

# Visual outcomes following implantation of a multifocal toric intraocular lens in patients with corneal astigmatism

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**PURPOSE:** To assess visual acuity (VA) and refractive outcomes following implantation of a multifocal toric intraocular lens (IOL) in patients with corneal astigmatism ( $> 0.75$  D).

**SETTING:** OftalmoCentro, Porto Alegre, Brazil.

**METHODS:** In this consecutive case series, patients underwent phacoemulsification and bilateral or unilateral IOL implantation with the M-flex T IOL (Rayner Intraocular Lenses Ltd.). All underwent refractive assessment and corneal topography preoperatively and postoperatively. Outcome measures included uncorrected distance VA, spherical and cylindrical refraction, and spherical equivalent (SE) (3-month follow-up).

**RESULTS:** Of 43 eyes (29 patients, mean age 57 years [35–89 years], 12 males), 15 patients underwent bilateral implantation of a Rayner M-flex<sup>®</sup> T IOL, while 14 had unilateral M-flex T implantation with a non-toric multifocal IOL in the fellow eye. There was a clinically and statistically significant improvement in spherical refraction ( $1.71 \pm 2.40$  D preoperative;  $0.05 \pm 0.20$  D postoperative;  $p < 0.001$ ), cylindrical refraction ( $-1.36 \pm 2.00$  D;  $-0.30 \pm 0.70$  D;  $p < 0.001$ ), and SE ( $1.03 \pm 2.50$ ;  $-0.09 \pm 0.40$  D;  $p = 0.003$ ). Eighty-eight percent of eyes were within  $\pm 0.5$  D of emmetropia, and 88% had a cylindrical correction within  $\pm 0.5$  D. At 3 months, 95% and 91% of eyes had uncorrected distance and near VA of 20/30 or better and J2 or better, respectively.

**CONCLUSION:** The M-flex T IOL improved spherical and cylindrical refractive error in patients with corneal astigmatism undergoing lens extraction, while providing a full range of vision correction.

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Although conventional monofocal intraocular lenses (IOLs) can provide a significant improvement in distance vision after cataract surgery, their effect on near and intermediate vision is inadequate<sup>1</sup>. This traditional approach leaves the patient dependent on spectacle use for daily activities such as reading and computer use.

Modern multifocal IOLs address this issue by providing a more acceptable range of near to distance vision<sup>2-6</sup>. However, they are often contraindicated for patients with corneal astigmatism greater than 1.0 D, a subset of cataract patients that makes up approximately 15–20% of cataract surgery patients<sup>7-11</sup>. In this patient population, multifocal IOLs are sometimes associated with poor postoperative visual acuity (VA) and refractive outcomes, often requiring postoperative laser adjustments to correct residual refractive errors<sup>12-15</sup>. Toric multifocal IOLs claim to improve refractive outcomes in cataract patients with co-existing corneal astigmatism<sup>16,17</sup>.

This study was conducted to determine the visual and refractive outcomes provided by the M-flex<sup>®</sup> T multifocal toric IOL (Rayner Intraocular Lenses Ltd., Hove, UK) when implanted in the eyes of patients with existing corneal astigmatism.

Over the past 40 years, numerous studies have been published on the topic of surgical reduction of astigmatism. As part of this, several authors have developed

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mathematical and statistical techniques to facilitate meaningful analyses of data arising from multiple sets of patients with pre-existing astigmatism<sup>18-24</sup>. This has resulted in the development of analytical tests that can be employed to assess the probabilities of whether surgical interventions were successful. Additionally, they enable the prior estimation of sample sizes required for group studies that result in measurements on continuous, binary and ordered categorical scales.

Alpins stressed the key point that reduction or elimination of astigmatism as a single or combined procedure is possible only if one understands astigmatic change in its component parts of magnitude and axis<sup>20</sup>. The axes of surgically induced astigmatism (SIA) may vary considerably within the 180° range of arc, which can make meaningful comparisons of different sets of data challenging without a comprehensive understanding of concomitant astigmatic changes. In order to address this, he proposed a new vector analysis method that ensures the comparison of preoperative and postoperative astigmatism results in a 360° sense. This is achieved by doubling the angles of the steepest axes both preoperatively and postoperatively, before subsequent transformations and comparisons take place.

