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ORIGINAL PAPER

Visual, refractive and topographic outcomes of progressive thickness intrastromal corneal ring segments for keratoconic eyes

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Abstract
Purpose To evaluate one-year visual, refractive, and topographic outcomes of 58 eyes of 53 keratoconus patients who underwent surgery with a progressive thickness intrastromal corneal ring segment (ICRS).
Methods This multi-center, retrospective, observational study evaluates the one-year effects of progressive thickness ICRS implanted in keratoconus patients meeting the inclusion criteria. One or two progressive ICRS were implanted in the selected eyes after creating an intrastromal tunnel with a femtosecond laser. Pre- and postoperative uncorrected distance visual acuity, best-corrected distance visual acuity, manifest refraction (both spherical equivalent and cylindrical refractions), corneal astigmatism, maximum keratometry, corneal thickness, and corneal topography measurements and indices were evaluated.
Results In this retrospective case series, 58 eyes of 53 keratoconus patients were included with a follow-up of 12 months. The mean age was 30.89 ± 11.90 years. There were improvements postoperatively in mean values of visual acuities, both uncorrected from 0.71 (preoperatively) to 0.28 (log MAR), and best-corrected from 0.28 to 0.10 (log MAR), mean cylindrical refraction from − 2.35 ± 1.51 to − 4.15 ± 2.23 D, and mean spherical equivalent from − 2.10 ± 2.25 to − 4.64 ± 3.2 D. There was also a reduction in maximal keratometry from 54.21 D preoperatively to 50.93 D postoperatively.
Conclusion The implantation of the progressive thickness ICRS is an effective and safe method to improve the vision of keratoconic eyes. Corneal stability was maintained at the 12-month mark.

Keywords Intrastromal corneal ring segments · Keratoconus · Progressive thickness intrastromal corneal ring segments · ICRS

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Introduction

Keratoconus is a progressive, corneal ectatic disease that has an estimated prevalence of 265 cases per 100,000 [1]. It is characterized by corneal thinning that leads to irregular astigmatism as well as a decrease in visual acuity and optical quality. There are several surgical therapeutic options to slow or halt the disease

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progression or to correct visual disturbances such as intrastromal corneal ring segment (ICRS) implantation, corneal cross-linking (CXL), toric phakic intraocular lens implantation, topography-guided photorefractive keratectomy (TG-PRK) or all these combined treatments [2].

ICRSs add material to the cornea periphery to alter the geometry and refractive power of the cornea. The segments induce a flattening effect, regularizing the cornea and thus improving vision. They have been used with success for the treatment of keratoconus since the early 2000s [3, 4]. Designs of rings vary by optical zone, arc length, and base width.

However, in keratoconic eyes, the irregularities are often not uniform. They can be steeper in one area of the cornea and flatter in another.

Previously available ICRSs all had a uniform thickness, so the flattening effect was the same across the length of the ring. The surgeon has to make a decision on which area to flatten most at the expense of another.

Recently, a progressive thickness ICRS (Keraring AS, Mediphacos Ltd, Belo Horizonte, Brazil) was introduced to treat non-uniform irregularities of the cornea in ectatic corneal disorders. Progressive thickness ICRSs vary in ring thickness from one end to the other, which produces a progressive corneal flattening effect.

This article aims to evaluate the long-term (12 months) visual, refractive, and topographic outcomes of this progressive thickness ICRS treatment in keratoconus patients.

Patients and methods

This retrospective, observational, multi-center clinical study included 58 eyes of 52 keratoconus patients (18 implants at Dunya Eye Hospital, Istanbul, 18 implantations at Instituto de Olhos Renato Ambrósio, Rio de Janeiro, 18 implantations at NeoVízia Eye Clinic, Bratislava, and four implantations at NovaVision Institute, México City). Surgeries were done between 2016 and 2017. The study followed the tenets of the Declaration of Helsinki, and all patients signed an informed consent form before treatment.

