

# Pupillodynamics and corneal spherical aberrations in a set of Indian cataract patients and its implications for aberrometric customisation of intraocular lenses

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**Purpose:** Assessment of pupil diameter in various light conditions and the corresponding corneal spherical aberrations in a cohort of Indian eyes with bilateral senile cataracts and the possible use of this data in aberrometric customization of intraocular lenses (IOLs). **Methods:** In this prospective observational study done at a tertiary eye care centre in India, the selected patients were subjected to measurement of their pupil diameters in scotopic, mesopic, and photopic conditions as well as the corresponding corneal spherical aberrations, using the Sirius Topographer (Costruzione Strumenti Oftalmici, Florence, Italy). Shapiro–Wilk test, Independent *t*-test, ANOVA with Bonferroni correction on post-hoc testing were used for statistical analysis. **Results:** 104 eyes of 52 patients were enrolled for the study. The mean age was 53 ± 11.88 years. The mean scotopic, mesopic, and photopic pupil sizes were 4.37 mm (4.11–4.63 mm), 3.92 mm (3.71 mm–4.15 mm), and 3.37 mm (3.18–3.67 mm), respectively. There was a statistically significant difference ( $P = <0.001$ ) in the mean corneal spherical aberration measured at the 6 mm zone ( $0.23 \pm 0.02$  microns) and at the 4 mm zone ( $0.06 \pm 0.01$  microns). **Conclusion:** The mean corneal spherical aberration corresponding to the average mesopic pupil size of our patient population was substantially lower than that of the scotopic pupil size and also less than the amount corrected by most of the negative aspheric IOLs. This perhaps indicates the need for customising IOLs based on the spherical aberrations of cornea at the zone corresponding to the mesopic pupil diameter for optimal residual total postoperative spherical aberrations.

**Key words:** Aspheric IOLs, corneal spherical aberration, pupillometry

The application of wave-front technology to cataract surgery has totally changed the way we look at post-cataract visual rehabilitation. The goal now is to achieve aberration-free vision that is far superior to conventional emmetropia. One of the biggest improvements toward this goal was the advent of aspheric intraocular lenses (IOLs). It is well known that the cornea is a source of positive spherical aberrations (SAs) that are balanced by the negative SAs of the crystalline lens.<sup>[1-3]</sup> This balance between the crystalline lens and the cornea gets disturbed with the development of cataract and also post cataract surgery when IOLs with positive SAs are implanted.<sup>[4]</sup> To address this problem, aspheric IOLs with negative SAs were introduced to cancel out the positive corneal spherical aberrations (CSAs).<sup>[1,5]</sup> The amount of negative SAs in different IOLs have been derived from different sets of normative data, defining the mean CSAs in the representative populations.<sup>[1,6-8]</sup>

Spherical aberrations are a function of the pupillary diameter which in turn is a function of the amount of pigment in the iris

that differs in people of different ethnicities.<sup>[7,9,10]</sup> Aspheric IOLs have been designed using aberration data either from studies where the subject's pupils were dilated or in populations where the iris is lightly pigmented and hence have a larger pupillary diameter at similar ambient light conditions.<sup>[1,11-13]</sup> To the best of our knowledge the mean pupil diameter and corresponding CSAs have not been studied in Indian eyes in the context of patients undergoing cataract surgery. In this study we have measured the mean pupillary diameter at different light conditions and the CSAs corresponding to those pupil diameters. In future this might help in designing IOLs that are better customised to the aberration profile of Indian cataract patients whose numbers are projected to be 8.25 million by the year 2020.<sup>[14]</sup>

## Methods

This prospective observational study was performed at a tertiary eye care hospital. The guidelines laid by the declaration of Helsinki were adhered to during the study. Patients who

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presented in the outpatient department with complaints of diminution of vision and found to have cataract in both eyes on slit-lamp evaluation were enrolled in the study after obtaining informed consent. Those patients with corneal scars, pterygiums, ocular surface disorders and previous corneal or refractive surgery procedures were excluded from the study. This was done to exclude the effect of corneal irregularities on the measured CSAs. Those patients with active infection or intraocular inflammation, systemic comorbidity, or on treatment with topical or systemic medications that could affect pupil size were also excluded from the study.

