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Research Article

Novel Microscope Mounted Digital Keratoscope for Intra-Operative Toric IOL Alignment

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Abstract

A novel intra-operative device-Polaris keratoscope-was used to measure and display astigmatism angle during cataract surgery with 1-degree accuracy. The astigmatism angle guidance from Polaris was compared to hospitals standard practice using Zeiss IOL Master 500. 6 degrees difference was observed. The infrared retro-illumination provided by Polaris had sufficient contrast for toric IOL marks observation.

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

Abbreviations

IOL: Intra-Ocular Lens; IOP: Intra-Ocular Pressure; D: Diopter; fps: Frames Per Second

Introduction

Toric IOLs received acceptance in Europe for ocular astigmatism correction in late nineties-before they have become mainstream in the United States [1]. The first toric IOL approved by FDA in 1998 was STAAR toric IOL (STAAR Surgical Co, Monrovia, CA, USA) [2]. It had issues with long-term rotational stability and was not widely accepted. Only in 2005, with FDA approval of the one-piece acrylic Acrysof Toric IOL (Novartis/Alcon, Inc., Fort Worth, TX, USA) a wide acceptance of the technology was achieved among US ophthalmologists.

Currently, majority of toric IOLs are aligned by measuring astigmatism angle using keratometry function of IOL Master 500 (Carl Zeiss Meditec, AG, Jena, Germany), Lenstar (Haag-Streit Holding, AG, Koeniz, Switzerland) or corneal topographers, such as Atlas 9000 (Carl Zeiss Meditec, AG, Jena, Germany). A zero angle (horizontal line) is then marked with ink and those ink marks are used during surgery to mark astigmatism angle with angle markers like Bores Two-Ray Corneal Meridian Marker (Mastel Precision Surgical Instruments, Inc., Rapid City, SD, USA). Such ink mark techniques have up to 5-degrees astigmatism angle error. Corneal micro-scratches marking astigmatism angle have smaller angular size and may provide for better alignment. Efforts were made to use image registration of the eye to display intra-surgically the astigmatism axis that was measured during office visit-Verion (Novartis/Alcon, Fort Worth, TX), Callisto (Carl Zeiss Meditec, AG, Jena, Germany), IOL Compass (Leica Microsystems, Wetzlar, Germany). But the accuracy of this method is limited by significant difference of the eye condition of patient's eye during office measurement, when reference image and astigmatism measurement are taken, and patient's eye during surgery due to anesthetics and pupil dilation.

The only widely recognized instrument for intra-operative astigmatism measurement and toric IOL alignment currently is the ORA aberrometer (Novartis/Alcon, Fort Worth, TX). ORA aberrometer measures the combined refractive power of patient's eye-anterior and posterior cornea and lens. As such, cataractous lens is typically removed and ORA measurement is done on aphakic eye. Special eye prepping is required-lowering IOP, closing incisions-for ORA measurement, which takes time, skill and contributes to measurements variability.

40% to 65% of patients over 65 y.o. by different estimates can benefit from astigmatism correction in their vision [3]. But current acceptance of toric IOLs is much lower due to lack of precise and economical instruments for intro-operative toric IOL alignment. This paper is describing first clinical tests done with new intra-operative device that can change toric IOL acceptance levels-Polaris microscope-mounted keratoscope (Keen Sight, Inc., Minneapolis, MN) with Digital Assistant automatic astigmatism angle guidance.

Materials and Methods

A prototype of the microscope-mounted Polaris keratoscope with Digital Assistant function has been used during a single case (two eyes) of high-diopter astigmatic cataract patient phacoemulsification cataract microsurgery (Figure 1).

Figure 1: *Polaris Keratoscope with tablet PC display, mounted on Zeiss OPMI Visu 200 S8 microscope (under microscope objective using dove tail adapter) during clinical tests at Grodno Regional Clinical Hospital.*

Patient's consent was received. The results of Polaris measurements were not used for patient's toric IOL alignment. These results were only used to compare to an astigmatism alignment through standard hospital's procedure for toric IOL alignment.

The standard hospital's toric IOL alignment procedure consists of office IOL Master 500 astigmatism angle measurement (Table 1) and marking angle with two scratches of patient's peripheral cornea using thin hypodermic needle. These scratches are visible during surgery and are used for toric IOL alignment. The scratches heal in about 2 - 3 days. Because scratches have smaller angular dimension-they allow for better alignment accuracy, then ink marks.

