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Comparison Between Digital and Manual Marking for Toric Intraocular Lenses

A Randomized Trial

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Abstract: To compare the clinical outcome of digital and manual marking for toric intraocular lens (IOL) alignment.

This is a prospective clinical study that included 60 eyes of 60 patients undergoing cataract surgery with coexisting corneal astigmatism more than 1 diopter (D). The eyes were randomly assigned to either digital image guidance using VERION digital marker (Alcon Laboratories, Ft. Worth, TX) or manual slitlamp-assisted preoperative marking using pendulum-attached marker. Tecnis toric IOL (Abbott Medical Optics, Inc, Santa Ana, CA) was implanted in all cases.

The mean postoperative uncorrected distance visual acuity (UCDVA) for the digital-marking group was $0.12 + 0.12 \log\text{MAR}$, and for the manual-marking group was $0.18 + 0.14 \log\text{MAR}$ ($P = 0.104$). The mean deviation from targeted induced astigmatism (TIA) for the first group was $0.10 + 0.08 \text{ D}$ and for the second group was $0.20 + 0.14 \text{ D}$ ($P = 0.001$). The mean postoperative toric IOL misalignment measured by the slitlamp was $2.4^\circ + 1.96^\circ$ for the first group and $4.33^\circ + 2.72^\circ$ for the second group ($P = 0.003$).

Accurate alignment of the toric IOL is important to achieve the desired astigmatism correction. VERION system has the advantage of preoperative planning and intraoperative digital guidance of the toric IOL alignment. The use of VERION system resulted in less postoperative deviation from TIA and showed less postoperative toric IOL misalignment than using manual-marking technique.

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Abbreviations: D = dioptres, IOL = intraocular lens, TIA = targeted induced astigmatism, UCDVA = uncorrected distance visual acuity.

INTRODUCTION

Many patients undergoing cataract surgery have a significant corneal astigmatism. The prevalence of corneal astigmatism more than 1.5 diopters (D) ranges between 15% and 29% as reported by different studies.^{1–4} The difference in the reported percentages may reflect racial differences among included samples from different countries. This reported

prevalence may reach up to 47% for corneal astigmatism more than 1 D.²

There are several methods for treating coexisting astigmatism in patients undergoing cataract surgery. These methods include steep meridian incision,^{5,6} opposite clear corneal incisions,^{5,7–9} toric intraocular lens (IOL),^{10–12} and limbal or corneal relaxing incisions.^{12–14} Nowadays, femtosecond laser platforms can improve the precision of corneal incisions.^{15–17}

Toric IOL is used to correct coexisting corneal astigmatism in patients undergoing cataract surgery. Good alignment of toric IOL is important to achieve effective astigmatism correction. Improper alignment of the toric IOL may be due to wrong alignment from the start or postoperative IOL rotation.^{18,19}

Many methods are used to align the toric IOL. The most important step is the preoperative marking of the horizontal meridian (0° – 180°) while the patient is sitting. Marking of the horizontal meridian can be done manually under the guidance of different methods that includes slitlamp-assisted marking with a horizontal slit beam, slitlamp-assisted marking with a pendulum-attached marker, or nonpendular marker with a surgeon's direct visualization.^{20,21}

Newer technologies can provide digital image guidance for toric IOL alignment. These include the Callisto Eye with Z-Align (Carl Zeiss Meditec AG, Jena, Germany), the iTrace with Zaldivar Toric Caliper (Tracey Technologies, Houston, TX), the TrueGuide software (TrueVision 3D Surgical, Inc., Santa Barbara, CA), and the VERION Digital Marker (Alcon Laboratories, Ft. Worth, TX).^{22–25}

The aim of the current study was to compare the clinical outcome of digital and manual marking for toric IOL alignment.

PATIENTS AND METHODS

This is a prospective clinical study that included 60 eyes of 60 patients undergoing cataract surgery with coexisting corneal astigmatism more than 1 diopter (D). Cases with ocular comorbidities that affected the visual acuity such as amblyopia, maculopathy, glaucoma, and uveitis were excluded. Cases with intraoperative complications that compromised the toric IOL position were excluded. All cases were performed by the same surgeon. All included patients signed an informed consent. This study was approved by the local research committee of Faculty of Medicine, Alexandria University, Egypt. The tenets of Declaration of Helsinki were followed.

