

Full-Ring Intracorneal Implantation in Corneas With Pellucid Marginal Degeneration

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Abstract

Background: Keratoconus (KCN) is a progressive, non-inflammatory ectatic disorder characterized by bilateral and asymmetrical conical protrusion of the cornea. MyoRing implantation and Collagen Crosslink (CXL) are two separate effective treatments for all stages of keratoconus. This study wants to show the effect of these treatments combination in patients with moderate and severe keratoconus.

Objectives: The aim of this study was to report on the visual and refractive outcomes of corneas with pellucid marginal degeneration following MyoRing implantation (DIOPTEX GmbH).

Patients and Methods: This study included 15 eyes of 15 patients, with an age range from 22 to 40 years old, and pellucid marginal degeneration. An intrastromal corneal ring (MyoRing) was inserted by the means of a manual lamellar dissection using a PocketMaker microkeratome. The main outcome measures were uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refraction, and keratometry readings. The mean postoperative follow-up was ten months (range 6 - 12 months).

Results: The mean UDVA (LogMAR) improved significantly from 1.13 ± 0.21 preoperatively to 0.24 ± 0.13 postoperatively ($P < 0.001$), and the mean CDVA (LogMAR) improved significantly from 0.39 ± 0.12 to 0.19 ± 0.09 ($P < 0.001$). The mean cylinder of manifest refraction decreased significantly by 4.00 diopter (D) ($P < 0.001$). The mean spherical equivalent error also decreased significantly from -6.00 ± 3.60 D to -0.70 ± 1.90 D, at the end of the follow-up period. Furthermore, with regard to corneal topography, a significant reduction was observed in keratometric values. The Kmax, Kmin and Kaverage decreased significantly by 5.0, 1.10 and 4.00 D, respectively ($P < 0.001$).

Conclusions: MyoRing implantation using the PocketMaker microkeratome appears to provide an effective method for treating pellucid marginal degeneration. Both UDVA and CDVA improved significantly. The corneal steepening and astigmatism were reduced in all subjects after MyoRing implantation.

Keywords: Pellucid Marginal Corneal Degeneration, Intrastromal Corneal Ring Implantation, MyoRing

1. Background

Pellucid marginal corneal degeneration (PMD) is a rare, non-inflammatory ectatic disorder of the inferior peripheral cornea characterized by a crescent-shaped band of inferior corneal thinning. The area of thinning is typically around 2 mm in width, which extends from 4 to 8-o'clock positions (1). The gold standard diagnostic test for PMD is corneal topography. The topographic appearance is a classical "butterfly" pattern demonstrating a large amount of against-the-rule astigmatism that makes the fitting of contact lenses difficult. Visual symptoms include long-standing poor visual acuity, which results from high irregular against-the-rule astigmatism (2-5).

The management of PMD depends on the severity of the disease. The non-surgical management of PMD includes spectacles and different groups of contact lenses (6-8), yet these procedures lose their effectiveness as the disease progresses. Patients with high or irregular astigmatism cannot be corrected with spectacles; in these cases,

contact lens fitting is more difficult in pellucid eyes than keratoconic eyes as a result of central flattening and peripheral steepening (9-12).

In patients who cannot tolerate contact lenses or in those who do not achieve adequate visual acuity with contact lenses because of the degree of ectasia, several surgical procedures including penetrating keratoplasty, deep anterior lamellar keratoplasty, crescentic wedge resection, thermokeratoplasty, epikeratoplasty, and crescentic lamellar keratoplasty, have been proposed. However, all of these techniques are irreversible which require a long period of rehabilitation with unpredictable visual results (13-17). Due to the unsatisfactory results of the available treatments for PMD, the use of intracorneal ring segments (ICRS) has been proposed, in order to improve visual outcomes (18-24).

The MyoRing (Dioptex GmbH) is a 360° continuous intracorneal ring that is implanted into the cornea using the PocketMaker Microkeratome or femtosecond laser. The use of the MyoRing implantation has proven safe and

effective in patients with high myopia, post LASIK ectasia, and keratoconus (25-32).

2. Objectives

The present study evaluated the visual and refractive outcomes as well as the patient satisfaction and ocular symptoms after MyoRing implantation in patients with pellucid marginal degeneration. To the best of our knowledge, this is the first study on MyoRing implantation for patients with pellucid marginal degeneration.

