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Comparison of Visual, Refractive and Aberration Measurements of INTACS versus Toric ICL Lens Implantation; A Four-year Follow-up

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ABSTRACT

This study was performed to evaluate the visual, refractive, and aberration measurement results of 2 implants, including Intacs Intracorneal Ring Segments (ICRS) and phakic Toric Implantable Collamer Lens (TICL), in patients with moderate Keratoconus (KCN). In this retrospective cross-sectional study, 30 patients with KCN with a mean age of 29.83 years were included in 2 groups, including the Intacs Intracorneal Ring Segments (ICRS) group and the phakic Toric Implantable Collamer Lens (TICL) group. Preoperative data as well as 6-month, 1-, 2-, 3- and 4-year follow-up data after the operation were collected and analyzed with the SPSS software (ver. 23.0, SPSS, Inc., Chicago, IL), using the paired t-test, independent t-test, repeated measures Analysis of Variance (ANOVA), and one-way ANOVA. This study included 30 patients with KCN with a mean age of 29.83 years and range of 25 to 35 years, including 17 males with a mean age of 30.11 years and 13 female with a mean age of 29.25 years. Except for preoperative Uncorrected Distance Visual Acuity (UCDVA), Spherical Equivalent (SE) and astigmatism, there was a significant difference between the 2 groups regarding other variables. The TICL group had a significantly better UCDVA and Best Corrected Distance Visual Acuity (BCDVA) in all post-operative follow-ups, and SE and astigmatism values were significantly lower in all post-operative follow-ups when compared with the ICRS group. There was a significant reduction in corneal and total coma as well as internal trefoil aberrations ($P<0.01$, $P<0.01$, and $P=0.014$, respectively) in the ICRS group, and TICL led to a significant reduction in internal trefoil aberration with $P<0.03$. Comparison of the 2 groups revealed a significant difference in corneal spherical ($P<0.01$) and total coma ($P=0.02$) aberrations and no significant differences in other HOA. Both ICRS and TICL are useful in patients with moderate KCN. However, TICL appears to have more stable and predictable vision results.

KEY WORDS

Keratoconus; Intacs intracorneal ring segments; Phakic toric Lens; Higher-order aberrations

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INTRODUCTION

Keratoconus (KCN), as an asymmetric non-inflammatory ectatic disorder of the cornea, is almost always bilateral. In this disorder, progressive stromal thinning leads to conic deformation and protrusion of cornea at the thinnest point. Prevalence of KCN varies amongst different studies from 1 per 2000 to 5.4 per 10000 individuals [1],[2]. Progression of KCN begins with progressive deterioration of Visual Acuity (VA), which is not corrected with spectacles [2],[3].

Based on severity of KCN, there are different modalities of treatment, including strengthening procedures, optical optimization, and combined procedures [4]. In mild to moderate stages, spectacles [1] and hard contact lenses [5] are appropriate options. However, in advanced stages, keratoplasty [6] may be required, with the disadvantage of being costly, requiring lifelong follow-up, risk of graft-rejection or infection and suture-related complications [7]. Therefore, other safe and effective treatment modalities, including implantation of Intacs Intracorneal Ring Segments (ICRS) and phakic Toric Implantable Collamer Lens (TICL), have been introduced [8],[9],[10],[11],[12],[13],[14],[15],[16],[17],[18],[19],[20]. Besides improvement of VA, attention to quality of vision is also important. By assessment of ocular Higher-Order Aberrations (HOA), a wave-front analyzer could evaluate optical quality and irregular astigmatism [21]. Several studies have evaluated optical aberrations in patients with KCN and revealed increased HOA, especially coma and spherical aberrations. Significant increase in HOA results in reduced VA, which is not correctable with spectacles or conventional contact lenses [22],[23],[24].

The current study aimed at evaluating visual, refractive, and aberration measurement values (corneal, internal optics and total aberrations), preoperatively and at the 6-month, and 1-, 2-, 3- and 4-year follow-up in TICL and ICRS implantation.

MATERIALS AND METHODS

This retrospective cross-sectional study was conducted on one eye of 30 patients with non-progressive (8 months prior to surgical procedure) moderate KCN, aged 25 to 35 years, who had undergone ICRS (Intacs, Addition Technology Inc., Fremont, California, USA) or TICL (ICL; STAAR Surgical, Nidau, Switzerland) implantation at Negah Eye Hospital, Tehran, Iran, by a single surgeon (SH. R.) and were followed-up postoperatively for the subsequent 4 years. Ethical approval was received from the Ethical Committee of Shahid Beheshti Medical University and all subjects signed informed consent forms. Diagnosis of KCN was based on the Amsler–Krumeich classification [25]. Patients' VA was measured by the Snellen VA chart, based on the logMAR scoring system. Furthermore, refraction was assessed with auto-refraction (Topcon RM800, USA) and aberrometry measurement was done with the iTrace (ray-tracing; Tracey Technologies, Houston, TX).

