Accuracy of Toric Intraocular Lens Axis Alignment Using Manual Slit Lamp Method and CALLISTO Eye Image-Guided System

ABSTRACT

Aims: Image-guided systems are the gold standard for determining toric intraocular lens (IOL) axis alignment. However, their high cost prevents widespread use of these systems. As an alternative, a simpler and affordable method could be performed manually using a slit-lamp biomicroscope. This study aims to compare the accuracy of manual toric IOL axis marking using a slit-lamp compared to the CALLISTO eye image-guided system.
Study Design: Prospective comparative
Methods: In this prospective study, toric IOL axis alignment of 42 eyes with cataract and coexisting corneal astigmatism were evaluated using manual slitlamp method and CALLISTO eye image-guided method. Preoperative and postoperative uncorrected visual acuity, best corrected visual acuity, amount of spherical and astigmatic refractive errors, and postoperative IOL axis alignment were evaluated. Intraclass correlation of the manual method was calculated and the difference of IOL axis alignment to the image-guided method was compared.
Results: Toric IOL implantation reduced the amount of astigmatic refractive error from -1.63 ± 0.65 D to -0.50 ± 0.19 D in the image-guided group and from -1.93 ± -0.90 D to -0.87 ± 0.26 D in the manual slitlamp group. As many as 90.5% of eyes in the image-guided group and 81.0% of eyes in the manual slitlamp group reached the target induced astigmatism (p=0.38). Manual axis marking showed intraclass correlation of 99.3%. However, when the manual method was compared to the image-guided method a mean difference in axis alignment of 10.98^{o} (95% confidence interval: 9.32^{o} - 12.63^{o}) was observed.
Conclusions: Alignment of toric IOL axis using the manual method demonstrated a consistent result; yet producing a considerable difference to the result of the image-guided method.

Keywords: Astigmatism; axis alignment; image-guided method; manual slit-lamp method; toric intraocular lens.

1. INTRODUCTION

Advances in cataract surgery have increased patient's expectation of post-surgical spectacle free outcomes [1, 2]. One of the fundamental aspects to meet this expectation is the choice of intraocular lens (IOL). Recently, toric IOL implantation has become more common due to the fact that there are approximately one third of patients undergoing cataract surgery with more than 1 D of corneal astigmatism requiring correction [3, 4]. Toric intraocular lens (IOL) enables correction of large amount of corneal astigmatism during cataract surgery. However, the biggest challenge of toric IOL implantation this far has been its precision in terms of the axis alignment [2].

Several methods for toric IOL axis marking have been established, including manual marking using pre-operative corneal marker, slit-lamp, bubble marker or pendulum and

digital image-guided system using Image Guiding system e.g., Zeiss CallistoEye™ and Alcon Verion Digital Marker™ [5-8]. Currently, image-guided systems are considered the gold standard due to its accuracy to determine IOL axis alignment [7-9]. However, there are limitations of this system including the effect of conjunctival chemosis, deep socket, and narrow eyelid fissure on the accuracy of IOL axis marking [10]. In addition, the high cost of this system may also potentially limit its affordability particularly in low resource setting [9].

For this reason, manual corneal axis marking using the three-step method is a more cost-effective alternative for determining toric IOL alignment, particularly in low resource setting. This method only requires the use of a slit-lamp biomicroscope and a marker (needle marker, bubble marker, or sterile ink) [6, 7, 9]. Therefore, it has the potential for widespread use, including in low-resources settings. However, this manual three-step method is considered less accurate and requires experience of the surgeon to attain precise axis marking [6].

This study aims to compare the accuracy of toric IOL marking with a manual three-step method using a slit-lamp biomicroscope and an image-guided system using the CALLISTO eye™ (Carl Zeiss Meditec, AG, Jena, Germany) in the management of cataract with corneal astigmatism.

2. MATERIAL AND METHODS

This was a prospective comparative study. All study procedures followed the tenets of the Declaration of Helsinki. Ethical approval was obtained from Medical Research Ethics Committee, Faculty of Medicine Public Health and Nursing, Universitas Gadjah Mada. We consecutively recruited 40 patients from the Jakarta Eye Centre cataract clinics between January 2019 - July 2020 who had cataract and astigmatism and planned to do a phacoemulsification procedure followed by Toric IOL implantation. These patients were diagnosed with cataract and more than 1.00D of astigmatism. We included less than grade 3 cataract according to Burrato criteria with presenting visual acuity better (VA) than 3/60. All patients were informed about the study procedures and willing to participate in this study by signing a written consent form.

