Clinical & Experimental Ophthalmology

Ghoreishi and Mohammadinia, J Clin Exp Ophthalmol 2014, 5:4
http://dx.doi.org/10.4172/2155-9570.1000351

Research Article Open Access

Correlation between Preoperative Sizing of Implantable Collamer Lens (ICL) by White-to-white and Sulcus-to-sulcus Techniques, and Postoperative Vault Size Measured by Sheimpflug Imaging

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Received date: April 07, 2014, **Accepted date:** August 04, 2014, **Published date:** August 10, 2014

Abstract

Purpose: To evaluate correlations between preoperative sizing of Implantable Collamer Lens (ICL) by white-to-white and sulcus-to-sulcus techniques, and postoperative vault size measured by Sheimpflug imaging.

Setting: Persian Eye Clinic, a private eye clinic located in Isfahan city, Iran

Design: Prospective, nonrandomized clinical trial

Methods: This prospective clinical trial included 63 eyes of 49 patients who were candidates for implantation of Implantable Collamer Lens (ICL). Preoperatively, both WTW and horizontal STS were measured in all eyes. Patients were divided into 3 groups based on ICL sizing method used for lens ordering (WTW group, STS group and M group). In the third group ICL size was determined according to the average of WTW and STS. Postoperative vault was measured 3 months after surgery by means of Scheimpflug tomography.

Results: Mean WTW and STS diameters were 11.68 ± 0.52 mm and 11.82 ± 0.74 mm, respectively. Linear regression analysis found a statistically significant correlation ($p=0.004$) between them, however, there was a large degree of scatter as indicated by R2=0.128. Ideal vault (400-550 μm) was achieved in 20% of WTW, 28% of STS and 13% of M group. There was no statistical difference in achieved ICL vault between three groups ($p=0.273$). Based on the statistical analysis of our results, we developed equations for better optimization of ICL sizing.

Conclusion: According to our results, there is poor correlation between STS and WTW. Sulcus-to-sulcus measurement did not significantly improve ICL sizing, and Sizing based on each technique alone may result in poor vaults in considerable number of cases. Comparison of WTW and STS to postoperative vaults provided regression models that allowed the development of new equations. Farther studies are needed for evaluating accuracy and reliability of these models.

Keywords: White-to-white; Sulcus-to-sulcus; Postoperative vault; ICL sizing

Introduction

Phakic Intraocular Lens (PIOL) implantation has been accepted as a safe alternative treatment for patients who are not suitable candidates for corneal reshaping procedures. Different designs of phakic intraocular lenses have been suggested for this purpose. The most widely used posterior chamber PIOL is the Visian Implantable Collamer Lens (ICL, STAAR Surgical Co, Monrovia, California) which is made of a hydrophilic collagen copolymer (Collamer) that is currently approved by the United States Food and Drug Administration (FDA) for the treatment of moderate to severe myopia [1]. It is designed to be implanted in the posterior chamber, behind the iris and in front of the anterior capsule of the lens, with the haptics resting in the ciliary sulcus. Since there is variability of sulcus diameter between individuals, different ICL sizes are available for different patients. Currently the main challenge for successful ICL implantation is accurate sizing. While undersizing may lead to low vault and cataract formation, oversizing may result in excessive vault and thereby can cause angle closure glaucoma. Central vault is defined as the distance between posterior central surface of ICL and anterior central surface of the crystalline lens [2-11].

Traditionally, white to white (WTW) measured by caliper or scanning-slit topography has been the most common and standard method of ICL size determination. Due to variability of measurement by this method, recently ultrasound biomicroscopy (UBM) has been suggested as preferred technique for this purpose [18]. Although some studies have confirmed the advantages of UBM for measurement of STS, over WTW to propose better ICL sizing [12-15], the issue still needs more investigations to be proved.

This study was performed to evaluate correlations between WTW and STS measurements and the value of each method for prediction of more accurate ICL sizing. Postoperative vault measurement was used to assess the accuracy of each method and propose equations for better prediction of ICL sizing [7].

