Original Research Article



Outcomes of a 320-degree intrastromal corneal ring segment implantation for keratoconus: Results of a 6-month follow-up European Journal of Ophthalmology I-8 © The Author(s) 2018 Article reuse guidelines: sagepub.com/journals-permissions DOI: 10.1177/1120672118818018 journals.sagepub.com/home/ejo



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Abstract

Importance: This study shows that a newer long-arc length intrastromal corneal ring segment is efficient and safe for keratoconus treatment.

Background: To evaluate visual, tomographic results and complications of a 320-degree intrastromal corneal ring segment implantation with the femtosecond laser for keratoconus treatment.

Design: A prospective, nonrandomized, and interventional study.

Participants: A total of 34 eyes of 31 patients diagnosed with keratoconus were enrolled.

Methods: Patients were divided into two groups based on the strategy used for 320-degree intrastromal corneal ring segment thickness selection. In one group, this selection was based on spherical equivalent (SE group) and in the other on the mean asphericity (Q group). The uncorrected and corrected distance visual acuities, spherical equivalent, K_1 , K_2 , K_m , K_{max} , and mean asphericity (Q) on corneal tomography were evaluated preoperatively and at 3 and 6 months postoperatively. For astigmatism improvement, we analyzed the corneal tomographic vectorial astigmatism change preoperatively and at 6 months postoperatively. The mean follow-up period was 6.63 \pm 0.96 months.

Results: The mean uncorrected distance visual acuity and corrected distance visual acuity improved with a significant spherical equivalent improvement (p < 0.05), with no differences between the 320-degree intrastromal corneal ring segment groups. All corneal tomographic parameters improved significantly (p < 0.05) between the preoperative and postoperative intervals, with a significant better performance when we used spherical equivalent for the 320-degree intrastromal corneal ring segment thickness selection. Finally, the mean vectorial corneal tomographic astigmatism significantly improved after 6 months, again with no differences between groups.

Conclusion: This study suggests that implanting a 320-degree intrastromal corneal ring segment is a safe and effective procedure for treating patients with keratoconus. It also suggests that for thickness selection spherical equivalent is the better strategy.

Keywords

Keratoconus, astigmatism, myopia, refractive surgery

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Introduction

Keratoconus is a progressive, bilateral, and asymmetric corneal ectatic disease, characterized as steepening in corneal curvature with the corresponding decrease in its thickness, resulting in gradual visual acuity worsening and patient inability to perform daily activities.¹

Intrastromal corneal ring segments (ICRS) are implanted in the corneal stroma to induce changes in corneal shape ¹Hospital Oftalmológico de Brasília (HOB), Brasília, Brazil ²Private Clinic, Belo Horizonte, Brazil ³Private Clinic, Pará de Minas, Brazil ⁴Escola Paulista de Medicina (EPM), Federal University of São Paulo (UNIFESP), São Paulo, Brazil

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Guilherme Andrade do Nascimento Rocha, Hospital Oftalmológico de Brasília (HOB), SGAS 607, Módulo G, Avenida L2 Sul, Brasília 70.200-670, Brazil. Email: drguilhermerocha@hotmail.com and refractive power, leading to better visual performance, as predicted by the Barraquer² thickness law.

The first implanted intrastromal corneal rings were implanted for low myopia treatment and were a full ring, with an arc length of 360 degrees.³ After the introduction of *excimer laser* for corneal refractive surgery, the rings were abandoned as a refractive procedure, because of the low predictability of ametropia correction. Intracorneal ring segments have been used to correct ectatic corneal diseases to reduce the corneal steepening, reduce irregular astigmatism, and improve the visual acuity.⁴ Many studies have demonstrated the efficacy of intrastromal rings to treat many corneal conditions like keratoconus, post-LASIK (laser-assisted in situ keratomileusis) corneal ectasia, post-radial keratotomy ectasia, astigmatism, and myopia.^{4–9}

Recently, femtosecond laser introduction improved the precision and safety of ICRS implantation.¹⁰ Using this new technology, new long-arc length segments have been introduced in clinical practice. Since 2013, an arc length of 355 degrees (Keraring; Mediphacos, Belo Horizonte, Brazil) was proposed and implanted with good results in nipple keratoconus.¹¹ However, some complications were reported,¹² and the reduction to an arc length of 340 degrees (Keraring; Mediphacos) was proposed to reduce the complication rate.¹³

In order to increase even more the safety of this new ICRS, a 320-degree-arc length intrastromal corneal ring segment (320-ICRS; AJL Ophthalmics, Vitoria, Spain) was developed with the aim of keeping the excellent results achieved with anterior long-arc ICRS, minimizing potential complications, especially those related to segment proximity to the surgical incision.

