ARTICLE

Prospective multicentre evaluation assessing visual acuity and patient satisfaction in pseudophakic patients with bilaterally implanted supplementary Trifocal intraocular lens.

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ABSTRACT

Purpose: To evaluate the postoperative visual outcomes, safety, efficacy and patient satisfaction in pseudophakic patients implanted with the new Sulcoflex Trifocal supplementary intraocular lens (IOL) (Rayner, UK).

Methods: This prospective multicentre non-randomised study included pseudophakic patients who underwent bilateral implantation of Sulcoflex Trifocal supplementary IOL (Sulcoflex Trifocal 703F) in the ciliary sulcus to achieve spectacle independence. All eyes previously had capsular bag monofocal or toric IOLs implanted. Outcome measurements at one month included manifest refraction, monocular and binocular uncorrected and distance corrected visual acuity for near, intermediate and distance, defocus, contrast sensitivity and patient satisfaction. One-month data are presented in this study.

Results: Data from 68 pseudophakic eyes were analysed. The mean spherical equivalent was 0.39 D ± 1.27 D (range -2.75 to +3.50 D) preoperatively and reduced to mean -0.15 ± 0.26 D (range -0.75 to +0.25 D). Postoperatively 94% of eyes were within ±0.50 D and 100% were within ±1.00 D of emmetropia.

At one-month follow up, 100% of the patients achieved monocular uncorrected distance visual acuity (UDVA) of 0.10 logMAR (Snellen 20/25) or better and 65% of patients achieved 0.00 logMAR (Snellen 20/20). Monocular uncorrected near vision (UNVA) was 0.00 logMAR (J1 equivalent) in 41% of eyes and 100% of eyes achieved 0.18 logMAR or better (J3 equivalent or better). Monocular uncorrected intermediate vision (UIVA) was 0.00 logMAR (J1 equivalent) in 71% of the eyes and 100% of eyes achieved 0.18 logMAR (J3 equivalent) or better. There was high spectacle independence and patient satisfaction with visual outcomes. There were no significant adverse events reported.

Conclusions: Sulcus implantation of the new Sulcoflex Trifocal supplementary IOL (Rayner, UK) is a safe and effective method for enhancing the refractive outcome and reducing spectacle dependence for near, intermediate and distance in pseudophakic eyes. The IOL was well tolerated in all eyes.

Financial Disclosure: M. Amon is the inventor of Sulcoflex and is a third-party consultant to Rayner.

INTRODUCTION

The most commonly performed surgical procedure worldwide is cataract surgery with over 4.2 million cataract procedures performed across the European Union member states per year[1]. The global population of pseudophakic patients is estimated to be approx. 100 million people [*2013 Market Scope Comprehensive Report on the Global IOL Market*], many of whom may benefit from enhancement or correction of their pseudophakic vision[2]. Standard monofocal intraocular lenses (IOLs) improve visual outcomes in patients undergoing cataract surgery[3], however they primarily improve distance vision which, can leave patients spectacle dependent for many professional and domestic tasks requiring near and intermediate vision such as the use of computers, reading and watching TV[4]. Post cataract surgery patients increasingly demand spectacle independence due to changes in lifestyle, and with new developments in IOL technology there is now a possibility for patients to achieve a higher degree of spectacle independence after cataract or refractive surgery[5,6].

It has been shown that the use of multifocal IOLs can improve both near and distance visual acuity and therefore reduce spectacle dependency[7-12]. Multifocal IOLs have at least two focal points, one for distance and one for near, thus creating pseudo-accommodation; however, recent developments in trifocal technology means multifocal intraocular lenses can feature a third focal point to provide intermediary vision[4,13-16]. The use of multifocal IOLs in capsular bag implantation is not recommended for all patients; those at risk of developing age-related macular degeneration, diabetic retinopathy, glaucoma, amblyopia or corneal disorders may not be suitable for this technology[17]. These patients can suffer from low contrast sensitivity and potentially poor visual acuity. In addition, dysphotopic phenomena such as halo and glare can be a significant cause of patient dissatisfaction, which in some cases necessitates an explanation of the IOL[18], thus increasing the risk of capsular rupture or zonular dehiscence[19]. The explantation survey carried out at ESCRS/ASCRS in 2012 (Mamalis N) reports that dissatisfaction with dysphotopsia, mainly in multifocal IOLs, is the second most frequent reason for IOL explantation. These types of patients may instead be considered for a supplementary multifocal IOL instead of a capsular bag fixated version as the positioning of supplementary IOLs means they can be explanted with less surgical trauma.

Previous supplementary multifocal IOLs with refractive bifocal technology (Sulcoflex Multifocal 653F, Rayner, UK) and diffractive bifocal technology (Reverso, Cristalens, Humanoptics, Schrecker et al) have been used to correct presbyopia in pseudophakic patients, however these have only improved near and distance visual acuity in pseudophakic[5] and cataract patients, even those with retinal abnormalities[6]. A new type of supplementary IOL model featuring diffractive trifocal technology and the addition of an intermediate focus point was developed by Rayner, UK in 2018. The positioning of this supplementary trifocal lens in the ciliary sulcus for both pseudophakic and cataract patients means that in the event of patient dissatisfaction, the supplementary trifocal lens can be removed and effects of multifocality reversed with less surgical trauma.

The objective of this study is to evaluate the postoperative visual outcomes, safety, efficacy and patient satisfaction in pseudophakic patients implanted with the new Rayner Sulcoflex Trifocal supplementary IOL. To our knowledge there are no current published studies on this new trifocal supplementary IOL and therefore our findings are the first.

PATIENTS AND METHODS

This prospective multicentre non-randomised study included pseudophakic patients who had a desire for postoperative spectacle independence. The study was performed at 7 different sites across Europe between October 2018 and February 2019. All patients provided their informed consent to participate in this study prior to surgery. Inclusion criteria were pseudophakic patients over the age of 18 with a primary capsular bag fixated intraocular lens and residual astigmatism equal to or less than 1.5 D. Further exclusion criteria were any co-existing ocular morbidities including macular degeneration, proliferative

Figure 1. Illustration of Sulcoflex Trifocal.

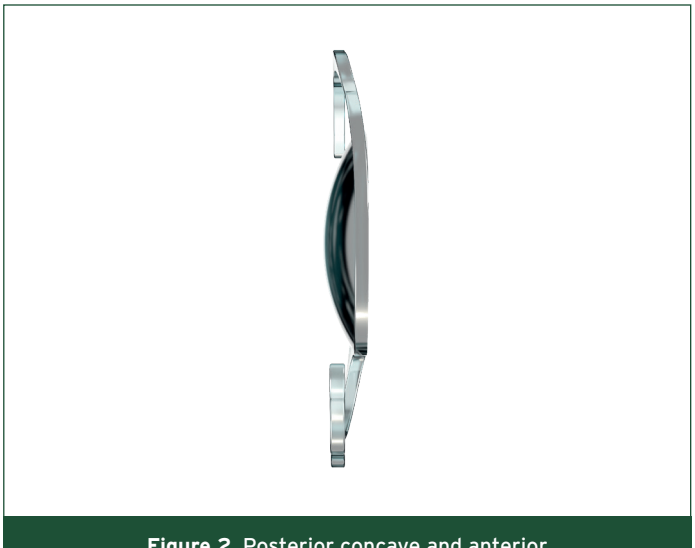

Figure 2. Posterior concave and anterior convex surface of Sulcoflex Trifocal.

diabetic retinopathy or chronic glaucoma, microphthalmia or corneal oedema, patients with amblyopia, strabismus or corneal decompensation and endothelial insufficiency, pseudophakic patients with unstable or malpositioned capsular bag IOL, patients with a multifocal capsular bag fixated IOL, capsule or zonular anomalies including pseudoexfoliation syndrome, pigment dispersion syndrome and finally insufficient pupil dilation.