3. Patients and Methods

This retrospective study included 15 eyes of 15 patients, eleven males and four females, with a diagnosis of pellucid marginal degeneration (PMD) in whom MyoRing was implanted using the PocketMaker Microkeratome for PMD correction at Bina eye hospital, Tehran, Iran, between October 2012 and November 2013. All patients in this study had poor visual acuity with spectacles, contact lens intolerance or dissatisfaction, a clear central cornea, a minimum corneal thickness of 350 microns, and a mean keratometry between 45 and 52 D. The exclusion criteria were other ocular diseases, systemic conditions with a potential to cause refractive instability (pregnancy and diabetes), and previous ocular surgery on the implanted eye. All patients were informed about the operation as well as advantages and disadvantages of the procedure.

The diagnosis of PMD was made on the basis of slit lamp examination (inferior corneal thinning and ectasia above the area of maximum thinning), corneal topography with the “butterfly” or “kissing birds” pattern, steep contour in the peripheral inferior cornea with high keratometric powers radiating toward the center from the inferior oblique meridians and refractive findings (significant against-the-rule astigmatism with CD loss). In all patients, preoperative and postoperative examinations included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refraction, slit lamp biomicroscopy, contact microscopy, Goldmann tonometry, corneal topography (Topscan II, Baush and Lomb) and ultrasound pachymetry. Visual acuity was measured using the Snellen chart and transformed into a LogMAR value for statistical analysis.

Regarding visual symptoms and patient satisfaction, a subjective symptom Likert scale (0 = no, 1 = very low, 2 = low, 3 = moderate, 4 = high, 5 = very high) was used to measure overall satisfaction and visual symptoms, postoperatively.

3.1. 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 the intrastromal corneal ring. Additionally, the appropriate MyoRing di-

mensions were determined according to the MyoRing nomogram, which takes into account the corneal thickness at its thinnest point and the average keratometry (K)-reading.

An intrastromal pocket with 9 mm of diameter and 300 μ m of depth was created via a small incision of 3 mm using the PocketMaker Microkeratome, as described in details elsewhere (25, 26). The Microkeratome has a suction ring and a motor-driven blade. First, the suction ring fixes the applanator to the cornea and then a microvibrating diamond creates the stromal pocket. Once the pocket is created, the MyoRing is inserted into the pocket using implantation forceps and centration is adjusted using a keratoscope. All procedures were performed with the temporal approach of self-sealing incisions. No intra-operative complications were noted during the surgical procedure in any of the cases. Postoperatively, a silicone bandage contact lens was placed on the cornea and removed 24 hours after the operation. Postoperative treatment included a combination of betamethasone drops (Sina Darou), chloramphenicol drops (Sina Darou), and non-preservative artificial tear (Artelac; Baush and Lomb), four times daily. Chloramphenicol was discontinued one week postoperatively whereas betamethasone was tapered during four to six weeks.

3.2. Statistical Analysis

Statistical analysis was performed using the SPSS version 16 for Windows (version 16; SPSS Inc. Chicago, IL, USA). All visual acuity measurements were converted from the Snellen notation to LogMAR. The normality of distribution was checked for all variables. Continuous variables are expressed as mean \pm standard deviation (SD). Qualitative variables are reported as frequencies (percentages).

The differences between pre and postoperative refractive and visual outcomes were tested using the paired t-test. The results were compared between preoperative and postoperative examinations, with a mean follow-up of ten months. The threshold of statistical significance was a P value of less than 0.05.

4. Results

The study evaluated 15 eyes of 15 patients (73% males and 27% females) with a mean age of 29.7 ± 8 years (range 22 to 49 years). The mean duration of follow-up was 10 months (range 6 - 12 months). Table 1 summarizes preoperative and postoperative outcomes.

4.1. Visual Outcome

The mean UDVA (LogMAR) improved significantly from 1.13 ± 0.21 , preoperatively, to 0.24 ± 0.12 , postoperatively ($P < 0.001$). The UDVA improved in all eyes (100%). The improvement in mean UDVA was approximately nine lines of LogMAR. At the end of the follow-up period, 12 (80%) of the 15 eyes had a UDVA of 20/40 or more. The UDVA was 20/50 in three (20%) eyes, 20/40 in one (6%) eye, 20/32 in

nine (60%) eyes, and 20/20 in two (13%) eyes.

