• Clinical Research •

Double intrastromal corneal ring segment implantation: a new approach for improved clinical outcomes in keratoconus patients

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Abstract

● **AIM:** To evaluate the clinical outcomes after subsequent implantation of a new intrastromal corneal ring segment (ICRS) model followed by an additional short-arc ICRS implant in keratoconus patients.

● **METHODS:** This retrospective single-arm cohort study evaluated 25 eyes of 21 keratoconus patients implanted with the new ICRS followed by 140-arch length ICRS (140-ICRS) implantation. Uncorrected distance visual acuity (UDVA, logMAR), corrected distance visual acuity (CDVA, logMAR), sphere, astigmatism, keratometry, spherical equivalent (SE), and asphericity were compared preoperatively and postoperatively after both ICRS implantation.

● **RESULTS:** The average follow-up time after 140-ICRS implantation was 6.40±2.20mo. The mean preoperative UDVA improved from 1.27±0.14 preoperative to 0.52±0.26 after both ICRS implantation (P=0.03). The mean sphere value reduced from -5.34±2.74 preoperatively to -2.06±1.84 postoperatively (P<0.001) after the first ICRS implantation and decreased to -0.59±1.54 postoperatively (P<0.001) after 140-ICRS implantation. The mean preoperative astigmatism was -3.72±1.56 and improved to -2.82±1.08 after the first ICRS implantation, and following the 140-ICRS implantation, the mean astigmatism was -1.37±0.67 (P=0.001). The SE and asphericity changes were statistically significant (P<0.001). The researchers did not find intraoperative or postoperative complications for both procedures.

● **CONCLUSION:** The combination of 2 different ICRSs can efficiently regularize the cornea, reduce the SE, and improve visual acuity in selected keratoconus patients.

● **KEYWORDS:** keratoconus; cornea; intrastromal corneal ring segments; refractive surgery
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INTRODUCTION

Keratoconus treatment has evolved with time. The disease is a progressive ectatic cornea disorder that leads to corneal thinning, protrusion, anterior and posterior surface distortions, and aberrations[1]. It most often manifests in the second decade of life and has a prevalence of 1 per 2000 people in the overall population[2]. Nonsurgical options for mild to moderate cases are usually preferred[3]. Advanced keratoconus, however, requires a more invasive approach, usually surgical interventions, for example, lamellar or penetrating keratoplasty.

Correction of corneal diseases that have their biomechanical properties altered can be achieved using the ancillary technology of intrastromal corneal ring segments (ICRS). ICRS has proven to be effective over the decades in partially correcting these altered characteristics. It has been demonstrated to reduce corneal steepening, decrease irregular astigmatism, and enhance visual acuity (VA)[3-5]. While it is considered a less invasive surgical option, ICRS can delay the need for corneal transplantation in patients who do not have corneal scarring and have low contact lens tolerance. Although the ability of ICRS to halt keratoconus progression remains debated in the literature, it appears to play a role in managing the condition[6-9].

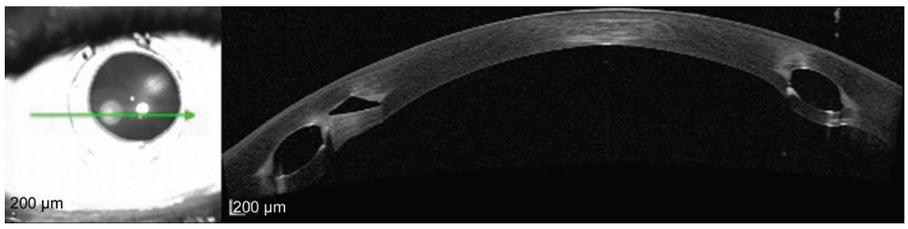

Figure 1 Anterior segment optical coherence tomography displaying both ICRSs (HM-ICRS fusiform and 140-ICRS triangular) ICRS: Intrastromal corneal ring segment; HM: High myopia.

ICRS implantation is very effective in various morphologies of keratoconus (oval, bow tie, nipple)[10-12]. The procedure aims to reshape the cornea, reduce steepening, make the anterior surface more regular, reduce aberrations, and improve VA.

