·Clinical Research·

High order aberration and straylight evaluation after cataract surgery with implantation of an aspheric, aberration correcting monofocal intraocular lens

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Abstract

• AIM: To evaluate the quality of vision in respect to high order aberrations and straylight perception after implantation of an aspheric, aberration correcting, monofocal intraocular lens (IOL).

• METHODS: Twenty-one patients (34 eyes) aged 50 to 83y underwent cataract surgery with implantation of an aspheric, aberration correcting IOL (Tecnis ZCB00, Abbott Medical Optics). Three months after surgery they were examined for uncorrected (UDVA) and corrected distance visual acuity (CDVA), contrast sensitivity (CS) under photopic and mesopic conditions with and without glare source, ocular high order aberrations (HOA, Zywave II) and retinal straylight (C-Quant).

• RESULTS: Postoperatively, patients achieved a postoperative CDVA of 0.0 logMAR or better in 97.1% of eyes. Mean values of high order abberations were +0.02±0.27 (primary coma components) and −0.04 ±0.16 (spherical aberration term). Straylight values of the C-Quant were 1.35±0.44 log which is within normal range of age matched phakic patients. The CS measurements under mesopic and photopic conditions in combination with and without glare did not show any statistical significance in the patient group observed ($P \geqslant 0.28$).

• CONCLUSION: The implantation of an aspherical aberration correcting monofocal IOL after cataract surgery resulted in very low residual higher order aberration (HOA) and normal straylight.

• KEYWORDS: cataract; aberrations; intraocular lens

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INTRODUCTION

Cataract surgery and intraocular lens (IOL) implants have developed tremendously over the past decades [1-6]. New diagnostic tools have improved our knowledge on high order abberations and optical quality of implants. An optimization of postoperative spherical aberration after cataract surgery can be currently achieved with the implantation of IOLs with aspheric optics [7-10]. These types of IOLs commonly have an anterior aspheric surface inducing a specific level of negative spherical aberration to compensate for the positive spherical aberration of the cornea[7-10].

The potential benefit of this specific type of IOL has been analysed in theoretical simulations by different authors, showing that optimization of ocular spherical aberrations is possible [11-13]. In clinical studies, IOLs based on this technology have shown to provide good visual function, contrast sensitivity and refractive outcomes after cataract surgery[6-10,14-19].

However, there are also reports with no clear benefit of aspheric over spherical IOL designs [5]. Some potential limitations of aspheric IOLs have been described, such as age-related miosis, tilt and decentration of IOL, or intersubject variability [20]. But differences between studies in patient characteristics, examination procedures and devices for characterizing visual quality as well as different IOL designs have also been influencing factors for these reports.

The purpose of the current study was to evaluate in a prospective manner clinical outcomes and IOL performance obtained with a specific model of an aspheric, aberration correcting IOL in patients after cataract surgery by analysing

visual acuity, refractive results, contrast sensitivity, ocular aberrometry and retinal straylight measurements in an early stage after surgery to rule out any effects of fibrotic changes of the capsule.

SUBJECTS AND METHODS

Subjects A total of 34 eyes of 21 patients with an age from 50 to 83y that underwent uneventful cataract surgery with the implantation of the aspheric, aberration correcting IOL tecnis ZCB00 (abbott medical optics) were enrolled in this prospective, non-randomized trial.

Exclusion criteria comprised of previous ocular surgery other than the cataract surgery, a history of uveitis, glaucoma, proliferative diabetic retinopathy, pseudoexfoliation syndrome, macular degeneration, neuro-ophthalmic disease, or history of ocular inflammation. Surgical complications (*e.g.* posterior capsule rupture, zonular dehiscence, incomplete continuous curvilinear capsulorhexis, severe iris or corneal trauma, inability to achieve secure placement in the designated location) were also considered as exclusion criteria.

Methods This prospective, non-randomized monocenter clinical study included 34 eyes of 21 consecutive patients undergoing cataract surgery with implantation of a monofocal Tecnis ZCB00 (Abbott Medical Optics, Santa Ana, CA, USA). Inclusion criteria for the study were significant cataract, estimated post-operative corneal astigmatism of 0.75 D or lower and estimated postoperative corrected distance visual acuity (CDVA) of 0.20 logMAR or better. Exclusion criteria included previous intraocular surgery, glaucoma, history of uveitis or retinal detachment, peripheral retinal lesions not treated prophylactically, iris atrophy, corneal disease, macular degeneration, unreal expectations, and any neuro-ophthalmological disease.

