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Research Article

A New Intra-Operative Tool for Toric IOL Alignment during Cataract Surgery

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Abstract

Purpose: To compare a novel intra-operative keratometry diagnostic technique to pre-operative manual marking technique (manual pre-operative reference marking and intra-operative axis marking) of toric intraocular lens alignment during cataract surgery.

Design: It is a retrospective study designed to identify and analyze differences between intra-operative digital marking system and pre-operative manual marking for steep meridian location on the anterior corneal surface. No randomization and masking were applied as all eyes were measured with both methods.

Methods: Patients with pre-existing corneal astigmatism planned for cataract surgery were selected between age 60 - 80 years. Exclusion criteria were inability to fixate due to any ocular pathology, patients who received retro or peribulbar block, and patients with any corneal pathology (Fuchs', EBMD, keratoconus, advanced pterygium, dry cornea), or amblyopia with inability to fixate. All patients were performed cataract surgery with pre-planned toric IOLs and aligned based on the axis indicated by Lenstar 900 (Haag-Streit AG). Sirius topographer (CSO) was used to confirm angle of astigmatism pre-operatively. Each eye was also measured intra-operatively with Polaris Keratoscope (Keen Sight, Inc.).

Results: 10 eyes were included. A large positive linear correlation was found between preoperative manual reference marking and intra operative axis marking as compared with Polaris Keratoscope ($r = 1.025$, $R^2 = 0.985$) with one outlier ($> 3\sigma$).

Conclusion: Polaris Keratoscope was found to be a useful and reliable new toric IOL alignment digital tool in the arsenal of cataract surgeons.

Keywords: *Toric IOL; Intra-Operative Diagnostics; Cataract Surgery; Biometry; Astigmatism; Aberrometry*

Abbreviations

IOL: Intra-Ocular Lens; D: Diopter

Introduction

The first toric IOLs appeared in Asia and Europe in late 1990-ies [1,2]. In US the first toric IOL approved by FDA in 1998 was STAAR toric IOL [3]. This early design had some rotational stability issues [3]. A wide acceptance of toric IOLs was achieved in US only in 2005, with FDA approval of the one-piece acrylic Acrysof Toric IOL [4]. The first generation of toric IOL alignment techniques comprised of pre-operative keratometry - IOL Master 500 (Carl Zeiss AG) and later Lenstar 900 (Haag-Streit AG) - and ink marking (reference marking of zero/180 deg) in sitting posture and axis marking intraoperatively (manual and ink) [5,6]. This is needed due to cyclotorsion of the eye in supine position [7]. The second generation of toric IOL alignment technology involved digital marking - Verion (Alcon, Inc.), Callisto (Carl Zeiss AG) and IOL Compass (Leica Microsystems AG). All the above devices mentioned here use a reference image, which is taken during keratometry on a patient in sitting position in the office. This image is later digitally registered against the video frame of patient in supine position. This allows to account for cyclotorsion without the need of ink marking. Because the eye during surgery is dilated and anesthetized - the iris and/or scleral blood vessels, which are used to perform such registration, may change from its original patient's sitting position in the office (the pre-op reference marking). This makes registration of the office eye image against surgery's video frame difficult and introduces additional registration error [8]. This error of translation of an office measurement into OR (Operating Room) is removed in third generation of toric IOL alignment - intra-operative diagnostics. ORA Aberrometer (Alcon, Inc.) is a first intra-operative diagnostic device that was used for toric IOL alignment. This article introduces a second intraoperative device for toric IOL alignment - Polaris Keratoscope (Keen Sight, Inc.). ORA is a wavefront aberrometer based on Talbot-Moiré grid patterns. ORA measures a combined refraction of all ocular media - anterior and posterior cornea, as well as lens. In cataractous eye the combined wavefront is distorted by scatter and imperfections of cataract. And so, ORA measurements are done on aphakic eye - after cataract is removed by surgeon. This requires a special preparation of the eye for measurement - lowering IOP, hydrating incisions - all in an effort to mimic a condition of unperturbed eye for best biometry results. Polaris Keratoscope is based on standard Purkinje image-1, that is, anterior corneal reflection. Polaris Keratoscope is mounted on surgical microscope and helps us in acquisition or localizing the steep meridian of the anterior corneal surface intra-operatively on patient in supine position. Thus, the cyclotorsion is accounted for automatically. Polaris Keratoscope displays guidance line for the alignment of the toric IOL, which coincides with the steep meridian of the anterior corneal astigmatism.