Naeser and Hjortdal addressed the interpretation of changes in astigmatism after surgical intervention using a different trigonometric notation, known as the polar method. In this approach, the meridional polar value AKP expresses the surgically induced correction of astigmatism, while the oblique polar value AKP (+45) indicates the torque. This pair of polar values characterizes a regular astigmatism completely. To conduct a bivariate polar value analysis, Naeser and Hjortdal state that AKP and AKP (+45) should be combined to give the mean SIA. They also developed an important method of examining the spread and variation in a set of astigmatic changes, based on the classical work of Hotelling<sup>23-25</sup>. In this development, the spread of data changes are presented in a confidence region delineated by an ellipse.

These two approaches appear to represent rather different methods for the examination of bivariate and concomitant changes in astigmatism following surgery. In fact, they are fundamentally the same. In this paper, a unified approach is used for the analyses of astigmatic changes in this patient population.

## PATIENTS AND METHODS

This study included astigmatic patients undergoing lens surgery at OftalmoCentro, Porto Alegre, Brazil, who were implanted with the M-flex® T multifocal IOL between December 2011 and December 2012. The study inclusion criteria were as follows: regular corneal astigmatism > 0.75 D and a potential VA of > 20/30. Patients with irregular astigmatism, astigmatism of

≤ 0.75 D, lenticular astigmatism, as well as those with macular or vitreous disease, were excluded from the study. All persons gave their informed consent prior to their inclusion in the study

In addition to a complete routine eye examination, the following exams were performed preoperatively: corneal topography (TMS-2, Tomey Corp, Phoenix, AZ, USA) to determine corneal astigmatism, corneal specular microscopy (Noncon Robo, Konan, Irvine, CA, USA), central corneal pachymetry (Accupach V, Accutome, Malvern, PA, USA), optical biometry (IOL Master 5.4, Carl Zeiss Meditech, Jena, Germany), potential VA (Guyton-Minkowski PAM, Mentor, Norwell, MA, USA), and optical coherence tomography (OCT) (RTVue, Optovue, Fremont, CA, USA). At 3 months after surgery, patients underwent a complete routine eye examination, including corneal topography.

## Intraocular lenses

All patients were implanted with the M-flex T multifocal toric IOL (models 588F and 638F, Rayner Intraocular Lenses Ltd.) with cylindrical power ranging from 2.0 to 4.0 D, and an addition of +4 D, which is equivalent to +3 D at the spectacle plane. The IOL is a proprietary hydrophilic acrylic copolymer with an ultraviolet (UV) light filter, with a water content of 26% and a refractive index of 1.46. The IOL has either four or five annular zones (depending on the IOL base power).

In patients who received the M-flex T IOL unilaterally, the fellow eye received one of the following non-toric IOLs: AT-Lisa 809M (Carl Zeiss), Tecnis ZMA00 (Abbott Laboratories, Abbott Park, Illinois, USA), Alcon ReStor MN6AD1 (Alcon Laboratories, Inc., Ft. Worth, TX, USA) or the Rayner M-flex 630F (Rayner Intraocular Lenses Ltd.).

## Surgical technique

All surgeries were performed by the same surgeon (S.K.) under peribulbar block, with a 2.75 mm, clear-corneal, self-sealing incision. All patients had the 180° axis marked at the slit-lamp with a pendular marker (Katena, Denville, NJ, USA) and IOL axis position was marked on the corneal surface with a toric IOL marker (Katena) to orient IOL axis position. IOL power calculations were performed using the online Rayner calculator ([www.raytrace.rayner.com](http://www.raytrace.rayner.com)). K1 and K2 obtained from the IOL Master were used for IOL calculations. All IOLs were implanted in the bag. All patients received a topical antibiotic, gatifloxacin 0.3%, four times the day before surgery and every 15 minutes for 2 hours before surgery. Postoperatively, all patients received topical gatifloxacin 0.3% and prednisolone 1% QID for 10 days, as well as a non-steroidal anti-inflammatory agent (ketorolac trometamine) BID for 30 days.

