Visual outcomes and patient satisfaction following implantation of a supplementary multifocal IOL in patients undergoing cataract surgery

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PURPOSE: To assess visual outcomes and patient satisfaction following implantation of the Sulcoflex® multifocal intraocular lens (IOL; Rayner Intraocular Lenses Ltd., Hove, UK) in a procedure combining capsular bag lens implantation with sulcus placement of the Sulcoflex® IOL.

SETTING: Instituto de Oftalmologia de Assis, Assis, SP, Brazil.

METHODS: Cataract patients > 45 years, with hyperopia ≥ 1.50 D and potential acuity measurement ≥ 20/30 undergoing Sulcoflex® multifocal IOL implantation were included. Monocular and binocular uncorrected near and distance visual acuity (VA) were evaluated at five days, one month, and three months postoperatively. Contrast sensitivity and refraction were measured in a subset of patients three months postoperatively. Patient satisfaction was assessed one month postoperative.

RESULTS: This non-consecutive case series comprised 25 eyes of 13 patients. Eleven eyes (52%) had pre-existing retinal pathologies. Monocular distance VA improved significantly at all follow-up visits. At final follow-up, 88% of eyes had monocular uncorrected distance VA (UDVA) of at least 20/25 and 24% had monocular UDVA of 20/20. All eyes had binocular UDVA of at least 20/25, and 58% had binocular UDVA of 20/20. Monocular uncorrected near vision (UNVA) was J1 in 68% of eyes and all patients had binocular UNVA of J1. Of all eyes studied, 92% and 58% achieved a spherical equivalent within 1 D and –0.5 D, respectively. The majority of patients reported satisfaction with visual outcomes. Complications included a postoperative intraocular pressure spike in four eyes.

CONCLUSION: The Sulcoflex® multifocal IOL improves near and distance VA in cataract patients with retinal abnormalities and good VA potential.

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Standard monofocal intraocular lenses (IOLs) improve visual outcomes in patients undergoing cataract surgery[1]. However, they primarily improve distance vision, leaving patients spectacle-dependent for near vision activities such as reading and computer work. Multifocal IOLs are a recognized solution for improving both near and distance visual acuity in cataract patients[2-6]. However, multifocality is not recommended for patients who have age-related macular degeneration, diabetic retinopathy, glaucoma, amblyopia or corneal

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disorders[7]. Reasons include low contrast acuity of multifocal IOLs and low potential for visual acuity recovery in these patients[8]. Patients without pre-existing eye conditions also complain of side effects such as glare and halos with multifocal IOLs[9]. The use of multifocal IOLs in such patients is discouraged because removal of the IOL in cases of intolerance would normally require an IOL exchange, which is an aggressive procedure associated with an increased risk of capsular rupture or zonular dehiscence with vitreous loss[10]. Furthermore, IOL exchange needs to be performed at early stages post-surgery, before the capsular bag forms adhesion. The Sulcoflex® multifocal IOL (Rayner Intraocular Lenses Ltd., Hove, UK) is a secondary sulcus IOL that can be implanted soon after primary IOL implantation within the same surgical session. Furthermore, since this IOL is implanted in the sulcus, it can be easily explanted, allowing the eye to be "deconverted" in cases of patient intolerance of multifocality, a desire to change refraction, or progression of retinal abnormality with visual acuity loss.

This non-consecutive case series was designed to assess visual outcomes and patient satisfaction following the implantation of the Sulcoflex® multifocal IOL in a consecutive phacoemulsification-secondary IOL implantation procedure in patients undergoing cataract surgery. This study is unique in that it includes patients who are normally excluded from multifocal IOL implantation, such as those with retinal abnormalities, due to the easy reversibility of multifocality provided by this IOL.