Inclusion criteria for the study included keratoconus grade I and II of the mean keratometry Krumeich classification parameters; decreased visual acuity or reduced visual quality due to aberrations; contact lens intolerance; age above or equal to 18 years old; maximum keratometry (Kmax) between 48 and 64 D; asymmetric bow tie (snowman) or oval (duck) or pellucid-like keratoconus topographic patterns as classified by Alfonso et al. [5] and Sinjab et al. [6]; and clear central corneas with at least 400 mm of corneal thickness at the thinnest point.

Exclusion criteria included patients with a history of corneal diseases in addition to keratoconus, autoimmune or systemic connective tissue diseases, intense atopy or hypersensitivity to the ICRS material, or acute or grade IV keratoconus including corneal scarring.

A detailed ophthalmologic examination was performed before surgery. It included the following: uncorrected distance visual acuity (UCVA), best-corrected visual acuity (BCVA), manifest refraction (both spherical equivalent and cylindrical refractions), slit-lamp biomicroscopy, Goldmann applanation tonometry, corneal thickness, and fundus evaluation. Corneal topographies of patients were measured by Pentacam (Oculus, Germany), and topographic indices were evaluated. The topographic indices used are described in further detail in the results and discussion section and have been used in other studies to validate interventional outcomes on keratoconus [7].

Results were obtained before any further refractive surgery procedure, such as photorefractive keratectomy and collagen cross-linking therapy, to evaluate the efficacy of the ICRS.

Progressive thickness ICRS design

The Keraring AS progressive thickness ICRS is made of polymethylmethacrylate (PMMA) (Fig. 1). In contrast to standard ICRS designs, the progressive thickness ICRS offers variable thickness within the same device—it is thin at one end and thicker at the opposite end. The two versions, 160°- and 330°-degree arcs, have gradual thickness variations of 150 µm to 250 µm and 200 µm to 300 µm. These rings are available in clockwise and counterclockwise directions. In this study, we implanted only the 160° version per the manufacturer nomogram tables.

The progressive thickness ICRS is indicated for keratoconus patients with asymmetric bow tie, oval, or

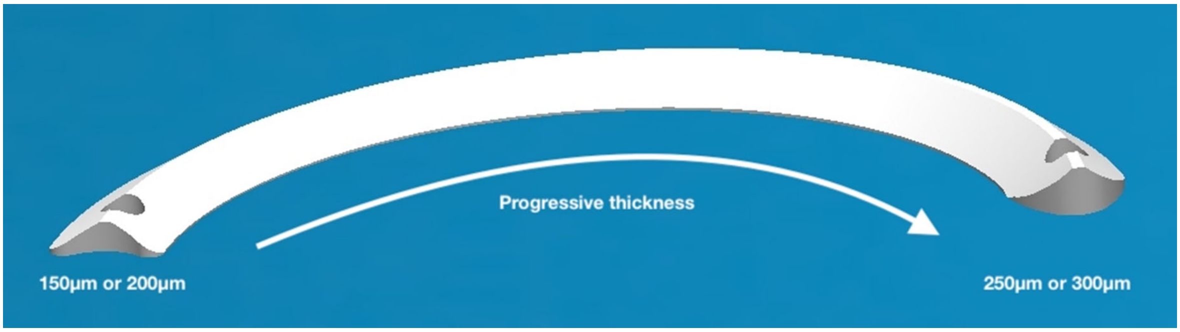

Fig. 1 The Keraring AS—progressive thickness ring

pellucid topographic patterns [5, 6] that have a non-uniform distribution of keratoconus severity.

Statistical analysis was performed using SPSS software (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). Kolmogorov-Smimov and Shapiro–Wilk tests were used for evaluating the normal distribution. Two-tailed paired samples *t* test (for normally distributed data) and Wilcoxon signed-rank test (for non-normally distributed data) were applied for difference analyses and the comparison of results before and after surgery. *P*-values of less than 0.05 were considered statistically significant.

