

Original Article

Clinical Outcomes after Continuous Intracorneal Ring Implantation in Post-LASIK Ectasia: Long-Term Follow-Up

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Abstract

Purpose: The aim of the present study was to evaluate the clinical outcomes after implantation of MyoRing in patients with ectasia secondary to LASIK.

Patients and Methods: This study was a retrospective, consecutive, nonrandomized interventional case series. The MyoRing was implanted after creation of a stromal pocket using a PocketMaker microkeratome (Dioptex, GmbH, Linz, Austria) in 6 eyes of 6 patients with ectasia secondary to LASIK. Uncorrected distance visual acuity, corrected distance visual acuity, sphere, cylinder and keratometric changes were reported after a 3 year follow-up period.

Results: Uncorrected distance visual acuity and corrected distance visual acuity were improved in 5 and 3 patients respectively. One patient showed decreased UDVA after 3 years and in 3 patients the corrected distance visual acuity decreased at the last visit compared to the preoperative reading. Maximum keratometry, sphere and cylinder were improved from preoperative values in 4, 2 and 5 patients respectively.

Conclusion: Because of the mixed results in our small group of patients, it seems that MyoRing implantation using mechanical dissection is not a very effective method for treatment of patients with post LASIK ectasia. However, large comparative multicenter studies are recommended to further verify these results.

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Introduction

Laser In situ Keratomileusis (LASIK) leads to some side effects, mainly ectasia, which may be observed one week to several years after LASIK¹⁻³. Though, the rate of post LASIK ectasia is not proved yet, some various rates from 0.04 % to 0.6 % have been reported, which seem unreliable due to the lack of long-term post LASIK follow-up⁴⁻⁶. Seiler et al., described post-LASIK ectasia in 1998⁷. Post-LASIK ectasia was considered as increasing myopia with or without developing astigmatism, reduction of uncorrected visual acuity, keratometric steepening with or without central and paracentral corneal thinning, and topographic evidence of asymmetric inferior corneal steepening after LASIK procedure⁷. To determine the high-risk patients preoperatively, Randleman et al.⁸, designed a screening tool using an evidence-based review of a large series of LASIK ectasia cases, named the Ectasia Risk Score System (ERSS). According to Randleman score system, abnormal preoperative topography⁹, low residual stromal bed (RSB) thickness¹⁰, age younger than 25 years, low preoperative corneal thickness and high myopia¹¹ are the most prevailing risk factors. Several remedies have been noted to handle the post LASIK ectasia such as contact lenses¹², intraocular pressure-lowering drugs, corneal collagen cross-linking (CXL)^{13, 14}, combination treatments^{15, 16}, penetrating keratoplasty (PKP)¹⁷ and intracorneal ring segments (ICRS)^{18, 19}. MyoRing (Dioptex, GmbH, Austria) is a continuous full-ring implant which is implanted into a corneal pocket using PocketMaker (Dioptex, GmbH, Linz, Austria) microkeratome technology. This device combines two features: rigidity for the modeling and stabilization of the corneal shape after implantation as well as flexibility (shape memory) for the implantation via a small pocket entry to preserve the corneal

biomechanics. MyoRing is available in a diameter range of 5 to 6 mm and thickness range of 200 to 320 μm in 20 μm increments. The width of the ring body is 0.50 mm. The implant is made of polymethyl methacrylate (PMMA). The anterior surface is convex and the posterior surface is concave with a radius of curvature of 8.00 mm^{20, 22}. Previous studies on MyoRing implantation have reported that MyoRing is an effective and safe method to correct high myopia and keratoconus²⁰⁻²⁴. Despite several reports about MyoRing effectiveness for correction of high myopia and keratoconus, there are not enough data about its efficacy in patient with ectasia after LASIK. The aim of the present study was to evaluate the clinical outcomes after implantation of the MyoRing in patients with ectasia secondary to LASIK after a long term follow-up.

Patients and Methods

In the present study six cases of post LASIK ectasia referred to Bina Eye Hospital, Tehran, Iran, between October 2011 and November 2014 were retrospectively studied. Exclusion criteria were a positive pregnancy test, breast-feeding, history of vernal and atopic keratoconjunctivitis, patients with dry eye, history of corneal stromal disorders, nystagmus, immunosuppressive drug users, hyperopia, advanced ectasia with inferior corneal thinning less than 360 μm , and patients with severe ocular and systemic pathologies. The preoperative and postoperative evaluation included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), sphere and astigmatism. Also maximum, minimum and average keratometry parameters were measured for all patients. The appropriate MyoRing dimensions (diameter and thickness) were selected according to a MyoRing nomogram derived from theoretical calculations developed by Albert Daxer on the

basis of experimental data ²⁵. This nomogram takes into account the corneal thickness at its thinnest point and the mean central keratometry (K) reading.

Surgical Procedure

The procedures were performed by the same surgeon (KH.J) under sterile conditions and topical anesthesia (Proparacaine hydrochloride 0.5 %). An operation microscope (OMS-800 standard, TOPCON Corporation, Japan) was used to mark the central point of intrastromal corneal ring.

