One-Year Results of Intrastromal Corneal Ring Segment Implantation (KeraRing) using Femtosecond Laser in Patients with Keratoconus

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• PURPOSE: To report the results of intrastromal corneal ring segment [ICRS] (KeraRing; Mediphacos, Belo Horizonte, Brazil) implantation using a femtosecond laser (IntraLase Corp, Irvine, California, USA) in keratoconic patients.

• DESIGN: Retrospective, noncomparative, interventional study.

• METHODS: Thirty-two keratoconic patients (50 eyes) who underwent ICRS insertion using a femtosecond laser for channel creation and completed at least one year of follow-up were included in this study. Uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), refraction, topographic findings, and adverse events were assessed.

• RESULTS: No intraoperative complications were demonstrated in this series of patients. At the first postoperative day, segment migration to the incision site was seen in three eyes (6%; early postoperative complication). To avoid melting, we repositioned the migrated segment away from the incision site. Serious second migration was not seen and we did not need to reposition any segment again. At the last postoperative examination, there was a statistically significant reduction in the spherical equivalent refractive error compared with that observed at the examination before implantation (mean ± standard deviation, −5.62 ± 4.15 diopters [D; range, −23.62 to 0.50 D] to −2.49 ± 2.68 D [range, −11.12 to 3.5 D]; $P < .001$). The UCVA before implantation was 20/40 or worse in 47 eyes (94%; range, counting fingers to 20/30), whereas at the last follow-up examination, 14 (28%) of 50 eyes had a UCVA of 20/40 or better (range, counting fingers to 20/25). Nine eyes (18%) maintained the preimplantation BSCVA, whereas 39 eyes (68%) experienced a BSCVA gain of one to four lines at the last follow-up examination. Only in two eyes (4%; two patients) with advanced keratoconus (stage III) was there a decrease of up to two lines. Despite this deterioration in BSCVA, the patients did not want to remove the ICRSs, because there was an increase of UCVA. No late postoperative complications were observed during the follow-up period.

• CONCLUSIONS: ICRS (KeraRing) implantation using femtosecond laser for tunnel creation is a minimally invasive procedure for improving visual acuity (both UCVA and BSCVA) in keratoconic patients. (Am J Ophthalmol 2008;145:775–779. © 2008 by Elsevier Inc. All rights reserved.)

THE IMPLANTATION OF SMALL ARC-LIKE POLYMETHYL methacrylate (PMMA) segments is a minimally invasive surgical option for keratoconic corneas or ectatic corneas occurring after laser in situ keratomileusis.[1–6] There are different types of intracorneal rings, depending on their curvature, width, and zone of implantation. KeraRings (Mediphacos, Belo Horizonte, Brazil) are newly developed segments made of PMMA that are characterized by a triangular cross-section that induces a prismatic effect on the cornea. Their apical diameter is 5 mm and the flat basis width is 0.6 mm with variable thickness (0.15- to 0.30-mm thickness with 0.5-mm steps) and arc lengths (90 degrees, 160 degrees, and 210 degrees). The optical zone provided by KeraRing segments is 5.0 mm in diameter.

The tunnel creation for segment implantation is made manually using mechanical devices. This step of the procedure correlated with a number of possible complications such as epithelial defects, perforation, infectious keratitis, shallow or uneven or asymmetric segment placement, corneal stromal edema around the incision, extension of the incision toward the central visual axis or the limbus, and persistent incisional gaping.[7–9]

Previous studies with ring segments similar to KeraRing segments (Ferrara intracorneal ring segments; Ferrara Ophthalmics, Belo Horizonte, Brazil) showed an increase rate of complications because of these technical difficulties.[10,11] To minimize these complications, tunnel creation now can be carried out with a femtosecond laser because it can deliver energy accurately to a precise depth in a programmed way. The first study using the femtosecond laser to insert Intacs (Addition Technology, Inc, Fremont, California, USA) for keratoconus compared with a mechanical spreader was performed by Rabinowitz and asso-

Accepted for publication Dec 14, 2007.

