• **Clinical Research** •

Effect of intracorneal ring segment implantation on corneal asphericity

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Abstract

● **AIM:** To evaluate the visual, refractive and corneal asphericity changes after intrastromal corneal ring segment (ICRS) implantation for visual rehabilitation of keratoconus.
● **METHODS:** A total of 42 eyes of 32 patients were included. After creation of intrastromal tunnels of 5.01±0.03 mm inner diameter, 5.71±0.03 mm outer diameter and at 384.21±34.12 μm depth, 1 or 2 ICRS of 150-300 μm thickness and 90°-210° arc length were implanted. Changes in uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), refractive errors, mean simulated keratometry readings (SimK$_{avg}$), anterior and posterior corneal asphericity values (Q$_{ant}$ and Q$_{post}$, respectively) measured with Scheimpflug topography were evaluated retrospectively.
● **RESULTS:** There was a significant improvement in UDVA and CDVA, along with a significant decrease in refractive spherical equivalent (SE), cylinder and SimK$_{avg}$ postoperatively (*P*<0.001 for all). Mean Q$_{ant}$ increased from -1.06±0.48 to -0.57±0.58 postoperatively (*P*<0.001). Change in mean Q$_{post}$ was insignificant (*P*=0.92). Postoperative changes in UDVA and CDVA were not correlated with the postoperative changes in SE and cylinder (*P*>0.05 for all); but were correlated with the preoperative SimK$_{avg}$ and Q$_{ant}$ values (*P*<0.001 for all).
● **CONCLUSION:** ICRS implantation seems to approximate the anterior corneal asphericity of "advanced prolate" shape to "optimal prolate" shape and an "ideal Q value" of -0.46; which may have a role in improved UDVA and CDVA postoperatively, besides decreased refractive cylinder values.
● **KEYWORDS:** cornea ectasia; corneal asphericity; intracorneal ring segments; keratoconus; Q value

INTRODUCTION

Intracorneal ring segments (ICRS) have long been used for the optical rehabilitation of corneal ectasia[1-2]. Experience in the ophthalmology literature has shown that ICRS implantation leads to unexpectedly high visual gain in select eyes, even though the amount of refractive correction is not significant. However, in other eyes even getting close to emmetropia does not guarantee visual satisfaction[3]. This unpredictability is due to insufficiency of lower order aberrations of the eye in exploring visual quality of the patient; whilst ICRS implantation decision and selection is currently based on them.

Corneal shape is not a perfect sphere but its central part has a stronger curvature than its periphery. Thus, corneal asphericity is the main source of spherical aberration of the eye. The corneal asphericity coefficient (*i.e.*, Q value) has a mean value of -0.26±0.18 in human cornea (range: -0.88 to +0.50)[4]. The Q value that would decrease primary spherical aberration to nil is calculated as -0.46[5]. However same Q value, with different curvatures will result in different amount of spherical aberration and adverse effects on visual quality. Therefore, Q value changes should be evaluated in association with the keratometric values[6].

A previous study has shown that ICRS can effectively reduce the excess of prolateness in keratoconus in relation to the thickness of the ring segment, modifying the corneal shape to a more physiologic, aspheric shape[7]. Herein, we aimed to analyze the effects of ICRS implantation on corneal curvatures, corneal asphericity values and visual acuity.

SUBJECTS AND METHODS

Patients with keratoconus, pellucid marginal degeneration and high corneal astigmatism ineligible for keratorefractive surgery who admitted for optical and visual rehabilitation were assessed for possible means of visual gain. Main indication for ICRS implantation in all patients was contact lens intolerance and/or insufficient visual gain by contact lens fit. After a complete ophthalmic examination and a thorough discussion

of the risks and benefits of the surgery, ICRS implantation was planned. Detailed signed informed consent was obtained from each subject before the surgery.

The preoperative and postoperative data of patients with keratoconus were analysed in this study. For the sake of patient homogeneity, patients with other indications were not included into the analysis. The study adhered to the tenets of the Declaration of Helsinki.