**Table 1.** Preoperative and postoperative changes in visual and refractive outcomes

	Preoperative		Postoperative		<i>p</i> value
	Mean ± SD	Median	Mean ± SD	Median	
<b>Spherical refraction (D)</b>	1.71 ± 2.40	2.0	0.06 ± 0.20	0	< <b>0.001</b>
<b>Cylindrical refraction (D)</b>	-1.36 ± 2.00	-1.5	-0.30 ± 0.70	0	< <b>0.001</b>
<b>SE (D)</b>	1.03 ± 2.50	1.4	-0.09 ± 0.40	0	<b>0.003</b>
<b>Distance Visual Acuity (logMAR)</b>	0.23 ± 0.20*	0.2	0.08 ± 0.10**	0.1	< <b>0.001</b>

SE = spherical equivalent; D = Diopters; SD = standard deviation; \*corrected distance visual acuity; \*\*uncorrected distance visual acuity; n = 43, except for preoperative spherical, cylindrical, and SE, where n = 39.

### Statistical analysis

Data were tested for normality using the Kolmogorov-Smirnov and Shapiro-Wilk tests. Statistical analysis was performed using the Wilcoxon Signed Rank Test with SPSS (IBM, New York, USA), except for the defocus analysis where a defocus equivalent formula was used, and then McNemar's Test and Fisher's Exact Test for the categorical data. Vector analysis was performed using the Alpins method, while a Polar analysis was performed using the Naeser method. Descriptive statistical tests were performed with SPSS and Microsoft Excel (Microsoft, WA, USA).

## RESULTS

This study involved 43 eyes from 29 patients (mean age 57 years, range 35–89 years, 12 males and 17 females). Fifteen patients underwent bilateral M-flex T IOL implantation. The remaining 14 patients had an M-flex T IOL implanted in one eye and a non-toric multifocal IOL implanted in the fellow eye due to astigmatism ≤ 0.75 D.

### Refractive and visual acuity outcomes

Mean preoperative spherical refraction, cylindrical refraction, and spherical equivalent were 1.71 ± 2.40 D, -1.36 ± 2.00 D, and 1.03 ± 2.50 D, respectively (Table 1). These values were obtained from 39 eyes because refraction could not be measured from the remaining eyes due to the cataract. Mean preoperative

**Table 2.** Distribution of the cylindrical power of IOLs used in this study

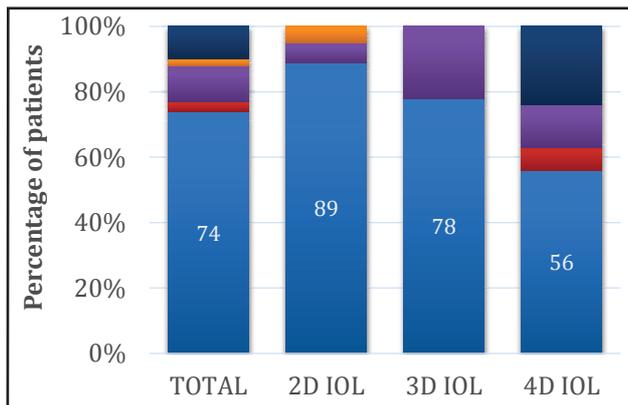
Cylindrical power (Diopters) of IOL	Number of patients
2.0	18
3.0	9
4.0	16

corneal astigmatism in 43 eyes was 2.3 ± 1.3 D (K1 42.00 ± 1.88 D, K2 44.26 ± 1.48 D). Mean spherical power of the implanted IOLs was 18.80 D. The cylindrical power of the IOLs used ranged from 2.00 D to 4.00 D (Table 2).