PATIENTS AND METHODS

This was a non-consecutive case series that included patients undergoing standard phacoemulsification cataract surgery followed by implantation of a capsular bag IOL and the Sulcoflex® multifocal IOL at the Instituto de Oftalmologia de Assis, Assis, SP, Brazil, between May and October 2012. This study was approved by the Ethics Committee for Research in Humans of Hospital Regional de Assis, Assis, SP, Brazil. Patients gave their informed consent to participate in this study. The series was non-consecutive because not all patients would be candidates for Sulcoflex® implantation. Inclusion criteria for patients included (1) presence of a cataract, (2) hyperopia ≥ 1.50 D, (3) > 45 years, (4) potential acuity measurement (PAM) ≥ 20/30. Preoperative visual assessment included best-corrected visual acuity (BCVA; EyeTech chart projector, Surrey, UK), PAM (Gutton/Minkowski Potential Acuity Meter, Mentor O&O Inc. Norwell, MA, USA), topography (Shin-Nippon CT-1000, Tokyo, Japan), tomography (Pentacam HR, Arlington, WA, USA), specular microscopy (Topcon Specular Microscope SP 2000P, Oakland, NJ, USA), and immersion biometry (Ocuscan RxP, Alcon, Ft. Worth, Texas, USA and IOL Master, Carl Zeiss Meditec AG, Jena, Germany). A retinal specialist also performed a retinal evaluation and optical coherence tomography (Stratus, Carl Zeiss Meditec AG, Jena, Germany).

Intraocular lenses

Patients received the AcrySof IQ WF monofocal IOL and AcrySof IQ toric IOL (Alcon, Ft. Worth, Texas, USA) as the primary capsular bag IOL. For eyes with an axial length between 22 and 26 mm, the power of the IOL was calculated with the IOL Master (Carl Zeiss Meditec AG, Jena, Germany) using the Holladay 1 formula. For eyes with an axial length smaller than 22 mm, we used the Hoffer Q formula, and for eyes with axial length greater than 26 mm, we used the SRK/T formula. Toric IOLs corrected up to 1 D of cylinder. All eyes were implanted with the Sulcoflex® Multifocal IOL (653F, Rayner IOLs) with 0 D and +3.5 D addition. The Sulcoflex® IOL is a hydrophilic acrylic injectable IOL. It has an optic diameter of 6.50 mm, length of 14 mm and a haptic angulation of 10°.

Surgical procedure

All surgeries were performed by VACA. One day preoperatively, eyes were treated with Zypred® (gatifloxacin 0.3% and prednisolone 1%), an antibiotic and corticosteroid combination, four times a day and ketorolac trometamine ophthalmic solution 0.4% (AcularLS, Allergan, Irvine, CA), a nonsteroidal anti-inflammatory agent, twice a day as prophylaxis against infection and inflammation. With the patient seated, limbus marks were made at 0° and 180° to guide the incision on the steep topographical axis. A drop of iodopovidone 5% was applied for one minute as prophylaxis against infection. Topical anesthesia was used in the form of three drops of proxymetacaine 0.5%, after which a 1.0 mm diamond blade was used to make two paracenteses; and 0.1 mL of preservative-free lidocaine hydrochloride 1%, an intracameral anesthetic, was placed in the anterior chamber. The anterior capsular bag was stained with 0.1 mL of Trypan blue. A 2.75 mm diamond blade was used to make the main incision. Two percent methylcellulose was used for endothelial protection, and a DisCoVisc® (sodium chondroitin sulfate, sodium hyaluronate) was used to maintain space for a 5.5 mm capsulorhexis. Capsulorhexis was performed with Utrata forceps (Duckworth & Kent, UK) and controlled using a caliper (Storz Ophthalmics, Rochester, NY, USA). Phacoemulsification was performed with the Infinity platform (Alcon, Ft. Worth, TX, USA) using a 30° tip. The stop and chop surgical technique was used. Bimanual irrigation aspiration was performed with anterior capsule polish

after primary monofocal IOL implantation in the capsular bag. Viscoelastic removal and paracentesis hydration were performed under balanced salt solution (BSS, Alcon, Ft. Worth, TX, USA). The Sulcoflex® multifocal IOL was loaded using BSS on the cartridge. Irrigation was positioned on the anterior chamber to maintain it and the secondary lens was injected. After injection, the lens was fixed into the ciliary sulcus using a Lester hook. In the anterior chamber, 0.3 mL of carbachol chloride 0.01% (Ophthalmos, São Paulo, Brazil) was injected for miosis. At the end of surgery, one drop of Vigamox® (moxifloxacin hydrochloride ophthalmic solution 0.5%), an antiobiotic, was applied as prophylaxis against infection.