Preoperative Assessment

Preoperatively, all patients had an ophthalmologic examination including uncorrected (UDVA) and corrected (CDVA) distance visual acuities using an Early Treatment of Diabetic Retinopathy Study (ETDRS) backlit chart at 4 m (Precision Vision, Illinois, USA), manifest refraction, slitlamp biomicroscopy, Goldmann applanation tonometry and fundoscopy. Preoperative contrast sensitivity was measured using Functional Acuity Contrast Test (F.A.C.T.) charts. Axial length (AL), anterior chamber depth (ACD), back vertex distance and keratometric values were determined using biometry (IOL Master, Carl Zeiss Meditec). The Sulcoflex Trifocal lens calculation was performed using the manufacturer's web-based online calculation programme with in-built formula, Raytrace (Rayner, UK) https://www.raytrace.rayner.com/. Manifest refraction was the most important variable in the Sulcoflex Trifocal lens calculation. Calculations can also take into consideration surgically induced astigmatism (SIA) and axis for any new incision to achieve a target refraction of distance emmetropia. The new incision was specified on the steep meridian in the calculations for all patients to minimise any significant SIA affecting the postoperative result.

Intraocular Lens

The Sulcoflex Trifocal aspheric 703F lens (Rayner, UK) has been specifically designed for ciliary sulcus fixation and correction of pseudophakic ametropia and presbyopia. It is composed of a hydrophilic acrylic co-polymer (Rayacryl), which has high uveal biocompatibility[20,21]. This is important for ciliary sulcus placement of the IOL, to prevent adhesions to adjacent uveal structures or increased uveal tissue-reaction. In addition, Rayacryl has a refractive index of 1.46 and includes a benzophenone ultraviolet-absorbing agent with a 10% ultraviolet cut-off at 380 nm. The Sulcoflex Trifocal is a one-piece, injectable IOL with a proprietary diffractive trifocal design on the posterior of the optic. Near vision is achieved by the addition of +3.5 D and intermediate vision is achieved by the addition of +1.75 D at the IOL plane in a far dominant format (**Figure 1**). Light energy split at 3.0 mm aperture is 52% to distance, 22% to intermediate and 26% to near. The power ranges from -3.0 D to -1.0 D (0.5 D increments), -1.0 D to +1.0 D (0.25 D increments) and +1.0 D to + 3.0 D (0.5 D increments). The new addition of 0.25 D steps between -1.0 D and +1.0 D allows for finetuning and the ability to offer multifocality with more accurate emmetropic results. The optic has a diameter of 6.5 mm and is shaped convex anteriorly and concave posteriorly, which improves its fit in front of the anterior convex surface of a primary IOL (**Figure 2 & 3**). The lens has undulating round-edged haptics that are angulated at 10° so that the optic vaults slightly posteriorly relative to the haptics (**Figure 4**). This feature ensures separation from the posterior iris and minimizes the risk of subsequent pigment dispersion due to iris chafe. The optics and haptics have soft, round edges to prevent optic-iris capture, to minimize risk of iris chafing and pigment dispersion, and to reduce the potential for edge glare and dysphotopsias. The overall diameter of the lens is 14.0 mm, the haptics are 0.33 mm in thickness and the optic thickness is between 0.25 and 0.75 mm depending on the dioptric power[22]. The lens is manually loaded into a Medicel Accuject 1.8-1P (LP604540) soft-tipped lens injector system at point of use. This injector has a syringe-style design to aid a single-handed IOL delivery technique. This is a change from the original R-INJ-04 injector supplied with other models of Sulcoflex.

Surgical Technique

Surgeries were performed across 7 sites by 7 different surgeons. Treatments were carried out with an established protocol and procedures at the discretion of the study centres. All supplementary IOL implantations were performed using topical anaesthesia and followed standard protocol. The implantation procedure involved pupil dilation followed by the creation of an on-axis, self-healing clear corneal incision (2.2 mm) using a standardised technique. The ciliary sulcus and anterior chamber

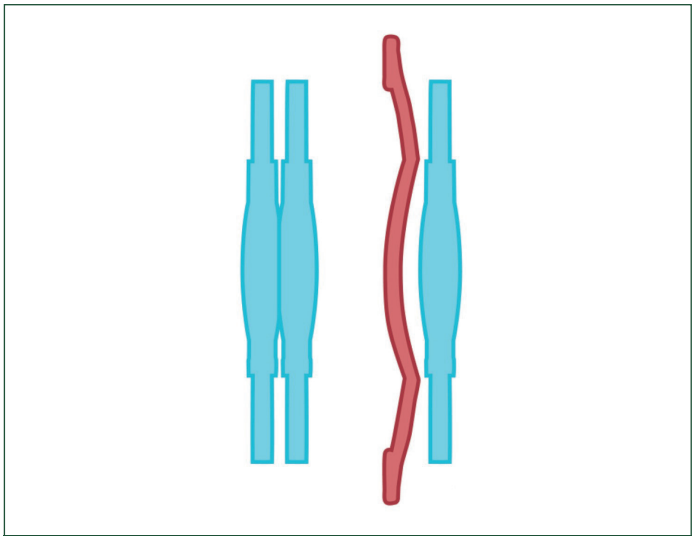

Figure 3. Illustration to demonstrate the unique shape of the Sulcoflex IOL compared with other conventional piggyback IOLs.

