Clinical Outcomes of an Asymmetric Model of Intrastromal Corneal Ring Segments for the Correction of Keratoconus

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Purpose: To evaluate the clinical outcomes of a new model of intrastromal corneal ring segments (ICRSs) (Keraring AS) in patients with keratoconus and quantify subsequent changes in refraction and corneal topography.

Methods: This nonrandomized, single-center, retrospective observational study explores the effect of progressive thickness ICRS implantation in patients with keratoconus with a 3-month follow-up. After creating an intrastromal tunnel using a femtosecond laser, 1 or 2 ICRSs of progressive thicknesses (150/250 μm or 200/300 μm) and 160-degree arc length were implanted. Changes in uncorrected distance visual acuity, best-corrected distance visual acuity, refractive outcomes, corneal astigmatism, and maximum keratometry readings were recorded before and after surgery.

Results: The study cohort consisted of 82 patients (104 eyes) with a mean age of 31.2 ± 10 years. At 3 months, ICRS implantation significantly improved uncorrected and corrected visual acuities from 0.82 to 0.46 (logarithm of the minimum angle of resolution [LogMAR]) and from 0.31 to 0.21 (LogMAR), respectively ($P < 0.001$). The mean spherical error reduced from −1.74 diopters (D) to −0.90 D ($P < 0.001$), and the mean cylindrical error reduced from −4.22 D to −2.01 D ($P < 0.001$). The manifest refraction spherical equivalent reduced from −3.85 D to −1.91 D ($P < 0.001$). All topographic parameters were reduced, including maximum keratometry (53.6 D vs. 50.3 D) and keratometric astigmatism (−4.6 D vs. −2.2 D) ($P < 0.001$).

Conclusions: The Keraring AS provides a new, apparently safe, and effective means of improving visual acuity and reducing the refractive error and mean keratometry in eyes with asymmetric keratoconus.

Key Words: keratoconus, intrastromal corneal ring segments, Keraring AS, asymmetric

(*Cornea* 2019;00:1–6)

Keratoconus is a progressive noninflammatory ectatic corneal disease resulting in progressive myopia, astigmatism, and vision loss due to corneal steepening, thinning, and scarring.[1,2] The disease usually occurs during the second decade of life, but it can also occur later.[3] Although the decreased visual acuity in the early stages of the disease can be improved with rigid permeable contact lenses or spectacles, they often fail to provide useful vision in cases of advanced keratoconus.

The conservative management of keratoconus in early stages consists of spectacle correction or rigid contact lenses. As the disease progresses, some patients may require corneal grafting in the form of penetrating or lamellar keratoplasty.[4] Although success rates are good for keratoplasty surgery, the procedure does carry a significant risk to the patient regarding graft rejection or infection, glaucoma, cataract formation, suture-related problems, and wound dehiscence.[5]

Over the past 20 years, new treatment modalities for keratoconus have emerged: intrastromal corneal ring segments (ICRSs), topography-guided photorefractive keratectomy (TGPRK), and corneal crosslinking (CXL).[6] Both ICRSs and photorefractive keratectomy can reduce refractive error and improve visual acuity, whereas CXL can slow the advancement of keratoconus and strengthen the cornea. Often, these treatments are combined to achieve the best results.

The use of an ICRS is considered a safe and effective option in reshaping a keratoconic cornea and improving vision.[7–9] The segments are small devices made of polymethyl methacrylate synthetic material, which are implanted within the corneal stroma to induce a change in the geometry and refractive power of the tissue. There are different types of intracorneal rings with variable optical diameters, angular lengths, and thicknesses.

Because keratoconus is a disease in which the cornea deforms into a cone-like shape, a flattening effect occurs when the material is added to the corneal periphery or removed from the corneal center,[10] the greater the thickness of the ring implanted, the greater the effect induced in the cornea. To date, standard ICRSs have been designed with uniform thickness, but further customization of the corneal effect has now been made possible with the introduction of new asymmetric Keraring AS models (Mediphacos Ltd, Minas Gerais, Brazil). These rings are thicker at one end and thinner at the other, offering a gradient of thickness which ensures that the flattening effect on the cornea is more pronounced at the thicker end of the ring.

This new asymmetric ICRS design is more tailored to specific types of keratoconus and allows the surgeon to remodel the patient's cornea more precisely. In our clinic, candidates for the implantation of asymmetric ICRSs represent approximately 60% of patients treated for keratoconus.

