



Combined implantation of toric and spherical intraocular lenses for low corneal astigmatism correction

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ABSTRACT

Background: This study compared outcomes of combined toric versus spherical intraocular lens (IOL) implantation in patients with low corneal astigmatism.

Methods: In this retrospective contralateral study, patients with corneal astigmatism who received combined toric (FIL 611 T, Soleko, Rome, Italy) and spherical IOL (FIL 611 T, Soleko, Rome, Italy) implants were recruited. Eyes were examined preoperatively and then again 3 months postoperatively. Postoperatively, uncorrected distance visual acuity (UCDVA), residual astigmatism, and spherical equivalent (SE) were compared between the toric IOL-implanted eyes and the spherical IOL-implanted fellow eyes.

Results: Among the 46 included cases (age 69 ± 12.7 years [mean \pm standard deviation]; range: 60-78 years), 86.9% of eyes ($n = 40$) in the toric IOL group had a postoperative refractive cylinder of ≤ 0.25 diopters (D), compared with 4.3% ($n = 2$) of eyes in the spherical IOL group. Both groups showed a statistically significant reduction in refractive cylinder and improvement in UCDVA after cataract surgery (both $P = 0.01$). Similarly, toric IOLs were superior (69.6%) to spherical lenses (2.2%) in obtaining a SE of ≤ 0.25 D.

Conclusions: To our knowledge, no previous study had sought to compare low-power toric and spherical IOLs in low corneal astigmatism in the same patient's eyes. Our findings suggest that low-power toric IOLs may result in good refractive outcomes as compared with spherical IOLs implanted in the fellow eye of the same patient, although both result in significant UCDVA improvement. Well-designed clinical research studies with a longer follow-up and more participants are necessary to confirm these findings.

KEY WORDS

cataract, toric IOL, spherical IOL, intraocular lenses, astigmatism, cornea, cataract surgery

INTRODUCTION

The cornea is the main optical surface of the eye. It has a central thickness of about 550 micrometers (μm) and vertical and horizontal diameters of about 11.5 millimeters (mm) and 12.5 mm, respectively [1]. It is responsible for two-thirds of ocular refractive power, while the remaining one-third is attributable to the crystalline lens [2].

The corneal surface shows much refractive astigmatism [3], as it has a toroidal shape [4]. Total corneal astigmatism is defined as the sum of the anterior and posterior surfaces [5]. Corneal astigmatism is classified, according to the axis of astigmatism, as being either with-the-rule, oblique, or against-the-rule, and this classification is very useful for clinical investigation [6]. Although the sum of both the corneal astigmatism (anterior and posterior corneal astigmatism) and lenticular astigmatism (internal astigmatism) is known as total or refractive astigmatism [7]. However, we refer to

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astigmatism as corneal astigmatism in this report.

Intraocular lens (IOL) implantation following cataract surgery should compensate for refractive astigmatism, particularly that of the cornea, which can be marked [8]. Astigmatism correction using toric IOLs is an effective option [9]. Toric IOLs were introduced by Shimizu et al. in 1992 as three-piece, non-foldable, polymethyl methacrylate implants to be inserted through a 5.7-mm incision [10]. Toric IOLs are single-vision, folding, non-symmetric lenses and entail power measurement based on at least two different meridians [11]. Standard toric IOLs are designed to correct preexisting corneal astigmatism ranging from 1.00 diopter (D) to 4.75 D [12].

It is not always easy to establish what amount of corneal astigmatism should be corrected. This study investigated the outcomes of combined toric surgery in patients with low degrees of corneal astigmatism as compared with those of fellow eyes implanted with spherical IOLs.

