

# Femtosecond Laser-Assisted MyoRing Implantation in Postoperative LASIK Ectasia

Mahmoud Jabbarvand, MD; Mohammadnaser Hashemian, MD; Hesam Hashemian, MD; Fatemeh Bazvand, MD; Mehdi Khodaparast, MD

## ABSTRACT

**PURPOSE:** To evaluate the effect of MyoRing implantations (DIOPTEx GmbH, Linz, Austria) in patients with ectasia after LASIK.

**METHODS:** MyoRing implantation was performed in 15 eyes of 14 patients with ectasia after LASIK using a femtosecond laser. Uncorrected and corrected distance visual acuity, refraction, keratometry, central corneal thickness, corneal biomechanical profile, and corneal aberrometry were evaluated preoperatively and at 1, 3, and 6 months, and 1 year postoperatively.

**RESULTS:** Uncorrected distance visual acuity ( $1.02 \pm 0.48$  to  $0.30 \pm 0.18$  logMAR), maximum keratometry ( $50.14 \pm 1.82$  to  $43.80 \pm 1.21$  diopters), and sphere ( $-4.4 \pm 4.8$  to  $+1.50 \pm 0.61$  diopters) were significantly improved from preoperative values at 1 month after surgery with no significant change afterward. Corrected distance visual acuity did not improve significantly 1 month after implantation, but between the 1- and 3-month follow-up visits, a significant improvement ( $0.30 \pm 0.1$  to  $0.17 \pm 0.13$  logMAR) was observed without any additional improvement thereafter. A nearly significant ( $P = .05$ ) increase in central corneal thickness ( $439.4 \pm 19$  to  $452.2 \pm 20$   $\mu\text{m}$ ) was observed during the 1-month postoperative period. Primary coma, higher-order aberrations, and trefoil showed an insignificant decrease 1 month after surgery and afterward. Spherical aberration significantly increased between the preoperative visit and the first postoperative visit. Corneal hysteresis and corneal resistance factor showed no significant change between visits.

**CONCLUSIONS:** MyoRing is a safe and effective method in patients with ectasia after LASIK. It can improve corrected distance visual acuity and reduce refractive error in these patients.

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Intrastromal corneal ring segments (ICRS) have been recognized as an acceptable alternative treatment for myopia, astigmatism, and mild keratoconus.<sup>1</sup> The implantation of ICRS in the mid-periphery of the cornea converts corneal curvature to a more regular, flatter cornea, which reduces myopia leading to uncorrected vision improvement and a reduction in corneal higher-order aberrations.<sup>2-4</sup> Ring implantation is considered a substitute for keratoplasty in some cases. One advantage of this treatment is its reversibility with explantation, which results in the corneal shape reversing to preoperative status.<sup>4</sup> Safety and efficacy of Intacs in keratoconus and ectasia after LASIK has been demonstrated in several studies.<sup>5-11</sup> Recently introduced complete intrastromal ring (MyoRing; DIOPTEx GmbH, Linz, Austria) implantation is considered an alternative option for myopia, astigmatism, and corneal ectasia.<sup>2,12-15</sup> The results of the Intacs implantation is reported to be better in earlier stages of keratoconus.<sup>7</sup> On the other hand, MyoRing implantation is reported to be effective in more severe ectatic disorders.<sup>14,15</sup> The newly proposed femtosecond laser seems to act more precisely compared to previous manual techniques in creating corneal pockets, despite similar visual and aberrometric outcomes reported for Intacs.<sup>4,16</sup> This study evaluated clinical outcomes of MyoRing implantation in patients with postoperative LASIK ectasia.