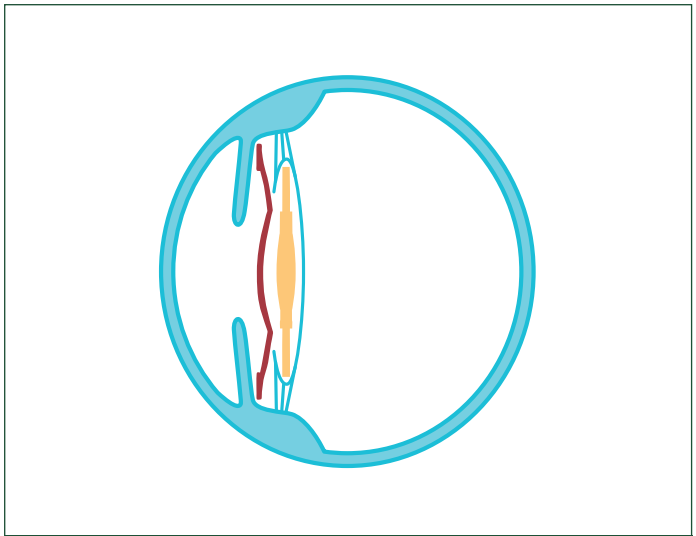

Figure 4. Illustration to demonstrate the position of the Sulcoflex IOL in the ciliary sulcus.

were filled with a cohesive ophthalmic viscoelastic device (OVD) and the supplementary IOL was implanted into the ciliary sulcus with a one-piece single use injector (Accuject 1.8, Medicel AG). The haptics of the supplementary IOL were orientated in the same direction as the haptics of the primary IOL or were aligned 90 degrees to the haptics of the primary IOL. Implantation was followed by meticulous aspiration of the OVD, hydration of the wound, and intracameral administration of cefuroxime 1.0mg in 0.1mL at the end of the surgery. After surgery all patients received topical steroidal anti- inflammatory 0.1% dexamethasone eye drops for 4 weeks and 2 x Yellox (Bromfenac).

Postoperative measurements

Postoperative measurements were performed at 1 month following surgery and included the same tests performed in the preoperative assessment. The primary outcome measures were UDVA, CDVA, uncorrected intermediate visual acuity (UIVA), distance corrected intermediate visual acuity (DCIVA), UNVA and distance corrected near visual acuity (DCNVA). The distance visual acuities were determined using ETDRS charts at 4 m distance. Near visual acuity and intermediate visual acuity were determined with ETDRS at 40 cm and 70 cm respectively. Subjective refraction was determined with test lenses and the cross-cylinder method using the maximum plus method (as these methods are non-invasive and non-contact). The binocular defocus curve was evaluated under photopic conditions (85 cd/m2) using defocusing lenses from +1.00 to -4.00 D in 0.50 D steps. Contrast sensitivity was measured binocularly at spatial frequencies of 1.5, 3,6,12 and 18 cycles per degree using F.A.C.T charts under photopic 85 cd/m2 and mesopic 3cd/m2 conditions. Patients were shown pictures representing dysphotopic phenoma (specifically halos, glare and starburst) and informed about their presence and meaning, they were then asked to classify each of these 3 visual symptoms according to a 5-point Likert scale through the question, "Do you find the halos/ glare/starburst disturbing and troublesome?" (0= no, 1= hardly, 2= somewhat, 3= quite, 4= highly). Patients were also asked "Do you wear spectacles for distance/intermediate/near vision?" with 4 response options (never, sometimes, often and always). Finally, patients were asked to scale their satisfaction according to a 5-point Likert scale when asked "How satisfied are you with your near/intermediate/ distance and overall vision?" (0= Extremely dissatisfied, 1= Dissatisfied, 2= Neutral, 3= Satisfied and 4= Extremely Satisfied). All data were collected in an Excel database (Microsoft Office 365 Business). Summary statistics (means and standard deviations) were presented to describe the study population. All data were analysed using Microsoft Office Excel. Results are expressed as the mean ± standard deviation. Visual acuity measurements were converted to LogMAR for statistical analysis.

RESULTS

Data were collected from 68 eyes of 34 patients after a 1 month follow up. Mean patient age was 61.21 years ± 10.87 (SD) (range 43 to 81 years). The implanted Sulcoflex Trifocal power ranged from -2.5 D to +2.5 D. Eighty four percent (57 eyes) of eyes had a monofocal intraocular lens implanted in the capsular bag from previous cataract surgery and sixteen percent (11 eyes) of eyes had a toric IOL implanted in the capsular bag from previous cataract surgery. Preoperative and postoperative statistics are summarised in **Table 1**.

TABLE 1
Preoperative and Postoperative Characteristics (N=68)

Characteristics	Preoperative	Postoperative
Age at time of surgery (yrs)		
Mean ± SD	61.21 ± 10.87	
Range	43 to 81	
Primary IOL implanted		
Monofocal	84%	
Toric	16%	
Sphere (D)		
Mean ± SD	0.31 ± 1.13	-0.08 ± 0.24
Range	-2.50 ± 3.00	-0.50 ± 0.50
Cylinder (D)		
Mean ± SD	0.26 ± 0.81	-0.16 ± 0.24
Range	-1.50 ± 1.50	-0.50 ± 0.50
Spherical Equivalent (D)		
Mean ± SD	0.39 ± 1.27	-0.15 ± 0.26
Range	-2.75 ± 3.50	-0.75 ± 0.25

D = Diopters, SD = Standard Deviation. The Sulcoflex Trifocal 703F intraocular lens is manufactured by Rayner, Worthing, United Kingdom.

Refraction

Both sphere and cylinder reduced postoperatively (**Table 1**). Postoperative mean spherical equivalent refraction at 1 month was -0.15 ± 0.26 D (range -0.75 to 0.25 D). Postoperative mean sphere at 1 month was -0.08 ± 0.24 D (range -0.50 to 0.50 D). All eyes were within ±1.00 D of emmetropia and 94% of eyes were within ±0.50 D. **Figure 5A** demonstrates the postoperative spherical equivalent refractive accuracy. **Figure 5B** plots the change in pre vs postoperative cylinder; 71% of eyes were within 0.25 D and 100% of eyes were within 0.50 D of cylinder.

Visual acuity

Table 2 shows the postoperative monocular and binocular visual acuities at 1 month follow up. **Figure 5C** shows the percentage of eyes with accumulative Snellen visual acuity of 20/x or better after the surgery. Mean monocular UDVA was 0.01 ± 0.04 logMAR and binocular UDVA was -0.02 ± 0.04 logMAR. The UDVA was 0.10 logMAR (Snellen equivalent 20/25) or better in 68 eyes (100%) and 0.00 logMAR (Snellen equivalent 20/20) or better in 44 eyes (65%). Mean monocular CDVA was -0.01 ± 0.04 logMAR and mean binocular CDVA was -0.03 ± 0.05 logMAR. All eyes achieved 0.1 logMAR CDVA (Snellen equivalent 20/25) or better and 62 eyes (91%) achieved 0.00 logMAR (Snellen equivalent 20/20) or better. The mean monocular UIVA at 70 cm was 0.03 ± 0.05 logMAR and mean binocular UIVA was 0.01 ± 0.03 logMAR. The UIVA was 0.10 logMAR (J2 equivalent) or better in 64 eyes (94%) and 0.00 logMAR (J1 equivalent) or better in 48 eyes (71%). Mean monocular and binocular DCIVA was 0.01 ± 0.02 logMAR. All eyes achieved 0.10 logMAR (J2 equivalent) or better and 56 eyes (82%) achieved 0.00 logMAR (J1 equivalent) or better.

