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SHORT REPORT

A New Methodology for Evaluating the Potential Impact of Residual Refractive Astigmatism in Pseudophakic Patients

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Purpose: To validate a new methodology to evaluate the impact of astigmatism in pseudophakia using an astigmatic defocus curve.
Setting: Hospital Oftalmológico de Brasilia, Brazil.
Design: Non-randomized cohort study.
Methods: For every point of the defocus curve, from −2.00 to +3.00 with 0.50D intervals, visual acuity was assessed with optically induced astigmatism (0.50D, 1.00D and 1.50D at 90 and 180 degrees) in pseudophakic patients implanted with a refractive-enhanced intraocular lens.
Results: Twelve patients were analyzed. A statistically significant difference was found between the 90° (ATR) and 180°(WTR) axis with 1.50D astigmatism, providing better visual acuity in ATR astigmatism ($p < 0.05$).
Conclusion: This new methodology is reproducible, useful and may predict residual astigmatism tolerance in pseudophakic patients, which may help with surgery planning and IOL decision-making.
Keywords: cataract, surgery, phacoemulsification, optics, residual astigmatism, visual performance

Introduction

Cataract surgery now incorporates a refractive component, aiming to simultaneously correct refractive errors alongside cataract extraction. The primary objective is to achieve minimal reliance on spectacles for both distance and near vision tasks in pseudophakic patients. Introduction of presbyopia-correcting intraocular lenses (IOLs), such as trifocals, extended depth of focus lenses and enhanced monofocal, has significantly expanded the options for achieving spectacle independence following lens replacement surgery.[1–11]

To achieve optimal refractive outcomes, it is imperative to address corneal astigmatism during cataract surgery. Treatment options include toric intraocular lenses (IOLs) and corneal limbal relaxing incisions. However, many patients may still experience residual refractive astigmatism despite these interventions. A recent meta-analysis revealed that residual astigmatism of 0.50D or less was achieved in 45% to 85% of cases with certain types of IOLs. This variability may be attributed to factors such as IOL tilt and effective position, which are beyond the direct control of the surgeon. Hence, intraocular lenses that can provide patients with optimal vision even in the presence of remaining astigmatism would be preferable.[2,9,12–27]

In 2010, Hayashi et al demonstrated the impact of residual astigmatism on visual acuity with diffractive IOLs by directly assessing the visual acuity of patients with varying degrees of cylinder. Defocus curves have emerged as a reliable method for evaluating the performance of presbyopia-correcting IOLs across various focal points, particularly

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emphasizing their efficacy in near-vision tasks without additional visual correction. However, the impact of astigmatism on visual acuity may be influenced by residual myopia or hyperopia. A modified defocus curve approach can be employed to isolate the effect of the residual cylinder on visual acuity at different focal distances. This involves inducing a cylinder at each point of the defocus curves.

The Tecnis Eyhance ICB00 IOL (Johnson & Johnson in New Jersey, USA) is a monofocal lens with a modified anterior surface asphericity and variable power distribution, with lower power in the periphery progressively increasing toward the center. While the Eyhance IOL aims to enhance vision for intermediate tasks compared to standard monofocal IOLs, it's important to note that it does not meet ANSI criteria for classification as an EDOF IOL. Nevertheless, it compensates for spherical aberrations in the cornea. Clinical observations strongly support its capacity to improve intermediate-distance vision compared to conventional monofocal IOLs, and notably, it lacks diffractive rings typical of diffractive IOLs.[4,23]

Recent studies have compared the astigmatic tolerance of an EDOF IOL with different multifocal IOLs. The EDOF IOL has a slightly better astigmatic tolerance of 1.00 D compared to those of bifocal IOLs at 0.75 D and trifocal IOL at 0.50 D. Despite the well-known advantages of multifocal and EDOF IOLs, the one-major concern is the significant impact of residual astigmatism on visual acuity (VA) and patient satisfaction.[7–10]

This study proposes and validates a new methodology to evaluate the impact of residual astigmatism in pseudophakic patients using a defocus curve with induced astigmatism.

Methods

This prospective and non-randomized cohort study included patients older than 40 with a normal ophthalmological examination besides senile cataracts. This study was conducted within the Department of Cataract at the Hospital Oftalmológico de Brasilia (HOB). Before surgery, written informed consent was secured from all patients, and the study received approval from the local ethics committee (approval code: 42915320.3.0000.5667). All procedures adhered rigorously to the ethical standards the responsible human experimentation committee set forth and followed the principles outlined in the Helsinki Declaration.

Pre-Operative Evaluation and Patient Selection

Patients were recruited for this study from a single site between October 4, 2022, and January 20, 2023.