The eyes were randomly assigned to 1 of 2 groups according to the method of toric IOL alignment. The first group included 30 eyes with digital image guidance using VERION digital marker (Alcon Laboratories, Ft. Worth). The second group included 30 eyes with manual slitlamp-assisted preoperative marking using pendulum-attached marker. Lenstar LS 900 optical biometer (Haag-Streit or Allegro Biograph, Wavelight) was used to measure the axial length used in IOL power

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calculations for both groups. The least amount of residual astigmatism was targeted and the incision site was modified according to the treatment plan. Tecnis toric IOL (Abbott Medical Optics, Inc, Santa Ana, CA) was implanted in all cases. Follow-up visit 3 to 5 weeks postoperative was performed to record patients' uncorrected distance visual acuity (UCDVA), manifest refraction including residual refractive astigmatism, best corrected distance visual acuity, and the amount of toric IOL misalignment at the slitlamp.

For the first group, VERION system was used for toric IOL power calculation and surgical planning with the input of the Lenstar LS 900 measured axial length. Maximum possible correction of the astigmatism was attempted taking into consideration the surgically induced astigmatism. A high resolution preoperative image of the eye was captured by the unit. This image was registered intraoperatively. The VERION system matches the preoperative high resolution image with the eye intraoperatively using scleral vessels, limbal vessels, and iris features. This allowed real-time tracking of the eye during the surgery. A limbal protractor and the calculated toric IOL axis were displayed over a live view of the eye on an external monitor during the surgery. This allowed toric IOL alignment guided by the digital overlay.

For the second group, Lenstar LS 900 was used for toric IOL power calculation. Maximum possible correction of the astigmatism was attempted taking into consideration the surgically induced astigmatism. Manual marking was a 3-step procedure. First step was preoperative slitlamp-assisted marking of the horizontal meridian of the eye using a pendulum-attached marker. The eye should be marked while the patient is sitting upright and fixing with the other eye at a distant target to avoid cyclotorsion. The second step was intraoperative aligning a second device with angular graduations to the horizontal marks. The third step was intraoperative marking of the desired toric IOL axis of alignment using a gentian violet surgical marking pen.

Clinical findings were statistically evaluated using Excel 2007 (Microsoft Corp.) and SPSS software version 15.0 (SPSS Inc, Chicago, IL). Means and standard deviations were calculated. To check for normal distribution, the Kolmogorov-Smirnov test was applied. Comparisons of the means of normally distributed data were performed with the *t*-tests. Percentages of cases with postoperative UCDVA > 20/40 were calculated for both groups. Percentages of cases with postoperative refractive cylinder < 0.5 D were also calculated for both groups. Chi-square test was used to compare between different percentages. A *P* value less than 0.05 was considered statistically significant. Vector analysis was used to calculate the deviation between actual and planned postoperative residual astigmatism.

RESULTS

The mean age of the first group (with digital marking) was 49.5 + 11.4 years (*n* = 30, range 28–68 years). The mean age of the second group (with manual marking) was 52.0 + 13.0 years (*n* = 30, range 25–70 years). There was no statistically significant difference between the 2 groups (*t* = -0.780, *P* = 0.439). The first group included 15 males and 15 females, while the second group included 17 males and 13 females.

The mean preoperative corneal astigmatism for the first group (measured by the VERION system) was 2.58 + 0.89 D (range from 1.30 to 4.51 D), and for the second group (measured by the Lenstar LS 900) was 2.49 + 0.87 D (range from 1.34 to

4.90 D). There was no statistically significant difference between the 2 groups (*t* = 0.394, *P* = 0.695).

The mean postoperative UCDVA for the first group was 0.12 + 0.12 logMAR (range from 0 to 0.5 logMAR), and for the second group was 0.18 + 0.14 logMAR (range from 0 to 0.5 logMAR). The difference was not statistically significant (*t* = -1.654, *P* = 0.104). In the first group, 28 eyes (93.3%) had postoperative UCDVA of 0.3 logMAR or better. In the second group, 27 eyes (90%) had postoperative UCDVA of 0.3 logMAR or better. There was not statistically significant difference between the 2 groups (*P* = 0.399). For both groups, no eyes lost lines of visual acuity and all eyes had a best corrected distance visual acuity of 0.3 logMAR or better.

The mean postoperative residual refractive cylinder for the first group was 0.28 + 0.28 D (range 0.0–1.0 D) representing 89% of reduction in the astigmatism from preoperative levels. The mean postoperative residual refractive cylinder for the second group was 0.34 + 0.33 D (range 0.0–1.5 D) representing 86.3% of reduction in the astigmatism from preoperative levels. This difference was not statistically significant (*t* = -0.837, *P* = 0.406). Eyes with postoperative residual refractive cylinder of 0.5 D or less represented 90% (27 eyes) of the first group versus 83.3% (25 eyes) of the second group (*P* = 0.164).