We excluded patients with all degree of corneal opacity, keratoconus, irregular astigmatism, uveitis, glaucoma, retinal disease, pterygium, and all form of optic nerve abnormalities. Patients with visual potentiometer or retinometry result less than 6/6, patients with a history of ophthalmic operation procedure such as refractive surgery (LASIK, Relex Smile, Peripheral corneal relaxing incision), trabeculectomy, and retinal surgery were also excluded.

2.1. Clinical examination, marking protocol and surgical procedures

All patients underwent the same procedures in this study. To ensure the consistency of the study protocol, all examinations were performed by a single person (S.B.R) who had extensive experience in cataract and refractive surgery and confirmed by other senior cataract specialist (T.D.G). Comprehensive eye examinations were performed prior to the surgery that included monocular uncorrected (UCVA) and best corrected VA (BCVA) of each eye, optical coherence tomography (OCT)–assisted biometry using Zeiss IOLMaster 700 (Carl Zeiss Meditec AG), refraction and auto-refracto-keratometry, slit-lamp biomicroscopy and dilated retinal examination. The toric IOL power was calculated using dedicated software available from Zeiss (Z-Calc software, Carl Zeiss Meditec AG). Corneal topography measurement using orbscan was performed to exclude the presence of keratoconus.

Slit-lamp axis marking was done with the patients positioned upright and head in front of the slit lamp (chin and forehead fixed). A drop of 0.5% pantocaine was used to anesthetize the eye. Corneal limbus was dried with an absorbent spear or sterile cotton bud. Patient was asked to fixate on a distant target at head straight. The slit beam was set to the longest beam, then rotated to horizontal position at 0° and 180° and was moved forward to focus on the centre of the cornea. For image-guided procedure, all preoperative information obtained from the IOLMaster 700 biometry was exported into the Callisto eye system (Carl Zeiss Meditec AG). This system has been pre-programmed and would display a graphical overlay of the Toric alignment, guiding the surgeon during the operation. We performed both manual marking and Callisto-guided marking in each patient to assess the agreement between both methods; however, patients then were divided into two groups in a consecutive manner (20 patients in each group). The first patients went to group 1, the second patient went to group 2, the third patient went to group 1 and so forth. This was a blinded process performed by a research assistant. The surgeon did not aware which one went to which group. In group 1, the surgeon implanted the IOL in keeping with the Callisto marking, whereas in group 2, the IOL was implanted following the manual marking.

All cataract surgery was performed by a single surgeon (S.B.R) under topical anesthesia using Alcon Infinity phacoemulsification system (Infiniti® Vision System; Alcon, Fort Worth, USA). A sutureless 2.2 mm clear corneal incision was made at the 0^0 for the left eye or 180^0 meridian for the right eye to minimize the surgeon factor and surgical induced astigmatism. Following phacoemulsification, a single-piece toric IOL (RayOne^{TM} Toric Lens; Rayner, UK) was implanted in the capsular bag, with the IOL axis aligned according to the aforementioned method. At the end of the surgery, viscoelastic device was thoroughly aspirated, and a final check was performed to ensure correct IOL axis alignment. Patient who developed intraoperative complications, required wound enlargement, or wound suture was dropped out from the study.

All patients were followed-up for 30 days months after the surgery and each of them had post-operative evaluation at day 1, day 7, and day 30. Post-operative toric IOL alignment was determined at day 7 and day 30 post-surgery using Mendez degree gauge toric marker. Patients with residual astigmatism of ±0.5 Diopter were considered as reaching the target induced astigmatism.

2.2. Statistical Analyses

Statistical analysis was performed using SPSS v.22.0 (IBM Corporation, New York, USA). Pearson's chi-square test or two-tailed Fisher's exact test were used to compare proportion difference between the two groups, while student's t-test and Mann-Whitney U tests were used to compare means. Agreement for IOL axis alignment between both groups was evaluated using Bland Altman plot to determine the mean difference.

3. RESULTS AND DISCUSSION

Forty-two eyes from 34 patients were eligible for analysis. Twenty-one eyes were categorized in each group. The baseline data of both study groups are presented in Table 1. Patients in the CALLISTO eye group had younger mean age, although the majority of patients in both groups were more than 60 years of age. Mean corneal astigmatism in the CALLISTO eye and slit-lamp groups were -1.63 D and -1.93 D, respectively. Patients with against-the-rule astigmatism comprised 38.1% and 40.5% of the CALLISTO eye and slit-lamp groups.

Table 1. Baseline characteristics of study subjects (n=42 eyes).

