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Original research

Effects of single-segment Intacs implantation on visual acuity and corneal topographic indices of keratoconus

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Abstract

Purpose: To assess the changes in visual acuity and topographic indices after implantation of single-segment Intacs.
Methods: Forty-two keratoconic eyes received Femtosecond-assisted single-segment Intacs. Uncorrected distance visual acuity (UDVA) and best spectacle corrected visual acuity (BSCVA), refractive error, keratometry (K1, K2, Km, and KMax.), and seven Pentacam measured topographical indices; index of surface variance (ISV), index of vertical asymmetry (IVA), keratoconus index (KI), central keratoconus index (CKI), index of height asymmetry (IHA), index of height decentration (IHD), and minimum radius of curvature (R Min) were assessed 4 months after surgery. Correlations between changes of visual acuity and topographical indices changes were evaluated.
Results: UDVA increased from 0.92 ± 0.35 to 0.49 ± 0.31 logMAR ($P < 0.001$), and BSCVA increased from 0.39 ± 0.15 to 0.23 ± 0.11 logMAR ($P < 0.001$). Subjective refraction spherical equivalent (SRSE) decreased from −3.92 ± 1.66 diopters (D) to −2.00 ± 1.51 D ($P < 0.001$). Mean central Keratometry decreased 2.16 ± 1.09 D from the preoperative readings ($P < 0.001$). All Pentacam topographical indices except CKI significantly improved (for IHA $P = 0.046$, for five others $P < 0.001$). The correlation between improvement in topographical indices and visual acuity improvements was not week.
Conclusion: Intacs implantation in keratoconic eyes increased visual acuity and made corneal shape less irregular. However, the improvements of visual acuity and corneal shape were not strongly correlated.

Keywords: Intracorneal ring segment; Pentacam; Corneal topographic indices; Keratoconus

Introduction

Keratoconus is a chronic, progressive, non-inflammatory condition in which irregular astigmatism and myopia is induced by corneal thinning.[1] It is manifested asymmetrically between the two eyes of the same patient and impairs quality and quantity of vision.[2]

Intracorneal ring segments (ICRSs) have been offered as a treatment option for keratoconus.[3] It is used as an alternative to corneal graft in contact lens intolerant patients with mild to moderate keratoconus with a clear optical zone.[4] ICRSs act by exerting an 'arc-shortening effect' on the corneal lamellae and flatten the central cornea.[5] The procedure is safe and reversible, and the central cornea is not manipulated.[6] Implanting ICRSs has been proven to be effective at improving visual acuity and refractive error.[3,7–9] However, evaluating the changes occur in topographic irregularity indices can give a better understanding of the physical changes that occur in the cornea after ring segment implantation.

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In this study, the effect of ICRS on visual acuity, refractive error and corneal topographic indices of keratoconic eyes and their correlations were evaluated.

Methods

This interventional prospective case series included 42 eyes of 32 patients with keratoconus who had received femtosecond-assisted single-segment intacs (Addition Technology Inc., Sunnyvlae, CA, USA) from April 2014 to April 2015. All patients signed informed consent before the study. The tenets of the Declaration of Helsinki were followed. Diagnosis of keratoconus was established by clinical examination and corneal imaging using Pentacam.[2]

Inclusion criteria were contact lens intolerance and clear cornea, the maximum keratometric reading less than 58.00 diopters (D), mean keratometric reading less than 55.00 D, and the peripheral corneal thickness more than 450 μm. The patients with previous eye disease or surgery, diagnosed autoimmune disease and systematic connective tissue disease were excluded from the study.[3,4]

A complete ophthalmologic examination, including uncorrected visual acuity (UCVA) and best spectacle corrected visual acuity (BSCVA), manifest and subjective refraction, biomicroscopic, fundoscopic and corneal topography using Pentacam (Oculus Inc., Germany) were performed in all eyes before surgery.

Topographical indices provided by Pentacam were extracted from the related topography maps. These included flattest central keratometry (K1), steepest central keratometry (K2), mean central keratometry (Km), maximum keratometry (K Max.), index of surface variance (ISV, a descriptor of corneal surface curvature variance), the index of vertical asymmetry (IVA, a measure of the curvature difference between superior and inferior cornea), the keratoconus index (KI), the central keratoconus index (CKI), the index of height asymmetry (IHA, a measure of the height difference between superior and inferior cornea), the index of height decentration (IHD, vertical decentration of height data), and the minimum radius of curvature (R Min, a measurement of the smallest radius of curvature of the cornea).