METHODS

In this retrospective contralateral study, we performed consecutive evaluations of medical records from September 2019 to August 2020 to select patients whose eyes were within 1.00 D of corneal astigmatism, who underwent cataract surgery at the Eye Clinic of Polyclinic University Hospital of Bari, Italy. We included eyes with no previous refractive surgery, no corneal pathology, and presumably uncomplicated cataract surgery. Subjects with other ocular or systemic diseases, such as corneal disease, glaucoma, uveitis, retinopathy, diabetes mellitus, hypertension, or undergoing some secondary treatment (IOL repositioning or refractive surgery) were excluded. Routine preoperative assessments included anterior and posterior segment examination using slit lamp examination, intraocular pressure (IOP) measurement by Goldmann applanation tonometry, and optical coherence tomography (OCT) imaging, for both eyes of the study subjects. The data were treated in accordance with the tenets of the Declaration of Helsinki. All participants signed an informed consent form before surgery. Ethical approval for the study was obtained from the Interregional Ethics Committee, located in Policlinico di Bari - P.zza G. Cesare n. 11, Bari- 70124 (n.5135).

The preoperative spherical IOL power was measured via a biometric algorithm, using the Holladay formula for eyes with an axial length (AL) between 22.00 and 26.00 mm, the SRK/T formula with an AL \geq 26.00 mm, and the Hoffer Q formula with an AL \leq 22.00 mm [13]. Preoperative toric IOL calculations were performed using the biometric data for the Barrett Toric calculator, which is a standardized system of calculation that accounts for the amount of posterior corneal astigmatism [14]. The spherical power of the IOL was calculated by assuming that the mean keratometry (K) value was equivalent to the K value of the steepest meridian and by using the standard equations for IOL power calculation. The spherical power was also calculated assuming a mean K value equivalent to that of the flattest meridian. The difference between the spherical power obtained from the steepest and flattest K values represents the astigmatic power of the implant required [15].

A single surgeon performed all surgeries (G.A.) as a sequential bilateral cataract surgery with a 1-month interval. The corneal cut was located at 180° in the right eye and 0° in the left eye. For eyes planned to be implanted with a toric IOL, the steepest axis was identified using an image-guided system (Callisto eye; Carl Zeiss Meditec AG, Jena, Germany).

Each patient received a toric IOL (FIL 611 T, Soleko, Rome, Italy) in one eye, and a spherical IOL (FIL 611, Soleko, Rome, Italy) in the fellow eye, and the outcomes between eyes were compared. The choice of eye that received the toric IOL or spherical IOL was independent of biometric characteristics. Patients were informed which eye received the toric IOL and spherical IOL. Postoperative eye drops were similar for both eyes including nonsteroidal anti-inflammatory (indomethacin 0.5 mL, 0.5 %, Indom®, Alfa Intes, Naples, Italy, 3 times daily), a fixed-combination antibiotic corticosteroid (betamethasone 0.2% + chloramphenicol 0.5%, Betabiophtal®, Thea Farma, Milan, Italy, 3 times daily), and hyperosmolar ophthalmological solution (sodium chloride 5% + hyaluronic acid 0.15%, ODM5®, Ascoli Piceno, Italy), with the same frequency for both eyes. The preoperative biometric data for each eye were acquired using the IOL Master 700 (Carl Zeiss Meditec AG, Jena, Germany). Biometry assessed the AL and K readings and anterior chamber depth (ACD). The preoperative and 3-month postoperative evaluations included uncorrected distance visual acuity (UCDVA), employing the logarithm of the minimum angle of resolution (logMAR) visual acuity chart, and manifest refraction using a Nidek AR-1 Auto Refractometer (Nidek Co, LTD, Aichi, Japan). Postoperative residual astigmatism and spherical equivalent (SE) were considered as the final refractive outcomes. Preoperative estimation of postoperative refractive data was indicated as the estimated outcome, while the 3-month postoperative follow-up refraction results were considered as the actual outcome.

Statistical analyses were performed using SPSS Statistics for Windows (version 23.0; IBM Corp., Armonk, NY). The Wilcoxon signed-rank test was used to compare preoperative and postoperative data, and the Mann-Whitney U test was used for comparison between groups. Categorical comparisons of postoperative outcomes were made using Pearson's chi-squared test. Statistical significance was assumed at $P < 0.05$.

