Clinical Outcomes and Capsular Bag Stability of a Four-Point Haptic Bitoric Intraocular Lens

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ABSTRACT

PURPOSE: To evaluate the visual, refractive, and aberrometric outcomes of a bitoric intraocular lens (IOL) and its stability and alignment within the capsular bag.

METHODS: A retrospective study including 41 eyes of 24 patients with preexisting corneal astigmatism of 0.75 diopters or greater undergoing cataract surgery with implantation of the bitoric IOL AT TORBI 709M (Carl Zeiss Meditec, Jena, Germany). Visual and refractive outcomes were evaluated during a 3-month follow-up period. The misalignment between intended and real axis and the levels of corneal, internal, and ocular aberrations (KR-1W; Topcon, Tokyo, Japan) were also evaluated.

RESULTS: A total of 76% and 97% of eyes had a postoperative spherical equivalent within ±0.50 and ±1.00 diopters of emmetropia, respectively. Likewise, a total of 86% and 95% of eyes had a postoperative absolute value of refractive cylinder of 0.50 or less and 1.00 or less diopters, respectively. Mean postoperative corrected distance visual acuity was 0.00 logMAR (20/20 Snellen). Mean values of postoperative monocular and binocular uncorrected distance visual acuity were 0.10 and 0.00 logMAR (20/25 and 20/20 Snellen), respectively. The aberrometric analysis confirmed that the magnitude of ocular higher-order aberrations was mainly due to corneal optics and that the corneal astigmatism correction was sufficient with the toric IOL. Mean absolute IOL misalignment was 3.5º with values ranging from 0º to 10º.

CONCLUSIONS: The bitoric IOL AT TORBI 709M is able to provide a predictable correction of corneal astigmatism with low postoperative levels of ocular higher-order aberrations.

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cataract surgery were included. Inclusion criteria were patients with cataract or presbyopia/pre-presbyopia suitable for refractive lens exchange seeking spectacle independence, and a preexisting corneal astigmatism of 0.75 diopters (D) or greater. Exclusion criteria were patients with a history of glaucoma or retinal detachment, abnormal iris, corneal irregular astigmatism, macular degeneration or retinopathy, neuroophthalmic disease, a history of ocular inflammation, or previous ocular surgery. In all cases, cataract surgery with implantation of the bitoric IOL AT TORBI 709M had been performed. All patients had been adequately informed about the surgery and signed a consent form. The study adhered to the tenets of the Declaration of Helsinki and was approved by the local ethics committee.

EXAMINATION PROTOCOL

Before surgery, a complete ophthalmological examination had been performed in all cases, including manifest refraction, keratometry, monocular and binocular uncorrected and corrected distance visual acuity, Goldmann applanation tonometry, slit-lamp examination, corneal topography, biometry (IOLMaster v.4.3; Carl Zeiss Meditec), and funduscopy. Postoperatively, patients were examined at 1 day and 1 and 3 months after surgery. After this initial follow-up, all patients were examined annually. The postoperative examination protocol was identical to the preoperative protocol, with the additional evaluation of corneal, internal, and ocular aberrations (KR-1W; Topcon, Tokyo, Japan).

This analysis was performed under pupil dilation and considered a pupil aperture of 5.0 mm for the analysis. The following parameters were calculated and recorded for the corneal, internal, and ocular optics: astigmatism ($Z_{1}^{0,1}$, $Z_{2}^{0,1}$), coma ($Z_{3}^{0}$), higher-order aberrations (HOA) root mean square, and the Zernike coefficient for spherical aberration ($Z_{4}^{0}$). The results of the last postoperative visit were considered for the analysis of the outcomes achieved (4 years after surgery).

SURGERY

All surgeries were performed by the same experienced surgeon (DB) using a standard technique of micro-incision sutureless microcoaxial phacoemulsification. All incisions were made at the steepest corneal meridian that was marked with a Pendl marker (G-33764; Geuder, Heidelberg, Germany) prior to surgery with the patient’s head vertically aligned to control and prevent cyclorotation during surgery. Topical anesthesia and mydriatic drops were instilled in all cases before initiating the surgical procedure. After capsulorhexis creation and phacoemulsification, the IOL was inserted into the capsular bag using the A6 injector and AT Smart cartridge (Carl Zeiss Meditec AG, Jena, Germany). Once inserted into the capsular bag, the IOL was rotated to align the IOL cylinder axis with the steepest corneal axis. The same postoperative treatment was administered to all patients, consisting of corticosteroid-antibiotic combination eye drops.

