

Visual Outcomes and Rotational Stability of a Single-Piece Hydrophilic Monofocal Toric Intraocular Lens

Resultados Visuais e Estabilidade Rotacional de uma Lente Intraocular Tórica Monofocal Hidrofílica de Peça Única

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ABSTRACT

INTRODUCTION: Corneal astigmatism greater than 1.5 diopters is a common refractive error present in approximately 15% to 22% of patients scheduled for cataract surgery. If not corrected, it will cause residual refractive astigmatism and spectacle dependence. Toric intraocular lenses allow the correction of astigmatism during cataract surgery. The purpose of this study is to assess the visual outcome and rotational stability of a single-piece hydrophilic monofocal toric intraocular lens after cataract surgery in patients with preexisting corneal astigmatism.

METHODS: In this prospective clinical study, a total of 117 eyes were implanted with RayOne® toric intraocular lenses after phacoemulsification surgery at Unidade Local de Saúde de Matosinhos in Matosinhos, Portugal, between September 2022 and March 2024. Patients with cataract and corneal astigmatism greater than 1.5 diopters measured with the IOLMaster 700® were included. Calculations of the intraocular lens power and axis placement were performed using the intraocular lens manufacturer's online calculator (Raytrace®). Outcomes of uncorrected, best corrected visual acuities and refractive status were analyzed at 1 and 6 months postoperatively. Intraocular lens rotation and posterior capsule opacification were evaluated at 6 months postoperatively.

RESULTS: The median postoperatively uncorrected visual acuity improved compared to the median of preoperative best corrected visual acuity (0.00 (0.10) logMAR vs 0.30 (0.3) logMAR, $p < 0.001$). The mean preoperative keratometric cylinder was 2.80 ± 1.22 diopters (range 1.50-8.18) and the mean postoperative refractive cylinder was 0.68 ± 0.50 diopters (range 0.00-2.50 D) ($p < 0.001$). A mean rotation relative to the intended axis of $1.41^\circ \pm 2.22^\circ$ (range 0° - 10°) was recorded at 6 months. At the last follow-up, 94.6% of the eyes showed no signs of posterior capsule opacification.

CONCLUSION: Toric intraocular lens implantation can provide spectacle independence for distance vision and is becoming increasingly significant in modern cataract surgery. RayOne® toric intraocular lens implantation after cataract surgery was stable and effective in correcting preexisting regular corneal astigmatism.

KEYWORDS: Astigmatism; Cataract Extraction; Lens Implantation, Intraocular; Lenses, Intraocular.

RESUMO

INTRODUÇÃO: O astigmatismo corneano superior a 1,5 dioptrias é um erro refrativo comum, presente em aproximadamente 15% a 22% dos doentes a serem submetidos a cirurgia de catarata. Quando não corrigido, pode causar astigmatismo refrativo residual e dependência de óculos. As lentes intraoculares tóricas permitem a correção do astigmatismo durante a cirurgia de catarata. O objetivo deste estudo é avaliar os resultados visuais e a estabilidade rotacional de uma lente intraocular tórica monofocal hidrofílica de peça única após cirurgia de catarata em doentes com astigmatismo corneano preexistente.

MÉTODOS: Neste estudo clínico prospetivo, num total de 117 olhos, foi implantada a lente intraocular RayOne® tórica após cirurgia de facoemulsificação na Unidade Local de Saúde de Matosinhos, em Matosinhos, Portugal, entre setembro de 2022 e março de 2024. Foram incluídos doentes com catarata e astigmatismo corneano superior a 1,5 dioptrias, medido com o IOLMaster 700®. Os cálculos da potência da lente intraocular e do posicionamento do eixo foram realizados utilizando a calculadora online do fabricante da lente intraocular (Raytrace®). Os resultados das melhores acuidades visuais não corrigidas e corrigidas, bem como o estado refrativo, foram analisados 1 e 6 meses após cirurgia. A rotação da lente intraocular e a opacificação da cápsula posterior foram avaliadas 6 meses após cirurgia.

RESULTADOS: A mediana da melhor acuidade visual não corrigida pós-operatória melhorou em comparação com a mediana da melhor acuidade visual corrigida pré-operatória (0,00 (0,10) logMAR *vs* 0,30 (0,3) logMAR, $p < 0,001$). O cilindro queratométrico pré-operatório médio foi de $2,80 \pm 1,22$ dioptrias (variação de 1,50-8,18) e o cilindro refrativo pós-operatório médio foi de $0,68 \pm 0,50$ dioptrias (variação de 0,00-2,50) ($p < 0,001$). Aos 6 meses, registou-se uma rotação média em relação ao eixo pretendido de $1,41^\circ \pm 2,22^\circ$ (variação de 0° - 10°). Na última avaliação, 94,6% dos olhos não apresentavam sinais de opacificação da cápsula posterior.

