Original Article

Changes in the Optical Corneal Densitometry, Visual Acuity, and Refractive Error after the Annular Intracorneal Inlay Implantation

Mahmoud Jabbarvand[1], Mehdi Khodaparast[1], Alireza Jamali[2], Hooman Ahmadzadeh[1], Soodeh Bordbar[3]

[1]Eye Research Center, Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran, [2]Rehabilitation Research Center, Department of Optometry, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran, [3]English Department, Iran University of Medical Sciences, Tehran, Iran

Abstract

Purpose: To investigate the changes in the optical corneal densitometry as an objective method in assessing the corneal light back-scattering before and 1 year after the annular intracorneal inlay (AICI) implantation into the keratoconic corneas.

Methods: Changes in the optical corneal densitometry, visual acuity, refractive, and tomographical status were assessed before and 1 year after the AICI implantation into the corneas with different stages of keratoconus. Optical corneal densitometry was evaluated using the Pentacam-HR in 0–2, 2–6, 6–10, and 10–12 mm rings in the anterior 120 µ, central layers, posterior 60 µ and also the total value were measured for cornea in the Grey Scale Unit criterion.

Results: Totally, 34 patients with keratoconus were studied; the uncorrected and best corrected visual acuity were increased after the surgery (0.98 ± 0.25 to 0.53 ± 0.30 logMAR, $P < 0.001$ and 0.26 ± 0.18 to 0.19 ± 0.14, $P = 0.007$ logMAR, respectively); the spherical equivalent was decreased from −4.45 ± 2.25 to − 2.06 ± 2.01 D ($P = 0.004$). AICI implantation led to an increase in the amount of optical corneal densitometry in 0–2 mm central, 2–6 mm central, 6–10 mm central, total central, 2–6 mm posterior, and 2–6 mm total rings (all, $P < 0.05$); however, a decrease was observed in 0–2 mm anterior ring ($P = 0.049$). Results of statistical analysis showed that the total optical corneal densitometry, anterior total, and posterior total back-scattering did not change after the AICI implantation (all, $P > 0.05$).

Conclusions: Our results revealed a significant improvement in the visual function, including refractive error and visual acuity following the AICI implantation. Changes in the optical corneal densitometry were different in distinct regions and layers however, the total amount did not change after the AICI implantation.

Keywords: Annular intracorneal inlay, Keratoconus, Optical corneal densitometry, Pentacam-HR

Address for correspondence: Alireza Jamali, Rehabilitation Research Center, Department of Optometry, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran.
E-mail: alirezajamali.1371@gmail.com
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Introduction

Optical corneal densitometry is referred to the value of the back-scattered light from the cornea, which can be used as a quantitative method for objective evaluation of the corneal health and light scattering in the cornea.[1,2] Some ocular diseases, such as keratoconus, reduce the corneal transparency and increase the scattering of light (depending on the severity of keratoconus), while others, such as high myopia reduce it.[2,3] It has been shown that the back-scattered light increases due to the damage to the collagen fiber arrangement and enhancement in the keratocyte density in the central parts of the keratoconic corneas[4]; therefore, any changes in these

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two factors will alter the optical corneal densitometry. Pentacam-HR calculates the optical corneal densitometry in the range of 0 (minimum scattering) to 100 (maximum scattering) in the Gray Scale Unit (GSU) criterion using the Scheimpflug imaging technology and provides a map of the posterior scattered light.[5]

The use of the intrastromal corneal rings was proposed in 1978 for myopia adjustment. The purpose of this method is lessening the spherocylindrical refractive error by reducing the corneal curvature and diminishing the higher-order aberrations to increase the corneal regularity.[6-8] Currently, the intracorneal rings are commonly used for the corneas with mild-to-moderate keratoconus provided that the cornea has no central scar and the patient cannot tolerate the contact lenses.[9] Inserting the rings inside the cornea increases the centrality of the corneal apex, thereby facilitating the fitting of the contact lens and enhancing the comfort; besides, it has been well-documented that adding the material into the corneal mid-periphery creates a flattening effect in its central parts,[10,11] changing the corneal condition towards its normal status and increasing the uncorrected and best corrected visual acuity.

