Continuous intracorneal ring implantation for keratoconus using a femtosecond laser

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PURPOSE: To assess the clinical outcomes after continuous intracorneal ring (ICR) implantation for the management of keratoconus using femtosecond laser technology.

SETTING: Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran.

DESIGN: Prospective nonrandomized consecutive case series.

METHODS: All patients presented with reduced visual acuity, contact lens intolerance, and a central corneal thickness of more than 360 μm. A Myoring ICR was inserted in an intrastromal pocket created by a femtosecond laser. The visual, refractive, aberrometric, and corneal biomechanical outcomes were measured preoperatively as well as 1, 3, and 6 months and 1 year postoperatively.

RESULTS: The study comprised 98 keratoconic eyes of 98 patients with a mean age of 30.7 years ± 9.01 (SD). Fifteen eyes (15.3%) had grade I keratoconus, 37 eyes (37.7%) had grade II keratoconus, 24 eyes (24.5%) had grade III keratoconus, and 22 eyes (22.4%) had grade IV keratoconus. The uncorrected and corrected distance visual acuities and spherical and cylindrical errors improved 1 month after surgery ($P<.001$); however, no changes were detected thereafter ($P>.05$). The mean keratometry and corneal astigmatism decreased 1 month after surgery ($P<.001$); however, no significant change was observed at the 3-month or 1-year visits compared with the 1-month values ($P>.05$). Primary coma decreased significantly ($P=.03$), and spherical aberrations increased significantly ($P<.001$) postoperatively.

CONCLUSION: Continuous ICR implantation in keratoconus appears to be an acceptable substitute for keratoplasty in advanced keratoconus.

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Online Video

Keratoconus, the most common corneal ectatic disorder, is characterized by progressive corneal thinning due to ultrastructural changes in the corneal matrix.[1] Various treatment modalities have been proposed to manage this entity.[2–4] It has been postulated that adding extra material at the corneal midperiphery using an intrastromal ring would cause the anterior surface of this portion to shift forward and therefore modify the central corneal curvature and corneal steepening (arc-shortening effect).[5]

The continuous intracorneal ring (ICR) was introduced with the aim of managing myopia through insertion via a single circumferential corneal tunnel.[6] However, the failure of this approach to gain popularity due to its incision-related complications resulted in refashioning of the continuous ring into corneal ring segments.[7] Intrastromal corneal ring segments (ICRS) have been widely studied since then for the management of keratoconus and other corneal ectatic disorders, including pellucid marginal degeneration and post-laser in situ keratomileusis ectasia.

The concept of the continuous ICR reappeared in the literature after the introduction of the corneal intrastromal implantation system, a new technique to create a stromal pocket that has recently been studied for the treatment of highly myopic and keratoconic eyes.[8,9] However, it is well established that femtosecond laser technology gives the surgeon the ability to perform a more accurate corneal stromal dissection at a predetermined depth and prevents the potential inaccuracies of mechanical dissection.[10] The role of ICR implantation in the management of ectatic

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disorders using the femtosecond laser has been observed in 1 pilot study with 12 cases during 6 months of follow-up.[11]

In the present study, we looked at the visual, refractive, aberrometric, and biomechanical outcomes in 98 eyes after Myoring ICR (Dioptex, GmbH) implantation using femtosecond laser technology during a 12-month follow-up. To our knowledge, this study reports the largest series of cases with keratoconus who have been treated with this ICR and has the longest follow-up of this surgical technique. In addition, for the first time, we compared the outcomes between grades of keratoconus and age groups.

PATIENTS AND METHODS

This was a prospective nonrandomized consecutive case series. Informed consent was obtained from all patients after they received an explanation of all possible treatment options. Institutional ethical review board approval was obtained for the procedures, and the tenets of the Helsinki Declaration were followed.