At the 3-month follow-up, mean spherical refraction had reduced significantly to 0.05 ± 0.20 D ( $p < 0.001$ ), mean cylindrical refraction had reduced significantly to -0.30 ± 0.70 D ( $p < 0.001$ ), and mean spherical equivalent (SE) had reduced significantly to -0.09 ± 0.40 D ( $p = 0.003$ ) (Table 1). There was no clinically significant change in the corneal astigmatism (2.30 ± 1.30 D vs. 2.00 ± 1.20 D).

The intended refractive correction was achieved in the majority of patients, with those with smaller manifest refractive cylinder showing better refractive outcomes (Figure 1). Overall, 88% of patients were within ± 0.50D of the intended correction, which was

emmetropia, and 88% of eyes achieved a cylindrical correction within  $\pm 0.50$  D. In the group implanted with the 2.00 D cylinder IOL, 89% of eyes achieved the targeted refraction of emmetropia. In the 3.00 D cylinder group, 78% of eyes achieved the intended refractive correction, with 100% within  $\pm 0.50$  D. Finally, in the 4.00 D cylinder group, 56% of eyes achieved the intended refraction and 75% were within  $\pm 0.50$  D.

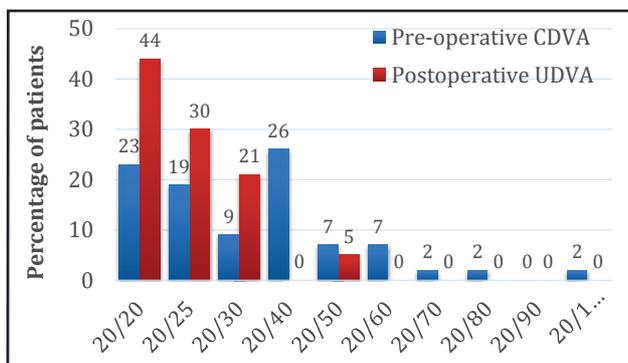


**Figure 1.** Distribution of postoperative residual cylinder 3 months after IOL implantation (n = 43 eyes).

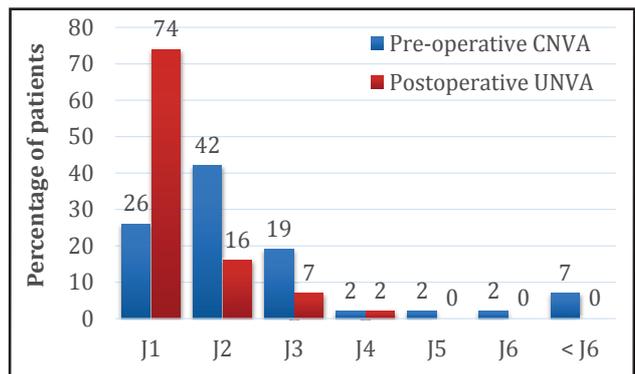
**Defocus Curve Results**

Near and distance VA improved with the M-flex T IOL. Postoperative uncorrected distance visual acuity (UDVA) was significantly better than preoperative corrected distance visual acuity (CDVA) (preoperative CDVA 0.23 logMAR vs. postoperative UDVA 0.08 logMAR) (Table 1). Ninety-five percent of eyes had a postoperative UDVA of 20/30 or better and 91% of eyes had an uncorrected near visual acuity (UNVA) at 35 cm of J2 or better at the 3-month follow-up (Figures 2 and 3).

The defocus curve analysis showed that there was a very highly significant reduction, with a mean preoperative measurement of 3.12 and a postoperative



**Figure 2.** Distribution of preoperative corrected distance visual acuity (pre-op CDVA) compared with distribution of postoperative (3 months) uncorrected distance visual acuity (post-op UDVA) (n = 43 eyes).



**Figure 3.** Distribution of preoperative corrected near visual acuity (pre-op CNVA) at 35 cm compared with postoperative (3 months) uncorrected near visual acuity (post-op UNVA) at 35 cm (n = 43 eyes).

mean of 0.38 (SD = 0.307 and 0.116, respectively,  $p < 0.001$ ). Nearly all patients who were above 1.00 D of astigmatism preoperatively achieved  $< 1.00$  D after surgery: Preoperatively, the percentage of patients above 1.00 D was 92.3%, while postoperatively the percentage was reduced to 11.6%. The percentage above 0.50 D was 100%, which reduced to 13.9%, postoperatively. The results demonstrated a highly significant reduction:  $p < 0.001$ .

