Comparison of 2 intrastromal corneal ring segment models in the management of keratoconus

Anil Kubaloglu, MD, Yasin Cinar, MD, Esin Sogutlu Sari, MD, Arif Koytak, MD, Burak Ozdemir, MD, Yusuf Ozertürk, MD

PURPOSE: To compare the outcomes of implantation of 2 models of intrastromal corneal ring segments (ICRS) to manage keratoconus.

SETTING: Kartal Training and Research Hospital, Istanbul, Turkey.

METHODS: This study evaluated eyes with keratoconus that had implantation of Keraring ICRS (Group A) or Intacs ICRS (Group B). The corneal tunnels were created mechanically or with a femtosecond laser. The uncorrected (UDVA) and corrected (CDVA) distance visual acuities, refraction, keratometry (K) readings (Orbscan II), and complications in the 2 groups were compared.

RESULTS: Group A comprised 100 eyes and Group B, 68 eyes. The postoperative increase in UDVA and CDVA was statistically significant in both groups (P<.05). Group A had greater improvement in CDVA than Group B at 6 months and 1 year (both P<.001). At 1 year, the decrease in the mean maximum K power was statistically significant in Group A (51.27 diopters [D] $\pm$ 4.46 [SD] to 47.87 $\pm$ 3.39 D) and in Group B (51.12 $\pm$ 4.54 D to 47.58 $\pm$ 3.66 D) (P<.05). The mean reduction in maximum K was statistically significantly greater in Group A at 6 months and 1 year (P = .018 and P = .024, respectively). There were no statistically significant differences in visual or refractive results between femtosecond laser and mechanical tunnel creation.

CONCLUSION: Although both ICRS models were effective and safe in managing keratoconus, the Keraring ICRS led to more improvement in CDVA and UDVA and a greater reduction in the maximum K value.

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Penetrating keratoplasty (PKP) is accepted as the definitive surgical procedure in patients with keratoconus who are contact lens intolerant. Immunologic rejection, which is a major cause of graft failure, occurs in 20% to 30% of eyes that have had PKP.[1] Although there are several surgical alternatives to manage keratoconus, including photorefractive keratectomy, epikeratophakia, and sectorial keratotomy,[2–7] they have not gained popularity because of disappointing results and lack of predictability and stability.[8,9]

Deep anterior lamellar keratoplasty has recently been used to manage keratoconus. In this technique, pathologic corneal stromal tissue is removed down to Descemet membrane and replaced by a donor tissue transplant. However, the technical difficulty of removing the corneal stroma to achieve a bare Descemet membrane with no interface opacities has limited the procedure's application.

Intrastromal corneal ring segments (ICRS), which were initially designed to correct mild to moderate myopia,[10] have been evaluated as a way to manage keratoconus in cases with a clear cornea and contact lens intolerance. The main advantages of ICRS are safety, reversibility, and stability.[11] In addition, the surgery preserves the integrity of the central cornea. Several studies[11–16] have shown the efficacy of ICRS implantation for keratoconus. In this study, we compared the visual, refractive, and keratometric results and the complications in eyes having implantation of 1 of 2 ICRS models. To our knowledge, this is the first study to compare the 2 models in the management of keratoconus.

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PATIENTS AND METHODS

Data were retrieved from computerized databases of patients with keratoconus, clear central corneas, and contact lens intolerance who had ICRS implantation. All patients provided informed consent and had a follow-up of at least 6 months.

Patients were placed into 1 of 2 groups based on ICRS model. Group A had implantation of a Keraring ICRS (Mediphacos Ltda.), which has a 5.0 mm optical zone with varying arc lengths and a triangular cross-sectional design that induces a prismatic effect on the cornea. Group B had implantation of an Intacs ICRS (Addition Technology, Inc.), which has a 7.0 mm optical zone, a crescent arc length of 150 degrees, and a transverse hexagonal shape.

The following parameters were compared between the 2 groups: uncorrected (UDVA) and corrected (CDVA) distance visual acuities (Snellen charts, decimal scale), refraction, keratometry (K) readings (Orbscan II, Bausch & Lomb), and preoperative and postoperative complications. These parameters were also compared between mechanical and femtosecond-assisted corneal tunnel creation.

Surgical Technique

All surgical procedures were performed using topical anesthesia.

Mechanical Tunnel Creation In Group A, the Purkinje reflex was marked as a central point and corneal thickness was measured by ultrasound pachymetry at the 5.0 mm corneal diameter; the ring location area was then marked. The entry incision was created on the steepest corneal topographic axis with a diamond blade. The intrastromal tunnel depth was set at 70% of the thinnest corneal thickness at the incision site. A suction ring (Moria) was placed to minimize decentration. The tunnel was created using a counterclockwise and clockwise spatula. The technique was the same in Group B except the tunnel was created peripherally with a 7.0 mm optic zone.