In all cases, Z CALC software (Carl Zeiss Meditec AG) was used for the calculation of the IOL power to implant, considering the emmetropia as the target refraction. Z CALC is a web-based computer program for the calculation of toric IOLs (https://zcalc.meditec.zeiss.com/zcalc/#login).

THE IOL

The AT TORBI 709M toric IOL is a foldable, one-piece, bitoric, monofocal, and aspheric (aberration neutral) lens made of a hydrophilic acrylic material with hydrophobic surface properties. It has an overall length of 11.0 mm and an optic diameter of 6.0 mm. The angulation of haptics in relation to the IOL optic is 0°. The lens powers are available from -10.0 to +32.0 spherical diopters and 1.0 to 12.0 cylindrical diopters. This IOL has been designed to be implanted through a 1.8-mm corneal incision.

STUDY DESIGN

The concept of the study was developed in cooperation with the International Vision Correction Research Centre & David J. Apple International Laboratory for Ocular Pathology, Department of Ophthalmology, University of Heidelberg, Heidelberg, Germany. The International Vision Correction Research Centre & David J. Apple International Laboratory for Ocular Pathology, Department of Ophthalmology, University of Heidelberg also served as the reading center for objective data, analysis, and evaluation.

STATISTICAL ANALYSIS

SPSS version 15.0 (IBM, Armonk, NY) for Windows was used for statistical analysis. The Kolmogorov–Smirnov test was used to check the normality of the data distribution. When parametric analysis was possible, the Student’s $t$ test for paired data was performed for all parameter comparisons between preoperative and postoperative examinations. Otherwise, when parametric analysis was not possible, the Wilcoxon rank sum test was applied to assess the significance of differences between consecutive examinations. In all cases, the same level of significance ($P < .05$) was considered. The relationship between variables was evaluated by means of the Pearson or Spearman correlation coefficient whether the condition of normality could be assumed or not.
RESULTS

The study enrolled a total of 41 eyes of 24 patients with ages ranging from 50 to 75 years (mean age: 63 years). Mean preoperative manifest sphere and cylinder were -1.50 D (range: -13.75 to +7.00 D) and -1.70 D (range: -0.25 to -7.00 D), respectively. Mean preoperative spherical equivalent (SE) was -2.40 D (range: -14.00 to +6.12 D) and mean preoperative logMAR corrected distance visual acuity was 0.30 (20/40 Snellen) (range: 0.00 to 0.90 logMAR [20/20 to 20/160 Snellen]).

VISUAL ACUITY AND REFRACTIVE OUTCOMES

A statistically significant change was observed after surgery in manifest sphere, cylinder, and SE ($P < .05$) (Figure 1). Mean postoperative manifest sphere, cylinder, and SE were +0.08, -0.35, and -0.05 D, respectively. A total of 76% and 97% of eyes had a postoperative SE within ±0.50 and ±1.00 D of emmetropia, respectively (Figure 2). Regarding manifest cylinder, a total of 86% and 95% of eyes had a postoperative absolute value of 0.50 D or less and 1.00 D or less, respectively (Figure 3).

Figure 4 displays the distribution of preoperative corneal astigmatism and postoperative refractive astigmatism in a single angle plot. Although the distribution of preoperative corneal astigmatism was largely scattered, the distribution of postoperative refractive cylinder was concentrated around the value of zero (Figure 4). Neither overcorrection nor undercorrection was observed when the magnitude of the attempted correction in terms of SE was plotted against the level of achieved correction (Figure 5). The cylindrical power of the implanted IOL was moderately correlated with the magnitude of postoperative refractive cylinder ($r = -0.43$) and poorly correlated with the postoperative manifest sphere ($r = 0.24$) (Figure 6). When the refractive results were stratified according to the preoperative magnitude of corneal
astigmatism (group 1: ≤ 1.00 D; group 2: between 1.01 and 2.5 D; and group 3: > 2.50 D), no statistically significant differences in postoperative sphere (group 1: -0.25 ± 0.87 D; group 2: +0.15 ± 0.87 D; and group 3: +0.31 ± 0.51 D, P = .32), cylinder (group 1: -0.29 ± 0.24 D; group 2: -0.21 ± 0.28 D; and group 3: -0.67 ± 0.56 D, P = .07), or SE (group 1: -0.39 ± 0.86 D; group 2: +0.05 ± 0.86 D; and group 3: -0.03 ± 0.43 D, P = .35) were noted among the corneal astigmatism subgroups.