Purpose of the Study

The purpose of this study was to study correlation between Gen 1 toric IOL alignment technique (manual ink marking) and Gen 3 Polaris Keratoscope toric IOL guidance. We would also carefully analyze any discrepancies and clinical factors affecting the accuracy of Polaris Keratoscope measurements.

Materials and Methods

All patients, who are planned for cataract surgery pre-operatively, are taken through basic refraction using streak retinoscope under ambient low light room illumination. Wherever applicable the patient's subjective refraction is noted. Patient is subjected to optical biometry reading (Lenstar 900). In those cases, with dense cataract the patient undergoes manual keratometry (B&L) and immersion biometry (Tomey AL-100). Detailed dilated slit lamp examination was done for all the patients. Anterior segment findings were documented. Cataract was graded based on LOCS III grading. Using the Toric calculator by the respective Toric IOL manufacturer companies the Toric IOL power was calculated. All patients were ink marked (reference marking 0/180) with ASICO reference bubble marker in sitting posture. Sirius (CSO) topographer was used to confirm regular astigmatism and to rule out dry eye. Sirius combines Placido disk topography with Scheimpflug tomography (dual rotating and 3D) of the anterior segment. Sirius was used to identify irregular astigmatism and posterior cornea issues. Polaris Keratoscope is an FDA listed device available for sale in the United States. FDA devices are recognized in India and so IRB approval was not required to use Polaris Keratoscope on patients in India. Polaris Keratoscope guidance was not used to align toric IOL in this study. The Toric IOL was aligned according to the manual marking, done intraoperatively, and compared with the Polaris Keratoscope green guidance line. Figure 1 shows Polaris keratoscope mounted on our Lumera I (Zeiss Meditec AG) microscope.

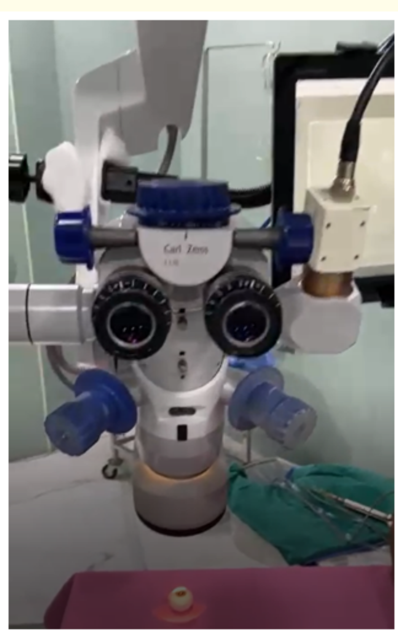

Figure 1: *Polaris Keratoscope mounted on Lumera I microscope in our OR.*

The procedure was started with Polaris Keratoscope measurement on patient in the OR in supine position prior to any incisions. Using a 4.75 mm rhexis marker as a guiding tool, the anterior corneal surface is marked for performing capsulorhexis. Two 1 mm limbal corneal side port incisions were made and one 2.2 mm limbal corneal incision was made temporally using Alcon blades. A 5 mm well centered Continuous Curvilinear Capsulorhexis was performed. Then phacoemulsification [9] was done with Active Fluidics Centurion surgical console (Alcon) using Balanced Tip with Balanced Energy System. Toric IOLs were implanted in the capsular bag and aligned as indicated by the ink markings. Lastly, a photo was taken using Polaris Keratoscope with the infrared retro illumination.

The toric IOL marks are well visible in Polaris Keratoscope image due to infrared retro-illumination. The 860 nm retro-illumination is not visible to patient and does not distract patient in any way. This way the patient is able to fixate on a 2 Hz blinking Red LED of Polaris Keratoscope for best results. Retro-illumination is only visible to a surgeon on a 11" side display of Polaris Keratoscope. The images like the one shown in figure 2 were recorded anonymously in a time-stamped folder and later transferred through a USB stick on a computer used for data analysis.

This helped us document the toric IOL marks on the IOL, as well as the Toric IOL Alignment Guidance Green Line shown on the anterior cornea surface by the Polaris Keratoscope. The green guidance line was calculated by Polaris Keratoscope based on the Purkinje-1 corneal reflections of 12 LED ring. The objective was to see how close or super imposed the green guidance line was with the markings on the Toric IOL, which was aligned with the help of manual axis ink markings.

10 eyes were included in this introductory study of Polaris Keratoscope capability. All patients were implanted toric IOLs. We have focused on determination of the linear correlation between Polaris Keratoscope astigmatism angle guidance and toric IOL alignment based on Lenstar 900 angle readings. The similar linear correlation study was performed between IOL Master 500 and Lenstar 900 at the introduction of the Lenstar 900 [10]. We have excluded patients unable to fixate (retro or peribulbar block) and having corneal pathologies or corneal opacities. Patients with nystagmus were excluded.