Femtosecond-Assisted Tunnel Creation The intracorneal tunnel entry was created on the steepest corneal topographic axis using a 15 kHz femtosecond laser (IntraLase, Abbott Medical Optics, Inc.). The tunnel depth was set at 70% of the thinnest corneal thickness at the incision site. In Group A, the inner to outer diameter of the tunnel was from 4.8 to 5.6 mm, the entry cut thickness was 1 μm, the ring energy for channel creation was 1.30 μJ, and the entry cut energy was 1.30 μJ. In Group B, the inner to outer diameter was from 6.8 to 7.8 mm, the entry cut thickness was 1 μm, and the entry cut energy was 6.00 μJ.

After the intrastromal tunnels were created, the ICRS were implanted. Postoperatively, lomefloxacin and dexamethasone were prescribed 4 times a day and artificial tears 6 times a day.

Statistical Analysis

The data were entered into a spreadsheet, and statistical analysis was performed using SPSS for Windows software (version 11.5, SPSS, Inc.). Data were presented descriptively using means for continuous variables and proportions for categorical variables. Preoperative and postoperative values were compared statistically between Group A and Group B and between mechanical and femtosecond tunnel creation. A 2-tailed probability of 5% or less was considered statistically significant.

RESULTS

Group A included 100 eyes of 77 patients and Group B, 68 eyes of 42 patients. Table 1 shows the patients' characteristics and preoperative data. There was no statistically significant difference between the 2 groups in any preoperative parameter. The ICRS were successfully implanted in all eyes in both groups.

Visual Acuity

The increase in UDVA and CDVA from preoperatively to postoperatively was statistically significant in both groups ($P < .05$) (Table 2). There was no significant between-group difference in mean UDVA 6 months and 1 year after surgery (P = .15 and P = .44, respectively) (Table 3). The mean gain in UDVA from preoperatively was 2.5 Snellen lines in Group A and 1.8 Snellen lines in Group B at 6 months and 2.6 Snellen lines and 2.0 Snellen lines, respectively, at 1 year. The increase in UDVA was statistically significantly greater in Group A than Group B at 6 months (P = .044). In Group A at 1 year, the UDVA was improved (range +1 to +8 lines) in 59 eyes (83.0%), unchanged in 7 eyes (9.8%), and worse (range −1 to −2 lines) in 5 eyes (7.0%); 24 eyes (33.3%) had a UDVA of 20/40 or better. In Group B at 1 year, the UDVA was improved (range +1 to +8 lines) in 36 eyes (81.8%), unchanged in 5 eyes (11.3%), and worse (−2 lines) in 3 eyes (6.8%); 14 eyes (31.8%) had a UDVA of 20/40 or better (Figure 1).

The mean CDVA was statistically significantly better in Group A than in Group B at 6 months and 1 year (P = .005 and P = .017, respectively (Table 3). The mean gain in CDVA from preoperatively was 3.0 Snellen lines in Group A and 1.6 Snellen lines in Group B at 6 months and 3.7 Snellen lines and 1.7 Snellen lines, respectively, at 1 year. The increase in CDVA was statistically significantly greater in Group A than Group B at 6 months and 1 year (both P = .001). In Group A at 1 year, the CDVA was improved (range +1 to +8 lines) in 61 eyes (85.0%), unchanged in 7 eyes (9.8%), and worse (−1 line) in 3 eyes (4.2%); 58

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From Dr. Lütfi Kırdar Kartal Training and Research Hospital, Istanbul, Turkey.

Corresponding author: Esin Sogutlu Sari, MD, Kartal Dr Lütfi Kırdar Eğitim ve Araştırma Hastanesi, Cevizli/Istanbul, Turkey. E-mail: dresinsogutlu@hotmail.com.

Table 1. Between-group comparison of preoperative parameters.

Parameter	Group A	Group B	*P* Value
Eyes (n)	100	68	
Male/female	41/36	21/21	
Age (y)			.49†
Mean	26.44 ± 9.36	25.53 ± 6.99	
Range	18–57	18–45	
Keratoconus,* n (%)			.72‡
Stage I	28 (28.0)	21 (30.8)	
Stage II	43 (43.0)	27 (39.7)	
Stage III	16 (16.0)	8 (11.7)	
Stage IV	13 (13.0)	12 (17.6)	
Mean UDVA (Snellen)	0.15 ± 0.15	0.16 ± 0.15	.30§
Mean CDVA (Snellen)	0.33 ± 0.22	0.37 ± 0.22	.25§
Mean SE (D)	−5.00 ± 3.41	−4.08 ± 2.77	.07§
Mean sphere (D)	−3.53 ± 3.03	−3.26 ± 2.58	.78§
Mean cylinder (D)	−3.33 ± 1.86	−3.13 ± 1.29	.39§
Mean Kmax (D)	51.27 ± 4.46	51.12 ± 4.54	.83†
Mean Kmin (D)	46.41 ± 4.06	46.04 ± 2.75	.52†
Mean average K (D)	48.84 ± 4.07	48.58 ± 3.51	.67†
Mean thinnest pachymetry (μm)	424.37 ± 51.38	410.03 ± 54.80	.10†

