A Single 210-Degree Arc Length Intrastromal Corneal Ring Implantation for the Management of Pellucid Marginal Corneal Degeneration

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• PURPOSE: To determine the visual and refractive outcomes of 210-degree arc length intrastromal corneal ring segment (ICRS) implantation in eyes with pellucid marginal corneal degeneration (PMCD).

• DESIGN: Retrospective, consecutive case series.

• METHODS: Sixteen consecutive eyes of 10 patients who underwent a single 210-degree ICRS implantation by femtosecond laser for the management of PMCD and completed at least 1 year follow-up were included. A complete ophthalmic examination was performed preoperatively and postoperatively, including uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest spherical and cylindrical refractions, spherical equivalent, and keratometric readings.

• RESULTS: The mean follow-up period was 30.7 months (range 12 to 36 months). No intraoperative complication was observed. White deposits around the segments were noted in 2 of 16 eyes (12.5%) at the first postoperative year. The mean UCVA showed significant improvement, from 1.69 ± 1.02 logarithm of the minimal angle of resolution (logMAR) preoperatively to 0.64 ± 0.43 logMAR at the 36th month (n = 11, $P < .001$). The mean preoperative BSCVA was 0.88 ± 0.68 logMAR; after 36 months, this improved to 0.35 ± 0.34 ($P < .001$). At the 36th month, UCVA was improved in all eyes (n = 11, range: gain of 1 to 6 lines), whereas BSCVA was improved in 9 eyes (81.8%, range: gain of 2 to 7 lines) and remained unchanged in 2 eyes (18.1%); UCVA was 20/40 or better in 3 eyes (27%) and BSCVA was 20/40 or better in 8 eyes (72.7%). There was a significant reduction in the spherical equivalent refractive error, from −4.40 ± 1.85 diopters (D) preoperatively to −1.86 ± 0.60 D ($P < .001$), and the mean maximum keratometric power decreased from 49.70 ± 4.32 D to 46.08 ± 2.84 D ($P < .001$) after 36 months. The mean cylindrical refraction decreased from −4.39 ± 1.86 D preoperatively to −2.38 ± 1.35 D at 36 months ($P < .001$).

• CONCLUSION: A single 210-degree arc length ICRS implantation using a femtosecond laser for patients with PMCD provides good visual and refractive outcomes. (Am J Ophthalmol 2010;150:185–192. © 2010 by Elsevier Inc. All rights reserved.)

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PELLUCID MARGINAL CORNEAL DEGENERATION (PMCD) is a noninflammatory corneal thinning disorder that is characteristically distinct from other disorders that fall under the same category, including keratoconus and keratoglobus. The topographic pattern of PMCD is defined by a steep contour, usually in the inferior corneal periphery, extending into the center from the inferior oblique corneal meridians, and a flattening in the vertical meridian.[1–3] As the disorder progresses, the topographic changes makes it impossible to achieve spectacle correction of vision.[4]

Several treatments for PMCD have been explored in the literature, including rigid gas-permeable contact lens implantation, which has been reported to provide adequate results in eyes that are in an early stage of the disorder.[5] Refractive surgery as a treatment option for patients with PMCD and other similar corneal disorders is not recommended as studies show that there is significant potential for poor visual outcomes and the progression of corneal ectasia attributable to the iatrogenic thinning of the cornea.[6–8]

Intrastromal corneal ring segment implantation has been reported to provide safe and effective outcomes for the treatment of patients with corneal thinning disorders like keratoconus and post-LASIK ectasia.[9–12] Also, 1 type of intracorneal ring segment (Intacs; Addition Technology, Fremont, California, USA) provided successful outcomes in the management of PMCD.[13] The Keraring (Mediphacos, Belo Horizonte, Brazil) is another type of intrastromal corneal ring segment (ICRS) made of polymethyl-methacrylate with various arc lengths (90 degrees, 120 degrees, 160 degrees, and 210 degrees) that regularizes corneal ectatic distortions by providing the addition of segments in the mid-periphery. The 210-degree arc length ICRS has advantages such as less induction of astigmatism, more corneal flattening, and implantation of a single segment.[14] The purpose of the current study was to determine the visual and refractive outcomes of a single

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TABLE 1. Segment Thickness by Spherical Equivalent Values for a Single 210-Degree Arc Length Intrastromal Corneal Ring Implantation in Pellucid Marginal Corneal Degeneration

SE (Diopters)	Segment Thickness (μm)
Up to −2.00	150
−2.25 to −4.00	200
−4.25 to −6.00	250
−6.25 to −8.00	300
>−8.00	350

SE = spherical equivalent.

