Influence of decentration and tilt of Tecnis ZCB00 on visual acuity and higher order aberrations.

Running title: Effect of Tecnis ZCB00 decentration and tilt on visual quality

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ABSTRACT

Background/Objectives: To determine the influence of decentration and tilt of a pseudophakic aspheric intraocular lens (IOL) on visual acuity (VA) and higher-order aberrations (HOAs), and to analyze the agreement between pupil center/axis and iridocorneal angles center/axis when assessing IOL decentration and tilt.

Subjects/Methods: A prospective interventional case series study including thirty-three patients undergoing Tecnis ZCB00 (Abbott Medical Optics) implantation. IOL decentration and tilt with respect to two reference systems (pupil and iridocorneal angles centers/axes), in cartesian (X,Y) and polar (radius/tilt, polar angle/azimuth) coordinates, were assessed with optical coherence tomography . VA and internal and ocular HOAs were evaluated. Multiple linear regression models and intraclass correlation coefficient (ICC) were computed.

Results: IOL decentration only showed a significant effect on internal HOAs for Z_3^3 (R^2=.20,P=.04). IOL decentration with respect to the pupil center showed a significant effect on ocular Z_3^{-3} (R^2=.18,P=.05), Z_3^1 (R^2=.36,P=.001) and Z_4^{-4} (R^2=.24,P=.02); and with respect to the center of iridocorneal angles, on ocular Z_3^3 (R^2=.21,P=.03), Z_4^2 (R^2=.32,P=.003), primary coma (R^2=.41,P<.001), and coma-like (R^2=.40,P=.001). Poor agreement between both reference systems was found for IOL decentration measurements (ICC≤.41), except for the polar angle coordinate (ICC=.83). Tilt measurements showed good agreement (ICC≥.75).

Conclusions: Tecnis ZCB00 decentration and tilt values after uneventful implantation appear not to have influence on VA, and their effect on HOAs are not high enough to clinically affect quality of vision. Pupil and iridocorneal angles used as reference systems may be interchangeable for IOL tilt measurements, but not for decentration.

INTRODUCTION

The positive primary spherical aberration (SA) of the cornea is usually compensated by the negative SA of the crystalline lens in the youthful eye. Morphological changes experienced by the lens with age (e.g., thickness and opacification) can result in less negative or even positive SA, degrading the optical quality of the eye.[1-3] Crystalline lens opacification is the leading cause of ophthalmological surgery worldwide, with phacoemulsification and pseudophakic intraocular lens (IOL) implantation being the standard procedures used in cataract surgery within developed countries.[4]

Several optical designs for pseudophakic IOLs have been developed which vary in the amount of SA induced. Spherical IOL designs add positive SA,[5] in contrast, aspheric IOL designs either; avoid the induction of SA (aberration-free IOLs), partially compensate the SA of the cornea (i.e., SA of -0.20 µm),[6] or fully compensate the SA of the cornea (SA of approximately -0.27 µm).[7-9] Numerous authors have reported that aspheric IOLs provide better photopic and mesopic contrast sensitivity in comparation to spherical IOLs.[10-14] However, decentration and tilt of aspheric IOLs have a greater impact on optical quality than spherical ones.[15]

Decentration and tilt are one of the most frequent complications that can be present even after uneventful IOL implantation.[16] Numerous theoretical and experimental works have analyzed the influence of decentration and tilt of aspheric IOLs on optical quality using model eyes or simulators.[17-19] Nonetheless, *in-vivo* clinical studies continue to be of great interest to properly understand the effect of aspheric IOL decentration and tilt on visual performance. In addition, there is not a gold standard method to assess decentration and tilt. Previous studies have used different methods such as Purkinje images, Scheimplflug images or Optical Coherence Tomography, with no universal reference points and axes.[20]

The aim of the present study was to determine the influence of decentration and tilt on visual acuity (VA) and higher-order aberrations (HOAs) after the implantation of an aspheric IOL with negative SA (Tecnis® ZCB00, Abbott Medical Optics; Santa Ana, CA). Additionally, the agreement between pupil center and axis and iridocorneal angles center and axis to assess decentration and tilt was also evaluated.

METHODS

The present work is a prospective case series study. It was approved by the United Kingdom National Health Service (NHS) and the University of Plymouth faculty of Health Research ethics committee. Procedures were performed in accordance with the Declaration of Helsinki and all participants provided written informed consent.