CONCLUSÃO: A implantação de lentes intraoculares tóricas pode proporcionar independência dos óculos para a visão de longe e é cada vez mais relevante na cirurgia moderna de catarata. A implantação da lente intraocular tórica RayOne® após cirurgia de catarata mostrou-se estável e eficaz na correção do astigmatismo corneano regular preexistente.

PALAVRAS-CHAVE: Astigmatismo; Extração de Catarata; Implante de Lente Intraocular; Lentes Intraoculares.

INTRODUCTION

Cataract surgery is considered a combined rehabilitative and refractive procedure. In recent years, with the advancement of modern surgical techniques, patients' expectations for postoperative vision have increased.

Corneal astigmatism is a common refractive error estimated to be greater than 1.5 diopters (D) in 15%-22% of patients scheduled for cataract surgery.^{1,2} Residual postoperative astigmatism is an important cause of residual ametropia after surgery and spectacle dependence.

Toric intraocular lens (IOL) implantation is the most commonly used method to correct astigmatism during cataract surgery.³ A variety of toric intraocular lenses (IOLs) are available to correct astigmatism during cataract surgery.⁴⁻⁶ The RayOne® (Rayner) hydrophilic acrylic toric IOL (RAO610T) is a monofocal posterior chamber IOL that compensates for corneal spherical aberrations and corneal astigmatism.

Like the other toric IOLs, its efficacy is highly dependent on its ability to remain aligned at the pretended axis.

Postoperative rotation of toric IOLs remains a significant concern in cataract surgery.⁷⁻⁹ Studies indicate that if an IOL rotates 10° off the intended axis, about one-third of the astigmatism correction is lost; with a 20° rotation, two-thirds of the correction is diminished; a rotation greater than 30° can increase astigmatism. For this reason, a 10° rotation is the considered threshold for planning IOL repositioning. Studies with large sample sizes and designed to evaluate the rotational stability of the RayOne® toric IOL are still lacking.

This study aimed to evaluate the visual outcomes and rotational stability of the RayOne® toric IOL after cataract surgery in patients with preexisting corneal astigmatism.

MATERIAL AND METHODS

STUDY DESIGN

This was a prospective noncomparative study conducted at Hospital Pedro Hispano – Unidade Local de Saúde de Matosinhos in Matosinhos, Portugal, between September 2022

and March 2024. The study followed the tenets of the Declaration of Helsinki and was approved by the local ethics committee of Unidade Local de Saúde de Matosinhos. Written informed consent was obtained from all patients before surgery.

PATIENTS

This study included patients with uncomplicated cataract that were submitted to phacoemulsification surgery with implantation of RayOne® toric IOL. Inclusion criteria were cataract and preexisting keratometric astigmatism greater than 1.5 D. Exclusion criteria were previous ocular surgery, irregular astigmatism, corneal disease, glaucoma, maculopathy, retinopathy, optic neuropathy and history of ocular trauma. In cases of bilateral surgery, only the first eye was included in the study.

STUDY LENSES

The implanted lens was the Rayner RayOne® Toric IOL (model RAO610T), a single-piece hydrophilic, acrylic, monofocal, aspheric lens. The lens has a closed loop with an anti-vaulting haptic design with no angulation, with a biconvex optic shape for positive powers and a convex/concave posterior surface for negative powers. It has a 6.0 mm optic diameter and an overall diameter of 12.5 mm. The delivery system used was a fully preloaded IOL single-use. The available spherical power ranged from -9.5 to +34.5 D (0.5 D increments) and cylinder power from +1.0 to +11.0 D (0.5 increments).