210-degree arc length ICRS implantation in eyes with PMCD.

METHODS

A RETROSPECTIVE ANALYSIS WAS CONDUCTED ON THE outcomes of patients who underwent a single 210-degree arc length ICRS implantation for the management of PMCD from June 16, 2006 to July 18, 2008. Sixteen consecutive eyes of 10 patients (6 female and 4 male) with a diagnosis of PMCD were included. Only patients unsatisfied with spectacle- and contact lens–corrected vision were considered for ICRS implantation. The eyes that had a corneal thickness of 400 μm or less at the location where ICRS inserts were placed (5-mm optical zone) and had a history of eye rubbing and/or vernal keratoconjunctivitis were excluded. All eyes had a clear central cornea and reduced best spectacle-corrected visual acuity (BSCVA) (more than 2 lines), and all patients completed at least 12 months of follow-up. The diagnosis of PMCD was based on slit-lamp findings, including inferior corneal thinning and ectasia above the area of maximum thinning. The diagnosis was verified by corneal topography, which demonstrated a steep contour in the inferior peripheral cornea with high keratometric powers radiating from the inferior oblique meridians toward the center. All patients were informed about the study as well as advantages and disadvantages of the procedure.

• **SURGICAL PROCEDURE:** All surgeries were performed under topical anesthesia. A reference point for centration (pupil center) was chosen and marked under the operating microscope preoperatively. A 5-mm marker was used to locate the exact ring tunnel. Then a disposable vacuum ring was inserted to prevent movement of the eye and reduce the incidence of decentration. The 60-kHz IntraLase femtosecond laser (Abbott Medical Optics Inc, Santa Ana, California, USA) was used for femtosecond-assisted tunnel creation. The entry incision had a length of 1 mm in all cases and it was placed and centered on the steepest corneal axis. The planned tunnel depth was 70% of the corneal thickness, with an inner diameter of 4.8 mm and an outer diameter of 5.6 mm. The corneal thickness at the location site where the ICRS was placed ranged from 432 to 556 μm and the mean actual depth used to create the tunnel was 341.12 ± 24.5 μm (standard deviation; range from 302 to 389 μm). Femtosecond channel creation was achieved using 1.30 μJ of energy and was completed in approximately 15 seconds. The single 210-degree arc length Keraring intrastromal corneal ring segments (Mediphacos, Belo Horizonte, Brazil) were implanted with the manufacturer's forceps following tunnel creation. The segment thickness was determined based on spherical equivalent values according to the nomogram (Table 1). The Keraring segment thickness ranges from 0.15 mm to 0.35 mm, with 0.05-mm increments. The thicknesses of the segments used in the 16 eyes were 0.15 mm in 1 eye (6.2%), 0.20 mm in 7 eyes (43.7%), 0.25 mm in 6 eyes (37.5%), 0.30 mm in 1 eye (6.2%), and 0.35 mm in 1 eye (6.2%). Lomefloxacin 0.3% (Okacin; Novartis Pharma AG, Basel, Switzerland) and dexamethasone 0.1% (Dexa-Sine SE; Alcon-Thilo, Frieburg, Germany) eye drops were prescribed 4 times a day for 2 weeks after surgery.

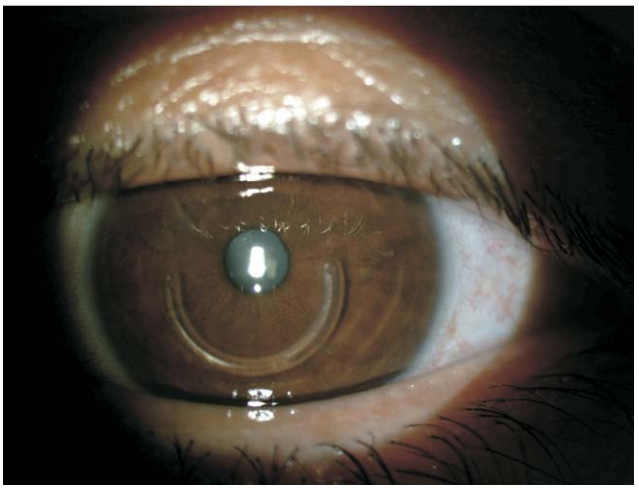

FIGURE 1. Pellucid marginal corneal degeneration with implanted a single 210-degree arc length intrastromal corneal ring segment (Keraring) with no complications associated with channel creation or segment implantation.

