Effects of Dry Eyes on Corneal Keratometry Measured by VERION™ Image Guided System

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Background: *It is important to obtain precise pre-operative measurement of pre-existing corneal astigmatism in cataract surgery with toric intraocular lens (IOL) implantation. There have been reports of irregular corneal surface and topographic patterns in dry eye patients which have affected the corneal parameters in some corneal measurement devices.*

Objective: *To investigate the effect of dry eye and artificial tears on parameters associated with corneal curvature, corneal astigmatism, recommended IOL placement axis, recommended IOL spherical power, recommended IOL cylindrical power and calculated residual astigmatism measured by VERION™ Image Guided System in subjects who planned to undergo cataract surgery with toric IOL implantation.*

Material and Method: *This was a prospective, quasi-experimental study. All subjects were classified into a non-dry eye anda dry eye group. All parameters were obtained using VERION™ at baseline, and 5 and 30 minutes after artificial tear instillation, and all measurements were analyzed using repeated measures ANOVA.*

Results: *Seventy eyes of 35 subjects were included in this study. Twenty-eight 28 (40.0%) eyes were classified as dry eye level 1, 19 (27.1%) as level 2, 8 (11.4%) as level 3, 1 (1.4%) as level 4, and 14 (20.0%) eyes were non-dry eye. In subgroup analysis, there were no statistically significant differences in the mean corneal curvature, amount of refractive cylinder, recommended IOL placement axis, recommended IOL spherical power, recommended IOL cylindrical power between baseline and 5 and 30 minutes after artificial tear instillation in all subgroups ($p>0.05$). There was a statistically significant difference in calculated residual astigmatism between baseline and 30 minutes inthe dry eye level 2 subgroup ($p = 0.012$).*

Conclusion: *The accuracy of measurement by VERION™ may be affected by dry eye disease, especially in cases higher than level 2. Accurate corneal parameters must be obtained in order to calculate the correct IOL placement axis, and toric IOL spherical and cylindrical power.*

Keywords: *Dry eye, Cataract surgery, Phacoemulsification, Toric intraocular lens, Corneal curvature, Keratometry, Corneal astigmatism, IOL calculation, VERION™ image-guided system*

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The most common type of cataract procedure performed today is phacoemulsification with intraocular lens (IOL) implantation. The IOL has focusing power which is different in each individual patient, and it is calculated by their ocular biometries (*e.g.* corneal curvature, axial length, and anterior chamber depth). Currently, trying to eliminate postoperative residual refractive error and limit spectacle dependence as much as possible is one of the goals of cataract surgery. There are many different IOL options available such as monofocal IOL, multifocal IOL, trifocal IOL, toric IOL, accommodating IOL.

Hoffmann and Hutz reported that in their large study (23,239 eyes) of corneal astigmatism, 36.0% of eyes had corneal astigmatism of more than 1.00 D; 8.0% of eyes had corneal astigmatism greater than 2.00 diopters (D), and 2.6% had more than 3.00D[1]. Yuan et al also reported the prevalence of corneal astigmatism in northern China in a study of 12,449 eyes, and they found that 20.8% of eyes had 0.50D or less, 27.0% had 1.00D, while 2.00D or more was found in 13.2% of eyes, and 3.00D or more was identified in 3.8%[2]. After cataract removal, the lenticular component of the astigmatism is eliminated, and therefore the total astigmatism is exclusively determined by the cornea, which can be corrected by toric IOL implantation at the time of cataract surgery.

Addressing the amount and meridian of corneal astigmatism pre-operatively is an important step in planning toric IOL implantation. To obtain the precise measurement, the stability of the tear film plays an important role in the optical quality of the eye[3], corneal surface irregularities (surface regularity index (SRI), and

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surface asymmetry index (SAI))[4]. There were significant differences in SRI and SAI in dry eye patients 1 minute after instillation of artificial tears[4]. Mean astigmatism decreased significantly after artificial tear instillation in cases of Stevens-Johnson Syndrome (before instillation 1.53±1.47D to 1.08±1.18 D)[5].

The purpose of this study was to determine the effect of dry eye and artificial tears on indices associated with corneal curvature, corneal astigmatism, and recommended IOL placement axis, IOL power, IOL model, and calculated residual astigmatism by VERION™ Image Guided System on patients who planned to have cataract surgery with toric IOL implantation.

