Reproducibility of intraocular lens decentration and tilt measurement using a clinical Purkinje meter

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PURPOSE: To determine the reproducibility of intraocular lens (IOL) decentration and tilt measurements with a new Purkinje meter instrument.

SETTING: Moorfields Eye Hospital NHS Foundation Trust, London, United Kingdom.

METHODS: After pupil dilation, images of pseudophakic eyes with a plate-style IOL (Akreos Adapt) were obtained using a recently developed Purkinje meter. Intraocular lens decentration and tilt were evaluated by analyzing the captured images using a semiobjective method by marking the reflexes in the images and automatic calculation using a dedicated software program. In study 1, examiner 1 examined the eyes first followed by examiner 2. Ten minutes later, examiner 1 performed a second measurement, after which the intraexaminer and interexaminer reproducibility were determined. In study 2, a Purkinje meter was used to measure pseudophakic eyes with slitlamp finding of clinical IOL decentration, IOL tilt, or both. The results were compared with retroillumination photographs and slitlamp findings.

RESULTS: In study 1, there was high intraexaminer reproducibility for decentration ($r = 0.95$) and tilt ($r = 0.85$) and high interexaminer reproducibility for decentration ($r = 0.84$) and tilt ($r = 0.75$). In study 2, even in extreme cases of decentration and/or tilt, the Purkinje meter measurements were possible and appeared to correlate well with slitlamp findings.

CONCLUSIONS: Acquisition of images in pseudophakic eyes with the Purkinje meter was simple and rapid. The method was highly reliable for 1 examiner and between 2 examiners.

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The theoretic impact of intraocular lens (IOL) misalignment on visual quality in the pseudophakic eye has been studied extensively.[1–5] Intraocular lens misalignment is thought to play a negative role in the optical performance in eyes with IOLs that have an aspheric, toric, or multifocal optic.[6–12] For example, even slight decentration and tilt of aspheric IOLs can not only result in the loss of the effect of reducing spherical aberrations but also, in more severe cases, lead to worse optical quality than that obtained with spherical IOLs. Decentration of toric IOLs can cause misalignment of the toric axis of the IOL, reducing the astigmatic correction and inducing higher-order aberrations. Decentration of multifocal IOLs can cause different light distribution patterns between the distance focus and the near focus.

There are several methods of measuring IOL misalignment in the clinical setting. A recent study assessing IOL position[13] used subjective grading methods at the slitlamp or Scheimpflug imaging to evaluate IOL decentration and tilt. Subjective grading at the slitlamp can vary considerably between examiners. The method is more qualitative than quantitative and does not allow fine resolution of IOL decentration, with even less resolution for IOL tilt. Also, there is no standardized target for patients to focus on, making the method even less reliable. Scanning methods such as Scheimpflug imaging require a very well dilated pupil (>6.0 mm) to assess IOL position, and it can be difficult to identify the anatomic structures of the eye that serve as points of reference. Scheimpflug images have been used to assess IOL decentration and

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tilt; however, erroneous results, often due to corneal magnification, have diminished the widespread use of the images for this purpose.[1]

An alternative method of IOL assessment is retroillumination photograph analysis using Adobe Photoshop (Adobe Systems Inc.).[14] The drawback of this method is that IOL tilt cannot be measured. Furthermore, sufficient pupil dilation is required for good-quality retroillumination photographs.

A recent method uses light reflections of Purkinje images at ocular surfaces to evaluate ocular alignment.[15–20] The method has also been used to measure IOL decentration and tilt[1,21] based on the principle that light is reflected at all interfaces of media with a difference in refractive index; the reflections, the so-called Purkinje reflexes, can be used to assess IOL tilt and decentration. A Purkinje meter was developed that takes a video camera–based photograph of the reflections from the cornea and the IOL; then, using dedicated software, the device calculates the position of the IOL.[1] This noncontact technique does not use a flash and is quick and easy to perform. Improvement and advancements in the system may allow it to more accurately measure IOL alignment and evaluate the effect of IOL misalignment on optical performance.

This study assessed the intraexaminer and interexaminer reproducibility of IOL decentration and tilt measurement using a new Purkinje meter system. The system's new calculation software was used to calculate various degrees of IOL misalignment to determine the reliability of the new device.

