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ORIGINAL PAPER

Outcomes of toric supplementary intraocular lenses for residual astigmatic refractive error in pseudophakic eyes

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Abstract

Purpose To evaluate rotational stability and visual and refractive outcomes of supplementary toric IOLs (Sulcoflex Toric 653T, Rayner Intraocular Lenses Ltd) for residual astigmatic refractive error in pseudophakic eyes.

Methods A retrospective interventional case series was conducted in a single surgeon practice. Charts of patients who had Sulcoflex Toric supplementary IOLs inserted between June 2009 and September 2015 were reviewed. Outcomes were compared between eyes with and without prior corneal transplant. Patients with at least 3-months follow-up were included.

Results In 51 eyes, mean UDVA improved from 20/86 to 20/43 ($p = 0.002$), though UDVA was better in eyes without corneal grafts (20/31) than eyes with (20/62). The proportion of eyes achieving 20/20 UDVA was 43%, 61% and 17% overall, in eyes with prior graft and in eyes with no prior graft, respectively. Sixty-four percentage achieved a spherical equivalent of within 0.5D of target (84% no graft, 34% prior graft). Fifty-three percentage of eyes achieved a cylinder of within 0.5D of target (no graft: 73%, prior graft: 0%). Mean lens rotation was 8.23° on day 1, and mean maximal rotation during follow-up was 17.63°. Sixty-two percentage of IOLs required repositioning. Of those that required repositioning, this was conducted a mean of 2.3 times. The mean final IOL rotation (following repositioning if required) was 6.17°.

Conclusion Sulcoflex Toric supplementary IOLs result in good visual and refractive outcomes in eyes with no prior corneal graft. However, outcomes are sub-optimal in eyes with prior corneal transplantation, and the majority of lenses require repositioning.

Keywords Astigmatism · Toric · Supplementary · Intraocular lens

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Introduction

Following cataract surgery, residual astigmatism may result in sub-optimal uncorrected distance visual acuity (UDVA), with each dioptre of astigmatism corresponding to a reduction in UDVA of 1.5 lines [1]. The result of this may be spectacle dependence for distance vision, a situation which is likely to be unacceptable to a cohort of patients with increasingly

high expectations [2, 3]. Indeed, there may be medico-legal implications of post-operative residual astigmatism [4].

In the event of residual astigmatism following cataract surgery, several treatment options exist to improve UDVA. Non-surgical options include the use of spectacles and contact lenses. Surgical options include photo-refractive keratectomy (PRK), laser in situ keratomileusis (LASIK), insertion of toric iris-clip IOLs and/or supplementary ("piggyback") IOL insertion [5–8]. Limbal/corneal relaxing incisions are limited by their predictability and ability to treat higher degrees of astigmatism and their inability to change the spherical equivalent in isolation [9, 10].

Sulcoflex Toric IOLs (653T, Rayner Intraocular Lenses Ltd, East Essex, United Kingdom) are one type of toric supplementary IOL designed for insertion in the ciliary sulcus of pseudophakic eyes [11]. Like all toric IOLs, their efficacy is highly dependent on their ability to remain aligned at the desired axis (rotational stability), as rotation from this axis can have deleterious effects on vision. Although rotation of up to 10° has minimal effect on visual outcomes, greater degrees of rotation can diminish UDVA, with almost all of the effect of a toric lens being nullified by 30° of rotation [12]. Furthermore, the effect of toric IOL rotation is more magnified in higher power lenses, making their rotational stability particularly critical [10, 13].

In certain circumstances, supplementary IOL insertion may be contraindicated, for example, in eyes with a reduced endothelial cell count, pigment dispersion syndrome, loose zonules or the presence of posterior synechiae [14]. Possible complications of supplementary IOL insertion include pigment dispersion, pigmentary glaucoma, interlenticular opacification, iridocyclitis and hyphema [15, 16].

The aim of this study is to describe the visual and refractive outcomes as well as rotational stability of Toric Sulcoflex IOLs in what is, to the author's knowledge, the largest published cohort of patients treated with these lenses for residual astigmatic refractive error in pseudophakic eyes.