Intracorneal rings generally fall into two categories: (1) intracorneal ring segments with up to 355° arc, such as Ferrara ring (Ferrara Ophthalmic Ltd.), Intacs (Addition Technology Inc.), and KeraRing (Mediphacos Ltd.) and (2) intracorneal continuous complete rings including MyoRing (Dioptex GmbH, Austria) and Annular IntraCorneal Inlay (AICI, Ophthalight cor. Tehran, Iran). The AICI is available in four different thicknesses (140, 160, 180, and 200 μ) selected depending on the corneal conditions. As can be seen in Figure 1, one of the features of the AICI is that its surface is not flat; these rings have a curved shape with a base curve of 7.4 mm. Therefore, the changes in the corneal conditions will be expected to be different from other intrastromal rings due to more similarity of the AICI to the corneal curvature.

Different studies have evaluated the keratoconic corneal changes after implantation of various types of intracorneal rings; the changes resulting from the insertion of the corneal rings can be evaluated by different objective and subjective methods. Therefore, the present study was carried out to evaluate the changes in the optical corneal densitometry in different regions of the cornea after the AICI implantation.

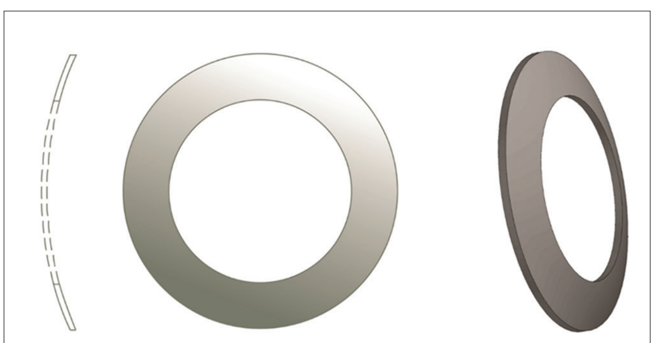

Figure 1: Annular intracorneal inlay curved view

Methods

This retrospective study was designed to investigate the changes in the keratoconic corneal status after the AICI implantation. All the examinations and surgery were performed during 2016–2019 in the Bina-Afarin Ophthalmology Clinic in Tehran, Iran. Inclusion criteria included a central corneal thickness of >350 μ, corneas without a central scar having keratometry values of <65.00 D in all the meridians, and no history of using the topical eye drops, cataracts, or retinal diseases. Study participants were excluded if they had undergone the restoration or dislocation surgery after insertion of the AICI into the cornea. Furthermore, the cases for the AICI surgery were selected based on the fitting of the rigid gas-permeable contact lens. The study was approved by the Ethics Committee of Tehran University of Medical Sciences (code no: IR.TUMS.FARABIH.REC.1398.003) and it was performed in accordance with the tenets of the Declaration of Helsinki. Informed written consent was obtained from all the participants after full explanation of the surgery procedure for them.

Clinical examinations included the slit-lamp evaluation (Haag-Streit corp., Swiss), assessment of the uncorrected visual acuity, subjective refraction, best corrected visual acuity, and finally, evaluation of the corneal tomography (Pentacam-HR, Oculus Optigeräte, GmbH, Wetzlar, Germany) that were performed before the surgery and a year after the AICI implantation. Visual acuity was recorded using a Snellen chart within a 4-meter distance and was reported as logMAR criterion. Subjective refraction was performed without fogging and under room lightening conditions by a skilled optometrist. A darkroom was used to perform the corneal tomography. Furthermore, records with high-quality states were analyzed (OK in presurgery; OK, and DATA GAPS after the AICI implantation).

The AICIs implanted in the evaluated eyes had the thicknesses of 200 and 180 μ. All the surgeries were performed by a professional surgeon (M.J.) using the VisuMax 500 kHz femtosecond laser system (Carl Zeiss, Meditec, Jena, Germany). During the surgery, three drops of Anestocaine (Tetracaine 0.5%, Sina Darou, Tehran, Iran) were instilled in the eye, and a pocket was created within the required depth using the VisuMax device. AICI (with a thickness of 200 or 180 μ, a base curve of 7.4 mm, internal radius of 4 mm, and external radius of 6 mm) was implanted in the pocket through an incision in the steep meridian. Corticosteroid and antibiotic eye drops were prescribed for 2 weeks after the surgery.