RESULTS

The study identified 96 eyes of 48 patients in the specified period with the relevant planning and postoperative refractive data available. Four of these eyes (4.2%) were excluded after cataract surgery because of misalignment, leaving 92 eyes for analysis, including 46 toric IOL-implanted eyes and 46 spherical IOL-implanted eyes. Misalignment resulted in a reduction of refractive outcomes: the mean \pm standard deviation (SD) of IOL misalignment was 11.3 ± 4.8 degrees, the mean estimated reduction in astigmatic correction was 0.65 ± 0.45 D, and the actual reduction was 0.95 ± 0.42 D, resulting in undercorrection of refractive error.

The age range of the 46 included cases was 60–78 years (mean \pm SD; 69 ± 12.7 years). Of the 92 eyes selected, 56 had with-the-rule and 40 eyes had against-the-rule astigmatism. The demographic characteristics and preoperative biometric data of the study participants are summarized in Table 1. The baseline data, including preoperative UCDVA, AL, ACD, and mean K were not statistically significantly different between the two groups (P -values > 0.05) (Table 1).

Postoperatively, no ocular complications were observed, and no binocular symptoms or image distortion were reported by the study subjects. Table 2 summarizes the mean \pm SD of pre- and postoperative UCDVA, postoperative estimated and actual SE, and postoperative estimated and actual refractive astigmatism in both study groups. The mean \pm SD of UCDVA improved significantly in the toric IOL group and in the spherical IOL group (both $P < 0.01$) by 3 months postoperatively, with no significant differences between them ($P = 0.33$). The actual and estimated postoperative SE were not significantly different in the toric IOL group ($P = 0.65$), while the actual postoperative SE was significantly higher than the estimated postoperative SE in the spherical IOL group ($P < 0.01$). The actual postoperative refractive astigmatism was significantly lower than the estimated value in the toric IOL group ($P < 0.01$). However, there was no significant difference between the actual and estimated postoperative refractive astigmatism in the spherical IOL group ($P = 0.1$). The actual postoperative SE and refractive astigmatism were significantly lower in toric IOL group than the spherical IOL group (both $P = 0.01$) (Table 2).

Of the eyes implanted with toric IOLs, 32 (69.6%) and 13 (28.3%) were within ± 0.25 D and ± 0.50 D of the actual postoperative SE, respectively. A lower percentage of eyes implanted with spherical IOLs were within ± 0.25 D ($n = 1$, 2.2%) and ± 0.50 D ($n = 19$, 41.3%) of the actual SE. The percentage of eyes within ± 0.25 D and ± 0.50 D of the actual

Table 1. Demographic characteristics and preoperative data of the study participants in both groups

Characteristics	Toric IOL Group	Spherical IOL Group	P-value
Eyes, n (OD/OS, total)	22/26, 48	25/23, 48	-
Age in 46 included cases (y), Mean \pm SD	69.1 \pm 8.9		-
Sex, n (M/F)	27/21, 48		-
AL (mm), Mean \pm SD	23.25 \pm 2.87	23.70 \pm 2.45	0.35
ACD (mm), Mean \pm SD	3.2 \pm 0.43	3.4 \pm 0.52	0.20
Mean-K (D), Mean \pm SD	44.50 \pm 1.00	44.25 \pm 1.25	0.11
Pre-UCDVA (logMAR)	0.78 \pm 0.26	0.75 \pm 0.28	0.40

Abbreviations: IOL, intraocular lens; OD, right eye; OS, left eye; SD: standard deviation; n, number; M, male; F, female; AL, axial length; ACD, anterior chamber depth; Y, years; mm, millimeters; D, diopter; Estimated DC, estimated post-operative refractive cylinder; Pre-UCDVA, preoperative uncorrected distance visual acuity in logMAR notation; logMAR, logarithm of the minimum angle of resolution. (Mann-Whitney U test).