The mean monocular UNVA at 40 cm was 0.06 ± 0.06 logMAR and mean binocular UNVA was 0.05 ± 0.05 logMAR. 62 eyes (91%) achieved 0.10 logMAR (J2 equivalent) or better and 28 eyes (41%) achieved 0.00 logMAR (J1 equivalent) or better. Mean monocular DCNVA was 0.05 ± 0.06 logMAR and mean binocular DCNVA was 0.04 ± 0.05 logMAR. 62 eyes (91%) achieved 0.10 logMAR (J2 equivalent) or better and 30 eyes (44%) achieved 0.00 (J1

equivalent) or better. **Figure 5D** shows the cumulative percentage of eyes within each monocular near, intermediate and distance visual acuity.

Defocus Curve

Figure 6 shows the binocular mean visual acuities (logMAR) and their standard deviations for different values of defocus under photopic conditions. At 1 month postoperatively, defocus curve showed a smooth transition phase between the far and the near focus with the best visual acuity results obtained at 0.00 D defocus corresponding to distance vision. At -1.50 D, corresponding to intermediate vision at 70 cm, visual acuity was on average 0.04 LogMAR and at -2.50 D, corresponding to near vision at 40 cm, visual acuity was on average 0.07 LogMAR. The defocus curve remained stable along the intervals providing continuous and acceptable visual acuity at all distances.

Contrast Sensitivity Curve

Figure 7A demonstrates that the contrast sensitivity was comparable under both photopic and mesopic conditions 1 month after surgery; at lower spatial frequencies of 1.5 and 3.0cpd the contrast sensitivity was 1.76 ± 0.24 log units and 1.86 ± 0.31 log

TABLE 2
Monocular and binocular logMAR distance visual acuities 1 months postoperatively. (N=68)

Visual Acuity	Monocular	Binocular
UDVA		
Mean ± SD	0.01 ± 0.04	-0.02 ± 0.04
Range	-0.10 ± 0.00	-0.10 ± 0.00
CDVA		
Mean ± SD	-0.01 ± 0.04	-0.03 ± 0.05
Range	-0.10 ± 0.05	-0.10 ± 0.00
UIVA		
Mean ± SD	0.03 ± 0.05	0.01 ± 0.03
Range	0.00 ± 0.17	0.00 ± 0.17
DCIVA		
Mean ± SD	0.01 ± 0.02	0.01 ± 0.02
Range	0.00 ± 0.10	0.00 ± 0.05
UNVA		
Mean ± SD	0.06 ± 0.06	0.05 ± 0.05
Range	0.00 ± 0.18	0.00 ± 0.18
DCNVA		
Mean ± SD	0.05 ± 0.06	0.04 ± 0.05
Range	0.00 ± 0.18	0.00 ± 0.10

D = Diopters, SD = Standard Deviation, UDVA = Uncorrected Distance Visual Acuity, CDVA = Corrected Distance Visual Acuity, UIVA= Uncorrected Intermediate Visual Acuity, DCIVA = Distance Corrected Intermediate Visual Acuity, UNVA = Uncorrected Near Visual Acuity, DCNVA= Distance Corrected Near Visual Acuity. The Sulcoflex Trifocal 703F intraocular lens is manufactured by Rayner, Worthing, United Kingdom.

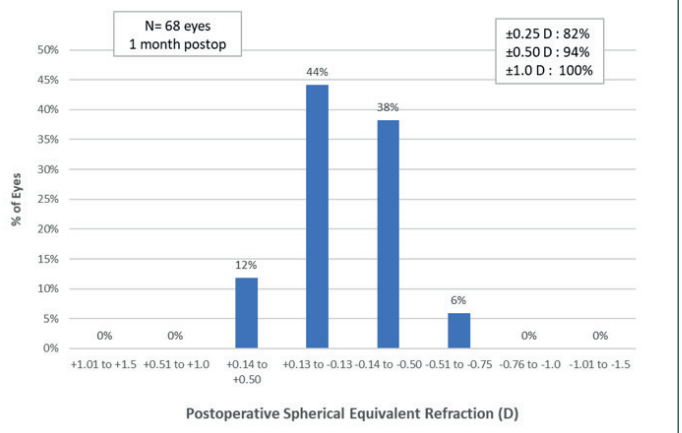

Figure 5A. Spherical Equivalent Refractive Accuracy

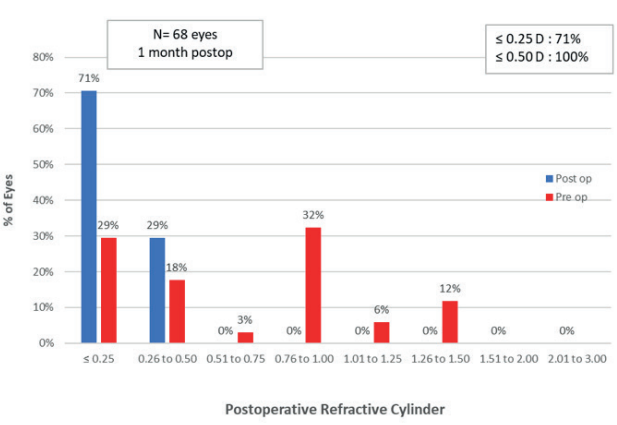

Figure 5B. Refractive Cylinder

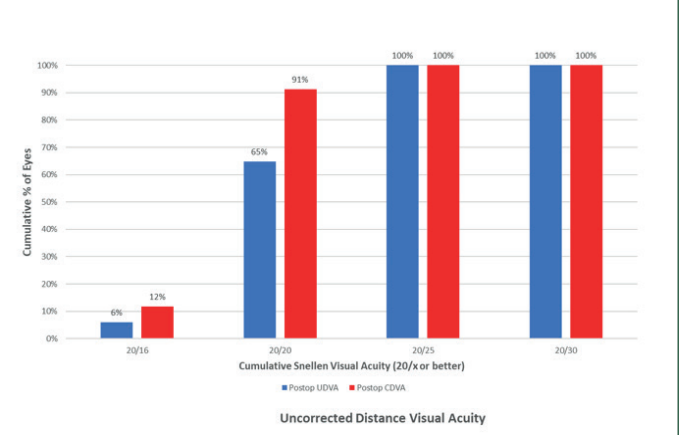

Figure 5C. Cumulative Snellen Visual Acuity (20/x or better)

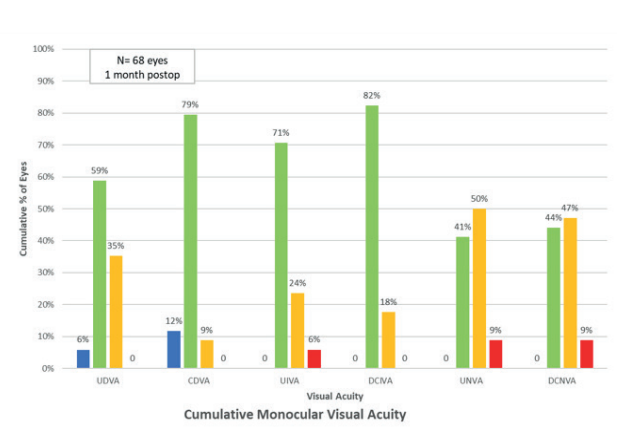

Figure 5D. Cumulative Snellen visual acuity

units under photopic (85cd/m2) and 1.77 ± 0.23 log units and 1.81 ± 0.32 log units under mesopic (3cd/m2) conditions, whilst at higher spatial frequencies of 6, 12 and 18cpd, mesopic (1.69 ± 0.30 log units, 1.37 ± 0.34 log units and 0.92 ± 0.32 log units) was slightly lower than photopic (1.81 ± 0.30 log units, 1.52 ± 0.39 log units and 1.07 ± 0.40 log units) contrast sensitivity. The best contrast sensitivity under both conditions was achieved at low to medium (1.5- 6cpd) spatial frequencies.