Optical corneal densitometry data were recorded simultaneously with the performance of Pentacam-HR tomography in the GSU criterion. Values presented within the range of 0 (minimum scattering) to 100 (maximum scattering) for the posterior 60 μ, central, and anterior 120 μ of the cornea were calculated separately for the following concentric rings: 0–2, 2–6, 6–10, and 10–12 mm as well as the total value for cornea; Figure 2 shows these classifications.[3]

Figure 3 shows an example of an optical corneal densitometry report before and 1 year after implantation of the AICI into the cornea; the changes can be seen clearly in different areas.

The Statistical Package for the Social Sciences software version 25 for windows (SPSS, IBM corp., Armonk, NY, USA) was used for analyzing the data. Descriptive analyses including calculation of the mean, mean difference (MD) (the mean of the difference between pre-and 1-year post-surgery values), standard deviation, minimum and maximum values were done for all the parameters. The normality of the parameters was checked using the Kolmogorov-Smirnov test. Paired-samples *t*-test and Wilcoxon signed-rank tests were used to evaluate the changes between the pre and postoperative examinations. Correlation between the parameters was studied by the Spearman or Pearson correlation tests. A value of $P < 0.05$ was considered statistically significant.

Results

From 34 eyes of 34 patients, 23 of them belonged to the male participants; the mean age of the individuals was equal to 33.61 ± 6.80 years old (age range, 25–56 years old). AICI implantation led to an increase in the uncorrected and best corrected visual acuity, the MDs were −0.45 ± 0.30 logMAR, $P < 0.001$, and −0.07 ± 0.14 logMAR, $P = 0.007$, respectively. The mean spherical equivalent was decreased from −4.45 ± 2.25 D to −2.06 ± 2.01 D, $P = 0.004$; the decrease in the spherical equivalent was due to a decline in the values of the sphere (−2.19 ± 2.62 D to −0.99 ± 1.97 D, $P = 0.004$) and cylinder (−4.52 ± 1.46 D to −2.14 ± 1.12 D, $P < 0.001$). Table 1 summarizes the values and MDs of visual acuity, as well as refractive error components before and after the AICI implantation.

As shown in Table 2, pairwise comparisons in both anterior flat and steep keratometry values showed a reduction after the surgery (MD = −2.77 ± 1.37 D, $P < 0.001$ and −4.93 ± 1.58 D, $P < 0.001$, respectively), but AICI implantation increased the steepness of posterior flat and steep meridians (both, $P < 0.001$). Moreover, there was a decrease in the asphericity values at the anterior surface (MD = +1.10 ± 0.51, $P < 0.001$) and an increase in the posterior surface (MD = −0.60 ± 0.62, $P < 0.001$). The thinnest pachymetry in the studied subjects was increased from 430 ± 34.65 to 437 ± 41.88 μ ($P < 0.001$).

AICI implantation changed the optical corneal densitometry in different layers. As shown in Table 3 and Figure 4, there was an increase in the mean optical corneal densitometry values in most regions of the central layer including 0–2 (MD = +0.90 ± 3.60 GSU, $P = 0.016$), 2–6 (MD = +3.14 ± 4.72 GSU, $P < 0.001$), 6–10 mm (MD = +1.47 ± 2.99 GSU, $P < 0.001$ and the total amount (MD = +1.67 ± 3.27 GSU, $P < 0.001$) as well as 2–6 mm posterior (MD = +0.75 ± 3.04 GSU, $P = 0.004$) and 2–6 mm total (MD = +1.63 ± 3.65 GSU, $P < 0.001$), but there was a decrease in the mean densitometry value of 0–2 mm anterior (MD: −1.76 ± 5.39 GSU, $P = 0.049$). The optical corneal densitometry was changed in other regions, but they were not statistically significant (all, $P > 0.05$). Despite the changes in the optical corneal densitometry values in different layers and regions after the AICI implantation, the amount of total optical corneal densitometry did not change (MD = +0.56 ± 0.32 GSU, $P = 0.119$).