Table 2. Comparison of preoperative and 3-month postoperative UCDVA, SE, and refractive astigmatism of the two study groups

Variable	Toric IOL Group	Spherical IOL Group	P-value
Preoperative UCDVA (logMAR), Mean \pm SD	0.78 \pm 0.26	0.75 \pm 0.28	0.40
Postoperative UCDVA (logMAR), Mean \pm SD	0.14 \pm 0.12	0.20 \pm 0.14	0.33
P- value	< 0.01	< 0.01	
Estimated Postoperative Refractive SE (D), Mean \pm SD	-0.25 \pm 0.75	-0.15 \pm 0.80	0.30
Actual Postoperative Refractive SE (D), Mean \pm SD	-0.20 \pm 0.05	-0.55 \pm 0.16	0.01
P- value	0.65	< 0.01	
Estimated Postoperative Refractive Astigmatism (D), Mean \pm SD	-0.81 \pm 0.33	-0.78 \pm 0.36	0.40
Actual Postoperative Refractive Astigmatism (D), Mean \pm SD	-0.15 \pm 0.23	-0.63 \pm 0.42	0.01
P- value	< 0.01	0.10	

Abbreviations: UCDVA, uncorrected distance visual acuity in logMAR notation; logMAR, logarithm of the minimum angle of resolution; SE, spherical equivalent; IOL, intraocular lens; D, diopter. Wilcoxon test for preoperative and postoperative data, Mann-Whitney U test for comparison between groups ($P < 0.05$ is shown in bold).

SE was significantly higher for the toric IOL group ($n = 45, 97.8\%$) than for the spherical IOL group ($n = 20, 43.5\%$) (chi-squared test, $P = 0.01$). Of the eyes implanted with toric IOLs, 40 (86.9%) and 5 (10.9%) were within ± 0.25 D and ± 0.50 D of the actual postoperative refractive astigmatism, respectively. A lower percentage of eyes implanted with spherical IOLs were within ± 0.25 D ($n = 2, 4.3\%$) and ± 0.50 D ($n = 20, 43.5\%$) of actual postoperative refractive astigmatism. The percentage of eyes with residual refractive astigmatism $\leq \pm 0.50$ D was significantly higher in toric IOL-implanted eyes ($n = 45, 97.8\%$) than in those with spherical IOL ($n = 22, 47.8\%$) ($P = 0.01$).

DISCUSSION

The demographic and preoperative data of the two groups were similar. Three months postoperatively, UCDVA improved significantly in both groups, with no significant differences between them. The number of eyes with postoperative refractive outcomes within ± 0.25 D and ± 0.50 D of the actual SE in the toric group was higher than that in the spherical IOL group.

IOL implantation in cataract surgery aims to achieve effective results in terms of refractive outcome, spectacle independence, and patient expectation [16]. Choosing a spherical lens in low corneal astigmatism does not always obtain the expected refractive outcome and consequent patient satisfaction, while a low-power toric lens may prove to be more effective in achieving the required refractive result [17]. However, more precise individualized IOL power selection requires valid methods for predicting the magnitude and axis, as well as the alignment of the toric IOL during surgery [10].

Toric IOLs are commonly recommended in cases with significant preoperative corneal astigmatism of ≥ 1.5 D. Most of the comparison studies between toric and spherical lenses have been carried out on eyes with high corneal astigmatism (≥ 2 D) [18-26]. However, only a few studies have compared eyes with low corneal astigmatism (< 1.5 D) implanted with toric and spherical lenses [27]. To our knowledge, no previous study has sought to compare refractive outcomes of toric and spherical IOLs in fellow eyes of the same patient with corneal astigmatism ≤ 1 D. In the current study, more eyes implanted with toric IOLs than with spherical IOLs achieved SE and refractive astigmatism within ± 0.25 D, while UCDVA was not significantly different.

Statham et al. [28] obtained a significant ($P = 0.01$) improvement in UCDVA with toric IOLs around 1 D (logMAR 0.046) as compared with spherical IOLs (logMAR 0.278). Although, in the current study, UCDVA was not significantly different between groups ($P = 0.33$), we found a significant improvement in both groups ($P = 0.01$) by 3 months postoperatively.

