Toric trifocal plate-haptic intraocular lenses: refractive outcomes and quality of vision after refractive lensectomy

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PURPOSE: To evaluate the visual and refractive outcomes of toric trifocal plate-haptic intraocular lens (IOL) implantation for presbyopia correction.

SETTING: Ophthalmology Department, Hospital CUF Porto and Hospital de Braga, Portugal.

METHODS: Prospective interventional case series including 30 patients who had bilateral implantation of a trifocal AT LISA tri toric 939MP multifocal IOL. Inclusion criteria were age 50 to 70 years, need for bilateral cataract extraction or refractive lens exchange, and regular corneal astigmatism from 0.75 to 5.0 D. Six-month evaluations included spherical equivalent (SE), refractive and corneal cylinder, visual acuity (VA) at various distances, defocus testing, and IOL rotation.

RESULTS: Thirty patients (60 eyes) completed the 6-month visit. Mean SE was \(-0.35 \pm 0.36\) D at 6 months (\(\pm 1.00\) D in 100%). Mean refractive cylinder decreased from \(1.04 \pm 1.46\) D to \(0.45 \pm 0.29\) D. Mean toric IOL power implanted was \(2.19 \pm 0.95\) D. Mean binocular uncorrected VA was \(0.08 \pm 1.09\) logMAR at near (\(\pm 40-50\) cm), \(0.02 \pm 1.22\) logMAR at intermediate (\(\pm 70-80\) cm), and \(0.10 \pm 0.82\) logMAR at 4 meters. Mean IOL rotation was \(3.50 \pm 1.00\) degrees. No secondary intervention for IOL repositioning was required during the study follow-up. Contrast sensitivity testing showed results within normal limits.

CONCLUSION: Trifocal AT LISA tri toric 939MP IOLs provided excellent distance, intermediate and near visual outcomes. Predictability of the refractive results and optical performance were excellent, and all patients achieved spectacle independence.

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Refractive lensectomy with multifocal intraocular lens (IOL) implantation is the current state of the art for the refractive correction of ametropia and presbyopia in patients over the age of 50-55 years. Traditional bifocal IOLs have been unable to fully correct the intermediate distance for reading1-3, extremely important for desktop and computer work. Multifocal IOL implantation is a refractive procedure aimed at emmetropia. However, corneal astigmatism of 1.25 diopters (D) or more is prevalent in approximately 30% of eyes that undergo cataract surgery4,5, while residual refractive astigmatism is one of the most common causes of patient dissatisfaction after multifocal IOL implantation for presbyopia correction. Multifocal IOLs have been shown to have poor performance in patients with moderate degrees of residual postoperative astigmatism6-8. The recent introduction of trifocal optics on multifocal diffractive IOLs was a breakthrough in refractive outcomes, allowing patients to read more comfortably between far and intermediate distances (70-90 cm) and without a clear gap between intermediate and near (40-50 cm) distances9,10, which had previously been observed on the defocus curves of most traditional diffractive bifocal IOLs2,10-12. In the present study, bilateral implantation of an AT LISA tri toric 939MP IOL (Carl Zeiss AG, Jena, Germany), a new diffractive plate haptic IOL with a toric trifocal design, was assessed. The aim of this study was to evaluate the visual outcomes obtained for distance, intermediate and near visual acuity (VA), IOL stability inside the capsular bag, efficacy of astigmatism correction, the defocus curve and contrast sensitivity curves after implantation of the trifocal IOL.
PATIENTS AND METHODS

Study design

This was a prospective, single-arm, 6-month study performed from May 2013 to May 2014. The study was conducted in compliance with good clinical practices, including International Conference on Harmonisation Guidelines, and consistent with the tenets outlined in the Declaration of Helsinki.

Study criteria

Patients had bilateral clear lens extraction with AT Lisa tri toric 939MP IOL implantation for presbyopia correction. The inclusion criteria were refractive lens exchange for presbyopia, aged 50 years old or over, bilateral surgery, corneal astigmatism equal to or greater than 1.0 D, uneventful surgery, and IOL power between 0.0 D and +32.0 D. The exclusion criteria were previous ocular surgery, ocular disease, intraoperative complications, retinal or optic nerve disease, amblyopia, diabetic patients and corneal astigmatism lower than 1.0 D.

