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CATARACT

Correlation between pupillary size and depth of focus after the implantation of extended depth of focus intraocular lenses

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Abstract

Purpose To evaluate whether depth of focus after the implantation of extended depth of focus (EDoF) intraocular lenses (IOLs) correlates with pupillary size.

Methods This retrospective case series study evaluated eyes undergoing cataract surgery with implantation of EDoF IOLs. At least one month postoperatively, the depth of focus (DoF) was measured to determine the correlation with pupillary size, age, anterior chamber depth (ACD), axial length (AXL), and corneal spherical aberrations (SA).

Results The study evaluated 64 eyes of 49 patients. The mean depth of focus was 2.67 diopters (D). The mean preoperative photopic pupil size was 3.36 mm. A significant negative association was found between preoperative photopic pupil size and depth of focus ($r = 0.30$, Pearson's correlation coefficient) and between preoperative mesopic pupil size and depth of focus ($r = 0.274$, Pearson's correlation coefficient).

Key messages

What is known:

• Optical and visual performance of a multifocal IOL likely depends on pupil size.

What is new:

• Smaller pupil size (including preoperative photopic, mesopic pupil size) had strong association with good post-operative depth of focus, with Extended Depth of Focus Intraocular Lenses.

• No significant correlation was observed between age, anterior chamber depth, axial length, corneal spherical aberra?tions, and depth of focus in the Extended Depth of Focus Intraocular Lenses.

Keywords Pupil size · Depth of focus · Extended depth of focus intraocular lenses · Cataract

Introduction

With the advancement of cataract surgery techniques, more and more patients are expressing a desire to decrease their reliance on glasses post-operatively. The development of extended depth of focus (EDoF) intraocular lenses (IOLs) is intended to address the issue of photic phenomena and improve distance and intermediate vision while sacrificing some near vision [1]. The Tecnis Symfony intraocular lens utilizes innovative optical technology to deliver continuous high-quality vision with an extended range of vision (EROV) and enhanced contrast sensitivity [2, 3].This is achieved through the use of a proprietary achromatic diffractive echelette design that corrects corneal chromatic aberration [4]. The measurement of lens design known as depth of focus (DoF) holds considerable significance. Determining visual acuity can be achieved by assessing defocus curves, which involve measuring the patient's vision [5] at varying distances or with trial lenses [6] that induce different levels of defocus.It is defined as the range of lens powers (from zero defocus to the largest negative power) over which the mean acuity is 0.2 logMAR (20/32) or better [2, 4].

The changes in optical quality with pupil diameter define the phenomenon of pupil dependency in patients who have

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undergone intraocular lens surgery. Multifocal intraocular lenses (MIOLs) have extensively employed this term, particularly in the context of evaluating their performance [7, 8]. Previous research indicates that the size of a person's pupil is likely to impact the optical and visual effectiveness of a MIOL [9, 10]. The relationship between MIOLs and visual performance is affected by the size of the pupil, as it influences the proportion of the pupil that is devoted to near and distance corrections, according to Monte´s-Mico´et al. Moreover, the modulation transfer function (MTF) plays a crucial role in maintaining contrast in the original object as detected [10]. Currently, no substantial findings have been documented regarding the correlation between pupil size and depth of field when utilizing EDoF IOLs.

Hence, we investigated the correlations between DoF and age, anterior chamber depth (ACD), axial length (AXL), corneal spherical aberrations (SA), and preoperative and postoperative pupil size in cataract patients who undergo phacoemulsification and Symfony IOL implantation. For this purpose, the pre- and postoperative pupil diameter were evaluated using three different measurements: photopic, mesopic, and the mean of both were recorded.

Patients and methods

Patients

Eyes meeting the following criteria were included: pseudophakia with a specific EDoF IOL (Tecnis Symfony IOL, ZXR00, Abbott Medical Optics, Inc.) after standard phacoemulsification techniques through a superior clear corneal incision (2.8 mm),

complete preoperative and postoperative data, and no intraoperative or postoperative complication. All eyes underwent uneventful cataract extraction by one surgeon (Yulan Wang) at the Shanghai Eye Diseases Prevention &Treatment Center from Jul 2019 to Dec 2023.