Surgical technique

As noted above, we used only the 160° version of the progressive thickness ICRS in this study. The implant size and position was selected based on the manufacturer nomogram tables-based specific algorithms for each morphological type of keratoconus [5] and severity according to keratoconus grade, corneal tomography, axial curvature, anterior and posterior elevation best-fit sphere, visual acuity, pupil diameter, pachymetry, and manifest refraction. For more severe keratoconus patients, we selected the thickest ring, as well as in cases with higher preoperative astigmatism.

One or two progressive thickness segments were implanted immediately after tunnel creation according to the topographic pattern. One segment was implanted in oval or pellucid-like keratoconus patients. Two progressive thickness segments were implanted symmetrically in advanced asymmetric bow tie keratoconic patients. If the difference of keratometric values in the topographic map was lower than or equal to 5 D, we implanted the 150/250 µm ICRS version; if the difference was more than 5 D, we implanted the 200/300 µm ICRS version.

Initially, the cornea was marked at 3 and 9 o'clock positions using slit-lamp biomicroscopy to avoid cyclotorsion. The surgical procedure was performed under sterile conditions using topical anesthesia. The Purkinje reflex was chosen and marked as the central point under the microscope. The locations of the tunnels were planned according to cone location on topography. The tunnel depth was set at 75% of the thinnest corneal thickness, measured by Pentacam, on the tunnel location. The tunnel incision was made on the steepest topographic axis in advanced asymmetric bow tie keratoconus patients and 30° away from the steepest topographic axis in oval or pellucid-like keratoconus patients with an entry cut length of 1.10 µm and thickness of 1 µm. Should the incision be created on the steep axis, the ring would be only 10° from the incision. We performed the incision about 30° from the steep axis and implanted the ring at the flat axis to avoid any migration or extrusion of the segment.

The ring tunnels, which have an inner/outer diameter of 5/6.1 mm for SI6, were created approximately in 8 s using a 150 kHz femtosecond laser. IFS (IntraLase Corp., Irvine, CA, USA) was used in 22 eyes and VisuMax (Carl Zeiss Meditec, Jena, Germany) was used in 36 eyes. One or two rings were implanted according to the topographic pattern as outlined above.

Postoperatively, a bandage contact lens was applied until the first visit on postoperative day one. The postoperative regimen consisted of moxifloxacin 0.5% (Vigamox, Alcon, Fort Worth, TX, USA) and prednisolone acetate 1% QID (Pred forte, Allergan, Mougins, France) eye drops for 2 weeks.

Preservative-free artificial tear substitutes were also prescribed as needed for 3 months, and patients were instructed to avoid rubbing the eye.

The patients were examined postoperatively at one-year. In all postoperative follow-ups UCVA, BCVA, manifest refraction, biomicroscopic, and topographic examinations were performed.

Results

The study cohort consisted of 58 eyes of 53 patients. The mean age was 30.89 ± 11.90 years.

At 12 months follow-up, the mean preoperative UCVA was 0.71 (log MAR), and the mean postoperative UCVA was 0.28 (log MAR) with a gain of 0.43. At the 12-month visit, 50% of patients had a UCVA 20/32 (Snellen) or better, and 28% had 20/25 (Snellen) or better.

The mean preoperative BCVA was 0.28 (log MAR), and the mean postoperative BCVA was 0.10 (log MAR) with a gain of 0.18. At 12 months, 91% of patients had a BCVA of 20/32 (Snellen) or better, 76% had 20/25 (Snellen) or better, and almost half of the eyes (43%) achieved 20/20 (Snellen) (Fig. 2a, b).

We also categorized the visual acuity results by keratoconus phenotypes (Table 1) and by keratoconus severity (Table 2) although the sample of each group was not always large enough to produce statistically significant results, like for the snowman phenotype group.

The mean spherical power was reduced by 1.63 D, from − 2.56 D preoperatively to − 0.93 D postoperatively. Also, the mean refractive cylindrical error was significantly reduced by 1.81 D, from − 4.15 D preoperatively − 2.35 D postoperatively. Both differences were statistically significant ($P < 0.005$).

Like the refractive parameters, the topographic parameters also showed improvement. The maximal keratometry (Kmax) decreased from 54.21 D preoperatively to 50.93 D postoperatively, and the difference was statistically significant ($P < 0.005$).

