Original Article

Evaluation of Scheimpflug imaging system as an added tool in improving the accuracy of reference marking (as compared to the slit lamp marking system) for toric intraocular lens implantation

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Purpose: To assess the role of Scheimpflug imaging in improving the accuracy of reference marking for toric IOL implantation. **Methods:** In this prospective, randomized, clinical trial all patients with cataract and pre-existing significant regular corneal astigmatism, who required implantation of a toric IOL were included in the study, and patients with any ocular pathology or abnormality were excluded. Patients were divided into two groups: For one group of patients, Group I (GI), reference marking was finalized using slit lamp only, and for the second group, Group II (GII), after slit lamp marking, the reference marks were checked using Goniometer of Scheimpflug imaging. The primary outcome was to determine the axis of toric intraocular lens (IOL) postoperatively (within 1 hour) and compare it with the desired axis of placement. **Results:** We found a statistically significant difference in the two groups ($P < 0.001$) suggesting Group II (4 step technique) is better than Group I (3 step technique). **Conclusion:** Scheimpflug imaging, an extra step preoperatively, is an effective measure to reduce errors in reference marking and thereby improving the refractive outcome of toric intraocular lens.

Key words: Reference marking, Scheimpflug imaging, slit lamp biomicroscope, toric IOL

In the present era of refractive cataract surgery, accurate biometry and astigmatism correction have become extremely important for a spectacle free vision. Using the advancement in technology, it is now possible to have accurate and precise results with toric intraocular lenses (IOLs), thereby meeting the rising expectations of the patients.

Some known factors that contribute to unexpected residual astigmatism after surgery are errors in measurement and calculation of total corneal astigmatism, errors in the alignment of toric IOLs, and surgically induced astigmatism (SIA).[1]

With the advent of toric IOLs correcting a wider range of astigmatism; proper lens alignment becomes a key factor in determining the outcome. Moreover, it is a known fact that every 5° of misalignment can decrease the anticipated effect by 17%.[2] Hence, the preoperative corneal-marking procedure is an initial and important step for toric IOL alignment and is considered to be the most common cause of toric IOL deviation or misalignment.[3] At present, there are several techniques to perform horizontal meridian marking which includes slit lamp marking with a horizontal slit beam, pendulum assisted marking, tonometer-assisted marking and bubble marking.[3,4]

However, evaluating the accuracy of corneal reference marks is very important as it improves the predictability of the axis of toric IOL placement. The purpose of our study was to analyze the corneal reference marking with the help of Scheimpflug imaging preoperatively and compare it with control.

Methods

This prospective, randomized, comparative clinical study comprised patients with cataract and pre-existing significant regular corneal astigmatism, who required implantation of a toric IOL. The surgeries were performed at the above-mentioned center from January 2017 to April 2018 by a single surgeon. The study complied the tenets of the Declaration of Helsinki and Good Clinical Practices. All patients provided informed written consent before the surgery.

A total of 157 eyes of 121 patients were included in the study. Patients were divided into 2 groups Group I, (80 eyes) reference marking using slit lamp only (3 step technique) and Group II, (77 eyes) reference marking using slit lamp followed by Scheimpflug imaging to confirm the position of the marks (4 step technique). Patients were randomly distributed in the two groups using envelope technique. Exclusion criteria included corneal disease, previous corneal surgery, irregular astigmatism, extensive macular disease, neuro-ophthalmic disease, and history of ocular inflammation.

