Correction of Undesirable Pseudophakic Refractive Error With the Sulcoflex Intraocular Lens

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ABSTRACT

PURPOSE: To evaluate the visual outcomes, efficacy, predictability, and short-term safety of implanting the Sulcoflex (Rayner Intraocular Lenses Ltd) intraocular lens (IOL) to correct residual pseudophakic errors.

METHODS: Retrospective study of patients undergoing implantation of the Sulcoflex IOL. Uncorrected (UDVA) and corrected (CDVA) distance visual acuity and refractive outcomes were evaluated. Postoperative follow-up was at 1 week and 1, 3, 6, and 12 months.

RESULTS: Fifteen eyes (13 patients) were evaluated. Mean follow-up was 20 months (range: 14 to 30 months). The Sulcoflex aspheric (653L) and toric (653T) IOLs were implanted in 3 and 12 eyes, respectively. Preoperatively, mean logMAR (Snellen) UDVA and CDVA were 0.44 (20/55) and 0.05 (20/22), respectively. At 3 months, all eyes achieved logMAR UDVA of 0.20 (20/32) or better, with 10 (67%) eyes achieving UDVA of 0 (20/20) or better. Preoperative mean spherical and astigmatic errors were 1.07 ± 0.83 dioptries (D) and −1.45 ± 0.98 D, respectively. Preoperative mean spherical equivalent refraction was −0.54 ± 1.11 (D). Postoperative mean sphere and astigmatism at 3 months were −0.25 ± 0.38 D and −0.50 ± 0.57 D, respectively. Postoperative mean spherical equivalent refraction at 3 months was −0.15 ± 0.28 D. All patients were within 1.00 D of attempted correction, with 93% within 0.50 D. Linear regression analysis showed good correlation (R² = 0.72) between attempted versus achieved spherical equivalent refractions. No significant intra- or postoperative complications occurred.

CONCLUSIONS: Implantation of the Sulcoflex IOL was found to be an effective and predictable option for enhancing postoperative refractive results and reducing spectacle dependence for distance after surgery. The IOL was well tolerated in all eyes. [J Refract Surg. 2012;28(9):614-619.]

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Unexpected postoperative refractive surprises are a common cause of patient dissatisfaction and remain an important and challenging issue for ophthalmic surgeons. Surgical options for subsequent correction of residual refractive error after cataract surgery include corneal and limbal relaxing incisions, intraocular lens (IOL) exchange, and keratorefractive laser surgery. More recently, a light adjustable intraocular lens (LAL; Calhoun Vision Inc, Pasadena, California) has been introduced. An alternative approach is the implantation of a new supplementary sulcus IOL using the piggyback technique.

Secondary piggyback lenses offer various advantages over IOL exchange including decreased intraoperative maneuvers that could lead to capsule rupture and a simpler method of IOL power calculation. Piggyback lenses also potentially allow for a smaller incision unless the primary foldable IOL is cut in half prior to explantation. However, IOLs designed solely for the capsular bag are not appropriate for placement in the ciliary sulcus. Complications related to placement of a conventional IOL in the sulcus include pigment dispersion, iris transillumination defects, dysphotopsia, elevated intraocular pressure (IOP), intraocular hemorrhage, and cystoid macular edema.

The recently introduced Sulcoflex IOL (Rayner Intraocular Lenses Ltd, East Essex, United Kingdom) is designed for implantation as a piggyback IOL in the ciliary sulcus of the pseudophakic eye and has design attributes calculated to overcome the disadvantages of conventional IOLs. The technology of a compound IOL that could be placed in the sulcus over a previously implanted IOL has been available, at least conceptually, for more than 10 years. The objective of this study was to evaluate the visual outcomes, efficacy, predictability, and short-term safety of this novel piggyback
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IOL to correct residual pseudophakic spherical and cylindrical errors.

**PATIENTS AND METHODS**

A chart review was conducted for all patients (identified from an electronic database) who received a Sulcoflex IOL for correction of residual refractive error between January 2010 and April 2011. One patient with previous penetrating keratoplasty was excluded. The time interval between primary surgery and secondary Sulcoflex surgery was a minimum of 3 months. Preoperative assessment prior to Sulcoflex implantation surgery included measurement of Snellen uncorrected (UDVA) and corrected (CDVA) distance visual acuity, refraction, and keratometry. All patients had at least two stable subjective refractions prior to secondary surgery. Axial length and anterior chamber depth were measured with the IOLMaster (Carl Zeiss Meditec AG, Jena, Germany). Slit-lamp microscopy, application of tonometry, and fundus examination were performed for all patients. Written informed consent was obtained from all patients before surgery. This research followed the tenets of the Declaration of Helsinki.