**Astigmatism Results**

In order to assess the reduction in astigmatism following surgery, vector analysis was performed using the Alpsins method (Figure 4) combined with the Polar analysis method developed by Naesar (Figure 5).

The astigmatism analysis found that there was borderline statistical significance ( $p = 0.05$ ), as well as a clinically significant reduction in astigmatism. The differenced x-axis result was 0.15 and the y-axis result was  $-0.04$ . The overall SIA was 0.16 ( $p = 0.05$ ). The correlation between the two axes was 0.126 (not significant), with the rotation at  $26^\circ$ .

**DISCUSSION**

The aim of this study was to evaluate the visual and refractive outcomes after lens extraction in patients with corneal astigmatism  $> 0.75$  D who received the M-flex T multifocal toric IOL. The present results show a significant improvement in refractive outcomes and a significant decrease in refractive astigmatism after surgery, with 88% of patients achieving within  $\pm 0.50$  D of the targeted SE refraction. This suggests that the M-flex T IOL can achieve effective refractive correction and reduce astigmatism in patients with low to moderate levels of pre-existing corneal astigmatism.

**Double the angles Pre- and Post-Op**

**Convert Polar coordinates to rectangular coordinates as follows**

(I.E.)  $x_1 = r_1 \cos(2\alpha_1)$       **Pre-Op**  
 $y_1 = r_1 \sin(2\alpha_1)$

**and**

$x_2 = r_2 \cos(2\alpha_2)$       **Post-Op**  
 $y_2 = r_2 \sin(2\alpha_2)$

**Compute  $x_2 - x_1 = x_{12}$**

**Compute  $y_2 - y_1 = y_{12}$**

**Compute double angle for difference**  
 i.e.  $\alpha_{12} = \text{ARC TAN}(y_{12} / x_{12})$

**Compute  $r_{12} = y_{12} / \sin \alpha_{12}$**

**To estimate Surgically Induced Astigmatism (SIA),  $\alpha_{12}$ , and convert angle back by halving**

**$x_{12}$  represents a change in magnitude - flattening if positive**

**$y_{12}$  represents a change in direction (Clockwise (plus)/Anti-clockwise (minus) change in angle)**

Figure 4. Alpines vector analysis calculation formula.

Refractive multifocal toric IOLs were developed to provide patients with a satisfactory range of near through distance vision while simultaneously correcting corneal astigmatism<sup>26</sup>. They work by splitting the light entering the eye and creating two or more focal points. Five types of multifocal toric IOLs are currently available: the refractive M-flex T IOL, the Sulcoflex supplementary pseudophakic IOL (Rayner Intraocular Lenses Ltd.), the diffractive AT Lisa toric IOL (Carl Zeiss), the diffractive ReStor IQ toric IOL (Alcon), and the zonal refractive/diffractive Lentis Mplus toric IOL (Oculentis GmbH, Berlin, Germany). At the time of writing, there were no published studies using the M-flex T IOL, making this the first study to present results with this IOL.

The results presented here compare favorably with the limited amount of data that has been published to date on clinical outcomes with a multifocal toric IOL<sup>26</sup>. A single, bilateral case study of the Sulcoflex toric IOL reported emmetropia in one eye and +0.125 D residual refraction in the other<sup>27</sup>.

As there was no clinically significant change in corneal curvature after surgery in our study, a finding

**Same nomenclature as astigmatism**

**Different conversion formulae to Cartesian axes**

$x = r(\sin^2(\alpha + 90) - \cos^2(\alpha + 90))$   
 and  $y = r(\sin^2(\alpha + 45) - \cos^2(\alpha + 45))$

**Convert Pre-Op and Post-Op values, then compute differences**

**Requires variance and covariance (or correlations of differenced results)**

i.e. Matrix A =  $\begin{bmatrix} \text{Var} & \text{Covar} \\ \text{Covar} & \text{Var} \end{bmatrix}$