Regarding the visual outcomes, a statistically significant improvement was observed in corrected distance visual acuity after surgery (P < .05), with a mean postoperative value of 0.00 ± 0.05 logMAR (range: -0.10 to 0.20 logMAR) (20/25 Snellen) compared to a mean preoperative value of 0.314 ± 0.206 logMAR (range: 0.20 to 0.90 logMAR) (Figure A, available in the online version of this article). Mean postoperative values of monocular and binocular uncorrected distance visual acuity of 0.10 ± 0.20 (range: -0.12 to 0.54 logMAR) and 0.00 ± 0.10 logMAR (range: -0.16 to 0.34 logMAR) (20/25 and 20/20 Snellen), respectively, were found (Figure A).

**ABERROMETRIC OUTCOMES**

Figure B (available in the online version of this article) displays the postoperative levels of ocular, corneal, and internal astigmatism, HOAs, coma, and spherical aberration. The correction of corneal astigmatism results from the IOL are also shown in Figure B. Likewise, the magnitude of HOAs was shown to be mainly due to the corneal optics.

**IOL POSITION**

Mean absolute IOL misalignment was 3.5°, with values ranging from 0° to 10° (Figure A). When the postoperative axis of the IOL was plotted against the axis of implantation, no clear trend to clockwise or counterclockwise rotation was observed (Figure 7).

**DISCUSSION**

In the current study, mean values of postoperative monocular and binocular uncorrected distance visual acuity were 0.10 and 0.00 logMAR (20/25 and 20/20 Snellen), respectively. This excellent visual outcome suggests that the bitoric IOL evaluated is able to provide a high level of precision in the refractive correction of corneal astigmatism after cataract surgery. Indeed, a good level of refractive predictability was obtained in our series, with 76% and 97% of eyes having a postoperative SE within ±0.50 and ±1.00 D of emmetropia, respectively, and 86% and 95% of eyes having a postoperative absolute value of manifest cylinder of 0.50 D or less and 1.00 D or less, respectively.

These outcomes are similar to those reported previously evaluating the same type of bitoric IOL.1-4 Bascaran et al., using exactly the same toric IOL and vector analysis, found that 100% of eyes were within ±1.00 D and
95.2% within ±0.50 D for the astigmatic power vector components \( J_0 \) and \( J_{45} \). Scialdone et al.\(^2\) found in a prospective, randomized, comparative study aimed at evaluating a conventional toric IOL and the AT TORBI 709M that 94.4% of eyes in both groups had a polar value along 90° meridian of refractive astigmatism within ±0.50 D.

Likewise, our results in terms of predictability of refractive correction were also comparable to those reported for other modalities of toric IOLs\(^5-8\) and in some cases even better.\(^9,10\) Visser et al.\(^9\) found that residual refractive astigmatism of -1.00 D or less was achieved in approximately 90% of samples of eyes implanted with a toric multifocal IOL. Ahmed et al.\(^6\) found in a sample of eyes implanted with a toric IOL that the SE was within ±0.50 D of target in 77% of eyes.

The optimization of the constant and formulas for IOL power calculation with this type of toric IOL seems to be one of the main reasons for the achieved refractive precision. Indeed, a limited correlation was found between the cylindrical power of the IOL implanted and the postoperative refractive cylinder. An acceptable level of refractive precision was achieved even when the correction of high levels of astigmatism was intended. Cylindrical overcorrection or undercorrection is not uncommon with toric IOLs when high astigmatisms are corrected.\(^11-13\) Hoffmann et al.\(^11\) found in a case series enrolling 40 eyes of 30 patients implanted with high cylinder powers (range: 3.00 to 6.00 D) of a specific toric IOL (Acrysof toric IOL; Alcon Laboratories, Inc., Fort Worth, TX) a mean residual cylinder of 0.67 ± 0.32 D. Visser et al.\(^13\) reported that the residual refractive cylinder after implantation of the same toric IOL was less than 0.75 D in 62% of eyes and less than 1.00 D in 81% of eyes. All of these outcomes are better in our study, with 95% of eyes showing a postoperative refractive cylinder of 1.00 D or less and a mean residual refractive cylinder of -0.35 D.