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PATIENTS AND METHODS

This study consisted of 2 parts. Study 1 assessed intraexaminer and interexaminer reproducibility of the method. Study 2 compared Purkinje meter measurements with the clinically apparent IOL decentration and/or tilt found at a slitlamp examination. After receiving an explanation of the measurement procedure, all patients provided informed consent. This research adhered to the tenets of the Declaration of Helsinki and was approved by an ethics committee.

Protocol

Study 1 Inclusion criteria for study 1 were age 21 years or older and age-related cataract. Exclusion criteria were pseudoexfoliation, glaucoma, traumatic cataract, and systemic disease that could affect capsular bag stability (eg, Marfan syndrome). Each patient had uneventful phacoemulsification cataract surgery followed by implantation of an Akreos Adapt IOL hydrophilic foldable IOL (Bausch & Lomb) in the capsular bag. The IOL is symmetrically biconvex with a plate-style design. After pupil dilation, postoperative IOL misalignment measurements were taken using the Purkinje meter system.

Study 2 Inclusion criteria in study 2 were slitlamp findings of IOL decentration, IOL tilt, or both. Decentration was measured at the slitlamp. Retroillumination photographs were taken, and IOL decentration relative to the limbus was measured on the images. This was performed with a fully dilated pupil to allow identification of the center of the IOL. The slitlamp and the retroillumination photograph decentration data were compared with measurements taken using the Purkinje meter.

Purkinje Meter System

Intraocular lens decentration and tilt were determined using a recently developed Purkinje meter system. The Purkinje meter captures and records Purkinje images, which appear as a semicircular ring of light-emitting diodes (LEDs), for several fixation positions. One photograph is obtained in approximately 3 seconds.

The technical details of the Purkinje meter system have been described.[1,21] In brief, the patient fixates on a light. An array of LEDs is projected onto the eye, and the 3 reflected images (Purkinje I+II, Purkinje III, and Purkinje IV) are captured with the digital camera setup of the Purkinje meter. The captured image of the anterior segment, which contains the 3 Purkinje reflexes, is recorded at each fixation point. The distance from the center of the pupil to each reflection is obtained. The distances are plotted as an angular fixation function. From the plots, the fixation angle at which Purkinje III and Purkinje IV overlap is determined. Intraocular lens decentration is determined from the distance of the overlapping point to the entrance point at the center of the pupil. The fixation angle with respect to a central stimulus at each foveal target is known, allowing determination of IOL tilt.

Measurements and Data Analysis

The quality of the photograph was analyzed on a computer monitor, after which the image was saved to the computer's hard disk. Intraocular lens decentration and tilt were evaluated by analyzing the captured images; Purkinje reflexes I, III, and IV were manually marked on the images. Figure 1 shows an image captured with the Purkinje meter. The 3 reflections (Purkinje I+II, Purkinje III, Purkinje IV) are visible, as is the manual marking of the 3 reflexes. After the images were obtained, the software automatically calculated angle κ, IOL tilt, and IOL decentration. Analysis of the images was performed offline at a later time. Decentration was classified as temporal, nasal, superior, or inferior. Temporal IOL tilting, for example, indicated that the optical axis of the IOL was tilted toward the temporal side of the pupillary axis.

Study 1 In study 1, examiner 1 performed the first Purkinje meter measurement and examiner 2, the second measurement. Ten minutes later, examiner 1 performed another measurement. The patient was asked to sit back after each measurement, and the chin rest and the position of the Purkinje meter were changed slightly to allow for system realignment. Defocusing or focusing more on the Purkinje reflexes other than Purkinje I did not affect the final results of data; therefore, bias resulting from slightly defocused measurements was not expected. The images were analyzed using the system's software, and the automatically calculated data were used to determine intraexaminer and interexaminer reproducibility.

Study 2 In study 2, a single Purkinje meter measurement was taken in each eye. The results were compared with slitlamp evaluation of IOL decentration performed by the same experienced examiner who performed the Purkinje meter measurements. Intraocular lens tilt was also assessed (yes or no) at the slitlamp. Retroillumination photographs were taken with the pupil well dilated and the results were compared with Purkinje meter measurements.

RESULTS

Study 1

Study 1 comprised 15 eyes of 15 patients (8 men, 7 women) with a mean age of 71 years (range 52 to 86 years). The mean IOL power was 22.6 diopters (D) (range 17.5 to 27.5 D). Partly due to insufficient pupil dilation, only one third of Purkinje III was visible in 2 cases (Figure 2, *top*) and only two-thirds in 6 cases (Figure 2, *bottom*). In the other 7 eyes, all 3 Purkinje reflexes were visible in their entirety.