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0002-9394/08/$34.00
doi:10.1016/j.ajo.2007.12.022

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TABLE. Preoperative and Last Follow-up Examination Data of Patients with Keratoconus after Intrastromal Corneal Ring Segment (KeraRing) Implantation

	Preoperative	Last Postoperative Examination	
No. of eyes		50	
No. of patients		32	
Gender			
Male		18	
Female		14	
Age (yrs)			
Mean ± SD		28.32 ± 7.28	
Range		18 to 44	
Follow-up (mos)			
Mean ± SD		15.6 ± 3.2	
Range		12 to 24	
Spherical equivalent (D)			
Mean ± SD	−5.62 ± 4.16	−2.50 ± 2.68	$P < .001$
Range	−0.50 to −23.62	3.50 to −11.12	
Cylinder (D)			
Mean ± SD	−4.13 ± 2.02	−2.18 ± 1.27	$P < .001$
Range	−0.5 to −9.50	−0.5 to −6.00	
Topographic K values (D)			
Mean ± SD	50.63 ± 3.97	47.56 ± 4.46	$P < .001$
Range	42.05 to 60.95	36.00 to 61.50	

D = diopters; SD = standard deviation; mos = months.

ciates, whereas additional studies indicate that Intacs implantation with the use of a femtosecond laser is a safe and effective procedure for treating keratoconic corneas.[12–15] Recently, Shabayek and Alió published a series of keratoconic patients who were followed up six months after intrastromal corneal ring segment (ICRS) implantation with KeraRings and a femtosecond laser.[16] In the current study, we evaluated the outcomes and long-term complications (all patients completed at least one year of follow-up) of this type of intracorneal ring segments using a femtosecond laser for tunnel creation (IntraLase Corp, Irvine, California, USA) in keratoconic patients.

METHODS

FIFTY EYES OF 32 KERATOCONIC PATIENTS (18 MALES [26 eyes] and 14 females [24 eyes]) who underwent ICRS implantation of KeraRings using a femtosecond laser for tunnel creation were included in this study. All procedures performed by the same surgeon (E.C.) at Dunya Eye Hospital, Istanbul, Turkey. The mean patient age was 28.32 ± 7.28 years (range, 18 to 44 years). All patients completed at least one year of follow-up. The Table summarizes patient demographic and refractive data.

All patients demonstrated clear central corneas and contact lens intolerance. Corneal thickness was at least 350 μm at the thinnest corneal point and at least 450 μm at the incision side. Patients were excluded if any of the following criteria applied after the preoperative examination: history of herpes, keratitis, corneal dystrophies, diagnosed autoimmune disease, systemic connective tissue disease, acute or grade IV keratoconus, and endothelial cell count of less than 1000 cells/mm^2.

A complete ophthalmologic examination performed before surgery included uncorrected visual acuity (UCVA) and best spectacle-corrected visual acuity (BSCVA) assessment, manifest refraction, biomicroscopy, corneal topography (using Orbscan IIz [Bausch & Lomb GmbH, Feldkirchen, Germany] or WaveLight Allegretto Topolyzer [WaveLight Technologie, Erlangen, Germany]), and endothelial cell measurement with specular microscopy (Konan Specular Microscope SP 9000; Noncon Robo Pachy Konan Medical, Inc, Hyogo, Japan).

• **SURGICAL PROCEDURE:** The surgical procedure was carried out under sterile conditions and topical anesthesia. Purkinje reflex was chosen as the central point and was marked under Wavelength Allegretto Biomicroscope. A 5-mm marker was used to locate the exact ring channel. Corneal thickness was measured during surgery using ultrasonic pachymetry (Sonogage, Cleveland, Ohio, USA) along the ring location markings. Tunnel depth was set at 75% of the thinnest corneal thickness on the tunnel location in the femtosecond laser.

