Outcomes of iris-fixated toric phakic intraocular lens implantation in the correction of myopic astigmatism

Rita Anjos, MD, MSc; Barbara Borges, MD, MSc; Arnaldo Santos, MD, MSc; Vitor Maduro, MD; Nuno Alves, MD; Joao Feijao, MD; Miguel Trigo, MD

PURPOSE: To evaluate the refractive outcomes of iris-fixated toric phakic intraocular lens (pIOL) in the surgical correction of myopic astigmatism.

SETTING: Department of Ophthalmology, Centro Hospitalar Lisboa Central. Lisboa, Portugal.

METHODS: Retrospective analysis of data from patients who underwent toric iris-fixated pIOL (Artiflex® and Artisan®) implantation in Centro Hospitalar Lisboa Central between 2009 and 2013. The main parameters evaluated were best corrected visual acuity (BCVA), uncorrected visual acuity (UCVA), manifest refraction, intraocular pressure (IOP), central endothelial cell count (ECC) and complications.

RESULTS: The study enrolled 25 eyes of patients aged from 24 to 47 years. An improvement of one or more Snellen lines was achieved in 20 patients (80%), with no cases of BCVA loss. All patients achieved an UCVA of 0.5 or better, with mean UCVA 0.92 ± 0.12. Safety and efficacy indexes were 1.17 and 1.10, respectively. Spherical equivalent decreased from −12.69 ± 3.39 D to −0.78 ± 0.74 D, with a reduction in absolute cylinder from −2.51 ± 0.96 D to −0.62 ± 0.48 D. There were no major complications. However, a transitory IOP increase to 25 mmHg was measured in one patient, pigment deposits were observed in 10 patients (60%), and an overall mean ECC loss of 8.7% was found.

CONCLUSION: Toric iris-fixated pIOL is an excellent solution for selected patients with moderate to high myopic astigmatism.

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The management of moderate to severe myopic astigmatism remains a modern day challenge. Patients for whom optical correction is unsatisfactory, or for whom keratorefractive surgery is unsuitable, are very common in refractive specialist clinical practice. Surgical correction with phakic intraocular lenses (pIOL) has been reported as the procedure of choice in cases where accommodative power is still present.

Several pIOL and posterior and anterior chamber models (for which angle-supported and iris-fixating variations are included) have been developed in recent decades. The first iris-fixated intraocular lens was created in 1978 by Dr. Jan Worst, who designed a polymethyl methacrylate (PMMA) lens that is fixated on the mid-peripheral iris stroma for primary implantation after intracapsular cataract extraction, or secondary implantation in aphakic eyes. The first toric model of an iris-fixated lens was introduced on the market in 2001. The aim of our study was to evaluate the efficacy, safety and predictability of the iris-fixated toric pIOL in the surgical correction of myopic astigmatism.

METHODS

Retrospective study conducted at the Ophthalmology Department of Centro Hospitalar Lisboa Central (Lisboa, Portugal), consisting of a record review of patients who underwent toric iris-fixated pIOL.
implantation between 2009 and 2013. The following inclusion criteria were adopted: aged between 18 and 55 years; stable refraction at least one year before surgery; endothelial cell count (ECC) according to age (with a minimum of 2400 cells/mm²); anterior chamber depth (ACD) ≥ 3 mm; absence of major iris abnormalities; scotopic pupil > 6.0 mm (5-mm optic) or 7.0 mm (6-mm optic); no previous history of ophthalmologic surgery or significant pathology (glaucoma or ocular hypertension, cataract, iritis, retinal detachment, retinopathy, or amblyopia, among others). Diabetic patients, pregnant and breastfeeding women were also excluded.

We used the van der Heijde formula to perform the lens calculation, using the corneal curvature, ACD and subjective refraction to calculate the spherical and cylindrical power of the pIOL.

The following items were evaluated during the preoperative (pre-op) assessment: best corrected visual acuity (BCVA), intraocular pressure (IOP), ECC and ACD. Postoperative (post-op) assessment included: pIOL parameters, uncorrected visual acuity (UCVA), BCVA, manifest refraction, ECC, IOP and biomicroscopy findings. Visual acuity was obtained in Snellen decimal scale and transformed to logMAR for statistical purposes when necessary.

The data were described in terms of mean ± standard deviation, and the analysis included descriptive and frequency statistics. We adopted the standardized format for describing refractive surgical results as described by Koch et al.6, which takes into account the following criteria: safety, efficacy, predictability and complications. Safety and efficacy indices were calculated based on analysis of Snellen scale visual acuities (VA), while the predictability index was based on the spherical equivalent and astigmatic correction in dioptres (D). SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 20 for Windows was used for statistical analysis.

