·Clinical Research·

Evaluation of anterior and posterior surfaces of the cornea using a dual Scheimpflug analyzer in keratoconus patients implanted with intrastromal corneal ring segments

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Abstract

• AIM: To evaluate corneal parameters measured with a dual Scheimpflug analyzer in keratoconus patients implanted with intrastromal corneal ring segments (ICRS).

• METHODS: Fifty eyes of 40 keratoconus patients had Ferrara ICRS implantation from November 2010 to April 2014. Uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), refraction, keratometry, asphericity, elevation, pachymetry, root mean square (RMS), spherical aberration and coma were studied. All patients were evaluated using a dual Scheimpflug system.

• RESULTS: The mean follow-up time after the procedure was 12.7mo. The mean UCVA improved from 0.82 to 0.31 (*P*<0.001); the mean BCVA improved from 0.42 to 0.05 (*P*<0.0001), the mean spherical refraction changed from -3.06±3.80 D to -0.80±2.5 D (*P*<0.0001) and the mean refraction astigmatism reduced from -4.51±2.08 D to -2.26±1.18 D (*P*<0.0001). The changes from preoperative to postoperative, in parameters of the anterior and posterior surface of the cornea, were statistically significant except the elevation posterior at the apex of the cornea and posterior asphericity.

• CONCLUSION: The implantation of Ferrara ICRS induces changes in both anterior and posterior surfaces of the cornea.

• KEYWORDS: keratoconus; intrastromal corneal ring segments; dual Scheimpflug.
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INTRODUCTION

Intrastromal corneal ring segments (ICRS), which were initially designed to correct mild to moderate myopia [1], have been successfully used for the treatment of keratoconus in cases with a clear cornea and contact lens intolerance[2-5]. The main advantages of ICRS are safety, reversibility, and stability [6-8]. In addition, the surgery preserves the integrity of the central cornea. The efficacy of ICRS implantation for keratoconus has been widely described in the literature [5-7]. The main goals of segment implantation are to improve visual acuity and to delay or avoid corneal grafts in patients with keratoconus.

The Galilei dual Scheimpflug analyzer (Ziemer Ophthalmic Systems AG, Port, Switzerland) is a relatively new dual Scheimpflug imaging system combined with Placido-disk technology, which allows for an extensive evaluation of corneal features[9].

The aim of the present study was to evaluate changes in the anterior and posterior corneal surfaces, pachymetry, visual and refractive outcomes after implantation of Ferrara ICRS (AJL, Vitoria, Spain) using a dual Scheimpflug imaging system.

SUBJECTS AND METHODS

This retrospective case series study enrolled patients examined at Campineiro Microsurgery Eye Center, Campinas, Brazil, between November 2010 and April 2014. All patients were informed about inclusion in the study and provided informed consent in accordance with the Declaration of Helsinki.

The study comprised 50 eyes of 40 patients that had Ferrara ICRS implantation by the manual technique. Twenty-eight operated eyes were right and the remainder (22) were left eyes. Twenty patients were male and 20 patients were female. The mean age of patients was 30.2 years old [range

16 to 53, standard-deviation (SD): 8.3]. The mean follow-up time was 12.7±10.9mo.

The main indication for ICRS implantation was contact lens intolerance and/or progression of the ectasia. The progression of the disease was defined by: worsening of uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA) and/or progressive intolerance to contact lens wear and/or progressive corneal steepening.

Inclusion criteria were keratoconic eyes with clear central corneas, contact lens intolerance and a BCVA of 20/800 or better. Eyes with advanced keratoconus (mean keratometry higher than 60 D) and apical scarring were excluded.

The selection of the thickness and arch length of the ICRS to be implanted was made based on the Ferrara ring nomogram, third generation (topographic astigmatism)[5]. This nomogram is based on the position of the ectasia area on the cornea, topographic astigmatism, and the pachymetric map.