Patients received either a Sulcoflex aspheric (653L) or toric (653T) IOL based on two stable preoperative refractions, keratometry, and axial length measurements. The Sulcoflex multifocal IOL was not assessed in our study. Calculation of the required spherical and cylindrical powers of the IOL to achieve distance emmetropia and maximum astigmatic correction was performed using a web-based customized formula (Raytrace toric calculator, http://www.rayner.com/raytrace/) developed by the manufacturer. Calculations can also take account of 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 minimize any significant SIA affecting the postoperative result.

The same surgeon (O.G.S.) performed all secondary IOL implantations. The cornea was marked preoperatively at the slit lamp using a needle to mark the horizontal meridian with the patient sitting upright and looking straight ahead. The steep meridian was marked intraoperatively using the Mendez ring (Malosa Medical, Elland, England) and ink. An on-axis, self-sealing, clear corneal incision (2.75 mm) using a standardized technique was performed. The anterior chamber and retroiridial space were filled with an ophthalmic viscosurgical device (OVD). The secondary IOL was implanted in the ciliary sulcus using the supplied one-piece, single-use injector. The IOL was rotated to the desired axis by aligning the cylinder axis with the steep corneal meridian. The IOL has linear marks on its anterior surface to allow correct surgical alignment. The OVD was meticulously washed out and cefturoxime (1.0 mg in 0.1 mL) was injected intracameral. Correct alignment of the IOL was verified at the end of surgery and at the slit lamp. After surgery, all patients received topical tobramycin-dexamethasone eye drops for 4 weeks.

All patients were examined 2 hours, 1 week, and 1, 3, 6, and 12 months postoperatively and as required. At each follow-up examination, Snellen UDVA was determined. Snellen CDVA was obtained following subjective refraction performed at 3 months postoperatively. Slit-lamp examination was performed to subjectively assess anterior chamber flare, iris transillumination, and pigment dispersion. Intraocular pressure measurement was followed by dilated funduscopy. Dilation allowed subjective verification of correct axis alignment but alignment was not formally measured with digital retroillumination imaging or anterior segment ultrasound biomicroscopy.

For statistical analysis, Snellen acuity was converted to logarithm of the minimum angle of resolution (logMAR) acuity. Descriptive statistics were calculated for various clinical characteristics. All data were analyzed using a Microsoft Excel (Microsoft Corp, Redmond, Washington) spreadsheet to produce standardized graphs. Linear regression analysis was performed to assess predictability. Vector analysis using pre- and postoperative refractive measurements was performed with Datagraph-med (version 4.10; Datagraph-med, Wendelstein, Germany).

**RESULTS**

The study evaluated 15 eyes from 13 patients. Mean patient age was 63 years (range: 52 to 81 years). Mean follow-up was 12 months (range: 5 to 21 months). The Sulcoflex aspheric (653L) and toric (653T) IOLs were implanted in 3 and 12 eyes, respectively. Preoperatively, mean logMAR (Snellen) UDVA was 0.44±0.21 (20/55) (range: 0.20 to 0.78) and mean logMAR CDVA was 0.05±0.07 (20/22) (range: −0.20 to 0.10). All patients had improved UDVA postoperatively. At last follow-up, all eyes achieved logMAR UDVA of 0.20 (20/32) or better, with 10 (67%) eyes achieving logMAR UDVA of 0 (20/20) or better (Fig 1). No patient lost any lines of UDVA or CDVA (Fig 2).

Postoperatively, mean sphere at 3 months was −0.25±0.38 diopters (D) (range: 0.25 to −0.50 D). Postoperative mean spherical equivalent refraction at 3 months was −0.15±0.28 D (range: 0.38 to −0.75 D). All patients were within 1.00 D of attempted correction, with 93% within 0.50 D (Fig 3). Linear regression...
Figure 1. Cumulative plot of pre- and postoperative uncorrected distance visual acuity (UDVA). Figure 2. Change in corrected distance visual acuity (CDVA). Figure 3. Equivalency plot of attempted versus achieved spherical equivalent refraction. Figure 4. Spherical equivalent refractive accuracy. Figure 5. Change in magnitude of astigmatism.
analysis showed good correlation ($R^2=0.72$) between attempted versus achieved spherical equivalent refractions (Fig 4).