• **FOLLOW UP EVALUATION:** A complete ophthalmic examination was performed preoperatively and for months 12, 18, 24, and 36 postoperatively, including uncorrected visual acuity (UCVA), BSCVA, manifest spherical and cylindrical refractions, and keratometric readings using the Orbscan II (Bausch & Lomb, Rochester, New York, USA). Visual acuity readings were converted to logMAR values for statistical analysis. Vectorial analysis of the cylindrical correction was made by means of the Alpins method, which was based on the refractive data.[15]

• **STATISTICAL ANALYSIS:** Statistical analysis was carried out using SPSS version 10 for Windows (SPSS Inc,

TABLE 2. Preoperative and Postoperative Outcomes of Patients With Pellucid Marginal Corneal Degeneration After a Single 210-Degree Arc Length Intrastromal Corneal Ring Implantation

N	Preoperative 16	12 Months 16	18 Months 14	24 Months 13	36 Months 11	*P* Value[a] (Preoperative to 36 Months) —
UCVA (logMAR), mean±SD	1.69±1.02	0.83±0.55	0.78±0.55	0.75±0.54	0.64±0.43	<.01
Range	0.4 to 3	0.3 to 1.3	0 to 1.3	0.1 to 1.3	0.1 to 1.3	—
BSCVA (logMAR), mean±SD	0.88±0.68	0.41±0.45	0.35±0.30	0.34±0.32	0.35±0.34	<.01
Range	0.18 to 2	0.18 to 2	0 to 1	0 to 1	0 to 1	—
SE (D), mean±SD	−4.40±1.85	−1.89±1.07	−1.89±0.66	−1.86±0.69	−1.86±0.60	<.01
Range	−0.50 to −9.00	0.00 to −4.75	−0.50 to −3.25	−0.50 to −3.25	−0.50 to −2.50	—
Spher (D), mean±SD	−2.43±1.92	−0.75±0.82	−0.80±0.63	−0.79±0.55	−0.72±0.61	<.01
Range	+2.00 to −7.00	0.00 to −2.25	0.00 to −2.25	0.00 to −2.00	0.00 to −2.00	—
Cylinder (D), mean±SD	−4.39±1.86	−2.35±1.00	−2.32±1.03	−2.25±1.18	−2.38±1.35	<.01
Range	−2.00 to −8.50	−1.00 to −4.25	−1.00 to −4.00	−1.00 to −5.00	−1.00 to −5.25	—
Kmax (D), mean±SD	49.70±4.32	46.53±3.14	46.51±3.30	45.96±2.60	46.08±2.84	<.01
Range	45.20 to 61.70	43.90 to 54.70	43.10 to 54.7	42.80 to 51.00	42.90 to 51.00	—
Kmin (D), mean±SD	43.00±4.28	41.44±3.28	41.32±3.53	40.82±2.22	40.42±1.87	.03
Range	39.4 to 46.3	38.40 to 45.10	38.20 to 45.40	38.30 to 45.20	38.20 to 44.00	
Thinnest (μm), mean±SD	463.22±57.65	469.00±51.15	454.91±31.18	450.90±31.54	455.40±22.19	.84

BSCVA = best spectacle-corrected visual acuity; Cylinder = manifest cylindrical refraction; D = diopters; Kmax = maximum keratometric power; Kmin = minimum keratometric power; logMAR = logarithm of the minimal angle of resolution; SD = standard deviation; SE = spherical equivalent; Spher = manifest spherical refraction; UCVA = uncorrected visual acuity.

[a]Paired *t* test was used for data with normal distribution, Wilcoxon test was used for data without normal distribution.

