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Original Article

Long-Term Quality of Life Results of Intrastromal Corneal Ring Segment Implantation in Keratoconus Patients Using the National Eye Institute Visual Function Questionnaire

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Keywords: Intrastromal corneal ring segments; keraring; keratoconus; National Eye Institute Visual Function Questionnaire 25.

ABSTRACT

Objective: The aim of this study was to investigate the long-term quality of life and vision level of keratoconus patients who underwent implantation of intrastromal corneal ring segments (ICRS).

Methods: During February 2012, 23 keratoconus patients that had ICRS implanted were included in this retrospective study. The patients were divided into 3 severity subgroups. After 4 years, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BCVA) and Kmax values were recorded. A Turkish version of the National Eye Institute Visual Function Questionnaire 25 (NEI-VFQ 25) was administered to all of the patients retrospectively.

Results: There was a notable increase in all patients' BCVA (p=0.001) and UCVA (p=0.021). The Kmax values were reduced in all cases (p=0.01); however, this reduction was not statistically significant in subgroup 2 (p=0.285). The peripheral vision score was also lower in type 2 (p=0.049). A significant correlation was found between BCVA/UCVA and NEI-VFQ 25 scores, except for general health, social functioning, general vision, dependency, and driving.

Conclusion: Patients' quality of life and vision scores support ICRS implantation as an acceptable option before penetrating keratoplasty for keratoconus treatment. But, the satisfaction and vision levels were not better in patients in the early stages of keratoconus. So it may be considered that early treatment of ICRS implantation is not a necessary protocol.

INTRODUCTION

Keratoconus is a bilateral, non-inflammatory disorder of the cornea that is associated with progressive stromal thinning and irregular astigmatism.[1] Irregular astigmatism decreases best-corrected visual acuity (BCVA), and may reduce contrast sensitivity and increase visual aberrations, depending on the magnitude of the irregularity.[2]

Current treatment options vary according to the severity of the disease. In mild cases, conservative management options, including spectacle correction or rigid contact lenses, may be preferred in cases of corneas with no scarring. But tolerance of rigid lenses is very low in the young and active keratoconus population.[3] A simpler, more useful and effective solution that can be applied before surgical options appeared in the late 1990s in the form of intrastromal corneal ring segments (ICRS).[4]

ICRS, also known as keraring, was first introduced to cor-

rect myopia, but once the therapeutic effect on corneal curvature was discovered, it was also used to treat mild to moderate keratoconus before performing penetrating keratoplasty, due to its reversibility and safety.[5–7] The ring segment acts as a passive element that flattens the central cornea, reshaping the keratoconic cornea with ring segments and improving the corneal surface.[8] Clear improvement of visual acuity can be observed directly after surgery. However, the vision level achieved and the satisfaction of ICRS patients varies. In some cases, there may be new aberrations that occur after implantation. Low-grade aberrations like astigmatism can usually be resolved with ICRS, and there is a corresponding increase in vision level, but higher-order aberrations (spherical and coma) cannot always be prevented. The procedure might induce glare and halo phenomenon with low-contrast sensitivity. Low vision quality naturally leads to low patient satisfaction levels.

Impaired vision results in an impaired quality of life (QoL), and the level of vision significantly worsens and continues to decrease over time in cases of progressive keratoconus.[9,10] The National Eye Institute Visual Functioning Questionnaire 25 (NEI VFQ-25) is designed to assess vision-related QoL and the effect of vision quality on daily activities.[11] This 25-item assessment measures quality of life using the subscales of overall vision, mental health, social status, peripheral, and color vision.

The primary objective of this study was to evaluate the long-term vision related QoL of keratoconus patients who underwent ICRS implantation with type 1, type 2, and type 3 corneal ectasia using the NEI VFQ-25 instrument.

MATERIAL AND METHODS

In February 2012, 30 eyes of 23 keratoconus patients (11 women, 12 men) who underwent ICRS implantation between December 2007 and April 2008 were included in this retrospective study. The patients were aged between 21 and 55 years (mean: 34.7±8.4 years) at the time of implantation. The patients were followed up for 4 years after the surgery.

