ORIGINAL ARTICLE

Manual versus Markerless (Image-guided System) Toric Intraocular Lens Implantation Outcomes for Astigmatic Correction in Cataract Surgeries

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ABSTRACT

Objective. Toric intraocular lens implantation has been used to correct corneal astigmatism during cataract surgery. The study aimed to compare the visual outcomes between manual vs markerless toric intraocular lens implantation in astigmatic correction.

Methods. The medical records of patients at American Eye Center who underwent phacoemulsification by multiple surgeons with insertion of monofocal or multifocal toric lenses via manual marking and markerless method from 2010-2019 were reviewed.

Results. A total of 70 patients were included in the study. Results showed no significant difference in the following characteristics between manual and markerless method at one month and two months post-cataract surgery: uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), uncorrected near vision acuity (UNVA), corrected near vision acuity (CNVA), refraction spherical equivalent. The UDVA, CDVA, UNVA, CNVA and astigmatism had significantly lower median/mean-rank at one and two months postoperatively compared to preoperative values.

Conclusion. In conclusion, our findings indicated that both manual-based and markerless systems effectively facilitated accurate placement of the toric IOL on the desired axis. Notably, there was no significant difference observed between the two methods. Both systems are straightforward to execute. In low-resource settings like the Philippines, the manual marking method can be employed when markerless guidance equipment is unavailable.

Keywords: Toric intraocular lens, phacoemulsification, astigmatism, Philippines

INTRODUCTION

Advancements in the technology of diagnostic equipment and intraocular lenses (IOL) have paved the way for the vast improvement of cataract surgeries and its outcomes, and have allowed surgeons to reach patient expectations regarding visual outcomes. One of the main goals of cataract surgeries is to approach a vision which suits the patient's lifestyle. However, the presence of corneal astigmatism has become one of the issues that needs to be addressed to achieve this goal. Corneal astigmatism may be corrected through the following ways: (1) wound size and location of corneal incisions, (2) limbal relaxing incisions, (3) laser refractive surgeries, and (4) toric intraocular lenses.[1] The use of toric IOL in cataract surgery was first reported by Shimizu et al. in 1994. Toric IOLs correct corneal astigmatism by aligning

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the intraocular lens to the desired axis, which relies on corneal marking. Toric IOLs have been believed to be a predictable treatment in general for these astigmatisms.[1,2] Toricity can be incorporated in aspheric IOLs; that is, a monofocal toric IOL corrects for distance vision with astigmatism. On the other hand, multifocal or extended depth of focus (EDOF) IOLs correct for distance vision and possibly, intermediate and near vision, along with astigmatism correction. Despite the good outcomes of toric IOLs, these practically require surgical skills and knowledge particularly in the postoperative IOL rotation, which may occur due to the size of capsular bag or IOL design.[1-3]

The visual outcomes obtained from implanting toric IOLs are dependent on several factors, which include (1) surgical skills, (2) preoperative evaluation, and (3) visual potential of the eye. Ideally, patients for toric implantation are those with regular astigmatism[2], with allowable room for mild and stable irregular corneal astigmatism such as those seen with mild keratoconus, post-operative penetrative keratoplasty and pellucid marginal degenerations. In such cases, there should be a symmetrical power and alignment within the 4-millimeter center of the cornea.[1-3] Toric IOLs should be avoided in patients with large irregular corneal astigmatism in cases with severe ocular diseases as mentioned.

Additional predictor of outcomes of the implantation of a toric IOL is the surgical-induced astigmatism (SIA). The extent of SIA depends on several factors including shape, location, and size of incision, and the response of the cornea. The SIA is a consequent result of flattening in the incision axis and its steepening 90 degrees in the opposite direction of the incision.[1-3] Surgeons must be particular about their SIAs to approach a minimally induced surgical astigmatism intraoperatively.

Before the surgery, the surgeon identifies the astigmatism based on markers given by keratometric readings, corneal pachymetry, topography, optical coherence tomography, and Scheimpflug imaging. Pre-operatively, the surgeon reviews these keratometric values, and either (1) marks the cornea using a pen marker or scar the cornea (with marker), or (2) aligned along the appropriate axis as guided by a digital overlay (markerless). Automated systems using digital overlay through topographic landmarks in guiding toric intraocular lens alignment have already been used worldwide. However, the efficacy of these systems still needs clinical studies.[2]

Toric IOLs have been in the practice worldwide for almost a decade, but in countries like the Philippines, toric IOLs have just been introduced gradually over the recent years, therefore data on toric IOLs locally are limited. The manual marking method needs basic instruments such as tissue marking pen, slit lamp biomicroscope, and the toric marker surgical instrument. Manual marking is cheaper as compared to the markerless system which is equipment dependent. Currently, there are two major brands that provide the markerless system. Due to the small number of studies reporting the outcomes, this study conducted a local evaluation on the outcomes of implantation of toric intraocular lenses with and without markers.