As some patients had a significant cataract on both eyes, both were included in the study. All patients were informed about the study and provided informed consent to undergo the clinical examination and the surgical procedure in accordance with the tenets of the Declaration of Helsinki. The study received the approval of the local ethics committee.

Preoperative and postoperative clinical evaluation Preoperative data analysed included a complete preoperative ophthalmological examination, uncorrected distance visual acuity (UDVA) and CDVA, subjective refraction, slitlamp biomicroscopy, goldmann tonometry, biometry (IOLMaster-500, Carl Zeiss Meditec, Jena, Germany), and fundus examination under pupil dilation.

Postoperatively, patients were evaluated the day after surgery as well as between 2mo and 4mo after surgery. The clinical evaluation at the end of the follow-up included the same tests as preoperatively and some additional examinations: corneal topography (Pentacam system, Oculus GmbH, Wetzlar, Germany), contrast sensitivity evaluation (CST 1800, Vision Science Research, Walnut Creek, USA) under photopic (85 cd/m^2) and low mesopic conditions (3 cd/m^2) with and without a glare source, characterization of ocular high order aberrations (HOA, Zywave II, Bausch & Lomb Inc., Rochester, USA), retinal straylight measurements with the C-Quant device (Oculus Optikgerate, Wetzlar, Germany). Straylight data of each patients were analysed according to Coppens *et al* [20] when repeated measurements showed a standard deviation parameter, Esd, below 0.08 and measurement quality parameter, Q, above 0.5.

Surgical technique All surgeries were under topical anaesthesia through a 2.5 mm incision. Continuous curvilinear capsulorhexis of approximately 5 mm of diameter was done with an Utrata forceps (Geuder, Heidelberg, Germany). After cataract removal, the Tecnis ZCB00 IOL was inserted into the capsular bag by using the Platinum Unfolder (Abbott Medical Optics, Santa Ana, USA). The IOL power was calculated using the IOLMaster 500 software (Carl Zeiss Meditec, Jena, Germany), the Holladay (27 eyes, 79.4%) and Haigis (7 eyes, 20.6%) formulas depending on the axial length.

Intraocular lens The aspheric IOL Tecnis ZCB00 (Abbott Medical Optics) is a single-piece IOL with a 6.0 mm biconvex optic and an overall length of 13.0 mm. It has an anterior aspheric surface designed according to the ACE (Average Cornea Eye) model to compensate for the spherical aberration of the cornea with -0.27 μm[4,7,13]. The IOL is made of a soft foldable hydrophobic acrylic material with a covalently bound ultraviolet (UV) absorber and is available in powers ranging from +6.00 to +34.00 D in 0.5 D increments. The haptic has a modified C shape with TriFix design, which allows three points of capsular bag fixation. The posterior edge of the optic has a 360°-squared design to provide uninterrupted contact at the haptic-optic junction.

Statistical Analysis Data analysis was performed using the software SPSS for Windows version 19.0 (IBM, Armonk, NY, USA). Normality of data samples was evaluated by means of the Kolmogorov-Smirnov test. When parametric analysis was possible, the Student test for paired data was used for comparisons between the preoperative and postoperative data, whereas the Wilcoxon rank sum test was applied to assess the significance of such differences when parametric analysis was not possible. For all statistical tests, a P of less than 0.05 was considered as statistically significant. Correlation coefficients (Pearson or Spearman depending if normality condition could be assumed) were used to assess the correlation between different variables.

Table 1 Summary of preoperative and postoperative visual and refractive data in the analyzed sample

Mean (SD); Median (range)	Preoperative	Postoperative	*P* (Wilcoxon test)
logMAR UDVA[1]	0.61 (0.45); 0.44 (0.10 to 1.30)	0.00 (0.14); 0.04 (-0.26 to 0.18)	<0.01
Sphere (D)	-3.31 (6.76); -1.25 (-19.00 to +4.75)	-0.43 (1.09); 0.00 (-2.75 to +1.50)	0.11
Cylinder (D)	-1.05 (1.22); -0.75 (-5.00 to 0.00)	-0.74 (0.50); -0.75 (-1.75 to 0.00)	<0.32
SEQ (D)	-3.83 (7.18); -1.63 (-21.50 to +4.50)	-0.80 (1.06); -0.38 (-2.75 to +0.75)	0.09
J_0 (D)	-0.19 (0.51); -0.01 (-2.30 to +0.47)	+0.02 (0.38); +0.08 (-0.87 to +0.87)	0.03
J_{45} (D)	-0.20 (0.56); -0.08 (-2.33 to +0.73)	-0.01 (0.24); -0.01 (-0.49 to +0.70)	0.13
B (D)	5.71 (5.80); 3.54 (0.53 to 21.64)	0.94 (1.04); 0.65 (-2.75 to +2.63)	<0.01
logMAR CDVA	0.25 (0.19); 0.20 (-0.02 to 0.80)	-0.11 (0.09); -0.10 (-0.30 to 0.10)	<0.01