Discussion

Insertion of the intrastromal rings inside the cornea causes many kinds of changes. Several studies have evaluated the changes in the cornea, such as refractive status, visual acuity, and corneal tomography after implantation of various corneal rings.[8,12-16] However, the dearth of research about the AICI effects on the keratoconic corneas necessitates to study these issues from different perspectives.

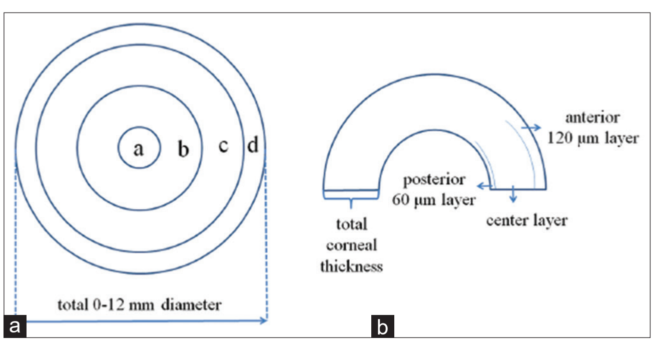

Figure 2: Schematic diagram of standard optical corneal densitometry analysis using Pentacam-HR. (a) optical corneal densitometry of annular zones (a: 0–2 mm, b: 2–6 mm, c: 6–10 mm, d: 10–12 mm); (b) optical corneal densitometry based on depths (anterior layer: first 120 μ, center layer: from 120 to the last 60 μ, posterior layer: last 60 μ), reprinted from dong study[3]

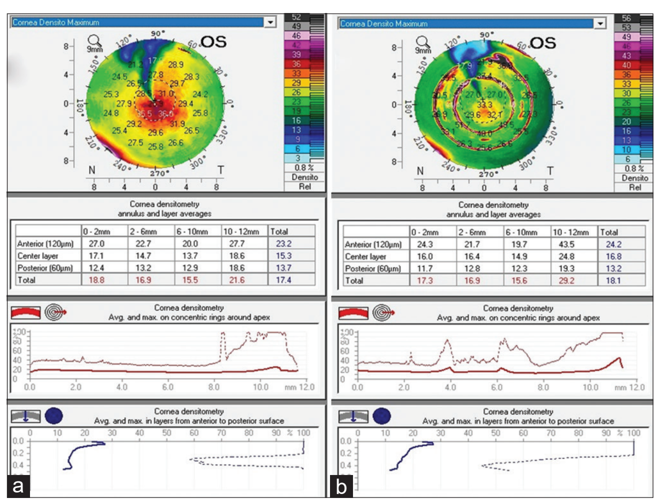

Figure 3: Optical corneal densitometry report, Pentacam-HR. (a) virgin keratoconic cornea, (b) the same keratoconic cornea 1 year after annular intracorneal inlay implantation

Table 1: Visual acuity and refractive error components, pre- and post-surgery

	Pre-surgery (*n*=34)	Post-surgery, 12 months (*n*=34)	Mean difference±SD	*P**
UCVA (logMAR)				
Mean±SD	0.98±0.28	0.53±0.30	−0.45±0.30	**<0.001**
Range	0.4-1.4	0.1-1.2	−1.1-0.0	
BCVA (logMAR)				
Mean±SD	0.26±0.18	0.19±0.14	−0.07±0.14	**0.007**
Range	0.1-0.7	0.00-0.6	−0.50-0.1	
Sphere (D)				
Mean±SD	−2.19±2.62	−0.99±1.97	+1.19±2.13	**0.004**
Range	−9.00-0.00	−8.50-+1.50	−2.00-+7.00	
Cylinder (D)				
Mean±SD	4.52±1.46	2.14±1.12	−2.37±1.08	**<0.001**
Range	1.00-6.00	0.00-4.50	−4.00-+0.50	
Axis (°)				
Mean±SD	91.50±32.23	88.44±40.86	−8.76±46.79	0.553
Range	35.00-175.00	10.00-180.00	−115.00-+85.00	
SE (D)				
Mean±SD	−4.45±2.25	−2.06±2.01	+2.38±1.90	**<0.001**
Range	−11.00-−2.00	−9.25-0.00	−0.25-+7.88	

