Continuous Corneal Intrastromal Ring Implantation for Treatment of Keratoconus in an Iranian Population

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• PURPOSE: **To evaluate the effect of mechanical implantation of a continuous intrastromal ring in keratoconus.**
• DESIGN: **Prospective, interventional, nonrandomized, case series.**
• METHODS: **The MyoRing (Dioptex GmbH) was implanted after creation of an intrastromal pocket for 95 eyes of 95 patients with moderate and advanced keratoconus. All patients had at least 12 months of follow-up. Preoperative and postoperative visual acuity, keratometry, aberrometry, and refraction were the main outcome measures of the study.**
• RESULTS: **A significant improvement in uncorrected and corrected distance visual acuity was observed 1 month after surgery, which was consistent with the significant reduction in sphere (5.74 diopters [D]) and cylinder (3.02 D). No significant changes were detected in these parameters afterward. Furthermore, a significant corneal flattening of a mean value of 9.78 D was found. Both spherical myopia and astigmatism underwent reduction, but the reduction in myopia was more remarkable than astigmatism. Higher-order aberrations and coma-like aberrations decreased significantly, but spherical aberrations increased after surgery. No significant change in central corneal thickness was observed at any point after operation. There were no significant differences between 2 keratometry groups (higher or lower than 53 D) in visual gain after the procedure. There were no major complications during or after surgery. MyoRing explantation was performed in 4 eyes (4%). The refraction, visual acuity, and corneal topography returned to the preoperative status 1 month later for all 4 eyes.**
• CONCLUSIONS: **MyoRing implantation has an acceptable efficacy profile in moderate and advanced keratoconus. (Am J Ophthalmol 2013;155:837–842.**

KERATOCONUS IS A RARE (PREVALENCE OF 1 IN 2000) chronic corneal disease affecting a young population.[1] The cornea assumes a conical shape as a result of progressive, noninflammatory thinning. Nonsurgical therapeutic options for keratoconus are spectacles and contact lenses. In more advanced cases and in cases of deformed or opaque cornea, corneal grafts, either lamellar or penetrating, are the main treatment options.[1,2] Although keratoplasty has acceptable results, ongoing research seeks less invasive methods, including corneal collagen cross-linking and intrastromal corneal rings, to treat keratoconus. Intrastromal corneal ring segment implantation has been proved to be safe approach to reinforce corneal structure in mild to moderate keratoconus and other ecstatic disorders.[3] However, they are not as effective in more advanced cases.[4]

The recently proposed MyoRing (Dioptex GmbH, Linz, Austria) is a complete intrastromal ring designed to be placed into a corneal pocket.[5,6] A potential advantage of the MyoRing over ring segments is its effectiveness on advanced keratoconus and also its ability to reduce keratometric power of the cornea much more.[5,6] The present study aimed to evaluate the effect of MyoRing implantation in eyes with moderate to severe keratoconus.

METHODS

THE PRESENT STUDY WAS AN INTERVENTIONAL CASE SERIES. All procedures were performed by 2 surgeons (M.J. and A.S.) in 2010, with identical surgical techniques. All patients gave informed consent to participate in research and to undergo the proposed treatment, after explanation of other options of treatment. The tenets of the Helsinki Declaration were followed, and the Institutional Review Board of Tehran University approved both the procedures and use of the MyoRing for keratoconic patients prospectively.

We included keratoconic patients with clear central corneas, contact lens intolerance, mesopic pupil diameter of 5.5 mm or less (according to Orbscan (Bausch & Lomb, Rochester, New York, USA) report in mesopic conditions), minimum central corneal thickness of 360 μm, and a corneal thickness of at least 400 μm at the location of the proposed incision site and along the location of the proposed MyoRing placement. We graded the severity of keratoconus according to Amsler-Krumeich classification[7]:

1. Stage I: eccentric steeping; myopia or induced astigmatism of less than 5.00 diopters (D), or both; and mean central K readings less than 48.00 D.

