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Accuracy of Astigmatism Angle Measurements by Means of Optical Keratometry at Different Astigmatism Values

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Abstract

A novel intra-operative device - Polaris keratoscope - was used to measure and display astigmatism angle of astigmatic cornea models to determine accuracy of optical keratometry measurement at different values of astigmatism.

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

Abbreviations

IOL: Intra-Ocular Lens; IOP: Intra-Ocular Pressure; D: Diopter

Introduction

The first proper design of an optical keratometer was produced almost 300 years ago in 1728 in Paris. It was more of an ophthalmometer as it could also measure other than corneal curvature parameters like anterior chamber. German physiologist Hermann von Helmholtz proposed a popular optical keratometer design in 1851 [1]. The next big step in optical keratometry was Javal and Schiotz keratometer (1881), which is sometimes referred as simply "Javal" [2]. It was produced by various manufacturers, including Woodlyn and Haag-Streit. Javal uses the Scheiner principle: operator views converging reflected rays coming towards the eyepiece through two separate symmetrical apertures. It is not easy to operate as operator needs to maintain in focus multiple mire patterns. But for almost a century it was considered a golden standard. The next influential optical keratometer design came from Bausch and Lomb in 1926.

With the introduction of radial keratotomy method of refractive correction in the 1980-ies the need appeared in doing live optical keratotomy during the surgery. A number of microscope mounted keratometer designs have been proposed. US Patent 4,046,463 gives a design of Placido rings based keratometer that is mounted under surgical microscope. US Patent 4,597,648 describes compact microscope mounted keratometer that uses linear video sensor with scanning optics to capture image of Placido rings, reflected from cornea. US Patent 5,307,096 suggests that computer, analyzing Placido ring Purkinje 1 image, should display an image, representing shape of the cornea. US Patent 5,349,398 suggests that such image be topography map displayed concurrently with surgical operation on the eye. But none of these designs was ever mass produced.

The invention of phacoemulsification by Dr. Kelman [3] has produced a need in a biometry device that can measure all or most of ocular parameters required for biometry formulas to accurately prescribed IOL. Currently, majority IOLs are prescribed using IOL Master 500 (Carl Zeiss Meditec, AG, Jena, Germany), Lenstar 900 (Haag-Streit Holding, AG, Koeniz, Switzerland) and some other devices. Like many designs proposed earlier they use LED ring to produce a reflection in cornea, which is captured by a camera and processed by computer software to calculate Ks and Angle. IOL Master 500 has 6 LEDs ring and Lenstar 900 has 2 rings of 16 LEDs each. The elliptical elongation of the ring image allows systems to calculate astigmatism angle.

The adoption of toric IOL technology for astigmatism correction (2005 in US with FDA approval of the one-piece acrylic Acrysof Toric IOL (Novartis/Alcon, Inc., Fort Worth, TX, USA) increased the demand of accurate astigmatism angle measurements. This is because rotation of toric IOL by 1 degree leads to 3% decrease of astigmatism correction. 10 deg error leads to 33% decrease of astigmatic correction efficiency. 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 most widely used method at this time is to do office astigmatism measurements using biometers, like IOL Master 500 or Lenstar 900 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 which is under anesthesia with pupil dilation/cyclotorsion and under totally different illumination condition.

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.

We have reported the first clinical tests done with new intra-operative device that can change toric IOL acceptance levels - microscope-mounted Polaris Keratoscope (Keen Sight, Inc., Minneapolis, MN) in earlier paper [5]. It is based on the computer analysis of the Purkinje-1 image of 12 LED ring, similar to IOL Master 500 and Lenstar 900, but intra-operatively. As the amount of cornea astigmatism decreases the ellipticity of ring image decreases and the error of determining the angle grows. Because we believe correction of 0.5 Diopter astigmatism can benefit the patient, we explore in this paper the dependence of astigmatism angle accuracy measured via optical keratometry on astigmatism value.

Materials and Methods

A microscope-mounted Polaris keratoscope with Digital Assistant function has been used (Figure 1). We have manufactured 4 acrylic anterior cornea models with astigmatism amounts of 0.5D, 1.0D, 2.0D and 3.0D. The cornea models were mounted on automated angular rotation stage.

Results

The angular accuracy of Polaris microscope-mounted keratoscope was measured by rotating cornea model with 1D of corneal astigmatism on a precision automated rotation stage with an accuracy of 0.01 degree. The dispersion of Polaris keratoscope measurements was found to be $\sigma = 0.94$ deg (Figure 2).

