Enhancement of Refractive Results after Intraocular Lens Implantation

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Abstract

Summary: An overview on polypseudophakia ('piggyback' intraocular lens [IOLs]) is given. Requirements on a sulcus-supported supplementary IOL are defined. Two-year results of a new IOL (Sulcoflex®) are presented and indications for this IOL are defined. **Methods:** The IOL is especially designed for implantation into the ciliary sulcus in pseudophakic eyes (piggyback). It is a single-piece implant made of hydrophilic acrylic. Optic- and haptic-edges are round. The optic has a diameter of 6.5mm and a concave/convex shape for perfect fit on the anterior convex surface of the primary IOL. The haptic is angulated, and has an undulated design to preclude IOL rotation. A monofocal, a multifocal or a toric version of the sulcoflex IOL were implanted into the ciliary sulcus of pseudophakic eyes. All IOLs were implanted by injector through a 3mm clear cornea incision. After surgery near and far uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA) and eye pressure were assessed. Inflammation was measured by laser flare/cell meter. Position and rotational stability of the IOL were documented regularly at all control visits. Furthermore, Scheimpflug photography and ultrasound biomicroscopy were performed. **Results:** Surgery was performed without any complication in all cases. Two years after surgery there were no severe intra- or post-operative complications detected. Emmetropia was achieved in all cases (±0.25dpt) and the refraction was stable. Flare values were lower than the values measured after standard cataract procedures. Rotational stability and centration were excellent. Intraocular pressure was within the normal range at all visits. After one year of follow-up no iris-chafing was documented. In all cases, a good distance was found between iris and the Sulcoflex-IOL and primary implant and the Sulcoflex-IOL. In those cases with the multifocal IOL-version all patient achieved independency from glasses. **Conclusion:** Surgery with implantation of a sulcus-IOL is safe and less traumatic than IOL-exchange. The material and design of the Sulcoflex IOL ensure that the implants are well tolerated within the eye. The implant can be used at the same time with the primary implant or as secondary implant. Indications for implantation of this IOL are the correction of 'post-surgical' ametropia, of astigmatism (toric IOL) of higher order aberrations (aspherical IOL) and of 'pseudophakic presbyopia' (multifocal IOL). In the future, other potential indications will be established.

Keywords

Sulcoflex®, sulcus implantation, piggyback IOL, polypseudophakia, post-operative ametropia

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There is a great demand for exact refractive results following cataract surgery or after refractive lens exchange. Patients are becoming more and more informed about new technologies and surgical methods of refractive correction. Today's patients expect 20/20 uncorrected visual acuity (UCVA) after routine cataract surgery. Despite advances in intraocular lens (IOL) designs, IOL power calculation formulas and accurate biometry techniques, pseudophakic refractive errors are unavoidable in some cases. Certainly, the advent of optical coherence biometry (OCB, i.e. IOLMaster), which uses partially coherent light to measure the axial length of the eye along its visual axis and provides the surgeon with keratometry readings and anterior chamber depth measurements, has significantly increased refractive accuracy during cataract surgery. However, unexpected post-operative refractive events can still occur, albeit less frequently, for which a secondary surgical intervention can often be indicated.

No doubt that the accuracy in calculating the true IOL power after keratorefractive surgery will improve, but can still be less accurate than would otherwise be expected. This is widely due to difficulties that may be encountered during the pre-determination of corneal refractive powers, such as using the wrong keratometry values or biometry formulas. This is particularly true after myopic keratorefractive surgery because the corneal refractive powers may easily be overestimated, which in many cases, leads to a hyperopic shift in the post-operative refractive outcome.

Correction of Refractive Errors

Several options are available for the subsequent correction of refractive surprises, including prescription of spectacles or contact lenses, IOLs exchange, keratorefractive surgery or implantation of a supplementary IOLs (i.e. polypseudophakia). What is polypseudophakia? If you implant more than one IOL into the same eye, that would be polypseudophakia. The polypseudophakia technique, first described by Gayton in 1993 to provide adequate power in highly hyperopic patients, has been extended to secondary cases in which additional power is added or subtracted to an underpowered or overpowered pseudophakic eye.[1–4] Spectacles may not be the best option, especially with the younger, more self-aware patient. Similarly, contact lenses are often inappropriate for older patients as well as infirm elderly patients. Keratorefractive surgery, for example, laser-assisted *in situ*

Figure 1: Sulcoflex® Intraocular Lenses

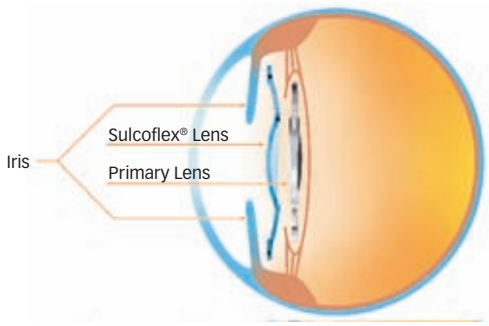


Figure 2: Scheimpflug Image Demonstrating Adequate Iris–Intraocular Lens (IOL) and IOL–IOL Distance