All surgeries were performed under topical anaesthesia using proparacaine hydrochloride 0.5% sterile eye by one experienced surgeon (K.A.). Before the surgery the corneal thickness was measured by ultrasonic pachymeter (UP-1000 Ultrasound Pachymeter, Nidek, Japan) at the area of the incision site and marked with the Viscot surgical marker. If the best corrected visual acuity (BCVA) was better than 4/10 and the difference between the steep topographical axis and BCVA positive cylinder axis was more than 10°, positive cylinder axis determined the incision site. When BCVA was less than 4/10, the steep topographical axis was used to determine the incision site with some other considerations according to the surgeon's clinical experience and manufacturer's nomogram. The tunnel was performed using a Femtosecond laser (FS200 Femtolaser; Alcon, Fort Worth, TX) at 1.2 mJ in three to four sec at 70% of the corneal thickness at the incision site. An inner diameter of 6.8 mm and outer diameter of 8.1 mm was programmed with the laser software, which is equivalent to the Intacs segment width. In all cases, single-segment Intacs was implanted. The thickness of ring was determined based on spherical equivalent of refraction as recommend in manufacturer's nomogram. The incision was sutured using 10-0 nylon, which was removed six to eight weeks after the operation. Levofloxacin was administered every six hr. for three days after the operation. Betamethasone 0.1% ophthalmic drops were administered for five days. The patients were instructed to avoid eye rubbing and use preservative-free artificial tears for four to six weeks after the operation.

To evaluate the ring location and healing of the incision site, the patients were examined using slit-lamp postoperatively at one day and one month after the surgery by the same surgeon. Postoperative Pentacam examination repeated at 4 months. A complete ophthalmologic examination was also performed in this visit. In this study, we limited data collection to about 4 months after surgery to isolate the effect of ICRS implantation from the possibility of keratoconus progression and to analyse the real effects of ring segments implantation.[10,11]

Data analysis was performed using SPSS for Windows, version 21 (SPSS Inc., Chicago, IL, USA). Normality was checked by Kolmogorov–Smirnov test. Wilcoxon test or paired t-test was performed to compare means of preoperative and postoperative values. Spearman or Pearson correlation coefficients (r) were applied for testing correlation of non-parametric and parametric values, respectively.

Correlations between corneal topographic indices improvements and visual acuity improvements were also investigated. *P*-values less than 0.05 were considered statistically significant.

Results

Of the 42 subjects, 76.2% were male, and 23.8% were female. The mean age of the participants was 30.5 ± 8.11 years (range, 19–41 years). The mean follow-up time was 4.7 ± 0.6 months (range, 3.7–5.5 months). No complication was observed during or after operation.

At the four-month follow-up examination, the mean of visual acuity and spherical equivalent change was statistically significant (Table 1).

Preoperatively, the UCVA ranged from 0.3 to 1.3 (logMAR) and the BSCVA, from 0.2 to 0.7 (logMAR). The mean UCVA and BSCVA increased significantly after surgery (both $P < 0.001$) (Table 1).

The UCVA remained at the preoperative level in three eyes (7.14%) and decreased 0.2 logMAR in one eye (2.38%). Thirty-five eyes (83.33%) gained more than 0.1 (logMAR). The BSCVA remained at the preoperative level in 9 eyes (21.43%), decreased 0.1 (logMAR) in one eye (2.38%), and increased more than 0.1 (logMAR) in 47.62% of the eyes. In two eyes (4.76%) BSCVA improved from 0.3 to 0.00 (logMAR) (Fig. 1).

Table 1
Visual acuity and spherical equivalent changes after single-segment Intacs implantation.