Clinical Measurements All patients had a complete ophthalmologic examination that included logMAR UCVA, logMAR BCVA, manifest refraction (spherical and astigmatism), spherical equivalent (SE), and slit-lamp and fundus evaluations. Corneal evaluation was performed using a dual Scheimpflug imaging system (Galilei 2, SW version 6.1.3, Ziemer Ophthalmic Systems AG, Port, Switzerland). This noninvasive system measures and characterizes the anterior segment. The Galilei combines and integrates Placido topography and the Scheimpflug photographic system. When both technologies complement each other, 122 000 points are recognized in the anterior segment of the eye. Simultaneously to each pair of Scheimpflug images, in a 180° rotating movement, 17 frontal images are routinely taken on the same alignment, 2 of them with the reflection of Placido rings. The first is taken with cameras at 12 and 6 o'clock and the second at 3 and 9 o'clock, so that the defects of the first are covered by the second. On the anterior curvature maps, everything that Placido topography does not achieve is being deduced from the Scheimpflug images. Meanwhile, the elevation and pachymetry are more dependent on the dual Scheimpflug slits. After processing the information, the internal software provides several calculations and parameters centered to the first Purkinje defined as the center of four dots reflected on the anterior corneal surface. The system may also provide all data aligned to the pupil.

Simultaneously, the system allows for corneal aberration analysis separately from aberrations of the lens and displays the total higher order corneal wavefront aberrations calculated from the front and back surface. Both the displayed wavefront maps and the RMS indices are recalculated re-centered on the pupil center over optical zones from 3- to 6-mm-diameter.

The following anterior and posterior corneal surface parameters were evaluated with the dual Scheimpflug system: anterior (flat SimK) and posterior (flat Kpost) corneal dioptric power in the flattest meridian of the 3.0 mm central zone, anterior (steep SimK) and posterior (steep Kpost) corneal dioptric power in the steepest meridian in the 3.0 mm central zone anterior (SimK) and posterior (Kpost) median corneal power in the 3.0 mm zone, anterior (TopoAstig) and posterior (PostAstig) anterior corneal astigmatism in the 3.0 mm zone, best-fit sphere (BFS) anterior and posterior elevation at the center of the cornea (ElevAnt), BFS anterior and posterior at the thinnest point of the cornea (ElevThin), asphericity in the 8-mm-diameter central zone aligned to the first Purkinje, pachymetry at the center of the cornea, and at the thinnest point. The root mean square (RMS), total coma and spherical aberration (SA) were also analyzed in the 6-mm-diameter central zone aligned to the pupil. All clinical examinations were performed in a standardized manner by an experienced examiner (Signorelli A).

Surgical Technique Corneal tunnels for ICRS segment insertion were performed by the manual technique. The incision was located on the steepest meridian of the anterior corneal surface in all patients. The visual axis was marked by pressing a Sinskey hook on the first Purkinje identified as the corneal light reflex on the central corneal epithelium while asking the patient to fixate at the microscope light. For the incision, a calibrated diamond knife was set at 80% of the corneal thickness at the incision site determined by the pachymetry map of Galilei. Two semicircular dissectors were placed sequentially into the lamellar pocket to be advanced steadily by a rotational movement (counterclockwise and clockwise dissectors). The ICRS was then placed inside the tunnel using a McPherson forceps. All surgeries were performed by the same surgeon (Signorelli A).

The postoperative regimen consisted of gatifloxacin 0.5% (Zymar®, Allergan, USA) and dexamethasone 0.1% (Maxidex®, Alcon) eye drops four times daily for two weeks. The patients were instructed to avoid rubbing the eye and to frequently use preservative-free artificial tears (Fresh Tears® 0.4%, Allergan). The patients were examined postoperatively at 1d, 1, 3, 6mo, and 1y after the surgery. The mean follow-up time was based on the time of the last visit.