Inclusion criteria were keratoconic eyes (Pentacam [Oculus GmbH] pattern consistent with keratoconus according to Amsler-Krumeich classification[12]) with clear central corneas or mild corneal scarring, corrected distance visual acuity (CDVA) worse than 0.25 logMAR, contact lens intolerance, minimum central corneal thickness (CCT) not less than 360 μm, and corneal thickness of at least 400 μm at the location of the proposed incision site and along the location of the proposed ICR in the corneal stroma. Patients were classified according to the Alió-Shabayek grading system[12] into 4 groups based on keratoconus severity as follows: grade I = mean central keratometry reading of 48.00 D or less, root mean square (RMS) of coma-like aberration from 1.50 to 2.50 μm, and no scarring; grade II = RMS of coma-like aberration from greater than 2.50 μm to 3.50 μm, mean central keratometry readings of greater than 48.00 D to 53.00 D, no scarring, and minimum corneal thickness of greater than 400 μm; grade III = mean central keratometry readings of greater than 53.00 D to 55.00 D, RMS of coma-like aberration from greater than 3.50 μm to 4.50 μm, no scarring, and minimum corneal thickness of 300 to 400 μm; grade IV = RMS of coma-like aberration of greater than 4.50 μm, mean central keratometry readings of greater than 55.00 D, central corneal scarring, and minimum corneal thickness of 200 μm.

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Exclusion criteria were incomplete follow-up at any time before 1 year, ICR explantation in the first postoperative year, mesopic pupil size larger than 5.5 mm, other vision-threatening ocular pathology (eg, glaucoma, cataract, diabetic retinopathy, age-related macular degeneration), history of herpes keratitis, plano or hyperopic spherical equivalent (SE), previous intraocular or corneal surgery, systemic connective tissue disease, and pregnancy.

Surgical Technique

All procedures were performed by 1 of 2 surgeons (M.J., A.S.). Using a femtosecond laser (Technolas 520F), a stromal pocket was created at a depth of 300 μm and diameter of 9.0 mm followed by a 4.5 mm wide tunnel incision as described in detail by Alio et al.[11] The tunnel incision was placed on the steep meridian of the cornea. Then, the ICR was inserted into the pocket (Video, available at http://jcrsjournal.org). An adapted nomogram was used to calculate the size of the ICRs (Table 1).

Topical chloramphenicol and betamethasone eyedrops were used postoperatively every 6 hours for 1 week. Topical lubricants (hypromellose [Artelac]) were also prescribed every 6 hours for 1 month.

Outcome Measures

Preoperatively and at all postoperative visits, patients had a complete ocular examination. The examination included uncorrected distance visual acuity (UDVA), CDVA, manifest refraction, slitlamp biomicroscopy, Goldmann tonometry, and fundus evaluation. Total aberrometric analysis with the iTrace system (Tracey Technologies), pachymetry (SP3000, Tomey Corp.), anterior segment optical coherence tomography (Carl Zeiss Meditec AG), biomechanical assessment with the Ocular Response Analysis system (Reichert, Inc.), and Pentacam Scheimpflug imaging were performed preoperatively and at all postoperative examinations after 1 month. Also, higher-order RMS, primary coma RMS, and primary spherical RMS aberrometric data were evaluated and recorded.

The primary outcome measure was the safety of the procedure, defined as the number and percentage of eyes losing more than 2 lines of Snellen UDVA, and the safety index, defined as mean postoperative CDVA/mean preoperative CDVA.[13] The UDVA, CDVA, manifest refraction, keratometry, corneal higher-order aberrations (HOAs), pachymetry, corneal hysteresis (CH), and corneal resistance factor (CRF) were also main outcome measures.

Table 1. The modified nomogram.