Methods

Charts of all patients who had Sulcoflex Toric IOLs inserted for residual astigmatism following cataract surgery between July 2009 and September 2015 were reviewed. Those with at least 3-months follow-up and complete data were included in the study. At follow-up appointments, repositioning of the toric IOLs could be performed if there was rotation away from the desired axis and if the UDVA could be improved with pinhole. Repositioning was initially attempted at the slit lamp under topical anaesthesia with a 31G insulin needle. After administration of a topical mydriatic, a speculum was inserted, 5% iodine drops administered, and the IOL was rotated with the needle until the desired IOL orientation was achieved, as determined by a slit lamp beam. A few minutes later, the correct orientation was confirmed. If the IOL was not adequately oriented after being repositioned 3 times at the slit lamp, the patient was taken to the operating theatre and the IOL was sutured to the sclera. This was performed using a 10/0 prolene suture on a straight needle. The initial pass of the needle posterior to the haptic was transscleral (external to internal), with a second pass anterior to the haptic being made from internal to external. The knot was tied and buried under a scleral flap. Each haptic was secured in this manner, 180° apart.

The following data were collected: patient age at time of surgery, sex, UDVA, corrected distance visual acuity (CDVA), refractive sphere and cylinder (based on subjective refraction) and duration of follow-up. Whether there was a history of corneal transplantation was also documented. With respect to the IOL, the following were collected: intended IOL axis, day 1 post-operative IOL rotation from intended axis, greatest IOL rotation from desired axis during follow-up, final IOL axis, whether IOL repositioning was required, how many times repositioning was required and when repositioning occurred in the post-operative period. No identifying information was collected.

Efficacy was assessed by determining the percentage of eyes that achieved 20/20 and 20/40 UDVA, the number of eyes achieving post-operative UDVA equal to that of pre-operative CDVA and the percentage of eyes achieving within 0.5D of target refractive sphere and cylinder. Safety was assessed through assessment of any complications.

As Shapiro–Wilk significance testing demonstrated that the data were not normally distributed, nonparametric tests were used to compare groups. Significance testing within groups was performed with a Wilcoxon signed-rank test, while significance tests between groups were completed using the independent 2-group

Mann–Whitney *U* test. Statistical analysis was completed using R statistical software (Foundation of Statistical Computing, Vienna, Austria).

Results

Fifty-one eyes of 44 patients had Sulcoflex Toric IOLs inserted by a single surgeon. Mean patient age was 67 years (SD 11.9 years). Twenty-six eyes were from males, and 25 eyes were from females. Thirty-two eyes had no prior history of corneal transplantation, while 19 eyes had a corneal graft. Eighteen of these grafts were penetrating keratoplasty, and 1 was a Descemet's stripping endothelial keratoplasty.

Following the insertion of Toric Sulcoflex IOLs, there was a statistically significant improvement in mean UDVA, mean refractive sphere and mean refractive cylinder. There was no statistically significant difference in mean CDVA (Table 1). Forty-three percentage of eyes achieved 20/20 UDVA or better, while 73% achieved 20/40 or better (Fig. 1). Forty-three percentage of eyes achieved a post-operative UDVA which was equal to or better than the pre-operative CDVA with 57% of eyes having a post-operative UDVA at least 1 line worse than pre-operative CDVA (Fig. 2). Twenty-four percentage of eyes gained 1 or more line of CDVA, 45% had no change in CDVA, and 21% lost 1 or more line of CDVA (Fig. 3).

In terms of refractive outcomes, Fig. 4 shows the attempted versus achieved SE for each eye. Overall, 64% of eyes achieved a spherical equivalent within 0.5D of target (Fig. 5). Fifty-three percentage of eyes achieved 0.5D or less of residual astigmatism, while residual astigmatism of 2D or more was present in 47% of eyes (Fig. 6).

Figure 7 shows a vector analysis of the target induced astigmatism vector, surgically induced astigmatism vector, difference vector and correction index for each eye.