Outcomes

Monocular and binocular uncorrected near visual acuity (UNVA) and uncorrected distance visual acuity (UDVA) were measured at five days, one month, and three months postoperative. Contrast sensitivity was measured at the 3-month follow-up using a chart projector. Refraction was measured at the 3-month follow-up using the Nidek AR-600 auto-refractor (Nidek, Aichi, Japan), VT-10 refractor (Topcon, Tokyo, Japan), and EyeTech Digital Vision Chart (EyeTech, Surrey, UK). Intraocular pressure (IOP) was measured using an applanation tonometer (Haag-Streit, Koeniz, Switzerland). Patient satisfaction was measured one month postoperative using a previously published questionnaire[11].

Statistical analysis

Visual acuity data were tested for normality using the Kolmogorov-Smirnov and Shapiro-Wilk tests. Statistical analysis was performed using the Wilcoxon Signed Rank Test with SPSS (IBM, New York, USA). Descriptive statistical tests were performed with SPSS and Microsoft Excel (Microsoft, WA, USA).

RESULTS

This study comprised 25 eyes from 13 patients (7 female, 6 male) of mean age 70 years (range 63–80 years). The majority of patients reported as being housewives (31%) or being retired (31%) (Figure 1). Forty-eight percent of eyes (12 eyes) had no pre-existing associated pathology, whereas a total of 52% of eyes (13 eyes) demonstrated foveolar reflex absence, diffuse retinal pigment epithelium atrophy, initial retinal membrane, macular drusen, or posterior vitreous detachment (Figure 2). Eight percent of eyes (2 eyes, 1 patient) had undergone previous refractive surgery. Eighty percent of patients received a primary aspheric distance IOL while the rest received a toric distance IOL.

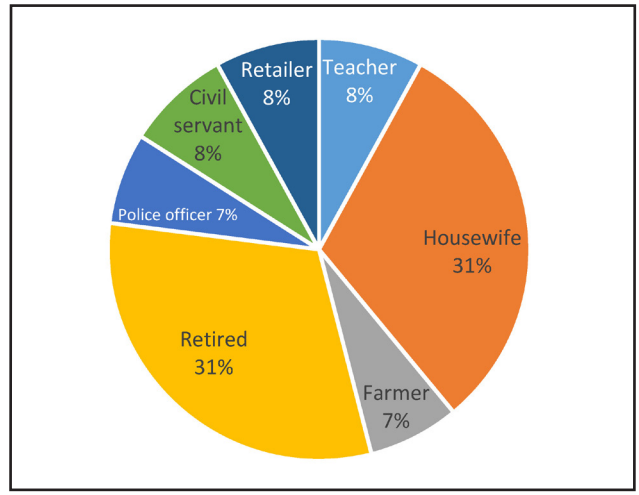

Figure 1. Patient occupation information.

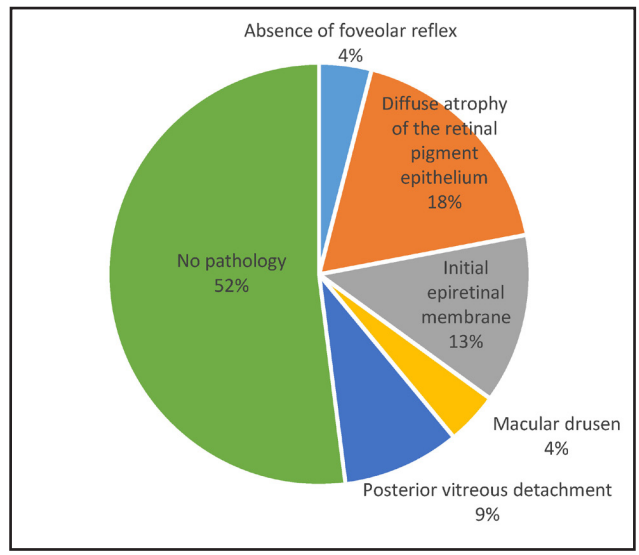

Figure 2. Pre-existing patient ocular pathologies.