Intraocular lens

The AT Lisa tri toric 939MP with its plate-haptic design is a diffractive trifocal preloaded IOL with an overall diameter of 11.0 mm and a 6.0 mm optical zone. It is a foldable hydrophilic IOL with a hydrophobic coating. The physical properties of the diffractive structure include a central 4.34 mm trifocal zone and a peripheral bifocal zone from 4.34 mm to 6.00 mm; the IOL asphericity is −0.18 μm. The addition for near is 3.33 D and for intermediate is 1.66 D at the IOL plane. Light distribution is 50% to distance focus, 20% to intermediate focus and 30% to near focus, with global light transmittance of 85.7%. The IOL is independent of pupil diameter up to 4.5 mm. It is available from 0.00 D to +32.00 D in 0.50 D increments, while the toric version is available from 1.0 D to 4.0 D of cylinder correction.

Preoperative evaluation

Preoperatively, patients had a complete ophthalmologic evaluation, including subjective and objective refraction, slit lamp examination, tonometry, mesopic and photopic pupil diameter measurements, and fundus examination in mydriasis. Corneal astigmatism was evaluated using corneal topography (Pentacam HR, Oculus Optikgeräte GmbH, Wetzlar, Germany) and automated keratometry. Axial length was measured using the IOL Master (Carl Zeiss Meditec AG). IOL spherical and toric power was calculated using the online calculator provided by the manufacturer, based on ray-tracing. Corneal incision was performed on the steepest axis, and −0.25 D of surgically induced astigmatism (SIA) was used. Contrast sensitivity measurements were performed under photopic (85 candelas/m²) and mesopic conditions (10 candelas/m²) using the Vista Vision screen.

Surgical technique

Prior to the surgical procedure, and with the patient sitting upright, the 3 o’clock and 9 o’clock positions were marked with a preoperative pendulum positions marker (Geuder, Heidelberg, Germany). A Mendez ring marker was used intraoperatively to mark the axis of the corneal incision and the axis for IOL placement calculated by the manufacturer’s online software. A capsular tension ring was implanted in the capsular bag before IOL implantation. The IOL was placed in the capsular bag through a capsulorhexis of approximately 5 mm in diameter. The IOL marks on the posterior surface of the optic were aligned with the corneal axis marking. After alignment, the ophthalmic viscosurgical device was carefully removed and the correct IOL position was confirmed before the wound was closed.

Postoperative medical treatment included moxifloxacin four times daily for 1 week, dexamethasone four times daily for 1 week and nepafenac three times daily for 6 weeks.

Postoperative evaluation

Evaluations were performed 1, 3, and 6 months after the second-eye surgery. Primary efficacy endpoints were assessed 6 months after the second-eye surgery and included manifest refraction and VA with and without distance correction at far, intermediate, and near distance. Manifest refraction was performed using the 100% contrast Early Treatment Diabetic Retinopathy Study (ETDRS) chart (Precision Vision, La Salle, IL, USA) under photopic lighting. Distance VA was assessed using the 100% contrast ETDRS chart under photopic lighting at 4 m. Near and intermediate VA were measured using the Precision Vision Logarithmic Visual Acuity Series 2000 ETDRS chart at near (40 cm) and intermediate (80 cm) distance.

Defocus testing

Defocus curves were determined through VA measurement under photopic conditions with the ETDRS chart at 4 m. Various IOL powers were placed in front of the manifest refraction from −4.0 D to +2.0 D in 0.5 D increments, and the logMAR VA measured.

Intraocular lens alignment assessment

The IOL placement was recorded at the end of surgery, and alignment was assessed by slit lamp examination 1 month and 6 months postoperatively, after pupil dilation.
Safety

Adverse events were collected over the course of the study. All patients who were enrolled in the study and who had surgery, independent of having undergone IOL implantation, were considered evaluable for the safety analysis.

Statistical analysis

Statistical analyses were performed using SPSS software. A paired t test was used to compare the main differences; \( p = 0.05 \) was considered statistically significant. When normality of the distribution was not assumed, differences were compared using the nonparametric Wilcoxon signed-rank test or the sign test. Results are expressed as mean ± standard deviation (SD), unless otherwise indicated.

RESULTS

Demographics

Sixty eyes of 30 patients were included in the study. All patients had bilateral surgery. Table 1 shows the patient demographics and preoperative data. Mean keratometric astigmatism was 1.78 ± 0.81 D and mean IOL cylinder power was 2.19 ± 0.95. The mean expected refractive residual cylinder after toric IOL calculation was −0.16 ± 0.11 D.