SEQ: Spherical equivalent; J_0 and J_{45}: Power vector components of manifest cylinder; B: Overall blurring strength of the manifest spherocylindrical error; UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; D: Diopters; SD: Standard deviation. [1]Only the eyes targeted for emmetropia are included in the UDVA analyses.

For an integral analysis of changes in the magnitude and axis of astigmatism, the spherocylindrical refractions were converted to vectorial notation using the power vector method described by Thibos and Horner [21]. According to the power vector method, manifest refractions in conventional script notation [(S (sphere), C (cylinder) × φ (axis)] were converted to power vector coordinates and overall blurring strength (B) by the following formulas: $M=S+C/2$; $J_0=(-C/2)\cos(2\varphi)$; $J_{45}=(-C/2)\sin(2\varphi)$; and $B=(M^2+J_0^2+J_{45}^2)^{1/2}$. In addition, polar plots were used for displaying the distribution and variability of astigmatisms.

RESULTS

A total of 34 eyes from 21 patients with a mean age of 66.2y (SD: 9.4; median: 69.0, range: 50 to 83y) were included in the study. This sample included a total of 9 (42.9%) males and 12 females (57.1%), and a total of 16 right (47.1%) and 18 left eyes (52.9%). Mean preoperative anterior chamber depth (ACD) was 3.25 mm (SD: 0.54; median: 3.30, range: 2.14 to 4.23 mm) and mean axial length (AL) was 24.77 mm (SD: 2.39; median: 23.98, range: 21.58 to 29.62 mm). Mean power of the implanted IOL was 18.94 D (SD: 6.27; median: 20.50, range: 8 to 28 D). Target was emmetropia in 20 eyes (58.8%) whereas in the remaining 14 eyes, a residual myopia of more than 1 D was targeted to achieve monovision or residual binocular myopia for spectacle independence at near distances. In the overall sample, mean target for the spherical equivalent (SEQ) was -0.96 D (SD: 1.06; median: -0.23, range: -2.90 to +0.07 D). In the emmetropic eyes the mean target for the SEQ was -0.09 D (SD: 0.09, range: -0.26 D to +0.07 D) compared to a mean target SEQ in the myopic eyes of -2.31 D (SD: 0.52, range: -2.90 D to -1.24 D). Mean follow-up was 2.50mo (SD: 0.51; median: 2.50, range: 2.00 to 3.00mo).

Visual and Refractive Outcomes Table 1 summarizes the preoperative and postoperative visual and refractive data in the analysed sample. As shown, significant changes were found in refraction with a significant reduction in the magnitude of the power vector components J_0 and B (Wilcoxon test, $P \leqslant 0.03$, Table 1). The mean prediction error for the SEQ was +0.21 D (SD: 0.43; median: +0.11, range: -0.73 to +1.05 D, Table 1). A total of 67.6% (23) and 94.1% (32) of eyes had mean prediction error for the SEQ within ±0.50 D and ±1.00 D, respectively. A statistically significant improvement was observed in logMAR UDVA (only emmetropic targeted patients were evaluated) and CDVA (Wilcoxon test, $P<0.01$, Table 1). A logMAR CDVA of -0.1 or better and of 0.0 or better was found postoperatively in 82.4% (28) and 97.1% (33) of eyes, respectively.

Ocular Aberrometric Outcomes Mean postoperative values of the Zernike terms (6 mm pupil) corresponding to the primary coma (Z_3^{-1} and Z_3^1) and primary spherical aberration (Z_4^0) were +0.02 μm (SD: 0.27; median:+0.04, range:-0.87 to+0.42 μm), -0.04 μm (SD: 0.16; median: -0.03, range: -0.37 to+0.07 μm), and -0.06 μm (SD: 0.12; median: -0.09, range: -0.37 to+0.12 μm), respectively (Figure 1). Mean postoperative values of total and higher order root mean square (RMS) were 1.74 μm (SD: 0.98; median: 1.73, range: 0.49 to 3.93 μm), and 0.51 μm (SD: 0.19; median: 0.46, range: 0.25 to 1.12 μm), respectively (Figure 1). No correlation was found between all the aberrometric parameters and postoperative CDVA ($-0.064 \leqslant r \leqslant 0.250$, $P \geqslant 0.18$).