The mean CDVA in LogMAR improved significantly from 0.40 ± 0.12 before the surgery to 0.18 ± 0.09 after the surgery ($P < 0.001$). The improvement in mean UDVA was two lines, postoperatively.

By the last visit of each patient, 73% of the eyes gained \geq two lines of CDVA: two (13%) of 15 eyes gained five lines, three (20%) eyes gained three lines, six (40%) eyes gained two lines, and four (26%) eyes gained one line.

4.2. Refractive and Keratometry Outcomes

The mean decrease in spherical power, cylinder and spherical equivalent was 3.19, 4.00 and 5.00 D, respectively ($P < 0.001$).

The mean sphere of the manifest refraction decreased significantly from -3.20 ± 3.40 , preoperatively to 0.01 ± 1.90 , postoperatively ($P < 0.001$). The mean cylinder was -5.50 ± 1.20 , preoperatively that reduced to -1.50 ± 1.00 at the end of the follow-up period ($P < 0.001$).

There was a significant reduction in the Spherical equivalent error (SE) from -6.00 ± 3.60 , preoperatively to -0.70 ± 1.90 , postoperatively at the end of the follow-up period ($P < 0.001$). Moreover, 10 of 15 eyes (66%) had a SE ranging from $+1.00$ to -1.00 D at the end of the follow-up period.

A significant reduction was observed in maximum, minimum, and average keratometry after MyoRing implantation. The amount of reduction was 5.00 D for the maximum keratometry reading ($P < 0.001$; Table 2).

4.3. Patient Satisfaction and Visual Symptoms

Based on the six-point Likert scale, mentioned in the methods section, all patients were satisfied with the MyoRing implantation. The level of satisfaction was very high in seven patients (46.7%), high in five patients (33.3%), moderate in two patients, and low in one patient.

Regarding the visual symptoms, we asked the patients about the most common symptoms following IOL implantation including glare, halo, night vision fluctuation and activity limitation. The majority of the patients had no severe symptoms. Nine patients (60%) declared no fluctuation in their vision, postoperatively, while four patients (26%) had very low and two (13%) had low fluctuation.

Halo, glare, and night vision were high in one (6%) patient. With respect to the activity limitation, 12 patients (80%) had no activity limitation after MyoRing implantation. Table 3 demonstrates the score of the visual symptoms and the overall satisfaction, postoperatively.

Table 1. Visual and Refractive Outcomes^a

Parameter	Preoperative		Postoperative		P Value
	Mean \pm SD	Range	Mean \pm SD	Range	
UDVA (log MAR)	1.13 ± 0.21	0.7 to 1.5	0.14 ± 0.12	0 to 0.5	< 0.001
CDVA (log MAR)	0.4 ± 0.12	0 to 0.7	0.18 ± 0.09	0 to 0.4	< 0.001
Sphere (D)	-3.20 ± 3.40	-7.00 to 0	0.01 ± 1.90	-5.00 to 2.50	< 0.001
Cylinder (D)	-5.50 ± 1.20	-7.00 to -3.00	-1.50 ± 1.00	-3.50 to 0	< 0.001
SE (D)	-6.00 ± 3.60	-13.00 to -3	-0.70 ± 1.90	-6.00 to +1.75	< 0.001

^aAbbreviations: D, diopters; CDVA, corrected distance visual acuity; SE, spherical equivalent; UDVA, uncorrected distance visual acuity.

Table 2. Mean of the Keratometry (K) Values Preoperatively and Postoperatively and the Amount of Reduction^a

K-Values	Preoperative	Postoperative	Pre-Post ^b	P Value
Kmax (D)	46.1 ± 2.40	46.1 ± 2.00	5.00 D	< 0.001
Kmin (D)	43.8 ± 2.00	43.7 ± 2.10	1.10 D	< 0.001
Kaverage (D)	48.0 ± 2.20	44.0 ± 2.60	4.00 D	< 0.001

^aAbbreviations: D, Diopter; Kmax, maximum K value in diopters; Kmin, minimum K value in diopters; Kmean, average K value in diopters.

^bDifference between preop and postop K.