Statistical Analysis The Graph Pad Prism (GraphPad2014, Chicago, IL, USA) was used for descriptive statistics, including means ±standard deviations. Student's t-test for paired data was used to compare preoperative and postoperative data. A two-tailed probability of 5% or less was considered statistically significant.

RESULTS

The mean UCVA improved from 0.82 to 0.31 (P<0.001); the mean BCVA improved from 0.42 to 0.05 (P<0.0001), the mean spherical refraction changed from -3.06±3.80 D to -0.80±2.5 D (P<0.0001) and the mean refractive astigmatism reduced from -4.51±2.08 D to -2.26±1.18 D (P<0.0001) (Table 1). The change in coma was not statistically significant. The SA reduced from 0.14±0.59 μm to -0.20±

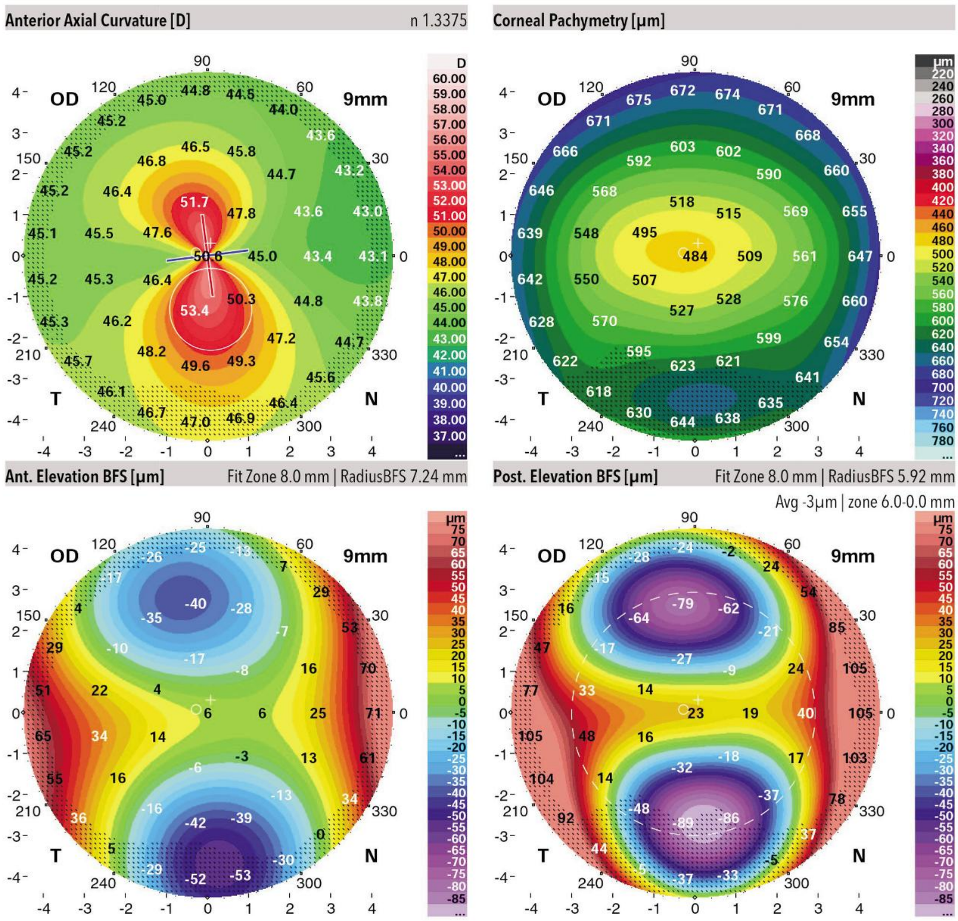

Figure 1 Preoperative axial anterior and elevation map.

0.78 µm (P=0.0003) and RMS reduced from 4.43±2.19 D to 3.88±1.83 D (P=0.0017). The pachymetry at the center of the cornea increased from 482±49.6 D to 519±53.8 D (P< 0.0001) and the thinnest pachymetry increased from 461 ± 37.7 D to 473±35.5 D (P<0.0001).