The creation of intrastromal pocket (9 mm in diameter and 300 µm in depth), via a small incision of 3 mm was performed using a Pocket Maker microkeratome as described in detail previously ^{21, 26}. The microkeratome consist of

the surgical procedure. Postoperatively, a silicone bandage contact lens was placed on the cornea and removed 24 hours after operation. Postoperative treatment included combination of betamethasone eye drop (SinaDarou, Iran), chloramphenicol eye drop (SinaDarou, Iran) and non preserved artificial tear (Artelac®; Bausch & Lomb, UK) four times daily. Chloramphenicol was interrupted one week postoperatively whereas betamethasone was tapered during 4-6 weeks.

Results

The present study evaluated 6 eyes of 6 patients (4 OD and 2 OS). All cases were male (Table 1). The mean age of patients was 34.33 ± 8.47 years (range 20-41 years). The mean follow-up duration was 36 months.

Table 1: Demographic characteristics of patients entering the study

Characteristic	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient6
Demographics						
Sex	Male	Male	Male	Male	Male	Male
Age	20	41	30	41	41	33
Eye	OD	OS	OD	OD	Os	OD

a suction ring and a motor-driven blade. First the suction ring fixates the applanator to the cornea and then the micro-vibrating diamond creates the stromal pocket. Once the pocket was created, the MyoRing was inserted into the pocket using implantation forceps and centration was adjusted using keratoscope. All procedures were performed with the temporal approach and self-sealing incisions. No intraoperative complications occurred during

UDVA

In 5 cases (83.33 %) the UDVA improved at the final follow-up compared to the pre-operation. The most improvement was observed in patient No.4 who was fully recovered after 3 years and his UDVA reached from 0.2 (LogMAR) to 1 (LogMAR) by 8 lines. Patient No.2 showed decreased UDVA after 3 years. In this case UDVA decreased 3 lines in the last follow-up (Table 2).

Table 2: Results of the visual parameters before and after MyoRing implantation

Characteristic	Time	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
UDVA (Log MAR)	Preoperative	0.1	0.2	0.2	0.2	0.1	0.05
	Last follow - up	0.3	0.1	0.6	1	0.2	0.2
CDVA (Log MAR)	Preoperative	0.6	0.5	0.4	0.4	0.4	0.3
	Last follow - up	0.5	0.4	0.7	1	0.2	0.7
Sphere (D)	Preoperative	- 1.5	3.5	- 1	- 1	- 6	- 8
	Last follow - up	- 7	3.5	- 1	1.5	- 2	- 3
Ast (D)	Preoperative	- 4.5	- 6.5	- 4	- 4.5	- 1.5	- 7
	Last follow - up	- 3	- 1	- 1	- 1.5	- 2	- 1.5

D = Diopters, UDVA = Uncorrected Distance Visual Acuity, CDVA = Corrected Distance Visual Acuity; Log MAR = logarithm of the minimum angle of resolution

CDVA

In three eyes (50 %), CDVA improved in the last follow-up. The highest improvement was observed in patient No.4, where the CDVA reached from 0.4 to 1 (4 lines). In 3 other patients (50 %) the CDVA decreased at the last visit compared to the preoperative reading. The most reduction was observed in patient number 5 with 2 lines reduction in CDVA.

Sphere

In terms of sphere, only 2 patients (33.33 %) showed a relative improvement in the last follow-up (patients No.5 and 6). The best recovery belonged to the patient No.6 who showed a decrease by 5 diopters (D) in the last follow-up compared to the preoperative reading. The highest worsening in sphere was observed in the patient No.1. The preoperative amount of sphere was -1.5 which reached - 7 three

years after surgery. As shown in table 2 spheres in 2 patients remained unchanged in the last visit.

Cylinder

Five patients (83.33%) showed an improvement in cylinder at the last follow-up; among these patients No.2 and 6 had the sharpest decline (5.5 D) in the amount of cylinder. In one case (patient 5) cylinder was increased (16.6 %).

Keratometry

In regard to corneal topography, K_{max} , K_{min} and K_{mean} keratometric values were measured. In 4 patients a decrease in the postoperative maximum keratometry was observed compared to the pre-operation. The greatest reduction in the keratometry belonged to the patient No.3, which showed 5.4 D reduction at last follow-up. Patients number 1 and 2 showed increased keratometric values of 0.2 D and 0.5 D respectively at the last follow-up (Table 3).

Table 3: Changes in pre and postoperative keratometry

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
K_{max} (D)						
Preoperative	48	48.6	51.7	46.2	47.2	50.3
Postoperative	48.2	49.1	46.3	40.6	46.3	45.4
K_{min} (D)						
Preoperative	41.7	42	49.8	40.7	44.8	43
Postoperative	46.7	43.8	45.3	37.9	42.9	41.1
K_{mean} (D)						
Preoperative	44.85	45.3	50.75	43.4	46	46.65
Postoperative	47.75	46.45	45.8	39.25	44.6	43.25

D = Diopters, K_{max} = Maximum K value in diopters, K_{min} = Minimum K value in diopters, K_{mean} = Average K value in diopters.