Means ± SD
CDVA = corrected distance visual acuity; K = keratometry; Kmax = maximum keratometry; Kmin = minimum keratometry; SE = spherical equivalent; UDVA = uncorrected distance visual acuity
*According to Amsler-Krumeich keratoconus classification
†Student *t* test
‡Chi-square test
§Mann-Whitney *U* test

eyes (81.6%) had a CDVA of 20/40 or better. In Group B at 1 year, the CDVA was improved (range +1 to +8 lines) in 36 eyes (81.8%), unchanged in 5 eyes (11.3%), and worse (range −1 to −3 lines) in 3 eyes (6.8%); 26 eyes (59.0%) had a of CDVA 20/40 or better (Figure 2).

At 6 months, the UDVA in Group A was 20/40 or better in 36 eyes (36.0%), 20/25 or better in 6 eyes (6.0%), and 20/20 or better in 2 eyes (2.0%). The CDVA was 20/40 or better in 78 eyes (78.0%), 20/25 or better in 31 eyes (31.0%), 20/20 or better in 11 eyes (11.0%). Fifty-four eyes (54.0%) required spectacles and 11 eyes (11%), contact lenses. Based on patients' subjective reports, the postoperative UDVA was satisfactory in 62 eyes (62.0%).

At 6 months, the UDVA in Group B was 20/40 or better in 20 eyes (29.4%), 20/25 or better in 2 eyes (2.9%), and 20/20 or better in 1 eye (1.4%). The CDVA was 20/40 or better in 42 eyes (61.7%), 20/25 or better in 17 eyes (25%), and 20/20 or better in 6 eyes (8.8%). Thirty-five eyes (51.4%) required spectacles and 9 eyes (13.2%), contact lenses. Based on patients' subjective reports, the postoperative UDVA was satisfactory in 39 eyes (57.3%).

Refraction

The postoperative decreases in the maximum, minimum, and average K values were statistically significant in both groups ($P<.05$) (Table 2). In Group A, the mean maximum K values ranged from 48.2 to 63.4 D preoperatively, from 44.7 to 60.3 D 6 months postoperatively, and from 44.2 to 60.0 D at 1 year. In Group B, the ranges were 48.3 to 61.8 D, 44.4 to 60.2 D, and 44.3 to 60.2 D, respectively. The mean reduction in the maximum K values was statistically significantly greater in Group A than in Group B at 6 months and 1 year ($P = .018$ and $P = .024$, respectively) (Table 3). Although there were no significant differences in the mean spherical and cylindrical

Table 2. Within-group comparison between preoperative and postoperative data.

	Group A			Group B		
Parameter	Preop	1 Y Postop	*P* Value*	Preop	1 Y Postop	*P* Value*
Mean UCVA (Snellen)	0.15 ± 0.15	0.35 ± 0.21	≤.05	0.16 ± 0.15	0.36 ± 0.21	≤.05
Mean BSCVA (Snellen)	0.33 ± 0.22	0.54 ± 0.22	≤.05	0.37 ± 0.22	0.57 ± 0.25	≤.05
Mean SE (D)	−5.00 ± 3.41	−2.17 ± 1.13	≤.05	−4.08 ± 2.77	−2.21 ± 0.94	≤.05
Mean sphere (D)	−3.53 ± 3.03	−1.28 ± 0.88	≤.05	−3.26 ± 2.58	−1.26 ± 0.84	≤.05
Mean cylinder	−3.33 ± 1.86	−2.00 ± 1.29	≤.05	−3.13 ± 1.29	−1.96 ± 0.89	≤.05
Mean Kmax (D)	51.27 ± 4.46	48.51 ± 4.10	≤.05	51.12 ± 4.54	47.58 ± 3.66	≤.05
Mean Kmin (D)	46.41 ± 4.06	44.04 ± 2.75	≤.05	46.04 ± 2.75	43.49 ± 2.29	≤.05
Mean average K (D)	48.84 ± 4.07	46.28 ± 3.21	≤.05	48.58 ± 3.51	45.53 ± 2.67	≤.05
Mean thinnest pachymetry (μm)	424.37 ± 51.38	415.30 ± 58.24	>.05	410.03 ± 54.80	419.61 ± 59.95	>.05

Means ± SD
CDVA = corrected distance visual acuity; K = keratometry; Kmax = maximum keratometry; Kmin = minimum keratometry; SE = spherical equivalent; UDVA = uncorrected distance visual acuity
*Student *t* test

Table 3. Between-group comparison of postoperative data.