The excluding criteria were a keratometric value >65.00 diopters (D), apical scarring, a history of acute hydrops, or any measurement <400 microns in the 5-mm central corneal thickness zone.

The diagnosis of keratoconus was established using the Amsler-Krumeich classification, based on astigmatism, corneal power, corneal transparency, and corneal thickness, and was obtained using a rotating Scheimpflug imaging and placido disc instrument (Sirius 3D rotating Scheimpflug camera & topography system; Bon Optic, Lübeck, Germany).[12] The patients were divided into 3 groups based on severity and the implantation technique was modified based on corneal ectasia subgroups. In all, 6 eyes (20%) were included in subgroup 1, 4 eyes (13.3%) were classified in subgroup 2, and 20 eyes (66.7%) that were in subgroup 3 were included in this study. ICRS could not be implanted in any patient in subgroup 4 as a result of the extreme severity of the stage of keratoconus (Table 1).

Intrastromal ICRS were implanted manually or with the aid of a femtosecond laser (IntraLase Corp., Irvine, CA, USA) in patients whose vision had not improved or who were unsatisfied with eyeglasses and contact lenses when the central cornea was clear. All of the surgeries were performed by the same surgeon in the 5-mm central corneal zone. Of the 30 eyes, manual implantation was performed on 23 (80%) and ICRS were implanted in 7 (20%) eyes using the laser.

Preoperatively, as well as during the follow-up period, all of the patients underwent a detailed ophthalmic examination, including uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), refraction, slit-lamp biomicroscopy, fundus examination, and keratometric measurements.

On their last visit before the procedure, all of the patients provided written, informed consent in accordance with the Declaration of Helsinki. Subsequently, a Turkish version of the National Eye Institute Visual Function Questionnaire 25 (NEI-VFQ 25) was administered to all of the patients retrospectively. The questionnaire includes 25 main items and additional optional items.6 All of the questions were explained by the staff and read when necessary for patients who were unable to read because of their poor eyesight.

Table 1. Amsler- Krumeich clinical classification of keratoconus by stage

Stage	Characteristics
I	Eccentric steepening
	Induced myopia and/or astigmatism of ≤5.00 D
	Keratometric reading ≤48.00
	Vogt's lines, typical topography
II	Induced myopia and/or astigmatism 5.00 to ≤8.00 D
	Keratometric reading ≤53.00
	Pachymetry ≥ 400 µm
III	Induced myopia and/or astigmatism 8.00 to ≤10.00 D
	Keratometric reading >53.00
	Pachymetry 200 to 400 µm
IV	Refraction not measurable
	Keratometric reading >55.00 D
	Central scars
	Pachymetry ≤ 200 µm

D: Diopters.

The subscales of the questionnaire were graded between 0 and 100 with higher scores representing better function. The NEI-VFQ 25 was scored according to the guidelines set by the authors.[13]

Statistical analysis

Descriptive analyses were presented as a mean±SD. The Mann-Whitney U test, Kruskal-Wallis test, and Pearson's correlation coefficient were used to compare the scale scores. The statistical analysis was performed using IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA). A p value of <0.05 was considered statistically significant.

RESULTS

In this retrospective study of 23 keratoconus patients there was no significant difference in age and gender of the patients between the laser group and the manual implantation group or between subgroups 1, 2, and 3 (p>0.05).

Intracorneal segment implantation provided an increase in the BCVA (p=0.001) and the uncorrected visual acuity (UCVA) (p=0.021) of all of the patients. No significant difference was noted between the manual and laser groups or between the subgroups (p>0.05).

After segment implantation, an evident decrease in Kmax values was observed in all cases (p=0.01). But this reduction was not statistically meaningful in subgroup 2 (p=0.285). Subgroups 1 and 3 were comparable with respect to Kmax values (p=0.87). The flattening in keratometric scales was better in the IntraLase group than in the manual implantation group (p=0.005).

The comparison of gender and subscale scores in all patients was not statistically significant. However, we found a negative correlation in the analysis of color vision and age in all keratoconus patients (p=0.037) (Table 2).