Figure 7B shows the contrast sensitivity pre and postoperatively under photopic conditions. Post-op photopic contrast sensitivity was very comparable to pre-op measurements. The mean contrast sensitivity at low spatial frequencies (1.5cpd) changed from 1.79 ± 0.19 log units to 1.76 ± 0.24 log units. For medium spatial frequencies (6cpd), from 1.87 ± 0.28 log units to 1.81 ± 0.30 log units and for high frequencies (18cpd) from 1.23 ± 0.39 log units to 1.07 ± 0.40 log units. Figure 7C shows the contrast sensitivity pre and postoperatively under mesopic conditions. Post-op mesopic contrast sensitivity decreased slightly compared to pre-op at higher spatial frequencies. The mean contrast sensitivity at 1.5cpd changed from 1.83 ± 0.19 log units to 1.77 ± 0.23 log units, at 6cpd from 1.83 ± 0.21 log units to 1.69 ± 0.30 log units and at 18cpd from 1.32 ± 0.27 log units to 0.92 ± 0.32 log units.

Dysphotopic Phenomena and Patient Satisfaction

Figures 8A to 8C show the results of the subjective evaluation of patient satisfaction. Three questions were asked of the patients based on dysphotopic phenomena encountered, spectacle independence and overall patient satisfaction. When questioned on experience of disturbing or troublesome dysphotopic phenomena, 76% (26) of patients answered none or 'hardly' encountered for halos, 76% (26) answered none or 'hardly' for glare and 91% (31) none or 'hardly' for starburst. 24% (8) of patients answered 'somewhat' or 'quite' for halo, 24% (8) for glare and 9% (3) for starburst . No patients reported 'high' levels of disturbing or troublesome dysphotopic phenomena across any of the three categories.

97% (33) of patients reported complete spectacle independence post- surgery for distance vision (3% (1) reported wearing spectacles 'sometimes' at distance), 94% (32) reported complete spectacle independence for intermediate distances (6% (2) reported wearing spectacles 'sometimes') and 76% (26) reported complete independence for near tasks (24% (8 reported wearing spectacles 'often'). Finally, when looking at overall patient satisfaction 94% (32) of patients reported they were

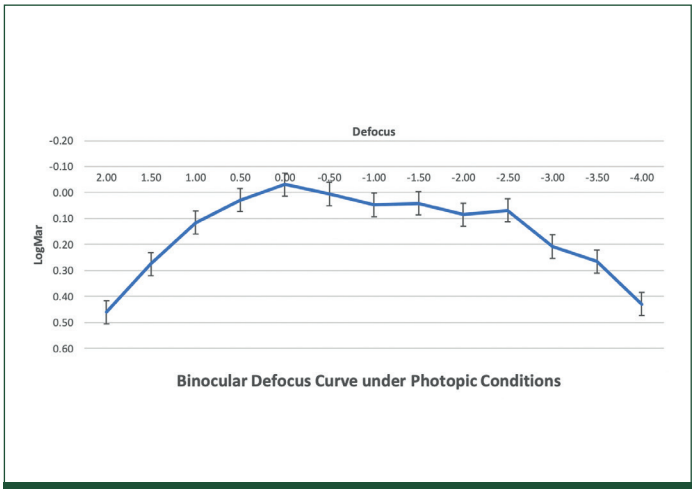

Figure 6. Binocular Defocus Curve under Photopic conditions

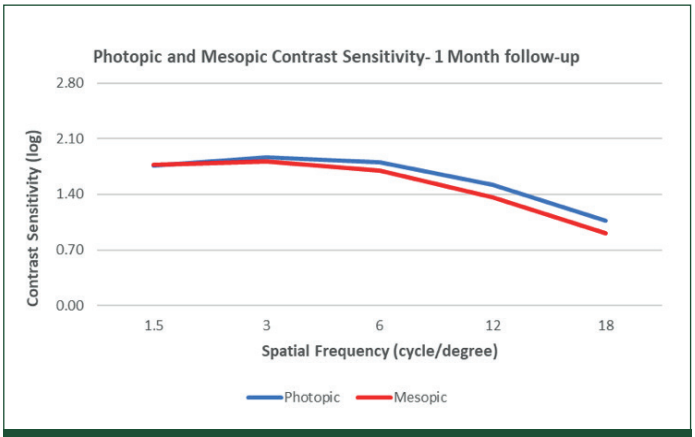

Figure 7A. Contrast sensitivity curve under photopic and mesopic conditions. Contrast sensitivity at different spatial frequencies (cpd = cycles per degree)

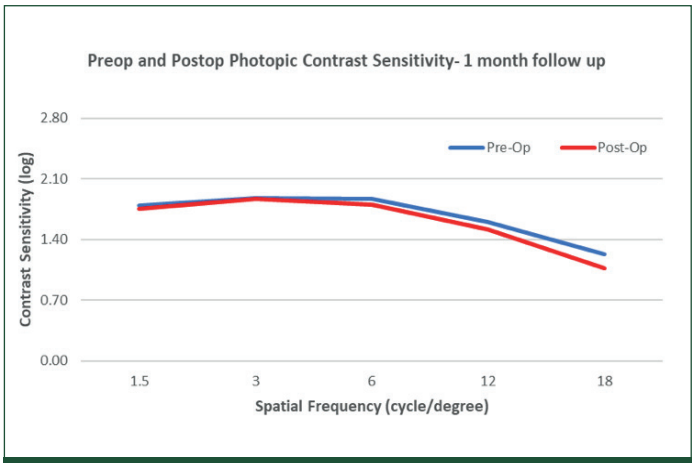

Figure 7B. Contrast sensitivity curve under Photopic conditions - preoperative and postoperative comparison

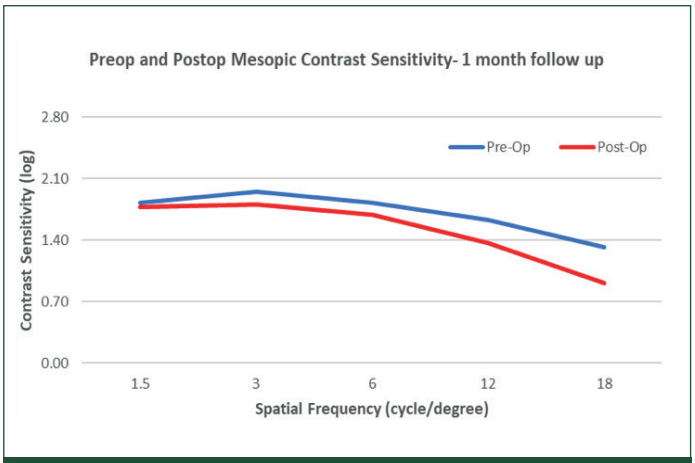

Figure 7C. Contrast sensitivity curve under Mesopic conditions - preoperative and postoperative comparison

satisfied or extremely satisfied with their overall visual outcomes at all distances, 6% (2) of patients were neutral. No patients reported dissatisfaction with their overall vision at distance, near and intermediate.

