·Clinical Research·

Predictive factors for photic phenomena after refractive, rotationally asymmetric, multifocal intraocular lens implantation

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Abstract
● AIM: To investigate the independent factors associated with photic phenomena in patients implanted with refractive, rotationally asymmetric, multifocal intraocular lenses (MIOLs).

● METHODS: Thirty-four eyes of 34 patients who underwent unilateral cataract surgery, followed by implantation of rotationally asymmetric MIOLs were included. Distance and near visual acuity outcomes, intraocular aberrations, preferred reading distances, preoperative and postoperative refractive errors, mesopic and photopic pupil diameters, and the mesopic and photopic kappa angles were assessed. Patients were also administered a satisfaction survey. Photic phenomena were graded by questionnaire. Independent-related factors were identified by correlation and bivariate logistic regression analyses.

● RESULTS: The distance from the photopic to the mesopic pupil center (pupil center shift) was significantly associated with glare/halo symptoms [odds ratio (OR)=2.065, 95% confidence interval (CI)=0.916-4.679, *P*=0.006] and night vision problems (OR=1.832, 95% CI=0.721-2.158, *P*=0.007). The preoperative photopic angle kappa was significantly associated with glare/halo symptoms (OR=2.155, 95% CI=1.065-4.362, *P*=0.041). The photopic angle kappa was also significantly associated with glare/halo symptoms (OR=2.155, 95% CI=1.065-4.362, *P*=0.041) and with night vision problems (OR=1.832, 95% CI=0.721-2.158, *P*=0.007) in patients implanted with rotationally asymmetric MIOLs.

● CONCLUSION: A large pupil center shift and misalignment between the visual and pupillary axis (angle kappa) may play a role in the occurrence of photic phenomena after implantation of rotationally asymmetric MIOLs.

● KEYWORDS: rotationally asymmetric multifocal intraocular lens; pupil center; photic phenomena; dysphotopsia; kappa angle; pupil center shift
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INTRODUCTION
Multifocal intraocular lenses (MIOLs) were developed to provide patients with an intraocular lens (IOL) of more than one focal point, enabling good visual acuity at more than a single distance[1]. Despite high levels of overall patient satisfaction after MIOL implantation, some patients are dissatisfied with this surgical procedure, even when uncorrected visual acuity (UCVA) was excellent, because of visual artifacts such as glare, halos, and dysphotopsia.

To increase patient satisfaction after MIOL implantation, these lenses have undergone modifications over time to enhance not only visual outcomes but also visual quality including photic phenomena. The latest modified Lentis Mplus (Oculentis GmbH, Berlin, Germany) is an IOL that provides multifocality by using a refractive, rotationally asymmetric design[2]. This latest generation of MIOL was designed to reduce unwanted side effects, such as postoperative dysphotopsia and reduced visual contrast[3-4]. Although results with these newer MIOLs have improved with better contrast sensitivity outcomes and intermediate vision than those of diffractive multifocal IOLs[3,5], some patients continue to experience glare or dysphotopsia, particularly when compared with monofocal IOLs. The causes associated with photic phenomena noted in previous studies have included IOL decentration, retained lens fragments, posterior capsular opacification, dry-eye syndrome, UCVA, use of spectacles for distance purposes, postoperative astigmatism, and postoperative spherical equivalent[6-7]. Except for these factors, Prakash *et al*[8] suggested that kappa angle could be associated with dysphotopsia after MIOL insertion. However, few studies have evaluated the angle kappa and pupil factors as specific predictors of photic phenomena. Therefore, in this study, we assessed factors independently associated with photic phenomena for refractive, rotationally asymmetric MIOLs, including kappa angle and pupil-related factors.

