Effects of decentration and tilt on the optical performance of 6 different aspheric intraocular lenses in a model eye

Short Title: DECENTRATION AND TILT OF 6 DIFFERENT ASPHERIC IOLS

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Purpose: To compare the effect of decentration and tilt on the optical performance of 6 different aspheric intraocular lenses (IOLs) in a model eye.

Setting: Department of Ophthalmology, Dokkyo University Graduate School of Medicine, Japan.

Design: Theoretical simulation and experimental studies.

Methods: In theoretical simulations, the amount of spherical aberration (SA) in the IOL was varied to produce residual ocular SA, ranging from -0.15 to 0.30 μm at 6-mm entrance pupil. Wavefront aberration analyses were performed using the ZEMAX® optical design program version August 20, 2014 (Zemax LCC, Kirkland, WA, USA) to obtain the ocular root mean square (RMS) values of astigmatism, coma, trefoil, and higher-order aberrations (HOA) when the IOL was centered on the insertion position and misaligned at 4-mm entrance pupil. The retinal visual images were also calculated using the same conditions. Six 20.0 diopter (D) aspheric IOLs and one 20.0 D spherical IOL were used for the experimental studies. Each IOL was inserted into the model eye. The actual alignments were measured using NIDEK EAS-1000 (NIDEK, Co. Ltd., Gamagori, Japan) and the wavefront aberrations and visual images were gauged using the Wavefront Analyzer KR-1W (Topcon Corporation, Tokyo, Japan) at several IOL alignments.

Results: IOL decentration and tilt increased wavefront aberrations and degraded optical performance. Astigmatism, coma, and HOA generated by misaligned IOLs were related to the amount of SA correction of the IOLs, while the extent of SA remained unchanged by the amount of misalignment. Experimental results obtained using a model eye revealed trends similar to the theoretical results.

Conclusions: The SA correction amount in the aspheric IOL design was critical for the astigmatism, coma, and HOA generated by the IOL misalignment. Additional SA corrections led to a more sensitive optical performance degradation owing to the IOL misalignment.

IOL implantation faces new challenges and opportunities. Several studies have attributed the decline of contrast sensitivity (CS) to changes in wavefront aberrations of the crystalline lens as a function of age, particularly for higher-order SAs.[1–3]

Numerous aspheric IOLs are now available. Although these lenses possess aspheric optics, the SA's deviation from a true sphere tends to vary. Some IOLs have negative aspheric optics and are designed to compensate for the average positive SA of the human cornea (approximately 0.27 μm) to produce a total ocular SA close to zero. Others correct some of the corneal SAs, but leave the total ocular SA slightly positive (approximately 0.1 μm). However, these negative SA aspheric IOLs are designed to function best when perfectly centered on the visual axis. Some aspheric IOLs are neutral or aberration-free, neither adding nor reducing the SA of the cornea. Like spherical IOLs, they are relatively insensitive to decentration or tilt.[4] The degree of image improvement obtained from these lenses lies somewhere between a spherical and a negative SA lens.

Several studies have demonstrated improved CS, particularly under low-light (mesopic) conditions, with aspheric IOLs instead of spherical IOLs (for a comprehensive review, see Montés-Micó[5]). Well-designed aspheric IOLs decrease the SA and enhance the quality of the retinal visual images. The drawback of these lenses is that they function best when perfectly aligned with the visual axis. Lens decentration and tilt can induce wavefront aberrations that lower visual performance.[6–9]

Because of the wide variations in currently available aspheric IOLs, we performed comparative theoretical and experimental studies of the effect that IOL decentration and tilt has on a model eye.