There was an improvement in average monocular UDVA at each follow-up post-surgery. The UDVA at each follow-up was significantly better than the pre-operative BCVA (Table 1). The average monocular and binocular UDVA at the 3-month follow up were 0.08 and 0.04 logMAR, respectively. Binocular UDVA remained stable postoperatively, whereas monocular UDVA showed gradual improvement over time (Tables 1 and 2). At the 3-month follow up, 24% of eyes had a monocular distance VA of 20/20 and all patients had a monocular UDVA of at least 20/30 (Table 3). Similarly, monocular and binocular near vision improved from five days follow-up to the 3-month follow-up (Figures 3 and 4). By the 3-month follow-up, all tested patients had a monocular UNVA of at least J2 (68% had UNVA of J1; Figure 3) and all tested patients had a binocular UNVA of J1 (Table 4; Figure 4).

Table 1. Postoperative monocular uncorrected distance visual acuity (logMAR) compared to preoperative best corrected distance visual acuity (N = 25)

	Mean	SD	Median	Min	Max	p-value
Pre-operative BCVA	0.24	0.18	0.17	0.00	0.60	0.24
5 days post-operative UDVA	0.13	0.09	0.10	0.00	0.40	0.28
1 month post-operative UDVA	0.09	0.07	0.10	0.00	0.30	0.001
3 months post-operative UDVA	0.08	0.05	0.10	0.00	0.17	< 0.001

BCVA: Best corrected visual acuity; UDVA: Uncorrected distance visual acuity; SD: Standard deviation; Min: Minimum; Max: Maximum

Table 2. Binocular uncorrected distance visual acuity (logMAR) over time (N = 12)

	Mean	SD	Median	Min	Max
5 days post-operative	0.04	0.05	0.00	0.00	0.10
1 month post-operative	0.03	0.05	0.00	0.00	0.10
3 months post-operative	0.04	0.05	0.00	0.00	0.10

SD: Standard deviation; Min: Minimum; Max: Maximum

Table 3. Uncorrected distance visual acuity frequency at 3 months

	Eyes, N (%)		
	20/20	**20/25**	**20/30**
Monocular UDVA (n = 25)	6 (24)	16 (64)	3 (12)
Binocular UDVA (n = 12)	7 (58)	5 (42)	0 (0)

UDVA: uncorrected distance visual acuity

Table 4. Uncorrected near visual acuity frequency at 3 months

	Eyes, N (%)	
	J1	**J2**
Monocular UNVA (n = 25)	17 (68)	8 (32)
Binocular UNVA (n = 12)	12 (100)	0 (0)

UNVA: uncorrected near visual acuity

We measured refraction in a subset of 12 eyes at the 3-month follow-up. The mean spherical equivalent (SE) was –0.5 D (Table 5). Fifty-eight percent of patients had SE within –0.5 D whereas 92% had SE within –1.0 D (Figure 5).

Contrast sensitivity was measured at the 3-month follow-up using a chart projector. At 20/25 binocular vision, 42% of eyes showed 10% contrast sensitivity, 50% of eyes had 15% contrast sensitivity, and 8% of eyes had 20% contrast sensitivity. Compared to the contrast sensitivity of 5% seen in normal patients, these patients lost between 5% and 15% contrast sensitivity, with the majority of patients (50%) losing 10% contrast sensitivity.

Patient satisfaction was measured using a questionnaire at the 1-month follow-up. Forty-five percent and 36% of patients reported excellent and good visual outcomes, respectively. Although patients reported good outcomes with general, near, distance and night vision and daily activities such as cooking, watching television, reading and shopping, 45% of patients reported poor outcomes with respect to glare

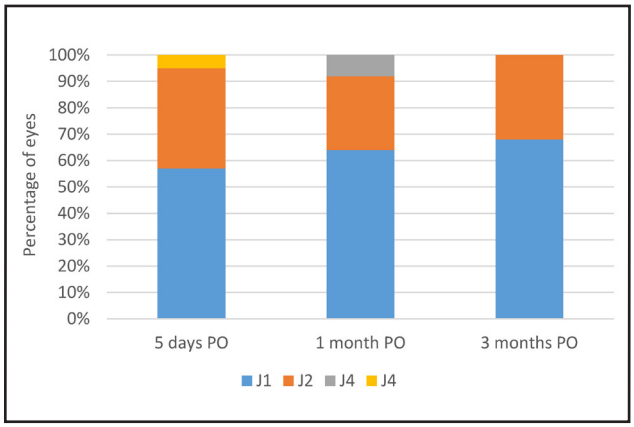

Figure 3. Monocular uncorrected near visual acuity over time (n = 25 except where indicated). PO, postoperatively