The exclusion criteria were (1) patients diagnosed with glaucoma who exhibited visual field loss, (2) patients with ocular disease other than cataract (e.g., uveitis, amblyopia, retinal detachment, retinitis pigmentosa, diabetic retinopathy, macular degeneration), (3) patients with a history of previous ocular surgery such as prior refractive surgery (lens/non lens), combined surgery, intraoperative and postoperative complications, active ocular infection, and systemic diseases affecting vision, (4) patients with a follow-up time less than one month, and (5) patients with a postoperative corrected distance visual acuity of 20/50 or lower at least one month after the IOL implantation.

The study was approved by the local ethics committee of the Shanghai Eye Diseases Prevention & Treatment Center(2021SQ015) and carried out in accordance with the principles outlined in the Declaration of Helsinki. All patients provided written informed consent prior to inclusion to the study.

Preoperative measurements

Biometric measurements, including anterior corneal keratometry (flattest meridian (Kf), steepest meridian (Ks)), anterior chamber depth (ACD, epithelium to lens), white-to-white (WTW) values, and AXLs, were taken using an IOLMaster 700 (Carl Zeiss Jena, Germany). The Auto Keratorefractometer (KR)-8800 (Topcon, Japan) uses a rotary prism measuring system and offers a measurement range from −25.00 D to +22.00 D for the determination of spherical refractive errors and ±10.00 D for cylindrical refractive errors. The IOL power was calculated with the Barrett Universal II Formula using optimized constants from the User Group for Laser Interference Biometry (ULIB)B database. Macular morphology was examined using SS-OCT (Topcon DRI OCT Triton; Topcon Corp.). Preoperative pupil information (including Photopic Pupil (PP) Size and Mesopic Pupil (MP) Size) and corneal spherical aberrations (SA) were obtained using OPD-Scan III (Nidek Inc., Tokyo, Japan).

Postoperative measurements

At 1 month after surgery, when stable refraction can be expected [11], pupil information (including the PP size, MP size), and corneal spherical aberrations (SA) were obtained using OPD-Scan III. The average between PP and MP (AP) was also calculated and included in the analysis. Postoperative DoF was measured manually using the "defocus curve" assessment technique (RT-5100, Nidek). A monocular defocus curve was obtained by using the best corrected distance refraction and measuring the visual acuity in 0.5 diopter defocus steps between +2.0 D and −4.0 D [2]. The postoperative pupil diameters were measured on the same day that defocus testing was performed and under the same photopic light conditions as the test [2]. The pupil diameters (PP, MP, AP) were stratified into small (<3.0 mm), medium (3.0 to 3.5 mm), and large (>3.5 mm) pupil diameters [2]. Stratified analyses of "depth of focus" and defocus curve plots were conducted to evaluate the effect of pupil size and axial length [2].

Statistical analysis

Statistical analysis was performed using SPSS software (Version 22.0, SPSS Inc., Chicago, USA). The normality of data distributions from variables included in the study was tested with the Shapiro–Wilk test. Correlations between the DoF and pupil diameter, age, anterior chamber depth, axial length, and corneal spherical aberrations were evaluated with the Pearson correlation coefficient or Spearman correlation coefficient. Differences between the two groups were tested with the t test for independent samples or the Mann–Whitney test if the groups were not normally distributed. A probability of <5% ($P<0.05$) was considered statistically significant.

Results

Patient characteristics

Table 1 shows the patient demographic and biometric data. A total of 64 eyes from 49 patients (36 female, 13 male, mean age 57.23 ± 10.31 years) was included. The AXLs ranged from 21.31 to 31.94 mm with a mean value of 24.55 mm. The ACDs ranged from 2.21 to 4.16 mm with a mean value of 3.26 mm. The average preoperative corneal spherical aberration (SA) was 0.281 ± 0.115 µm, the average postoperative cornea SA was 0.268 ± 0.108 µm, the postoperative corneal SA was significantly lower than the preoperative corneal SA ($P=0.03$). The average preoperative PP size was 3.36 ± 0.58 mm (ranging from 2.14 to 4.81 mm), the average preoperative MP size was 5.19 ± 0.85 mm (ranging from 3.27 to 6.89 mm), the average postoperative PP size was 3.09 ± 0.49 mm (ranging from 1.99 to 4.19 mm), and the average postoperative MP size was 4.70 ± 0.64 mm (ranging from 3.34 to 6.26 mm). The implanted IOL power ranged from 5.0 to 26.5 D with a median value of 20.5D.