Parameter	Preoperative	4 months postoperatively	Changes	*P*
	Mean ± SD	Mean ± SD	Mean ± SD	
UCVA (logMAR)	0.92 ± 0.35	0.49 ± 0.31	0.43 ± 0.28	<0.001
BSCVA (logMAR)	0.39 ± 0.15	0.23 ± 0.11	0.16 ± 0.14	<0.001
SRSE (D)	−3.92 ± 1.66	−2.00 ± 1.51	−1.94 ± 1.25	<0.001
K1(D)	46.53 ± 2.82	44.67 ± 2.69	1.86 ± 1.08	<0.001
K2 (D)	49.49 ± 3.00	47.24 ± 2.74	2.25 ± 1.34	<0.001
Km (D)	48.03 ± 2.80	45.87 ± 2.61	2.16 ± 1.09	<0.001
K max. (D)	55.95 ± 5.23	52.93 ± 4.16	3.02 ± 2.88	<0.001

UCVA: Uncorrected visual acuity, BSCVA: Best spectacle corrected visual acuity, SRSE: Subjective refraction spherical equivalent, SD: Standard deviation, K1: Flattest central keratometry, K2: Steepest central keratometry, Km: Mean central keratometry, K Max: Maximum keratometry power, D: Diopter.

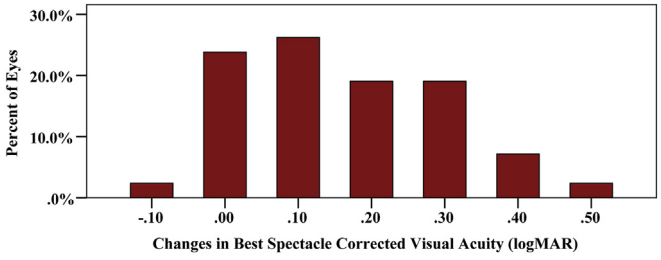

Fig. 1. Best spectacle corrected visual acuity (BSCVA) changes after single-segment Intacs implantation.

Preoperatively, the mean of spherical equivalent of subjective refraction was -3.92 ± 1.66 D. Postoperatively, it improved by 2.00 D or more in 20 eyes (47.62%), and in one eye (2.38%) remained at the preoperative level. The mean of spherical equivalent of subjective refraction decreased significantly after surgery ($P < 0.001$) (Table 1) (Fig. 2).

At the four-month follow-up examination, the change in keratometric parameters (k1, K2, Km, and K Max) was statistically significant ($P < 0.001$). The results showed that on average, central corneal power decreased 2.16 ± 1.09 (D), which made the cornea flatter (Table 1).

Out of seven corneal topography indices, five indices significantly decreased after surgery (for IHA, $P < 0.046$, for four others $P < 0.001$); while, R Min and CKI significantly increased ($P < 0.001$) (Table 2).

No strong correlations were observed between improvements of BSCVA and UCVA and improvements of corneal topography indices (Table 3).

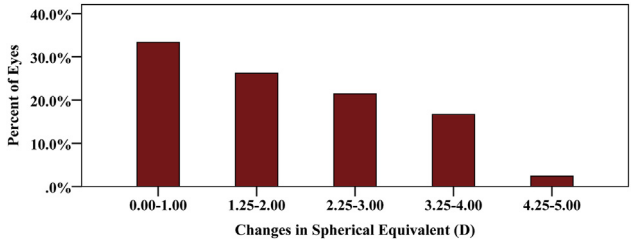

Fig. 2. Spherical equivalent changes after single-segment Intacs implantation.

Table 2
Pentacam corneal topography indices changes after single-segment Intacs implantation.

Parameter	Preoperative	4 months postoperatively	Changes	*P*
	Mean ± SD	Mean ± SD	Mean ± SD	
ISV	96.76 ± 30.22	72.88 ± 21.28	23.88 ± 16.47	<0.001
IVA (mm)	1.133 ± 0.42	0.74 ± 0.32	0.38 ± 0.25	<0.001
KI	1.27 ± 0.11	1.13 ± 0.09	0.14 ± 0.09	<0.001
CKI	1.06 ± 0.05	1.08 ± 0.04	−0.02 ± 0.02	<0.001
IHA (μm)	34.24 ± 23.58	27.97 ± 21.93	6.26 ± 19.71	0.046
IHD (μm)	0.16 ± 0.11	0.08 ± 0.05	0.08 ± 0.11	<0.001
R min.(mm)	6.09 ± 0.54	6.39 ± 0.53	−0.3 ± 0.3	<0.001

ISV: Index of surface variance, IVA: Index of vertical asymmetry, KI: Keratoconus index, CKI: Central keratoconus index, IHA: Index of height asymmetry, IHD: Index of height decentration, R Min: Minimum radius of curvature, SD: Standard deviation.

Table 3
Correlation between corneal topography indices improvements and visual acuity improvements resulted from single-segment Intacs implantation.