Material and Method

The protocol of this research was reviewed and approved by the ethics committee of Rajavithi Hospital (No. 106/2559). Patients were recruited from the Ophthalmology Department, Rajavithi Hospital, Bangkok, Thailand from February 2016 to May 2017. Study enrollment consisted of consecutive patients who planned to undergo cataract surgery with toric IOL implantation, who were able to follow the study protocol, and read, understand, and sign an informed consent form. Exclusion criteria were patients with anterior segment pathology other than dry eyes and diseases which affect the obtained parameters (e.g., corneal scar, corneal decompensation, pterygium, previous corneal surgery, and previous glaucoma surgery).

The trial was conducted as a prospective, quasi-experimental study, and the protocol was fully explained to the enrollment subjects, who were evaluated for dry eye signs and symptoms, which were evaluated by slit lamp examination, fluoresce in dye staining and tear breakup time. All subjects were classified into a non-dry eye or dry eye group, and the latter were further classified into 1 of 4 levels of severity according to Delphi panel classification[6].

The VERION™ Image Guided System (Alcon Laboratories, Inc., Fort Worth, TX, USA) is a new pre-operative measurement device, consisting of a VERION™ Reference Unit and a VERION™ Reference Marker. The Verion™ Reference Unit captures a high-resolution, digital registration of the eye which is then used to map out the center of the undilated pupil, the scleral vessels, the limbus, and the landmarks of the iris. It also measures location and amount of pre-operative corneal astigmatism so that the digital marker can account for cyclorotation once the patient is lying down awaiting surgery. Other useful data for pre-operative planning are pupilometry, IOL power calculation (power and cylinder of IOL), and estimated residual astigmatism. In the operating room, VERION™ Reference Marker displays the overlays outline of the patient's data on the operating microscope to help the surgeon position the axis of IOL more accurately without the need of preoperative ocular marking (Fig. 1)[7].

Pre-operative measurement using the VERION™ Reference Unit was performed by the same ophthalmologist in all subjects, who were seated in an upright position with their chin and forehead properly resting against the chinrest. The patients were instructed to blink several times and open their eyes after which several images were taken until the green color signal reflected accuracy. A drop of 0.5% Cellufresh MD artificial tear (Allergan Pharmaceuticals (Pty) Ltd), which contains carboxymethylcellulose sodium 5 mg/mL, was then instilled once into the inferior conjunctival sac. The images were taken again within 5 minutes and then approximately 30 minutes after instillation, and the best-quality images were selected for analysis. Corneal curvature (flattest and steepest curvature), amount of refractive cylinder, recommended IOL placement axis, recommended IOL spherical power, recommended IOL cylindrical power, and calculated residual astigmatism were recorded.

Statistical analysis

Statistical analysis was performed using SPSS for Windows Software (version 17.0, SPSS, Inc.). The flattest curvature, steepest curvature, amount of

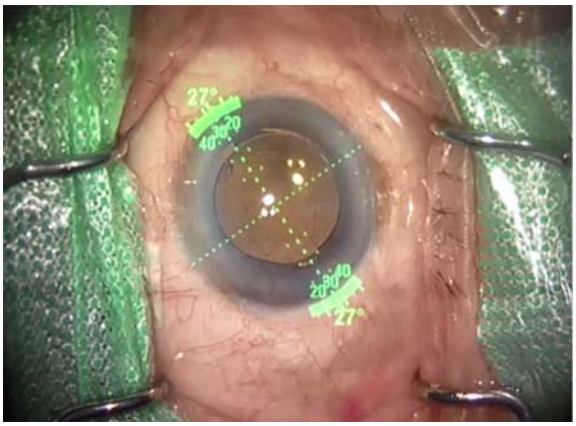

Fig. 1 Screenshot of the VERION™ Digital Marker showing an overlay intended toric intraocular lens axis of the patient's eye on operating microscope.

refractive cylinder, recommended IOL placement axis, recommended IOL spherical power, recommended IOL cylindrical power and postoperative calculated residual power after toric IOL placement at baseline, and 5 minutes and 30 minutes after artificial tear instillation were analyzed using repeated measures ANOVA. Recommended IOL cylindrical power data from Verion were displayed in the form of Alcon lens models (SN6AT2, SN6AT3, SN6AT4, SN6AT5, SN6AT6, SN6AT7, SN6AT8, SN6AT9) which were then converted to a form more appropriate for statistical analysis, yielding cylindrical power at corneal plane 0.68D, 1.03D, 1.55D, 2.06D, 2.57D, 3.08D, 3.60D, and 4.11D respectively. Differences were considered statistically significant when the *p*-value was less than 0.05.