## PATIENTS AND METHODS

This study was a prospective, interventional case series. All procedures were performed by one surgeon (MJ) between September 2010 and August 2013. Informed consent was obtained from all patients after explanation of other options of treatment. The tenets of the Declaration of Helsinki were followed and approval was obtained from the institutional ethical review

*From Ophthalmology Research Center, Farabi Eye Hospital, University of Medical Sciences, Tehran, Iran.*

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*Correspondence: Hesam Hashemian, MD, Eye Research Center, Farabi Eye Hospital, South Kargar Street, Tehran, Iran. E-mail: h-hashemian@tums.ac.ir*

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board of Tehran University. This study was performed in the Farabi Eye Hospital, Tehran, Iran. We recruited patients with ectasia after LASIK. According to previous studies,<sup>10,17</sup> patients were characterized by existence of all five criteria: progressive steepening and myopia; loss of corrected distance visual acuity (CDVA); inferior superior asymmetry index greater than 1.2 (according to corneal topography map); highest elevation value of greater than 0.042 and 0.071 mm for anterior and posterior best-fit spheres, respectively (according to Orbscan elevation map); and progressive corneal thinning.

We excluded patients with central corneal scar, glasses or contact lens tolerance, mesopic pupil diameter of greater than 5.5 mm (according to an Orbscan report in mesopic conditions), and minimum central corneal thickness less than 360  $\mu\text{m}$ . We also excluded patients with a follow-up period of less than 1 year (2 eyes). Other exclusion criteria were additional severe ocular pathologies (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, and pregnancy.

Visual acuity of patients was evaluated by Snellen chart and converted to logMAR for analysis. All patients were examined preoperatively and at 1 day, 1, 3, and 6 months, and 1 year postoperatively. At each follow-up visit, we performed a complete ocular examination, including evaluation of uncorrected distance visual acuity (UDVA) and CDVA, refraction, slit-lamp biomicroscopy, Goldmann applanation tonometry, and funduscopy. Preoperatively, all patients underwent Visante (Carl Zeiss Meditec, Jena, Germany) anterior segment optical coherence tomography to evaluate flap thickness in different parts of the cornea. We also performed ultrasonic pachymetry (SP3000; Tomey Corporation, Nagoya, Japan), Pentacam corneal imaging (Oculus Optikgeräte GmbH, Wetzlar, Germany), corneal topography (Tomey TMS; Tomey Corporation, Nagoya, Japan), Ocular Response Analyzer (Reichert Corp., Buffalo, NY), and aberrometry (iTrace; Tracey Technologies, Houston, TX) at all follow-up visits except for the first postoperative day.

## SURGERY

Using the femtosecond laser, a stromal pocket was created at the depth of 300  $\mu\text{m}$  and a diameter of 9 mm followed by a 4.5-mm wide tunnel incision superiorly as described in detail by Alio et al.<sup>2</sup> Then, the MyoRing was inserted into the pocket. We used our adapted nomogram to calculate the MyoRing size (**Table 1**). The surgery was performed under topical anesthesia. Subsequently, bandage contact lens with no sutures was used. Topical chloramphenicol and betamethasone drops were admin-

TABLE 1  
**Modified Nomogram for Corneal Intraström Ring Implantation**

Keratometry	Mesopic Pupil (mm)	Ring Dimension	
		Diameter (mm)	Thickness ( $\mu\text{m}$ )
$K \leq 44$	$< 5.5$	6	240
$44 < K \leq 48$	$< 4.5$	5	240
	$\geq 4.5$	6	280
$48 < K \leq 52$	$< 4.5$	5	280
	$\geq 4.5$	6	320
$K \geq 52$	$< 4.5$	5	320

*K* = keratometry

istered every 6 hours for 1 week and topical lubricant every 4 hours was continued for 1 month.

## STATISTICAL ANALYSIS

The data were analyzed using SPSS software (SPSS, Inc., Chicago, IL). We compared the preoperative data versus postoperative data using the Student's paired *t* test. If not indicated otherwise, statistical measures were mean  $\pm$  standard deviation and a *P* value less than .05 was considered significant. Safety, efficacy, and stability were determined based on methodology reported by Koch et al.<sup>18</sup>

## RESULTS

### DEMOGRAPHIC DATA

Fifteen eyes of 14 patients were included in this study with a mean age of  $31.8 \pm 4.54$  years (range: 27 to 39 years). Six patients (42.85%) were male and 8 (57.15%) were female; 7 (46.6%) eyes were right eyes and 8 (53.3%) eyes were left eyes. Thirteen patients had a history of myopic LASIK and one of them had a history of hyperopic LASIK. The duration between the LASIK procedure and MyoRing implantation was  $78.4 \pm 14.4$  months (range: 36 to 132 months).