The results of the parameters of the anterior surface of the cornea are summarized in the Table 2. The mean flat SimK reduced from 47.28±4.71 D to 43.31±3.61 D (P<0.0001), the mean steep SimK reduced from 50.89±6.32 D to 47.11± 5.19 D (P<0.0001) (Figures 1, 2). The anterior BFS elevation increased from 21.1±27.8 µm to 27.7±22.5 µm (P=0.036). The anterior BFS elevation at thinnest point reduced from 18.2±20.5 µm to 5.8±15.6 µm (P<0.0002). The anterior asphericity changed from -1.23±1.08 to -0.41±1.24 (P=0.0019).

The results of the parameters of the posterior surface of the cornea are summarized in the Table 3. The mean flat Kpost become flatter from -6.93±0.97 D to -6.60±0.96 D (P< 0.0001), as well as the mean steep Kpost from -7.89±0.98 D to -7.31±0.96 D (P<0.0001). The posterior BFS elevation increased from 31.3±33.4 µm to 35.4±27.6 µm, however this change was not statistically significant (P=0.47). The posterior BFS elevation at thinnest point reduced from 35.4± 33.5 µm to 21.7±20.7 µm (P<0.0014). The posterior asphericity did not change (from -1.48±1.30 to -1.47±1.58, P=0.97).

We stratified the main parameters according with the implanted ICRS. All the patients had implanted 5 mm

Table 1 Preoperative and last follow-up examination data of patients implanted with Ferrara intrastromal corneal ring segments implantation $\bar{x}\pm s$

Parameters	Preoperative	Postoperative	P
UCVA	0.82±0.12	0.31±0.25	<0.0001
BCVA	0.42±0.25	0.05±0.16	<0.0001
Spherical refraction (D)	-3.06±3.80	-0.80±2.57	<0.0001
Refractive astigmatism (D)	-4.51±2.08	-2.26±1.18	<0.0001
SE (D)	-4.48±3.90	-1.54±2.42	<0.0001
SA (µm)	0.14±0.59	-0.20±0.78	0.0003
RMS (µm)	4.43±2.19	3.88±1.83	0.0017
Coma (µm)	1.96±1.33	1.64±1.02	0.0095
Pach (µm)	482±49.6	519±53.8	<0.0001
PachThin (µm)	461±37.7	473.6±35.5	<0.0001

UCVA: Uncorrected visual acuity; BCVA: Best corrected visual acuity; SE: Spherical equivalent; SA: Spherical aberration; RMS: Root mean square; Pach: Pachymetry at the center of the cornea; PachThin: Minimal pachymetry.

Table 2 Comparison of preoperative and postoperative data of anterior cornea $\bar{x}\pm s$

Parameters	Preoperative	Postoperative	P
Flat SimK (D)	47.28±4.71	43.31±3.61	<0.0001
Steep SimK (D)	50.89±6.32	47.11±5.19	<0.0001
SimK (D)	49.10±4.81	44.31±7.91	<0.0001
AntBFSElev (µm)	21.1±27.8	27.7±22.5	0.036
AntBFSElevThin (µm)	18.2±20.5	5.8±15.6	0.0002
QAnt	-1.23±1.08	- 0.41±1.24	0.0019

Flat SimK: Keratometry at the flattest meridian; Steep SimK: Keratometry at the steepest meridian; SimK: Mean keratometry; AntBFSElev: Elevation anterior at the apex of the cornea; AntBFSElevThin: Elevation anterior at the thinnest point of the cornea; QAnt: Asphericity anterior.