OD	K1	42.13D @ 7°	42.13D @ 7°	42.08D @ 7°
	K2	47.14D @ 97°	47.14D @ 97°	47.14D @ 97°
	D	-5.01D @ 7°	-5.01D @ 7°	-5.06D @ 7°
	Avg (D)	42.13/47.14		
OS	K1	42.29D @ 0°	42.29D @ 0°	42.24D @ 0°
	K2	47.40D @ 90°	47.47D @ 90°	47.60D @ 90°
	D	-5.11D @ 0°	-5.18D @ 0°	-5.36D @ 0°
	Avg (D)	42.29/47.47		

Table 1: *IOL Master 500 patient's data.*

The angular accuracy of Polaris microscope-mounted Keratoscope was measured by rotating cornea model with 1D of corneal astigmatism on a precision goniometer. The dispersion of Polaris keratoscope measurements was found to be $\sigma = 0.94$ deg (Figure 2). The Polaris accuracy will further improve for astigmatism higher than 1D.

Because rotation by 5 degrees results in cylindrical power loss of 17% the toric IOL standard ANSI Z80.30-2010 requires that combined accuracy of toric IOL markings and alignment method is less than 5 degrees [4].

The Infiniti cataract surgical console (Novartis/Alcon, Fort Worth, TX, USA) was used for phacoemulsification cataract surgery. OPMI Visu 200 S8 microscope (Carl Zeiss Meditec, AG, Jena, Germany) was used and equipped with Polaris keratoscope (Figure 1).

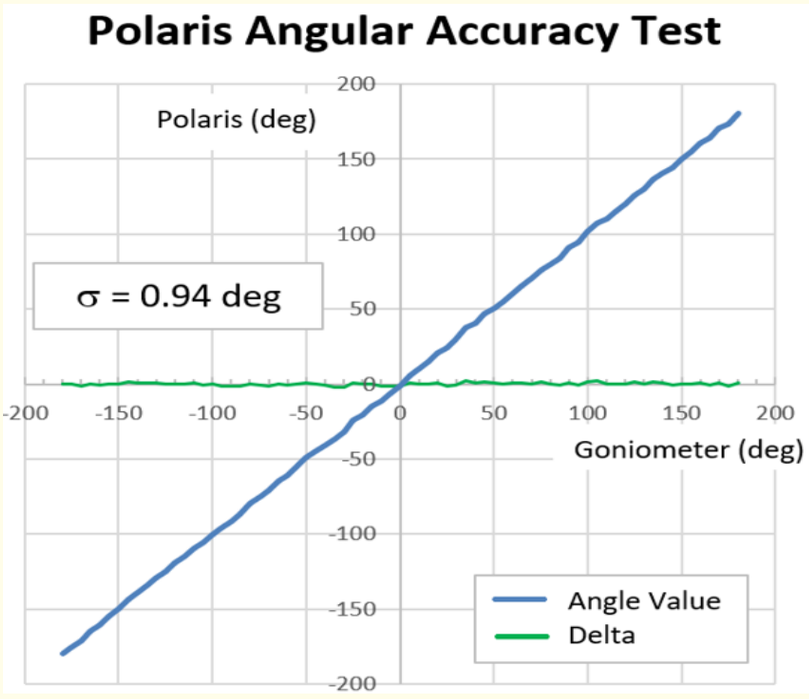

Figure 2: *Polaris angular accuracy plot. Polaris angle measurements are plotted against goniometer angle values (45-degree line). The difference between two angle values is plotted as horizontal line. When statistical dispersion of the Polaris angular measurement is calculated it came to σ = 0.94 deg-approximately 1 deg accuracy.*

Result

A novel instrument for intraoperative diagnostics-Polaris keratoscope with Digital Assistant automatic astigmatism angle guidance function by Keen Sight, Inc. (Minneapolis, MN)-was tested in clinical case of a Toric IOL patient with strong astigmatism (5D). The image of 12 infrared LEDs ring reflected by anterior cornea is acquired by Polaris camera and processed live at 50 fps to determine astigmatism angle (Figure 3).