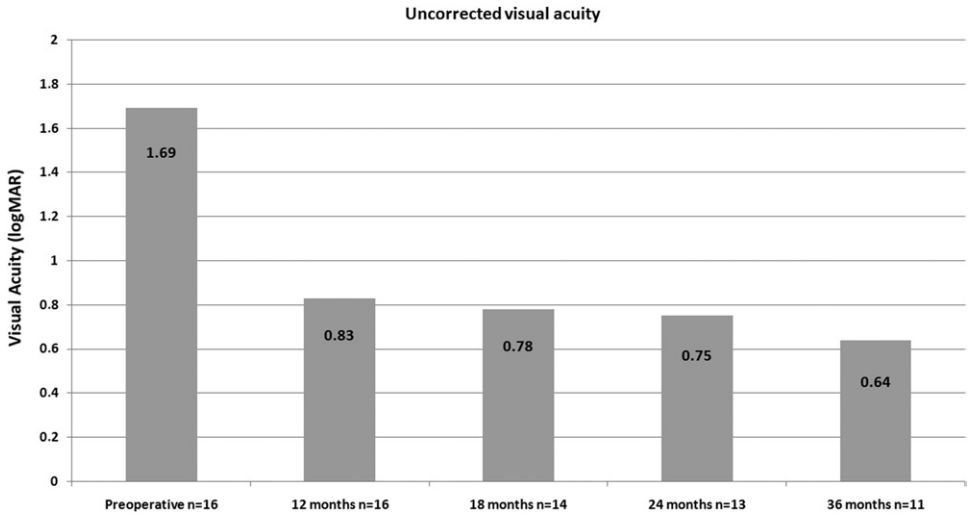

FIGURE 2. Bar graphs demonstrating uncorrected visual acuity (logarithm of the minimal angle of resolution [logMAR]) before and after 210-degree arc length intrastromal corneal ring segment (Keraring) implantation in pellucid marginal corneal degeneration.

Chicago, Illinois, USA). For comparison between preoperative and postoperative data, paired *t* test was used for data with normal distribution and Wilcoxon test was used for data without normal distribution. A 2-tailed probability of 5% or less was considered statistically significant.

RESULTS

THE MEAN AGE OF THE PATIENTS WAS 43.8 ± 9.3 YEARS (standard deviation; range 38 to 56 years). All Keraring segments were implanted successfully, as demonstrated in Figure 1, with no problems associated with channel cre-

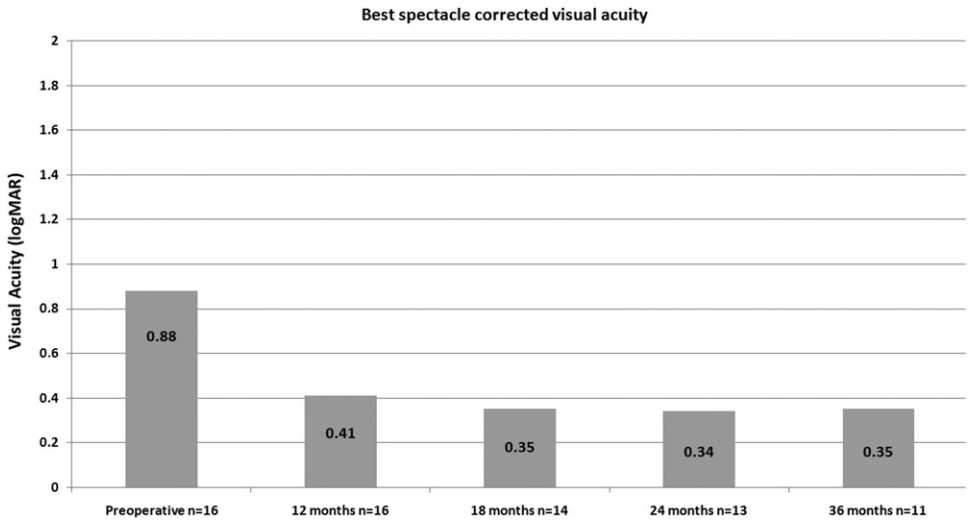

FIGURE 3. Bar graphs demonstrating best spectacle-corrected visual acuity (logarithm of the minimal angle of resolution [logMAR]) before and after 210-degree arc length intrastromal corneal ring segment (Keraring) implantation in pellucid marginal corneal degeneration.