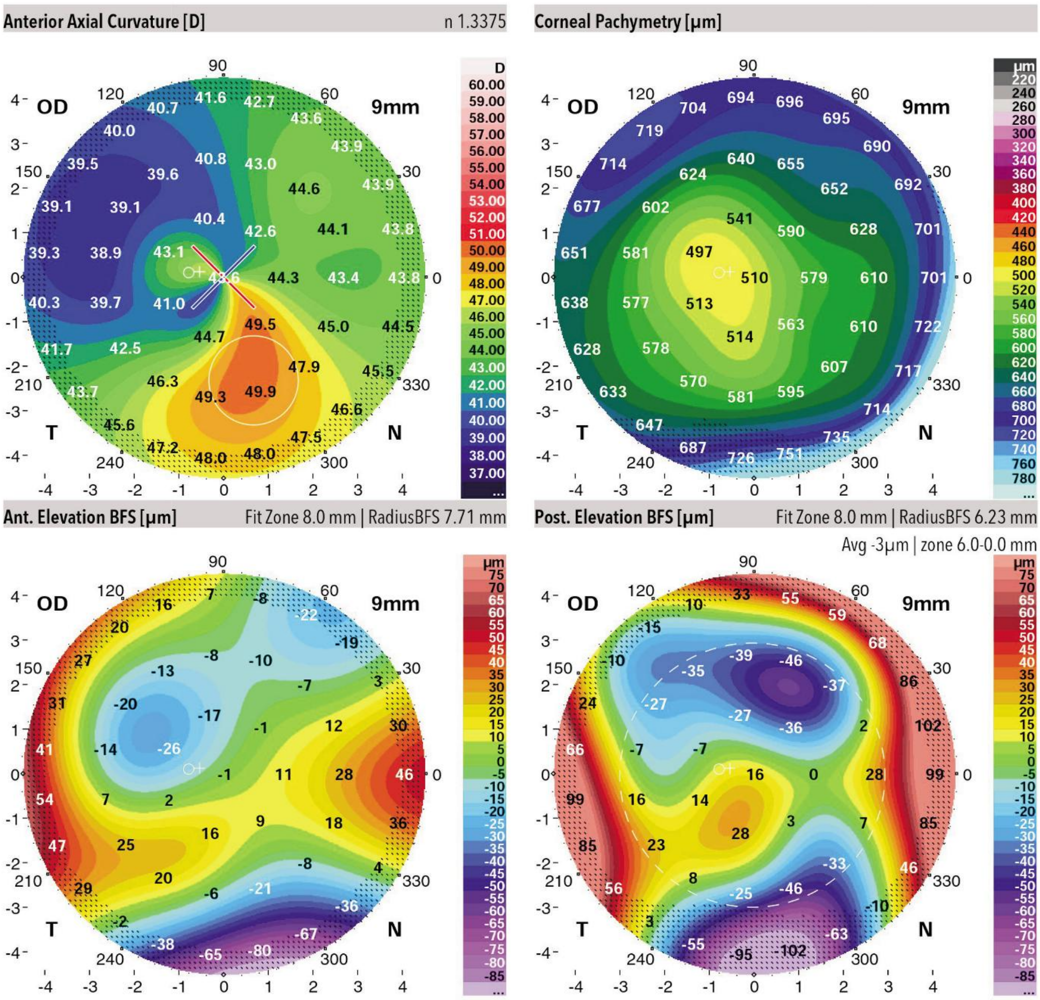

Figure 2 Postoperative axial anterior and elevation map.

Table 3 Comparison of preoperative and postoperative data of posterior cornea $\bar{x}\pm s$

Parameters	Preoperative	Postoperative	*P*
Flat Kpost (D)	-6.93±0.97	-6.60±0.96	<0.0001
Steep Kpost (D)	-7.89±0.98	-7.31±0.96	<0.0001
SimKpost (D)	-7.41 ± 0.95	-6.82±1.35	0.0004
PostBFSElev (µm)	31.3±33.4	35.4±27.6	0.47
PostBFSElevThin (µm)	35.4±33.5	21.7±20.7	0.0014
Qpost	-1.48±1.30	-1.47±1.58	0.97

Flat Kpost: Keratometry at the flattest meridian; Steep Kpost: Keratometry at the steepest meridian; Kpost: Mean keratometry; PostBFSElev: Elevation posterior at the center of the cornea; PostBFSElevThin: Elevation posterior at the thinnest point of the cornea; QPost: Asphericity posterior.