Intraocular lens specifications

Tecnis ZCB00 is a biconvex one-piece monofocal IOL with an anterior prolate surface (aspheric design) inducing a negative SA of -0.27 µm. This lens is made by hydrophobic acrylic material with a continuous 360° posterior square edge design and offset haptics. IOL presents a 6.0 mm optical diameter with a range correction from +5.0 diopters (D) to +34.0 D.

Sample

Thirty-three eyes of 33 volunteers who underwent Tecnis ZCB00 implantation in at least one eye were assessed. Inclusion criteria were patients aging 18 years or older, and uneventful phacoemulsification with IOL implantation surgery performed 3 to 12 months prior to the examination visit. Exclusion criteria were patients with amblyopia, glaucoma, retinal or corneal diseases, iris and pupil anomalies or any previous ocular surgery.

In cases where patients underwent Tecnis ZCB00 implantation in both eyes, the study eye selected was the first implanted one. The contralateral eye was occluded during eye examinations.

Study parameters

Monocular uncorrected distance visual acuity (UDVA) was assessed using a computerized test chart (POLA VistaVision - DMD Med Tech, Italy) at 6 m distance. The logarithm of the minimum angle of resolution (logMAR) was recorded for each patient.

Internal and ocular aberrations were obtained with the OPD-Scan III system (Nidek Technologies, Japan). The following second-order Zernike coefficients and higher-order aberrations (HOAs) for a 4 mm pupil diameter were selected for study purposes: second-order Zernike coefficients (Z_2^{-2}, Z_2^0 and Z_2^2), third and four-order Zernike coefficients (Z_3^{-3}, Z_3^{-1}, Z_3^1, Z_3^3, Z_4^{-4}, Z_4^{-2}, Z_4^0, Z_4^2 and Z_4^4), secondary spherical aberration (Z_6^0), primary (Z_3^{-1} and Z_3^1) and secondary (Z_5^{-1} and Z_5^1) coma root mean square (RMS), coma-like (Z_3^{-1}, Z_3^1, Z_5^{-1} and Z_5^1) RMS, spherical-like (Z_4^0 and Z_6^0) RMS, and total HOAs RMS (from 3rd to 6th order). Keratometry and asphericity data were also obtained from OPD-Scan III system. Axial length measurements were performed preoperatively using the IOLMaster 500 (Zeiss, Jena, Germany).

Assessment of intraocular lens tilt and decentration

A swept-source optical coherence tomography (ss-OCT) system (Casia SS-1000, Tomey, Japan) was used to obtain anterior segment images selecting the radial 3-D angle analysis. The measurements were performed under mydriasis after instilling one drop of Phenylephrine 2.5% (Minims Phenylephrine Hydrochloride®; Bausch & Lomb, United Kingdom) and Tropicamide 1.0% (Minims Tropicamide®; Bausch & Lomb, United Kingdom), respectively.

Firstly, 12 sectional images, corresponded to the following meridians: 0-180, 15-195, 30-210, 45-225, 60-240, 75-255, 90-270, 105-285, 120-300, 135-315, 150-330 and 165-345 degrees were selected. The anatomical structures of the anterior segment of the eye (including the IOL) were properly identified using the manual tool of the ss-OCT software and the RStudio software (1.0.143 version) (Figure 1). Thus, the distance between the center of each reference system (pupil center or iridocorneal angles) and the center of the IOL was measured for each image. In addition, the angular distance between each reference system axis and the IOL axis was also determined for each image. This measurement procedure was performed in the 12 selected images per subject.

To measure the IOL decentration parameters, the 12 images were grouped into perpendicular pairs (A: 0-180 and 90-270 degrees, B: 15-195 and 105-285 degrees, C: 30-210 and 120-300 degrees, D: 45-225 and 135-315 degrees, E: 60-240 and 150-330 degrees, and F: 75-255 and 165-345 degrees) creating six individual reference systems, each rotated 15° from the anterior one (Supplemental Figure S1). Distance values between each reference system (pupil center or iridocorneal angles) and IOL previously calculated in the 12 sections, were considered as x' or y' coordinates (Supplemental Figure S1). The resultant distance and the resultant angle of each individual reference coordinates system (From A to F) were calculated. Finally, the mean values of the six systems were also calculated. The IOL decentration was determined using cartesian (X, Y) and polar coordinates (radius and polar angle). Regardless of the eye evaluated, positive values of the X-coordinate indicated nasal decentrations, while negative values indicated temporal decentrations. Regarding the Y-coordinate, positive values meant superior decentrations.