Patients today are more demanding, even in keratoconus cases, in which the refractive outcome used to be secondary. New approaches are being developed to improve VA and provide better refractive outcomes to answer patients' high expectations towards the refractive outcome after ICRS implantation. One new surgical approach combines two distinct ICRS types to improve refractive and visual outcomes in keratoconus patients[10].

Recently, a new model of ICRS was designed to reduce myopia, allowing subsequent photorefractive keratectomy (PRK) for myopia correction[13]. By combining these two techniques, the objective is to have a corneal tissue-saving procedure as a surgical option for the correction of moderate to high myopia.

This new ICRS was initially named high myopia (HM)-ICRS, as it was perceived to correct high degrees of myopia. Previous clinical studies demonstrated that the myopia reduction ranged from 3.0 to 5.0 D, on average[13]. Despite that, the name remained HM-ICRS, a refractive device beneficial for low to moderate myopia. The Ferrara HM-ICRS has a fusiform shape, a long arch length (320), a diameter of 5.7 mm, and 400 µm thickness. This model can correct most of the myopia besides allowing subsequent additional ICRS implantation in a smaller optical zone (OZ), to enhance the effect of the former.

This study intends to evaluate the clinical results after implantation of a new ICRS (HM-ICRS) in patients with keratoconus, followed by the implantation of a 140 arch length ICRS (140-ICRS; Figure 1). This combined procedure could reduce myopia and astigmatism while improving spherical equivalent (SE) value, uncorrected distance VA (UDVA), keratometry, and corneal regularity in keratoconus patients.

SUBJECTS AND METHODS

Ethical Approval This single-arm cohort retrospective study assessed the impact of visual rehabilitation, clinical outcomes, and safety of combined implantation of a novel ICRS design segment and a conventional ICRS segment in patients with keratoconus. The ophthalmological evaluations and surgeries were performed at a private clinic (Private Eye Clinic, Belo Horizonte). It was accepted by the Boards/Ethics Committee of the Department of Refractive Surgery, Ciências Médicas Eye Institute of Faculty of Minas Gerais, and Ennio Coscarelli Eye Clinic, Belo Horizonte and follows the ethical principles of the Declaration of Helsinki. ICRS implantation description, inclusion, and exclusion criteria were depicted to all study participants who provided written informed consent. The chart review comprised cases operated from December 2019 to February 2022, with clinical follow-up until July 2022. It was registered at: https://plataformabrasil.saude.gov.br under the number: 58896122.6.0000.5134.

Study Design The primary inclusion criteria were: 1) keratoconus diagnosis–central type with high asphericity; 2) maximum keratometry (Kmax) <60 D; 3) myopia >3.0 D with or without concomitant astigmatism; 4) clear corneas. Corneal topography readings using Pentacam (Oculus Optikgeräte GmbH, Gernany) were considered screening tools during the selection stage. Preoperatively and postoperatively, Scheimpflug tomography (Oculus Pentacam, Germany) readings were used to assess all tomographic evaluated parameters.

Exclusion criteria were: 1) previous corneal or intraocular surgical procedures; 2) local or systemic infections present during surgery; 3) corneal scars; 4) other vision-limiting disorders besides keratoconus.

Clinical Measurements and Data Collection Data was retrieved from medical records and extended from December 2019 to July 2022 to include clinical data of follow-up, preserving patient identity. All patients included in the study had complete ophthalmological evaluation preoperatively and postoperatively. The clinical assessment included the manifest refraction, UDVA, CDVA, SE, central pachymetry, topographic corneal astigmatism, minimum-maximum keratometry (K) values, and corneal asphericity.

Ophthalmologic examination and supportive tests mentioned were performed preoperatively, postoperatively, after the final visit of the first procedure (HM-ICRS segment implantation), at the last visit after the second procedure (140 arc-length ICRS segment implantation), and after 6mo on the final follow-up visit. After the surgical procedures, the patients were evaluated postoperatively at 1, 14, 30, 60, 90, 120, and 180d.

CDVA, refraction, slit-lamp examination, tonometry, and corneal topography were evaluated preoperatively and postoperatively. Higher-order aberrations (HOAs) were measured in scotopic conditions after 10min of dark adaptation, and the data were assessed within a 5 mm analysis diameter.