To our knowledge, to date, this is the first published study on this new ring type specifically designed for

Received for publication April 29, 2019; revision received August 5, 2019; accepted August 16, 2019.
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The authors have no funding or conflicts of interest to disclose.
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asymmetric keratoconus phenotypes. This study aims to report the results with these new ICRSs and describe the procedures and indications for the use of these devices to restore the regular shape of the cornea, improve the associated refractive error, and delay or avoid corneal graft surgery.

MATERIALS AND METHODS

This retrospective observational single-center clinical study included 104 eyes of 82 patients (60 men and 22 women) with keratoconus with a mean age of 31.2 ± 10 years (range 13–57 years). All procedures were performed by the same surgeon (O.P.) from February 2017 to July 2018. The study followed the tenets of the Declaration of Helsinki, and all patients were asked to sign an informed consent form before treatment.

Inclusion criteria to be a candidate for Keraring AS implantation were keratoconic eyes, graded 1, 2, or 3 according to the Krumeich classification, with a clear central cornea, minimum corneal thickness of 400 μm at the site of tunnel creation, maximum keratometry (Kmax) lower than 64 diopters (D), topographical astigmatism greater than 2.0 D, and intolerance to contact lenses.

Exclusion criteria were previous corneal or intraocular surgery, history of herpes, corneal scarring, associated ocular diseases (glaucoma, cataract, retinal disorders, and uveitis), and patients with autoimmune disorders.

A complete ophthalmic examination was performed preoperatively and postoperatively, including uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), manifest refraction, and keratometry readings. Corneal topography was measured using the Pentacam system (Oculus, Inc) and Orbscan II (Bausch & Lomb)—all patients were followed up with both systems; however, the Kmax data used in this study were obtained using the Pentacam system. Keratometric measurements were obtained using a kerato-refractometer (Topcon KR-8000 PA, Topcon Corp, Japan). Visual acuity was measured using the Snellen notation and converted to logarithm of the minimum angle of resolution (LogMAR) for statistical analysis.

The Keraring AS is made of medical-grade polymethyl methacrylate with an ultraviolet blocker and a triangular prismatic cross-section designed to mitigate visual disturbances in low light. It has a 5-mm optical zone, a base width of 600 μm, and a 160-degree or 330-degree arc length (we used the 160-degree model). Unlike standard ICRSs, which have a constant thickness, Keraring AS models have variable thickness profiles of 150/250 μm or 200/300 μm within the same implant. The ICRS is thinnest at the proximal end (located near the incision) and gradually increases by 100 μm toward the opposite end, where it is thickest. The thickness increase can be clockwise or counterclockwise.

The Keraring AS is particularly indicated for patients with keratoconus who present with an asymmetric corneal topographic phenotype, either with a parallel axis (snowman) or skewed axis (duck) phenotype. The appropriate implant size and position were chosen based on the manufacturer's nomogram, according to the keratoconus grade, topographic astigmatism, and manifest refraction. Furthermore, the decision to implant the 150/250 μm or 200/300 μm model depended on several factors based on the manufacturer's nomogram. The 150/250 μm model was generally implanted in eyes with a Kmax lower than 53 D, and the other model, the 200/300 μm model, was instead implanted in eyes with a Kmax equal to or higher than 53 D. We also opted to implant the 200/300 μm model in cases where we encountered a high magnitude of difference between the inferior and superior axis.

The surgical procedure was performed under sterile conditions and under topical anesthesia. Preoperatively, the horizontal axis was marked with the patient sitting upright to control for potential cyclotorsion, which is particularly important because the rings have a powerful toric effect, and the optical axis was marked using the Purkinje reflex. A femtosecond laser delivery system (IntraLase; Johnson & Johnson Vision) was then used to create the intrastromal tunnel with an inner diameter of 5 mm and an outer diameter of 5.9 mm. The incision was performed on the axis of the steepest keratometry reading, with a 70% depth of the thinnest point measured in the tunnel area. The ring was placed in the corneal tunnel using disposable forceps, with the thinnest end of the ICRS oriented nearest the incision and the center of the implant aligned on the flattest meridian. When the device was in place, we verified the corneal regularity and the centering of the ring with a keratoscope.