Vector analysis was used to calculate the deviation vector (DV) which represents the difference between the targeted induced astigmatism (TIA) and the actual postoperative refractive cylinder. The mean deviation from TIA for the first group was 0.10 + 0.08 D (range 0.02–0.40 D). The mean deviation from TIA for the second group was 0.20 + 0.14 D (range 0.04–0.6 D). There was a statistically significant difference between the 2 groups (*t* = -3.449, *P* = 0.001). All eyes of the first group were within +0.5 D of the TIA versus 29 eyes (96.67%) of the second group.

The mean postoperative toric IOL misalignment measured by the slitlamp was 2.4° + 1.96° (range from 0 to 7°) for the first group and was 4.33° + 2.72° (range from 1° to 12°) for the second group. This was significantly different (*t* = -3.159, *P* = 0.003). Postoperative toric IOL misalignment of 5° or less occurred in 27 eyes (90%) of the first group in comparison to 25 eyes (83.3%) of the second group. Table 1 summarizes the comparison between VERION-guided group and manual-marking group.

DISCUSSION

Reduction of residual postoperative refractive astigmatism improves UCDVA after the cataract surgery. Toric IOL implantation during cataract surgery allows treating coexisting corneal astigmatism. Villegas et al²⁶ mentioned that correcting corneal astigmatism of < 0.50 D does not improve visual outcome after the cataract surgery. In the current study, patients were selected to have > 1 D of corneal astigmatism to get benefit from toric IOL. Holland et al²⁷ stated that patients with > 0.75 D of corneal astigmatism had better visual outcome with implantation of toric IOLs more than with implantation of monofocal IOLs as more patients achieved an UCDVA > 0.3 logMAR and had a lower mean absolute residual refractive astigmatism.

The toric IOL has marks that indicate the flat meridian (plus cylinder axis). Precise alignment of the toric IOL during surgery is the most important step in achieving the desired effect of the calculated astigmatism correction. When the toric IOL is misaligned or rotates postoperatively, there is a reduction in its effect on the planned axis of alignment and introduction of a new astigmatism in another axis. Approximately, there is 3% to

TABLE 1. Comparison Between VERION-Guided Group and Manual-Marking Group

	VERION-Guided Group Mean ± SD	Manual-Marking Group Mean ± SD
Age, years	49.5 ± 11.4	52.0 ± 13.0
Preoperative cylinder, D	2.58 ± 0.89	2.49 ± 0.87
Postoperative UCDVA, logMAR	0.12 ± 0.12	0.18 ± 0.14
Postoperative cylinder, D	0.28 ± 0.28	0.34 ± 0.33
Deviation from TIA, D	0.10 ± 0.08	0.20 ± 0.14
Toric IOL misalignment, °	2.40 ± 1.96	4.33 ± 2.72

D = diopter, IOL = intraocular lens, TIA = targeted induced astigmatism, SD = standard deviation, UCDVA = uncorrected distance visual acuity.

3.5% residual astigmatism for every 1° of toric IOL rotation. This means that with 30° of rotation there is 100% of residual astigmatism but on a different axis.²⁸ Preoperative manual marking or capturing of the reference image should be done while the patient is in a sitting position to avoid the effect of cyclotorsion. Upon lying down, around 2° to 3° of cyclotorsion occurs. It is reported that this cyclotorsion can reach up to 14°.^{20,29}

The advantage of the VERION system is the integration of preoperative capturing of a reference image, obtaining the keratometry readings, preoperative planning of the surgery including incision site and toric IOL choice and power, and intraoperative guidance with an overlay over the live view. In the current study, manual preoperative marking was done by pendulum-attached marker because studies showed it had more accurate results among manual-marking techniques.^{20,21}

As regards the included patients of the 2 groups, there was no statistically or clinically significant difference in their age, sex composition, and preoperative corneal astigmatism levels. Patients with digital marking showed clinically better visual outcome as regards mean postoperative UCDVA and the percentage of cases with UCDVA > 0.3 logMAR. This difference was not statistically significant. In the current study, patients achieving postoperative UCDVA > 0.3 logMAR represented around 90% to 93% of the cases. The reported percentage of patients achieving postoperative UCDVA > 0.3 logMAR after toric IOL implantation represented 70% to 100% of the cases.^{30,31}

As regards the refractive outcome, both groups showed marked reduction of preoperative astigmatism around 86% to 89% with no statistically significant difference between the 2 groups. The reported percentage of patients with postoperative residual refractive astigmatism < 0.5 D after toric IOL implantation represented 25% to 100% of the cases.^{32,33} However, the digital-marking group showed statistically significant better refractive outcome as regards the mean deviation from TIA which was 0.10 ± 0.08 D and all eyes were within +0.5 D of the TIA.