The inclusion criteria were having complete medical files available at Negah Eye Hospital; lack of progression of KCN; visual dissatisfaction with spectacles; contact lens intolerance; age of ≥ 25 years; Best Corrected Distance Visual Acuity (BCDVA) log MAR 0.4 (equivalent 20/40); maximum of 58 diopters of keratometry; Intraocular Pressure (IOP) of less than 20 mm Hg with Anterior Chamber Depth (ACD) of at least 3 mm, measured from the endothelium of the cornea; anterior chamber angle of >30°; and corneal endothelial cell density proportional to patient's age of at least 2000 mm².

The exclusion criteria were having the thinnest corneal thickness of ≥ 380 µm; history of previous intraocular surgery; history of herpetic corneal infections; lack of ocular media clarity, such as the presence of corneal scar or cataract; the presence of ocular diseases, such as glaucoma, active vernal kerato-conjunctivitis, intraocular inflammation, and retinal diseases except for KCN; history of systemic diseases, such as diabetes mellitus, immune deficiency, and collagen vascular disease, which could delay corneal wound healing; drug history of sumatriptan, amiodarone, and isotretinoin; being pregnant or breastfeeding; and having files with incomplete information or data belonging to a health care center other than Negah Eye Hospital.

Preoperative as well as 6-month, and 1-, 2-, 3- and 4-year follow-up data were collected and analyzed with the SPSS software (ver. 23.0, SPSS, Inc., Chicago, IL), using the paired t-test, independent t-test, repeated measures Analysis of Variance (ANOVA), and one-way ANOVA. The paired t-test was used to measure pre- and post-operative differences; independent t-test was used to assess the mean difference between ICRS and TICL groups; repeated measures ANOVA test was used to compare pre- and post-operative values; and one-way ANOVA was used to compare the values between the 2 groups. P values of less than 0.05 were considered significant.

RESULTS

The current study was conducted on one eye of 30 patients with KCN and a mean age of 29.8 years and a range of 25 to 35 years. The sample included 17 males

with a mean age of 30.1 years and 13 female with a mean age of 29.2 years. In the TICL group, there were 7 males and 8 females with a mean age of 32.9 and 30.5 years, respectively, and in the ICRS group, there were 6 males and 9 females with a mean age of 28.55 and 27.33 years, respectively.

Table 1 shows mean ± Standard Deviation (SD) of preoperative as well as 6-month, and 1-, 2-, 3- and 4-year postoperative BCDVA, UCDVA, Spherical Equivalent (SE), and astigmatism values of the ICRS and TICL groups. As revealed in this table, except for preoperative UCDVA, SE, and astigmatism, there was a significant difference between the 2 groups regarding the other variables. Patients in the TICL group showed significantly better UCDVA and BCDVA during all post-operative follow-ups, and SE and astigmatism values in this group were significantly lower in all post-operative follow-ups when compared with the ICRS group, which implies better postoperative results in the TICL group.

Table 2 and 3 show values of corneal, internal, and total HOA in the preoperative assessment as well as 6-month, and 1-, 2-, 3- and 4-year postoperative follow-ups for ICRS and TICl groups, respectively. There was a significant reduction in corneal and total coma as well as internal trefoil aberrations (P<0.01, P<0.01, and P=0.014, respectively) in the ICRS group (Table 2) and TICL led to a significant reduction in internal trefoil aberration with a P value of <0.03 (Table 3). Between-group comparison revealed a significant difference in corneal spherical (P<0.01) and total coma (P=0.02) aberrations (Table 3). However, no significant difference was observed in other HOA.