Results

Seventy eyes of 35 subjects were included in this study, and baseline characteristics are detailed in Table 1. Female subjects predominated, accounting for 71.4% (50/70 eyes), compared to males at 28.6% (20/70 eyes). The mean age and standard deviation (SD) of the subjects was 65.34±11.06 years, with an age range of 39 to 94 years.Twenty-eight (40.0%) eyes were classified as dry eye level 1, 19(27.1%) as level 2, 8 (11.4%)as level 3, 1 (1.4%) as level 4 while 14 (20.0%) were classed as non-dry eye. Mean and standard deviation of flattest curvature, steepest curvature, refractive cylinder, recommended IOL spherical powerat corneal plane, recommended IOL axis placement, recommended IOL cylindrical power and postoperative calculated residual power after toric IOL placement of each dry eye level aredetailed in Table 1.

Table 2 shows mean difference and SD, 95.0% confidence interval (CI), and *p*-values of flattest curvature, steepest curvature, amount of refractive cylinder, recommended IOL spherical power, recommended IOL placement axis, recommended IOLspherical power, recommended IOL cylindrical power and calculated residual astigmatism after toric IOL placement between baseline and 5 and 30 minutes after artificial tear instillation in all subjects (n = 70). There were no statistically significant differences betweenany of the parameters ($p>0.05$).

Subgroup analysis is shown in Table 3; however, as there was only one subject in level 4, the mean difference and 95.0% CI of the parameters in this group could not be calculated. The subject in levels 4 had flattest curvature, steepest curvature, amount of refractive cylinder, recommended IOL spherical power, recommended IOL placement axis, recommended IOL cylindrical power and calculated residual astigmatism after toric IOL placement of 46.68D, 47.20D, -0.52D, 18.00D, 104 degrees, 1.03D, -0.15D respectively at baseline; 45.79D, 46.17D, -0.38D, 19.00D, 112 degrees, 0.68D, -0.09D, respectively after 5 minutes; and 45.98D, 46.55D, -0.75D, 19.50D, 123 degrees, 0.68D, 0.00D, respectively 30 minutes after artificial tear instillation.

There were no statistically significant differences in the mean flattest curvature, steepest curvature oramount of refractive cylinder between baseline and 5 and 10 minutes after artificial tear instillation in the non-dry eye and dry eye subgroups ($p>0.05$). With regard to the recommended IOL placementaxis, recommended IOL spherical power, and recommended IOL cylindrical power, there were no statistically significant differences between baseline and 5 and 10 minutes after artificial tear instillation in either thenon-dry eye or dry eye subgroups ($p>0.05$).

Table 1. Baseline characteristics expressed in mean and standard deviation (SD) in each subgroup (n = 70)

Parameters	Non-dry eye (n = 14)	Level 1 (n = 28)	Level 2 (n = 19)	Level 3 (n = 8)	Level 4 (n = 1)
Age (years)	55.43±10.12	66.89±10.54	66.68±8.99	73.88±9.28	67
Flattest curvature (D)	43.55±1.49	44.21±1.44	44.12±1.82	44.37±1.39	46.68
Steepest curvature (D)	44.94±1.85	45.29±1.37	45.23±1.66	45.80±1.62	47.2
Refractive cylinder (D)	-1.39±1.36	-1.08±0.65	-1.18±0.62	-1.43±0.81	0.52
Recommended IOL placement axis (degrees)	92.79±73.76	100.57±64.04	89.68±53.09	78.88±67.48	104
Recommended IOL spherical power (D)	-18.85±5.59	21.82±3.10	21.26±1.96	21.31±2.07	18
Recommended IOL cylinder (D)	1.41±1.17	1.08±0.55	1.27±0.59	1.41±0.70	1.03
Calculated residual astigmatism (D)	-0.19±0.31	-0.15±0.08	-0.86±0.73	-0.13±0.08	18

Values are represented as mean ± standard deviation (SD). D = diopters, IOL = intraocular lens

Table 2. Comparison of parameters between baseline and 5 and 30 minutes after artificial tear instillation (n = 70)