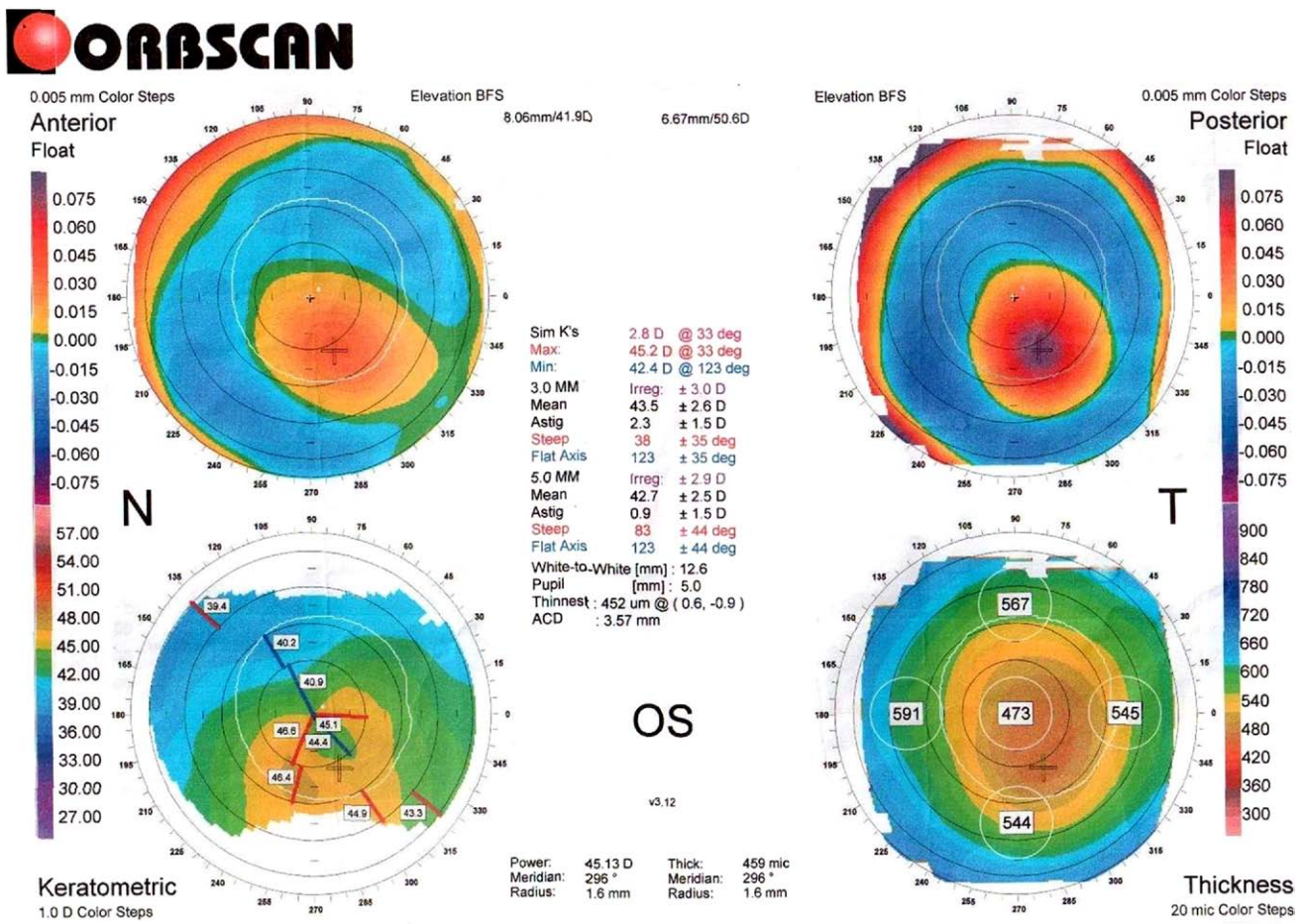

FIGURE 4. Preoperative topography of pellucid marginal corneal degeneration demonstrated a steep contour in the inferior peripheral cornea with high keratometric powers radiating from the inferior oblique meridians toward the center and flattening in central cornea with the against-the-rule astigmatism.