(optical zone) Ferrara segments, of different arch length: 140° (140-ICRS) (13 eyes), 160° (160-ICRS) (25 eyes) and 210° (210-ICRS) (12 eyes). The parameters evaluated for the types of segments were: keratometry, asphericity and astigmatism (Table 4). The flattening effect (keratometry reduction) was more significant in cases implanted with 210° -ICRS. The asphericity change induced was similar among the segments. The cylinder induction was less with the 210°-ICRS.

DISCUSSION

Complete characterization of the corneal structure that includes analysis of the anterior and posterior corneal surface and other objective factors is important for better comprehension of visual performance after ICRS implantation. The purpose of the current study was to evaluate and characterize the anterior segment parameters given by a dual Scheimpflug analyzer in keratoconus patients implanted with Ferrara ICRS.

The visual outcomes in our study were satisfactory and similar to the reported in the literature [10-12]. There was improvement of UCVA, BCVA, spherical and astigmatism refraction. The mean SE value decreased from -4.48±3.90 D to -1.54 ±2.42 D as well as keratometric and anterior asphericity values, reducing the corneal irregularity.

In this study there were significant decreases in sphere and cylinder after ICRS implantation, agreeing with results of other studies. Shabayek and Alio [10] reported a mean difference of 3.37 D in anterior keratometry power and 2.23 D in SE with Keraring ICRS (Mediphacos, Belo Horizonte, Brazil). Coskunseven *et al* [11] reported a mean decrease in anterior K power of 3.07 D. In a study by Ertan *et al* [12], the mean SE decreased from - 7.57 D to - 3.72 D and the mean anterior keratometry value decreased from 51.56 D to 47.66 D, 1y after Intacs ICRS (Addition Technology, Chicago, USA) implantation.

We found a significant increase in corneal thickness after the

Table 4 Preoperative and last follow-up examination data of patients implanted with Ferrara ICRS implantation, according with the arch length of segment $\bar{x} \pm s$

Parameters	140º-ICRS	160º-ICRS	210º-ICRS	*P*
SimK (D)				
Preop.	48.49±3.50	48.37±1.87	50.92±1.97	0.33
Postop.	44.88±3.82	44.39±2.62	45.45±1.81	0.56
Mean change	3.61±2.78	3.98±2.51	5.47±1.47	0.27
P	0.0005	<0.0001	< 0.0001	
Asphericity anterior				
Preop.	-1.34±0.80	-1.19±0.93	-1.69±0.75	0.059
Postop.	-0.13±1.47	-0.39±1.11	-0.52±1.05	0.23
Mean change	1.21±1.27	0.80±1.53	1.17±0.90	0.44
P	0.0069	0.015	0.0047	
Refractive astigmatism (D)				
Preop.	-7.25±2.69	-4.21±1.83	-5.96±1.53	0.032
Postop.	-2.93±1.45	-2.14 ± 1.33	-3.24±1.45	0.19
Mean change	2.77±3.01	2.06±1.98	1.40±1.60	0.33
P	0.026	<0.0001	0.12	

ICRS implantation. This can be explained by a theoretically corneal collagen remodeling induced by the implantation of ICRS. As acting as "spacers" the ring segments could interfere in corneal collagen turnover, with consequent increase in corneal pachymetry[13].