Intraexaminer reproducibility in study 1 was high for angle κ (r = 0.94), IOL decentration (r = 0.95), and IOL tilt (r = 0.85) (Figure 3). Furthermore, there was a high correlation between decentration assessed at the slitlamp and that measured by the Purkinje meter (r = 0.72). The mean measured decentration was 0.30 mm ± 0.26 (SD) and the mean measured tilt, 4.05 ± 5.60 degrees.

Although interexaminer reproducibility of angle κ (r = 0.84), IOL decentration (r = 0.84), and IOL tilt (r = 0.75) was high, it was slightly lower than intraexaminer reproducibility (Figure 3).

Study 2

In study 2, 15 eyes with a clinically apparent decentered or tilted IOL were measured. As expected, study 2 had more cases of incomplete Purkinje images than study 1. This occurred in cases in which the iris

Figure 1. Image with 3 Purkinje reflexes and manual marking of the reflexes before calculation is performed using the software (PI = Purkinje reflex I; PIII = Purkinje reflex III ; PIV = Purkinje reflex IV).

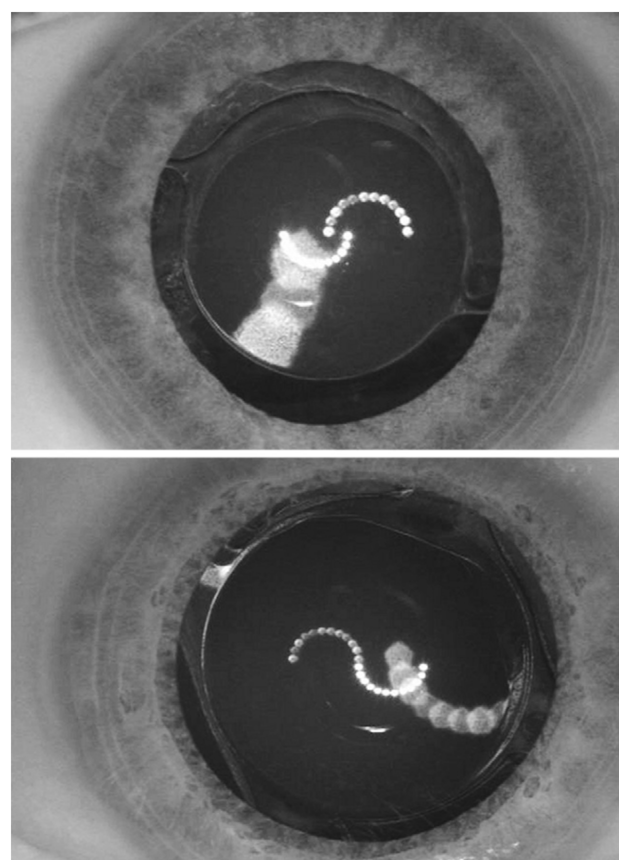

Figure 2. *Top*: Case in which only one third of Purkinje III is visible. *Bottom*: Case in which only two-thirds of Purkinje III is visible.

