Iris Registration Capsulotomy Marking Versus Manual Marking for Toric Intraocular Lens Alignment in Cataract Surgery

QINGZHONG CHEN AND GUANGBIN ZHANG

• PURPOSE: To compare the accuracy of toric intraocular lens (IOL) alignment and visual outcomes using femtosecond laser–assisted capsulotomy marking (CM) versus conventional slit lamp−assisted manual marking (MM).
• DESIGN: Prospective cohort study.
• METHODS: A total of 57 patients who required cataract surgery and toric IOL implantation (Acrysof SN6AT3-T8) were assigned to the CM group (26 eyes) or the MM group (31 eyes). Uncorrected distant visual acuity (UCDVA), best-corrected distant visual acuity (BCDVA), residual astigmatism (RA), IOL misalignment, and modulation transfer function (area ratio [AR] value) were measured 1 and 3 months after surgery.
• RESULTS: Postoperative UCDVA (logarithm of minimal angle of resolution [logMAR]) was significantly lower in the CM group than that in the MM group ($P < .05$). Postoperative RA and IOL misalignment were significantly lower in the CM group than that in the MM group (both $P < .05$). No significant difference between the groups was observed for BCDVA or AR value (both $P > .05$). UCDVA (logMAR) was positively correlated with RA ($r = 0.339$; $P < .05$) and IOL misalignment ($r = 0.317$; $P < .05$) and negatively correlated with the the AR value ($r = -0.272$; $P < .05$); RA was positively correlated with IOL misalignment ($r = 0.405$; $P < .05$).
• CONCLUSIONS: The accuracy of the axis alignment was significantly higher in the CM group, which resulted in lower residual astigmatism and better visual outcomes. (Am J Ophthalmol 2021;221:97–104. © 2020 Elsevier Inc. All rights reserved.)

IT IS COMMON KNOWLEDGE THAT CATARACT SURGERY has gradually transformed from traditional restorative surgery to refractive surgery; with modern techniques, expectations regarding refractive outcomes continue to increase.[1] Previous studies have shown that 47.27% of patients with cataracts in Northern China have had corneal astigmatism >1.00 diopter (D)[2]; ocular residual astigmatism may influence postoperative outcomes.[3] The correction of pre-existing corneal astigmatism at the time of cataract surgery results in better postoperative visual outcomes that can lead to higher satisfaction with vision and minimize postoperative spectacle dependence, compared with astigmatism correction with postoperative vision correction.[4] The major techniques for the correction of pre-existing corneal astigmatism during cataract surgery are limbal relaxing incisions on the steep meridian, astigmatic keratotomy, and toric intraocular lens (IOL) implantation. Among these techniques, toric IOL implantation appears to be safe and effective, indicating good predictability and stability as a correction of high range of pre-existing corneal astigmatism during cataract surgery.[5] Clinical evidence suggests that with each degree of toric IOL misalignment, there is approximately a 3.3% loss of astigmatic correction; an error of 30° to the intended meridian results in a complete loss of the effect.[6] Accurate alignment of toric IOLs is essential to achieving effective astigmatism correction and satisfactory postoperative outcomes.

To ensure high accuracy, it is important that toric IOLs have a precise axial position, which, in turn, depends on exact corneal marking. Several methods have been described to determine the best toric IOL position marking. A classic (and common) method is based on manual markers, which could be done by slit lamp−assisted marking with a horizontal slit beam, a pendular marker, and a nonpendular marker. However, the method has a risk of inaccurate marking of the axis when performed by inexperienced surgeons; the patient's head position at the time of slit lamp evaluation also affects the accuracy of axis marking.[7] Another method uses anterior segment photographs to identify iris and/or conjunctival vessel patterns that provide objective marking methods through digital overlay imaging during surgery to evaluate the alignment of the toric IOL, such as with Verion Digital Marker System (Alcon Laboratories, Ft. Worth, Texas, USA), Callisto Eye System (Carl Zeiss Meditec AG, Jena, Germany), and TrueGuide software (TrueVision 3D Surgical, Inc., Santa Barbara, California). Digital imaging markers have shown advantages over manual marking (MM)—in particular, less postoperative toric IOL misalignment and surgical time. However, controversy remains as to whether digital guidance marking produces better visual outcomes than MM.[8,9]