Complications

There were no serious adverse events reported intraoperatively and all surgeries were relatively uneventful. Postoperative complications included 2 cases of increased intraocular pressure (IOP) immediately after the surgery which resolved in both cases. One lens had to be explanted and replaced during surgery due to haptic capture upon delivery of the lens however this replacement was completed with relative ease and no further complications were observed. No signs of pigment dispersion, iris bulging, interlenticular opacification (ILO) or foreign body giant cell formation were observed in any eyes during the follow up (**Figure 9**). All IOLs centred well and there were no cases of IOL tilt or rotation. Ultrasound biomicroscopy images confirm that the IOL position was stable in all cases and there was good distance between the primary IOL and supplementary IOL (**Figure 10**).

DISCUSSION

Approximately 92% of all cataract surgeries worldwide are monofocal IOL implantations and the global population of pseudophakic patients is approx. 100 million people[1]. Patients are becoming increasingly aware, well-informed and the demand for spectacle independence and refractive enhancements post-cataract surgery is growing. Despite there also being several advances in IOL technology, meticulous patient selection and preoperative assessment; refractive errors can still occur. Studies have shown that over 50% of operated eyes do not achieve emmetropia[2] postoperatively. These refractive errors can lead to dissatisfaction in patients who may continue to demand the expected outcome for their vision. Furthermore, patients may question why the option of spectacle independence was not offered at the time of their routine cataract surgery.

New advances in trifocal multifocal IOLs include an intermediate foci point and have been shown to achieve better near, intermediate and visual outcomes than monofocal IOLs after capsular bag implantation at the time of cataract surgery[4,13-16]. However not all patients are suitable for multifocal technology as they may report unwanted side effects such as loss of contrast or dysphotopic phenomena[18]. This can result in a difficult IOL explantation potentially leading to additional postoperative complications. In fact IOL explanation can be necessary in 8% of multifocal implantations[18,23]. In this study we explored the use of the new Sulcoflex Trifocal supplementary IOL to provide pseudophakic patients spectacle independence, improved visual outcomes and overall satisfaction with their vision. Due to the ease of reversibility, the implantation of the multifocal supplementary IOL may be an attractive option for patients who are undecided about the potential benefits of multifocality or who may otherwise be advised against having a multifocal IOL. To our knowledge there are no current published studies on this new supplementary IOL and therefore our findings are the first.

The Sulcoflex Trifocal is a diffractive trifocal supplementary IOL which is designed for placement in the sulcus. It has a concave

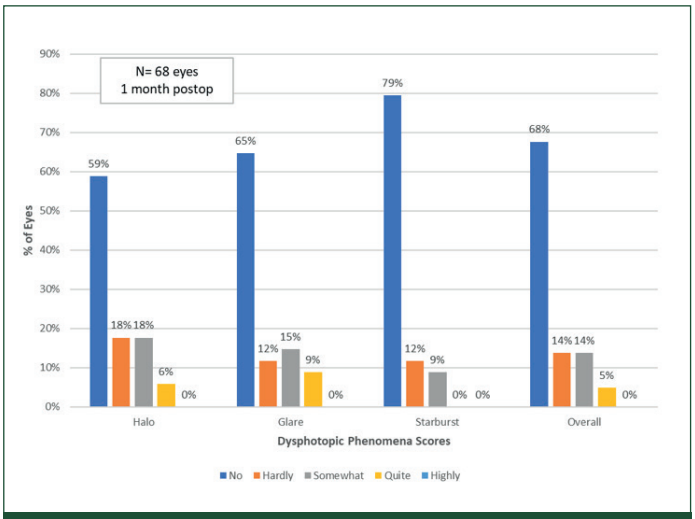

Figure 8A. Patient Satisfaction Scores - Do you find the following phenomena disturbing and troublesome? (Likert Scale Scoring)

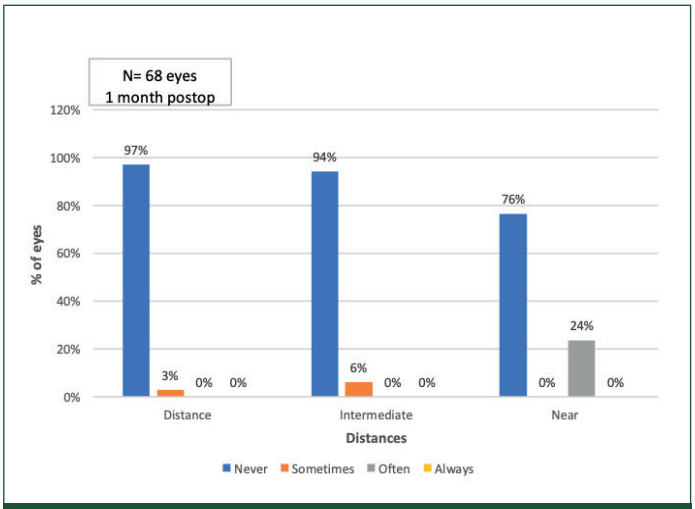

Figure 8B. Spectacle Independence - Do you wear spectacles for distance/intermediate/near vision?

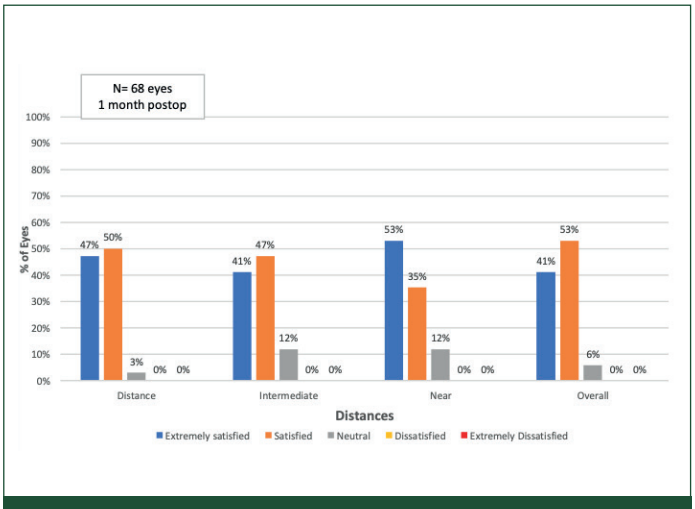

Figure 8C. Patient Satisfaction - "How satisfied are you with your near/intermediate/distance and overall vision?" (Likert Scale Scoring)