Visual acuity

The mean binocular corrected distance VA (CDVA, Snellen scale) was 0.96 ± 0.08. Binocular distance-corrected intermediate VA was 0.95 ± 0.13, and mean near VA was 0.79 ± 0.11 (Table 2). All patients had 20/40 corrected VA at all distances at the 6 month follow-up visit, and there was no loss of lines of corrected VA. Almost all patients (94%) had 20/25 distance-corrected intermediate and distance vision and 80% had 20/25 distance-corrected near VA (Figure 1).

Defocus testing

The binocular defocus curve was consistent with a VA of 20/25 or better (0.10 logMAR) across a vergence of 0.0 D to −2.0 D (Figure 2). Near-visual peaks from the vergence of −2.0 D to −2.5 D (equivalent to 40 to 50 cm from the eye) showed a mean logMAR of 0.20 (Snellen equivalent 20/30). The intermediate-visual trough at a vergence of −1.5 D (67 cm from the eye) showed a mean logMAR of 0.1 (a mean Snellen equivalent of 20/25). Fifteen percent of patients had +3.00 near add spectacles prescribed for small print reading or for detailed work and near distance (33-40 cm).

Table 1. Patient preoperative demographics.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyes (n)</td>
<td>60</td>
</tr>
<tr>
<td>Patients (n)</td>
<td>30</td>
</tr>
<tr>
<td>Age (years)</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td></td>
<td>53.2 ± 5.7</td>
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<tr>
<td></td>
<td>Range</td>
</tr>
<tr>
<td></td>
<td>48 - 61</td>
</tr>
<tr>
<td>Female (%)</td>
<td>72</td>
</tr>
<tr>
<td>Mean axial length (mm, mean ± SD)</td>
<td>23.06 ± 1.19</td>
</tr>
<tr>
<td>Anterior chamber depth (mm, mean ± SD)</td>
<td>2.66 ± 0.37</td>
</tr>
<tr>
<td>Astigmatism Magnitude (D, mean ± SD)</td>
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</tr>
<tr>
<td>Refractive</td>
<td>−1.04 ± 1.462</td>
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<tr>
<td>Corneal</td>
<td>1.78 ± 0.81</td>
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<tr>
<td>Mean IOL power (D, mean ± SD)</td>
<td></td>
</tr>
<tr>
<td>Sphere</td>
<td>19.8 ± 4.03</td>
</tr>
<tr>
<td>Cylinder</td>
<td>2.19 ± 0.95</td>
</tr>
<tr>
<td>Mean pupil diameter (mm, mean ± SD)</td>
<td></td>
</tr>
<tr>
<td>Scotopic</td>
<td>5.66 ± 0.92</td>
</tr>
<tr>
<td>Photopic</td>
<td>4.40 ± 0.96</td>
</tr>
<tr>
<td>Mean expected residual cylinder (D, mean ± SD)</td>
<td>−0.16 ± 0.11</td>
</tr>
</tbody>
</table>

Table 2. Visual Results, binocular.

<table>
<thead>
<tr>
<th></th>
<th>Uncorrected</th>
<th>Distance Corrected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Near (40-50 cm)</td>
<td>0.08 ± 1.09</td>
<td>0.10 ± 0.95</td>
</tr>
<tr>
<td>Intermediate (70-80 cm)</td>
<td>0.02 ± 1.22</td>
<td>0.01 ± 1.09</td>
</tr>
<tr>
<td>Distance</td>
<td>0.10 ± 0.82</td>
<td>0.01 ± 1.09</td>
</tr>
</tbody>
</table>

Data provided as mean ± SD of LogMAR.
Table 3: Refractive results: manifest refraction sphere, cylinder and spherical equivalent.

<table>
<thead>
<tr>
<th></th>
<th>n = 60</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sphere</td>
<td></td>
<td>-0.10</td>
<td>0.37</td>
</tr>
<tr>
<td>Cylinder</td>
<td></td>
<td>-0.45</td>
<td>0.29</td>
</tr>
<tr>
<td>Spherical equivalent</td>
<td></td>
<td>-0.35</td>
<td>0.36</td>
</tr>
<tr>
<td>Mean expected residual Cylinder (D)</td>
<td></td>
<td>-0.16</td>
<td>0.11</td>
</tr>
</tbody>
</table>

**Manifest refraction and cylinder reduction**

Table 3 shows the subjective refractive results after the 6 month follow-up period. Mean spherical equivalent was within ±0.50 D of emmetropia in 63% of eyes and within ±1.00 D in 100% of eyes. Mean postoperative refractive astigmatism was −0.45 ± 0.29 D, with 69% within ±0.50 D of refractive astigmatism, and all eyes within ±1.00 D of refractive astigmatism. Mean IOL misalignment 1 month after surgery (measured after pupil dilation) was 3.5 ± 1.0 degree, with all eyes with IOL misalignment below 5 degrees of rotation. No secondary intervention for IOL repositioning was required during the study follow-up.