*Wilcoxon signed ranks test. Bold values are significant. *P*<0.05 is statistically significant. UCVA: Uncorrected visual acuity, BCVA: Best corrected visual acuity, D: Diopter, SE: Spherical equivalent, SD: Standard deviation

Table 2: Keratometry components, pre- and post-surgery

	Pre-surgery (*n*=34)	Post-surgery 12 months (*n*=34)	Mean difference±SD	*P**
KF-front (D)				
Mean±SD	48.18±3.22	45.50±3.05	−2.77±1.37	**<0.001**
Range	43.20-56.00	40.30-53.00	−6.20-−0.30	
KS-front (D)				
Mean±SD	52.75±3.40	47.82±3.40	−4.93±1.58	**<0.001**
Range	47.80-62.90	43.30-58.60	−8.60-−2.00	
Q-val.-front				
Mean±SD	−1.10±0.48	0.00±0.63	+1.10±0.51	**<0.001**
Range	−2.22-−0.03	−1.52-1.01	−0.13-+2.34	
KF-back (D)				
Mean±SD	−7.11±0.77	−7.55±0.71	−0.44±0.36	**<0.001**
Range	−9.10-−5.80	−9.70-−6.30	−1.10-+0.30	
KS-back (D)				
Mean±SD	−8.00±0.65	−8.41±0.62	−0.42±0.30	**<0.001**
Range	−9.90-−7.20	−10.20-−7.40	−1.30-+0.10	
Q-val.-back				
Mean±SD	−1.35±0.65	−1.95±0.72	−0.60±0.62	**<0.001**
Range	−2.38-0.27	−3.46-−0.62	−1.85-+0.57	
Thinnest pachimetry (microns)				
Mean±SD	430±34.65	437±41.88	7.12±21.33	**<0.001**
Range	359-527	360-572	−78-+45	

*Paired sample *t*-test, Bold values are significant. *P*<0.05 is statistically significant. KF: Flat keratometry, KS: Steep keratometry, Q-Val: Asphericity, D: Diopter, SD: Standard deviation

Clinical evaluation of the back-scattered light or, in other words, optical corneal densitometry plays an important role in the evaluation of the corneal status and progression of some ocular diseases, such as keratoconus.[17-20] As mentioned earlier, optical corneal densitometry is the outcome of the order of collagen fibers, extracellular matrix, and keratocyte harmony;[19,21] therefore, it can be expected that the placement of an intracorneal ring would alter the balance of the above-mentioned factors and eventually change the optical corneal densitometry. In a study on 18 rabbits, Salamatrad *et al*., observed that the keratocyte cell density was not different between the control and inlay-treated groups that had an AICI ring placed into their corneas.[22] To the best of our knowledge, no previous study has investigated these changes