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Preoperative workup

Before cataract surgery, all patients had a complete ophthalmic examination which included manifest refraction, slit lamp examination, tonometry, and fundus examination. Axial length, keratometry, and AC depth were measured with the partial coherence interferometry (PCI) (IOL Master [Carl Zeiss Meditec AG]). Keratometry measurement was also obtained using an auto refractor and keratometer (KR-8800, Topcon Co., Ltd.). Tomography was performed using Scheimpflug system-Sirius (CSO, Italy) for all patients to determine the Sim K and total K values. Calculation of IOL power, axis placement, and incision location to achieve emmetropia was performed using third and fourth generation formulas, Baylor nomogram, and Barrett toric calculator (ASCRS). The Barrett toric calculator uses the Universal II formula to calculate an ELP, which is also influenced by the spherical equivalent and cylindrical toric IOL power. This calculator predicts posterior corneal astigmatism based on a theoretical model and was recently modified to include a regression component. In the online Barrett toric calculator, we used the average K measurements from the auto K device without adjustment. The SIA for the surgeon using this type of incision was previously determined to be 0.12 D of corneal flattening. This value was added to the online calculator and astigmatism was corrected and the final axis of placement was determined.

IOL selection

The Toric IOL used in our study (Tecnis, Johnson and Johnson Surgical Vision, Inc.; USA) is available in 10 models (ZCT100 to ZCT 800), each of which treats different amounts of astigmatism (ranging from 0.69D to 5.48D on the corneal plane). All toric IOL models have reference marks that indicate the axis of the astigmatic correction.
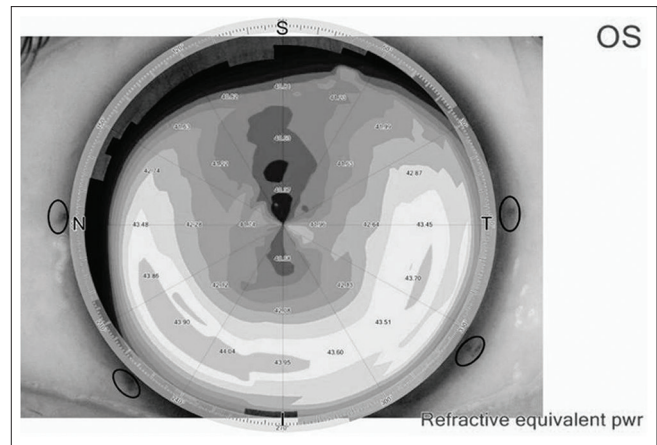
Reference marking

Prior to surgery, patients were seated at a slit lamp biomicroscope; both eyes were aligned properly to avoid head-tilt errors and then a narrow microscope slit was oriented vertically and horizontally. A sterile ink pen was used to make two reference marks on the horizontal meridian at 3 o'clock and 6 o'clock on the limbus, with the patient sitting upright at the slit lamp to avoid ocular torsion. Following this, Group I patients were taken directly to the operation theatre.

In Group II patients, three reference marks were made on the corneal limbus at 3 o'clock, 6 o'clock, 9 o'clock positions, and two additional marks were placed between 3 o'clock and 6 o'clock and between 6 o'clock and 9 o'clock positions with the patient seated on the slit lamp biomicroscope. After reference marking, Scheimpflug imaging (Sirius) was done. This imaging system has a Goniometer [Fig. 1] which shows axis in the 1° interval; the degrees corresponding to the position of the reference marks (as shown in the imaging) were noted down, and this was cross-checked by two experienced optometrists.

Surgical technique

The same experienced surgeon performed all surgeries using the same technique under topical anesthesia. Intraoperatively, after draping the eye, in Group I, a Mendez gauge was aligned over the two reference points (0° and 180°) and the desired orientation of the toric IOL was marked on the cornea with a meridian marker. In group II, two nasal and two temporal marks were aligned together first and their axis were

Figure 1: Scheimpflug image (Sirius) with Goniometer showing reference marks. (circled)

cross-checked with the axis shown by Scheimpflug imaging and once the axis of the reference marks matched with the imaging, Mendez ring was placed according to these marks and the desired orientation of the toric IOL was marked on the cornea with a meridian marker.

Phacoemulsification was performed through a 2.2 mm limbal wound at 0° in OD and 30° in OS. After phacoemulsification, a foldable toric IOL (Tecnis, J and J, USA) was inserted in the capsular bag using an injector. Once the IOL was placed in the eye, viscoelastic was removed from behind the IOL and the surgeon then rotated the IOL to align with the desired axis marked on the cornea following which minimal wound hydration was done. No sutures were used to close the wound.