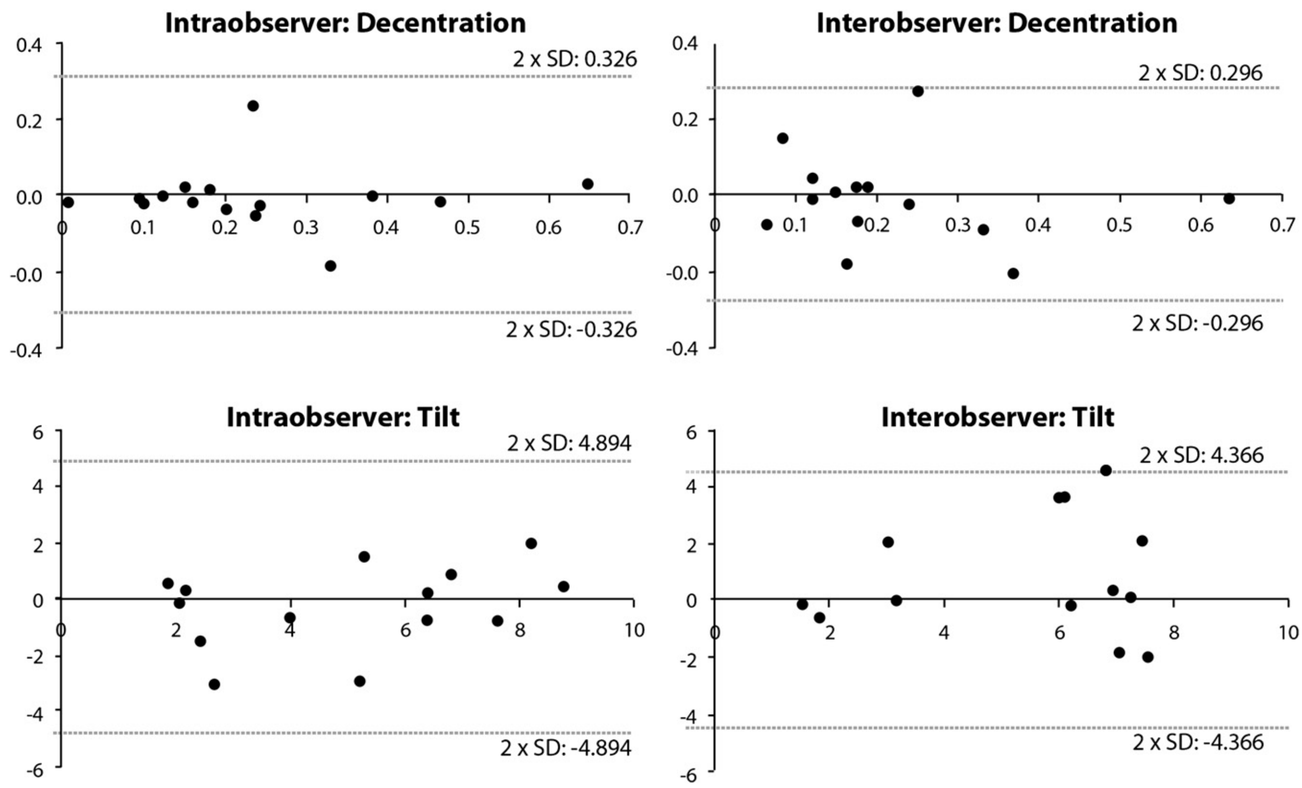

Figure 3. Bland-Altman plots of intraobserver and interobserver reproducibility of measurement of IOL decentration (mm) and tilt (degrees). The x-axis shows the mean values of the 2 measurements and y-axis, the difference between the measurements.

covered large areas of the IOL as a result of significant IOL misalignment (Figure 4) and in cases with poor pupil dilation and a history of surgical complications.

Reliability of the Purkinje meter imaging was satisfactory in all cases, including those with more significant IOL misalignment. The mean absolute difference in decentration between slitlamp grading and Purkinje meter measurements was 0.5 $\pm$ 0.6 mm (range 0.0 to 2.3) (r = 0.57). In 2 cases, the difference was greater than 1.0 mm; in 1 case, the slitlamp value was lower and in the other, the Purkinje meter value was lower. The mean absolute difference in decentration between retroillumination photograph measurements and Purkinje meter measurements was 0.6 $\pm$ 0.6 mm (range 0.0 to 2.4) (r = 0.59). In 3 cases, the difference was greater than 1.0 mm, with the Purkinje meter measurement being lower in all cases.

The Purkinje meter system found IOL tilt in all cases in which it was observed at the slitlamp. The Purkinje meter and slitlamp findings were in agreement in most cases. Because slitlamp assessment of tilt does not allow quantitative grading, it was not possible to determine any correlations. The mean Purkinje meter tilt measurement was 8.6 $\pm$ 9.9 degrees in cases with obvious tilt at the slitlamp and 4.7 $\pm$ 4.9 degrees in cases with no obvious tilt at the slitlamp.

DISCUSSION

Intraexaminer and interexaminer reproducibility of measurements of IOL decentration and tilt with the new Purkinje meter was high. We found that good pupil dilation was necessary for the system to capture good-quality images with 3 clear Purkinje reflections and to obtain accurate data. The reproducibility of the measurements was good, even in cases in which some Purkinje reflexes were not entirely visible.

The measurements used in our data analysis were obtained by examiners experienced in the use of the Purkinje meter system. In addition, patients were asked to sit back from the chin rest after each measurement, after which the position of the Purkinje meter was changed slightly.

