

# Combined Kerarings and Artisan/Artiflex IOLs in Keratectasia

Hanefi Cakir, MD; Canan Asli Utine, MD, MSc

## ABSTRACT

**PURPOSE:** To evaluate the results of combined intracorneal ring (Keraring, Mediphacos Ltd) and anterior chamber, iris-fixated, phakic intraocular lens (pIOL) (Artisan and Artiflex, Ophtec BV) implantation in patients with ectatic corneal conditions and secondary high myopic and astigmatic refractive error.

**METHODS:** Ten eyes of eight consecutive patients with different ectatic corneal diseases underwent sequential intracorneal Keraring and iris-fixated pIOL implantation. Two eyes with keratoconus, one eye with pellucid marginal degeneration, and one eye with iatrogenic corneal ectasia were implanted with the Artisan pIOL; six eyes with keratoconus were implanted with the Artiflex pIOL. Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refraction spherical equivalent (MRSE), topographic findings, and complications were recorded.

**RESULTS:** Mean UDVA improved from  $0.02 \pm 0.10$  preoperatively to  $0.11 \pm 0.06$  after Keraring implantation and to  $0.54 \pm 0.18$  after pIOL implantation ( $P < .001$  for all). Mean CDVA improved from  $0.18 \pm 0.12$  preoperatively to  $0.39 \pm 0.13$  after Keraring implantation and to  $0.66 \pm 0.18$  after pIOL implantation ( $P < .001$  for all). Mean MRSE reduced from  $-12.50 \pm 6.31$  D preoperatively to  $-12.08 \pm 5.17$  D after Keraring implantation ( $P = .10$ ) and to  $-0.10 \pm 0.84$  D after pIOL implantation ( $P < .001$ ). No intra- or postoperative complications were observed.

**CONCLUSIONS:** Sequential intracorneal Keraring segments and Artisan/Artiflex pIOL implantation resulted in visual and refractive improvements in patients with different corneal ectatic conditions with high myopic refractive errors. [*J Refract Surg.* 2010;xx:xxx-xxx.] doi:10.3928/1081597X-20100407-01

**K**eratoconus, pellucid marginal corneal degeneration, and corneal ectasia after LASIK are believed to share common pathophysiologic mechanisms and management options.<sup>1</sup> In their advanced stages, characterized by high myopia and irregular astigmatism, it is often impossible to correct the whole refractive error by a single procedure.

The bioptics approach is a sequential combination of different refractive techniques to treat large and complex refractive errors.<sup>2,3</sup> The use of this approach in the management of refractive errors secondary to keratectasia has been reported previously, combining phakic intraocular lens (pIOL) implantation with Intacs intracorneal ring segments (Addition Technology Inc, Des Plaines, Ill).<sup>4-6</sup>

The current study is the first report in which intracorneal Keraring segment (Mediphacos, Belo Horizonte, Brazil) implantation was combined with iris-fixated pIOL (Artisan and Artiflex; Ophtec BV, Groningen, The Netherlands) implantation in patients with primary and secondary corneal ectatic conditions.

## PATIENTS AND METHODS

Consecutive patients with different corneal ectatic diseases, who had been admitted to Turkiye Hospital Eye Clinic, were included in the study. All patients were intolerant to contact lens use and had clear corneas. Patients with corneal apical scarring, history of systemic diseases that may have an adverse effect on the cornea and ocular surface, or any ocular disease except corneal ectasia and related refractive error were excluded.

From Turkiye Hospital Eye Clinic (Cakir); and Yeditepe University Eye Hospital (Utine), Istanbul, Turkey.

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Correspondence: Canan Asli Utine, MD, MSc, Yeditepe University Eye Hospital, Gazi Umur Pasa sok. No: 28, Besiktas Balmumcu, 34345 Istanbul, Turkey. Tel: 90 533 5587635; Fax: 90 212 2112500; E-mail: cananutine@gmail.com

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TABLE 1

**Pre- and Postoperative Data for Eight Patients Who Underwent Keraring and Phakic Intraocular Lens Implantation for Corneal Ectasia**