Another factor contributing to the good level of refractive predictability observed in our study was the positional stability of the IOL. Toric IOL rotation may lead to an ineffective correction of astigmatism.\(^14-17\) Viestenz et al.\(^17\) estimated that 11.5° of toric IOL rotation would lead to residual astigmatism that is 40% of the initial astigmatic power and 3° resulting in 10% of the initial power. In our sample, a mean deviation of 3.5° was found, with only 1 case showing 10° of misalignment and all of the remaining eyes showing deviations of 8° or less. This confirms that the rotational stability of the evaluated bitoric IOL was good in most cases, which is consistent with the level of rotational stability reported for other toric IOLs.\(^8,18,19\) Mendicute et al.\(^8\) reported a mean IOL rotation of 3.63° in eyes implanted with the Acrysof toric IOL, with 96% of eyes showing an IOL rotation of 10° or less. With the same type of toric IOL, Alíó et al.\(^18\) obtained a mean value of IOL rotation of 3.35° ± 3.56°. Sheppard et al.\(^8\) found a mean absolute IOL misalignment from the intended axis of 3.4° (range: 0° to 12°) in a sample of eyes implanted with the Tecnis toric IOL (Abbott Medical Optics, Inc.,
Santa Ana, CA). In comparison to previous studies also evaluating the AT TORBI 709M IOL, a similar rotational stability was observed.3,2 Vickovic et al.3 reported a median IOL axis rotation of 3.0° (interquartile range: 2.0° to 4.0°) and Scialdone et al.2 found an IOL misalignment of less than 5° in 66.6% of eyes (maximum 11°). In contrast, Bascaran et al.1 reported a higher mean value of rotation (4.42° ± 4.31°), with only 86% of cases showing an IOL rotation of less than 10°. Besides differences in the evaluated sample, differences in the procedure for evaluating IOL misalignment or rotation may account for part of the discrepancies with other study results.

Conical, internal, and ocular aberrometric outcomes were also investigated to obtain more information about the optical behavior of the evaluated toric IOL. As may be expected, large amounts of postoperative internal astigmatism were present due to the implantation of the toric IOL. This internal astigmatism provided a compensation for conical astigmatism leading to reduced levels of ocular astigmatism, which was the aim of the surgical procedure. Regarding HOAs, low internal levels of this type of optical aberration were found in our series, confirming the contribution of the optimized optics of the evaluated bitoric IOL to the preservation of the ocular optical quality, as reported in a previous study.2 Therefore, the magnitude of ocular HOAs after the implantation of the evaluated bitoric IOL seems to be mainly due to the corneal optics. An analysis of corneal aberrations is recommended before the implantation of toric IOLs to obtain information about the potential levels of ocular HOAs that are going to be present after surgery. It should be considered that reduced levels of internal aberration have been observed after the implantation of other modalities of toric IOLs, with the majority of postoperative ocular HOAs arising from the cornea.20,21

The AT TORBI 709M bitoric IOL is able to restore distance visual function in eyes with cataract and corneal astigmatism, providing a predictable correction of conical astigmatism with low postoperative levels of ocular HOAs due to its minimal trend of misalignment and rotation and its optimized optical properties.

AUTHOR CONTRIBUTIONS
Study concept and design (FTAK, DB, KK, GUA, HK); data collection (DB); analysis and interpretation of data (FTAK, DB, KK, GUA, HK); writing the manuscript (FTAK); critical revision of the manuscript (FTAK, DB, KK, GUA, HK); statistical expertise (FTAK, HK); and writing the manuscript (FTAK); critical revision of the manuscript (DB); analysis and interpretation of data (FTAK, DB, KK, GUA, HK).

REFERENCES
Figure A. (1) Change in monocular corrected distance visual acuity (CDVA) and (2) mean values of monocular and binocular uncorrected distance visual acuity (UDVA) and CDVA.
Figure B. (1) Mean values of ocular, corneal, and internal astigmatism, (2) root mean square (RMS) for higher-order aberrations (HOAs), (3) coma, and (4) spherical aberration.