Parameter	6 Months Postop Group A	6 Months Postop Group B	6 Months Postop P Value	1 year Postop Group A	1 year Postop Group B	1 year Postop P Value
Eye (n)	100	68	—	71	44	—
UDVA (Snellen)						
Mean	0.40 ± 0.21	0.35 ± 0.21	.15*	0.40 ± 0.22	0.36 ± 0.21	.44*
Mean increase	0.25 ± 0.19	0.18 ± 0.18	.044*	0.26 ± 0.20	0.20 ± 0.19	.099*
CDVA (Snellen)						
Mean	0.64 ± 0.22	0.54 ± 0.22	.005†	0.68 ± 0.23	0.57 ± 0.25	.017*
Mean increase	0.30 ± 0.21	0.16 ± 0.22	<.001*	0.37 ± 0.21	0.18 ± 0.23	<.001*
SE (D)						
Mean	−2.04 ± 1.58	−2.17 ± 1.13	.58*	−2.13 ± 1.44	−2.21 ± 0.94	.32†
Mean decrease	2.95 ± 2.98	1.91 ± 2.35	.005†	3.19 ± 3.22	2.15 ± 2.56	.029†
Mean sphere (D)	−1.40 ± 1.31	−1.28 ± 0.88	.98	−1.34 ± 1.10	−1.26 ± 0.84	.66
Mean cylinder (D)	−2.01 ± 1.02	−2.00 ± 1.29	.92	−1.86 ± 0.96	−1.96 ± 0.89	.60
Kmax (D)						
Mean	47.72 ± 3.36	48.51 ± 4.1	.17†	47.87 ± 3.39	47.58 ± 3.66	.66*
Mean decrease	3.54 ± 2.52	2.60 ± 2.48	.018*	3.41 ± 2.38	2.37 ± 2.36	.024*
Mean Kmin (D)	44.84 ± 3.81	44.04 ± 2.75	.13*	44.43 ± 6.19	43.49 ± 2.29	.24†
Mean average K (D)	46.28 ± 3.43	46.28 ± 3.21	.99†	46.15 ± 4.28	45.53 ± 2.67	.39*
Mean thinnest pachymetry (μm)	427.97 ± 50.94	415.30 ± 58.24	.13*	429.48 ± 51.19	419.61 ± 59.95	.26*

Means ± SD
CDVA = corrected distance visual acuity; K = keratometry; Kmax = maximum keratometry; Kmin = minimum keratometry; SE = spherical equivalent; UDVA = uncorrected distance visual acuity
*Student *t* test
†Mann-Whitney *U* test

refractions at any postoperative period, the mean reduction in SE was statistically significantly greater in Group A than in Group B at 6 months and 1 year ($P = .005$ and $P = .029$, respectively) (Table 3). At 6 months, 31 eyes (31.0%) in Group A and 19 eyes (27.9%) in Group B were within ±1.00 D of emmetropia. No eye in either group required additional refractive surgery.

Table 4 shows the results of vectorial analysis of the cylindrical correction. Over the 1-year follow-up, there were no statistically significant differences between the 2 groups ($P > .05$).

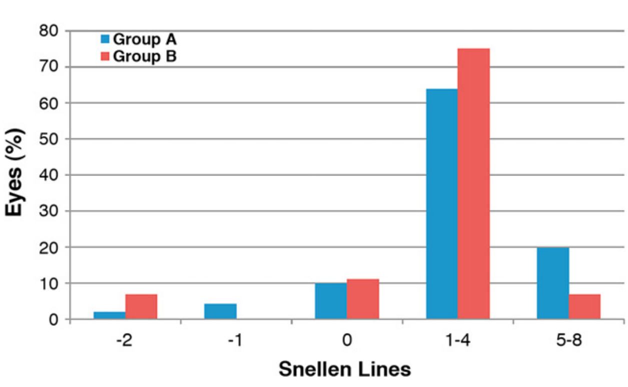

Figure 1. Change in lines of UDVA from preoperatively to 1 year.

Mechanical Versus Femtosecond Tunnel Creation

There were no statistically significant differences in the visual, refractive, and keratometric results between femtosecond and mechanical tunnel creation in either group (Tables 5 and 6).