Table 1 Summary of demographic and biometric data

Parameter	Mean ± SD	Range
Age(y)	57.23 ± 10.31	32, 79
Axial length (mm)	24.55 ± 2.10	21.31, 31.94
Anterior chamber depth (mm)	3.26 ± 0.46	2.21, 4.16
IOL power implanted (D)	20.5 (15.125, 22.875)	5, 26.5
Pupil size(mm)		
Pre-Photopic	3.36 ± 0.58	2.14, 4.81
Pre-Mesopic	5.19 ± 0.85	3.27, 6.89
Post-Photopic	3.09 ± 0.49	1.99, 4.19
Post-Mesopic	4.70 ± 0.64	3.34, 6.26
Cornea spherical aberration		
Preoperative	0.281 ± 0.115	0.028, 0.61
Postoperative	0.268 ± 0.108	0.04, 0.52
Depth of focus	2.71 ± 0.63	1.0, 4.5

Correlation between pupillary size and depth of Focus

A significant negative association was found between preoperative PP size and depth of focus ($r=0.30$, Pearson's correlation coefficient). A significant negative association was found between preoperative MP size and depth of focus ($r=0.274$, Pearson's correlation coefficient) (Fig. 1). However, no significant association was found between preoperative MP-PP size (the difference between MP and PP) and DoF ($r=0.182$, $P=0.197$, Pearson's correlation coefficient). The average preoperative pupil size between the photopic and mesopic conditions was 4.23 mm ($r=0.329$, $P=0.017$, Pearson's correlation coefficient). A significant negative association was found between postoperative PP size and depth of focus ($r=0.313$, Pearson's correlation coefficient). A significant negative association was found between postoperative MP size and depth of focus ($r=0.399$, Pearson's correlation coefficient) (Fig. 1). However, no significant association was found between postoperative MP-PP size (the difference between MP and PP) ($r=0.213$, $P=0.096$, Pearson's correlation coefficient). When the PP diameters were stratified into small (<3.0 mm), medium (3.0 to 3.5 mm), and large (>3.5 mm) categories, small pupil diameters showed a better DoF (Table 2). The average postoperative pupil between the photopic and mesopic states was 3.90 mm ($r=0.394$, $P=0.002$, Pearson's correlation coefficient).

No significant correlation was observed between age, ACD, AXL, SA, and DoF in the Symfony (see Supplementary Table 1).

Correlation between preoperative and postoperative pupil size

Significant positive associations were found between preoperative and postoperative pupil size (PP, MP, AP, all $P<0.001$), also we found the pupil size was significantly decreased after phacoemulsification surgery (respectively PP 8.2%, MP 8.9%, AP 8.7%) (see Supplementary Table 2).

Discussion

Extended Depth of Focus Intraocular Lense is highly valued for its ability to provide a significant depth of focus. The level of pupil dependence following the insertion of a multifocal intraocular lens has been extensively discussed in optical lab experiments [12–14] but its assessment in clinical investigations is rare [15], especially in EDoF lenses, remains limited. The main objective of this research was to investigate the correlations between DoF