K Value (D)	Mesopic Pupil (mm)	Ring Dimensions	
		Diameter (mm)	Thickness (mμ)
≤44	<5.5	6	240
>44 to ≤48	<4.5	5	240
	≥4.5	6	280
>48 to ≤52	<4.5	5	280
	≥4.5	6	320
>52	<4.5	5	320

K = mean central keratometry

Secondary parameters included intraoperative and postoperative complications and other adverse events. Efficacy was defined as the number and percentage of eyes achieving a UDVA of 6/12 (20/40).[13] In addition, the number and percentage of eyes achieving a CDVA of 6/12 (20/40) were assessed as secondary parameters of efficacy. Stability, defined as the number and percentage of eyes with change in SE of less than 1.00 diopter (D) during postoperative visits, was also calculated. Per the study protocol, no patient had an enhancement procedure or ICR exchange during the 1-year follow-up.

Statistical Analysis

Preoperative data versus postoperative data were analyzed using the paired *t* test. If not otherwise indicated, statistical measures are the mean ± standard deviation and significant *P* values are less than 0.05. Statistical analysis was performed using SPSS software (version 11, SPSS, Inc.).

RESULTS

Demographic Data

Ninety-eight eyes (40 [40.8%] right; 58 [59.2%] left) of 98 patients were included in this study. The mean age of the 43 men (43.9%) and 55 women (56.1%) was 30.70 ± 9.01 years (range 18 to 49 years). Patients were categorized into 3 groups according to age as follows: 31 patients (31.6%) were younger than 25, 37 patients (37.7%) were 25 to 34 years old, and 30 patients (30.6%) were 35 years or older. Fifteen eyes (15.3%) had keratoconus grade I, 37 eyes (37.7%) had keratoconus grade II, 24 eyes (24.5%) had keratoconus grade III, and 22 eyes (22.4%) had keratoconus grade IV.

Refraction and Visual Acuity

Table 2 shows the visual and refractive outcomes over time. The UDVA was significantly improved 1 month after surgery ($P<.001$, paired Student *t* test). However, there was no statistically significant additional improvement between any postoperative time points (all $P>.05$, paired Student *t* test). The CDVA improved significantly 1 month postoperatively ($P<.001$, paired Student *t* test) but showed no additional improvement thereafter. The reduction in sphere, cylinder, and SE was statistically significant 1 month after surgery ($P<.001$, paired Student *t* test), with no significant additional reduction afterward.

The effect of ICR implantation on UDVA, CDVA, sphere, cylinder, and SE was not significantly different between the 4 grades of keratoconus ($P>.2$, 2-way mixed analysis of variance [ANOVA]) (Table 3).

The effect of ICR implantation on visual acuity and refractive outcomes was independent of the age of the patients ($P>.5$, 2-way mixed ANOVA).

Keratometry

Regarding corneal topographic outcomes (Table 2 and Figures 1 and 2), there was significant central corneal flattening 1 month after surgery (mean keratometry: $P<.001$, paired Student *t* test and Wilcoxon test). However, there was no further improvement between the 1-month and 1-year postoperative values (mean keratometry: $P=.7$, paired Student *t* test and Wilcoxon test). Also, the mean value of corneal astigmatism (keratometry in flat meridian − keratometry in steep meridian) decreased significantly during the first month of follow-up ($P<.001$) but showed no significant changes thereafter ($P=.4$) (Table 2).

In contrast, the effect of ICR implantation on the keratometric outcomes was similar between the 4 keratoconus severity groups ($P>.2$, 2-way mixed ANOVA) and the 3 age groups ($P>.3$, 2-way mixed ANOVA).

Aberrometry

Table 4 shows the total aberrometric outcomes over time. A significant decrease in primary coma was detected 1 year after surgery ($P=.03$, paired Student *t* test). Corneal HOAs and trefoil showed an

Table 2. Visual and refractive outcomes over time.