Methods

This prospective clinical trial included 63 eyes of 49 patients who were candidates for implantation of Implantable Collamer Lens (ICL; STAAR Surgical Co, Monrovia, California). Preoperatively, all patients underwent complete ophthalmic examination including external ocular evaluation, slit lamp examination, dilated fundoscopy, Manifest and cycloplegic refraction, uncorrected and corrected visual acuity measurement. Topography and tomography was done using Pentacam HR System (Oculus Optikgerate GmbH, Wetzlar, Germany) and Orbscan (Bausch & Lomb, Rochester, NY) to exclude any corneal irregularity and to measure anterior chamber depth (ACD) and white to white corneal diameter (WTW). Corneal endothelial cells were measured by specular microscopy (Tomey Corp, Japan). Ultrasound sulcus to sulcus (STS) was measured by UBM 50 MHz (Compact Touch STS, Quantel Medical, France).

Inclusion criteria were age between 20 and 40 with myopic refraction between -2.00 and -16.00 diopters and cylinder between -1.00 and -5.00 diopters. Refractions had to be stable for at least one year before the operation. Patients were excluded if they had ACD (From endothelium) less than 3 mm, WTW less than 10.00 mm and endothelial cell count less than 2300 cells/square millimeter and if corrected distance visual acuity was less than 20/40. Patients with other ocular pathologies such as severe dry eye, corneal opacity and irregularity, glaucoma, cataract, uveitis and retinochoroidal diseases (except for myopic changes) were also excluded from the study. Other exclusion criteria were systemic diseases with possible ocular involvement such as diabetes and collagen vascular disease. All patients were informed about the goals and procedure of the study and signed an informed consent.

Measurement and choosing ICL size

In all eyes both Orbscan WTW and UBM STS were measured by the same investigator (MMN). Patients were divided into 3 groups. In one group the ICL size was ordered according to white-to-white measurement (WTW group). In this group, WTW value was entered into the ICL calculation formula which was proposed by the manufacturer. Usually 0.5 to 1 mm is added to WTW, which will be the size of ICL to be implanted [7,18].

In the second group, ICL size was ordered based on horizontal sulcus-to-sulcus measurement (STS group). The value of STS was rounded in such way that less than 0.5 decimal was considered as 0.5 and more than that was considered 1 mm. For example if it was 12.30 mm, it was considered as 12.5 mm and an ICL size of 12.5 mm was ordered and if it was 12.7 mm, a 13 mm ICL was ordered. No modification was employed regarding other parameters such as ACD. These 2 groups were randomized, since the values obtained by WTW and STS were matching, i.e., within 0.50 mm difference. In the third group that was nonrandomized, according to discrepancies that existed between WTW and STS measurements (more than 0.50 mm difference between these 2 parameters) ICL size was modified (M group). In this group ICL size was determined according to average or value of these 2 parameters. In all eyes version V4B of ICL was used.

Surgical procedure

All surgeries were performed by one surgeon (MG) and under topical anesthesia (tetracaine 1%, every 5 min for 2 doses). Vertical corneal meridian was marked in upright position in case of toric ICL. After full pharmacological mydriasis (tropicamide 1% eye drop), the eye was prepared with Povidone-iodine scrub and draped. Intraoperative alignment marks were made by means of Mendez Guage in toric cases. A 2.8 mm clear cornea incision was made at horizontal meridian and the lens was inserted by means of STAAR ICL injector under protection of Ophthalmic Viscosurgical Device (OVD), the lens was moved into posterior chamber and aligned to desired position which was determined according to the preoperative calculation. The OVD was subsequently washed out of the anterior chamber with balanced salt solution, and 0.5 ml of intracameral acetylcholine was injected into the anterior chamber to constrict the pupil. After adequate miosis, small peripheral iridectomy was made via a superior side-port incision.

Postoperatively, topical Levofloxacin and Bethamethasone eye drops were administered 8 times daily for first week and 4 timed daily for the second week. Follow up evaluation were done at 1 day, 1 week, 1 month and 3 months after surgery. Postoperative vault (distance between ICL and crystalline lens) was measured 3 months after surgery in all eyes using the Scheimpflug tomography (Pentacam HD, Oculus Optikgerate GmbH, Wetzlar, Germany). Vault measurements were performed by an experienced optometrist (MMN) who was masked of the groups. Average of 3 measurements was taken into account for statistical analysis. Central vault was considered low and poor (L&P), if it was less than 200 microns, low and acceptable (L&A) if it was 200 to 400 microns, ideal (I) if it was 400 to 550 microns, high but acceptable (H-A) if it was 550 to 650 microns and high and poor (H-P) if it was more than 650 microns. According to these criteria, vaults may also be classified as poor, acceptable and ideal. Ideal vault would be 400-550 μm, acceptable vault would be 200-400 or 550-650 μm and poor vault would be defined as values less than 200 μm or more than 650 μm.