The purpose of this study is to report the clinical outcomes after implantation of the 320-degree-arc length ICRS (320-ICRS). To our knowledge, there are no other reports on the effect of this long-arc ICRS insertion.

Patients and methods

This prospective, consecutive, nonrandomized, interventional study included a total of 34 eyes of 31 patients (15 female and 16 male) with a mean age of 25.47 ± 10.44 years (range: 11–63 years). All patients were diagnosed with keratoconus based on complete ophthalmological exam and corneal tomographic findings (Pentacam; Oculus, Jena, Germany). Keratoconus cases were classified according to the Amsler-Krumeich grading system.

The inclusion criteria of this study were as follows: patients diagnosed with keratoconus, poor spectacle-corrected visual acuity (corrected distance visual acuity (CDVA) $\geq 0.3 \log$ MAR), inability to wear contact lenses, minimum K_{max} of 52.0D, maximum mean corneal power (K_{m}) of 65.0D, and minimum corneal thickness (thinnest point) of 360 µm. Since this is a new arc length, we decided

to study its performance in any pattern of keratoconus, including central and paracentral steepening, with low or high topographic astigmatism. We excluded patients with prior corneal surgical procedures, such as keratorefractive surgery, crosslinking, or keratoplasty, and those with a history of any corneal diseases other than keratoconus and active ocular disease.

Preoperative evaluation included a comprehensive ophthalmological examination and included uncorrected distance visual acuity (UDVA), CDVA, manifest refraction in the form of spherical equivalent (SE), slit-lamp biomicroscopy, Goldmann tonometry, fundus evaluation, and corneal tomographic analysis with Pentacam. The following tomographic data were evaluated: corneal dioptric power in the flattest meridian (K_1), corneal dioptric power in the steepest meridian (K_2), mean corneal power (K_m), maximum keratometric reading (K_{max}), and mean asphericity at an angle of 30 degrees (Q 30°).

After thoroughly explaining the purpose and procedures of the study, all patients were asked to sign an informed consent form before treatment. This study was approved by Federal University of São Paulo (UNIFESP) Review Board at the Department of Ophthalmology and followed the tenets of the Declaration of Helsinki.

320-ICRS

This new long-arc ICRS polymethylmethacrylate (PMMA) has an arc length of 320 degrees (AJL Ophthalmics, Vitoria, Spain) is implanted leaving its tips 20 degrees apart from each side of the incision. It preserves the triangular cross section of previous Ferrara Ring, with a basis of $600 \,\mu\text{m}$, an internal optical zone of 5.0 mm, and an apex placed at 5.4 mm distant from the pupil. It is currently available in different thicknesses ranging from 150 to $300 \,\mu\text{m}$ in 50- μm increments.

Surgical procedure

All surgical procedures were performed under topical anesthesia with proxymetacaine hydrochloride 0.5% (Anestalcon; Alcon, Fort Worth, TX, USA) drops by the same surgeon (G.A.d.N.R.) at Hospital Oftalmológico de Brasília (HOB; Brasília, Brazil) between May 2016 and October 2017. Creation of incision and stromal tunnel for ICRS insertion was performed using a 60-kHz IntraLase femtosecond technology (Abbott Medical Optics Inc., Santa Ana, CA, USA) in all cases. IntraLase parameters included the following: (1) incision placed at the steepest tomography axis; (2) incision and tunnel depth of 70% of corneal thickness at the thinnest point in the ring track; (3) an inner diameter of 5.0 mm; (4) an outer diameter of 6.0 mm; (5) an entry cut length of 1.2 mm; (6) an entry cut thickness of $1 \mu m$; (7) a ring energy of $1.3 \, m$ J, and (8) an entry cut energy of 1.3 mJ.