The analysis of the subscale items and the follow-up period revealed notable data in the following areas: vision-specific (p=0.037), mental health (p=0.049), role difficulties (p=0.027), and peripheral vision (p=0.041). A longer follow-up period improved those subscale points (Table 2). However, no significant correlation was found in the subscale items between a follow-up period of less or more than 4 years.

When we compared the NEI-VFQ-25 scores between the keratoconus subgroups, the peripheral vision score was lower only in type 2 ectasia patients (p=0.049) compared with the other subgroups (Table 3).

The UCVA and BCVA QoL scores were compared. A significant p value was found in the examination of UCVA and the subscales of near activities (p=0.02), distance activities (p=0.015), role difficulties (p=0.029), peripheral vision (p=0.001), ocular pain (p=0.011), and general health quality (p=0.01). All of these scores were better in patients with higher levels of UCVA (Table 4).

Table 2. Subscale correlations between gender, age, and follow-up period

No. of eyes: 30	Gender (p value between men/women)	Age p value (2-tailed)	Folow-up period p value (2-tailed)
General health	0.219	0.837	0.612
General vision	0.639	0.676	0.233
Ocular pain	0.917	0.724	0.293
Near activities	0.588	0.581	0.158
Distance activities	0.464	0.831	0.188
Vision specific	0.635	0.889	0.037*
Social functioning	0.516	0.205	0.457
Mental health	0.400	0.799	0.049*
Role difficulties	0.886	0.439	0.027*
Dependency	0.788	0.809	0.054
Driving	0.966	0.155	0.888
Color vision	0.515	0.037	0.818
Peripheral vision	0.895	0.936	0.041*
General life quality	0.761	0.779	0.067

* p<0.05 meaningfull for statistically.

Table 3. Subscale correlations between keratoconus ectasia subtypes

No. of eyes: 30	Subtype 1	Subtype 2	Subtype 3	p
	Mean±SD	Mean±SD	Mean±SD	
General health	61±13.5	56±15.2	54±15.1	0.613
General vision	61±10.8	62±13.2	57±17.8	0.702
Ocular pain	72±13.6	57±19.7	65±20.5	0.352
Near activities	64±21.4	69±18.1	72±17.4	0.632
Distance activities	73±17.3	61±17.4	75±20.8	0.224
Vision specific	70±21.80	67±22.7	77±19.8	0.459
Social functioning	78±20.0	87±14.8	84±16.1	0.595
Mental health	65±21.2	54±30.5	63±28.2	0.672
Role difficulties	67±30.1	58±27.6	74±23.2	0.249
Dependency	71±27.0	71±27.6	86±23.5	0.201
Driving	33±47.1	58±30.7	76±30.4	0.193
Color vision	80±20.9	90±17.4	92±11.5	0.230
Peripheral vision	70±20.9	52±27.5	76±20.0	0.049
General life quality	68±16.2	65±16.5	73±15.4	0.391

SD: Standard deviation.

Table 4. Subscale correlations between uncorrected visual acuity and best corrected visual acuity

No. of eyes: 30	UCVA Sig. (2-tailed)	BCVA Sig. (2-tailed)
General health	0.120	0.072
General vision	0.691	0.425
Ocular pain	0.011*	0.043*
Near activities	0.020*	0.019*
Distance activities	0.015*	0.029*
Vision specific	0.064	0.006*
Social functioning	0.910	0.096
Mental health	0.060	0.004*
Role difficulties	0.029*	0.002*
Dependency	0.084	0.109
Driving	0.078	0.384
Color vision	0.128	0.010*
Peripheral vision	0.001*	0.002*
General life quality	0.010*	0.002*

* p<0.05 meaningfull for statistically.
BCVA: Best corrected visual acuity; UCVA: Uncorrected visual acuity.

Table 5. Subscale correlations between manual and laser implantation subgroups

No. of eyes: 30	Manual	IntraLase	p
	Mean±SD	Mean±SD	
General health	53±15.0	63±13.0	0.129
General vision	60±14.9	53±16.9	0.368
Ocular pain	64±19.2	62±20.9	0.817
Near activities	73±16.0	61±21.3	0.220
Distance activities	72±19.6	69±21.9	0.541
Vision specific	75±20.1	72±22.6	0.684
Social functioning	85±17.2	84±13.3	0.829
Mental health	63±27.1	60±31.0	0.683
Role difficulties	72±25.0	65±27.5	0.585
Dependency	82±24.7	80±26.0	0.545
Driving	63±36.8	77±10.4	0.724
Color vision	91±15.5	87±13.6	0.409
Peripheral vision	72±23.9	66±25.8	0.636
General life quality	71±15.2	69±18.1	0.768

SD: Standard deviation.