Surgical Technique The intrastromal channels for ICRS implantation were created with the femtosecond laser device (iFS, Advanced Femtosecond laser, Abbott Laboratories Inc. Abbott Park, Illinois, USA) with a ring energy and side cut energy of 1.30 µJ. As per the KeraRing[8] 2009 nomogram based on visual, refractive and topographic parameters, 1 or 2 ring segments were implanted at 75%-80% depth of the thinnest stromal thickness at the implantation site. Inner diameter of implanted ICRS was 5 mm, thicknesses were 150-300 µm and arc lengths were 90°-210°. Selection of the ICRS and implantation parameters, as well as ICRS implantation (KeraRing; Mediphacos, Belo Horizonte, Brazil) was performed by the same surgeon at Dokuz Eylul University, Department of Ophthalmology, Cornea Division (Utine CA).

The postoperative regimen included moxifloxacin 0.5% (Vigamox®, Alcon, USA) and dexamethasone 0.1% (Maxidex®, Alcon, USA) eye drops four times daily for one week. Patients were instructed to avoid rubbing the eye and to use preservative-free artificial tears frequently-sodium hyaluronate 15% (Eyestil®; SIFI, Rome, Italy).

A complete ophthalmologic examination was performed preoperatively and postoperatively at 1st week, 1st, 3rd months. Changes in uncorrected and corrected distance visual acuities (UDVA and CDVA, respectively) in Snellen lines, refractive errors, mean simulated keratometry readings (*i.e.*, SimK$_{avg}$), anterior and posterior corneal asphericity coefficients (*i.e.*, Q$_{ant}$ and Q$_{post}$, respectively) measured with Scheimpflug tomography (Pentacam, Oculus®, Germany) at the postoperative 3rd month were evaluated. Postoperative data of 1st week and 1st month were not included into the analysis as final refractive and visual results are expected to be achieved after 3mo. Relationship between these parameters and number/thicknesses of implanted ICRS were analyzed retrospectively.

An Excel 2016 spreadsheet was used to analyze the data. A paired *t*-test was used to evaluate the postoperative data in relation to the preoperative data of the patients. The relationship between the selected parameters were analyzed by Pearsons' correlation analysis (correlation coefficient *r* value for the strength of the linear relationship between two variables, coefficient of determination r^2 value for the proportion of the variance in the dependent variable that can be explained by variation in the independent variable and related *P* values for statistical significance). A *P* value <0.05 was deemed statistically significant.

Table 1 The preoperative and postoperative visual and refractive parameters of the patients

Parameters	Preoperative	Postoperative	*P*
UDVA	0.09±0.10	0.42±0.26	<0.001
CDVA	0.29±0.14	0.62±0.24	<0.001
SE (D)	-6.35±4.58	-3.59±3.86	<0.001
Refractive cylinder (D)	-5.89±2.40	-2.27±1.66	<0.001
SimK$_{avg}$	50.08±4.12	47.49±3.78	<0.001
Q$_{ant}$	-1.06±0.48	-0.57±0.58	<0.001
Q$_{post}$	-1.02±0.59	-1.02±0.57	0.92

UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; SE: Spherical equivalent; SimK$_{avg}$: Average simulated keratometry reading; Q$_{ant}$: Q value of the anterior corneal surface; Q$_{post}$: Q value of the posterior corneal surface.

RESULTS

Data of 42 eyes of 32 patients with keratoconus was retrospectively reviewed. The age of patients at the time of surgery ranged 6-51y (median: 27, mean: 28.5±9.74). There were 20 right, 22 left eyes in this cohort. The intrastromal channels were created with the following parameters: 5.01±0.03 mm inner diameter, 5.71±0.03 mm outer diameter and 384.21±34.12 µm depth.

There was a significant improvement in UDVA and CDVA, along with a significant decrease in refractive spherical equivalent (SE), cylinder and SimK$_{avg}$ postoperatively (*P*<0.001 for all; Table 1). There was a significant increase in mean Q$_{ant}$ from -1.06±0.48 towards a more physiological Q value of -0.57±0.58 postoperatively (*P*<0.001) but there was no significant change in mean Q$_{post}$ (*P*=0.92).

Postoperative values of Q$_{ant}$ and SimK$_{avg}$ were strongly dependent on their preoperative values (*r*=0.74, r^2=0.56, *P*<0.001; *r*=0.86, r^2=0.74, *P*<0.001, respectively). There was a strong negative correlation between the postoperative change in Q$_{ant}$ and the postoperative change in SimK$_{avg}$ (*r*=-0.70, r^2=0.49, *P*<0.01).

