Accuracy and precision of a new system for measuring toric intraocular lens axis rotation

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We determined the accuracy and precision of a new system for measuring postoperative toric intraocular lens (IOL) axis rotation. The system performs high-resolution retroillumination photography to identify toric IOL axis markings and then takes a photograph of the iris and conjunctival/scleral vessels. Built-in software measures the toric axis to within 0.2 degree. If performed twice on the same eye, the system will correct the 2 toric axis measurements for cyclorotation/head tilt using iris/vessel registration. Testing in 37 eyes showed that using iris/vessel registration correction reduced the mean absolute toric IOL axis rotation by a factor of 4.5. We conclude that this system seems to be both accurate and precise for measuring postoperative toric IOL axis rotation.

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With the proliferation of toric intraocular lens (IOL) designs, postoperative rotational stability becomes an important factor in choosing a toric IOL for clinical use. Several studies have reported toric IOL rotational stability outcomes with measuring methods ranging from slitlamp estimation\(^1\)–\(^3\) to photographic systems; some do not attempt to correct for head tilt/cyclorotation\(^4\)–\(^6\) and some do.\(^6\)–\(^8\) Factors to be considered in deciding on a method of measuring toric IOL rotational stability include accuracy and ease of use. These 2 factors frequently compete with each other; the easiest to use systems (slitlamp estimation) are also the least accurate and vice versa. We describe a new commercially available system intended to be both accurate and easy to use.

TECHNIQUE

The Discovery System (corneal topography and ocular wavefront) (Innovative Visual Systems) was used to examine patients to determine the amount of toric IOL axis rotation observed between 2 postoperative examinations (Figure 1). High-resolution imaging that simulates retroillumination photography was performed with the 830 nm wavelength (near infrared) super-luminescent diode wavefront beacon as the light source (Figure 2, A). The system has built-in image enhancement capabilities including brightness, contrast and sharpness controls, and the ability to zoom into areas in which the toric axis marks are present (Figure 2, B). The software allows the user to place marker spots on the toric axis marks on both sides of the center of the toric IOL (Figure 2, C) and then automatically draws a line through the spots, which defines the axis of the toric IOL. The spot graphics are moved to bisect the axis marks, and under high magnification, a 0.2 degree difference in axis is obvious (Figure 2, D). When spots have been selected on both sides of the optical center, the toric IOL orientation in the eye image is defined (Figure 2, E). At the time of capture of the simulated retroillumination image, the system automatically takes a simultaneous image of the iris and conjunctival/scleral vessels using visible white light-emitting diodes (LEDs). This visible white LED source is part of the corneal topography system. The retroillumination and iris with conjunctival/scleral vessel imaging examinations usually take about 20 seconds, and the spot placement with toric IOL axis determination takes about 40 seconds per eye.

Once the examinations have been performed twice (either same day or separate days), iris and vessel registration of the 2 evaluations can be performed to determine the effect of head tilt and/or cyclorotation.
Again, the imaging and measurement system software can be used to optimize brightness and contrast of the images (Figure 3, A). The user then identifies 2 “good features” on the iris or conjunctival/scleral vessels (ideally greater than 90 degrees apart) on the first image and interactively places marking spots on those points. Good features are located at the intersection of 2 linear features, such as those forming corners (Figure 3, B). The software finds the corresponding good features on the second iris image and places marking spots on the second image (Figure 3, C). If the software for any reason fails to place the spots on the second image in a corresponding location, it can be corrected interactively. High-magnification imaging can be used to document the correspondence of the 2 iris and vessel spots on the 2 images (Figure 3, D). Proper iris registration can be determined by use of an image blend display in which the first eye image is rotated relative to the second eye image based on spot pair placement. In this display, the right and left images are blended together in 10% increments and presented as a static image. A blend fraction of 0% corresponds to the left image and a blend fraction of 100%, to the right image. If the images are not registered as a slide bar moves the image from 0 to 100%, the registration points in the 2 images do not coincide, the iris detail is blurry, and unaligned iris patterns or vessels appear to cyclorotate in the blended image (Figure 4, A). If iris registration is correct, the registration points in the 2 images coincide, the iris detail is clear, and no cyclorotation is seen in the blended image (Figure 4, B). Iris registration of 2 eye examinations takes approximately 60 seconds.