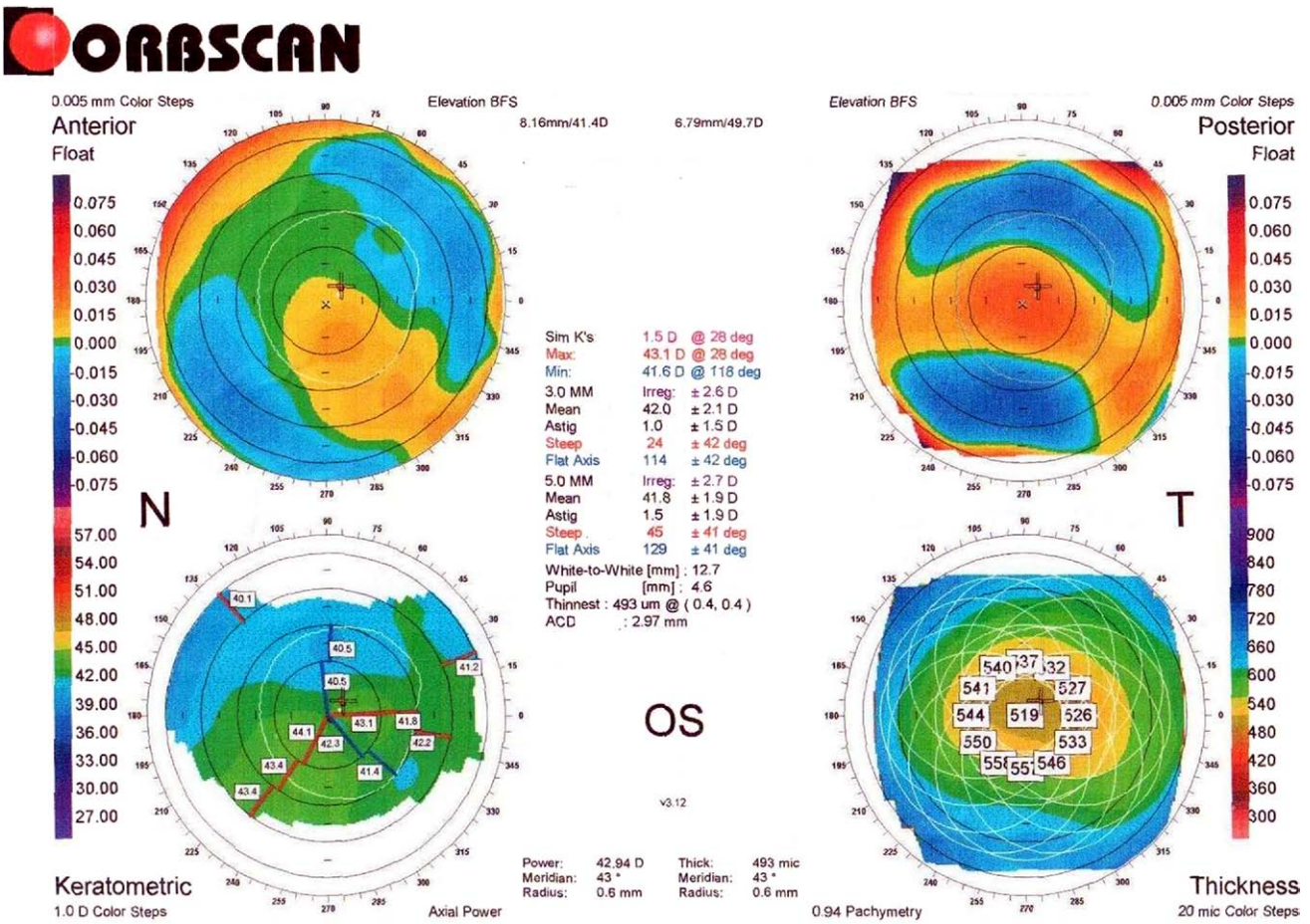

FIGURE 5. At 24 months, topography of the same patient who underwent a single 210-degree arc length intracorneal ring segment (Keraring) implantation for the management of pellucid marginal corneal degeneration demonstrated more regular central optical zone and against-the-rule astigmatism was reduced.

ation or segment implantation. The mean follow-up period was 30.7 ± 9.1 months (range 12 to 36 months). All eyes had inferior PMCD and none of the patients had a history of eye rubbing and/or vernal keratoconjunctivitis.

Visual acuity results at the preoperative and postoperative examinations are summarized in Table 2. The mean UCVA showed statistically significant improvement, from 1.69 ± 1.02 logMAR (range 0.4 to 3) preoperatively to 0.64 ± 0.43 (range 0.1 to 1.3, $P < .001$) at the 36th postoperative month. The mean preoperative BSCVA was 0.88 ± 0.68 (range 0.18 to 2). After 36 months, this improved to 0.35 ± 0.34 (range 0 to 1, $P < .001$). At the 36th month, UCVA was improved in all eyes (range gain of 1 to 6 lines), whereas BSCVA was improved in 9 of 11 eyes (81.8%, range gain of 2 to 7 lines) and remained unchanged in 2 of 11 eyes (18.2%). The mean line gains between preoperative and month-36 UCVA and BSCVA measurements was 2.4 ± 2.1 lines and 3.3 ± 1.8 lines respectively (Figures 2 and 3). At the 36th month UCVA was 20/40 or better in 3 of 11 eyes (27%) and 20/25 or better in 1 of 11 eyes (9%), while none of the eyes had a UCVA of 20/20 or better. BSCVA was 20/40 or better in 8 of 11 eyes (72.7%), 20/25 or better in 2 of 11 eyes (18.2%), and 20/20 or better in 1 eye (9%).

Refractive results are summarized in Table 2. There was a significant reduction in the spherical equivalent refractive error, from −4.40 ± 1.85 diopters (D) (range −0.50 to −9.00 D) preoperatively to −1.86 ± 0.60 D (range −0.50 to −2.50 D, $P < .001$) at the 36th month; also, the mean maximum keratometric power decreased from 49.70 ± 4.32 D (range 46.00 to 61.70 D) to 46.08 ± 2.84 D (range 42.90 to 51.00 D, $P < .001$) after 36 months. Figures 4 and 5 show the topographic changes of the same eye from the preoperative period to the 24th postoperative month.