Results

Not all angle measurements coincided for Lenstar 900 and Sirius. We believe this is due to different ways of measuring astigmatism in these two instruments, because of difference in technology [10,11]. The typical data that was used to process difference between Polaris Keratoscope astigmatism green angle guidance line and manual intra operative axis mark guidance is shown in figure 2. Here the toric IOL is already injected and aligned using ink marks based on Lenstar measurements.

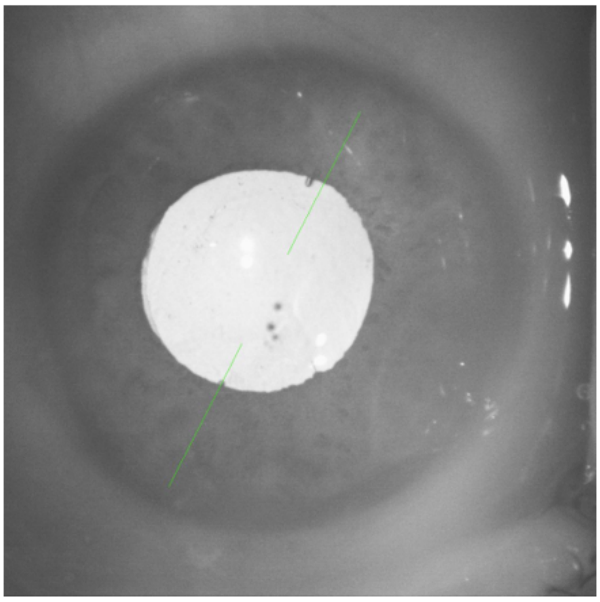

Figure 2: *Patient eye image with Polaris Keratoscope angle guidance line. Toric IOL marks are well visible in Polaris infra-red retro-illumination.*

We have used an InkScape software to manually determine angle of IOL toric marks and angle of Polaris Keratoscope green guidance line for each patient. The accuracy of such angle measurement method was determined by measuring Polaris Guidance line in one image multiple times. The standard deviation of angle measurement (1σ) with such method was found to be 0.06 deg, which was more than sufficient for our analysis. Table 1 gives the result of such analysis for 10 eyes.

Patient No	Angle (deg)		Angle difference D (deg)
	Toric IOL marks with Lenstar 900	Polaris Keratoscope guidance line	
1	107.41	115.54	8.13
2	81.86	79.2	-2.66
3	22.28	21.89	-0.39
4	85.25	81.61	-3.64
5	87.24	78.14	-9.1
6	138.06	147.72	9.66
7	32.78	59.54	26.76
8	66.7	62.99	-3.71
9	95.86	99.51	3.65
10	12.9	3.2	-9.7

Table 1: *Comparison of angle for Polaris Keratoscope guidance line and toric IOL marks, based on ink marking with Lenstar 900.*

The average difference between IOL markings, aligned per Lenstar 900 angle measurement, and Polaris Keratoscope guidance line is 7.7-deg with standard deviation of 5.6-deg. The early versions of Lenstar 900 manuals were giving Angle repeatability of 9-degrees. The angular estimate of an ink mark after 24 hours is typically 5-degrees. We expected to see an error of SQRT(9^2+5^2) = 10-deg, so 7.7-deg is within our expectations. The angle accuracy of Polaris was measured as 1-deg in earlier study [12]. The ANSI Z80.30-2010 standard requires that combined accuracy of toric IOL marks and alignment method should be less than 5-degrees.

There is one outlier in linear correlation plot (Figure 3) - Patient #7 has angle difference between toric IOL marks of Lenstar 900 and Polaris Keratoscope guidance line of 26.76 degrees. This is almost 5 standard deviations out of typical difference and needs to be analyzed for unaccounted factors involved in this patient's measurements.

The plot of Polaris Keratoscope guidance line vs. toric IOL marks per ink marks guided by Lenstar 900 is shown on figure 3.