Main outcome measures were comparison of postoperative vault heights and percentage of eyes with achieved good vault between groups.

Statistical analysis

Statistical analysis was performed with SPSS version 18 (SPSS. Inc, Chicago, Illinais). Descriptive statistics of the WTW, STS and postoperative vault height in each group were performed by one of the investigators who were trained in statistics (MMN). Statistical analysis to compare between WTW and STS was performed using the t-test. The central vault heights were compared between groups using analysis of variance (ANOVA). The mean difference between WTW and STS was calculated and linear regression analysis was performed between them. The standard deviation and 95% confidence interval (CI) of the residuals were calculated for parameters. Weighted multiple regression analysis was performed in order to determine the optimal ICL size that will be expected to achieve a 0.5 mm vault, and the regression equation was calculated. The standard deviation and 95% CI of the residuals were calculated to represent the potential error in predicting lens size using the independent variables. A p value of 0.05 or less was considered to be statistically significant.

Results

This study included 63 eyes of 49 patients (37 female, 12 male) with mean age of 25.78 ± 4.94 years and manifest refractive spherical equivalent (MRSE) from -2.50 to -15.50 diopter (D). Preoperative evaluations showed the mean WTW and STS diameters in all eyes studied were 11.68 ± 0.52 mm (ranged 10.2 to 13.4 mm) and 11.82 ± 0.74 mm (ranged 10.21 to 13.45 mm), respectively. The difference was not statistically significant (p=0.13).The mean difference was -0.14 ± 0.74 mm (ranged -1.70 to 2.23 mm). In 56% of the eyes, WTW was less than STS, in 41%, WTW was more than STS and in the remaining eyes, WTW and STS were equal. Linear regression analysis found a poor correlation (R2=0.128) between them (p=0.004). The linear regression equation was

$$sts = 5.831 + 0.513 \times wtw \qquad \text{Eq. (1)}$$

The standard deviation of residuals was 0.70 mm. and 95% CI of estimating sulcus diameter using Eq. (1) was ± 1.4 mm. Figure 1 shows a scatter-plot between Orbscan WTW and UBM STS diameters.

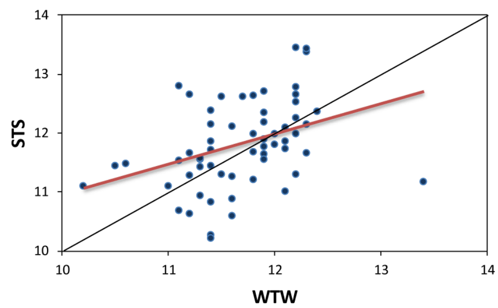

Figure1: Scatter plot of WTW against STS.

Since for a long period of time it has been assumed that sulcus diameter is greater than white to white diameter by an average value of 0.5 mm, we added 0.5 mm to the white-to-white diameter and repeated statistical analysis, which again showed the same results (R2=0.128).

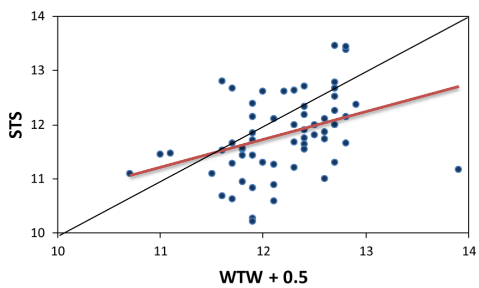

Figure 2: Scatter plot of WTW + 0.5 against STS.

Regarding postoperative vault measurement, the mean central vault heights in all eyes studied was 411.43 ± 217.21 (ranged 80-1010 µm). More information about central vault in three groups is shown in Table 1. Although the average of central vault in M group (471 ± 272.62 µm) was more than two other groups but There was no statistically difference in achieved ICL vault height between three groups (p=0.273).

Group	Mean ± SD (Range), µm
WTW	368.57 ± 165.661 (100 to 750)
STS	365.40 ± 207.735 (110 to 1010)
Modify	471 ± 272.621 (80 to 1000)
Total	411.43 ± 217.21 (80 to 1010)
WTW: White-to-white; STS: Sulcus-to-sulcus; µm: Micrometer	

Table1: Central vault heights in each group.