In study 1, intraexaminer reproducibility and interexaminer reproducibility of the Purkinje system measurements were high. Intraexaminer reproducibility was assessed for 1 examiner only, which is a possible shortcoming of the study design. However, because intraexaminer reproducibility and interexaminer reproducibility were very high, it is unlikely that the intraexaminer reproducibility of examiner 2 would have been worse. The effect of defocus on measurements was easily checked and did not affect the final results, indicating good measurements even in the presence of

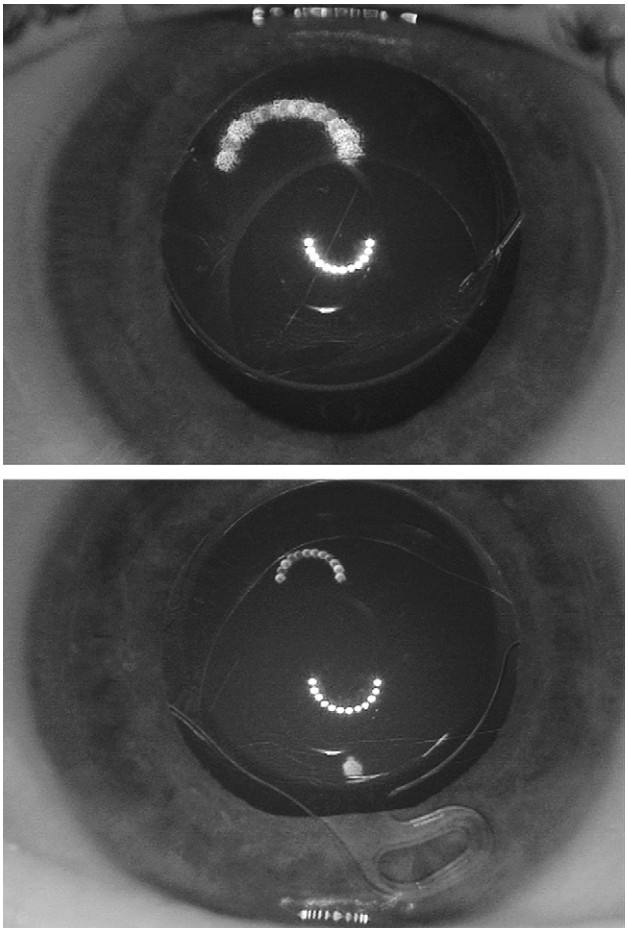

Figure 4. Example of a decentered 3-piece IOL (*top*) and a severely dislocated 1-piece IOL (*bottom*). In both cases, Purkinje reflex III is not visible.

slight defocus. Although both intraexaminer reproducibility and interexaminer reproducibility were high, the results showed that intraexaminer reproducibility was slightly higher. The interexaminer reproducibility indicates the technique would be valid in clinical use in long-term trials. The high correlation between the IOL decentration measured at the slitlamp and that measured with the Purkinje meter showed routine clinical reliability and the potential for the Purkinje meter to be used in assessing postoperative IOL decentration.

In study 2, the Purkinje meter system had more difficulty measuring extreme cases of IOL tilt or decentration because some parts of the IOL were covered by the iris as a result of severe IOL decentration; this caused insufficient views of Purkinje reflexes from the IOL. Nevertheless, measurement of IOL tilt was possible in all cases in which tilt was observed at the slitlamp. The mean Purkinje meter tilt measurement was 8.6 $\pm$ 9.9 degrees in cases with obvious tilt at the slitlamp and 4.7 $\pm$ 4.9 degrees in cases with no obvious tilt at the slitlamp. The IOL decentration in retroillumination photographs correlated well with the Purkinje meter measurements. In 3 cases, the difference was more than 1.0 mm, with the Purkinje meter values being lower in all cases. Slitlamp evaluation of IOL decentration also correlated well with the Purkinje meter measurements. In 2 cases, the difference was more than 1.0 mm; in 1 case the slitlamp value was lower and in the other case, the Purkinje meter measurement. Considering that Purkinje meter measurements are based on acquiring both Purkinje III and Purkinje IV reflexes, the reliability of the system was satisfactory in severe cases of IOL misalignment.