There was a statistically significant reduction in manifest spherical refraction from −2.43 ± 1.92 D (range +2.00 to −7.00 D) to −0.72 ± 0.61 D (range 0.00 to −2.00 D, $P < .001$) at the 36th postoperative month. The mean cylindrical refraction decreased from −4.39 ± 1.86 D (range −2.00 to −8.50 D) preoperatively to −2.38 ± 1.35 D (range −1.00 to −5.25 D, $P < .001$) after 36

TABLE 3. Vectorial Analysis of Cylindrical Correction 36 Months After 210-Degree Arc Length Intrastromal Corneal Ring Implantation for Pellucid Marginal Corneal Degeneration

	TIA (D)	SIA (D)	DV (D)	AE	ME (D)
Mean	4.11	2.18	2.21	5.27	−1.93
Standard deviation	1.69	0.72	1.95	21.22	1.10
Range	7.37 to 1.78	3.21 to 1.06	0.95 to 4.95	−34 to 42	−4.16 to −0.72

AE = angle of error; D = diopters; DV = differences of vector; ME = magnitude of error; SIA = surgically induced astigmatism; TIA = target-induced astigmatism.

TABLE 4. Stability of Outcomes After a Single 210-Degree Arc Length Intrastromal Corneal Ring Implantation in Patients (N = 11) With Pellucid Marginal Corneal Degeneration Who Completed Each Follow-up Visit

	Preoperative (Mean ± SD)	12 Months (Mean ± SD)	24 Months (Mean ± SD)	36 Months (Mean ± SD)	*P* Value[a] (12–36 Months)
UCVA (logMAR)	1.63±0.98	0.75±0.52	0.67±0.44	0.64±0.43	.39
BSCVA (logMAR)	1.00±0.73	0.47±0.53	0.34±0.34	0.35±0.34	.12
SE (D)	−5.25±1.46	−2.20±0.96	−1.95±0.61	−1.86±0.60	.24
Spher (D)	−3.13±1.56	−0.84±0.63	−0.77±0.57	−0.72±0.61	.51
Cylinder(D)	−4.68±1.94	−2.43±1.07	−2.36±1.23	−2.38±1.35	.77
Kmax (D)	49.10±3.24	46.71±2.72	46.06±2.82	46.08±2.84	.77
Kmin (D)	41.74±2.33	40.70±1.87	40.40±1.97	40.42±1.87	.44
Thinnest (μm)	451.72±42.12	456.72±37.53	456.36±32.27	455.40±22.19	.74

BSCVA = best spectacle-corrected visual acuity; Cylinder = manifest cylindrical refraction; D = diopters; Kmax = maximum keratometric power; Kmin = minimum keratometric power; logMAR = logarithm of the minimal angle of resolution; SD = standard deviation; SE = spherical equivalent; Spher = manifest spherical refraction; UCVA = uncorrected visual acuity.

[a]Paired *t* test was used for data with normal distribution, Wilcoxon test was used for data without normal distribution.

months. Vectorial analysis of cylindrical correction was seen in Table 3.

When comparing 12-month and 36-month outcomes in patients who completed each follow-up visit, there was no statistically significant difference in any parameter (Table 4).

• COMPLICATIONS: White deposits around the segments were noted in both eyes of the same patient 12 months postoperatively. No other intraoperative or postoperative complications were noted.

DISCUSSION

SURGICAL TREATMENT OPTIONS FOR PMCD INCLUDE PENETrating keratoplasty, deep lamellar keratoplasty, corneal wedge excision, phakic intraocular lenses, thermokeratoplasty, and epikeratophakia, but such treatments are invasive and have been reported to provide inadequate long-term reduction in astigmatism, or have resulted in higher incidence of long-term astigmatic drift.[16–21] ICRS implantation for the treatment of PMCD using Intacs has been explored in various case studies, and the results have been promising.[22–24] In our study, we investigated the outcomes of a single 210-degree arc length Keraring implantation in 16 eyes, supporting the findings reported in previous case studies.

Rodriguez-Prats and associates[2] first reported a case with PMCD that was treated with Intacs segments, showing that UCVA and BSCVA improved, but myopic refraction increased from −2.00 D to −8.00 D. Also, Ertan and associates[13] reported statistically significant improvements in UCVA, BSCVA, keratometric readings, and cylindrical refraction following the implantation of Intacs in pellucid marginal degeneration; however, the decrease in spherical refraction was not found to be statistically significant. In our study we treated 16 eyes with PMCD by implanting 210-degree Keraring segments using a femtosecond laser and there were statistically significant improvements in visual acuities as well as in spherical and cylindrical refractive errors and keratometric readings postoperatively.