After surgery, tobramycin 0.3% and dexamethasone 0.1% eye drops were prescribed 4 times daily for 1 week. Postoperative visits were scheduled at 1 and 90 days after surgery. On each visit, UCVA, BCVA (LogMAR), manifest refraction, manifest refraction spherical equivalent (MRSE), slit-lamp biomicroscopy (Keraring position and corneal integrity), and corneal topographic analysis were observed. Data in this study are presented at 3 months because CXL and TGPRK were performed thereafter on most patients. These patients presented with medium to severe keratoconus: in these cases, we prefer to implant ICRSs before performing TGPRK because they have a greater capability to reshape the cornea. In addition, patients with keratoconus usually present with a fragile cornea, and ICRSs, being an additive procedure, allow the surgeon to preserve the biomechanical integrity of the cornea.[11,12]

TABLE 1. Vision Measurements: Preoperative Versus 3 Months Postoperative

	Pre-op (LogMAR)	Post-op (LogMAR)	*P*
UCVA			
All	0.82	0.46	<0.001
One asymmetric ICRS	0.8	0.44	<0.001
Two asymmetric ICRSs	0.89	0.53	<0.001
BCVA			
All	0.31	0.21	<0.001
One asymmetric ICRS	0.3	0.18	<0.001
Two asymmetric ICRSs	0.34	0.29	0.063

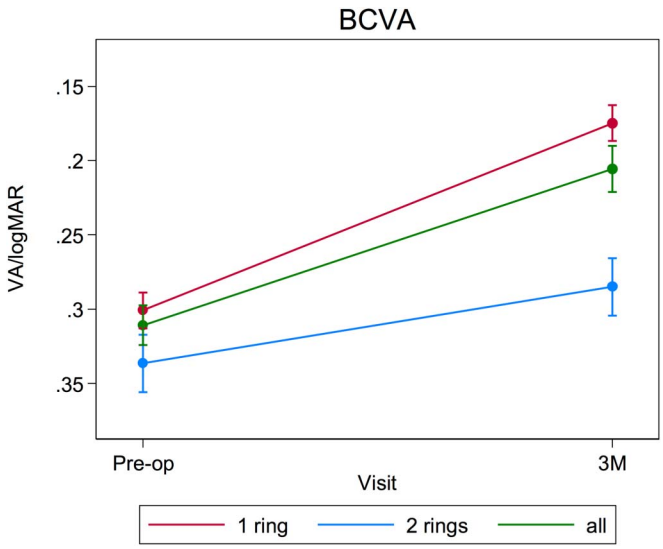

FIGURE 1. Preoperative BCVA versus 3 months postoperative.

Statistical analysis was performed using a commercially available statistical software package (IBM Corp, Released 2015, IBM SPSS Statistics for Windows, version 20.0; IBM Corp, Armonk, NY). A paired *t* test was applied to analyze all the outcomes at baseline and at the 3-month follow-up. A *P* value < 0.05 was considered statistically significant. A repeated measure analysis of variance was computed to compare eyes implanted with 1 ring and 2 rings for visual, refractive, and keratometric outcomes.

RESULTS

The study cohort consisted of 104 eyes of 82 patients (60 men and 22 women) with a mean age of 31.2 ± 10 years (range 13–57 years) who met the inclusion criteria, provided consent for follow-up, and completed baseline visits. Of the 104 eyes treated, 75 eyes were implanted with 1 ring and 29 eyes with 2 rings.

ICRS implantation significantly improved both uncorrected and corrected visual acuity at 3 months (Table 1). Overall, UCVA was enhanced from 0.82 to 0.46 (LogMAR) ($P < 0.001$). There were no significant differences in UCVA improvements between eyes implanted with 1 (from 0.8 to 0.44) or 2 rings (from 0.89 to 0.53). BCVA improved from 0.31 to 0.21 for all eyes ($P < 0.001$) (Fig. 1). BCVA in the one-ring group improved significantly (from 0.3 to 0.18) ($P < 0.001$). In the 2-ring group, BCVA also improved (from 0.34 to 0.29), but this improvement was not statistically significant ($P = 0.063$).

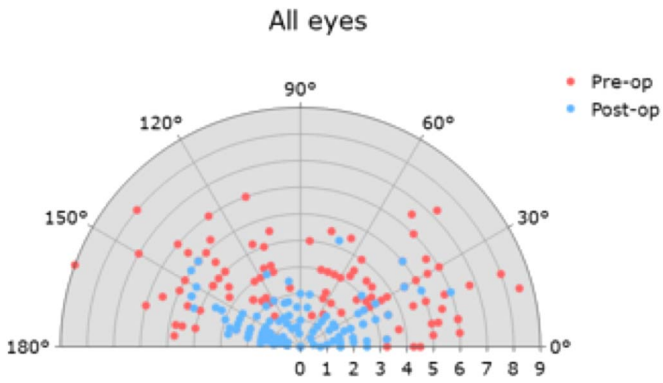

FIGURE 2. Cylinder and axis polar chart for all eyes: preoperative versus 3 months postoperative.