OBJECTIVES

This study aimed to compare the visual outcomes between manual and markerless toric intraocular lens implantation in astigmatic correction. The following primary parameters were compared in marker and markerless systems: one (1) month and two (2) months corrected distance visual acuity (corrected visual acuity (CDVA) and uncorrected visual acuity (UCVA)) from baseline distance visual acuity; one (1) month and two (2) months near visual [corrected (BCVA) and uncorrected (UCVA)] from baseline near visual acuity; one (1) month and two (2) months postoperative residual astigmatism from preoperative astigmatism; one (1) month and two (2) months postoperative residual sphere from pre-operative sphere; and, visual outcomes of monofocal versus multifocal toric intraocular lenses.

METHODS

This was a single-center study that employed a retrospective chart review of patients from January 1, 2010 to December 31, 2019 at the Medical Records Section of the American Eye Center. This study was approved by the University of the Philippines-Manila Research Ethics Board (UPM-REB). Participants of the study included patients who underwent uneventful cataract surgery using monofocal toric or multifocal toric lens (AT Torbi, IQ toric, AT LISA, Restor Toric and Panoptix Toric lens) implantation either via manual marking or markerless system (Carl Zeiss Meditec AG, Jena, Germany). The surgeries were performed by six experienced surgeons. Post-LASIK patients, those with significant preoperative eye diseases such as severe glaucoma, age-related macular degeneration etc., and those with incomplete charts were excluded. Variables including demographics (age, gender, laterality), type of cataract surgery, type of toric IOL implanted (monofocal or multifocal), surgically induced astigmatism, axial length, manifest refractions (sphere and cylinder), biometry cylinder in dioptric power, and correlation between the parameters were collected.

Standard Practice of Procedure at the American Eye Center

The surgeons who performed the procedures had at least ten years of experience in a refractive ambulatory center. They perform high volume phacoemulsification procedures using premium lenses such as toric and multifocal IOLs. Likewise, licensed optometrists measured the manifest refractions. Preoperatively, a complete eye examination which included determination of the following: uncorrected visual acuity (UCVA), corrected distance visual acuity (CDVA), uncorrected near visual acuity (UNVA), corrected near

visual acuity (CNVA) and spherical equivalent refraction (SE), astigmatic refraction (AR), biometry, and meridian registration using an IOLMaster 700 biometer (Carl Zeiss, Oberkochen, Germany) and Lenstar biometer (Haag Streit, USA), slitlamp biomicroscopy, intraocular pressure, and dilated fundus examination was performed on all patients. Preoperative and postoperative manifest refractions were measured by optometrists. Keratometry values were measured with the IOL Master 700 and Lenstar biometer by three trained ophthalmic technicians. Intraocular lens calculations for both sphere and toric corrections were performed using softwares available in the internet by Alcon, Zeiss and Barrett Toric calculator.

With Marker Measurements Standard Procedure

Preoperatively, with the use of a marker pen, manual markings at 12, 3, 6 and 9 o'clock of limbus were done using a narrow slitbeam by the surgeon under a slitlamp biomicroscope. Intraoperatively, prior to side port creation, target axis was marked using surgical pen and intraoperative axis marker guided by Henderson Degree Gauge and the initial markings done at the slit lamp. No additional applications were added in the manual computation.

Markerless Measurement Standard Procedure

For markerless option, a reference image was taken with the IOL Master 700 prior to the surgery. The data collected from the image were transferred to the Callisto eye image-guided system, which is connected to Lumera 700 surgical microscope (Carl Zeiss, Oberkochen, Germany) during surgery. Images from the microscope were captured by the Callisto eye system, and registered images were overlayed. In the next step, three parallel blue lines represented the toric IOL axis and a yellow line represented the 0–180˚ axis. The toric IOL was positioned at the target axis.

A monofocal or multifocal single-piece, hydrophobic, biconvex, toric aspheric IOL (Acrysof IQ_SN6AT; IQ_Toric, Restor Toric and Panoptix Toric; Alcon Laboratories, Fort Worth, TX, USA), AT Torbi and AT Lisa (Carl Zeiss, Oberkochen, Germany) lens was implanted. In order to promote capsular adhesion, the viscoelastic device behind the toric IOL was completely removed. The optic zone diameters of these lenses were at 6.0 mm with a total diameter of 13.0 mm, and the IOLs were manufactured with cylinders from 1.50 D to 6.00 D in 0.75 D increments. A high-fluid phacoemulsification machine (Centurion Vision System, Alcon Laboratories, Fort Worth, TX, USA) was used during cataract surgery, and all surgeons used a 2.2-mm temporal clear corneal incision.

