·Clinical Research·

The refractive outcome of Toric Lentis Mplus implant in cataract surgery

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Abstract

• AIM: To evaluate the refractive outcome of Toric Lentis Mplus intraocular lens (IOL) implant.

• METHODS: This is a retrospective case series. Consecutive patients with corneal astigmatism of at least 1.5 D had Toric Lentis Mplus IOL implant during cataract surgery. The exclusion criteria included irregular astigmatism on corneal topography, large scotopic pupil diameter (>6 mm), poor visual potential and significant ocular comorbidity. Postoperative manifest refraction, uncorrected distance visual acuity (UDVA), best-corrected distance visual acuity (BCVA), uncorrected intermediate visual acuity at (UIVA) 3/4 m and uncorrected near visual acuity (UNVA) were obtained.

• RESULTS: There were 70 eyes from 49 patients in this study. Patients were refracted at a median of 8.9wk (range 4.0 to 15.5) from the operation date. Sixty-five percent of eyes had 6/7.5 (0.10 logMAR) or better, and 99% 6/12 (0.30 logMAR) or better postoperative UDVA. Eighty-nine percent could read Jaeger (J) 3 (0.28 logMAR) and 95% J5 (0.37 logMAR) at 40 cm. The median magnitude of astigmatism decreased from 1.91 D to 0.49 D (Wilcoxon, *P*<0.001) after the operation. The range of the cylindrical error was reduced from 1.5-3.95 D (keratometric) preoperatively to 0.00-1.46 D (subjective refraction transposed to corneal plane) postoperatively.

• CONCLUSION: Toric Lentis Mplus IOL has good predictability in reducing preexisting corneal astigmatism.

• KEYWORDS: Toric Lentis Mplus; multi-focal intraocular lens implant; refractive outcome
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INTRODUCTION

Multifocal intraocular lenses (IOLs) were first introduced in the 1980s [1-2]. Meta-analyses of randomised control trials showed these IOLs improve uncorrected near visual acuity without compromising distance visual acuity and reduce spectacle dependence [3-5]. However, the presence of more than 1 diopter (D) astigmatism has been shown to have an adverse effect on the performance of these IOLs[6-8]. This is a significant issue especially corneal astigmatism of 1.25 D or more is prevalent in up to 30% of eyes that have cataract surgery [9-12]. Toric IOL has been reported to provide better predictability in reducing moderate corneal astigmatism compared to opposite clear corneal incision or arcuate keratotomy[13-14].

Today's patients are more demanding, and they seek total visual rehabilitation and spectacle independence. These requirements have spurred the development of toric multifocal IOLs. These IOLs simultaneously correct corneal astigmatism and the loss of accommodative ability after crystalline lens extraction. The implantation of toric monofocal IOLs during phacoemulsification has been shown to be effective in correcting preexisting corneal astigmatism[15-17].

The Lentis Mplus is refractive rotational asymmetry IOL designed to overcome the drawbacks of multifocal IOLs by providing high contrast sensitivity and minimizing halos and glare [16]. The Lentis Mplus IOL consists of 2 radial sectors-one for distance and the other for near vision. Currently there are three strengths of addition (add) for near ±3.00 D (LS-312 MF30), +2.00 D (LS-312 MF20) and +1.50 D (LS-312 MF15). Eighty-four percent of patients with bilateral Lentis Mplus +3.00 D add implants have been shown to be spectacle independent for distant, intermediate and near vision [16]. A toric version of this IOL (LU-313 MF30T) is available however there is no data published to date. The purpose of this study is to evaluate the refractive outcome of the Toric Lentis Mplus IOL.

SUBJECTS AND METHODS

Subjects This is a retrospective case series with 70 consecutive eyes implanted with Toric Lentis Mplus IOL during phacoemulsification. The patients were operated between January 2011 and December 2012 by a single surgeon (Quah SA) at Optegra Manchester Eye Hospital, UK. The tenets of the Declaration of Helsinki were followed for all study procedures. Because this is a retrospective study informed consent was not obtained from the subjects.

The inclusion criteria for the toric IOL implant were regular corneal astigmatism of at least 1.5 D. The exclusion criteria included irregular astigmatism on corneal topography, large scotopic pupil diameter (>6 mm), poor visual potential and significant ocular comorbidity *e.g.* macular disease and glaucoma.

Intraocular Lens Toric Lentis Mplus (model LU-313 MF30T) is a biconvex 1-piece multifocal acrylic IOL made

with an aspheric posterior surface design. The IOL has an 11.0 mm overall length, a 6.0 mm optic, and a square haptic design with 0-degree angulation. The non-rotational symmetric multifocal IOL with a refractive design combines an aspheric asymmetric distance vision zone with a sector-shaped near vision zone with a +3.00 D add. All Toric Lentis Mplus lenses are custom made and ordered using an online toric intraocular lens calculator (www.lentistoric.com).