Outcomes by Keratoconus Stage

Table 7 compares the 1-year postoperative results by keratoconus stage; that is, mild (stages I and II) and advanced (stages III and IV). In Group A, the increases in UDVA and CDVA were statistically significantly

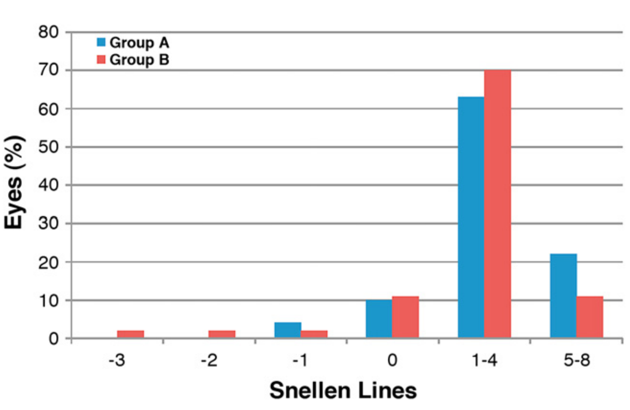

Figure 2. Change in lines of CDVA from preoperatively to 1 year.

Table 4. Vectorial analysis of cylindrical correction after first year.

	Mean ± SD				
Group	TIA (D)	SIA (D)	DV (D)	AE	ME (D)
Group A	3.11 ± 1.60	2.47 ± 1.75	1.67 ± 0.97	−1.41 ± 23.76	−0.68 ± 1.40
Group B	2.86 ± 1.06	2.11 ± 1.36	1.68 ± 0.78	−6.26 ± 24.15	−0.74 ± 1.08
P value	.37*	.27*	.60†	.23*	.82*

AE = angle of error; ME = magnitude of error; DV = differences vector; SIA = surgically induced astigmatism; TIA = target induced astigmatism
*Student *t* test
†Mann Whitney *U* test

better in eyes with mild keratoconus ($P<.01$ and $P = .03$, respectively) and the decreases in SE and maximum K were statistically significant higher in eyes with advanced keratoconus ($P<.01$). In Group B, there were no statistically significant differences between the mild keratoconus and advanced keratoconus groups in the increase UDVA and CDVA or in the decrease in SE ($P>.05$); however, the decrease in maximum K was statistically significant higher in eyes with advanced keratoconus ($P<.01$).

Complications

Table 8 shows the surgical complications. The ICRS was implanted successfully in the eye with intraoperative anterior corneal perforation during mechanical tunnel creation (Group A). After surgery, scar tissue formed in the perforation site, although no other complication was observed. The eye with segment extrusion in Group A had stage II keratoconus. The eyes with segment extrusion in Group B had stage IV keratoconus. Patients with segment extrusion had atopy and reported rubbing their eyes. In cases of segment movement, the patients had no complaints and required no surgical intervention. In the eye with shallow ICRS placement (Group A), the intrastromal corneal tunnel was recreated in at the appropriate depth and the segment was implanted again. Intrastromal yellow–white deposits were seen postoperatively in 55 eyes (55.0%) in Group A and 42 eyes (61.7%) in Group B.

DISCUSSION

Studies[11–16] show that ICRS implantation using mechanical or femtosecond tunnel creation is a safe method of managing corneal ectasia, astigmatism, and keratoconus. In eyes with keratoconus, ICRS implantation is a surgical alternative to other techniques, with the aim being to delay the need for corneal transplantation.[15,17–19] In this study, we compared the visual, refractive, and topographic results and the

Table 5. Comparison of parameters between mechanical and femtosecond tunnel creation in Group A.

	Preoperative			Postoperative					
				6 Months			1 Year		
Parameter	Mechanical	Femtosecond	*P* Value	Mechanical	Femtosecond	*P* Value	Mechanical	Femtosecond	*P* Value
Eye (n)	76	24	—	76	24	—	56	15	—
Mean UDVA (Snellen)	0.16 ± 0.15	0.11 ± 0.14	.21†	0.39 ± 0.21	0.43 ± 0.20	.25†	0.40 ± 0.23	0.40 ± 0.22	.98*
Mean CDVA (Snellen)	0.31 ± 0.20	0.37 ± 0.26	.29†	0.62 ± 0.21	0.70 ± 0.24	.09†	0.67 ± 0.22	0.69 ± 0.26	.87*
Mean SE (D)	−4.67 ± 3.17	−6.04 ± 3.96	.08*	−1.89 ± 1.44	−2.54 ± 1.91	.08*	−1.98 ± 1.33	−2.71 ± 1.73	.08*
Mean sphere (D)	−3.21 ± 2.73	−4.54 ± 3.72	.12*	−1.32 ± 1.29	−1.64 ± 1.37	.31*	−1.29 ± 1.06	−1.55 ± 1.26	.35*
Mean cylinder (D)	−3.28 ± 1.87	−3.51 ± 1.83	.60*	−2.04 ± 1.05	−1.91 ± 0.95	.59*	−1.90 ± 1.01	−1.70 ± 0.72	.47*
Mean Kmax (D)	51.21 ± 4.28	51.45 ± 5.09	.82*	47.81 ± 3.18	47.44 ± 3.96	.64*	47.59 ± 3.12	48.89 ± 4.20	.19*
Mean Kmin (D)	46.30 ± 3.82	46.75 ± 4.82	.63*	44.94 ± 3.61	44.53 ± 4.47	.64*	44.01 ± 6.5	46.0 ± 4.73	.55†
Mean average K (D)	48.75 ± 3.81	49.10 ± 4.91	.72*	46.38 ± 3.20	45.98 ± 4.15	.62*	45.80 ± 4.21	47.45 ± 4.42	.18*