RESULTS

Sample characteristics

The sample for this study consisted of 25 eyes from 16 patients with a mean age of 33.5 ± 7.1 years (24-47 years), and mean follow-up of 19.7 ± 5.4 months (12–25 months). Twenty-two (88%) pIOL were implanted in women, 13 (52%) in right eyes and 12 (48%) in left eyes. All surgeries were performed by two experienced surgeons.

In the contralateral eye, 13 patients (52%) were aphakic, 3 (12%) had a spherical anterior chamber pIOL and 9 (36%) had a toric anterior chamber pIOL.

The average pre-op spherical equivalent was −12.69 ± 3.39 D (−5.75 to −20.00 D), with mean absolute cylinder −2.51 ± 0.96 D (−0.75 to −4.00 D). Pre-op IOP was obtained for 18 eyes, with mean 13.5 ± 2.3 mmHg (10-17 mmHg). Mean ACD was 3.21 ± 0.22 mm (3.0-3.7 mm). BCVA was 0.84 ± 0.12 on the Snellen decimal scale (0.53-1.00), corresponding to 0.08 ± 0.07 logMAR (0.00-0.28).

A total of 21 Artiflex® pIOL and 4 Artisan® pIOL with a spherical dioptric power between −5 and −17 D and cylinder between −1 and −4 D (as described in Figure 1) were implanted by two experienced surgeons. Figure 2 describes the 25 pre- and post-op BCVA, and post-op UCVA.

Safety

In the post-op assessment, patients had a mean BCVA of 0.97 ± 0.07 (0.68-1.00) on the Snellen decimal scale, which corresponded to 0.01 ± 0.03 logMAR (0.00-0.17). Sixty percent of patients (15/25) had a BCVA of 10/10, while 96% (24/25) had a BCVA better than or equal to 9/10. One patient had a BCVA of 0.68. An improvement in Snellen lines was achieved in 20 patients (80%) and maintained in 5 (20%). There were no cases of BCVA loss. The overall gain in Snellen lines
is shown in Figure 3. The safety index (mean BCVA post-op/mean BCVA pre-op) in our study was 1.17.

**Efficacy**

Mean UCVA in the post-op period was 0.92 ± 0.12 (0.55-1.00) on the Snellen decimal scale, or 0.04 ± 0.07 logMAR (0.00-0.26). Post-op UCVAs are shown in Figure 4. Twenty-four percent (6/25) of patients had UCVA 10/10; 80% (20/25) better than or equal to 9/10; and 100% better than 5/10. The efficacy ratio (mean post-op UCVA/mean pre-op BCVA) was 1.10.

**Predictability**

Spherical equivalent: The spherical equivalent decreased from −12.69 ± 3.39 D (−5.75 to −20) to −0.78 ± 0.74 D (−3.00 to 0.13). The relationship between desired and achieved dioptric power is shown in Figure 5. Twelve patients (48%) had a residual spherical equivalent between ±0.5 D and 20 patients (80%) between ±1 D. Five patients had a correction superior to −1 D. There was one post-op overcorrection of 0.125 D.

Astigmatism correction: Absolute cylinder was reduced from pre-op values of −2.51 ± 0.96 D (−0.75 to −4) to −0.62 ± 0.48 D (−2.5 to 0). Sixty-eight percent of patients (17/25) had a post-op astigmatism ≤ 0.5 D and 92% (23/25) ≤ 1 D. Pre- and post-op absolute cylinder values are shown in Figure 6.

**Complications**

Post-op IOP was obtained for all patients, with a mean value of 13.5 ± 2.0 (10-18) mmHg. Mean pre-op ECC was 2659.5 ± 251.0 cells (2401-3070), while post-op was 2444.1 ± 286.9 cells (1798-2962), corresponding to a variation of −231.0 cells (8.7%). A transitory IOP increase to 25 mmHg was measured in one patient.

There were no major intraoperative complications in our study. During the data collection period, there were no known cases of iris prolapse or atrophy, pIOL contact with the anterior capsule of the lens, persistent corneal oedema, cataract formation, retinal detachment, endophthalmitis or other serious complications. Pigment deposits were observed in 10 patients (60%).

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**Figure 3**: Snellen line change in best-corrected visual acuity, comparing preoperative and postoperative values.

**Figure 4**: Percentage of patients presenting each post-operative uncorrected visual acuity (D).

**Figure 5**: Relationship between desired and achieved dioptric power.

**Figure 6**: Distribution of pre- and post-operative absolute cylinders.
Table 1. Comparison of experience with Artisan® and Artiflex® lenses in the published literature.