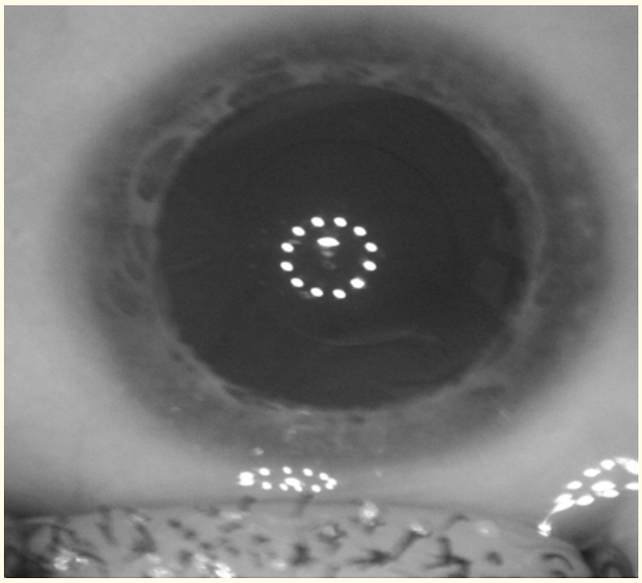

Figure 3: *A frame from Polaris keratoscope infrared HD camera, depicting 12 infrared LEDS of keratometer ring, reflected in patient's cornea. A visible ellipticity of the ring can be used in visual keratoscope mode.*

The Polaris measurements were done prior to making any incisions in the eye. A clear grouping of measured astigmatism angle was observed for each eye, with some statistically insignificant outliers, due to first time clinical use of the instrument by the surgeon (Table 2).

Eye	Meas. 1	Meas. 2	Meas. 3	Meas. 4	Average	St. Dev.	Delta w/ IOL Master 500
OD	2.43	0.91	5.02	0.45	2.20	2.06	- 4.80
OS	-1.25	-2.22	-1.86	-0.51	-1.46	0.75	- 1.46

Table 2: *Polaris keratoscope intra-operative anterior astigmatism angle measurements and angular difference (Delta) with IOL Master 500/corneal scratches method (In Degrees).*

In a second stage, the Polaris infra-red retro reflection was turned on to provide a "Red Reflex" effect for high contrast visibility of ocular structures and toric IOL markings. The surgeon has found image contrast as sufficient for toric IOL alignment using a microscope mounted 11" touch screen display of Polaris (Figure 4).

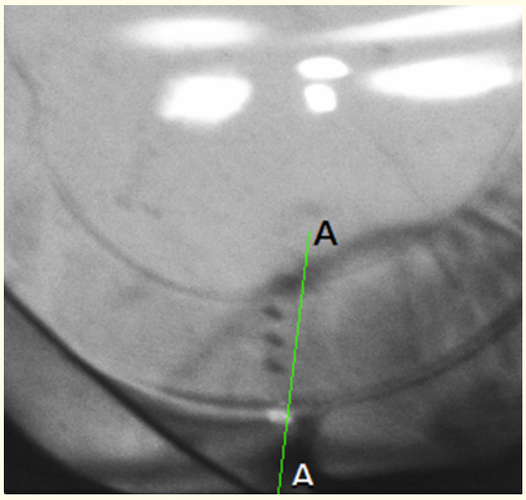

Figure 4: *Digital Assistant software of Polaris keratoscope allows for automatic calculation and projection of astigmatism angle line, superimposed on live camera image of patient's eye. This image demonstrates 6-degree angular difference between toric IOL alignment, using pre-operative IOL Master 500 measurement with corneal scratch marks and digital guidance by Polaris keratoscope (A-A line).*

Patient was a 57 y.o. Caucasian male with high astigmatism in both eyes (Table 1). The toric IOLs (OD: Alcon Acrysof IQ Toric IOL SN6AT9, OS: Alcon Acrysof IQ Toric IOL SN6AT9) were implanted in both patient's eyes in two surgeries, separated 1 week apart. Because patient was used to be myopic all his life target refraction was chosen to be not emmetropic, but moderately myopic-2.5D, for patient's comfort. Post-operatively patient had 20/20 best corrected vision in both eyes. For distance vision patient was prescribed glasses with OD = -2,5D and OS = -2,5D sphere correction. No cylinder correction was needed, as residual astigmatism was measured at OD = 0,25D, OS = 0,5D. The residual astigmatism was "with-the-rule"-patients are normally tolerable to 0.5D of "with-the-rule" astigmatism, unlike "against-the-rule" astigmatism. As a result, patient was highly satisfied with surgery outcomes.