Means ± SD
CDVA = corrected distance visual acuity; K = keratometry; Kmax = maximum keratometry; Kmin = minimum keratometry; SE = spherical equivalent; UDVA = uncorrected distance visual acuity
*Student *t* test
†Mann-Whitney *U* test

Table 6. Comparison of parameters between mechanical and femtosecond tunnel creation in Group B.

	Preoperative			Postoperative					
				6 Months			1 Year		
Parameter	Mechanical	Femtosecond	*P* Value	Mechanical	Femtosecond	*P* Value	Mechanical	Femtosecond	*P* Value
Eye (n)	40	28	—	40	28	—	29	15	—
Mean UDVA (Snellen)	0.17 ± 0.16	0.15 ± 0.13	.76†	0.33 ± 0.22	0.38 ± 0.20	.32*	0.33 ± 0.21	0.43 ± 0.21	.16*
Mean CDVA (Snellen)	0.36 ± 0.22	0.39 ± 0.21	.61*	0.52 ± 0.24	0.57 ± 0.24	.39*	0.52 ± 0.24	0.67 ± 0.25	.07*
Mean SE (D)	−3.92 ± 3.20	−4.31 ± 2.04	.10†	−2.12 ± 1.24	−2.23 ± 0.98	.71*	−2.13 ± 1.03	−2.36 ± 0.76	.44*
Mean sphere (D)	−2.98 ± 2.78	−3.66 ± 2.24	.08†	−1.21 ± 1.01	−1.39 ± 0.65	.44†	−1.19 ± 0.99	−1.39 ± 0.47	.47*
Mean cylinder (D)	−3.40 ± 1.32	−2.980 ± 1.14	.08*	−2.13 ± 1.54	−1.82 ± 0.81	.32*	−2.15 ± 0.98	−1.63 ± 0.54	.06*
Mean Kmax (D)	51.36 ± 4.55	50.77 ± 4.59	.60*	48.36 ± 4.09	47.73 ± 4.19	.71†	47.55 ± 3.21	47.63 ± 4.53	.94*
Mean Kmin (D)	46.10 ± 2.90	45.96 ± 2.89	.84*	44.13 ± 2.83	43.91 ± 2.68	.74*	43.42 ± 1.86	43.60 ± 3.04	.81*
Mean average K (D)	48.73 ± 3.51	48.36 ± 3.57	.67*	46.25 ± 3.24	46.32 ± 3.23	.92†	45.48 ± 2.27	45.62 ± 3.41	.87*

Means ± SD
CDVA = corrected distance visual acuity; K = keratometry; Kmax = maximum keratometry; Kmin = minimum keratometry; SE = spherical equivalent; UDVA = uncorrected distance visual acuity
*Student *t* test
†Mann-Whitney *U* test

complications between implantation of Keraring ICRS (Group A) and Intacs ICRS (Group B). Both ICRS models have an arc-shortening effect on the cornea, which flattens the central cornea.

Our visual findings are similar to those in other studies of the 2 ICRS models. In a study of Keraring ICRS by Shabayek and Alió,[15] the mean preoperative to 6-month postoperative increase was 0.06 to 0.30 in UDVA and 0.54 to 0.71 in CDVA. Coskunseven et al.[16] report a mean gain in UDVA of 1.7 lines at 1 year; the CDVA increased in 68% of eyes postoperatively. Several studies[11,13,20,21] report significantly improved UDVA and CDVA after Intacs ICRS implantation as well. In a recent study,[22] the Snellen UDVA and CDVA increased significantly from preoperatively to 1 year postoperatively (1.32 to 4.20 lines and 3.29 to 6.02 lines, respectively). Although UDVA and CDVA increased in both groups in our study, Group A had a greater gain of Snellen lines 6 months and 1 year after surgery.