Before the preoperative examination, contact lens wearers who were wearing rigid lenses were discontinued for at least 4wk and for at least 2wk for those who were wearing soft lenses.

Clinical examinations were performed according to the guidelines of the 320-ICRS multicentric study.

First Surgical Procedure (HM-ICRS) The corneal surgical reference point was the Purkinje reflex marked with a Gentian violet solution. It was performed under topical anesthesia and complied with all sterile conditions. All patients underwent femtosecond laser-assisted (LDV, Ziemer, Switzerland, Inc.) to create the ring channel, performed by the same surgeon (Coscarelli S), followed by implantation of the first ICRS segment (HM Ferrara Ring, AJL, Ophthalmic S.A, Spain). The diameters of the inner and outer channels were adjusted to 5.55 mm and 7.32 mm, respectively, using 1.30 J of energy. Tunnel depth was set at 75% of the thinnest corneal thickness point on the desired location in the femtosecond laser. The HM-ICRS (400 μm) was implanted after channel creation before the vanishing of the bubbles and final positioning with the assistance of a Sinskey hook. The HM-ICRS was placed with equidistant ends (20° from each ICRS end) apart from the entry incision.

The postoperative care included moxifloxacin 0.5% with dexamethasone 0.1% (Vigadexa, Alcon, Inc., Switzerland) 4 times a day for 7d. Artificial eyedrops were used 2 to 4 times daily for at least 30d.

Surgical Planning Before the Implant of the Second ICRS The main goal of placing the HM-ICRS was to improve corneal regularization and myopia reduction. The surgical planning for implantation of the 140-ICRS was not done following the Ferrara Nomogram. The nomogram indicates the ICRS thickness to be implanted in accordance with topographic astigmatism, as follows: 1) up to 4.00 D – one 150 μm ICRS; 2) from 4.00 to 8.00 D – one 200 μm ICRS; 3) >8.00 D – one 250 μm ICRS. However, a 200 μm 140-ICRS was implanted in all cases to standardize the procedure and the study.

Second Surgical Procedure (Conventional 140-ICRS) The additional surgery was performed within a minimum of 3mo after the first procedure. The same surgical technique was applied for the second ICRS, assisted by the femtosecond laser (LDV, Ziemer, Switzerland, Inc.) to produce the ring channel. The additional ICRS, a 200 μm 140 arc length, was placed in a tunnel created inside the inner diameter of the HM-ICRS. The diameters of the inner and outer channels were adjusted to 4.4 and 5.72 mm, respectively.

The postoperative regimen was replicated based on the first surgical procedure.

Statistical Analysis The statistical analysis was performed using SPSS (version 26.0) and VECTrAK (version 2.4.6; ASSORT Pty, Ltd; Cheltenham, Australia). The sample profile description was done by absolute frequency, relative frequency, average, and standard deviation.

Data normality was verified by the Shapiro-Wilk test. The parameters comparison (HM-ICRS and after 140-ICRS) was done using the Friedman ANOVA test followed by pairwise analysis corrected by Bonferroni. A 5% significance level was considered for all analyses (P<0.05).

Sample Size The size sample was calculated from the difference and average variation of data using G Power software (version 3.1). We verified a minimal estimate of 12 eyes [95% confidence interval (CI), 8 to 22], with a significance level of 5%, a CI of 95%, and a sample power of 80%.

RESULTS

Twenty-five eyes of 21 keratoconus patients with ICRS-HM implantation followed by 140-ICRS insertion were evaluated. There were 13 females and 8 males with a mean age of 28.95±8.34 (range 14 to 40 years old).

The mean follow-up time after 140-ICRS implantation was 6.40±2.20mo. The mean UDVA improved from 1.27±0.14 logMAR preoperative to 0.52±0.26 logMAR after ICRS-HM and 140-ICRS implantation (P=0.03). The mean preoperative CDVA was 0.36±0.19 logMAR and improved to 0.34±0.17 logMAR after HM-ICRS implantation. Following the 140-ICRS implantation, the mean CDVA was 0.27±0.15 logMAR (P=0.22; Table 1). The mean sphere value decreased from -5.34±2.74 preoperatively to -2.06±1.84 postoperatively (P<0.001) after HM-ICRS insertion and decreased to -0.59±1.54 postoperatively (P<0.001) after 140-ICRS implantation. The mean preoperative SE was -7.20±3.13 and decreased to -3.47±1.93 after HM-ICRS implantation. Following 140-ICRS, the SE was -1.27±1.53, statistically significant (P<0.001; Table 1).