The digital-marking group showed statistically significant better results as regards the mean postoperative toric IOL misalignment measured by the slitlamp which was 2.4° ± 1.96°. Postoperative toric IOL misalignment of < 5 occurred in 27 eyes (90%). The reported mean postoperative toric IOL misalignment ranged from 2.5 to 4 D.^{34–36}

In conclusion, accurate alignment of the toric IOL is important to achieve the desired astigmatism correction. VERION system has the advantage of preoperative planning and intraoperative digital guidance of the toric IOL alignment. The use of VERION system resulted in less postoperative deviation

from TIA and showed less postoperative toric IOL misalignment than using manual-marking technique.

REFERENCES

- Lyall D, Srinivasan S, Jia Ng, et al. Changes in corneal astigmatism among patients with visually significant cataract. *Can J Ophthalmol.* 2014;49:297–303.
- Yuan X, Song H, Peng G, et al. Prevalence of corneal astigmatism in patients before cataract surgery in Northern China. *J Ophthalmol.* 2014;Article ID 536412, 7 pages.
- Ninn-Pedersen K, Stenevi U, Ehinger B. Cataract patients in a defined Swedish population 1986–1990. II. Preoperative observations. *Acta Ophthalmol (Copenh).* 1994;72:10–15.
- Hoffer KJ. Biometry of 7500 cataractous eyes. *Am J Ophthalmol.* 1980;90:360–368.
- Aminifard M, Barkhordari-Yazdi H, Eskandari S. Opposite clear corneal incisions versus steep meridian incision phacoemulsification for correction of pre-existing astigmatism. *ZJRMS.* 2015;17:23–26.
- Khan A, Alam M, Afridi MR, et al. Effect of incision site on pre-existing astigmatism in phaco-emulsification. *Pak J Ophthalmol.* 2014;30:46.
- Lee H, Kim EK, Kim HS. Fourier-domain optical coherence tomography evaluation of clear corneal incision structure according to blade material. *J Cataract Refract Surg.* 2014;40:1615–1624.
- Na JK, Kim MS. The comparison of astigmatic outcomes after cataract surgery of inferior versus superior clear corneal incision. *J Kor Ophthalmol.* 2014;55:1470–1475.
- Nemeth G, Kolozsvari B, Berta A, et al. Paired opposite clear corneal incision: time-related changes of its effect and factors on which those changes depend. *Eur J Ophthalmol.* 2014;24:676–681.
- Waltz KL, Featherstone K, Tsai L, et al. Clinical outcomes of TECNIS toric intraocular lens implantation after cataract removal in patients with corneal astigmatism. *Ophthalmology.* 2015;122:39–47.
- Goggin M, Zamora-Alejo K, Esterman A, et al. Adjustment of anterior corneal astigmatism values to incorporate the likely effect of posterior corneal curvature for toric intraocular lens calculation. *J Refract Surg.* 2015;31:98.
- Hirschall N, Gangwani V, Crnej A, et al. Correction of moderate corneal astigmatism during cataract surgery: toric intraocular lens versus peripheral corneal relaxing incisions. *J Cataract Refract Surg.* 2014;40:354–361.
- Lim R, Borasio E, Ilari L. Long-term stability of keratometric astigmatism after limbal relaxing incisions. *J Cataract Refract Surg.* 2014;40:1676–1681.
- Ouchi M. High-cylinder toric intraocular lens implantation versus combined surgery of low-cylinder intraocular lens implantation and limbal relaxing incision for high-astigmatism eyes. *Clin Ophthalmol (Auckland, NZ).* 2014;8:661.