All cases received an intracameral injection of 0.5% w/v moxifloxacin at the end of the surgery and a standard topical antibiotic and steroid regimen was followed.

Postoperative follow up

Postoperative assessments were performed immediately (within 1 hour), on the first day, the fourth day, eleventh day, 3 weeks, and 3 months after surgery. Within 1 hour postoperatively, the axis of the toric IOL was measured through dilated pupils by slit lamp after aligning both eyes to avoid head-tilt errors by an ophthalmologist (1 hour was chosen to avoid post-operative rotation afterwards. A thin slit beam was rotated until it aligned with the axis markings of the IOL. The orientation of the IOL was then estimated. Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), refraction, keratometry were also recorded at 3 weeks and 3 months, postoperatively. However, to avoid measurement and calculation errors as confounding factors for any residual astigmatism after surgery; only the axis of IOL implanted was analyzed.

Statistical analysis

In statistical analysis, the differences between the target and the achieved axis of IOL implantation were determined. This data was compared between the two methods used (i.e., slit lamp marking and Scheimpflug imaging). Statistical software STATA 15 (StataCorp) for Windows was used to perform statistical analysis. The sample size $n = \dfrac{Z^2.p.q.De.Nr}{d^2}$ was

calculated to n = 45. However, to increase the power of the study, more than 45 cases were included. The differences in misalignment between the two groups were analyzed using a two-sample t-test for unequal variance called Welch's t-test. This test assumes that data from both groups are sampled from Gaussian populations but does not assume that those two populations have the same standard deviation. This is helpful if the goal is to quantify how far apart the two means are. Results were considered significant to a P value <0.001 at 95% confidence interval (CI). Excel was used to create some basic graphs for data visualization.

Results

A total of 157 eyes were analyzed [Fig. 2]. In terms of laterality, 75 (33 in GI, 42 in GII) were right eyes and 82 (47 in GI, 35 in GII) were left eyes.

For group I, the mean desired axis of placement (AOP) was 133.19 ± 65.14° (ranging from 5°-180°) and the actual AOP was 134.88 ± 67.7° (ranging from 0°-180°). For group II, the mean desired AOP was 126.43 ± 75.86° (ranging from 0°-180°) and the actual AOP was 127.08 ± 75.56° (ranging from 5°-180°).

Fig. 3 shows the outcomes of toric IOL alignment in group I and II. In group I, 64% (51 eyes) were within ± 5° of the desired axis, 30% (24 eyes) were within ±10° however, 6% (5 eyes) showed a deviation of >10° of which 2 eyes showed up to 20° misalignment whereas 97.4% (75 eyes) in group II showed axis misalignment within ±5° and only 2.6% (2 eyes) showed ±10° deviation from the desired axis.

The absolute values of axis misalignment were 4.8 ± 5.4° when only slit-lamp was used and 1.43 ± 2.5° when reference marks were confirmed by the Scheimpflug imaging system. We found a statistically significant difference in the axis misalignment of toric IOL between the two groups. (P < 0.001) [Fig. 4].

In Group II, we also assessed the deviation of the reference marks from the horizontal axis, as shown in the Goniometer of Sirius imaging. Fig. 5 shows a scatter plot demonstrating that most marks deviated anticlockwise and the mean deviation from the horizontal axis was 3.10°.

Discussion

The purpose of this study was to analyze the utility of Scheimpflug imaging as an additional step in improving the toric IOL placement; as accurate alignment of the IOL is critical in achieving the desired refractive result. The five reference marks help centration of gauge on the visual axis and confirmation of marks on imaging system may reduce the errors in toric IOL alignment as well as eliminate cyclotorsion component.