SUBJECTS AND METHODS

Subjects This retrospective case series included 34 eyes of 34 patients who underwent a Lentis 313 implantation between January 2012 and June 2015 and developed photic symptoms. The patients included 16 men (47.1%) and 18 women (52.9%), with a mean age of 62.54±18.3y (range, 50-75y). All patients underwent unilateral cataract surgery with implantation of a rotationally asymmetric MIOL [Lentis Mplus LS-313MF30; +3.00 diopters (D)]. This study was approved by the institutional review board of the University of Ulsan College of Medicine, Asan Medical Center, Seoul, South Korea. In accordance with our hospital protocol, written informed consent was obtained from all patients before initiating any surgical procedures or investigations. Patients with active ocular diseases or topographic astigmatism >1.50 D, or who were illiterate, were excluded.

Surgery All operations were performed by the same experienced surgeon (Tchah H) under topical anesthesia using a standard phacoemulsification technique. A 2.25 mm clear incision was made with a diamond knife on the steepest meridian to minimize postoperative astigmatism. After removing the crystalline lens, the IOL was implanted through the incision into the capsular bag, using an injector specifically developed for this purpose (Viscoject2.2 Cartridge-Set LP604240M, Oculentis GmbH, Berlin, Germany). At the end of the surgery, the operator confirmed that the IOL was placed in the capsular bag.

Pre- and Postoperative Examinations All patients underwent a full preoperative ophthalmologic examination, including evaluation of their refractive status, distance and near visual acuities, slit-lamp examination, optical biometry (IOLMaster; Carl Zeiss Meditec, Jena, Germany), tonometry, and funduscopy. Distant (4 m), intermediate (60 cm), and near (40 cm) visual acuities were evaluated using the Early Treatment for Diabetic Retinopathy Study charts.

Pupil Examinations and Aberrations An OPD scan aberrometer (NIDEK Co. Ltd., Gamagori, Japan) was used to evaluate preoperative mesopic and photopic pupil diameters, distances from the alignment light to the mesopic (mesopic kappa angle) and photopic (photopic kappa angle) pupil centers, and distance from the photopic to the mesopic pupil center (pupil center shift) (Figure 1). All patients were followed-up for 6mo. At all follow-up examinations, visual acuity, intraocular aberrations determined by OPD scan, refraction, and the integrity of the anterior segment were evaluated. Patients were asked to complete a satisfaction questionnaire by an investigator during a face-to-face interview

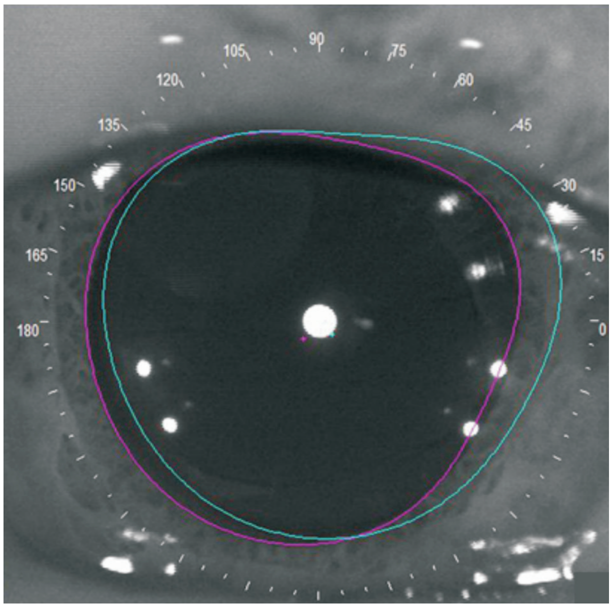

Figure 1 Image showing a photopic pupil center (violet cross) and amesopic pupil center (cyan cross) PDist and MDist: Distances from the alignment light to the photopic and mesopic pupil centers, respectively. MPDist: Distance from the photopic to the mesopic pupil center.

6mo after surgery. The questions included discomfort from glare under mesopic and photopic conditions, with responses scored on a 5-point scale ranging from very dissatisfied (1 point) to very satisfied (5 points). The questionnaire also included two questions about photopic phenomena: "How much difficulty do you have with your vision because of glare, halos, or starbursts (*e.g.* from unwanted images including rings)?"; and "how much difficulty do you have with your vision at night (*e.g.* night vision problems)?" The responses ranged from no symptoms (0 points) to severe symptoms (5 points). Patients who gave a score of 4-5 points for glare and halo and for brightness at night were grouped into the severe glare and halo and severe night photic groups, respectively.