Once iris and vessel registration is verified, the toric IOL axis change analysis, which incorporates the data from the previously performed toric IOL axis marking and iris registration (Figure 5), can be run. This display lists the raw change in axis, which is the observed signed difference in toric IOL axis between the second and first examination (with a counterclockwise change being positive), the degrees of iris rotation between the second and first examination (with a counterclockwise change being positive), and the actual change in toric IOL axis after correcting for iris rotation.

Results

Thirty-seven eyes of 23 patients with previous toric IOL implantation were examined with the imaging and measurement system. In 24 eyes, the 2 examinations were performed on the same day with the patients removing their heads from the chinrest between examinations. In 13 eyes, the 2 examinations were performed 2 days apart; the toric IOL surgery had been performed at least 3 months earlier. The expectation for all 37 eyes was that the true axis of the toric IOL relative to the iris would be fixed over this time period so the true toric IOL axis rotation would be zero. Toric IOL rotation analysis with and without iris/vessel registration correction was performed as described. The signed and absolute mean and standard deviation (SD) as well as the maximum rotation were calculated for the analytical data.

Figure 6, A, plots the toric IOL axis difference without iris/vessel registration between the 2 examinations in the 37 eyes studied. The mean difference was 0.07 degree ± 1.35 (SD) and the maximum difference was 4.4 degrees; the mean absolute difference was 0.94 ± 0.96 degree. Figure 6, B, plots the toric IOL axis difference with iris/vessel registration and the mean difference was 0.04 ± 0.29 degree and the maximum difference was 0.8 degree; the mean absolute difference was 0.21 ± 0.20 degree.

Discussion

Two studies have attempted to quantify the measurement error caused by head tilt or cyclorotation in their measurement of rotational stability.4,10 In the first study,4 2 examinations were taken 10 minutes apart, with new positioning of the patient’s head in the chinrest in 10 eyes. No correction for head tilt or...
Cyclorotation was made. The mean absolute rotation was 1.9 ± 0.8 degrees. In the second study, the effect of head tilt or cyclorotation was analyzed by taking 2 photographs with a fundus camera 6 or more months apart in 400 patients and measuring the rotation of the vessels leaving the optic nerve between the 2 photographs. The mean absolute change in axis was 2.3 ± 1.7 degrees.

Figure 2. Method of marking and measuring toric IOL axis. A: Captured retroillumination image of a toric IOL. B: High magnification of toric axis marking regions on IOL shown in A. The markings are not as clear in the right image, probably due to overlying capsular haze. C: Marker spots are placed in the center of the toric axis markings on both sides of the optic center. The size of the spots can be changed. In this case, the spots take up the entire axis mark. D: The software will place a line through these marks, defining the toric IOL axis. Using smaller axis marks, the spots can be centered in the middle of the toric axis. Movement of the spots even as little as 0.2 degree off-axis is obvious. E: Final retroillumination image of this case shows toric IOL orientation (13.0 degrees) in the eye.

Figure 3. Method of performing iris and vessel registration. A: The first and second images from 2 examinations demonstrate iris and vessels to determine head tilt or cyclorotation. B: “Good” features are identified by the user in the first image. C: Software finds the corresponding good features on the second iris image. D: High-magnification imaging (inset lower right of each image) documents correspondence of the 2 iris points.
The American National Standards Institute (ANSI) standard for toric IOLs states that stability of a toric IOL axis is achieved if 90% of the treated eyes rotate less than or equal to 5 degrees between 2 consecutive visits at least 3 months apart. Chang reported using a slitlamp to estimate toric IOL axis, and although he did not say why, he reported axis to the nearest 5 degrees; this level of accuracy would not meet ANSI standards. In fact, the standard further states that given the degree of toric IOL axis accuracy recommended, every effort should be made to include in the method reference to unchanging anatomical features such as the iris, sclera, or conjunctiva. Thus, the standard recommends a method that corrects for head tilt and/or cyclorotation. In the 2 studies cited above, the precision error due to head tilt and/or cyclorotation when combined with other potential errors could introduce false-positive cases in which the toric IOLs appeared to rotate 5 degrees or more when in fact they did not.