Surgical Technique All operations were performed without any complications. Marks were made on the cornea under topical anaesthetic on the slit-lamp preoperatively. A narrow slit beam was directed at the centre of the pupil across the cornea horizontally. Peri-limbal scratches at 30° and the steepest axis of alignment were made with a sterile needle. A surgical marker pen was then used to stain these scratches.

At the start of the operation 5.5 mm diameter was marked on the cornea to facilitate the desired diameter of capsulorrhexis. Phacoemulsification was performed through a 2.75 mm clear corneal incision placed 30° temporally in all cases. The IOLs were implanted using a disposable injector (viscoject BIO 2.2 injector). The reference marks on the optic of IOL were then aligned with the premarked steepest axis and the near sector of the IOL optic placed inferiorly.

The targeted spherical equivalent was zero or the first negative (myopic) figure. Postoperative patients were advised to use topical steroid for a month and antibiotic for a fortnight. The fellow eye was operated within 1mo later.

Patient Examination Preoperatively, all patients underwent a complete ophthalmic evaluation including subjective refraction, biometry with IOL Master 500 (Carl Zeiss), corneal topography and pupillometry with Schwind Sirius and Combi Wavefront Analyzer, slit lamp examination, fundoscopy and applanation tonometry. Uncorrected distance visual acuity (UDVA), best-corrected distance visual acuity (BCVA), uncorrected intermediate visual acuity at (UIVA) 3/4 m and uncorrected near visual acuity (UNVA) were obtained.

Data and Statistical Analysis The data were collected in Microsoft® Office Excel® 2007 spreadsheet and analyzed with IBM® SPSS® Statistics version 20. Snellen acuities were converted into logMAR for statistical calculations.

The magnitude of refractive change induced by the clear corneal main incision at the beginning of the surgery was taken as 0.50 D and factored into the toric IOL calculation. The postoperative astigmatism is the manifest refractive cylindrical error obtained postoperatively. The latter was vertexed on the cornea plane for comparison with preoperative keratometric astigmatism.

Shapiro-Wilk test was used to ascertain the data distribution for normality. Paired Student's *t*-test and Wilcoxon signed rank test were used to analyse parametric and non-parametric data respectively. The post-operative astigmatism was determined whether it was different from zero using dioptric power matrix transformation. Where appropriate the results were reported as mean±standard deviation.

The difference vector (DV) is the vector that allows the induced surgical astigmatism effect to intended surgical astigmatism effect. This is an absolute measure of success and ideally should be zero. The magnitude of error (ME) is the arithmetic difference between the magnitudes of the induced surgical astigmatism effect and intended surgical astigmatism effect. The ME is positive if there is an overcorrection and negative for undercorrection. The angle of error (AE) is the angle between the induced surgical astigmatism effect and intended surgical astigmatism effect vectors. If AE is positive, this means the achieved correction is counterclockwise to the intended axis; if negative it is clockwise to the intended axis. The absolute angle of error (AAE) is the sum of the absolute difference between the intended and induced angle of correction. The correction index (CI) was calculated as the ratio of the absolute values of Induced surgical astigmatism effect to the Intended surgical astigmatism effect. An ideal correction index is 1.0. If this is greater than 1.0, it means the operation has caused an overcorrection, and if less than 1.0 refers to undercorrection.

RESULTS

There were 70 eyes from 49 patients in this study. There were 34 female (47 eyes) patients. The mean age was 60.2± 7.7 year-old (range 47 to 81). Thirty-seven right and 33 left eyes were operated. There were no intraoperative complications. Seven eyes with amblyopia and documented visual potential of at least 0.30 logMAR were included.

The set of data distributed in a Gaussian fashion were pre and postoperative spherical equivalent only (Shapiro-Wilk, P=0.21 and P=0.18). The rest was non-Gaussian.

Visual Outcome Patients were refracted at a median of 8.9wk (range 4.0 to 15.5) from the operation date. Table 1 shows the preoperative and postoperative various distance visual acuities. Sixty-five percent of eyes had 6/7.5 (0.10 logMAR) or better, and 99% 6/12 (0.30 logMAR) or better postoperative UDVA. Eighty-nine percent could read Jaeger (J) 3 (0.28 logMAR) and 95% J5 (0.37 logMAR) at 40 cm.