Factors Associated with Photic Phenomena The associations of 27 factors with photic phenomena were assessed by univariate and bivariate analyses. The associated 27 factors: postoperative distance (4 m) & intermediate (60 cm) & near (40 cm) VA; postoperative preferred reading distance; pre/postoperative factors; pre/postoperative astigmatism; pre/postoperative sphere; pre/postoperative cylinder; pre/postoperative spherical equivalent; pre/postoperative photopic & mesopic pupil sizes; pre/postoperative photopic angle kappa; pre/postoperative mesopic angle kappa; pre/postoperative pupil center shift; postoperative total root mean square (RMS); postoperative coma-like RMS; postoperative trefoil-like RMS; postoperative spherical-like RMS; postoperative strehl ratio.

Statistical Analysis Statistical analyses were performed using SPSS software for Windows ver. 19.1 (SPSS Inc., Chicago, IL, USA). Pre and postoperative data were compared using paired *t*-tests. All patients were grouped into a no-symptom group (patients with 1-3 points) and a severe-symptom group (patients with 4-5 points) from the satisfaction questionnaire results. Correlation and bivariate logistic regression analyses of each factor were performed to calculate the *P*-values, odds ratios (ORs), and 95% confidence intervals (CIs). A *P*-value<0.05 was considered significant.

RESULTS

All patient underwent a postoperative slit-lamp examination with dilated pupil and anterior segment OCT (Visante OCT; Carl Zeiss Meditec, Germany) imaging. No deceneration or tilt of IOL was detected.

Visual Acuity IOL implantation resulted in significant improvements in uncorrected near (P<0.01) and distant (P=0.023) visual acuity, with near vision showing a significant reduction (P<0.01; Table 1). The mean preferred reading distance 6mo after surgery was 37.8±7.67 cm.

Pupil Demographics and Ocular Aberrations Mean pupil diameters under photopic and mesopic conditions were 3.67±1.43 mm (range, 2.67-5.25 mm) and 5.32±1.13 mm (range, 3.43-7.74 mm), respectively. The mean distances between the pupil center and the vertex under photopic and mesopic conditions were 0.25±0.13 mm (range, 0.06-0.55 mm) and 0.23±0.12 mm (range, 0.08-0.48 mm), and the mean distance from the photopic to the mesopic pupil center (pupil center shift) was 0.14±0.10 mm (range, 0.01-0.46 mm). Table 2 summarizes the postoperative levels of intraocular higher order aberrations. The setting was a pupil size of 4 mm and six orders.

Questionnaire Responses The mean general satisfaction score was 2.68±1.55, the mean glare, halo, and starbursts score was 3.57±1.01, and the mean night vision problems score was 3.44±1.33. Nineteen patients (55.8%) reported severe glare and halos, and 17 (50%) reported severe brightness at night (Table 3). The pupil center shift was significantly different in the mild and severe symptoms groups (Table 3).

Factors Related to Glare, Halo, and Starburst The correlation analysis did not identify any factors related to general satisfaction. However, in photopic phenomena analysis, postoperative astigmatism (R=0.358, P=0.037), preoperative photopic kappa angle (R=0.388, P=0.041), and preoperative pupil center shift (R=0.504, P=0.006) were significantly associated with glare, halo, and starburst. None of the other 23 factors were correlated. Bivariate logistic regression analysis showed that postoperative astigmatism (OR=1.612, 95% CI=1.014-2.561), preoperative photopic angle kappa (OR=2.155, 95% CI=1.065-4.362), and preoperative pupil center shift (OR=2.065, 95% CI=0.916-4.679) were significantly associated with glare, halo, and starburst.