After incision and tunnel creation with femtosecond technology, the 320-ICRS was inserted into the circular tunnel using an implantation forceps. A total of 18 eyes received a 200- or 250-µm 320-ICRS based on SE (SE group) and the other 16 eyes received a 150-, 200-, or 250-µm 320-ICRS based on mean asphericity at 30 degrees (Q group). Subsequently, a silicone hydrogel bandage contact lens (AIR OPTIX; Alcon, Fort Worth, TX, USA) was placed on the cornea. The postoperative regimen included moxifloxacin 0.5%-dexamethasone 0.1% eye drops (VIGADEXA; Alcon, Fort Worth, TX, USA) four times a day for 10 days and topical lubricants (Systane UL; Alcon, Fort Worth, TX, USA). No intraoperative complications occurred.

Postoperative follow-up

Postoperative ophthalmological exam and tomographic analysis were performed at 3 and 6 months. On the first day postoperatively, UDVA measurement, slit-lamp examination, and bandage contact lens removal were performed. No postoperative complications occurred.

Statistical analysis

IBM SPSS Statistics for Mac 2016 version 24 was used for statistical analysis. Continuous variables with normal distribution are presented as mean \pm standard deviation (SD). When a parametric analysis was possible, Student's *t*-test for paired data was performed for all parameter comparisons between preoperative and postoperative examinations, and when a nonparametric analysis was necessary, the Wilcoxon signed-rank test was performed, between preoperative and postoperative examinations. For both, we considered p < 0.05 as a level of significance.

Results

In this study, a total of 34 eyes of 31 patients were included. The mean age of patients was 25.47 ± 10.44 years (range: 11–63 years), 15 were female, and 16 were male. According to the Amsler-Krumeich keratoconus grading system,¹⁴ 4 eyes had keratoconus grade I (11.76%), 16 eyes had keratoconus grade II (47.05%), and 14 eyes had keratoconus grade III (41.17%). The mean follow-up period was 6.63 ± 0.96 months.

Surgical parameters

In total, 15 right eyes and 16 left eyes were operated. The mean incision axis was 89.21 ± 24.32 degrees and the mean incision depth was $358.18 \pm 39.06 \,\mu\text{m}$. ICRS thicknesses were as follows: (1) in six: $150 \,\mu\text{m}$; (2) in fourteen: $200 \,\mu\text{m}$; and (3) in fourteen: $250 \,\mu\text{m}$, as shown on surgical procedure explanation.

Preoperative	Postoperative			
	3 months	Þ*	6 months	Þ*
$\textbf{I.36} \pm \textbf{0.48}$	0.66 ± 0.41	<0.01	$\textbf{0.63} \pm \textbf{0.42}$	<0.01
0.51 ± 0.22	0.20 ± 0.13	<0.01	0.18 ± 0.12	<0.01
$\textbf{-7.52} \pm \textbf{4.18}$	-3.87 ± 3.72	<0.01	$\textbf{-3.61} \pm \textbf{3.79}$	<0.01
	Preoperative 1.36 ± 0.48 0.51 ± 0.22 -7.52 ± 4.18	Preoperative Postoperative 1.36 ± 0.48 0.66 ± 0.41 0.51 ± 0.22 0.20 ± 0.13 -7.52 ± 4.18 -3.87 ± 3.72	$\begin{tabular}{ c c c c } \hline Preoperative & Postoperative \\ \hline 3 months p^* \\ \hline 1.36 ± 0.48 & 0.66 ± 0.41 < 0.01 \\ 0.51 ± 0.22 & 0.20 ± 0.13 < 0.01 \\ -7.52 ± 4.18 & -3.87 ± 3.72 < 0.01 \\ \hline \end{tabular}$	PreoperativePostoperative $3 \mod b$ p^* $6 \mod b$ 1.36 ± 0.48 $0.66 \pm 0.41 < 0.01$ 0.63 ± 0.42 0.51 ± 0.22 $0.20 \pm 0.13 < 0.01$ 0.18 ± 0.12 -7.52 ± 4.18 $-3.87 \pm 3.72 < 0.01$ -3.61 ± 3.79

UDVA: uncorrected distance visual acuity; CDVA: corrected distance visual acuity; SE: spherical equivalent.

UDVA and CDVA are expressed in logMAR, whereas SE is expressed in diopters (D).

*Student's *t*-test; p < 0.05 for statistical significance.