Similarly, the same significant correlation was found between the BCVA and the subscales of near activities (p=0.019), distance activities (p=0.029), role difficulties (p=0.02), peripheral vision (p=0.002), ocular pain (p=0.043), and general health quality (p=0.02), as well as the subscales of vision-specific (p=0.06), mental health (p=0.04), and color vision (p=0.01) (Table 4).

Interestingly however, there wasn't any significant relationship seen between corrected/uncorrected visual acuities and the subscales of general health, social functioning, general vision, dependency, and driving (Table 4).

Finally, there was no statistically significant difference between the type of surgery (manual, IntraLase) and the subscale scores (p>0.05) (Table 5).

DISCUSSION

Keratoconus is a progressive ectatic corneal disorder featuring a protrusion of the central cornea, which decreases vision and QoL in young people.[3]

The Collaborative Longitudinal Evaluation of Keratoconus (CLEK) study demonstrated that QoL is adversely affected by keratoconus. It was also noted that keratoconus patients have both role difficulties and mental health scale results similar to those reported by the Age-Related Eye Disease Study patients with advanced (category 4) age-related macular degeneration.[14]

ICRS implantation uses an arc-like surgical instrument that was first used for the correction of low myopia.[5–7] It was later proposed that intracorneal rings could make the corneal center flatter and more regular and provide a better visual acuity, and ICRS placement became an additive keratorefractive procedure that has been used for keratoconic eyes in Europe since 1997.[15–20]

Until recently, studies of ICRS implantation in keratoconus patients used only quantitative data, such as visual acuity according to the Snellen chart, keratometry readings, contrast sensitivity, and corneal aberration markers to evaluate the outcomes.8 According to the conventional approach, the success of surgical or clinical situations has been assessed by the increase in the distance vision levels.

In 2010, the study conducted by Piermarocchi et al.[21] noted that the quantification of vision by traditional methods could be inadequate to investigate the quality of vision. A psychometric questionnaire on visual function could allow better information of patients' QoL.

In this context, the NEI-VFQ was first introduced to give a self-reported measure of visual function. The original form was a 51-item questionnaire for a variety of patients with major ocular diseases.[22] Later, it was shortened to 25 items, and has been used to show that are those with ocular disease and accompanying visual impairment have lower scores compared to a reference group without ocular disease.[11,23–25]

We preferred to evaluate the QoL of keratoconus patients with ICRS implantation using the latest NEI-VFQ-25 instrument.

In 2010, Paranhos et al.[8] used the NEI Refractive Error Quality of Life instrument (NEI-RQL) test to evaluate 42 keratoconus patients who had undergone ICRS before and 4 to 8 months after surgery. This article concluded that there was a significant improvement in all of the NEI-RQL scales, as well as the overall scale postoperatively. The same study also reported recoveries in BCVA, keratometric values, contrast sensitivity, and low order aberrations with ICRS implantation.

To the best of our knowledge, this is the first study in the literature that assessed QoL scores in ICRS implant patients of different keratoconus severity stages.

The aim of the present research was to examine if the keratoconus stage or implantation method produced a difference in terms of the QoL of ICRS patients. Our results indicated that manual and laser implantation groups had similar NEI-VFQ-25 scores.

Also, there were no significant differences in the NEI-VFQ-25 scores in the 3 keratoconus subgroups, with the exception of peripheral vision scores. In subgroup 2, the peripheral vision score was lower than in other subgroups. Similarly, the reduction in Kmax value was minimal in subgroup 2. ICRS implantation may be a less convenient method in subgroup 2 keratoconus patients. Unfortunately, we have no reasonable argument as to why this keratometric and subscale data is worse only in subgroup 2, particularly given that subgroup 3 had a more serious stage of the disease. Perhaps information about aberrometric changes could be helpful to explain this finding.