Eye	Age (y)	Right/Left	Diagnosis*	UDVA (Decimal)			CDVA (Decimal)		
				Preop	After Keraring	Final	Preop	After Keraring	Final
1	30	R	1	0.03	0.05	0.4	0.3	0.5	0.6
2	22	R	2	0.015	0.05	0.2	0.4	0.4	0.4
3	23	R	2	0.005	0.05	0.4	0.05	0.3	0.4
4	23	R	2	0.01	0.15	0.5	0.1	0.5	0.7
5	35	R	3	0.01	0.05	0.6	0.05	0.15	0.6
6	45	L	2	0.02	0.20	0.8	0.15	0.5	1.0
7	34	R	2	0.03	0.10	0.5	0.1	0.3	0.8
8	34	L	2	0.03	0.10	0.6	0.1	0.25	0.7
9	32	R	2	0.01	0.15	0.7	0.2	0.5	0.7
10	32	L	2	0.01	0.15	0.7	0.3	0.5	0.7

UDVA = uncorrected distance visual acuity, CDVA = corrected distance visual acuity, K value = keratometric value, SE = spherical equivalent  
 \*1: Pellucid marginal degeneration; 2: Keratoconus; 3: Postoperative LASIK ectasia.

Preoperatively, all patients underwent Snellen uncorrected and corrected distance visual acuities (UDVA and CDVA), refraction, slit-lamp examination, Goldmann applanation tonometry, Orbscan II topography (Bausch & Lomb, Rochester, NY), ultrasonic pachymetry (Sonagage 50 Hz; Sonogage Inc, Cleveland, Ohio), and dilated fundus examination. Because these patients suffered from corneal ectasia, CDVA was determined by fitting rigid gas permeable

contact lenses (Rose K; Menicon Co Ltd, Nagoya, Japan) at the first examination and by spectacle correction during postoperative follow-up.

This study adhered to the tenets of the Declaration of Helsinki and written informed consent was obtained from all participants preoperatively. All surgical procedures were performed under topical anesthesia by the same surgeon (H.C.). A 60-kHz femtosecond laser (Abbott Medical Optics [AMO], Santa Ana, Calif) was

TABLE 2

**Characteristics of Keraring and Phakic Intraocular Lens Implantation in Eight Patients for Correction of Corneal Ectasia**

Eye	No. of Kerarings	Ring 1 Arc Angle (°)	Ring 1 Thickness (µm)	Ring 2 Arc Angle (°)	Ring 2 Thickness (µm)	Intracorneal Channel Inner Diameter (mm)
1	1	210	200	—	—	4.8
2	2	120	250	120	250	4.9
3	2	120	250	120	250	5.0
4	2	90	200	90	200	4.9
5	2	160	300	160	300	5.0
6	2	90	300	90	300	5.0
7	2	90	200	90	200	4.9
8	2	90	200	90	200	4.9
9	2	160	150	160	150	4.9
10	2	160	200	160	200	4.9

pIOL = phakic intraocular lens, AK = astigmatic keratotomy

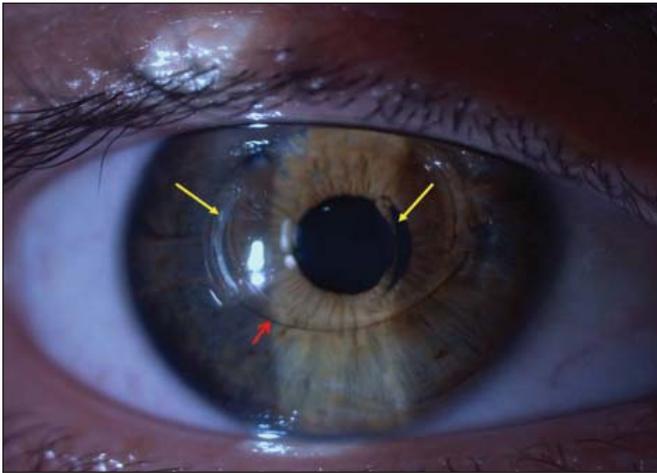
K Value (D)		Refraction/SE (D)		
Preop	After Keraring	Preop	After Keraring	Final
52.70/49.20	52.50/50.70	-13.00 -5.00 × 60/-15.50	-9.00 -0.25 × 180/-9.13	-1.50 -2.00 × 170/-2.50
61.90/50.80	58.40/51.20	-11.00 × 27/-5.50	-8.75 -5.00 × 13/-11.25	+1.00 -5.00 × 50/-1.50
73.12/64.37	57.20/54.40	-22.00 -6.00 × 170/-25.00	-18.00/-18.00	+0.50/+0.50
55.80/51.20	54.50/50.50	-9.00 -5.00 × 180/-11.50	-9.00 -3.00 × 20/-10.50	-2.00 × 45/-1.00
57.60/51.10	48.50/45.50	-20.00 -6.00 × 10/-23.00	-24.00 -4.00 × 80/-26.00	+2.00 -1.00 × 85/+1.50
62.50/54.90	61.25/53.12	-9.00 -9.00 × 170/-13.50	-10.00 -0.75 × 180/-10.38	+1.00 -1.00 × 150/+0.50
56.20/50.70	54.00/53.00	-10.00 -7.00 × 180/-13.50	-10.00 -1.50 × 20/-10.75	-1.00 × 10/-0.50
58.40/53.70	54.90/52.40	-11.00 -7.00 × 180/-14.50	-10.00 -2.50 × 165/-11.25	-1.25 × 165/-0.63
58.20/56.30	54.00/51.80	-17.00 -3.00 × 50/-18.50	-8.00/-8.00	-1.00/-1.00
57.00/53.10	55.10/49.50	-14.00 -6.00 × 130/-17.00	-14.00 -1.50 × 45/-14.75	-1.00 -1.50 × 45/-1.75