Visual acuity and refraction

mean UDVA improved significantly The from $1.36 \pm 0.48 \log MAR$ preoperatively to 0.66 ± 0.41 logMAR (p < 0.01) and $0.63 \pm 0.42 \log$ MAR (p < 0.01), respectively, 3 and 6 months after implantation. The mean preoperative CDVA was $0.51 \pm 0.22 \log$ MAR with a mean SE of -7.52 ± 4.18 D. The mean CDVA improved to $0.20 \pm 0.13 \log MAR$ (p < 0.01) with a mean SE of $-3.87 \pm 3.72 \text{ D}$ (p < 0.01) and $0.18 \pm 0.12 \log \text{MAR}$ (p < 0.001) with a mean SE of -3.61 ± 3.79 D (p < 0.01), respectively, 3 and 6 months after implantation. All results are shown in Table 1.

Corneal tomography outcomes

Our results showed a significant reduction in *K* readings at both postoperative evaluations. K_1 , K_2 , K_m , and K_{max} significantly reduced both at 3 and 6 months postoperatively (p < 0.01): flat keratometry (K_1) mean reduced 2.96 and 3.11 D; steep keratometry (K_2) mean reduced 5.44 and 5.43 D; mean keratometry (K_m) mean reduced 4.09 and 4.16 D, and maximum keratometry (K_{max}) mean reduced 4.05 and 4.24 D; Figure 1 shows all the results.

The mean preoperative tomographic astigmatism was 5.46 ± 2.27 D. We used a vectorial analysis and reached a mean 3.09 ± 1.49 D of vectorial astigmatism change (VAC) at 6 months postoperatively, representing a 56.59% reduction.

The mean asphericity at an angle of 30 degrees (Q 30°) improved from -1.14 ± 0.28 to -0.32 ± 0.28 and -0.35 ± 0.26 at 3 and 6 months, respectively (p < 0.01 for both intervals). Comparison between postoperative intervals showed no statistical significance; Figure 2 shows all the results.

Outcomes based on ICRS selection

We used two different strategies for surgical 320-ICRS thicknesses selection. In 18 eyes, our selection was based on preoperative SE (SE group): (1) when SE < 6.0D, we



Figure 1. Mean preoperative and postoperative interval keratometric reading results. Flat $K(K_1)$, steep $K(K_2)$, mean keratometry (K_m), and maximum keratometry (K_{max}) are expressed in diopters (D).



Figure 2. Mean preoperative and postoperative interval asphericity results at 30 degrees.

used a 200-µm implant and (2) when SE \ge 6.0, we used a 250-µm implant. In 16 eyes, our selection was based on preoperative mean Q 30° (Q group): (1) 150 µm for mean Q 30° > -1.04; (2) 200 µm for -1.04 < mean Q 30° < 1.30; and (3) 250 µm for mean Q 30° < 1.30. As shown in Table 2, both groups had comparable preoperative data.

Both groups showed significant improvement in UDVA, CDVA, and SE between preoperative and postoperative intervals. When comparing the performance of both groups, we found no significant differences (Wilcoxon signed-rank test; p > 0.05 for all comparisons). Table 3 shows all the results.

Regarding corneal tomography outcomes, both groups again showed significant improvement (p < 0.05). Between groups, the SE group showed a significantly better performance compared with the Q group. In the SE group, mean K_1 after 6 months improved 2.22 D, while in the Q group it improved 0.69 D (p=0.03); mean K_2 after 3 and 6 months improved 6.14 and 6.17 D in the SE group, while in the Q group it improved 4.47 and 4.43 D (p=0.006

Table 2.	Preoperative	data
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	SE group	Q group	þ *
Age (years)	25.06 ± 10.51	25.94 ± 10.68	0.81
UDVA (logMAR)	$\textbf{1.45}\pm\textbf{0.46}$	$\textbf{1.25}\pm\textbf{0.50}$	0.25
CDVA (logMAR)	$\textbf{0.53}\pm\textbf{0.19}$	$\textbf{0.49} \pm \textbf{0.25}$	0.60
SE (D)	-8.54 ± 4.12	-6.37 ± 4.07	0.13
K ₁ (D)	$\textbf{49.36} \pm \textbf{4.03}$	$\textbf{48.16} \pm \textbf{2.87}$	0.33
K_2 (D)	$\textbf{54.70} \pm \textbf{4.12}$	$\textbf{53.75} \pm \textbf{4.39}$	0.52
dK (D)	$\textbf{5.35} \pm \textbf{2.24}$	$\textbf{5.59} \pm \textbf{2.37}$	0.77
<i>K</i> _m (D)	51.88 ± 3.92	$\textbf{50.77} \pm \textbf{3.45}$	0.39
$K_{\rm max}$ (D)	$\textbf{60.33} \pm \textbf{4.25}$	$\textbf{59.57} \pm \textbf{5.32}$	0.65
Mean Q 30°	-1.15 ± 0.28	-1.13 ± 0.29	0.82

UDVA: uncorrected distance visual acuity; CDVA: corrected distance visual acuity; SE: spherical equivalent.