Our favorable outcomes may be explained by the advantages of extended segment arc length, such as more corneal flattening and less unpredictable astigmatic induction, and by the advantages of the single-segment implantation, such as less corneal trauma and lower risk of infection, segment extrusion, glare, and halos.[14] Although undercorrection was observed in our vectorial analyses, cylindrical refraction reduced significantly after 3 years of follow-up. The insertion of ICRS in the corneal stroma induces a

modification of the central corneal curvature and corneal shape. These changes are in direct proportion to the thickness and diameter of the segments.[25] An extended segment arc length produces more central corneal flattening and less astigmatic induction than conventional segments. This effect was predicted by finite element modeling and has been demonstrated in eye bank tissue studies with intrastromal corneal rings.[26]

In the current study, the corneal incision was placed on the steepest axis in all eyes. Regarding the effect of the incision, it should be noted that there is no study proving if the location of the incision has an effect on the final outcome. Recently, Piñero and associates[24] proved in a sample of eyes with PMCD implanted with ICRS that almost all flattening effect occurred on the steepest meridian. They postulated that probably this effect was attributable to the combination of the effect of the ring and the weakening effect of the incision. In the current study, we have observed a similar trend. Therefore, probably the incision plays an important role in the flattening effect achieved with ICRS in these cases.

Sharma and associates[27] evaluated the efficacy of a single-segment Intacs and compared it with double-segment Intacs in post–laser in situ keratomileusis (LASIK) ectasia and keratoconus. Using preoperatively matched groups, they found that single-segment implantation resulted in more favorable outcomes compared with double-segment implantation for cases of peripheral keratoconus. The PMCD defined by a steep contour, usually in the inferior corneal midperiphery, extending to a wide area (from the 4-o'clock to 8-o'clock meridian), and has a delineated inferior-steeper and superior-flatter topographic pattern. We preferred in our study group the implantation of a single 210-degree arc length ICRS to provide a localized flattening in a wide field. Our favorable results with this segment are based on the biomechanical change that occurs in the corneal ectatic area. The implantation of a single segment induces steepening in the superior cornea, instead of flattening seen with the implantation of double segments. We believe that this is why a single 210-degree arc length ICRS implantation provides a more regular optical zone and a greater improvement in BSCVA. In addition, traditional 150-degree segments placed to superior and inferior quadrants were found to yield successful visual and refractive results in PMCD.[22,24] However, in some of these studies the improvement in spherical refraction was not statistically significant and even myopic shifts were observed.[2,13] In order to have a more definitive opinion, a comparative study in PMCD patients similar to the study comparing implantation of single and double ICRS in keratoconic eyes would be useful.

In patients with very advanced stages of PMCD, the progressive inferior thinning of the cornea can make implantation of intrastromal corneal ring segments with a 7-mm optical zone difficult, as it may result in Descemet detachment.[28] In such cases, a thinner segment can be used.[23] Corneal perforation or Descemet detachment did not occur in our study. The Keraring provides a 5-mm optical zone and theoretically it may be implanted in a thicker zone of the corneal ectatic area. This may reduce the risk of surgical complications.

Other treatment options, such as refractive surgery and corneal transplantation, have been reported in the literature to occasionally lead to unpredictable results, with poor visual outcomes and a long-term prevalence of astigmatism.[6–8,16–20] Keraring implantation is a minimally invasive and reversible procedure that has shown promising results in the treatment of eyes with keratoconus and post-LASIK ectasia.[9–12] The procedure can be performed under topical anesthesia and allows patients to return to their normal daily routines shortly after treatment. The efficacy of combined collagen crosslinking (CXL) and ICRS implantation in keratoconus was demonstrated by Coskunseven and associates and implantation of ICRS followed by CXL resulted in greater improvement of keratoconus.[29] Recently Kymionis and associates[30] performed simultaneous photorefractive keratectomy and CXL with riboflavin–ultraviolet-A irradiation for the treatment of progressive PMCD and found satisfying results. Considering that both keratoconus and PMCD are variants of corneal ectatic disorders, CXL alone or combined with ICRS implantation could be effective in the management of PMCD.

In conclusion, the application of a single 210-degree arc length ICRS implantation with femtosecond laser tunnel creation in patients with PMCD has proven to be safe and effective in reshaping the cornea, flattening the ectatic tissue, and significantly decreasing the asymmetrical astigmatism associated with the disorder. The most important weakness of the current study is the small number of cases. More studies with larger groups are required to investigate the stability of the results. Furthermore, we also recommend further studies comparing results between superior and inferior implantation of 2 intrastromal rings and a single implantation of a 210-degree intrastromal ring for the management of PMCD.

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Biosketch

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