The mean keratometry (KM) reduced from 47.08±4.16 D preoperatively to 45.54±3.10 D (P<0.01), after HM-ICRS. After 140-ICRS implantation, the mean keratometry was 43.72±3.64 (P<0.01). The change in topographic astigmatism was statistically significant (P=0.001; Table 1). After both procedures, the asphericity increased from -0.72±0.29 preoperatively to 0.25±0.71 (P<0.001) postoperatively. One line of CDVA was lost in 4% of eyes (Figure 2). In 63% of cases, there was a gain of at least one line of CDVA.

In 43% of eyes, the UDVA remained the same or better than the CDVA. In 61%, the UDVA was within 1 line of the CDVA (Figure 2). No intraoperative or postoperative complications were observed for both procedures (HM-ICRS and 140-ICRS implantation).

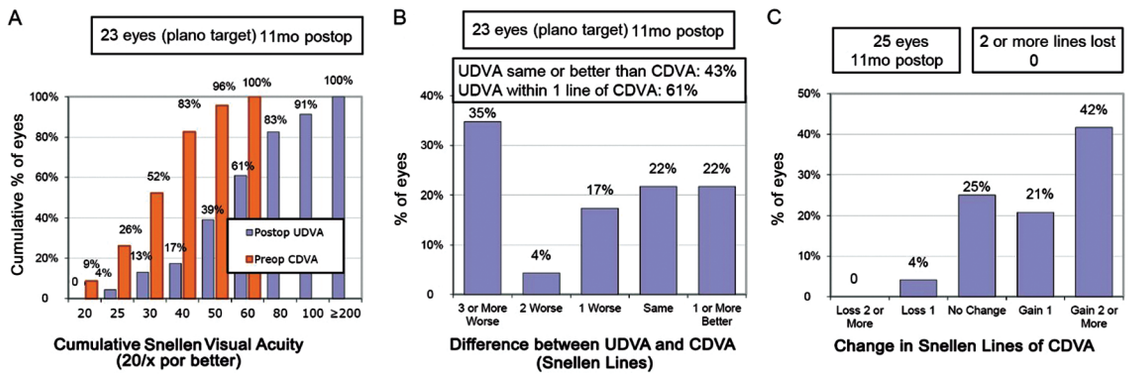

Figure 2 Changes in Snellen lines postoperatively A: UDVA; B: UDVA *vs* CDVA; C: CDVA lines won/lost. UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity.

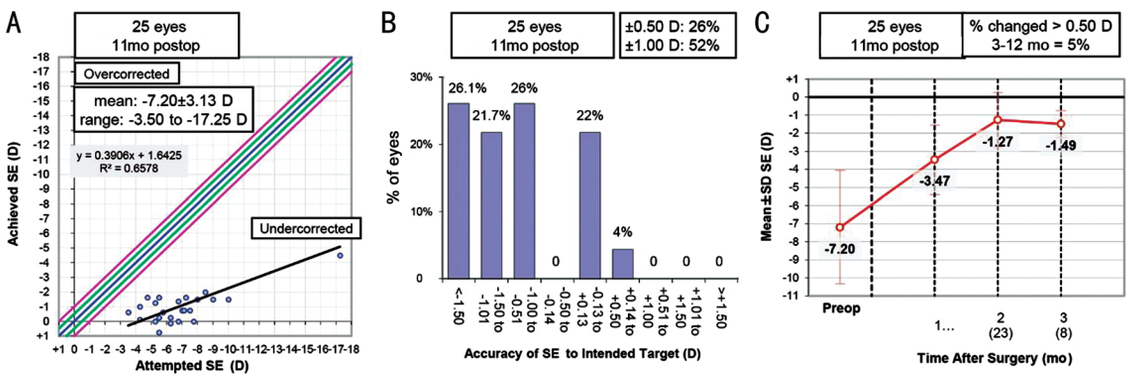

Figure 3 Refractive predictability based on SE after HM-ICRS and 140-ICRS A: SE attempted *vs* achieved; B: SE accuracy; C: SE stability. SE: Spherical equivalent; ICRS: Intrastromal corneal ring segment; HM: High myopia.