Parameter	Spearman correlation	
	With UCVA	With BSCVA
ISV	0.32[a]	0.23
IVA (mm)	0.27	0.05
KI	0.24	0.19
IHD (μm)	0.14	0.06
IHA (μm)	−0.085	0.04
R min. (mm)	−0.016	−0.32[a]

ISV: Index of surface variance, IVA: Index of vertical asymmetry, KI: Keratoconus index, IHA: Index of height asymmetry, IHD: Index of height decentration, R Min: Minimum radius of curvature, UCVA: Uncorrected visual acuity, BSCVA: Best spectacle corrected visual acuity.
[a] Correlation is significant at the 0.05 level (2-tailed).

Discussion

ICRSs have been proposed as a surgical procedure for correction of keratoconus. It has been investigated by many researchers, and its efficacy in increasing visual acuity and in decreasing refractive error and keratometry has been confirmed.[7,12–16] In the present study, the improvements in visual acuity, refractive error, and keratometry were in agreement with the previous studies. We assessed the changes happen in corneal topography indices after ICRS implantation. Moreover, we evaluated the correlation between improvements of these indices and visual acuity improvements. Evaluating changes of topographic indices provides comprehensive analysis of the changes happen in corneal shape after ICRS implantation.

Compared to normal eyes, in keratoconus, all of the Pentacam provided topographic indices except for R Min are higher.[17] R Min is the inverse of corneal steepness, and it is expected to decrease in keratoconus. The results of this study showed improvement for the values of all topography indices postoperatively except for CKI. It has been mentioned in previous studies that CKI compares central corneal curvature with peripheral curvature, and it shows the ratio between mean radius values in a peripheral ring divided by a central ring.[17,18]

It seems that increased peripheral curve after implantation of ICRS elevates the value of this ratio in keratoconus, and CKI has less significance in evaluating the effect of ICRS implantation inside ring area of the cornea.

Significant improvement in the ISV shows reduced variation in corneal curvature which could result in more regular corneal surface. Improvements in the IVA and IHA are indicative of curvature and height difference reduction between superior and inferior curvature and height of the cornea respectively. Improvement in the IHD indicates that the cone becomes more central by this intervention.[19] Finally, significant improvement in KI indicates normalization of corneal topography in keratoconic eyes and keratoconus severity reduction.[17,20] These results suggest that ICRS implantation flattens the cornea and reduces its irregularity. All these changes reduce keratoconus severity and normalize keratoconic cornea.

Assessing correlation between topographical indices changes and visual acuity improvement, no statistically significant correlation between the changes of topographic indices and UCVA and BSCVA changes were observed. Other studies investigated these correlations in patients after corneal cross-linking and reported similar results.[20,21] Considering this result, it seems that more regular corneal surface does not mean better subjectively tested visual acuity. In other words visual acuity values do not correlate with keratoconus severity. According to the literature, visual acuity test cannot be a reliable tool for assessing keratoconus and its progression.[17,22] Clinical experiences with keratoconic patients shows similar results. In clinics, we find many keratoconic patients with topographically irregular cornea but with visual acuity of 10/10 or near 10/10.

Testing visual acuity in keratoconic patients is subjective, and many factors including multifocal cornea, patients' neural adaptation, and head tilt could affect the result of visual acuity tests.[17] Many studies have considered visual acuity and keratometry changes as indicators of corneal stability, regression, or progression after ICRSs implantation.[7,15,16,23] However, corneal changes may continue despite stable visual acuity or keratometry measurements in central 3 mm of cornea.[24]

In this study, corneal topography indices were calculated by Pentacam software. It has been proven that the Pentacam system provides repeatable and accurate measurements of the cornea.[19,25,26] Although the studies have shown good repeatability for most of corneal irregularity indices in keratoconic eyes,[19,27] further studies are required to investigate and evaluate these indices' merit for assessing keratoconus regression or progression after surgical intervention.

This study has several limitations. The sample size is small. Also, we did not have control groups of patients treated with other modalities. In addition, other imaging modalities may provide different results.

In conclusion, this study shows that corneal topography indices improve after ICRS implantation mostly independent of changes in visual acuity. Topographic indices changes make corneal surface less irregular and reduce keratoconus severity. It seems that these indices along with other clinical factors may be good indicators of corneal changes after ICRS implantation.

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