PREOPERATIVE EVALUATION, IOL, POWER CALCULATION

Every patient underwent extensive evaluation, including: patient age at the time of surgery, sex, medical history, objective refraction, monocular uncorrected (UDVA) and best corrected visual acuity (BCVA) measurements. Objective refraction was evaluated using autokeratometry (HRK 8000A®, Huvitz) and subjective refraction was based on the logarithm of the minimum angle of resolution (logMAR) chart. Furthermore, slit-lamp examination, intraocular pressure, dilated funduscopy, macular evaluation using spectral-domain optical coherence tomography (Spectralis®, Heidelberg Engineering) and corneal topography (Sirius®, CSO) were performed. Keratometry (K) and biometry measurements, including axial length and anterior chamber depth, were obtained with swept-source optical coherence biometer IOL Master 700®, Carl Zeiss Meditec AG. The spherical and cylindrical power and the axis placement were calculated using the IOL manufacturer's online calculator (Raytrace®, premium IOL calculator for RayOne Toric & T-flex®, available at <http://raytrace.rayner.com/>). For every calculation, we considered biometry data, a null surgically induced astigmatism (SIA), a 120° location for the main incision and the effect of posterior corneal astigmatism. The target postoperatively spherical equivalent (SE) was the closest to emmetropia.

The Raytrace® calculator used for IOL power and axis placement estimation incorporates a theoretical model of posterior corneal astigmatism. Although the value of in-

cluding posterior corneal data remains under debate in the literature, it was considered in this study based on growing evidence of its potential benefit, particularly in against-the-rule and oblique astigmatism.

SURGICAL TECHNIQUE

Surgeries were performed by one of fourteen surgeons using the same technique. Before surgery, the 0°-180° axis of the patient's eye was marked while the patient was sitting at the slit-lamp to prevent ocular cyclotorsion. Using an insulin needle, small superficial incisions were made on the limbus at the 3- and 9-o'clock positions and at the axis of the recommended lens at 2 points, 180° apart. For better visibility during surgery, the incisions were highlighted with a sterile blue marking pen. Phacoemulsification was performed through a 2.2 mm clear corneal incision. The anterior chamber was filled with an ophthalmic viscosurgical device (OVD). A continuous curvilinear capsulorhexis with approximately 5.5 mm of diameter and hydrodissection was performed. The cataract was removed with phacoemulsification and the toric IOL was implanted in the capsular bag. Following insertion, the IOL was rotated, aligning the toric reference lines on the IOL with the limbal implantation marks. The OVD was aspirated, with special care to remove the OVD from behind the lens, and replaced by a balanced salt solution, with incision hydration. The postoperative care included antibiotics, corticosteroids and nonsteroidal anti-inflammatory eye drops.

OUTCOME MEASURES

Patients were evaluated at 1 and 6 months postoperatively. Examinations included UDVA, BCVA, objective refraction and slit-lamp examination. At 6 months, IOL rotation and posterior capsule opacification (PCO) were also evaluated. Rotation of the IOL was assessed with dilated pupils (1% tropicamide and 2.5% phenylephrine) and using slit-lamp digital photographs in retroillumination (Fig. 1).

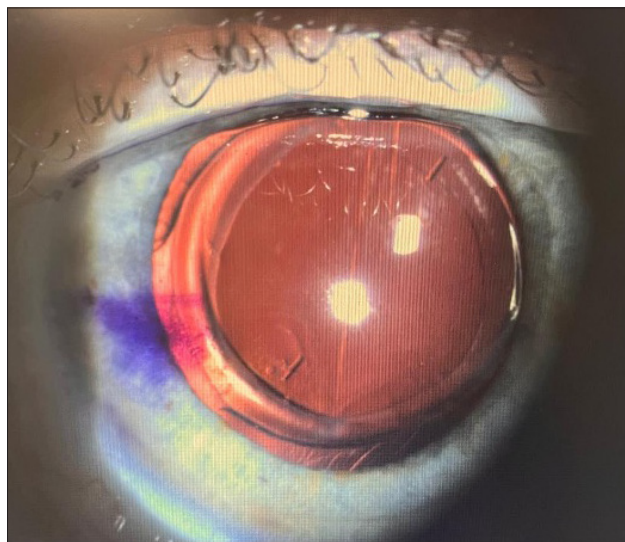


Figure 1. Slit-lamp digital photographs of RayOne® toric IOL for rotation analysis.

Postoperative axes were compared with the intended implanted axis at the surgery, and IOL rotation was recorded. PCO was evaluated with full mydriasis. Other complications during follow-up were analyzed.

STATISTICAL ANALYSIS

Statistical analysis was performed with SPSS Statistics, version 29.0. Characteristics of the patients were presented as frequencies for categorical variables, and means and standard deviations, or medians and interquartile ranges for continuous variables without or with skewed distributions, respectively. The normality of data was evaluated using the Shapiro-Wilk test. When parametric analysis was possible, Student's t-test for paired data was performed for parameter comparisons between pre- and postoperative evaluations. When parametric analysis was not possible, the Wilcoxon rank-sum test was used. Bonferroni correction was applied for multiple comparisons. A p -value < 0.05 was considered statistically significant.