MATERIALS AND METHODS

Model Eye

The artificial cornea of the model eye was designed to closely mimic the optical conditions of an IOL when implanted in the human eye using acrylic poly(methyl methacrylate) material. In addition, the cornea was optimized to have 43 diopter

(D) refractive power and 0.20 μm SA at 6-mm entrance pupil when the model eye was filled with distilled water (refractive index of 1.333).[10] The details are provided in Table 1. The model eye, with an IOL holder to experimentally simulate the decentration and tilt, was fabricated using precision machinery tools (Nippon Seiki Laboratory, Co., Ltd., Numazu, Japan). Figure 1 reveals the model eye configuration and the IOL holder that was used for the experiments. Decentration values of 0.0 (on-axis), 0.5, and 0.7 mm and tilt values of 0, 5, and 7 degrees were considered. Moreover, an artificial plane retina, which can be moved back and forth to adjust the axial length, was also included. This retina was used merely to reflect light generated by the wavefront aberrometer; therefore, in this study, specific materials and designs were not necessary as long as the Hartmann image obtained by the aberrometer was acceptable.

IOL Designs for Simulations

For simplification, the IOL was designed using an optical glass material with a refractive index of 1.5. The IOL refractive power was 20 D with an equiconvex lens design. Different lens designs, refractive indices, and powers will result in varied optical performance. To minimize the differences in optical function, we selected 1.5 for the IOL refractive index, which is the median refractive index value of commercially available IOL (ranging from 1.46 to 1.55). A lens refractive power of 20 D was chosen since it is the median IOL refractive power and mostly used in experimental studies. To reduce the corneal SA with an amount of 0.0 μm to 0.3 μm in 0.1-μm increments, the even asphere surface was optimized on the IOL's anterior side. The 4th and 6th order aspheric polynomials for the even asphere were optimized using the Zemax optical design program. Table 2 presents all of the IOL design parameters used for the theoretical study.

Types of IOLs for Experiments

Six 20.0 D aspheric IOLs Avansee™ Natural AN6K (Kowa, Co. Ltd., Tokyo, Japan), Nex-Acri AA NS-60YG (NIDEK, Co. Ltd., Gamagori, Japan), Eternity Natural Uni W-60 (Santen Pharmaceutical, Co., Ltd., Osaka, Japan), HOYA Vivinex™ iSert® XY1 (HOYA Surgical Optics, Tokyo, Japan), AcrySof® IQ SN60WF (Alcon Laboratories, Inc., Fort Worth, TX, USA), TECNIS® OptiBlue ZCB00V (Johnson & Johnson Vision Care, Inc./Abbott Medical Optics, Inc., Santa

Ana, CA, USA) and a 20.0 D spherical IOL SENSAR® AR40e (Johnson & Johnson Vision Care, Inc./Abbott Medical Optics, Inc., Santa Ana, CA, USA) were used for the experimental studies. Table 3 shows all IOL types corresponding to each group. Five lenses were evaluated for each IOL type.

Wavefront Aberrations and Landolt Ring Simulations

The wavefront aberration calculations and the corresponding orthonormal Zernike standard coefficients of 15 radial power orders were performed using the Zemax optical design program with a green light of 546.074 nm. The RMS values of astigmatism (C_2^{-2} and C_2^{+2}), coma (C_3^{-1} and C_3^{+1}), trefoil (C_3^{-3} and C_3^{+3}), and HOA (all 3rd–6th order coefficients) were calculated externally using a simple MATLAB program version 7.6.0 (the MathWorks, Inc., Natick, MA, USA). The primary SA (C_4^0) was reported without any other calculation. The Zernike coefficients were expressed according to the ANSI Z80.28-2017 standard.

Simulated Landolt rings at 4-mm pupil size were obtained from the wavefront aberrations in the best image position with the highest Strehl ratio. As iterations are necessary in the calculations, the in-house MATLAB software was developed to convolve the original Landolt ring image with the wavefront aberrations that had been derived using the Zemax optical design program. The calculation was confirmed to provide exactly the same results as the Zemax. The original image resolution was 512 X 512 pixels with 5 pixels for Landolt ring’s gap for 0.0 logMAR visual acuity. Zero-padding process to obtain 1024 X 1024 pixels was applied in the convolution calculations. The resultant images were then cropped to the appropriate size for reporting.

