Patient satisfaction after femtosecond-assisted intracorneal ring segment implantation in the treatment of keratoconus

Alaa Ghaith, Mohamed Sobhy, Mohsen Abou Shousha, Amr El Kamshoushi

Department of Ophthalmology, Alexandria University, Egypt

Correspondence to Alaa Ghaith, MD, Department of Ophthalmology, Faculty of Medicine, Alexandria University, Alexandria, 22311, Egypt; Tel: 01060222674; e-mail: alaaghaith1@gmail.com

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Purpose
The aim of this article is to evaluate patient satisfaction after femtosecond-assisted intracorneal ring segment (ICRS) implantation in the treatment of keratoconus.
Patients and methods
The study was carried out in two private eye centers and Department of Ophthalmology at Alexandria University. This study is a retrospective type. The study included 30 keratoconus patients with moderate to severe keratoconus and clear central cornea. All patients underwent KeraRings ICRS implantation. All patients answered a specially designed questionnaire to evaluate their visual function and satisfaction within a period of 6 months to 1 year postoperatively. The correlations between questionnaire scores and the clinical parameters were studied.
Results
The clarity of vision in general was good for 50% of the cases, acceptable for 26.7%, and bad for 16.7%. Regarding night vision, 40% of the patients complained of bad night vision; while for 46.7% of the patients it was acceptable. Additionally, the analysis revealed that regarding 'reading' 73.4% of patients were satisfied. Sixty percent of the patients were satisfied with their far vision, postoperatively. Ninety-three percent and 90% of the patients complained of glare and haloes, respectively; 12 patients complained of fluctuation of vision. Significant correlations were those of SEQ (spherical equivalent of manifest refraction) and K_{max} at the sixth month with general satisfaction with P value less than 0.001 and 0.013, respectively. Conclusively 70% of the patients were satisfied after ICRS implantation.
Conclusion
Most patients (70%) are generally satisfied after ICRS implantation for the treatment of keratoconus. However, night vision disturbance, glare and haloes are the main complaints for a large number of them (about 90%).

Keywords:
femtosecond laser, ICRs, keratoconus, rings

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Introduction

Keratoconus is a progressive, noninflammatory ectatic disorder of the cornea that results in the development of irregular astigmatism and reduction of visual acuity. Management of keratoconus includes the use of glasses and contact lenses for visual rehabilitation at early stages, corneal collagen cross-linking in the case of progression to achieve stabilization and penetrating or deep lamellar keratoplasty in advanced cases [1].

Intrastromal corneal ring segment (ICRS) implantation is a less invasive surgical option with acceptable clinical results [2–6]. After ICRS implantation, visual rehabilitation is faster than after penetrating keratoplasty or deep anterior lamellar keratoplasty, and without the risk of graft rejection [7].

The channels for the insertion of the segments can be created mechanically or with a femtosecond laser. The use of the femtosecond laser reduces the risk of complications during the creation of tunnels [8].

Management of keratoconus by the use of ICRS has been proven to be successful from the objective point of view; however, it has also been proven that vision rehabilitation in keratoconus patients is not totally explained by clinical measurements, probably due to the long-term adaptation to optical blur [7].

To judge an intervention as being successful it must do so objectively and more importantly subjectively.

The aim of this study was to evaluate the quality of vision of keratoconus patients after ICRS implantation and to identify the main clinical parameters affecting patient's satisfaction. This was achieved through the use of a questionnaire based on the National Eye Institute Visual Function Questionnaire.

Patients and methods

This is a retrospective study that evaluated the satisfaction of keratoconus patients after ICRS implantation. Ethics Committee Faculty of Medicine, Alexandria University approved this study. All patients gave their informed consent prior to the study and all the tenets of the Declaration of Helsinki were adhered to.