RESULTS

PATIENT DEMOGRAPHICS

The study enrolled 117 eyes of 117 patients. 39 patients were men (33.3%) and 78 were women (66.7%), with a mean age of 66.4 ± 13.0 years. Concerning laterality, 61 were right eyes (52.1%) and 56 left eyes (47.9%). All patients were followed up for 6 months.

PREOPERATIVE DATA

Table 1 shows the mean values for preoperative UDVA, BCVA, refractive astigmatism, keratometric measures and the IOL power of the implanted lens.

VISUAL ACUITY OUTCOMES

There was a statistically significant improvement in UDVA and BCVA after surgery. In all eyes, the postoperative UDVA was better or equal to the preoperative BCVA. The median preoperative BCVA was 0.30 (0.30) logMAR (range 0.0 – 1.3 logMAR), while at 6 months postoperatively, the mean UDVA was 0.00 (0.10) logMAR (range 0.00 – 0.30 logMAR) – Fig. 2, representing a statistically significant improvement ($p < 0.001$). A postoperative UDVA of 0.0 logMAR was achieved in 62.2% of eyes, while 87.4% of eyes attained a UDVA of 0.1 logMAR or better.

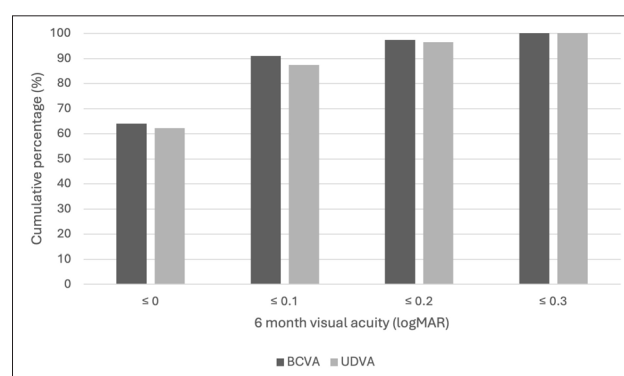


Figure 2. Cumulative postoperative best corrected (BCVA) and uncorrected (UDVA) visual acuities at 6-month visit (n = 117 eyes).

REFRACTIVE OUTCOMES

The mean SE of the studied eyes significantly decreased from -1.89 ± 4.94 D (range -15.75 to 14.63 D) at referral to -0.47 ± 0.80 D (range -5.00 to +2.00 D) at 6 months after surgery ($p < 0.001$).

Table 1. Preoperative data (117 eyes of 117 patients). Mean $\pm$ SD for Gaussian variables and median (interquartile range) for non-Gaussian variables.

Variable	Mean $\pm$ SD, median (IQR), absolute number (%)	Range
UDVA (logMAR)	1.00 (0.69)	0.30, 1.40
BCVA (logMAR)	0.30 (0.30)	0.00, 1.30
Refractive astigmatism (D)	3.10 ± 1.39	0.00, 6.75
Spherical equivalent (D)	-1.89 ± 4.92	-15.75, 14.63
Corneal astigmatism (D)	2.80 ± 1.22	1.50, 8.18
Axial length (mm)	23.46 (1.78)	21.06, 28.99
Anterior chamber depth (mm)	3.13 ± 0.44	1.90, 4.04
K1 (D)	42.98 ± 1.68	39.70, 47.95
K2 (D)	45.75 ± 1.85	41.88, 50.07
Spherical IOL power (D)	19.15 ± 5.42	5.50, 29.50
Cylinder IOL power (D)	3.33 ± 1.33	1.50, 7.00
Predicted residual astigmatism (D)	0.22 ± 0.38	0.01, 1.50

UDVA – uncorrected distance visual acuity; BCVA – best corrected visual acuity; D – diopters; SD – standard deviation; IQR – interquartile range.

At 6 months after surgery, 75.6% of the eyes were within ± 0.75 D of the target emmetropia.

The mean corneal astigmatism to be corrected was 2.80 ± 1.22 D (range 1.5, 8.18) and the mean refractive astigmatism of these eyes was 3.08 ± 1.38 D (range 0.00 to 6.75 D) at referral and 0.68 ± 0.50 D (range 0.00 to 2.50 D) ($p < 0.001$) at 6 months. At the last follow-up, 70.9% of eyes had a postoperative residual refractive astigmatism of -0.75 D or less.