Variable	CALLISTO eye group (21 eyes)	Slit-lamp group (21 eyes)	p
Age, years	61.44 ± 11.6	69.35 ± 9.4	0.04
Males, %	10 (55.6)	10 (62.5)	0.68
Right eye, %	7 (33.3)	9 (42.9)	0.53
UCVA	0.1 ± 0.14	0.1 ± 0.18	0.35
BCVA	0.4 ± 0.33	0.3 ± 0.29	0.42
Spherical refractive error, D	-0.71 ± 2.20	-1.27 ± 3.14	0.89
Astigmatic refractive error, D	-1.63 ± 0.65	-1.93 ± -0.90	0.20
Keratometry axis, ^{o}	90.0 ± 74.91	122.1 ± 70.3	0.16
Axial length, mm	24.03 ± 1.29	24.25 ± 1.72	0.64
Astigmatism type			0.54
With the rule	2 (4.8)	3 (7.1)	
Against the rule	16 (38.1)	17 (40.5)	
Oblique	3 (7.1)	1 (2.4)	

BCVA, best-corrected visual acuity; D, Diopter; UCVA, uncorrected visual acuity.

No patients experienced intraoperative complications and postoperative evaluation was performed on all patients. The postoperative results are presented in Table 2. In postoperative day 7 and 30, patients in the CALLISTO eye group showed a significantly higher mean UCVA (0.7 ± 0.2 D and 0.8 ± 0.2 D) compared to patients in the slitlamp group (0.5 ± 0.1 D and 0.5 ± 0.1 D). The mean residual astigmatic error on postoperative day 7 was -0.50 ± 0.19 D and -1.02 ± 0.2 D in the CALLISTO eye and slitlamp group. On postoperative day 30, the residual astigmatic error in the CALLISTO eye group remained the same, while patients in the slitlamp group showed improvement (-0.87 ± 0.26 D).

Table 2. Results of postoperative evaluation in study subjects (n=42 eyes).

Variable	CALLISTO eye group (21 eyes)	Slitlamp group (21 eyes)	p
UCVA			
Day 7	0.7 ± 0.2	0.5 ± 0.1	0.02
Day 30	0.8 ± 0.2	0.5 ± 0.1	<0.01
BCVA			
Day 7	0.9 ± 0.1	0.9 ± 0.1	0.52
Day 30	0.9 ± 0.1	0.9 ± 0.1	0.17
Residual spherical error, D			
Day 7	-0.25 ± 0.4	-0.06 ± 0.5	0.20
Day 30	-0.25 ± 0.4	0.02 ± 0.5	0.12
Residual astigmatic error, D			
Day 7	-0.50 ± 0.19	-1.02 ± 0.37	<0.01
Day 30	-0.50 ± 0.19	-0.87 ± 0.26	<0.01
Keratometry axis, ^{o}			
Day 7	77 ± 53	82 ± 19	
Day 30	77 ± 53	83 ± 20	
Eyes reaching TIA, %			
Day 7	17 (81.0)	16 (76.2)	0.71
Day 30	19 (90.5)	17 (81.0)	0.38

BCVA, best-corrected visual acuity; D, Diopter; TIA, target induced astigmatism; UCVA uncorrected visual acuity.

The accuracy of IOL axis marking was evaluated and compared to the CALLISTO eye method as the gold standard. The intraclass correlation for IOL axis alignment using the slitlamp method was 0.993, which demonstrated excellent correlation for the manual slitlamp method compared to the gold standard. The mean difference for IOL axis alignment between both groups was 10.98^{o} (95% CI 9.32^{o} - 12.63^{o}), which corresponded to degree of IOL axis misalignment in the manual slitlamp method compared to the CALLISTO eye method.

Figure 1 shows the agreement between alignment in Callisto group and manual marking group. The mean difference for IOL axis alignment between was 10.98^{o} (95% CI 9.32^{o} - 12.63^{o}).