An incision was made on the steepest topographic axis. One or two segments were implanted according to the distribution of the ectatic area on the corneal surface,

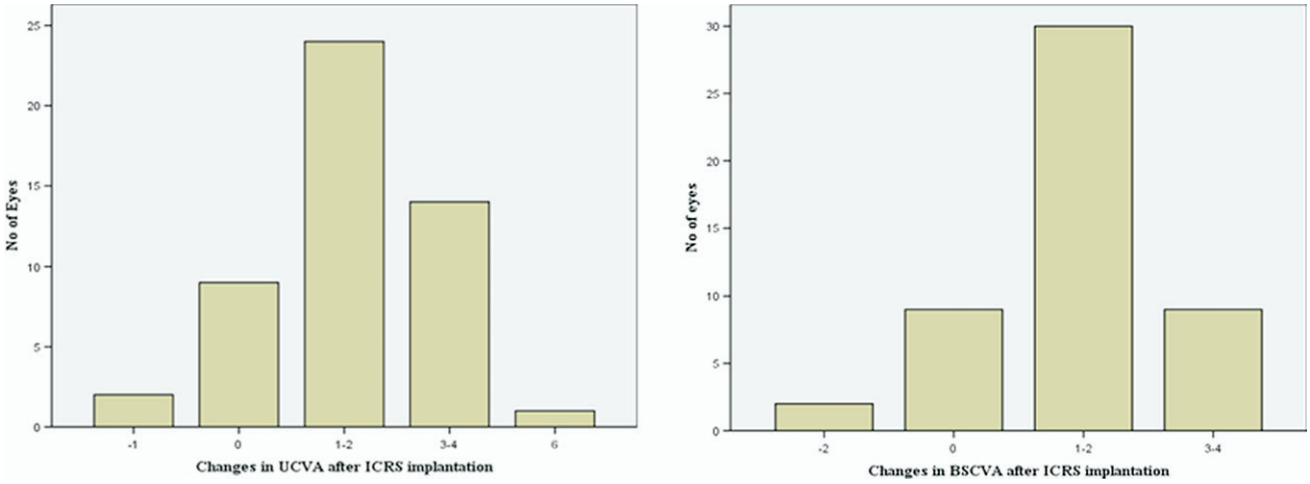

FIGURE 1. Bar graphs demonstrating (Left) uncorrected visual acuity and (UCVA) and (Right) best spectacle-corrected visual acuity (BSCVA) changes (lines of Snellen acuity) after intrastromal corneal ring segment (KeraRing) implantation in keratoconic patients.

whereas the thickness of the segment was decided according to the distribution of the ectatic area as well as the spherical equivalent (SE). A 60-khz femtosecond laser was used to create the ring channels. Special attention was given in centralizing the disposable suction ring to mark the central point to minimize decentration. The channel's inner diameter was set to 4.4 mm, the outer diameter was 5.6 mm, the entry cut thickness was 1 μm (at the steepest topographic axis), the ring energy used for channel creation was 1.30 μj, and the entry cut energy was 1.30 μj. Channel creation timing with the femtosecond laser was 15 seconds. The intracorneal ring segments were implanted immediately after channel creation before the disappearing of the bubbles, which reveals the exact tunnel location. To avoid any injury to the incision area, we directly implanted the segment with the special KeraRing forceps. The KeraRing segment was implanted uneventfully in all cases. After surgery, antibiotic steroid eye drops four times daily for two weeks were prescribed. The patients were instructed to avoid rubbing the eye and to use preservative-free artificial tears frequently. On the first postoperative day, slit-lamp biomicroscopic examination was performed. Healing of the wound and migration of the segments were evaluated. At the last follow-up examination, manifest refraction, UCVA and BSCVA, slit-lamp, and topographic examinations were performed.

• **STATISTICAL ANALYSIS:** Group differences for continuous variables were tested using the paired Student *t* test. Results are presented as mean ± standard deviation (SD). A *P* value less than .05 was regarded as statistically significant.