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A novel approach to toric IOL alignment guidance creates a pair of small, opposite pointers or capsular marks on the capsular rim while performing femtosecond laser—assisted capsulotomy. The guidance is based on automated image registration by capturing a reference image preoperatively, followed by intraoperative iris registration in which the patient's peripheral iris landmarks are used for automatic axis determination.[10] The toric IOL misalignment angle could be calculated by using Adobe Photoshop (San Jose, CA, USA) software after the pupils are fully dilated. The purpose of this prospective study is to compare the alignment accuracy of toric IOL and visual outcomes between iris registration capsular marking (CM) and MM techniques.

PATIENTS AND METHODS

• **PATIENTS:** A total of 57 patients with cataracts (57 eyes) who underwent implantation of toric IOLs (Acrysof SN6ATx; Alcon Laboratories) in Xiamen Eye Centre from November 2016 to May 2017 were enrolled. The enrollment of the participants was non-randomized. The marking methods used in the participants were decided by themselves with full understanding of the potential benefits and risks of the 2 marking methods. Participants provided formal informed consent. According to the marking method, the patients were divided into 2 groups: slit lamp—assisted MM was used with 31 eyes, whereas femtosecond laser-assisted CM was used in the 26 eyes in the second group. All the participants were older than 18 years and had corneal astigmatism >1.00 D. Exclusion criteria were previous intraocular surgery, amblyopia, lens dislocation, pseudoexfoliation, glaucoma, corneal opacities, macular degeneration, diabetic retinopathy, or irregular astigmatism. The study was designed as a prospective cohort study, which was approved by the ethics committee of Xiamen Eye Center Affiliated Xiamen University (Approval Number: XMYKZX-2016-LW-009) and adhered to the guidelines of the Declaration of Helsinki and all federal or state laws in our country. All the participants were informed of the purpose of the study and provided informed consent.

• **ASSESSMENTS:** Preoperatively, all the patients underwent a comprehensive ophthalmologic examination that included measurement of uncorrected distant visual acuity (UCDVA), best-corrected distant visual acuity (BCDVA), manifest refraction, slit lamp examination, dilated fundus evaluation, and optical biometry using the Lenstar LS 900 system (Haag-Streit AG, Switzerland), Scheimpflug topography (Pentacam, Oculus Optikgeräte GmbH, Germany), and OPD-Scan III aberrometer (Nidek Co., Ltd, Gamagori, Japan). Toric IOL power was determined using the online toric calculator (http://www.myalcon-toriccalc.com/#/calculator). The patients were evaluated at 1 and 3 months postoperatively. The postoperative assessments included UCDVA, BCDVA, manifest refraction, and OPD-Scan III aberrometer. The modulation transfer function was used as an objective measure of visual quality, which was provided by the OPD-Scan III aberrometer. Visual quality was defined as the ratio of the area under the curve of the actual eye and the area under the curve of a diffraction limited curve (area ratio [AR] value). The higher the AR value, the better the objective visual quality of the eye; when the ratio approximated 100%, the curve closely approximated normal. Afterward, the pupils were pharmacologically dilated using tropicamide 1.0% eyedrops. After the pupils were fully dilated, the toric IOL images were captured by a digital camera connected to the slit lamp and computer. The toric IOL misalignment angle was calculated using Adobe Photoshop software. The rotation of toric IOL was defined as the difference between the planned implantation axis and the exact toric IOL axis. All examinations were carried out by the same team.

• **TARGET AXIS MARKING METHODS:** MM *group*. MM was performed with topical anesthesia. The patient sat upright with the other eye fixed at a distant target. The slit beam was turned to the horizontal position and centered on the corneal apex of the patient after ensuring a lack of head tilt. The eye was marked at 0 and 180° on the corneal limbus using a 27-gauge needle and marking pen. The target meridian was marked intraoperatively using a Mendez gauge and sterile surgical marker pen.