Table 3. Postoperative Visual Symptoms and Patient Satisfaction Score^a

Parameter	No	Very Low	Low	Moderate	High	Very High
Halo	5 (33.3)	5 (33.3)	2 (13.3)	2 (13.3)	1 (6.7)	0
Glare	5 (33.3)	3 (20)	5 (33.3)	1 (6.7)	1 (6.7)	0
Night vision	6 (40)	2 (13.3)	3 (20)	3 (20)	1 (6.7)	0
Fluctuation	9 (66.6)	4 (26.7)	2 (6.7)	0	0	0
Activity limitation	12 (80)	2 (13.3)	1 (6.7)	0	0	0
Overall satisfaction	0	0	2 (13.3)	1 (6.7)	5 (33.3)	7 (46.7)

^aData are presented as No. (%).

5. Discussion

Appropriate and effective treatment of PMD is a challenge in ophthalmology. The management of PMD depends on the severity of the disease. The ICRS are semi-circular mechanical devices that have been successfully used in PMD to delay penetrating keratoplasty, improve contact lens intolerance, and visual results. Various studies have shown that ICRS implantation is a safe and irreversible method for the management of pellucid marginal degeneration (18-24).

The MyoRing is a full-ring intracorneal implant that reduces corneal irregularity in keratoconic eyes as a result of the flattening effect (27-32). This corneal flattening could be useful in pellucid corneas for minimizing corneal protrusion and consequently the refractive error. Relative centration and minimization of the peripheral corneal protrusion have been observed after ICRS implantation in corneas with PMD (18-20).

It has been demonstrated that the treatment of keratoconus and post-LASIK ectasia with MyoRing implantation is effective, minimally invasive and easy to perform (27-32).

This research studied the eyes of 15 patients with PMD who had MyoRing implantation. Moreover, the study concentrated on two major areas. Firstly, visual and refractive outcomes were assessed. Secondly, patients' satisfaction was acquired post-operatively along with the ocular symptoms. To the best of our knowledge, there has been a lack of academic publications in association with MyoRing implantation using Pocketmaker micro-tome on patients with PMD, and the uniqueness of this study regarding content and the considerable differences in the findings have made this unreported work more valuable. The outcomes of the study showed that MyoRing implantation in PMD was efficient in flattening the cornea and thereby improving UDVA and CDVA in the patients. The maximum k-value decreased by 5.00 D. The improvement in the mean UDVA after MyoRing implantation was approximately 9 lines. Furthermore, the mean CDVA gain was 10 lines. A significant reduction (5.30 D) was observed in the spherical equivalent error (SE), postoperatively. These outcomes were consistent with changes reported in previous studies on ICRS implantation in pellucid corneas (19-24). However, we observed a greater reduction in spherical equivalent error and keratometric values when compared with other studies.

Mularoni et al. (22) reported a reduction of 3.40 D in SE in eyes with PMD implanted by Intacs. In a study by Kubaloglu et al. (24) the mean reduction in SE was approximately 2.50 D after 210° arc length KeraRing implantation in 16 eyes with PMD. Pinero et al. (23) carried out KeraRing and Intacs insertion for 21 pellucid corneas and reported that SE was reduced by 2.75 D, after six months of follow-up.

In our study, a statistically significant reduction (4.00 D) was observed in the manifest cylinder, postoperative-

ly. The amount of reduction was in agreement with the results of the study by Mularoni et al. (22) that reported a more significant change in cylinder (4.59 D) based on ICRS implantation in PMD.

The amount of reduction in the spherical component of the manifest refraction varied in different studies. In particular, in the studies of Pinero et al. (23), Kubaloglu et al. (24) and Ertan et al. (21) this reduction was equal to 0.00, 2.70 and 1.09 D, respectively. However, the experienced reduction in the current paper was calculated as 3.21 D, which surpasses all the formerly presented values.

These findings indicate that MyoRing implantation, similar to ICRS, is able to decrease corneal irregularity and reshape the pellucid corneas without their removal.

With respect to corneal topography, we observed a significant reduction in keratometric values. Corneal topography showed a strong decrease in astigmatism in all cases. In our study, the maximum and average k-values decreased by 5.00 and 1.00 D, respectively. However, Ertan et al. (21) reported that the average k-value decreased by 1.30 D following Intacs insertion at six months of follow-up. In the study of Pinero et al. (23) and Mularoni et al. (22) found that the average k-value decreased by 1.76 and 2.00 D, respectively. However, in the study of Pinero et al. (23), a significant reduction for the flattest central curvature (K_{min}) was not observed.