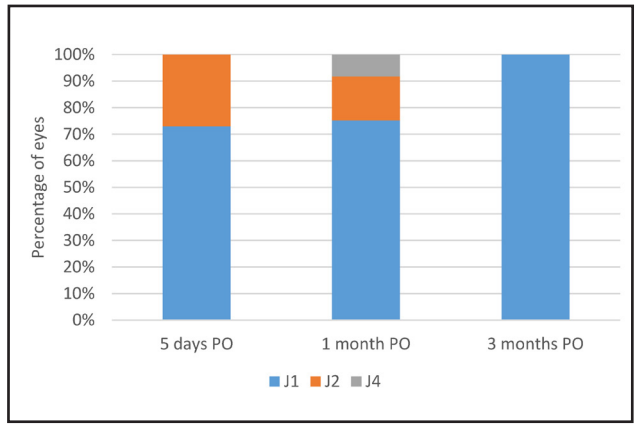

Figure 4. Binocular uncorrected near visual acuity over time (n = 12)

Table 5. Refraction results at 3 months (N = 12)

	Mean	SD	Median	Minimum	Maximum
Spherical equivalent	−0.5	0.4	−0.375	−1.25	0.00

SD: Standard deviation

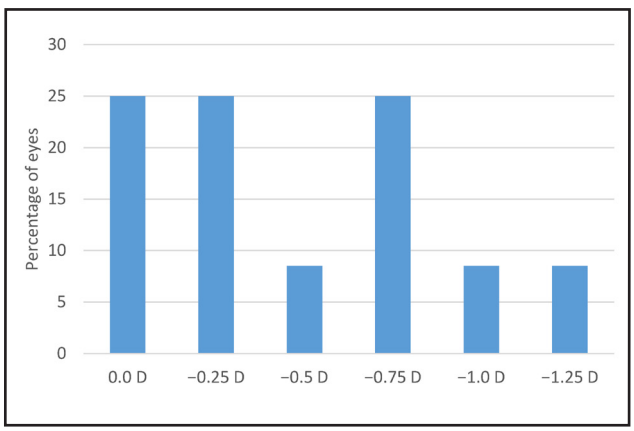

Figure 5. Spherical equivalent results at 3-month follow-up (n = 12)

and 36% reported the presence of halos. Higher rates of satisfaction were detected in patients who were either retired or housewives.

Complications included an increase in IOP in four eyes post-surgery. IOP increased by four or more points compared to preoperative IOP in these eyes at the 5-day and 1-month post-operative follow-ups. However, IOP stabilized in these patients, with or without treatment by the 3-month follow-up. All patients had an IOP between 9 and 14 mmHg at the 3-month follow-up. During surgery, two sulcus IOLs had to be removed due to problems with the haptics. No retina disease that could decrease VA occurred during the follow-up period, and hence no IOL was removed because of this, or because of patient dissatisfaction.

DISCUSSION

In spite of advances in IOL technology and power calculations, refractive errors are unavoidable in certain cases and are a major cause of patient dissatisfaction and spectacle-dependency. Furthermore, although the use of multifocal IOLs has been shown to achieve better near and visual outcomes than monocular IOLs[2–6], patients report various undesirable effects with multifocal IOLs[9], and multifocal IOLs are contraindicated in patients with retinal disorders[7]. In this study, we demonstrated the use of the Sulcoflex® multifocal supplementary IOL to improve visual outcomes post-cataract surgery. The easy reversibility of the supplementary IOL provides the possibility of offering multifocality to patients who are otherwise advised against it.