RESULTS

MEAN FOLLOW-UP WAS 15.6 ± 3.2 MONTHS (RANGE, 12 TO 24 months). At the last follow-up examination, SE error was statistically significantly reduced (preimplantation mean ± SD, −5.62 ± 4.15 diopters [D; range, −23.62 to 0.50 D]; postimplantation mean ± SD, −2.49 ± 2.68 D [range, −11.12 to 3.5 D; $P < .001$; Table).

UCVA and BSCVA were measured using Snellen scale charts. UCVA was improved in 39 eyes (78%) compared with the preoperative levels. Preoperative UCVA was 20/40 or worse in 47 eyes (94%; range, counting fingers to 20/30), whereas at the last follow-up examination, 14 (28%) of 50 eyes had UCVA of 20/40 or better (range, counting fingers to 20/25). The mean difference between preoperative and postoperative UCVA was a gain of 1.7 lines (range, loss of one UCVA Snellen line to gain of six lines; Figure 1, Left).

BSCVA was maintained to the preimplantation level in nine eyes (18%), whereas 39 eyes (68%) experienced a BSCVA gain of one to up to four lines at the last follow-up examination. Only in two eyes (4%; two patients) with advanced keratoconus (stage III) was there a decrease of up to two lines. Despite this deterioration in BSCVA, the patient did not want to remove the ICRSs because there was an increase of UCVA. The mean difference between preoperative and postoperative BSCVA was a gain of 1.3 lines (range, loss of two lines to a gain of four lines; Figure 1, Right).

A significant reduction in keratometric values was found at the last follow-up examination (Table). Mean preoperative keratometry was 50.63 ± 3.97 D (range, 42.05 to 60.95 D) and changed significantly to 47.56 ± 4.46 D (range, 36.00 to 61.50 D; $P < .001$). Similarly, mean preoperative keratometric astigmatism was 4.71 ± 2.64 D (range, 0.60 to 12.50 D) and statistically significantly changed to 3.17 ± 2.27 D (range, −1.50 to 9.80 D; $P < .001$) at the last follow-up examination (Table).

Furthermore, in patients with more pronounced keratoconus (stage III;[15] 31 eyes), the mean reduction in keratometric values was −3.62 ± 3.72 D (range, −11.25 to 8.75 D). This reduction was higher compared with the

mean reduction in patients with stage I (eight eyes; 1.88 ± 3.01 D [range, −6.50 to 1.15 D]) or stage II (11 eyes; −2.37 ± 1.93 D [range, −5.8 to 0.45 D]) keratoconus, but it did not reached statistically significant levels ($P > .05$).

• **ADVERSE EFFECTS AND COMPLICATIONS:** At the first postoperative day, segment migration to the incision site was seen in three eyes (6%; early postoperative complications). To avoid melting, we repositioned the migrated segment away from the incision site, advised the patients not to rub the eye, and again applied a bandage contact lens. Serious second migration was not seen and we did not need to reposition any segment again. No late postoperative complications occurred in this series of patients.

DISCUSSION

INTRACORNEAL RING SEGMENTS WERE FIRST IMPLANTED in human eyes by Nosé and associates, and a few years later, Colin and associates reported their preliminary results regarding the management of keratoconus with Intacs.[4,17] The procedure is effective in most keratoconic patients, but the predictability is low and the results are variable.[17–22]

Intacs inserts have a crescent-shaped arc length of 150 degrees. Their inner diameter is 6.8 mm and the outer diameter is 8.1 mm when placed in the cornea. However, KeraRings have a smaller optical zone (apical diameter, 5.0 mm). Theoretically, KeraRings may have a greater effect than Intacs because they are placed more centrally, but the procedure may be more difficult (they are implanted in thinner corneal areas).

In the current study, one year after KeraRing implantation, UCVA was improved in 39 eyes (78%) compared with the preoperative levels, with a mean gain of 1.9 lines (range, loss of one to gain of six lines). BSCVA was maintained to the preimplantation level in nine eyes (18%), whereas 39 eyes (68%) experienced a BSCVA gain of one to up to three lines at the last follow-up examination (mean gain, 1.3 lines; range, loss of two lines to gain of four lines). Only in two eyes (two patients) with advanced keratoconus (stage III) was a decrease of two lines with an increase of UCVA found.