**Table 2** summarizes the visual and refractive outcomes after MyoRing implantation. UDVA significantly improved 1 month after surgery (**Figure 1**). However, we did not find any statistically significant additional improvement between postoperative time periods. On the other hand, CDVA did not improve significantly 1 month after implantation, but it had a significant improvement between 1 and 3 months. It showed no additional improvement thereafter. The reduction in sphere was significant at 1 month after surgery, but we observed no significant additional reduction afterward.

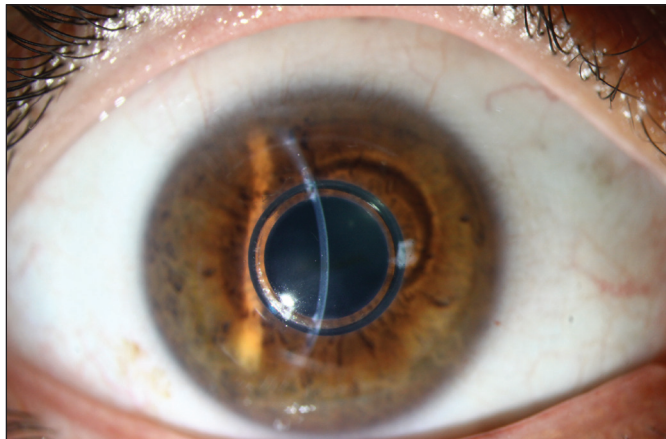
Regarding corneal topographic outcomes (**Table 2**), we found significant central corneal flattening 1 month

TABLE 2

**Summary of Visual, Refractive, Aberrometric, and Biomechanical Outcomes Before Intrastromal Corneal Ring Implantation for Treatment of Keratoconus and During the Postoperative 1-Year Follow-Up Period<sup>a</sup>**

Parameters	Preoperative	Postoperative				P	
		1 Month	3 Months	6 Months	12 Months	Preoperative to 12 Months	1 to 12 Months
UDVA	1.02 ± 0.48	0.30 ± 0.18	0.29 ± 0.11	0.25 ± 0.11	0.3 ± 0.16	.014	1
CDVA	0.30 ± 0.1	0.27 ± 0.13	0.17 ± 0.13	0.14 ± 0.16	0.11 ± 0.16	.03	.09
Sphere (D)	-4.4 ± 4.8	1.50 ± 0.61	1.35 ± 0.96	1.38 ± 0.94	1.6 ± 0.7	.04	.37
Cylinder (D)	-6.90 ± 6.48	-2.80 ± 1.35	-2.45 ± 1.72	-2.45 ± 1.72	-2.5 ± 1.0	.06	.20
Km	50.14 ± 1.82	43.80 ± 1.21	43.48 ± 1.03	43.54 ± 1.00	43.42 ± 1.26	.002	.20
CCT	439.4 ± 19	452.2 ± 20	451.4 ± 23	451.8 ± 24	454.0 ± 23	.05	.60
CH	7.8 ± 1.78	8.1 ± 1.51	7.8 ± 1.09	7.8 ± 1.09	7.4 ± 2.07	.70	.20
CRF	8.2 ± 3.27	9.0 ± 2.91	8.8 ± 3.11	9.0 ± 2.73	8.4 ± 3.47	.60	.30
HOA	4.26 ± 0.74	4.62 ± 1.63	4.30 ± 1.51	3.88 ± 1.34	3.64 ± 1.19	.20	.10
Coma	3.72 ± 1.51	3.64 ± 1.56	3.38 ± 1.80	3.46 ± 1.77	2.96 ± 1.7	.10	.10
SA	-0.64 ± 0.63	1.18 ± 1.07	1.34 ± 1.23	1.38 ± 1.16	1.34 ± 0.9	< .001	.20
Trefoil	1.04 ± 0.52	1.16 ± 0.60	1.10 ± 0.61	1.28 ± 0.72	0.91 ± 0.57	.40	.20

UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; D = diopters; Km = maximum keratometry; CCT = central corneal thickness; CH = corneal hysteresis; CRF = corneal resistance factor; HOA = higher-order aberrations (root mean square); SA = spherical aberrations (root mean square); <sup>a</sup>Data are given as mean ± standard deviation. P values calculated using Student's t test.