Data Analysis

The demographic and clinical profile of participants were summarized by descriptive statistics. Target sample size was computed using Cochrane equation where the confidence interval was set at 95%. Using this equation, the adjusted sample size was 58. Using the same Cochrane formula as above, sample size for each population is 29 for marker and 29 for markerless. Numerical variables were described as median and interquartile range because the distribution was not normal as assessed by Shapiro-Wilk test of normality. Categorical variables were described by count and proportion. The demographics and baseline clinical profile were compared between the two intervention groups by Mann-Whitney U test to determine the homogeneity of the distribution of the participants between the two groups. The difference in the median/mean-rank of the different ophthalmologic parameters of interest (UDVA, CDVA, UNVA, CNVA, spherical equivalent, and astigmatism) were compared between the two intervention groups across the different time-points (pre-operative, one month post-op, and two months post-op) by Friedman's ANOVA. A post-hoc analysis by Wilcoxon sign-rank test for matched pairs after a significant Friedman's ANOVA on comparison of the three-time points of interest was performed comparing one month post-op and two months post-op from the pre-operative values. Boxplots were constructed to visualize these comparisons. The participants were also grouped according to type of intraocular lens, i.e., monofocal vs multifocal, and the lens characteristics were compared by Mann-Whitney U test. All analysis were performed using Stata version 17.0 and were evaluated at α=0.05 significance level.

RESULTS

A total of 70 eyes from 50 patients underwent toric IOL implantation. Thirty-seven eyes (52.85%) used markerless method and the remaining 33 eyes (47.14%) used manual marking method. There was female preponderance in both the markerless and manual marking methods which included 24 females (64.86%) and 20 females (60.61%), respectively. Visual acuity was presented as logarithm of the minimal angle of resolution or logMAR units in both uncorrected and corrected for both distance and near. Table 1 presents the demographics of the subjects. The participants recruited between the two treatment groups were homogenous.

Table 2 shows the preoperative and postoperative results. Comparison of outcomes of visual acuity, and residual spheres and cylinders is presented on the table. Similar to Table 1, visual acuity was represented as logarithm of the minimal angle of resolution or logMAR units. Spherical equivalent and astigmatism were presented in diopters. Results showed no sufficient evidence to conclude a significant difference in the following characteristics between manual and markerless across different time-points: UDVA, CDVA, UNVA, CNVA, spherical equivalent. The UDVA, CDVA, UNVA, CNVA, spherical equivalent and astigmatism had significantly lower median/mean-rank at one and two months postoperatively compared to preoperative values. Comparing the astigmatism power results, no significant difference was seen between the two. The alignment in axis was corrected with remaining 1-2

Table 1. Demographics of Patients who Underwent Toric Intraocular Lens Implantation

	Manual Marking Median (IQR)/ Count (%)	Markerless Median (IQR)/ Count (%)	*p*-value
Total patient (eyes)	33 (47.14%)	37 (52.86%)	
Sex			0.713
Male	13 (39.39%)	13 (35.14%)	
Female	20 (60.61%)	24 (64.86%)	
Laterality			0.642
Right	17 (51.52%)	17 (45.95%)	
Left	16 (48.48%)	20 (54.05%)	
Preoperative astigmatism (D)	1.71 (2.12)	1.94 (1.4)	0.573
Preoperative UDVA (logMAR)	0.54 (1.0)	0.48 (0.4)	0.336
Preoperative CDVA (logMAR)	0.1 (0.2)	0.18 (0.2)	0.095
Preoperative UNVA (logMAR)	1.47 (0.6)	1.17 (0.3)	0.087
Preoperative CNVA (logMAR)	0.1 (0)	0.1 (0)	0.169
Preoperative MR sphere	1.5 (2.75)	1 (2.25)	0.068
Preoperative MR cylinder	1.25 (1.5)	1 (1.13)	0.086
Preoperative MR axis	95 (87.5)	102.5 (52.5)	0.754
Preoperative biometry cylinder	1.42 (0.52)	1.59 (0.65)	0.642

D – Diopters; UDVA – Uncorrected distance visual acuity; CDVA – Corrected distance visual acuity; UNVA – Uncorrected near visual acuity; CNVA – Corrected near visual acuity; MR – Manifest refraction