Irregularity indices including, index of surface variance (ISV), index of vertical asymmetry (IVA), index of height decentration (IHD), and keratoconus index (Kindex) were significantly reduced (Table 3). Vertical coma was also significantly reduced. Furthermore, the minimum radius of curvature (Rmin), the inverse of corneal steepness, increased postoperatively, suggesting a reduction in the extent of the corneal cone. Central keratoconus index (CKI) demonstrated a non-statistically significant ($P = 0.08$) decrease after ICRS implantation. Additionally, vertical coma and front asphericity demonstrated statically significant reductions. However, there was a statistically significant increase in spherical aberration.

We did not encounter any intraoperative or postoperative complications, nor were required to remove any ICRS during the follow-up period of 1 year.

Discussion

ICRS implantation is an effective option for the treatment of spherocylindrical error and corneal irregularity in keratoconus and leads to improvement in visual acuity [3, 8, 9]. These PMMA ring segments are inserted on the mid-peripheral cornea in the deep stroma, and modify the central corneal curvature and corneal shape by flattening its central portion due to the newly introduced tension forces on the collagen structure in the stroma [10].

There are several ring types commonly used that differ in geometric profile: hexagonal (Intacs); elliptical (Intacs SK); curved (MyoRing); and triangular (Kerarings/Ferrara Rings). They differ in shape, inner/outer diameter (5.0–8.1 mm), arc length (90°–360°), optical zone (5.0–6.0 mm), and thickness (150–450 µm). Topographic and refractive results of ICRS implantation with different designs have been compared to determine the best ring for a given type of keratoconus [11, 12]. However, all these ICRSs have uniform thickness throughout the entire segment.

In this study, we used a new model of ICRS that has a progressive thickness in addition to all the other general features of a triangular regular ICRS. These include a cross-section with a 5 mm optical zone, 160 degrees arc length, 5.0/6.0 mm inner/outer diameter, and a 0.6 mm flat basis width.

Following the manufacturer instructions, we drew a line across the steep axis, dividing the corneal topography into two halves: flatter and steeper. By doing so, we were able to observe the irregularity difference between the flat and steep corneal regions. This difference was used in the nomogram to determine the type, arc length, and thickness of the ring.