Patients then underwent preoperative pupillary size measurement using the in-built pupillography measurement software of the Sirius Topographer (Costruzione Strumenti Oftalmici, Florence, Italy). It measures the scotopic pupil diameter at 0.4 lux, mesopic pupil at 4 lux, and photopic pupil at 50 lux [Fig. 1]. The stimulus for pupillometry is a Placido disc with a central Gallium Aluminium Arsenide Red light emitting diode. On pressing the joystick the image is taken a few milliseconds after the stimulus. Technically, it is not possible to create a capture at a “true scotopic” (0 lux) situation and therefore, this device did a “near scotopic” measurement at 0.4 lux (these settings were provided by the device manufacturer and were not alterable). The examination was done in a completely dark room with the pupillometer as the only light source. All the illumination settings were re-confirmed using the LX-103 luxmeter (HTC™ Instruments). A single clinician performed all measurements to avoid inter-operator variability. No miotics or mydriatic eye drops were used and the patients were asked to blink repeatedly between measurements to spread the tear film uniformly over the corneal surface. The scotopic pupil diameter was measured first in the right eye (RE) and then in the left eye (LE). This was followed by the measurement of the mesopic and photopic pupil size in the right and left eyes respectively.

The Sirius integrates a Placido-based (22 rings) videokeratoscope with a rotating Scheimpflug camera. Corneal wavefront analysis used the ray tracing method to document the type and size of all existing optical aberrations in the cornea. The aberration of interest in our study was the CSA. The in-built software of the topographer can calculate the corneal spherical aberration at different corneal diameters using the Zernike principle [Fig. 2]. The CSAs were measured at two corneal zones, first at the zone equal to mean mesopic pupillary size and second at the 6 mm zone. Subsequently, routine pre-cataract surgery evaluations that included intraocular pressure measurements, detailed anterior segment evaluation, dilated retinal evaluation and biometry for IOL power measurements were performed.

The expected population standard deviation as reported by Chan<sup>[11]</sup> and Wang<sup>[15]</sup> was 0.8 and employing the t-distribution to estimate the sample size, the study would require a sample size of 100 to estimate a mean with 95% confidence and a precision of 0.16.<sup>[16]</sup> The parameters evaluated were assessed using Shapiro–Wilk test for Normal distribution. The mean pupil diameter was calculated at each light condition separately for right and left eye in order to ensure independence of variables for statistical analysis. The statistical difference between means was tested using ANOVA with Bonferroni post-hoc correction and

independent samples *t*-test. A “*P*” value of less than 0.05 was taken as significant.

## Results

104 eyes of 52 patients were evaluated for this study. The demographic distribution was 31 males and 21 females with bilateral cataracts with mean age of 53.17 ± 11.88 years.

### Pupil diameter

The mean pupil diameter in scotopic conditions in the RE was 4.41 ± 0.90 mm (95% confidence interval (CI) 4.15–4.66 mm) while in the LE eye it was 4.33 ± 0.96 mm (95% CI 4.06–4.60 mm). The difference between the scotopic pupil size in the RE and LE was not statistically significant (*P* = 0.603). In mesopic conditions, the mean pupil diameter of the RE

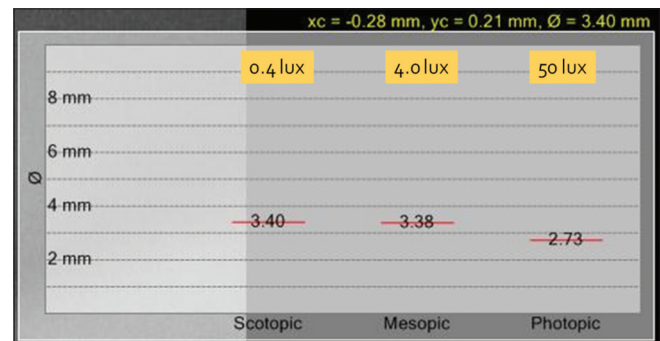


Figure 1: Pupil diameter measurement by Sirius Topographer CSO

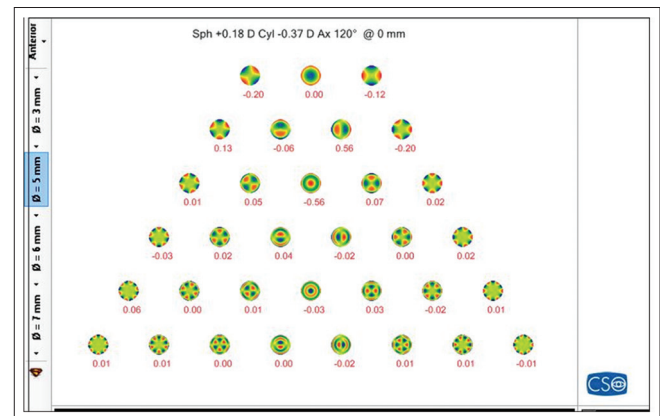


Figure 2: Shows Corneal Spherical aberrations (CSA) measured by Sirius topographer CSO. The pupil diameter at which CSA is measured can be selected from Bar on Y-axis