CM *group*. Before the surgery, corneal astigmatism and an iris photo of patients were captured by the OPD-Scan III system, which offered iris registration and was coupled with the LENSAR laser platform (LENSAR LLC, Orlando, Florida, USA). The LENSAR software (Streamline IV) allowed for the creation of marks on the capsulotomy edge. At the same time of femtosecond laser-assisted capsulotomy, 2 tabs were created 180° apart to define the desirable axis (Figure 1A). Femtosecond laser was used only to make CM; the corneal incision and lens fragmentation steps were not used in the group.

• **STATISTICAL ANALYSIS:** Data analysis was performed using SPSS 23.0 software (IBM, Armonk, New York, USA), and measurement data were expressed as mean ± SD. The normality of data samples was evaluated using the Kolmogorov-Smirnov and Shapiro-Wilk tests. For data with a normal distribution, the independent-sample *t*-test was used to compare differences between the groups; the paired-samples *t*-test was used for comparison of the pre- and postoperative data. For data with a non-normal distribution, the Wilcoxon rank-sum test was applied to compare differences between the groups, and the Wilcoxon signed-rank test was used for comparison of the pre- and postoperative data. The χ^2 test was used for statistical

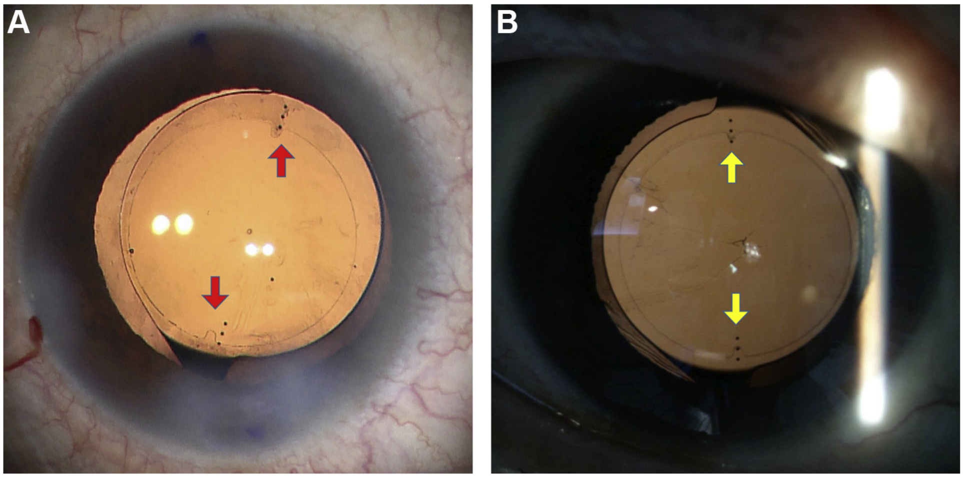

FIGURE 1. Capsulotomy markings for the alignment of toric IOLs. (A) The capsulotomy markings produced by femtosecond laser during the surgery to define the desirable axis (red arrows). (B) The capsulotomy markings were still present at postoperative follow-up as an anatomical landmark and facilitated the assessment of intraocular lens alignment (yellow arrows).

analysis of quantitative data. Correlation between variables was assessed using Pearson's correlation test. A *P* value < .05 was considered statistically significant.

RESULTS

THE MM GROUP INCLUDED 31 EYES (31 PATIENTS; 12 MEN AND 19 women), and the mean age was 68.94 ± 11.52 years (range: 31-89 years); the CM group included 26 eyes (26 patients; 12 men and 14 women), and the mean age was 72.69 ± 10.75 years (range: 52-94 years). No significant difference in sex or age distribution between the groups was observed ($P > .05$). The degree of lens nucleus hardness was classified according to the Emery-Little classification (grades I-V), and there was no significant difference between the MM group (grade II: 2 eyes; grade III: 19 eyes; grade IV: 10 eyes) and the CM group (grade II: 0 eyes, grade III: 19 eyes; grade IV: 7 eyes) in lens nucleus hardness ($P > 0.05$). For preoperative UCDVA, the logarithm of minimal angle of resolution [logMAR] was 0.79 ± 0.33_{MM} and 0.81 ± 0.34_{CM}; for BCDVA, the logMAR was 0.51 ± 0.31_{MM} and 0.54 ± 0.32_{CM}. Corneal astigmatism was 1.90 ± 0.64_{MM} and 2.06 ± 0.71_{CM}, and the AR value was 17.00 ± $6.92\%_{MM}$ and 18.37 ± $6.75\%_{CM}$. No significant difference was noted between the groups ($P >$ .05) (Table 1).