used to create the intrastromal channels for the intra-corneal rings. Intraoperatively, corneal thickness was measured with ultrasonic pachymetry at the incision site and peripherally along the ring placement markings. The Keraring segments were inserted at 70% depth of the corneal thickness at the area of implantation. A disposable suction ring and applanation cone were used to stabilize and flatten the cornea, to maintain a precise distance from the laser head to the focal

point. The pulse duration was 600 femtoseconds (fs). The femtosecond laser settings were: entry cut thickness 1 μm, ring energy 1.50 to 2.50 μJ, and entry cut energy 1.50 μJ. The original insertion sites were opened with a Sinsky hook (BD, Franklin Lakes, NJ), and the Keraring segments were implanted into the channels.

Iris-fixated pIOL implantation was performed after the Keraring implantation, once the corneal edema disappeared and the refractive and visual outcomes

Intracorneal Channel Outer Diameter (mm)	Channel Depth (μm)	Intracorneal Channel Incision Axis	pIOL Type	pIOL Power (D)	pIOL Optic/Total Diameter (mm)	Additional Procedure
5.7	400	210	Artisan	-9.00	6.00/8.50	—
5.6	380	120	Artisan	-8.50	6.00/8.50	—
5.8	370	37	Artisan	-17.00	5.00/8.50	—
5.6	370	90	Artiflex	-10.50	6.00/8.50	AK
5.7	380	38	Artisan	-20.00	5.00/8.50	—
5.8	400	80	Artiflex	-12.50	6.00/8.50	AK
5.7	360	105	Artiflex	-11.00	6.00/8.50	—
5.7	360	70	Artiflex	-12.00	6.00/8.50	—
5.6	360	90	Artiflex	-7.50	6.00/8.50	—
5.6	360	50	Artiflex	-11.50	6.00/8.50	—



**Figure 1.** Anterior segment image (eye 7) after 90°-arc Keraring (yellow arrows) and Artiflex phakic intraocular lens (red arrow) implantation.

stabilized, as determined by sequential examinations performed every month. The pIOL implantation procedure was as follows: under peribulbar anesthesia, a scleral tunnel of 5.5-mm width was marked between the 1:30 and 10:30 positions. Two vertical paracentesis sites were placed at the 2- and 10-o'clock positions. If the pupil was not adequately constricted, acetylcholine was injected into the anterior chamber. The anterior chamber was filled with sodium hyaluronate 1.4% (Healon GV, AMO). The scleral tunnel was completed with a 45° diamond knife, at the previously marked site. The Artisan pIOL was inserted with a special forceps into the anterior chamber and was centered on the pupil. At the same time, an enclavation needle was inserted through one of the paracentesis sites to lift an approximately 1.0-mm iris fold and enclave it on the claws of the haptic. The same procedure was completed on the other haptic. A peripheral iridotomy was created either superonasally or superotemporally. Intracameral sodium hyaluronate was flushed to prevent postoperative intraocular pressure elevation. The scleral tunnel and overlying conjunctiva were then closed with 8-0 vicryl sutures (Ethicon Inc, Westwood, NJ).