Even when using a method that corrects for head tilt and/or cyclorotation, actual rotational stability of a toric IOL can be unclear if there is an inability to obtain images or poor compliance with follow-up in a significant number of cases. In 1 study, 80 eyes of 40 patients were enrolled, but only 60 eyes of 30 patients were available for the 1-month examination (25% loss to follow-up). Inability to identify the critical toric IOL details to measure rotation occurred in 14 of the 60 eyes (23%); thus, the efficacy measure was not tested in 34 of the 80 eyes (42%) originally enrolled. In 1 group of a second study, 4 (16%) of the 25 patients enrolled could not be examined at the 2-week postoperative visit because of technical issues (equipment failure, poor quality images, poor dilation). Similarly, in a third study with 59 patients enrolled and

Figure 4. Update and blend functions of iris/vessel registration process. The images in both parts of the figure are a 50:50 blend of image 1 and image 2. A: Before the system’s update button is selected, the 2 images are not registered. Because the corresponding points in the 2 images are not coincident with one another, iris detail is blurry. B: After the update button is selected, the corresponding points are coincident with each other and greater iris detail is seen. The first image is rotated 4.61 degrees relative to the second image.

Figure 5. Toric IOL axis change analysis. Integration of the processes described in Figures 3 and 4 demonstrate that in this case, the toric IOL axis in the first image is rotated 4.46 degrees clockwise relative to the second image, while the iris image is rotated 4.61 degrees clockwise for an actual rotation (unaccounted for by head tilt or cyclorotation) of 0.14 degree (0.01 degree difference due to rounding).
examinations scheduled for 1 day, 5 weeks, and 6 months, usable photographs were obtained in 46 eyes (78%) at 5 weeks, in 28 eyes (47%) at 6 months, and in only 15 eyes (25%) at all 3 postoperative visits. In contrast, all patients brought in to be tested in our study had usable examinations and were included. We attribute this to the examiner being able to tell immediately whether the toric IOL axis marks were visible and whether the iris/vessel image was in good focus at the time of the examination. Loss to follow-up was not an issue in our study since patients were seen on a single day or 2 days apart.

The system for imaging and measuring postoperative toric IOL rotation involved a short patient examination (20 seconds per eye) following acceptable pupil dilation. The examinations could be viewed immediately to determine whether image quality was sufficient to visualize toric IOL axis marks and iris and vessel detail, and actual measurement of the axis alignment and image registration was fast (40 seconds per eye for axis alignment and 60 seconds for image registration of 2 examinations) and assisted by software enhancement features. The entire process for examination and processing of 2 eye examinations was approximately 3 minutes. Measurement error was extremely low, making measurements of toric IOL axis rotation between visits possible to within 1 to 2 degrees.

WHAT WAS KNOWN
- Prior to the development of the new system, available methods of measuring toric IOL axis alignment and rotation postoperatively suffered from loss of accuracy, precision, and/or ease of use.

WHAT THIS PAPER ADDS
- The new system photographs the toric IOL axis marks under high magnification, measures the axis of alignment interactively, and corrects for head tilt/cyclorotation using iris and vessel registration.
- The examinations are easy to perform and take fewer than 2 minutes per eye. Examination quality can be evaluated immediately.
- Accuracy and precision of the method allows toric IOL axis rotation between visits to be measured routinely to within 1 to 2 degrees, something not possible in the past.
REFERENCES