Table 3: Optical corneal densitometry in different parts, pre- and post-surgery

	Pre-surgery (n=34)	Post-surgery 12 months (n=34)	Mean difference±SD	P
0-2 mm				
Anterior (GSU)				
Mean±SD	31.34±9.91	29.58±8.48	−1.76±5.39	**0.049***
Range	21.60-78.20	21.40-69.00	−19.10-+8.10	
0-2 mm				
Center layer (GSU)				
Mean±SD	17.82±3.77	18.72±3.70	+0.90±3.60	**0.016***
Range	13.50-31.70	13.70-29.60	−14.90-+6.70	
0-2 mm				
Posterior (GSU)				
Mean±SD	13.28±3.36	12.92±2.34	−0.37±3.18	0.629*
Range	8.40-25.70	10.00-21.10	−14.30-+5.50	
0-2 mm				
Total (GSU)				
Mean±SD	20.82±5.20	20.14±4.66	−0.68±3.38	0.197*
Range	15.50-41.30	13.70-39.10	−16.10-+5.90	
2-6 mm				
Anterior (GSU)				
Mean±SD	24.89±4.06	25.67±4.86	+0.78±4.36	0.304**
Range	18.30-35.20	18.50-40.00	−10.70-+12.80	
2-6 mm				
Center layer (GSU)				
Mean±SD	15.44-3.60	18.58±4.71	+3.14±4.72	**<0.001***
Range	11.40-24.70	13.00-39.60	−10.90-+15.30	
2-6 mm				
Posterior (GSU)				
Mean±SD	13.42-2.87	14.17±2.79	+0.75-3.04	**0.004***
Range	9.90-26.20	11.30-27.10	−12.70-+6.90	
2-6 mm				
Total (GSU)				
Mean±SD	17.85±3.13	19.49±3.92	+1.63±3.65	**<0.001***
Range	13.40-29.20	14.30-35.60	−11.40-+9.10	
6-10 mm				
Anterior (GSU)				
Mean±SD	19.69±3.32	20.14±3.58	+0.45±3.51	0.457**
Range	15.60-29.70	14.70-28.50	−12.60-+8.00	
6-10 mm				
Center layer (GSU)				
Mean±SD	13.94±2.74	15.40±2.57	+1.47±2.99	**<0.001***
Range	11.10-25.90	11.30-21.20	−11.80-+7.00	
6-10 mm				
Posterior (GSU)				
Mean±SD	13.06±2.78	12.89±1.89	−0.16±2.79	0.443*
Range	10.20-25.40	10.60-17.60	−13.10-+4.50	
6-10 mm				
Total (GSU)				
Mean±SD	15.59±2.84	16.50±2.61	+0.56±3.03	0.286**
Range	12.50-27	12.40-21.30	−12.50-+6.30	
10-12 mm				
Anterior (GSU)				
Mean±SD	29.61±8.44	28.87±8.98	−0.74±7.96	0.732*
Range	17.60-52.60	18.10-57.70	−22.40-+15.80	
10-12 mm				
Center layer (GSU)				

Contd...

Table 3: Contd...

	Pre-surgery (n=34)	Post-surgery 12 months (n=34)	Mean difference±SD	P
Mean±SD	20.61±5.10	20.17±4.76	−0.44±5.04	0.952*
Range	13.50-32.00	13.50-37.20	−14.70-+8.40	
10-12 mm				
Posterior (GSU)				
Mean±SD	18.65±5.01	18.15±4.07	−0.50±4.92	0.817*
Range	11.00-31.40	12.20-29.70	−13.30-+10.60	
10-12 mm				
Total (GSU)				
Mean±SD	22.76±5.45	22.23±5.31	−0.52±5.25	0.565**
Range	14.80-35.50	14.70-39.50	−14.50-+8.40	
Anterior				
Total (GSU)				
Mean±SD	24.94±3.57	24.84±3.83	−0.10±3.81	0.804*
Range	18.80-34.20	17.90-33.40	−13.20-+8.90	
Center layer total (GSU)				
Mean±SD	15.99±2.59	17.67±2.80	+1.67±3.27	**<0.001***
Range	12.50-27.90	12.80-27.00	−12.20-+7.00	
Posterior total (GSU)				
Mean±SD	13.93±2.67	13.98±1.87	+0.04-2.85	0.771*
Range	11.00-26.10	11.30-19.90	−13.00-+4.60	
Total (GSU)				
Mean±SD	18.29±2.72	18.85±2.67	+0.56±3.22	0.119*
Range	14.10-29.40	14.00-26.30	−12.80-+6.40	

*Wilcoxon signed ranks test, **Paired sample t-test. Bold values are significant. P<0.05 is statistically significant. GSU: Grey scale unit, SD: Standard deviation