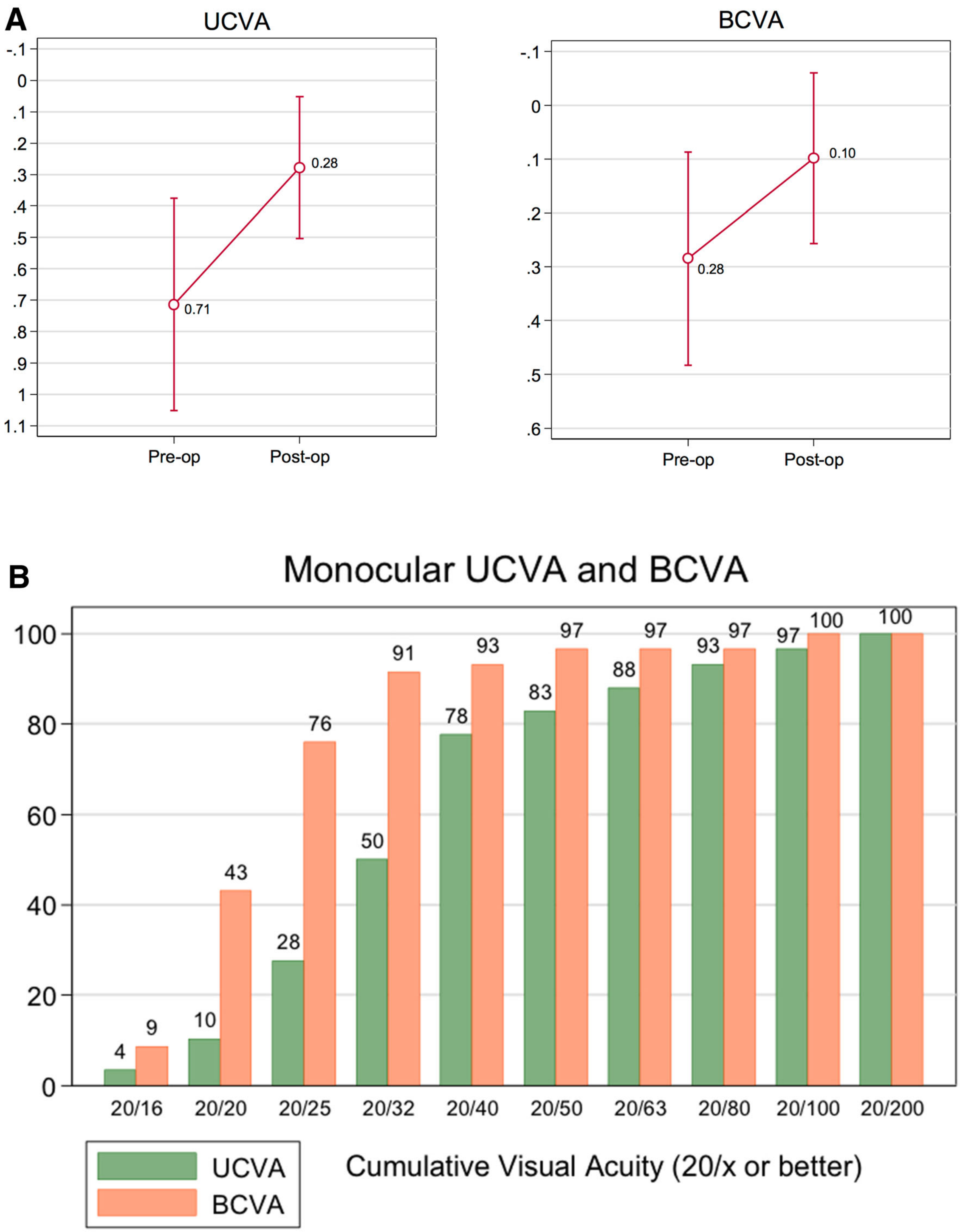

Fig. 2 **a** Uncorrected and best-corrected visual acuity progression from preoperative to postoperative. **b** Distribution of visual acuity groups from preoperative to postoperative

Table 1 Corrected and uncorrected visual acuity data (UCVA and BCVA) preoperative and at 12-month follow-up split by keratoconus phenotype

Visual acuity	Alfonso phenotype classification (log MAR)					
	Croissant		Duck		Snowman	
	Pre	Post	Pre	Post	Pre	Post
Mean UCVA	0.68	0.30	0.72	0.28	0.78	0.18
Gain UCVA	0.38		0.44		0.60	
Mean BCVA	0.31	0.13	0.28	0.09	0.26	0.08
Gain BCVA	0.18		0.19		0.18	
Subtotal	14	14	39	39	5	5

Table 2 Corrected and uncorrected visual acuity data (UCVA and BCVA) preoperative and at 12-month follow-up split by Amsler-Krumech (mean keratometry) classification

Visual acuity	Amsler- Krumech (Mean K)			
	1		2	
	Pre	Post	Pre	Post
Mean UCVA	0.66	0.27	0.81	0.29
Gain UCVA	0.39		0.52	
Mean BCVA	0.27	0.06	0.31	0.17
Gain BCVA	0.21		0.14	
Subtotal	38	38	20	20

When looking at the steep half of the topography, one half of that section, or quarter, tends to be significantly steeper or thinner than the other quarter. Since a standard ICRS has a continuous thickness, it produces the same amount of correction in both quarters, and this means that the steeper or thinner quarter is under-corrected compared to the flatter or thicker quarter. A variable thickness ICRS can compensate for the changes in the two quarters by adding greater thickness to the steeper quarter and less thickness to the flatter quarter. This can reduce postoperative astigmatism more than standard thickness ICRSs.