Table 1 Pre and postoperative data mean±SD

Items	Pre HM-ICRS	Post HM-ICRS	Post 140-ICRS	Last follow-up	*Z*	*P*[a]
Sphere	-5.34±2.74	-2.06±1.84	-0.59±1.54	-0.72±0.60	45.51	<0.001
AST	-3.72±1.56	-2.82±1.08	-1.37±0.67	-1.53±0.77	25.72	0.001
CDVA	0.36±0.19	0.34±0.17	0.27±0.15	0.28±0.14	2.45	0.22
K1	46.10±3.93	44.59±2.98	42.83±3.59	43.74±3.37	29.21	0.007
K2	48.97±4.56	46.54±3.34	44.63±3.73	45.40±4.00	11.27	0.012
KM	47.08±4.16	45.54±3.10	43.72±3.64	44.54±3.61	11.73	0.008
Q	-0.72±0.29	-0.19±0.55	0.25±0.71	-0.01±0.98	19.50	<0.001
SE	-7.20±3.13	-3.47±1.93	-1.27±1.53	-1.49±0.75	23.53	<0.001

[a]Friedman ANOVA test. ICRS: Intrastromal corneal ring segment; HM: High myopia; CDVA: Corrected distance visual acuity; SE: Spherical equivalent; AST: Astigmatism, K1: Keratometry values (flat); K2: Keratometry values (steep); KM: Keratometry values (mean); Q: Corneal asphericity.

Regarding the SE accuracy after both procedures: 26% of eyes were within ±0.50 D, and 52% of eyes were within ±1.00 D (Figure 3). Concerning refractive astigmatism after ICRS implantation: 43% of eyes were within ±1.00 D (Figure 4). There was a significant under-correction of SE after the procedures. The postoperative SE kept stable on the follow-up.

The vectorial analysis showed a significant reduction of topographic and refractive astigmatism after both procedures (Figure 5). The reduction in centroid values was statistically significant in both analysis (P<0.05).

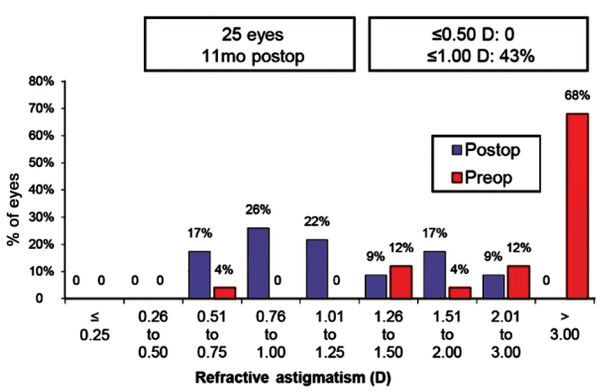

Figure 4 Refractive astigmatism (D) pre and postoperative.