Factors Related to Night Vision Problems The correlation analysis revealed that the preoperative photopic kappa angle (R=0.438, P=0.020), and preoperative pupil center shift (R=0.501, P=0.007) were significantly associated with night vision problems. None of the other 23 factors showed this association. The bivariate logistic regression analysis revealed that preoperative photopic kappa angle (OR=2.513, 95% CI=1.094-4.412) and preoperative pupil center shift (OR=1.832, 95% CI=0.721-2.158) were significantly associated with night vision problems (Table 4).

Table 1 Pre- and postoperative conditions of eyes that underwent cataract surgery with implantation of the Lentis Mplus IOL $\bar{x} \pm s$

Parameters	Preoperative	Postoperative	P
UNVA (logMAR)	0.45±0.16	0.28±0.18	<0.01
UIVA (logMAR)	-	0.34±0.15	
UDVA (logMAR)	0.33±0.17	0.11±0.16	0.023
Near addition (D)	2.75±0.43	0.42±0.51	<0.01
Axial length (mm)	23.52±1.39		
Preferred reading distance (cm)		37.8±7.68	

Table 2 Postoperative intraocular higher order aberration data of eyes that underwent cataract surgery with implantation of the Lentis Mplus IOL

Postoperative high order aberration data	$\bar{x} \pm s$
Total RMS	1.95±1.25
Coma-like RMS	0.24±0.15
Trefoil-like RMS	0.71±0.33
Spherical-like RMS	0.07±0.06
Strehl ratio	0.013±0.02

Table 3 Results of the satisfaction questionnaire and pupil center shift $\bar{x} \pm s$

Satisfaction questionnaire	Number	Pupil center shift	P
Glare, halos & starbursts			
Score 1-3 (mild)	15	1.10+0.75	0.038
Score 4 & 5 patients (severe)	19	2.01+1.30	
Night vision problems			
Score 1-3 (mild)	17	1.13+0.76	0.037
Score 4 & 5 patients (severe)	17	2.01+1.33	

DISCUSSION

MIOLs have been developed to provide patients with good visual acuity at more than one distance. However, despite high levels of patient satisfaction after implantation of IOLs, some patients remain dissatisfied and require explantation of these lenses[6]. Blurred vision, thought to be due to ametropia and posterior capsule opacification in most instances, is the leading cause of dissatisfaction among patients with MIOLs[6]. Another important factor associated with dissatisfaction is dysphotopsia (glare and halo/brightness)[9]. A 2006 Cochrane review of MIOLs[10] found that photic phenomena are 3.5-fold more likely to arise with multifocal than with monofocal IOLs.

Table 4 Bivariate logistic analysis of factors independently associated with night vision problem

Variables	Coefficients	*P*	OR	95% CI
Postoperative astigmatism	0.249	0.155	0.987	0.682-2.561
Preoperative photopic angle kappa	0.438	0.020	2.513	1.094-4.412
Preoperative mesopic angle kappa	0.300	0.121	1.235	0.914-3.681
Preoperative pupil center shift	0.501	0.007	1.832	0.721-2.158

Recently developed segmented asymmetric refractive MIOLs have demonstrated better contrast sensitivity outcomes than that of diffractive MIOLs[11]. IOLs with refractive rotational asymmetry were developed to minimize side effects, such as glare, halos, and reduced contrast sensitivity[6,12]. In our study, however, we found that many patients complained of photic phenomena. Although all of our dissatisfied patients had subjective visual complaints, their corrected distance visual acuity was 20/20 or better and they showed significant near visual acuity improvements, indicating that visual acuity is not always a good measure of subjective symptoms or patient satisfaction following implantation of MIOLs. Decentration and tilt of MIOL are very important for visual quality after inserting an asymmetrical MIOL[13-14]. Thus, the haptic of initial asymmetric IOL was replaced with plate haptic. The replaced plate haptic asymmetric IOL (LS 313) is stable in the capsular bag with no case of IOL tilt and decentration in 9366 patients[3]. We found no decenteration or tilt of MIOL during a dilated pupil slit lamp examination and anterior segment OCT.