The Artiflex implantation procedure was performed in the same way as the Artisan implantation procedure, except the folded pIOL was inserted through a 3.2-mm corneal self-sealing incision using a special forceps instead of creating a scleral tunnel.

All surgeries were completed uneventfully in all eyes. Postoperative management included topical ofloxacin 0.3% four times a day (Exocin; Allergan, Mougins, France) and prednisolone acetate 1% four times a day (Predforte, Allergan). An eye-shield was placed to cover the eye of all patients. Patients were instructed to avoid eye rubbing and to use preserva-

tive-free artificial tears (Refresh Plus; Allergan, Irvine, Calif) six to eight times a day.

The UDVA, CDVA, spherical and cylindrical refractive error, and manifest refraction spherical equivalent (MRSE) parameters were analyzed preoperatively, after Keraring implantation before pIOL implantation, and at last follow-up. On the Orbscan corneal topographies, the minimum/maximum simulated keratometric readings and anterior/posterior difference values from the best-fit sphere were recorded, and the values after Keraring implantation were compared to preoperative values. The Orbscan parameters after pIOL implantation were not included in the analysis, as scleral tunnel incisions and 3.2-mm corneal self-sealing incisions are expected to induce only minimal cylinder.<sup>7,8</sup>

The safety, safety index, the efficacy, and efficacy index were also assessed. Safety was defined as the number and percentage of eyes that did not lose more than two lines of CDVA. The safety index was defined as mean postoperative CDVA divided by mean preoperative CDVA. Efficacy was defined as the number and percentage of eyes achieving UDVA >0.5 (decimal). The efficacy index was defined as the mean postoperative UDVA divided by mean preoperative CDVA.

Statistical analysis was done using SPSS software, version 15.0 (SPSS Inc, Chicago, Ill). A one-way repeated measures of analysis of variance (ANOVA) test was used to analyze the change in each of the parameters at three different time points. If a parameter was significantly changed, a protected dependent *t* test was performed as a post-hoc analysis. Paired sample *t* test was used to compare the pre- and postoperative parameters in each group. A *P* value <.05 was considered statistically significant for repeated measures of ANOVA and paired sample *t* tests, and a *P* value <.017 was considered statistically significant for post-hoc tests.

## RESULTS

A total of 10 (7 right and 3 left) eyes of 8 patients were included in the study; 3 were women and 5 were men. Mean patient age was 31.00±7.01 years (range: 22 to 45 years).

Pre- and postoperative data for each eye are summarized in Table 1. Eight eyes had keratoconus, one had iatrogenic corneal ectasia, and one had pellucid marginal corneal degeneration. Preoperatively, mean central and thinnest pachymetric readings were 375.0±65.90 μm (range: 313 to 508 μm) and 351.5±69.63 μm (range: 279 to 487 μm), respectively.

Characteristics of the implanted Keraring segments and pIOLs in each patient are summarized in Table 2. Keraring segments were implanted as per manufacturer's