	Mean ± SEM					
		Postoperative				
Variable	Preoperative	1 Month	3 Months	6 Months	1 Year	*P* Value*
UDVA (logMAR)	1.17 ± 0.36	0.66 ± 0.31	0.60 ± 0.25	0.61 ± 0.27	0.62 ± 0.28	<.001
CDVA (logMAR)	0.85 ± 0.26	0.51 ± 0.24	0.48 ± 0.21	0.47 ± 0.23	0.52 ± 0.22	<.001
Sphere (D)	−5.48 ± 4.30	0.08 ± 2.81	0.08 ± 2.90	0.10 ± 2.90	0.09 ± 2.91	<.001
Cylinder (D)	−5.30 ± 1.92	−2.21 ± 1.47	−2.22 ± 1.69	−2.21 ± 1.71	−2.23 ± 1.68	<.001
Mean K (D)	51.9 ± 3.5	45.0 ± 2.9	44.9 ± 2.8	44.9 ± 2.8	45.0 ± 2.9	<.001
Corneal astigmatism (D)	5.6 ± 2.1	2.2 ± 1.4	2.2 ± 1.5	2.2 ± 1.5	2.2 ± 1.5	<.001

CDVA = corrected distance visual acuity; K = keratometry; UDVA = uncorrected distance visual acuity
*Change from preoperatively to 1 year postoperatively (paired Student *t* test)

Table 3. Changes in different variables in 4 keratoconus groups (according to Alio-Shabayek grading system[12]) between preoperative and final visit.

	Mean ± SD								
						Aberration			
KC Grade	UDVA (LogMAR)	CDVA (LogMAR)	Sphere (D)	Cyl (D)	Km (D)	HOAs (μm)	Coma (μm)	SA (μm)	Trefoil (μm)
1	0.75 ± 0.29	0.35 ± 0.24	5.60 ± 1.40	3.70 ± 0.90	5.30 ± 1.60	0.39 ± 1.20	0.61 ± 0.59	1.67 ± 0.28	0.19 ± 0.49
2	0.58 ± 0.26	0.34 ± 0.21	5.92 ± 2.10	2.76 ± 1.38	7.04 ± 1.37	0.10 ± 0.87	0.42 ± 0.47	1.91 ± 0.80	0.02 ± 0.60
3	0.45 ± 0.36	0.35 ± 0.24	5.00 ± 2.23	2.88 ± 1.60	7.70 ± 0.90	0.37 ± 1.04	0.55 ± 1.12	1.59 ± 0.60	0.07 ± 0.70
4	0.47 ± 0.34	0.32 ± 1.62	5.65 ± 1.68	3.30 ± 1.32	7.20 ± 1.90	0.04 ± 1.13	0.59 ± 0.88	2.01 ± 0.70	0.17 ± 0.52

CDVA = corrected distance visual acuity; Cyl = cylindrical part of refraction; HOAs = higher-order aberrations; KC = keratoconus; Km = mean keratometry; SA = spherical aberration; SE = spherical equivalent; UDVA = uncorrected distance visual acuity

insignificant decrease 1 month after surgery and afterward ($P > .05$, paired Student t test). Primary spherical aberration increased significantly between the preoperative evaluation and the first postoperative month ($P < .001$, paired Student t test) and between the 1-month and 3-month visits ($P < .001$, paired Student t test). No significant change was observed in this parameter afterward ($P > .05$, paired Student t test).

The effect of ICR implantation on aberrometric outcomes showed no difference between the grades of keratoconus ($P > .05$, 2-way mixed ANOVA). The aberrometric outcomes, except corneal trefoil, were not significantly different between the 3 age groups ($P > .05$, 2-way mixed ANOVA). The effect of ICR implantation on decreasing corneal trefoil was more significant in younger patients ($P < .05$, 2-way mixed ANOVA).

Pachymetry and Corneal Biomechanics

The CCT increased significantly postoperatively compared with preoperatively. There were no significant changes between postoperative visits ($P > .05$, Wilcoxon test). Corneal hysteresis did not significantly change between any visits ($P > .05$, paired Student t test). The CRF increased significantly after surgery compared with preoperative values ($P = .001$, paired Student t test). No significant change was detected in corneal-compensated intraocular pressure (IOP) or Goldmann-correlated IOP during the follow-up visits ($P > .05$, paired Student t test). Similarly, IOP measured by Goldman tonometry showed no significant change between the preoperative measurement and either of the postoperative measurements ($P > .05$, paired Student t test) (Table 5).