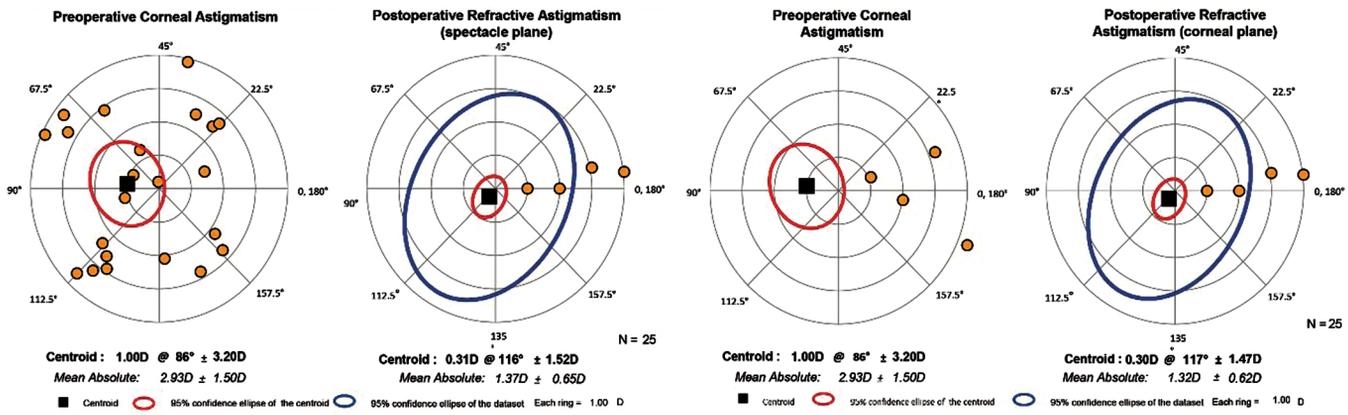

Figure 5 Vectorial analysis of refractive and topographic astigmatism Double angle polar plots for corneal astigmatism and topographic astigmatism, before and after the 2 procedures.

Table 2 Post-hoc analysis by Bonferroni corrected pairwise from preop. to last follow-up

Pairs	Sphere	AST	K1	K2	KM	Q	SE
Pre HM-ICRS *vs* post HM-ICRS	0.488	1.000	1.000	0.878	0.599	0.728	0.728
Pre HM-ICRS *vs* post 140-ICRS (last follow-up)	0.002	0.121	0.317	0.121	0.317	0.040	0.006
Pre HM-ICRS *vs* post 140-ICRS	0.001	0.012	0.008	0.008	0.004	0.001	0.000
Post HM-ICRS *vs* post 140-ICRS (last follow-up)	0.395	0.121	1.000	1.000	1.000	1.000	0.488
Post HM-ICRS *vs* post 140-ICRS	0.156	0.012	0.071	0.488	0.488	0.040	0.022
Post 140-ICRS (last follow-up) *vs* post 140-ICRS	1.000	1.000	1.000	1.000	0.878	0.728	1.000

ICRS: Intrastromal corneal ring segment; HM: High myopia; SE: Spherical equivalent; AST: Astigmatism, K1: Keratometry values (flat); K2: Keratometry values (steep); KM: Keratometry values (mean); Q: Corneal asphericity.

Biomicroscopy Examination At the last postoperative follow-up visit, the ICRSs were successfully implanted in all eyes and no complications were diagnosed.

DISCUSSION

ICRS implantation in keratoconus treatment has been proven safe and effective[4,10-11]. ICRS were used for myopia correction in the past, but due to their low predictability, they were replaced by other surgical techniques, especially the excimer laser. Today, ICRS is an essential tool for treating ectatic and irregular corneas, including post-refractive surgery corneal ectasia.

Recently, long arch ICRS have been used to treat advanced keratoconus[14-16]. Based on the same working principles as the long-arch segments ICRS, a new model was idealized for the correction (or reduction) of myopia (HM-ICRS). Alfonso *et al*[15] in a study using a 300 degree of arch ICRS, found that postoperatively, the CDVA improved by two or more lines in 45.2% of the eyes, increased by one line in 19.1%, and remained unchanged in 35.7% of the eyes, and none of the patients lost lines of CDVA. The SE decreased from a preoperative value of -4.24±3.33 D to a 6-month postoperative value of -2.78±2.61 D (P<0.0001). Supporting results were found in a study using an ICRS with 320 arch length[14]. Compared with the HM-ICRS, the 300 and 320-ICRS induce more corneal flattening and less SE reduction due to the smaller OZ (5 mm) of these long arch segments.

The sequential treatment of HM-ICRS followed by 140-ICRS in patients with moderate to high myopia, astigmatism, and keratoconus, significantly reduces the SE while improving UDVA, KM, and corneal regularity. Using a Bonferroni corrected pairwise analysis (Table 2), we clearly see a boost effect after the implantation of the second segment. Both ICRS act synergistically, improving their effectiveness.

The predictability and accuracy of refractive correction after HM-ICRS implantation alone showed to be poor, as showed by a previous study[13]. However, it allows, safely, due to its 6 mm OZ, to implant an additional 140-ICRS, which can decrease not only part of residual myopia, but also significantly reduce astigmatism.