With the increased use of aspheric, toric, and multifocal IOLs, it is more important to assess the effect of IOL tilt and decentration on visual performance. Aspheric IOLs may be more sensitive to IOL misalignment than spherical IOLs.[1] Developments in wavefront technology have resulted in aspheric IOLs that correct corneal spherical aberrations, which was not possible with conventional spherical IOLs.[22–24] However, the potential of aspheric IOLs to correct spherical aberrations could be impaired by additional induced off-axis aberrations caused by IOL misalignment.[1] It has been reported that decentration of aspheric IOLs has a more critical effect on optical performance than IOL tilt, indicating that the focus should be on preventing decentration, rather than tilt, with aspheric IOLs.[9]

The lower tolerance of aspheric IOLs to misalignment demands accurate techniques for measuring it. Yang et al.[10] evaluated misalignment of a multifocal IOL using an anterior segment analysis system. Dick et al.[12] used Scheimpflug photography and analysis of retroillumination photographs to assess the multifocal IOL. In both studies, the functional results of the IOLs were satisfactory during the short postoperative period. Future long-term follow-up of more recent results is required. Approaches to evaluate IOL misalignments include the Nidek EAS-1000,[10] the Adobe Photoshop image analysis program,[14] the Pentacam Scheimpflug camera (Oculus),[18] and the Purkinje meter system[15-20]; however, Scheimpflug cameras have been the main method in use to date.

There are few studies of Purkinje imaging for this purpose. A recent study[18] evaluated the correlation between Scheimpflug imaging and Purkinje imaging in IOL decentration and tilt, resulting in a limited correlation between horizontal parameters. Further studies are necessary to assess the correlation between Purkinje imaging and Scheimpflug techniques. To our knowledge, no study has evaluated the intraexaminer and interexaminer reproducibility of IOL tilt and decentration measurements using the Purkinje meter system, which is necessary to interpret results in clinical trials that use this technique.

As early as the 19th century, Purkinje reflexes were observed using candles to generate ocular reflections. In 1990, Guyton et al.[25] proposed a laser and LED setup in which a simple hand light illuminates the eye, allowing determination of the alignment point of Purkinje III and of Purkinje IV. Their study provided qualitative information on IOL alignment. Newer methods allow calculation from images. This approach is based on a series of theoretic assumptions derived from 3 equations with 7 parameters that must be calculated or measured in advance.[17–19] Therefore, the method is slightly complicated and the calculation procedure could lead to more uncertainty. The recently developed clinical Purkinje meter system is intuitive and requires fewer predetermined parameters.[1] It is more compact than a large laboratory setup, lending itself to routine clinical application.

Although the reproducibility of Purkinje meter system was high and reliable, there are several points to be clarified or improved in future studies. One is the state of the pupil dilation. Even in the absence of a dilated pupil, the IOL position could be measured with the Purkinje meter.[26] Future studies should be performed to confirm this finding. Comparison of Purkinje meter measurements with slitlamp measurements and retroillumination photograph analysis showed large discrepancies, probably because Purkinje III was not visible or only partially visible in eyes with a small pupil. Also, new software programs that allow evaluation of the parameters controlling IOL tilt and decentration should be developed to permit automatic calculation of absolute vector values. In our study, the examiner calculated the values. We also believe that manual marking should be automated.

Theoretically, a toric IOL would create elliptical semicircular reflections (Purkinje reflex III and IV), making the Purkinje reflections too distorted for appropriate analysis. A smaller illumination ring would be helpful and induce less distortion.

Last, Mester et al.[27] and Schaeffel[28] recently introduced another Purkinje meter. The images representing the Purkinje reflexes have single dots rather than the semicircle of the system we used in our study. A possible advantage of the semicircular array is that its geometry is not symmetric. This allows simple identification of Purkinje reflexes because the third and the fourth Purkinje reflex are inverted with respect to each other. Also, the extended array allows one to locate the largest Purkinje reflex (III), even if it is not completely visible, as in eyes with a small pupil.[21]

In summary, the recently developed clinical Purkinje meter systems allowed rapid acquisition of images of high-quality and highly reproducible measurements.[21,27,28] The instrument may prove to be useful in assessment of IOL tilt and decentration in clinical trials comparing IOLs with different haptic designs. This is of clinical importance, especially with modern IOLs that correct spherical aberrations and with multifocal IOLs, in which even minor variations in IOL tilt or decentration can impair final visual acuity.

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