Discussion

MyoRing implantation was performed in 6 eyes of 6 patients with post LASIK ectasia using the PocketMaker Microkeratome. Uncorrected and corrected distance visual acuity, keratometry, sphere and cylinder were evaluated preoperatively and at 1, 3, 6, 12 and 36 months postoperatively. UDVA increased less than 7 lines in all patients except in patient number 2. Based on the protocol of our clinic regarding surgical success, an increase less than 1 line indicates an improper operation. An increase in the UDVA between 1 and 6 lines indicates the relative success of the operation, while an increase equal to 7 or more indicates that the operation has had the best result. With this protocol, 4 patients had moderate success and one patient (patient number 5) had the worse outcome. The CDVA improved in 5 cases less than or equal to 0.4 LogMAR, with no improvement in one patient (patient No.2) after 3 years. Of the 6 patients, only in one patient the sphere recovery was 5 D, while in other cases the value was less than or equal to 4 D and in one patient it increased by -5.5 D. Apart from patients 2 and 6, the cylinder improvement in the samples was less than or equal to 3, and in the patient No.5, the cylinder deteriorated by -0.5 D in the last follow-up

compared to pre-operation. MyoRing implantation in patients with post LASIK ectasia has been previously performed by Jabbarvand et al.²⁷. They reported that UDVA, CDVA, K_{max} and sphere significantly improved one year postoperatively. They concluded that MyoRing implantation is an effective method in patients with ectasia after LASIK²¹. Contrary to our study findings, result of Jabbarvand et.al, indicated the effectiveness of MyoRing in improving the corrected distance visual acuity²¹. We think the different outcomes may be explained by their short term versus our long term follow-up. Also, Jabbarvand et al., in a study on 98 patients with severe keratoconus demonstrated that UDVA and CDVA decreased by 0.55 and 0.33, respectively, one year after MyoRing implantation and the mean keratometry and astigmatism decreased by 5.9 D and 3.4 D, respectively²⁸. In another study on 95 eyes of 95 Iranian patients, it was shown that the mean improvement in UDVA and CDVA over a period of 12 months was equal to 0.63 and 0.26, respectively²³. In this group of patients, reduction of sphere, cylinder and Km values were observed²³. In a study conducted by Daxer et al., the MyoRing was implanted in 15 eyes of 11 patients²². Follow-up results showed that postoperatively, there was statistically

significant improvement in UDVA, CDVA, K readings, manifest spherical and cylindrical refractive errors²². They reported that UDVA and CDVA were improved about 10 and 3 lines respectively. Reduction of the mean K was 5.76 D at 1 year after operation²². Based on these results they concluded that treatment of keratoconus with MyoRing implantation significantly improves visual function. Alio et al.,²⁹ implanted MyoRings in 12 patients using femtosecond technique, one of which was post LASIK ectasia, and showed its usefulness in treatment of keratoconus. In comparison with the previous studies, our results showed less success in MyoRing implantation to treat post LASIK patients. The authors believe that, since our patients have already undergone LASIK, post LASIK corneal biomechanical changes are probably the main reason for this outcome. In several studies, a significant decrease has been observed in corneal hysteresis (CH) and corneal resistance factor (CRF) after LASIK³⁰⁻³⁵. These studies showed the partial recovery occurs during 1-12 month following the surgery, however, the CH and CRF values still remain lower than the preoperative values. The lack of full recovery indicates the irreversibility of some changes in cornea caused by surgery. The mechanism of the decrease of CH and CRF after LASIK has been previously investigated in numerous studies. Ortiz et al.,³⁸ reported a statistically significant correlation between corrected refractive error and

the changes in CH and CRF. Based on their proposed hypothesis, the creation of a flap and corneal thinning may be important factors in the weakening of the corneal structure. Also, in a study by Jaycock et Al.,³⁹ authors used an interferometric method to detect the corneal biomechanics changes caused by refractive surgery, and concluded that the creation of a corneal flap leads to the loosening of corneal biomechanical structure and the corneal softening. Similarly a study by Hjortdal et al.,⁴⁰ confirmed this result. The present study had some limitations. Our sample size was very limited and we did not measure the corneal hysteresis (CH) and corneal resistance factor (CRF) to detect the corneal biomechanics changes. However, the strengths of our study, was the long term follow-up period to further verify the results. The present study highlights the fact that reduced corneal thickness in patients with post LASIK ectasia might reduce the chance of ring to be fixed properly, which leads to a reduced success in MyoRing implantation.

Conclusion

Because of the mixed results in our small group of patients, it seems that MyoRing implantation using mechanical dissection might not be a very effective method for treatment of patients with post LASIK ectasia. However, large comparative multicenter studies are recommended to further verify these results.

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Footnotes and Financial Disclosures

Conflict of Interest:

The authors declare no conflict of interest with the subject matter of the present manuscript.