Table 2 compares the visual and refractive outcomes between eyes with and without prior corneal

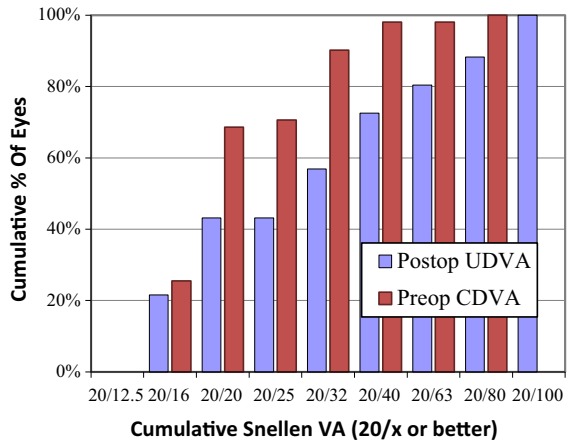

Fig. 1 Cumulative post-operative UDVA versus pre-operative CDVA

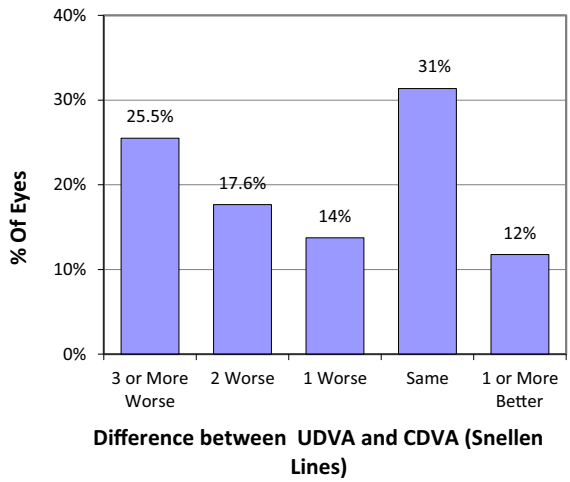

Fig. 2 Difference between pre-operative CDVA and post-operative UDVA

Table 1 Visual and refractive parameters in 51 eyes with Sulcoflex Toric Supplementary IOLs (653T)

Parameter	Pre-operative	Post-operative	*P* value
Mean uncorrected distance visual acuity (SD logMAR)	20/86 (0.34)	20/43 (0.23)	0.002
Mean corrected distance visual acuity (SD logMAR)	20/24 (0.14)	20/17 (0.20)	0.089
Mean refractive sphere (D)	1.73(1.85)	0.56 (0.77)	0.001
Mean refractive cylinder D (SD)	2.51D (2.08)	1.32D (1.56)	0.002