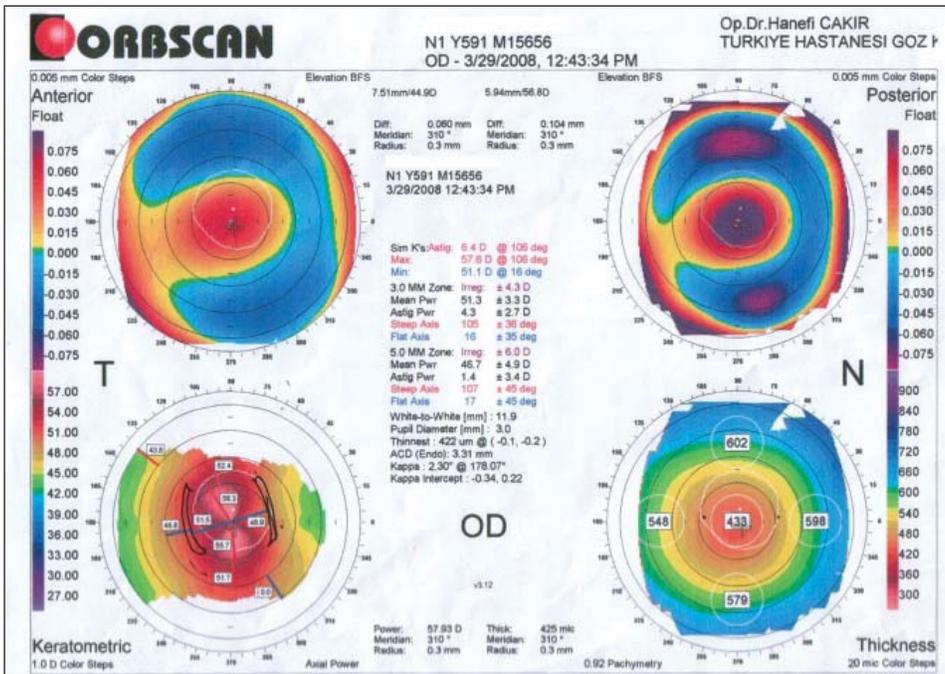


Figure 2. Preoperative Orbscan II corneal topography (eye 5).

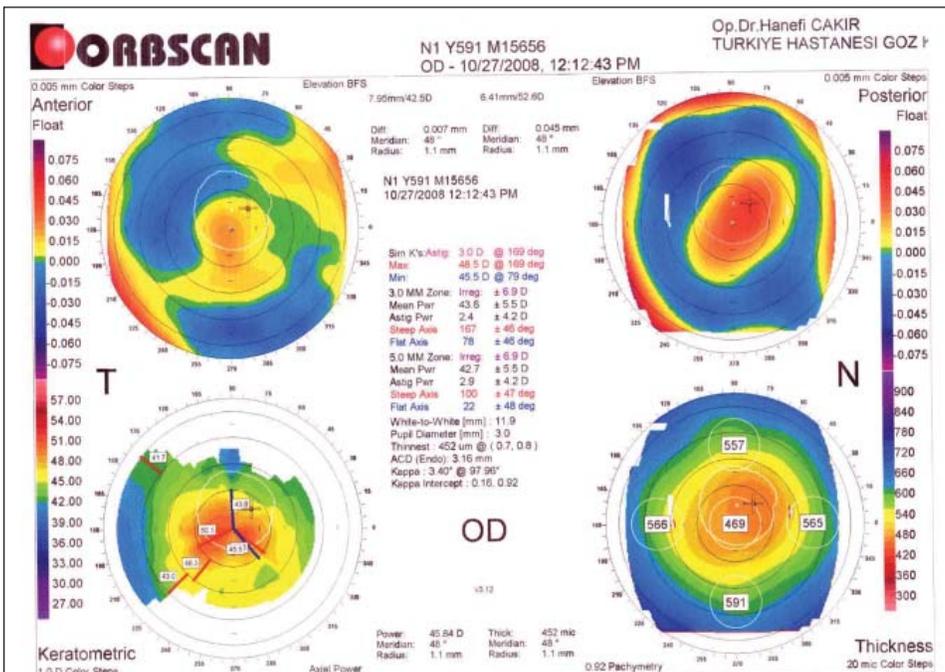


Figure 3. Orbscan II corneal topography after Keraring implantation at last follow-up before phakic intraocular lens implantation (eye 5).

5.00 mm) and  $5.68 \pm 0.08$  mm (range: 5.60 to 5.80 mm), respectively.

The iris-fixated pIOL implantation was performed  $6.6 \pm 5.2$  months (range: 3 to 18 months) after Keraring implantation. The Artisan pIOL was implanted in four eyes, and the Artiflex was implanted in six eyes. Mean power of the implanted pIOL was  $-11.95 \pm 3.86$  diopters (D) (range:  $-7.50$  to  $-20.00$  D). Patients were followed for  $13.8 \pm 4.05$  months (range: 12 to 24 months) after pIOL implantation. Post-operative slit-lamp image of an eye after 90° arc Keraring and Artiflex pIOL implantation is shown in Figure 1.

Table 3 displays mean UDVA, CDVA, spherical and cylindrical refractive errors, and MRSE, at three different time points, and mean K readings and anterior and posterior difference from the best-fit sphere values at two different time points. Orbscan II corneal topography before and after Keraring implantation is shown in Figures 2 and 3.