Distance between the ICRS implant and tunnel entry is a significant and well-known risk factor for displacement that could lead to infections and corneal ulcers[16-17]. The HM-ICRS, as 320-arc length ICRS, should be left 20 degrees on each side, far from the incision, which makes it safer to be used. Moreover, at the tunnel positioning, we aim to slightly decenter it inferiorly to leave the ICRS farther from the limbus, thus reducing the risk of neovascularization of the incision and tunnel. Therefore, besides the pupil and light reflex on the cornea, the limbus is an important point of reference for the HM-ICRS implantation. It should be placed equidistant from the superior and inferior limbus.

For the placement of the 140-ICRS, we should consider the position of the previously implanted HM-ICRS as the point of

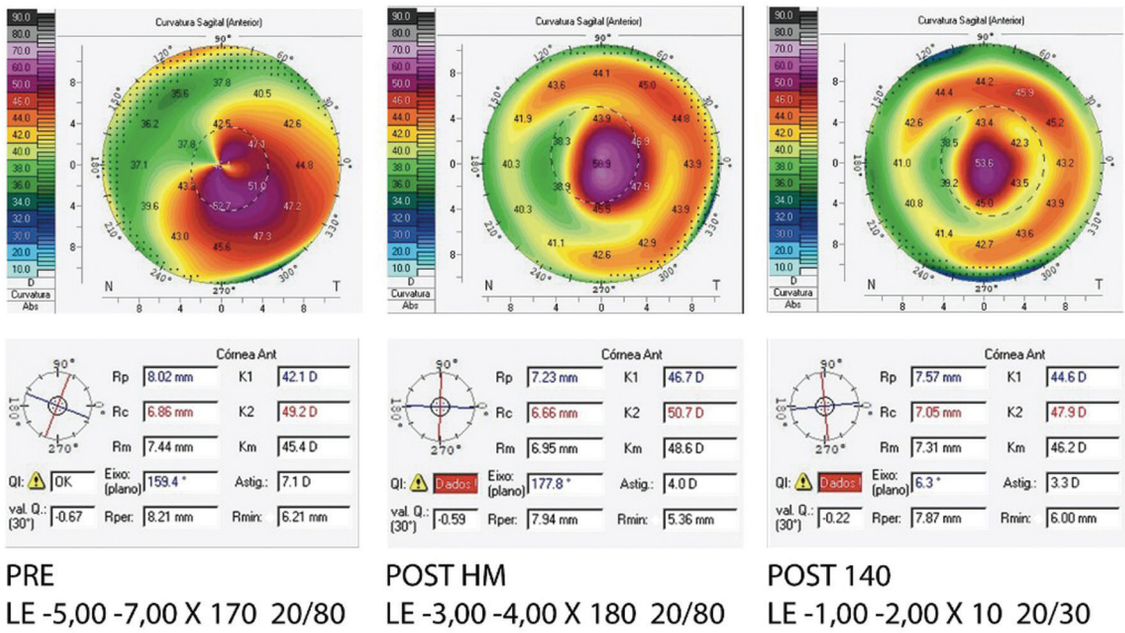

Figure 6 Pre HM-ICRS; post HM-ICRS; post 140-ICRS Pentacam ICRS: Intrastromal corneal ring segment; HM: High myopia.

reference for the segment positioning and implant it as close as possible to the HM-ICRS. In all cases, the 140-ICRS was implanted with the femtosecond laser in this study, but it can be done using the manual technique as well[18].

The HM-ICRS is available on a fixed thickness of 400 μm. Therefore, this only model of HM-ICRS is used for every case, which is helpful in parametrization and avoidance of a possible influence related to ICRS depth. In the majority of cases, the relation ICRS thickness/cornea thickness (ICRS-T/cornea-T) in the track was about 60% to 65%. Usually, 50% of the cases have been considered safe for circumventing future extrusion in keratoconus cases using the late-developed technique, manual. However, the corneal metabolism at a 6 mm OZ is different compared with a 5 mm OZ (where this rule may apply)[19]. Therefore, a 60% ICRS/cornea thickness ratio is safe in these cases.