SD standard deviation, *D* dioptre

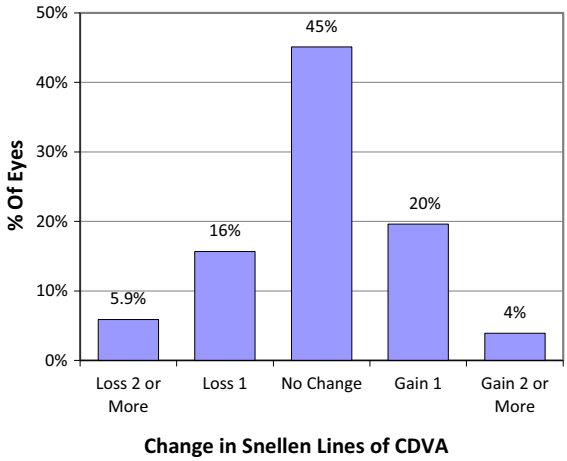

Fig. 3 Change in CDVA

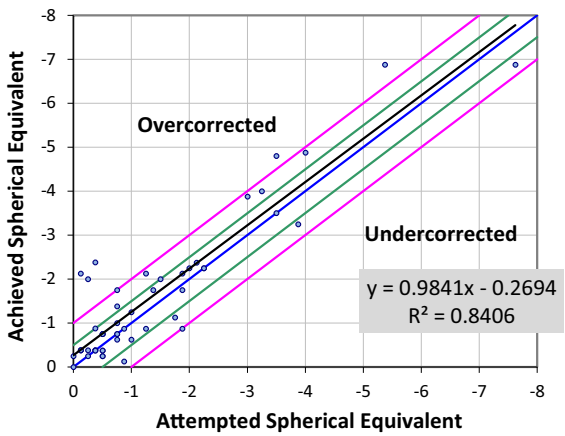

Fig. 4 Spherical equivalent attempted versus achieved

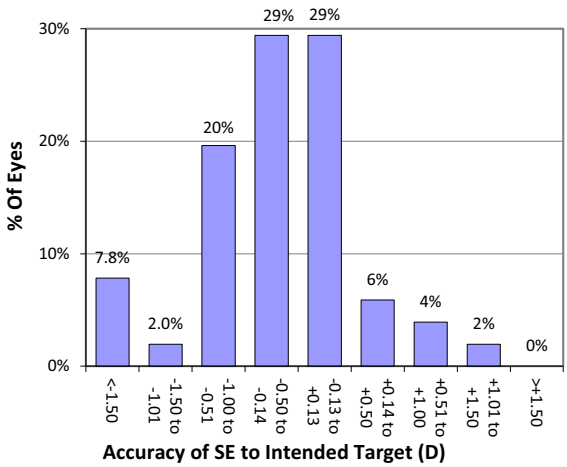

Fig. 5 Spherical equivalent accuracy

transplant following the insertion of Sulcoflex Toric IOL. Eyes with prior corneal graft had poorer outcomes in all parameters. Figures 8 and 9 show that, although the final outcomes were better in eyes with no prior graft, the baseline UDVA was significantly poorer and refractive cylinder was significantly higher in the group with prior corneal graft. Furthermore, there was no significant difference in the change in UDVA and cylinder between the 2 groups induced by Sulcoflex Toric IOL.

Analysis of rotational stability of Sulcoflex Toric IOLs shows that, although mean day 1 rotation was only 8.23° from the desired axis, there was a tendency for the IOLs to rotate further post-operatively, with a mean maximum rotation of 17.63° throughout the follow-up period. In cases requiring IOL repositioning, the rotation occurred in a clockwise direction in 91% of cases and in a counterclockwise direction in 9% of cases. Overall, 62% of IOLs required post-operative repositioning. Of these, repositioning was conducted a mean of 2.3 times, with 30 cases being performed at the slit lamp and 2 cases requiring scleral fixation sutures in the operating theatre. In 31% of cases, repositioning of the IOL was required 3 months or later in the post-operative period. At the last review, the mean rotation from desired axis was 6.17°.

There were no complications from any of the procedures performed.