All the operations were successfully completed; no capsular tears or any other specific complications occurred in the 2 groups. Postoperatively, both groups achieved good outcomes for visual acuity and astigmatism correction. One and 3 months postoperatively, the mean UCDVA (logMAR) of the MM group was 0.22 ± 0.10 and 0.23 ± 0.11, respectively. The mean UCDVA (logMAR) of the CM group was 0.16 ± 0.09 and 0.15 ± 0.09, respectively, which were both significantly different from preoperative assessments ($P < .05$). The residual astigmatism (RA) of the MM group was 0.62 ± 0.28 D and 0.64 ± 0.26 D, whereas the RA of the CM group was 0.35 ± 0.22 D and 0.30 ± 0.18 D 1 and 3 months postoperatively, respectively, which were both significant decreases from that at preoperation ($P < .05$). The AR value of the MM group was 39.61 ± 14.55% and 41.16 ± 15.46%, and the AR value of the CM group was 45.92 ± 12.83% and 46.86 ± 12.81% 1 and 3 months postoperatively, respectively, which were both significant increases ($P < .05$) (Figure 2).

The UCDVA (logMAR) of the CM group was significantly better than that of the MM group 1 and 3 months postoperatively ($P < .05$). However, the BCDVA (logMAR) of the groups was not significantly different at 3 months after surgery ($P > .05$). The mean AR value of the CM group was higher than that of the MM group at 1 and 3 months, but the difference was not significant ($P > .05$). The RA of the CM group was significantly lower than that in the MM group at 1 and 3 months ($P < .05$), whereas the misalignment of IOL of the CM group was also significantly lower at 1 and 3 months ($P < .05$) (Figure 3). One month after surgery, the RA of 9 eyes (29.03%) of the MM group was no more than 0.50 D. By contrast, 21 eyes (80.77%) of the CM group had an RA within 0.50 D ($P < .05$). Three months postoperation, 38.71% (12 eyes) of the MM group and 88.46% (23 eyes) of the CM group were no more than 0.50 D, which was a significant difference ($P < .05$). The difference in the RA percentage within 1.00 D of the 2 groups was not significant at either 1 or 3 months after surgery ($P > .05$) (Table 2).

The results of the correlation analysis indicated that postoperative UCDVA (logMAR) was positively correlated with RA ($r = 0.339$; $P < .05$) and IOL misalignment

TABLE 1. Demographic and Clinical Characteristics of Participants

	Age, y ± SD	Sex, n		Nuclear Hardness, n			UCDVA, LogMAR ± SD	BCDVA, LogMAR ± SD	RA, D ± SD	AR value, % ± SD
		Male	Female	II	III	IV				
MM group	68.94 ± 11.52	12	19	2	19	10	0.79 ± 0.33	0.51 ± 0.31	1.90 ± 0.64	17.00 ± 6.92
CM group	72.69 ± 10.75	12	14	0	19	7	0.81 ± 0.34	0.54 ± 0.32	2.06 ± 0.71	18.37 ± 6.75
t/χ^2 tests	−1.264	0.321			2.107		−0.261	−0.371	−0.901	−0.753
P Value	.212	.571			.349		.795	.712	.455	.455

AR = area ratio (the ratio of the area under the curve of the actual eye and the area under the curve of a diffraction limited curve); BCDVA = best corrected distant visual acuity; CM = capsulotomy marking; D = diopter; LogMAR = logarithm of the minimum angle resolution; MM = manual marking; RA = residual astigmatism; UCDVA = uncorrected distant visual acuity.

(r = 0.317; $P < .05$) and negatively correlated with AR value (r = −0.272; $P < .05$). Postoperative RA was positively correlated with IOL misalignment (r = 0.405; $P < .05$). No correlation was observed between BCDVA and RA, IOL misalignment, or AR value ($P > .05$) (Figure 4).