IOL Misalignment Measurements

The NIDEK EAS-1000 Scheimpflug camera (NIDEK, Co., Ltd, Gamagori, Japan) was used to confirm the amount of decentration and tilt of the inserted IOL in the model eye. Although this system was commercially available in the past, it has now been discontinued. The slit was oriented horizontally and vertically, and the images were taken at 640 X 800 pixels with a dynamic range of 8 bits of gray values.

The standard NIDEK EAS-1000 software was unable to make the required corrections to the Scheimpflug images. Therefore, decentration and tilt were calculated manually using Adobe Photoshop (Adobe System, Inc., San Jose, CA, USA). The 0.021-mm pixel size was initially determined using the average value obtained from images of all lens diameters without decentration and tilt.

Wavefront Aberrations and Landolt Ring Measurements

The wavefront aberrations of the model eye with an implanted IOL were measured using a front-open Hartmann-Shack aberrometer Wavefront Analyzer KR-1W (Topcon Corporation, Tokyo, Japan). The aberrations were expanded to the sixth order of Zernike standard polynomials and analyzed in a manner that was similar to the explained previously theoretical calculations.

Simulated Landolt rings at 4-mm pupil size were obtained using the standard KR-1W software for 0.0–0.5 logMAR visual acuity in 0.1 increments.

RESULTS

Wavefront Aberrations and Landolt Ring Simulations

As expected, IOL decentration and tilt augmented the wavefront aberrations. By increasing the SA amount, the effect of decentration and tilt on astigmatism, coma, and HOA also increased, while the SA amount remained unchanged. Figure 2 indicates the corresponding aberration values at 4-mm entrance pupil for all IOL designs and misalignment conditions. RMS trefoil was not included in this figure since the values were negligible. The design’s extent of SA correction did not affect the amount of induced astigmatism and coma related to IOL tilt.

For complex misalignment conditions, the wavefront aberrations will depend on the decentration orientation and the tilt angle. Extreme effects occurred when the decentration and tilt were at 0.7 mm, 7 degrees and -0.7 mm, 7 degrees alignment conditions. For spherical design, in the case of IOL induced positive SA, the minimum wavefront aberration impact was felt at 0.7 mm, 7 degrees alignment condition. In contrast, for neutral or negative SA IOL design and IOL induced zero or negative SA, the minimum impact was experienced at -0.7 mm, 7 degrees alignment condition.

Figure 3 shows the corresponding Landolt ring simulations at 4-mm pupil size. The images were consistent with the wavefront aberration results. The contrasts were calculated, and the results for 0.0, 0.2, and 0.4 logMAR were plotted in Fig. 4. Here, as well, the results consistently revealed that the images displayed higher contrast for lower wavefront aberrations.

IOL Misalignment Measurements

Before examining the wavefront aberration measurement and the Landolt rings, the amount of decentration and tilt were confirmed when the IOL was placed in the model eye for each condition. Figure 5 demonstrates the measurement results for the amount of decentration and tilt associated with each misalignment condition. All measurements validated the expected amount of misalignment conditions with only small deviations. These changes were thought to have insignificant effects on the analyses, except for the IOLs in Groups A and B, which exhibited higher deviations for 0 degrees tilt condition. Such variations may have been caused by the 3-piece IOL design. A previous study[11] reported that the degree of IOL decentration and tilt in eyes with a 1-piece acrylic IOL were similar to that of the 3-piece IOL. However, another recent study[12] found the 1-piece IOL was more stable than the 3-piece IOL.

Wavefront Aberrations and Landolt Ring Measurements

Agreeing with the theoretical results and as expected, IOL decentration and tilt exacerbated the wavefront aberrations. By increasing the SA amount, the effect of decentration and tilt on astigmatism, coma, and HOA also escalated; however, the SA amount remained unchanged. Figure 6 depicts the corresponding aberration values at 4-mm entrance pupil for all IOL designs and misalignment conditions. The remaining SAs were consistent with the respective SA reductions, as shown in the IOL specifications of Table 3, except for IOL Group B, which presented more pronounced corrections. Inconsistency at -0.7 mm, 7 degrees alignment condition for Group D was also observed because of higher astigmatism and coma. This issue is under investigation and the cause remains unknown.