A one-way repeated measures of ANOVA calculated comparing UDVA, CDVA, spherical/cylindrical refractive errors, and MRSE of patients at three time points demonstrated a significant effect in all parameters ( $F(2,18)=86.3$ ,  $P<.001$ ). Follow-up protected *t* tests were performed to analyze the change in each of these parameters at different time points. The results revealed that both UDVA and CDVA increased significantly after Keraring implantation compared to preoperatively, and after pIOL

implantation compared to after Keraring implantation ( $P<.001$  for all). The spherical refractive error and MRSE decreased significantly after pIOL implantation ( $P<.001$  for both) but not after Keraring implantation ( $P=.79$  and  $P=.10$ , respectively). On the other hand,

nomogram ([http://www.amedophchile.cl/Images/Keraring\\_New\\_Nomogram.pdf](http://www.amedophchile.cl/Images/Keraring_New_Nomogram.pdf)), at a mean depth of  $374.0 \pm 15.78$   $\mu$ m (range: 360 to 400  $\mu$ m) in the corneal stroma. Mean inner and outer diameters of the intra-corneal channels were  $4.92 \pm 0.06$  mm (range: 4.80 to

TABLE 3  
**Study Parameters at Different Time Points**

	Mean ± Standard Deviation							
	UDVA	CDVA	Spherical Error (D)	Cylindrical Error (D)	MRSE (D)	Keratometric Value (D)	Anterior Difference From BFS (μm)	Posterior Difference From BFS (μm)
Preoperative	0.02±0.10	0.18±0.12	-12.50±6.31	-6.50±2.22	-15.75±5.60	56.44±4.85	0.065±0.019	0.123±0.042
Before pIOL implantation	0.11±0.06	0.39±0.13	-12.08±5.17	-1.85±1.74	-13.00±5.34	53.12±2.75	0.045±0.018	0.115±0.034
Final	0.54±0.18	0.66±0.18	-0.10±0.84	-1.08±1.77	-0.064±1.20	—	—	—

UDVA = uncorrected distance visual acuity, CDVA = corrected distance visual acuity, MRSE = manifest refraction spherical equivalent, BFS = best-fit sphere, pIOL = phakic intraocular lens

cylindrical refractive error decreased significantly after Keraring implantation ( $P<.01$ ) but not after pIOL implantation ( $P=.20$ ).

A paired sample *t* test was calculated comparing the mean K reading and anterior difference values from best-fit sphere preoperatively and after Keraring implantation, and a significant decrease in both parameters was found ( $P=.03$  for both). However, a paired sample *t* test to compare the posterior difference values from best-fit sphere preoperatively and after Keraring implantation did not reveal a significant change ( $P=.63$ ).

This study demonstrated 100% safety in both surgeries with no complications, including cataract, glaucoma, or clinically significant endothelial compromise. The safety and efficacy indices were 2.17 and 0.61 after Keraring implantation, respectively, and 1.69 and 1.38 after pIOL implantation, respectively. Overall, the safety index was 3.67 (ie, 267% gain in CDVA), efficacy was 70%, and the efficacy index was 3 (ie, final mean UDVA of three times the preoperative mean CDVA).

Nine of the 10 eyes gained  $\geq 3$  lines of UDVA and CDVA, and 6 eyes achieved a final CDVA of  $\geq 0.7$ . In only 1 eye (eye 2), UDVA improved from counting fingers at 1.5 m to 0.2; CDVA did not change. In this patient, preoperative cylindrical refraction of  $-11.00$  D decreased to  $-5.00$  D postoperatively. A future astigmatic keratotomy will enhance further decrease in cylinder correction, with a possible improvement of CDVA.

**DISCUSSION**

In corneal ectatic conditions, laser refractive procedures are widely accepted to be contraindicated.<sup>9</sup> Collagen cross-linking treatment, which has been developed to address the problem of ectasia, does not create a significant amount of refractive correction.<sup>10</sup>

Bioptics techniques currently performed mostly involve pIOL implantation or refractive lens exchange combined with keratorefractive surgery.<sup>11,12</sup> Colin and

Velou<sup>13</sup> were first to publish results of implantation of intracorneal rings and anterior chamber pIOL to correct refractive error in keratoconus. Other studies report pIOL implantation and Intacs intracorneal ring implantation in patients with keratoconus.<sup>4,6</sup>

Intracorneal ring implantation aims to reshape and improve the topographic and optical properties of the cornea and to secondarily improve visual acuity. Its efficacy in both primary and secondary keratectasias has been shown by several studies.<sup>14,15</sup> The procedure is shown to be more efficient in terms of refractive and optical correction in eyes with keratectasia compared to eyes with simple myopic refractive errors.<sup>16</sup> However, in the majority of cases, the whole refractive error is not corrected.