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2. Stage II: myopia or induced astigmatism from 5.00 to 8.00 D, or both; mean central keratometry readings of less than 53.00 D; absence of scarring; and minimum corneal thickness more than 400 μm.
3. Stage III: myopia or induced astigmatism from 8.00 to 10.00 D, or both; mean central keratometry readings of more than 53.00 D; absence of scarring; and minimum corneal thickness of 300 to 400 μm.
4. Stage IV: nonmeasurable refraction, mean central keratometry readings of more than 55.00 D, central corneal scarring, and minimum corneal thickness of 200 μm.

We excluded patients with stage I keratoconus according to the Amsler-Krumeich classification,[7] incomplete follow-up of less than 1 year (6 eyes), or ring extrusion (4 eyes) in the first postoperative year. Other exclusion criteria were additional severe ocular pathologic features (eg, glaucoma, cataract, and diabetic retinopathy), spherical equivalent of plano or hyperopic, previous ocular surgery, history of herpes keratitis, diagnosed autoimmune disease, systemic connective tissue disease, pregnancy, and age younger than 19 years. We had no upper limit for age.

Ninety-five eyes of 95 patients with a mean age of 27.1 ± 4.79 years were included in the study and completed the 12-month follow-up. Most of the patients were male (70.5%). According to Amsler-Krumeich classification,[7] there were 56 eyes with stage II keratoconus, 18 eyes with stage III keratoconus, and 21 eyes with stage IV keratoconus.

A complete ocular examination, including ultrasound pachymetry (Nidek UP1000; Nidek Technologies, Gamagori, Japan), total aberrometry using iTrace (Tracey Technologies, Houston, Texas, USA), and Orbscan IIz (Bausch & Lomb, Rochester, New York, USA) imaging were performed before surgery and also 1 week, 1 month, 6 months, and 1 year after surgery. We calculated aberration coefficients and root mean square (RMS) values for a 5.5-mm pupil. Also, the following aberrometric values were calculated: higher-order RMS, coma-like RMS (third-order component Z3, fifth-order component Z5, and seventh-order component Z7), and spherical-like RMS (fourth-order component Z4 and sixth-order component Z6) in each visit. We used ultrasound pachymetry to measure peripheral and central corneal thickness at the time of surgery.

The stromal pocket was created at the depth of 300 μm and diameter of 9 mm using the PocketMaker microkeratome (Dioptex GmbH) as described in detail by Daxer (Supplemental Video available at AJO.com).[5] The microkeratome consists of a suction ring and a motor-driven blade. First suction ring fixates the microkeratome to the cornea, and then the blade creates the stromal pocket. It also creates a temporally located 4.0-mm wide incision tunnel. In the next step, the suction ring is removed and the MyoRing is inserted into the pocket. We used our adapted nomogram to calculate the size of the MyoRings (Table 1).

TABLE 1. Modified Nomogram for Corneal Intrastromal Ring Implantation for Treatment of Keratoconus

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

K = keratometry.

No complications occurred to any case during the procedure. Safety of the procedure was defined as the percentage of eyes losing more than 2 lines of Snellen corrected distance visual acuity (CDVA).[8] The safety index was calculated by dividing mean postoperative CDVA by mean preoperative CDVA.[8,9] Uncorrected distance visual acuity (UDVA), CDVA, manifest refraction, keratometry, and pachymetry also were the main outcome measures.

Secondary measures included procedure complications, efficacy, and stability index. Efficacy of a refractive procedure was defined as the percentage of operated eyes, achieving a UDVA 20/40 or more.[9] The efficacy index was calculated by dividing the mean postoperative UDVA by the mean preoperative CDVA, and the stability index was the percentage of eyes with a less than 1-D change in spherical equivalent (SE) between the first and twelfth postoperative months.[9]

We analyzed the preoperative versus 1-month, 6-month, and 1-year postoperative data using a paired *t* test. If not indicated otherwise, statistical measures are presented as mean ± standard deviation and significant *P* values are < .05. Statistical analysis was performed using SPSS software version 11 (SPSS Inc, Chicago, Illinois, USA).