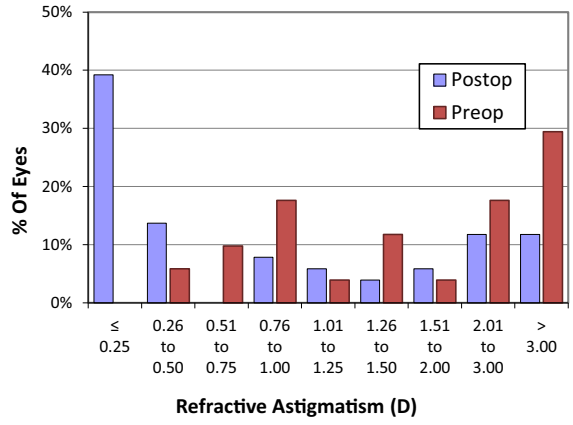

Fig. 6 Achieved refractive astigmatism

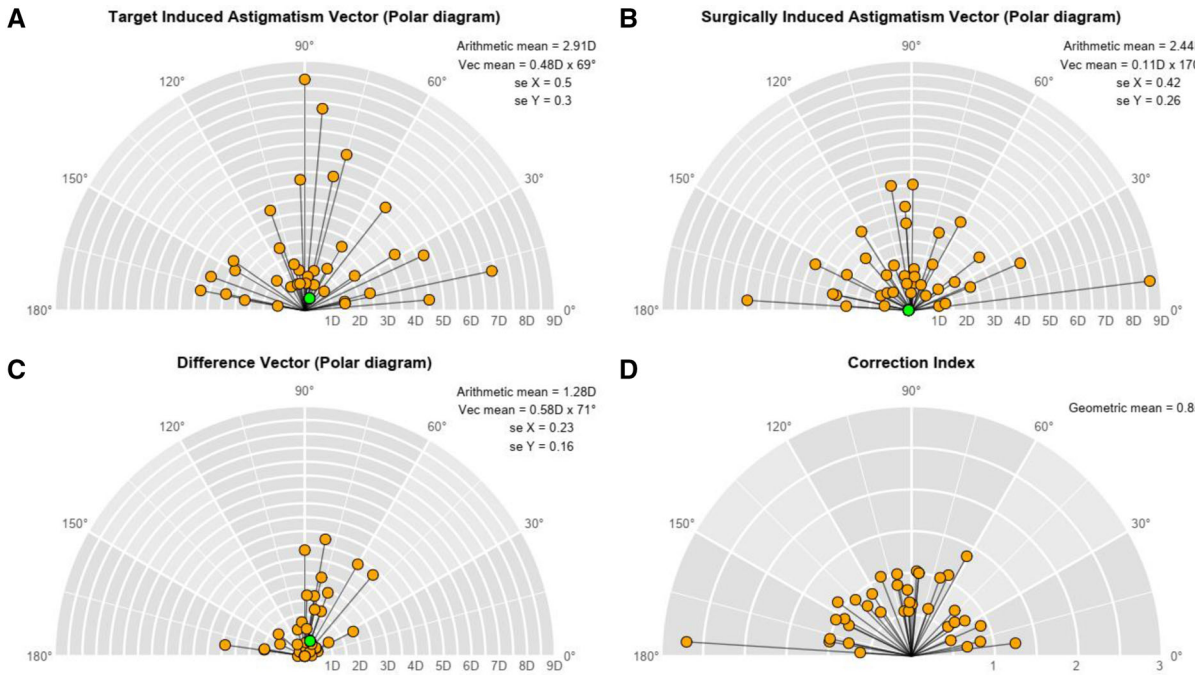

Fig. 7 Vector analysis of 51 eyes with Sulcoflex Toric Supplementary IOLs (653T). Green dot = mean value

Table 2 Comparison of visual and refractive outcomes in eyes with and without prior corneal transplantation

Parameter	No prior graft (%)	Prior graft (%)
% of eyes with 20/20 UDVA post-operatively	61	17
% of eyes with 20/40 UDVA post-operatively	85	56
% of eyes with post-op UDVA ≥ pre-op CDVA	54	28
% of eyes achieving within 0.5D of target SE	84	34
% of eyes achieving within 0.5D of target astigmatism	73	0
% of eyes losing at least 1 line of CDVA	15	39

Discussion

To date, several studies have examined the outcomes of Sulcoflex Toric IOLs [11, 17, 18]. This study is, to the authors' knowledge, the largest case series examining rotational stability and visual and refractive outcomes. It is also unique in that it compares outcomes in patients with and without a prior history of corneal transplantation.

The results of this study suggest that, overall, Sulcoflex Toric supplementary IOLs result in a significant improvement in UDVA, refractive sphere and refractive astigmatism. However, the overall final mean UDVA (20/42) as well as the percentage of eyes achieving 20/20 UDVA (43%) and 20/40 (75%) would be considered sub-optimal by most surgeons and patients. When a sub-analysis is performed of eyes without a history of corneal transplantation, the outcomes (20/31 mean UDVA, 61% achieving 20/20 UDVA and 85% with 20/40 UDVA) are much more satisfactory. It is important to note that, in this study, the baseline visual and refractive parameters were significantly worse in the group with prior corneal transplantation and analysis showed that there was no significant difference in the improvement in UDVA and cylinder between the groups. Nonetheless, the final visual and refractive outcomes in eyes with prior corneal transplantation are sub-optimal. Given that astigmatism in eyes with a history of prior corneal transplant (particularly penetrating keratoplasty) often