Figure 1: *Polaris Keratoscope with tablet PC display, mounted on Leica M844 microscope (under microscope objective using dove tail adapter) during clinical tests at Pacific ClearVision Institute at Eugene, OR.*

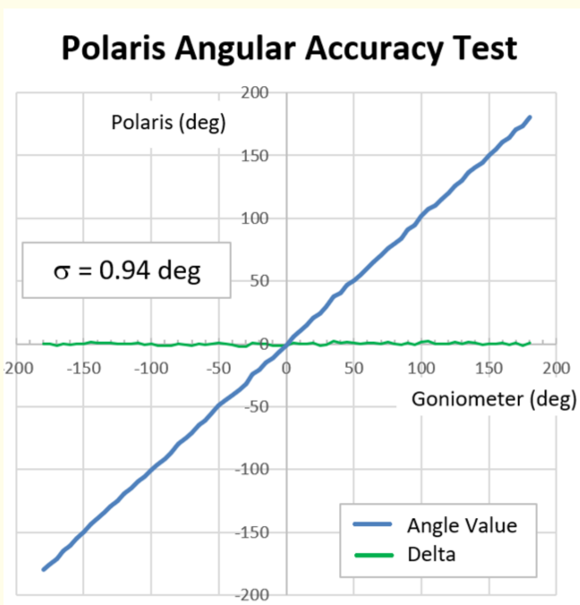

Figure 2: *Polaris angular accuracy plot. Polaris angle measurements are plotted against goniometer angle values (45-degree line). The difference between two angle values is plotted as horizontal line. When statistical dispersion of the Polaris angular measurement is calculated it came to σ = 0.94 deg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

We have studied the manufacturing variability of angle accuracy at 1D-astigmatism on a batch of Polaris Keratoscope units. We have found a batch of 9 units all falling within 0.8 degrees - 1.2 degrees. The averaged by the batch angle accuracy was determined as 0.96°± 0.17°.

We have then proceeded and did the same measurement with cornea models having astigmatism of 0.5D, 2D and 3D. The results are shown in figure 3.

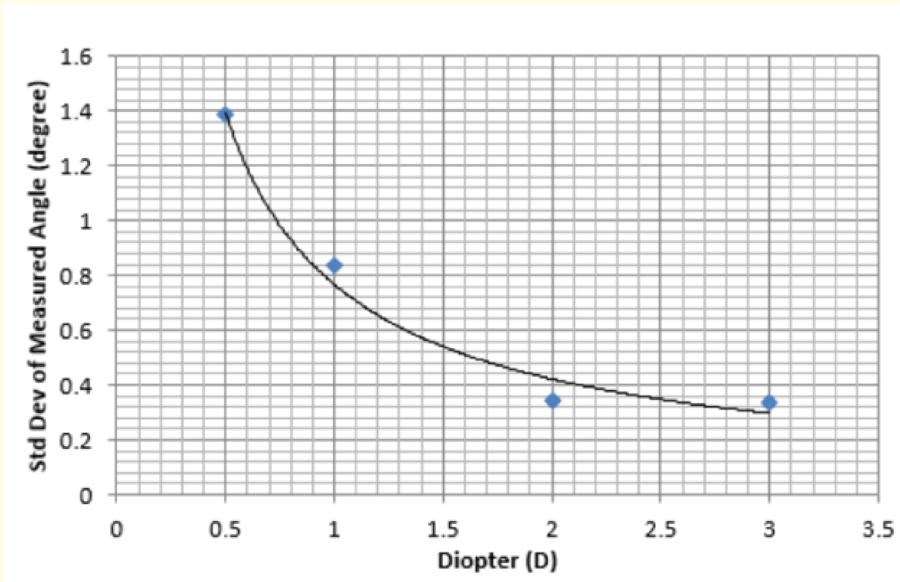

Figure 3: *The dependence of astigmatism angle measurement accuracy of Polaris Keratoscope on the astigmatism value.*

Discussion

We believe that a 1-deg angle accuracy for astigmatism measurement is sufficient to satisfy the ANSI Z80.30-2010 standard, requiring combined error of IOL marking and IOL alignment to be less than 5 deg. IOL toric markings error may be as high as 3 degrees, per our conversations with IOL manufacturers. The manufacturing variability of 0.2 deg that we observed assures that all manufactured Polaris Keratoscope units comply with ANSI Z80.30-2010 standard.

Another interesting observation was the dependence of astigmatism angle measurement accuracy on astigmatism value. As we expected going to smaller astigmatism values has increased the astigmatism angle measurement error. And yet, even at astigmatism value as low as 0.5D the accuracy of 1.4 Degree is achieved. This accuracy is still sufficient to remain compliant with ANSI Z80.30-2010 standard. As was measured in [6] during European population study 40% of 6o year old and older people have astigmatism of 1D and higher. 65% of the same population has astigmatism of 0.5D and higher. And so by staying accurate at 0.5D, Polaris Keratoscope expands the percentage of cataract patients, eligible for toric IOL astigmatism correction from 40% to 65%.

Conclusion

A Novel intra-operative device - Polaris keratoscope - was used to measure dependence of optical keratometry astigmatism angle measurement on the amount of astigmatism from 0.5D to 3D. The accuracy was found to improve even further from 1.4 Degrees at 0.5D astigmatism to 0.4D at 2D and 3D of astigmatism. We conclude that Polaris Keratoscope can be used for intra-operative guidance of toric IOL alignment in patients with astigmatism as low as 0.5D. This expands toric IOL eligibility to 65% of all cataract patients.

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