Comparison of result based on central vault values between three groups is shown in Table 2. As it is shown, 20% of the eyes in WTW group, 28% of eyes in the STS group and 13% of the eyes in M group had an achieved vault in ideal range (400-550 µm). The percentages of eyes in acceptable ranges were slightly higher in WTW group. The achieved vault was poor in 23% and 24% of eyes in WTW and STS groups respectively, while 60% of the eyes in M group fall within poor range.

Central vault (µm)	result	WTW group	STS group	modify group	total eyes
>200 & >650	poor	23%	24%	60%	34.9%
200-400 & 550-650	acceptable	57%	48%	27%	42.9%
400-550	ideal	20%	28%	13%	22.2%

Table 2: Displaying central vault height in each group.

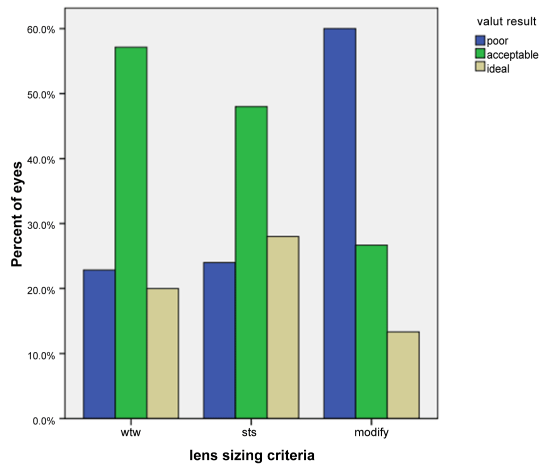

Figure 3: Comparing postoperative vault between 3 groups.

In trying to systematically select lens size we use linear regression to determine whether the lens size can be predicted by optimization of ICL size selection according to WTW and STS. To establish a relationship between these variables, weighted multiple linear regression was used to model the lens size (dependent variable) based

Citation: Ghoreishi M, Mohammadinia M (2014) Correlation between Preoperative Sizing of Implantable Collamer Lens (ICL) by White-to-white and Sulcus-to-sulcus Techniques, and Postoperative Vault Size Measured by Sheimpflug Imaging. J Clin Exp Ophthalmol 5: 351. doi: 10.4172/2155-9570.1000351

on its linear relationship to independent variable. This equation, combined with the information provided by the regression output, allows researchers to predict the value of the lens size for any value of the WTW and STS.

First, Weight of cases is determined by central vault heights (Table 3).

Central vault (um)	result	weight
< 200 & > 650	poor	0
200-400 & 550-650	acceptable	0.4
400-550	ideal	0.6

Table 3: Weight of cases based on central vault.

Second, to estimate suitable lens size, we proposed three models that represent relationship between lens size and WTW and STS.

Model can now be written as:

$y=4.017+0.370\times x_1+0.333\times x_2$ Eq. (2)

Where y is lens size, x_1 and x_2 are WTW and STS respectively. This meant that a lens size was derived using WTW and STS according to formula. In this model R2=0.651 that indicates a strong relationship between variables. It shows that about 65% of lens size cases are explained by this model.

The standard deviation of residuals was 0.288 mm. the 95% CI of estimating lens size using Eq.(2) was ± 0.58 mm. Therefore for 95% of favorable cases rang difference between used and estimated lens size is -0.58 to 0.58.

Predictability is demonstrated in Figure 4, where expected lens size versus observed lens size was plotted.

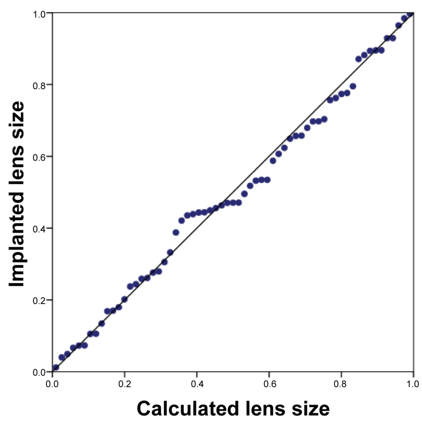

Figure 4: Predictability of lens size by formula (2).