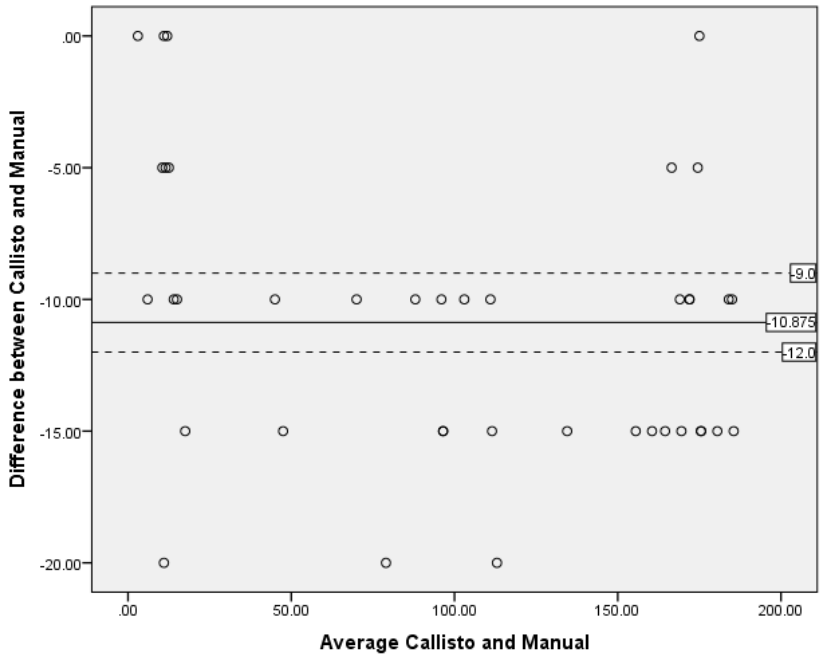

Figure 1. Bland Altman Curve of Agreement Axis Alignment between Callisto and manual marking group

The present study demonstrated that toric IOL axis alignment using both the CALLISTO eye image-guided method and the manual slitlamp method gave excellent results. As many as 90.5% of eyes in the CALLISTO eye group and 81.0% of eyes in the slitlamp method reached the target induced astigmatism of <0.5 D on postoperative day 30. The use of toric IOL has previously been demonstrated as an effective method in the management of corneal astigmatism, with predictable long-term visual outcome [2, 11]. Various factors could affect the amount of postoperative residual astigmatic refractive error, including preoperative axis marking error, the presence of posterior corneal astigmatism, imprecise estimated lens position, and postoperative IOL rotation [10]. From postoperative day 7 to day 30, there was no change in the amount of residual astigmatic refractive error in the CALLISTO eye group, while there was only small change in the slit-lamp group. This finding demonstrated that postoperative IOL rotation occurred and could affect the final visual outcome.

Image-guided method has been demonstrated as the gold standard method for IOL axis alignment. The use of image-guided modalities was not affected by the effect of ocular cyclotorsion which occurred when the patients changed their position from sitting to supine position. Ocular cyclotorsion due to changes in body position consisted of excyclotorsion,

which occurred in 74.2% of patients, and incyclotorsion, which occurred in 23.9% of patients. The degree of ocular cyclotorsion amounted to a mean of $+1.43^0 \pm 3.41^0$ (-8.3^0 to $+9.20^0$) [12]. Therefore, the result of manual axis marking using the slit-lamp, which is performed when the patient is in a sitting position, is influenced by the effect of ocular cyclotorsion.

Our study demonstrated that compared to the CALLISTO eye method, IOL axis marking with the slit-lamp method resulted in a mean difference of 10.98o. This finding was still found, in spite of the consistently performed manual axis marking procedure, as shown by the high intraclass correlation of 99.3%. The effect of toric IOL on eliminating corneal astigmatism would be cancelled when IOL misalignment of 30^0 occur. Therefore, using the manual slit-lamp method for toric IOL alignment resulted in the elimination of roughly 30% of the IOL effectivity.

In low resources developing countries, the availability of image-guided methods for toric IOL alignment is still limited and is further hindered by its high cost. Therefore, despite its lower accuracy in comparison with image-guided system, manual slit-lamp method for toric IOL alignment has wider potentials. The findings from this study highlights the need for further studies to identify confounding factors, other than the effect of ocular cyclotorsion, which may affect misalignment of manual method for IOL axis marking. Furthermore, these confounding factors could be incorporated to formulate correcting factors when utilizing the manual method for axis marking. The limitations of this study include the small number of subgroup of patients with with-the rule and oblique astigmatism, despite the appropriate sample size. Therefore, the result of this study mainly applies to patients with against-the-rule astigmatism. Future studies need to incorporate proportionate number of subjects with the three types of astigmatism to enable wider generalization of the study results.

4. CONCLUSION

In conclusion, the use of manual method of toric IOL axis marking using the slit-lamp demonstrated a consistent result, with an excellent intraclass correlation of 99.3% compared to the gold standard image-guided method. However, a considerable difference in toric IOL axis alignment of 10.98^0 was observed when using the manual method compared to image-guided method.

COMPETING INTERESTS

None of the authors has any conflict of interest to declare.

AUTHORS' CONTRIBUTIONS

S.B.R. designed and conceptualized the study, lead data collection, wrote the initial manuscript and performed data analysis; D.C.R. supervised, designed the study and provided significant contribution to manuscript writing; T.D.G. supervised, conceptualized the study, reviewed and edited the manuscript; S supervised, conceptualized the study, reviewed and edited the manuscripts; M.B.S. contributed to study design, significantly edited the manuscripts, and contributed to data analysis.

CONSENT

All authors declare that 'written informed consent was obtained from each participant of this study.

ETHICAL APPROVAL

All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

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