Figure 7 displays the corresponding Landolt ring measurements at 4-mm pupil size. In this case, the images were also consistent with the wavefront aberration results.

DISCUSSION

Wavefront aberrations are common and useful optical properties for evaluating the general optical system, including the human eye. We used our own design to closely mimic an IOL's optical conditions when implanted in the human eye. We did not apply the widely accepted Liou-Brennan model eye[13] or other common schematic model eyes because we needed to construct the model eye for experimental use. Model cornea fabrication was performed by Nippon Seiki Laboratory, Co., Ltd., Numazu, Japan, and the SA amount was confirmed by using the same wavefront aberration measurements. Nonetheless, the corneal wavefront aberrations were analyzed at 6-mm entrance pupil. From the measurement results of the 7 IOL models for each of the 5 lenses at 7 different misalignment conditions, the fabricated model cornea's SA was 0.2049 ± 0.0036 μm. This result assured that the fabrication of the corneal SA met the design value of 0.20 μm with a deviation of <0.01 μm. Moreover, the low standard deviation of the results established the precision of the aberrometer.

We evaluated the effect of IOL misalignment on the optical performance of the model eye filled with distilled water (refractive index of 1.333). The different in refractive index between distilled water and aqueous humor (refractive index of 1.336) or balanced saline solution is 0.003, which can change the wavefront aberration value by 1.83%. The effect of this small difference in refractive index on the wavefront analyses was trivial; therefore, distilled water can replace balanced saline solution in the experiments. The IOL's design data were provided by specifications derived from the manufacturer's information. Calculations were performed with monochromatic green light (546.074 nm wavelength) using the Zemax optical design program combined with the self-developed MATLAB program. The evaluation of wavefront aberrations will provide clear differences for each IOL design at 6-mm entrance pupil. However, since the IOLs in Groups A, C, and G only have approximately 5-mm effective diameter optics, the analysis for 6-mm entrance pupil with misalignment becomes incorrect. For this reason, all calculations and measurements were performed using a 4-mm entrance pupil.

Although multiple studies of IOL decentration and tilt's effect on aspheric IOLs' optical performance have been conducted, to the best of our knowledge, this report is the first such study combining both IOL decentration and tilt for 6 aspheric IOL optics designs. Dietze and Cox[7] conducted their study in wavefront aberration using ray tracing calculation and provided clinical data for spherical and aspheric IOLs. The investigators also analyzed the effects of tilt, decentration, and a combination of these factors. Nevertheless, the analyses were limited to the RMS wavefront aberrations and merely compared the higher levels of positive SA spherical IOL and aspheric IOL that was designed to produce an ocular SA-free lens. Aspheric IOLs with varying amounts of SAs were compared in vitro by Pieh et al., who reported the effect of IOL tilt and decentration on the Strehl ratio values.[14] HOA's influence due to tilt and decentration of the spherical and aspheric IOLs was studied by Baumeister et al.[15] The work described the clinical results; however, because of insignificant intergroup tilt or decentration, the effect of these factors on HOA was unclear. The work provided a mean decentration of 0.27 ± 0.16 mm (ranging from 0.05 to 0.55 mm) and a mean tilt of 2.85 ± 1.36

degrees (ranging from 0.77 to 7 degrees), which closely resemble our selected range of values. A complete analysis of the effects of decentration and tilt on the image quality of aspheric IOL designs in a model eye was furnished by Eppig et al.[16] Nonetheless, only the modulation transfer function for the optical properties was stated, and the combination of decentration and tilt was not evaluated.