<table>
<thead>
<tr>
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<th>Safety index (BCVA)</th>
<th>Efficacy index (UCVA)</th>
<th>Predictability Spherical Eq.</th>
<th>Predictability Cylinder</th>
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<td><strong>Our study 2014</strong></td>
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<tr>
<td>1.17</td>
<td>1.10</td>
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<td>48% ±0.5 D</td>
<td>68% ±0.5 D</td>
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<td>96%</td>
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<td>80%</td>
<td>≥0.8</td>
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<td>60%</td>
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<td>24%</td>
<td>=1.0</td>
<td>92% ±1.0 D</td>
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<td><strong>Doors et al. 2012</strong></td>
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<td>(Artiflex®)</td>
<td>1.12</td>
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<td>81% ±0.5 D</td>
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<td>95%</td>
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<td>83%</td>
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<td>66%</td>
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<td><strong>Muñoz et al. 2012</strong></td>
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<td>(Artiflex®)</td>
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<td>100%</td>
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<td>98% ±1.0 D</td>
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<td><strong>Tehrani et al. 2006</strong></td>
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<td>70% ±1 D</td>
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<td><strong>Dick et al. 2003</strong></td>
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<td>(Artisan®)</td>
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<td>10%</td>
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BCVA, best corrected visual acuity; UCVA, uncorrected visual acuity.

DISCUSSION

The surgical correction of myopic astigmatism with pIOL is a reversible refractive procedure known to be safe and effective⁵. The implantation of iris-fixated pIOLs has been growing in popularity, mainly due to their rotational stability, which is essential to achieve the desired astigmatic effect⁵. In this study, we present our experience with two types of toric iris-fixated pIOL: Artiflex® and Artisan®. Although both have shown good refractive results⁵,⁸,⁹, the Artiflex® pIOL has been gaining ground against its rigid PMMA predecessor Artisan® because of the smaller incision required (3.2 mm vs. 5.5 mm) and its larger optic diameter (6.0 mm vs. 5.0 mm). This last modification is less demanding for the surgeon, as it has fewer adverse consequences when the lens is not well centered⁵,¹⁰.

The final refractive results in our work were satisfactory, with outcomes similar to those reported in other published papers on toric pIOLs (Table 1). There was no BCVA loss in any patient, and a gain in Snellen lines was observed in most. Sixty percent of subjects reached a BCVA of 100%, with a safety index of 1.17. As a refractive surgery, its goal is centred not only on achieving a BCVA at least similar to pre-op but, ideally, to gain independence from any extra optical correction. One quarter of our patients had a post-op UCVA of 100%, while the majority reached at least 80%, which translates into a good efficacy index (1.10). These results are consistent with those described in previous studies, demonstrating that, in terms of refractive results, pIOL Artisan® and Artiflex® are safe and effective solutions⁵,⁸,⁹.

Most patients achieve a predictable refractive result, although the final refraction varies significantly in the published data (Table 1). Even though we only had one case of a small overcorrection (0.125 D), our predictability index was slightly lower than desired. This may be explained by inadequate pre-op subjective refraction or incorrect alignment of the toric pIOL. A prospective evaluation will be necessary to understand these results. Nevertheless, this discrepancy did not compromise our results, in the sense that our final BCVA and UCVA were relatively similar to some published studies⁵,⁷.

One of the major concerns with pIOL is continuous ECC loss, which is higher than expected when compared with age-matched subjects⁸. Endothelial cell loss may be a consequence of immediate surgical trauma or long term loss (due to pIOL or natural age-related decrease). Mean ECC loss with age with pIOL is reported to be approximately 5% at 12 months, with stabilization after 1 to 2 years¹¹. Although our ECC loss was higher than that described in some populations with this type of pIOL implantation⁵,⁸,⁹, it was similar to the findings of Muñoz et al.⁷ and did not exceed acceptable levels for these types of procedures (Table 2). There were no major intra- or post-operative complications, with non-significant changes in IOP.

Toric iris-fixated pIOL is proposed as a first line solution in patients with moderate to high myopic astigmatism. The advantage of preserving accommodation together with the overall corneal
structure, with appealing refractive outcomes and good safety and efficacy indices, explain its growing popularity. Our experience with this type of pIOL is consistent with that reported in the literature, and consolidates the evidence of this solution as the refractive procedure of choice in these patients.

In conclusion, toric iris-fixed pIOL is an excellent solution for selected patients with moderate to high myopic astigmatism.

REFERENCES