Table 1. Pre and Post-Operative Vision and Refraction Results in the Intacs Intracorneal Ring Segments (ICRS) and Phakic Toric Implantable Collamer Lens (TICL) Groups

Variable	Mean (SD)		P-value
	ICRS Group	TICL Group	
LogMar UCDVA (Snellen)			
Pre-operative	0.65 (0.22)	0.82 (0.30)	0.09
6 months post-operative	0.39 (0.08)*	0.11 (0.08)*	<0.01
1 year post-operative	0.39 (0.09)*	0.13 (0.10)*	<0.01
2 years post-operative	0.40 (0.13)*	0.10 (0.10)*	<0.01
3 years post-operative	0.43 (0.12)*	0.09 (0.08)*	<0.01
4 years post-operative	0.41 (0.12)*	0.10 (0.07)*	<0.01
LogMar BCDVA (Snellen)			
Pre-operative	0.37 (0.11)	0.15 (0.11)	<0.01
6 months post-operative	0.32 (0.08)*	0.09 (0.11)*	<0.01
1 year post-operative	0.35 (0.09)	0.04 (0.17)*	<0.01
2 years post-operative	0.34 (0.09)*	0.07 (0.15)*	<0.01
3 years post-operative	0.34 (0.10)*	0.06 (0.14)*	<0.01
4 years post-operative	0.33 (0.09)*	0.09 (0.14)*	<0.01
Spherical Equivalent (D)			
Pre-operative	-5.70 (3.14)	-8.57 (4.86)	0.06
6 months post-operative	-3.65 (1.39)*	-0.85 (0.29)*	<0.01
1 year post-operative	-3.67 (1.32)*	-0.97 (0.26)*	<0.01
2 years post-operative	-3.57 (1.42)*	-0.70 (0.19)*	<0.01
3 years post-operative	-3.58 (1.28)*	-0.75 (0.23)*	<0.01
4 years post-operative	-3.15 (2.19)*	-0.73 (0.26)*	<0.01
Astigmatism (D)			
Pre-operative	-6.25 (2.93)	-4.83 (2.06)	0.14
6 months post-operative	-4.67 (1.97)*	-1.05 (0.74)*	<0.01
1 year post-operative	-4.10 (2.81)*	-0.97 (0.55)*	<0.01
2 years post-operative	-4.03 (2.82)*	-1.00 (0.58)*	<0.01
3 years post-operative	-4.17 (2.81)*	-1.02 (0.51)*	<0.01
4 years post-operative	-4.98 (1.68)*	-1.00 (0.53)*	<0.01

SD= standard deviation; ICRS= Intacs intracorneal ring segments; TICL=phakic toric Implantable Collamer Lens; UCDVA=uncorrected distance visual acuity; BCDVA= best corrected distance visual acuity; Snellen= Snellen visual acuity chart; D= diopters. *= P values less than 0.05.

Table 2. Visual and Refractive Values Pre and Postoperatively in Intacs and Toric Implantable Collamer Lens Groups

Variable	(Mean ± SD)	Post-operation					P-value
	Pre-operation	6 months	1 Year	2 Year	3 Year	4 Year	
Corneal							
Coma	1.70 (0.35)	1.21 (0.27)	1.26 (0.29)	1.28 (0.27)	1.28 (0.26)	1.29 (0.27)	<0.01
Spherical	2.27 (0.74)	2.27 (0.75)	2.27 (0.76)	2.27 (0.74)	2.30 (0.77)	2.27 (0.75)	0.51
Trefoil	0.44 (0.19)	0.43 (0.17)	0.43 (0.18)	0.43 (0.18)	0.42 (0.18)	0.43 (0.18)	0.26
Internal							
Coma	0.92 (0.14)	0.90 (0.13)	0.93 (0.18)	0.93 (0.18)	0.96 (0.23)	0.97 (0.23)	0.11
Spherical	1.90 (0.63)	1.91 (0.61)	1.91 (0.61)	1.91 (0.59)	1.91 (0.55)	1.90 (0.56)	0.99
Trefoil	0.43 (0.25)	0.33 (0.14)	0.32 (0.13)	0.32 (0.13)	0.33 (0.13)	0.34 (0.13)	0.014
Total							
Coma	1.42 (0.28)	1.05 (0.17)	1.27 (0.25)	1.38 (0.26)	1.31 (0.25)	1.26 (0.24)	<0.01
Spherical	2.62 (0.58)	2.13 (0.69)	2.22 (0.62)	2.21 (0.54)	2.21 (0.54)	2.18 (0.57)	0.27
Trefoil	0.43 (0.20)	0.40 (0.20)	0.42 (0.20)	0.42 (0.19)	0.41 (0.19)	0.40 (0.19)	0.59

SD= standard deviation; ICRS= Intacs Intracorneal Ring Segments.

*= P values less than 0.05.