Inclusion Criteria

Patients who underwent bilateral phacoemulsification surgery with the implant of an enhanced monofocal lens (Tecnis Eyhance ICB00) IOL with residual refractive astigmatism of less than 0.50D in both eyes.

Exclusion Criteria

Previous ocular surgery; central endothelial cell count <2000 cells/mm2; glaucoma, intraocular pressure >21 mmHg; amblyopia; retinal abnormalities; steroid or immunosuppressive treatment, connective tissue diseases; patients who had complicated cataract surgery (eg, posterior capsule rupture, vitreous loss, or an IOL unplaced in the capsular bag); irregular astigmatism or keratoconus.

Pre-Operative Evaluation

All patients had a complete ophthalmological examination, and we performed the following auxiliary exams: IOL Master 700 (Zeiss, Germany), OPD Scan (NIDEK, Japan), and Pentacam (Oculus, Germany).

Study Lens

Tecnis Eyhance ICB00 (Johnson & Johnson Vision) is a single-piece biconvex hydrophobic acrylic IOL with a negative spherical aberration of −0.27 μm. It features a continuous increase in power profile on its aspheric anterior surface, devoid of diffractive rings or zones. This aims to extend the depth of focus, which can provide patients with an intermediate-distance focal point.

Surgeries

All procedures were consistently conducted by the same experienced surgeon, following standard protocols. Phacoemulsification surgery was executed through a temporal clear corneal incision, and a foldable posterior chamber intraocular lens (IOL) was inserted into the capsular bag. The Surgeries were performed using the Centurion phacoemulsification device (Alcon, Texas, USA).

Defocus Curve

Only one eye per patient was included in the study (the dominant one). Astigmatic defocus was induced over the manifest distance refraction with negative refractive cylinder lenses (CYL) from −0.50 to −1.50 D in 0.50 D steps at two axis' orientations (0 and 90 degrees) to induce ATR and WTR simple hyperopic astigmatisms, respectively. The defocus curves were obtained in corrected distance visual acuity with the Early Treatment Diabetic Retinopathy Study (ETDRS) reading charts, at intervals of 0.50 spherical diopters from −3.00D to +2.00D associated with astigmatism induced (astigmatic defocus). This method allowed us to evaluate the impact of induced refractive astigmatism on visual performance on the defocus curve and compare the results between the two groups of patients implanted with Tecnis Eyhance ICB00.

Statistical Analysis

A statistical software, SPSS (Version 24.0 for Windows; IBM, Armonk, NY), was used for statistical analysis. The Kolmogorov–Smirnov test was used to check the normality of the data distribution. When parametric analysis was possible, Fisher exact test data was performed. In cases when parametric analysis was not possible, the Mann–Whitney *U*-test was applied. An independent two-sample *T*-test was performed for the statistical analysis of pupil size, uncorrected distance visual acuity (UDVA), and age. P value < 0.05 was considered statistically significant in all cases.

The sample size of 12 patients was sufficient to detect a medium-to-large effect size (DZ = 0.66) with a 5% significance level for a one-tailed test and a statistical power of 0.8 (type II error < 20%). We conducted a sensitivity analysis using GPower 3.1VR software.

Results

This study included twelve eyes of twelve patients. This population comprises patients between 53 and 79 (mean age of 64 ±1.06). Table 1 shows summary statistics for subject demographics, photopic pupil size, baseline UDVA, manifest refractive sphere, and manifest refractive cylinder. In our sample, seven patients presented right eye dominancy (58.3%) and five left dominancy (41.7%).

A statistically significant difference was found between the 90° (ATR) and 180° (WTR) axis with 1.50D astigmatism, providing better visual acuity in ATR astigmatism ($p < 0.05$) (Table 2).

Additionally, when analyzing the worst performance in the defocus curve with the addition of −1.00D spherical or +0.50 spherical with ATR or WTR astigmatism, we encounter the same visual acuity with +0.50 and 1.0 (ATR or WTR) astigmatism and −1.00 sphere and 1.0 (ATR or WTR) astigmatism. On the other hand, when we induce −1.00 sphere and 0.5 or 1.5 (ATR or WTR) astigmatism, we find statistically significant better visual acuity with WTR astigmatism (Table 3).

Table 1 Subject Demographics and Baseline Characteristics (Mean Values and Standard Deviation)

	Values	N (Eyes)
IOL power *(Diopters)*	19.93 (3.62)	12
UDVA. *(LogMar)*	−0.12 (0.03)	12
Manifest refraction sphere. *(Diopters)*	0.00 (0.00)	12
Manifest refraction cylinder. *(Diopters)*	0.18 (0.06)	12
Mesopic pupil size (postoperative) *(mm)*	5.40 (0.20)	12
Photopic pupil size (postoperative) *(mm)*	3.92 (0.17)	12

Table 2 Influence of Induced Astigmatism on Distance VA

Induced Astigmatism	LogMar Visual Acuity (Mean±SD)	P value
ATR 0.50D	−0.10 (0.024)	0.6691
ATR 1.00 D	−0.06 (0.035)	0.3301
ATR 1.5 D	−0.06 (0.026)	0.4543
WTR 0.50D	−0.09 (0.031)	0.5485
WTR 1.00D	−0.02 (0.065)	0.3702
WTR 1.50D	0.03 (0.028)	0.1624

Note: SD – Standard Deviation. Results with Mann–Whitney test.