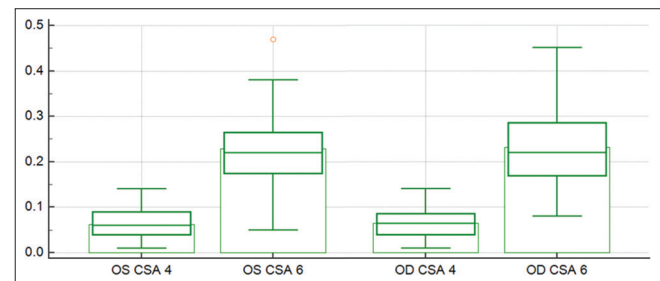


Figure 3: Shows measured OD and OS corneal spherical aberrations measured at 4 mm (CSA4) and 6 mm (CSA 6) zone

was  $4.00 \pm 0.8$  mm (95% CI 3.78–4.23 mm) and the LE mean pupil diameter was  $3.84 \pm 0.78$  mm (95% CI 3.63–4.06 mm), there was no statistically significant difference ( $P = 0.300$ ) between the two. In photopic conditions, the mean RE pupillary diameter was  $3.42 \pm 0.67$  mm (95% CI 3.24–3.61 mm) and the LE pupil diameter was  $3.32 \pm 0.96$  mm (95% CI 3.13–3.50 mm). This difference was also not statistically significant ( $P = 0.423$ ) [Table 1]. The mean bilateral scotopic, mesopic and photopic pupil size was 4.37 mm (95% CI 4.11–4.63 mm), 3.92 mm (95% CI 3.71–4.15 mm) and 3.37 mm (95% CI 3.18–3.67 mm), respectively, with statistically significant differences among the groups (ANOVA  $P < 0.001$ ) and on post-hoc testing with Bonferroni correction ( $P < 0.001$ ).

### Corneal spherical aberrations

The CSA at 6 mm zone and at 4 mm zone for right and left eyes separately is shown in Table 2. The mean mesopic pupil size of 3.92 mm (95% CI 3.71–4.15 mm) was rounded off to 4.0 mm for practical purposes as there is no provision in the Sirius topographer to measure the corneal spherical at 3.92 mm. The combined RE and LE data showed that mean CSA when measured at 6 mm corneal zone is  $0.23 \mu\text{m}$  and at 4 mm corneal zone is  $0.06 \mu\text{m}$  [Fig. 3]. There was no statistically significant difference between the mean combined CSAs for the right and left eyes, both at the 6 mm ( $P = 0.82$ ) as well as at the 4 mm zone ( $P = 0.54$ ). However, there was a statistically significant difference between the mean combined CSAs at 6 mm zone compared to the mean CSAs at 4 mm, for both the eyes ( $P < 0.0001$ ).

## Discussion

CSAs are the only rotationally symmetrical aberrations on-axis that can be corrected with an IOL. They have conventionally been studied at the 6 mm zone primarily for standardization purposes.<sup>[17,18]</sup> Holladay *et al.* reported the mean CSA at the 6 mm zone for a set of 71 Swedish patients to be  $0.27 \pm 0.02 \mu\text{m}$  which is very close to our observed value at the 6 mm zone of  $0.23 \pm 0.08 \mu\text{m}$ .<sup>[1]</sup> Similarly, Wang *et al.* in the United States reported mean CSAs at the 6 mm pupil to be  $0.281 \pm 0.086 \mu\text{m}$ .<sup>[19]</sup> The fact that the pupil diameter governs the total aberrations of the eye has been well established.<sup>[20]</sup> The lack of variation in the amount of CSAs in different ethnicities noted above is a consequence of standardising the pupil diameter at 6 mm.

A review of literature revealed a lack of normative data pertaining to the mean mesopic pupil diameter for different ethnicities and their corresponding CSAs. In this study we reported the mean pupil diameter in different light conditions and spherical aberrations at different pupil diameter zones for our cohort of Asian Indian eyes.