The intracorneal rings used in this study have small optic diameters of 5.0 mm. This property creates two advantages. First, because the intracorneal rings are implanted closer to the visual axis, the corneal flattening effect is increased and the change in MRSE is greater.<sup>17</sup> Additionally, if refractive and visual outcome is unsatisfactory, future penetrating keratoplasty would be easier technically when the diameter of the implanted intracorneal ring segment is smaller compared to larger.

In eyes with keratectasia, the anterior chamber is generally wider than that in normal eyes and provides adequate space for implantation of anterior chamber pIOLs. We prefer iris-fixation anterior chamber pIOLs, which do not cause damage to the angle structures, and have “one-size-fits-all” characteristics. Implantation of toric versions of the anterior chamber iris claw and posterior chamber implantable collamer lens (Visian ICL; STAAR Surgical, Monrovia, Calif) pIOLs have been performed successfully for the correction of high astigmatism.<sup>4,6,18</sup> In our opinion, the ICL pIOL seems to be the second line of choice due to limited potential space for its implantation and risk of capsu-

lar opacification and rotation in the early postoperative period. There have been no reports of angle-supported anterior chamber pIOL implantation in bioptics procedures, except for the first case of Colin and Velou.<sup>13</sup>

The eyes enrolled in this study had high K readings, and high spherical/cylindrical errors that were either uncorrectable with only intracorneal ring implantation, or it was impossible to use the necessary ring thicknesses due to thin pachymetric readings. Four of the study eyes had been recommended for penetrating keratoplasty in other clinics (eyes 1, 3, 5, and 6). In two patients, the fellow eye had undergone penetrating keratoplasty (eyes 3 and 5); and in three eyes, the K reading exceeded 60.00 D (eyes 2, 3, and 4).

In this case series, all patients had increased UDVA and CDVA and decreased spherical and cylindrical refractive errors. These results are probably better than penetrating keratoplasty outcomes. The high K readings and irregular shape of the recipient cornea would create technical difficulties in keratoplasty, and postoperative high astigmatism resulting in a less favorable visual acuity outcome would be a major issue. Considering the risk of graft rejection/graft failure and the required intensive postoperative care, preserving their own corneas seems to be in the patients' best interest. On the other hand, bioptics procedures with sequential intracorneal ring and pIOL implantation allow us to improve the corneal characteristics and visual acuity in eyes with corneal ectasia. For an experienced surgeon, both procedures are not difficult to perform. If a successful outcome is not obtained, the procedures are easily reversible and do not prevent future penetrating keratoplasty.

It is important to note that intracorneal ring implantation should always be performed first, which corrects the refractive myopia and astigmatism in a limited manner. Also, the axis of astigmatism is likely to be changed postoperatively. Because postoperative outcomes of intracorneal ring implantation are often unpredictable in different stages of the ectatic disease, it is important to wait until the corneal edema disappears and the refractive error stabilizes before proceeding to the next step of the bioptics procedure.

The main drawback of this study is the lack of adequate postoperative endothelial cell density counts, especially after pIOL implantation, which would enable comparison with preoperative cell counts. However, we did not encounter any eyes with clinically apparent corneal decompensation. The aim of this study was to demonstrate the refractive and visual results of the bioptics approach with sequential intracorneal ring and pIOL implantation. The safety of each of these procedures with respect to endothelial cell count has been demonstrated previously.<sup>19-21</sup>

Sequential intracorneal Keraring segments and Artisan/Artiflex iris-fixated pIOL implantation yielded satisfactory visual and refractive results and could be considered as an alternative to penetrating keratoplasty in patients with different corneal ectatic conditions with high myopic refractive errors.

#### AUTHOR CONTRIBUTIONS

*Study concept and design (H.C., C.A.U.); data collection (H.C., C.A.U.); analysis and interpretation of data (H.C., C.A.U.); drafting of the manuscript (C.A.U.); critical revision of the manuscript (H.C.); statistical expertise (C.A.U.); supervision (H.C.)*

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