK segment of 210 µm thickness). The cracked segments were kept in place inside the channel.

Recurrent epithelial erosions at the incision site occurred in 1 eye. This ultimately led to scarring of the incision area with no visual sequelae.

There were no segment extrusions. One eye had a localized infiltrate at the suture site that was successfully treated with suture removal and an increase in the topical moxifloxacin drops.

DISCUSSION

Poly(methyl methacrylate) ICRS were initially implanted to reduce myopia by the flattening they induce.[12,13] By their effect on corneal curvature, ICRS improves the refractive and topographic characteristics of patients with keratoconus. There is no evidence in the literature suggesting that the disease progression is altered; however, the clinical need for corneal transplantation in these patients might be delayed. Contact lens fitting becomes easier, and previously contact lens–intolerant eyes will better tolerate rigid gas-permeable contact lenses.[9,10,14–18] Intacs ICRS were approved under a Humanitarian Device Exemption by the U.S. Food and Drug Administration in July 2004, allowing them to be used for treating keratoconus.

The use of ICRS in keratoconus is a matter of debate among refractive surgeons. Many variables come into play and dictate the choice of ICRS for patients with keratoconus. These include 1 or more of the following:

1. The incision site: Should it be at the steep topographic axis, at the steep refractive axis, or at the axis of coma?
2. The method of channel creation: Are there advantages to using a femtosecond laser to create the tunnels over the use of the manual mechanical trephine?
3. Centration: Should we center over the pupillary axis or over the visual axis?
4. Segment characteristics: What diameters should be used? What is the best depth of insertion? What is the best optical zone of implantation? Should we insert 1 or 2 segments? If 2 segments are implanted, should they be of equal sizes?
5. Type of the ring used: Should it be Intacs, Keraring, or Ferrara (Ferrara Ring Inc.) Should we follow the manufacturer's nomogram, or modify the nomogram according to personal experience?

Table 4. Between-group comparision of refractive characteristics 1 year postoperatively by keratoconus grade.

Keratoconus Group/Parameter	Mean ± SD		*P* Value
	Group 1	Group 2	
All patients			
UDVA (logMAR)	0.30 ± 0.14	0.24 ± 0.18	.10
CDVA (logMAR)	0.18 ± 0.15	0.16 ± 0.13	.36
Manifest sphere (D)	−3.60 ± 2.30	−3.10 ± 1.94	.13
Manifest cylinder (D)	3.08 ± 1.23	1.90 ± 1.02	<.001
SE (D)	−2.06 ± 1.90	−2.13 ± 1.08	.76
TIA* (D)	4.18 ± 2.19	3.83 ± 2.04	.29
SIA* (D)	2.52 ± 2.09	3.37 ± 2.10	.06
DV* (D)	2.87 ± 1.17	2.24 ± 1.18	.05
MoE* (D)	−1.89 ± 1.60	−0.74 ± 1.58	<.001
AoE* (D)	14.30 ± 30.11	−2.62 ± 28.50	<.001
IoS* (D)	0.73 ± 0.29	0.75 ± 0.72	.83
K (flat) (D)	46.55 ± 4.88	45.80 ± 1.24	.13
K (steep) (D)	50.50 ± 8.49	49.83 ± 1.93	.18
CCT (μm)	452.10 ± 29.03	466.11 ± 29.71	.06
Thinnest pachymetry (μm)	443.02 ± 29.12	447.83 ± 29.34	.30
Anterior elevation (μm)	26.01 ± 6.12	22.67 ± 9.40	.11
Posterior elevation (μm)	63.10 ± 20.02	61.10 ± 19.94	.52
Primary Coma RMS (μm)	2.52 ± 1.18	2.08 ± 1.17	.19
Mild–moderate			
UDVA (logMAR)	0.57 ± 0.29	0.63 ± 0.23	.23
CDVA (logMAR)	0.10 ± 0.09	0.08 ± 0.10	.30
Manifest sphere (D)	3.08 ± 2.16	3.37 ± 1.98	.47
Manifest cylinder (D)	0.82 ± 1.28	1.35 ± 1.45	.06
SE (D)	2.67 ± 2.28	2.64 ± 2.41	.95
K (flat) (D)	1.59 ± 1.28	1.35 ± 1.70	.44
K (steep) (D)	0.97 ± 1.08	1.15 ± 1.13	.42
Moderate–severe			
UDVA (logMAR)	0.69 ± 0.27	0.72 ± 0.24	.64
CDVA (logMAR)	0.14 ± 0.11	0.11 ± 0.10	.27
Manifest sphere (D)	4.03 ± 2.33	4.50 ± 2.39	.44
Manifest cylinder (D)	1.24 ± 1.18	3.02 ± 2.03	.002
SE (D)	3.40 ± 2.31	3.10 ± 2.50	.63
K (flat) (D)	2.60 ± 1.19	2.10 ± 1.63	.18
K (steep) (D)	1.63 ± 1.15	2.19 ± 1.19	.07