$y=2.365(x_1)^{0.329}(x_2)^{0.337}$ Eq. (3)

All variables are defined as previously. The linear regression analysis then revealed a reasonable model with a statistical acceptable predictability (R2=0.645).

The standard deviation of residuals was 0.016 mm. the 95% CI of estimating lens size using Eq. (3) was ± 0.05 mm. Therefore for 95% of favorable cases rang difference between used and estimated lens size is -0.05 to 0.05.

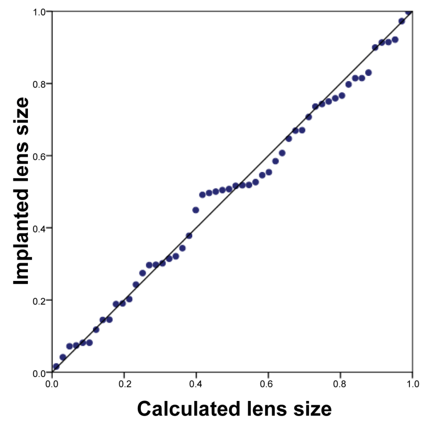

Figure 5: Predictability of lens size by formula (3).

Also predictable lens size based on WTW and STS can be achieved by using lens-sizing formula (4).

$y=0.362(x_1)^{5.357}(x_2)^{-3.373}e^{-0.429x1+0.312x2}$ Eq. (4)

All variables are defined as previously. R2=0.775, that indicates this formula is strongest model and about 80% of lens sizes which achieved by this formula are suitable.

The standard deviation of residuals was 0.013 mm. the 95% CI of estimating lens size using Eq. (4) was ± 0.05 mm. Therefore for 95% of favorable cases rang difference between used and estimated lens size is -0.05 to 0.05.

All coefficients in three models are statistically significant and the significant value of the F statistic in models is less than 0.05, which means that the variations explained by them are not due to chance.

Best lens size can be selected by considering three models and select a size that more models suggest it.

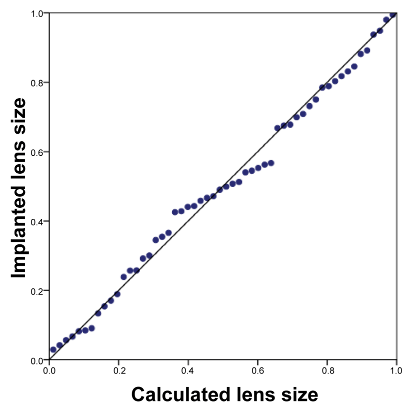

Figure 6: Predictability of lens size by formula (4).

Discussion

WTW and Sulcus diameter comparison

According to the present study, although the correlation between horizontal WTW and STS diameter, was statistically significant with a Pearson's correlation coefficient of R2=0.128, it was clinically poor, due to large degree of scatter. This result agrees with those in several studies in the literature [12-22]. So, with regard to these findings, we cannot use this regression model for the determination of sulcus diameter based on WTW alone.

Reinstein et al. [21] found that WTW diameter was smaller than sulcus diameter with a mean difference of -0.89 ± 0.57 mm, which was statistically significant (p<0.001), while in other study by Reinstein et al., they showed that mean WTW diameter was 0.58 ± 0.46 mm (range: - 0.30 to + 1.45 mm) greater than the sulcus diameter [15]. Our results disagree with those of Reinstein et al. in both studies [15,21]. In our study, the mean difference between WTW diameter and sulcus diameter was -0.14 ± 0.74 mm (ranged -1.70 to 2.23 mm). This high SD meant that STS was smaller than WTW in some cases and was greater in some other. For this sample of eyes, in 56% of cases, WTW was less than STS, in 41% WTW was more than STS and in other cases WTW and STS were equal. With the standard ICL sizing formula, assuming that STS is more than WTW by 0.50 to 1.00 mm, this value is added to WTW diameter to predict STS diameter and calculate ICL size. The potential for sizing complications, when using WTW-based estimates, comes from the high degree of variability in the difference between WTW and STS diameters (i.e., the standard deviation of the difference/poor coefficient of correlation). The standard deviation of 0.74 in our study indicates that the actual difference between WTW and sulcus diameters deviated from the mean difference (0.014). This difference was more than 0.50 mm in 47.6% of eyes and by more than 1.00 mm in 19% of eyes that may lead to difference in ICL sizing near to 0.50 or 1.00 mm.