The mean spherical error was reduced for all eyes from −1.74 D preoperatively to −0.90 D postoperatively ($P < 0.001$), and the mean cylindrical error reduced from −4.22 D to −2.01 D ($P < 0.001$) (Table 2). The refractive correction was stronger in eyes implanted with 2 rings than in eyes implanted with 1 ring. In the 2-ring group, the mean spherical error reduced from −2.85 D to −0.82 D ($P < 0.001$), and the mean cylinder reduced from −5.15 D to −2.03 D ($P < 0.001$), whereas in patients implanted with 1 ring, the mean spherical error only reduced from −1.31 D to −0.94 D ($P = 0.034$) and the mean cylinder reduced from −3.86 D to −2.00 D ($P < 0.001$) (Fig. 2).

MRSE for all patients reduced from −3.85 D to −1.91 D ($P < 0.001$) at 3 months. Both groups experienced postoperative improvement in MRSE, but implantation with 2 rings (from 5.42 D to 1.83 D) ($P < 0.001$) had a stronger effect than with 1 ring (from 3.24 D to 1.94 D) ($P < 0.001$).

All topographic parameters (Table 3) significantly improved at the 3-month follow-up. Overall, the mean Kmax reduced from 53.6 D preoperatively to 50.3 D at 3 months (*P*

TABLE 2. Refractive Measurements: Preoperative Versus 3 Months Postoperative

	Pre-op (D)	Post-op (D)	*P*
Sphere			
All	−1.74	−0.90	<0.001
One asymmetric ICRS	−1.31	−0.94	0.034
Two asymmetric ICRSs	−2.85	−0.82	<0.001
Cylinder			
All	−4.22	−2.01	<0.001
One asymmetric ICRS	−3.86	−2.00	<0.001
Two asymmetric ICRSs	−5.15	−2.03	<0.001
MRSE			
All	−3.85	−1.91	<0.001
One asymmetric ICRS	−3.24	−1.94	<0.001
Two asymmetric ICRSs	−5.42	−1.83	<0.001

TABLE 3. Topography Measurements: Preoperative Versus 3 Months Postoperative

	Pre-op (D)	Post-op (D)	*P*
Kmax			
All	53.6	50.3	<0.001
One asymmetric ICRS	52.6	50	<0.001
Two asymmetric ICRSs	56.0	51	<0.001
Corneal astigmatism			
All	−4.6	−2.2	<0.001
One asymmetric ICRS	−4.2	−2.4	<0.001
Two asymmetric ICRSs	−5.5	−1.9	<0.001

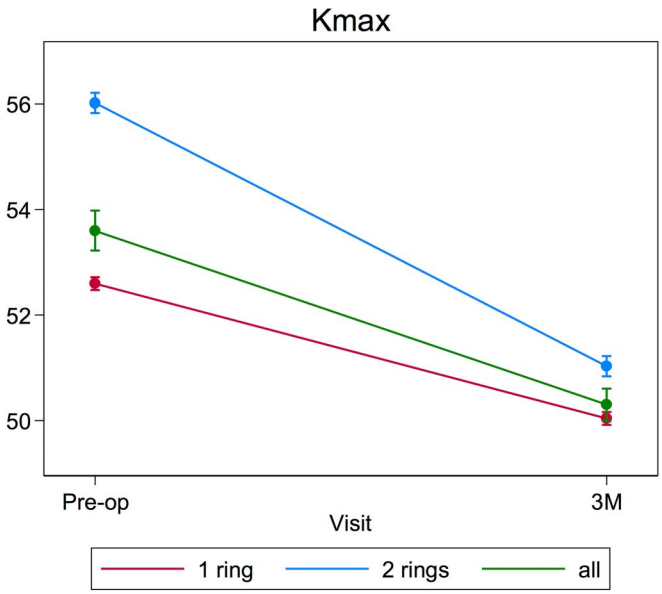

FIGURE 3. Kmax: preoperative versus 3 months postoperative.