Tilt was defined as the angle between the reference plane (pupil axis and iridocorneal angles axis) and the IOL plane. Azimuth was defined as the IOL tilt orientation (angle of the IOL tilt normal vector projected on the reference plane). Similar to the IOL decentration assessment performed, IOL tilt was measured using the 12 images grouped into perpendicular pairs (From A to F) to calculate cartesian (X, Y) and polar coordinates (tilt and azimuth). The geometrical method developed to calculate IOL tilt and azimuth is provided in the Supplemental information (Figure S2). Regardless of the eye evaluated, positive values of IOL tilt in the X-coordinate indicated nasal azimuths, while negative values indicated temporal azimuths.

Statistical analysis

The statistical analysis was performed using R statistical package version 4.0.0 (The R Foundation, Vienna, Austria). Sample size was estimated taking into account that two independent variables were considered in each regression model, establishing a large effect size (f^2) of 0.35[21] and assuming a two-sided level of significance of 0.05 and a statistical power of 80%. The minimum sample size needed was 31 patients.

The agreement between IOL decentration and tilt values for both reference systems, pupil center/axis and center/axis of the line joining iridocorneal angles, was analyzed by the absolute agreement intraclass correlation coefficient (ICC).[22] To analyze the angular differences in polar angle and azimuth parameters, when angular differences between reference systems exceeded 180 degrees, coterminal angles were calculated for pupil center/axis reference system.

The effect of age and IOL power on the decentration and tilt parameters was analyzed by using simple linear regressions. The assumptions of normality, homoscedasticity, linearity and lack of outliers were check using the residuals of the fitted models.

The effect of the IOL decentration on the study parameters was analyzed by fitting two multiple linear regression models per each study variable, including the cartesian (X, Y) or polar coordinates (radius, polar angle), for each reference system. Similarly, two multiple linear regression models per variable were used to analyze the effect of tilt coordinates (X, Y) or total tilt coordinates (tilt and azimuth), for each reference system. The required model assumptions (normality, homoscedasticity, linearity and lack of outliers) were checked. Two-sided P-values ≤ 0.05 were considered statistically significant.

RESULTS

Study population

A total of 33 (23 females and 10 males) patients with a mean age of 72.9 ± 6.9 years were included. The mean axial length was 23.49 ± 1.32 mm. The mean IOL power was 21.98 ± 4.35 D. The mean UDVA and the mean spherical equivalent was 0.13 ± 0.13 logMAR and -0.48 ± 0.40 D, respectively. The mean flat and steep keratometry was 43.03 ± 1.86 D and 44.26 ± 1.78 D, respectively. The mean corneal asphericity was -0.15 ± 0.26. Table 1 shows the mean HOAs values.

Decentration and tilt

The mean horizontal decentration of the IOL was nasal according to both the pupil center (0.04 ± 0.17 mm) and iridocorneal angles (0.18 ± 0.16 mm). For vertical decentration, on average, a superior location was observed (pupil center, 0.17 ± 0.19 mm; iridocorneal angles 0.06 ± 0.26 mm. Table 2; Figure 2A).

Absolute tilt was similar according to both the pupil axis (2.52 ± 1.21 degrees) and axis of the line joining iridocorneal angles (2.64 ± 1.09 degrees) (Table 2; Figure 2B).

The agreement between decentration and tilt for both reference systems is shown in table 2.

No effect of age on decentration and tilt was found ($P \geq .16$). However, a significant relationship was found between IOL power and Y-coordinate with respect to the pupil center (β = 0.02, 95% confidence interval (CI): 0.00/0.04; P = .02), and between IOL power and X-coordinate with respect to the center of iridocorneal angles (β = 0.01, 95% CI: 0.00/0.03; P = .04).

Effect of IOL decentration and tilt on visual acuity and aberrations

Neither IOL decentration or tilt had a significant influence on UDVA ($P \geq .13$) or second-order Zernike coefficients ($P \geq .06$).

IOL decentration, as measured with cartesian coordinates, with respect to the center of the line joining iridocorneal angles showed a significant influence on the internal Z_3^3 (R^2 = .20, P = .04), specifically, the X-coordinate (β = -0.19; 95% CI: -0.35/-0.02; P = .03). No significant ($P \geq .14$) effect of IOL decentration with respect to the pupil center system was found on internal HOAs. Similarly, IOL tilt did not have a significant ($P \geq .09$) effect on any internal HOA with respect to any reference system.