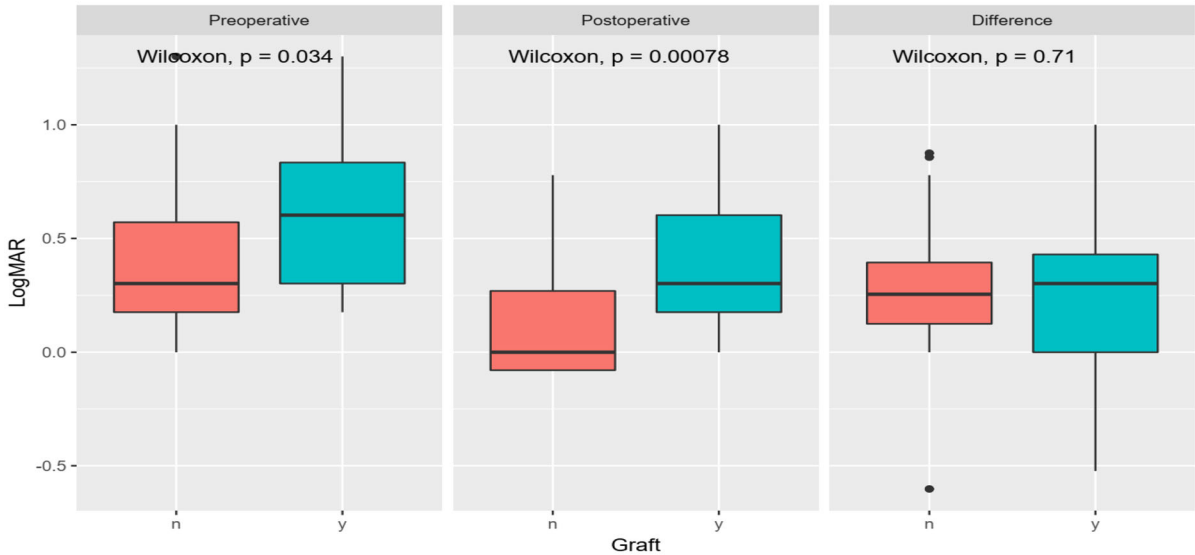

Fig. 8 **a** Comparison of pre-operative UDVA between eyes with (*y*) and without corneal graft (*n*). **b** Comparison of post-operative UDVA between eyes with (*y*) and without (*n*) corneal graft. **c** Comparison of the difference in pre-operative and post-operative UDVA between eyes with (*y*) and without corneal graft