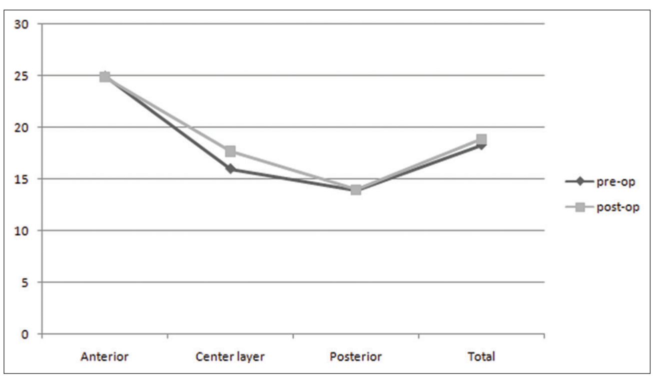

Figure 4: Change in total values of optical corneal densitometry, before and after annular intracorneal inlay implantation

after the AICI implantation in the human cornea. Therefore, considering the optical corneal densitometry evaluation as a method indirectly assessing the changes in the order of collagen fibers and keratocyte cell density, the present study was designed to investigate the changes in the optical corneal densitometry following implantation of the AICI into the keratoconic corneas.

Several pieces of research have reported that the arrangement of collagen fibers is disturbed in the ecstatic cornea and it can be expected that the value of optical corneal densitometry in the keratoconic corneas would be greater than the normal ones and every intervention may change it.[2,5] As mentioned in the results section, mean optical corneal densitometry and light back-scattering were increased in most parts of the central layers (except for central 10–12 mm) after the AICI implantation; the maximum change was related to the 2–6 mm central layer, directly related to the placement of the AICI into the central layers of the corneal mid-periphery. However, the AICI implantation caused a decrease in the value of light back-scattering in the 0–2 mm anterior layers. Results of statistical analyses showed different changes in the optical corneal densitometry values in various parts and layers of the cornea; although, the total value did not change after the AICI implantation. These findings are in line with the results of the study by Salamatrad *et al*., so it can be stated that the density of the keratocyte cells in the human cornea will not change after the AICI implantation.[22]

It has been found that the difference in the corneal refractive index from the air and aqueous humor results in the highest corneal reflection in the anterior layers of the cornea, and the lowest amount would be in the posterior layers of a normal cornea.[23] Moreover, the transparency of light decreases from the anterior toward the posterior layers of the cornea[2] herein, this order did not change in the keratoconic corneas even after the AICI implantation.

Review of the literature showed that two studies have evaluated the changes in the optical corneal densitometry after placement of the intracorneal rings inside the corneas with keratoconus. Sedaghat *et al*. in their study observed that the mean values of optical corneal densitometry were increased in most regions and layers after the KeraRing implantation, except for 10–12 mm annulus.[24] Regarding this, they also observed that the highest change in the optical corneal densitometry was in the 2–6 mm anterior layer, which is not consistent with our findings.[24] Furthermore, Alzahrani *et al*., studied the optical corneal densitometry for monitoring the progression of keratoconus in two groups of the patients only treated by the contact lenses versus those treated by the Intacs implantation plus the contact lenses. They observed that the mean optical corneal densitometry did not change in the latter group.[25] It is noteworthy that the implanted rings in these three above-mentioned studies were different (segment and complete), which led to different outcomes. Therefore, changes in the amount of optical corneal densitometry can be attributed to the difference in the quality of vision obtained by the patient along with other objective and subjective parameters after implantation of various intracorneal inlays.

In the current study, different parameters influencing the obtained optical densitometry values were evaluated, but no correlation was found. However, Shen *et al*., in their study found the correlations between the maximum keratometry with anterior 0–2 and 2–6 mm values in the keratoconic corneas;[2] Sedaghat *et al*. found a negative correlation between the anterior keratometry with optical corneal densitometry changes in 2–6 mm annulus.[24]

Among the limitations that we encountered in our research, limited sample size and non-randomized sampling were highlighted. Thus, it is recommended to evaluate the changes in the optical corneal densitometry in every four stages of the Amsler-Krumeich classification separately in future studies (requiring different types of AICI). Alteration in the various post-surgery visits also needs to be taken into account.

In total, our findings revealed that the AICI implantation into the keratoconic corneas causes flattening of the anterior surface, steepening of the posterior surface, increasing the uncorrected and best corrected visual acuity, and causing a reduction in the amount of spherical and cylindrical refractive error. Changes in the optical corneal densitometry are different in various depths and layers of the cornea, but the total amount would not change after the AICI implantation.

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Conflicts of interest

There are no conflicts of interest.

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