In our study with the Sulcoflex® IOL, we found an average monocular UDVA of 0.09 logMAR and an average binocular UDVA of 0.03 logMAR at 1-month follow-up. These visual outcomes are comparable with those achieved with other multifocal IOLs such as the M-Flex® IOL (Rayner IOLs, Hove, UK) and AcrySof® ReSTOR® IOL (Alcon, Inc., Ft. Worth, TX, USA)[5,12-22]. Using the M-Flex®® IOL, a 32-eye study by Cezón-Prieto and Bautista found a mean monocular UDVA of 0.10 and mean UNVA of 0.28 logMAR one month postoperative[18]. Studies with the AcrySof® ReSTOR® IOL reported mean binocular UDVA and UNVA of 0.15 logMAR and 0.25 logMAR, and mean monocular UDVA and UNVA of 0.13 logMAR and 0.10 logMAR, respectively[13,15]. Similarly, findings from a 6-month, 20-eye prospective study by Akaishi et al. in which

patients received piggyback implantation with the Tecnis® ZM900 multifocal IOL (Abbott Medical Optics, Inc., Abbott Park, Illinois, USA), demonstrated a significant improvement in preoperative UDVA, i.e., 20/29 versus 20/400 before referral ($p < 0.001$). At the last follow-up, 90% of the eyes achieved a UNVA of J1, and 83.3% of patients were spectacle independent for near and distance vision. The authors also noted statistically-significant improvements in BCVA (–0.01 [20/20; range 0.00 to –0.10; SD, ± 0.03]), and mean SE (–0.35 ± 0.55 [range –1.50 to +0.50 D]) at the 1-month follow-up visit[23]. Additionally, data from a case series study of six eyes implanted with the AMO Array® refractive multifocal IOL (Abbott Medical Optics, Inc.), also showed that good results were obtained in UNVA and UDVA. Specifically, 80% of eyes achieved a UNVA of J1.5 or better, while all eyes had a UDVA of 20/40 or better[24]. Findings from a prospective noncomparative case series that included six pseudophakic emmetropic patients also showed that secondary piggybacking with the Acri.Twin bifocal diffractive IOL (Carl Zeiss Meditec AG) provided improvements in pseudoaccommodation in these patients[25].

The refraction and VA results seen in our study are consistent with those from other studies that implanted the Sulcoflex® secondary IOL into the sulcus of pseudophakic eyes using the piggy-back technique[22,26,27]. A 15-eye study by Falzon and Stewart showed that the implantation of the Sulcoflex® lens in pseudophakic patients showed an improvement in the UDVA with all patients achieving at least 20/32, 10% achieving 20/20, and 93% of patients achieving SE of within 0.5 D[26]. In our study, all patients achieved monocular UDVA of at least 20/30, and 24% achieved monocular UDVA of 20/20 at three months. However, in terms of SE, fewer patients in our study (53%) achieved SE of within 0.5 D. Similarly, average SE in our study was higher than that of the foregoing study (–0.5 D ± 0.4 D vs –0.15 ± 0.5 D)[26]. This difference may be due to differences in the types of IOL used in the Falzon and Stewart study and this study. The Falzon and Stewart study implanted only the Sulcoflex® aspheric and toric lenses, and not the Sulcoflex® multifocal IOL. Furthermore, residual astigmatism in the eyes that were implanted with the primary toric IOL may have contributed to the higher spherical error after surgery. A series of case studies by Khan and Muhtaseb that implanted the multifocal Sulcoflex® IOL in pseudophakic eyes showed visual results similar to ours[27]. The four patients who received the Sulcoflex® multifocal IOL in a secondary procedure achieved UDVA of at least 0.10 logMAR and UNVA of J4 or better[27]. In our study, the mean UDVA was 0.08 logMAR at the 3-month follow-up, all patients had better near VA and at least J2 at three months. Our results are also comparable or superior to those achieved using toric multifocal IOLs. A study by Visser et al. with the AT Lisa Toric IOL (Carl Zeiss Meditec AG, Jena, Germany) found an average UDVA postoperatively of 0.04 logMAR, similar to the 3-month UDVA seen in our study. However, our near vision and refractive results are superior to those seen in the Visser et al. study. In that study, only 29% of patients achieved UNVA of J2 or greater, and 38% achieved cylindrical refraction within ± 0.5 D, whereas in our study all patients achieved UNVA of J2 or better and 54% achieved cylindrical refraction within ± 0.5 D[28].