The satisfaction levels on other subscales of near activities, distance activities, role difficulties, peripheral vision, ocular pain, general health quality, vision specific, mental health, color vision, social functioning, general vision, dependency, and driving were similar in all of the study patients, including a lack of gender difference.

This study, like previous research, may contribute to improvements in BCVA, UCVA, and keratometric readings for all ICRS groups of keratoconus patients.

Earlier studies have shown that manual and laser implantation technics were similar in terms of postoperative keratometric changes and visual acuity.[26–28] In our study, the keratometric reduction was more significant in the IntraLase group (p=0.05); however, this difference was not observed in the UCVA and BCVA levels (p>0.05).

In conclusion, the patients' QoL scores 4 years postoperatively were quite good, which supports the fact that ICRS implantation is an acceptable option to be used before penetrating keratoplasty for keratoconus treatment. We also put forward that the satisfaction and vision levels were not better in early stages of keratoconus as expected after ICRS implantation. So it may be that early ICRS implantation is not a necessary protocol. However, more studies with a larger study population are needed to clarify the actual benefit of this procedure.

Ethics Committee Approval

Approved by the local ethics committee.

Informed Consent

Retrospective study.

Peer-review

Internally peer-reviewed.

Authorship Contributions

Concept: A.P., I.K.K.; Design: A.P., A.K.; Data collection &/or processing: A.P.; Analysis and/or interpretation: I.K.K., E.S.S.; Literature search: E.S.S., A.P.; Writing: A.P.; Critical review: I.K.K.

Conflict of Interest

None declared.

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Keratokonuslu Hastalarda İntrastromal Kornea Halka Segmentinin Uzun Dönem Yaşam Kalitesi Sonuçlarının Ulusal Göz Enstitüsü-Refraktif Kusur Yaşam Kalitesi Testi İle Değerlendirilmesi

Amaç: İntrastromal kornea halka segmentleri (IKRS) uygulanmış keratokonus hastalarında yaşam kalitesinin ve görme düzeylerinin uzun dönem sonuçlarını araştırmak.

Gereç ve Yöntem: Şubat 2012 boyunca, IKRS uygulanmış olan keratokonuslu hastaların 30 gözü geriye dönük olarak çalışmamıza dahil edildi. Dışlama kriterleri; 65.00 D'nin üzerinde keratometrik değer, apikal skarlaşma olmasıydı. Elle veya İntralase ile halka takılmış olan hastalar dört yıllarında keratokonusun şiddetine göre üç grupta değerlendirildi. Düzeltilmemiş görme keskinliği (DGK) en iyi gözlükle düzeltilmiş görme keskinliği (EDGK) ve Kmax değerleri kaydedildi ve NEI-VFQ 25 anketi geriye dönük ve Türkçe olarak uygulandı.

Bulgular: Tüm hastalarda EDGK (p=0.001) ve DGK (p=0.021) oldukça belirgin artış gösterdi. Tüm olgularda Kmax değerleri azaldı (p=0.01). Ancak bu azalma, alt grup 2'de istatistiksel olarak anlamlı değildi (p=0.285). Ayrıca grup 2'de periferik görüş skoru daha düşüktü (p=0.049). Genel sağlık, sosyal işlevsellik, genel görüş, bağımlılık ve sürüş haricinde BCVA/UCVA ile tüm NEI-VFQ 25 skorları arasında anlamlı bir korelasyon bulundu. Tüm skorlar manuel ve intralase gruplarında benzerdi.

Sonuç: Çalışmamızın sonuçları keratokonus tedavisi için IKRS penetran keratoplastiden önce kabul edilebilir bir seçenek olduğunu desteklemektedir. Ancak, IKRS uygulanmış erken evre hastalarda memnuniyet ve görme düzeylerinin beklendiği gibi daha iyi olmadığını gördük. Bu nedenle IKRS tedavisinin erken uygulanmasının gerekli bir protokol olmadığı düşünülülebilir.

Anahtar Sözcükler: İntrastromal korneal halka segmenti; keraring; keratokonus; NEI-VFQ 25.