Table 3 Comparison of Induced ATR and WTR on Distance VA

Induced Sphere (Diopters)	Induced Astigmatism (Diopters)	LogMar Visual Acuity (Mean Values)	P value
−1.00 D −1.00 D	ATR 0.5 D WTR 0.5 D	−0.108 −0.058	0.002
−1.00 D −1.00 D	ATR 1.0 D WTR 1.0 D	−0.025 −0.025	1
−1.00 D −1,00 D	ATR 1.5 D WTR 1.5 D	0.166 0.0167	0.002
+0.50 D +0.50 D	ATR 1.0 D WTR 1.0 D	0.033 0.033	1

Note: Mann–Whitney test was used.

Discussion

Spectacle independence is the primary objective for patients opting to implant presbyopia-correcting intraocular lenses (IOLs). Significative refractive residual error can reduce visual acuity and decrease patient satisfaction. Toric IOLs may be necessary for patients with corneal toricity of 0.75D or more.[7,11]

Knowledge of the astigmatic tolerance of IOLs is crucial for surgical planning as it can affect the outcome of the surgery. Astigmatic tolerance limits of multifocal IOLs are usually around 0.75D. However, a recent study found that an EDOF IOL had a slightly higher astigmatic tolerance of 1.00D than bifocal IOLs (0.75D) and trifocal IOLs (0.50 D). Surgeons can use this information to select the appropriate IOL for patients with different levels of astigmatism to minimize the need for secondary management and improve patient satisfaction.[6,9]

Residual astigmatism interferes with the functional advantage of simultaneous focal points in multifocal IOLs. Studies have also found a high retreatment rate in eyes implanted with multifocal IOLs due to significant residual astigmatism. Compensating for residual astigmatism, even as low as 0.50–0.75D, has been shown to improve contrast and quality of vision, leading to improved patient satisfaction.[2,9,12–14]

Hayashi et al studied the impact of residual astigmatism in monofocal and multifocal IOL. They found that residual astigmatism greater than 1 D worsened vision in bifocal IOLs and 0.75 D in trifocal IOLs, so it is crucial to understand each IOL behavior with residual astigmatism before implantation. However, the study was done by analyzing visual acuity in patients with manifest post-operative astigmatism.[17,22]

Pérez-Sanz et al also studied astigmatism tolerance, comparing patients with a monofocal IOL and an EDOF IOL through an in vitro measurement. They analyzed the optical quality and assessed it on an optical bench for 2.0, 3.0, and 4.5 mm pupils. The effect of residual astigmatism was investigated from through-focus images recorded with increasing amounts of regular positive astigmatism induced with a deformable mirror. They also compared WTR and ATR-induced astigmatism and found statistically better VA Results with ATR astigmatism with both lenses.[24]

Our study corroborates with the findings of Rocha et al regarding better ATR astigmatism tolerance for distance vision. Our study adds that this effect also occurs in the negative side of the defocus curves, emphasizing that keeping some ATR astigmatism may have a beneficial impact on near vision.[25]

This study employed both a defocus curve and distance monocular visual acuity to analyze the tolerance to optically induced astigmatism in pseudophakic eyes with the refractive-enhanced monofocal intraocular lens Tecnis Eyhance and to determine the extent of possible vision loss attributable to the induced astigmatism. The validation of this new methodology will provide an additional tool for surgeons to determine whether a toric IOL is necessary when evaluating a patient before phacoemulsification. Moreover, it will bring new information when deciding which IOL should be implanted, especially when there is a difference in the corneal astigmatism measurements between diagnostic devices. Our results will also provide valuable information to patients and surgeons regarding the outcomes of toric IOL implantation.[13–15]

Our study has several limitations, mainly the sample size. More research is needed to confirm these findings and fully understand the factors that may impact the results.

In conclusion, this new methodology is reproducible and useful and may predict residual astigmatism tolerance in pseudophakic patients, which may help with surgery planning and IOL decision-making.

Ethics

The study was approved by the Hospital Oftalmologico Brasilia Ethics committee (No: 42915320.3.0000.5667).

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Disclosure

Wilson Takashi Hida is a consultant for Johnson and Johnson Vision Care Research, Ltd. The authors report no other conflicts of interest in this work.

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