To choose if we need to implant a progressive thickness ring or a uniform thickness one (the standard version), we evaluate the anterior corneal topography and measure the dioptric difference along the planned path of the ring. If the difference of keratometric values on the topographic map is below 3 D, we implant a uniform thickness ring. If that difference is above 3 D, we implant a progressive thickness ring.

Then, we need to select the most appropriate progressive thickness ring among those available. We implanted rings with a thickness of 150/250 µm if the difference of keratometric values on the topographic map was between 3 and 5 D, and we implanted the 200/300 µm version if the difference was more than 5 D.

The thinner end of the ring was positioned in the thicker/flatter part of the cornea, and the thicker end was placed in the thinner/steeper portion, creating the effect of adding the greatest thickness at the part that is most needed thinner/steeper (Fig. 3). Progressive thickness rings are available in both clockwise and counterclockwise options that give a surgeon more flexibility to place the ring(s) precisely to mitigate the differences in the thickness between the two steep quarters (Fig. 4).

Following the ring implantation, we often make additional treatments such as topography-guided laser to regularize the cornea as much as possible, and we adjust the refraction accordingly, also using toric phakic intraocular lenses.

The number of segments implanted, the insertion location, and the use of multiple segments of different styles was decided based on the literature of standard ICRSs. Alio et al. [13] reported that the number of implanted segments should be based on the topographic pattern of the keratoconus: implanting two segments gives better outcomes in central cones, while one implant usually suffices in cases of inferior steepening. Siganos et al. [14] implanted two segments of 160° arc length, adjusting the thickness according to the patient's refractive error, and obtained satisfactory visual results.

Publications in the literature agree that standard ICRS implantation improves the UCVA and the BCVA [8, 15–17]. A 2007 12-month study recorded an improvement of UCVA of 1.7 Snellen lines and BCVA of 1.3 Snellen lines postoperatively [9]. In this study using the progressive thickness ICRS the improvement of UCVA and BCVA was a significant gain of 0.43 (log MAR) and 0.18 (log MAR), respectively. As well as the UCVA/BCVA, all topographic and refractive parameters showed improvement.

Table 3 Summary table demonstrated the summarized values and statistics for key keratoconus topography readings

	Pre-op mean	SD	Post-op mean	SD	Difference	*P*-values
KM front	46.86	2.10	44.94	2.26	1.92	< 0.05
KM back	− 13.83	0.50	− 6.84	0.50	− 6.99	< 0.05
Cylinder front	− 3.87	1.71	− 2.63	1.39	− 1.24	< 0.05
Cylinder back	− 0.94	0.45	− 0.71	0.42	− 0.23	< 0.05*
Pachymetry apex	469.71	37.60	0.02479	37.49	469.69	< 0.05*
Pachymetry thin	454.48	37.72	467.76	36.33	− 13.28	< 0.05*
ISV	88.16	30.75	65.57	25.75	22.59	< 0.05
IVA	1.02	0.43	0.76	0.36	0.26	< 0.05
CKI	1.05	0.03	1.04	0.03	0.01	0.08
IHD	0.10	0.05	0.08	0.89	0.02	< 0.05*
Kindex	1.24	0.11	1.14	0.10	0.10	< 0.05
Rmin	6.23	0.44	6.66	0.43	− 0.43	<0.05
Vertical coma	− 2.51	1.81	− 1.74	1.71	− 0.77	< 0.05
Spherical aberration	0.16	0.76	0.72	0.97	− 0.56	< 0.05
Asphericity front (8 mm)	− 0.72	0.30	− 0.39	0.35	− 0.33	< 0.05
Asphericity back (8 mm)	− 0.70	0.39	− 0.72	0.44	0.02	0.55

KM mean K readings, *ISV* index of surface variance, *IVA* index of vertical asymmetry, *CKI* central keratoconus index, *IHD* index of height decentration, *Kindex* keratoconus index, *Rmin* minimum radius of curvature. *P*-values without an *demonstrated a normal distribution and were calculated using a paired *t*-test. Those with an *were not normally distributed and the Wilcoxon signed-ranks test was used instead