Table 2. Postoperative Summary Results

Parameters	Pre-operative		One month post-op		Two months post-op		Friedman's ANOVA		Post-hoc analysis*	
	Manual	Markerless	Manual	Markerless	Manual	Markerless	Between groups	Between time-points	One month vs baseline	Two months vs baseline
	Median (IQR)						*p*-value			
UDVA (logMAR)	0.54 (1.0)	0.48 (0.4)	0.1 (0.18)	0 (0.1)	0.1 (0.18)	0.1 (0.1)	0.180	<0.001	<0.001	<0.001
CDVA (logMAR)	0.1 (0.2)	0.18 (0.2)	0 (0.1)	0 (0.1)	0 (0)	0 (0)	0.198	<0.001	<0.001	<0.001
UNVA (logMAR)	1.47 (0.6)	1.17 (0.3)	0.1 (0.08)	0.1 (0.04)	0.1 (0)	0.1 (0.08)	0.823	<0.001	<0.001	<0.001
UDVA (logMAR)	0 (0.1)	0 (0.1)	0 (0.1)	0 (0.1)	0.1 (0)	0.1 (0)	0.274	0.001	0.003	0.002
Sphere (D)	1.5 (2.75)	1 (2.25)	0 (0.25)	0.25 (0.5)	0 (0.5)	0.25 (0.5)	0.897	<0.001	<0.001	<0.001
Astigmatism (D)	1.25 (1.5)	1 (2.25)	0 (0.25)	0.25 (0.5)	0.5 (0.88)	0.5 (0.25)	0.120	<0.001	<0.001	<0.001
Axis (degrees)	95 (87.5)	102.5 (52.5)	1.2 (0.73)	1.3 (0.71)	1.5 (0.72)	1.4 (0.81)	0.117	<0.001	<0.001	<0.001

**Post-hoc analysis by Wilcoxon sign-rank test for matched pairs after a significant Friedman's ANOVA for difference in median/mean-ranks between time-points while accounting for treatment groups. logMAR – logarithm of minimal angle of resolution; D – diopter*

diopters off axis for both groups. Comparison between the two was not statistically significant.

Figures 1 and 2 presented comparison outcomes of pre-operative and postoperative spheres and astigmatism. As seen in both figures, both spheres and astigmatism markedly improved postoperatively which revealed a significantly lower median/mean-rank at one and two months postoperatively. However, comparison of results between the two groups showed no superiority of either system in the spherical refraction and astigmatism (p = 0.120).

Table 3 showed the distribution of the type of intraocular lens implanted either a monofocal or a multifocal IOL. There is no sufficient evidence to conclude that there is significant difference in the residual cylinder astigmatisms between monofocal and multifocal IOLs used.

DISCUSSION

There is no question that implantation of intraocular lenses per se contributed to a statistically significant improvement of vision in patients. As seen in the results, both distance and near visions were significantly improved across different postoperative time points (p<0.001). On the other hand, it is well published that residual spherical equivalents and astigmatisms both improved after toric intraocular lens implantation. Implantation of toric intraocular lenses seems to be working with corneal astigmatisms of more than 0.75 diopters. On the other hand, it is well published that residual spherical equivalents and astigmatisms both improved after toric intraocular lens implantation.[2]

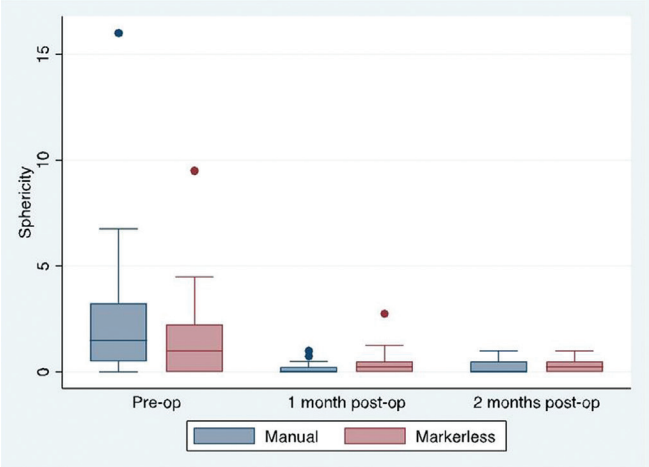

Figure 1. Comparison of spherical refraction between manual and markerless toric intraocular lens implanted for astigmatic correction in cataract surgery, across different time points.