We also found significant decreases in sphere and cylinder with both ICRS models, again agreeing with results in other studies. Shabayek and Alió[15] report a mean difference of 3.37 D in K power and 2.23 D in SE with Keraring ICRS. Coskunseven et al.[16] report a mean decrease in K power of 3.07 D.[16] In a study by Ertan et al.,[22] the mean SE decreased from −7.57 D to −3.72 D and the mean K value decreased from 51.56 D to 47.66 D 1 year after Intacs ICRS implantation. In our study, there were no significant differences between the 2 ICRS groups in the postoperative mean SE or K values; however, the decrease from preoperatively to postoperatively were statistically significantly greater in Group A than in Group B. Intacs ICRS are located more peripherally than Keraring ICRS, which may affect the corneal flattening effect.

Table 7. One-year results by keratoconus stage.

	Group A			Group B		
Parameter	Mild (Stages I and II)	Advanced (Stages III and IV)	*P* Value*	Mild (Stages I and II)	Advanced (Stages III and IV)	*P* Value*
Mean increase in UDVA	0.31 ± 0.21	0.15 ± 0.14	<.01	0.22 ± 0.20	0.19 ± 0.18	.70
Mean increase in CDVA	0.40 ± 0.21	0.28 ± 0.16	.03	0.18 ± 0.23	0.15 ± 0.30	.76
Mean decrease in SE (D)	2.40 ± 2.39	5.05 ± 4.38	<.01	1.80 ± 1.67	3.52 ± 4.55	.07
Mean decrease in Kmax (D)	2.55 ± 1.69	5.77 ± 2.46	<.01	1.89 ± 1.59	4.22 ± 3.80	<.01

Means ± SD
CDVA = corrected distance visual acuity; Kmax = maximum keratometry; SE = spherical equivalent; UDVA = uncorrected distance visual acuity
*Student *t* test

Table 8. Complications by group and method of tunnel creation.

	Group A		Group B	
Complication	Mechanical	Femtosecond	Mechanical	Femtosecond
Anterior perforation	1	0	0	0
Extrusion	1	0	3	1
Decentration	2	2	2	1
Shallow placement	1	0	0	0

Several studies[5,17,21,23,24] report complications associated with ICRS implantation using mechanical tunnel creation; complications include epithelial cell defects, anterior or posterior perforation with the mechanical spreader, shallow placement of the ICRS, persistent incision gaping, ICRS decentration, stromal thinning, extension of the incision to central cornea or toward the limbus, infectious keratitis from the introduction of epithelial cells into the tunnel, and corneal stromal edema around the channel. We found relatively more complications in eyes in which the tunnel was created mechanically; the complications included segment extrusion and anterior corneal perforation. Similarly Kanellopoulos et al.[21] report a postoperative complication rate of 35% with mechanical tunnel dissection. Yellow–white intrastromal deposits are another complication. In a study of Intacs ICRS in myopic eyes,[10] these deposits occurred in 74% of cases. A study comparing 2 channel sizes[25] found a deposit rate of 10.3% in the wide channel (0.75 mm) and 46.77% in the narrow channel (0.50 mm). We found deposits in 55 eyes (55.0%) in Group A and 42 eyes (61.7%) in Group B.

Corneal tunnel creation by a femtosecond laser makes the procedure faster, easier, and more comfortable for patients and surgeons. The main advantages of this method over mechanical tunnel creation are that the depth of implantation is more precise and there are fewer complications.[16,23] However, mechanical tunnel creation is cost effective. Rabinowitz et al.[23] compared femtosecond and mechanical tunnel creation in ICRS implantation and found no statistically significant differences in visual and refractive outcomes between the 2 methods, which agrees with our results.

In conclusion, although we found that implantation of both ICRS models was effective and safe, the increases in CDVA and UDVA and decreases in SE and maximum K were greater after Keraring ICRS implantation. There were fewer intraoperative and postoperative complications in cases in which the femtosecond laser was used to create the tunnels. In addition, femtosecond laser–assisted surgery was as effective as surgery using the mechanical method and was also faster and easier.