IOL decentration, as measured with cartesian coordinates, in relation to the pupil center showed a significant effect on ocular Z_3^{-3} (R^2 = .18, P = .05), Z_3^1 (R^2 = .36, P = .001) and Z_4^{-4} (R^2 = .24, P = .02). In addition, IOL decentration, as measured with cartesian coordinates, with respect to the center of iridocorneal angles had a significant effect on the following ocular HOAs: Z_3^3 (R^2 = .21, P = .03), Z_4^2 (R^2 = .32, P = .003), primary coma (R^2 = .41, P < .001), and coma-like (R^2 = .40, P = .001). Likewise, when IOL decentration was described in terms of polar coordinates, it showed a significant effect on ocular Z_4^2 (R^2 = .26, P = .02). Table 3 shows the coordinates with a significant effect on ocular HOAs. Regarding ocular Z_3^{-3}, the linear regression model showed a significant effect on this HOA, however, each individual coordinate (X,Y) respect to the pupil did not show any significant ($P \geq .06$) effect on ocular Z_3^{-3}. Besides, IOL tilt did not have a significant effect on any ocular HOA with respect to any reference system ($P \geq .06$).

DISCUSSION

The present study showed the Tecnis ZCB00 decentration and tilt after uneventful cataract surgeries using two reference systems (pupil center (or axis) and center (or axis) of iridocorneal angles), and analyzed its effect on VA and HOAs. Decentration and tilt of the Tecnis ZCB00 as measured with a new method based on ss-OCT images, did not have a significant effect on VA, but had an influence on some ocular HOAs and internal Z_3^3 aberration. Additionally, the agreement between both reference systems in cartesian and polar coordinates was also evaluated. It was observed that decentration values are not interchangeable except for polar angle, whilst the tilt reference angles showed high agreement.

To our knowledge, there is not a gold standard method for measuring IOL decentration and tilt,[20] thus, the present study assessed the agreement between two reference systems: pupil center/axis and iridocorneal angles center/axis. The agreement found for decentration measurements was poor (ICC ≤ 0.41) except for the polar angle coordinate, which presented good agreement (ICC = 0.83). The lack of agreement is likely a consequence of a discrepancy between the location of the pupil center and the center of the iridocorneal angles.[23] However, tilt measurements in cartesian and polar coordinates with respect to the pupil and iridocorneal angles axes showed good (ICC ≥ 0.75) or even excellent agreement (Azimuth: ICC = 0.92). It seems that, in absence of structural abnormalities, the plane for both reference axes is very similar, suggesting that both reference systems could be used interchangeable for tilt measurements. In the present study it was observed that the IOL power might have a slight influence on IOL decentration after implantation. Nonetheless, this effect was different depending on the reference system selected. It was significant for the X-coordinate using the iridocorneal angle system and for the Y-coordinate using the pupil center system. Therefore, these outcomes emphasize the importance of selecting a proper reference system based on the primary outcome measure targeted, because both reference systems are not interchangeable.

The mean internal and ocular HOAs found after uneventful implantation of the Tecnis ZCB00 are in concordance with Song et al.[24] who used same IOL and pupil diameter. For a 4 mm pupil diameter, we found that the mean ocular primary SA was -0.018 µm, and -0.064 µm the internal one (Table 1). The aspheric design of the IOL compensated the corneal SA resulting in a mean ocular SA value close to zero, while the mean internal SA was similar to the value reported for the Tecnis ZCB00 IOL at 4 mm (-0.05 µm).[25]

The lack of significant results in the present study for the second-order Zernike coefficients suggests that the ZCB00 decentration and tilt found has no important impact on the postoperative refraction. In addition, the influence of IOL decentration on internal and ocular oblique trefoil (Z_3^3) was significant for X-coordinate using the iridocorneal angles system. It was observed that the longer the temporal displacement was, the higher the internal and ocular aberrations were. Fernández-Sánchez et al.[26] showed that low values of induced coma and trefoil (0.13 and 0.17 µm, respectively) had no effect on VA or contrast sensitivity. Considering the regression coefficients of our results for Z_3^3 (β = -0.19 and β = -0.27 internal and ocular, respectively), it would require higher decentration values, approximately 0.62 mm, to induce a Z_3^3 value of at least 0.17 µm. Therefore, our results suggest that the level of IOL decentration after uneventful surgery is not high enough to negatively affect postoperative quality of vision from a clinical viewpoint.