Parameters	Baseline	5 minutes after artificial tear instillation			30 minutes after artificial tear instillation		
	Mean (SD)	Mean (SD)	Mean difference (95% CI)	*p*-value	Mean (SD)	Mean difference (95% CI)	*p*-value
Flattest curvature (D)	44.11±1.57	44.18±1.43	-0.07(-0.21 to 0.06)	0.590	44.10±1.46	-0.12(-0.13 to 0.06)	1.000
Steepest curvature (D)	45.29±1.57	45.31±1.44	-0.02(0.18 to 0.13)	1.000	45.27±1.54	-0.02(-0.12 to 0.17)	1.000
Refractive cylinder (D)	-1.20±0.84	-1.13±0.84	-0.69 (-0.19 to 0.05)	0.540	-1.11±0.79	0.09(-0.20 to 0.02)	0.140
Recommended IOL placement axis (degrees)	93.63±62.27	92.24±56.36	1.38 (-15.12 to17.89)	1.000	99.41±56.48	5.78(-21.49 to 9.92)	1.000
Recommended IOL s pherical power (D)	20.96±3.52	20.89±3.57	0.07 (-0.09 to 0.23)	0.080	21.06±3.46	0.10(-0.30 to 0.11)	0.720
Recommended IOL cylinder	3.20±2.13	2.13±0.84	0.008 (-0.04 to 0.5)	1.000	2.21±0.88	0.01(-0.06 to 0.03)	1.000
Calculated residual astigmatism (D)	-0.14±0.16	-0.14±0.11	-0.07 (-0.21 to 0.06)	0.590	-0.12±0.09	-0.12(-0.13 to 0.06)	1.000

Values are presented as mean±standard deviation (SD), Mean difference (95% confidence interval (lower to upper)).
D = Diopters, IOL= intraocular lens, SD = Standard deviation

There was a statistically significant difference in mean calculated residual astigmatism between baseline and 30 minutes in the dry eye level 2 subgroup ($p = 0.012$). The dry eye level 3 subgroup showed a tendency toward higher mean differences in each parameter compared to lower dry eye levels, but they were not statistically significant.

Discussion

To perform a successful toric IOL implantation, accurate preoperative data such as steepest curvature, flattest curvature, and amount of refractive cylinder are essential because these data will be used to further identify the desired meridians for the incision, IOL cylindrical power and alignment axis.Using the axial length data from the axial length measurement device, the IOL spherical power can be calculated.

Corneal astigmatism can be measured by several devices e.g. corneal topography(8), manual keratometer(9), autokeratometer(8,10) and VERION™(7). VERION™ is a surgical planning device for toric IOL implantation which not only measures axis and amount of preoperative corneal astigmatism but also registration of eye for intra-operative digital marker to precisely gauge the IOL centration and alignment(7). According to Hill(11), for every 1degree where the toric IOL is off axis, there will be a 3.3% reduction orin other words, if the toric IOL is off by 30 degrees, it has no effect on astigmatism correction of toric IOL, and if the toric IOL is off more than 30 degrees, it will induce more astigmatism. Elhofi(12) studied 60 eyes of 60 patients and found that the mean postoperative toric IOL misalignment measured by slitlamp was 2.40±1.96 degrees for the group with digital image guidance using VERION™, and 4.33±2.72 degrees for the group with manual slitlamp-assisted pre-operative marking using pendulum-attached marker ($p = 0.003$).

The VERION™ image guidance system uses the reflection of concentric light emission diodes from the corneal surface to determine corneal parameters. Many studies have reported that patients with aqueous tear deficiency have an irregular corneal surface, that the SRI and SAI were significantly elevated in dry eye patients compared with normal subjects, and that irregular topographic pattern was decreased after the instillation of artificial tears(4,13,14).

We suspect that dry eye disease may reduce the accuracy and reliability of measurement from VERION™, and that artificial tear drops may smooth corneal surface irregularities and improve the accuracy

Table 3. Comparisons of parameters of each dry eye level (n = 70)