**And solve  $A\underline{x} = \underline{\lambda x}$**

**Where  $\underline{x}$  is an eigenvector**

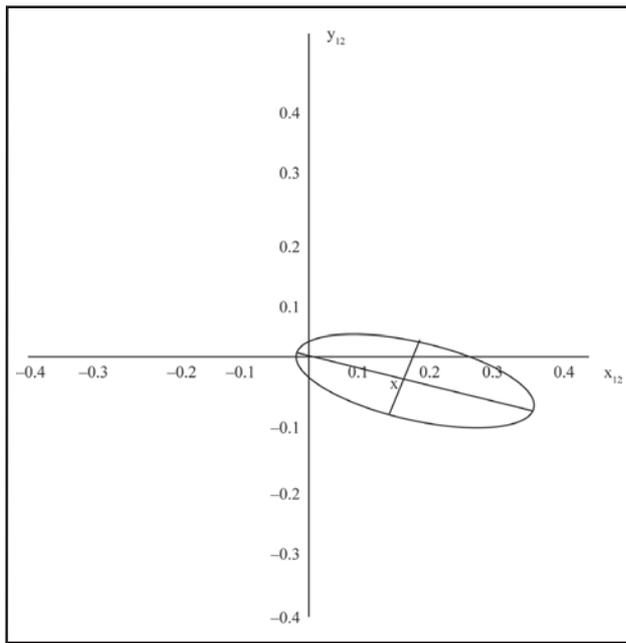
**And  $\underline{\lambda}$  is an eigenvalue**

Figure 5. Naeser polar analysis calculation formula.

similar to other studies, the reduction of postoperative refractive astigmatism seen here is likely due to IOL toricity compensating for corneal astigmatism. In addition, our refractive results are comparable to those obtained with other toric monofocal IOLs, including those obtained with the Rayner T-flex toric IOL<sup>1</sup>.

In this study, we found that there was a higher likelihood of residual cylinder in patients implanted with the 3 D and 4 D cylinder IOLs: 22% and 44%, respectively. As the manufacturer's software takes into account the spherical power and anterior chamber depth in its toric IOL power calculations, this may be due to the effect of posterior corneal astigmatism or large pupil size.

Additional analysis performed using defocus curves, as well as Vector/Polar analysis, supported the reduction in astigmatism. Using the Vector Analysis of Alpines and the Polar analysis of Naeser, including the bivariate confidence limits approach of the latter, no statistically significant differences were found in the differenced results, preoperatively and postoperatively, calculated on the Cartesian plane. There were also no statistically significant differences found when both were examined simultaneously, as demonstrated in the graph of the final VA results (Figure 6). It is important to note that over 80% of (SIA, pre-astigmatism) results were less than or within 20% of zero ( $p \leq 0.001$ ). The remaining results (classed as overcorrections by Alpines) were not deemed to be excessive. The mean reduction in astigmatism for negative (SIA, pre-astigmatism) results was almost 40% ( $p < 0.001$ ).



**Figure 6.** Final visual acuity results based on vector/polar analysis showing 95% confidence limits for differenced astigmatism data.

A large percentage of patients in this series achieved spectacle independence after M-flex T implantation. Mean postoperative UDVA was 0.08 logMAR and 95% of eyes had a postoperative UDVA of 20/30 or better; 91% achieved postoperative UNVA of J2 or better at the 3-month follow-up. These results compare favorably with other studies using multifocal toric IOLs.

Although our results are encouraging, and the first to be presented with the M-flex T IOL, there are several limitations in the present study. First, contrast sensitivity, which is known to be compromised in patients using multifocal IOLs, was not measured. Second, higher-order aberrations (HOAs), glare and halos were not assessed. This study is also limited by the lack of a case-control design. Direct comparisons with other multifocal toric IOLs could yield more information on the predictability and efficacy of the M-flex T IOL.

In conclusion, the M-flex T IOL effectively corrects refractive errors and astigmatism in patients with mild to moderate astigmatism, while providing patients with improved near and distance vision with a reduction in the need for correction following surgery.

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