The study included 30 keratoconus patients with moderate to severe keratoconus and clear central cornea. All patients underwent KeraRings ICRS implantation (Mediphacos, Belo Horizonte, Brazil). All patients answered the specially designed questionnaire between 6 months and 1 year, postoperatively. All patients answered the questionnaire before clinical examination to avoid any influence of the exams performed during the medical appointment on the patients' answers.

The questionnaire assessed the following: clarity of vision, far vision, reading, night vision, and general satisfaction using a scale from 1 to 5 (1 means very bad and 5 means very good). It also assessed the dependence on glasses or contact lenses. Also glare, haloes, foreign body sensation, fluctuation of vision, and monocular diplopia were checked for being present or absent.

Preoperative evaluation included detailed ocular, medical, and surgical history, thorough ophthalmic examination including: uncorrected visual acuity (UCVA), manifest refraction, best spectacle-corrected visual acuity (BSCVA), Pentacam (Allegro® Oculyzer, WaveLight AG, Germany), topography (Allegro Topolyzer; WaveLight AG), and anterior segment OCT (Visante; Carl-Zeiss Meditec Inc., Dublin, California, USA).

Inclusion criteria

The study included keratoconus patients who had ICRS implantation with the following criteria: clear central cornea, corrected visual acuity greater than or equal to 20/200, intolerance to rigid contact lenses, *K* readings between 45 and 60 D, and pachymetry at least 350 μm at the thinnest location and at least 450 μm at the incision site.

Surgical technique and postoperative care

The same surgeon planned all surgeries and two experienced surgeons did the surgeries. The manufacturer's nomogram was used to calculate the dimensions of the ICRS to be used in each case. All cases were done under topical anesthesia using benoxinate HCL eye drops. The conjunctival sac was disinfected with 10% povidone-iodine and 3% povidone-iodine solution. The femtosecond laser (Visumax; Carl-Zeiss Meditec Inc.) was used in all cases for tunnel and incisions creation. The access incision and the tunnel were tested to ensure their patency, then implantation of the KeraRing segments (Mediphacos) was carried out under full aseptic technique with the aid of KeraRing forceps and a Sinskey hook.

Postoperatively, the patients were given topical moxifloxacin and prednisolone acetate 1% every 6 h for 2 weeks. Artificial tears were prescribed every 4 h for 1 month. Patients were examined 1 day after surgery to assess ICRS location, 1 week later to assess the cornea and UCVA, and after 1 and at least 6 months to perform a complete ophthalmic examination including UCVA, BSCVA, manifest refraction, and Pentacam. All patients underwent corneal collagen cross-linking 1 month after (ICRS) implantation.

Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS (IBM Co., New York, USA) software package, version 20.0. Qualitative data were described using number and percent. Quantitative data were described using range (minimum and maximum), mean, SD, and median. The distributions of quantitative variables were tested for normality using Kolmogorov–Smirnov test, Shapiro–Wilks test, and D'Agstino test. If it reveals normal data distribution, parametric tests were applied. If the data were abnormally distributed, nonparametric tests were used. For normally distributed data, comparison between different periods using analysis of variance with repeated measures and post-hoc test was assessed using least square difference adjustment. For abnormally distributed data, to compare between the different periods Friedman test was applied and Wilcoxon's signed-ranks test was used to compare between two periods. Correlations between two quantitative variables were assessed using Spearman's coefficient. Significance of the obtained results was judged at the 5% level.

Results

The study included 30 keratoconus patients with a mean age of 26.60±6.23 years. Sixty percent were men and 40% were women. The mean value of UCVA increased from a preoperative value of 1.02±0.30 (logMAR units) to 0.40±0.15 and 0.34±0.20 at 1 and 6 months postoperatively, respectively. There was a statistically significant difference between the mean UCVA preoperatively and at the three visits ($P<0.001$). The mean value of preoperative BCVA

was 0.28±0.12 (logMAR units), while the mean value postoperatively at 1 and 6 months was 0.25±0.10 and 0.21±0.15, respectively. There was a statistically significant difference between the mean BCVA preoperatively and after 6 months (P=0.023).