DISCUSSION

THE CORRECTION OF BOTH ASTIGMATISM AND CATAracts with phacoemulsification and implantation of a toric IOL can be a safe, effective choice for patients with preexisting astigmatism. The effect of astigmatism correction depends on preoperative assessments, calculation of IOL power, and the accuracy and stability of toric IOL alignment. The horizontal beam of a slit lamp and a Mendez gauge are commonly used to mark the target meridian of a toric IOL; this method was reported to be a safe and reliable.[6] In the present study, the postoperative RA of the MM group was significantly lower than the preoperative astigmatism, which resulted in significantly better UCDVA. These results were consistent with previous research.[4,7,9] Nevertheless, the method had limitations, such as harming the corneal epithelium or inaccurate marking of the axis, especially if performed by inexperienced surgeons. In addition, the 2-step marking method may increase the risk of error because the surgeon has to use a second device to determine the target axis based on the horizontal 0-180°.[7,11] Therefore, it is of great significance and urgency to explore a more accurate marking technique for toric IOL implantation.

In this study, astigmatism was significantly decreased in both the MM and CM groups; toric IOL alignment was also excellent in both groups. However, toric IOL misalignment was significantly lower in the CM group than that in the MM group. Furthermore, the proportion of RA of no more than 0.50 D was higher in the CM group. The results suggested that compared with slit lamp-assisted MM, femtosecond laser–assisted CM might have higher accuracy in the alignment of toric IOLs. Because CM determines the axis of the toric IOL based on peripheral iris

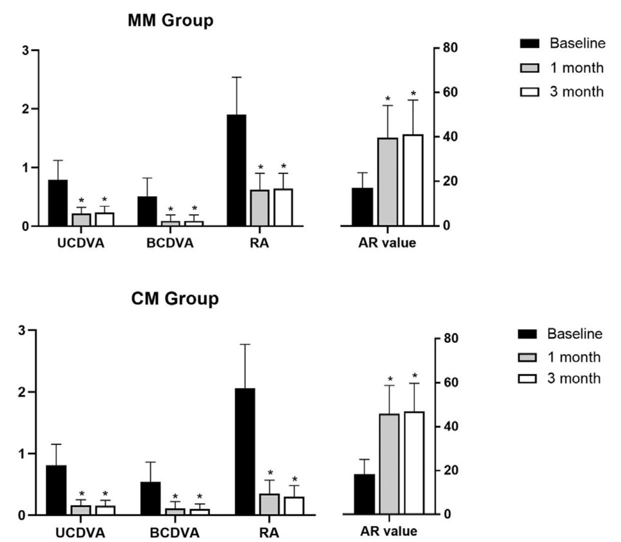

FIGURE 2. The residual astigmatism and visual outcomes of the patients 1 and 3 months after surgery. AR = area ratio (the ratio of the area under the curve of the actual eye and the area under the curve of a diffraction limited curve); BCDVA = best corrected distant visual acuity; CM group = capsulotomy marking group; D = diopter; LogMAR = logarithm of the minimum angle resolution; MM group = manual marking group; RA = residual astigmatism; UCDVA = uncorrected distant visual acuity. *$P < .05$.

features, it is not influenced by a change of body position. A previous study demonstrated that using iris registration during femtosecond laser–assisted cataract surgical procedures could minimize postoperative residual cylindrical error; the technique also provided more precise positioning of the toric IOL axis in patients with corneal astigmatism.[12] In addition, the use of a broad manual ink-marking, halo, and blurring of ink mark during surgery might also reduce efficacy after toric IOL implantation. In addition to toric IOL alignment, the postoperative RA of the CM group was also significantly lower than that of the MM group. There was no significant difference in preoperative astigmatism between the 2 groups, and the power and axis of