Figure 3: Multifocal Sulcoflex® Intraocular Lens One Year after Implantation

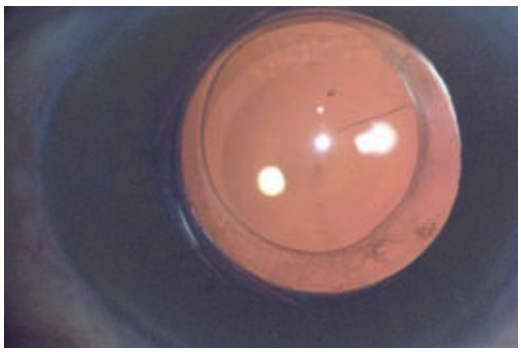
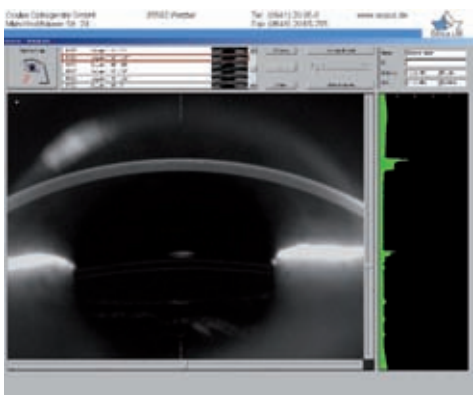


Figure 4: Scheimpflug Image with Good Distance Between the Two Intraocular Lenses



keratomileusis (LASIK) or laser epithelial keratomileusis (LASEK), may also not be the solution because of the inherent risks associated with further corneal surgery. In many instances, such an option may not even be possible or available as it is also a costly alternative.

Since an IOL exchange may be associated with increased risk of capsular rupture or zonular dehiscence with vitreous loss, the implantation of a supplementary IOL may be a more acceptable option. Supplementary IOLs, implanted in the ciliary sulcus anterior to the primary implant, are easier and safer surgical options, especially when capsular changes may have firmly fixated the primary implant within the capsular bag. If we have to correct refractive surprises after cataract surgery, we typically implement the use of supplementary IOLs.

Supplementary Intraocular Lens is Predictable and Reversible

If pseudophakic refractive error is suggestive of a secondary intervention, there is often an underlying uncertainty as to whether the correct implant power was used in the primary procedure. If an IOL exchange were to be used in this situation, especially if an original power miscalculation was repeated, it would affect the refractive result, assuming that the primary implant was not mislabelled. Alternatively, the power calculation for the supplementary IOL depends solely on the patient's current refraction. If the surgeon chose to perform an IOL exchange, he cannot be confident that the replacement IOL would be implanted in exactly the same plane as the original IOL. For these reasons, our choice is the supplementary IOL, which ensures predictable results. A further advantage of polypseudophakia is reversibility. Unlike the option of corneal laser surgery, the supplementary IOL implantation is reversible. If necessary, the additional IOL may be removed from the eye easily. Even though in our series we have not removed a single implant, an explantation could become necessary, if the wrong implant is used, if the patient is not happy with his/her refraction.

Which Intraocular Lens to Choose?

With a supplementary IOL, care must be exercised in choosing what lens to use. Conventional IOLs designed primarily for in-the-bag placement are not appropriate for supplementary procedures because their performance dynamics differ considerably.[5,6] The IOLs designed for capsular bag implantation may be too small for sulcus implantation (usually haptic diameters vary between 12.5 and 13mm). This may lead to decentration or rotational instability, causing further complications such as optic capture of IOL. Implanting a conventional uniplanar IOL (i.e. IOLs without posterior haptic angulation) in the sulcus ciliaris, may cause iris chafing and pigment dispersion due to iris IOL contact.[7,8] Additionally, relatively steep anterior surface of uniplanar IOLs may cause unwanted pigment adhesion to the implant surface. Pigment dispersion may also result an increase in intraocular pressure with a higher risk of developing glaucoma. Another disadvantage of conventional IOLs used in conjunction with higher power primary implants, is contact between IOLs due to steeper anterior surfaces, thereby increasing possibility of anterior vaulting of the secondary lens.[9] Any physical contact, especially with foldable or injectable IOLs, may cause deformation of the optic surfaces at the point of contact, which causes a hyperopic shift and may result unwanted photopic effects. Implanting two IOLs in the capsular bag raises concerns about the possibility of the formation of interlenticular opacification (ILO) within Elschnig pearl proliferation in the peripheral interface between two piggyback lenses. ILO may lead to decreased vision secondary to a post-operative hyperopic shift as well as opacification.[9]