Postoperative central vault: comparison between groups

Reistein et al. [15] reported poor vault height (<0.09 mm) in only 1 eye (2%), when sulcus diameter was used for ICL size measurement, whereas it was predicted that the vault height would have been less than 0.09 mm in 13 (26%) eyes, had the lens sizing been done using the WTW formula. According to a study by Choi et al. [18], postoperatively ICL vault was within the ideal range (0.25 to 0.75 mm) in 100% of eyes in UBM method group and only 52.9% of eyes in conventional method group (WTW method).

Our results showed there was no statistical difference in achieved ICL vault height between three groups (p=0.273). Although the mean central vault in M group was more desirable than other groups, but percentage of eyes with poor vault (inadequate/excessive) in this group was higher than WTW and STS groups. Therefore results of postoperative vaults in modify group were weak in comparison to WTW and STS groups. The percentage of acceptable vault height was more in WTW group, the percent of ideal vault height was more in STS group, but the percentage of acceptable plus ideal vault heights were not different between STS and WTW groups. On the other hand, the percentage of poor vaults did not differ between these two groups either, meaning that STS measurement, by itself, did not improve the ICL sizing results in our study. This results also contradict the findings of other series published in the literature [12-15]. The rationales behind the differences between the results of our study and some other studies, with regards to both STS and WTW correlation and role of each technique in achieved vault height, are not clear, but maybe due to difference in measurement devices or differences in population (eg. race, refraction, age…) between the studies.

A proposal model for ICL size selection

According to our study, if ICL sizing is done by either WTW or STS measurement alone, a chance of 24% exists that a poor vault height will occur postoperatively. This necessitates a modified regression model to incorporate both WTW and STS parameters. The modification we applied resulted in worse outcomes, since it had no statistical basis. The other reason may be due to the fact that this group contained eyes with higher variability between WTW and STS measurements. Recently Dougherty et al. [13] and Kojima et al. [14] reported regression equations to calculate optimal ICL size. They used STS, ICL power, ACD and distance between STS plane and anterior crystalline lens surface (STSL) as explanatory variables.

We used preoperative Orbscan WTW and UBM STS data and postoperative vault height values in 63 eyes, for statistical analysis to develop equations for better optimization of ICL sizing. These models propose a different size lens compared to the three used methods in some cases, especially those large discrepancy between WTW and STS values. As an example, in Table 4, lens sizing based on conventional WTW or STS formula in these eyes resulted in poor achieved vaults. If lens size were selected by our models, these ICLs were sized more properly, which possibly led to more acceptable vault heights.

Eye	WTW	STS	Implanted lens size	Group	central vault	Result	Model 1	Model 2	Model 3	Proposal lens size
1	11.1	11.53	11.5	WTW/STS	130	Poor	11.96	11.90	11.78	12
2	12.3	12.15	13	WTW	680	Poor	12.61	12.53	12.41	12.5
3	12.3	11.65	12	M	195	Poor	12.45	12.35	12.23	12.5
4	12.2	13.45	12.5	WTW	160	Poor	13.01	12.93	13.20	13
WTW: White-to-white; STS: Sulcus-to-sulcus; M: Modify										

Table 4: Compression of lens sizing between conventional and proposed method.

Conclusions

Our results showed that ICL sizing based on only WTW or STS methods may result in poor vaults in some cases. Comparison of preoperative WTW and STS measurements to postoperative vaults provided regression models that allowed the development of new equations. These models use STS and WTW diameters as explanatory variables.

More studies are needed for evaluating accuracy and reliability of these models and future refinement of these models may allow improvement in higher and lower range of vault.

What was known

- There is poor correlation between STS and WTW. Therefore WTW diameter alone may not predict Sulcus diameter for ICL sizing.

What this paper added

- Sulcus-to-sulcus measurement did not significantly improve ICL sizing. ICL Sizing based on WTW or STS technique alone may result in poor vaults in considerable number of cases.
- Comparison of preoperative WTW and STS measurements to postoperative vaults provided regression models that allowed the development of new equations.

Acknowledgements

We would like to thank Dr. Farzan Kian-Ersi, ophthalmologist, and Mrs. Soroor sadeghinejad, epidemiologist, for their great technical support during the research.

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