In our set of patients, the mean mesopic pupil diameter was found to be  $3.92 \pm 0.08$  mm. This result was different from studies done in a predominantly Caucasian population. Chan *et al.* studied 102 eyes in Stanford University, United States and reported the mean mesopic pupil diameter as  $6.0$  mm  $\pm$  0.08. In their group there were 31 (31%) small (<5.5 mm) pupils, 36 (36%) medium (5.4–6.4 mm) pupils, and 32 (32%) large (>6.5 mm) mesopic pupils. Applying the same classification in our group, 100 (96%) mesopic pupils were small (<5.5 mm), and the remaining 4 (3.8%) were in the lower range of the medium sized pupils between 5.64 and 5.83 mm. This highlights an ethnic variation in the mesopic pupil size.<sup>[11]</sup>

Linke SJ *et al.* in their study of 13,959 eyes in Hamburg, Germany found the mean mesopic pupil diameter to be  $6.45 \pm 0.82$  mm. They evaluated factors that may affect mesopic pupil size in refractive surgery candidates, and concluded that the sum of all analysed factors (age, refractive state, keratometry, and pachymetry) can only predict the expected pupil size in <20%.<sup>[12]</sup> Our study suggests an ethnic factor, possibly linked to iris pigmentation, which might have the strongest impact on pupil size. Wang *et al.* did a similar study in Beijing with 4,403 individuals and reported the mean pupil diameter to be  $4.08 \pm 0.80$  mm which is closer to our observed value.<sup>[16]</sup> The reason for the values reported by Wang *et al.* being closer to our values for the mesopic pupil size, as compared to the other studies mentioned, may be attributed to the fact that the degree of iris pigmentation of the Chinese eyes is comparable to the Indian eyes.

It has been reported that the ideal total post-operative spherical aberration should be in the range of 0.07–0.1  $\mu\text{m}$  to get the best balance of objective contrast sensitivity as well as subjective depth perception.<sup>[21]</sup> In our study the CSAs corresponding to the mean mesopic pupil diameter was  $0.06 \pm 0.01 \mu\text{m}$ . This was substantially lower than the CSA at the 6 mm zone and was also less than the amount corrected by most of the negative aspheric IOLs used in clinical practice.

**Table 1: The arithmetic mean, 95% confidence interval and Standard deviation of OD and OS pupil size in scotopic, mesopic and photopic conditions**

	Photopic pupillary size (mm)		Mesopic pupillary size (mm)		Scotopic pupillary size (mm)	
	OD	OS	OD	OS	OD	OS
Arithmetic mean	3.42	3.32	4.00	3.84	4.41	4.33
95% CI for the mean	3.24-3.61	3.13-3.50	3.78-4.23	3.63-4.06	4.15-4.66	4.06-4.60
Standard deviation	0.67	0.66	0.80	0.78	0.90	0.96

**Table 2: The combined data of corneal spherical aberrations CSA in microns for the right and left eyes**

	OD CSA 4 mm ZONE	OD CSA 6 mm ZONE	OS CSA 4 mm ZONE	OS CSA 6 mm ZONE
Arithmetic mean	0.07	0.23	0.06	0.23
95% CI for the mean	0.06-0.07	0.21-0.25	0.05-0.07	0.21-0.25
Standard deviation	0.03	0.08	0.03	0.08

Implantation of these negative aspheric IOLs could result in residual negative total postoperative spherical aberrations for the entire eye that may result in the final visual outcome being less than ideal. Selecting IOLs based on the spherical aberrations of cornea at the zone corresponding to the mesopic pupil diameter may result in optimal postoperative entire eye spherical aberration and visual quality. This may not be possible at an individual level but customisation based on ethnic data is certainly achievable.

## Conclusion

Aspheric IOLs have become an integral part of cataract management as they improve the quality of vision by correcting the corneal spherical aberrations. However, the normative data regarding mesopic pupil size and the corresponding size CSAs for Indian patients undergoing cataract surgery has never been reported. Most of the commercially available aspheric IOLs are based on data that has been derived from studies done on Caucasian eyes. We found that the mesopic pupil size as well as the corresponding CSAs in the Indian cataract patients was substantially lower than what is generally corrected by most of the aspheric IOLs. Our study therefore indicates that perhaps target population-based customization of aspheric IOLs may be the way forward for the future.

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## Conflicts of interest

There are no conflicts of interest.

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