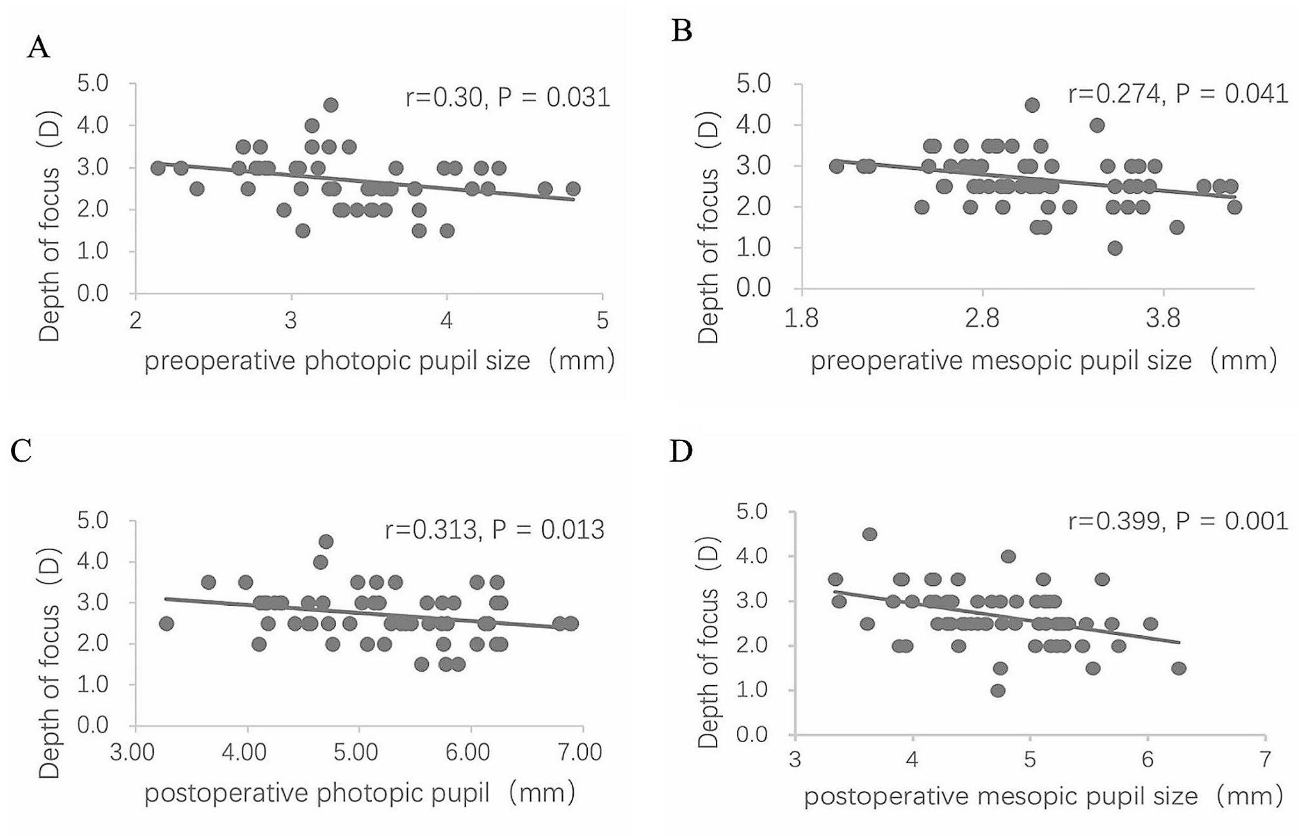

Fig. 1 Scatterplot of association between the pupil size and Depth of focus in EDoF IOLs. **A** Depth of focus was significantly correlated with the preoperative photopic pupil size ($r=0.30$, $P=0.031$, Pearson's correlation coefficient). **B** Depth of focus was significantly correlated with the preoperative mesopic pupil size ($r=0.274$, $P=0.041$, Pearson's correlation coefficient). **C** Depth of focus was significantly correlated with the postoperative photopic pupil size ($r=0.313$, $P=0.013$, Pearson's correlation coefficient). **D** Depth of focus was significantly correlated with the postoperative mesopic pupil size ($r=0.399$, $P=0.001$, Pearson's correlation coefficient)

Table 2 Analysis of pupil-dependency of the EDOF IOLs between pupil diameters stratified and Depth of focus

Parameter	Depth of focus(D)	Range
preoperative photopic pupil diameters		
Small (<3.0 mm)	2.96	r_R=-0.436, $P=0.001$
medium (3.0 to 3.5 mm)	2.86	
large (>3.5 mm)	2.40	
postoperative photopic pupil diameters		
Small (<3.0 mm)	2.86	r_R=-0.357, $P=0.004$
medium (3.0 to 3.5 mm)	2.74	
large (>3.5 mm)	2.31	

and age, ACD, AXL, SA, and preoperative and postoperative pupil size with Symfony. Pupillary responses were assessed in both photopic and mesopic conditions, before and after the surgical intervention, to determine the mean pupil size.