Contrast Sensitivity Outcomes Figure 2 displays graphically the postoperative photopic and mesopic contrast sensitivity function with and without a glare source. As shown, no statistically significant differences were found in mesopic and photopic contrast sensitivity measured with and without a glare source for any of the spatial frequencies evaluated (Wilcoxon test, $P \geqslant 0.28$). As expected, photopic contrast sensitivity was higher compared to mesopic values for 3, 6, 12 and 18 cycles/° under both photopic and mesopic conditions (Wilcoxon test, $P \leqslant 0.10$). A limited but

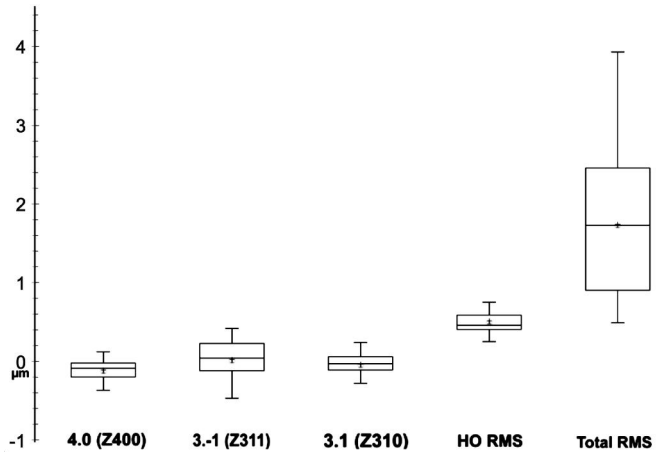

Figure 1 Ocular aberrations 4.0 (Z400): Spherical aberration; 3.-1 (Z311): Primary coma on X-axis; 3.1 (Z310): Primary coma on Y-axis; HO RMS: High order root mean square; Total RMS: Total root mean square.

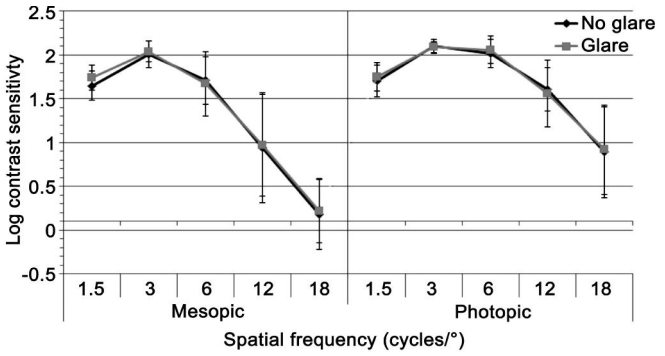

Figure 2 Postoperative photopic and mesopic contrast sensitivity function with and without glare.

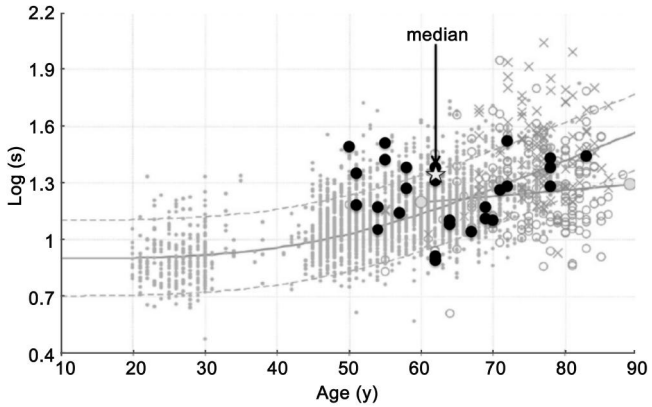

Figure 3 Straylight measurements in relation to normal curve of distribution adapted of Van Den Berg *et al* [22] Log (s): Log straylight parameter.

statistically significant correlation between contrast sensitivity and higher order RMS was only found for the measurement performed under mesopic conditions for the spatial frequency of 3 cycles/° (r=-0.495, P=0.01). No correlation was detected between the magnitude of postoperative spherical aberration and contrast sensitivity (-0.254≤r≤0.283, P≥0.05).