The postoperative changes in neither UDVA nor CDVA were correlated with the postoperative changes in SE and cylinder (*P*>0.05 for all). There was a strong negative correlation between the postoperative changes in UDVA, CDVA and the preoperative SimK$_{avg}$ (*r*=-0.56, r^2=0.31, *P*<0.001; *r*=-0.55, r^2=0.30, *P*<0.001, respectively). When a polynomial regression analysis is performed, the r^2 values improved to 0.36 and 0.31, respectively (Figures 1, 2).

Similarly, there was a strong positive correlation between the postoperative changes in UDVA, CDVA and the preoperative Q$_{ant}$ (*r*=0.62, r^2=0.38, *P*<0.001; *r*=0.54, r^2=0.29, *P*<0.001, respectively). When a polynomial regression analysis is performed, the r^2 values improved to 0.55 and 0.35, respectively (Figures 3, 4).

A negative correlation was also present between postoperative SimK$_{avg}$ and changes in UDVA/CDVA (*r*=-0.56, r^2=0.31,
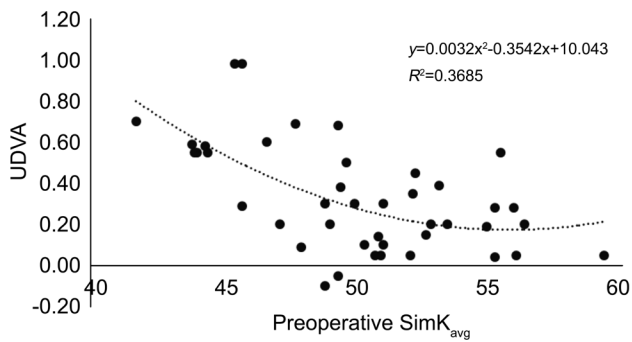
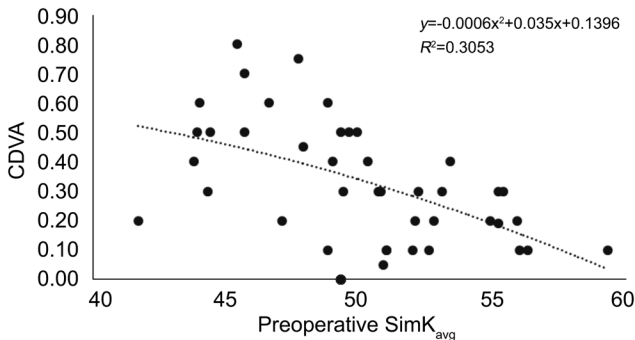**Figure 1 The correlation between preoperative SimK$_{avg}$ and change in UDVA.**

Figure 2 The correlation between preoperative SimK$_{avg}$ and change in CDVA.
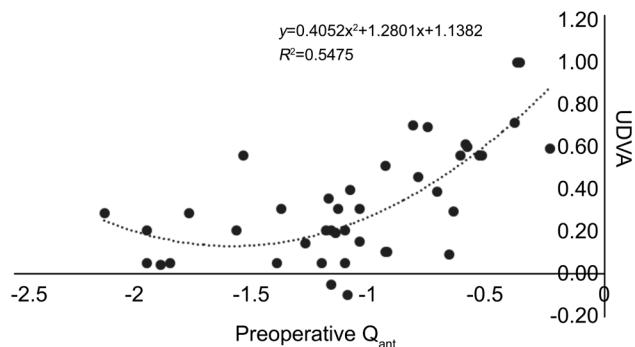

Figure 3 The correlation between preoperative Q$_{ant}$ and change in UDVA.

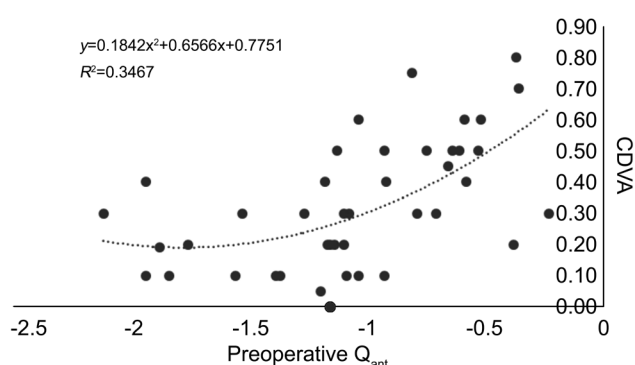**Figure 4 The correlation between preoperative Q$_{ant}$ and change in CDVA.**

$P<0.001$; $r=-0.50$, $r^2=0.25$, $P<0.001$, respectively). Similarly, a positive correlation was detected between postoperative Q$_{ant}$ and changes in UDVA/CDVA ($r=0.59$, $r^2=0.35$, $P<0.001$; $r=0.50$, $r^2=0.25$, $P<0.01$, respectively).