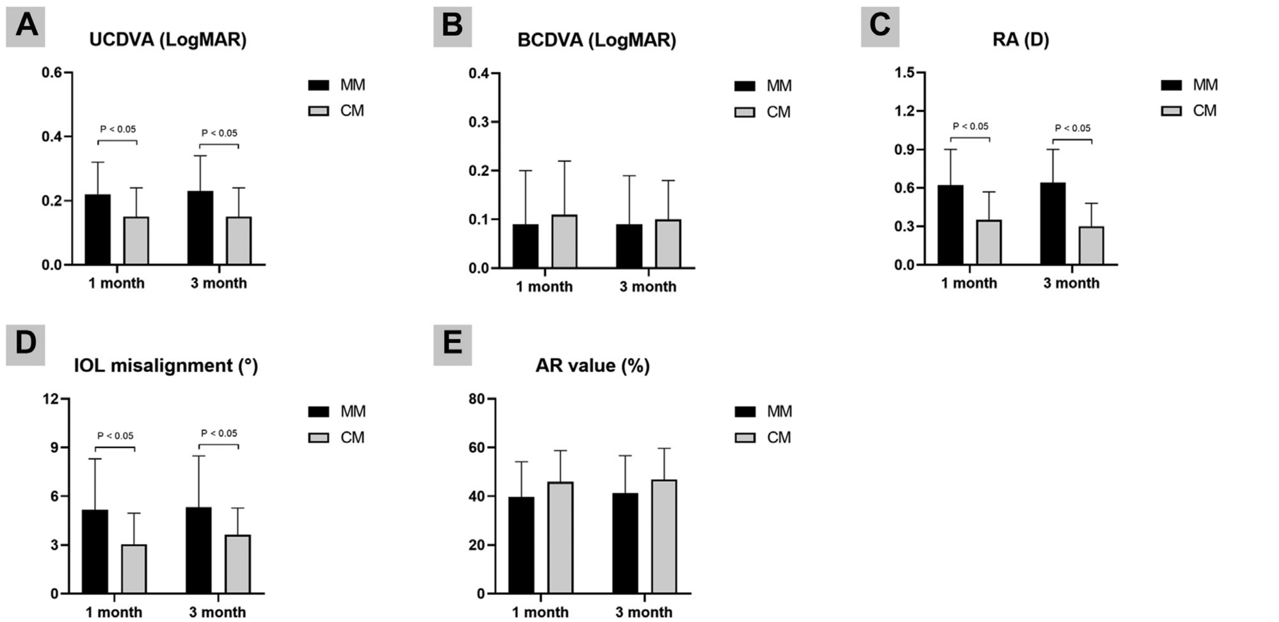

FIGURE 3. The difference between residual astigmatism, intraocular lens (IOL) misalignment, and visual outcomes between the 2 groups 1 and 3 months after surgery. (A) For UCDVA (LogMAR), CM group was significantly lower than MM group 1 month or 3 months after surgery. (B) For BCDVA (LogMAR), no significant difference was noted between the groups. (C) For RA, CM group was significantly lower than MM group 1 month or 3 months after surgery. (D) For the degree of IOL misalignment, CM group was significantly lower than MM group 1 month or 3 months after surgery. (E) For AR value, no significant difference was noted between the groups. AR = area ratio (the ratio of the area under the curve of the actual eye and the area under the curve of a diffraction limited curve); BCDVA = best corrected distant visual acuity; CM group = capsulotomy marking group; D = diopter; LogMAR = logarithm of the minimum angle resolution; MM group = manual marking group; RA = residual astigmatism; UCDVA = uncorrected distant visual acuity.

TABLE 2. Residual Astigmatism of the Two Groups

	1-Month Postoperative		3-Months Postoperative	
RA	Within 0.50 D	Within 1.00 D	Within 0.50 D	Within 1.00 D
MM group, n (%)	9 (29.03)	29 (93.55)	12 (38.71)	28 (90.32)
CM group, n (%)	21 (80.77)	26 (100)	23 (88.46)	26 (100)
χ^2 test	15.182	1.738	14.769	2.656
P Value	.000[a]	.187	.000[a]	.103

CM = capsulotomy marking; D = diopter; MM = manual marking; RA=residual astigmatism.
[a]Statistically significant ($P < .05$).

the toric IOL was calculated using the same method. Theoretically, there should be no significant difference in postoperative RA between the groups. The better outcome of astigmatism correction in the CM group suggested that compared with the MM method, iris registration CM method was more accurate.