A reduction of 3.3% in astigmatism correction for every degree of misalignment of the toric IOL reflects the importance of perfect intraoperative alignment and postoperative rotation stability.[5] Moreover, the toric IOL has different optical powers in different meridians, therefore, the IOL must be correctly
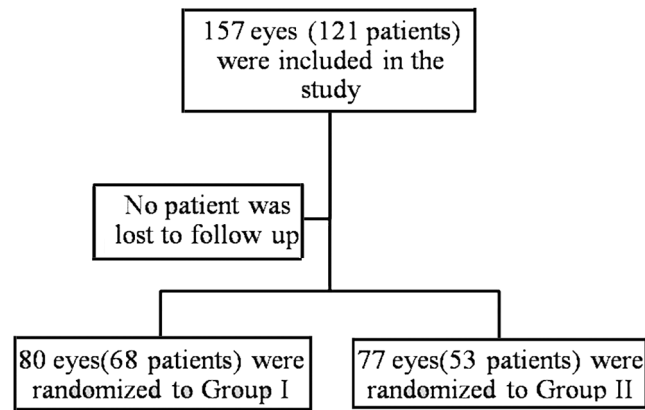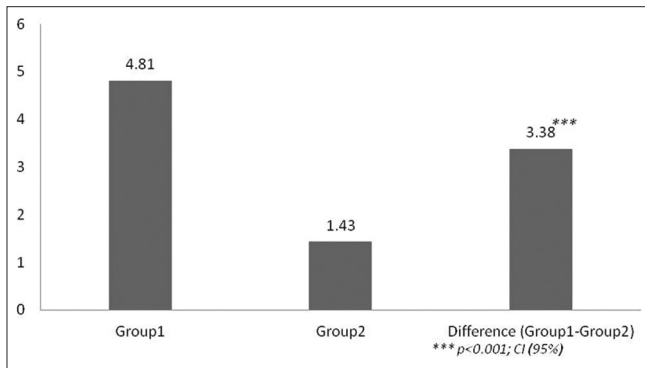

Figure 2: Patient screening and selection

Figure 3: Distribution of AOP difference (actual-desired) in the two groups assessed in the immediate postoperative period

Figure 4: Bar graph showing mean error in Group I and II with a statistically significant difference in mean between the two groups
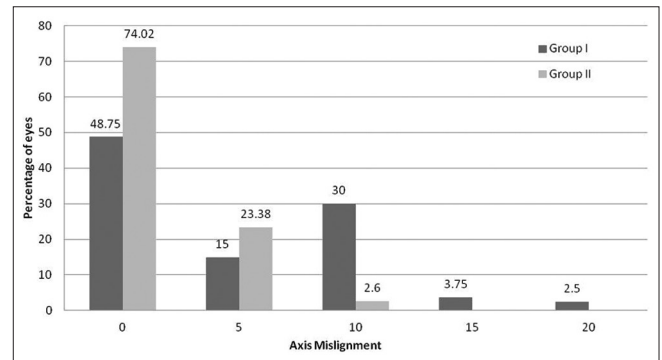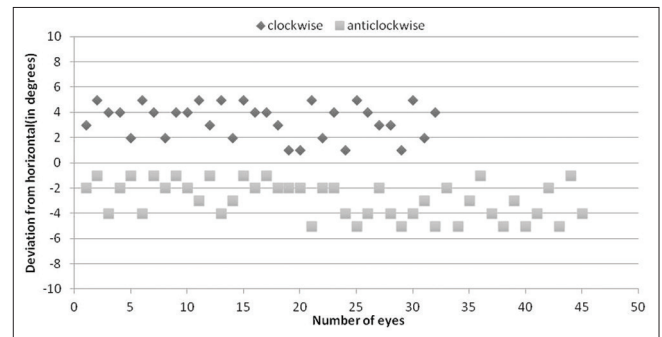

Figure 5: Deviation of reference marks from the horizontal reference line as measured on the Scheimpflug imaging system. The clockwise misalignment was defined as a positive sign and the anticlockwise misalignment as a negative sign

aligned to neutralize astigmatism in the cornea.[6] In addition, intraoperatively, cyclotorsion of the eye can also cause misalignment.[7,8]

Hence, most surgeons mark reference points on the cornea or limbus before surgery to act as a guide when implanting the IOL and to counteract cyclotorsion that can occur when the patient is supine.