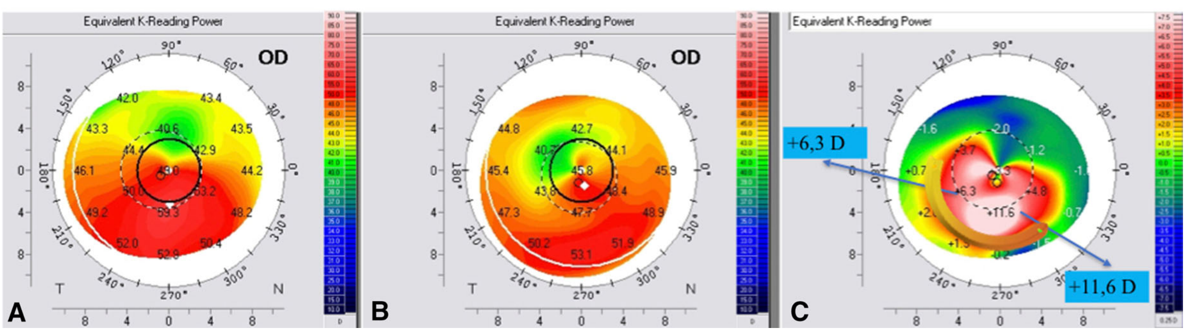

Fig. 3 **a** Pre- and **b** postoperative corneal ropography, with **c** difference map and schematic ring position

In 2019, using the progressive thickness ICRS in duck and snowman phenotypes, Prisant et al. [18] reported an improvement of 0.4 log MAR in UCVA and 0.1 log MAR in BCVA. There was also a reduction of the mean spherical error from − 1.74 to − 0.9 D, and the mean cylindrical error from − 4.22 to − 2.01 D. The Kmax decreased by 3.3 D.

Prisant et al. [18] reported the results at three months. We present similar topographic and refractive results at the one-year mark (except for the BCVA we obtained, which shows a higher improvement), which can be considered the point where the correction is stable.

Like Prisant et al. [18] we also categorized the visual acuity results by keratoconus phenotypes (Table 1) (Fig. 5), and by keratoconus severity (Table 2). We report that the progressive thickness ICRS improved more significantly the UCVA particularly when implanted in the snowman phenotype. However, the sample is too small to consider the difference statistically significant. We found slightly different results from Prisant in our phenotypes groups