We thought that independent factors associated with patient satisfaction would include kappa angle and pupil size with well-positioned MIOLs. Moreover, a previous study reported that the occurrence of photic phenomena is positively correlated with preoperative kappa angle[15]. Our current findings indicate that not only the photopic kappa angle but also the pupil center shift are associated with photic phenomena. The pupil center is usually located temporally in relation to the corneal vertex[16]. Previous studies have investigated shifts in pupil center location based on changes in pupil size due to illumination changes or mydriatic drugs[17-19]. The mean pupil center shift is 0.11-0.2 mm[16,20], with some patients show shifts up to 1.0 mm[20]. It appears that there is a growing interest in pupil center shift concerning dysphotopsia after MIOLs[21]. Fischinger *et al*[21] reported that MIOL should not be recommended for patients with a large pupil center shift, which is consistent with our result.

Similarly, in our study, patients with severe photic phenomena had large pupil center shifts, supporting the statistical association between photic phenomena and pupil center shift.

The Lentis Mplus IOL has a larger sector for distance vision and an inferior surface-embedded sector for near vision, with a smooth transition between them. There is only one transition zone between these two segments, resulting in less light dispersion and improved contrast sensitivity[22]. However, this unique design results in the pupil center being on the transition zone in patients with large shifts in the pupil center (Figure 2). The importance of confirming factors associated with postoperative photic phenomenon has been emphasized based on the growing demand for MIOL, and many possible risk factors for phototic phenomenon are being investigated. However, we found a positive relationship between photic phenomenon and kappa angle and pupil center shift.

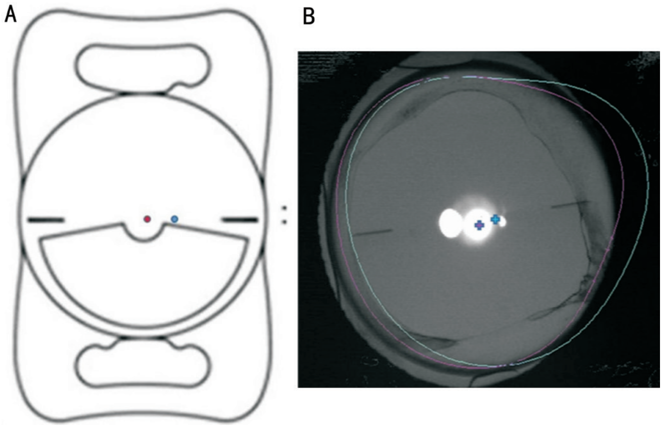

Figure 2 Offset of the pupil center associated by photopic and mesopic conditions A: Image showing superposition of the photopic pupil center (red circle) and the mesopic pupil center (blue circle), with the latter located on the transition zone; B: Retroillumination photograph, showing the mesopic pupil center on the transition zone.

Many clinical studies on postoperative visual quality have investigated a variety of MIOLs[8,23-24]; however, not many studies have investigated rotationally asymmetric MIOLs. Although a limitation of our report is a small number of monocular patients, this is the first study to describe postoperative visual quality in patients with rotationally asymmetric MIOLs. Further studies of more binocular patients should be pursued for a better understanding.

Further studies are needed due to the increasing use of the latest generated refractive, rotationally asymmetric MIOLs, and the results would be useful for selecting suitable patients for surgery. Patients showing a large kappa angle and large pupil center shift during a preoperative examination could be considered for other types of IOL.

In conclusion, despite that most patients have a positive experience with rotationally asymmetric MIOLs, some complain of associated with photic symptoms. In addition to factors previously associated with the perception of photic phenomena[6,25], our results suggest the involvement of preoperative photopic kappa angle and pupil center shift. Although likely to be small, these shifts affect visual quality and may affect the postoperative results of IOL implantation. Additional studies with a larger sample size are warranted to further optimize use of these lenses.

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Conflicts of Interest: Tchah H, None; **Nam K,** None; **Yoo A**, None.

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