Consequently, the risk of extrusion is minimized even with this relation at a 6 mm OZ. For the 140-ICRS implanted at a 5 mm OZ, the 50% ratio should be applied.

The principal constraints of this clinical study are the small sample and the short-term follow-up. These could also partially explain why the variable CDVA within the studied group (P=0.22; Table 1) and its variation were not in the range of significance. Currently, we are conducting a more extensive sample study and planning to follow the patient for an extended period to evaluate the long-term refractive stability of the combination of procedures.

In most cases there was significant VA improvement. In 63% of cases, there was a gain of at least one line of CDVA. One line of CDVA was lost in 4% of eyes. It reinforces the safety and efficacy of the procedure. The UDVA remained the same or was better than CDVA in 43% of eyes. In 61%, the UDVA was within 1 line of CDVA.

The procedures showed to be safe, as there were no complications (intraoperative or postoperative) after the procedures (HM-ICRS and 140-ICRS implantation). The use of femtosecond laser for tunnel creation ensures deep and well-centered implants[20].

The SE accuracy after both procedures was: 26% of eyes were within ±0.50 D and 52% of eyes were within ±1.00 D. It could be considered as a poor refractive outcome. However, the goal of this approach is not the same as refractive surgery. As we are treating keratoconus patients, plano is not the goal, but reducing as much as possible the SE. In most cases, we achieve reduction of myopia (most of it) and astigmatism (less than myopia) after HM-ICRS implantation. After ICRS-140 implantation, there is usually a reduction of astigmatism (most of it), myopia (less than astigmatism), and significant corneal regularization improvement (Figure 6).

As expected, there was significant under correction of SE after the procedures. The postoperative SE kept stable on the follow-up.

The vectorial analysis showed a significant reduction of topographic and refractive astigmatism after both procedures. The addition of the 140-ICRS plays a significant role in reducing astigmatism, therefore, most of this change is attributed to the 140-ICRS and not the HM-ICRS.

One of the main drawbacks of this approach is the need of two surgical procedures. The surgical procedures (HM-ICRS and 140-ICRS implantation) should be done at least 3mo apart from each other. Only after achieving the full effect of HM-ICRS the next surgical plan for the 140-ICRS must be made.

As the refraction, keratometry, and steepest location may vary after HM-ICRS implantation, the 3-month time between procedures is mandatory to get stable and reliable data and then proceed with the surgical planning using the 140-ICRS.

Despite being a very controversial theme, the personal experience of the authors shows that the ICRS placement seems to have an effect on reducing keratoconus progression[4,21]. As this is the very first report of a double ICRS implantation in keratoconus, we do not know how this combination could influence keratoconus progression. However, if there is any correlation between the amount of tissue implanted into the cornea stroma and the progression of keratoconus, at least, in theory, this approach (double ICRS implantation) could be beneficial in terms of delaying keratoconus progression[7,22].

The main goal in this association of procedures is to obtain the best possible CDVA and least possible SE. It is well established in the literature the effect of HM-ICRS on myopia reduction. Besides, the short arch ICRS is mainly used for the correction of astigmatism. Therefore, this association of ICRS is useful for the reduction of both myopia and astigmatism and, at the same time, improving aberrations by the decrease in corneal asymmetry and corneal irregularity caused by the ectasia.

The combination of different types of ICRS is a fine-tuning approach to achieving better clinical outcomes for keratoconus patients with moderate to high myopia associated with moderated astigmatism. It has been shown to be a safe and effective procedure. Long-term studies may be conducted to warrant the stability of the data presented in this paper.

Value Statement Previous systematic research and studies have shown that using a short arch segment of ICRS in patients with keratoconus is well-established for reducing astigmatism. However, improving visual outcomes for patients with moderate to advanced keratoconus, particularly those with moderate to high myopia and astigmatism, remains challenging for corneal surgeons. This study demonstrates that a combination of a long arch ICRS segment followed by the implantation of a short 140-ICRS segment in selected keratoconus patients can efficiently and safely reduce SE, decrease astigmatism, and improve aberrations by decreasing corneal asymmetry. Notably, this strategy has shown enhanced visual outcomes for keratoconus patients with moderate to high myopia associated with moderate astigmatism after 6mo of follow-up.

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