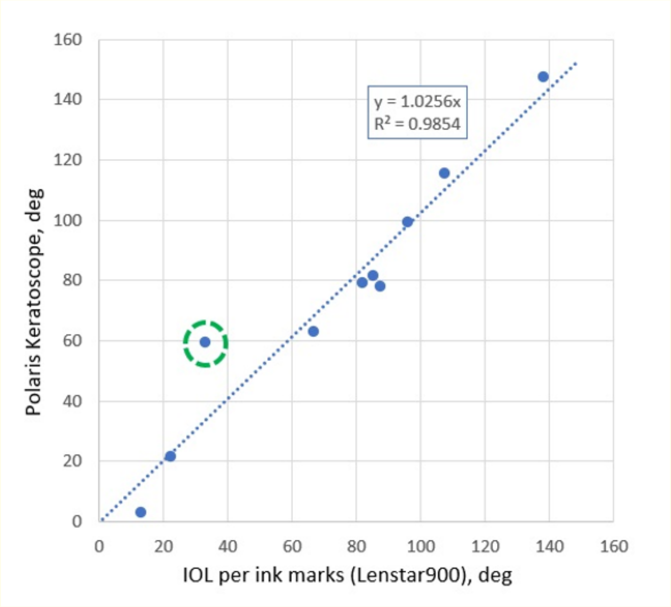

Figure 3: *Linear correlation of Polaris Keratoscope angular guidance with toric IOL aligned per ink marks guided by Lenstar 900.*

Discussion

One can see a good linear correlation in figure 3: y = 1.0256*x and R^2 = 0.9854 ($p < 0.001$ at $\alpha = 0.05$). In case, when we remove outlying Patient #7 data point, it becomes even better: y = 1.0128 * x and R^2 = 0.9946 ($p < 0.001$ at $\alpha = 0.05$). This is a significant linear correlation. And so, we can state that a new Generation 3 intra-operative toric IOL alignment tool has arrived - the Polaris Keratoscope. It adds to the arsenal of tools available for a cataract surgeon to perform toric IOL alignment. The advantage of it is that Polaris Keratoscope provides live intra-operative identification of the steep meridian of the anterior corneal surface with a 1-deg accuracy [12].

Let's review the outlying patient #7 (74-year-old male) data. First, let us check patient's fixation compliance. The pupil is centered in the image of patient's #7 eye taken during Polaris Keratoscope measurement (Figure 4).

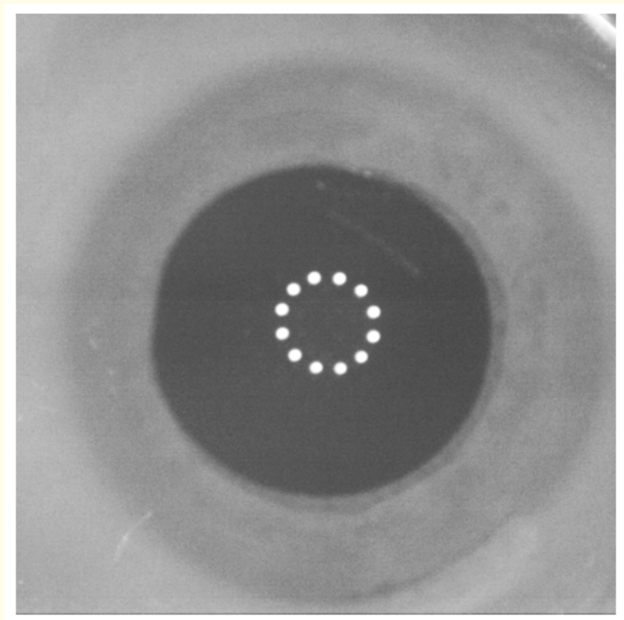

Figure 4: *Patient #7 eye image taken during Polaris Keratoscope angle measurement.*

The algorithm of Lenstar 900 measurement prevents measurements of non-fixated eye. Both Polaris and Lenstar 900 perform Purkinje-1 image based optical keratometry of anterior corneal surface. So, the difference cannot be explained with posterior corneal irregularities. The anterior corneal map of Patient #7 is shown on figure 5.