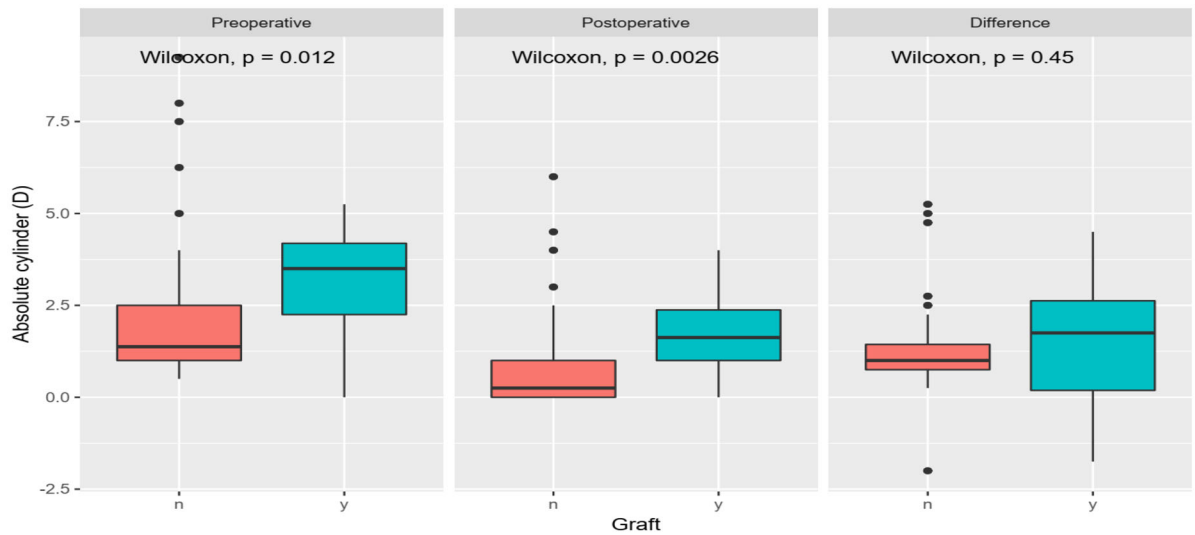

Fig. 9 **a** Comparison of pre-operative refractive astigmatism between eyes with (*y*) and without corneal graft (*n*). **b** Comparison of post-operative refractive astigmatism between eyes with (*y*) and without (*n*) corneal graft. **c** Comparison of the difference in pre-operative and post-operative refractive astigmatism between eyes with (*y*) and without (*n*) corneal graft

has a significant irregular component which cannot be corrected with toric IOLs, it is not surprising that final mean UDVA was poorer in this group. Furthermore, subjective refraction is also often more difficult and variable in patients with corneal grafts meaning that the choice of lens power is conceivably more prone to error which will consequently affect the visual and refractive outcomes.

In this cohort of eyes, analysis of Sulcoflex Toric supplementary IOLs shows that the IOL required repositioning in almost 2/3 of cases, frequently multiple times. We note that these findings are at odds with other studies of these lenses which have

reported good rotational stability [11, 17], and as such, further studies are required into the rotational stability of these lenses to clarify this issue. We also note that these studies had a significantly smaller cohort than our case series.

In light of the findings of our study, it seems reasonable that patients who are undergoing insertion of Sulcoflex Toric supplementary IOLs should be advised that IOL repositioning is likely to be required post-operatively. It is also important to advise patients in whom high power lenses are implanted that lens orientation is even more vital in such cases and that smaller degrees of rotation may require repositioning.

The results of this paper also suggest that clinicians should be aware of the possibility of late rotation with these lenses. This study found that adequate IOL orientation at the day 1 review does not correlate with longer-term stability at the desired orientation. Of note, with approximately 1/3 of cases requiring repositioning after the 3-month follow-up appointment, longer-term follow-up would appear to be prudent.

The absence of any intra-operative or post-operative complications in any of the cases suggests a good safety profile of these lenses.

Limitations of the study include its retrospective nature and the fact that examiners were not masked. Having chosen a minimum follow-up period of 3 months, it is outside the scope of this study to comment on longer-term outcomes of Sulcoflex Toric supplementary IOLs. As this study has not compared Sulcoflex Toric IOL insertion with any other method of treating post-cataract surgery astigmatic refractive error, no conclusions regarding their relative efficacy can be drawn. Further studies comparing the Sulcoflex Toric supplementary IOLs to other toric supplementary IOLs and to other treatment modalities for residual astigmatism (for example, LASIK/PRK) would be very helpful.

In conclusion, Sulcoflex Toric supplementary IOLs (653T) result in a significant improvement in UDVA, refractive sphere and refractive astigmatism in patients with residual astigmatic refractive error following cataract surgery. Visual and refractive outcomes are good in those with no prior history of corneal transplantation, but poor in those with prior corneal graft. Furthermore, these lenses seem to have a relatively high degree of rotational instability, with more than half of them requiring repositioning at least once in the post-operative period. This warrants further investigation to confirm our findings.

Compliance with ethical standards

Conflict of interest All authors declare no conflict of interest.

Ethical standard All procedures performed were in accordance with the ethical standards of the involved institutions and with the 1964 Declaration of Helsinki and its later amendments. Ethics approval was obtained from the Metro South Human Research Ethics Committee (Brisbane, Australia). Informed consent was obtained from all individual participants included in the study.

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