A significant correlation was detected neither between postoperative changes in Q$_{ant}$ or SimK$_{avg}$ and average thickness of implanted ICRS; nor between postoperative changes in Q$_{ant}$ or SimK$_{avg}$ and number of implanted ICRS ($P>0.05$, for all).

DISCUSSION

The normal human anterior corneal surface is not spherical but rather like a conoid. The typical corneal section is a prolate ellipse, with a more curved central apex and progressive flattening towards the periphery. In the inverse profile, *i.e.* when the cornea is flattened in its center and becomes steeper towards the periphery, corneal shape is said to be oblate. The physiologic asphericity of the cornea shows a significant individual variation ranging from mild oblate to moderate prolate[4,9]. Q value is the unitless best fit ellipsoid (conic constant) to describe apical ratio of change and is a measure of deviation of any surface from sphere. In other words, it defines the conical shape that best fits the cone shape. Q value of an ideal spherical surface is 0.00. A prolate surface has negative, an oblate surface has positive Q value.

The shape of a surface does affect spherical aberration. The Q value that will decrease the primary spherical aberration of the eye to nil is calculated as -0.46[5]. A parabola is, on the other hand, a prolate surface that eliminates all spherical aberration and has a Q value of -0.52. The mean Q value of human cornea is known to be -0.26±0.18 (range: -0.88 to +0.50) which reduces spherical aberration by half[4,10]. For a particular Q value, increase in radius at the apex (flattening of the surface) decreases the distance to the best-fit-sphere. On the other hand, for fixed keratometric readings, as the Q value is more negative (hyperprolate cornea), the distance to the best-fit-sphere increases. As an example with an apical radius of 7.75 mm, when corneal asphericity decreases from -0.1 to -0.5, the distance to best-fit-sphere increases by 4-fold. Keratometry and Q value could be used to calculate the spherical aberration of a single refracting surface. For a corneal Q value of -0.26 and SimK$_{avg}$ of 44.00 D, the calculated spherical aberration is 0.18 μm[11]. With equal curvature, the longitudinal spherical aberration becomes negative if the surface is more prolate than perfect Cartesian oval[9]. A hyper-prolate cornea, where peripheral rays are focused behind central rays, creates a larger depth of field; but a negative spherical aberration causes hyperopic shift in refraction. Therefore, not only the SimK readings but also the Q value determines severity of the cone and affects visual acuity.

ICRS implantation surgery has long been used for the treatment of ectatic diseases of the cornea and complies with Barraquer and Blavatskaya postulates, according to which the thickness of the addition in peripheral cornea determines the amount of flattening, and the diameter of the added ring determines how much the cornea will be flattened[12]. Postoperative outcome is a central flattening of the cornea while the periphery is

displaced forward[13]. The resultant cornea is flattened at the areas corresponding to the segments extremities and making it curve at the ring's body area[3]. Current nomograms for ICRS selection use preoperative subjective refraction, topographical keratometry and cone location data. However, postoperative surprises are not rare in terms of visual gain. The lack of correspondence between postoperative visual acuity and residual ametropia has also been observed before[3]. Similarly in this study, the postoperative changes in UDVA or CDVA were not correlated with the postoperative changes in refractive SE or cylinder ($P>0.05$ for all). Thus, decrease in refractive error may not necessarily indicate visual improvement; and success of the surgery should not be evaluated by postoperative refraction, only. Indeed, basic requirements for visual gain after ICRS implantation surgery are yet to be clarified.

Given the fact that postoperative values or the amount of changes in refractive errors are not indicative of improvement in visual acuity, attention has already been turned on corneal asphericity which serves as a marker of visual quality and turning it "normal" can be a predictor of visual gain. Ferrara and Torquetti[14] have argued that in patients with significant corneal flattening after ICRS implantation without considerable improvement of UDVA and CDVA, oblate corneal shape (positive Q values) could explain the lack of visual improvement. They found a direct correlation between ring thickness and reduction of Q values, on which they built their fourth generation nomogram[14]. However, integration of this nomogram and previous one that takes cone distribution and subjective/topographic astigmatism into account, is not clear.