In our study, to confirm the axis of the reference marks, we used the Sirius Scheimpflug imaging system as a reference tool. As Goniometer displays axis in a degree's interval, it makes it accessible to determine the precise location of the reference marks which guides in placing gauge intraoperatively for accurate axis marking. We found that there was a significant difference in the achieved axis of placement between the two groups, favoring the use of Scheimpflug imaging as a measure to confirm the corneal reference marks thereby improving the accuracy of toric IOL placement. This gives an added advantage while placing IOL in the oblique axis.

In the past few years, various techniques for toric reference marking have been described. Huelle et al. in their study illustrated the three-step technique that involves marking the eye at the horizontal meridian using slit lamp or other marking devices; intraoperatively using another device with angular gradations and then marking the limbus or cornea at the desired axis of alignment with a marking pen or needle. The marking procedure with a bubble marker in their study showed a mean error in the axis of 2.48° and a total error in toric IOL alignment of 4.98°.[9,10] In another study, various methods of marking the eye preoperatively, namely, coaxial slit beam turned to the 3-o'clock and 9-o'clock position, a bubble marker, a pendular marker, or a tonometer marker were compared, and results demonstrated that both pendular marking and slit lamp marking had similar rotational deviation from the reference meridian, with the least vertical misalignment observed in the slit lamp marking device, as shown by Popp et al.[4] A one-step technique using a slit lamp eyepiece in which the slit beam is rotated to the meridian of interest has also been described by Packer et al.[11]

Several manual alignment techniques can be used to determine the axis of alignment postoperatively. The most common clinical methods are assessment via a slit lamp eyepiece reticule or alignment of the slit lamp beam with the IOL markings.

In a study conducted by Paul et al., they included 51 eyes of 36 patients and found no statistically significant difference in measurement of IOL position between the slit lamp method and the method using the internal map of the corneal analyzer.[6]

These studies signify that slit lamp marking is an easy, nonexpensive and accurate way for reference marking and postoperative axis of placement determination. However, as we know the preoperative corneal-marking procedure is an initial and vital step for toric IOL alignment, confirmation of axis of the reference marks with Goniometer of Scheimpflug imaging can play a valuable role in improving toric IOL outcomes. This can improve the results of manual marking in the absence of a markerless system.

Moreover, a study done by Liem et al. on marker-based vs markerless system for toric IOL alignment showed that the differences between intended and achieved postoperative

IOL axis were 4.7 ± 2.8° and 3.6 ± 1.5° in the manual and automated (markerless) groups respectively, and were not statistically significant.[12] Erin et al. also compared marker-based to the markerless system and found that the mean toric misalignment for the two groups at 1 hour (postoperatively) was 2.8 ± 1.8 degrees vs. 1.3 ± 1.6 degrees. At 3 months postoperatively it was 3.1 ± 2.1 degrees vs. 1.7 ± 1.5 degrees, favoring markerless system. However, there was no statistically significant difference in the postoperative uncorrected visual acuity and mean residual cylinder in both the groups.[13]

We found a study in accordance with ours, which assessed the horizontal meridian misalignment of limbal marking done using a slit lamp microscope through anterior segment imaging. In this study, 32 eyes of 16 subjects were included and the slit lamp marking was done by using a marker pen or a toric marker. They quantitatively evaluated the accuracy of axis alignment by determining the deviation from the horizontal reference line using a corneal topographer with an anterior segment image. They concluded that "horizontal limbal marking using a slit lamp microscope showed the axis misalignment by an average of 3.4° to 6.9° and this alignment error can lead to a reduction of the effectiveness of astigmatism correction by an average of 10% to 20%, which is not necessarily negligible, when we aim to correct astigmatism completely". Moreover, for successful astigmatic surgical procedures, accurate preoperative limbal markings leading to decreased misalignment errors of the astigmatism axis are essential.[14]

One of the limitations that we faced was that we couldn't eliminate the bias in recording postoperative AOP completely. Though there was a difference in the number of reference marks in both the groups, the ophthalmologist recording AOP was kept blindfolded from the study and also the marks tend to fade after the surgery making it difficult to distinguish.