15. Nagy ZZ, Dunai A, Kránitz K, et al. Evaluation of femtosecond laser-assisted and manual clear corneal incisions and their effect on surgically induced astigmatism and higher-order aberrations. *J Refract Surg.* 2014;30:522.
16. Sklar J, Tan J, Nadji EF, Donnenfeld ED. Corneal astigmatic correction by femtosecond laser incisions. In. *Cataract Surgery: Maximizing Outcomes Through Research.* Japan.: Springer; 2014
17. Mori Y, Nejima R, Terada Y, et al. Femtosecond laser-assisted astigmatic keratotomy for astigmatic correction in pseudophakic eyes. *Invest Ophthalmol Vis Science.* 2014;55:1553–1555.
18. Visser N, Berendschot TT, Bauer NJ, et al. Accuracy of toric intraocular lens implantation in cataract and refractive surgery. *J Cataract Refract Surg.* 2011;37:1394–1402.
19. Farooqui JH, Sharma M, Koul A, et al. Evaluation of a new electronic pre-operative reference marker for toric iol implantation by two different methods of analysis: adobe photoshop versus iTrace. *Adv Ophthalmol Vis Syst.* 2015;2:57.
20. Popp N, Himschall N, Maedel S, et al. Evaluation of 4 corneal astigmatic marking methods. *J Cataract Refract Surg.* 2012;38:2094–2099.
21. Woo YJ, Lee H, Kim HS, et al. Comparison of 3 marking techniques in preoperative assessment of toric intraocular lenses using a wavefront aberrometer. *J Cataract Refract Surg.* 2015;41:1232–1240.
22. Holzer M. Evaluation of Image Guidance System During Cataract and Refractive Surgery. In 2015 ASCRS ASOA Symposium and Congress. Ascrs, 2015.
23. Coleman M, Stark W, Daoud Y. A comprehensive guide to managing astigmatism in the cataract patient. *Exp Rev Ophthalmol.* 2014;9:539–544.
24. Chaudhary G, Holladay J, Sarayba M, et al. Surgical guidance and planning software for astigmatism treatment. *US Patent Application 14/312,187, filed June 23.* 2014.
25. Ventura BV, Wang L, Weikert MP, et al. Surgical management of astigmatism with toric intraocular lenses. *Arquivos Brasileiros de Oftalmologia.* 2014;77:125–131.
26. Villegas EA, Alcon E, Artal P. Minimum amount of astigmatism that should be corrected. *J Cataract Refract Surg.* 2014;40:13–19.
27. Holland E, Lane S, Horn JD, et al. The AcrySof Toric intraocular lens in subjects with cataracts and corneal astigmatism: a randomized, subject-masked, parallel-group, 1-year study. *Ophthalmology.* 2010;117:2104–2111.
28. Ma JJ, Tseng SS. Simple method for accurate alignment in toric phakic and aphakic intraocular lens implantation. *J Cataract Refract Surg.* 2008;34:1631–1636.
29. Febbraro JL, Koch DD, Khan HN, et al. Detection of static cyclotorsion and compensation for dynamic cyclotorsion in laser in situ keratomileusis. *J Cataract Refract Surg.* 2010;36:1718–1723.
30. Entabi M, Harman F, Lee N, et al. Injectable 1-piece hydrophilic acrylic toric intraocular lens for cataract surgery: efficacy and stability. *J Cataract Refract Surg.* 2011;37:235–240.
31. Cervantes-Coste G, Garcia-Ramirez L, Mendoza-Schuster E, et al. High-cylinder acrylic toric intraocular lenses: a case series of eyes with cataracts and large amounts of corneal astigmatism. *J Refract Surg.* 2012;28:302–304.
32. Dick HB, Krummenauer F, Trober L. Compensation of corneal astigmatism with toric intraocular lens: results of a multicentre study. *Klin Monbl Augenheilkd.* 2006;223:593–608 German.
33. Lichtinger A, Sandstedt CA, Schwartz DM, et al. Correction of astigmatism after cataract surgery using the light adjustable lens: a 1-year follow-up pilot study. *J Refract Surg.* 2011;27:639–642.
34. Chang D. Comparative rotational stability of single-piece open-loop acrylic and plate-haptic silicone toric intraocular lenses. *J Cataract Refract Surg.* 2008;34:1842–1847.
35. Bauer, Noël JC, de Vries NE, et al. Astigmatism management in cataract surgery with the AcrySof toric intraocular lens. *J Cataract Refract Surg.* 2008;34:1483–1488.
36. Carey PJ, Leccisotti A, McGilligan VE, et al. Assessment of toric intraocular lens alignment by a refractive power/corneal analyzer system and slitlamp observation. *J Cataract Refract Surg.* 2010;36:222–229.