IOL ROTATION

Analysis of the rotational stability of the implanted lens showed a mean rotation relative to the intended axis of $1.41^\circ \pm 2.22^\circ$ (range 0° - 10°) recorded at the last visit. At 6 months, 58.6% of the IOLs showed a rotation less than 1° , and 93.7% had a rotation equal to or less than 5° . At that last visit, IOL rotation was clockwise in 30 eyes and counterclockwise in 18 eyes. One patient required IOL repositioning due to IOL rotation of 10° , with successful repositioning. No IOL was misaligned by more than 10° .

ASTIGMATISMO RIENTATION SUBANALYSIS

Based on the steepest meridian, eyes were categorized as with-the-rule (WTR), against-the-rule (ATR), or oblique astigmatism. A total of 48 eyes were classified as WTR, 56 as ATR, and 13 as oblique. The mean IOL rotation was not significantly different among the subgroups (WTR: $91.08^\circ \pm 82.01^\circ$; ATR: $88.70^\circ \pm 13.28^\circ$; oblique: $70.92^\circ \pm 39.48^\circ$; $p = 0.496$).

PCO AND OTHER COMPLICATIONS

All surgeries were uneventful. At the last follow-up, 94.6% of the eyes showed no signs of PCO. No persistent ocular adverse events were registered during the study.

DISCUSSION

Due to the high prevalence of significant levels of corneal astigmatism in the population, the interest in different astigmatism treatment modalities has risen in recent years. Procedures involving manipulation of corneal curvature, such as limbal relaxing incisions and laser refractive surgery, are possible approaches, although dependent on the corneal healing response and associated with increased risk of infection and dry eye symptoms, respectively. Toric IOL is the preferred choice to correct high level astigmatism and is not dependent on the unpredictable cornea healing process.

The goal of toric IOL implantation is to minimize postoperative residual astigmatism and providing optimized uncorrected distance visual acuity. Several studies evaluating the clinical and optical outcomes after implantation of IOLs found that patients report good satisfaction and high levels of spectacle independence.¹⁰⁻¹² However, careful patient selection, IOL calculation, correct placement during surgery and rotational stability are essential factors for its success.

Several studies have compared the refractive outcomes

and rotational stability of different toric intraocular lenses. A recent meta-analysis by Kessel *et al* demonstrated that hydrophobic acrylic toric IOLs tend to present better rotational stability compared to hydrophilic models.¹² Bachernegg *et al* reported that the AcrySof toric IOL had a mean rotation of $2.4^\circ \pm 2.3^\circ$, while the AT TORBI 709M had a mean rotation of $3.1^\circ \pm 3.0^\circ$, both showing acceptable stability.⁷ In contrast, our study with the RayOne® lens showed a mean rotation of $1.41^\circ \pm 2.22^\circ$, suggesting that this hydrophilic model can achieve stability comparable to some hydrophobic designs.

That said, considering that functional results are better in patients with regular astigmatism, in our study, corneal topography was performed and patients with irregular astigmatism were excluded.

UDVA is a crucial factor for surgeons to consider in modern cataract surgery, which can be enhanced through the implantation of toric IOLs. In this study, 87.4% of eyes achieved UDVA of 0.1 logMAR or better after cataract surgery, resulting in great efficacy and patient satisfaction. Good UDVA with different IOLs was also reported in other studies.^{4,13-15}

In what concerns to refractive results, in our study, patients had a significant reduction in refractive astigmatism after surgery from a mean 3.08 ± 1.38 D (range 0.00 to 6.75 D) to 0.68 ± 0.50 D (range 0.00 to 2-50 D) ($p < 0.001$). Comparing to other studies with different IOLs, postoperative refractive astigmatism was lower at Shimoda *et al* (-0.44 ± 0.27 D)¹⁶ but greater at Ng *et al* (0.81 ± 0.40 D).¹⁷ The lower residual astigmatism in our study aligns more closely with results from multifocal IOLs, highlighting the effectiveness of the RayOne® in reducing astigmatic errors.

We also explored the impact of astigmatism orientation on lens rotation. No statistically significant difference was observed between WTR, ATR or oblique groups, which is in line with previous reports. However, the sample size for this subgroup analysis may limit definitive conclusions.

The prediction of residual astigmatism can be difficult, even considering preoperatively measured corneal astigmatism, ACD measured before surgery, axial length of the eye, cylinder power of the IOL and surgically induced astigmatism. This fact indicates that several factors can reduce the predictability of residual astigmatism, such as inaccuracies in preoperative keratometry,¹⁸ unexpected postoperative deep or flat ACD,¹⁹ failure to include the posterior corneal surface,²⁰ errors in preoperative marking,²¹ mislabeling of the toric IOL, improper placement of the IOL during surgery, incomplete OVD aspiration and IOL decentration or tilt.