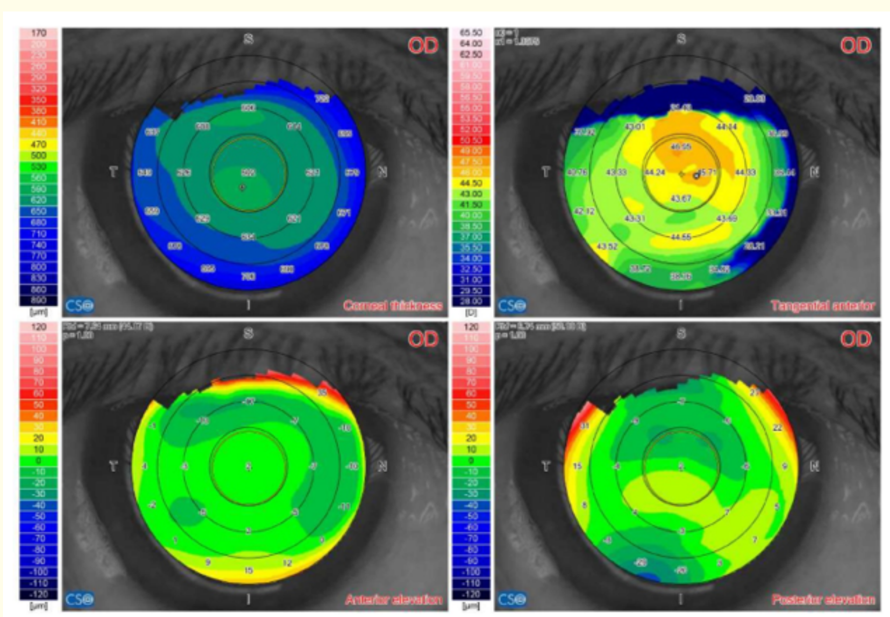

Figure 5: *Patient #7 anterior cornea map taken with Sirius.*

This patient according to the Lenstar had an anterior corneal astigmatism of 0.6D preoperatively. However, as per the Sirius, the anterior corneal astigmatism (sim-K) was 0.3D, which did not match with the Lenstar. But, in this case, we chose to go ahead with a Toric IOL as Lenstar data is always taken into consideration as per normal practice in the hospital. Considering the Sirius sim K values were below Toric recommendation, as a one off case we calculated the net corneal astigmatism by entering the Lenstar anterior corneal values and Sirius posterior corneal values in the online Barrett Toric calculator. The Barrett suggested a T2 toric IOL.

The Polaris did not agree with the steep meridian as indicated by manual marking based on Lenstar axis. We were interested to analyze what could be the reason of this discrepancy. We realized that patient had a N-TBUT (non invasive tear film break up time) of 5.2s, which indicates ocular surface challenges. This was corroborated by the 'damage stream' map and the ' break up map'. Normal tear film and ocular surface is essential to capture the Purkinje-1 based corneal readings properly, the absence of which may interfere with the data acquisition. The anterior topographic map, as displayed in the figure 5, indicates some amount of irregularity. Lenstar uses two diameters to calculate Ks and Angle - 1.65 mm and 2.3 mm. Polaris calculates angle at diameter of 1.8 mm. Because of irregular astigmatism some difference in angle readings may have been due to difference of corresponding diameters of measurement. However, the patient is 6/6 UCVA from one month after surgery and very satisfied.

The first published case of clinical use of Polaris Keratoscope was a European case study [13]. The researchers have reported a 6-deg difference of Polaris Keratoscope astigmatism angle guidance and toric IOL marks aligned per ink marks based on IOL Master 500 (Carl Zeiss Meditec, AG). Our average difference of 7.7-deg (with outlier datapoint) and 5.6-deg (without outlier datapoint) are consistent with this early report. 6-deg is significant for toric IOL alignment as each 3-deg misalignment leads to 10% loss of astigmatism correction efficiency by toric IOL. Thus 6-deg error in toric IOL alignment leads to a 20% loss of astigmatism correction. We believe, this angular difference predominantly comes from angle repeatability error of Lenstar 900 and ink marks angular size. Intra-operative keratometry using a 1-deg accurate Polaris Keratoscope may eliminate such measurement translation errors. This conclusion may also apply to Gen. 2 alignment tools as they too have the translation error - an image registration error.

Conclusion

Until recently only one intra-operative diagnostic instrument existed for toric IOL alignment - ORA Aberrometer (Alcon, Inc.). A second intra-operative diagnostic tool - Polaris Keratoscope (Keen Sight, Inc.) was introduced in 2019 by European researchers [13]. Only one clinical case was reviewed with Polaris Keratoscope and no correlation with any known toric IOL alignment methods was studied until this paper.

In conclusion, a novel microscope mounted intraoperative diagnostic tool for toric IOL alignment - Polaris Keratoscope (Keen Sight, Inc.) - was used clinically in this study. 10 eyes were measured. The statistically significant positive linear correlation with toric IOL aligned via Lenstar 900 ink marks was observed with an average 7 degrees difference. The light loss in microscope due to Polaris Keratoscope was minimal or not appreciable by the operating surgeon. We believe this new instrument will be a welcome addition to the arsenal of diagnostic tools for cataract surgeons.

Acknowledgments

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Disclosure

No financial interest with Keen Sight, Inc.

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