RESULTS

THE MEAN PREOPERATIVE SPHERE WAS −4.6 ± 4.36 D (range, −16.00 to 2.00 D), mean cylinder was −5.3 ± 2.17 D (range, −2.00 to −11.00 D), and mean spherical equivalent was −7.28 ± 4.69 D. Also, the mean keratometry reading was 51.77 ± 3.65 D (range, 48 to 59 D).

Preoperative and postoperative measurements are shown in Table 2. Before surgery, 58% eyes had a UDVA of 20/200 or worse, whereas after 12 months, 42% eyes had a UDVA of 20/40 or better. No significant change in central corneal thickness was observed at any point before or after operation.

Table 2 sums up aberrometric outcomes after MyoRing implantation during the 1-year follow-up. A statistically

TABLE 2. Summary of Visual and Refractive Outcomes before Corneal Intrastromal Ring Implantation for Treatment of Keratoconus and during the Postoperative 1-Year Follow-up Period

		After Surgery			*P* Value		
	Before Surgery	1 Month	6 Months	1 Year	Before Surgery vs 1 Month	1 Month vs 1 Year	Before Surgery vs. 1 Year
UDVA (logMAR)	1.02 ± 0.24	0.39 ± 0.18	0.4 ± 0.19	0.39 ± 0.15	<.001	.948	<.001
CDVA (logMAR)	0.43 ± 0.2	0.16 ± 0.15	0.17 ± 0.15	0.17 ± 0.1	<.001	.909	<.001
Sphere (D)	−4.63 ± 4.36	1.15 ± 1.95	1.12 ± 1.95	1.11 ± 1.94	<.001	.486	<.001
Cylinder (D)	−5.3 ± 2.17	−2.30 ± 1.17	−2.26 ± 1.09	−2.28 ± 1.01	<.001	.709	<.001
SE (D)	−7.28 ± 4.69	0.03 ± 2.24	−0.05 ± 2.14	−0.03 ± 2.13	<.001	.186	<.001
CCT (μm)	431 ± 47.7	430 ± 48.4	429 ± 47.9	430 ± 47.8	.105	.681	.101
Km (D)	51.77 ± 3.6	42 ± 3.66	42 ± 3.64	41.99 ± 3.56	<.001	.818	<.001
HOA (μm)	5.01 ± 2.46	4.67 ± 2.6	4.66 ± 2.58	4.56 ± 2.62	.022	.239	.014
Coma-like (μm)	4.7 ± 1.62	4.51 ± 1.73	4.49 ± 1.8	4.35 ± 1.79	.010	.044	.001
Spherical-like (μm)	1.42 ± 0.65	2.03 ± 1.07	2.13 ± 1.12	2.04 ± 1.19	<.001	.93	<.001

CCT = central corneal thickness; CDVA = corrected distance visual acuity; Coma-like = Coma-like aberrations (root mean square); D = diopters; HOA = higher-order aberrations (root mean square); Km = mean keratometry; logMAR = logarithm of the minimal angle of resolution; SE = spherical equivalent; Spherical-like = spherical-like aberrations (root mean square); UDVA = uncorrected distance visual acuity.

Visual acuity and refractive outcomes are shown as mean ± standard deviation. *P* values was calculated using *t* test.

significant increase in spherical aberration was found at all follow-up points compared with preoperative values. Between postoperative follow-up time points, spherical aberration remained constant with no significant changes. Both higher-order and coma-like aberrations decreased significantly after operation, but remained constant with no significant changes between follow-up visits (*P* values are presented in Table 2).

According to the proposed definition for safety,[8,9] this procedure was 100% safe because no patient lost more than 2 lines of Snellen CDVA. The safety index (mean postoperative CDVA/mean preoperative CDVA) was 1.8 at 1 year, indicating an 80% increase of visual acuity (visual acuities changed to Snellen to calculate ratios). Efficacy (percentage of eyes reaching UDVA of 20/40 or better) of our study was 40%. The efficacy index (mean postoperative UDVA/mean preoperative CDVA) was 0.9 at 1 year, suggesting that after 1 year, the MyoRing alone could achieve 90% of the baseline best spectacle-corrected visual acuity. Stability (percentage of eyes with SE change of less than 1 D from 1 month to 1 year) of the study was 97.9% (93 patients).