**Contrast sensitivity testing**

Figure 3 shows the contrast sensitivity measured under photopic and mesopic conditions for 3 groups: the AT LISA trifocal group, a monofocal IOL group and a control group of non-operated patients. The results show that the contrast sensitivity curve measured for the AT LISA trifocal IOL was within normal limits for all special frequencies of both illumination conditions, and did not show any statistically significant differences from a monofocal IOL.

**DISCUSSION**

Previous studies in the last decade have shown good visual and refractive outcomes with multifocal IOLs, namely diffractive bifocal optics, which are the most commonly used IOLs for presbyopia correction. The main disadvantages of a bifocal diffractive optic IOL are decreased contrast sensitivity, poor intermediate VA and near VA dependent on lighting conditions, especially for apodized diffractive optics. Two trifocal IOL models have been available for presbyopia correction since 2012, one apodized and the other non-apodized, and relatively pupil-independent, which is the IOL used in our study. Recent studies on trifocal IOLs show promising results in terms of intermediate distance, namely for working on computers and electronic devices. We found similar refractive and visual outcomes to those reported for the trifocal apodized IOL (Finevision PhysIOL, Liège, Belgium) and the AT LISA trifocal pupil-independent IOL. All patients achieved 20/25 or
more in distance uncorrected, intermediate (80-90 cm) uncorrected, and distance corrected vision. The defocus curve shown in our study shows a VA level above 20/25 from +0.00 to −2.00 add, which accounts for distance and intermediate vision up to 100 cm.

Multifocal IOLs have been shown to have poor performance in eyes with moderate to high degrees of residual postoperative astigmatism. So managing pre-existing corneal astigmatism at the time of cataract surgery is critical to achieve optimum refractive outcomes. Approximately 40% of patients having cataract surgery are estimated to have astigmatism of more than 1.00 D. Several studies have demonstrated that refractive residual astigmatism after multifocal IOL implantation is the factor that most adversely affects the visual performance of any kind of multifocal IOL. Our study shows similar results in terms of efficacy of astigmatism correction, similar to studies published for the toric bifocal AT LISA 909M (Carl Zeiss Meditec AG) and the toric bifocal AcrySof ReSTOR (Alcon Surgical). Bauer et al. found a mean absolute misalignment of 3.5 ± 1.99 degrees with the Acrysof toric IOL, with no eyes having misalignment greater than 10 degrees. The outcomes reported for the same plate haptic platform (AT Liza 909M) previously showed a significant reduction in postoperative refractive cylinder, good distance VA, and acceptable intermediate and near VA.

Intraocular stability is a chief concern with toric and multifocal IOLs. Stability is influenced by IOL design and material, post-operative rotation, tilt, decentration, and axial position, all of which can affect visual outcomes. Astigmatic correction can be reduced with each degree of misalignment, ultimately resulting in a complete loss of cylinder power if misaligned by 30 degrees. Our results are similar to others reported: no IOL had to be rotated in the post-operative period, and the mean IOL rotation was below 5 degrees for all patients.

Contrast sensitivity is a reliable tool that can be used to assess the quality of vision after refractive surgery, and in multifocal IOLs in particular. Our results show a normal distribution for contrast sensitivity of the trifocal optic at low and high spatial frequencies, both in photopic and mesopic conditions, with results always within the normal range and very similar to a monofocal IOL in some conditions. This could be explained by the fact that among diffractive multifocal IOLs, the trifocal IOL AT LISA tri 939MP shows the least loss of light due to the diffractive optics.

In conclusion, the trifocal IOL AT LISA tri 939MP shows excellent refractive and visual outcomes after implantation for presbyopia correction. Our results show high efficacy for correction of astigmatism for the toric IOL model studied, with no IOL rotation observed during the follow-up period. The extended range of visual correction demonstrated on the defocus curve indicates this IOL as a first-line option for refractive lensectomy for presbyopia correction.

REFERENCES