Straylight Outcomes Mean value of the straylight parameter was 1.35 log (SD: 0.44; median: 1.28, range: 0.89 to 2.91 log; Figure 3). No significant correlations were found between the straylight and aberrometric parameters (-0.254≤r≤0.283, P≥0.05). Likewise, the straylight parameter was found to be significantly correlated with the mesopic contrast sensitivity with (r=-0.564, P<0.01) and without a glare source (r=-0.564, P<0.01) for 6 cycles/°, the mesopic contrast sensitivity measured with glare for 12 cycles/° (r=-0.473, P=0.01), and the photopic values measured with (r=-0.50, P=0.01) and without a glare source (r=-0.60, P<0.01) for 18 cycles/°.

DISCUSSION

In the current series, a good predictability of the refractive correction was achieved with the evaluated aspheric IOL. Mean prediction error using the Holladay or Haigis formulas, and therefore the Gaussian paraxial optics, was +0.21 D. The logMAR UDVA after surgery in patients targeted for emmetropia in this trial had a mean postoperative value of 0.00 (range -0.26 to 0.18). Regarding the CDVA, 97.1% of eyes achievied a value of 0.0 logMAR (range -0.30 to 0.10) or better. This result is comparable with other studies evaluating visual outcomes after implantation of aspheric IOL[6-10,14-19,23].

Postoperative ocular primary coma and spherical aberration were minimal and comparable to those that can be found in the normal human eye[24]. Specifically, the postoperative level of primary spherical aberration was very close to zero (+0.02 μm), which was expected as the evaluated IOL is aimed for compensating the positive spherical aberration, which is normally present in the elderly cornea.

Rekas and colleagues [8] found in a comparative study that spherical and coma aberrations were similar in eyes with an aspheric IOL and younger phakic eyes, with a mean spherical aberration of +0.06 ±0.04 μm after the implantation of a specific model of aspheric IOL. Other authors have also reported levels of postoperative ocular spherical aberration very close to zero after implantation of different modalities of aspheric IOL[6,9,10,14-19], as in our series.

The potential impact of ocular scattering on the visual quality achieved with this IOL was evaluated by means of straylight parameters measured with the C-Quant device. A mean value of straylight of 1.35 log was obtained which is a straylight level within the limits that can be found in the healthy eye for the same age range (mean values of 1.2 at 70 years old and 1.4 at 80 years old)[22]. Likewise, similar straylight values to that obtained in our study have been reported by other authors evaluating the optical performance with different modalities of aspheric IOLs[3,25,26].

Contrast sensitivity outcomes were good under both photopic and mesopic conditions. No clinically relevant correlations were found between the postoperative magnitude of higher order aberrations and contrast sensitivity. This confirms the minimal impact of optical aberrations on the visual function as a consequence of their optimized levels after the implantation of the evaluated aspheric IOL.

Nochez *et al* [27] reported in a recent study that three ocular aberrations (2^{nd}-order astigmatism, trefoil, spherical aberration) seemed to interact with objective contrast sensitivity and depth of focus after the implantation of the aspheric IOL Acri.Smart. In our study, this potential interaction seems to be negligible. This preliminary evidence should be confirmed in future studies evaluating larger sample sizes and comparing the level of interaction between contrast sensitivity and aberrations with different modalities of IOLs. Concerning the correlation between straylight and contrast sensitivity with the evaluated IOL, the straylight parameter was found to be significantly correlated with the mesopic contrast sensitivity for 6 cycles/° and the photopic contrast sensitivity for 12 cycles/° . However, these correlations were moderate and limited for medium spatial frequencies. It should be considered that there is also a potential relationship between straylight and contrast sensitivity in phakic eyes, especially in eyes with poor ocular optical quality, as the straylight is a factor contributing to the retinal image degradation [28,29]. More studies evaluating the relationship between straylight and contrast sensitivity after the implantation of different models of IOL should be performed in the future in order to evaluate the relevance of the scattering factor with different types of IOL optic designs.

In accordance with the limited levels of straylight (Figure 3) and ocular aberrations (Figure 2) with the implantation of the evaluated IOL, the impact of a specific glare source on contrast sensitivity was found to be limited (Figure 1), with no statistically significant differences in mesopic and photopic contrast sensitivity measured with and without a glare source for any of the spatial frequencies evaluated.

In conclusion, the implantation of the aspheric IOL Tecnis ZCB00 after cataract surgery allows the restoration of distance visual function, providing optimized image quality and good levels of contrast sensitivity. The low incidence of disturbing visual symptoms leads to high levels of patient satisfaction. Future studies should be conducted in order to evaluate long term outcomes obtained with this modality of aspheric IOL as well as studies aiming at the *in-vivo* optical performance of the IOL, including the potential effect of small decentrations, fibrotic capsular changes and corneal aberrometric variations.

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