We divided patients to 2 groups based on their preoperative keratometry (group 1, keratometry < 53; group 2, keratometry ≥ 53) and compared the changing parameters between the 2 groups. No significant difference was noted between the identical values of the 2 groups (Table 3).

All procedures were performed under topical anesthesia. MyoRing explantation was performed in 4 eyes (4%). Most cases demonstrated a mild haze around the ring, especially in the first 3 months, whereas it did not influence the visual axis. Subconjunctival hemorrhage developed in some of the eyes, probably because of the suction ring of the pocket-maker. It dissolved spontaneously and completely in less than 1 week. We observed no important complications such as keratitis.

TABLE 3. Comparison of Different Parameter Changes between 2 Keratometry Groups (before and after Corneal Intrastromal Ring Implantation for Treatment of Keratoconus)

Mean Keratometry, Before Surgery to 1 Year after Surgery (D)		Mean	*P* Value
SE	≥53	−7.8 ± 3	.064
	<53	−6.8 ± 2.1	
Sphere	≥53	−6.2 ± 2.9	.150
	<53	−5.4 ± 1.9	
Cylinder	≥53	−3.36 ± 1.26	.615
	<53	−2.75 ± 1.16	
CCT	≥53	1.32 ± 12	.504
	<53	2.3 ± 7.6	
CDVA	≥53	0.29 ± 0.12	.057
	<53	0.25 ± .083	
UDVA	≥53	0.65 ± 0.11	.057
	<53	0.62 ± 0.07	

CCT = central corneal thickness; CDVA = corrected distance visual acuity; D = diopters; Km = mean keratometry; SE = spherical equivalent; UDVA = uncorrected distance visual acuity.

Patients divided based on preoperative keratometry (≥53 D or <53 D). Visual acuity and refractive outcomes are shown as mean ± standard deviation. *P* values calculate using the *t* test.

DISCUSSION

THE CONCEPT OF CONTINUOUS RING IMPLANTATION INTO an intrastromal pocket was proposed first in 2008.[10] Its

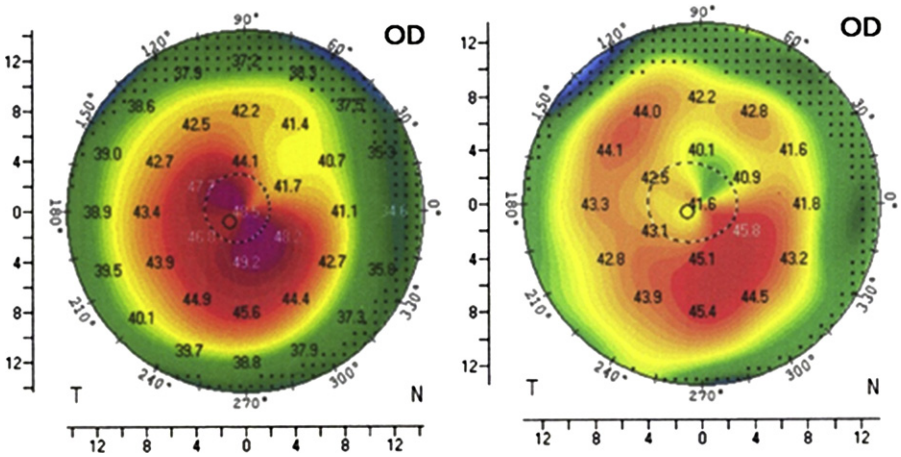

FIGURE 1. (Left) Preoperative and (Right) postoperative topography results 12 months after corneal intrastromal ring implantation for treatment of keratoconus, showing a significant reduction in the K values. OD = right eye.

safety and efficacy for myopia correction and keratoconus have been shown and proved in many prior studies.[6,10,11] In the present study, we demonstrated a reduction in corneal power and astigmatism after MyoRing placement. The reduction in the mean corneal keratometry (9.78 D) and spherical power (5.74 D) was more significant than the cylindrical power reduction (3.02 D; Figure 1). Therefore, it can be concluded that MyoRing can reduce some degrees of astigmatism; however, its effect is more remarkable in the reduction of spherical myopic power.