The mean value of preoperative spherical equivalent (SEQ) was −5.75±3.27 D, while the mean value of postoperative SEQ at 1 month and 6 months was −1.78±1.40 and −0.95±1.25 D, respectively. There was statistically significant difference between preoperative and postoperative SEQ (P<0.001).

The flattening effect of ICRS was evident as the mean K_{max} value was 57.40±2.60 D in the preoperative period, while postoperative mean values of K_{max} at 1 and 6 months were 54.93±4.20 and 53.85±4.24 D, respectively. There was statistically significant difference between preoperative and postoperative values at different periods (P≤0.001). Regarding K_{mean}: The K_{mean} preoperatively was 50.67±2.93 D, while postoperatively at 1 and 6 months the mean value of K_{mean} was 48.46±3.43 and 47.97±3.14 D, respectively. There was statistically significant difference between preoperative and postoperative values of K_{mean} (P<0.001).

Analysis of patient satisfaction

The statistical analysis of the questionnaire data revealed that the clarity of vision in general was good for 50% of patients, and none of them complained of very bad clarity of vision. However, this was different with night vision, as 40% of patients complained of bad night vision; while for 46.7% of the patients it was acceptable. It was very bad for only two patients and good for another two (Table 1).

Also the analysis revealed that regarding far vision, reading, and general satisfaction, the patients were almost equally distributed between good, acceptable, and bad. Table 1 shows the distribution of the studied cases according to satisfaction.

Moreover by analyzing the questionnaire we noticed that 93 and 90% of the patients complained of glare and haloes, respectively; 12 patients complained of fluctuation of vision, and five patients complained of monocular diplopia and foreign body sensation. Twenty (66.7%) patients were independent of glasses or contact lenses, while 10 patients were dependent on either of them. Table 2 shows the distribution of side effects and dependence on glasses or contact lenses among the study population.

The correlations between the questionnaire parameters and the clinical parameters were studied. These clinical parameters included UCVA and BSCVA (preoperatively and postoperatively), manifest refraction (postoperatively), Pentacam findings including K_1, K_2, K_{mean}, and K_{max} (preoperatively and postoperatively).

The univariate analysis of these correlations revealed many interesting and important correlations. The 'clarity of vision in general' was strongly and negatively correlated with K_1 front at the sixth month, K_{max} at the sixth month, K_{mean} preoperatively, and K_{mean} at the sixth month with statistically significant correlations.

The 'reading' was strongly and positively correlated with the SEQ at the sixth month and this correlation was statistically significant. While regarding 'far vision' there were the following statistically significant correlations: strong negative correlation with K_1 front at the sixth month, and strong negative correlation with K_{max} at the sixth month.

The statistical analysis of the data revealed that the 'night vision' did not have any strong correlations, while general satisfaction has the following statistically significant correlations: strong negative correlation with K_1 front at the sixth month, strong negative correlation with K_2 front preoperatively, strong negative correlation with K_2 front at the sixth month, very strong negative correlation with K_{max} at the sixth month, and strong negative correlation with K_{mean} at the 6th month (r=−0.721).

Although there were many significant strong and very strong correlations in the univariate analysis, the multivariate analysis revealed that the only significant correlations were those of SEQ and K_{max}

Table 1 Distribution of the studied cases according to satisfaction

	1: Very bad [*N* (%)]	2: Bad [*N* (%)]	3: Acceptable [*N* (%)]	4: Good [*N* (%)]	5: Very good [*N* (%)]
Clarity of vision in general	0 (0.0)	5 (16.7)	8 (26.7)	15 (50.0)	2 (6.7)
Night vision	2 (6.7)	12 (40.0)	14 (46.7)	2 (6.7)	0 (0.0)
Reading	0 (0.0)	8 (26.7)	11 (36.7)	9 (30.0)	2 (6.7)
Far vision	4 (13.3)	8 (26.7)	7 (23.3)	10 (33.3)	1 (3.3)
General satisfaction	0 (0.0)	9 (30.0)	10 (33.3)	11 (36.7)	0 (0.0)

at the sixth month with general satisfaction with a *P* value less than 0.001 and 0.013, respectively.