The actual Ferrara ICRS nomogram [14-15] is based on the corneal asphericity, measured by the Pentacam (Oculus Optikgerate GmbH). Most current videokeratoscopes mainly consider asphericity a unique parameter. Meridian differences in asphericity have been pointed out using Scheimpflug imaging [16], and some corneal topographers and autokeratometers provide different asphericity values for the main corneal meridians [17]. Significant variability in asphericity values between different corneal topographers is expected; the values depend on where the peripheral reference points are taken, the area analyzed, the alignment of data to different referential centers, and how many meridians are involved in the calculation. Recently, Read *et al* [18] using a method that combines several corneal topography images to provide a full cornea topography map, observed marked differences in corneal asphericity depending on the annular area taken as reference.

According to this nomogram, the asphericity should be the first parameter to be considered in the ring selection. However, all other parameters are considered as well, secondarily (topographic astigmatism and pachymetry). A target postoperative asphericity value equal to -0.23 is the goal after Ferrara ring implantation[19].

A significant change in asphericity values after implantation of ICRS has been demonstrated in some studies [14-15]. In our study, there was a significant change in the anterior asphericity, after the surgery, however the magnitude of this change was not in agreement with previous studies in which the asphericity change was evaluated by the Pentacam[20]. Due to the size of the studied sample we could not predict the asphericity change according with every ICRS thickness. For these reasons, we advise that the actual Ferrara ICRS nomogram based on cornea asphericity should not be used in patients that the asphericity values were obtained with Galilei.

According to the mechanism of action of ICRS, it is expected that the shorter the segment, the larger the cylinder reduction and the lesser the asphericity change and keratometry reduction (140°-ICRS, for example)[21]. Moreover, the longer the arch segments, the lesser cylinder reduction and the larger the asphericity change and keratometry reduction (210° -ICRS, for example)[22]. The 160º -ICRS can induce moderate changes in these 3 parameters (keratometry, astigmatism and asphericity). The results obtained in our study confirm these mechanism of action (Table 4).

It was expected, in the analysis, that the 140°-ICRS had more effect on cylinder reduction when comparing these data with the 160° -ICRS. However, if we remove the 140° -ICRS sample from patients with astigmatism less than 1.50 D, the mean astigmatism reduced even more in 4.10 ±1.82 (P= 0.001). In all cases implanted with 140° -ICRS, which the preoperative astigmatism was equal or less than 1.50 D, there was increase of the postoperative astigmatism, *i.e.* induction of astigmatism. For this reason, it is strongly advised to avoid implant short arch segments in patients with low astigmatism, due to the risk of increasing the postoperative cylinder.

The SA, coma and RMS significantly changed after ICRS implantation in the present study. Pinero *et al* [23] in a study comparing two different types of ICRS (Intacs and Keraring), found that coma-like aberrations tended to decrease after ICRS implantation, and the change occurred more rapidly with the Keraring. They also compared the visual and wavefront outcomes between the manual and the femtosecond laser, and found that both procedures provided similar visual and refractive outcomes. A more limited aberrometric correction was observed in the manual technique. They found that the use of mechanical tunnelization specifically for Intacs implantation in eyes with early to moderate keratoconus limited the potential aberrometric correction of these implants because the procedure itself generated new aberrations, especially negative primary SA and primary coma.

The magnitude of change in parameters in the posterior surface of the cornea was less when compared with the anterior surface of the cornea. The only two parameters that did not show a statistically significant change alter ICRS implantation were posterior BFS elevation and posterior asphericity.

Anterior segment parameters determination is important for surgical planning in keratoconus patients and to determine the effect of ICRS implantation. The actual Ferrara nomogram based on the corneal asphericity should not be used in patients evaluated solely by Galilei. The presented data could be used, in future studies, to aid in the development of more predictable ICRS nomograms. Moreover, it emphasizes the need of development of a nomogram that would be universal to any device used to image the cornea.

In summary, we showed that the implantation of Ferrara ICRS induces changes in both anterior and posterior surfaces of the cornea. A limitation of this study is the relatively small sample of patients studied and its retrospective nature. Future studies with larger samples should be done in order to confirm the results obtained.

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