Mairot et al. [29] observed very good refractive outcomes in terms of residual astigmatism (SE ± 0.50 D) with both low-power (0.43 D) and medium-power (0.27 D) toric IOL implantation. Levitz et al. [30] analyzed the postoperative refractive data following implantation of low-power toric IOLs in patients with corneal astigmatism < 1.25 D and found a significant reduction in postoperative refractive cylinder (< 0.25 D, $P = 0.001$). Likewise, our results showed that the postoperative actual refractive astigmatism value (mean \pm SD; -0.15 ± 0.23 D) was far less than the estimated value (mean \pm SD; -0.81 ± 0.33 D) in the toric IOL group.

It is advised to aim for residual astigmatism < 0.50 D [31] and SE refraction within ± 0.50 D in the majority of patients in order to achieve spectacle independence [27]. Moreover, Buscacio et al. [32] have proven that a change from a mean postoperative corneal astigmatism of -1.06 ± 0.27 D to -0.34 ± 0.39 D correlated with an improvement in patients' quality of life. In line with this, the percentage of eyes within ± 0.25 D and ± 0.50 D of the actual spherical correction were significantly higher for the toric than for the spherical IOL group in our study. Likewise, the percentage of eyes with residual refractive astigmatism $\leq \pm 0.50$ D was significantly higher in eyes implanted with toric IOLs than in eyes implanted with spherical IOLs.

The present study had the following strengths. First, although previous studies have already looked into the differences in IOL sphere and cylinder power and orientation [33-35], no previous study had examined eyes with a degree of corneal astigmatism less than 1 D or compared the implantation of the two different IOLs in the eyes of the same patient. Second, using data from the two eyes of the same patient, the current study provided a clinically relevant examination between the postoperative residual refractive astigmatism in two groups of eyes with very similar preoperative refractive features. We are aware that the optical biometry measurements may have some limitations. However, in our subjects, the corneal curvature was homogeneous, and it allows a reliable and easy refractive acquisition, regardless of the operator effect. A limitation was that we did not conduct repeated follow-ups over a longer-term, whereas follow-up in previous reports was long or frequent [19-25, 36]. Nevertheless, the acquired refractive values remained constant. Another limitation of the study is that we did not assess overall patient satisfaction rates along with a check for preservation of fine stereopsis. However, postoperatively, no binocular symptoms or image distortion was reported by the study subjects.

As a future direction, we suggest the need for well-designed clinical research studies with longer follow-up periods and more sophisticated and detailed measurements and with more participants to confirm these findings. Furthermore,

the current study examined different lenses implanted in one subject to evaluate eyes with very close biometric characteristics and the tolerability profile of low-power toric lenses. We suggest that the aberrometry value and contrast sensibility after implantation should be assessed to obtain more evidence-based results and a better conclusion. The development of low-power toric IOLs may make it possible to correct eyes with low amounts of corneal astigmatism without resorting to intraoperative or secondary surgical adjustments, or to other forms of treatment at a later time, to benefit optical independence after cataract surgery. Evidence of good refractive outcomes and a high degree of tolerability of low-power toric IOLs may suggest that implantation is suitable in all cases where spherical IOLs do not provide the required refractive and astigmatic correction meeting the patient's expectations. However, one should consider the cost-benefit of this implant for patients with low corneal astigmatism, as we found that UCDVA was not significantly different between toric IOL-implanted eyes and spherical IOL-implanted fellow eyes.

CONCLUSIONS

To our knowledge, no previous study has sought to compare low-power toric IOLs and spherical IOLs in the fellow eyes of patients with low corneal astigmatism. Our findings suggest that low-power toric IOLs may result in good refractive and astigmatic outcomes as compared with spherical implanted fellow eyes, despite significant UCDVA improvement in both cases. Well-designed clinical research studies with longer follow-up periods and more participants are required to confirm these findings.

ETHICAL DECLARATIONS

Ethical approval: This study was a retrospective study. It does not contain any personal information that could identify the patient, and the data were treated in accordance with the tenets of the Declaration of Helsinki. All participants signed an informed consent form before surgery. Ethical approval was obtained from the Interregional Ethics Committee, located in Policlinico di Bari - P.zza G. Cesare n. 11, Bari- 70124. (n.5135).

Conflict of interest: None.

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