AoE = angle of error; CDVA = corrected distance visual acuity; DV = difference vector; ICRS = intracorneal ring segments; IoS = index of success; K (flat) = keratometry in the flat axis; K (steep) = keratometry in the steep axis; MoE = magnitude of error; RMS = root mean square; SE = spherical equivalent; SIA = surgically induced astigmatism vector; TIA = target-induced astigmatism vector; UDVA = uncorrected distance visual acuity
*Vectorial analysis of astigmatism components

Each refractive surgeon has his or her own technique and preferences. This variability makes comparison of results and outcomes between studies difficult. Overall, studies evaluating the efficacy of Intacs and Keraring ICRS[9,10,14–26] found good results, with significant postoperative improvement in visual acuity, refraction, and topography.

In the present study, the incision site was placed at the steepest topographic meridian, the tunnels were made using the femtosecond laser, and the characteristics (thicknesses, arc lengths) and number of segments used (1 or 2) depended on the nomograms provided by the respective manufacturers. To our knowledge, this is the first study comparing 2 different 6.0 mm optical zone ICRS—the Intacs SK and the Keraring SI6. Previous studies have compared Intacs ICRS and Keraring ICRS; however, the first generation of Intacs ICRS and Keraring ICRS had a 7.0 mm and a 5.0 mm optical zone, respectively.[27–29] The smaller optical zone ICRS (Keraring 5.0 mm) has a stronger corneoplastic effect but has higher risk for glare and halos.[27,29]

In our study, there was a significant improvement in UDVA, CDVA, mean SE, mean cylinder, keratometric

curvatures, anterior and posterior corneal elevations, and primary coma RMS in both groups at 1 year. Both groups were comparable preoperatively. Both groups had a similar improvement in visual acuity, refraction, and keratometry except for the mean cylinder and the magnitude of error of vectorial astigmatism, which were better in the Keraring SI6 group. However, we believe that this statistical difference is not significant in practice and that both ICRS types result in similar astigmatism correction because all other vectorial astigmatism parameters, especially the index of success of astigmatism correction, were not statistically significantly different between the 2 groups.

By performing vector analysis of astigmatism change, the TIA and SIA were not statistically different between the 2 groups. It is known that ICRS insertion changes the anterior surface and thus induces corneal astigmatism. The induced astigmatism is not always regular and is not easy to predict. The TIA, therefore, contrary to the case in treatments targeting complete reversal of corneal astigmatism, is difficult to envision preoperatively and the target desired cylinder might be very different than the obtained cylinder correction. The actual astigmatic change (SIA) was higher in Group 2, indicating that Keraring SI6 ICRS might induce more astigmatism postoperatively. The magnitude of error showed a tendency toward undercorrection in both groups because the cornea behaves in a not-so-predictable way after ICRS insertion. The angle of error was statistically different between the 2 groups. The correction was on an axis counterclockwise to what was intended in Group 1 and on an axis clockwise to that intended in Group 2. The index of success was less than 1 in both groups.

When we started this study and were gathering data on follow-ups, our team had a few subjective impressions. These included a speedier effect of the Keraring SI6 ICRS with an earlier "wow-factor" for the patients and a stronger astigmatic correction than with the Intacs SK ICRS. None of these impressions was proven statistically, and we cannot favor 1 ring over the other in terms of any postoperative outcome.

There was no ring extrusion in our study; this may be partly due to the wide optical zone used. When the tunnel is dissected at a wider optical zone, it is usually done in a thicker area of the cornea (except probably in the cone area). This leaves more tissue above the ICRS, providing a thicker buffer zone against eyelid rubbing, blinking, and extrusion. Another reason for the lack of extrusion could be the cross-sectional design of the newer ICRS.

Another issue is the depth of the ring insertion, which ranges between 65% and 80% of the thinnest midperipheral pachymetry for most ICRS types. We noticed that with K values exceeding 60.0 D, the achieved depth was deeper than intended, with 2 patients having a pre-Descemet implantation. We believe this is related to the weaker, more compressible corneal lamellae in those patients, which thin out more during applanation. For this reason, we started programming the laser to cut at 60% depth in eyes with K values over 60.0 D.

In conclusion, both Intacs SK ICRS and Keraring SI6 ICRS have a place in the visual rehabilitation of patients with mild to severe keratoconus. Their implantation significantly improved visual acuity, refraction, topography, and coma at 1 year. Both procedures were safe and yielded comparable results.

WHAT WAS KNOWN

- Intracorneal ring segments have been used to correct corneal curvature irregularities in eyes with keratoconus by flattening the central cornea and leading to improvement in myopia and astigmatism.

WHAT THIS PAPER ADDS

- This is the largest reported comparison of ICRS types inserted at the same optical zone.
- The use of Intacs SK ICRS or Keraring SI6 ICRS led to postoperative improvement in visual function.

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