Although the postoperative UCDVA was markedly improved in both groups, the postoperative UCDVA of the CM group was significantly better. Better UCDVA means a higher rate of spectacle independence, which contributes a profound influence on the postoperative quality of life and satisfaction of patients with cataracts with corneal astigmatism. According to the manifest refraction results, there was no difference in the postoperative BCDVA between the groups, which indicated that the difference of postoperative UCDVA might be attributed to postoperative RA. Postoperative visual acuity was related not only to UCDVA but also to entire ocular aberrations. Visual acuity as quantified by the AR value was higher in the CM group than that in the MM group at 1 and 3 months

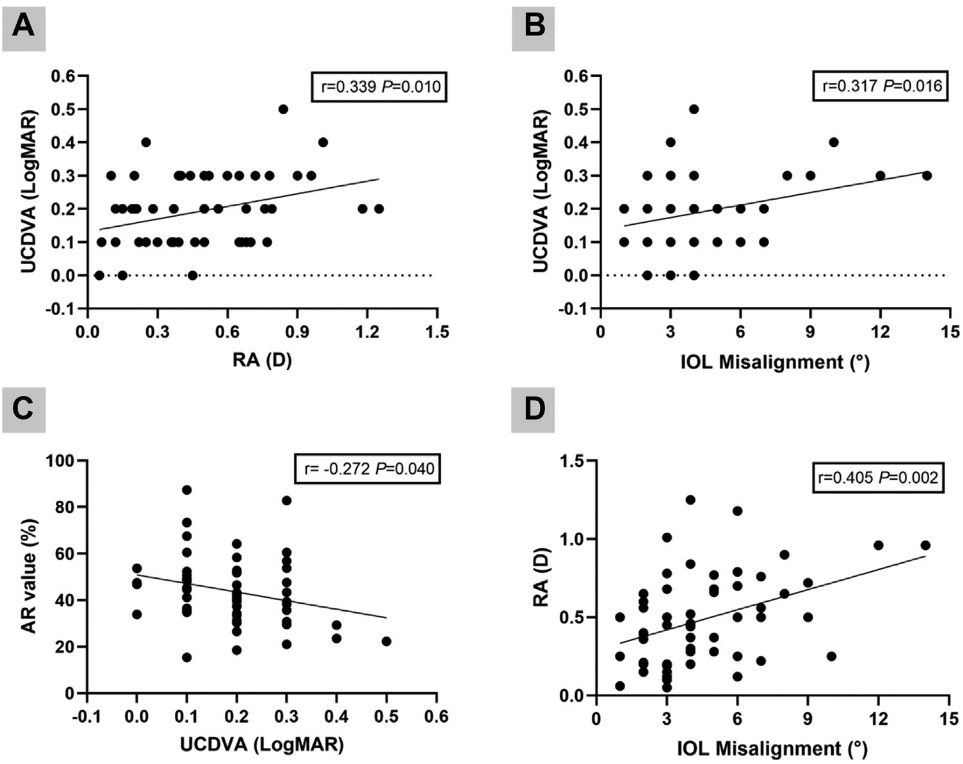

FIGURE 4. The correlation analysis between the variables. (A) The RA was positively correlaed with UCDVA (LogMAR). (B) The degress of IOL misalignment was positively correlated with UCDVA (LogMAR). (C) The AR value was negatively correlated with UCDVA (LogMAR). (D) The degree of IOL misalignment was positively correlated with RA. AR = area ratio (the ratio of the area under the curve of the actual eye and the area under the curve of a diffraction limited curve); BCDVA = best corrected distant visual acuity; CM group = capsulotomy marking group; D = diopter; IOL = intraocular lens: LogMAR = logarithm of the minimum angle resolution; MM group = manual marking group; RA = residual astigmatism; UCDVA = uncorrected distant visual acuity.

follow-up, although the difference was not statistically significant. The results indicated that the outcome of visual quality was better in the CM group.