Complications in our study include an increase in postoperative IOP in four eyes. IOP increased by four points or more at either five days or one month postoperative compared with preoperative IOP. This is similar to previous results with the Sulcoflex® lens[22,27]. For instance, in the study by Falzon and Stewart one eye showed an increase in IOP to 23 mmHg one month postoperative[26]. This increase in IOP may be a result of pigmentary dispersion due to the manipulation of the Sulcoflex® IOL. In this study, patients with an increase in IOP were treated with Combigan® (brimonidine tartrate/timolol maleate; Allergan Inc.) ophthalmic solution 0.2%/0.5% twice a day for 30 days until the pressure was normal again. One patient was not treated for IOP increase, yet achieved stable IOP by the 3-month follow-up. There were no other complications in these patients. However, other preliminary studies that we have performed have shown a small number of cases of Sulcoflex® IOL explantation due to haptic amputation. These complications were due mostly to difficulty in sulcus IOL cartridge loading, suggesting a short learning curve for the procedure. Explantation of the Sulcoflex® IOL was a safe and simple procedure.

Because multifocal IOLs distribute incoming light to several focal points, they are associated with a loss in contrast sensitivity. Indeed, in our study patients lost between 5 and 10% contrast sensitivity. However, this is comparable with results obtained with other multifocal IOLs[29]. It should also be noted that one of our patients (two eyes) had undergone previous refractive surgery and hence the contrast sensitivity results may have been affected. Longer follow-up is needed before we can draw firm conclusions.

Studies of multifocal IOLs have reported difficulties with glare and halos[5]. In our study, 45% and 36% of patients reported glare and halos, respectively. This is slightly higher than in other studies. For example, a study by Kohnen et al. reported that approximately 33% of patients reported glare and 20% reported halos[5]. Another study by Chiam et al. reported that approximately 20% of their patients suffered from glare and halo[15]. However, in spite of these visual effects, 82% of patients reported satisfaction with the multifocal Sulcoflex® IOL.

Current spectacle-independent approaches to treating residual ametropia or refractive surprise after cataract surgery include keratorefractive laser surgery, IOL exchange, and secondary IOL implantation. Although laser surgery is effective and safe, it is associated with potential side effects such as dry eye and difficulty with wound healing, especially in older patients[30]. Furthermore, laser surgery is not a viable option for patients with higher order aberrations and corneal topography abnormalities[31]. If the refractive error is discovered early after surgery, the IOL can be replaced by an IOL exchange. However, this process is challenging and can increase the risk for retinal tears, cystoid macular edema, cyclodialysis, and posterior and anterior capsule rupture[32]. Secondary IOL implantation in the sulcus is a relatively safer procedure, but using conventional IOLs in the sulcus can cause intraocular lens opacification (ILO)[33], iris chafing, and pigmentary dispersion[34]. The main advantages of the single surgical session procedure with the Sulcoflex® IOL as compared with other approaches is the ease of implantation of a sulcus IOL and the atraumatic reversibility of the procedure. Furthermore, the use of a secondary IOL implanted in the sulcus is associated with a lower incidence of ILO[35] and the haptics of the Sulcoflex® lens allow the maintenance of distance from the iris, thus reducing the occurrence of pigmentary dispersion[33]. Finally, the Sulcoflex® IOL can be used to correct refractive errors in pseudophakic eyes. In this study, in one patient with a previous history of refractive surgery, sulcus IOL implantation was performed 15 days after primary IOL implantation. Refraction was assessed prior to Sulcoflex® IOL implantation to correct any ametropia post-primary IOL implantation. Therefore, the Sulcoflex® IOL can be used to correct ametropia following cataract surgery.

Limitations of our study include the small number of eyes evaluated and a lack of a case–control design. Furthermore, postoperative evaluation was not uniform over follow-up visits, with only a subset of patients undergoing refraction. Additionally, follow-up was limited to three months. Therefore, future studies with a larger number of eyes will be necessary to determine the long-term visual outcomes of Sulcoflex® multifocal IOL implantation.

In conclusion, the Sulcoflex® multifocal IOL is an effective approach for obtaining superior visual outcomes after cataract surgery even in patients with retinal abnormalities.

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