We noticed that according to general satisfaction the patients were divided into three groups: group 1 included patients who were not satisfied, that is, score 2 (n=9), group 2 included patients who reported acceptable satisfaction, that is, score 3 (n=10), and group 3 included patients who reported good satisfaction, that is, score 4 (n=11). The K_{max} mean values at the sixth month were 57.91±2.28, 54.55±2.42, and 49.90±3.18 D in groups 1, 2, and 3, respectively. The SEQ mean values at the sixth month were −1.67±1.29, −1.20±0.90, and −0.14±1.11 D in groups 1, 2, and 3, respectively (Table 3).

Discussion

Most studies evaluating ICRS in keratoconus evaluate the clinical parameters such as visual acuity, refraction, and *K* readings; however, these clinical parameters are not enough to evaluate visual experience in keratoconus patients because of their adaptation to the long-term blur they suffer from.

This study included 30 keratoconus patients. Cases of post-Lasik ectasia were not included in this study. All patients underwent femtosecond laser-assisted KeraRings ICRS implantation. Corneal collagen cross-linking was done in all cases 1 month after ICRS implantation. All patients answered a specially designed questionnaire at least 6 months postsurgery.

The results of the questionnaire assessing patients' satisfaction with postoperative quality of vision were analyzed and correlated with a number of preoperative and postoperative clinical parameters.

Comparison of UCVA and BCVA at different periods demonstrated that UCVA and BCVA in our study improved progressively. There were statistically significant differences between preoperative UCVA and UCVA at 1 month and after 6 months (P<0.001). There was a statistically significant improvement in BCVA after 6 months (P=0.023). None of our patients experienced deterioration of UCVA. However, four cases showed deterioration of BCVA but they were still satisfied.

Regarding the refractive outcome after ICRS implantation, the mean value of preoperative SEQ decreased by about 4.80 D after the sixth month. This decrease was statistically significant (P<0.001). There was a gradual flattening of the cornea with K_{max} and K_{mean} values declining progressively over the follow-up period (P≤0.001).

All eyes showed excellent corneal tolerance to the segments with no extrusion or vascularization around the incision or the tunnels. In one patient there was migration of one of the ICRS. Repositioning was done with no complications.

Table 2 Distribution of the studied cases according to side effects and dependence on glasses or contact lenses

	No [*N* (%)]	Yes [*N* (%)]
Fluctuation of vision	18 (60.0)	12 (40.0)
Haloes	3 (10.0)	27 (90.0)
Glare	2 (6.7)	28 (93.3)
Monocular diplopia	25 (83.3)	5 (16.7)
Dependence on contact lenses or glasses	20 (66.7)	10 (33.3)
Foreign body sensation	25 (83.3)	5 (16.7)

Analysis of patient satisfaction

The satisfaction of patients in our study was assessed using a specially designed questionnaire, which revealed

Table 3 Relation of general satisfaction with K_{max} and SEQ

	Generally			*F*	*P* value
	Bad (n=9)	Acceptable (n=10)	Good (n=11)		
K_{max} (D)					
6 months					
Minimum–maximum	52.90–61.0	50.80–57.90	45.0–56.20	22.424*	<0.001*
Mean±SD	57.91±2.28	54.55±2.42	49.90±3.18		
Significance between groups		P_1=0.011*, P_2<0.001*, P_3=0.001*			
SEQ					
6 months					
Minimum–maximum	−4.25–0.0	−2.75–0.50	−2.25–1.38	5.147*	0.013*
Mean±SD	−1.67±1.29	−1.20±0.90	−0.14±1.11		
Significance between groups		P_1=0.365, P_2<0.001*, P_3=0.001*			