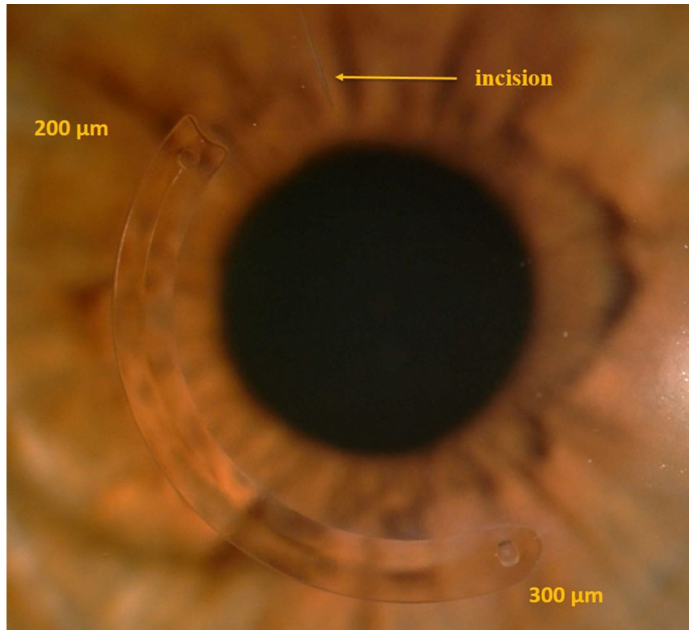

Fig. 4 Surgical picture of an implanted ring

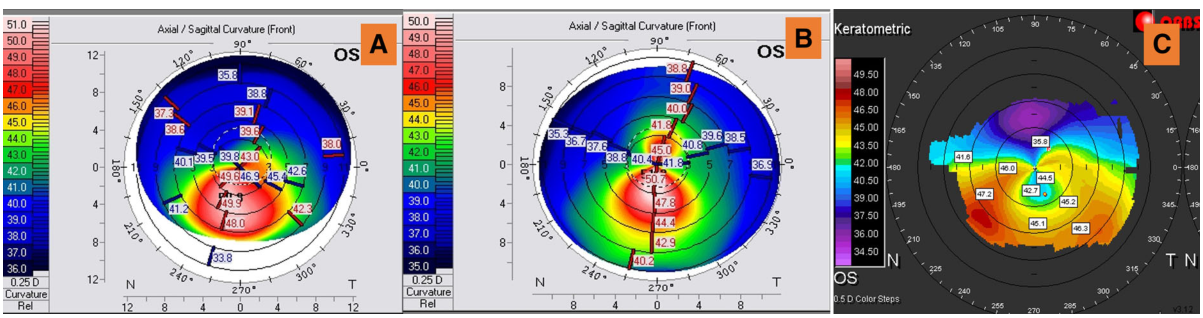

Fig. 5 Morphological classification of keratoconus phenotypes. **a** Oval or duck, **b** asymmetric bow tie or snowman and **c** pellucid-like keratoconus

and we think that further studies focused on the implantation of the progressive thickness ICRS on specific keratoconus phenotypes are needed to evaluate the efficacy of the device in different keratoconus morphologies.

Also, we noticed that with more severe keratoconus, the greater the effect of the segment on the UCVA. Conversely, the less severe the keratoconus stage, the more the ICRS seems to improve the BCVA both in absolute terms of gains and of nearing perfect vision.

The majority of irregularity indices (ISV, IVA, KI, IHD, and IHA) were significantly reduced (Table 3). The specifics of each index are outside of the scope of this article but are reviewed by Salomão et al. [19] Together, reduction in these indices suggests a reduction in corneal irregularity after ICRS implantation. One irregularity index, CKI, failed to reach significance although it did demonstrate a trend for improvement after ICRS implantation. CKI defines the ratio between the mean peripheral radius values divided by the central values. It is typically high in central keratoconus with values > 1.03 thought to be pathological [20]. Our patients had a preoperative CKI mean of 1.05, which suggests that our cohort did not have significantly raised CKI, which reduces the sensitivity of this measure in irregularity analysis and may explain why it failed to reach significance. Rmin, the inverse of corneal steepness, increased postoperatively suggesting a reduction in the severity of the corneal cone.

It is interesting to note that pachymetry, both apical and at the thinnest point, increased from 469.7 to 479µ and from 454.5 to 467.8µ, respectively—a change of 9µ and 13µ, respectively. However, both the anterior and posterior elevation decreased from 23.2 to 12.3µ and from 59.4 to 38.4µ, respectively—a change of 11µ and 21µ, respectively, after the progressive ICRS implantation. We hypothesize that a significant tissue reorganization took place not only above the ring itself but also in the optical zone inside the inner diameter of the rings. Further studies are required to investigate if the implantation of progressive thickness ICRS induces corneal tissue changes and the curvature gradient of the cornea.

Technological advances have increased the demands for newer classification systems that aid diagnosis as well as treatment planning. The existing systems do not combine topographical and tomographical parameters as agreed upon in the global consensus on keratoconus [21].

In conclusion, we found that progressive thickness ICRS implantation is a long-term, effective method for the improvement of UCVA and BCVA in an advanced asymmetric bow tie, oval, or pellucid-like keratoconus eyes. The retrospective nature, small sample of treated eyes, and the absence of a control group were limitations of this study. Further research is needed to evaluate the safety, stability, and efficacy of this newly developed ICRS in greater detail, especially long-term results.

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Compliance with ethical standards

Conflict interest :Drs. Coşkunseven and Ambrósio are paid consultants for Mediphacos. Drs. Smorádková, Sánchez León, Sahin, Kavadarlı and Jankov have no conflict of interest.

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