Pre- and postoperative mean refractive astigmatism were $-1.45\pm0.98$ D (range: $-0.25$ to $-3.00$ D) and $-0.50\pm0.57$ (range: 0 to $-1.25$ D), respectively. Thirteen (87%) eyes were within 1.00 D postoperatively, with 10 (67%) eyes within 0.50 D (Fig 5). Double-angle plots of the pre- and postoperative refractive astigmatism are shown in Figure 6.

No intraoperative complications occurred. None of the Sulcoflex IOLs needed to be repositioned at the end of surgery. One (6.7%) eye had an IOP increase to 23 mmHg 1 month postoperatively. The IOP remained stable without treatment throughout follow-up (4 months). Three (20%) eyes had increased anterior chamber flare 1 month postoperatively treated with a further 4 weeks of topical prednisolone acetate (1%). Following dilation and retroillumination, all IOLs were well-centered and no cases of IOL rotation or tilt were observed. No interlenticular opacification or other postoperative complications related to piggyback IOLs (eg, pigment dispersion syndrome, pupillary block glaucoma) were observed. No eyes required further surgery or removal of the secondary IOL. At last follow-up, 12 (92%) patients were spectacle-independent for distance. One patient with logMAR UDVA of 0.2 (20/32) was prescribed distance spectacles achieving logMAR CDVA of $-0.1$ (20/16). No other visual disturbances were reported.

**DISCUSSION**

In this study, the Sulcoflex IOL offered an effective method to correct unexpected postoperative visually significant refractive error and astigmatism. All patients achieved logMAR UDVA of 0.20 (Snellen 20/32) or better associated with a reduction in refractive astigmatism.

Refractive surprises are usually due to placement of an incorrect power IOL as a result of a preoperative error in axial length measurement or keratometry. However, postoperative decentration or axial shift of the IOL can lead to a discrepancy between expected and final visual outcome, despite remarkable developments in biometry, IOL manufacture, and operative techniques. During the healing process, anterior movement of the IOL results from postoperative capsular bag fibrosis and contraction. Studies have shown mean myopic shifts in spherical equivalent refraction of 0.70 D from 1 day postoperatively out to 2 months.

The time interval in our study between primary surgery and secondary Sulcoflex surgery was a minimum of 3 months. Furthermore, all patients had at least two stable subjective refractions prior to secondary surgery to minimize errors in refraction due to axial movement of the primary IOL.

Pentacam (Oculus Optikgeräte GmbH, Wetzlar, Germany) studies of the implanted Sulcoflex IOL have shown a significant distance between the IOL from the iris anteriorly and the primary IOL posteriorly, significantly reducing the risk of iris chafing. Very high-frequency digital ultrasound (Artemis; ArcScan Inc, Morrison, Colorado) assessment of Sulcoflex IOL insertion in the ciliary sulcus in pseudophakic human cadaver eyes showed overall appropriate centration and minimal or no tilt. Follow-up examinations to date showed no evidence of iris chafing, pigment dis-

![Figure 6. Double-angle plots of the A) pre- and B) postoperative refractive astigmatism.](image-url)
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persion, or interlenticular opacification in our series indicating minimal interaction of the Sulcoflex IOL with the primary IOL and uveal tissues.

Alternative surgical methods for subsequent correction of unexpected residual refractive error after cataract surgery include corneal and limbal relaxing incisions, keratorefractive laser surgery, IOL exchange, or more recently, implantation of a LAL.6-9 Relaxing incisions can correct low and moderate astigmatic errors, but are less precise, and can be complicated by placement on the incorrect axis, perforation, pain, and infection.2 One patient in our series who had previous unsuccessful limbal relaxing incisions achieved an improvement in logMAR UDVA from 0.3 (20/40) to 0 (20/20) following Sulcoflex IOL implantation. Laser refractive surgery is also effective and safe for the correction of residual refractive error. However, it could create potential complications that might be more common in older patients related to dry eye and wound healing.18

Although the overall incidence of IOL exchange for correcting unexpected refractive errors after cataract surgery has decreased over the past decade, incorrect IOL power remains a common indication for foldable IOL exchange.19 If the error is discovered early in the postoperative course, the visual outcome can be very good after IOL exchange and remains an effective option for the timely treatment of incorrect IOL power after cataract surgery. Intraocular lens exchange is a challenging process, especially if delayed, as it involves removing the existing IOL before implantation of a new one. The additional manipulation required due to strong IOL adhesion to the capsular bag increases the risk for retinal tears, cystoid macular edema, cyclodialysis, and posterior or anterior capsule rupture.1 Nd:YAG laser capsulotomy performed after primary surgery also significantly increases the rate of anterior vitrectomy, further complicating the secondary IOL exchange procedure.4 The sulcus implantation of the secondary IOL was safe and relatively atraumatic. No serious intra- or postoperative complications were noted in our series and no patient lost any lines of CDVA.