One month after surgery, we observed a significant reduction in myopia and cylinder, with no significant changes during the remaining follow-up period. The level of refractive and keratometric changes were consistent with those of previous MyoRing studies; however, we had a greater reduction in keratometry compared with other studies. The correction levels were larger than previous reports for Intacs (Addition Technology Inc, Des Plaines, Illinois, USA) segments in keratoconus (Table 4).

The thicknesses of ring segments in previous studies on Intacs mostly were larger than the thickness of the MyoRing used in our study. According to an Intacs nomogram,[12] thicker segments have greater effect on corneal power. Therefore, a larger effect of the MyoRing must be related to its continuous design that leads to a more significant arc-shortening effect on the cornea. The level of keratometry change in our study was closely related to vision improvement. The mean change in keratometry in this study (9.78 D) was comparable only with that of previous studies on MyoRing and a study by Miranda and associates after Ferrara ring placement.[6,10,11,13] Ferrara segments are thicker implants with a smaller diameter. Both of these factors increase the flattening effect of the ring.[6] Alio and associates reported significant thickening of the central cornea after MyoRing implantation[6]; in our study with larger sample sizes, no significant changes were observed.

We also analyzed corneal aberrations in this study. Higher-order aberrations and coma-like aberrations were reduced significantly after surgery. Previous studies reported reduction of coma and higher-order aberrations after ring segment implantation in keratoconus.[14–16] In a previous study by Alio and associates, higher-order aberrations did not change significantly and also coma-like aberrations were reduced nonsignificantly.[6] In the same study, sample size was fairly small (12 eyes), pupil size was not considered as an inclusion criterion, and all the rings had a diameter of 5 mm. Because of the small optical zone of the MyoRing, we considered mesopic pupil size of less than 5.5 mm for MyoRing with a 6-mm optical zone and mesopic pupil size of less than 4.5 mm for implants with a 5-mm optical zone. These differences may explain the significant reduction of higher-order aberrations and coma-like aberrations in our study. Spherical aberration in our study increased significantly (0.6 μ) after ring implantation. However, Alio and associates reported a 2-μ increase in spherical aberration.[6] The increase was expectable because of flattening of the central part of the cornea and changing the shape of the cornea from prolate to oblate. The difference between the degrees of increase can be attributed to the mentioned difference in pupil size and the ring size between the 2 studies. We may conclude that larger diameters of the ring can improve aberrometric parameters more significantly. Patel and associates predicted the same results through a corneal modeling of ring implantation.[17]

Alio and associates reported a nonsignificant increase in CDVA after 5-mm MyoRing implantation.[6] However, Daxer and Mahmoud and associates reported a significant increase that is consistent with our study.[10,11] We believe that poor results of CDVA in Alio and associates' study may have been caused by small ring size in proportion to the patient's pupil.

TABLE 4. Review of Previous Studies of Implantation of Different Types of Corneal Intrastromal Rings for Keratoconus

Study	Ring Type	Year	No. of Eyes	Follow-up (mos)	Change in UDVA (logMAR)	Change in CDVA (logMAR)	Change in Km (D)	Change in Sphere (D)	Change in Cylinder (D)	Change in SE (D)	Change in CCT (μm)
Miranda and associates[11]	Ferrara	2003	36	12	?	?	9.60	?	?	2.49	Reduction
Shetty and associates[8]	Intacs	2008	14	12	0.13	0.20	3.98	4.06	1.87	5	?
Daxer and associates[9]	MyoRing	2010	15	12	0.97	0.28	5.76	5.23	2.23	5.75	?
Mahmood and associates[10]	MyoRing	2011	6	6	0.73	0.173	8	6	1	7	?
Alio and associates[6]	MyoRing	2011	12	6	0.75	0.11	9.5	5.13	4.3	7.31	+11.7
Present study	MyoRing	2012	95	12	0.63	0.26	9.78	5.74	3.02	7.25	−1.8

? = variable not reported in the results of the study; CCT = central corneal thickness; CDVA = corrected distance visual acuity; D = diopters; Km = mean keratometry; SE = spherical equivalent; UDVA = uncorrected distance visual acuity.
Changes have been reported for 1 year after surgery or at the end of the study, if shorter.