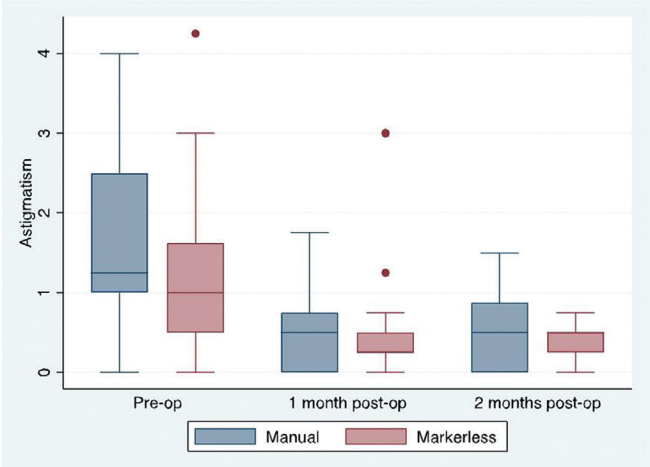

Figure 2. Comparison of astigmatism between manual and markerless toric intraocular lens implanted for astigmatic correction in cataract surgery, across different time points.

Table 3. Distribution of the Type of Intraocular Lens

	Monofocal Median (IQR) / Count (%)	Multifocal Median (IQR) / Count (%)	*p*-value
Total patient (eyes)	50 (71.43%)	20 (28.57%)	
Axis	99 (122)	96 (40.5)	0.235
Cylinder	2.2 (0.75)	1.5 (1)	0.139

Among retrieved journals, the reported percentage of patients achieving a visual acuity of more than 20/40 with toric IOL implantation is from 70 to 100%.[2-6] A study by Kose and Erdogan[7] in 2020 showed that of the 80 eyes, 52 had with-the-rule astigmatism; 16 eyes had oblique astigmatism; and 12 eyes had against-the-rule astigmatism. The preoperative SE, corneal cylinder, UDVA, and CDVA values for both groups were statistically similar. There were no significant differences between groups in the values of UDVA, CDVA, or degree of misalignment of the toric IOL. A randomized controlled trial performed by Kodavoor et al.[8] in 2020 where they compared the outcomes as to the residual astigmatism and postoperative alignment of post-toric implantation patients showed no significant difference in the outcomes, namely UDVA ($p = 0.85$) and CDVA ($p = 0.74$). However, in both groups, the preoperative period to postoperative period UDVA and CDVA were observed to have a significant improvement at 1 week, 6 weeks, and 2 months ($p < 0.00001$ for both groups in all visits) which was similar to the results of our study. There was a significant difference in the residual refractive cylinders between the two groups two months postoperatively ($p = 0.03$), but not during the earlier parts of the study. Toric IOL misalignment differences were not found to be statistically significant.[8] Elhofi et al.[9] in 2015 showed no significant differences between manual marking and digital marking in terms of postoperative UDVA or CDVA. The studies by Jain et al.[10] and Trinh et al.[11] also showed no significant differences between the two groups.

However, in terms of alignment and astigmatism diopter correction, there had been studies pointing to markerless systems being the more superior system. In the studies by Elhofi et al.[9] and Mayer et al.[12], significant difference was noted showing better outcomes and postoperative alignment for markerless image-guided alignment as opposed to with corneal markers. Mayer et al.[12] obtained significantly different results in terms of mean deviation from the target-induced astigmatism and mean toric IOL alignment time in the markerless group. In our study, there was no significant difference between the alignments and astigmatism correction between the two groups. Due to the divergent findings observed in various studies, it is therefore recommended to undertake a meta-analysis, which involves the synthesis and analysis of pooled data from larger populations. This approach aims to achieve statistical significance and consolidate the outcomes into a unified conclusion.

In developing countries such as the Philippines, this study is applicable such that rural hospitals find it a cost dilemma to procure equipment capable of performing markerless implantation. Most markerless systems are often seen in urban cities and rarely in rural areas. This study hoped to address questions amongst local surgeons with regard to

the results of marker-based system compared to technology-dependent markerless system present in technology-advanced cities. With only a few equipment needed for manual marking, this procedure is cheaper as compared to the equipment-dependent markerless system.

The retrospective nature of this study had no control over the consistency of the surgical protocol, follow-up appointments, and the strict uniformity of techniques of the surgeons. To obtain more precise information about the most suitable surgery for individuals, it is advisable to conduct longer-term studies with a larger pool of patients.

CONCLUSION

In conclusion, our results demonstrated that the marker and markerless system both enabled precise positioning of the toric IOL on the intended axis, however no significant difference was seen between the two. Both systems are easy to perform. In developing countries such as the Philippines, the manual marking method may be used in the absence of equipment markerless guidance equipment. Provided the inherent limitations of this study, it is expected that readers take caution in the treatment of results.

Statement of Authorship

All authors certified fulfillment of ICMJE authorship criteria.

Author Disclosure

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