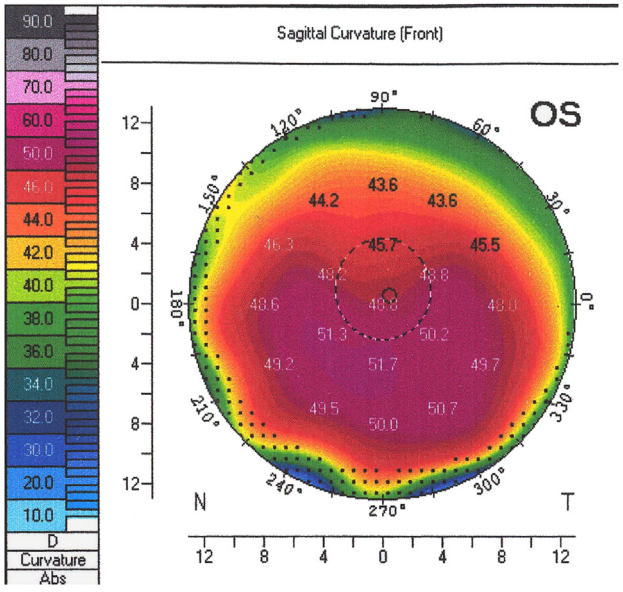

Figure 1. Preoperative keratometry map of a keratoconic patient planned for ICR insertion.

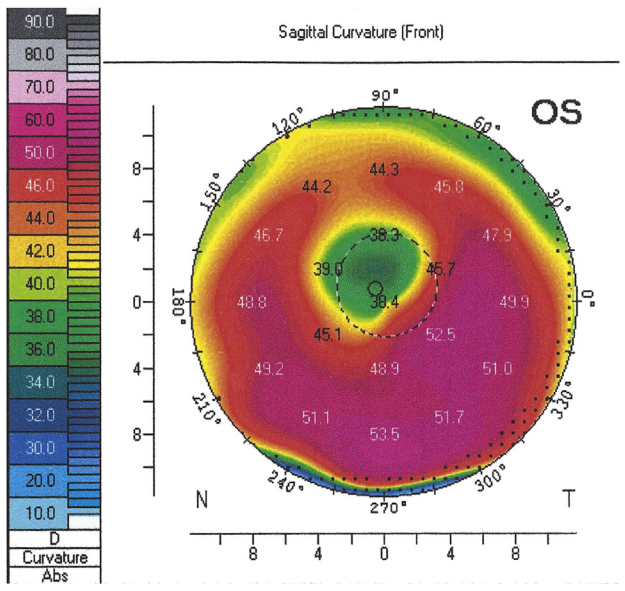

Figure 2. Keratometry map of the patient in Figure 1 after ICR insertion.

Table 4. Aberrometric outcomes over time.

Variable	Mean ± SEM					*P* Value*
	Preoperative	1 Month	3 Months	6 Months	1 Year	
HOAs (μm)	3.42 ± 0.88	3.35 ± 1.16	3.27 ± 1.18	3.25 ± 1.18	3.21 ± 1.31	.34
Primary coma (μm)	3.72 ± 1.29	3.68 ± 1.27	3.60 ± 1.37	3.38 ± 1.22	3.38 ± 1.20	.03
Primary SA (μm)	0.10 ± 0.64	1.35 ± 0.71	1.81 ± 0.81	1.82 ± 0.82	1.93 ± 0.92	<.001
Trefoil (μm)	1.10 ± 0.47	1.10 ± 0.53	1.10 ± 0.65	1.10 ± 0.68	1.20 ± 0.67	.4

HOAs = higher-order aberrations; RMS = root mean square; SA = spherical aberration
*Change from preoperatively to 1 year postoperatively (paired Student *t* test)

Safety, Efficacy, and Stability

No eye lost lines of Snellen CDVA or UDVA; thus, the safety of the procedure was 100%. The safety index was 2.2 at 1 year. The efficacy of the procedure was 22.5%. The stability of the procedure was 74%.