We did not find any other influence of IOL decentration on internal HOAs except for the abovementioned internal and ocular oblique trefoil (Z_3^3). However, we found that the IOL decentration, using the pupil center as reference system, had an effect on three ocular HOAs: vertical trefoil (Z_3^{-3}), horizontal coma (Z_3^1) and vertical tetrafoil (Z_4^{-4}). And using the iridocorneal angles system, IOL decentration had an effect on ocular primary coma, coma-like and vertical secondary astigmatism (Z_4^2). The fact that these results were only found in ocular HOAs but not in internal ones, could suggest that the IOL has minimal or no influence. Nevertheless, the magnitude of the relationships found ($-0.25 \leq \beta \leq 0.13$) appears to be too low to be considered as clinically relevant.

Tecnis ZCB00 tilt did not have a significant effect on VA or internal and ocular HOAs. Similarly, previous authors[27] (only abstract available in English) reported that the tilt of Tecnis ZCB00 had no significant effect on internal HOAs. Therefore, IOL tilt appears not to have a clinically relevant impact on visual quality, when tilt values are representative of the ones commonly observed after uneventful Tecnis ZCB00 implantations.

Some authors have described tolerable decentration and tilt values after the implantation of aspheric IOLs. Holladay et al.[7] reported that an aspherical IOL allows a better wavefront quality than a spherical one even under a decentration < 0.4 mm and tilt < 7 degrees. Likewise, Piers et al.[28] observed better optical quality in aspherical IOLs decentered < 0.8 mm and tilted < 10 degrees, in comparison with spherical ones. However, decentration and tilt values simulated at experimental settings could be higher than values observed in the clinical practice,[29,30] as occurs in our study sample. Thus, the influence of aspheric pseudophakic IOL decentration and tilt observed in clinical practice appears to have negligible effects on the quality of vision.

One limitation of the present study could be that a pupil diameter of 4 mm was selected for HOAs analyses. This diameter was used because it is close to the one usually found in population older than 70 years in mesopic conditions.[31] Additionally, it must be considered that smaller pupil diameters could considerably decrease the magnitude of the HOAs measured, while larger diameters could not represent our sample. Finally, a large effect size was considered to estimate sample size, expecting to achieve the most relevant findings. However, most of the significant results found in the present study were considered to have low clinical impact. Thus, future studies selecting smaller effect sizes are likely to find outcomes of even lower clinical relevance.

In conclusion, the IOL decentration and tilt values commonly observed after in-the-bag implantation of the aspheric pseudophakic Tecnis ZCB00, considering the pupil and iridocorneal angles as reference systems, result in ocular and internal HOAs that are not high enough to negatively affect quality of vision from a clinically relevant viewpoint. Additionally, pupil and iridocorneal angles considered as reference systems can be used interchangeably for IOL tilt measurements when assessed with ss-OCT technology. In contrast, IOL decentration measures are different depending on the reference system considered.

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Data availability: The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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FIGURE LEGENDS.

Figure 1. Segmentation of the swept-source optical coherence tomography image showing an implanted Tecnis® ZCB00.

Manual segmentation of the cornea (continuous tracing) is shown. Coordinates and line between iridocorneal angles (L, dashed lines tracing), coordinates and line between inner edges of the iris (P, tracing with circle symbols), intraocular lens surfaces (tracing with filled circle symbols) and intraocular lens tilt (tracing with plus symbols).

Figure 2. Polar plots of the decentration (A) and tilt (B) of the Tecnis® ZCB00 in relation to the pupil center or axis (left) and center or axis of iridocorneal angles (right).

In the decentration plots (A), the radius (mm) and polar angle (degrees) are shown as the distance from the center of the axis (0.2 mm per ring) and the orientation, respectively. In the tilt plots (B), tilt (degrees) and azimuth (degrees) are shown as the distance from the center of the axis (2 degrees per ring) and the orientation, respectively. (0°: nasal; 180°: temporal).

Supplemental Figure S1. Representation of a rotated coordinate system with respect to the main reference coordinate system.

Supplemental Figure S2. Representation of the intraocular lens (IOL) tilt and azimuth calculation based on two perpendicular optical coherence tomography (OCT) sections.