	No dry eye (n = 14)		level 1(n = 28)		level 2 (n = 19)		level 3 (n = 8)		level 4 (n = 1)	
	After 5 minutes MD (*p*-value)	After 30 minutes MD (*p*-value)	After 5 minutes MD (*p*-value)	After 30 minutes MD (*p*-value)	After 5 minutes MD (*p*-value)	After 30 minutes MD (*p*-value)	After 5 minute MD (*p*-value)	After 30 minutes MD (*p*-value)	After 5 minutes MD	After 30 minutes MD
Mean flattest curvature (D)	-0.004 (1.000)	0.12 (0.401)	-0.14 (0.421)	-0.05 (1.000)	-0.002 (1.000)	-0.02 (1.000)	-0.23 (0.325)	0.03 (1.000)	NA	NA
Mean steepest curvature (D)	0.03 (1.000)	0.19 (0.201)	-0.07 (1.000)	-0.10 (1.000)	-0.03 (1.000)	0.01 (1.000)	-0.05 (1.000)	0.14 (0.200)	NA	NA
Mean refractive cylinder (D)	0.07 (1.000)	-0.10 (0.597)	-0.07 (1.000)	-0.50 (1.000)	-0.40 (1.000)	-0.06 (1.000)	-0.11 (0.531)	-0.32 (0.238)	NA	NA
Mean recommended IOL placementaxis (degrees))	-20.21 (0.563)	-35.14 (0.103)	11.82 (1.000)	6.64 (1.000)	10.52 (1.000)	-3.10 (0.574)	-17.87 (0.213)	-2.62 (1.000)	NA	NA
Mean recommended IOL power (D)	-0.03 (1.000)	-0.53 (0.247)	0.14 (0.310)	0.07 (1.000)	0.10 (1.000)	-0.53 (1.000)	0.06 (1.000)	0.00 (1.000)	NA	NA
Mean recommended IOL cylinder(D)	-0.02 (1.000)	-0.08 (0.562)	0.07 (0.941)	-0.02 (1.000)	-0.05 (1.000)	-0.07 (0.464)	0.08 (1.000)	0.08 (1.000)	NA	NA
Mean calculated residual astigmatism (D)	-0.08 (1.000)	-0.03 (1.000)	-0.01 (1.000)	-0.04 (0.089)	0.03 (0.272)	0.05 (0.012)*	0.03 (0.951)	-0.01 (1.000)	NA	NA

D = Diopters, MD = mean difference, * significant at $p<0.05$

of measurement.

In the present study, more than half of the subjects (47/70 eyes), who planned to have cataract surgery with toric IOL implantation, were graded as dry eye level 1 or 2. There were no statistically significant differences in flattest curvature, steepest curvature, amount of refractive cylinder, recommended IOL spherical power, recommended IOL placement axis, recommended IOL cylindrical power and calculated residual astigmatism after toric IOL placement between baseline and 5 and 30 minutes after artificial tear instillation in the non-dry eye, dry eye level 1 and 3 groups. In the dry eye level 2 group, the parameters were not statistically significantly different between baseline and 5 and 30 minutes after artificial tear instillation with the exception of the mean difference of calculated residual astigmatism between baseline and 30 minutes after artificial tear instillation, which was statistically significant (0.05D, *p*-value = 0.012); however, this was not clinically significant according to Villegas[15], who found that correction of corneal astigmatism of less than 0.50D does not seem to improve visual performance; however, while the sample size in this study in each group was small, it would be statistically and clinically significant if the sample size were increased, especially in higher levels of dry eye. In the dry eye level 4 group, severe dry eye, only 1 case was included in this study. There was no change in axial length data at each time point, and the recommended IOL power changed from 18.00D at baseline to 19.00D after 5 minutes and 19.50D 30 minutes after artificial tear instillation. The toric IOL model also changed from SN6AT3 at baseline to SN6AT2 at 5 and 30 minutes. The recommended placement axis changed from 104 degrees at baseline to 112 degrees at 5 minutes and 123 degrees at 30 minutes, which is 19 degrees maximal difference and will yield 62.7% reduction in cylindrical correction. This unreliable data may have been caused by tear film instability in dry eye disease. According to recommendations in Visser's study[16] regarding patient selection for toric IOL, stable corneal astigmatism must be obtained for calculating IOL, and therefore, this case did not proceed to cataract surgery, and dry eye treatment was recommended before the surgery.

Conclusion

The accuracy and reliability of measurement by the VERION™ Image Guided System may be affected by dry eye disease, especially in cases higher than level 2. Stable and reliable corneal parameters must be obtained for calculating and choosing the correct toric IOL spherical power, IOL cylindrical power and for planning optimal alignment.

What is already known on this topic?

In cataract surgery with toric IOL implantation, it is important to perform accurate pre-operative measurement of pre-existing corneal astigmatism in order to calculate the correct intended meridian alignment and spherical and cylindrical power of the toric IOL, and to ensure successful astigmatism correction with the toric IOL. There have been reports of irregular corneal surface and irregular topographic patterns in dry eye patients which have affected the corneal parameters in some corneal measurement devices.

What this study adds?

In dry eye disease, measurements from VERION™ may be inaccurate and unreliable, and the incorrect parameters of corneal astigmatism could lead to incorrect calculation of the incision location, spherical power and cylindrical power of the IOL; moreover, it could induce more astigmatism if the IOL axis alignment is incorrect. The recommendation is that patients found to have dry eye must have it treated before reliable measurement is possible.

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Potential conflicts of interest

None.

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