Intrastromal corneal ring segments act by an "arc-shortening effect" on the corneal lamellae, and flatten the cornea. The better outcomes of keratometric values and spherical equivalent error in this study are probably due to greater arc-shortening effect of MyoRing implantation in comparison with Intacs and KeraRing segments.

We believe that the considerable corneal flattening in the present study is due to the circular shape of the MyoRing, which leads to a more significant arc-shortening effect on the cornea. However, additional comparative studies should be performed to compare MyoRing and ICRS in patients with PMD.

Regarding the improvement in postoperative UDVA, we observed a remarkable increase in UDVA (nine lines), which was in accordance with the results of studies by Mularoni et al. (eight lines improvement) (22) and Kubaloglu et al. (seven lines improvement) (24). In contrast to our study, Pinero et al. (23) reported no improvement in UDVA at six months after the surgery. We also observed a significant increase in CDVA postoperatively, which was in agreement with previous studies.

We believe that the significant improvement in UDVA and CDVA was the result of two factors; first, the specific continuous design of the MyoRing, which could have a greater effect on the corneal power, and second, the surgical technique (the corneal incision was placed on the steepest meridian in all cases) that probably provided a more flattening effect in the steepest meridian. Pinero et al. (23) evaluated the eyes of a group of patients with PMD in which almost all flattening effects had occurred on the steepest meridian as a consequence of the weak-

ening effect of the incision and the effect of the ring. On the other hand, there is no study suggesting that the location of the incision has an effect on the final outcome and therefore additional comparative studies are required to compare the outcomes between flat and steep incisions.

In terms of postoperative clinical complications, we did not observe any serious complications including decentration, extrusion, explantation, keratitis, or vascularization. It has been shown that MayoRing implantation is a safe technique with a low incidence of complications to correct keratoconus and post LASIK ectasia (28-32).

Although diurnal changes in the visual acuity as well as visual symptoms are well-known phenomena after ICRS insertion (33, 34), they were not a significant cause of patient dissatisfaction in our study. The majority of the patients were satisfied with MayoRing implantation; 47% of the patients were very highly satisfied at the end of the follow-up. Only one patient had low satisfaction at six months follow-up because of severe glare and night vision problems. In order to minimize these symptoms, pilocarpine 1% eye drops were prescribed.

The most frequent postoperative complication after ICRS implantation is extrusion, which leads to the explantation of the ring. Explantation may be performed if the patient is dissatisfied with the visual outcomes. The food and drug administration (FDA) and European studies have reported ICRS dissatisfaction due to vision or unbearable visual symptoms in up to 8% of eyes (35, 36). Since MayoRing is a continuous full ring with no free ends, no extrusion was observed as a postoperative complication, following MayoRing implantation.

In the present study, no patient lost lines of acuity as a result of serious complications; two patients had little and four patients had very little fluctuating vision. The fluctuation in vision was likely the result of an unstable tear film after MayoRing implantation. For these cases, we recommended the use of viscous artificial tears.

Despite the limited number of patients in this study, MayoRing implantation using the PocketMaker was a safe and effective procedure that reduced corneal steepening and refractive error in patients with PMD. MayoRing implantation significantly improved UDVA and CDVA, although the increase in UDVA was more impressive.

Following MayoRing implantation in the current study, more significant reduction was obtained in keratometric values and spherical equivalent error, compared to Intacs and Keroring. Therefore, it could be concluded that MayoRing implantation in patients with PMD appears to have a greater effect on corneal power. We believe that this new technique with unique and specialized characteristics of MayoRing implantation by means of PocketMaker Microkeratome could explain the reliability of the results of this study. Considering the fact that PMD is an ecstatic disorder, it remains uncertain whether MayoRing can control the progression of the disease.

In spite of the good visual and refractive outcomes following MayoRing implantation in pellucid corneas, fur-

ther randomized prospective studies with longer follow-up periods are required to evaluate the stability of the MayoRing and its impact on disease progression.

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Footnote

Authors' Contribution: Sahar Mojaled Nobari participated in study design and wrote draft of the manuscript. Consuelo Villena conceived of the study and revised the manuscript. Khosrow Jadidi conceived of the study and carried out the statistical analysis. All authors read and approved the final manuscript.

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