Discussion

Because of cyclotorsion the absolute value of astigmatism angle in sitting patient and lying (decubitus) one is expected to be from 0 to 17 degrees [5]. Additionally, the position of surgeon with respect to patient may differ from 0, 90 and 180 degrees, that Polaris can correct for. We expected up to 5 degrees of angle difference just due to surgeon's position factor. The observed differences between astigmatism angle measured intra-operatively by Polaris keratoscope and IOL Master 500 during office measurements are shown in table 2. These differences are lower than can be expected based on expected cyclotorsion and doctor position misalignment. More statistics needed to understand this quantitatively.

Regardless of absolute values of astigmatism angles both methods-IOL Master 500 and Polaris-should ultimately result in identical toric IOL alignment. Figure 4 depicts alignment of toric IOL, which was done using IOL Master 500 measurements and cornea scratch marks, the three toric IOL marks depict final IOL alignment angle. The green line A-A is digitally projected astigmatism angle guidance line, as generated by Polaris keratoscope Digital Assistant. This line will be used in future by Polaris users to align toric IOLs. The angle between Toric IOL marks line and green line A-A is 6 degrees. This is due to a combined error of Polaris (1 deg) and IOL Master 500/scratch marks method (unknown degree value).

Another interesting observation is a good contrast of IOL marks in infra-red retro-illumination, generated by Polaris. We believe this contrast is sufficient for toric IOL alignment, using Polaris keratoscope Digital Assistant generated green astigmatism angle guidance line A-A (Figure 4). The brightness of retro-illumination can be adjusted to account for different patient's fundus reflectivity.

The time of Polaris alignment on patient's eye was around 1 - 2 minutes. The time of measurement was around 1 sec. Each Polaris measurement acquires and processes N = 50 images of 12-LED keratometer ring reflected by patient's cornea. We believe this measurement does not disrupt overall surgery flow and is acceptable timewise. No special eye preparation is needed for measurement. Polaris has red blinking (2Hz) fixation light for patient to fixate.

For those rare patients, having significant posterior cornea astigmatism, as measured during office visit using Cassini keratometer (Cassini Technologies), OCT or Scheimpflug instruments-a Total Cornea astigmatism angle must be used. Polaris keratoscope has an ability to set pre-determined difference between anterior and total cornea astigmatism. In this case, Polaris will measure anterior cornea astigmatism angle, but will rotate astigmatism guidance line, displayed to surgeon by the amount of the offset, to display Total Cornea astigmatism angle.

The outcomes of cataract surgery using toric IOL were favorable for patient that underwent the study. Post-operative examination demonstrated that patient does not require reading glasses. Target refraction of myopia (-2.5D) was achieved. Distance corrective glasses (OD = -2.5D, OS = -2.5D) were prescribed. Patient demonstrated 20/20 best corrected vision in both eyes. The remaining astigmatism was measured at OD = 0.25D, OS = 0.5D. Patient was highly satisfied.

Conclusions

A Novel intra-operative device-Polaris keratoscope-was used in parallel with standard IOL Master 500 technique to measure and display astigmatism angle for toric IOL alignment. A 6 degrees astigmatism angle difference was observed between two methods in single high astigmatism (5D) patient. The infrared retro-illumination, provided by Polaris, achieved high contrast enough for toric IOL marks on-screen observation during alignment.

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Financial Interest

No financial interest with Keen Sight, Inc.

Bibliography

1. A Frohn., *et al*. "Implantation of a toric poly (methyl methacrylate) intraocular lens to correct high astigmatism". *Journal of Cataract and Refractive Surgery* 25.12 (1999): 1675-1678.

2. Majed Alkharashi., *et al*. "Advances in cataract surgery". *Expert Review of Ophthalmology* 8.5 (2013): 447-456.

3. Jos J Rozema. "Optical anatomy variations of the components of normal ocular aberrations". 2015 Wavefront Congress, Hyatt Santa Barbara (2015).

4. Daniel H Chang. "ANSI Standards for Toric IOLs". CRST (2010).

5. Amy E Ciccio., *et al*. "Ocular Cyclotorsion During Customized Laser Ablation". *Journal of Refractive Surgery* 21.6 (2005): S772-S774.

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