In this study, smaller pupil size was strongly associated with good postoperative DoF, including the preoperative photopic, mesopic and average pupil size and the postoperative photopic, mesopic and average pupil size. However, no significant correlation was observed between age, ACD, AXL, SA, and postoperative DoF in the Symfony.

The depth of field of the monofocal intraocular lens and pupil regulation are also involved. However, monofocal IOLs have limited pseudo adjustment. Normal pupils are unable to produce enough near addition. The monofocal intraocular lenses (IOLs) enable clear vision at only one distance, thus necessitating the use of either reading glasses or glasses for distant targets [16]. The EDoF technology for intraocular lenses (IOLs) has the potential to enhance vision at intermediate distances and minimize visual disturbances, thus bridging the gap between monofocal and multifocal IOLs. Additionally, it may improve contrast sensitivity [17]. Small-aperture design, bioanalogic IOL, diffractive optics, and nondiffractive optical manipulations are the four primary EDoF technologies [17, 18]. With the increasing use of EDoF IOLs in patients, an increasing number of studies has reported refractive outcomes, photopic phenomena, and patient satisfaction with EDoF. However, limited research has been conducted to assess the impact of pupil size on postoperative outcomes [19, 20]. Based on the analysis of peer-reviewed literature, there is a limited body of research on the relationship between pupil size and DoF following cataract surgery. Therefore, in this study, the influence of pupil size on the DoF of EDoF IOLs was observed as an independent factor that could better predict postoperative effectiveness.

The Symfony IOL group showed significantly higher levels of DoF than the bifocal IOL and trifocal IOL groups [21]. Knowledge of pupil size is helpful to ensure that the 6.0 mm diameter IOL will effectively cater to patients in both mesopic and photopic environments [22]. Pupil characteristics play a crucial role in determining depth of field and the level of illuminance on the retina, affecting visual performance [23].

In this study, the pupil size was significantly decreased after uncomplicated in-the-bag IOL implantation (respectively, PP decreased by 8.2%, MP decreased by 8.9%, and AP decreased by 8.7%), consistent with previous studies, which showed that the pupil diameter decreased by approximately 10% [23–25]. These changes might be related to the increased ACD and volume after the removal of the bulky crystalline lens [23].

MIOLs exhibit variations in the distribution of light energy, depending on the aperture, have approximately a 30% loss of contrast sensitivity (0.2 log units or 2 dB) and a decrease of slightly less than one line of best corrected visual acuity (0.1 logMAR). Hence, there may be differences in visual performance as well as the occurrence of certain negative effects, such as dysphotopsia, based on this parameter [26, 27]. Refractive MIOLs provide multifocality by changing the IOL refraction based on pupil size [28]. Smaller pupil size (<3.0 mm) was associated with worse near visual acuity [29, 30]. For pupil size less than 2.5 mm, a refractive multifocal may not be recommended [31]. In eyes implanted with a diffractive MIOL, a pupil diameter of ≤3.0 mm deteriorates contrast sensitivity [15]. Consequently, the measurement of pupil size is crucial when conducting a screening to choose between various designs of MIOLs and EDoF IOLs. In contrast, diffractive IOLs, such as TECNIS Symfony with a large central zone(1.6 mm) [32], provide distance focus and near focus by a diffractive grating, the effect of which is independent of pupil size. In this study, smaller pupils showed better DoF, especially PP diameters < 3.0 mm. Hence, for patients with small preoperative PP diameters (< 3.0 mm), diffractive EDoF IOLs are a better choice than refractive MIOLs. The concern of using EDoF IOLs in clinical practice may be that near vision is not as good as MIOLs. Still, for patients with relatively small pupils, EDoF IOLs can obtain the best synergistic effect of extending the depth of field. The contrast reduction and visual symptoms that may occur in MIOLs with small pupils are avoided.