Table 3. Aberrometry Values in the Toric Implantable Collamer Lens Group

Variable	Pre-operation	Post-operation					P1-value	P2-value*
		6 months	1 Year	2 Year	3 Year	4 Year		
Corneal								
Coma	1.31 (0.28)	1.31 (0.28)	1.32 (0.33)	1.29 (0.31)	1.31 (0.30)	1.34 (0.29)	0.93	0.76
Spherical	2.34 (1.04)	2.34 (1.04)	2.34 (1.03)	2.32 (0.97)	2.36 (0.94)	2.37 (0.94)	0.80	<0.01
Trefoil	0.42 (0.15)	0.42 (0.15)	0.41 (0.14)	0.40 (0.14)	0.39 (0.15)	0.39 (0.15)	<0.21	<0.11
Internal								
Coma	0.90 (0.18)	0.90 (0.18)	0.91 (0.11)	0.92 (0.14)	0.94 (0.16)	0.90 (0.18)	0.91	0.34
Spherical	1.90 (0.87)	1.90 (0.87)	1.90 (0.85	1.91 (0.83)	1.90 (0.75)	1.90 (0.87)	0.99	0.99
Trefoil	0.34 (0.11)	0.34 (0.11)	0.40 (0.10)	0.35 (0.12)	0.34 (0.11)	0.34 (0.11)	0.03	0.74
Total								
Coma	1.10 (0.18)	1.10 (0.18)	1.16 (0.20)	1.15 (0.18)	1.13 (0.12)	1.13 (0.12)	0.17	0.02
Spherical	2.28 (1.05)	2.28 (1.05)	2.27 (1.05)	2.29 (1.04)	2.73 (1.03)	2.27 (1.03)	0.52	0.40
Trefoil	0.41 (0.13)	0.41 (0.13)	0.42 (0.11)	0.42 (0.12)	0.41 (0.12)	0.41 (0.12)	0.98	1.00

SD= standard deviation; TICL=phakic Toric Implantable Collamer Lens; ICRS= Intacs intracorneal Ring Segments; HOA= Higher Order Aberrations.

P1 value: In TICL group and P2 value: Comparison between ICRS and TICL groups.

*= P values less than 0.05.

DISCUSSION

Results of the current study revealed that ICRS and TICL were both useful and effective in patients with KCN, yet TICL seemed to have better and more predictable VA results in moderate non-progressive cases. Despite recent advances, treatment of KCN still remains a challenge. Treatments, such as spectacles and contact lenses, although used for many mild cases, are not appropriate for many other patients as they do not have the proper BCDVA or tolerance for their use. Many patients, who have not resolved their visual impairment with non-surgical methods, can be treated with approaches, such as ICRS or TICL implantation, to prevent or at least delay keratoplasty. This retrospective study investigated VA, refractive, and aberrometry changes following ICRS and TICL insertion. According to a comprehensive literature review, this study was one of the few long-term post-operative follow-ups of patients with non-progressive KCN (8 months prior to surgery) [18],[26],[27],[28],[29]. Significant improvement of UCDVA, which was noted in both groups of this study, is one of the most important parameters in clinical evaluations [18]. In the current study, the TICL group had significantly better UCDVA in all post-operative follow-ups. These results could be partly explained by the significantly lower amount of residual SE in all post-

operative follow ups in the TICL group, so that the amount of residual SE, 4 years post-operatively, in the TICL and ICRS groups was -0.73 D and -3.15 D, respectively. This high prediction capacity of the TICL is due to the precise positioning of the Intraocular Lens (IOL), which is confined to a narrow space between the posterior surface of the iris and the anterior surface of the crystalline lens in ciliary sulcus. It is worth noting that problems of accurate refraction and keratometry in patients with KCN are important issues, which also influence accurate measurement of IOL power [26]. Therefore, repeated refraction and keratometric measurements are recommended in these cases. Also, the rate of postoperative residual astigmatism was improved with both methods during all post-operative follow ups, which was significantly better in the TICL group. This lower post-operative residual astigmatism in the TICL group could be attributed to the small corneal incision, because these lenses require only a 3-mm peripheral corneal incision for insertion, which ultimately results in less post-operative astigmatism [30].

Improvement in BCDVA ranged from 0.37 ± 0.11 to 0.33 ± 0.09 and from 0.15 ± 0.11 to 0.09 ± 0.14, pre- and post-operatively in the ICRS and TICL groups, respectively, based on Log MAR, which indicates the safety and effectiveness of such methods.

Implantation of intracorneal rings, such as Intacs, which is the method of choice for treating patients with KCN, is based on corneal shape change. In the current study, although the amount of myopia and astigmatism decreased significantly following ICRS, this reduction was significantly less than that of TICL. In addition, ICRS had lower predictive refractive results, especially at higher values, which is in line with a number of previous studies [28],[30].However, the predictability of TICL [18] results has been confirmed in recent studies [31],[32],[33].