UDVA and CDVA are expressed in logMAR, whereas SE is expressed in diopters (D).

SE group (surgical planning based on spherical equivalent).

Q group (surgical planning based on mean asphericity).

*Student's t-test; p < 0.05 for statistical significance.

and 0.02), respectively; mean $K_{\rm m}$ after 3 and 6 months improved 4.65 and 4.77 D in the SE group, while in the Q group it improved 3.26 and 3.30 D (p=0.01 and 0.03), respectively; mean $K_{\rm max}$ after 3 months improved 5.30 D in the SE group, while in the Q group it improved 2.80 D (p=0.01). Figure 3 shows all the results.

For VAC, the SE group mean improved 3.60 ± 1.40 D and the Q group mean improved 2.60 ± 1.52 D, but this difference showed no statistical significance (*p*=0.056).

The mean Q 30° significantly improved in both groups comparing the preoperative and postoperative periods (p < 0.01 for both groups in every comparison; Figure 4).

Comparison between both groups showed significantly better performance for the SE group at 3 months postoperatively, with an improvement of 0.88 in the SE group, while it improved 0.71 in the Q group (p=0.03).

Discussion

Treatment of keratoconus was significantly improved in the last decades since the introduction of ICRS. The possibility of delaying or preventing corneal transplantation was a significant advance in keratoconus therapy, because of all known possible complications in keratoplasty.¹⁵

The ICRS implantation for keratoconus has evolved with time. The introduction of femtosecond laser assistance for tunnel and incision creation marks a new era for the procedure.¹⁰ Despite the proved equal visual acuity results compared to the manual technique used by experienced surgeons,¹⁶ this technology reduces potential complications, provides faster healing, and increases reproducibility of the surgical technique and the possibility of using longer arc ICRS, which were abandoned in the past due to complications and lack of a surgical method suitable for this ICRS. Several studies have shown the role and behavior of each arc length and thickness on the ICRS surgery.^{4–10,17} The reintroduction of a long-arc ICRS has the primary objective of increasing corneal flattening and prolatism reduction, especially for the nipple type of keratoconus and advanced cases.¹¹ Few publications are available, and first results are being published. Jadidi et al.¹¹ published their results and complications¹² using a 355-degree arc ICRS and recently Sadoughi et al.¹³ released their results using a 340-degree arc ICRS.

Since this is a new arc length, we decided to study its performance in any pattern of keratoconus, including central and paracentral steepening, with low or high topographic astigmatism. In future studies, with a larger number of patients enrolled, we intend to compare the results between different patterns of keratoconus to determine if there is advantage on its effect in central keratoconus pattern as previously reported.¹¹

The Amsler-Krumeich keratoconus grading system¹⁴ comprises for keratometric index classification the value of mean keratometry at 3 mm. In our study, 58.81% had Amsler-Krumeich classification of keratoconus grades I and II. The use of corneal tomography has changed corneal analysis. In most cases, the steepest keratometry is not within 3 mm. This explains why despite a majority of keratoconus grades I and II we had maximum keratometries (K_{max}) above 52.0 D for all patients in this study.