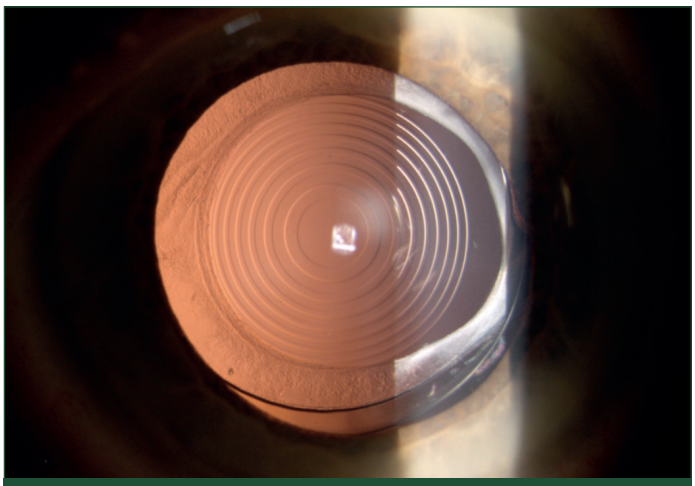

Figure 9. Digital retroillumination image 1 month postoperatively shows no sign of pigment dispersion and both IOLs clear.

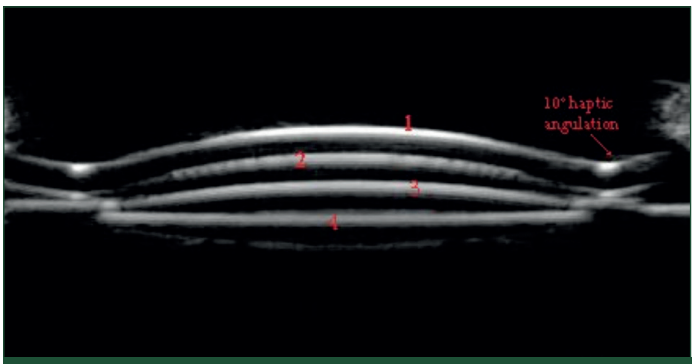

Figure 10. Ultrasound biomicroscopy shows good distance and no central contact between the primary IOL in the capsular bag and the large optic of the supplementary IOL in the sulcus. (1 = anterior surface of supplementary IOL, 2 = posterior surface of supplementary IOL, 3 = anterior surface of primary IOL, 4 = posterior surface of primary IOL)

posterior surface and 10-degree haptic posterior angulation to avoid contact with the optic of the primary IOL in the capsular bag and uveal tissues. Its large overall length with undulating haptics aids stable self- fixation and the large optic size is designed to reduce the risk of pupillary block, optic iris capture and photic effects like edge glare. The new injector system, Accuject 1.8 (Medicel AG) recommended for use with the lens means that an incision as small as 2.2 mm allows safe, reliable and efficient delivery of the lens through minimally invasive surgery. In this study there was one case of haptic capture and damage however the older model R-INJ-04 injector was used to deliver this lens. The damaged lens was explanted with ease and a replacement Sulcoflex Trifocal implanted using the new Accuject 1.8 injector with no further complications, demonstrating the easy reversibility of this new IOL.

This is currently the only diffractive trifocal supplementary IOL available for commercial use, therefore offering a significant advantage compared to existing diffractive bifocal supplementary IOLs such as Reverso IOL (Cristalens) and AddOn Progressive (1stQ). As there are no current studies published on trifocal supplementary IOLs, we therefore compare the findings of our study with published studies on capsular bag diffractive trifocal IOLs and bifocal refractive and diffractive supplementary IOLs.

The subjective refraction results from our study show 94% of patients were within ±0.50 D SE postoperatively with a mean SE of -0.15 ± 0.26 D; results consistent with findings from other studies. Kahraman and Amon[24] evaluated Sulcoflex Aspheric 653L (Rayner, UK) in a prospective study in 12 pseudophakic eyes with ametropia and achieved a postoperative spherical equivalent of -0.25 ± 0.40 D. Falzon and Stewart[25] reported 93% of patients achieving within ±0.5 D SE in a retrospective study in 15 eyes. The findings in our study are superior to a prospective study conducted by Antunes et al[6] on the Sulcoflex refractive bifocal model in 25 eyes where only 58% of eyes achieved a SE within ±0.5 D. This may be because the Sulcoflex refractive bifocal IOL was implanted into cataract patients of which the primary IOL could have resulted in residual astigmatism therefore contributing to a higher spherical error after surgery. When comparing directly to a prospective study on a diffractive bifocal supplementary IOL (Reverso, Cristalens), Cassagne et al[26] report only 72% of patients achieving an SE within ±0.5 D, therefore placing Sulcoflex Trifocal at an advantage.

Distance and near visual acuities results reported from this diffractive trifocal study can be compared to results published on diffractive bifocal supplementary IOLs. In this study the mean monocular and binocular results for UDVA were 0.01 ± 0.04 logMAR and -0.02 ± 0.04 logMAR; CDVA were -0.01 ± 0.04 logMAR and -0.03 ± 0.05 logMAR, UNVA were 0.06 ± 0.06 logMAR and 0.05 ± 0.05 logMAR and DCNVA were 0.05 ± 0.06 logMAR and 0.04 ± 0.05 logMAR. A prospective study in 56 eyes carried out by Gerten et al[27] on the diffractive bifocal MS 714 PB Diff supplementary IOL (Humanoptics AG) reports monocular and binocular UDVA 0.10 ± 0.11 logMAR, 0.02 ± 0.07 logMAR, CDVA 0.02 ± 0.06 logMAR, -0.02 ± 0.05 logMAR, UNVA 0.16 ± 0.13 logMAR, 0.08 ± 0.08 logMAR and DCNVA 0.12 ± 0.14 logMAR and 0.05 ± 0.08 logMAR respectively, therefore demonstrating diffractive trifocal technology as more effective on the Sulcoflex platform at near distances. However, a larger scale study is advised to confirm these findings.

As there are no trifocal supplementary IOL studies published, we have to look at findings reported in capsular bag trifocal IOL studies to compare the intermediate visual acuity performance. In our study we report the mean monocular UIVA was 0.03 ± 0.05 logMAR and DCIVA was 0.01 ± 0.02 logMAR. Mojzis et al[4] reported in a prospective study of 60 eyes implanted with AT Lisa Tri 839MP (Carl Zeiss Meditec, AG) mean UIVA was 0.08 ± 0.11 logMAR and DCIVA was 0.07 ± 0.10 logMAR after 1 months. Another prospective comparative study in 30 eyes (15 eyes implanted with Finevision Micro F IOL (PhysIOL, S.A) and 15 eyes implanted with AT Lisa Tri 839MP (Carl Zeiss Meditec, AG)) carried out by Marques & Ferreira[13] reported mean monocular UIVA and DCIVA was 0.09 ± 0.13 logMAR and 0.04 ± 0.07 logMAR respectively (Finevision Micro F IOL) and 0.14 ± 0.09 logMAR and 0.18 ± 0.18 logMAR respectively (AT Lisa Tri 839MP), the intermediate visual acuity results from our study are superior to those of these studies, therefore demonstrating that diffractive trifocal technology is more effective on the Sulcoflex platform at intermediate distances. Ideally a comparison study to another diffractive trifocal supplementary would be required to support these findings.