One major advantage of piggybacking with the Sulcoflex IOL is predictability. The power calculation for the supplementary IOL depends solely on the patient’s current postoperative, not preoperative, measurements. Each Sulcoflex IOL was chosen using the web-based customized calculator. Insertion of keratometric data and desired postoperative spherical equivalent refraction produced a selection of appropriate lenses. Surgically induced astigmatism and incision axis can also be factored into the lens choice. Our results showed good predictability of secondary piggyback Sulcoflex IOL implantation. In contrast, one of the limitations of IOL exchange is the difficulty predicting the power of the replacement IOL. Few studies have evaluated power calculation for in-the-bag IOL exchange20 and it requires an accurate knowledge of the IOL power of the previous surgery, which may not always be available.1 Moreover, the accuracy of the power calculation can be affected if the original IOL had been unknowingly mislabeled or axial displacement of the IOL occurred due to capsular contraction. A further advantage is reversibility. Unlike refractive laser correction, the supplementary Sulcoflex IOL may be explanted from the sulcus if necessary. No eyes required removal of the secondary IOL in our series.

Recent studies have shown promising results for correction of residual hyperopic or cylindrical refractive errors following cataract surgery using LAL technology (Calhoun Vision Inc). The refractive power of the IOL can be adjusted and “locked-in” postoperatively by the application of near-ultraviolet light.6,8,21 Also, because most cataract surgeons may not have equal access to a refractive laser, the Sulcoflex IOL may provide an excellent, yet cheaper, alternative to laser adjustment of IOL power in the eye.

A large cohort of postoperative refractive laser surgery patients will require cataract surgery in the near future, all of whom will have high expectations. As corneal power is often overestimated, these patients are frequently left hyperopic after cataract surgery. The Sulcoflex IOL may be a feasible method for correcting any residual hyperopic error following cataract surgery in this patient cohort. The multifocal Sulcoflex IOL also enables correction of pseudophakic presbyopia, thereby significantly reducing the need for additional near correction. Successful spectacle independence following secondary Sulcoflex insertion in one patient after bilateral LASIK and refractive lens exchange with an accommodating IOL has recently been reported.11 In the same study, the authors achieved logMAR UDVA of 0.1 (20/25) or better and uncorrected near visual acuity of N6 (Jaeger 4) or better using the multifocal Sulcoflex IOL.11 The multifocal Sulcoflex IOL was not assessed in our series.

Our study has several limitations including its retrospective nature and small patient cohort. First, piggyback IOL implantation with placement of two foldable IOLs in the capsular bag can be followed by a significant hyperopic shift occurring between 1 and 2 years after implantation.22 This may be caused in part by interlenticular opacification, resulting in displacement of the IOLs as demonstrated using Scheimpflug photography.23 This was not observed in our series. Although this could be due to shorter follow-up and
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small study sample size, it is most likely due to implantation of the secondary IOL in the ciliary sulcus with all primary IOLs in the capsular bag in our series. Second, postoperative evaluation was not uniform over time. Third, correct axis alignment, decentration, and tilt, which are major concerns, were only performed subjectively and were not assessed further during the study period with digital retroillumination imaging or ultrasound biomicroscopy. Furthermore, specific tests other than UDVA (eg, contrast sensitivity, wavefront analysis) or patient satisfaction questionnaires may be better indicators of subjective satisfaction. However, 92% of patients in this study were satisfied with the outcomes of the IOL exchange procedure, with the surgery improving or resolving their visual symptoms. Despite these limitations, our data suggest the viability of the Sulcoflex IOL as a surgical option for the treatment of such eyes.

Implantation of the Sulcoflex IOL was a predictable and effective method for enhancing the refractive outcome and reducing spectacle dependence for distance in pseudophakic eyes. Appropriate patient selection, accurate preoperative measurements, good intraoperative technique, and careful postoperative management can result in excellent outcomes with minimal risk of complications. As with all refractive procedures, realistic expectations should be established before surgical intervention.

AUTHOR CONTRIBUTIONS

Study concept and design (K.F., O.G.S.); data collection (K.F.); analysis and interpretation of data (K.F.); drafting of the manuscript (K.F.); critical revision of the manuscript (K.F., O.G.S.); statistical expertise (K.F.); supervision (O.G.S.)

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