No intraoperative complications occurred. The ICR was explanted in 1 eye with severe keratoconus (preoperative keratometry was 59.0 D) after 3 months of surgery because of visual dissatisfaction. The refraction, visual acuity, and corneal topography returned to the preoperative status 1 month after explantation. According to exclusion criteria, the eye was excluded from the analysis.

DISCUSSION

In the present study, the UDVA, CDVA, sphere, and cylinder improved 1 month after surgery compared with preoperative values. No significant change was noted in these variables thereafter. Although it was not significant, a slight regression in visual acuity and refractive error was found 1 year postoperatively compared with 3 months postoperatively. The UDVA improved by more than 5 lines (mean 1.17 ± 0.36 logMAR to 0.62 ± 0.28 logMAR) and CDVA improved by approximately 4 lines (mean 0.85 ± 0.26 logMAR to 0.52 ± 0.22 logMAR) during the 1-year follow up. The mean change in sphere and cylinder 1 year after surgery was 5.39 D and 3.07 D, respectively. Thus, the magnitude of the refractive correction achieved by Myoring ICR implantation was considerably larger than the mean corrections observed after ICRS insertion.[14–17] Our findings are consistent with the results reported after Myoring ICR implantation using femtosecond laser technology or mechanical dissection.[8,11,18]

Like Alio et al.,[11] we believe that a complete, continuous ring may induce a more powerful arc-shortening effect for modifying the corneal curvature than incomplete ring segments. In the present study, we evaluated the effect of Myoring ICR implantation in eyes with different grades of keratoconus. In another study evaluating the effect of ICRS implantation in moderate and severe keratoconus,[19] 27% of patients had no change in refractive and visual outcomes and 9% of cases lost 1 to 2 lines in Snellen acuity. In the present study, we found that the effect of ICR implantation on the refractive outcomes was similar between higher grades and lower grades of keratoconus. Hence, ICR implantation could be an option for patients with advanced keratoconus who want to avoid more invasive procedures, such as penetrating keratoplasty. We also observed that the age of the patient did not affect the visual and refractive outcomes of Myoring ICR insertion.

Table 5. Pachymetric and biomechanical outcomes over time.

Variable	Mean ± SEM					*P* Value*
	Preoperative	1 Month	3 Months	6 Months	1 Year	
CCT (μm)	426.17 ± 33.8	438.00 ± 34.7	435.00 ± 32.4	434.00 ± 34.0	439.00 ± 39.7	<.001
CH (mg)	7.52 ± 1.48	7.88 ± 1.57	7.94 ± 1.56	7.93 ± 1.56	7.40 ± 1.84	.48
CRF (mg)	6.44 ± 2.24	7.30 ± 2.08	7.04 ± 2.38	7.10 ± 2.25	7.10 ± 2.34	.001
IOPcc (mm Hg)	15.52 ± 2.23	15.45 ± 2.30	15.28 ± 2.76	15.30 ± 2.90	15.52 ± 2.97	.9
IOPg (mm Hg)	14.12 ± 2.57	13.9 ± 2.44	13.47 ± 2.53	13.50 ± 2.68	13.40 ± 2.83	.06
Goldmann IOP (mm Hg)	14.32 ± 2.49	14.33 ± 2.86	14.19 ± 3.30	14.16 ± 3.38	14.24 ± 3.00	.64

CCT = central corneal thickness; CH = corneal hysteresis; CRF = corneal resistance factor; IOPcc = corneal-compensated intraocular pressure; IOPg = Goldmann-correlated intraocular pressure
*Change from preoperatively to 1 year postoperatively (paired Student *t* test)

Regarding the topographic outcomes, central corneal flattening occurred 1 month after surgery, with a mean change of 6.9 D. This amount of change, which is consistent with the results reported by Alio et al.,[11] has not been achieved in similar studies evaluating the role of ICRS in keratoconus except in 2 studies[20,21] reporting Intacs SK (Addition Technology Inc.) and Ferrara (Ferrara Ophthalmics) ICRS implantation in patients with high grades of keratoconus.

