

Evaluation of axis alignment and refractive results of toric phakic IOL using image-guided system

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Abstract

• **AIM:** To evaluate accuracy of axis alignment and refractive results of toric phakic intraocular lens (IOL) implantation using a digital imaging system.

• **METHODS:** This retrospective study investigated toric implantable collamer lens (ICL) implantation in 30 eyes of 21 patients with myopic astigmatism more than 2.0 D guided with digital imaging system. Data were collected during the first week after phakic IOL implantation.

• **RESULTS:** Thirty eyes of 21 patients were included in our study. Patients includes 9 males and 12 females. The mean age of the patients was 26.5±7.1 (range 21-44)y. The mean preoperative manifest astigmatism was 3.2±1.7 (range from 2.25 to 4.75) D. The mean postoperative uncorrected distance visual acuity (UCDVA) were 0.07±0.07 (range from 0.1 to 0.0) logMAR. The mean postoperative residual refractive cylinder was 0.25±0.29 (range 0-0.75) D. Eyes with postoperative residual refractive cylinder of 0.5 D or less represented 80% (24 eyes). The mean postoperative toric IOL misalignment measured by the OPD scan III was 1.9°±1.45° (range from 0 to 5°).

• **CONCLUSION:** Image guided system allows accurate alignment of toric ICL. This is associated with good postoperative visual acuity and low residual refractive astigmatism which correlates with the precision of toric phakic IOL alignment.

• **KEYWORDS:** myopic astigmatism; toric intraocular lenses; image guided system

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INTRODUCTION

Phakic intraocular lens (pIOL) is a good treatment option for patients who are not suitable for laser refractive surgery^[1]. pIOL designed for either anterior chamber (AC PIOL) or posterior chamber (PC PIOL) implantations. Both designs offer correction of high spherical and astigmatic errors. Toric pIOL has shown high efficacy and satisfactorily results for correction of high myopic astigmatism after corneal transplantation^[2] or in patients with stable keratoconus^[3]. Proper alignment is crucial to achieving effective astigmatism correction. One degree of IOL rotation off axis can reduce the astigmatic correction by 3.3%, five degrees of misalignment will reduce the expected results by about 17%^[4].

A three-step procedure helps in IOL alignment within 5° of the targeted axis^[5]. The most important step is the preoperative marking of the horizontal axis (0-180°) while the patient in upright sitting to avoid cyclotorsion. Marking the horizontal meridian can be done manually under the guidance of different methods that include slit lamp with a horizontal slit beam, slit lamp-assisted marking with a pendulum-attached marker, or non-pendular marker with a surgeon's direct visualization^[6].

New technologies aim to decrease subjective mistakes associated with manual marking. Many image-guided modalities have been developed to provide guidance and ensure precise alignment of toric IOL^[7-9].

The most common used image-guided systems are: the Alcon Verion Image-Guided System (Alcon Laboratories, Inc., Fort Worth, Texas, USA), Callisto Eye and Z align (Carl Zeiss Meditec AG, Dublin, CA, USA) the iTrace with Zaldivar Toric Caliper (Tracey Technologies, Houston, TX, USA) and TrueVision 3-D Surgical System (TrueVision Systems, Inc., Santa Barbara, California, USA)^[10-11].

The main aim of the current study is to investigate accuracy of axis orientation, visual and refractive outcome of toric pIOL implantation using digital imaging system.

SUBJECTS AND METHODS

Ethical Approval All patients signed written informed consent. The study conforms to the tenets of the Declaration of Helsinki. Clinical study registration number: ACTRN12619000875101. Thirty eyes of 21 patients underwent toric pIOL implantation [implantable collamer lens (ICL), Visian; STAAR Surgical, Nidau, Switzerland] to correct high myopia and myopic

astigmatism. Intraoperative image guided system was used to rotate the toric ICL to the planned axis.

Patients should be over 21 years of age with stable refraction for at least 2y. Anterior chamber depth (ACD) should be equal or greater than 3.0 mm from the endothelium. Patients with other ocular pathology were excluded.

Power calculation was performed using manufacture software (STAAR Surgical Co.). It allows the calculation of the spherocylindrical power and lens size. It also generates an implantation diagram to demonstrate the amount and direction of rotation from the horizontal axis (Figure 1).

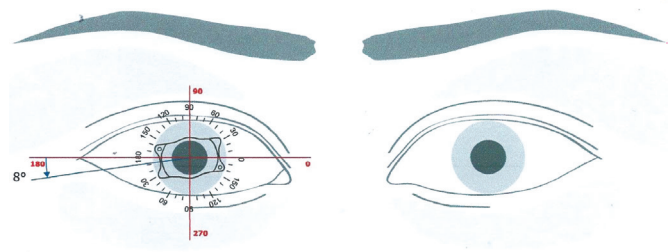
VERION (Alcon Laboratories, Inc., Fort Worth, Texas, USA) uses high-resolution preoperative image. The software auto-detects limbus, the location of limbal vessels, scleral vessels, and iris features, which were used for intraoperative image registration. Data was exported to the VERION digital marker (VDM) in the operating room. The VERION system matches the high-resolution image which was taken preoperatively with the eye during surgery. A limbal protractor and the intended toric IOL axis were displayed over a live view of the eye on an external monitor and through one of the oculars of operating microscopes in real time (Figure 2). It helps to correctly rotate the IOL to an exact degree and control the IOL centration.