Our results suggest that IOL decentration and tilt increase the wavefront aberrations. Astigmatism (C_2^{-2} and C_2^{+2}), defocus (C_2^{-0}), and coma (C_3^{-1} and C_3^{+1}) were significantly affected. All other Zernike coefficients changed insignificantly with respect to the total optical performance. Defocus affected the focal-shift, but this problem could be corrected easily with the use of spectacles. Similar to defocus, astigmatism can also be corrected with appropriate spectacles. Therefore, regarding IOL misalignment, the total HOA that mainly depends on coma and SA is the most important component for consideration in the visual performance analysis. Coincidently, this was also observed in the clinical results reported by Bellucci at al.[17] A combination of decentration and tilt affects the values of astigmatism, defocus, and coma akin to independent decentration or tilt. However, the resultant effects will depend on the orientation/angle of decentration and tilt. This report focuses on extreme cases, in which the combination of decentration and tilt induced maximum and minimum aberrations. In a clinical situation, a pseudophakic patient is likely to have a random orientation of IOL misalignment. In the literature, the studies of de Gracia et al.,[18] which discuss the possibility of combining coma and astigmatism to improve the visual image, can be found.

Notably, our results on both wavefront and visual image analyses indicate that a combination of the processes can lead more or less to independent decentration or tilt, depending on the orientation. These research findings agree with the Strehl ratio analyses reported by Pieh at al.[14] In clinical practice, highly corrected SA aspheric designs such as TECNIS® OptiBlue ZCB00V, are critical to decentration. As discerned from Fig. 7, the image was worse compared to spherical IOL with 0.5-mm decentration. Although the degraded image might be theoretically acceptable, in clinical practice, with corneal aberrations, pupil function, contrast sensitivity, and other aspects influencing the visual performance of the patients, 0.5-mm decentration may serve as the threshold for this type of aspheric design.

In conclusion, correcting SA aspheric IOL provided better optical performance than the standard spherical lens. However, the optical degradation due to IOL misalignment exhibited a greater effect with a higher degree of negative SA correction IOL design. These findings indicate that, in clinical practice, the degraded quality of vision obtained with aspheric IOL design can be minimized with a careful compromise between the degree of asphericity and possible IOL misalignment.

WHAT WAS KNOWN

- Aspheric IOL which is designed to decrease corneal SA can improve the retinal visual image quality.
- IOL misalignment implanted eye affects visual performance.

WHAT THIS PAPER ADDS

- The model eye allows objective quantification of the wavefront aberration and image deterioration induced by IOL misalignment.

- The effect of IOL tilt is not sensitive to the IOL design.
- In contrast, the effect of IOL decentration is sensitive to the IOL design. The optical performance is affected more with higher SA correction aspheric design.

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FIGURE LEGENDS

Fig. 1. Model eye and IOL holder for experiments. The amounts of decentration and tilt of the IOL holder are fabricated to represent the decentration and tilt of the IOL.

Fig. 2. Theoretical results of ocular wavefront aberrations at 4-mm entrance pupil. Horizontal values reveal the amount of decentration and tilt in millimeter and degree, respectively.

Fig. 3. Theoretical simulation results of Landolt-C retinal visual imaging using model eye at 4-mm entrance pupil. C-images represent 0.0 logMAR visual acuity (smallest) to 0.5 logMAR visual acuity (biggest) in 0.1 increments.

Fig. 4. Contrast values of the corresponding Landolt ring images in Fig. 2 for logMAR 0.0, 0.2, and 0.4.

Fig. 5. Measurement results of the amount of decentration and tilt due to misalignment conditions. Error bars in the plot indicate the maximum and minimum measurement values. Red horizontal dotted lines show the

nominal decentration and tilt values (0, 0.5, and 0.7 mm for decentration and 0, 5, and 7 degrees for tilt).

Fig. 6. Measurement results of ocular wavefront aberrations at 4-mm entrance pupil.

Fig. 7. Measurement results of Landolt ring retinal imaging based on the HOA aberration generated by the Topcon aberrometer KR-1W. The sizes of C-images were similar to those used in the theoretical evaluation.