Conclusion

In conclusion, our results demonstrate that horizontal axis marking using slit lamp biomicroscope shows a deviation of 3.10° when confirmed with Scheimpflug imaging which can result in the loss of astigmatism correction by 10%, which is clinically significant. Moreover, the use of Scheimpflug imaging system to confirm the reference marks can significantly reduce the errors in axis marking as compared to the slit lamp marking system for toric IOL implantation; so it can be used as a routine procedure to increase the accuracy of lens placement.

Conflicts of interest

There are no conflicts of interest.

References

1. Abulafia A, Koch DD, Wang L, Hill WE, Assia EI, Franchina M, et al. New regression formula for toric intraocular lens calculations. J Cataract Refract Surg 2016;42:663-71.

2. Webers VSC, Bauer NJC, Visser N, Berendschot TTJM, van den Biggelaar FJHM, Nuijts RMMA. Image-guided system versus manual marking for toric intraocular lens alignment in cataract surgery. J Cataract Refract Surg 2017;43:781-8.

3. Woo YJ, Lee H, Kim HS, Kim EK, Seo KY, Kim TI. Comparison of 3 marking techniques in preoperative assessment of toric intraocular

lenses using a wavefront aberrometer. J Cataract Refract Surg 2015;41:1232-40.

4. Popp N, Hirnschall N, Maedel S, Findl O. Evaluation of 4 corneal astigmatic marking methods. J Cataract Refract Surg 2012;38:2094-9.

5. Cha D, Kang SY, Kim SH, Song JS, Kim HM. New axis marking method for a toric intraocular lens: Mapping method. J Refract Surg 2011;27:375-9.

6. Carey PJ, Leccisotti A, McGilligan VE, Goodall EA, Moore CB. Assessment of toric intraocular lens alignment by a refractive power/corneal analyzer system and slit lamp. J Cataract Refract Surg 2010;36:222-9.

7. Tjon-Fo-Sang MJ, de Faber JT, Kingma C, Beekhuis WH. Cyclotorsion: A possible cause of residual astigmatism in refractive surgery. J Cataract Refract Surg 2002;28:599-602.

8. Kim H, Joo CK. Ocular cyclotorsion according to body position and flap creation before laser *in situ* keratomileusis. J Cataract Refract Surg 2008;34:557-61.

9. Huelle JO, Katz T, Druchkiv V, Pahlitzsch M, Steinberg J,

Richard G, *et al*. First clinical results on the feasibility, quality and reproducibility of aberrometry-based intraoperative refraction during cataract surgery. Br J Ophthalmol 2014;98:1484-91.

10. Thulasi P, Khandelwal SS, Randleman JB. Intraocular lens alignment methods. Curr Opin Ophthalmol 2016;27:65-75.

11. Packer M. Effect of intraoperative aberrometry on the rate of postoperative enhancement: A retrospective study. J Cataract Refract Surg 2010;36:747-55.

12. Trinh L, Villette V, Dupont-Monod S. Marker-based versus Markerless Toric Iol Alignment: Demonstrated Benefit of an Automated Markerless System 2014.

13. Boese E. Toric lens alignment: A review of a digital image-guided system versus traditional manual marking. Eye World. Available from: https://www.eyeworld.org/toric-lens-alignment-review-digital-image-guided-system-versus-traditional-manual-marking. Published June 2, 2017. [Last accessed on 2018 Dec 20].

14. Igarashi A, Kamiya K, Shimizu K. Clinical evaluation of accuracy of horizontal meridian limbal marking. Optom Vis Sci 2013;90:540-5.