In this study, V4C ICL design was used. Under local anesthesia, dilating agents were administered. In a temporal approach, after injection of viscoelastic material (Provisc, Alcon), a 3.2 mm temporal clear corneal incision was made, and the ICL was injected through this incision into the anterior chamber and allowed to slowly unfold. After the injection and unfolding of the toric ICL into the anterior chamber, haptics were inserted under the iris. Toric ICL was positioned on the planned axis intraoperatively by the guide of VERION digital marking. Viscoelastic material was removed with irrigation aspiration.

In postoperative follow up visit: slit lamp examination, tonometry was performed. Residual refractive astigmatism, uncorrected distance visual acuity (UCDVA) and best corrected distance visual acuity (BCDVA) were assessed. Axis alignment was evaluated with OPD scan III (NIDEK Inc., Gamagori, Japan).

RESULTS

Our retrospective clinical study includes 30 eyes of 21 patients. Patients include 9 males and 12 females. The mean age of the patients was 26.5±7.1 (range 21-44)y. The mean preoperative manifest astigmatism was 3.2±1.7 (range from 2.25 to 4.75) D. The mean postoperative UCDVA 0.07±0.07 (range from 0.1 to 0) logMAR. The mean postoperative residual refractive cylinder was 0.25±0.29 (range 0-0.75) D. Eyes with a postoperative residual refractive cylinder of 0.5 D or less represented 80% (24 eyes). Eyes with postoperative residual refractive cylinder of 0.75 D or less represented 100% (30



Rotate lens **counterclockwise 8°** after horizontal implantation
No PIs are required with this lens

Figure 1 Toric ICL implantation diagram.

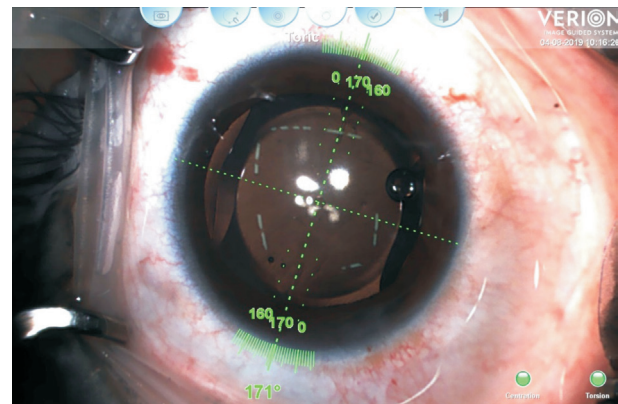


Figure 2 Image from VERION to guide toric lens alignment.

eyes). The mean toric lens misalignment measured by the OPD scan III was 1.9°±1.45° (range from 0 to 5°).

DISCUSSION

Accurate alignment of a toric pIOL is critical factor to achieve the best cylinder correction. In this study, we evaluated the accuracy of a digital imaging system, used to align the toric pIOL intraoperatively.

The mean postoperative UCDVA 0.07±0.07 (range from 0.1 to 0) logMAR. The mean postoperative residual refractive cylinder was 0.25±0.29 (range 0-0.75) D. Eyes with postoperative residual refractive cylinder of 0.5 D or less represented 80% (24 eyes). Eyes with postoperative residual refractive cylinder of 0.75 D or less represented 100% (30 eyes). The mean toric pIOL deviation was 1.9°±1.45° (range from 0 to 5°).

Visser *et al*^[5] evaluated the accuracy of a 3-step ink marker technique for toric IOL and pIOL implantation. They concluded that a commonly used 3-step ink-marker procedure led to a mean error in IOL orientation of 4.9°. They found that the error is more common when high cylinder power IOLs were implanted.

In a study compared the visual outcome of digital and manual marking for toric IOL alignment. The mean postoperative UCDVA was 0.12+0.12 logMAR and 0.18+0.14 logMAR, for the digital-marking group and manual-marking group respectively, which was not statistically significant. The mean postoperative toric IOL misalignment measured by the slit

lamp for the digital-marking group ($2.48^{\circ} \pm 1.968^{\circ}$) was lower than that for the manual-marking group ($4.338^{\circ} \pm 2.728^{\circ}$), which is clinically significant. They concluded that the VERION system resulted in more accurate toric IOL alignment than using manual-marking technique^[9].

In a study compared efficacy and outcome of phakic toric ICL and refractive clear lens extraction with toric IOL for the treatment of myopic astigmatism (1-4 D). Preoperatively, horizontal axis was marked at the slit lamp. The mean postoperative cylinder value was -0.46 ± 0.53 D in toric ICL group and -0.32 ± 0.41 D in toric IOL group. Postoperative cylinder was less than 1 D in 76.47% of eyes in toric ICL group and 79.31% of eyes in toric IOL group^[12].