F, *F*-test (analysis of variance), test of significance between groups was done using post-hoc test (least square difference). P_1, *P* value for comparing between bad and acceptable. P_2, *P* value for comparing between bad and good. P_3, *P* value for comparing between acceptable and good. *Statistically significant at P£0.05.

that 50% of patients reported 'good' for the clarity of vision in general. However, 40% of patients complained of bad night vision. Moreover the analysis revealed that regarding far vision, reading, and general satisfaction, patients were almost equally distributed between good, acceptable, and bad.

General satisfaction of the patients had moderate to strong correlations with the following postoperative parameters UCVA, BCVA, K_1 front, K_2 front, SEQ, K_{max}, and K_{mean}. It was moderately to strongly correlated with K_1, K_2, and K_{mean} preoperatively.

From these correlations we can conclude that there is a trend toward higher general satisfaction with lower K_1, K_2, and K_{mean} preoperatively. However, these correlations did not prove to be statistically significant in the multivariate analysis. This trend partly agrees to the predictors of ICRS effects found in the literature. Alio ? *et al*. [9] have reported good outcomes in a group similar to our study, with a mean age of 29.5±7.05 years. The poor results and complications rate were higher in older and female patients [9,10]. The preoperative predictors of a good outcome have been reported to be lower initial keratometric readings (K<53 D), better preoperative CDVA, lower astigmatism, and spherical myopia [9].

Torquetti *et al*. [11] have concluded that the best clinical outcomes are seen in patients between 20-year and 30-year old and initial cases of keratoconus (K_{mean}<46 D). The more advanced the keratoconus, the larger the magnitude of curvature reduction after ICRS implantation. Collins *et al*. [12] have stated that the predictors of ICRS failure were higher K readings and thinner corneas before surgery. Our study results confirm some of these data.

Although there were many significant strong and very strong correlations in the univariate analysis, the multivariate analysis revealed that the only significant correlations were those of SEQ and K_{max} at the sixth month with general satisfaction with a P value less than 0.001 and 0.013, respectively.

We noticed that according to general satisfaction the patients were divided into three groups: group 1 included patients who were not satisfied, that is, score 2 (n=9); group 2 included patients who reported acceptable satisfaction, that is, score 3 (n=10), and group 3 included patients who reported good satisfaction, that is, score 4 (n=11). The mean K_{max} values at the sixth month were 57.91±2.28, 54.55±2.42, and 49.90±3.18 D in groups 1, 2, and 3, respectively. The mean SEQ values at the sixth month were −1.67±1.29, −1.20±0.90, and −0.14±1.11 D in groups 1, 2, and 3, respectively. As most studies report a flattening effect by about 4 D, the satisfied patient must have a preoperative K_{max} value of less than 58 D.

Also by analyzing the questionnaire we noticed that most of the patients complained of night glare (93%) and haloes (90%). This may be related to the pupil scotopic diameter. Twelve patients complained of fluctuation of vision, and five patients complained of monocular diplopia and foreign body sensation. Twenty patients were independent of glasses or contact lenses, while 10 patients were dependent on either of them. So we also recommend assessment of the pupil diameter and will the patient accept the night vision expected problems and his night visual needs.

Conclusion

ICRS implantation is a safe and efficient surgical option in the management of keratoconus. Most patients (70%) are generally satisfied after ICRS implantation for the treatment of keratoconus. Night vision disturbance, glare, and haloes are the main complaints for a large number of them (about 90%). Satisfied patients are usually those who have postoperative flatter cornea and lower spherical equivalent. Follow up for longer duration, with a larger sample is recommended especially for a more proper assessment of patients satisfaction and related clinical parameters. A new nomogram for ICRS, which takes into account different factors affecting patients' satisfaction, and the variable corneal biomechanical properties among patients with KC, is needed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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