As expected and already shown in other studies, ICRS significantly improved UDVA and CDVA with SE reduction, considerably gaining in lines of visual acuity and most patients achieved CDVA better than or equal to 0.3 logMAR.^{4-10,17} Using the 320-ICRS, we found that 85.29% of patients gained at least two lines of UDVA, 79.41% gained at least two lines of CDVA with a mean reduction of 51.93% in SE, and 88.23% reached at least 0.3 logMAR of CDVA at the end of the postoperative follow-up period, compared to 23.53% preoperatively. Our results are very similar to the 355-degree arc report,¹¹ with significant improvements in UDVA, CDVA, and SE. On the other hand, the 340-degree arc report¹³ showed different results, with a lower percentage of patients gaining at least two lines of UDVA (66.67% vs 85.29%) and surprisingly no statistical significance in CDVA improvement (p=0.09) with only 50.0% of patients gaining at least two lines of CDVA. Sadoughi et al.13 related this poor result to the advanced stage of the disease (patients with $K_{\rm m} > 55.0 \,{\rm D}$ and $K_2 > 57.0 \,\mathrm{D}$). When they analyzed their data without these patients, the CDVA improvement was statistically significant. In our study, we had five eyes with $K_{\rm m} > 55.0 \,{\rm D}$ and $K_2 > 57.0 \text{ D}$ and 60% gained at least two lines of UDVA and CDVA; 80% of patients achieved at least 0.3 logMAR of CDVA. None of the patients lost lines of UDVA or CDVA in our study.

From corneal tomography outcomes, we also observed a significant improvement in all evaluated parameters (K_1 ,

		Preoperative	Postoperative			
			3 months	Þ*	6 months	Þ*
SE group	UDVA	1.45 ± 0.46	$\textbf{0.60} \pm \textbf{0.44}$	<0.01	$\textbf{0.57} \pm \textbf{0.45}$	<0.01
	CDVA	$\textbf{0.53}\pm\textbf{0.19}$	$\textbf{0.18} \pm \textbf{0.15}$	<0.01	$\textbf{0.16} \pm \textbf{0.13}$	<0.01
	SE	-8.54 ± 4.12	-4.35 ± 4.36	<0.01	-3.97 ± 4.63	<0.01
Q group	UDVA	$\textbf{1.25}\pm\textbf{0.50}$	$\textbf{0.72}\pm\textbf{0.36}$	<0.01	$\textbf{0.69} \pm \textbf{0.38}$	<0.01
	CDVA	$\textbf{0.49} \pm \textbf{0.25}$	0.22 ± 0.11	<0.01	$\textbf{0.20}\pm\textbf{0.12}$	<0.01
	SE	-6.37 ± 4.07	-3.33 ± 2.88	0.01	-3.22 ± 2.63	<0.01

Table 3. Mean preoperative and postoperative interval visual acuity results considering two different surgical planning strategies (SE group vs Q group).

UDVA: uncorrected distance visual acuity; CDVA: corrected distance visual acuity; SE: spherical equivalent.

UDVA and CDVA are expressed in logMAR, whereas SE is expressed in diopters (D).

SE group (surgical planning based on spherical equivalent).

Q group (surgical planning based on mean asphericity).

*Wilcoxon signed-rank test; p < 0.05 for statistical significance.



Figure 3. Mean preoperative and postoperative interval keratometric reading results considering two surgical planning strategies (SE group vs Q group).

Flat K (K1), steep K (K2), mean keratometry (Km), and maximum keratometry (Kmax) are expressed in diopters (D).

 K_2 , K_m , K_{max} , and Q 30°) as shown in other studies.^{4–10,17} In each of these comparisons between preoperative and post-operative measurements, these improvements were statistically significant (p < 0.01). Both 355- and 340-degree arc ICRS reports^{11,13} showed similar results regarding keratometry changes.

Nomograms are surgical guides based on previously achieved results. To start using a new ICRS, we decided to follow other study recommendation for a similar long-arc ICRS, based on SE.¹¹ The first 18 implants' thickness selection was made following the SE, as proposed by other report based on Keraring 355° ,¹¹ and only 200- and 250-µm ICRS were used. Ferrara nomogram for ICRS surgery planning is in its fourth generation and among other parameters it takes mean asphericity at 30 degrees (Q 30°) as an important role for surgery result,¹⁸ and our desired mean asphericity postoperative result is -0.23 ± 0.08 .^{18,19}

Ferrara et al.5 showed in a large series of ICRS implantation the results of 160- and 210-degree arc ICRS on mean asphericity improvement. They concluded that 210-ICRS better improved the mean asphericity due to its higher length. Comparing to the 160-degree arc ICRS, it improved 80.55% more with 150 µm (0.07 vs 0.36), 48.33% with 200 µm (0.60 vs 0.31), and 58.53% with 250 µm (0.82 vs 0.34). Since the 320-ICRS has 110 degrees more than 210-ICRS and this has 50 degrees more than 160-ICRS, we predicted a double mean asphericity improvement, to avoid oblate cornea (mean $Q \, 30^{\circ} > -0.23 \pm 0.08^{5,18,19}$), as an undesirable result. We decided to change our thicknesses selection based on a possible mean asphericity change: (1) 150 μ m for mean Q 30° > -1.04; (2) 200 μ m for $-1.04 < \text{mean } Q \ 30^{\circ} < 1.30$; and (3) 250 µm for mean $Q 30^{\circ} < 1.30$. A total of 16 subsequent procedures were performed under this surgical plan.