< 0.001) (Fig. 3) and the mean keratometric astigmatism reduced from −4.6 D to −2.2 D ($P < 0.001$). As with the outcomes for refractive sphere and cylinder, eyes implanted with 2 rings seemed to have a higher Kmax reduction (from 56 D to 51 D) ($P < 0.001$) and a higher topographic astigmatism reduction (from −5.5 D to −1.9 D) ($P < 0.001$) than eyes implanted with 1 ring (Kmax reduced from 52.6 D to 50 D and corneal astigmatism from −4.2 D to −2.4 D) ($P < 0.001$).

No serious complications were observed intraoperatively or postoperatively. Specifically, no infections occurred, no explantations were needed, and no significant ring decentration was recorded, except for 1 case that required a slight repositioning of the ICRS.

DISCUSSION

We evaluated the efficacy and visual and refractive outcomes of a new asymmetric subtype of ICRSs (Keraring AS), which is indicated for the treatment of specific keratoconus phenotypes presenting with corneal topography curvature maps commonly known as asymmetric so-called snowman or duck types. These phenotypes are 2 of 5 distinct categories based on the morphological characteristics of the disease described by Alfonso.[13] They are considered paracentral with noncoincident topographic and coma axes, whereas of the 3 other phenotypes, nipple and bow tie are classified as central types of keratoconus and croissant is paracentral but with a coincident topographic and coma axis.

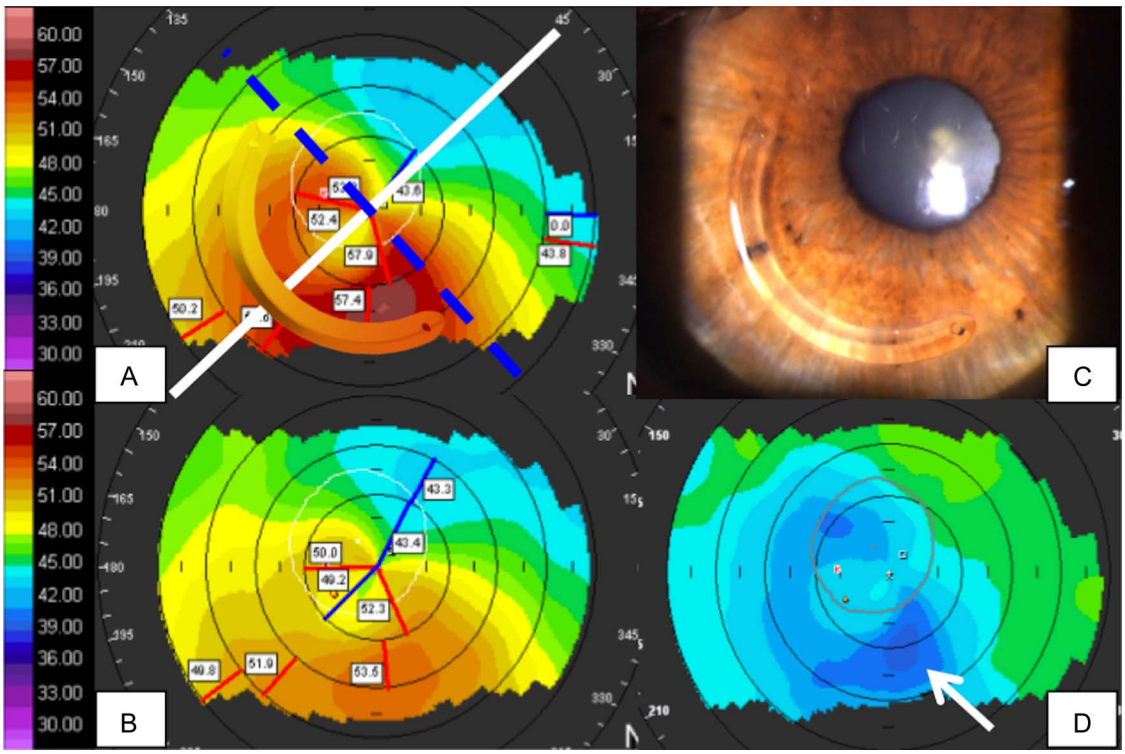

FIGURE 4. A, Corneal topography of baseline values in a 41-year-old male patient implanted with a single Keraring AS 160 degrees (200–300 μm) counterclockwise centered on the flat axis (white line). The patient had a preoperative BCVA of 6/10 (decimal), refraction of −0.50 (−4.00) 60 degrees, corneal astigmatism of 5.2 D, and Kmax 52.5 D. B, Postoperative axial map showing a significant reduction of the keratoconus. C, Slit-lamp photography of Keraring AS 160 degrees. D, Differential map showing the flattening effect of the Keraring AS. The white arrow shows a greater flattening toward the thickest end of the Keraring AS. This resulted in a postoperative BCVA of 9/10 (decimal), refraction of −0.25 (−1.75) 75 degrees, corneal astigmatism of 2.7 D, and Kmax of 48 D.