Fifty-six eyes (80%) had a manifest astigmatic error of 0.75 D or less. In these eyes, the median UDVA was 0.10 logMAR (range -0.10 to 0.30), UIVA 0.05 (range -0.10 to 0.20) and UNVA 0.13 (range 0.00 to 0.60). The remaining fourteen eyes had astigmatic error of more than 0.75 D (maximum was 1.5 D). In this group, the median UDVA was 0.23 logMAR (range 0.10 to 0.50), UIVA 0.10 (range 0.10 to 0.30) and UNVA 0.20 (range 0.10 to 0.53). The Wilcoxon P values for each distant was 0.0001, 0.003 and 0.008.

Refractive Outcome Table 2 shows the preoperative and postoperative refractive changes. The spherical equivalent (SE) before and after the Toric Lentis Mplus implant was not statistically significant (paired Student's t-test, P=0.71). The median magnitude of astigmatism decreased from 1.91 D to 0.49 D (Wilcoxon, P<0.001) after the operation. The mean spherical equivalent postoperative was 0.00±0.36 D and the range was -1.00 to +1.00 D.

Table 3 reveals the vectorial analysis of the astigmatic change. The DV was not significantly different from zero (P= 0.48). There was a slight overcorrection, as indicated by a CI of 1.07.

Table 1 Preoperative and postoperative visual acuity and refractive error

Visual Acuity	Preoperative (logMAR)	Postoperative (logMAR)	*P*
Median UDVA	0.90	0.10	
Range	-0.10 to 1.70	-0.1 to 0.5	<0.001[a]
Mean UDVA	0.76	0.10	
Median BCVA	0.10	0.00	
Range	-0.10 to 0.60	-0.10 to 0.30	0.001[a]
Mean BCVA	0.10	0.03	
Median UIVA	0.35	0.10	
Range	0.00 to 0.40	-0.10 to 0.30	0.002[a]
Mean UIVA	0.28	0.06	
Median UNVA	0.63	0.13	
Range	0.10 to 0.90	0.00 to 0.60	<0.001[a]
Mean UNVA	0.55	0.18	

[a]Wilcoxon signed rank test.

Table 2 Preoperative and postoperative refractive changes

Refractive error	Preoperative (D)	Postoperative (D)	*P*
Spherical equivalent			
Mean±SD	-0.27±5.05	0.00±0.36	0.71[a]
Range	-10.00 to +9.13	-1.00 to +1.00	
Astigmatism	(Keratometric)	(Subjective refraction at corneal plane)	
Vector	1.41 at 89.5°	0.18 at 28.7°	
Median magnitude	1.91	0.49	<0.001[b]
Range	1.5 to 3.95	0.00 to 1.46	

[a]Paired student's *t*-test; [b]Wilcoxon signed rank test.

Table 3 Preoperative and postoperative astigmatism analysis $\bar{x} \pm s$

Parameters	Astigmatism
Intended surgical astigmatism effect	1.41 D at 179.5°
Induced surgical astigmatism effect	1.51 D at 2.4°
Difference vector	0.18 D at 28.7°[a]
Magnitude of error (D)	0.10±0.36
Angle of error	2.8°±4.5°
Absolute angle of error	3.7°±5.2°
Correction index	1.07

[a]Not significantly different from zero; *P*=0.48 (dioptric power matrix transformation).

Forty-eight eyes (69%) had a postoperative subjective refractive cylinder (at spectacle plane) of up to 0.50 D, and 56 eyes (80%) up to 0.75 D. Two eyes from different patients had a residual cylinder of 1.25 D and 1.50 D. These were the only ones higher than 1.00 D. The range of the cylindrical error was reduced from 1.5-3.95 D (keratometric) preoperatively to 0.00-1.46 D (subjective refraction transposed to corneal plane) postoperatively. Figure 1 shows the individual change in preoperative keratometric astigmatism compared to postoperative subjective refraction. The double angle vector diagram showed a reduced range of astigmatic spread after the IOL implant (Figure 2).

Patient Satisfaction All patients were satisfied with the IOL implant and would recommend the procedure to a friend. These included the two patients with residual postoperative astigmatism of 1.25 D and more. Their preoperative astigmatisms were 2 and 3 D respectively. Despite the photopic phenomenon was not formally evaluated, no patients complained of severe symptoms requiring explantation.

DISCUSSION

Our results show that Toric Lentis Mplus IOL has good predictability in reducing the amount of preexisting corneal astigmatism which is crucial in allowing the maximum multifocal utility. Preoperatively the median keratometric astigmatism was 1.91 D, and this was reduced to a median of

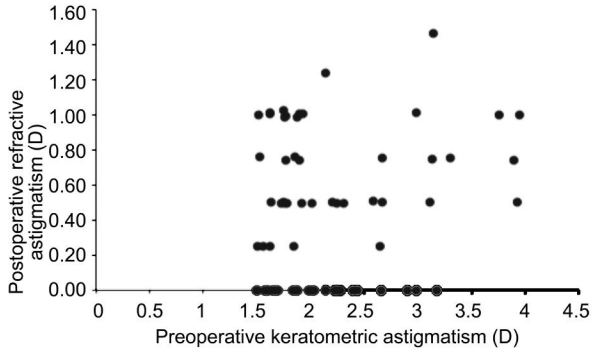

Figure 1 Change in preoperative keratometric astigmatism versus postoperative subjective refractive astigmatism.