**Figure 1.** Slit-lamp photography 1 month after MyoRing (DIOPTEX GmbH, Linz, Austria) implantation in a patient with ectasia after LASIK.

after surgery. However, there was no further improvement between 1 month and 1 year postoperative values.

**Table 2** summarizes the total aberrometric outcomes of the patients after MyoRing implantation. Primary coma, higher-order aberrations, and trefoil showed an insignificant decrease 1 month after surgery and afterward. Primary spherical aberration significantly increased between the preoperative and the 1 month postoperative evaluations, with no significant change afterward.

Central corneal thickness increased insignificantly in postoperative visits compared to preoperative values. There were no significant changes between postoperative visits. The corneal hysteresis and corneal resistance factor showed no significant change in the postoperative visits.

No eye lost lines of Snellen CDVA or UDVA and, therefore, the safety of the procedure was 100%. The safety index was 1.6 at the 1-year follow-up visit. Efficacy was 26.7%. Stability of the procedure was 67%. All of the remaining 33% of eyes changed toward hyperopia and no eye had myopic change of more than one D during the 1-year follow-up period.

No complication occurred during the surgical procedure or during the 1-year follow-up except for mild corneal haziness around the MyoRing implants.

## DISCUSSION

Although there are some studies on different aspects of clinical outcomes of MyoRing implantation in keratoconus, no study is available on MyoRing implantation for ectasia after LASIK.<sup>2,13-15</sup> In this report, we have evaluated the clinical effect of MyoRing implantation in ectasia after LASIK.

Intracorneal rings perform as spacer elements between stromal collagen bundles, resulting in shortening of the central arc length proportional to the implant thickness.

TABLE 3

### Review of Previous Studies of Different Types of Intraström Corneal Ring Implantation in Ectasia After LASIK<sup>a</sup>

Study	Ring Type	No. of Eyes	Follow-up (mo)	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 ( $\mu$ m)
Kymionis et al. <sup>11</sup> (2003)	Intacs	10	15	7.4 line	1 line	3.07	NA	NA	3.85	NA
Tan et al. <sup>19</sup> (2006)	Intacs	8	6	0.1	0.1	NA	NA	2.77	No change	NA
Kymionis et al. <sup>1</sup> (2006)	Intacs	20	60	3.1 line	1.1 line	3.68	NA	NA	2.91	NA
Carrasquillo et al. <sup>4</sup> (2007)	Intacs	8	10.3	0.4	0.2	NA	NA	NA	1	NA
Piñero et al. <sup>8</sup> (2009)	Intacs	34	12	No change	0.07	1.54	0.45	0.78	0.93	NA
Tunc et al. <sup>17</sup> (2011)	Keraring	20	12	0.92	0.45	7.06	NA	3.82	4.8	No change
Current study (2013)	MyoRing	15	12	0.72	0.19	6.7	5.2	4.4	7.4	15

UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; Km = maximum keratometry; D = diopters; SE = spherical equivalent; CCT = central corneal thickness; NA = not available

<sup>a</sup>Changes have been reported for 1 year postoperatively or at the end of the study if shorter.

Implantation of the ring in the intrastromal pocket reconfigures corneal shape, resulting in a flatter, more regular central cornea. Degree of central flattening seems to have a linear relationship to the ring thickness. Flattening and regularizing the central cornea corrects regular astigmatism and myopia and eliminates sources of higher-order aberrations. Because the MyoRing is a full ring and has a smaller optical zone than Intacs, the flattening effect is much greater. On the other hand, placement of the implant in a pocket has the advantage that the ring position can be adjusted according to postoperative results. This allows refining the optical effect of the ring.