It is essential for surgeons to consider certain crucial elements related to this subject matter. First, pupil size decreases with age, with a larger decrease per year in dim lighting than in bright lighting conditions [33, 34]. This means that the candidates for MIOLs often have significantly smaller pupils compared to younger patients. Meanwhile, pupils vary with vergence distance, and a mean reduction of approximately 0.5 mm can appear at near versus far distances under conditions of normal lighting [35]. This can result in variances between the direct measurements of visual acuity that have been adjusted for distance and the measurements obtained through defocus curves.

Defocus curves, a commonly used technique in assessing the effective visual range in techniques for correcting presbyopia, such as accommodating and multifocal intraocular lenses (IOLs), have gained significant popularity [36]. Proposed as a means of measuring the amplitude of accommodation (AoA) in phakic eyes [36, 37], research studies have introduced defocus curves. The technique was also employed to evaluate the extent of pseudo accommodation (AoP) offered by accommodating IOLs in extended depth of focus (EDoF) IOLs [38, 39]. Defocus curves provide insights into both the near addition's effectiveness (measured in diopters between the distance and near peak) and the visual acuity at different levels of spectacle defocus [36]. The DoF, in this research, is defined as the range of lens powers (from zero defocus to the largest negative power) over which the mean acuity is 0.2 logMAR (20/32) or better.

Liu et al [20] demonstrated that six preoperative ophthalmological attributes had a robust correlation with good postoperative DoF, including a low ACD, smaller pupil size, low-to-mid axial length, minimal astigmatism degree, low IOP, and medium lens target refractive error. However, in our study, DoF only showed a strong association with a smaller pupil size. This may be related to the fact that most of the eyes included in this study had a normal ocular axis. Several studies showed that the size of the pupil in a multifocal intraocular lens (IOL) has an impact on the balance between two trade-offs (1) the depth of field and the in-focus, defocus MTF and (2) the far and near MTFs [9, 40].

The Tecnis Symfony intraocular lens (IOL) offers a prolonged focal range instead of multiple focal points. Symfony was designed with a negative spherical aberration of [40] − 0.27 μm for an aperture of 6 mm. In our study, one month after surgery, the patients' corneal spherical aberration was significantly reduced by 0.019 ($P = 0.03$), suggesting that phacoemulsification in our study reduced corneal spherical aberration. Combined with the reduction of Symfony IOLs, the overall aberration of patients after surgery will be reduced, and good postoperative visual function can be achieved.

The study has a few limitations. The results may not apply to hospitals outside of China as the study was conducted in a single center in China. This study evaluated only the visual acuity defocus curve but not the contrast sensitivity defocus curve. Fernández et al. demonstrated that the use of the contrast sensitivity defocus curve is generally preferable to the use of the visual acuity defocus curve in order to detect small changes in optical quality with pupil diameter changes [34]. The mean axial length was 24.55 mm, and most of the axial lengths were below 27 mm because the pupil was observed as an independent factor in this study. The effect of axial length on DoF needs further verification. Further studies with other MIOLs and larger samples are required to confirm our findings.

These discoveries could be applied in a clinical setting to evaluate visual function following cataract surgery and may have implications for the design of intraocular lenses (IOLs). The information provided in this study can assist clinical investigators in designing future studies on pupil dependence and visual performance with multifocal EDoF intraocular lenses.

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Data availability The datasets generated during and/or analyzed in this study are not publicly available due to privacy regulations set by the Shanghai Eye Diseases Prevention & Treatment Center but are available but are available from the corresponding author on reasonable request.

Declarations

Ethical approval The study was approved by the local ethics committee of the Shanghai Eye Diseases Prevention & Treatment Center(2021SQ015) and conducted according to the tenets of the Declaration of Helsinki. All patients provided written informed consent prior to inclusion to the study.

Competing interests The authors declare that they have no competing interests.

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