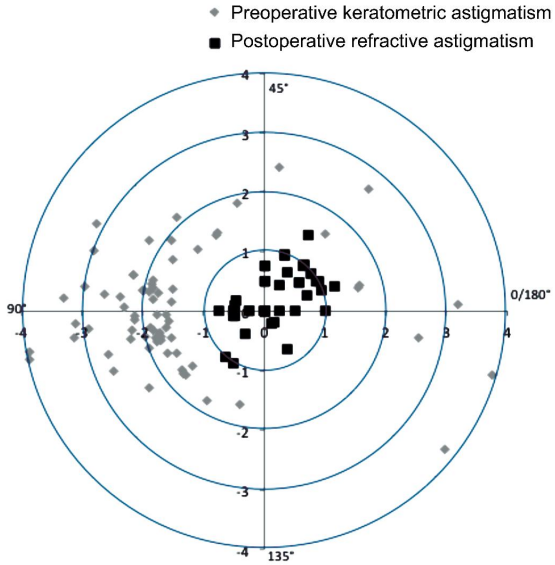

Figure 2 Double-angle vectorial diagram for positive cylinder (D) pre and postoperation.

0.49 D in the postoperative subjective refractive astigmatism. Currently, the published literature on the visual outcome of Toric Lentis Mplus is limited. In our study, 69% of eyes had a subjective manifest astigmatism of 0.50 D or less; and 80.0% had 0.75 D or less after the operation. This is comparable to the only published data on Toric Lentis Mplus by Venter and Pelouskova[18] where 65% of eyes had a refractive astigmatism of 0.50 D or less despite their range of preoperative astigmatism was slightly wider. The mean preoperative keratometric astigmatism in our study was only 2.2 D, while the study aforementioned was 3.0 D. In other types of toric multifocal IOL studies with comparable preoperative astigmatism, the mean postoperative refractive cylinders were found to be 0.40±0.25 D and 0.71±0.42 D[19-20]. Another series with higher preoperative astigmatism of 3.4±1.17 D revealed a 3-month postoperative result of 0.80±0.42 D[21].

Vector analysis of the overall astigmatic change shows that the Toric Lentis Mplus has excellent predictability in correcting astigmatism as shown by the small indices of ME, AE, AAE and CI. Our study could no demonstrate a clear relationship between the amount of preoperative astigmatism with the residual postoperative astigmatism as shown by Figure 1. A larger study is required for this.

The UDVA in our study was 0.10 logMAR which was slightly worse but within one Snellen line of Venter and Pelouskova's [18] result of 0.03. One of the reasons might be due to the inclusion of 7 amblyopic eyes albeit their best recorded visual potential was at least 0.3 logMAR or better. Excluding these eyes, our UDVA improved to 0.09 logMAR. Our findings on UNVA was 0.18 logMAR which was almost the same as Venter and Pelouskova's [18] finding of 0.17. In a large series non-Toric Lentis Mplus data, the mean UDVA was 0.05 logMAR and UNVA 0.21[22].

Patients found with residual objective astigmatism of more than 0.75 D are more likely to be dissatisfied with their vision [23-24]. Our results showed acuities at all distances were statistically significantly worse when the astigmatism was more than 0.75 D. This shows the importance of residual astigmatism to be corrected below this level. It's not in the remit of this study to discuss the options available to enhance the refractive error in these cases.

The mean postoperative spherical equivalent in our study was excellent at 0.00±0.36 D. A large study of non-Toric Lentis Mplus, with a follow-up of more than 5000 eyes at 3-month found a SE of -0.02 ±0.60 D which is comparable our findings [22]. This shows the predictability of Toric Lentis Mplus is comparable to the non-Toric Lentis Mplus.

Our study found the Toric Lentis Mplus LU-313 MF30T has similar visual acuities at distance and near compared to the non-toric version of the same IOL. Eyes with no or a residual astigmatism of less than 0.75 D has the best acuity outcome. The refractive outcomes confirm the correction of astigmatism by this IOL has a good predictability in majority of cases.

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Chiam PJ analysed and wrote the manuscript, Quah SA conceived the study idea, collected the data and provided critical review.

The study was performed at the Optegra Manchester Eye Hospital, United Kingdom.

Conflicts of Interest: Chiam PJ, None; **Quah SA,** None.

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