After the MyoRing implantation, significant improvement of UDVA was obtained after 1 month, whereas significant improvement in CDVA was achieved after 3 months. There were no significant changes in CDVA values between the 6-month and 1-year follow-up visits. This implies that 3 months after MyoRing implantation, the corneal status is relatively stable. We observed that CDVA improved more slowly compared to UDVA. This may be due to the fact that MyoRing reduces the myopic refractive error significantly and improves UDVA earlier. But improvement in CDVA needs reduction of higher-order aberrations and coma that improves after 1 month along with improvement in CDVA (Table 2). Delay in improvement of higher-order aberrations may in turn be due to ocular surface problems in the early postoperative period. Previous studies on MyoRing implantation in keratoconus reported the same favorable results with improvement of both UDVA and CDVA after MyoRing implantation.<sup>13-15</sup> Contrary to our results, Alio et al.<sup>2</sup> re-

ported significant improvement of only UDVA and not CDVA in keratoconic eyes. That may be explained by the disparity of the study population (keratoconus vs ectasia after LASIK). Another probable reason for these different results is considering the large pupil as an exclusion criterion in the current study to reduce a light distorting the effect of internal rim of the ring. It could be concluded that careful case selection is necessary to get good results. The improvement of UDVA was more significant compared to CDVA in our patients, which was consistent with previous studies.<sup>12,13</sup> It may reveal that MyoRing is more effective in reduction of refractive error and less effective in reducing corneal irregularities. Alio et al.<sup>2</sup> reported a significant improvement in UDVA at the first week after surgery with no significant changes afterward.<sup>2</sup> Because we believe that many confounding factors, including ocular surface problems and stromal edema, may affect visual acuity in the first few postoperative days, we evaluated visual acuity of our patients 1 month after surgery.

Table 3 compares this study with previous studies of intrastromal ring implantation for ectasia after LASIK. The mean reduction in spherical refraction was 6 D in ectasia after LASIK after the 12-month follow-up visit. In previous studies, reduction in spherical power was between 4 and 6 D for MyoRing and Intacs in different studies.<sup>2,20</sup> The reduction was significant during the first month after surgery and was not significant in the next follow-up visits. The reduction was more than previous studies with ICRS implants in patients with keratoconus and ectasia after LASIK.<sup>6,7,9,10,16,21</sup> Mean value of cylindrical corrections after 12 months

was 4.4 D for ectasia after LASIK. Previous studies reported a reduction in cylindrical value between 2.23 and 4.3 D for MyoRing implantation in keratoconus,<sup>2,13</sup> between 0.29 and 1.37 D for ICRS in keratoconus,<sup>5,6</sup> and between 1.58 and 5.69 D for ICRS in ectasia after LASIK.<sup>9</sup> It seems that the reduction of myopia in the MyoRing is significantly higher than ICRS. The flattening effect of ICRS is reported to be directly correlated to the thickness of the corneal implant; moreover, the full ring implant has more arc shortening effect compared to ring segments.<sup>2</sup>

The level of keratometric changes was significant after 1 month in our patients with no significant changes afterward. The change is comparable to previous reports of MyoRing implantation in keratoconic patients.<sup>2,12,13</sup> It is greater than the result of ICRS in the patients with ectasia after LASIK.<sup>1,9</sup> Alio et al.<sup>2</sup> reported a small regression of keratometry at the 6-month follow-up visit, which was not observed in our results.

The corneal biomechanical properties (corneal hysteresis and corneal resistance factor) did not change significantly with MyoRing implants. It was possibly due to implantation of the additional material in the mid-periphery of the cornea and not in the center. The other reason may be low sensitivity of the Ocular Response Analyzer to detect minor changes.<sup>22</sup> There was an insignificant increase of these parameters in the previous studies on MyoRing and ICRS segments.<sup>2,23</sup> In patients with corneal ectatic disorders, corneal hysteresis and corneal resistance factor were reported to be lower than in those with normal corneas.<sup>1,17,24</sup>

#### AUTHOR CONTRIBUTIONS

*Conception and design (MJ, MH, HH); data collection (HH, FB, MK); analysis and interpretation of data (HH, MK); writing the manuscript (HH, FB, MK); critical revision of the manuscript (MJ, MH, HH); statistical expertise (HH, FB, MK); administrative, technical, or material support (MJ, MH); supervision (MJ, HH)*

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