Although toric IOLs are commonly used to correct astigmatism, rotational stability in the capsular bag over time is crucial to achieve successful refractive outcomes. IOL rotation occurs mainly in the early postoperative period before the capsular bag healing process is complete and due to the presence of residual OVD, IOP fluctuations and IOL material properties.^{3,22} In the late post-surgical stage, IOL stabilization can be compromised by the capsule shrinkage and compression of the haptics.^{22,23} The closed-loop haptics design of this IOL is longer than the plate-haptic design, conferring good initial friction and better stability.

Different monofocal toric IOLs are currently available on the market, but published rotational stability data is limited to some of them. A retrospective interventional case series evaluated patients submitted to duet procedure with implantation with different monofocal toric lenses, including RayOne® toric IOL, into the capsular bag and a trifocal-diffractive IOL into the ciliary sulcus.²⁴ A prospective observational study with 27 eyes of 22 patients evaluated the rotational stability of Rayner T-flex® toric IOL.²⁵ A recent meta-analysis by Kessel *et al* demonstrated that hydrophobic acrylic toric IOLs tend to present better rotational stability compared to hydrophilic models.¹² Bachernegg *et al* reported that the AcrySof toric IOL had a mean rotation of $2.4^\circ \pm 2.3^\circ$, while the AT TORBI 709M had a mean rotation of $3.1^\circ \pm 3.0^\circ$, both showing acceptable stability.⁷ In contrast, our study with the RayOne® lens showed a mean rotation of $1.41^\circ \pm 2.22^\circ$, suggesting that this hydrophilic model can achieve stability comparable to some hydrophobic designs. However, studies with larger sample sizes evaluating the rotational stability of the RayOne® toric IOL isolated were still lacking. In our study, the mean absolute rotation of this hydrophilic acrylic closed-loop haptic toric IOL was found to be low. However, it must be considered that the measurement of small differences in postoperative IOL rotation is difficult. Some limitations of this study include the possibility of cyclorotation of the eye and of misalignment of the patient's head during standard photography at slit-lamp.²⁶ Furthermore, objective measurement methods of IOL rotation such as wavefront aberrometry were not used in this study.²⁷

Another relevant consideration is the lens material. Although the RayOne® toric IOL demonstrated good rotational stability, potential disadvantages compared to other hydrophobic acrylic toric IOLs include a higher susceptibility to glistening formation and a less established long-term track record regarding PCO rates and biocompatibility.²⁸⁻³⁰

PCO remains a significant problem after cataract surgery. In our study, the incidence of PCO requiring Nd:YAG capsulotomy was 5.4%. To the authors' knowledge, there are no studies evaluating the incidence of PCO in the study lens. However, a study with the Rayner C-flex 570C IOL found a rate of Nd:YAG capsulotomy of 0.6% at 12 months and 1.7% at 24 months.³¹ In our study, a larger sample and longer follow-up period would be desirable to better estimate the incidence of PCO.

CONCLUSION

In summary, the RayOne® toric IOL reduces the effect of preoperative corneal astigmatism on postoperative refraction after cataract surgery, demonstrating great rotational stability and providing improved uncorrected distance vision. With a careful selection of patients and IOLs, this lens demonstrates a good safety profile.

CONTRIBUTORSHIP STATEMENT / DECLARAÇÃO DE CONTRIBUIÇÃO

CF: Drafting of the text, sourcing and editing of investigation results, and critical revision for important intellectual content.

JR: Sourcing and editing investigation results.

CF, JR, RCB, EN, AL, RAR, PT: Critical revision for important intellectual content.

All authors approved the final version to be published.

CF: Redação do texto, obtenção e edição dos resultados da investigação e revisão crítica do conteúdo intelectual importante.

JR: Obtenção e edição dos resultados da investigação.

CF, JR, RCB, EN, AL, RAR, PT: Revisão crítica do conteúdo intelectual importante.

Todos os autores aprovaram a versão final a ser publicada.

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Conflitos de Interesse: Os autores declaram a inexistência de conflitos de interesse na realização do presente trabalho.

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Proteção de Pessoas e Animais: Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pela Comissão de Ética responsável e de acordo com a Declaração de Helsínquia revista em 2024 e da Associação Médica Mundial.

Proveniência e Revisão por Pares: Não comissionado; revisão externa por pares.

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