Figure 4. Mean preoperative and postoperative interval asphericity results at 30 degrees considering two surgical planning strategies (SE group vs Q group).

For the visual acuity and refraction results, both surgical strategies showed statistically significant effects. In the SE group, 88.88% of patients gained at least two lines of UDVA, 87.5% gained at least two lines of CDVA with a 46.42% reduction in mean SE and 87.5% reached at least 0.3 logMAR of CDVA, compared to 18.75% preoperatively. In the Q group, 81.25% of patients gained at least two lines of UDVA, 68.75% gained at least two lines of CDVA with a 50.56% reduction in mean SE, and 87.5% reached at least 0.3 logMAR of CDVA compared to 31.25% preoperatively.

On the other hand, corneal tomography outcomes significantly showed a difference in performance between the preoperative strategy groups, with a better improvement in the SE group. We found a significant difference for K_1 at 6 months postoperatively (p=0.03), K_2 at both 3 and 6 months postoperatively (p=0.006 and 0.02, respectively), K_m at both 3 and 6 months postoperatively (p=0.01 and 0.03, respectively), and K_{max} at 3 months postoperatively (p=0.01). These results show that the use of preoperative SE for ICRS thickness selection as shown in previous studies with long arc lengths (355- and 340-ICRS)^{11,13} is a good strategy for starting using these ICRSs. It also showed that we overestimate the 320-ICRS improvement on mean asphericity.

No intra- or postoperative complications occurred. Jadidi et al.¹² enrolled five patients in a study for Keraring 355-degree arc ICRS using a femtosecond laser for tunnel creation. In all cases, postoperative complications happened and the worst one was corneal melting, near the incision site. Proximity between the ICRS tip and the incision is the leading risk factor for extrusion, infection, and corneal melting. The 320-ICRS, in theory, can provide similar corneal changes (when compared with the 355-ICRS); the main advantage of this ICRS is to be 20 degrees on each side, far the incision, which makes it safer to be used.

The present results suggest that implanting a 320-ICRS is a safe and effective procedure for treating patients with keratoconus. It also suggests that the thickness selection strategy should consider preoperative SE.

As previously stated, Ferrara et al.⁵ studied a large series of 160- and 210-ICRS implantations. In their study, 1073 eyes were implanted with these ICRSs (972 eyes with 160-ICRS and 101 eyes with 210-ICRS). In group A (160-ICRS), 521 implanted ICRSs were single and 451 were pairs. In group B (210-ICRS), only single ICRSs were implanted. In our study, we implanted 34 single 320-ICRSs.

Their analysis on improving lines in CDVA showed 64.7% of patients gaining at least two lines in group A (160-ICRS) and 48.9% in group B (210-ICRS). We found 79.41% of patients gaining at least two lines of CDVA. For mean keratometry reduction, they found a mean reduction of 3.46D in group A and 3.82D in group B. We found a mean reduction of 4.17D. Finally, for mean asphericity, they found a mean improvement of 0.53 with 160-ICRS and 0.61 with 210-ICRS. We found a mean improvement of 0.79.

This is the first study about the clinical outcomes after implantation of 320-ICRS. This study showed that the 320-ICRS, despite the small sample of patients, could be a valuable tool to provide excellent topographic and visual outcomes. It also showed results similar to previous studies with 355-ICRS,¹¹ with fewer complications,¹² but showed better results than the other long-arc ICRS (340-ICRS)¹³ and previously known smaller arcs (160- and 210-ICRS).⁵ Further studies with larger samples and more extended follow-up periods must be warranted to confirm the presented results.

Declaration of conflicting interests

The author(s) declared following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: P.F.d.A.C. is a shareholder of Ferrara Ophthalmics, Brazil.

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