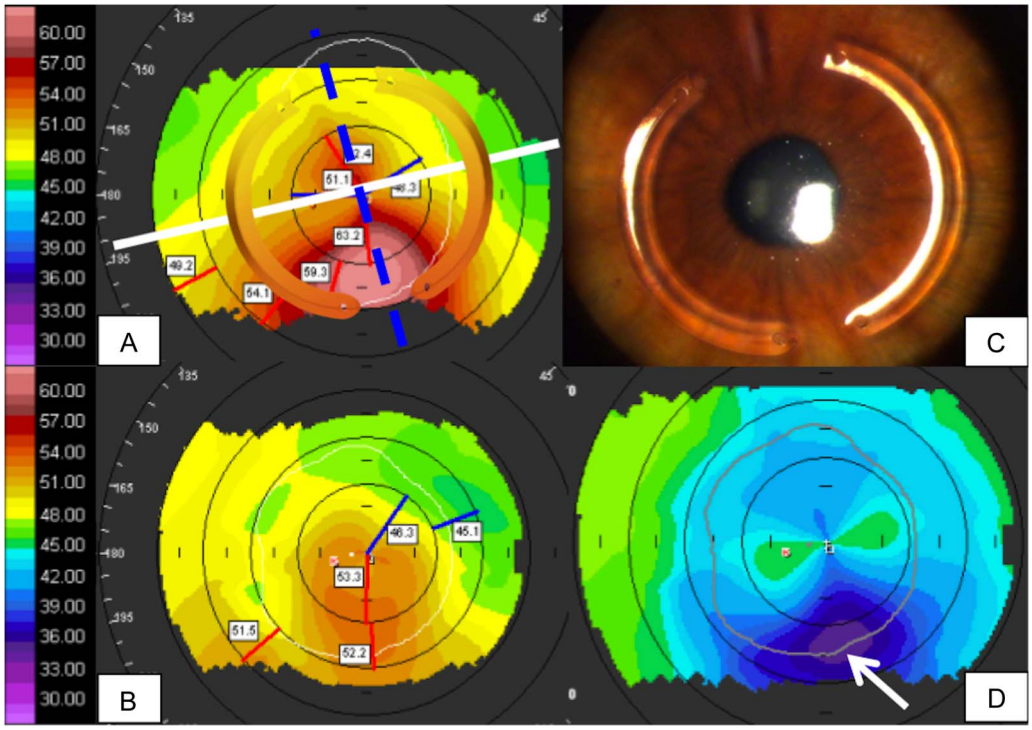

FIGURE 5. A, Corneal topography of baseline values in a 33-year-old female patient implanted with 2 Keraring AS segments 160 degrees (200–300 μm) clockwise and counterclockwise centered on the flat axis (white line). The patient had a preoperative BCVA of 7/10 (decimal), refraction of −2.00 (−5.50) 20 degrees, corneal astigmatism of 5.4 D, and Kmax of 57 D. B, Postoperative axial map showing a significant reduction of the keratoconus. C, Slit-lamp photography of 2 Keraring AS segments 160 degrees. D, Differential map showing the flattening effect of the Keraring AS. The white arrow shows a greater flattening effect toward the thickest end of the 2 Keraring AS segments. This resulted in a postoperative BCVA of 8/10 (decimal), refraction of −0.50 D, corneal astigmatism of 0.9 D, and Kmax 47.9 D.

Patients received either 1 or 2 ring segments depending on the classification of their keratoconus phenotype. Single Keraring AS implantation was indicated in cases of duck-type paracentral keratoconus in which both steep hemimeridians were not aligned and presenting with a skewed radial axis greater than 20 degrees. In these cases, 1 Keraring AS was inserted (Fig. 4) with the thickest end oriented toward the steepest hemimeridian and the middle of the ICRS centered on the flat topographical axis. Patients with the snowman-type paracentral keratoconus, in whom both hemimeridians were aligned but with the inferior hemimeridian steeper than the superior one, were implanted with 2 Keraring AS segments (Fig. 5). The rings were inserted—one clockwise and one counterclockwise—with the thickest end of the segments oriented toward the steepest hemimeridian. The midpoint of each ICRS segment was aligned on the flat topographical axis.