In another study, Alió and associates reported favorable outcomes after Intacs implantation as a 2.11-D decrease in spherical power, 1.5 D decrease in cylinder, 2.81 D decrease in SE, and 4.30 D reduction in the mean keratometry.[2] We reported a 5.74-D, 3.02-D, and 7.25-D reduction in the sphere, cylinder, and SE, respectively, at 1 year consecutively. The best results in our series belonged to the young male population, which agrees with previous studies that mentioned young age and male sex as favorable outcome predictors.[2,9]

Stability of visual, refractive, and aberrometric values between 1 month and 1 year in our study is consistent with the findings in previous studies of Intacs and MyoRing devices.[2,12,18] It may indicate that the MyoRing can influence the progression of keratoconus. However, the 1-year follow-up may not be enough to evaluate keratoconus progression, and studies with longer follow-up periods are needed.

In contrast to previous studies of Intacs, which reported poorer visual outcomes for keratometries of more than 53 D, our study demonstrated good results with the MyoRing for keratometry groups both more and less than 53 D. Because 3 of 4 patients who had experienced extrusion had a keratometry of higher than 59 D, we may conclude that the MyoRing is not a good option for this subgroup of patients with severe keratoconus.

Busin and associates reported 1-year results of lamellar keratoplasty, as the final keratoconus treatment.[19] In their series, after a 1-year follow-up, postoperative CDVA was or 20/40 or better in 88% of patients, mean spherical error was −4.09 D, and mean cylindrical error was 2.67 D. In our report, after 1 year of operation, CDVA of more than 20/40 was 92%, mean spherical error was −4.09 D, and cylindrical error was 2.67 D. Mahmood and associates reported better results for MyoRing implantation in comparison with lamellar keratoplasty.[11] A previous study reported Intacs results superior to those of penetrating keratoplasty.[20]

We report 4 cases of MyoRing explantation. In 3 cases, this was carried out because the patient was unhappy with the postoperative vision quality. In these 3 cases, the severity of keratoconus might have been a cause of poor vision, because all 3 eyes had mean keratometry of more than 59 D (59 D, 61 D, and 62 D). In the fourth eye, the ring extruded spontaneously, so we explanted it. The reason was creation of a shallow stromal tunnel (230 μm). The refraction, visual acuity, and corneal topography returned to the preoperative status 1 month later in all the 4 eyes.

It should be noted that our study had potential limitations, including the short follow-up period (longer follow-up is required to tell if the ring can affect the progression of keratoconus) and lack of a control group. We did not combine corneal collagen cross-linking with MyoRing implantation in our study. Future studies should address these issues. We used safety and efficacy indices proposed by Koch and associates to evaluate safety and efficacy of the procedure.[8] However, because the safety index accounts for only visual acuity and not for complication rate, the final index may overestimate the safety of the procedure and should be interpreted with caution.

In conclusion, it can be said that MyoRing implantation in keratoconus improves both UDVA and CDVA significantly. It also reduces spherical power of the cornea and keratometry significantly, especially in advanced cases. Furthermore, it reduces corneal astigmatism, albeit not as much as spherical errors.

ALL AUTHORS HAVE COMPLETED AND SUBMITTED THE ICMJE FORM FOR DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST, and none were reported. Involved in Conception and design of study (M.J., A.S., H.H.); Analysis and interpretation of data (A.S., H.H., M.K.); Data collection (H.H., M.K.); Provision of materials, patients, or resources (M.J., M.K.); Statistical expertise (A.S., H.H.); Obtaining funding (M.J., H.H.); Literature search (H.H., M.K.); Administrative, technical, or logistic support (M.J.); Writing the article (A.S., H.H., M.K.); Critical revision of article (A.S., H.H.); Final approval (M.J., A.S., M.K.).

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Biosketch

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Biosketch

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