To explore the factors that influenced the astigmatism correction effect and visual outcome of the groups, we analyzed the correlations of each variable. We found that postoperative UCDVA (logMAR) was positively correlated with postoperative RA, which indicated that suboptimal correction of astigmatism directly influences visual outcomes. Considering that there was no statistical difference in BCDVA (logMAR) between the groups and postoperative BCDVA (logMAR) was not correlated to RA, the difference of UCDVA (logMAR) between the 2 groups might be attributable to postoperative RA. Further analysis revealed that postoperative RA was positively correlated with the degree of IOL misalignment; UCDVA (logMAR) was also positively correlated with the degree of IOL misalignment. The results demonstrated that IOL misalignment was the main cause of postoperative RA, which resulted in suboptimal postoperative UCDVA. A previous study showed that IOL misalignment decreased the effect of astigmatism correction and led to unsatisfactory visual outcome,[13] which corresponded with the findings of the present study. In contrast, postoperative BCDVA (logMAR) showed no correlation with IOL misalignment or RA, perhaps because the RA caused by IOL misalignment could be corrected by wearing spectacles. We also found a negative correlation between UCDVA (logMAR) and the AR value, which indicated that better UCDVA produced better visual acuity. Although there was no statistical difference between the groups with regard to the postoperative AR value, the mean AR value of the CM group was higher than that in the MM group at every follow-up. In consideration of the results of the correlation analysis, we believed that the increase of UCDVA had a positive effect on the improvement of postoperative visual quality.

To the best of our knowledge, this was the first study to compare the CM method to the traditional manual method by assessing the accuracy of IOL alignment and visual outcomes. Several image-guided systems, such as the Verion (Alcon Laboratories) and Callisto Eye systems (Carl Zeiss Meditec AG), could facilitate the alignment of toric IOL through an overlay on a live image seen through a widefield microscope during surgery. Previous studies showed that image-guided systems provided better results than using MM in terms of postoperative IOL alignment. However, there was still controversy regarding whether an image-guided system could provide better visual outcomes than the MM method.[7,9,11,14] In contrast to an image-guided system, the CM method creates a pair of permanent marks on the capsulotomy edge. The marks can be small tabs at the capsulotomy edge with a height of 300 μm and an arc length of 5° at their base.[10] Once the marks are made, they do not move or flicker when the eye moves during the surgery, which minimizes visual interference to the operator. The other benefit of the CM method is that the capsulotomy marks remain present after surgery as an anatomical landmark to facilitate the assessment of IOL alignment at postoperative follow-up (Figure 1B). The main concern of CM is that the capsular rim might become weakened and tear during surgery. In view of this concern, Teuma et al. confirmed that the capsulotomies created by CM were as strong as standard femtosecond laser capsulotomies and showed promise for aligning toric IOLs intraoperatively, which indicated that CM was an accurate and safe choice for toric IOL implantation.[15]

• **STUDY LIMITATIONS:** Our study had limitations. First, instead of femtosecond laser—assisted cataract surgery, the MM group underwent standard phacoemulsification cataract surgery. The different surgical methods in the 2 groups might have affected the astigmatism correction effect and rotational stability of the toric IOL. To minimize the possible influence of surgical methods on the results, we used femtosecond laser only for CM; the corneal incision and lens fragmentation steps were not used in the CM group. A previous study showed that there was no significant difference between femtosecond laser—assisted cataract surgery and standard phacoemulsification cataract surgery in the rotation stability of toric IOLs.[16] To completely eliminate the influence of operation methods, an additional study will be performed to compare the CM method with femtosecond laser—assisted cataract surgery combined with the MM method. Second, postoperative toric IOL alignment measurement using a slit lamp had inherent errors mostly attributable to head tilt and ocular position. When we performed the postoperative examinations, patients were asked to stare at an indicator lamp to ensure the eyes were at an appropriate position. Deviation was diminished to a large extent by referring to conjunctival vessels. To avoid bias, the IOL axis was read without knowing the intended IOL implantation axis at every visit.

CONCLUSIONS

IN CONCLUSION, CM IS A SAFE AND ACCURATE METHOD for toric IOL marking and provides better astigmatism correction and visual outcomes than using MM for postoperative IOL alignment.

CRediT AUTHORSHIP CONTRIBUTION STATEMENT

QINGZHONG CHEN: FORMAL ANALYSIS, DATA CURATION, Writing - original draft, Writing - review & editing. **Guangbin Zhang:** Methodology, Investigation.

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