The reduction in VA of patients with KCN is not due to spherocylindrical refractive errors (lower order aberrations), yet is rather the result of a wider range of HOA. This could be explained explicitly by the fact that in many cases, the spectacle is not capable of perfect refinement of VA. This has led some scholars to modify the typical Amsler–Krumeich classification, based on coma aberration [34]. In KCN, the coma aberration, especially the vertical type, as well as trefoil and tetrafoil aberrations, appear to be the dominant ones [35],[36],[37],[38],[39],[40]. In the current study, ICRS significantly reduced corneal coma aberration, while it significantly improved spherical aberration in comparison with TICL, which ultimately led to a reduction in total coma aberration. However, TICL is significantly more effective in reduction of trefoil aberration and does not have much effect on other HOA. The justification for these changes in HOA could be explained by examining of the Zernike polynomials. This, in the TICL group, changes in peripheral corneal aberrations, such as trefoil, caused by peripheral corneal incision for its insertion. Whereas in the ICRS group, the reduction in central corneal aberrations, such as coma, is due to a change in the shape and regularity of the cornea and the location of Intacs insertion [28],[40]. Also, aberrations associated with center of cornea, such as coma, compared with peripheral aberrations, such as trefoil, have a greater effect on the quality of vision [38]. In the current study, there was no significant difference between the 2 groups regarding internal aberrations. Here it should be noted that corneal surface aberrations are the most important part of ocular errors, due to the greater difference in the refractive indices of air and cornea versus other refractive levels of the eye, and this is more pronounced in patients with KCN as the cornea is the main source of aberration [38]. Applegate et al. stated that ocular aberrations are not equal, so that different coefficients of Zernike polynomials with equal values in Root Mean Square (RMS) levels vary in degrees of effect on contrast sensitivity [36].

In general, the relationship between HOA and the function of the visual system is very complicated and not fully understood [41]. In the ICRS group, there was a significant improvement in UCDVA, 6 months post-operatively. However, observations during the 4-year post-operative follow-up did not show any significant changes, which is consistent with previous studies [38]. Also, in the TICL group, the postoperative outcome did not show significant change in the subsequent follow-up intervals, and was associated with relative stability, even at the end intervals; this stability and predictability was consistent with the results of Alfonso et al. [39]. Therefore, TICL insertion does not stimulate re-development of the KCN due to changes in the performance of the visual system. This result is likely due to the mean age of 30 years of the patients and the stability of their refraction during a minimum period of 12 months before surgery. Since this disease is usually more progressive at younger age and more stable at older age, similar to other studies, the current authors do not recommend the use of TICL in case of uncertainty about the progression of KCN [40]. Nowadays, TICL is available up to the diameter of -23 diopters for myopic correction and 6 diopters for correction of astigmatism, which, due to the placement of TICL lenses in the posterior chamber and the back of the iris, is better in

appearance and leads to greater patient satisfaction [28],[37]. It could be suggested that determining the exact criteria for selecting an appropriate patient has a key and determinant role. Furthermore, TICL has a high ability in correcting myopia and stigmatism, and in contrast to intra-corneal ring segments, it is more capable of correcting aberrations, [16],[15],[18]. It seems that a useful method in this area is to compare BCDVA with spectacles and hard contact lenses. Therefore, if there is a significant difference between these 2 approaches, using TICL, the results of postoperative visual quality are less than expected. However, based on the long-term results of this 4-year follow-up study, TICL in correction of myopia and astigmatism was very effective in patients with moderate and non-progressive KCN, and post-operative results were almost constant over time and the ability to predict post-operative results was excellent. According to the current research and other studies [37]. using TICL lenses is an effective treatment for patients with non-progressive KCN, especially in those with good preoperative BCDVA. Based on the mentioned results, the authors recommend TICL for patients after taking in account other preoperative evaluations. However, prospective studies and randomized controlled clinical trials with larger sample sizes are needed to provide more reliable evidence.

It is necessary to mention that the use of TICL in advanced KCN, which is often associated with large amounts of corneal aberrations, more irregular corneas, and corneal opacities, is not applicable. The combination of intracorneal ring implants and phakic IOLs at 2 stages, with sequential aberrations and ametropia correction, may be used separately in progressive KCN patients with high myopia [15],[16]. However, in advanced KCN cases, lamellar keratoplasty is preferred.

One of the limitations of this study was its retrospective design, low number of patients, and being limited to Tehran city. Also, for futures studies, it is better to use more comprehensive examinations, such as assessment of contrast sensitivity to obtain better and more citable results.

DISCLOSURE

No funding or sponsorship was received for this study. All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this manuscript, take responsibility for the integrity of the work as a whole, and have given final approval for the version to be published.

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