This observation seems to be correct both for primary ectasias and for iatrogenic ectasias. Torquetti and Ferrara[15] have shown that in patients with corneal ectasia after refractive surgery, whose ablated oblate corneas have turned into prolate with the development of ectasia, mean asphericity decreased from -0.95 preoperatively to -0.23 after ICRS implantation.

In this study, the change in Q_{ant} was correlated with the change in $SimK_{avg}$ ($P<0.01$). Indeed, not only the preoperative values of Q_{ant} and $SimK_{avg}$, but also their resultant values seem to be determinants of improvement in visual acuity. Maximum increase in UDVA and CDVA were seen in eyes with postoperative Q_{ant} of >-0.50. Therefore, getting close to the ideal prolate structure from a hyperprolate one seems to be beneficial for sound improvement in the visual acuity. Thus, it would be wise if one could choose ICRS parameters to aim a target Q value postoperatively. However, this approach is not merely unrealistic, but also requires development of new nomograms. Simply, as postoperative Q_{ant} and $SimK_{avg}$ are strongly dependent on their respective preoperative values, these parameters may be used as predictors of visual gain and aid in patient selection (Figures 1-4). It has been shown that corneal curvature and asphericity indices were the parameters best positioned to detect keratoconus progression in mild to moderate disease[16]. This is particularly important as measurement error in keratoconic eyes is significantly greater than healthy eyes, and reliable preoperative patient selection criteria are needed for surgery planning. The results of this study were in agreement with that of Torquetti et al[17] and Lyra et al[18] although they reported best correlation of visual outcomes with anterior corneal astigmatism.

Interestingly, postoperative changes in Q_{ant} or $SimK_{avg}$ were correlated with neither the number nor the thicknesses of implanted segments in this study. A previous study on post-laser-assisted in situ keratomileusis ectasia patients revealed better correction of SE with two segments compared to single segment implantation; nonetheless, the level of astigmatism in the single-segment group was significantly better than that in the double-segment group[19]. In this study, we could detect no correlation with the number or thickness of implanted rings with the visually predictive topographic parameters. All implanted ICRS had the same 5.0 mm diameter, therefore a correlation with the ring diameter could not be examined. A significant correlation was only detected between the change in Q_{ant} and the change in $SimK_{avg}$, each of which were strongly dependent on their preoperative values.

In a multicenter, retrospective, nonrandomized study of 611 keratoconic eyes, Vega-Estrada et al[20] have found that ICRS implantation provides significantly better results in patients with a severe form of the disease. However in that study, keratoconus grading was performed according to the degree of visual limitation, not the keratometric data. There were overlapping keratometry readings in different keratoconus severity groups. Furthermore, patients with most severe keratoconus grades had a wide range of preoperative $SimK_{avg}$ values between 38.48 D and 82.62 D. Thus, the study population was not accurately grouped in terms of corneal curvatures, which is the main parameter for ICRS segment selection. In our practice we also note that the lesser preoperative visual acuity, the greater visual gain patient achieves; but the expected visual gain decreases significantly when preoperative $SimK_{avg}$ value is greater than 55 D.

Limitations of this study include small sample size and not being able to measure corneal aberrations other than spherical aberration, as the study was conducted with the Scheimpflug tomography device Pentacam which does not provide other corneal aberrometric data.

In conclusion, ICRS implantation seem to approximate the anterior corneal asphericity of "advanced prolate" shape to "the optimal prolate" Q value of -0.52 and "spherical aberration-free" human corneal Q value of -0.46. This improvement in corneal asphericity may have a role in improvement in UDVA and CDVA, in addition to the effect of decreased refractive cylinder. It should be kept in mind that ICRS implantation

serves as the last resort for optical and visual rehabilitation before corneal transplantation surgeries, in ectatic diseases[21]. If planned and performed properly, it offers a minimally invasive method for improvement in corneal asphericity and visual acuity. For this reason, further improvements on the nomograms and patient selection criteria are mandatory.

ACKNOWLEDGEMENTS

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