REFERENCES

1. Arentsen JJ. Corneal transplant allograft reaction: possible predisposing factors. Trans Am Ophthalmol Soc 1983; 81:361–402. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1312459/pdf/taos00018-0385.pdf. Accessed February 1, 2010
2. Barraquer JI. Modification of refraction by means of intracorneal inclusions. Int Ophthalmol Clin 1966; 6(1):53–78
3. McDonald MB, Kaufman HE, Durrie DS, Keates RH, Sanders DR. Epikeratophakia for keratoconus; the nationwide study. Arch Ophthalmol 1986; 104:1294–1300
4. Buratto L, Belloni S, Valeri R. Excimer laser lamellar keratoplasty of augmented thickness for keratoconus. J Refract Surg 1998; 14:517–525
5. Koch DD. Refractive surgery for keratoconus: a new approach [editorial]. J Cataract Refract Surg 2000; 26:1099–1100
6. Sekundo W, Stevens JD. Surgical treatment of keratoconus at the turn of the 20th century. J Refract Surg 2001; 17:69–73
7. Brierley SC, Izquierdo L Jr, Mannis MJ. Penetrating keratoplasty for keratoconus. Cornea 2000; 19:329–332
8. Doyle SJ, Hynes E, Naroo S, Shah S. PRK in patients with keratoconic topography picture. The concept of a physiological 'displaced apex syndrome.' Br J Ophthalmol 1996; 80:25–28. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC505378/pdf/brjopthal00001-0027.pdf. Accessed February 1, 2010
9. Kremer I, Schochot Y, Kaplan A, Blumenthal M. Three year results of photoastigmatic refractive keratectomy for mild and atypical keratoconus. J Cataract Refract Surg 1998; 24:1581–1588
10. Ruckhofer J, Twa MD, Schanzlin DJ. Clinical characteristics of lamellar channel deposits after implantation of Intacs. J Cataract Refract Surg 2000; 26:1473–1479
11. Alió JL, Shabayek MH, Artola A. Intracorneal ring segments for keratoconus corrections: long term follow-up. J Cataract Refract Surg 2006; 32:978–985
12. Colin J, Cochener B, Savary G, Malet F. Correcting keratoconus with intracorneal rings. J Cataract Refract Surg 2000; 26:1117–1122
13. Lovisolo CF, Fleming JF. Intracorneal ring segments for iatrogenic keratectasia after laser in situ keratomileusis or photorefractive keratectomy. J Refract Surg 2002; 18:535–541
14. Colin J, Cochener B, Savary G, Malet F, Holmes-Higgin D. INTACS inserts for treating keratoconus; one-year results. Ophthalmology 2001; 108:1409–1414
15. Shabayek MH, Alió JL. Intrastromal corneal ring segment implantation by femtosecond laser for keratoconus correction. Ophthalmology 2007; 114:1643–1652
16. Coskunseven E, Kymionis GD, Tsiklis NS, Atun S, Arslan E, Jankov MR, Pallikaris IG. One-year results of intrastromal corneal ring segment implantation (KeraRing) using femtosecond laser in patients with keratoconus. Am J Ophthalmol 2008; 145:775–779
17. Ruckhofer J, Stoiber J, Alzner E, Grabner G. One year results of European multicenter study of intrastromal corneal ring segments.

Part 2: complications, visual symptoms, and patient satisfaction; the Multicenter European Corneal Correction Assessment Study Group. J Cataract Refract Surg 2001; 27:287–296
18. Alió JL, Shabayek MH, Belda JI, Correas P, Diez Feijoo E. Analysis of results related to good and bad outcomes of Intacs implantation for keratoconus correction. J Cataract Refract Surg 2006; 32:756–761
19. Alió JL, Shabayek MH. Intracorneal asymmetrical rings for keratoconus: where should the thicker segment be implanted? J Refract Surg 2006; 22:307–309
20. Boxer Wachler BS, Christie JP, Chandra NS, Chou B, Korn T, Nepomuceno R. Intacs fort the keratoconus. Ophthalmology 2003; 110:1031–1040
21. Kanellopoulos AJ, Pe LH, Perry HD, Donnenfeld ED. Modified intracorneal ring segment implantation (INTACS) for the management of moderate to advanced keratoconus: efficacy and complications. Cornea 2006; 25:29–33
22. Ertan A. Kamburoğlu G, Bahadır M. Intacs insertion with the femtosecond laser for the management of keratoconus: one year results. J Cataract Refract Surg 2006; 32:2039–2042
23. Rabinowitz YS, Li X, Ignacio TS, Maguen E. INTACS inserts using the femtosecond laser compared to the mechanical spreader in the treatment of keratoconus. J Refract Surg 2006; 22:764–777
24. Bourcier T, Borderie V, Laroche L. Late bacterial keratitis after implantation of intrastromal corneal ring segments. J Cataract Refract Surg 2003; 29:407–409
25. Ertan A. Kamburoğlu G, Akgün Ü. Comparison of outcomes of 2 channel sizes for intrastromal ring segment implantation with a femtosecond laser in eyes with keratoconus. J Cataract Refract Surg 2007; 33:648–653

First author:
Anil Kubaloglu, MD

Dr. Lütfi Kırdar Kartal Training and Research Hospital, Istanbul, Turkey