Alio et al.[11] state that the main reason for improvement after Myoring ICR implantation is the use of thicker implants with smaller diameters. Because we found that the effect of ring implantation on topographic outcomes of keratoconus is more significant in higher grades of disease, we believe that the selection of patients with severe keratoconus in this study played the most important role in improving the results.[20]

As expected, a significant increase in primary spherical aberration was observed in our patients. We believe that the small size of corneal rings we used, and therefore the significant impact on corneal asphericity, is the probable explanation for this finding. Therefore, like Alio et al.,[11] we believe that to have the least detrimental effect on corneal asphericity, corneal rings with larger diameters should be used. Selecting cases with smaller pupils is desirable as well to minimize glare induced by the Myoring ICR.

In our study, a significant decrease in primary coma and a nonsignificant decrease in HOAs and trefoil occurred after surgery. This finding was different from the results in the pilot study by Alio et al.[11] They found no significant improvement in CDVA and no significant decrease in corneal HOAs. We believe that our better results were due to our excluding patients with a mesopic pupil diameter larger than 5.5 mm, while Alio et al. did not set a limit of pupil diameter as an inclusion criterion. The other reason may be that we evaluated total aberrometric data directly using the iTrace system, which analyzes the total aberration in the eye. Alio et al.[11] used a topography system and software to convert the measured corneal elevation profile into corneal wavefront data. Improvements in corneal aberrometry were also reported in studies of the role of ICRS in keratoconus.[22]

In this study, we also evaluated the pachymetric and biomechanical outcomes after Myoring ICR implantation. Although CH showed a trend toward an increase in the first 6 months after surgery, the decrease at the 1-year follow-up visit was insignificant. This finding agrees with results in a study by Piñero et al.[23] that evaluated the biomechanical changes after ICRS implantation in keratoconus. In the study by Alio et al.,[11] no significant change in Ocular Response Analyzer findings was detected.

We did not find a significant change in the IOP measured by the Ocular Response Analyzer or the Goldmann tonometer. The CCT significantly increased after ICR implantation in our patients. This agrees with findings in the study by Alio et al.[11] and was probably due to structural changes in corneal structure.

To our knowledge, no study has compared the outcomes of Myoring ICR implantation via femtosecond laser technology versus mechanical dissection. Kubaloglu et al.[24] compared these 2 surgical techniques in ICRS implantation. They concluded that although the visual and refractive outcomes were similar between the 2 groups of patients, the incidence of postoperative complications was significantly lower in the femtosecond laser group than in the mechanical group. In addition, they confirmed that the femtosecond laser technique is easier, faster, and more comfortable for the patient and surgeon; gives the surgeon the ability to perform more accurate corneal stromal dissection at a predetermined depth; and prevents the potential inaccuracies of mechanical dissection.

In conclusion, we believe that Myoring ICR implantation using femtosecond laser technology is a safe and effective option in moderate to advanced keratoconus, especially in patients with significant myopia.

WHAT WAS KNOWN

- Continuous ICR implantation has been proposed as a treatment for keratoconus in pilot studies with small sample sizes and short follow-ups.

WHAT THIS PAPER ADDS

- Assessment of 98 keratoconic patients with a 1-year follow-up found femtosecond-assisted ICR implantation to be a safe and effective treatment for moderate to severe keratoconus, including in different age groups and in eyes with different severities of keratoconus.

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