The Sulcoflex Pseudophakic Supplementary IOL (Rayner Intraocular Lenses Ltd, East Sussex, UK) is an exciting development in IOL design, allowing piggyback implantation in pseudophakic eyes and offering exact refractive results after cataract surgery or refractive lens exchange. Unlike conventional IOLs, the Sulcoflex was specifically

designed for polypseudophakia with biomaterial attributes calculated to overcome the disadvantages of using conventional IOLs (see *Figure 1*). This single-piece IOL is designed with a hydrophilic acrylic co-polymer noted for its high uveal biocompatibility,[10,11] an important factor for IOLs specifically designed for ciliary sulcus placement. The large 6.5mm optic diameter, with an anterior convex and posterior concave configuration, creates a perfect fit with the anterior convex surface of the primary IOL. The 13.5mm diameter large haptics are posteriorly angulated with undulated edges to prevent IOL rotation, a factor particularly important for the post-operative refractive accuracy when correcting corneal astigmatism using a toric IOL. The haptic angulation is also effective in maintaining the distance from the iris, thereby reducing the occurrence of pigment dispersion syndrome and optic capture.[7] Additionally, round-edge haptic design may reduce sulcus ciliaris irritation. Since the posterior capsular opacification is not a consideration for sulcus fixation, optic edges are rounded to reduce minimal edge glare and dysphotopsia. The Sulcoflex Pseudophakic Supplementary IOL is intended solely for ciliary sulcus placement; interlenticular opacification, seen when both IOLs are implanted in the bag, is not a characteristic of this design.[12–14] These supplementary IOLs may be implanted simultaneously with the primary implant (in special cases with head of high hyperopia, myopia or corneal astigmatism) or a secondary implant procedure. They are available with an aspheric monofocal, aspheric toric (see *Figure 2*), or aspheric multifocal design (refractive type, see *Figure 3*).

Indications for Pseudophakic Intraocular Lens Implantation

There are many indications to consider a secondary supplementary IOL implantation. For example, the correction of post-surgical pseudophakic and post-keratorefractive surgical ametropia, the correction of higher-order aberrations (HOAs; obtained with the aspheric design), the correction of supplementary residual pseodophakic astigmatism (with the toric design) and for the correction of pseudophakic presbyopia (with the multifocal design). Especially in eyes with dynamic refraction, such as pediatric cases, keratoconus, after silicone oil filling and keratoplasty, the use of supplementary IOL may be advantageous since this procedure is reversible. Additionally Sulcoflex can be performed as a primary surgical procedure. This technique may be applied in eyes requiring the insertion on an IOL with a lens power greater than +30 dioptres to achieve desired power (e.g. eyes with an extremely short axial length). The reversibility of sulcus IOL implantation has other advantages too. For instance the multifocal Sulcoflex may be implanted primary with a conventional IOL in the same surgical procedure. In case of visual discomfort or disphotopsia the multifocal IOL may be easily removed.

Pilot Study Design

In a recent pilot study, Sulcoflex monofocal aspheric or multifocal models were implanted into the ciliary sulcus of pseudophakic eyes. Twenty-six eyes of 19 patients were included. The subjects who had unsatisfactory far-distance correction with spectacles were included. Only patients without pre-existing ocular pathology, other than previous cataract extraction by phacoemulsification following in the capsular bag IOL implantation, were selected. All the implantations were performed through a self-sealing 3mm clear corneal incision under topical and intracameral anaesthesia. After clear corneal incision, the anterior chamber and the retro-iridial space were filled with an ophthalmic viscoelastic device (sodium hyaluronate 1% [Healon]). Sulcoflex IOLs were implanted in the ciliary sulcus, using the supplied single-piece single-use injector. Good IOL centration was ensured. The ophthalmic viscosurgical device (OVD) was washed out and a miotic (acetylcholine 1% Miochol E®) was injected intracamerally. Additionally, 1mg Cefuroxime (Curocef 0.3ml) was administered. After the surgery, all patients received topical gentamicin–dexamethasone (Dexagenta-POS) and diclofenac sodium 0.1% (Voltaren Optha) eye drops, three times daily for four weeks. Post-operatively near and far UCVA, BCVA and IOP were assessed. Anterior chamber inflammation was measured with the laser flare/cell meter, and position and rotational stability of the IOL were regularly documented at all control visits. Additionally, Scheimpflug images were taken. In some cases, ultrasound biomicroscopy to determine IOL position was performed.

Results

All surgeries were uneventful. Post-operative emmetropia (±0.25 D) was achieved in all cases with stable refractions through all the follow-up time. (Mean follow-up period 14 ± 3.2 months) Post-operative laser flare values were lower than the values measured after standard cataract procedures. Rotational stability and centration were excellent. Except one case who showed slight IOL decentration (axial length >30mm), which was less than 0.5mm. Since the patient had no vision decrease we decided not to remove the Sulcoflex IOL. Intraocular pressure was within the normal range at all visits. No iris chafing was documented, and in all cases, a good distance was observed between the iris and the Sulcoflex Pseudophakic Supplementary IOL (see *Figure 4*). Similarly, a good distance was also observed between the supplementary IOL and the primary implant. In those cases with the multifocal Sulcoflex version and in cases with multifocal primary IOL, all patients achieved spectacle independence. In conclusion, the correction of pseudophakic ametropia, or the enhancement of post-surgical refractive results with the Sulcoflex Pseudophakic Supplementary IOL offers a safer and less traumatic option than IOL exchange. Because of its material and design, this supplementary IOL is well tolerated within the eye. ■

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