Our postoperative results showed a significant improvement in UCVA and BCVA and are in concordance with other studies of ICRSs.[14–18] For example, Coskunseven et al[19] reported an improvement of 1.7 lines of mean UCVA (Snellen) and 1.3 lines of mean BCVA (Snellen) compared with the preoperative levels and a decrease in the mean keratometry from 50.6 D to 47.6 D after ICRS implantation at 1 year. In addition, Wilde et al[20] in a 12-month retrospective case series of standard Keraring implantations in 70 eyes of 70 patients, in which patients were classified into 3 groups according to disease severity, and Heikal et al[21] in another study of 30 eyes of 20 patients with a 6-month follow-up reported similar improvements in both uncorrected and BCVA after Keraring segment implantation.

By comparison, our cohort had significantly improved UCVA and BCVA from 0.82 to 0.46 (LogMAR) and from 0.31 to 0.21, respectively, at 3 months, and all refractive (mean spherical and mean cylindrical error) and topographic parameters (including Kmax and keratometric astigmatism) also improved significantly.

Our study shows differences in the results obtained implanting 1 or 2 rings. Implanting a single ring improved the mean BCVA more than implanting 2 rings. Implanting 1 ring enhanced the mean BCVA from 0.3 (LogMAR) preoperatively to 0.18 postoperatively, whereas implanting 2 rings resulted in a mean BCVA improvement from 0.34 preoperatively to 0.29 postoperatively although this change was not statistically significant. Our hypothesis to account for the different outcomes in BCVA is related to the keratoconus phenotype being treated. The single ring was implanted in duck phenotypes, where the cone is more decentered than that in snowman phenotypes, and this had more effect in recentering the cone: the consequence, compared with implanting 2 rings in snowman phenotypes, was a more significant reduction in higher-order aberrations[22,23] and a greater improvement in BCVA.

By contrast, the refractive and topography parameters, especially Kmax and MRSE, seemed to have a more significant improvement when using 2 rings. Our hypothesis to explain this difference is that implanting 2 rings in the snowman phenotype had a greater flattening effect than using 1 ring in the duck phenotype, leading to a higher Kmax reduction. Because refraction is closely linked to keratometry, a greater reduction in the Kmax resulted in a greater reduction of the sphere and MRSE.

We observed that the best results are obtained in less advanced keratoconus, and a limitation of this procedure is that it is not applicable to very severe keratoconus. However, the data available in this study (104 eyes) do not enable us to categorize the results by Kmax and perform a significant statistical analysis. Further studies are needed to collect more data, stratify the results by Kmax, and understand at which stage of keratoconus the procedure can be the most efficient.

Although the aim of this study is to evaluate the efficacy of the ICRS, the results we report are limited to 3 months after ICRS surgery because thereafter, most patients underwent TGPRK to remodel the cornea further, improve BCVA, and fine-tune any residual refractive error. Patients also simultaneously underwent CXL treatment to increase the tensile strength of the cornea, as described by Kanellopoulos and Binder.[24] Based on the available evidence, it seems that a combination of the procedures is advantageous (particularly in younger patients) with ICRS implantation and TGPRK reshaping the cornea and CXL slowing the keratoconus progression and stabilizing the cornea.[25,26] Therefore, given the combined nature of the treatments, it is difficult to assess with any degree of certainty the effect that the ring segments, or rather the CXL and the photorefractive keratectomy, may have on improving vision beyond the 3-month follow-up.

To our knowledge, this is the first study to describe the clinical outcomes of this new ICRS design in a large sample of consecutive surgical patients with asymmetric keratoconus. However, a key question that remains unanswered is whether progressive thickness ICRSs enhance vision more than standard ICRSs of constant thickness. Although our clinical experience indicates that specific keratoconus phenotypes are ideal candidates for the progressive thickness ICRSs, other comparative studies are needed to fully assess the difference between various models of ICRSs and validate our hypothesis.

In conclusion, the Keraring AS is an apparently safe and effective treatment for specific keratoconus phenotypes and keratectasia. The procedure is minimally invasive and reversible and yields good visual, refractive, and keratometric outcomes.

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