In comparison with other studies of intracorneal rings implantation with mechanical devices,[7–9] there was a significant reduction of complication rate. Regarding Ferrara rings (similar to KeraRings), Siganos and associates reported an incidence of 7.7% of improper implantation, whereas Kwitko and Severo reported a higher incidence of complications (such as ring extrusion in 19.6% of the eyes).[10,11] In the current study, no explantation was performed (in three eyes [6%], segments were repositioned at the first postoperative day without any further intervention needed), mainly because of the precise depth of implantation with femtosecond laser (Figure 2). Recently,

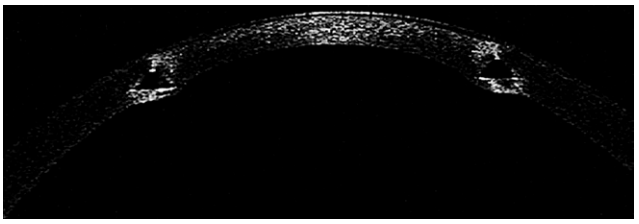

FIGURE 2. Visante OCT AC Imaging demonstrating intrastromal corneal ring segments (KeraRing) inserted using Femtosecond laser in a keratoconic eye.

Shabayek and Alió first published a series of keratoconic patients followed up for six months after ICRSs implantation with KeraRings using a femtosecond laser.[16] They concluded that this method is effective and safe for keratoconus.

A few studies (most of them with limited treated eyes) used a femtosecond laser for segment implantation in keratoconic patients.[14–16] Ertan and associates published a series of keratoconic patients who underwent Intacs implantation using a femtosecond laser.[14] Intacs were implanted successfully in all eyes. At the end of the first postoperative year, 81.3% of eyes had improved UCVA and 73.7% had improved BCVA. Similarly in our study, UCVA was improved in 78% of the eyes compared with the preoperative levels, whereas 68% of the studied eyes experienced a BSCVA gain of one to up to three lines at the last follow-up examination. All these studies concur that femtosecond laser-assisted intracorneal ring segments insertion in most keratoconic eyes improves the UCVA and BSCVA (gain of more than six Snellen lines) and reduces patient manifest refraction and corneal astigmatism (up to 4 D). These refractive and topographic results are comparable with the results of mechanical Intacs channels creation.[1–6,10,11,17–22]

The use of the femtosecond laser in corneal tunnel creation made the procedure faster, easier (especially for inexperienced surgeons), and more comfortable for the patient. However, the main advantage of IntraLase-assisted channel creation over the mechanical technique seems to be the precise depth of implantation. From the published data[14–16] and our experience, the safety of the procedure seems to be very high.

A few potential limitations are apparent in this study, with the small sample of treated eyes, the lack of a comparative group (keratoconic eyes after KeraRing insertion using mechanical devises), and the absence of follow-up data in the intermediate period being the major reservations in concluding sufficient results.

In conclusion, KeraRing implantation using a femtosecond laser seems to be a minimally invasive treatment with good visual and refractive outcomes. Future larger, comparative studies focusing on the nomogram modification and the possible complications of the technique are needed.

THE AUTHORS INDICATE NO FINANCIAL SUPPORT OR FINANCIAL CONFLICT OF INTEREST. DR COSKUNSEVEN IS A SCIENTIFIC consultant to Mediphacos, Belo Horizonte, Brazil. Involved in design and conduct of the study (E.C., G.D.K., N.T., M.J., I.G.P.); collection, management, analysis, and interpretation of the data (E.C., E.A., S.A.); and preparation, review, and approval of the manuscript (E.C., G.D.K., N.T., S.A., E.A., M.J., I.G.P.). All patients were appropriately informed of risks and benefits before operation, and they gave their written informed consent in accordance with the Institutional Review Board of Dunya Eye Hospital, Istanbul, Turkey, according to the Declaration of Helsinki.

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Biosketch

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