The classic defocus curve of a bifocal IOL usually shows 2 peaks corresponding to distance and near vision with a loss in image quality at the intermediate distance[8-12]. In our study, the curve remains almost constant in the interval between -2.5 D to -0.5 D, this corresponds to distances between 40 cm and 2 m. The mean

change in visual acuity in this range was 0.05 logMAR (from 0.07 to 0.01 logMAR). Moreover, variations along the defocus curve were minimal and continuous which indicates that useful intermediate vision was maintained in this range. The trifocal design, with the inclusion of a third focus for intermediate vision, seems to be the explanation for this behaviour. The peak at 0.00 D showed maximum visual acuity corresponding to distance vision with a mean distance visual acuity of -0.03 logMAR (range -0.08 to 0.10 logMAR). These findings are superior to Sheppard et al[28] whom also report an extended range of clear vision for the Finevision Micro F IOL however no apparent peak in visual acuity in the intermediate zone. This may be attributed to the differences in the diffractive trifocal pattern, even though the additions aligned to near and intermediate distances are the same on both trifocal platforms (+3.5 D at 37.5 cm reading plane and +1.75 D at 75.0 cm reading plane) the light distribution is not (15% directed to intermediate in Finevision Micro F and 22% to intermediate in Sulcoflex Trifocal).

Multifocal IOLs split light into several foci point in order to provide sharp focus at various distances, for trifocal optics this is three foci points and therefore may be expected to result in higher loss of contrast than that experienced with monofocal IOLs[28]. For this study of pseudophakic patients, contrast sensitivity was recorded pre-operatively and postoperatively to give an accurate measure of the supplementary IOL performance. The contrast sensitivity values in our study are similar to the findings of Schrecker et al's prospective study[29] of 34 eyes with a capsular bag multifocal IOL versus a sulcus fixated multifocal supplementary IOL, the results from that study show that there were significantly better contrast sensitivity in eyes with supplementary multifocal IOL at all spatial frequencies and under all ambient light conditions. The results of this study are also in agreement with those reported for other diffractive multifocal supplementary IOLs[26] which have been found to have higher contrast sensitivity than refractive multifocal supplementary IOLs[6].

As this study was a multicentre evaluation, a self-administered questionnaire using a Likert scoring scale to record patient satisfaction and subjective feedback was used in order to limit variance and ensure simplicity. The three main dysphotopic phenomena recorded were halo, glare and starburst as these complaints are among the most common causes for patient dissatisfaction[18,23]. Overall dysphotopic phenomena were only perceived by 19% (6) of patients and 81% (27) of patients perceived hardly any or no dysphotopic phenomena. 94% (32) of patients were satisfied or extremely satisfied with their overall visual performance at all distances. These results are better than those reported in the study by Cassagne et al[26] on the diffractive bifocal Reverso (Cristalens) IOL where halo and glare were reported by 66% of patients and 89% of patients considered their overall vision good. The results are also better than those presented by Antunes et al[6] on the bifocal refractive Sulcoflex multifocal where 45% and 36% of patients reported glare and halos respectively and 82% patients reported overall satisfaction with their visual performance at all distances.

Complications such as interlenticular opacification (ILO), pigment dispersion and contact or chafing of the iris related to piggybacking have been reported in previous studies[30-32]. The piggyback implantation technique has evolved over the years from placing two IOLs in the capsular bag[33] to new supplementary IOL designs[24,26] such as the Sulcoflex (Rayner, UK); its placement in the ciliary sulcus, posterior concave optic surface, haptic angulation and large optic and overall length means that the complication rate has also reduced[6,24,26,27]. There were no reports of ILO, pupillary block, iris chafing and pigment dispersion in our case series[6,27], however in accordance with the exclusion criteria and previous studies, the IOL is not recommended for use in patients with pseudoexfoliation or pigment dispersion syndrome. As the supplementary IOL was a multifocal, we also measured the anatomical tolerance of the sulcus fixated IOL. Ultrasound biomicroscopy was used to show a significant space between the capsular fixated and sulcus fixated IOLs. Good stability of the Sulcoflex Trifocal supplementary IOL was observed, with no issues of decentration or tilt. This is confirmed by findings from a retrospective study by Prager et al[34] in 48 eyes of which Sulcoflex showed significantly better centration than the studied capsular bag fixated IOLs. One clinical implication of this study is that placement of trifocal supplementary IOLs in the sulcus could provide better centration and visual outcomes than implanting multifocal IOLs directly into the capsular bag. This strategy then offers the benefit of easy reversibility, which capsular bag fixated IOLs may not. A prospective study by Liekfeld et al[35] in 52 eyes reports implanting a multifocal add-on IOL in the sulcus produced similar visual outcomes than a standard multifocal IOL in the capsular bag 6 months postoperatively. These findings are also supported by Schrecker et al[29].

The limitations of our study are the small sample size, although the data gathered from 68 eyes provides encouraging evidence in favour of good visual outcomes and patient satisfaction with the Sulcoflex Trifocal sulcus fixated supplementary diffractive trifocal IOL. Larger cohort of patients and studies would be invaluable to support our findings. The second limitation is the inability to draw direct comparisons with further studies on diffractive trifocal sulcus fixated supplementary IOLs, as the Sulcoflex Trifocal (Rayner, UK) is the only current diffractive trifocal supplementary IOL on the market and to our knowledge these are the first findings published in pseudophakic patients. Therefore we can only assess visual acuities and patient satisfaction in comparison with current published data on diffractive bifocal supplementary IOLs[26,27], older refractive bifocal supplementary models[5-6] or diffractive trifocal capsular bag fixated IOLs[4,13-16,28]. Performing a study which directly compares Sulcoflex Trifocal to a capsular bag fixated diffractive trifocal such as RayOne Trifocal which shares the same trifocal technology on its optic would be valuable. Additionally, follow up time was limited to 1 month therefore a longer follow up is ideally required. The final limitation was recruitment of pseudophakic patients which proved to be somewhat challenging as pseudophakic patients may not be so aware there are further opportunities to have a refractive enhancement once their initial cataract surgery with monofocal IOL implantation has been performed.

In conclusion, the current findings suggest that implantation of the Sulcoflex Trifocal in the sulcus is a safe and effective method for enhancing patient refractive outcomes and reducing spectacle dependence for near, intermediate and distance vision. Furthermore through careful patient selection and management, those patients that were not offered a presbyopia correcting IOL at the time of initial cataract surgery may still be able to benefit from spectacle independence through the addition of Sulcoflex Trifocal later in life.

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Other resources

Reinstein D, Archer T, Srinivasan S et al. Standard for reporting refractive outcomes of intraocular lens-based refractive surgery.

Mamalis N, Brubaker J, Davis D et al. Complications of foldable intraocular lenses requiring explantation or secondary intervention-2007 survey update. J Cataract Refract Surg 2008; 34:1584-91.

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