In two studies of Webers *et al*^[8,13] compared the accuracy of toric IOL alignment with the VERION Image-Guided System versus a manual marking method. The mean error of toric IOL alignment was significantly lower in the image-guided group comparing with the manual group in the first hour ($1.3^{\circ} \pm 1.6^{\circ}$ vs $2.8^{\circ} \pm 1.8^{\circ}$) and at three months ($1.7^{\circ} \pm 1.5^{\circ}$ vs $3.1^{\circ} \pm 2.1^{\circ}$) postoperatively. The mean residual refractive astigmatism was 0.36 ± 0.32 D and 0.47 ± 0.28 D in the image-guided group and manual group, respectively. The mean UCDVA was 0.03 ± 0.10 logMAR and 0.04 ± 0.09 logMAR, respectively. All eyes achieved a refractive cylinder of 1.0 D or less. A refractive cylinder of 0.5 D and 0.25 D was achieved in 81% and 50% in the VERION-group compared to 71% and 33% in the manual-group. They concluded that although the error of IOL alignment was significantly less with digital marking, this did not improve the UCDVA or decrease the residual astigmatism. In a study compared the efficacy of image guided system for toric IOLs (Callisto Eye System) with manual marking techniques. More precise alignment of toric IOL was found with image-guided system group comparing with the manual group ($2.0^{\circ} \pm 1.86^{\circ}$ vs $3.4^{\circ} \pm 2.37^{\circ}$). No statistically significant difference was found in visual outcome in both groups^[7].

A comparative study assessed the accuracy of alignment of toric IOL assisted by manual bubble marker and Callisto Eye image-guided system. Deviation from the planed axis is significantly lower with Callisto Eye image-guided system ($3.6^{\circ} \pm 2.6^{\circ}$) compared to that with manual marking ($5.5^{\circ} \pm 3.3^{\circ}$). Postoperative astigmatism was -0.89 ± 0.35 D in manual marking group and -0.64 ± 0.36 D in image guided system. They concluded that although visual acuity was comparable between the two groups, visual quality was better in the image-guided group and this difference was clinically significant^[14].

Misalignment Many studied concluded that image-guided systems is more accurate than different methods of manual marking. Our findings showed that the mean axis misalignment of our patients was 1.9° . These results are comparable to those seen in other studies in which axis misalignment ranged from

1.3° to 3.6° ^[5,7-9,12-14]. The mean axis misalignment of manual marking patients in other studies ranged from (1.8° to 5.5°)^[5,7-9,12-14]. It is crucial to measure the axis misalignment in the early postoperative period to eliminate the factor of possible lens rotation^[15]. Woo *et al*^[6] concluded that the pendulum is the most accurate method of all manual marking techniques.

Residual Astigmatism The mean postoperative residual refractive cylinder in our patients was 0.25 ± 0.29 D. In other studies, the mean residual astigmatism of the image-guided system ranged from 0.36 to 0.64 D^[8,12-14]. While the mean residual astigmatism of manual marking patients ranged from 0.46 to 0.89 D^[12-14]. About 80% of the eyes in our study have a postoperative residual refractive cylinder of 0.5 D or less, and 100% (30 eyes) have a refractive cylinder of 0.75 D or less. In a study conducted by Webers *et al*^[8,13], 100% of eyes achieved a refractive cylinder of 1.0 D or less. A refractive cylinder of 0.5 D and 0.25 D was achieved in 81% and 50% in the VERION-group compared to 71% and 33% in the manual-group. Titiyal *et al*^[14] reported that astigmatism was less than 1 D in 76.47% of eyes in toric ICL group and in 79.31% of eyes in toric IOL group. Manual marking was used in both groups. A study conducted by Raucau *et al*^[6] concluded that residual astigmatism due to axis deviation becomes higher in proportion to the cylinder power of the toric IOL.

Visual Acuity The mean postoperative UCDVA in our study is 0.07 ± 0.07 (range from 0.1 to 0) logMAR. The range of the mean postoperative UCDVA in the other reviews was 0.03 to 0.12 logMAR for the image-guided group and 0.04 to 0.18 logMAR for the manual marking group. It was observed that all studies did not report any significant difference between digital and manual groups regarding UCDVA and BCDVA at follow-up timepoint^[8-9,13-14]. One study reported significant improvement of quality of vision in the image-guided group^[14]. In a clinical survey performed by the ASCRS in 2018, more than 65% of respondents think 5 degrees of postoperative rotation or less is acceptable before it can affect the visual quality and acuity^[17].

In conclusion, digital marking system is more accurate in aligning toric IOLs and toric pIOLs to the planned axis. Many studies did not show a significant advantage in terms of visual acuity using the digital marking system. Further studies needed to assess whether the current difference between manual marking and digital marking is clinically significant, especially in cases with high degree of corneal astigmatism.

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Conflicts of Interest: Emerah S, None.

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